HOUSE OF COMMONS
CHAMBRE DES COMMUNES
CANADA

# Standing Committee on Health

HESA • NUMBER 036 • 1st SESSION • 42nd PARLIAMENT

**EVIDENCE**

## Thursday, December 8, 2016

## Chair

**Mr. Bill Casey**

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● (0850)

[*English*]

**The Chair (Mr. Bill Casey (Cumberland—Colchester, Lib.)):** Order. We are to start a study today. On November 1, the House of Commons Standing Committee on Health agreed that the committee would dedicate the meeting of Thursday, December 8 to initiate a study on the current restrictions when it comes to blood donation imposed on men who have sex with men.

We're very pleased that our guests are here today. We're looking forward to the testimony. At the end of this, we'll decide where we go next with this study. We have invited several groups, as proposed by the members of the committee, but many have declined to come, so we're very appreciative of the witnesses who did agree to come today.

With us today from the Canadian AIDS Society, we have Gary Lacasse and Janne Charbonneau. From the Canadian Blood Services, we have Dr. Graham Sher and Dr. Dana Devine. From the Department of Health, we have Catherine Parker.

We're going to start with the Canadian AIDS Society. You may have 10 minutes for an opening statement, if you like.

**Mr. Gary Lacasse (Executive Director, Canadian AIDS Society):** Good morning, Chair, Vice-Chairs, and members of the Standing Committee on Health.

My name is Gary Lacasse. I'm the executive director of the Canadian AIDS Society. Thank you for inviting CAS to appear before your committee at its inaugural meeting to discuss the current blood donation restrictions imposed on men who have sex with men, or MSM, as we call them in the health portfolio.

The Canadian AIDS Society is a national coalition of community-based organizations dedicated to strengthening Canada's response to HIV and AIDS, which includes ongoing collaboration with community partners and Canadian stakeholders to monitor and maintain the safety of Canada's blood supply, particularly since 1997, with the release of Justice Krever's report of the Commission of Inquiry on the Blood System in Canada.

Over the years, the Canadian AIDS Society has worked closely with Canadian Blood Services and other stakeholders to realize in July 2013 a change to the blood donation deferral policy affecting men who have sex with men from “indefinitely” to a period of five years since the last sexual encounter. At the time, we saw the change as a positive incremental step towards a deferral policy that would ultimately focus on gender-neutral, behaviour-based, risk-factor criteria, rather than sexual orientation.

Since then, CAS has continued its collaborative and consultative role with CBS to review evidence and scientific data collected over the last several years, and we supported Minister Philpott's announcement in June 2016 to move to a one-year deferral step. We find that this is the right direction, with a view to ultimately removing any remaining barriers to MSM blood donation.

The long-standing CAS position on this issue is quite simple and straightforward. We believe that there should be a behaviour-based screening policy for blood donations, rather than one that focuses on populations based only on their sexual orientation or gender.

In essence, CAS continues to advocate for a safe blood supply that is also respectful of human rights. That fact is that screening guidelines have been and remain discriminatory for both male and female donors. The current screening questions in CBS donor questionnaires single out specific population groups, and in particular. men who have sex with men, regardless of their actual behaviours and practices.

For male donors, the screening questionnaire asks, “In the last 12 months, have you had sex with another man?” For female donors, it asks, “In the last 12 months, have you had sex with a man who, in the last 12 months, has had sex with another man?” Replying in the affirmative to these questions renders one ineligible to donate blood.

Similarly, transgender persons are also subject to a screening policy that discriminates based on whether or not a transperson has undergone gender-confirming surgery, regardless of their risk behaviour.

The current deferral period, which is not evidence-based practice, operates by assuming that certain groups are more likely to taint the blood supply. CAS has advocated and continues to advocate for studies to provide behavioural research evidence to support the move towards non-discriminatory screening criteria based on behavioural risk. With behavioural research, it will be possible to gather data on low-risk versus high-risk donors based on their sexual behaviour, irrespective of their sexual orientation or gender identity.

To this end, we welcome the recent announcement by CBS for a two-day meeting to be held in January 2017 with national and international stakeholders to identify research priorities for closing knowledge gaps that impact donor eligibility for men who have sex with men. The stated goal of the meeting is to examine alternative screening approaches for blood donors and alternative technologies to provide data to change the current donor eligibility requirements.

There is currently no international consensus on deferrals for MSM. Many countries, such as the United States, the United Kingdom, Australia, New Zealand, Sweden, and the Netherlands, have implemented or are implementing a one-year deferral. Others, such as Italy and Spain, have no deferral periods for MSM, preferring to assess donor risk through specific behaviour.

In conclusion, I would like to emphasize that stigma and discrimination remain key concerns and barriers in our struggle to reduce and ultimately eradicate HIV transmission in this country. Despite the reduction in the deferral period to one year since the last sexual encounter, this restriction applying to MSM blood donors continues to foster a culture of discrimination and stigma that hinders our ability to reach our goal.

● (0855)

Over the years, CAS has consistently advocated for a scientific evidence-based approach and has worked closely with Canadian Blood Services and various stakeholders to create a safe blood system without discriminating against certain groups. Even though we are not there yet, in recent years we have certainly been moving in the right direction, from a total ban on MSM in the past, to a five-year deferral period in 2013, and then moving to a one-year deferral period implemented this past August.

In the near future, we look forward to scientific and behavioural-based alternative screening approaches for blood donors, maximizing the use of new available technologies, to change donor eligibility requirements to create a safe blood supply that is also respectful of human rights. This is a realistic and achievable goal.

I thank you again for the opportunity to provide our views on this important matter.

**The Chair:** Thank you very much.

Now we'll move to Canadian Blood Services.

**Dr. Graham Sher (Chief Executive Officer, Head Office, Canadian Blood Services):** Thank you very much, Mr. Chair and committee members, for the opportunity to discuss the blood donor eligibility criteria for MSM.

As you are aware, this is a sensitive and emotionally charged topic involving the people on both sides of the donation experience: the blood donor wishing to contribute to Canada's blood system and the patient receiving the blood product.

I'll begin by briefly reviewing how we screen blood donors and then provide an overview of the risk assessment and blood testing. I'd also like to outline some of the historical context around MSM and HIV risk as it affects the blood system, touch on what other blood operators are doing internationally, and then discuss the effect of changes to these eligibility criteria on the blood supply.

My colleague, Dr. Devine, will then conclude with an overview of our specific next steps.

As you are well aware, in Canada, blood is regulated as a drug by Health Canada. This means that Canadian Blood Services must demonstrate that the changes to policies and procedures potentially affecting patient safety will not introduce any measurable additional risk to the blood supply system before we receive federal approval for adoption.

Before donating blood, donors are screened to ensure blood donation is safe for them and for the patients who will receive their products. Donors must first complete a questionnaire, and we expect donors to be honest about their exposure risks. Screening personnel then go over the donor's answers and perform additional assessments to determine whether the donor is eligible to donate. Based on their answers, donors are then separated into broad risk categories and are determined to be either eligible or ineligible to donate accordingly.

Donors may be ineligible to give blood for a varying and large number of reasons, including travel, vaccination, tattoos, and many lifestyle issues. This leads me to how we assess risk.

The eligibility criteria presented on the donor questionnaire are determined through multiple risk assessments related to transmissible diseases. As part of this process, Canadian Blood Services monitors transmissible disease testing in blood donations and investigates possible transfusion-transmitted infections in recipients of blood products. We also continually scan the international and domestic environment for emerging pathogens, including, most recently, the Zika virus.

Our risk models are informed by data related to pathogens of interest or related pathogens. We also consider data from population-based studies, such as those performed by the Public Health Agency of Canada. After any significant change to our donor eligibility criteria, we use anonymous surveys to assess the rate of our donors' compliance with the revised donor questions.

We certainly receive many questions from donors about our criteria and why, if we can test blood, we need to have these criteria in the first place. Canadian Blood Services does indeed test every donation for HIV-1 and HIV-2, hepatitis B, hepatitis C, human T-lymphotropic viruses I and II, and syphilis. We also test for Chagas disease on individuals identified as being at risk based on travel, and in the spring, summer, and fall months we also test for West Nile virus.

While our technology is indeed sophisticated and includes state-of-the-art nucleic acid testing, there is a brief period shortly after infection when pathogens are not detectible by current assays. If an individual donates blood during the so-called “window period”, the early stages of infection, our testing processes would not detect the virus, and the blood products manufactured from that donation could be infectious for patients. This window period is indeed now less than 10 days for HIV and hepatitis C, and less than two months for most other pathogens. No test is 100% perfect, however, and can fail for technical reasons or because the pathogen undergoes mutation.

Because of the history of the blood supply system in Canada in the tainted blood tragedy, changes to donor eligibility criteria for MSM have required substantial analysis and ongoing engagement with patient stakeholder groups, including the LGBT communities and many other organizations, to make sure we maintain public trust in the system. When Canadian Blood Services was first established in 1998, on the the heels of the tainted blood tragedy, the criteria for MSM were indeed stringent. If a man had had sex even one time with another man since 1977, he was permanently deferred and ineligible to donate blood. At that time, and for many years following, the MSM population was noted to be a particularly high-risk group. The year 1977 was chosen as ground zero for the arrival of HIV in North America, hence its inclusion in the criteria.

● (0900)

We moved, as the committee well knows, to a policy for a five-year deferral in July 2013. Following our application to make this change, Health Canada asked of Canadian Blood Services and Héma-Québec that we gather a minimum of two years' data to demonstrate that no further risk had been introduced to the blood system before requesting a further reduction in the waiting period for MSM. This was met without issue.

Our data showed that the current one-year deferral policy easily covers the window period for HIV, hepatitis B, and hepatitis C, with the residual risk for these three pathogens being less than one in one million units transfused. Similarly, post-implementation monitoring showed no adverse impacts on the prevalence of HIV in donors, donor compliance, or trust in the system. This data permitted Canadian Blood Services to submit a further application to Health Canada for what is now our one-year deferral policy. This past June, that was approved and took effect in August.

Still, according to the Public Health Agency of Canada's most recent figures, men who have sex with men account for 54% of new HIV infections in Canada, a higher proportion than other risk categories combined. Large cohort studies of MSM populations in Canada also show a high frequency of risk-related behaviours. The scientific evidence available, however, is inadequate. Most public health research has focused on individuals within the MSM population whose behaviours are considered high-risk for infectious disease. This is the evidence that has informed policies to date. There is little data for those with low risk, such as those in long-term monogamous relationships. New research must be done to generate the evidence required for low-risk groups to be identified and included as eligible donors without introducing risk to the blood system.

Because patterns, causes, and effects of HIV differ by country, there is no international scientific consensus on an optimal deferral policy. With our move to a one-year ineligibility period for MSM, we are asked what impact this will have on the adequacy of Canada's blood supply. Unfortunately, we don't have clear data there yet. After the change from permanent ineligibility to a five-year waiting period, about 100 donors who had previously been ineligible to donate due to having sex with another man returned to donate and were reinstated. Similarly, findings of the post-implementation compliance survey following the five-year deferral suggest that about 400 male donors who had had sex with a man after 1977 but at least five years ago would be eligible to donate annually.

A larger impact on supply may be related to how Canadian Blood Services is perceived by potential donors, particularly younger people who are most concerned about issues of social justice. This is why Canadian Blood Services makes extensive outreach to many organizations, including students, through campus presentations, and many meetings with interested groups. We acknowledge that frustration remains high amongst many stakeholder groups whose members feel that the most recent change to the eligibility criteria did not go far enough to address what they perceive as discrimination.

Our current one-year deferral for MSM is indeed only an incremental step towards more inclusive donor criteria. We recognize that the pace of change for many is frustratingly slow for the vast majority of MSM who are still unable to donate blood under the current criteria. We remain very grateful for the stakeholder collaboration and participation from across the spectrum of organizations, including the Canadian AIDS Society.

Dr. Devine will now briefly take you through the next steps of what lies ahead in terms of future potential changes to the MSM criteria.

● (0905)

**Dr. Dana Devine (Chief Medical and Scientific Officer, Head Office, Canadian Blood Services):** Thank you.

As Dr. Sher mentioned, we need solid evidence to support a further regulatory change, and that research and evidence do take some time to collect. In collaboration with scientists, the LGBTQ community, patient groups, and Health Canada, we are now focused on other possible changes to our eligibility criteria that we hope will permit more MSM to be able to donate blood.

With the recently available $3 million in research funding from Health Canada, we can plan and deliver research to work toward more inclusivity for our donors while maintaining the safety and adequacy of the supply of blood products for recipients.

One of the areas of research to explore is possible gender-blind or sexual-orientation-blind screening approaches, among others. For example, such an approach might include asking all donors whether they have had a new sexual partner or more than one sexual partner in a given time frame.

With the support of Health Canada, and in partnership with our sister organization, Héma-Québec, Canadian Blood Services will be holding a two-day meeting at the end of January in 2017 with national and international scientists. The meeting is being held in collaboration with leaders from the Egale Canada Human Rights Trust, the Community-Based Research Centre for Gay Men's Health, and the Canadian Centre for Diversity and Inclusion.

The objectives of this meeting are to inform and update participants on current national and international research, practices, and policy strategies, to identify key research questions to be answered, and then to develop a list of priority areas and potential research projects to answer those questions. We will discuss the barriers to research and how to overcome them. We will cultivate and promote new partnerships and collaborations to advance research in this area, and we will establish the processes for the application and granting of the research funds for this work. The patient and LGBTQ community representatives have been invited to attend the event as impacted observers and will be given an opportunity to address the attendees at the meeting.

Patients bear 100% of the risk associated with blood transfusion and, consequently, with those changes to donor eligibility criteria. Our goal is to maintain the safety of the blood supply while being as minimally restrictive as possible to donors.

We're really looking forward to the January meeting as our next step to help get us there.

Thank you.

**The Chair:** Thank you very much.

Now we will move to the Department of Health, with Catherine Parker.

**Ms. Catherine Parker (Director General, Biologics and Genetic Therapies Directorate, Health Products and Food Branch, Department of Health):** Thank you.

[*Translation*]

Good morning, everyone.

Thank you for having invited me to speak to the committee today. I am pleased to be here to speak to the role Health Canada, as a regulatory body, plays in optimizing the safety of Canada's blood supply. The issue, more specifically, is the role we play with regard to donor program exclusion criteria that apply to men who have had sex with men.

● (0910)

[*English*]

The federal government, through Health Canada, is responsible for regulating the safety of Canada's blood supply. Ensuring that Canadians have access to safe blood has been the cornerstone of Health Canada's response to the Krever Commission of Inquiry on the Blood System in Canada. Canada now has one of the safest blood systems in the world, thanks to the strict standards for the collection and processing of blood that are now in place in Canada. This has been highly effective, with no cases of HIV transmission by blood transfusion in over 25 years in Canada.

The lessons of the tainted blood crisis must never be forgotten, and the current regulatory system for blood safety has been designed to ensure that such a tragedy never happens again in Canada. It has also been designed to be sufficiently flexible to allow changes to be made to these standards when new information or technological developments warrant such a change. The safety of the system is paramount, and safety must be based on science.

In our commitment to maintain this high level of safety, Health Canada works in partnership with national and international stakeholders to actively look for any potential blood safety issues and to put into place any precautions, as needed, to stop the spread of infectious diseases through the blood supply. The cornerstone of those partnerships is our relationship with Canada's two blood operators: Canadian Blood Services and Héma-Québec, with whom we collaborate in an open and transparent way while still maintaining our arm's-length regulatory role.

As Dr. Sher has just stated, in Canada, blood is legally defined as a drug and is subject to the requirement of the Food and Drugs Act. A stand-alone set of regulations, known as the blood regulations under the Food and Drugs Act, describes all the stringent requirements that blood operators must meet for the collection, processing, testing, labelling, storage, and distribution of blood in Canada. These regulations are supplemented by comprehensive guidance, which interprets each clause of the regulation in non-legal terms. Blood collection sites across the country must be licensed by Health Canada and are subject to regular inspections by Health Canada inspectors.

The blood regulations mandate a series of steps that the operators must take when collecting blood, resulting in an overlayering of safety steps to maximize safety. The two most critical steps are advance donor screening and the use of state-of-the-art blood testing technology in order to eliminate the possibility of an infectious disease being transmitted to a recipient.

Blood recipients are among some of the most vulnerable of patients in the Canadian health care system, as many would not be able to fight potential infections that could be transmitted via blood. Donor deferrals, which attempt to identify prospective donors at higher risk of transmitting an infection and not allowing them to donate, are used extensively in blood donor screening. Donor testing is not sufficient alone, because, as Dr. Sher has described, despite advances in testing, there remains a period of time known as the window period between infection and the possible detection of a pathogen, during which there is a risk that infected units of blood may not be identified by testing.

Donors are therefore deferred for various periods of time if they are identified as being at higher risk for HIV, hepatitis, malaria, and other infectious diseases. However, specific deferrals are not part of regulatory requirements themselves. The blood regulations require that establishments collecting blood obtain from the donors information about their identity and their medical and social history that is relevant to determining their risk of infectious disease.

The blood operators themselves, meaning the CBS and Héma-Québec, can determine what types of questions are necessary. This is known as “performance-based regulation”, in which a standard is set in regulation but the regulated parties have the flexibility in determining how to meet this standard. Performance-based regulation allows for changes due to advances in technology and science to be implemented without the need for a complicated process to amend regulations and bring them up to date.

Under the blood regulations, the blood operators must have their processes, as well as any changes to these processes, approved by Health Canada. This is accomplished by the filing of a submission containing complete information pertaining to the process or change, which is reviewed by a team of Health Canada scientists.

In Canada, there are no regulations prohibiting MSM and other groups from donating blood. These donor deferrals are part of the processes that CBS and Héma-Québec have developed to meet the standard of safety by deferring a group that is statistically at a higher risk of transmission of certain diseases.

As we have seen recently, this is no longer a permanent deferral. Both CBS and Héma-Québec have worked diligently over the past few years to modify the MSM deferral, work which has resulted in two amendments: from a lifetime to a five-year deferral in 2013, and subsequently to a one-year deferral in 2016. Health Canada approved both of these changes following review of a comprehensive package of information filed by both CBS and Héma-Québec containing scientific information showing that these changes would not diminish the safety of the blood supply.

We acknowledge and support the efforts under way by CBS in researching possible alternatives to the MSM deferral as well as other deferrals. We are open to future submissions for further changes. However, our review of any request for a change to a deferral will be based on the principle that it is supported by current science and would not introduce unacceptable risk to the blood supply. This is a high bar to reach, but both CBS and Héma-Québec have reached it twice already with respect to MSM deferral.

Health Canada's decisions as the regulator must be based on scientific evidence. Therefore, should Health Canada be presented with sound evidence to support that the MSM-specific donor deferral policy can be eliminated without compromising the safety of Canada's blood system, this information will be assessed in accordance with Health Canada's standards.

*Merci beaucoup*.

● (0915)

**The Chair:** Thanks very much to all of you. I think we've all learned quite a bit already.

Our process is that we go now to a round of seven-minute questions. Then we have a round of five-minute questions and a short round of three-minute questions.

Today we're going to start with Dr. Eyolfson.

**Mr. Doug Eyolfson (Charleswood—St. James—Assiniboia—Headingley, Lib.):** Thank you, Mr. Chair.

Thanks to all of you for coming.

Dr. Sher, it's good to see you again. You may have referred to this in your presentation, but I want to confirm it. Do you have knowledge of the current prevalence and incidence of HIV in the MSM population?

**Dr. Graham Sher:** As I mentioned in my remarks, we do follow very closely the Public Health Agency of Canada's published data. We actually have it in front of us. It is true that the most recent set of published data, the 2014 data, show that for the prevalence of HIV, amongst all HIV cases, 54.3% represent the MSM population.

**Mr. Doug Eyolfson:** Okay. Would you say that's increasing or decreasing over time? What does the data say?

**Dr. Graham Sher:** In 2011, it was about 50%, and in the 2014 reported data, it was 54%. It's essentially been the same for quite a number of years. Dr. Devine has more information on this as well.

**Mr. Doug Eyolfson:** All right. I understand from the record that the safety record since these changes has been excellent. You've said that in 25 years there has not been a case of HIV transmission through the blood system.

**Dr. Graham Sher:** That's correct.

**Mr. Doug Eyolfson:** That's remarkable. I congratulate all of you for your efforts.

Now, on this deferral policy, when it comes to other jurisdictions, would you say that this one is among the more stringent or the less stringent? Would you say that other jurisdictions have even less stringent deferral policies than Canada's?

**Dr. Dana Devine:** I'll take that question for you.

If one looks at what's going on globally, we are amongst the countries that have led the change from a permanent deferral to something shorter. About a dozen countries now have either implemented or will be implementing a one-year deferral. Most of the other countries in the world are still on a permanent deferral.

● (0920)

**Mr. Doug Eyolfson:** All right.

You said that the current window for HIV is approximately 10 days for infection detectability. Is that right?

**Dr. Graham Sher:** That's right.

**Mr. Doug Eyolfson:** Do you see a potential, either in the near future or ultimately, to use that technology to further cut down the deferral to one of shorter duration?

**Dr. Graham Sher:** I'll make one short comment, Dr. Eyolfson, and then Dr. Devine can add to it.

The intent of the work we're going to do in January is really to examine two principal policy directions. Are we simply seeking to further shorten the time period but to keep it as an MSM policy? Or are we going to take a completely different approach, as both we and the Canadian AIDS Society have said, and embark on a policy that does not discriminate on the basis of gender or sexual orientation? We really need to understand that, because just an incremental shortening of the policy doesn't deal with the principal assertion of unfairness and discrimination.

It is possible that what you've mentioned would be one approach. I'm not necessarily sure that it's the ideal or the optimal one, but we need to gather the evidence and the research as to whether there is a different policy approach that we could take altogether, one that would not be simply an incremental shortening of the time period but keeping MSM as the target group. That's the analysis and the research questions that we're going to embark on and seek to answer before we can make the next policy change.

**Dr. Dana Devine:** I'm not sure I have anything to add to that. That really is the direction that we're going in.

**Mr. Doug Eyolfson:** Thank you.

Monsieur Lacasse, thank you for coming. I've practised medicine for 20 years, and I am familiar with the discrimination we see in the LGBT community in the general community and when they seek medical care. It is something that in medical education they've been trying to improve: to break down these barriers and to make sure that medical practitioners are aware of these issues and, from our profession's end, to try to fix them.

With regard to the fear and stigma around HIV/AIDS, what steps do you think need to be taken to help address this in the general population and in the medical community to decrease this fear and stigma?

**Mr. Gary Lacasse:** In regard to the stigma, are you talking about the population in general and not necessarily the blood services?

**Mr. Doug Eyolfson:** It's for the population in general.

**Mr. Gary Lacasse:** We need to have some behavioural data about stigma. There hasn't been that much behavioural research done for stigma for HIV. We are desperately looking for funds to be able to research behaviour, because we find that the key to any decrease in stigma or behaviour is through behavioural science. That's what we're looking for.

The stigma associated with it is that when we go to multi-windows of health providers, we get stigma repeatedly, at one window after another. We have people in the Maritimes who are not even getting tested for HIV because they live in a rural community, and they don't access care because it's their cousin who is behind the pharmacy window giving them their meds. That's the reality we live in Canada in rural settings. It's also in cities like Montreal, Toronto, and Vancouver. The stigma is everywhere. We encounter it in the workforce. We encounter it when we go for our groceries. It's in everything.

The stigma has to be addressed globally, really, but we also have to address self-stigmatization first, when somebody is first diagnosed with HIV. I think that's another key where we have to develop more behavioural research in order to understand first why people are self-stigmatizing themselves, so that they can face stigma, then, as they go through life.

**Mr. Doug Eyolfson:** I couldn't agree more. I remember finding out from people 20 years ago that insurance companies would refuse to insure them if they simply had an HIV test.

**Mr. Gary Lacasse:** Yes.

**Mr. Doug Eyolfson:** That was simply because, well, if you had reason to get an HIV test, you're obviously doing something that puts you at risk, so we're not going to take a chance on you and insure you. That was reality back in the 1990s.

I think a good piece of news is to show a piece of very faulty data that was out there. You probably heard the recent announcement in the last couple of months about the infamous “patient zero”, the Air Canada flight attendant who was basically blamed for the introduction of HIV to North America. It turns out that it was all based on faulty data and based on assumptions. On further review of that data, it turned out that it was completely wrong.

● (0925)

**Mr. Gary Lacasse:** Yes, exactly.

**Mr. Doug Eyolfson:** It was completely false that this patient was responsible for the introduction of it in North America. He was just one of the first that they found out about.

**The Chair:** I'm afraid your time's up.

**Mr. Doug Eyolfson:** All right.

Thank you very much for coming.

**The Chair:** Go ahead, Mr. Webber.

**Mr. Len Webber (Calgary Confederation, CPC):** Thank you, Mr. Chair.

First of all, I would like to begin my time by saying thank you to my fellow committee members for allowing this study to happen. I think it's long overdue. I appreciate your support for my motion back months ago.

Without question, our priority is a safe blood supply here in Canada. I know that our second priority is the expansion of the donor base for that blood system.

The government announced in June that they would reduce this ban from five years down to one year, and it showed me that science supported a reconsideration of our donation policies here in Canada. Is this one-year ban now based solely on science? Is the ban still somewhat arbitrary? That is what I was hoping to get from you here today. You've provided a lot of answers, and I appreciate that.

I do have some questions, and my first one is for Ms. Parker; I don't know if it's "Dr. Parker" or "Ms. Parker". Of course, Canadian Blood Services and Héma-Québec submitted their research to Health Canada in early 2016 in asking that the deferral for men having sex with men be dropped to one year. That was done in June, but you have not divulged the research to back up this decision. I know that others couldn't get this research through access to information, ATIP, and I suspect that most of this research was done with taxpayer dollars. Will you, or CBS, or Héma-Québec provide that supporting research to this committee?

**Ms. Catherine Parker:** Thank you for the question. The decision to authorize the reduction to one year was based on data that was submitted to us by CBS and Héma-Québec in a submission. We did in fact publish a summary of the research that we reviewed and how we came to the decision. That is on our website. I'm not familiar with why you would not have received additional information through an access to information request.

What we based our decision on was our scientists and statisticians reviewing the research data that the two blood operators provided to us.

**Mr. Len Webber:** That's interesting. Okay.

I have a question for the Canadian Blood Services. You mentioned in your presentation that in 25 years there has been zero transfer of HIV in blood transfusions. That's fantastic.

How many blood donations get rejected for testing positive for HIV? Can you give me some idea of the numbers?

**Dr. Dana Devine:** It's a handful. It's less than a dozen a year, typically.

**Mr. Len Webber:** Okay.

**Dr. Dana Devine:** Our screening system is quite effective with the questionnaire.

**Mr. Len Webber:** Do you take information from that, such as demographic information, or where this blood is coming from or from what clinics?

**Dr. Dana Devine:** We do contact every donor who has a positive test result for anything we test for. For the HIV-positive donors, we ask them a whole series of questions in trying to understand whether they were engaged in behaviours that would put them in a risk category, or whether they simply had no idea that they were HIV positive when they donated, or at risk of being HIV positive.

**Mr. Len Webber:** Okay.

I just want to talk a bit about your testing procedures. You have this antibody testing, this nucleic acid amplification testing, to test blood for HIV. Can this not be done with all blood that comes into your system?

**Dr. Dana Devine:** Every unit of blood that's donated to CBS is tested with all of those tests. In this country, we don't have any blood that's not tested.

● (0930)

**Mr. Len Webber:** Okay. Why is it necessary, then, to go through that initial screening with the questionnaires for those individuals who are wanting to donate blood? From there, you assess.... If you're testing it anyway for HIV, why would you even ask?

**Dr. Dana Devine:** The philosophy behind the maintenance of safety of the blood supply is a layered safety process. The first layer is the questionnaire. What we're trying to do in that process is to have only people come in to donate who are the least likely to test positive in any of the tests we're doing. Why do we do that? We do it in part because of this window period that Dr. Sher was speaking about. We do it also because none of our tests are completely perfect. We know that there can be errors in a test when it's conducted, because there are humans involved in the process. We also know that the pathogens themselves—the viruses, parasites, or bacteria that we're testing for—are living organisms, and their DNA mutates. They may mutate to the point where they're not picked up by the test, and we have actually seen that phenomenon happen.

All blood operators start with this screening process initially in trying to get donors who are least likely to be positive in their testing. That's the philosophy behind the screening assessment.

**Mr. Len Webber:** All right. That's interesting.

Let's talk a bit about this window period. Pardon my ignorance with respect to blood; I'm not a doctor or anything. On this window period, if you collect blood from somebody and you have no idea whether they have HIV or not, can that blood be stored for those 10 days, or whatever that window period is, to see whether or not that blood mutates, and then have it go through the testing in order to determine whether it has HIV in it?

**Dr. Dana Devine:** What you're talking about is a process that is used in some countries, not for whole blood donations, but for plasma donations. It's called "quarantine and retest". A donor would give a plasma donation that is frozen immediately. We freeze that anyway as part of the normal production. It then sits in the freezer for four or six months. The donor then subsequently comes back and gives another donation. If the donor tests negative on that second donation, then you're allowed to release the one that's been in the freezer for four to six months. That's the one place in which one can hold blood products for release.

For the fresh components, it doesn't work, because platelets only live for five days and you don't have enough time to wait.

**The Chair:** Your time is up.

Mr. Davies.

**Mr. Don Davies (Vancouver Kingsway, NDP):** Thank you, Mr. Chair.

Thank you to all the witnesses for being here.

For Health Canada, who initiated the reduction on the ban on the MSM population from donating blood from five years to one year? Was it Health Canada or was it Canadian Blood Services and Héma-Québec?

**Ms. Catherine Parker:** It was Canadian Blood Services and Héma-Québec. They have the responsibility to initiate the process to amend their approved conditions. They did that through a submission filing to Health Canada.

However, they had been in communication with us well before that point. We had been meeting and consulting together on their plans to submit that actual application.

**Mr. Don Davies:** Thank you, Ms. Parker. You anticipated my next question.

**Ms. Catherine Parker:** I'm sorry.

**Mr. Don Davies:** That's okay.

When did that request first come into Health Canada to review this policy and make the change?

**Ms. Catherine Parker:** To go to the one year, I believe we started discussing that in the previous year, 2015—what would be the data required, what type of information we would need to see—through a series of meetings and then subsequently received the submission.

**Mr. Don Davies:** There had been no prior requests from Canadian Blood Services or Héma-Québec to the previous government. The first request came to the current Liberal government? Or it came just toward the end of the Conservative government?

**Ms. Catherine Parker:** The only two actual requests we've had were for the change from the indefinite to five years in 2013, and then subsequently the change from five-year to one-year earlier this year.

**Mr. Don Davies:** Thank you.

Second, is there any country or jurisdiction in the world that has no restriction on the MSM population donating blood and simply relies on behaviour-based questioning?

**Dr. Dana Devine:** I'll take that one, if that's okay.

The answer is yes. There's a small number of countries that don't ask any questions about MSM at all. Spain and Italy are probably the most often cited countries who do that. They have a different process from what we have. Their donors are screened by physicians for the most part, so you have a different quality of ability to gather information about an individual's risk as opposed to the sort of bucket-screening that most blood operators do. There's a couple of countries in South and Central America that have also changed. I believe that Mexico removed their MSM questions about a year and half ago.

● (0935)

**Mr. Don Davies:** Is there any data from those jurisdictions that would indicate that there's any higher risk to the safety of the blood supply?

**Dr. Dana Devine:** The most thorough data that are out there come from Spain. They have actually seen an increase in the number of donors that they're picking up as HIV positive, and it is associated with MSM behaviour. In Spain right now, their health ministry is considering two different paths. For their data, part of which is the kind of behavioural research my colleague was speaking about, part of this relates to the fact that they think they might be asking the questions the wrong way and need to redesign their questionnaire. But they are also considering aligning themselves with most of the European countries that are moving to a 12-month deferral, so they would actually then reimpose a time-based deferral in Spain. Italy's data are not consolidated; I can't answer for Italy.

**Mr. Don Davies:** Okay.

In my next question, I want to rationalize two different parts of this. I think I may know the answer, but I want to make sure that I do. Both Dr. Sher and Health Canada have repeated several times that there is no 100%-safe test for pathogens.

You've talked about the window of between nine days and two months whereby a pathogen could get into the blood supply. You've said that safety is paramount and that it's based on the science. You look for potential risks and put in whatever protections are needed.

Also, Dr. Sher, I wrote down your words that you “expect donors to be honest”.

My question is about Health Canada's policy with respect to allowing paid plasma donors. The theory is that if you're paying donors to give plasma and you're appealing to vulnerable populations—poor people, drug users—you're creating an incentive for them to come. If they need money for the donation, the theory—and the worry—is that if you ask them about their behaviour, they have a financial incentive to be less than honest. I've been told and led to believe that there is no issue there with respect to plasma, yet....

I'm trying to square these two things. Are the tests 100%? Are donors' questions important or not? Or is it the difference between the way the plasma and the blood supply, whole blood, is stored and tested that makes these two different issues?

**Dr. Graham Sher:** I'll try to answer briefly. It's a complicated set of questions, Mr. Davies, but the short answer is that in blood donor systems around the world, such as Canadian Blood Services and many organizations like ours around the world, we do not pay donors. That's been a long-standing principle of non-remuneration for voluntary blood donors.

There is a commercial plasma industry whereby donors are reimbursed between $25 and $40, typically. The debate has often gone around whether the reimbursement process causes a higher-risk type of donor to come and participate. The evidence is abundantly clear—and I've actually presented it to this committee in a different setting—that when you look at the plasma products that come off the production line at the end of the process, whether they come from paid donors or unpaid donors, there is absolutely no safety difference whatsoever. The products are identically safe. The reason for this is not only the screening questions and testing, but also that plasma goes through a different set of additional purification and inactivation steps that render the product extraordinarily safe. But that's for plasma products: that's why the argument and the evidence is clear that paid donors and unpaid donors result in equally safe products.

What we're talking about here is whether the donors themselves have increased frequency of transmissible diseases. Because we don't have the pathogen reduction steps in the fresh blood system, it's one of the arguments against any reimbursement at all. We really need to distinguish the finished products coming off the production process contrary to what we're talking about here, which is the safety of blood that doesn't have that additional step in it yet. This is one of the reasons that, as Dr. Devine said, it's a tiered safety net. You don't reimburse, you ask questions, you test, and you rely on honesty, and this results in extremely safe blood components for recipients.

● (0940)

**Mr. Don Davies:** Thanks.

**The Chair:** Thank you very much.

Now we will go to Ms. Sidhu.

**Ms. Sonia Sidhu (Brampton South, Lib.):** Thank you, Chair.

Thank you to all our witnesses.

My question is for Dr. Sher. The court found that scientific evidence was lacking to support the indefinite deferral period for MSM to donate blood at the time. The deferral period has since been reduced twice, first to five years, and then to one year. In light of the present scientific evidence, what length of time do you recommend?

**Dr. Graham Sher:** Again, I'll perhaps provide the answer that I gave to Dr. Eyolfson. Dr. Devine can add to it.

We do not believe that it is a matter of randomly choosing a time period. The evidence was gathered in 2013 to support our five-year submission. The scientific evidence showed at the time that if we adopted that time period we would not negatively impact the safety of the system.

There is one very important element that, through your question, I would like to put on the table for the committee as a whole. A lot of the requirement that we had to do in 2013 was to ensure we could get the patient groups, who are the bearers of the risk here, onside with any policy change. For many, many years, patient groups in this country said they would not accept any change beyond the permanent deferral. We worked with them, as we did with advocates on the LGBTQ side, to say, let's take this in an incremental, evidence-based approach. We got all groups and a body of evidence to support a five-year policy. Once we had a further two years of evidence, we were able to show that a one-year policy would result in no further safety change.

The body of work we're now going to do, as Dr. Devine summarized, is to look at whether we go down to a shorter time period—six months, three months, four weeks—or we go to an entirely different screening process altogether that is not time based and that is much more inclusive for all donors, but doesn't alter the safety profile of the blood system? As Dr. Devine and I have both said, that's the evidence that is missing at the moment, and that's the research work that Dr. Devine and her colleagues are going to lead in Canada so that we can create a body of evidence to support our next submission to Health Canada.

I would argue that it's not good policy and it's not evidence-based policy to just choose another number—12 weeks or 24 weeks—because it doesn't deal with some of the concerns around this policy, which are concerns of inclusivity and fairness. We're trying to balance creating a body of evidence while at the same time recognizing the discriminatory aspects of the policy and also protect the safety of the blood for recipients, which is our ultimate mandate.

Put all of that together, and it could be another time period shorter than 12 months, or it could be a different set of approaches targeting either high-risk MSM individuals but not low risk, or not targeting anything at all. It's really that gamut of issues that we need to look at very carefully. Dr. Devine and her team will collaborate. It's behaviour-based research, social research, and scientific research all combined.

**Ms. Sonia Sidhu:** Thank you.

My next question is for the Canadian AIDS Society. Individuals who are infected with HIV are sometimes unaware they are infected. What initiatives should we take to promote testing?

**Mr. Gary Lacasse:** It's funny you should ask, because we launched this year's testing campaign just last week. We do testing campaigns across Canada, but the issue is also to get a national testing reference guide across Canada developed, because the testing is not at the same level in all territories and provinces across Canada, which is a hindrance to getting tested.

We do have broader-based testing campaigns specifically for high-risk populations. That's where we work and what we strive for. All of our members across Canada actively promote testing for people who are not infected with HIV, but also for those who are infected with HIV, because it's also extremely important for people living with HIV to have secondary prevention against other blood-borne diseases. That's an effort that's continuously being done with all community organizations and health providers across Canada.

● (0945)

**Ms. Sonia Sidhu:** Thank you.

My next question is for Health Canada.

On the federal government's role in ensuring the safety of the blood supply, I've heard about the safety procedures. Do you think they need to be improved or are you satisfied with the safety procedures?

**Ms. Catherine Parker:** I'm sorry. With our safety procedures and regulations...?

**Ms. Sonia Sidhu:** Yes.

**Ms. Catherine Parker:** The regulations for blood in Canada have been completely modernized and updated, and we are very committed to keeping them as updated as they need to be to reflect any changes in technology, so we're quite confident in the strength of our regulatory process. It is very intense. The regulatory requirements are very high. We have an inspection program of blood collection establishments. There is ongoing reporting that is necessary from the blood operators, so we're quite confident in our system.

**Ms. Sonia Sidhu:** Thank you.

**The Chair:** You still have another minute. Are you okay?

**Ms. Sonia Sidhu:** Yes.

**The Chair:** That completes our seven-minute round. We'll go to five-minute rounds now, with Dr. Carrie.

**Mr. Colin Carrie (Oshawa, CPC):** Thank you very much, Mr. Chair.

Thank you to all the witnesses for being here today.

My first question is for the Canadian AIDS Society.

First, Gary, I want to say thank you for all your good work over the years. We've heard that Canada is a leader, and I think a lot of it is due in part to organizations such as yours and the on-the-ground organizations.

When we learned recently that the health minister cut and reduced by a substantial amount funding to HIV and AIDS organizations across the country, I was a little shocked and surprised, frankly, particularly at how it was done. We know that organizations such as yours are on the front lines. You promote education and awareness, and you provide information and resources on the ground, on the front lines.

As we've heard, testing and prevention are the key to this issue. I was wondering if you could give us your opinion. How do you see these cuts affecting the progress that has been made in regard to HIV and AIDS to date, particularly in terms of the educational part of it, the prevention and the outreach?

**Mr. Gary Lacasse:** Well, we were happy to hear that we are getting transitional funding for the next year from the federal minister and from the Public Health Agency, but it is a band-aid reaction to the cuts that are happening. There's a change, a shift, and the landscape is changing, but it should not be to the detriment of people living with HIV. That's our stance. That will be our stance in our advocacy, and I'll be moving forward to get full funding for 2018 and increasing the funding to the community action fund, which will be pro-rated, with maybe an injection of more funds to our countrywide efforts against HIV.

The front-line services, which do prevention, treatment, and support work on the front lines, are the most affected by this funding cycle. Also, because we're focusing only on prevention for people who are HIV negative, for everybody who is living with HIV, it's about making sure that they stay undetectable, because we know now, with science, that people who are on their medication become undetectable and cannot transmit new HIV cases down the road. It's imperative, in the 90-90-90 approaches with UNAIDS, that we have a holistic approach to how we do prevention of HIV. We believe strongly that this is missing in the Canadian effort with the new funding cycle for community organizations.

That's what we'll be lobbying and going towards. I think that if we maintain a holistic approach to fighting HIV on all levels, it will ultimately be better for all Canadians, because we will reach zero transmission by 2030 if the money is put towards getting to that.

**Mr. Colin Carrie:** I hope you're successful with that. I'm certainly very supportive of it.

We were looking at your website. An estimated 75,500 people in Canada are living with HIV. This is more than ever before. The good news is that people are living, and they're living longer, but what surprised me is that one in five of them don't even know. This is what I find so important, and what is so important with the work that you guys do on the ground. We're talking today about MSM and gay men, who are the most affected by HIV and AIDS in Canada. As was stated earlier, they account for 56% of HIV/AIDS cases in Canada and 45% of new infections.

As we look at this issue, having more blood donors is obviously very positive, and it's something that I think we have to move towards, but the question again is whether the science behind a removal of the one-year ban sufficient enough to ensure the safe blood system in Canada? You mentioned something really important. You talked about the scientific and behavioural criteria, and you mentioned stigma. You mentioned an example in Nova Scotia. I know that Nova Scotia was hit quite hard with the cuts. What further research needs to be done, and what more can we do, for example, for the scientific and behavioural criteria? Do you have examples of that?

● (0950)

**Mr. Gary Lacasse:** Yes. There's been some behavioural and community-based research that has been done in the last couple of years, but very little. One of the trailblazers in behavioural research for HIV and related STBBIs is Joanne Otis from the University of Quebec in Montreal. She has based her whole life's work on behavioural science and behaviour to see why men will reduce their protection barriers in their sexual behaviour.

That, I think, is the key to understanding what the behaviour is in the MSM population and the whole population in general, because we must not lose sight of the fact that 32.6% of new HIV cases are heterosexual people. There's a big percentage that's heterosexually based.

When we look at MSM and the whole portfolio, at aboriginals, and at different populations, it's extremely important to understand what is the behaviour. Is it the users of opioids? Is it intravenous drug use? Is it because there are new immigrants coming into Canada who look for different alternatives or whatever? That has to be researched. If we're going to find the key, it will be based on behaviour, I find, but it's also scientifically based.

**The Chair:** Your time is up.

Mr. Kang.

**Mr. Darshan Singh Kang (Calgary Skyview, Lib.):** Thank you, Mr. Chair.

I would like to thank all the panel members for coming here and shedding some light on this issue.

On June 16, 2016, Health Canada granted Canadian Blood Services and Héma-Québec the authorization to change the donor criteria for MSM from requiring a deferral period of five years to a period of one year. What kind of donor increase did you have you changed from the indefinite deferral to five years? Do you have any data proving that the number of donors went up when you reduced that to one year from five years?

**Dr. Dana Devine:** I'll try to answer that. It's not a straightforward question to answer because we don't actually ask a question any longer. We don't really know what our denominator is, but we do know that in the days when we were having permanent deferrals, we would put a code on donors' files if they had reported MSM behaviour. We know that when we went to the five-year deferral, we gained back about 100 donors. As we've gone to the one-year deferral, we know that we've taken this code off about 400 donor files.

We do believe that the number of people who are now eligible to donate and who couldn't donate previously is larger than that, but because we're not actively asking for that information any longer, we're not completely sure. I would say that it's a few hundred. It would be less than 1,000.

**Mr. Darshan Singh Kang:** My next question is about the estimate of blood that will be accessible by eliminating the deferral time. What amount of blood will be accessible?

**Dr. Dana Devine:** We haven't tried to quantify in that way. There are satellite effects of changing this donation, which also includes the fact that as we are working to improve the eligibility of donors, others who have not been donating because they're angry about deferral practices that Canadian Blood Services has had, are starting to say that this is becoming more reasonable. They come back to donate or they start to donate a first time. Again, we don't have exact numbers for that.

● (0955)

**Mr. Darshan Singh Kang:** Thank you.

My question is for the AIDS Society about funding cuts. I think the funding remains at $26.4 million annually and there is no funding cut?

**Mr. Gary Lacasse:** The funding has been maintained at $26.4 million, yes. That stayed, but there was a shift in the funding landscape, and that had the repercussion that 33% of organizations across Canada, including at the Canadian AIDS Society, were defunded because we were not meeting the objectives of the new criteria, but the criteria were lacking a lot of transparency and were shifting continuously without any community engagement to see what the new funding should look like. We were blindsided by the new funding, but we also saw that, since 2008, $13.8 million out of the fund was not spent by previous governments.

What we're requesting is that the money that was not spent be re-addressed to address the shortfalls in the funding which we see now. When we look at the new transitional funding for the one year, a lot of the gaps are going to be addressed that were not addressed in the funding. Public Health said there were enormous gaps that they didn't address in the funding cycle this year, and that they didn't expect that there would be so many gaps. They're addressing it, so hopefully we'll have a better impact.

**Mr. Darshan Singh Kang:** So it's not the present government, but the previous government somehow. What was the reason not to spend that money?

**Mr. Gary Lacasse:** We saw that under the different portfolios of the federal initiative it was not spent. It could have been under research. It could have been under community action. It was different. It was throughout all the portfolios of the budget.

**Mr. Darshan Singh Kang:** But the reason.... I'm asking for the reason why the funding—

**Mr. Gary Lacasse:** We were never able to get the reasons why it was not spent.

**Mr. Darshan Singh Kang:** Okay.

**The Chair:** Your time is up.

Now we move to Ms. Harder.

**Ms. Rachael Harder (Lethbridge, CPC):** My first question is for Health Canada.

I understand that $3 million of funding has been given to do behavioural research. Can you explain a bit about how that funding is being used and about what you're hoping to accomplish through that funding?

**Ms. Catherine Parker:** Certainly.

The funding is $3 million for CBS and Héma-Québec, actually, and the use of that funding is to support research into alternatives to the MSM deferral. It would basically be supporting projects focused on examining alternative screening approaches, and also, perhaps, with respect to funding projects related to other types of technology, such as pathogen reduction, which is a type of potential treatment of blood.

The international conference in January, which Dr. Sher referenced in his remarks, is going to be used to set the research agenda, the priorities, and what the bulk of the funds would be used to support.

**Ms. Rachael Harder:** Okay.

Who's invited to that conference? Who are the stakeholders at the table who are helping to make that decision?

**Dr. Dana Devine:** Maybe I'll take that, since I'm organizing the conference. The stakeholders at the table are in two different categories, really.

The intention of this meeting is to set a research agenda, and we have invited a collection of researchers from the Canadian university setting, for the most part, and also some international folks who do research in this area internationally in countries that have looked at making changes or have made them. This group is being asked to come together to help us understand what are the research questions, what are the studies need to be conducted to answer those questions, and what are the barriers preventing us from doing that research in Canada.

We have also invited representatives of patient advocacy groups and representatives of LGBTQ stakeholder organizations to attend that meeting, and there will be some representatives there from ministries of health from other countries that are looking at changing their MSM deferral.

That's sort of the general group.

● (1000)

**Ms. Rachael Harder:** Okay. I'm sorry. Maybe I missed this on the list, but will there be patient advocacy groups there at all?

**Dr. Dana Devine:** Yes.

**Ms. Rachael Harder:** Ms. Parker, you talked a bit about the deferral window and about the fact that Spain and Italy do not actually have one. I understood from your statement that Spain has seen an increase in HIV-positive blood. Did I understand that correctly? Or was that not you?

**Dr. Dana Devine:** No, it was me.

**Ms. Rachael Harder:** That was you?

**Dr. Dana Devine:** Yes, it was, and, yes, you did understand that correctly.

**Ms. Rachael Harder:** Okay. Is that simply because they're basing their blood acceptance on, I guess, self-disclosure, basically, rather than actually testing the blood?

**Dr. Dana Devine:** They just don't ask that question at all if you're a man who's had sex with another man—

**Ms. Rachael Harder:** Okay. They don't ask the question at all?

**Dr. Dana Devine:** That's correct. When they removed the question.... They used to have a permanent deferral, like most other European countries did at the time. They removed it and they saw an increase in the number of donations that were showing up as HIV positive. Either these were men who didn't know that they were HIV positive, or there was some question in Spain at the time that they didn't have a very good system for getting tested, so there were people who were coming to donate blood to get tested.

**Ms. Rachael Harder:** Okay. Do you know what that increase was?

**Dr. Dana Devine:** It was about double.

**Ms. Rachael Harder:** It was double. Thank you.

This question is for CBS. From your perspective, how would patient advocacy groups respond to us totally doing away with the deferral process, let's say?

**Dr. Graham Sher:** I'll perhaps begin. I made that comment a few minutes ago.

I think it's a very important question. Certainly when Canadian Blood Services began its work in 1998, we initially made extensive outreach to the patient communities, because they were really the ones who bore the brunt of the consequences of the so-called tainted blood era in Canada. I think we have understood for many years that with every decision we make with respect to blood safety, the ultimate bearers of risk are those who receive blood. Donors are not obligated to be donors, but recipients are involuntary in their receipt of blood. If you have a car accident or cancer, and your physician prescribes blood, you don't really have a whole lot of choice, typically, in getting it. We have always recognized that every decision we make has to bear in mind the recipient as the ultimate bearer of that risk.

That said, with respect to the MSM policy, we have worked enormously hard with patient advocacy and patient stakeholder groups, as we have with stakeholders on the other side, the LGBT community. For many years the patient groups said, “We're not interested in a change to the policy. It suits us just fine. We don't care that it's broad and discriminatory.” But we were able to bring them along and have them recognize that there's a balance here. There a fairness issue. You can still protect safety at the same time.

That is why we landed on a five-year policy as step one. It is why, with greater trust and confidence, we moved to the one-year period. As Dr. Devine said, the patient groups will be front and centre in helping understand and inform the research agenda. It's essential that we keep onside that community along with the individuals who feel discriminated and left out. We really have to work with stakeholders on all sides of the equation here, but the patients are the ones who bear the risk.

**Ms. Rachael Harder:** Thank you.

**The Chair:** Your time is up.

Mr. Oliver.

**Mr. John Oliver (Oakville, Lib.):** Thank you very much, Mr. Chair.

Thank you very much for your testimony today.

Of the blood that's donated, what percentage is used in human transfusion and roughly what percentage goes into research and other purposes?

**Dr. Dana Devine:** It depends on which blood component we've made out of that. If we look at the red blood cells that we use for transfusion, the vast majority of this blood is transfused. A small proportion of it actually outdates, because you can only keep it for 42 days. It may not get used, particularly in some of our smaller hospitals who keep it because they might need it. The discard rates are in low single digits for donated blood.

Research blood is actually donated specifically for research.

**Mr. John Oliver:** So it's recognized by the donor at the time that it's going to research.

**Dr. Dana Devine:** Absolutely. The donors provide informed consent.

**Mr. John Oliver:** Okay.

In a previous life, I worked in a hospital that served a large population of people from the Jehovah's Witness faith group. We had a physician who was part of that faith group and worked through some quite robust strategies in ER and OR to manage the population without having to use blood transfusions. It was all done through the medical advisory committee reviews and whatnot. This was back just when the crisis hit. When we were doing all the look-backs, the patient notifications, and the work on transparency at that time, no one from the Jehovah's Witness group, that I can remember, was involved. That's going back 15 or 20 years.

Do we do enough to push for the non-use of blood products? I was looking at the research last night. There are volume replacement strategies. There are high inspired oxygen concentrators. There are patient blood management programs, both interoperative and post-operative. There are cell salvage strategies that could be employed, and autologous donations. Could we not be doing a lot more to reduce the risk of blood transfusion by doing a better job of using alternatives to blood transfusion?

● (1005)

**Dr. Dana Devine:** The simple answer is, yes, we can always do more. There has been a huge amount of work done in this area. I think society owes the Jehovah's Witnesses a debt, because they have driven surgeons to develop procedures that use less blood. They have changed the mindset around blood transfusion.

Essentially two decades later, most developed countries in the world have seen a dramatic decrease in the amount of blood that's transfused annually. It really is the culmination of better surgical techniques, some better drugs, and the thinking about who gets a transfusion—namely, that it is a medical procedure, and you only need to do it if it's absolutely necessary. I think the mindset about blood transfusion has shifted quite a bit in the way that physicians use blood products. We're probably one of the only businesses I can think of that's actively trying to not sell our products.

**Mr. John Oliver:** I noticed in your document that you're looking for 100,000 new whole blood donors in the next three years. Again, with trying to move away from the reliance on transfusion, what's driving that demand? Is it an aging population or...?

**Dr. Dana Devine:** Part of it is just that there's a large number of people every year who essentially stop donating, for one reason or another. Either they've stopped being a donor and turned into a patient, or they've moved to somewhere where we don't have clinics. We lose a lot of donors every year just for life circumstances, or because they didn't have a very positive experience donating and they don't want to come back. There's a whole lot of different reasons why people stop.

We are always recruiting new donors, all the time. We have brought in a couple of changes in the blood system. Recently, the most notable one is to actually change the amount of time between donations for women donors, because we want to make sure that we're not causing a loss of too much iron for women.

**Mr. John Oliver:** It's more about donor replacement than—

**Dr. Dana Devine:** It is about donor replacement.

**Mr. John Oliver:** —it is about increasing medical usage.

**Dr. Dana Devine:** That's right.

**Mr. John Oliver:** To the Department of Health and Catherine Parker, are we doing enough to promote and encourage alternatives to blood transfusion? There is risk in it. Some of the new technologies and the new strategies, and even the autologous donations, seem to have less risk.

**Ms. Catherine Parker:** In addition to regulating the blood supply, we are also responsible for the regulation of pharmaceutical and biologic drugs. I can confirm that there has been a great deal of development in the drug field in products that can be used as alternatives to blood, not just in developing new products, but in reformulating currently available drugs to make them more suitable for certain populations, such as the Jehovah's Witnesses, who do not want to have any trace of blood products at all. I would say that there's an extreme amount of development in that area.

**The Chair:** Your time is up.

**Mr. John Oliver:** Thank you very much.

**The Chair:** Now we'll go to our three-minute round with Mr. Davies.

**Mr. Don Davies:** Thank you.

I want to follow up on my earlier question on plasma to make sure I really understand that.

Dr. Sher, you said, if I understand correctly, that the transmission rate is low for recipients of plasma products because of virus removal and “inactivation”. Does that mean that residual risk of virus transmission is not influenced by the incidence rate of infection in the donor population for plasma products? In other words, it doesn't matter, in the donor population, whether they're infected or not. You're saying that the testing and processing of the plasma will eradicate the risk. Is that what your testimony is?

**Dr. Graham Sher:** It's a little bit of yes and no, Mr. Davies.

What I'm saying is that when you look at residual risk of the finished product, there is absolutely no difference between plasma products made from remunerated donors and plasma products made —

● (1010)

**Mr. Don Davies:** Dr. Sher, I'm going to interrupt you. You've said that already and I understand that. I'm delving deeper than that.

I'm trying to find out.... What I think you're saying is that the way that plasma is processed eliminates the risk, which would then logically say that it doesn't matter if donors walk in and are infected, because you're saying that it will be caught through the process. That's what I'm trying to understand. Is that what you're saying?

**Dr. Graham Sher:** What I'm saying is that if you look at the paid plasma system and the unpaid blood system, the donors coming in may indeed have different seroprevalence rates for hepatitis and HIV.

What we cannot say categorically is that it's simply because you're paying them. They collect in different markets. They have a slightly different set of questions. They have slightly different processes. Is it the act alone of paying that is causing that raw seroprevalence data to be slightly different? We don't know that for sure.

The only abundantly clear evidence, which I keep coming back to, is the finished product. What you're asking me is whether the act of paying, in and of itself, raises the risk of HIV in the donors coming in. What you have to recognize is that the way the paid plasma industry operates—where it sets up clinics, how it recruits donors—is markedly different from what the not-for-profit unpaid blood system does, so you're not comparing like for like. That's the important distinction I'm trying to make.

**Mr. Don Davies:** Let me ask Health Canada. I'm still not getting my answer, I don't think.

The reason we need to have the one-year ban on MSM, we say, is that there's a window period where you don't know if that blood is infected or not, so you want to ask the question, and obviously the testing is not 100%. Yet when it comes to paid plasma, we're saying that we can accept elevated risk in the process by paying people, thereby creating an incentive to be dishonest, perhaps—I think that's just logic—because the process will catch it down the road, whether it's by freezing the plasma or otherwise.

I'm trying to find out for sure: is the different attitude towards paid plasma and the MSM ban because of the technology of dealing with the plasma versus whole blood or not? Ms. Parker, can you help me with that?

**Ms. Catherine Parker:** Yes, I hope so. I'd like to clarify that plasma donors in Canada are very strictly regulated. Plasma donation is strictly regulated. Plasma donors, whether they are paid or not, go through a very rigid screening process.

**Mr. Don Davies:** Is it more rigid than for blood donors?

**Ms. Catherine Parker:** No, but it's equally rigid. There are various aspects of the plasma donation process designed to try to eliminate people who may be there just to collect the small payment. They need to provide proof of a fixed address and things like that. The donor screening and the donor testing are very rigid as well.

As I said earlier in my remarks, with blood safety, we're looking at overlaying rings of steps. The same is true with plasma donation. There is rigid regulation of the collection and the donor eligibility. There is also rigid regulation of what happens to that plasma after it is collected. It goes somewhere and it is made into plasma products. For those plasma products to come back into Canada, they must go through a whole separate drug authorization where every aspect of the viral inactivation, all the steps taken to address any contaminants that may be in the plasma, are—

**Mr. Don Davies:** More so than for blood products?

**Ms. Catherine Parker:** It's a different situation, because the plasma is processed, and it's actually processed into commercial drugs. There is that whole processing step.

**Mr. Don Davies:** You're saying it's that step that provides the certainty that the final product will—

**The Chair:** Mr. Davies, you're way over now.

**Mr. Don Davies:** I'm sorry. Thank you.

**The Chair:** That's all right.

That completes our rounds of questions. I thank the presenters very much.

I have a question, though. A few years ago, I went to donate blood as usual, and I was told I couldn't donate blood because I was too old. I had to have a doctor's certificate because I was over 65. That really screened me out from donating blood. Is there any other group that is discriminated against besides seniors? Is it a national standard or is this a local standard?

**Voices:** Oh, oh!

● (1015)

**Dr. Dana Devine:** You'll be glad to know that you're welcome back. Health Canada has granted us approval to remove the upper age limit, so come on back.

**The Chair:** There's no age limit?

**Dr. Dana Devine:** No, but we have other reasons why people would be deferred. It depends on where you take your warm vacations in the wintertime. That could get in the way. If you spent certain amounts of time in Britain during the mad-cow era, you'll be permanently deferred. We have a long list of other reasons why we defer donors, but ageism is no longer one of our problems.

**The Chair:** When did that rule change?

**Dr. Dana Devine:** It was eighteen months or two years ago.

**The Chair:** All right. Thanks very much.

Again, thanks very much for your presentations. It gives us a great foundation on which to move forward. Thanks to all of you for your attendance.

Thanks to the committee for the good questions and participation.

We're going to have a five-minute break. Then we have some committee business to discuss.

[*Proceedings continue in camera*]