

Long before Krever's report, blood scare had changed face of medicine

Charlotte Gray

In brief

THE DISASTER INVOLVING BLOOD-BORNE PATHOGENS and Canada's blood system was in the spotlight in November with the release of the Krever inquiry report. Many physicians consider the report anticlimactic because action has already been taken on several fronts and the use of donated blood has declined, but it will still have a far-reaching impact.

En bref

LA CATASTROPHE DES PATHOGÈNES HÉMATOGÈNES mettant en cause le système d'approvisionnement en sang du Canada a été sous les feux des projecteurs en novembre avec la publication du rapport Krever. Même si beaucoup de médecins considèrent que le rapport tombe à plat parce qu'on a déjà pris des mesures sur plusieurs fronts et que l'utilisation de sang donné a diminué, il reste que le rapport aura des répercussions d'envergure.

Last November, when Justice Horace Krever finally issued his long-awaited 3-volume report on Canada's blood system, his recommendations were the lead news story for a couple of days and then the story dropped out of sight. Physicians should not conclude that its brief time in the spotlight means the report can be ignored. Editorialists and experts agreed that it represents a formidable and impressive inquiry into Canada's failure to come to grips with blood-borne pathogens in the 1980s. Still, the mere appearance of 1138 pages of thoughtful narrative and analysis seems to have allowed most of the professionals involved to feel that after an unprecedented disaster, closure had finally been achieved.

"The report itself was almost an anticlimax," explains Dr. Bryce Larke, a clinical virologist who is a professor of pediatrics at the University of Alberta, with a cross-appointment as professor of medical microbiology and immunology. However, he says that does not mean that the Krever inquiry itself was unimportant.

Larke was the first director of the provincial AIDS program, which was established in 1988, and since 1990 has divided his time between that program — his official title is provincial medical consultant, HIV/AIDS/hepatitis — and the Red Cross blood service in Edmonton, where he is deputy medical officer. He appeared before the Commission of Inquiry on the Blood System in Canada — that's longhand for the Krever inquiry — and says that "those of us who sat in the courtroom and were cross-examined by lawyers could not fail to be affected by the process. We didn't have to read the final report to appreciate the impact of the process on Canada, and the re-evaluation of our professional approaches that it triggered for all of us."

Today, says Larke, he and his colleagues are far more likely to share information with colleagues, to err on the side of safety and to acknowledge their own uncertainty. "My generation absorbed the attitude in medical school that we knew what was best for our patients. The Krever inquiry proved to many of us that we don't necessarily know what's best for them." Because he was intimately involved with the events described by Krever through his professional and managerial responsibilities, Larke feels the commission of inquiry had "a profound effect on me. My life has divided into pre-Krever and post-Krever."



Features

Chroniques

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Can Med Assoc J 1998;158:89-91

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Justice Horace Krever: Will physicians, worried about further inquiries like Krever's, refuse to serve on advisory committees?

Dr. John Doyle, a staff anesthetist at the Toronto Hospital, also found the report's release anticlimactic. "The discussion had been going on for so long and we knew so much already that there were no surprises," he says. Unlike Larke but in common with many other clinicians Doyle did not feel personally affected by the commission because "over the past 10 years we have done so much to change the way we do things. I didn't feel personal responsibility because I wasn't involved in making the decisions that are now been criticized."

The lull after the report's release occurred largely because implementation was already under way for many of Krever's 50 recommendations. For medicine, the report not only covered old ground but also dealt with practices that have already changed dramatically. Hematologist Robert Turner, medical director at the Red Cross's Edmonton transfusion centre, vividly recalls a 1983 *Newsweek* cover that depicted a vial of donated blood and the cover line "Tainted Blood!"

"We were all shocked to discover that the treatment we were using to save the lives and limbs of our hemophiliac patients could kill them," he says. Since the early 1980s, the search for and use of alternatives to donated blood have intensified. Autologous donations were already in use in exceptional cases, but now (in spite of Red Cross resistance) physicians began to encourage patients to consider storing their blood for use during scheduled surgery.

The frequency with which transfusions were ordered was already starting to drop by the mid-1980s. "The transfusion trigger is significantly lower," observes Doyle.

In the operating room, for instance, the surgeon and anesthetist, who is responsible for ordering most of the blood products used in hospitals, no longer assume that failure to transfuse will automatically have dire consequences. "I'm probably using 15 to 20% less blood during surgery than I used before all this began," says Doyle. Today anesthetists make more of an effort to discuss the pros and cons of transfusions with patients, particularly because patients are more alert to the inherent dangers.

As well, there has been new interest in alternatives to blood products. Today "bloodless surgery" eliminates exposure to blood-borne diseases, minimizes immunosuppression reactions and avoids the liability concerns associated with donated blood. Jehovah's Witnesses, who oppose transfusions for religious reasons, have led the way in exploring the use of synthetic alternatives to blood and clotting agents. Now, other Canadians are beginning to ask about alternatives.

A February 1996 Gallup poll revealed that when faced with elective surgery, up to 89% of Canadians would prefer an alternative to donated blood. A July 1996 Environics poll showed that 90% of Canadians agreed that everyone should be given the opportunity to choose an alternative to blood.

Governments have already started to respond to Krever's report. When it was published, Health Canada immediately announced creation of a new Blood Safety Council, which will include consumers, physicians and scientists. Besides offering advice on blood safety, it will scrutinize the implementation of Krever's recommendations.

Health Minister Allan Rock says Ottawa has already taken large strides towards a new structure for the blood system that will improve safety procedures. Together with 9 provinces — Quebec is the only exception — it has set up a single agency, the Canadian Blood System, to eliminate the problems Krever identified; \$81 million in start-up money has been allocated. Krever harshly criticized the behaviour of Health Canada officials, because that department regulated the national blood system; he also chastised the Red Cross, which operated it, and the Canadian Blood Committee, which funded it for the provinces, and the companies that made the products. "The truth is that during the entire relevant period, no integrated system existed," Krever stated. He says officials were negligent in fulfilling their duty to protect the public. The new system, which should be up and running by September 1998, is designed to ensure that lines of accountability remain absolutely clear.

The federal government has tightened several other aspects of the blood system. Ottawa's Laboratory Centre for Disease Control is already investigating the next generation of potential threats to the blood supply, including Creutzfeldt-Jakob disease and hepatitis G. Tighter regu-



lations have been introduced for reporting adverse drug reactions and for improving manufacturing standards for blood and blood products. To make it easier to share information on transfusion risks, Canada has strengthened its ties with the US Centers for Disease Control and Prevention, the American Red Cross, the UK's National Blood Authority and Centre for Disease Surveillance and Control.

Nonetheless, for all the catharsis that Justice Krever's final report has provided, troubling questions still nag medical experts. One of the most fundamental is the suggestion that it is possible to have a completely pure supply of blood products. Krever himself acknowledges that "blood components and blood products will never be without risk." However, some physicians feel the public now assumes it has a right to risk-free transfusions. "Why is the blood supply subjected to safety expectations that are far beyond any other aspects of the medical system?" asks Edmonton's Turner. "A prescription for penicillin is far more dangerous today to my patients than a transfusion."

The same concern preoccupies Doyle, particularly as it relates to the issue of informed consent. The Krever recommendations do not deal with the question of whether a patient should be required to give a separate consent for a transfusion, in case it is necessary during surgery, in addition to the general consent that is already required. Doyle anticipates that a demand for separate consent might arise for legal reasons, but wonders: "If we need a separate consent for transfusions, what about for other, riskier procedures such as invasive monitoring?"

Among hematologists and transfusion specialists there is a degree of unease about a certain "antiscientific" tone in some parts of the report. "Post hoc judgements were made about decisions that had to be taken before all the necessary information was available," says Larke. He is particularly uncomfortable with the way Krever dealt with the failure of the Red Cross to implement surrogate testing to reduce the incidence of post-transfusion hepatitis in the late 1980s (chapters 22 to 25, final report.) On the basis of scientific knowledge available at the time, Larke suggests, the Red Cross decision is defensible.

Turner shares Larke's concern that some of the discussions on scientific evidence during the inquiry hearings were distorted by nonscientific issues. "Lawyers representing the interest groups were more interested in establishing points they could later sue on." He felt that the shortcomings of the blood system during the 1980s may have been exaggerated. "I realize that I may be overprotective because I was involved in the system here, but if you read the report the impression you get is that we were stupid and slow. Maybe we were just cheerleading when we said, in 1982, that we had the best blood system in the

world, but it wasn't as bad as it is now being portrayed. We had defeated the scourge of hepatitis B and by 1980 we had an effective treatment for hemophiliacs. Far fewer hemophiliacs were infected in Canada than in the US."

Many physicians fear that the negative portrayal of the blood system has exacerbated the loss of confidence in it. "The critical shortage of blood donations today is dangerous for my hemophiliac and cancer patients at the transfusion clinic," explains Turner. "They depend on the supply because they don't have many options."

One of Krever's most interesting suggestions (recommendation 9) is that "the operator of the blood-supply system promote appropriate use of, and alternatives to, blood components and blood products." He also recommended that hospitals pay for the blood products they use. Dennis Charland, director of hospital information services for the Jehovah's Witnesses, hopes that these 2 recommendations, taken together, will "level the playing field" between blood products and their alternatives and make it easier for Jehovah's Witnesses and others to find physicians who will use alternative products.

At present, blood is perceived to be "free" within the system, while hospitals must fund alternatives through their drug budgets. "This funding bias in favour of donor blood has hindered the widespread use of medical alternatives in Canada," says Charland. "The report will make it easier for our members to practise their beliefs."

In unflinching detail, the Krever report describes the magnitude of the human tragedy of death and illness visited upon unsuspecting Canadians. There cannot be a health care provider in the country who doesn't wish that blood-system operators had responded differently. But the commission's 247 days of hearings and its searing indictment of bureaucratic bungling has far-reaching implications that continue to unsettle those intimately involved in the issues.

"You know, this is a small country with a limited number of people with professional expertise," observes Larke. "All of us feel a professional responsibility to serve on government committees, usually with little or no remuneration. We advise governments in the light of the best available knowledge. But now we have discovered how vulnerable we are. We can be cast in a very negative light, and found culpable. And we have no cover in case of future litigation.

"I have seen physicians of extraordinary integrity and sensitivity profoundly hurt by what they have had to go through. They didn't willfully make the wrong decision: they made the appropriate decision based on the science of the day. Their experience may make physicians far more reluctant to serve on government advisory committees, in case of a similar inquiry 10 years down the road." ?