

## Catastrophic Failures in Risk Management, 3: Blood Donation Risk and Gay Men

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As we are now seeing in the long-running global financial crisis, the initial stages of catastrophic failures in risk management can have follow-on consequences over long periods of time. In the case of blood donation risk, the infection of blood recipients by the HIV and Hepatitis C viruses in many countries around the world, including Canada, in the 1980s was such a catastrophic failure. This risk is known as “transfusion-transmitted infection” (TTI). [Those unfamiliar with these events and their causes should consult the 3-volume report by Mr. Justice Horace Krever, *Final Report of the Commission of Inquiry on the Blood System in Canada* (1997): <http://www.hc-sc.gc.ca/ahc-asc/activit/com/krever-eng.php>.]

Because male homosexual activity was a key vector in the transmission of these viruses, leading to the contamination of donated blood, blood agencies around the world introduced, in the late 1980s, a policy of “deferral” – a curious euphemism for what amounts to a ban – on blood donations by “men who have had sex with men [MSM], even one time, since 1977.” This is the language of the lifetime ban that is in effect today in most countries of the world, including Canada, the U. S., and much (but not all) of Europe. Other countries have 5-year or 1-year deferrals, which means that blood donation will be accepted from gay men who have been sexually abstinent for specific periods of time prior to the donation. (See the useful Wikipedia entry: [http://en.wikipedia.org/wiki/MSM\\_blood\\_donor\\_controversy](http://en.wikipedia.org/wiki/MSM_blood_donor_controversy).)

Much has changed in the blood donation system since that time, including new forms of screening tests that are able to detect the presence of harmful viruses, capable of causing TTIs, at very low levels. The good news is that those who receive blood for reasons of medical necessity can be assured that the blood they are getting has never been as safe as it is now. But this is a risk scenario, where “very low risk” never means “zero risk.” There are many reasons for this, including limits to detection technologies at very low levels, operational errors, and the constant possibility that a novel pathogen, for which no detection procedure exists, may appear at any time.

In general it may be said that the current blood donor system is very precautionary and will remain so. Blood agencies constantly monitor their pathogen-detection systems under quality control regimes, conduct rigorous surveillance for early detection of novel pathogens, and regularly re-assess their risk estimations for what is known as “residual risk,” which is the risk that a harmful agent present in blood may escape detection prior to infusion in a patient. For Canada the most recent risk estimation for residual risk of HIV in donated blood is 1 in 8 million cases, which represents 1 case in about 10 years of blood donations.

Given the uncertainties that are inevitably present when we estimate very low risks, in this case the risk could be as low as 1 in 20 million donations. This illustrates a very important ethical principle that comes into play with the application of a precautionary approach to very low risks, namely, that we should not try to be more precautionary than our evidence allows us to be. Why is this so? Because these are risk estimations, and there is the possibility that what we fear – in this case, a harmful pathogen in donated blood – may not be there at all (see References: Hrudehy & Leiss 2003).

One reason for applying this principle to blood donation risk is that protecting the blood supply from harmful pathogens is by no means a cost-free exercise. The activities of screening and treating donated blood have very specific costs associated with them, and those costs have risen sharply over the last decade. In Canada provinces pay for the costs of the blood supplied for medical uses, and these charges become part of the overall health care budgets for provincial governments. Demanding more and more stringent safety standards for blood increases its cost and this competes against other demands on those budgets. At some point a judgment has to be made that residual risks in blood are “as low as reasonably achievable” and that, based on current residual risk estimates, blood is “safe enough.” (Of course, new information, such as the discovery of a novel pathogen, changes this calculus.)

The ethical principle that we should not try to be more precautionary than our evidence allows us to be also applies to policy choices. The policy that imposes a lifetime ban on blood donations by gay men in Canada is such a choice. It is made despite the fact that what was once a ten-year ban (the 1987 ban on men who have had sex with men since 1977) has become, with the mere passage of time, a 34-year ban. It is made despite all the subsequent changes in the specificity and sensitivity of screening and treating technologies for harmful pathogens in blood. It should not be allowed to stand or to go unchallenged. (For a technical review of these issues see References: Leiss et al. 2008.)

In the last few years good arguments have been made in the medical literature in support of a drastic shortening of the lifetime ban (see the References section at the end). In Australia, where the practice is a 1-year deferral, a policy that has been in effect for over a decade, there is now some evidence to support the conclusion that a 1-year ban represents no “increased recipient risk for HIV” (References: Seed et al. 2010). HIV is of course a known pathogen. But the greatly enhanced global surveillance for novel pathogens that has been introduced in the past 30 years ought to be regarded as providing substantial protection against the risk that a novel pathogen, using male homosexual activity as a vector, could re-infect donated blood before it was detected. Adding some extra precaution for novel pathogens strongly suggests that a 5-year deferral could be implemented without increasing residual risk. Once further evidence had been accumulated as a result of that policy change, one could be in a position to move more confidently to a 1-year deferral period or to some other appropriate policy choice.

This argument suggests, in effect, that the level of protection against the residual risk of TTI in blood donated by gay men that is mandated in the current lifetime ban is an ethical and legal violation of the right of gay men to be protected against an unreasonable form of discrimination based on sexual orientation.

This is, in fact, a case illustrating the theory of tragedy developed by the philosopher Hegel (1770-1831: see the Wikipedia entry, “Tragedy”). Hegel argued that tragedy originates not in the struggle between right against wrong, but between two competing and equally compelling rights. In the blood case, one of the unassailable rights is the right of blood recipients to be protected by all reasonable means against the threat of transfusion-transmitted infection. No one would argue against such a right. But, on the other side, the current policy of a lifetime ban against blood donations by gay men represents – in my view, unarguably – an unreasonable form of discrimination based on sexual orientation.

Why does this representation of the issue seem to depend on the contrast between “reasonable” and “unreasonable” forms of discrimination? This is because of the underlying argument that the policy choices we make in such matters ought to be firmly grounded on the evidence we possess – in this case, the risk assessment for residual risk in donated blood. The evidence we now possess is that donated blood is not safer, in any measurable sense, in choosing a lifetime ban against a 5-year (or perhaps even 1-year) deferral. Therefore the longer ban is unreasonable and should not be allowed to stand.

In a democratic society public policy choices are, and should be, ultimately political choices. And it is very clear that in Canada and elsewhere, there is no broad political appetite for taking up this issue.

But recently in Canada it also became a matter of legal dispute, in a case decided by Justice Aitken in the Superior Court of Ontario in September 2010 (*Canadian Blood Services v. Freeman*: See References for the complete text). The defendant claimed that the lifetime ban on gay men donating blood violates his Charter rights. In such cases Canadian courts will apply the so-called “Oakes test” (see the Wikipedia entry, *R. v. Oakes*), based on a 1986 decision at the Supreme Court of Canada written by then-Chief Justice Brian Dickson. The key issue is on what basis the courts will permit certain limitations on the rights and freedoms of individuals listed in Section 1 of the Charter. The Oakes test sets three hurdles that must be surmounted for a limitation on a fundamental right to be permitted:

1. The limitation must be “rationally connected” to the objective sought by the policy in question [the “rational connection” principle];
2. The means by which the limitation is implemented must impair the right “as little as possible” [the “minimal impairment” principle];
3. The effects of any limitation must be “proportional” to the achievement of the objective [in this case, the safety of the blood supply].

Much of the substance of the case became effectively moot when Justice Aitken ruled that Canadian Blood Services [CBS] was not subject to the Charter. However, in a

remarkable extension in what became a 177-page decision, Justice Aitken went on to ask how she might have ruled on the substantive Charter issues *if* she had found that CBS was indeed subject to the authority of the Charter – or, in legal terms, if a Section 1 analysis had been necessary in deciding the case. In the last paragraph of her decision she wrote (p. 177): “In conclusion, had a s. 1 analysis been required in this case, I would have found that CBS and Canada would not have met the test for minimal impairment with the MSM deferral period now being 33 years and increasing by an additional year annually.”

Justice Aitken further commented (p. 175) that, had she found that a s. 1 analysis was required in order to resolve the case, she would have, in effect, required both CBS and Health Canada, as the two cooperating regulators of blood safety in Canada, to return to the court with submissions, based on evidence, justifying their choice of a period of time shorter than 33 years (as it was in 2010) for a deferral period.

Thus, to sum up, the original catastrophic failure in the risk management of donated blood, in Canada and elsewhere during the 1980s, gave rise to a second failure, which continues down to the present day. This second failure, attributable to the blood regulatory agencies, is the unwillingness to adjust the deferral period for blood donations by gay men in accordance with evidence-based reasoning. It amounts to a clearly unreasonable form of discrimination based on sexual orientation, and it is a public policy scandal, a blemish on our devotion to the rights and freedoms of individuals that will persist until it is changed, as it must be.

*Additional Notes on CBS v. Freeman:*

I am not qualified to comment on the legal argument under which Justice Aitken ruled that CBS is not subject to the Charter and that therefore the appeal to the protection of Section 1 of the Charter must fail, even though the Government of Canada was also named as a defendant in Freeman’s counter-claim. Thus this may be good law; but it is certainly also bad public policy. All of the screening tests devised by CBS (including the lifetime ban on gay men) are subject to approval by Health Canada, which holds the relevant legal authority under the *Food and Drugs Act* (s. 12 and Schedule D), where blood is regulated as a drug. And CBS could not change the current policy on donations by gay men without approval by the superior authority of Health Canada. (As a federal department Health Canada is subject to the Charter.)

The CBS website contains the following statement:

“We are, and always have been open to changing the policy as long as safety can be maintained and the evidence supports it. Both patient groups and Canadian Blood Services agree that the current lifetime ban needs to be reconsidered, as was stated in a recent Ontario Superior Court decision.”

[http://www.blood.ca/centreapps/internet/uw\\_v502\\_mainengine.nsf/web/A4B9BA180CA282E085257826000F146B?OpenDocument](http://www.blood.ca/centreapps/internet/uw_v502_mainengine.nsf/web/A4B9BA180CA282E085257826000F146B?OpenDocument)

References:

Note: Unfortunately, the text of these materials (except for the first two) is not available free of charge to those using private computers, but can be downloaded as PDF files by those who have access to a university computer account.

Steve Hrudehy and William Leiss, "Risk Management and Precaution," *Environmental Health Perspectives*, vol. 111, no. 13 (October 2003), 1577-1581: [http://leiss.ca/wp-content/uploads/2009/12/risk\\_management\\_and\\_precaution\\_insights\\_on\\_the\\_cautious\\_use\\_of\\_evidence.pdf](http://leiss.ca/wp-content/uploads/2009/12/risk_management_and_precaution_insights_on_the_cautious_use_of_evidence.pdf)

Canadian Blood Services/Société Canadienne du Sang v. Freeman, 2010 ONSC 4885: [http://www.blood.ca/CentreApps/Internet/UW\\_V502\\_MainEngine.nsf/page/CanadianBloodServicesCEOGivesInitialReaction?OpenDocument&CloseMenu](http://www.blood.ca/CentreApps/Internet/UW_V502_MainEngine.nsf/page/CanadianBloodServicesCEOGivesInitialReaction?OpenDocument&CloseMenu) [statement by CBS and link to the complete text of the court decision, Part I (pp. 1-112) and II (pp. 113-end)].

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William Leiss, Michael Tyshenko, and Daniel Krewski, "Men Having Sex With Men Donor Deferral Risk Assessment: An Analysis Using Risk Management Principles," *Transfusion Medicine Reviews*, Vol 22, No 1 (January), 2008: pp 35-57.

*Note:* And earlier and substantially similar version of this article is available at: [http://leiss.ca/wp-content/uploads/2009/12/donor\\_deferral\\_risk\\_assessment.pdf](http://leiss.ca/wp-content/uploads/2009/12/donor_deferral_risk_assessment.pdf)

Eleftherios C. Vamvakas, "Scientific Background on the Risk Engendered by Reducing the Lifetime Blood Donation Deferral Period for Men Who Have Sex With Men," *Transfusion Medicine Reviews*, Vol 23, No 2 (April), 2009: pp 85-102.

Mark Wainberg et al., "Reconsidering the lifetime deferral of blood donation by men who have sex with men," *CMAJ*.2010; 182: 1321-1324.

Clive R. Seed et al., "No evidence of a significantly increased risk of transfusion transmitted human immunodeficiency virus infection in Australia subsequent to implementing a 12-month deferral for men who have had sex with men (CME), *Transfusion*, Volume 50, Issue 12, pages 2722-2730 (December 2010):

"We found no evidence that the implementation of the 12-month deferral for male-to-male sex resulted in an increased recipient risk for HIV in Australia. The risk of noncompliance to the revised deferral rather than its duration appears to be the most important modifier of overall risk."

Eleftherios C. Vamvakas, "Relative Risk of Reducing the Lifetime Blood Donation Deferral for Men Who Have Had Sex With Men Versus Currently Tolerated Transfusion Risks," *Transfusion Medicine Reviews*, Vol 25, No 1 (January), 2011: pp 47-60.