

Does Canada face a crisis? US considers ending plasma exports



Barbara Sibbald

In brief

A SHORTAGE OF INTRAVENOUS IMMUNOGLOBULIN has caused the US to question its exports of plasma. Since Canada relies on these exports to provide 60% of its plasma, closing the borders could have serious consequences.

En bref

UNE PÉNURIE D'IMMUNOGLOBULINE INTRAVEINEUSE aux États-Unis a incité ce pays à repenser ses exportations de plasma. Or, comme le Canada compte sur le plasma exporté pour combler 60 % de sa demande, la fermeture des frontières pourrait avoir ici de graves conséquences.

“Exports reduce the amount of immunoglobulin available to [American] patients. Blood and plasma donors provide a precious community resource with the expectation [their donations] will benefit their neighbours and countrymen, particularly in times of shortage. Yet exports of immunoglobulin made from US plasma held constant in 1997, at more than 20% of total production, even as domestic supplies fell by 10%. That is very troubling to many patients, and it is an issue that must be addressed by the manufacturers, regulators, and perhaps by Congress.”

Representative Christopher Shays, US Congress, May 7, 1998

Canada's blood crisis may be far worse than anyone expected. Although the new Canadian Blood Services (CBS), which is to take over responsibility for the blood system from the Red Cross in September, promises to solve long-standing problems surrounding areas such as accountability, another problem now looms: a potential shortage of the plasma used to make fractionated products.

Currently, Canadians provide only 40% of the blood plasma needed for their fractionated blood products; the remaining 60% is provided by American donors, some of whom are paid. However, in the face of a world-wide shortage of plasma-derived products, the US is considering closing its borders to exports. And that would be bad news for Canada.

“It's not outside the realm of possibility that we will face a truly critical shortage,” Ottawa bioethicist Burleigh Trevor-Deutsch said May 10 during the Joint Scientific Conference of the Canadian Society for Transfusion Medicine and the Canadian Red Cross Society.

In the US, the Committee on Government Reform and Oversight has asked its Subcommittee on Human Resources, which is headed by Representative Christopher Shays, to look into an American shortage of intravenous immunoglobulin (IVIG). Given the shortage, American politicians are asking why the 4 main US manufacturers are still exporting 20% of their plasma products, including IVIG, when the US itself doesn't have enough. Canada is the biggest single customer, accounting for 45% of these exports.” [Exports are] very troubling to many patients, and [this is] an issue that must be addressed by the manu-

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facturers, regulators, and perhaps by Congress,” Shays stated in a May 7 address, which was not reported in Canada.

In a presentation to Shays’ committee, the International Plasma Products Industry Association said the estimated 20% shortage during 1997 was caused by increased demand, plant renovations and the withdrawal of more than 40 000 doses of IVIG because of the “theoretical risk” posed by the potential transmission of Creutzfeldt-Jakob disease. In other words, the shortage may have arisen because of special circumstances.

The Bayer Corporation, which supplies virtually all of Canada’s fractionated blood products, also made a presentation. Rob Kloppenburg, Bayer’s director of federal public affairs in Ottawa, says he has the “impression” the US won’t cut off exports. “I feel that would only happen if they felt we were reckless, but we’re not and we are the sole supplier — they agreed that in Canada there was a special relationship.”

The Red Cross was understandably pleased when Bayer told it of the committee’s response. “We’re really glad of that situation,” says Dr. Antonio Giulivi, associate national director of medical and scientific affairs.

Not over yet

But Shays’ committee is still monitoring the shortage and the exports, and any action will depend on whether the shortages continue. During an Apr. 20 hearing on shortages of plasma-based derivatives, the US Advisory Committee on Blood Safety and Availability issued a short-term recommendation that “industry and government should explore the impact of a temporary decrease

in the exportation of plasma derivatives while they are in short supply in the United States.” Meanwhile, US demand for IVIG is increasing by about 10% yearly, primarily due to uses beyond those for which the product has been proven useful. Trevor-Deutsch, an adjunct professor

of bioethics at the University of Ottawa, says this leaves Canada in a precarious situation. “It’s scary,” he says.

Canada has long held the distinction of being one of the few developed countries that must purchase blood products abroad. According to Bayer, Canadians need about 400 000 units of plasma annually; last year, the Red Cross could supply only 167 000 units. A new blood-plasma collection centre in Thunder Bay, Ont., may eventually lessen Canadian dependency on foreign supplies (*CMAJ* 1998;158:380-1), but the country is still a long way from meeting its growing needs for plasma.

Michel Amar, director of communications for the Canadian Blood Service’s transition team, says the Canadian donor base has been declining for nearly a decade, but last year — against some very long odds created by the tainted-blood affair — began to edge up. Blood dona-

tion peaked in 1991–92 at 1.3 million units, but by 1996–97 it had plummeted to 882 636 units — a 32% decline. About half the donated blood is used to make plasma products and half is for transfusions.

Amar cites many factors for the decrease. He said employers are more reluctant to host drives because of the length of time it now takes to donate blood — 45 minutes or longer. As well, about 28% of Canadians still believe that they can contract a disease by donating blood, while many others find the health questions intrusive, even offensive. And then there’s the tainted-blood scandal.





Donors picking up

Amar thinks the donor decline has bottomed out. Between January 1997 and 1998, the number of donors actually rose by about 0.3% despite more rigorous — and time consuming — blood screening, the release of the Krever report and fallout from the hepatitis C issue.

The number of donors could increase still more under the direction of the CBS, which has vowed to work at retaining and increasing the donor base. “We can have a great CBS, but if people aren’t rolling up their sleeves we have no system,” Amar says.

Polls and focus groups conducted by the CBS have revealed that donors are primarily motivated by a desire to help others. They are concerned about continuity within the new system — they want to see the same people at the donor clinics — and they like the recognition program. A recent poll found that 20% of donors feel the system will be safer after the CBS is in place. The CBS plans to contact all 1.2 million Canadian donors with information about the new system and the reasons for the transfer. In addition, 150 000 to 200 000 former donors will be approached.

Amar says focus group results indicate that most Canadians seem willing to come back as donors. “The data are very promising. . . . The support for what CBS is planning to do is high and that’s really good news.” There is also great interest in the CBS itself — its Web site (www.cbstb-btscs.com) has had close to 100 000 hits since its December launch.

Trevor-Deutsch agrees that people want more information and that “we have to rebuild confidence in the blood system.” He favours a specific, well-explained consent form that conveys the risks and benefits associated with blood use. “There’s widespread distrust of Canada’s blood system,” says Trevor-Deutsch. “In this unusual and hopefully transitory situation [that has arisen] because of HIV, hepatitis C and Krever, we have to give more information.”

The CBS may have to give more than just information. Brian Crowell, director of the Canadian Blood Secretariat at Health Canada and a member of the transition board, says that to maintain volunteer donations, organizers will look at “other remuneration in kind.”

“Job number one [for the CBS] is donors, donors, donors,” says Trevor-Deutsch. “We are collectively at risk if we let blood supplies drop.” ?

Making the transition: tight deadline for establishing new blood agency

The new Canadian Blood Services Board of Directors has to deal with some 280 issues before officially taking over governance of the blood system from the Red Cross on Sept. 1.

“We think that it’s doable,” says Bernard Doyle, director of the recently dismantled CBS transition bureau. Issues include developing a communications plan, assessing Red Cross facilities and equipment, and hiring a CEO and other staff. “We want to make sure staff are transferred and in no way lose anything,” said Doyle.

When he addressed the Joint Scientific Conference of the Canadian Society for Transfusion Medicine and the Canadian Red Cross Society in Ottawa on May 8, Doyle said: “Some people think we are doing major reform while taking it over. Our major concern is to take it over as safely and seamlessly as possible.” Still, there will be some significant changes inherent in the new form of governance. Most importantly, there will be a single point of accountability: the CEO and Board of Directors.

The new board is also planning on establishing a different, closer relationship with hospitals so that

products are used more efficiently. “Donor and consumer feedback are also vital,” said Doyle.

The board may think it is busy now, but it should wait until after reforms begin Sept. 1. In the 6 to 18 months following the change in governance, the 13-member board will work with staff to assess key issues such as types of funding (government grants and cost recovery) and whether to continue providing core services. During the following 3 to 5 years, there will be a major review of the system.

Regulations and surveillance will also be improved to meet recommendations contained in the Krever report. Brian Crowell, director of the Canadian Blood Secretariat at Health Canada and a member of the transition board, says that regulation and surveillance have been “slow, passive and poorly resourced” and “the system was dysfunctional.” Crowell said Health Canada will help strengthen the regulatory role with better resources, integrated data collection and analysis, and by being more aggressive in raising standards. “We would like to become a world leader in regulation and surveillance,” said Crowell.