Canada’s Blood Donation Eligibility Criteria for Men Who Have Sex with Men

Dr. Graham D. Sher
Chief Executive Officer, Canadian Blood Services

Dr. Dana Devine
Chief Medical and Scientific Officer, Canadian Blood Services

Executive summary

- Patients bear 100 per cent of the risk associated with blood transfusion, and, consequently, with changes to donor eligibility criteria. Our goal in establishing and re-evaluating these criteria is to maintain the safety of the blood supply while being as minimally restrictive as possible.

- Blood is regulated as a drug by Health Canada. This means Canadian Blood Services must demonstrate changes to policies and procedures potentially affecting patient safety introduce no measurable additional risk to the blood supply system before receiving federal approval for adoption. Because of this requirement, substantial changes to donor eligibility criteria are structured, research-based, often consultative processes that take time.

- Because of the history of the tainted blood crisis of the 1980s and 1990s, changes to the donor eligibility criteria for men who have sex with men (MSM) have been incremental and have required substantial analysis and ongoing engagement with patient, LGBTQ (lesbian, gay, bisexual, trans and queer) and other stakeholder groups to maintain donor and public trust.

- In 2010, the Ontario Superior Court found that blood donation is a gift, not a right, and that Canadian Blood Services’ donor eligibility criteria for MSM are not discriminatory based on sexual orientation, but rather are based on epidemiology and safety considerations.

- Canadian Blood Services has reduced the five-year waiting period introduced in July 2013 to a one-year waiting period introduced in August 2016.

- Our current one-year deferral for MSM is an incremental step toward more inclusive donor criteria.

- We recognize the pace of change is frustratingly slow for the vast majority of MSM who are still unable to donate blood under the current criteria.

- We are now working on further possible changes to these criteria that hopefully will permit more MSM to donate blood.

- This work involves collaborating with scientists, the LGBTQ community, patient groups, and Health Canada to determine how to gather the scientific evidence required to reliably identify low-risk, sexually active MSM within the Canadian context.

- This research agenda and its outcomes are crucial to moving from a time-based deferral to criteria based on risk determination, and will include investigation of possible gender-blind or sexual-orientation-blind approaches, among others.
• With the recent grant of $3 million in research funding specific to this area from Health Canada, an essential next step is to hold a meeting in January 2017 with national and international scientists to identify possible research projects for closing knowledge gaps related to alternative screening approaches for donors.

• For example, there are no large cohort studies of MSM who have been in a long-standing monogamous relationship; such studies would aid in the development of evidence supporting alternate donor eligibility criteria.

**Canadian Blood Services**

Canadian Blood Services is an independent, not-for-profit organization that operates at arm’s-length from governments and serves health-care systems by providing products and services in the fields of transfusion and transplantation medicine. It is regulated by Health Canada and funded by the provincial and territorial (P/T) governments (excluding Quebec). The P/T ministers of health serve as corporate members and appoint the Canadian Blood Services board of directors.

The organization was created in 1998 in response to the inquiry led by Justice Horace Krever into the tainted blood tragedy. In the wake of the Krever Commission, the organization was given the mandate for a national blood supply system that assures access to a safe, secure and affordable supply of blood, blood products and their alternatives. Within this context, we manage the national supply of blood, blood products and stem cells and related services, for all provinces and territories excluding Quebec, whose blood supply is managed by Héma-Québec.

Our role includes development and management of the national public cord blood bank, and we are the sole procurer, contract manufacturer and distributor of plasma protein products in Canada (excluding Quebec). We also lead an integrated, interprovincial system for organ donation and transplantation for all of Canada and operate the groundbreaking Canadian Transplant Registry and related programs, which are improving and saving the lives of Canadians waiting for organ transplants.

Canadian Blood Services provides value to Canadians through improving patient outcomes, enhancing health-system performance and optimizing cost-efficiency. We operate an integrated, pan-Canadian service delivery model; our national scope, infrastructure and governance make our organization unique in the Canadian health-care landscape.

**Donor screening, risk assessment and the testing of blood products**

Canadian Blood Services is recognized by governments as having the medical and scientific expertise required to recommend criteria determining who is eligible to donate. At the same time, Health Canada regulates blood as a drug and Canadian Blood Services as a biologics manufacturer. Canadian Blood Services must demonstrate that changes to donation criteria and procedures potentially affecting patient safety introduce no additional measurable risk to the blood supply system before these changes are approved by Health Canada. The structured, research-based, often consultative processes required to meet this requirement take time.
Patients bear 100 per cent of the risk associated with blood transfusion, and, consequently, with 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. Like other blood operators nationally and internationally, we employ a number of tools to ensure our products are safe for patients to use and that we maintain an adequate supply of fresh blood and plasma products.

Donor screening
Before donating blood, donors are first screened to make sure blood donation would be safe both for them and for the patients who will receive blood products. Donors may complete an online screening process on the day of their donation, or complete the questionnaire at a donor clinic. We expect donors to be honest about their exposure risks. At the clinic, our screening personnel go over the donor’s answers to the questionnaire and perform additional steps to determine whether the donor is eligible to donate, including measuring blood pressure, temperature and hemoglobin levels. We do not perform individual risk assessments as would be done by a personal health-care provider.

Based on their answers, donors are separated into broad risk categories and are either determined to be eligible or ineligible to donate accordingly. Donors may not be eligible to give blood for a variety of reasons and for varying lengths of time. The following table highlights a few common reasons a donor may be ineligible to donate blood:

<table>
<thead>
<tr>
<th>Eligibility criterion</th>
<th>Waiting period before being eligible to donate blood</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dental extraction, root canal or dental surgery</td>
<td>72 hours after treatment, as long as donors have fully recovered</td>
</tr>
<tr>
<td>Zika risk</td>
<td>21 days after returning home for donors who have travelled outside of Canada, the continental U.S. and Europe</td>
</tr>
<tr>
<td>Vaccinations</td>
<td>Waiting period varies from three months to up to 52 weeks depending on the type of vaccination</td>
</tr>
<tr>
<td>Tattoo or body piercing</td>
<td>Six months due to increased risk of hepatitis B</td>
</tr>
<tr>
<td>Men who have sex with men</td>
<td>One year after last sexual contact</td>
</tr>
<tr>
<td>Malaria risk</td>
<td>One to three years, depending on how long donors were in the affected geographic region</td>
</tr>
<tr>
<td>Variant Creutzfeldt-Jacob disease (mad cow) risk</td>
<td>Permanently ineligible if donors have spent a cumulative total of three months or more in the U.K. or France between January 1980 and Dec. 31, 1996, or a cumulative total of five years or more in Western Europe outside of the U.K. or France since 1980 through to Dec. 31, 2007</td>
</tr>
</tbody>
</table>
In 2010, the Ontario Superior Court found that blood donation is a gift, not a right, and that Canadian Blood Services’ donor eligibility criteria for MSM are not discriminatory based on sexual orientation, but rather are based on epidemiology and safety considerations.

**Epidemiology and risk assessment**

Eligibility criteria presented on the donor questionnaire are determined through epidemiology and risk assessment 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 blood recipients. We also continually scan for emerging pathogens both at home and globally, such as the Zika virus.

We monitor Canadian and international data over time to observe trends, identify areas for further research, and determine actions to keep blood as safe as possible and the system as a whole operating smoothly and efficiently. Our risk models are informed by data related to pathogens of interest, or where this information is not available, related pathogens. We also consider data from population-based studies such as those performed by the Public Health Agency of Canada. After a significant change in donor eligibility criteria, we use anonymous surveys to assess the rate of our donors’ compliance with the revised donor questionnaire. This information is also an important contributor to the overall safety of the system.

**Blood testing**

Canadian Blood Services tests every donation for HIV I and II, hepatitis B and hepatitis C, human T-lymphotropic virus I and II, and syphilis. Testing for Chagas’ disease is performed on individuals identified as being at risk on the donor questionnaire. West Nile Virus testing is done during the at-risk period of the year (spring, summer and fall) and on certain travelers during the winter season. Testing is performed using automated equipment and assays specifically licensed for blood donor testing. We build in redundancy in testing, with more than one test for each of HIV, hepatitis B and hepatitis C.

While our technology is sophisticated and includes state-of-the-art nucleic acid testing (known as NAT), there is a brief period shortly after infection when pathogens still are not detectable. If an individual were to donate blood during this “window period” in the early stages of infection, our testing process would not detect the virus and the blood products manufactured from that donation would be infectious to patients. The window period is now less than 10 days for HIV and hepatitis C, and less than two months for all pathogens. No test is 100 per cent perfect, however, and can fail for technical reasons or because the pathogen has mutated.

**Factors informing the current one-year ineligibility period for MSM**

**Historical context**

Because of the history of the tainted blood tragedy, changes to the donor eligibility criteria for MSM have required substantial analysis and ongoing engagement with patient, LGBTQ and other stakeholder groups to maintain donor and public trust. Within this context, Canadian Blood Services has moved from a five-
year waiting period introduced in July 2013 to a one-year waiting period introduced in August 2016. Additional information on the origin of the eligibility criteria for MSM in Canada, as well as Canadian Blood Services’ history of stakeholder engagement in support of change over the past two decades, is provided in the closing sections of this document.

In its response to Canadian Blood Services’ application to move from permanent ineligibility to a five-year waiting period, Health Canada asked that Canadian Blood Services and Héma-Québec gather a minimum of two years of data demonstrating no further risk had been introduced to the blood system before requesting a further reduction in the waiting period for MSM. This requirement was met without issue: our data shows the current one-year deferral easily covers the window period for HIV, hepatitis B and hepatitis C, with residual risk for these three pathogens being less than one in 1,000,000 units transfused. (Residual risk is the risk to patients from the donation of a very recently infected donor.) Similarly, post-implementation monitoring showed no adverse impacts on the prevalence of HIV in donors, donor compliance, or trust in the blood system. This data permitted Canadian Blood Services to move forward with an application to Health Canada for a one-year deferral period.


MSM and HIV risk
According to the Public Health Agency of Canada, MSM remains a high-risk group for both prevalent and newly infected HIV cases in Canada. Men who have sex with men account for approximately half of new HIV infections. Large cohort studies on MSM populations in Canada also show a high frequency of risk-related behaviours, such as anal sex without condom use, or inconsistent or inadequate condom use. However, since their primary goal is to aid in the development of preventive health strategies, these studies tend to recruit participants from a highly sexually active subset of the MSM population.

Significantly, there are no large cohort studies focused on MSM who have been in a long-standing monogamous relationship, or who have not been sexually active for one year. Such studies would aid in the development of evidence supporting alternate donor eligibility criteria. Indeed, individuals who have not had male-to-male sex in the past year are usually excluded in these studies.

Portions of the MSM population may also be at risk for emerging agents that are sexually transmitted. Those individuals at particularly high risk would be MSM who are currently sexually active, have multiple partners, and are engaging in high-risk sexual practices. Men who have not had sex with a man for one year would be expected to be at lower risk for an emerging pathogen because by definition, the pathogen was not present at all or to the same extent one year ago. Overall, these individuals are also less likely to have had multiple recent partners, given that they have not had sex with a man for over one year.

Lack of international consensus
Because the patterns, causes and effects of HIV differ by country, there is no international scientific consensus on an optimal deferral period for MSM. While some European countries still permanently exclude blood donations from MSM, most have moved to a one-year waiting period from last sexual
contact, including France, the Netherlands, Sweden, Finland and the U.K. Some blood centres in Spain and Italy ask about safe sex practices or monogamy, but their blood systems are also structured differently than Canada’s. In those countries, physicians interview individual donors and may be able to perform individual health assessments. Australia has maintained a one-year waiting period since 2000, with a low, stable rate of HIV-positive donations before and after implementation of the criteria.

Impact on adequacy of supply
It is difficult to estimate the impact the one-year ineligibility period for MSM will have on the adequacy of Canada’s blood supply. After the change from permanent ineligibility to a five-year waiting period, almost 100 donors who had previously been ineligible to donate due to having had sex with a man much earlier in their lives returned to donate and were reinstated. Similarly, the findings of the post-implementation compliance survey following the five-year deferral suggest approximately 400 male donors who had had sex with a man after 1977 but at least five years ago would be eligible to donate annually. As demonstrated by previous anonymous surveys in Canada and internationally, however, some of these people may actually be giving blood already.

A larger impact on supply may be related to how Canadian Blood Services is perceived by potential blood donors, particularly by younger people who are most concerned about issues of social justice. New donors account for 15 per cent of all donations annually, and represent 20 per cent of active donors each year. With the aging of the general Canadian population, and the donor population in particular, failure to engage younger donors will become an increasing problem in maintaining the donor base.

We aim to expand the active donor base by at least 10 per cent over the next three years. This will require the recruitment of approximately 100,000 new whole blood donors each year. Canadian Blood Services has performed extensive outreach to students and faculty through campus presentations and meetings with interested groups. However, frustration remains high amongst student groups, whose members feel the most recent change to the eligibility criteria for MSM did not go far enough to address what they perceive as discrimination.

Next steps
We are now focused on further possible changes to our eligibility criteria that we hope will permit more MSM to donate blood. This work involves collaborating with scientists, the LGBTQ community, patient groups and Health Canada to determine how to gather the scientific evidence required to reliably identify low-risk, sexually active MSM within the Canadian context. This research is crucial to moving from a time-based deferral to eligibility criteria based on risk determination.

With the recent availability of $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 is to explore whether screening questions can be used to identify a low-risk population of donors, regardless of gender or sexual orientation. 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, in partnership with Héma-Québec, Canadian Blood Services will be holding a two-day meeting in January 2017 with national and international scientists. The meeting will be...
held in collaboration with leaders from 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 the meeting are to:

- Inform and update participants on current national and international research, practices and policy strategies.
- Identify the key research questions to be answered.
- Develop a list of priority areas and potential research projects to answer those questions.
- Discuss barriers to research and how to overcome them.
- Cultivate and promote new partnerships and collaborations to advance research in this area.
- Establish processes for the application and granting of research funds for this work.

Patient and LGBTQ community representatives have been invited to attend the event as impacted observers.
Appendix: Evolution of Blood Donor Eligibility for MSM in Canada

Origins
During the 1980s and 1990s, Canada experienced a massive failure in patient safety. Infected blood was transfused to patients, resulting in the deaths of thousands of people. Over many years, at least 2,000 Canadians were infected with HIV, and about 30,000 Canadians were infected with hepatitis C, with the hemophilia population being particularly devastated. Faced with this devastation, Canadians lost all trust in the blood system and many donors stopped giving blood, causing serious supply shortages. Approximately $2.7 billion was paid out in compensation. This tragedy was, and remains, Canada’s biggest public health disaster.

The Canadian Red Cross Society, the blood operator at the time, followed the United States’ lead in implementing a number of donor criteria and testing practices to protect the blood supply. One of these was permanent ineligibility for men who had had sex with a man even once since 1977. At that time, and in the years that followed, the MSM population was noted to be a particularly high-risk donor group. The year 1977 was thought to be “ground zero” for the arrival of HIV in North America, hence its inclusion in the criteria. In 1992, blood products became regulated by Health Canada and the ineligibility of MSM to donate blood was “grandfathered” into current regulations.

The tainted blood crisis culminated in the Krever Commission of Inquiry on the Blood System in Canada, which recommended the creation of a new blood operator. In response, federal, provincial and territorial governments created Canadian Blood Services, an independent, arm’s-length, not-for-profit organization to administer a new blood system. Canadian Blood Services became the national blood authority in September 1998 and maintained the MSM ineligibility.

History of eligibility criteria for MSM at Canadian Blood Services
Many of the Krever Commission’s recommendations are pillars of today’s blood system, including the patient safety imperative and the essential nature of openness, transparency, and stakeholder involvement in certain aspects of the national blood authority’s decision-making processes.

Understandably, however, the mismanagement of HIV and hepatitis C risk in the previous decades cast a long shadow. In the years that followed the tainted blood tragedy, Canadian Blood Services focused on rebuilding the trust of Canadians, physicians, and patient groups and still views maintaining that trust as a critical element of how it delivers value to Canadians. Part of this trust-building is our ongoing commitment to stakeholder involvement. Under these auspices, we have revised the eligibility criteria for MSM periodically, as we have done with donor eligibility criteria generally.

In 2001, Canadian Blood Services held a consensus conference on the rationale and criteria for the inclusion or exclusion of donors, based on the health assessment questionnaire of the time. Little common ground on the MSM issue was achieved, however, with student and LGBTQ groups advocating for a shift
to gender-neutral, behaviour-based questions while patient groups reiterated that safety of the blood supply was paramount and they were opposed to any change.

In 2006, the McLaughlin Centre for Population Health Risk Assessment from the University of Ottawa conducted an independent evaluation of the criteria based on risk management principles on Canadian Blood Services’ behalf. Their 2007 report concluded a one-year waiting period would be sufficient to mitigate risk for known pathogens, but also that a five- to 10-year period would address risk of potential emerging pathogens within the MSM population. Their assessment was shared with patient and LGBTQ groups in a consultation led by an independent facilitator with the goal of understanding the range of viewpoints related to the findings. Stakeholder positions, however, remained largely unchanged from those of the 2001 conference.

In 2008, Canadian Blood Services commissioned an anonymous survey of 40,000 active blood donors. Donors were asked risk-based questions that could potentially be used in donor screening within Canadian Blood Services’ regulatory context. Approximately 10 per cent of first-time and six per cent of repeat donors answered “Yes” to the question, “Have you had more than one sexual partner in the past 12 months,” while 15 per cent reported having more than 10 lifetime sexual partners. The majority of donors felt that most people do not know about the sexual experiences of their partner or partners well enough to accurately assess their partner’s HIV risk. The study suggested the use of simple risk-based questions was not specific enough and would lead to an unacceptable loss of currently eligible donors. Furthermore, criteria that require donors to assess HIV risk in their sexual partners would likely be problematic.

In 2009, Canadian Blood Services launched an LGBTQ Working Group, made up of both activist and patient groups. Its purpose was to improve communication and collaboration with the LGBTQ communities and to promote a research funding opportunity offered by Canadian Blood Services in partnership with the Canadian Institutes of Health Research related to the eligibility criteria for MSM. The group was disbanded later that year due to an adversarial climate linked to the Freeman court case.

Freeman court case

In 2009, Kyle Freeman informed Canadian Blood Services via an anonymous email that he had been donating blood without disclosing his MSM status. To trace the anonymous email and begin the process of tracking his donations within the blood system, Canadian Blood Services took the only legal recourse it had and sued him for negligent misrepresentation. He countersued, claiming that Canadian Blood Services violated his rights under the Canadian Charter of Rights and Freedoms. Social justice groups (EGALE and the Canadian AIDS Society), as well as the Canadian Hemophilia Society intervened in the case and presented expert witnesses.

Although the Ontario Superior Court determined the Charter did not apply to Canadian Blood Services, a complete analysis was performed as if the Charter did apply at the request of all parties. The judgment found that blood donation is a gift and not a right, and that the eligibility criteria for MSM were not discriminatory based on sexual orientation, but were based on epidemiology and safety considerations. The presiding judge also stated that there was not enough evidence of real concerns that would make permanent ineligibility for MSM necessary to maintain the current level of safety. She did not propose a
particular deferral period, but noted that a high level of deference would have to be shown to Canadian Blood Services and Health Canada in deciding the length of a revised deferral period.

**Moving to five years**

In the wake of the judge’s findings, and based on the evidence gathered to date, Canadian Blood Services’ board of directors instructed the organization to seek a defined period of deferral of at least five years (but no more than 10), to be determined through comprehensive consultation. Canadian Blood Services built support for this change in several steps, including a broad-based survey, a discussion paper and three face-to-face consultation sessions with patient groups and LGBTQ community groups. This consultation process was one of the most emotionally charged Canadian Blood Services has undertaken in its history. To reach consensus, it was recognized patient and LGBTQ groups would have to achieve mutual understanding, and that both groups would have to trust Canadian Blood Services in its role as blood operator. During the extensive consultation process, it was understood broadly by participants that if stakeholder support was obtained, Canadian Blood Services would rapidly make an application to the regulator, Health Canada, to take this first incremental change to the eligibility criteria.

Over the course of the next 12 months, a sincere mutual understanding emerged. First steps were taken in forging important relationships, and there was a commitment to seeking and providing ongoing advice and collaboration. In total, 17 stakeholder groups, including patient groups, wrote letters of support for a five-year ineligibility period to the federal minister of health. Both Canadian Blood Services and Héma-Québec submitted applications supporting this change to Health Canada in late 2012 and received approval to implement them in spring 2013. Both blood operators implemented the new five-year waiting period in July 2013.

While the revised criteria allowed only a small percentage of MSM to donate blood, it was significant as it was the first update to Canada’s blood donor eligibility criteria for MSM since the original deferral was implemented in the 1980s.