

## **Blood Donation Deferrals: Re-Evaluating the five year deferral period for blood donation by MSM**

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## **Background**

Every year, Canadian Blood Services (CBS) collects approximately 900 000 units of blood from across Canada (1). This supply is used in the transfusion of trauma victims, surgical patients, and in many other medical circumstances. In order to protect the integrity of the blood supply and to promote the safety of the blood recipients, CBS has instituted exclusion criteria for donors based on demographic information and medical history. One example of such exclusion is the current policy for men who have sex with men (MSM), who can only donate after a deferral period of five years after their last sexual contact with a man. Hema-Quebec, which follows the standards set by Health Canada, enforces the same donor exclusion criterion (3). Although CBS explains this policy as reflective of the higher rates of HIV among the MSM population, some have called into question the need for such a deferral (2) with recent medical advances in HIV testing (1). Given these advances and the Canadian Blood Service's constant efforts to increase their base of blood donors, the role of the 5-year deferral policy for MSM must be reassessed. The following document aims to present this policy in more detail, discuss its relation to the principles of the CFMS, and contrast it with other policy options, as implemented in other countries. Finally, a more modernized alternative will be presented in light of this discussion.

## **Problem Description**

Since 1983, Health Canada has supported and Public Health Canada has regulated the policies that restrict MSM from donating blood to varying degrees (4). The policy was modified in 2013 from a lifetime ban to a 5-year deferral period. Although congruent with current policy in many developed countries, this issue returned to public attention with the United States Food and Drug Administration's (FDA) change in policy from a lifetime ban to a 1-year deferral period announced in December of 2014 (5). In a press release, the FDA alluded to "the results of several recently completed scientific studies and recent epidemiologic data," as well as collaborative efforts with the Department of Health and Human Services (HHS) which justified the change in policy (5).

Firstly, it is fundamental to consider the social context in which any change can occur. Recent changes have in part been spurred by social momentum seeking to combat discrimination against, and marginalization of, sexual minorities. A poll conducted by Ipsos Reid on behalf of the Canadian Blood Services looked at public perception to change what was a lifetime ban (the policy in 2012) to the five-year deferral period instituted in 2013 (6). The survey found that "[t]here is resounding support for the MSM policy change among the [...] Canadian Federation of Students [...] with 8 in 10 who feel it is a step in the right direction and who strongly support the change; the majority of donors also support the change (53% right direction and 61% support). General public respondents express moderate support for the change (40% right direction and 45% support) and are most likely to indicate they are undecided." (6) Thus, this poll showed that there was public support for a change in deferral policy in 2012, particularly among students, and we believe that similar social support exists for further re-examination of the policy.

With recent triggers for policy re-consideration, it is important to understand the social, legal-political and economic context in which MSM blood donation policy was created. In the past, the main concerns used to justify the ban were an increased prevalence and incidence of HIV amongst MSM, and a history of blood supply contamination, presumably by MSM. According to an epidemiologic summary by the Public Health Agency of Canada in 2011 (more recent data will be available later in 2015), about 46.7% of individuals living with HIV are MSM, while those who

identify as heterosexual account for a total of 32.5%. The same report cites that 46.6% of incident infections are attributable to MSM, with heterosexual incidence accounting for a total of 37.2% (7). Furthermore, certain historical events are often cited as support for prolonged deferral periods. For instance, the distribution of contaminated blood products by the Canadian Red Cross (predecessor to CBS and Hema-Quebec) in the late 1980s and early 1990s resulted in about 1200 Canadians infected with HIV and about 25 000 infected with Hepatitis C. Although not attributed to donations by MSM, this event is cited as a potential risk if policy on donation is relaxed. Given the higher prevalence of HIV among MSM compared to the general population and the absence of any effective screening methods, banning high-risk groups from donating blood was arguably the only option available to limit blood contamination.

However, the situation today has changed compared to when the MSM deferral period was originally put into place. First, HIV screening tools have dramatically improved compared to 1983. Current blood donor screening employs a mix of pre-donation interviewing and serologic screening, with test sensitivities and specificities approaching 100% (9) (see table below). In addition, the window period has shrunk significantly from a 3-6 month period using the antibody tests (e.g. OraQuick) to a 2-3 week period with the introduction of the Nucleic Acid Test (e.g. Multispot) (9). Because of these new screening tools, the current risk of HIV contaminated blood entering the blood system shrank to 1 per 8 to 12 million donations (10). In comparison, the risk of a blood product being contaminated with hepatitis B is 1 in 1.1 to 1.7 million, and the risk for hepatitis C is 1 in 5 to 7 million (10). In fact, according to one FDA official, “our current risks are now so low that they cannot be measured directly and, hence, we rely on models to estimate the current residual risk, that is to say the risk after all the safeguards have been followed” (11). Indeed, according to another FDA official, “the probability that errors in routine screening will result in release of a unit [with hepatitis C virus or HIV] is so remote as to be inconsequential” (11). These conclusions are supported by quantitative modeling studies. For example, one study using Hema-Quebec data from 2000-2001 found that changing the current policy to a one-year deferral would increase the risk of inadvertent HIV transmission by 1 in 11 million; this represents a small fraction of the current “tolerated” risk of 1 per 2 million donations (12). Given the quantitative evidence and the experience of other countries with 1-year deferral periods for MSM who wish to donate blood, both the American Red Cross and the American Association of Blood Banks have argued that the current policy “is medically and scientifically unwarranted” (11). The American Association of Blood Banks has specifically argued that “the longest window required to detect HIV in blood was one year, making a deferral lasting more than one year unwarranted.”

**Table 1: HIV Screening Methods for Blood Products**

Test	Manufacturer	Sample Type	Sensitivity	Specificity
OraQuick Advance Rapid HIV1/2 Antibody Test	OraSure Technologies	Oral Fluid	99.3%	99.8%
		Whole Blood	99.6%	100%
		Plasma	99.6%	99.9%
Clearview Complete HIV1/2	Inverness Medical Professional Diagnostics	Whole Blood	99.7%	99.9%
		Serum and Plasma	99.7%	99.9%
Clearview HIV1/2 STAT-PAK	Inverness Medical Professional Diagnostics	Whole Blood	99.7%	99.9%
		Serum and Plasma	99.7%	99.9%
Reveal G-3 Rapid HIV-1	MedMira, Inc	Serum	99.8%	99.1%

Antibody Test		Plasma	99.8%	98.6%
Uni-Gold Recombingen HIV	Trinity Biotech	Whole Blood Serum and Plasma	100% 100%	99.7% 99.8%
Multispot HIV-1/HIV-2 Rapid Test	Bio-rad Laboratories	Serum Plasma	100% 100%	99.9% 99.9%
INSTI HIV-Antibody test	bioLytical Laboratories	Plasma Whole blood (venipuncture) Whole blood (finger stick)	99.9% 99.9% 99.8%	100% 100% 99.5%

Note: many of these tests are a combination of nucleic acid and antibody testing.

Despite advancements in screening technology, proponents of unnecessarily lengthy deferral periods warn of the potential rise of a new pathogen that could infect the blood supply. This argument, however, assumes that any new blood borne threats would preferentially emerge among MSM, and evidence suggests this is not the case. Out of the 8 emerging transfusion-transmitted agents identified by the American Association of Blood Banks as “high risk,” none are more likely to accumulate in MSM than in other donors (12).

The legal and political milieu must also be considered and evaluated when attempting to understand the context of MSM blood donation. This necessitates a discussion of the changing lego-political environment surrounding LGBTIQ (lesbian, gay, bisexual, transgender, two-spirit, and queer) issues at both federal and provincial levels. Multiple recent legislative events highlight steps taken to recognize the basic rights of individuals from the LGBTQ community and the major hurdles to changing the status quo in our current political atmosphere. One such example is the Civil Marriage Act, passed in 2005. An analysis of the voting pattern within the House of Commons shows that there was a considerable number of candidates from both the Liberal backbenches and the Conservative party (34% and 95% respectively) who voted *against* such legislation. In fact, 51% of the House of Commons voted against the bill (13). This highlights that controversy surrounding LGBTQ issues is significant within the legislative sphere, which is a challenge to changing MSM blood deferral policy.

On a provincial level, multiple rulings have addressed the issue of legal restrictions on members of the LGBTQ community. For example, in the ruling of *Blood Services v. Freeman* in 2010, the Ontario Superior Court upheld what was then an indefinite ban on MSM blood donation, based on epidemiological evidence. The Court also stated that the right to marry did not logically lead to the right to donate blood. Notwithstanding the fact that such a ruling relied on prevalence rather than detection methods, this ruling is a recent example of behavioural restrictions placed on members of the LGBTQ community.

One must also consider the potential benefits of an updated policy for the recipients of blood products. Relaxing the deferral period to one year would moderately increase the number of blood donors. One study using data from the United States and Canada found that the change in policy would increase the blood supply by 1-2% (14). Another study by the Fenway Institute – an American research, education, training and advocacy organization – calculated that the change would add 317 000 pints of blood to the United States’ annual blood supply, or an increase of 2-4% (15). This increase may be especially significant given that the blood supply continues to be critically

low in Canada; as recently as September 2014, Canadian Blood Services claimed its blood supply was in a “critical situation” and “at its lowest since 2008” (16). A change in policy could also indirectly increase the number of blood donations, given that “some student societies, universities and other organizations have stopped holding blood drives because of the indefinite deferral of men who have sex with men.” (17) Despite the potential for making available an entire group of people who could significantly contribute to eradicating this deficit, reducing the ban to one year for MSM blood donation has not been approved.

Lastly, it is important to consider differing international policy options in order to better adapt successes to a Canadian milieu and to learn from their challenges. Policies are clearly being updated worldwide to reflect recent understandings of sexual behaviour and changes to testing and screening processes. Several countries have implemented 1-year deferral policies for blood donations by MSM, including Australia and the UK. Other countries, including Italy, Spain, and Mexico, have implemented individual risk stratification strategies with no specific deferral period for MSM (18). In Italy, the risk assessment is conducted by a physician and applied to all individuals regardless of gender or sexual orientation. In a joint study completed by the National Institute of Health and the Bologna Local Health Authority published in 2013, the authors compared the percentage of HIV positive donors based on sexual status before and after the change in policy. Results showed that there was “no evidence of significant impact on the HIV epidemic in Italy.” (19)

In England, Scotland and Wales, a new policy of a 1-year deferral after sexual contact for MSM was instituted in 2011. This change was made in response to an evidence-based policy review by the Advisory Committee on the Safety of Blood, Tissues and Organs, in which they determined that the risks associated with a 1-year deferral were analogous to those posed by a lifetime ban. Additionally, they acknowledged that a policy of individual risk assessment would be ideal, but it was seen to be “complex, expensive and difficult to administer in a donation session.” (20) A survey conducted by the committee found that a 1-year deferral (as compared to a 5-year deferral) conferred eligibility to 46% of MSM respondents (20).

Finally, Australia changed its policy from a permanent ban to a 1-year deferral period between 1996 and 2000. A study conducted between 2005 and 2010 found that there was “no evidence for increased risk of transfusion-transmitted human immunodeficiency virus in Australia subsequent to implementing a 12-month deferral for men who have had sex with men.”(21) Of the 4 964 628 donations evaluated, 24 were HIV positive, 16 of whom were male. 5 of those 16 had male-to-male sex as a risk factor, and all 5 men had engaged in sex with another male within the past 12 months, and therefore would have been excluded from donating had they provided an accurate history (21).

This brings up the issue of compliance with the proposed deferral period. Seed et al. admit that “[t]he risk of noncompliance to the revised deferral rather than its duration appears to be the most important modifier of overall risk.” (21) The UK Advisory Committee on the Safety of Blood, Tissues, and Organs also stated that “compliance remains a key issue when considering any change to deferral criteria as non-compliance may lead to an increase in undetected window-period infection.” (20) However, another study conducted by Seed et al. found that, in a sample of nearly 15 000 male donors, the compliance with the current 12-month deferral policy in Australia is greater than 99.7% (22). This strongly alleviates concerns raised over decreased compliance with a new policy.

The demographic of HIV in Canada has changed significantly in the past few decades. When HIV reporting to the Public Health Agency of Canada (PHAC) began in 1985, MSM accounted for over 80% of all cases of HIV infection. Between 1980 and 2005, MSM exposure accounted for 58.0% of positive HIV test reports. This number dropped to 38.9% in 2006 and 48.6% in 2011, although the absolute number of positive tests decreased (520 in 2006 compared to 509 in 2011). In 2011, the second most important exposure to HIV amongst adults was through heterosexual contact, representing 29.5% of positive HIV tests. Heterosexual contact was in fact the main risk factor for females, present in 64.5% of positive HIV test reports. The third most important exposure was injection drug use (IDU), which accounted for 17.0% of positive tests amongst adults, and 29.9% of positive tests in women. Furthermore, the overall number of positive HIV reports is steadily decreasing. Only 151 cases were reported in 2011, which was 31.7% lower than the previous year, and over 12 times fewer cases than the 1,827 cases reported in 1993 (the highest number for a single year in Canada). Thus, the landscape of the HIV-positive population has shifted steadily over the past 40 years. Today, heterosexual contact and IDU represent a significant proportion of new HIV infections in Canada (23).

In summary, the current deferral period for blood donation by MSM was instituted at a time when testing methods for blood borne diseases were inferior to current methods, and these diseases had a much higher prevalence in the MSM population. For these reasons, the time has come to reconsider this policy. Technological progress has resulted in screening tools with specificity and sensitivity near to 100%, leading to a very low risk of undetected infections entering the blood supply. Furthermore, social and legal movements have arisen lately seeking to combat the marginalization of the LGBTQ community. One-year deferral policies have been instituted in various countries across the globe, and existing data does not suggest any increased rates of HIV in the blood supply. Although this paper is not meant to be a discussion of the “right to donate blood,” we do recognize that placing unnecessarily rigid limits on the ability to contribute to the healthcare system is unjustifiably exclusionary. We are therefore suggesting a change in the current policy from a 5-year deferral to a 1-year deferral.

## **Principles**

The 5-year deferral period for MSM blood donations is not compatible with the CFMS’ values due to the lack of evidence, the inequitable principles and the inconsistency with the needs of the Canadian population that underpin the policy. With improvements in blood screening technologies and shifting patterns of risk for HIV transmission, the evidence supporting the assumption that a 5-year deferral period is safer than a 1-year deferral period is unsubstantiated and translates into unfair practices.

According to the Canadian Medical Association code of ethics, physicians should “[c]onsider the wellbeing of society in matters affecting health.” As physicians in training, one of our major responsibilities is to address the needs of the Canadian population, and one of the most precious resources is the Canadian blood bank. Reducing the 5-year deferral period for MSM to one year will increase the pool of healthy potential donors and ultimately expand blood resources available to the public. The direct benefits of increasing the blood pool as well as the evidence supporting reduced risk of HIV contamination with improved technologies will not only reduce costs and challenge institutionalized stigma, but will save lives.

## Recommendations

### **1. Reduce the current 5-year deferral period for MSM donors to a 1-year deferral period.**

Banning MSM from donating blood was an understandable policy in 1983 given the high prevalence of HIV among MSM, the absence of effective screening HIV methods, and the epidemic of transfusion-borne HIV infections. However, as screening technology has improved, this policy has become outdated and is misaligned with current epidemiological and quantitative evidence. We believe decreasing the current deferral period for MSM to one year would align Health Canada's policy with those of many other nations worldwide, including the United States, Japan, Brazil, the United Kingdom, and Australia. A one-year deferral would also align the current MSM policy with that for other high-risk groups, such as donors who have had sexual contact with an HIV-positive partner. Finally, we believe that changing the current policy would increase the Canadian blood supply and help limit the impact of shortages.

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