Two Years after Krever

A Report Card for Canada's Blood System

November 1999

Two years after the publication of the Final Report of the Commission of Inquiry on the Blood System in Canada into this country's worst public health catastrophe, what has been the progress from the point of view of the Canadian Hemophilia Society (CHS), whose members were the most severely affected by the twin tragedies of HIV and hepatitis C?

Safety

Héma-Québec:	B
CBS:	C
Health Canada:	C
Provinces:	C-

The Commission of Inquiry revealed that many Canadians were infected with HIV and hepatitis C in the 1980's because Health Canada, the Red Cross and provinces were slow to bring in new safety measures. Recommendation #2 of the Final Report says, "Safety of the blood supply system is paramount." Commissioner Krever went so far as to say, "Preventive action should be taken when there is evidence that a potentially disease-causing agent is or may be blood-borne, even when there is no evidence that recipients have been affected."

Clearly, Canadian Blood Services (CBS), Héma-Québec (H-Q) and Health Canada have taken extensive, and expensive, measures to avoid contamination of the blood system by blood-borne pathogens, including ones that are only potential dangers. These measures include decisions to introduce *genome amplification testing* for hepatitis C, and leukodepletion of all blood donations. The operators should be commended for being in the forefront of the move to these new standards.

In addition, H-Q, CBS and Health Canada worked together to develop new screening measures designed to exclude donors at potentially higher risk of variant CJD from ingestion of British beef. CHS approves of the precautionary approach adopted in this instance.

However, it is worrisome to the CHS that some provinces have threatened not to pay for these safety measures. Such hesitations in the past led directly to the contamination of many Canadians.

Two of Commissioner Krever's key recommendations (#21 and 22) involved the development of a vein-to-vein tracking system involving blood collectors, donors, recipients, physicians, hospitals and public health authorities. Its purpose is to serve as an "early warning system" to identify blood-borne diseases before they affect large numbers of people. Such a system is not yet in place. Some provinces have begun the work. Quebec has created a hemovigilance system with coordinators in key hospitals, a system for reporting adverse reactions and the development of an integrated information system. British Columbia, too, has developed a linked surveillance system to detect problems. And Alberta is experimenting with a blood tracking system of its own. These achievements happen when provincial Ministries of Health accept their own responsibilities in the area of public health. While the CBS must still develop its own computerized tracking system for blood donations, it is increasingly clear that it will not create a national surveillance system designed to be used in hospitals. This is a provincial responsibility.

In recommendations #23 and 28, Commissioner Krever recommended that blood services require local distributors and hospitals be able to locate and recover blood products in the case of a recall or withdrawal. This is a long-standing concern of the CHS. During the quarantine of CJD-associated blood products in December 1998, the blood system in many parts of the country was again unable to quickly remove these products from people's homes. Only Quebec and northern Alberta, to our knowledge, have an effective system in place. A combined CBS-CHS working group established in February 1999 to deal with this problem once and for all has seen its recommendations shelved.

Supply of blood components

Héma-Québec:	B
CBS:	F

The safety of the blood system is also compromised when supplies of blood components (red cells, platelets and plasma) are inadequate.

Héma-Québec, through the creation of local volunteer blood donor recruitment committees and a public relations campaign emphasizing the benefits of blood

donation to recipients (especially children), has been very successful in facilitating the transition from the Red Cross to the new agency.

CBS, unfortunately, has been much less successful. Only in the last few weeks have we seen an aggressive campaign to attract donors. The success of the campaign remains to be evaluated. As a result, many elective surgeries have been cancelled.

While the CHS supports the prudent measures taken with regard to the potential danger from variant CJD, we recognize that this measure is not one that will promote overall safety if the security of supply is compromised as a result. It seems to CHS that Héma-Québec was very responsible in developing a plan to compensate for the lost donations and providing sufficient quantities of blood components to hospitals. Unfortunately, in the territory covered by CBS, no plans were in place prior to the introduction of the new donor screening procedures to cope with the loss of donations.

Self-sufficiency

Héma-Québec:	D
CBS:	D

In recommendation #2, Commissioner Krever wrote that Canada should become self-sufficient in the supply of plasma for blood products (notably, immune globulins and albumin). These products are manufactured mainly in the U.S.

Historically, Canadian volunteer donors have only supplied 40-50% of the plasma needed to manufacture these products. The rest has come from paid American donors. Since the publication of the Final Report, we have moved no closer to the goal of self-sufficiency. To attain self-sufficiency, H-Q and CBS need to open plasmapharesis centres licensed by both Health Canada and the U.S. FDA. (Plasmapharesis is a process in which people donate plasma, but not red cells. As a result, they can donate larger quantities of plasma more frequently.)

CHS has learned that CBS has recently awarded a contract to a multi-national pharmaceutical company to serve as consultants in developing plasmapharesis in Canada. To our knowledge, there has been no consultation on this issue with key CBS committees, little information provided to the CBS Board of Directors, no coordination with Héma-Québec and no discussion with other stakeholders. This is reminiscent of the old system in which key decisions were made behind closed doors, without public scrutiny.

Canadian hemophiliacs have made an almost complete transition to recombinant factor concentrates, made almost entirely without human plasma. This means that the human coagulation factors VIII and IX, needed to treat hemophilia and contained in Canadian volunteer blood donations, are no longer manufactured into blood products. They are wasted. There is a world shortage of these products while eighty percent of the world's hemophiliacs go untreated. CHS has repeatedly challenged the blood services to find a way to make these precious products available at low cost to those in need in other countries. So far, there has been no response.

Accountability, Decision-Making, Transparency

Héma-Québec	B
CBS	D
Health Canada	D

Commissioner Krever's Final Report included a series of recommendations on how Canada's blood services should be structured. In the end, of course, two independent operators were created - one in Québec and one in the rest of the country. One of the CHS' key concerns at the time was the splitting in two of the limited Canadian expertise in running a blood service. We continue to be concerned that Boards of Directors and key committees dealing with safety, science and consumer interests are not developing the experience, knowledge and information base to effectively play their roles. This problem has, in our opinion, been made worse by the decision made not to exchange observers between the Boards of Directors of the two operators.

Our concerns about the ability of the Boards and committees to be effective have proven well-founded, especially regarding CBS. It is the CHS perception that the CBS Board of Directors and its key committees are not being provided the opportunity to direct the agency. This is not meant as a criticism of the people on the Board or the committees, but rather a condemnation of the way these people have been isolated from the flow of information. All CBS committees report to the CEO, not to the Board of Directors. As a result, both Board and committee members are entirely reliant on the information provided by the CEO and are unable to take seriously their oversight role. In addition, members of the Board are not provided with independent audits, as Commissioner Krever recommends (#13). This is reminiscent of the Red Cross whose Board of Governors was uninformed on key issues affecting the blood supply.

Héma-Québec, on the other hand, has chosen to have its committees report to its Board of Directors, as recommended by Commissioner Krever (#14). This will facilitate the development of the knowledge base that will make Board members truly accountable for their decisions.

The CHS is also concerned about the continuing disregard for transparency in the CBS. The important questions about safety and supply during deliberations on the question of donors at higher risk for variant CJD were debated by a sub-committee sworn to secrecy. Again, a public health issue of interest to Canadians was treated with little public input or discussion.

The Bureau of Biologics and Radiopharmaceuticals, the arm of Health Canada that regulates blood and blood products, has repeatedly expressed its intention to be more open and accessible, as recommended by Commissioner Krever (#6, 34). The CHS has yet to see these good intentions put into practice. During the December 1998 quarantine and subsequent investigations into issues surrounding the "Utah donor", the BBR repeatedly refused to provide information, none of which could be termed confidential, to the CHS and to physicians. Despite many requests, physicians and CHS have yet to be officially informed of the Utah donor's autopsy results.

Compensation

Provinces:	D
Federal government:	D

Courts have recently approved the negotiated settlement for Canadians infected with hepatitis C between 1986 and 1990. Ontario has provided a $200 million fund for people infected outside those dates. Québec has agreed to pay $10,000, an amount criticized by all, to those not covered by the negotiated settlement.

However, Commissioner Krever's recommendation #1, no-fault compensation for all Canadians who have suffered adverse consequences from blood or blood products, awaits resolution.

Conclusion

In the opinion of the CHS, the greatest benefit of the Commission of Inquiry on the Blood System in Canada has been the huge increase in knowledge and awareness of blood issues among Canadians, in general, and the medical community, in particular. Vigilance to keep blood and blood products safe is higher than ever. This awareness is leading to the introduction of effective surveillance of the blood system in several provinces. However, much remains to be done to implement Commissioner Krever's recommendations, especially regarding adequate supply, self-sufficiency, accountability for decision-making and openness.