CASE STUDY
Notifying patients about exposure to blood products from a donor with CJD.

... it is possible that answers will not be found soon and that we will continue to have to make extremely difficult, highly controversial decisions in the absence of decisive information on risk. CJD may be but the first of a number of theoretical or very slight risks that will challenge, and even threaten, regulators, policy makers, blood banks and physicians in the post-HIV era. We need methods that will free us from the decision-making paralysis when demands for answers lead only to more questions.


In March 1995, the Commission of Inquiry on the Blood System in Canada, known as the Krever Commission, made an interim report on the safety of Canada's blood system. The commission was struck in response to concerns related to contamination of the blood supply by HIV and hepatitis. Capen, in an article published in the Canadian Medical Association Journal on May 15th 1995, discusses the Krever recommendations about issues and practices in obtaining informed consent from patients for blood transfusions and the use of blood products. Capen (1995) highlights that patients should be advised of the risks and benefits involved in blood transfusion, and possible alternatives. She notes Krever's comments in his recommendations that "few if any Canadian hospitals require patients to sign to consent form relating specifically to the possible administration of a blood transfusion". She also reports that the recommendations state that "information about blood or products used during the procedure should be recorded in the patients chart and on the discharge summary", and that "this information should be included in a letter by the attending physician or surgeon to the referring physician."

In July 1995, the Krever inquiry heard from a physician specialist that CJD (see Appendix 1) could be the next major threat to the blood supply and this was reported in the media (Wilson et al, 2001, 60):

A Vancouver woman who read the article informed the Vancouver branch of the Red Cross that her father, a regular blood donor, had developed CJD. Within days of receiving this information, the Red Cross, in conjunction with Bayer Inc., voluntarily decided to withdraw blood products connected with this donor and informed the Bureau of Biologics of their decision. The Bureau supported the voluntary nature of the recall, although it did not have an official policy available to guide decision-making on this issue. The immediate consequence of the recall was shortages of certain blood products. The total cost of the recall, the largest in Canadian history, was estimated at around $11 million. On October 20th, 1995, the Health Protection Branch of Health Canada announced its official policy on CJD, supporting the blood recall and deferring donations from donors at risk of acquiring CJD. (Wilson et al, 2001, 60-61)
In July and August, the Red Cross sent hospital blood banks information that they were voluntarily withdrawing certain lots of plasma derivative products. The products had been produced from pools that contained a unit from the Vancouver donor subsequently diagnosed as having probable CJD. It was up to the blood banks and hospitals to decide what to do next. Paediatric Hospital, a large, tertiary care teaching hospital, was one of the many faced with the dilemma. At Paediatric Hospital approximately 500 patients were identified as having received these products prior to the recall. Because there could be several different distribution systems in hospitals, not all products were distributed through the Pharmacy, and not all received units could be tracked. Consequently, not all recipients could be traced.

The Hospital treated a large population of haematology patients and other patients requiring blood products on a regular basis. There were several parent groups that were quite active in advocating for patients and members could be very knowledgeable about their children's diseases. Earlier experience with HIV made many people very sensitive to issues of potential risks and availability of information. Some of these parents were members of a Parents' Committee advising the Hospital on a variety of matters.

The Hospital Transfusion Committee, a multidisciplinary group of clinicians, scientists, and administrators, considered the medical evidence, and also asked the Parents' Committee for their opinion. The Parents' Committee advised that the hospital should notify recipients because they felt that the patient and family had a right to be informed.

Legal counsel for the Hospital commented that there was no absolute "right to know" on the part of patients. It was a judgement call on the part of the physician, balancing the benefits of having the information against any harm it may cause to the patient. Disclosure of risks was based on the standard of what the reasonable person in the patient's situation would want to know. The risk of HIV transmission to others, for example, weighed in favour of informing patients of HIV exposure. But based on current knowledge, CJV did not carry the same risks, but this could be proven to be inaccurate in the future.

In August 1995, the Ontario Hospital Association's legal counsel, taking into consideration the Krever recommendations, sent a memo to hospitals advising that patients should be notified if they received blood products implicated in the recall.

Peer hospitals were undecided about what to do, and some were contacting their colleagues at Paediatric Hospital to find out what they were planning to do. There was lobbying in both directions, some in favour of notification, others very concerned about the precedent that that would set. One dilemma for the hospitals would be to prove what the "average, reasonable, prudent" hospital would do in like circumstances. The hospital administration was concerned that the Hospital could be sued in the future if patients were not informed and harm ensued. On the other hand, if patients were informed and they received information they did not want and about which they could do nothing,
would they sue for emotional distress?

The Medical Advisory Committee (a committee that hospitals are required to have under provincial legislation, whose members were mostly physicians/clinical department heads and some administrators) deferred the decision about notification. They stated that they felt there was no medical basis for notification, but that there may be legal or social factors.

The Hospital's interdisciplinary Quality Management Committee was concerned that there was not a consistent, generic process for such decisions. It was possible that other viruses or currently unknown contaminants could be identified in the blood supply in the future. Some Hospital staff were concerned that notification in this instance would set a precedent for all future exposure to theoretical risks.

Some patients were already aware of the problem due to media reports and communications from other organizations such as the Haemophilia Society. Given the past history and public fear of HIV, some hospital staff members were concerned that silence on the part of the hospital could be misconstrued as secrecy and avoidance of the issue. Some patients had already been notified by their physicians. Many were concerned about potentially needless anguish for the patients and families, given that the risk was theoretical and that there were no diagnostic or therapeutic interventions available. On the other hand, some felt strongly that counselling support and information could be made available to patients and families. Given that some had already inquired about their exposure, all should have the same opportunity to ask questions and be informed.

Others were quite concerned about the potential financial cost of notification, arguing that the funds could be spent more wisely in delivering actual care. Costs would include locating and contacting each recipient through several registered mailings, providing adequate information and support, staffing an information line, and holding education meetings with families.

At the same time, the Transfusion Committee was discussing a proposal to use high efficiency filters prior to transfusion. This would provide additional protection against transfusion related viral infection. The additional costs involved could be around $200,000 to $350,000 per year. However, the risk of contamination could not be eliminated.

The Board of Directors was presented with all of this information. The decision was made to notify patients (or the parents/guardians) and the Transfusion Committee was charged with the task of developing a process for such decisions in the future.

QUESTIONS: Explain, using examples from the case:
1. What beliefs influenced the sense making and interpretation of the situation?
2. What knowledge gaps did Paediatric Hospital face?
3. Which model of decision making best describes what happened here?

[The following description is from the British Columbia Ministry of Health's web page titled "From the Health Files", Health File No. 55, September 1996. It can be found at http://www.hlth.gov.bc.ca/hlthfile/hfile55.html, last accessed on 2002 03 13.]

Creutzfeldt-Jakob Disease (CJD) is an extremely rare disease of the brain, which results in progressive forgetfulness, dementia, and eventual death. It is believed to be caused by an infectious protein. It has a long incubation period (up to 30 years) although once symptoms of CJD appear the survival rate is short, usually less than one year. CJD occurs in both men and women all over the world. It occurs in about one person in a million.

When a person develops CJD it is often not possible to explain how it occurred. A small proportion of cases run in families, or have been caused by specific medical procedures such as treatment with natural human growth hormone, or transplant in a certain body tissues. These medically-related means of transmission have now been reduced. Most cases of CJD however seemed to occur with no means of explanation. There is presently no test available to predict who will develop CJD. Further testing by a neurologist is required to distinguish CJD from other more common conditions.

There is currently no treatment or cure for this disease. The only known cases where this disease has been spread from one person to another are a few rare cases of CJD caused by injection of human growth hormone or transplantation of human tissue. It is not spread by person to person contact, sexual activity, or through the air. There is no scientific evidence that CJD is transmitted by blood and no recorded cases of this disease occurring through transfusion of blood or plasma products. The risk of CJD being spread through blood transfusion is only theoretical.

No current blood test exists for screening for CJD, although the Red Cross does screen and exclude donors with KNOWN risk factors such as having taken growth hormones or receiving tissue donations. There is at present no scientific evidence available to suggest that CJD can come from food, particularly meat. However, there are several similar rare diseases which maybe related to eating particular tissues. The possibility that CJD is related to eating particular types of meat cannot be proven at this time.

References in Case Study:
