

CANADIAN HEMOPHILIA SOCIETY POSITION:

CURRENT DONOR DEFERRAL CRITERIA ARE IN THE BEST INTERESTS OF BLOOD SAFETY

The Canadian Hemophilia Society (CHS) supports the current Canadian regulations regarding permanent deferrals of certain blood donors, including the restriction on donating blood by men who have had sex with a man (MSM) since 1977. These deferrals are mandated by Health Canada. The U.S. Food and Drug Administration (FDA) and the European Medicinal Evaluation Agency have similar regulations. (See annex 1 for the official CHS policy.)

The CHS is making its position public in the context of a joint statement on March 9, 2006 by AABB, America's Blood Centers, of which Canadian Blood Services and Héma-Québec are members, and the American Red Cross which urged the FDA to modify the deferral period for MSM,¹ and the increasing number of protests against the current regulations on university campuses across Canada. The one and only goal of the CHS is to maintain the highest level of safety for all recipients of blood and blood products in Canada.

Many people with bleeding disorders—von Willebrand Disease, hemophilia B and other rare factor deficiencies—receive plasma-derived blood products on a regular basis. Moreover, all people with bleeding disorders have a higher-than-normal chance of needing fresh blood components such as red blood cells, platelets and fresh frozen plasma. These latter products cannot be virally inactivated during the manufacturing process.

Our concerns are also for the hundreds of thousands of other Canadians who need fresh blood components—for example, those with thalassemia, sickle cell disease, chronic anemias and cancer, and those who have had a serious accident or who require surgery—or fractionated blood products to treat, for example, primary immune deficiencies.

Examples of permanent deferrals in place to safeguard the blood system are:

- people who have taken illegal drugs or illegal steroids with a needle, even one time;
- people who have taken money or drugs for sex, even one time;
- men who have had sex with a man, even one time, since 1977;
- people who have ever taken clotting factor concentrates, such as hemophiliacs;
- people who have visited certain countries in Africa where a strain of HIV not detectable by current tests is prevalent.²

Also permanently deferred are people who have spent more than three months in the United Kingdom or France between 1980 and 1996. This regulation is intended to reduce the risk from variant Creutzfeldt-Jakob disease (vCJD), caused by the ingestion of bovine products infected with bovine spongiform encephalopathy (BSE) or Mad Cow Disease. It was introduced years before the first case of transfusion-transmitted vCJD was identified. Since then the UK has reported four cases of vCJD from red blood cells, demonstrating the pertinence of this precautionary measure.

While the other permanent deferrals are not challenged, the justification for the deferral of men who have had sex with a man has been questioned many times for more than a decade.

Current epidemiological data shows that men who have had sex with a man are at greater risk for HIV/AIDS infection than other people. While HIV in Canada is not restricted to the MSM population, the infection rate is tragically high in this group. Assuming that 5% of the male Canadian population are MSM, current Canadian epidemiological data places the HIV/AIDS prevalence at approximately 4.2 per cent for MSM. This compares to 0.016 per cent in the non-MSM, non IV-drug user male population.³ In other words, using this analysis based on published Canadian data, a male truthfully answering YES to the MSM question is 263 times (4.2/0.016) more likely to be HIV infected than a male who truthfully answers NO.

The CHS position on this issue is the same as that adopted at the conclusion of the November 2001 Canadian Blood Services – Héma-Québec consensus conference on donor selection. The consensus statement reads:

Current laboratory tests used to test for HIV, HBV and HCV on collected blood are highly sensitive and can detect a unit as being potentially infectious for both prevalent infections and shortly after acquisition of infection. However, a small risk of undetected infectivity remains. Furthermore, there is a concern about unknown pathogens that may be transmitted in a similar way to that of known pathogens. It is prudent, therefore, to continue to select donors for donation through application of criteria that reduce the chance of infectious blood being collected.⁴

The Canadian Hemophilia Society is unaware of any new scientific data which would put into question the conclusions of the conference.

In November 2004, the Quebec Hemovigilance Committee, which advises the Quebec Minister of Health on blood safety, reviewed Héma-Québec's proposal to seek a change in the MSM deferral criteria from Health Canada. An excerpt from the summary of the meeting:

Héma-Québec would like to know the position of the Hemovigilance Committee concerning the possibility of modifying the permanent exclusion to a temporary exclusion for men having had sex with another man. For example, men who had been abstinent for 12 months would no longer be deferred.

Considering that:

- *such a measure would only have a minor impact on the number of donors;*
- *the deferral would in any case continue to be seen as discriminatory;*
- *an increase in risk, even minor, is not acceptable;*
- *the incidence and prevalence of hepatitis B is higher in this group;*
- *the incidence of blood-borne sexually transmitted diseases is increasing in this population as in the general population;*
- *such a decision could cause patients to refuse a transfusion because of a perception of increased risk;*
- *no new element suggests a change to the conclusions of the consensus conference held in 2001 on this subject.*

The members of the Hemovigilance Committee voted unanimously in favour of maintaining the current deferral measure.⁵

On June 21, 2007, Canadian Blood Services, following a literature review, analysis of surveillance data, assessment of international MSM policies, an independent risk assessment and consultations with the National Liaison Committee, the Canadian Federation of Students, Egale, healthcare professionals and associations representing recipients, came to this decision⁶:

After careful consideration, the Board of Directors has determined that Canadian Blood Services will maintain the current policy while actively gathering knowledge to close the gaps in information that were identified through the risk assessment and the consultations. As such, we will take steps to better understand emerging pathogens, examine the risks and benefits of behavioural-based questions and monitor the experiences of blood agencies that have modified or changed their MSM deferral policies.

It is recognized that the MSM policy is discriminatory against men who had sex with another man; however, legal decisions have upheld the legality of such discrimination as it was judged to be justified in the interest of public health. One example of this is the decision of the Quebec *Commission des droits de la personne et des droits de la jeunesse* which in 1995 found that the Red Cross' discriminatory deferral of men having had sex with another man was justified.⁷

Much of the recent debate has centred around the risk of HIV transmission through the blood supply should the permanent deferral be relaxed to a 12-month deferral. Nucleic amplification testing (NAT) of each blood donation has reduced the risk of an HIV-positive donation escaping detection. The risk, however, is not zero. False negative tests and laboratory errors mean that testing is not foolproof.

Recent epidemiological research has estimated that a change in regulation to a 12-month deferral would result in one infectious donation entering the blood system in Canada every 16 years.⁸ This would result in three new HIV infections among recipients every 16 years as each donation is divided into three components. Secondary infection to a sexual partner increases the impact of relaxing the regulation. While this is a small increase in risk, it seems unreasonable to adopt a policy which would increase risk to recipients while at the same time regulators and blood system operators are exploring the introduction of new measures to further decrease risk, even marginally. Nucleic amplification testing for hepatitis B virus is one example. Viral reduction applied to fresh components through the use of filters and chemical processes will soon be another.

Even more important from a safety perspective, in the opinion of the Canadian Hemophilia Society, is the increased risk from unknown or emerging blood-borne pathogens. The onset of symptoms could be several years. Evidence that the infection is blood-borne may take more time. Tests to detect the emerging pathogen may not yet be developed. HIV, for example, had an incubation period of between two and ten years between infection and first symptoms. Hepatitis C was suspected for many years before a test could detect its presence in blood donors, and it remained undetected in many victims for decades. In the intervals, thousands were infected. vCJD is thought to have an incubation period of 10 to 30 years. No test has yet been perfected.

Sadly, blood-borne pathogens have had a history of propagating through the MSM, IV-drug user and sex trade populations, and recipients of blood and blood products. Hepatitis B and HIV are but two of the best-known examples.

The Canadian Hemophilia Society believes it would be imprudent not to learn from history.

Recent epidemiology gives credence to this. Human herpesvirus 8 (HHV-8) is a virus that has long been known to cause serious disease in those who are immunocompromised, and to be more prevalent in MSM than in the general population. In October 2006, an article in the *New England Journal of Medicine* showed HHV-8 was transmissible by blood transfusion. No test to detect HHV-8 in blood donations currently exists.⁹ One can easily imagine the scenario in which a new blood-borne, sexually transmitted pathogen for which no screening test exists, and which has a lengthy period from infection to symptoms, enters the blood supply like hepatitis B or HIV. The donor selection questionnaire is the only tool to defend against this scenario.

The tainted blood tragedy is a sad chapter in the history of public health in Canada. Over 1100 Canadians were infected with HIV through tainted blood. Three-quarters of them have passed away. Approximately 20,000 others were infected with hepatitis C after transfusions. The number of deaths from liver disease is not precisely known but could be in the thousands. Fortunately, lessons were learned. The Commission of Inquiry on the Blood System in Canada¹⁰ (the Krever Commission) made recommendations which today are cited around the world. One of these was to take the precautionary approach when considering safety of the blood supply. Given the current evidence, the Canadian Hemophilia Society believes that the precautionary approach should apply to this particular issue.

By their very nature blood donor screening and deferral criteria are discriminatory; however, they are reasonably justifiable where they provide increased protection to public health. While the risk of HIV transmission through the transfusion of blood and blood products has been reduced significantly, the transmission of blood-borne pathogens including HIV remains significant among men who have sex with another man. In the absence of perfect testing, donor screening, including the existing MSM deferral, remains an essential component of blood safety.

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The Canadian Hemophilia Society Blood Safety and Supply Committee: Tom Alloway, Ph.D.; Bill Featherstone; Michael King, M.D.; Martin Kukczyk; James Kreppner; Wilma McClure, R.N.; Bill Mindell, MPH; Tina Morgan; John Plater; Mohammad Qadura; David Page; Bruce Ritchie, M.D.; Craig Upshaw; Pam Wilton, R.N.

Annex 1

Canadian Hemophilia Society policy on donor deferral with regard to men having had sex with another man since 1977

Given that there are discussions underway within the Canadian blood system to change the donor deferral criteria regarding men having had sex with another man since 1977;

Acknowledging that donor deferral criteria are by their very nature discriminatory, but that such discrimination can be justified for reasons of public health;

Given that there is a continued high prevalence of HIV, hepatitis B and other blood-borne pathogens, and a higher risk of emergent blood-borne pathogens in this population;

Given that screening tests are able to screen out known viruses, but unable to reduce risk from new or unidentified pathogens with long periods between infection and detection;

Given the conclusions of the 2001 CBS - Héma-Québec consensus conference on donor selection;

Given that any change to donor deferral criteria should be based on science;

Given that no new science has emerged that would justify a change to the donor deferral criteria regarding men who have had sex with another man since 1977;

Given the demonstrated value of the precautionary approach;

Be it moved that the CHS support no change to the blood donor deferral criteria regarding men who have had sex with another man since 1977.

Moved: Bruce Ritchie, M.D.

Seconded: Tom Alloway, Ph.D.

Carried unanimously by the CHS Board of Directors

November 2005

References

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- ³ Public Health Agency of Canada, HIV/AIDS Updates, May 2005 at http://www.phac-aspc.gc.ca/publicat/epiu-aepi/epi-05/pdf/epi_05_e.pdf
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- ⁶ http://www.bloodservices.ca/CentreApps/Internet/UW_V502_MainEngine.nsf/page/MSM_Statement?OpenDocument
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- ⁹ Wolfgang Hladik, M.D., Sheila C. Dollard, Ph.D., Jonathan Mermin, M.D., Ashley L. Fowlkes, M.P.H., Robert Downing, Ph.D., Minal M. Amin, M.S., Flora Banage, M.B., Ch.B., Esau Nzaro, M.B., Ch.B., Peter Kataaha, M.B., Ch.B., Timothy J. Dondero, M.D., Philip E. Pellett, Ph.D., and Eve M. Lackritz, M.D. Transmission of Human Herpesvirus 8 by Blood Transfusion. *N Engl J Med* 2006;355:1331-8.
- ¹⁰ Commission of Inquiry on the Blood System in Canada http://epe.lac-bac.gc.ca/003/008/099/003008-disclaimer.html?orig=/100/200/301/hcan-scan/commission_blood_final_rep-e/vol1-e.pdf