



Canadian Blood Services
Soci t  canadienne du sang

Report on Donor Selection Criteria Relating to Men Who Have Sex with Men

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Executive Summary

- Currently, men who have had sex with another man (MSM) even once are deferred for five years from blood donation.
- This change was introduced in July 2013, with the understanding that it would be evaluated for safety impacts two years post-implementation, and further changes would then be considered.
- Post-implementation monitoring has shown no adverse impacts on the prevalence of HIV in donors, donor compliance, or trust in the blood system, and we are now seeking approval for a change to a one year deferral.

Known infectious risks

- A one year deferral period would easily cover the window period for HIV, HCV, and HBV.
- Residual risks for these three pathogens are less than 1 in 1,000,000 units transfused.
- Redundancy in testing, process control, computerization and automation have reduced the risk of errors in testing and issuing of blood components.

Emerging pathogens

- In recent years, much attention has been devoted to tracking emerging infectious diseases.
- The AABB Transfusion Transmitted Diseases Committee has compiled a list of emerging infectious disease agents of interest. Risk factors for these agents are mainly geographic, with varying exposure routes. MSM is not a high risk group for any of these agents, with the exception of HHV-8.
- Canadian Blood Services has taken measures to reduce possible emerging infectious risks, often before these agents have been shown to be transmitted by blood transfusion.

MSM population

- The prevalence and incidence of HIV is considerably higher in the MSM population, compared to the general population. However, individuals who do not engage in male-to-male sex for at least one year likely represent a low risk subset.
- HHV-8 is more common in the MSM population compared to the general population, but has not been associated with post-transfusion disease transmission
- Since Canadian Blood Services was created in 1998, measures have been taken to reduce the threat of several emerging pathogens; MSM have not been a high risk group for any of these agents.

International criteria

- There is insufficient evidence to consider gender neutral risk behaviour based criteria as adequate to maintain the safety of the blood supply at the present time.
- Australia has had a 1 year deferral period since 2000. An analysis demonstrated a low stable rate of HIV positive donations before and after implementation of this policy.
- Several countries have recently adopted a one year defined term deferral period, including England, Scotland and Wales (changed from an indefinite deferral in 2012), New Zealand (decreased from a five year deferral in Dec 2014), and Sweden (changed from an indefinite

deferral in 2012-13) and to date have seen no negative safety impacts. Other European countries, such as France, are considering a change in deferral period.

- Recently, the US FDA has issued a draft guidance document for blood establishments, permitting a one year deferral period for MSM.

Risk modeling

- Mathematical models of incremental HIV risk associated with a five year deferral period have shown minute increases in risk (less than 1 infected unit per 500 years). Even this risk was likely over-estimated, since the actual prevalence of HIV in the donor population did not increase after changing to a five year deferral period. Similarly, the expected incremental risk is minute with change to a one year deferral.

Compliance

- Compliance with criteria is very important and has a large impact on safety. The compliance study performed by Canadian Blood Services before and after change to a five year deferral period did not show any change in the frequency of noncompliance with the MSM question for males with MSM in the last five years. Overall compliance improved, since male donors who have had sex with another man over five years ago are now eligible to donate.
- We therefore would not expect a change in compliance with a one year deferral.

Impact on adequacy of supply

- Canadian Blood Services faces considerable challenges in meeting increased transfusion requirements associated with an aging general population.
- The donor population is also aging, with disproportionate reliance on a small number of loyal donors.
- Cancellation of university clinics have led to small donation losses, but may reflect a broader disengagement of young people regarding Canadian Blood Services. Securing an adequate blood supply will involve mobilizing large numbers of new younger donors.
- Data from the post-implementation compliance study and from returning donors that were previously deferred for MSM over five years ago showed that several hundred individuals with MSM activity over five years ago but after 1977 are now donating.
- Surveys of MSM individuals indicate that a substantial number would be interested in donating, if eligible.

Legal challenges based on perceived discrimination

- Canadian Blood Services successfully defended against a claim of discrimination under the Canadian Charter of Rights and Freedoms. However, the Ontario Superior Court judge found that evidence did not support the need for a continually lengthening 33 year deferral to maintain blood safety.



Glossary

Deferral	This term is applied when people are excluded from blood donation for a specific reason either indefinitely (called indefinite or permanent deferral) or for a fixed period of time (defined term deferral).
Donor	A person who donates blood for transfusion.
Emerging Pathogen	Infectious agents whose incidence has increased or threatens to increase in the near future. Emerging pathogens may be known existing organisms that have evolved or expanded their geographic range, such as WNV and babesiosis. They may also be new, previously unknown agents, such as vCJD or SARS.
Incidence Rate	The rate at which new infections occur in the population.
Incident Infections	The number of individuals with new infections at a given time.
Prevalence Rate	The number of people with the infection at a given time divided by the population.
Prevalent Infections	The number of individuals in the population with an infection at a given time.
Residual Risk	The risk that an infectious donation could be missed by testing of the blood.
Risk Factors	An aspect of personal behaviour or life-style, an environmental exposure, or an in-born or inherited characteristic that, on the basis of epidemiologic evidence is known to be associated with a health condition. The association is not necessarily the cause of the health condition.
Window Period	The time between infection and detection of a pathogen with a blood test.



Abbreviations

AABB	American Association of Blood Banks
ACBSA	The U.S. Advisory Committee on Blood Safety and Availability
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HHV8	Human herpes virus 8
HIV	Human immunodeficiency virus
HTLV	Human T lymphotropic virus
IDU	Intravenous Drug User
ISBT	International Society for Blood Transfusion
LGBTQTQ	Lesbian, Gay, Bisexual, Transgender, Two-Spirited, Queer Working Group
MSM	Men Who Have Sex with Men
TD	Transmissible disease
WNV	West Nile virus

1. Introduction

Canadian Blood Services collects and distributes about 950,000 units of blood and blood products per year to all territories and provinces except the province of Québec, which is managed by Héma-Québec. Canadian Blood Services takes responsibility for the safety of the blood supply. Safety from transmissible disease is achieved by education of the public and donors about infectious risks, donor selection criteria, and transmissible disease testing of every donation¹. Another key contributor to safety has been improvements in good manufacturing practices and process control, including increased automation of testing and computerisation to manage the manufacturing process from donation through to release of blood products to the hospitals. Enhancements of transmissible disease testing and process control considerably decrease the risk of release of infectious units into the blood supply.

In the mid-1980's Canadian Blood Services' predecessor, the Canadian Red Cross Blood Transfusion Service introduced a donor selection criterion that excluded all men who have had sex with another man (MSM) since 1977 in order to protect the blood supply from HIV. In 1992 blood products became regulated by Health Canada and the criterion was 'grandfathered' into current regulations. Canadian Blood Services has periodically conducted reviews of deferral criteria, including a Consensus Conference on optimizing the donor selection process in 2002 and an independent risk assessment conducted by the McLaughlin Centre for Population Health Risk Assessment in 2006^{2,3}. In late 2012, a successful submission was made to the regulator, Health Canada, by Canadian Blood Services, to change to a five year deferral criterion. This change was supported by both patient and community stakeholder groups, with the understanding that close post-implementation monitoring would be performed and guide possible further changes in policy. The new policy was implemented in July 2013. The goals of this document are to summarize any safety impacts of the change to a five year deferral period and to provide information regarding risks and benefits of a possible further change in policy to a one year defined time deferral.

2. Known infectious risks

Canadian Blood Services performs testing on every donation for HIV1/2, HCV, HBV, HTLV I/II, syphilis and WNV. Chagas disease testing is performed on individuals identified as being at risk on the donor questionnaire. As part of the CBS epidemiology and surveillance department functions, all transmissible disease (TD) positive donors are interviewed to determine possible risk factors for infection, donor TD rates are tracked over time, and residual risk rates are calculated for each marker. Table 1 summarizes testing assays, window periods, TD rates per 100,000 donors, calculated residual risk per unit transfused, and risk factors identified in CBS TD positive donors for each agent.

Testing is performed using automated equipment and assays specifically licensed for blood donor testing. There is redundancy in testing, with more than one test for each of HIV, HCV and HBV. Automation, redundancy, computerisation, and a high degree of process control reduce the risk of errors in testing and release of untested components.

As shown in Table 1, the window period (time between when a donor may be infectious and when the test would be positive) is now less than 10 days for HIV and HCV, and less than two months for all agents. Therefore, window period risk would be more than adequately covered by a one year deferral for risk factors.

TD marker rates are amongst the lowest in the world¹. Rates in first time donors reflect prevalent infections, acquired at any time during the prospective donor's lifetime. Rates in repeat donors represent infections that have been acquired more recently, after the donor's previous donation. Therefore, rates are higher in first time, compared to repeat donors. Approximately 10% of donations are from first time donors, while 90% are from repeat donors. In terms of absolute numbers, there are approximately one to eight HIV positive, 60 HCV positive and 75 HBV positive donations a year, with close to 1 million donations tested. The residual risk of infection is calculated based on the window period and TD positive rates, and estimates the risk of infection per component transfused. As shown in Table 1, residual risks for HIV, HCV, and HBV are less than 1 in a million components transfused. Since syphilis is only transmitted by fresh blood that has been stored for less than 24 hours, components currently produced by CBS are likely to be non-infectious. The number of West Nile Virus (WNV) positive donations has fluctuated between 0 and 66 in recent years, so it is difficult to calculate residual risk.

Since the change in MSM deferral policy: There has been no change in the TD rates per 100,000 donations since the change in the MSM criteria. Six HIV positive donors were identified from July 22, 2013 to April 1, 2015 (close to two years).

Table 1. Infectious marker testing at CBS

Agent	Assays	Window Period (Days)	TD Rates per 100,000 donations, 2014		Residual Risk	Risk Factors
			First Time	Repeat		
HIV	anti-HIV-1, 2 (includes subtype O) HIV-1 NAT	9.5	2.1	0.2	1 in 8 million	From risk country, MSM
HCV	anti-HCV HCV NAT	8.0	48.3	1.1	1 in 6.7 million	IDU, from risk country
HBV	HBsAg anti-HBc HBV NAT	38.3	47.3	1.0	1 in 1.7 million	Sexual transmission, from risk country
HTLV	anti-HTLV I/II	51	9.3	0.2	1 in 2.5 million†	Mainly in families from risk country, IDU
Syphilis	Antibody	NA	29.8	0.4	Likely 0	Sexual transmission
WNV	NAT	2-3*	0	0.1	Varies by year	Mosquito bites in areas where WNV is found (varies by year)
Chagas	Antibody (donors with risk factors)	Unknown	4.1	0.1	NA	Born or lived in a risk country, mother to child

† Risk is much lower due to universal leukoreduction

* 2 days for individual NAT, 3 for minipool NAT

NA = not available

3. Emerging pathogens

In recent years, much more attention has been devoted to assessing the risk of emerging infectious diseases, both in the broad public health context and in the specific context of blood safety.⁴⁻⁵ Since HIV in the late 1970s was a new pathogen with a major impact on blood safety, the transfusion community is particularly aware of the possible threat of emerging pathogens. The term emerging pathogens is usually used to denote infectious agents whose incidence has increased or threatens to increase in the near future. Emerging pathogens may be known existing organisms that have evolved or expanded their geographic range, such as WNV and babesiosis, and most recently Chikungunya virus which has caused a large outbreak in the Caribbean, South and Latin America. They may also be new, previously unknown agents, such as vCJD, SARS or MERS CoV (Middle Eastern Respiratory Syndrome Coronavirus).

The AABB Transfusion Transmitted Diseases Committee (TTDC) reviewed information about agents with actual or potential risk of transfusion transmission in the US or Canada. An in depth assessment of 68 agents was published in August 2009, as a supplement to Transfusion.⁴ The agents were assigned a risk priority level based on both scientific and epidemiologic evidence regarding blood safety, and public and regulatory concern, ranging from red (highest priority), to orange, yellow, and finally white (lowest priority, no concern at present). New information regarding these agents is kept updated on the AABB website. The 16 agents in the red, orange, or yellow categories are shown in Table 2, along with risk factors and exposure routes. A number of these have been updated as additional information becomes available (see table for year of update). Most of the agents are common in other areas of the globe, but like Chikungunya, expanding their range into North America, and many are transmitted by insect bites. Only HHV-8, novel HIV strains, and novel HBV strains may be sexually transmitted. Novel HIV strains have been primarily identified in African countries, and not in the MSM population, although in theory, they may occur in any HIV infected group. HHV-8 is considered in section 4 below. There have been outbreaks of hepatitis A in MSM, likely sexually transmitted. However, it is an acute infection and does not have a chronic carrier state.

Several agents have been added to the list since the original 2009 publication (available on AABB website).⁴ None of these pathogens would be more frequent in the MSM population. Hepatitis E is a virus similar to hepatitis A in its symptomatology epidemiology and sequelae. Long thought to be a disease primarily of travellers to countries with poor sanitation, certain serotypes are now increasingly recognized as a cause of endemic hepatitis in North America, and may pose a risk to transfusion recipients. The epidemiology in North America is as yet unclear, but not linked to male-to-male sex. MERS CoV, mentioned above, has geographic risk and transmission from human to human and possibly camel to human. The measles virus occurs via direct human to human transmission in unvaccinated populations. Several arbovirus infections and yellow fever all have geographic risk and vector borne transmission. XMRV caused initial concern as an emerging threat, but in further studies was conclusively shown to be a nonhuman agent.

Table 3 summarises donor deferral policies, testing, or other measures taken since the creation of CBS in 1998 to address infectious or possibly infectious emerging agents. Several of these agents (vCJD, *T. cruzi*, influenza A, Simian Foamy Virus, Parvovirus B19, *Plasmodium*) are also higher priority agents listed in Table 2, while others are no longer considered emergent (WNV, SARS, and XMRV). These agents have diverse risk factors and exposure routes, however none are sexually transmitted.

In recent years, the time frame between identification of a potential threat and implementation of mitigating measures to protect the blood supply has shortened considerably for a variety of reasons. Major advances in the biological sciences, particularly in molecular biology, permit more rapid investigation and identification of novel organisms, and more rapid development of testing. For WNV, a commercial test was developed and implemented approximately one year after cases were first diagnosed in Canada. While the test was in development, Canadian Blood Services undertook interim safety measures based on geographical and public health information. Better global epidemiologic surveillance and international collaboration networks exist for emerging pathogens, many of which spread from one geographic area to another; vCJD emerged in the UK, while malaria outbreaks happen in many regions of the globe. Finally, there is a lower threshold for taking preventative action without waiting for complete information. In order for an emerging pathogen to be of concern for transfusion safety, it must have certain biological and epidemiological characteristics, such as the existence of an asymptomatic phase in otherwise healthy individuals when the agent is present in the blood stream. Since information about emerging threats may be incomplete, precautionary actions may need to be taken to protect the safety of the blood supply before complete scientific data are available regarding actual blood transmission, or even actual existence of an infectious agent. For example, risk mitigation efforts were taken for vCJD, SARS, SFV, Influenza A, and XMRV prior to demonstration of actual transmission of an infectious agent by blood transfusion.

Monitoring for emerging pathogens is a high priority at Canadian Blood Services and includes activities such as regular scanning of public health literature and web sites, regular interaction with public health workers in Canada and internationally, and participation in AABB and ISBT working groups on transfusion transmissible diseases and surveillance. As part of the risk management process mathematical models have been developed that consider a range of factors to estimate risk from emerging pathogens.⁵ Due to improvements in laboratory and clinical surveillance, public health authorities and blood operators have been able to more rapidly take measures to mitigate both real and theoretical risk.

Table 2. Emerging infectious disease agents, AABB TTDC, 2009

Agent	Risk factors/exposure routes
<p>Red Category vCJD (updated 2011) Dengue virus (updated 2014) <i>Babesia</i> species (updated 2013)</p> <p>Orange Category Chikungunya virus (updated 2015) St. Louis encephalitis virus Leishmania <i>Plasmodium</i> (malaria) <i>T. cruzi</i> (Chagas)</p> <p>Yellow Category Chronic wasting disease (updated 2011) HHV – 8* HIV variants* Parvovirus B19 (updated 2013) Influenza A, H5N1 Simian Foamy Virus <i>Borrelia burgdorferi</i> (Lyme disease) Hepatitis A⁺</p>	<p>geographic, BSE geographic outbreaks, mosquitoes geographic, ticks</p> <p>geographic outbreaks, mosquitoes geographic outbreaks, mosquitoes geographic, sandflies geographic, mosquitoes geographic, reduviid bugs</p> <p>? deer and elk consumption MSM, geographic (Africa) geographic (Africa), sexual transmission outbreaks - school, respiratory outbreaks - pandemic, respiratory exposure to nonhuman primates, bite geographic, ticks geographic, contaminated water, food</p>

*Agents that may be sexually transmitted

⁺ HAV outbreaks have occurred in MSM



Table 3. Measures taken by CBS to reduce possible emerging infectious risks

Agent	Risk factors/exposure routes	Measures
vCJD	geographic, BSE in diet	identification and deferral of at risk donors
SARS	geographic, respiratory	identification and deferral of at risk donors
WNV	geographic outbreaks, mosquitoes	donor testing
Parvovirus B19	outbreaks, respiratory	donor testing by manufacturer of pooled plasma protein products
Simian Foamy Virus	exposure to nonhuman primates, bite	identification and deferral of at risk donors
<i>T. cruzi</i> (Chagas)	geographic, reduviid bugs	identification of at risk donors, change in component production followed by testing
Influenza A, H5N1	possible pandemic, respiratory	comprehensive planning, including deferral of symptomatic donors
<i>Plasmodium</i> (malaria)	geographic, mosquitoes	frequent updating of donor deferral criteria due to shifting risk areas
Chikungunya virus	Mosquito borne, current large outbreak in the Caribbean	Travel survey to determine possible impact of a travel deferral, risk analysis
<i>Babesia microti</i>	Tick borne	Large seroprevalence study on Canadian blood donors – found 0 seropositives. Ongoing tick surveillance
Hepatitis E	Possible swine exposure, other farm animals, foods	Large seroprevalence study on Canadian blood donors-no infectious (NAT positive) donors found

4. MSM population

Known infectious risks

HIV: The Public Health Agency of Canada (PHAC) produces annual updates of reported HIV/AIDS cases and prepares more detailed evaluations of the epidemiology of HIV in Canada every few years.^{6,7} There are currently approximately 71,000 prevalent and 2,250 to 4,100 incident (newly infected) cases of HIV in Canada. The MSM population remains a high risk group for both prevalent and incident HIV infections in Canada, accounting for approximately half of new infections. Individuals with diagnosed HIV infection are unlikely to present to donate blood, and prospective donors are asked about having a positive test for HIV. Individuals who are infected with HIV but unaware of their diagnosis are of more concern, since they may present to donate. The PHAC estimates that approximately 26% of infected individuals are not aware of their diagnosis.

Large studies on MSM populations in Canada (the Omega Cohort, the Vanguard study, the Ontario Men's Study) demonstrate a high frequency of risk taking behaviours, such as anal sex without condom use, or inconsistent or inadequate condom use.³ HIV seroprevalence rates are approximately 10% and annual HIV seroconversion rates in these studies are as high as 1%. However, these studies recruit participants in venues that mainly cater to the gay community, such as bars and specialised health clinics, which attract a skewed subset of the MSM population. Since their primary goal is to aid in the development of preventative health strategies, they are understandably focused on MSM who are currently highly sexually active. 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 1 year. Indeed, individuals who have not had male-to-male sex in the past year are usually excluded in these studies.

Since the change in MSM deferral policy: Since moving to a five year deferral for MSM, we have not seen any increase in the number of HIV positive donations. Close to 100 previously deferred donors have returned to donate, including 6 female donors with a male partner who had male-to-male sex over five years ago. None of these donors has had positive TD test results. Analysis of the anonymous donor surveys performed on male donors before and after the change in policy suggest that there are several hundred male donors who have had sex with another man since 1977 but more than five years ago; there have been no HIV positive male donors who had a history of male-to-male sex over five years ago as a risk factor for HIV (see Section 8, Donor compliance). Although the number of donors is small, these data suggest that individuals who have not engaged in male-to-male sex recently have different behavioural risk characteristics and a lower infectious risk compared to individuals with more recent male-to-male sex included in large cohort studies.

Risks for other known pathogens: Risks for HBV and HCV are higher in the MSM population than in the general population, and co-infection with HIV also occurs. However, male-to-male sex is not the main risk factor for either of these infections. With the introduction of universal HBV vaccination, incidence rates are declining in the general population and blood donor population.¹ The main risk factor for chronic HBV infection in blood donors is immigration from a high prevalence country. HCV rates are also declining in both the general population and the blood donor population, for less well understood reasons¹. The primary risk factors for HCV infection are IDU, and immigration from high prevalence countries. Syphilis is also more prevalent in the MSM population, with increasing outbreaks being reported in MSM.⁸ However, as mentioned above, the infectious agent does not survive using modern blood processing procedures.

Since the change in MSM deferral policy: There has been no change in the rate of any TD markers since the change in policy.

Emerging pathogens

The MSM population remains at higher risk for emerging agents that are sexually transmitted. Those at particularly high risk would be MSM that are currently sexually active, have multiple partners, and are engaging in high risk sexual practices. Individuals who have had no male-to-male sex 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 been abstinent from male-to-male sex for over one year.

As discussed in the emerging pathogens section, male-to-male sex is a risk factor for only one of the 16 agents in the top three risk categories identified by the AABB TTDC, HHV-8, and is not a risk factor for the additional agents added since the 2009 original publication. HHV-8 is a member of the herpes virus family.^{4,9} It was discovered in 1994 in patients with Kaposi's sarcoma, and clinical disease increased during the HIV epidemic, before the development of effective retroviral treatment. HHV-8 is endemic in many African countries. HHV-8 has been shown to be sexually transmitted in the MSM population, and may also be transmitted by other routes, such as saliva, in endemic populations. The prevalence of HHV-8 may be up to 10-25% in MSM without HIV. However, HHV-8 has also been found in 3 to 3.5% of healthy US blood donors. Although HHV-8 is associated with Kaposi's sarcoma, primary effusion lymphoma, and multicentric Castleman's disease, no disease transmission has been demonstrated by

blood transfusion in low prevalence countries, in spite of the high frequency of the agent in blood donors. Several studies have shown that viral nucleic acid is not present in the peripheral blood of donors that are seropositive for HHV-8.

Since the change in MSM deferral policy: MSM are not at higher risk for any of the possible emerging infectious risks addressed by Canadian Blood Services with measures listed in Table 3, or for the more recent agents of interest, including hepatitis E, *Babesia microti*, Chikungunya virus and dengue virus.

5. Héma-Québec Perspective

Héma-Québec changed their MSM deferral criterion in July 2013 at the same time as Canadian Blood Services.

Since the change in MSM deferral policy: Similar to Canadian Blood Services, Héma-Québec has seen no increase in the HIV marker rate, and supports a change to a one year deferral.

6. International criteria

The MSM deferral policies in selected countries are shown in Table 4.^{10,11} Many countries such as New Zealand and the UK, as well as international groups such as the Steering Committee on Blood Transfusion of the Council of Europe, have convened expert committees to perform risk analysis and consider possible changes to criteria.^{11,14}

Gender neutral risk behaviour based criteria

In some countries such as Italy and Spain which do not have national blood programs, certain blood centres have adopted deferral criteria based on gender neutral, high risk sexual behaviour.^{11,15} For example, donors may be deferred for having more than one sexual partner of the same or opposite gender in the last 12 months. These countries do not have a national blood system, and do not operate in a highly regulated, manufacturing environment. Individual donor eligibility assessments are done by specially trained physicians in a face to face interview, rather than by clinic staff using a standardised questionnaire and criteria manual. In addition to these major differences from the Canadian context, the epidemiology of HIV is somewhat different, with higher rates of HIV in heterosexual populations. Although limited data are available from these countries, their HIV positive rates in donors are considerably higher than those reported in Canada, Australia, or other Western European countries.^{11,15} An Italian study showed much higher rates of HIV positivity compared to Canada for both first time and repeat donors (12.3/100,000 in first time Italian donors, vs. 2.1/100,000 in Canadian Blood Services' first time donors; 3.8/100,000 in Italian repeat donors vs. 0.2/100,000 in Canadian Blood Services' repeat donors).¹⁵ Therefore, we do not feel that gender neutral criteria applied to all donors are adequate to maintain the safety of the blood supply in Canada based on currently available data.

. The Council of Europe Steering Committee on Blood Transfusion similarly concluded that this approach could not be easily transposed to other European countries.¹¹

Defined term deferral periods

Several countries have adopted a defined term deferral period for donors with a history of male-to-male sex. Australia moved from a policy ranging from indefinite to five year deferrals in various states, to a uniform one year deferral policy in 2000. An analysis of HIV positive donations collected in the 5 years before and compared with those collected in the 5 years after the deferral change demonstrated a stable, extremely low HIV positive rate of approximately 5 per million donations.¹⁶ All 5 HIV positive donors with MSM as a risk factor had recent male-to-male sex, and should have been deferred. Several other countries have recently changed to a one year deferral period, after a detailed risk assessment. These include England, Scotland and Wales in 2011, New Zealand in Dec 2014, and Sweden in 2012-13.¹²⁻¹⁴

In the US, in Nov 2014, the Department of Health and Human Services' (HHS) Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) voted in favor of a move to a one year deferral period after male-to-male sex. In May 2015, the FDA issued a draft guidance document proposing a change to a one year deferral period.¹⁷ This change could therefore be implemented in 2016.

Since the change in MSM deferral policy: Since 2013, there has been considerable change in international deferral criteria, with a one year deferral period for MSM becoming the industry standard, rather than the exception. To date, no negative safety impacts have been seen (personal communications, Dr. Lorna Williamson and Dr. Rut Norda). However, with the exception of Australia, observation periods have been relatively short.

Table 4. MSM criteria in selected countries

Countries	MSM	Comment
United States	Indefinite (changing to 1 year)	America's Blood Centers and the American Red Cross have advocated for a 1 year deferral for many years. ACBSA (US Department of Health and Human Services) voted for a change to a one year deferral, and the FDA has issued a draft guidance document supporting a one year deferral in May, 2015
Canada	5 years	Change made in July, 2013
Sweden	1 year	Recent change
England, Scotland and Wales	1 year	Changed from an indefinite deferral to 1 year deferral in fall 2011 after a risk assessment
France	Indefinite	May be considering change in policy
South Africa	6 months	Changed from 5 years to 6 months. Epidemiology of HIV is very different in South Africa, and is primarily a disease of the heterosexual population
Australia	1 year	Changed from 5 years to 1 year deferral and published evaluation showing no increase in risk. Regulator did not approve a proposed change to 6 months, citing compliance concerns
New Zealand	1 year	Has changed from a 10 yr to a 5yr and since Dec, 2014 a 1 year deferral after a risk assessment
Japan	6 months	Deferral is for sexual activity with a new partner, not necessarily MSM
Italy	Specific behaviours	Physicians assess donor risk and there is variable practice by blood centre. Epidemiology of HIV is also different from Canada
Spain	Specific behaviours	Physicians assess donor risk and there is variable practice by blood centre. Epidemiology of HIV is also different from Canada



7. Risk modeling

Mathematical models of risk with different MSM donor criteria have been carried out in several developed countries, mainly focused on the risk of an HIV positive unit failing to be detected. The risk of window period infections is amply covered by possible deferral period of 1 year. Residual risks are therefore related to estimates of false negative test results and quarantine release errors (erroneous release of units before test results are available). These risks are now extremely low due to current policies and practices, including better process control and computerisation. Some of the underlying assumptions vary between the models, accounting for slight differences in results. An updated risk estimate for the Canadian blood supply was performed by Germain et al in 2013, and estimated that with a five year deferral, one additional HIV infectious unit would be released into the Canadian blood supply every 1,072 years, assuming compliance did not change.¹⁸ This model has not yet been updated for a one year deferral period; a 2009 version of the model predicted one additional HIV infectious unit would be released into the Canadian blood supply every 500 years (95% CI 105 to 8,333 years).¹⁹

By their very nature, modelling studies will never show a zero increment in risk. In a recent publication models used in the US, the UK and Canada were applied to estimate the number of HIV cases predicted for Australia where the deferral was changed to one year in 2000, and all predicted more than the number that was actually observed.¹⁰

Since the change MSM deferral policy: Risk modelling would have predicted an increase in the number of HIV positive donors in the year post-implementation of a five year deferral period in Canada. In reality, no change in the rate of HIV positive donors was seen at Canadian Blood Services or Héma-Québec (see Section 8, Compliance). The predicted numbers in these updated models are now so low as to constitute a negligible risk increase.

8. Compliance

Compliance with any deferral policy is fundamental to its effectiveness. Failure to admit risk factors and to accept the donor selection criteria is complex. Anonymous donor surveys were conducted before and after changing the selection criteria to five years (Table 5). Following implementation of the five year criteria there was no significant difference in the percentage of male donors who had a history of male-to-male sex in the last 5 years (0.37% pre-implementation vs. 0.43% post-implementation, $p=0.54$). There was a small increase in the percentage of male donors who had a history of male-to-male sex but not in the last 5 years (0.42% pre-implementation vs. 0.66% post-implementation, $p=0.04$). This was largely due to increase in newly eligible donors who had male-to-male sex since 1977 but not in the past 5 years.

We asked all HIV-positive donors identified since implementation of the criteria about possible risk factors. Lack of an acknowledged risk factor in many of these interviews makes it difficult to draw conclusions about recent or remote male-to-male sex. However, no HIV positive donor had male-to-male sex within 5 years prior to donation as an acknowledged risk factor (Table 6).

It is clear that deferral criteria will never be perfectly effective because some people fail to acknowledge their risk during screening, either as a deliberate choice, misinterpretation of the question, or belief that it

does not apply to them. However, experience with reducing the time frame of the MSM deferral has not shown any change in compliance with the criteria. Additionally, the percentage of male donors with undisclosed male-to-male sex in the last year prior to donating was almost identical to the percentage found in Australia (0.23%). This suggests that change to a one year deferral period, as exists in Australia, would not significantly change the noncompliance rate.

Since the change in MSM deferral policy: Compliance with the MSM criterion is at the same level, or slightly better than in earlier anonymous donor surveys performed by Canadian Blood Services.²⁰ If anything, compliance improved slightly after the change in criterion, as donors with remote male-to-male sex are now eligible to donate. There was no increase in donors with HIV positive test results. None of the HIV positive donors had male-to-male sex over five years ago as their sole risk factor.

Table 5. Estimated number and percentage of male whole blood donors with MSM history pre and post-implementation of the 5 year deferral criterion.

Had sex with another man:	Pre-Implementation			Post-Implementation		
	Percentage of Donors	Number of Donors	95% CI	Percentage of Donors	Number of Donors	95% CI
In the last year	0.21	426	239-612	0.19	394	181-608
In the last 5 years but not last year	0.16	335	169-500	0.24	500	259-740
Since 1977 but not last 5 years	0.29	604	382-826	0.49	1,024	680-1,368
Before 1977	0.13	275	125-426	0.17	360	156-564

Donors noncompliant with the criterion in effect at the time of their donation are in **bold**

Table 6. Demographic data and risk factors of 5 donors who tested positive for HIV between July 22, 2013 and March 31, 2015

	Donation Date	Sex	Age	Anti-HIV	NAT	Previous Donations	Risk Factors
1	Aug 2013	F	35	Positive	Positive	Nov 2010	Donor had multiple sexual partners, one of whom was known to be HCV positive.
2	Oct 2013	M	59	Positive	Negative	First-time donor	Donor knew he had HIV but deliberately failed to disclose this. He wanted to be tested for HIV to see if his new medication was working.
3	Apr 2014	M	34	Screen reactive Confirmatory testing not done	Positive	First-time donor	The donor did not acknowledge any risk factors. He had a serious illness about 3 months earlier that was consistent with prodrome and tested negative for HIV at that time.
4	May 2014	M	33	Positive	Positive	Aug 2013 Jul 2011 Mar 2011	Donor did not acknowledge any risk factors.
5	May 2014	M	28	Positive	Positive	First-time donor	The donor did not acknowledge any risk factors.
6	Sept 2014	F	40	Positive	Negative	Oct 2007 Mar 2004 9 previous	Married donor had a relationship with a bi-sexual man later



Canadian Blood Services
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						donations	discovered to be HIV-positive.
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9. Impact on adequacy of supply

A Canadian Blood Services study demonstrated that gender neutral, behaviour based screening criteria that could be implemented in a simple, standardised fashion would result in excessive loss of currently donating safe donors.²⁰ For example, approximately 10% of first time and 5% of repeat donors have had more than one sexual partner in the last year.

It is difficult to estimate the impact a change to a one year deferral policy would have on the adequacy of supply. A small minority of the MSM population that are currently ineligible would be expected to be eligible after a change to a one year deferral period. After the change to a five year deferral period, close to 100 donors who had previously been deferred for remote male-to-male sex returned to donate and were reinstated. Similarly, the post-implementation compliance survey suggests that approximately 400 male donors with a history of male-to-male sex after 1977 but at least five years ago would be expected annually (Table 5). As shown by anonymous surveys performed in Canada, the UK, Australia and the US, some of these individuals are likely currently already donating blood.²⁰⁻²² In a survey performed at two LGBTTTQ festivals in Chicago and New Orleans, 85% of participants expressed an interest in donating blood, and a large percentage mentioned that they had donated at some time in the past.²² A survey performed in San Francisco as part of the 2011 National HIV Behavioural Surveillance Study of MSM questioned participants about interest in blood donation, and various risk factors, such as IV drug use, that would lead to deferral. Approximately three quarters of participants responded affirmatively regarding interest in donating blood, and 2.3% had no male-to-male sex in the last 12 months or other identified risks that would lead to deferral.²⁴

A larger impact on supply may be related to how Canadian Blood Services is perceived by potential blood donors, particularly by younger people, such as university students, who are most concerned about issues of social justice. A small number of student groups across the country continue to take up the cause of seeking a change to the MSM deferral policy. Although these actions have led to a small number of clinics being cancelled or boycotted, they may be contributing to the small percentage of new, young donors recruited overall. Compared to other blood operators, Canadian Blood Services has a low percentage of new donors, and a high number of donations per donor per year. New donors account for 15% of all donations annually, and represent 20% of active donors each year. With the aging of the overall Canadian population in general, and the donor population in particular, failure to engage younger donors will become an increasing problem in maintaining the donor base. Canadian Blood Services is highly reliant on a loyal donor base, with an average donation frequency of 2.1 donations per year. There has been increasing realisation that frequent blood donation leads to iron deficiency in a large percentage of donors. Ideally, the burden of assuring an adequate blood supply for all Canadians should not fall so heavily on a small group of very loyal donors. Changing this paradigm and meeting increasing blood needs of an aging population will require substantial expansion of the donor pool. Operationally, Canadian Blood Services aims to expand the active donor base by at least 10% over the next three years. This will require the recruitment of approximately 80,000 new 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 who feel that the most recent change to the deferral policy did not go far enough to right what they perceive as blatant discrimination. To that end, they continue to promote their End the Ban campaign at local blood donor clinics.

Since the change in MSM deferral policy: Polling by Ipsos-Reid was performed in 2014 in three groups also surveyed before the change to a five year deferral: active donors, the general population, and the Community Based Research Centre (CBRC), a non-profit organisation based in BC with a focus on gay men's health. The Canadian Federation of Students, the fourth group surveyed in 2011 was not specifically surveyed in 2014. Results demonstrated that trust in Canadian Blood Services and perceptions of safety of the blood system remain high. A change to a one year deferral was overall seen as favorable or neutral by most groups, and according to respondents would maintain or increase their intentions to donate or the likelihood of those in their social circle to donate ([Appendix 1](#)).

10. Legal challenges based on perceived discrimination

A gay man, Kyle Freeman, purposely failed to disclose his MSM status in the screening process for blood donation. He informed Canadian Blood Services via an anonymous e-mail and protested the MSM deferral criterion. In order to trace the anonymous e-mail and apply the appropriate deferral code, Canadian Blood Services sued him for negligent misrepresentation. He countersued claiming that Canadian Blood Services violated his rights under the Canadian Charter of Rights and Freedoms. The Ontario Superior court ruled in favour of Canadian Blood Services, and found the criterion not to be discriminatory but rather allowable based on health and safety considerations. However, Justice Aitkin stipulated in her 2010 judgement 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”. It should be noted that the deferral period for MSM risk exposure was not the focus of this court case. Court imposed changes in deferral would place the blood operator in a difficult position as Health Canada regulatory approval would be required before any change in deferral policy could be implemented. The results of this trial created a pivotal shift that allowed for further review of the policy which led to the 2013 implementation of the current five year deferral for MSM.

In addition to the Freeman case, under the previous indefinite deferral criterion for MSM, there were several complaints to provincial human rights authorities alleging discrimination on the basis of sexual orientation. The complaints were dismissed for lack of jurisdiction as the matters fell within federal jurisdiction.

What about a future legal challenge?

Using the previous complaints brought under provincial human rights acts as a guide, it is assumed that any future complaint of discrimination brought under the Canadian Human Rights Act due to a MSM deferral would be grounded on the basis of sexual orientation. Under the Canadian Human Rights Act, it is a discriminatory practice to deny services or access to services that are customarily available to the public on the basis of sexual orientation or to differentiate adversely on the basis of sexual orientation in the provision of the services.

The Canadian Human Rights Commission would first determine whether the activity (i.e. blood donation) is a “service customarily available to the public” and then decide if there was a denial of “service” as a result of sexual orientation. If the answers are yes, then a *prima facie* case of discrimination is made out. The onus then falls on the organization to justify that the discriminatory policy or practice is reasonable and *bona fide* in the circumstances. The Supreme Court of Canada has set out a three-step test for determining whether a discriminatory standard, factor, requirement or rule can be justified as *bona fide*.

The organization must establish on a balance of probabilities that the standard, factor, requirement or rule:

1. was adopted for a purpose or goal that is rationally connected to the function being performed
2. was adopted in good faith, in the belief that it is necessary for the fulfillment of the purpose or goal and
3. is reasonably necessary to accomplish its purpose or goal, in the sense that it is impossible to accommodate the claimant without undue hardship.

Scientific and medical evidence would be required to demonstrate that the deferral criterion is justifiable in the circumstances, taking into consideration the Canadian context. In the Freeman case, requirements 1 and 2 were deemed to have been met by Justice Aitkin. However, as stated above, the trial did not focus on what length of deferral would be considered “reasonably necessary” to accomplish safety goals.

Since the change in MSM deferral policy: As more countries, such as England, New Zealand and the US adopt a one year deferral policy, it may become more difficult to justify why a longer deferral is necessary and not discriminatory in Canada.

11. Canadian Blood Services Outreach

Key Stakeholder Outreach:

In January of 2009, Canadian Blood Services launched the LGBTTQ (Lesbian, Gay, Bisexual, Transgender, Two-Spirit Queer) Working Group made up of LGBTTQ groups, patient groups, and other interested representatives. The purpose of the working group was to expand awareness of the blood program, foster relationships with the LGBTTQ communities and gain better understanding of sexual and gender diversity. The Working Group collaborated on several projects, such as an awareness pamphlet and a public statement on the Canadian Blood Services website. Canadian Blood Services has also participated in several gay pride events. However, following the Freeman trial, during which EGALE Canada, the Canadian AIDS Society and the Canadian Federation of Students (CFS) formally resigned, the LGBTTQ working group was stood down until such time as Canadian Blood Services could determine its next steps.

In September 2011, the Canadian Blood Services board of directors requested that a reduced time-based deferral of no less than five years but no more than ten be proposed to Health Canada based on extensive stakeholder consultation. A new MSM policy working group was therefore created in 2012 comprised of an equal amount of representatives from both patient advocacy and LGBTTQ advocacy groups. Many of the former LGBTTQ Working Group members were invited to return. Many members of this group sent letters to Health Canada in support of the submission for a five year deferral period. This group now provides leadership and advice on affecting any further change to the MSM deferral policy.²

12. Historical overview and environmental scan, LGBTTQ perspective

History of HIV: Starting in the 1970s, HIV and hepatitis C found their way into Canada’s blood supply. By 1990, more than 1,200 Canadians had contracted HIV from blood and blood products; three-quarters of whom have since died. A much larger number—up to 20,000 people—were infected with the hepatitis C virus (HCV), of which the exact number of deaths is unknown. This healthcare tragedy seriously undermined the overall confidence of Canadians, and more specifically, chronic blood users, in the blood

supply. A 1995 poll conducted by Compas Inc. for the Canadian Red Cross indicated that 33% of Canadians would refuse a transfusion fearing tainted blood.

Krever Commission: Governments, needing to bring about radical reform, convened the Commission of Inquiry on the Blood System led by Justice Horace Krever. Representatives from patient groups were among the nearly 500 witnesses during the inquiry. The final report, released on November 26, 1997, called for a single, integrated entity responsible and accountable for the safety and security of the blood system; one that would operate with transparency, collaborative decision-making and a commitment to the paradigm of 'safety is paramount'. This latter point is an approach that patient groups continue to hold the blood operators accountable for when providing input into decision-making.

Canadian Blood Services: Since its launch in 1998, Canadian Blood Services has stabilized the blood supply and restored public confidence. In addition, several fundamental changes have been brought about to ensure transparency and consultative decision-making. One example is that two members of the 13-person Board of Directors are dedicated to representing consumer interests. Other initiatives include opening two of the board meetings held each year to the general public. The National Liaison Committee, an external advisory committee, also ensures stakeholders have another means of access to decision-making in the organization. Over the years, Canadian Blood Services has demonstrated its agility and commitment to react appropriately when a threat to the system emerges; i.e. vCJD, Factor VIII shortage, West Nile Virus.

Patient concerns: Public confidence in the safety of blood and blood products is consistently maintained at a high level (increased from 56% in 1998 to 82% in 2014), and 91% of stakeholders are satisfied with their ability to provide input into the system. With Canadian Blood Services delivering approximately one million products to hospitals in a given year, patients bear the risk of potential transfusion complications.

Environmental Scan: LGBTTTQ Perspective

Self-worth: Any person who is, for whatever reason, unable to donate blood at their local clinic sometimes walks away with a horrible feeling of rejection which perhaps gets added to a lifetime of negative messages by people they trusted, the community they live in or the many large organizations and institutions with which they commonly interact.

HIV Stigmatization: At the beginning of the AIDS epidemic, gay men in many countries were frequently singled out for abuse as responsible for the spread of HIV. The ongoing fear of this deadly disease and the resulting stigma of AIDS as a 'gay' disease continue to occur alongside other forms of discrimination, such as racism and homophobia. In addition to the harmful effect stigmatization has on LGBTTTQ people, it also contributes to making AIDS the silent killer, as people fear the social disgrace of speaking about it, taking available precautions or seeking treatment. Many feel that the MSM deferral policy for blood donation perpetuates societal stigma and discrimination.

Homophobia is generally defined as hostility towards or fear of gay people. There are many different ways in which LGBTTTQ people experience homophobia, including gossip, intimidation, bullying, vandalism, discrimination, isolation, assault, or even being sentenced to death. Despite many countries repealing laws which discriminate against LGBTTTQ people, 80 countries maintain laws which make homosexuality illegal. A recent survey of 37 European countries found that over half of lesbian, gay, bisexual and transgender young people had experienced bullying in school. In addition, many LGBTTTQ

people have become homeless as a result of being rejected by their families after revealing their sexual orientation; in the US, between 20 and 40% of young homeless people are gay, lesbian, bisexual or transgender.

Institutional homophobia refers to the ways in which governments, businesses, educational, religious, and professional organizations systematically marginalize groups on the basis of sexual orientation or identity. While MSM understand they are in a high risk group for HIV and that the Freeman case found the deferral policy to be non-discriminatory, it does not negate the homophobic effect the policy has on LGBTTTQ people; it is another example of an organizational policy that reinforces peoples' fear of and hostility towards gay and other men who have sex with men.

Psychiatric problems: Living in a homophobic environment forces many people to conceal their sexuality. For those brought up to believe that homosexuality is wrong, the realization that they are gay can cause feelings of self-loathing and low self-esteem. Recent studies show homosexuals have a far greater risk of psychiatric problems than do heterosexuals with higher rates of suicide, depression, bulimia, antisocial personality disorder, and substance abuse. One study found suicide attempts among homosexuals were six times greater than the average.³¹

Since the change in MSM deferral policy: While the science supported the move to a five-year deferral, we knew that this incremental change would eventually lead to an even shorter deferral period. The public participation process clearly identified the LGBTTTQ community interest in achieving the ultimate goal of a gender-neutral, behaviour-based screening process, supported by further scientific evidence to ensure safety and adequacy. They are seeking consideration of a policy change to an alternative approach that would allow a safe subset of gay men (to be determined by research) to donate; participants were equally adamant that a shorter deferral period in and of itself was not acceptable. However, it would clearly be more feasible to implement any type of behaviour-based screening if the period of interest was reduced to one year from five years.

Since the implementation of the 2013 change to the policy, Canadian Blood Services has maintained its transparency by participating in several community pride events in order to engage in sometimes difficult conversations. We not only continue to inform and educate but reach out to those who are affected by this policy no matter what their perspective.



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