Donor criteria for men who have sex with men: a Canadian perspective

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Few blood donor criteria are as contentious as deferral for men who have sex with men (MSM).[1-5] The indefinite deferral for MSM even once since 1977 was instituted in the United States in the early 1980s, before the causal agent for AIDS was identified, when MSM was noted to be a particularly high-risk group. The Canadian Red Cross Society (CRCS) followed suit, and this criterion was in place in Canada until July 2013, when both Canadian Blood Services and Héma-Québec changed to a 5-year deferral from last MSM contact. Although from a practical perspective, this change will allow few gay men to donate blood, it is nonetheless significant, as it is the first change to be made to this policy since it was implemented more than 25 years ago.

As other jurisdictions are actively seeking to change their own MSM policies, we felt that it might be of value to others to share our experience.[6] Specifically, we outline the process used by Canadian Blood Services to engage high-interest groups in dialogue to achieve a consensus to support a 5-year deferral as the first step in incremental change to this policy; we also elaborate the principles behind meaningful participant engagement. Scientific analysis of a possible safety impact is necessary before considering any change in donor criteria. Additionally, in our experience, support from both patient groups who require frequent transfusion and student and gay rights activist groups was essential to gaining regulatory approval for the change in policy for MSM.

ABBREVIATIONS: CBRC = Community-Based Research Center; CRCS = Canadian Red Cross Society; LGBTTQ = lesbian, gay, bisexual, trans, two-spirit, queer; MSM = men who have sex with men.

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HISTORY OF THE USE OF MSM CRITERIA

The CRCS was solely responsible for the blood supply in Canada up until 1998. In the 1980s, the CRCS implemented criteria to defer MSM and female partners of MSM, following the US lead. Deferral criteria were first listed on the confidential unit exclusion (CUE) ballot and then added as individual questions to the donor health assessment questionnaire. There was a lag time between implementation of several measures to reduce transmission of AIDS/human immunodeficiency virus (HIV) in Canada compared to the United States and other jurisdictions, including donor deferral criteria, HIV antibody testing, and sole use of adequately virus-inactivated factor concentrates. These delays contributed to infection of many transfused patients, with the hemophilia population being particularly devastated by the HIV epidemic. These actions, in addition to the delay in adopting measures to reduce the risk of hepatitis C virus (HCV) transmission, eventually led to the Royal Commission of Inquiry into Canada's blood system led by Justice Horace Krever. His landmark 3-volume report was issued in 1997 and included both a detailed review of the response of the blood system to the emerging threats of HIV and HCV and recommendations to guide a new blood system moving forward.[7] In part due to the Krever commission recommendations, in 1998 the CRCS was replaced by two new organizations, Héma-Québec in the province of Québec and Canadian Blood Services in the rest of Canada.[8] In addition, since 1998, blood has been regulated as a drug and blood centers considered as biologics manufacturers, with much more stringent regulatory oversight by the federal regulatory body, Health Canada.

Many of the key recommendations of the Krever Commission formed the basis of the current Canadian blood system.[8] These include clear roles and responsibilities and the notion that safety is paramount in decision making. Another key recommendation was the need for openness, transparency, and collaborative decision making, with Justice Krever stating that "the public must have access to information about the policy, management and operations of the blood supply system and be represented in the decision making."[7,9] In spite of embracing these principles, understandably the anger and bitterness over the (mis)management of HIV and HCV risk by the blood system cast a long shadow over the new organizations. In a general population survey in 1998, only 56% of respondents answered affirmatively to the statement "I trust Canadian Blood Services to act in the best interest of the public." Many years were spent rebuilding the trust between the general public, physicians, and patient groups and the two new blood operators. Because of this history, involvement of high-interest groups in criteria changes that may have a recipient safety impact is particularly important in the Canadian context.

HIV IN CANADA

According to the Public Health Agency of Canada, as of 2011, there were approximately 71,000 prevalent and from 2250 to 4100 annual incident cases of HIV in Canada.[10] The MSM risk category remains high for prevalent and incident infections, accounting for approximately half of new infections. Large studies of MSM have demonstrated seroprevalence rates from 10% to 20% and an annual HIV seroconversion rate of 0.5% to 1%.[11,12] However, since these studies generally recruit participants in gay venues, and their primary goal is to aid in the development of preventative health strategies, they are understandably focused on MSM who are currently sexually active often with frequent partner change. There are no large cohort studies focused on MSM who have been in a longstanding monogamous relationship or who have not been sexually active for a lengthy period of time.

With the advent of highly sensitive antibody detection assays and minipool nucleic acid testing, the window period for HIV is estimated at 9 to 11 days. The residual risk for HIV is estimated at less than 1 in 8 million units at Canadian Blood Services.[13] The estimated residual risk for HIV in the United States is of the order of 1 in 1.5 million units, because of slightly higher rates of HIV-positive donors.[14] Advances in process control, computerization, and automated testing have similarly decreased the risk of testing and quarantine errors. An updated risk modeling study using actual error rates at Canadian Blood Services and Héma-Québec found that the incremental risk associated with a 5-year deferral for MSM was less than 1 infected HIV unit entering the blood supply in 1000 years.[15] Therefore, using a risk modeling method, a 5-year deferral for MSM would not substantially increase the risk of HIV associated with transfusion in Canada. Similar modeling studies have been performed in the United Kingdom, France, and the United States using relevant national data sources. Although modeling studies are useful to estimate small risk increments, they involve assumptions about many variables, where data are often sparse. Additionally, they do not provide information on novel or emerging threats.

A (LACK OF) CONSENSUS CONFERENCE, EARLY CONSULTATION, AND A COURT CASE

Canadian Blood Services has hosted several consensus conferences, often cosponsored by Héma-Québec, on issues of major national and international importance. In 2001, a consensus conference entitled "Blood Borne HIV and Hepatitis—Optimizing the Donor Selection Process" was held to focus on the rationale and the criteria for inclusion or exclusion of donors, based on the health assessment questionnaire.[1] Speakers addressed scientific, legal, ethical, and public perception issues. Presentations were also made by representatives of high-interest organizations, including student and gay rights activist groups, such as the Canadian Federation of Students, Equality for Gays and Lesbians Everywhere (EGALE), and the Canadian AIDS Society, and representatives of patient groups who rely on frequent use of fresh blood components or factor concentrates, such as the Canadian Hemophilia Society and the Thalassemia Foundation of Canada. The consensus panel was not asked to make recommendations on specific donor criteria, but rather on the principles that should guide the process and the areas where further information and research would be needed. However, it was evident from the presentations of the high interest groups that there was little common ground or consensus on any change to the criteria. Student and gay rights groups advocated for questions based on risk behavior without regard to the potential donor's gender or sexual orientation, while patient groups reiterated that safety of the blood supply was paramount and were opposed to any change. The strongly held, heart-felt views of all high-interest groups highlighted the larger issues of trust and concern for social justice that are linked to this particular donor eligibility issue.

The MSM deferral was revisited again in 2006, when Canadian Blood Services, with the support of its Board of Directors, contracted the McLaughlin Centre for Population Health Risk Assessment from the University of Ottawa to conduct an independent evaluation of the criterion based on risk management principles. The report, delivered in 2007, concluded that a 1-year deferral period would be sufficient for known pathogens. However, a

longer 5- to 10-year deferral period would pass the "risk hurdle" for emerging pathogens as well, which may emerge in MSM.[11] The risk deferral assessment was shared with patient and student and gay activist groups in a consultation led by an external, independent facilitator. The goals of the consultation were to engage in open dialogue and understand positions. It was clear in this consultation exercise that positions had not changed substantially from the 2001 consensus conference. After the consultation exercise, the Board of Directors passed a resolution to maintain the current policy but to actively gather information to close knowledge gaps, including the risks and benefits of behavioral-based donor selection criteria and developments in the areas of emerging pathogens. Canadian Blood Services would also monitor the experience of other blood agencies and the Board would reassess the data after a period of 5 years.

After the decision from the Board of Directors, a large anonymous survey was performed in 2008, of 40,000 individuals who had successfully donated. Donors were asked the type of simple, gender-neutral questions that might be used in donor screening in our regulatory context.[16] Approximately 10% of first-time and 6% of repeat donors answered affirmatively to the question "Have you had more than one sexual partner in the past 12 months," and 15% of donors had more than 10 lifetime sexual partners. The majority of donors felt that most people do not know about the sexual experiences of their partner(s) well enough to accurately assess their partner's HIV risk. Therefore, this study demonstrated that the use of simple gender-neutral questions was not specific and would lead to unacceptable loss of safe donors. Furthermore, criteria that require donors to assess HIV risk in their sexual partners would likely be problematic.[16]

In early 2009, Canadian Blood Services launched the LGBTTQ (Lesbian, Gay, Bisexual, Trans, Two-Spirit, Queer) Working Group, made up of LGBTTQ groups and patient groups. The purpose of the working group was to improve communication and collaboration with the LGBTTQ communities and to promote an ongoing research funding opportunity offered by Canadian Blood Services in partnership with the Canadian Institutes of Health Research. After several meetings, the working group was disbanded later in 2009, mainly due to an adversarial climate linked to the Freeman Court case.

Freeman court case

A gay man informed Canadian Blood Services via an anonymous e-mail that he had been donating and lying about his MSM status. To trace the anonymous e-mail and apply the appropriate deferral code, he was sued by Canadian Blood Services for negligent misrepresentation as the mechanism available to obtain his identity from his e-mail service provider. He countersued, claiming that Canadian Blood Services violated his rights under the Canadian Charter of Rights and Freedoms. The Charter, entrenched as part of Canada's constitution, applies to all government laws and actions and guarantees certain political and human rights. Gay rights groups (EGALE and the Canadian AIDS Society), and the Canadian Hemophilia Society intervened in the case and presented expert witnesses. Although the Ontario Superior court determined that 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.[17] Important elements of the judgment in favor of Canadian Blood Services were that blood donation is a gift and not a right, and that the MSM policy is not discriminatory based on sexual orientation, but is based on epidemiology and safety considerations. However, Justice Catherine Aitken, the presiding judge in the case, stated that ". . . evidence was lacking of the existence of real concerns that would make a deferral period of 33 years necessary in order to maintain the current level of safety." She did not propose a particular deferral period, mentioning that "A high level of deference would have to be shown to Canadian Blood Services and (Health) Canada in deciding the length of the deferral period." Although court cases are usually thought of as confrontational rather than conciliatory, the articulate, measured, lengthy judgment likely encouraged all parties involved to work toward a shorter deferral period for MSM, rather than holding fast to their opposing positions.

BOARD RESOLUTION AND SUCCESSFUL CONSULTATION PROCESS

In September 2011, the Canadian Blood Services Board of Directors returned to the MSM issue and passed a resolution to change the existing indefinite deferral to a defined period deferral, between 5 and 10 years. The Board felt that there was sufficient scientific evidence to support the safety of a defined period of deferral of at least 5 years, but that the exact period should be determined by an extensive consultative process. Our approach to gathering stakeholder input and achieving support for the change was carried out in several steps: the execution of a broad-based survey, the development of a discussion paper, the identification of key stakeholders, the conduct of three face-to-face consultation sessions with patient groups and LGBTTQ community groups, and a consultation session with the external advisory committee to the Board of Directors, the National Liaison Committee (NLC). This was one of the most critical and emotionally moving consultations Canadian Blood Services has undertaken in its 15-year history. To reach consensus, it was recognized that patient groups and LGBTTQ groups would have to achieve mutual understanding, and that both groups would have to trust Canadian Blood Services in moving forward carefully with their support. The high level of emotion and

agreement of all parties to compromise underpinned the importance of effective and values-based public participation. It was understood by participants that if stakeholder support was obtained, Canadian Blood Services would rapidly move to a submission to the regulator, Health Canada, to take this first incremental step in policy change. The major steps of the consultation process are described below. Although costs of the Web-based survey and face-to-face consultations were not negligible, on the order of $50,000 combined, these are a small percentage of the cost of court challenges to the blood supplier.

Web-based survey

To capture a broad range of perspectives, we developed a survey in partnership with the Canadian Federation of Students and the Community-Based Research Centre (CBRC), a Vancouver-based men's health organization that was managed online by an independent service provider. We wanted to examine respondents' awareness and opinions toward the MSM policy, including support or opposition for the proposed change, and the impact of changing this policy on perceptions of safety, intentions to donate, and trust in Canadian Blood Services. This online survey was administered from February 27 to March 2, 2012, and reached out to gather the views of individuals across several categories (students, LGBTTQ, existing blood donors, and the general public). Close to 6000 members of the general public were selected from the Ipsos-Reid Household Panel of approximately 200,000 Canadian households, excluding Québec. The participants were chosen to ensure a representative sample of the Canadian population by region, sex, and age. Similarly, close to 6000 representative active donors were selected. The Canadian Federation of Students, the national organization representing university and college students, and the CBRC, an organization dedicated to using research to guide community action, particularly in the area of gay men's health, sent an open link to all their members asking for their anonymous participation. The 12-question survey focused on awareness of the current policy, support or opposition to the proposed policy change, and impact of the possible policy change on trust and likelihood of donation by the individual or their friends and family circle. The response rate was 25% for blood donors and 18% for the general population; it was not possible to determine the response rate in the other groups. The results of the polling, with more than 9000 respondents (including 6100 students) indicated that awareness of the policy is high, particularly in students, existing donors, and CBRC members (89% in CSF and CBRC respondents, 90% in active donors, and 52% in the general public).[18] There was variation across different groups, but overall, there was more support than opposition to changing the policy. Many who opposed the change felt that it did not go far enough. It was also noted that a policy change might positively influence younger Canadians to donate, since students, younger donors, and younger members of the general population overall were more supportive of a change and thought that it would positively influence their likelihood of donating. Overall trust in CBS to "do what is best for the blood system" was high, ranging from 71% in the CBRC group to 87% in the general public. A change in the policy would have a small negative effect (2% decrease in trust) or a small positive effect (2% to 4% increase in trust) in the various groups.

Face-to-face consultations

In early 2012, an international panel of experts from various professional disciplines (public health, gay men's health, epidemiology, risk assessment, ethics, other international blood operators, and Héma-Québec) reviewed and endorsed the scientific content of a discussion paper covering the history of the deferral policy, epidemiologic data, emerging pathogens, existing international criteria, risk modeling for change, and societal impacts of the policy. This paper was shared with all consultation participants (and eventually, the general public via our Web site, http://www.blood.ca) to frame discussions with stakeholder groups.

In March 2012, we held our first face-to-face consultation with our National Liaison Committee, an advisory committee of the Board of Directors, seeking their support for the policy review and our overall approach to consultation. Their input was considered in the final recommendation to the Board of Directors along with results of consultations with broader stakeholder groups.

We developed an extensive list of possible participants that would fairly represent those affected by or interested in this policy decision. These included national, regional, and local organizations, as well as individuals, some of whom had been members of the LGBTTQ working group. When there was a perspective that might not otherwise be represented in the room, and/or an individual expressed an interest in the consultation process, an invitation was extended to ensure the fairness, transparency, and integrity of a meaningful engagement process. We ensured an equal number of voices representing all perspectives of the discussion were present in the room for the face-to-face consultation sessions. Canadian Blood Services subscribes to the theoretical and practical framework as set out by the International Association for Public Participation (IAP2). They are international leaders in public participation that seek to promote and improve the practice of public participation. These principles were utilized in designing our consultation process.

Goals were clearly set for the face-to-face consultations as follows:

- Identify and understand the perspectives and viewpoints of all participants;
- Engage in values-based dialogue that explores the impacts, consequences, and interests of different courses of action, from a variety of views;
- Collect and record the diverse and similar views so as to inform our decision making on the time-based deferral which would lead to a submission to our regulator;
- Undertake an open, fair, and transparent process for all participants;
- Create a supportive environment that respects all viewpoints and participants; and
- Set the foundation for future collaboration.

Additional consultations were facilitated by an external public participation expert and occurred in this order over the summer of 2012: patient groups, LGBTTQ or student groups, then a joint session with both groups together. Before the events, all participants received the scientific discussion paper, questions to consider, and an agenda. The methods for consulting were chosen to maximize opportunity for mutual understanding to emerge, validate different points of view, and explore medical and scientific information via interaction with a panel of experts. After each session, a full report, including a statement of the participants' values and beliefs along with their recommendations and evaluation results, was produced.

Overall, a sincere mutual understanding emerged, first steps were taken in forging important relationships, and there was a commitment to ongoing advice and collaboration. In total 17 different stakeholder groups wrote letters of support for a 5-year deferral period to the Minister of Health. Both Canadian Blood Services and Héma-Québec submitted the change to a 5-year deferral policy to Health Canada in late 2012 and received approval to implement in spring 2013. Both blood operators implemented the new deferral policy in July 2013.

A respectful, inclusive, transparent process throughout the consultations is what, we believe, resulted in willingness on the part of all stakeholders to work together toward consensus. After the consultations, participants expressed a desire to continue to work together and a working group was created with the following objectives:

- Support the development and delivery of communications that will inform progress and mitigate the negative impact of the existing policy;
- Provide guidance and ideas for education campaigns to inform the general public;
- Provide recommendations to Canadian Blood Services to support the need for further change to the MSM deferral policy;
- Leverage their networks and contacts to help increase the donor base; and
- Promote the current research agenda.

We recognize that for the LGBTTQ groups, the change does not allow the vast majority of their gay constituency to donate blood; however, they supported it as a first step. For patient groups, many of whom are chronic users of the blood supply, the change meant putting aside their fears of the past, assessing the available scientific information, and trusting in the system. Both blood operators are committed to ongoing surveillance to ensure that safety has not been compromised. Surveillance includes following transmissible disease marker rates before and after implementation and determination of risk factors in transmissible disease–positive donors. Additionally, an anonymous online survey of compliance with the MSM criterion is being performed before and after implementation. We feel that this is the first step in a series of incremental changes to the MSM policy.

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CONFLICT OF INTEREST

The authors report no conflicts of interest or funding sources.

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