

2005-2007 REPORT CARD on Canada's Blood System

Ten Years after the Commission of Inquiry
on the Blood System in Canada

Prepared by the Blood Safety and Supply Committee
of the Canadian Hemophilia Society
November 26, 2007

2005
2007 REPORT
CARD



Canadian Hemophilia Society
Help Stop the Bleeding

Grades

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

A-

Canadian Blood Services (CBS)

GRADES	HEADLINES	DETAILED COMMENTS
A	CBS continues to put a high priority on safety in the blood system	<p>CBS continues to put a high priority on safety in the blood system.</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"> • HIV: 1 in 7.8 million units • hepatitis C: 1 in 2.3 million units • hepatitis B: 1 in 153,000 units (less than 1 in 10 of these infections units actually causes chronic disease) • West Nile Virus: no cases of infection through blood in 2005, 2006 or 2007. <p>The biggest risks to recipients are now ABO-incompatible blood (receiving the wrong blood), bacterial infection and transfusion-related acute lung injury (TRALI). CBS has introduced bacterial detection tests for all platelets gathered via apheresis but, with the ongoing introduction of the buffy coat collection method, lags behind in the introduction of testing platelets from whole blood collections. To reduce the risk from TRALI (linked to plasma from women who have given birth), CBS will be sending male plasma for transfusion, and female plasma for fractionation.</p> <p>In response to political pressure, and despite the lack of new scientific evidence to warrant a change, CBS examined the issue of the permanent deferral of men who have had sex</p>

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		<p>with men (MSM). After extensive consultation with gay rights, student and recipient groups and the National Liaison Committee, CBS decided in June 2007 that making a change to the deferral at this time would not be in the interest of blood safety, and that it would not approach Health Canada to request a change. It will continue to actively gather knowledge to close the gaps in information. The CHS is in agreement with this decision.</p> <p>In 2007, CBS (in conjunction with Héma-Québec) held a consensus conference on emerging techniques to reduce pathogens in fresh blood components. The conclusions of this conference should help CBS to quickly introduce these improvements as they become available. Until pathogen inactivation of fresh components is in place, donor screening remains critical.</p> <p>In our opinion, CBS continues to place a strong emphasis on blood safety and consistently applies the precautionary approach.</p>
A	CBS has maintained an excellent supply	<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 fresh components was 99.17% 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>CBS has made considerable efforts to ensure supply through its public awareness ads, <i>Donors for Life</i> program, <i>Partners for Life</i> program, <i>What's Your Type?</i> program and the creation of a National Blood Donor Week. Its <i>Speakers' Bureau</i> facilitates presentations to encourage blood donation. In addition, CBS initiated the Ottawa Diversity Liaison Committee to help raise awareness and recruit new donors for ethnocultural recipients with unique blood types.</p>

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		<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.</p> <p>CBS involved key stakeholders from the bleeding disorders and primary immune deficiency patient groups in the Selection Advisory Committee to advise CBS on the choice of fractionated products in the 2008-2011 contract period. Such involvement is critical in ensuring that the needs of recipients are taken into account.</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>
C	CBS shows little measurable progress in its plan to move towards greater plasma self-sufficiency	<p>Three years into its 5-year plasma strategy, CBS continues to show little measurable progress in its efforts to collect more plasma for fractionation into manufactured products such as immune globulin and albumin. (Both CBS and Héma-Québec have their plasma fractionated into finished products by a specialized pharmaceutical company outside Canada.)</p> <p>While 100% self-sufficiency in plasma for fractionation is no longer desirable or realistic, CBS' own plasma strategy established the goal of collecting enough plasma to meet the needs for 40% of the required immune globulins and 100% of albumin. Current levels are 26% and 60% respectively. The balance of the products are manufactured from American source plasma.</p> <p>Increased self-sufficiency would reduce the risk of supply interruptions.</p> <p>It is hoped that the transition to the buffy coat blood collection method and the opening of plasmapheresis collection centres will help to reach this goal.</p>

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A	CBS continues to be accountable and transparent in its decision-making	<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 development of a plasma protein products strategy and the contentious MSM issue.</p> <p>Both consumer representatives on the Board of Directors have close connections to blood recipient groups, thus facilitating two-way communication.</p>
A+	Active Canadian blood donors get an "A+"	<p>Top marks to the 3% of adult Canadians 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 79,500 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> <p>Approximately half of the Canadian adult population is eligible to donate blood.</p>

A-

Héma-Québec

GRADES	HEADLINES	DETAILED COMMENTS
A	Héma-Québec deserves the highest marks for its commitment to safety	<p>Héma-Québec continues to put a high priority on safety in the blood system.</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"> • HIV: 1 in 12.8 million units • hepatitis C: 1 in 4.6 million units • hepatitis B: 1 in 950,000 units • West Nile Virus: no cases of infection through blood in 2005, 2006 or 2007. <p>The biggest risks are now ABO-incompatible blood (receiving the wrong blood), bacterial infection and transfusion-related acute lung injury (TRALI).</p> <p>Héma-Québec has introduced bacterial detection tests for all platelets, including those gathered via apheresis and via whole blood donations. Combined with the deviation tube introduced in 2003, this has meant a dramatic reduction in transfusion reactions due to bacterial infections in platelets. None were reported to the Quebec hemovigilance system in 2005, 2006 or 2007. To reduce the risk from TRALI (linked to plasma from women who have given birth), Héma-Québec will be using male plasma for transfusion, and plasma from females with a history of pregnancy for fractionation.</p> <p>In 2007, Héma-Québec (in conjunction with CBS) held a consensus conference on emerging techniques to reduce pathogens in fresh blood components. The conclusions of this conference should help Héma-Québec to quickly introduce these improvements as they become available.</p> <p>In our opinion, Héma-Québec continues to place a strong emphasis on blood safety and consistently applies the precautionary approach.</p>

GRADES	HEADLINES	DETAILED COMMENTS
A	Héma-Québec has also maintained an excellent supply	<p>Héma-Québec has also 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.</p> <p>The fill rate for hospital orders for fresh components has consistently reached 100%. As a result, Quebecers can count on receiving the blood products they need when in an accident, for surgery or to treat illness. Inventory of red cells has consistently exceeded the target of 6 days.</p> <p>Through its ties to the community, Héma-Québec has remained close to its donors. For the first time, more than 50% expressed complete satisfaction with the donation experience, a level rarely reached internationally. The time required to donate remains a sore point among donors, though dissatisfaction is decreasing.</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.</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>Héma-Québec is distributing sub-cutaneous immune globulin to hospitals that make the request. This alternative product, which is approved by Health Canada and widely used in Europe for the last decade, allows those with primary immune deficiency to treat themselves at home rather than have to rely on frequent hospital visits.</p> <p>Héma-Québec involved key stakeholders from the bleeding disorders and primary immune deficiency patient groups in the Selection Advisory Committee to advise on the choice of fractionated products for the 2008-2011 contract period. Such involvement is critical in ensuring that the needs of recipients are taken into account.</p>

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C	Héma-Québec has developed a plan to move towards greater plasma self-sufficiency	<p>In February 2006, Héma-Québec held a consensus conference entitled "Plasma Self-sufficiency in Quebec." Its goal was to reach consensus on strategies to move towards greater self-sufficiency in the plasma needed for the manufacture of fractionated products. (Both Héma-Québec and CBS have their plasma fractionated into finished products, notably immune globulins and albumin, by a specialized pharmaceutical company outside Canada.)</p> <p>While 100% self-sufficiency in plasma for fractionation is no longer desirable or realistic, the conference established a goal of collecting enough plasma to meet the needs for 30-40% of the required immune globulins. The balance of the products are manufactured from American plasma.</p> <p>Increased self-sufficiency would reduce the risk of supply interruptions.</p> <p>The opening of plasmapheresis collection centres will be needed to reach this goal.</p>
A	Héma-Québec continues to be open and transparent	<p>Héma-Québec continues to be open and transparent in its dealings with the public. Its <i>Comité de Liaison</i>, 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. Representatives of recipients sit on other key Héma-Québec committees. Its Safety Committee shares best practices with experts from around the world. Héma-Québec also regularly consults with the Québec Hemovigilance Committee.</p>
A+	Active Quebec blood donors get an "A+"	<p>Top marks to the 3% of adult Quebecers 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 (1.58 times per year) compared to other countries. Congratulations to the 30,000 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>Approximately half of the Quebec adult population is eligible to donate blood.</p>

B-**The Federal Government**

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

GRADES	HEADLINES	DETAILED COMMENTS
B	Health Canada has reduced the backlog in approvals of biologic therapies	The Biologics, Radiopharmaceuticals and Genetic Therapies Directorate of Health Canada deserves credit for its efforts to reduce 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.
D	Canada still has no Orphan Drug Policy	<p>Despite years of discussions at the federal level, 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>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>
D	Health Canada drug approval process remains secretive	<p>Canada, compared to Europe and the U.S., continues to have a drug approval process which is secretive. Despite calls for greater transparency, much remains hidden from the public, for example:</p> <ul style="list-style-type: none"> • the names of the drugs in the regulatory approval system; • results of clinical trials for these drugs; • full comments of Health Canada reviewers about information submitted; • names of drugs that are refused authorization to market.
B	Standard for Blood and Blood Components kept up to date	The Canadian Standards Association (CSA), through contract with Health Canada, is keeping the Standard for Blood and Blood Components up to date. The latest iteration is currently under public review. The Standard for fresh blood and blood components applies to all aspects, including manufacturing, transport, storage, transfusion, quality assurance and adverse reaction reporting. The Standard, distributed by the CSA, is unfortunately not available to Canadians free of charge.

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		<p>Health Canada does not yet refer to this Standard in its own regulations. Current plans are to have a first draft of the regulatory framework prepared by the end of 2007 and completion of the regulations by the end of 2008.</p>
B-	<p>Surveillance systems are essential in a world where new pathogens are emerging yearly</p>	<p>The Public Health Agency of Canada has funded the Blood-Borne Pathogens Surveillance Project (BBPSP) at the University of Alberta. The BBPSP monitors the possibility of new transfusion-transmitted diseases in the bleeding disorder population. It 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 this important initiative.</p> <p>Health Canada is to be commended for the creation of the Expert Advisory Committee on the Vigilance of Health Products. Post-marketing surveillance of drugs is critical to public health.</p>
A	<p>The federal government extends hepatitis C compensation to all</p>	<p>The federal government is commended for extending hepatitis C compensation to those infected through the blood system before January 1, 1986 and after June 30, 1990.</p> <p>While payments have been far too slow in coming, the administrator that oversees the program is now accepting and processing applications.</p>

F

Canada's Justice System

GRADES	HEADLINES	DETAILED COMMENTS
F	The verdicts in the "Armour case" send the wrong message	The not guilty verdicts announced October 1, 2007 in the "Armour case" send the wrong message to drug manufacturers and regulators. That message is that a company with knowledge that its product may be unsafe can suppress the publication of scientific research and withhold critical information from regulatory authorities, yet our justice system finds these actions to be blameless.

Provincial Governments

GRADES	HEADLINES	DETAILED COMMENTS
A (Quebec)	The provinces again deserve good marks for funding a safe, adequate supply of blood and blood products through CBS and Héma-Québec	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.
B (other provinces)		<p>The strength of the Canadian dollar over the last 3 years has made imported fractionated blood products much cheaper. It is hoped that the blood system will continue to be sufficiently funded even if the financial context is less favourable.</p> <p>On the negative side, the 9 provinces except Quebec, through the Canadian Agency for Drugs and Technologies in Health (CADTH), are taking too much time to make sub-cutaneous immune globulin universally available. This alternative product, which is approved by Health Canada and widely used in Europe for the last decade, allows those with primary immune deficiency to treat themselves at home rather than have to rely on frequent hospital visits. A parallel review committee in Quebec has approved sub-cutaneous immune globulin for funding.</p> <p>In addition, solvent-detergent-treated plasma should be provided to Canadian hospitals as an alternative to fresh frozen plasma. For certain indications SD-plasma offers safety benefits.</p>
B (Capital Health in Edmonton and the Calgary Health Region)	Provinces slow to introduce comprehensive care for rare blood disorders	Only the province of Alberta, through the efforts of Capital Health in Edmonton and the Calgary Health Region, has made progress in creating comprehensive care clinics for rare blood disorders such as hereditary angioedema, thalassemia and sickle cell disease, based on the model of comprehensive care for hemophilia. This was recommended by the Network of Rare Blood Disorder Organizations at its 2006 conference.
D (other provinces)		Such clinics would ensure improved standards of care and optimal utilization of blood products.

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D	Recommendation #1 of the Krever Report, no-fault compensation, not implemented	<p>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, has not been implemented.</p> <p>The province of Quebec adopted in principle such a no-fault scheme in November 2006; however, Bill 45 died when the session ended and it has not been re-introduced.</p> <p>None of the other provinces has acted.</p>
A	Quebec has excellent hemovigilance system	<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 the supplier.</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>
A	Ontario provides full cost-of-living indexation for HIV compensation payments	<p>With regard to the indexation of compensation for HIV contracted through blood and blood products, Ontario continues to provide to its citizens full cost-of-living indexation, with retroactivity, for the 1994 Multi Provincial / Territorial Assistance Plan (MPTAP).</p>
B	7 more provinces have acted to index MPTAP over the last 3 years	<p>In the 2005-2007 period, the provinces of Manitoba, Newfoundland and Labrador, Prince Edward Island, Saskatchewan, British Columbia, New Brunswick and Quebec all indexed MPTAP payments to the cost of living; however, none supplied retroactivity for the period of 1994 to the year indexation began.</p> <p>The province of Nova Scotia instituted a different program in 1994; some aspects of the program are indexed.</p>
F	Alberta stalls on MPTAP indexation	<p>One province, Alberta, continues to stall on MPTAP indexation. The beneficiaries of this program, small in number, are seeing the value of their pension-like payments diminish each year. When will the government of Alberta act?</p>

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This report card can be found at www.hemophilia.ca/en or www.hemophilia.ca/en/10.1.

Previous report cards can also be found at www.hemophilia.ca/en/10.1.