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Regulating the Risk of Blood-borne Related Infections: Men Who Have Sex with Men Deferral Policy

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Abstract

In Canada, from 1989 to 2013, a man who had had sex with another man (MSM), even once since 1977, was categorically excluded from the blood donor pool. Although the LGBTTTQ community and student groups argued that this exclusion, based solely on sexual orientation, was discriminatory and promoted homophobic attitudes, the painful legacy of the tainted blood scandal and the desire to maintain public trust in the blood supply, prevented Canadian Blood Services from relaxing the eligibility. The recent changes to the MSM blood deferral policy primarily aimed to align the ban with new epidemiological evidence of risk. Implicitly, another goal was to increase blood supply by enhancing young Canadian's perception of blood services, prompting them to become regular donors. An extensive consultation process, lasting almost a decade, was necessary to reach a compromise amongst patient groups opposed to changes to the legislation, and the LGBTTTQ and student groups who wanted to eliminate the deferral for MSM altogether and reform screening practices. A consensus amongst high interest groups was reached in 2013, resulting in the implementation of a 5-year deferral (meaning MSM become eligible donors after five years without sex with other men) and three years later, a change to a 1-year deferral. The changes to the deferral policy have had a small impact on net blood supply; nevertheless, they have succeeded at improving donor compliance, satisfying activists, and advancing the possibility of introducing novel and improved screening tools that tackle the risk inherent in sexual practices rather than the risk related to sexual orientation.

Un homme ayant eu ne serait-ce qu'un seul rapport sexuel avec un autre homme (HSH) après 1977 était catégoriquement exclu du don du sang au Canada entre 1989 et 2013. En dépit des objections de la communauté LGBTTTQ et d'associations étudiantes selon lesquelles cette exclusion, fondée uniquement sur l'orientation sexuelle, était discriminatoire et promouvait les attitudes homophobes, la Société Canadienne du Sang se trouvait empêchée par l'ombre portée du douloureux scandale du sang contaminé ainsi que par sa volonté de maintenir la confiance du public dans la qualité du sang d'assouplir les règles d'éligibilité. Les changements récents à la politique de moratoire sur les dons de sang de HSH visaient essentiellement à adapter l'exclusion aux nouvelles données épidémiologiques sur les risques encourus. Un autre objectif, implicite, était d'améliorer l'image des services de dons de sang auprès des jeunes Canadiens, les poussant ainsi à devenir des donneurs réguliers, afin d'augmenter l'offre de sang. Un processus de consultation approfondie ayant duré pas loin de dix ans a été nécessaire pour atteindre un compromis entre les associations de patients, opposées à tout changement à la législation, et les associations étudiantes ou la communauté LGBTTTQ qui souhaitaient éliminer tout moratoire pour les dons HSH et réformer les pratiques de dépistage. Un consensus fut atteint entre ces groupes d'intérêt en 2013, autour d'un moratoire de cinq ans (ce qui signifie que les HSH deviennent éligibles comme donneurs après cinq ans d'abstinence de rapports homosexuels), puis, trois années

plus tard, un moratoire d'un an. Ces changements de durées de moratoire n'ont eu qu'un effet limité sur l'offre de sang ; cependant, ils ont amélioré l'observance des donneurs, satisfait les activistes, et amélioré les perspectives d'innovation en matière de dépistage, de manière à cibler le risque lié aux pratiques plutôt qu'à l'orientation sexuelle.

Key Messages

- The lifetime ban for MSM on becoming blood donors has been the subject of much controversy since first introduced in 1989, with discourse centring on safety of the blood supply and the perceived discriminatory measures taken to ensure it remains so.
- In response to increasing epidemiological evidence of safety from countries that had curtailed the lifetime ban, and in trying to relieve increasing pressure from activism, the ban was changed to a 5-year deferral in 2013 and then to a 1-year deferral in 2016.
- Although changes to the policy have significantly lessened the stringent criteria for MSM blood donors and have improved donor compliance, the 1-year-deferral remains controversial on the basis that it still excludes potential donors based on orientation rather than sexual behavioural practices.

Messages-clé

- *L'exclusion à vie des HSH du droit à donner son sang a généré de nombreuses controverses depuis son introduction en 1989, entre le souci de préserver la qualité de l'offre de sang, et la perception que cette mesure était discriminatoire.*
- *En réponse aux données épidémiologiques internationales récentes montrant que la qualité du sang n'avait pas souffert dans les pays ayant aboli l'exclusion à vie, et afin d'atténuer le mécontentement de certains groupes de pression, l'exclusion a été réduite à un moratoire de cinq ans en 2013, puis d'un an en 2016.*
- *Même si ces changements ont sensiblement atténué les critères d'éligibilité des donneurs HSH et ont amélioré l'observance des donneurs, le moratoire d'un an reste controversé car il exclue toujours certains donneurs potentiels sur la base de leur orientation sexuelle plutôt que leurs pratiques et comportements sexuels.*

1 BRIEF DESCRIPTION OF THE HEALTH POLICY REFORM

Despite the societal need for adequate blood supply, not everyone can become a donor. To ensure the safety of the blood supply, a screening questionnaire is administered prior to donating blood. Those deemed to be at high risk for carrying blood-borne infections that cannot be detected in their blood (e.g., persons with Variant Creutzfeldt-Jakob disease or who are recently infected with HIV) are either banned from donating blood or are deferred for a set period of time before becoming eligible to donate. A group which historically has experienced strict regulations in becoming blood donors is males who engage, or have engaged, in sexual activity with other males (MSM). Due to the high prevalence of HIV in this group, an indefinite deferral period was put in place in 1989, effectively prohibiting them from donating blood (Krever 1997). In 2013, the regulation stipulating the lifetime ban for individuals identifying as MSM was modified to allow for their participation as blood donors if they abstain from sex with another man for a 5-year period prior to the date of donation (O'Brien *et al.* 2016). On 16 June 2016, further amendments were announced and a change from a 5-year deferral to a 1-year deferral was enacted (Tasker 2016).

2 HISTORY AND CONTEXT

- 1983:** The United States screens for donors at high risk of carrying HIV and excludes them from the donor pool (Berkman and Zhou 2015).
- 1984:** First known case of HIV infection contracted through blood transfusion in Canada (Norris 2008).
- 1985:** The Canadian Red Cross begins testing blood donations for HIV (Norris 2008).
- 1988:** The Canadian Red Cross screens for high-risk donors, banning MSM from donating blood (Krever 1997).
- 1993:** Increases in cases of blood transfusion related infections (“tainted blood crisis”) leads to the creation of The Commission of Inquiry on the Blood System in Canada (The Krever Commission). It is charged with investigating the circumstances surrounding the contamination of blood and related products (Norris 2008).
- 1997:** Justice Horace Krever releases a landmark report outlining faults at all levels of the national blood supply system and proposing a restructuring of blood collection organizations (Krever 1997). The precautionary principle is adopted to inform the policies and operations of blood services in Canada. In order to avoid serious and irreversible damage to individuals, risk control measures are implemented before scientific proof of risk is available (Smith *et al.* 2011).
- 1998:** The Canadian Red Cross Association is stripped of its blood collection capacity and two new agencies are created and given this responsibility: Héma-Québec (HQ) and Canadian Blood Services (CBS) (Norris 2008).

- 1998:** Blood begins to be regulated as are drugs. Health Canada, a federal regulatory body, closely oversees the production and distribution of blood and related products (Goldman *et al.* 2014).
- 2001:** MSM eligibility is revisited in a consensus conference. There is little agreement amongst high interest groups (patients on the one hand, potential donors at-risk on the other) and there is no change to the regulation (Goldman *et al.* 2014).
- 2007:** The McLaughlin Centre for Population Health Risk Assessment evaluated the potential risks associated with changes to MSM blood donor eligibility. They conclude that, for known pathogens, a 1-year deferral period would not increase the statistical risk of blood transfusion related infections for the Canadian public (Goldman *et al.* 2014).
- 2010:** The Ontario Superior Court releases its ruling in the case of *Blood Services v. Freeman*. The court rules that blood donation is a gift and not a right. Although the court deemed the MSM exclusion criteria not to be discriminatory, the judge asserted that the evidence to support the lifetime ban was insufficient (Goldman *et al.* 2014).
- 2013:** Policy is modified from lifetime exclusion to a 5-year deferral period (Goldman *et al.* 2014).
- 2014:** Food and Drug Administration (FDA) announces its decision to change the MSM lifetime ban in the United States to a 1-year deferral period (Berkman and Zhou 2015).
- 2015:** An end to the MSM ban features in the Liberal Party's winning campaign platform in the federal election (Tasker 2016).
- 2016:** Health Canada, pursuant to the *Blood Regulations Act*, accepts CBS's and HQ's proposed change to a 1-year deferral period for MSM blood donors (Tasker 2016).

3 GOALS OF THE REFORM

Since the inception of the regulation in the 1980s, medical advances have made it possible to reduce the time window between contracting HIV or HCV (Hepatitis C virus), and detecting its presence in blood, to about ten days (CBS 2015). Groups in opposition to the MSM lifetime ban used this fact to support their argument that the MSM indefinite deferral was outdated, inaccurately excluded donors, and in consequence, further limited the nation's scarce blood supply. Activists also argued that the ban perpetuated the misconception that MSM were solely to blame for the tainted blood scandal and prompted homophobic attitudes in Canadian society (Lomaga 2007). Thus, the change to the MSM blood donation policy had the following goals:

3.1 Stated

- Expand the blood donor pool.
- Align policy with medical and epidemiological evidence of risk.

- Enact policy that ensures the safety of the public without unfairly excluding specific sexual minorities.

3.2 Implicit

- Agencies in charge of blood collection worry about the aging of the donor population, in part due to lower donation rates among younger Canadians. They are also aware that the ban on MSM donors may be seen as unfair by groups with influence on the younger population. Even though it is never stated that reducing the deferral period might result in an increase in the pool of donors, it is significant that the two concerns (low donation rate among the young and poor image of agencies within that population) are often mentioned simultaneously by CBS or HQ.
- Reduce institutionalized stigma associated with sexual orientation.

4 FACTORS THAT INFLUENCED HOW AND WHY

4.1 The issue came onto the government's agenda

Initially, it was mainly the LGBTTQ community who protested against the indefinite deferral period imposed on MSM blood donors. However, in the mid 2000s, the Canadian Federation of Students (CFS) began to advocate for change to the reform and encouraged the cancellation or boycotting of blood drives on university campuses as a pressuring technique (CBS 2015). Although the boycott did not lessen blood availability, CBS feared that it reflected a disengagement from young individuals regarding blood services (CBS 2015). CBS and HQ recognized that a change of policy might facilitate the recruitment of younger donors and secure an adequate blood supply for the aging population (CBS 2015). Additional stress for a change to the MSM policy came from the *Blood Services v. Freeman* legal challenge. A gay man named Kyle Freeman was sued by CBS for intentionally concealing his MSM status when donating blood. Freeman countersued, claiming a violation of his rights under the Canadian Charter of Rights and Freedoms (Goldman *et al.* 2014). In 2010, the judge presiding over the case delivered a ruling, siding with CBS but declaring that evidence in support of the lifetime ban was lacking (CBS 2015). Indeed, mathematical models of incremental HIV risk related to implementing a 5-year deferral period had shown a minute increase in risk of less than one infected unit every 500 years (CBS 2015). The ruling in *Blood Services v. Freeman* helped to open the floor for discussion amongst high interest groups and later resulted in Health Canada relaxing the deferral period from indefinite to five years (Goldman *et al.* 2014). As England, New Zealand and the United States moved to change the deferral to a 1-year exclusion, it became increasingly difficult to justify a longer deferral period as necessary and non-discriminatory (CBS 2015). In particular, the FDA's 2014 decision to change its MSM eligibility to a 1-year deferral created pressure to change the policy in Canada. This decision was based on the review of studies from several

countries, including the United Kingdom and Australia, that reported no change in risk of contamination of the blood supply following the implementation of a 12-month deferral period for MSM (FDA 2015). The Liberal Party embraced this issue and the elimination of the ban was one of the political promises of the party's winning campaign during the 2015 federal election (Tasker 2016).

4.2 The final decision was made

The interest groups with the most vociferous stance against changes to the lifetime ban on MSM were the Canadian Hemophilia Society (CHS) and the Thalassemia Foundation of Canada, organizations representing patients' interests in the discussion (Goldman *et al.* 2014). Due to their blood-related medical conditions, these individuals would be disproportionately affected by any changes affecting the risk of blood transfusion related infections (CBS 2015). It was not until the 2010 court decision in *Blood Services v. Freeman* that the CHS revisited its position and agreed to a deferral period of at least ten years in place of the lifetime ban (Goldman *et al.* 2014). At this time, the informed opinion of medical experts and mathematical modellers was that the change would not increase the risk of blood transfusion related infections (CBS 2015). In the background, the LGBTTTQ community and student groups strongly supported a decrease, if not complete eradication, of the deferral, believing the nature of the policy to be discriminatory (Goldman *et al.* 2014). Following widespread discussions with various stakeholders, CBS moved to change the MSM policy to a 5-year deferral (Goldman *et al.* 2014). However, the idea that the policy discriminated against MSM on the basis of their sexual orientation rather than sexual practices continued to percolate in groups opposed to the deferral altogether (CBS 2015). This issue was taken onto the Liberal Party's platform in 2014 (Tasker 2016). With the Liberal's rise to power, the issue featured in the policy agenda once more and early in 2016, CBS submitted another application to shorten the deferral to one year which was approved in April 2016 (Tasker 2016).

5 HOW THE REFORM WAS ACHIEVED

5.1 Implementation plan

In 2011, CBS initiated an extensive consultation process aimed at obtaining various stakeholders' perceptions regarding the MSM deferral policy and ensure their support on changing the reform (Goldman *et al.* 2014). It first launched a survey in 2012 to examine the influence that amending the policy would have on perceptions of blood safety, intentions to donate and overall confidence in CBS. High interest groups such as students, LGBTTTQ, existing blood donors and the general public were targeted (Goldman *et al.* 2014). It was found that overall, more support than opposition existed to the proposed change and that reforming the policy might positively influence young Canadians to donate (Goldman *et al.*

2014). A panel of international experts from across various disciplines were then consulted and invited to appraise the scientific content of an article overviewing the history of the MSM deferral policy, current epidemiological data, risk modelling for change and the societal impacts of the policy. With the panel's endorsement, the article was then used to frame further discussion with stakeholders (Goldman *et al.* 2014). In the final step, CBS held face-to-face consultations with the public, ensuring equal representation of all stakeholders' perspectives in the discussion. Respectfulness, inclusiveness and transparency of the process are thought to have led to genuine understanding amongst interest groups, facilitating the consensus on the 5-year period (Goldman *et al.* 2014). Nonetheless, Health Canada's mandate to strictly adhere to the precautionary principle puts into question the importance of stakeholder consultations for changing the MSM policy (Smith *et al.* 2011). Smith *et al.* (2011) argue that the blood scandal and the resulting policy of complete safety regarding the blood supply effectively narrow the role of stakeholders to endorsing policy rather than contributing to policy reformation (Smith *et al.* 2011). Thus, the dialogue between CBS and stakeholders may have been aimed at appeasement rather than collaboration in the policy's reform. Following the introduction of the 5-year deferral in 2013, a minimum of two years of surveillance data were needed before requesting further amendments (CBS 2015). Surveillance included monitoring of transmissible disease testing in donors, investigation of possible transfusion transmitted infections in recipients and horizon scanning for new, emerging pathogens (CBS 2016). Evidence collected during the post-implementation period showed that changes to the policy did not increase the number of donations testing positive for blood-borne infections (O'Brien *et al.* 2016). As before, CBS consulted with all key stakeholders, presenting them with the collected evidence. With their approval, it submitted the request for a 1-year deferral to Health Canada (CBS n.d.)

5.2 Communication plan

Independently, high interest groups, such as patient-related associations and the LGBTTQ community groups, leveraged their networks to inform affected stakeholders of the change, outlining the evidence for supporting the legislation in documents which could be obtained from the organization's websites. However, it is not clear whether CBS commissioned a formal communication strategy for informing the public of the change to the MSM criteria.

6 EVALUATION

Surveillance data obtained from two years of monitoring blood donations revealed that introducing the 5-year deferral period had no impact on the rate of blood-borne related infections (O'Brien *et al.* 2016). Additionally, the reform resulted in a slight improvement in MSM donors' compliance with the criteria set forth by CBS and HQ for blood donation (CBS 2015). The improvement in donor compliance further reduced the risk of HIV-positive donations entering the blood supply. In 2014, CBS conducted a follow-up survey to evaluate

perceptions of blood safety and to examine the level of support for potentially relaxing the deferral further to one year. The general public, active donors and members of the Community-based Research Centre were targeted (Ipsos Reid 2014). Across all groups, overall trust in CBS and in the safety of the blood system remained high. Additionally, the 1-year deferral was seen as favourable or neutral by most groups and would reportedly maintain or increase respondents' intention to donate (Ipsos Reid 2014). CBS continues to closely monitor the impact of the 1-year deferral change on the safety of the blood supply (CBS n.d).

7 STRENGTHS, WEAKNESSES, OPPORTUNITIES AND THREATS

Table 1 summarizes potential benefits and drawbacks of the change in the MSM blood deferral legislation from various stakeholders' perspectives (LGBTTQ, student groups, the public, patient groups, physicians, CBS and HQ). These perspectives are listed in parentheses.

Table 1: SWOT Analysis

STRENGTHS	WEAKNESSES
<ul style="list-style-type: none"> ● Augmenting the population's blood supply by increasing the pool of eligible donors (students, physicians, CBS) ● Enacting policy that more closely aligns with current evidence and with the principle of social justice as it pertains to sexual minorities (LGBTTQ, students) ● Increased funding for research examining sexual behaviour and risk of blood transfusion related infections (LGBTTQ, CBS, physicians, patient groups, doctors) ● Increased donor compliance with the abstinence criteria set out by CBS and HQ. 	<ul style="list-style-type: none"> ● Relaxing the policy introduces the potential for novel and undetectable sexually transmitted infections to infiltrate the blood supply and this would disproportionately affect individuals with blood disorders (patient groups) ● Although we have moved to a 1-year deferral, the exclusion is still based on sexual orientation rather than sexual practices (LGBTTQ, students)

OPPORTUNITIES	THREATS
<ul style="list-style-type: none"> ● Implement improved screening tools for determining risk of carrying blood-borne diseases, targeting high-risk sexual behaviour rather than orientation (the public, LGBTTTQ) ● Improve public perception of CBS and HQ (CBS, HQ, the public) ● Increase the number of repeat blood donors by continuing to engage young Canadians in the evolving discourse concerning the policy (CBS, HQ) 	<ul style="list-style-type: none"> ● Sexual minorities (such as transgender individuals) might also voice concerns over being traditionally categorized based on sex rather than gender, increasing the complexity of screening measures. ● Risk of diminished trust in the blood system should a novel pathogen enter the blood supply (CBS, HQ)

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