The sensibility of safety: reflections on the Krever inquiry's final report

Editorial

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Although there are many lessons to be learned from the Commission of Inquiry on the Blood System in Canada, the result has been something of a disappointment. Justice Horace Krever's final report circles the core problem, clearly identifies the target and then fails to nail it clearly in its recommendations — particularly those that address the question of where policy-making authority with respect to the blood system should lie.

The crux of the matter is safety. How can we arrive at a reasonable working definition of a "safe" blood supply? How much will it cost to ensure an acceptable degree of safety, and who will pay? And who decides whether new and costly safeguards are worth it?

The controversy that now surrounds Creutzfeldt–Jakob disease (CJD) and the blood supply is a case in point. Krever's report reviews the recent history[1] (pages 1015-9). In the mid-1980s, 7 young adults in the US died of CJD after receiving growth hormone from a donor later discovered to have the disease, and results from experimental animal studies were raising the possibility that CJD might also be transmissible through blood. In November 1994, Bayer Corporation (then Miles Inc.) began voluntarily to withdraw certain lots of Prolastin, a product used in the US, because the donor of some of the plasma used in its manufacture had subsequently died of CJD. A meeting held the next month by the US Food and Drug Administration (FDA) and attended by staff members of the Canadian Blood Agency (CBA), the Canadian Red Cross (CRC) and the federal Bureau of Biologics led to a US policy decision to recall all red cells, platelets and plasma derived from blood donors subsequently discovered to have CJD. (A few months later the FDA also recommended that recipients of potentially contaminated blood be notified.) At that time the incidence of CJD was said to be 1 per million per year, and the risk of acquiring CJD through a blood transfusion was termed "theoretical."

What did Canadian officials do? Nothing — until July 1995, when Dr. Nathan Kobrinsky, a Manitoba physician, expressed his opinion before the inquiry that CJD might be transmissible through blood. Prompted by the considerable media coverage of this statement, a woman telephoned the Red Cross's Vancouver blood centre to report that her father, who had made 21 donations in the previous 6 years, had died of CJD. The CRC began to withdraw the man's most recent donation and products made from pools containing his plasma. There were further reports of blood donors with CJD, followed by more withdrawals. The CRC ordered the withdrawals independently of the CBA, considering this decision to be an operational matter consistent with its mandate to proactively maintain the safety of its products and services. The CBA, along with provincial and territorial ministries of health, balked; the response to the potential contamination of the blood supply with CJD was, in their view, a policy decision beyond the authority of the CRC. The cost of replacing the withdrawn products, which the CBA eventually absorbed, was estimated at $12 million.

There's the rub. Was the expense justified? Was it sensible to spend $12 million to protect recipients from a theoretical risk? Who should make decisions of this kind? One would have expected Krever's final report to resolve this question once and for all. It does not.

In 1989 the federal and provincial ministers of health agreed on a set of principles that were to govern blood supply policy in Canada; these principles formed the basis for the "master agreement" entered into by the CRC, the CBA and the provinces and territories in 1995. According to the fourth principle, the "[s]afety of all blood, components and plasma fractions should be paramount." At the same time, the sixth principle stipulated that a "cost-effective and cost-efficient blood system for Canadians should be encouraged." As Krever writes, these principles "did little to address the fundamental tension between the need for safety and the need for cost-efficiency and cost-effectiveness" (page 1003).

Four of Krever's recommendations bear on this pivotal issue (pages 1046-73). He proposes the creation of a single, national blood service (recommendation 3) governed by an independent board of directors composed of experts, donors and consumers (recommendation 12). The board is to be appointed by — but at arm's length from — the provincial and territorial ministers of health. The national blood service would be operated in accordance with 5 basic principles (recommendation 2), the last of which is that the "[s]afety of the blood supply system is paramount." This principle of safety, Krever emphasizes, "must transcend other principles and policies." The blood service is to be funded by payments from hospitals for the blood components and blood products supplied to them (recommendation 15).

Under this plan the board of directors of the national blood service, not the federal or provincial governments, will approve annual operating budgets consistent with the transcendent safety principle. Thus it might easily decide, on the basis of evidence from animal studies and theoretical estimates of risk, to spend $12 million to withdraw blood and blood products originating from donors with CJD. Perhaps this would be a good decision, perhaps not. The board would presumably also uphold the CRC's introduction, in March 1996, of testing for HIV-1 p24 antigen in all blood donations negative for HIV antibodies. The estimated cost of introducing this test was approximately $6.5 million, and its yearly cost is estimated at $5.8 million (Suzanne Meunier, Canadian Red Cross Society, Ottawa: personal communication, 1997). Current estimates of HIV prevalence indicate that the test will prevent, at most, 1.5 new HIV infections in Canada per year.[2]

Can the price of safety be benchmarked? It sure can, and the results are illuminating. A common benchmarking strategy is to compare the costs of implementing a new safety measure against the costs of existing ones. For example, the cost (in $US) per year of life saved has been estimated at $5000 for installing smoke alarms in homes, close to $2 million for improvements to school bus safety and almost $20 billion for benzene emission control at rubber tire manufacturing plants; on the other hand, installing defibrillators in emergency vehicles costs less than $40 per year of life saved.[3] Clearly, society's willingness to pay to reduce a risk is determined by social and contextual factors, including public perception of that risk.[2] In his report, perhaps Krever is correct to reflect the desire of Canadians for safety to be of paramount concern in all decisions affecting the blood supply.

But I don't think so. Under the Krever plan, funding for this additional safety will come from hospitals and, ultimately, health care budgets and taxes. Because governments do not want to increase taxes, the money needed to enhance the safety of the blood supply will come from provincial and territorial tax dollars allocated for health. This will leave less money for other aspects of the health care. Safety is *not* "paramount" in the rest of the health care system. In fact, some governments are recommending that we implement "evidence-based rationing" of health services. Many commentators would argue that we're already doing that.

Krever has done a remarkable job; most of his recommendations make eminent sense and should be implemented without delay. However, safety is not absolute, and assessments of risk require judgement. Moreover, the priority given to costly safety measures with marginal benefits at the expense of other services that promote public health must be established at the level of government. The CRC made this point before the Commission in 1996: "Cost vs. safety trade-offs are matters of public health policy that can only be decided by governments." As new pathogens emerge we will again be faced with difficult and costly decisions, with little evidence to guide us. We will need leadership, above all; at the end of the day this must be political.

References

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