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# 2008-2010 REPORT CARD ON CANADA'S BLOOD SYSTEM



**Canadian Hemophilia Society**  
**Help Stop the Bleeding**

PREPARED BY THE  
**Blood Safety and Supply Committee**  
OF THE  
**Canadian Hemophilia Society**

JANUARY 27, 2011

## Executive Summary

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# Blood system very safe but accountability takes giant step backwards

The 2008-2010 report on Canada's blood system, prepared by the Canadian Hemophilia Society, has found that blood, blood products and their alternatives are very safe and in sufficient supply; however, the system's accountability to recipients has taken a giant step backwards.

According to Canadian Blood Services (CBS) by-laws, and following recommendations of the 1997 Krever Report on Canada's Blood System, two of the 12 CBS Board positions are reserved for persons with "relevant knowledge or experience with organizations representing persons consuming blood and blood products." Over the last decade, almost all of these positions have been held by individuals with very close links to recipient organizations and extensive knowledge of safety and supply issues. However, during the 2009 and 2010 Board renewal process, the Members of CBS, the provincial/territorial Ministers of Health (except Quebec), named both "public directors" with no apparent links to recipient organizations and little knowledge of key issues from a recipient perspective. A number of recipient organizations have denounced the selection process as lacking transparency and resulting in the exclusion of an effective recipient voice at the top level of decision-making at CBS... to no avail. Members of recipient organizations see their exclusion as a clear contravention of CBS' own by-laws, and a giant step backwards in accountability.

Meanwhile, Héma-Québec has maintained Board positions for individuals with a recipient organization perspective.

On a more positive note, the report finds that CBS, Héma-Québec and Health Canada (the regulator of the blood system) have maintained a clear focus on safety. Blood and blood products are safer today than at any time in the past.

The provinces and territories continue to fund the suppliers of blood, blood products and their alternatives in such a way that they can provide life-saving products to Canadians in sufficient supply... with one exception. Solvent-detergent treated plasma is still unavailable, despite licensure by Health Canada in 2006, a lower risk of blood-borne pathogens and adverse reactions compared to fresh frozen plasma, and the fact that SD-plasma is the standard of care in many European countries.

The September 2010 decision by Justice Aitken of the Ontario Superior Court in the case of CBS vs. Freeman was welcomed by recipient organizations. The judgment found that current donor deferral criteria for men who have had sex with men are not discriminatory. As a result, decisions on screening procedures will continue to be made on the basis of the latest science and epidemiology.

The period covered by this report also saw the adoption of legislation in Quebec to provide no-fault compensation in the event that persons are injured by blood or blood products. Such a measure was the first recommendation of the Krever Commission. The other provinces and territories are relying on CBS' self-insurance scheme to provide compensation in the event of another tainted blood tragedy.

Unfortunately, the last three years have seen little progress in the development of a national Orphan Drug Policy that would facilitate the licensure and availability of therapies for rare diseases. Canada is the only highly developed nation without such a policy.

In addition, the Public Health Agency of Canada has, without notice or explanation, stopped funding the Blood-Borne Pathogen Surveillance Project at the University of Alberta. This bank of blood samples from frequently transfused individuals is critical to effective monitoring of emerging pathogens in the blood supply.

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The 2008–2010 Report on Canada's Blood System is the fifth to be released since the reform of the blood system in 1998 following the Krever Commission. In its preparation, the Canadian Hemophilia Society sought input from recipient organizations, Health Canada, manufacturers of fresh blood components, Canadian Blood Services and Héma-Québec.

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N.B. The 2008–2010 report card and the four previous report cards can be found on the CHS Web site at [www.hemophilia.ca/en](http://www.hemophilia.ca/en) or [www.hemophilia.ca/en/safe-secure-blood-supply/report-cards-on-canada-s-blood-system](http://www.hemophilia.ca/en/safe-secure-blood-supply/report-cards-on-canada-s-blood-system).

## Grades

- A** Excellent performance, no criticism  
**B** Very good performance, room for improvement  
**C** Room for considerable improvement  
**D** Not very good performance  
**F** Serious problems

		2003–2004	2005–2007	2008–2010
<b>Canadian Blood Services</b>	Safety	A	A	A
	Supply	A	A	A-
	Plasma self-sufficiency	C	C	B
	Project recovery	–	–	A
	Board appointments	–	–	F
	Accountability and transparency	A	A	B
	CBS' blood donors	A	A+	A+
<b>Héma-Québec</b>	Safety	A	A	A
	Supply	A	A	A
	Plasma self-sufficiency	D	C	C
	Project recovery	–	–	A
	Board appointments	–	–	A
	Accountability and transparency	A	A	A
	No-fault compensation	–	–	A
	Héma-Québec's blood donors	A	A+	A+
<b>Federal Government</b>	Commitment to safety	–	–	A
	Approval of biological therapies	C	B	B
	Orphan drug policy	–	D	D
	Standards for blood and blood components	B	B	B
	Surveillance	C	B-	F
<b>Canada's Justice System</b>	–	F	A	
<b>Provincial and Territorial Governments</b>	Accountability and transparency	–	–	Quebec: A Other provinces and territories: F
	Funding of the blood system	A	Quebec: A Other provinces and territories: B	B
	Comprehensive care for rare disorders	–	D	C
	No-fault compensation	–	D	Quebec: A Other provinces and territories: D
	Hemovigilance	Quebec: A	Quebec: A	Quebec: A Other provinces and territories: C

## Canadian Blood Services (CBS)

HEADLINES	GRADES	DETAILED COMMENTS
<p><b>Safety</b></p> <p>CBS continues to put a high priority on safety in the blood system</p>	<p><b>A</b></p>	<p>CBS continues to put a high priority on safety in the blood system.</p> <p>CBS has moved to the ISBT128 labelling standard to increase recipient safety by virtually eliminating product misidentification and reducing the risk of ABO incompatibility (receiving the wrong blood).</p> <p>In the Freeman court case on donor deferral criteria for men who have had sex with men (MSM), CBS vigorously defended maintaining a permanent deferral in the interest of blood safety. (See Canada's justice system.)</p> <p>CBS has reduced the threats to safety by introducing new deferrals for transfusion-related acute lung injury (TRALI) and Chagas disease. CBS has also introduced selective testing for Chagas.</p> <p>CBS has launched the first phase of a new information system for their Diagnostic Services business line to record and track transfusion related data among donors, hospitals and recipients, and respond to product recalls quickly.</p> <p>CBS has seen a 20 per cent reduction in the rate of recalls (due to error and accident or post-donation information) thanks to improvements in screening processes and a reduction in non-conformances.</p> <p>CBS locations were found to be fully compliant after Health Canada audits.</p> <p>Vigilance with regard to unknown or emerging pathogens must remain paramount though the risk of infection through transfusion from known blood-borne viruses is now extremely low, for example:</p> <ul style="list-style-type: none"> <li>▪ HIV: 1 in 7.8 million units</li> <li>▪ hepatitis C: 1 in 2.3 million units</li> <li>▪ hepatitis B: 1 in 153,000 units (less than 1 in 10 of these infections units actually causes chronic disease)</li> <li>▪ West Nile Virus: no cases of infection through blood in 2008, 2009 or 2010.</li> </ul> <p>In our opinion, CBS continues to place a strong emphasis on blood safety.</p>

HEADLINES	GRADES	DETAILED COMMENTS
<p><b>Supply</b></p> <p>CBS has maintained an excellent supply</p>	<p><b>A-</b></p>	<p>CBS has maintained an excellent supply of fresh components such as red blood cells, platelets and fresh frozen plasma for use in Canadian hospitals.</p> <p>The fill rate for hospital orders for red blood cells and O-negative blood was 98.9% over the last year. As a result, Canadians can count on receiving the blood products they need when in an accident, for surgery or to treat illness.</p> <p>Last year, CBS collected over a million components of blood (922,628 whole blood units; 42,691 platelet units and 56,367 plasma units). This equals 50,000 more units collected from a donor base of 20,000 additional donors compared to four years ago.</p> <p>CBS' active whole blood donor base has increased to 423,000 or 3.4 per cent of the population estimated eligible to donate. This represents an increase of 5 per cent from 2006. Donor frequency rate is the highest amongst CBS' benchmark partners (American Red Cross, America's Blood Centers, Australian Red Cross Blood Services and the NHSBT in the UK with a rate of 2.16 donations per year for whole blood, 8.8 for plasma and 5.6 for platelet donations. On average, only 9 per cent of CBS donors are new donors compared to their American counterparts with a 20 per cent new donor rate. About 90 per cent of CBS donors are repeat donors. (Repeat donors are considered to be the safest.) Surveys indicate a very high donor satisfaction rate.</p> <p>CBS has also contracted for an excellent supply of fractionated products, including clotting factor concentrates, immune globulins and albumin, to meet the needs of Canadians. CBS introduced the new subcutaneous IG formulation which facilitates home treatment.</p> <p>OneMatch – Since implementing EMDIS (European Marrow Donor Information System) in 2009, 70 per cent more Canadian donors are now registered for extended HLA typing. Work-up requests have increased by 19 per cent and CBS attained 250,000 registrants by reaching out to ethnic groups.</p> <p>9,000 blood donors were typed for the presence or absence of rare blood group antigens, increasing the availability of antigen negative blood across Canada.</p> <p>Unfortunately, the Provincial/Territorial Governments have consistently delayed approving introduction of a solvent-detergent plasma that would provide a lower risk of blood-borne pathogens and a decrease in other adverse reactions compared to fresh frozen plasma. This is of greatest</p>

HEADLINES	GRADES	DETAILED COMMENTS
		<p>concern in certain conditions needing frequent transfusion of plasma. (See provincial and territorial governments.)</p> <p>With regards to supply, the CHS takes the position that CBS should ensure access to the most innovative therapies available and allow for product specific physician-patient prescribing choice.</p> <p>A special mention must be made to recognize all the people who work in the background at CBS to ensure a steady supply of blood components and blood products for Canadians.</p>
<p><b>Plasma self-sufficiency</b></p> <p>CBS has increased the collection of plasma for fractionation and the number of different products made from Canadians' plasma</p>	<p><b>B</b></p>	<p>CBS has increased the amount of plasma available per year for fractionation from 150,000 litres in 2006–2007 to more than 180,000 litres in 2009–2010. This has been achieved through increased collection of source plasma through apheresis technology and the introduction of the buffy coat production process.</p> <p>Despite this increase and improved yields by manufacturers, IG (immunoglobulin) self-sufficiency from CBS plasma has only risen slightly to near 30%. This is due to a 23% increase in demand between 2006–2007 and 2009–2010. The balance of the products are manufactured from American source plasma.</p> <p>In 2010 CBS began receiving shipments of clotting factor products to treat von Willebrand disease (a bleeding disorder) that are manufactured from Canadian donor plasma, rather than from an American source. This is a significant achievement. Not only does this save the health care system several million dollars a year, it also makes greater use of each component of a blood donation.</p> <p>CBS has increased its security of supply in fractionated plasma products by awarding a contract to a second plasma fractionator. (Both CBS and Héma-Québec have their plasma fractionated into finished products by specialized pharmaceutical companies outside Canada.)</p>
<p><b>Project Recovery</b></p> <p>Canadian Blood Services has shown leadership in moving forward with this</p>	<p><b>A</b></p>	<p>As a direct result of a proposal from the Canadian Hemophilia Society and the World Federation of Hemophilia, Canadian Blood Services and Héma-Québec are exploring the potential use of their surplus cryoprecipitate paste for the manufacture of clotting factors for humanitarian distribution in regions of the world where these medications are unavailable. Legal, ethical and regulatory hurdles have been overcome. Full-scale</p>

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<p>important humanitarian project</p>		<p>production trials are underway with a fractionator of blood products. If successful, products will begin to be distributed in 2011 and will benefit thousands of patients.</p>
<p><b>CBS Board appointments</b></p> <p>CBS has been part of a flawed Board appointment process led by the Ministers of Health. As a result, the 2 public Board directors no longer adequately represent blood product recipient organizations. This is in violation of CBS' own by-laws.</p>	<p><b>F</b></p>	<p>During the 2009 and 2010 Board renewal process, the members of CBS, the Ministers of Health (except Quebec), replaced the "public directors" on the CBS Board of Directors with individuals who have been involved in the promotion of organ and blood donation but who have little or no knowledge or experience with blood recipient organizations or issues. This is in direct contravention of CBS by-laws and Justice Krever's recommendation.</p> <p>CBS by-law 16 states: "... two Directors shall be elected from the general public on the basis of their relevant knowledge or experience with organizations representing persons consuming blood and blood products [hereafter referred to as the "public directors"]".</p> <p>The Canadian Hemophilia Society believes the public directors should have...</p> <ul style="list-style-type: none"> <li>▪ a past history of being involved in blood safety and supply issues;</li> <li>▪ previously represented the interests of recipients;</li> <li>▪ formally developed their knowledge and expertise in blood safety and supply issues;</li> <li>▪ formal links with recipient organizations that take an active interest in the blood system.</li> </ul> <p>Over the last decade, almost all of these positions had been held by individuals with very close links to recipient organizations and extensive knowledge of safety and supply issues. Members of recipient organizations see their exclusion as a clear contravention of CBS' own by-laws, and a giant step backwards in accountability. Recipients have lost an effective voice at the decision-making level; CBS has lost valuable knowledge and experience.</p> <p>As well, the process for selecting new Board members was neither inclusive nor transparent in 2010. Recipient organizations were not notified that the 2010 selection process would only consider those who had applied during a previous appointment process. As a result, recipient organizations were unable to make new nominations.</p> <p>A number of recipient organizations have denounced the selection process to CBS and Ministers of Health... to no avail.</p>

HEADLINES	GRADES	DETAILED COMMENTS
		<p>Taken together, the flawed nomination process and unrepresentative appointments are contrary to the spirit of the Mission Statement of CBS, which states in part "... to operate the blood supply in a manner that gains the trust, commitment and confidence of all Canadians..."</p>
<p><b>Accountability and transparency</b></p>	<p><b>B</b></p>	<p>With the important exception of the Board appointment process, CBS has remained accountable and transparent.</p> <p>The National Liaison Committee (NLC) has continued to be a valuable forum for blood recipient groups to receive information on CBS activities and to provide input into CBS policy development. The preponderance of recipients on the NLC is a sign that CBS is listening to those most concerned by safety and supply issues.</p> <p>There has been open dialogue with recipient groups and through the NLC on a number of significant issues in CBS policy development, including the contentious MSM issue and the possibility that XMRV (xenotropic murine leukemia virus-related virus) may be associated with chronic fatigue syndrome and be transfusion-transmitted. NLC members were also consulted on a number of national initiatives including the multi-skilled workforce, OneMatch Stem Cell Patient Campaigns, the sale of surplus protein products, language and donor screening, organ and tissue donation and transplantation, and the humanitarian use of surplus proteins (Project Recovery).</p> <p>CBS continues to hold open Board meetings at which members of the public can raise concerns and make presentations.</p> <p>In 2008, CBS awarded contracts for the supply of plasma-derived blood products and their recombinant alternatives. The next Request for Proposals is expected within the next year for a 2013 contract start-up.</p> <p>The CHS encourages CBS to continue the progression to increased transparency by:</p> <ol style="list-style-type: none"> <li>1. Outlining clear decision-making criteria, including transparent weighting of criteria, for product selection, and more details on the timing and decision-making process;</li> <li>2. Ensuring a greater number of patients and physicians on the Selection Advisory Committee;</li> <li>3. Ensuring the involvement of the Selection Advisory Committee throughout the tendering and negotiating process.</li> </ol>

HEADLINES	GRADES	DETAILED COMMENTS
<p><b>Blood donors</b> Active Canadian blood donors get an "A+"</p>	<p><b>A+</b></p>	<p>Top marks to the 3.4% of Canadians eligible to donate blood who are active blood, plasma or platelet donors, and whose gifts save thousands of lives. These donors continue to have a high frequency of annual donations to CBS (2.16 times per year) compared to other countries. Congratulations to the 90,000 Canadians who last year gave blood for the first time! A new generation of young donors is critical to providing life-saving therapies to Canadians in need.</p>

# Héma-Québec

HEADLINES	GRADES	DETAILED COMMENTS
<p><b>Safety</b></p> <p>Héma-Québec deserves the highest marks for its commitment to safety</p>	<p><b>A</b></p>	<p>Héma-Québec continues to put a high priority on safety in the blood system.</p> <p>Héma-Québec has moved to the ISBT128 labelling standard to increase recipient safety by virtually eliminating product misidentification and reducing the risk of ABO incompatibility (receiving the wrong blood). In addition, it is collaborating with Global Standard 1 to introduce an international barcoding system for plasma and recombinant products.</p> <p>Héma-Québec has reduced the threats to safety by introducing new deferrals for transfusion-related acute lung injury (TRALI) and Chagas disease. Héma-Québec has also introduced selective testing for Chagas.</p> <p>Héma-Québec has applied a strategy to ensure that young children receive blood components containing very low levels of lead. It is one of the only suppliers in the world to offer this.</p> <p>Héma-Québec has introduced nucleic amplification testing for hepatitis B virus (HBV). This new test reduces the window period for HBV transmission. The window period is the time after infection when tests are unable to detect infection in a donor's blood.</p> <p>Hemophilia treatment centres, in collaboration with Héma-Québec and the manufacturer of blood products, introduced Helitrax, a system for reporting home factor concentrate usage and patient outcomes directly from patients' own computers directly to their treatment centres.</p> <p>Health Canada has completed audits of all Héma-Québec locations and they were found to be fully compliant.</p> <p>Vigilance with regard to unknown or emerging pathogens must remain paramount though the risk of infection through transfusion from known blood-borne viruses is now extremely low, for example:</p> <ul style="list-style-type: none"> <li>▪ HIV: 1 in 12.8 million units</li> <li>▪ hepatitis C: 1 in 4.6 million units</li> <li>▪ hepatitis B: 1 in 950,000 units</li> <li>▪ West Nile Virus: no cases of infection through blood in 2008, 2009 or 2010.</li> </ul>

HEADLINES	GRADES	DETAILED COMMENTS
		<p>In 2009 Héma-Québec received a <i>Grands Prix québécois de la qualité</i> award in the category of "Public bodies." Also in 2009 the Quebec Chapter of the Canadian Hemophilia Society awarded Dr. Francine Décary, Héma-Québec President and CEO, the distinction of <i>Grand Ambassador</i>.</p> <p>In our opinion, Héma-Québec continues to place a strong emphasis on blood safety.</p>
<p><b>Supply</b></p> <p>Héma-Québec has maintained an excellent supply of blood and blood products</p>	<p><b>A</b></p>	<p>Héma-Québec has maintained an excellent supply. It has consistently been able to meet the needs of Quebec hospitals for fresh components such as red blood cells, platelets and fresh frozen plasma. It has maintained an average inventory of red blood cells of 10.2 days, which is considered excellent. Strong inventory management and good manufacturing practices have lowered the outdating rate for red blood cells to 0.64%, also considered excellent.</p> <p>Héma-Québec has innovated in introducing "double red cell" collections in its GLOBULE collection sites to increase the availability of O-negative blood. (O-negative blood is precious when there is no time to check the recipient's blood type.)</p> <p>Héma-Québec has made a sustained effort to reach out to ethnic communities, notably the Haitian community, to make them aware of the need for certain blood types to treat conditions such as sickle cell disease.</p> <p>Héma-Québec has consistently well served its customers in Quebec's hospitals. In the most recent survey, it received a 98% satisfaction rate among technicians in blood banks, transfusion safety officers and hemophilia centre staff.</p> <p>Héma-Québec has also contracted for an excellent supply of fractionated products, including clotting factor concentrates, immune globulins and albumin, to meet the needs of Quebecers. Héma-Québec introduced the new subcutaneous immune globulin formulation that facilitates home treatment.</p> <p>Unfortunately, the <i>Comité consultatif national en médecine transfusionnelle</i> (CCNMT) has refused to approve the introduction of a solvent-detergent plasma that would provide a lower risk of blood-borne pathogens and a decrease in other adverse reactions compared to fresh frozen plasma. This is of greatest concern for certain conditions needing frequent transfusion of plasma. (See provincial and territorial governments.) Héma-Québec can only supply products approved for listing by the CCNMT.</p>

HEADLINES	GRADES	DETAILED COMMENTS
		<p>Héma-Québec is helping Venezuela cope with shortages of albumin and IVIG by sending its excess supernatant cryoprecipitate to a Venezuelan fractionator.</p> <p>A special mention must be made to recognize all the people who work in the background at Héma-Québec to ensure a steady supply of blood components and blood products for Quebecers.</p>
<p><b>Plasma self-sufficiency</b></p> <p>Much remains to be done in the area of plasma supply</p>	<p><b>C</b></p>	<p>Héma-Québec, which has a smaller supply of plasma for fractionation compared to CBS, remains dependent on a single fractionator for the manufacture of its plasma into immune globulins and albumin. Unlike in the rest of Canada, plasma-derived clotting factor VIII-VWF for the treatment of von Willebrand disease continues to be manufactured from American plasma.</p> <p>The opening of plasma collection centres using the TRIMA® technology has resulted in the collection of an additional 2300 litres of plasma annually in comparison to 2002–2007.</p>
<p><b>Project Recovery</b></p> <p>Héma-Québec has collaborated with Canadian Blood Services on this important humanitarian project</p>	<p><b>A</b></p>	<p>As a direct result of a proposal from the Canadian Hemophilia Society and the World Federation of Hemophilia, Canadian Blood Services and Héma-Québec are exploring the potential use of their surplus cryoprecipitate paste for the manufacture of clotting factors for humanitarian distribution in regions of the world where these medications are unavailable. Legal, ethical and regulatory hurdles have been overcome. Full-scale production trials are underway with a fractionator of blood products. If successful, products will begin to be distributed in 2011 and will benefit thousands of patients.</p>
<p><b>Board appointments</b></p>	<p><b>A</b></p>	<p>Héma-Québec has maintained representation on its Board by individuals with links to recipient organizations.</p>
<p><b>Accountability and transparency</b></p> <p>Héma-Québec continues to be open and transparent</p>	<p><b>A</b></p>	<p>Héma-Québec continues to be open and transparent in its dealings with the public. Its Recipient Representative Advisory Committee, made up of representatives from blood recipient and blood donor groups, is regularly consulted on new policies and practices, such as the introduction of new tests or changes in donor eligibility criteria. Representatives of recipients sit on other key Héma-Québec committees. Its Safety Committee shares best practices with experts from around the world.</p>

HEADLINES	GRADES	DETAILED COMMENTS
		<p>Héma-Québec also regularly consults with the Québec Hemovigilance Committee (CHV) and a member of the CHV sits as an observer on the Héma-Québec Board of Directors.</p> <p>Héma-Québec maintains close communications with transfusion medicine committees in Montreal and Quebec City and with blood bank technicians across the province.</p>
<p><b>No-fault compensation</b></p> <p>Héma-Québec was instrumental in the successful adoption of no-fault compensation</p>	<p><b>A</b></p>	<p>In November 2009 the Government of Quebec passed legislation to implement Recommendation # 1 of the Final Report on the Commission of Inquiry on the Blood System in Canada (Krever Report), statutory no-fault schemes for persons who suffer serious, adverse consequences as a result of the administration of blood products. This legislation will permit those injured to have access to compensation without having to go through a long judicial process.</p> <p>The other provinces have failed to act, though CBS has built a large insurance plan that could provide compensation in the event of blood injury.</p>
<p><b>Blood donors</b></p> <p>Active Quebec blood donors get an "A+"</p>	<p><b>A+</b></p>	<p>Top marks to the 3% of adult Quebecers eligible to donate who are active blood, plasma or platelet donors, and whose gifts save thousands of lives. These donors continue to have a high frequency of annual donations to Héma-Québec (1.59 times per year) compared to other countries. Congratulations to the 40,000 Quebecers who last year gave blood for the first time! A new generation of young donors is critical to providing life-saving therapies to Quebecers in need.</p> <p>Héma-Québec has introduced a pedagogical program entitled Rouge Sang! to make primary and secondary students aware of the importance of blood donation.</p>

# The Federal Government

(Biologics, Radiopharmaceuticals and Genetic Therapies Directorate, Health Canada)  
(The Public Health Agency of Canada)

HEADLINES	GRADES	DETAILED COMMENTS
<p><b>Commitment to safety</b></p> <p>Health Canada has shown a strong commitment to the safety of blood and blood products</p>	<b>A</b>	<p>The Government of Canada strongly supported principles of blood safety in the recent Freeman case on donor deferral of men who have had sex with men (MSM). Health Canada has consistently supported decision-making based on the latest epidemiological data rather than political pressure.</p> <p>Health Canada is now a participant on the WHO Expert Committee on Biologics Standardization (which includes blood and blood products). It is also part of the new WHO Blood Regulators Network working to converge regulatory work globally and facilitate quicker access to new blood components. Health Canada chairs the WHO Global Collaboration on Blood Safety and co-chairs the WHO Global Steering Committee for Hemovigilance.</p>
<p><b>Approvals of biologic therapies</b></p> <p>Health Canada has eliminated the backlog in approvals of new therapies</p>	<b>B</b>	<p>Health Canada, and specifically the Biologics, Radiopharmaceuticals and Genetic Therapies Directorate, deserves credit for eliminating the backlog in approvals of biologic therapies. It is to be hoped that as new therapies (for example, longer-lasting clotting factor concentrates) are developed, Canada will not lag behind Europe and the U.S. in their reviews.</p> <p>Although the timelines for submission approvals are respected, there continue to be challenges with Health Canada's review and approval process for biologics, including: insufficient level of scientific and clinical understanding to adequately assess submissions; inconsistencies in the guidance and directives from the team at Health Canada when reviewing submissions; and a reduced opportunity to discuss and consult on an outcome or decision from Health Canada.</p>
<p><b>Orphan drug policy</b></p> <p>Canada is the only highly-developed nation without an Orphan drug policy</p>	<b>D</b>	<p>Despite years of discussions at the federal level, and now with the provinces and territories, Canada, unlike the U.S. and other developed countries, still has no policy or legislation to facilitate access to drugs for rare diseases.</p> <p>Without an orphan drug policy which includes a definition of rare disorders, (e.g. 1 in 2000), expedited review of marketing applications, clinical protocol assistance, waiving of regulatory fees and market exclusivity, manufacturers of</p>

HEADLINES	GRADES	DETAILED COMMENTS
		<p>drugs for rare diseases have less incentive to apply for market authorization in Canada, or to attempt to market drugs at all.</p> <p>When products remain unlicensed and unmarketed, patients must resort to being part of a clinical trial or accessing the drug through Health Canada's Special Access Program; both options have severe limitations.</p> <p>The development of a national pharmacare plan to reduce the burden of expensive therapies on individuals with rare disorders is crucial.</p>
<p><b>Standards</b></p> <p>Standard for Blood and Blood Components kept up to date</p>	<p><b>B</b></p>	<p>The Canadian Standards Association (CSA), through contract with Health Canada, is keeping the Standard for Blood and Blood Components up to date. The second edition was published in 2010. The Standard for fresh blood and blood components applies to all aspects, including manufacturing, transport, storage, transfusion, quality assurance and adverse reaction reporting.</p> <p>Health Canada is proposing to remove the regulatory framework for blood and blood components from the Food and Drug Act and create a stand-alone tool. Large portions of the CSA Standard will be referenced in regulations. This will facilitate rapid updating. The high-risk areas (e.g. donor selection and testing) will not be referenced and will therefore require pre-marketing submissions by manufacturers.</p> <p>Current plans are to have this regulatory framework in place by 2011.</p>
<p><b>Surveillance</b></p> <p>PHAC cuts funding for surveillance project</p>	<p><b>F</b></p>	<p>Surveillance systems are essential in a world where new pathogens emerge yearly. The Public Health Agency of Canada (PHAC) has funded the Blood-Borne Pathogens Surveillance Project (BBPSP) at the University of Alberta. The BBPSP collects blood from frequently transfused individuals to monitor them for emerging or newly identified transfusion-transmitted diseases. These people include those with bleeding disorders, primary immune deficiencies, hereditary angioedema, thalassemia and sickle cell anemia.</p> <p>In 2010, PHAC cut its funding for the BBPSP without prior notice or explanation. This comes at the same time PHAC is requesting samples from the BBPSP to test for XMRV, a retrovirus potentially transmitted through blood.</p>

## Canada's Justice System

HEADLINES	GRADES	DETAILED COMMENTS
<p><b>CBS vs. Freeman</b></p> <p>The decision in the "Freeman case" ensures donor deferral criteria are based on science and epidemiology</p>	<p><b>A</b></p>	<p>Madam Justice Catherine Aitken of the Ontario Superior Court, in a meticulously written 188-page judgment, found that the current blood donor deferral criteria for men who have sex with men (MSM) are not discriminatory. The deferrals make distinctions for reasons of health and safety, not on the grounds of sexual orientation. The Canadian Hemophilia Society (CHS), which acted as an intervenor in the trial, and many other recipient organizations welcomed the decision. In our opinion, this judgment will support efforts to make the blood supply as safe as possible for Canadians who rely on it.</p>

## Provincial and Territorial Governments

HEADLINES	GRADES	DETAILED COMMENTS
<p><b>Accountability and transparency</b></p> <p>The Provincial and Territorial Ministers of Health (except Quebec) have contravened CBS' by-laws and the spirit of the Krever Report by naming public directors to the CBS Board with little knowledge or experience with blood recipient organizations or issues</p>	<p><b>A</b> (Quebec)</p> <p><b>F</b> (Other provinces and territories)</p>	<p>During the 2009 and 2010 Board renewal process, the members of CBS, the Ministers of Health (except Quebec), replaced the "public directors" on the CBS Board of Directors with individuals who have been involved in the promotion of organ and blood donation but who have little or no knowledge or experience with blood recipient organizations or issues. This is in direct contravention of CBS by-laws and Justice Krever's recommendation.</p> <p>CBS by-law 16 states: "... two Directors shall be elected from the general public on the basis of their relevant knowledge or experience with organizations representing persons consuming blood and blood products [hereafter referred to as the "public directors"]".</p> <p>The Canadian Hemophilia Society believes the public directors should have...</p> <ul style="list-style-type: none"> <li>▪ a past history of being involved in blood safety and supply issues;</li> <li>▪ previously represented the interests of recipients;</li> <li>▪ formally developed their knowledge and expertise in blood safety and supply issues;</li> <li>▪ formal links with recipient organizations that take an active interest in the blood system.</li> </ul> <p>Over the last decade, almost all of these positions had been held by individuals with very close links to recipient organizations and extensive knowledge of safety and supply issues. Members of recipient organizations see their exclusion as a clear contravention of CBS' own by-laws, and a giant step backwards in accountability. Recipients have lost an effective voice at the decision-making level; CBS has lost valuable knowledge and experience.</p> <p>As well, the process for selecting new Board members was neither inclusive nor transparent in 2010. Recipient organizations were not notified that the 2010 selection process would only consider those who had applied during a previous appointment process. As a result, recipient organizations were unable to make new nominations.</p> <p>A number of recipient organizations have denounced the selection process to CBS and the Ministers of Health... to no avail.</p>

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		<p>Taken together, the flawed nomination process and unrepresentative appointments are contrary to the spirit of the Mission Statement of CBS, which states in part "... to operate the blood supply in a manner that gains the trust, commitment and confidence of all Canadians..."</p>
<p><b>Funding of the blood system</b></p> <p>The provinces again deserve good marks for funding a safe, adequate supply of blood and blood products through CBS and Héma-Québec</p>	<p><b>B</b></p>	<p>The provinces again deserve good marks for funding a safe, adequate supply of blood and blood products through 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.</p> <p>On the negative side, the 9 provinces except Quebec, through the Canadian Agency for Drugs and Technologies in Health (CADTH), and Quebec, through its <i>Comité consultatif national en médecine transfusionnelle</i>, have so far refused to approve for funding solvent-detergent-treated plasma as an alternative to fresh frozen plasma for certain indications. SD-plasma offers safety benefits, including a lower risk of blood-borne pathogens and reduced adverse reactions, notably for patients who must receive large volumes of plasma. The 2005–2007 Report Card on Canada's Blood System made the identical criticism. Three years have passed with no action. SD-plasma is the standard of care in many European countries.</p>
<p><b>Comprehensive care for rare blood disorders</b></p> <p>Provincial health care systems still slow to introduce comprehensive care for rare blood disorders</p>	<p><b>C</b></p>	<p>Progress in creating comprehensive care clinics for rare blood disorders such as primary immune deficiency (PID), hereditary angioedema (HAE), thalassemia and sickle cell disease, based on the model of comprehensive care for hemophilia, and as recommended by the Network of Rare Blood Disorder Organizations at its 2006 and 2009 conferences, has been slow. Well-designed clinics are beginning to appear in British Columbia (PID), Alberta (PID and HAE), Winnipeg (PID), Toronto (thalassemia and sickle cell disease), Montreal and Quebec City (PID and HAE).</p> <p>Such clinics, supported by national physician networks, would ensure improved standards of care, better patient outcomes and optimal utilization of expensive blood products.</p>

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<p><b>No-fault compensation</b></p> <p>Recommendation # 1 of the Krever Report, no-fault compensation, was implemented in Quebec in 2009</p>	<p><b>A</b> (Quebec)</p> <p><b>D</b> (Other provinces and territories)</p>	<p>In November 2009 the Government of Quebec passed legislation to implement Recommendation # 1 of the Final Report on the Commission of Inquiry on the Blood System in Canada (Krever Report), statutory no-fault schemes for persons who suffer serious, adverse consequences as a result of the administration of blood products. This legislation will permit those injured to have access to compensation without having to go through a long judicial process.</p> <p>The other provinces have failed to act, though CBS has built a large insurance plan that could provide compensation in the event of blood injury.</p>
<p><b>Hemovigilance</b></p> <p>Quebec has maintained its excellent hemovigilance system</p>	<p><b>A</b> (Quebec)</p> <p><b>C</b> (Other provinces and territories)</p>	<p>Quebec continues to have one of the world's best-integrated surveillance systems for reporting adverse reactions to blood transfusions, involving hospitals, public health, a hemovigilance committee and Héma-Québec.</p> <p>The system not only identifies the greatest risks from blood and blood products but also allows the efficacy of safety measures to be tested.</p> <p>Surveillance systems in other provinces do not systematically record and analyze all adverse transfusion reactions.</p>

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N.B. The 2008–2010 report card and the four previous report cards can be found on the CHS Web site at [www.hemophilia.ca/en](http://www.hemophilia.ca/en) or [www.hemophilia.ca/en/safe-secure-blood-supply/report-cards-on-canada-s-blood-system](http://www.hemophilia.ca/en/safe-secure-blood-supply/report-cards-on-canada-s-blood-system).