

## 2003-2004 Report on Canada's Blood System

7 Years after The Commission of Inquiry  
on the Blood System in Canada

Prepared by the Blood Safety Committee  
of the Canadian Hemophilia Society  
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### Legend

- \*\*\*\* Excellent performance, no criticism
- \*\*\* Very good performance, still room for improvement
- \*\* Room for considerable improvement
- \* Not very good performance
- No stars Serious problems

### The Canadian Blood Services

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Evaluation	Headlines	Detailed comments
****	CBS continues to put a high priority on safety in the blood system	<p>The CBS continues to put a high priority on safety in the blood system with the approval in late 2004 of anti-hepatitis B core antigen testing and the prompt introduction of donor deferrals due to a malarial outbreak in the Dominican Republic in December 2004. Its exemplary efforts to introduce West Nile Virus (WNV) testing in time for the summer 2003 mosquito season have resulted in no cases of WNV being transmitted through blood transfusion in either 2003 or 2004. CBS responded promptly in informing physicians of the very small vCJD risk to their patients from the use of UK-sourced plasma products.</p> <p>These and past efforts mean that the risk of infection from blood-borne viruses through transfusion is extremely low, for example:</p> <ul style="list-style-type: none"> <li>• HIV: less than 1 in 4 million units</li> <li>• hepatitis C: less than 1 in 1 million units</li> <li>• West Nile Virus: not measurable in 2004</li> </ul> <p>Now the focus in blood safety must shift to hospital issues such as ABO-incompatible blood (getting the wrong blood type).</p>

****	The CBS has maintained an excellent supply	<p>The CBS has maintained a good supply of fresh components such as red blood cells, platelets and fresh frozen plasma for use in Canadian hospitals.</p> <p>It has also contracted for an excellent supply of factor concentrates to meet the needs of Canadians with hemophilia and other bleeding disorders. The CBS has indicated its readiness to immediately introduce a new plasma-free recombinant product to its inventory once Health Canada approval is granted.</p> <p>Supplies of other plasma-derived blood products (e.g. intra-venous immuno-globulins and albumin) have met the needs of Canadians.</p>
****	In the area of accountability, decision-making and transparency, the National Liaison Committee (NLC) has developed into a very positive forum for stakeholders (including blood recipient groups) to provide input into CBS policies, governance and operations	<p>The National Liaison Committee (NLC) has developed into a very positive forum for stakeholders (including blood recipient groups) to provide input into CBS policies, governance and operations. The CBS responded positively to a proposal, promoted through the NLC and other organizations, to add a public health representative to its Board of Directors, and an appointment was made in 2003. There was a great deal of consultation with stakeholder groups on the 5-year plasma strategy and a CHS proposal regarding the use of surplus proteins for humanitarian use has appeared on the CBS agenda for action. There has been open dialogue with consumer groups and through the NLC on a number of significant issues in CBS policy (Code of Conduct) and operations (e.g. Information System, National Call Centre). Significant improvements in consultations and transparency are noticeable. One of the consumer representatives on the Board of Directors has close connections to blood recipient groups.</p>
****	Top marks for CBS' blood donors	<p>Top marks to the 3% of adult Canadians who are blood, plasma or platelet donors, and whose gifts save thousands of lives.</p>
**	The CBS has made progress towards greater plasma self-sufficiency	<p>While 100% self-sufficiency in all plasma-derived fractionated products is no longer a desirable or realistic goal, the CBS has made progress towards greater self-sufficiency in products made from Canadian plasma with the development of a 5-year plasma strategy to realistically address its sufficiency issues.</p> <p>It has also established a national call centre to facilitate and manage its blood donor appointments and continues to expand its Community Liaison Committees across Canada to promote and facilitate blood donation.</p>

Evaluation	Headlines	Detailed comments
****	Héma-Québec also deserves the highest marks for its commitment to safety	<p>Héma-Québec also deserves the highest marks for its commitment to safety. It developed its own in-house West Nile Virus test in early 2003 in case the commercial test was late. It introduced anti-hepatitis B core antigen testing in April 2003. To reduce the risk of bacterial infections, it introduced bacterial cultures for apheresis platelets and derivation pouches in 2003, and is extending cultures to whole -blood derived platelets in December 2004. Héma -Québec was also quick to react to the issue of vCJD in plasma products from UK donors.</p> <p>These and past efforts mean that the risk of infection from blood-borne viruses through transfusion is extremely low, for example:</p> <ul style="list-style-type: none"> <li>• HIV: less than 1 in 4 million units</li> <li>• hepatitis C: less than 1 in 1 million units</li> <li>• West Nile Virus: not measurable in 2004</li> </ul> <p>Now the focus in blood safety must shift to hospital issues such as ABO -incompatible blood.</p>
****	Héma-Québec has also maintained an excellent supply	<p>Héma-Québec has also maintained an excellent supply. It has consistently been able to furnish Quebec hospitals with fresh components such as red blood cells, platelets and fresh frozen plasma.</p> <p>Héma-Québec has met the needs of Quebecers with hemophilia and other bleeding disorders for the purchase and distribution of factor concentrates. It has also succeeded in supplying the population with plasma-derived blood products (e.g. intra -venous immunoglobulin and albumin).</p>
****	Héma-Québec continues to be open and transparent	<p>Héma-Québec continues to be open and transparent in its dealings with the public. Its Comité de Liaison, made up of representatives from blood recipient and blood donor groups, is consistently consulted on new policies and practices, such as the introduction of new tests or changes in donor eligibility criteria. Héma -Québec also regularly consults with the Québec Hemovigilance Committee. Its Safety Committee shares best practices with experts from around the world. Héma -Québec has held meetings in the 20 regions of Québec to meet and hear from the public.</p>
****	Top marks for Héma-Québec's blood donors	<p>Top marks to the 3% of adult Quebecers who are blood, plasma or platelet donors, and whose gifts save thousands of lives.</p>

*	Greater self-sufficiency in plasma products does not seem to be a priority for Héma-Québec	While 100% self-sufficiency in all plasma-derived fractionated products is no longer a desirable or realistic goal, greater self-sufficiency in plasma products still has some potential benefits. This does not seem to be a priority for Héma-Québec.
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**The Federal Government**  
**Health Canada**  
 (The Biologics and Genetic Therapies Directorate)  
 (The Public Health Agency of Canada)  
 (The Expert Advisory Committee on Blood Regulation)  
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Evaluation	Headlines	Detailed comments
****	Health Canada deserves credit for facilitating the quick introduction of WNV testing	Health Canada deserves credit for its excellent efforts to approve the introduction of West Nile Virus testing at CBS and Héma -Québec before summer 2003. Never before has a blood screening test been introduced so quickly.
***	Health Canada, has finalized the development of comprehensive standards for fresh blood and blood components	<p>After many years in preparation, Health Canada, through contract with the Canadian Standards Association (CSA), has finalized development of comprehensive standards for fresh blood and blood components which apply to all aspects, including manufacturing, transport, storage, transfusion, quality assurance and adverse reaction reporting. The process allows for regular updates to the standards.</p> <p>Unfortunately, while blood recipient groups took part in the elaboration of the standards, they were barred from attending their unveiling. In addition, the standards, distributed by the CSA, are not available to Canadians free of charge.</p>
**	Health Canada's Biologics and Genetic Therapies Directorate is still slow in approving new biological therapeutics	Compared to U.S. and European regulatory authorities, Health Canada's Biologics and Genetic Therapies Directorate is still slow in approving new biological therapeutics. (The same situation prevails for the approval of other drugs.) Reviews take up to twice as long (800 vs. 400 days) in Canada compared to other jurisdictions. More resources are required to allow more timely evaluations.
**	Surveillance systems are essential in a world where new	Health Canada has created the Blood-Borne Pathogens Routine Surveillance System in the Health Care Acquired Infections Division (HCAID), Centre for Infectious Disease Prevention and Control. Such a

	<p>pathogens are emerging yearly</p>	<p>system is essential in a world where new pathogens are emerging yearly. It proved useful in late 2004 by conducting a Canadian risk assessment in response to the two cases of vCJD in the UK and the implications for Canadians who used UK-sourced plasma products.</p> <p>It has also funded the Blood-Borne Pathogens Surveillance Project (BBPSP) at the University of Alberta; however, funding has been cut back just as the system is becoming operational. The BBPSP monitors the possibility of new transfusion-transmitted diseases in the hemophilia-bleeding disorder population and has the potential to be expanded to other groups of blood recipients, including thalassemia, sickle cell anemia and primary immune deficiency.</p> <p>It remains to be seen if the new Public Health Agency of Canada will adequately fund these important initiatives.</p>
**	<p>The federal government should be commended for recognizing its error and considering opening the <i>86-90 Agreement</i> to all people infected with hepatitis C</p>	<p>The federal government should be commended for recognizing its error and considering opening the <i>86-90 Agreement</i> to all people infected with hepatitis C through the blood system, regardless of the date of infection, as Justice Horace Krever recommended.</p> <p>Should the actuarial study show that the current fund is insufficient to cover the additional applicants, the federal government should make a commitment to cover any potential shortfall.</p> <p>The federal government must be faulted for allowing a transfer of funds to the provinces in the "Care not Cash" program such that the provinces were legally free to spend the monies for other purposes than those originally announced.</p>
*	<p>Health Canada consultation process often secretive</p>	<p>Unfortunately, in the summer of 2003, the federal Minister of Health dissolved the National Blood Safety Council, created in the wake of the Krever Inquiry. The Council was open and transparent in its consultations with the public and its recommendations to the Minister.</p> <p>The only federal blood advisory body remaining is the Expert Advisory Committee on Blood Regulations (EAC-BR), which works in a highly secretive manner. The CHS calls on the Minister to make the EAC-BR truly responsive by opening it to the public on the model of the U.S. FDA's Blood Products Advisory Committee. This would allow input from diverse groups, including blood recipient groups.</p> <p>At the same time, the Biologics and Genetic Therapies Directorate has been extremely responsive in</p>

		consultations on specific issues such as West Nile Virus safety measures.
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### Hospitals and Provincial Ministries of Health

Ontario \*\*\*  
Quebec \*\*1/2  
BC \*\*1/2  
Manitoba \*\*1/2  
Other provinces \*\*

Evaluation	Headlines	Detailed comments
****	The provinces deserve top marks for funding a safe, adequate supply of blood and blood products through the CBS and Héma - Québec	The provinces deserve top marks for funding a safe, adequate supply of blood and blood products through the CBS and Héma - Québec. This has permitted both operators to introduce state -of-the-art safety measures, purchase top-quality commercial fractionated blood products and their substitutes, and attract a sufficient number of blood donors to supply Canadian hospitals.
****	Quebec has excellent hemovigilance system	Quebec continues to have one of the world's best-integrated surveillance systems for reporting adverse reactions to blood transfusions, involving hospitals, public health and a hemovigilance committee.
No stars	Hospital-based budgeting in Quebec a threat to good care	The Quebec Ministère de la Santé et des Services sociaux has introduced hospital-based budgeting for blood, blood products and their substitutes. Rather than accounting for the cost of blood products at the provincial level, each hospital will be charged for the products which go through its blood banks. While arguably this is reasonable for products used widely in most hospitals (e.g. red blood cells), the CHS believes the consequences of this administrative reform will be to weaken centres of excellence in hemophilia and other specialized conditions requiring blood products, and to threaten access to these life-saving products in outlying hospitals.
???	Will hospitals be able to introduce the new standards for blood and blood components?	Health Canada, through contract with the Canadian Standards Association, has finalized development of comprehensive standards for fresh blood and blood components which apply to all aspects, including manufacturing, transport, storage, transfusion, quality assurance and adverse reaction reporting. All stakeholders agree with the application of these standards. A study by Health Canada shows that application of these standards will save hundreds of million of dollars in the next 20 years.

<p>**</p>	<p>Ontario, Quebec, Manitoba and BC have provided compensation outside the 86-90 period, but where's the "Care not Cash" money?</p>	<p>Blood banks in many parts of the country, however, are equipped with out-of-date equipment. Staff are already overworked. Will they have the resources to make the required changes, and show they have done so through external audits they must pay for?</p> <p>Ontario, Quebec, Manitoba and BC have provided compensation for people infected with hepatitis C through the blood system when their infection occurred outside the 86-90 period. In 2004, the Quebec government increased the amount to \$24,500.</p> <p>To our knowledge, none of the "Care not Cash" funds given to these provinces in 1998 by the federal government were spent as originally intended; that is, to cover the non-insured additional costs of medical care for people who contracted hepatitis C through blood transfusions. For example, in Ontario, a provincially appointed Advisory Committee submitted recommendations on the use of these funds to the government; however, with a change in government, the recommendations were not followed up and the funds were used to offset the costs of general, already insured, hepatitis C related services.</p>
<p>No stars</p>	<p>Other provinces have done nothing to help those infected with hepatitis C outside the 86-90 window</p>	<p>Alberta, Saskatchewan, NB, NS, PEI, and Newfoundland and Labrador also abused the "Care not Cash" funds and have done nothing since the last report to compensate those infected through the blood system before 1986 and after 1990.</p>
<p>****</p>	<p>Ontario indexes HIV compensation payments</p>	<p>With regard to the indexation of compensation for HIV contracted through blood and blood products, Ontario is to be commended for having recognized an oversight in its original plan. Since 2001, the province has adjusted the 1994 Multi Provincial / Territorial Assistance Plan (MPTAP) payments to its citizens according to increases in the cost of living.</p>
<p>No stars</p>	<p>All other provinces refuse to index MPTAP</p>	<p>In the summer of 2004, the provincial Ministers of Health (with the exception of Ontario) refused to index the Multi Provincial / Territorial Assistance Plan (and its Nova Scotia equivalent) set up in 1994 to compensate 1200 Canadians infected with HIV-AIDS through the blood system. No reason was given. This, despite the fact that cost-of-living adjustments are an integral part of income support programs, including the politicians' own pension plans, and indexation for those still alive would cost very little.</p>