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Variant Creutzfeldt–Jakob disease and the Canadian blood system after the tainted blood tragedy

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Abstract

The transfusion transmission of hepatitis C and HIV to thousands of Canadian blood recipients was one of this country’s largest public health catastrophes. In response to this crisis, and in an effort to prevent such a tragedy from occurring again, the Canadian blood system has undergone substantial reform. Variant Creutzfeldt–Jakob (vCJD) disease was the first infectious threat faced by the blood system since undergoing reform. The response at the time to this risk provides insights into the Canadian blood system’s new approach to infectious threats. Our analysis of the decision-making concerning vCJD identifies two dominant themes characterizing the new blood system’s approach to safety:

1. the adoption of a precautionary approach to new risks which involves taking action in advance of definitive evidence, and
2. risk aversion amongst policy makers, which has contributed to the adoption of safety measures with comparatively high cost-effectiveness ratios.

Overall the principles governing the new blood system have contributed to the system both providing protection against emerging infectious risks and regaining the confidence of the public and recipients. However, the current set of policy factors will likely contribute to increasingly risk-averse policy making that will contribute to continued increases in the cost of the blood system. The challenge the blood system now faces is to find the appropriate balance between maximizing safety and ensuring the system remains affordable.

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Introduction

The transfusion of individuals with products infected with HIV and hepatitis C was, arguably, the largest public health catastrophe in Canada’s
history. Estimates suggest that infected transfusions led to more than one thousand individuals acquiring HIV and up to 30,000 individuals acquiring hepatitis C (Krever, 1997a). A national inquiry into the functioning of the blood system and how it could have led to the tragedy, headed by Justice Horace Krever, precipitated a transformation of the delivery of transfusion services in this country. This transformation involved the replacement of the Canadian Red Cross as the operator of the blood system and the creation of new financial arrangements and operating principles (Krever, 1997b). It has now been 8 years since Canada’s blood system has undergone reform and the opportunity exists to reflect on how successful the transition to a new system has been. From the perspective of managing infectious threats, the new blood system would have to be viewed as a major success. Canada has acted aggressively to protect the blood supply from real and theoretical risks such as variant CJD, West Nile virus and Severe Acute Respiratory Syndrome (Canadian Blood Services, 2004). In this regard, the post-Krever blood system has received high marks, including from hemophiliacs who were one of the primary groups affected by the tainted blood tragedy (Canadian Hemophilia Society, 2005). However, the blood system has not been without criticism, which has primarily been directed at the introduction of safety measures with prohibitive cost-effectiveness ratios that have contributed to escalating blood costs.

There are several opportunities to learn from the Canadian blood system’s reform efforts and in many ways the blood system provides an important model for other public health sectors which are addressing new and emerging risks in an increasingly risk averse environment. To better understand how decision-making has been transformed in the post-Krever era we provide a detailed examination of the Canadian blood system’s management of variant Creutzfeldt–Jakob disease, its first infectious threat since undergoing transition. While many faults could be found with how blood officials managed affairs leading to the tainted blood tragedy, one of the areas of particular concern was how scientific evidence was utilized to formulate policy. Our analysis is therefore assisted by the use of a descriptive policy analysis framework that focuses on the role of information in the policy process. We review our findings in the context of subsequent blood policy decisions to arrive at general principles governing policy making in the post-Krever environment.

The vCJD policy problem

In the late 1990s, the Canadian blood system and health officials were confronted with a true policy dilemma: how to manage the theoretical risk of blood transmission of CJD. This challenge emerged just as Justice Krever was releasing his final report and federal/provincial/territorial officials were creating a new blood system in line with many of the recommendations of this report. The challenge also presented itself as the United Kingdom was addressing the outbreak of Bovine Spongiform Encephalopathy, which eventually led to the emergence of vCJD in humans, and dealing with criticism of their response to this crisis. Thus, the potential transfusion transmission of CJD combined aspects of two of the highest profile public health controversies at the time.

Further contributing to the challenge of managing the infections risk posed by CJD to the blood supply was the unusual nature of the disease itself. CJD is a rare infectious condition that is believed to be caused by a new form of infectious agent, an infectious protein, known as a prion (Prusiner, 1982). The infection is devastating and affected patients suffer progressive neurological deterioration and dementia due to spongiform changes in the brains of the victims. Patients inevitably die from the infection, usually within a year of the diagnosis. While extremely rare (<1% of all cases), there have also been several documented cases of iatrogenic transmission of CJD. The documented iatrogenic transmission of CJD via human growth hormone, in particular, raised concerns in the United States and Canada about whether the condition may also be transmissible via blood products. This concern arose in the Canadian blood system, as it was recovering from the tragedy of hepatitis C and HIV blood transmission. As a consequence, the potential transfusion transmission of CJD was viewed as the first major test for the blood system after these infectious threats (Vaughan, 1996).

The challenge of managing the potential transmission of CJD via blood products was further complicated by the discovery, in 1996, of a variant form of CJD in the United Kingdom (Will et al., 1996). The condition was believed to have arisen from Bovine Spongiform Encephalopathy (BSE). While there was no epidemiological evidence of blood transmission of vCJD, the theoretical risk was considered higher than classical CJD for a variety of reasons (Cashman, 1999). Policy makers
in the United Kingdom decided to reject donations from their citizens and import their plasma requirements due to concerns over the potential blood transmission of vCJD. This prompted decision-makers in the United States and Canada to evaluate whether they should accept donations from individuals who had traveled to the United Kingdom. However, this would potentially reduce the blood supply and cause shortages. Ultimately Canadian policy makers decided to defer donations from individuals who had spent 6 months in the United Kingdom between the years 1980 and 1996 (the peak period of the BSE epidemic). It was anticipated that this policy would reduce the risk of vCJD to the blood supply and ensure that the blood supply remained adequate (Wilson et al., 2001). These policies have been modified as further evidence has accumulated of the prevalence of BSE and donor deferral policies have been instituted for individuals who have resided in France and all of Western Europe. Most significantly, scientific evidence has accumulated which validates the institution of the precautionary policies, both from animal models demonstrating transfusion transmission and from case reports of transfusion transmission in humans (Wilson & Ricketts, 2004).

A framework for understanding decision-making on health risks

To understand decision-making on issues of risk pertaining to the blood system, analytical tools that provide a comprehensive understanding of the multiplicity of factors that influence policy are required. Descriptive policy analyses are well suited to analyzing policy making concerning risks by identifying the critical factors influencing decision-making as well as providing insights on where decision-making breaks down and, equally important, where it works effectively (Hogwood & Gunn, 1984). Descriptive policy analyses in health, however, have often been based on the assumption that rational decisions are made on the basis of complete information (Pal, 1992). Given the uncertainty of scientific information on potential health risks, these information-based models may not be adequate. Alternative models to evaluate decision-making have focused on the role of value systems or institutions. However, to be truly comprehensive, approaches to policy analysis integrating the impact of information, values and institutions are needed to ensure that both the policy makers and the public understand how decisions are made concerning health risks.

Paul Sabatier has compiled some of the available frameworks for conducting descriptive policy analyses (Sabatier, 1993a). One of the criteria used for selecting frameworks is that they address the roles of conflicting values and interests, information flows, institutional arrangements and variations in socioeconomic environment on the policy process. The following frameworks were identified as useful for describing decision-making within a given political system or set of institutional arrangements: the stages heuristic, institutional rational choice, multiple-streams framework, punctuated equilibrium framework and the advocacy coalition framework. The last framework, the advocacy coalition framework (ACF), was proposed by Sabatier and suggests that decision making occurs in a policy subsystem involving individuals from a variety of public and private organizations who are actively concerned with a policy problem. Within this subsystem, individuals aggregate into advocacy coalitions based on shared ideologies and beliefs. The success of the coalitions in translating their beliefs into policy is dependent upon their resources (money, expertise, legal authority and size). Policy brokers attempt to mediate the conflict between the various advocacy coalitions. This process of conflict and mediation eventually results in policy outputs by the governing structures in the subsystem (Sabatier, 1987; Sabatier, 1993b). The ACF model has been identified as being effective in describing decision-making in a variety of policy sectors (Jenkins-Smith & Sabatier, 1994).

A modification of the ACF model has been put forward by Jonathan Lomas (Fig. 1) (Lomas, 2000). In this model individuals make policy in an “institutional structure for decision-making”. This structure consists of “formal” actors, who actually participate directly in the decision-making process, and “informal” actors, who influence decision-making through other means. Values in this model are divided into ideologies (views on how things ought to be), beliefs (causal assumptions on how things are), and interests (responses to incentives and rewards). In addition, this model pays greater attention to the role of information producers and purveyors. It specifically examines how information is produced and spread and how the value systems of those involved in the policy subsystem influence the interpretation and use of this information.

Our choice of the Lomas framework was based on face and content validity parameters; i.e. the
domains we felt would be important are appropriately captured in the framework. The vCJD decision was primarily characterized by how policy makers utilized scientific information. In this sense, the Lomas framework is well suited to conducting the analysis given its focus on knowledge development and knowledge transfer. The framework’s hypothesis that policy makers resolve conflicts between their various value systems through a process of cognitive dissonance reduction is also well suited to analyzing a policy problem where information is uncertain and value systems would necessarily play a particularly prominent role.

**Understanding the Canadian blood systems vCJD donor deferral policy**

The objective of our overall study was to understand and compare the decision-making processes concerning two Creutzfeldt–Jakob disease-related decisions: a 1995 withdrawal of blood products from a classical CJD donor and a 1999 decision to defer donations from individuals who had traveled to the United Kingdom for 6 months during the peak of the BSE outbreak (1980–1996). We present, here, the full analysis of the second decision, with the first decision acting as important historical context.

Our study consisted of a literature review and semi-structured interviews. The literature review included a systematic review of the risk of transmission of CJD via blood products, a content analysis of newspaper reporting as well as a review of important policy documents. In total we conducted 31 semi-structured interviews with key informants of all major decision-making organizations. Individuals were asked to describe decision-making leading to the 1995 and 1999 decisions as well as...
other relevant decisions. Individuals were also asked about the role of information, information purveyors, decision-making organizations and external factors in the decision-making process. All information from the interviews was coded using QSR Nudist, a qualitative software program. Findings of the study were fed back to decision-makers through member check sessions with key stakeholder organizations. Our findings have been presented in a series of papers, initially focusing on information (Wilson, Code, & Ricketts, 2000) and information purveyors (Wilson et al., 2004), then institutions (Wilson et al., 2001; Wilson, McCrea-Logie, & Lazar, 2004) and finally the role of values and changes in ideology (Wilson, Wilson, Hebert, & Graham, 2003). We synthesized the results of these studies using the Lomas framework. Based on this synthesis we isolate the key policy factors that are driving current decision-making in the Canadian blood system. We then propose mechanisms by which acting on these policy factors could influence future decisions.

### Factors influencing decision-making (Table 1)

#### Information

In Canada three pieces of information played an important role in influencing the decision-making process leading to the donor deferral decision: (1) the risk of transmission of vCJD via blood products, (2) the impact of deferral policy on the blood supply, and (3) the degree of reduction in the blood supply the blood system could sustain. All of these pieces of information had substantial levels of uncertainty associated with them. There were no epidemiological studies on risk of blood transmission of vCJD and an estimation of the risk was based primarily on biological models. Based on these models the theoretical risk possibility of blood transmission of vCJD was considered for the following reasons: vCJD had been demonstrated to be transmissible through a peripheral route (GI tract) and thus peripheral transmission via blood products was believed to be possible, the prion concentration in affected tissues was high in vCJD and prions are found in the lymphoreticular system in vCJD which is intimately linked to the blood supply (Cashman, 1999). Scientists argued that this evidence of risk based on biological models was substantial enough to warrant government action to protect the blood supply.

| Information | 1. Risk of transfusion transmission of vCJD |
|-------------|------------------------------------------|
|             | 2. Impact of deferral policy on blood supply |
|             | 3. Degree of reduction of blood supply that system can sustain |

#### Information purveyors

| 1. Think-tank |
| 2. Scientists |
| 3. Media |

#### Values

**Beliefs**: theoretical risk of transfusion transmission of vCJD

**Ideologies**: evidence-based decision-making vs. precautionary principle

**Interests**: protection of supply vs. safety of supply, legal, re-establishing confidence

#### Institutions

| 1. Existence of two operators |
| 2. Separation of regulatory and financial responsibilities |
| 3. Decisions in other policy subsystems (UK, US) |
| 4. Legacy of the Krever Inquiry |

Given the uncertainty of information on risk of blood transmission of vCJD the impact of a policy on the blood supply needed to be considered before proceeding. This information was obtained from a survey that suggested that a 3% reduction in the blood supply would occur with a 6-month deferral policy. Previous experience in the blood system indicated that a 3% reduction was sustainable, although there was considerable uncertainty over this estimate. In an attempt to integrate all of this information, as well as the likelihood of developing vCJD over different residency periods in the United Kingdom, a risk modeling exercise was performed. This analysis also suggested that the risk of contracting vCJD increased after 6 months residence in the United Kingdom. However, this model was based on infectivity rates of BSE that, to this date, remain unclear (ElSaadany & Giulivi, 2000).

#### Information purveyors

Three major information purveyors influenced the policy process leading to the donor deferral decision: scientists, the media and think tanks. The media’s primary role was to disseminate the release of a report by a think tank advisory committee on bioethics, which advocated that the Canadian blood
system should adopt a donor deferral policy (Bayer Advisory Council on Bioethics, 1998). In combination, this report and the media coverage it received played an important agenda setting function by bringing the emerging issue to the public’s attention (Wilson et al., 2004). Scientists also played an important role in communicating information on risk to policy makers. In particular, due to the lack of scientific expertise on the subject, one scientist came to play a prominent role in the decision-making process. This individual was a consultant on three separate sources of information that were supplied to the decision-makers. All of these recommended that the government take action to protect the blood supply from vCJD (Bayer Advisory Council on Bioethics, 1998; Cashman, 1999; Expert Advisory Committee on Blood Regulation, 1998).

Institutions

We had a unique opportunity to assess the impact of institutions on decision-making by being able to compare the vCJD donor deferral decision to another CJD related decision that took place prior to institutional change in the blood system; the 1995 recall of blood from a classical CJD donor. The major structural changes to the blood system that took place over this time period was the replacement of the Canadian Red Cross as sole operator of the blood system by two separate operators, Héma-Québec in the province of Quebec, and Canadian Blood Services in the rest of Canada. We observed that the movement to a two-operator system had an important impact on the decision-making process. The presence of a second operator introduced a form of “check and balance” on the decision-making processes of the larger operator by proposing competing policy options to address the vCJD problem. However, it also increased the complexity of the decision-making process and initially produced some inter-institutional conflict (Wilson et al., 2001).

Distribution of regulatory authority and funding also played an important role in the decision-making process, specifically the separation of these two functions. In Canada regulatory authority for blood products exists at a federal level. Financing of the blood system is the responsibility of the provinces. In this system, the incentive exists for the regulator to introduce policies that maximize the safety of the blood supply, and the financial considerations of the decision play a secondary role (Wilson, McCrea-Logie et al., 2004).

Other institutional effects include decisions made by institutions in parallel subsystems, in particular other countries’ blood systems. The UK decision to ban plasma donation from its own citizens played a large role in initiating the decision-making process in both Canada and the United States as to how to handle donations from individuals who had traveled to the United Kingdom. Of particular importance, Canadian policy makers attempted to coordinate Canada’s donor deferral policy with that of the United States. This was largely a consequence of the fact that Canada imports a substantial portion of its plasma requirements from the United States. In general, Canadian policy makers are expected to meet international standards in protecting the blood supply (Canadian Blood Services, 2003).

Value systems

We observed that most individuals shared a common belief, defined as a “causal assumption of what is”, on the risk of transmission of CJD; that transfusion transmission was a theoretical risk with no known documented cases of transmission. However, while the risk was viewed as theoretical, the type of risk which was presented is one to which the public and policy makers would be particularly averse. The factors contributing to this perception of risk include the potentially catastrophic, involuntary nature of the risk, the lack of knowledge of the risk and the lack of trust in the system’s ability to manage the risk (Slovic, 1987).

Ideologies, defined as “causal assumptions of how things ought to be”, played an important role in determining how information was interpreted and utilized to develop policy. Two dominant ideologies on how decision-making should take place on issues of risk were at play: evidence-based decision-making and the precautionary principle. The precautionary principle came to play a particularly prominent role largely as a consequence of the Krever Inquiry into the blood system use. However, we observed a clear tension in which decision-makers struggled with the idea of introducing a policy that could create a health risk (blood shortages) to protect against a risk for which no epidemiological evidence existed (Wilson, Wilson et al., 2003).

At the institutional level, we found competing interest systems at work. The regulator’s primary
responsibility was to protect the safety of the blood system. The operators, in contrast, were interested in balancing safety with adequacy of supply. However, all players in the blood system recognized the crucial need to reestablish public confidence in the blood system and their responsibility to protect the blood supply on behalf of the public. At the level of the policy-maker, the lasting effects of the Krever Inquiry played an important role in influencing individuals’ actions. The spotlight that was placed on previous decision-makers in the blood system and the legal consequences of the subsequent criminal probe created a climate that encouraged implementation of a risk-averse policy (Picard, 2002).

Synthesis

Reconstructing the policy process from the factors we have analyzed presents us with the following explanation of why events unfolded as they did. Agenda setting in Canada primarily occurred due to policy decisions made in other countries (e.g. the UK blood system). Public awareness was raised by the release of a think-tank report and the dissemination of the information from this report via the print media. The decision to introduce a partial measure to protect against the theoretical risk, in the absence of definitive evidence of the risk, was largely influenced by the knowledge that the United States would proceed with a similar decision. The Canadian decision-making process was also shaped by the emergence of the precautionary principle as a dominant ideology in public health. However, perhaps the most important driving factors in the decision-making process were the past experience of the blood supply with hepatitis C and HIV, the general shadow cast by the recent Krever Inquiry, policy maker fiduciary duty to the public and their need to re-establish public trust by being seen to be acting pro-actively.

Blood policy making after the tainted blood tragedy: precaution and risk aversion

The vCJD policy decision deserves closer examination for several reasons. It demonstrated how policy was made to address an, at the time, theoretical risk. The Canadian vCJD donor deferral decision was also emblematic of how other nations addressed the vCJD threat. In addition to withdrawing blood products derived from individuals subsequently diagnosed with vCJD and importing fractionated products from abroad, the UK has recently decided to ban donations from individuals who had previously received a transfusion. France also has instituted precautionary policies including the introduction of leukoreduction, which theoretically would remove infectious material from donated blood (Lee, 2001). The US policy regarding vCJD was similar to Canada’s, choosing to introduce donor deferral policies for individuals who had traveled to countries in which BSE was endemic (FDA, January 2002). The vCJD decision-making process in all of these countries reflected a paradigm shift in how to manage emerging risks. This new paradigm involved the institution of protective measures at an early stage of the risk identification process and reflected a conscious decision by policy makers to act in advance of complete scientific information.

Important lessons can be learned from the Canadian vCJD policy-making process and the decision-making process stands in stark contrast to the decisions concerning hepatitis C and HIV in the pre-Krever blood system. In particular, two key themes that have come to dominate decision-making in the post Krever era deserve further analysis—the application of the precautionary principle to blood policy and the challenge of rising costs in a risk-averse blood system.

Precautionary decision-making

Blood policy makers, in addressing the potential threat of vCJD, ultimately embarked upon a strategy that they believed balanced the reduction in blood supply with reducing the risk of exposure of Canadians to potentially infected blood products. This decision explicitly acknowledged the possibility of risk in the absence of epidemiological studies and represented a critical shift from the previous mechanism of policy making. Many criticisms exist of blood policy making in several countries leading to the transfusion transmission of hepatitis C and HIV. Particularly, in the instance of HIV, the criticisms surround unacceptable delays implementing policies recognized as providing some protection to blood recipients (Gilmore & Somerville, 1999; Picard, 1998; Weinberg et al., 2002). However, one of the primary limitations of pre-Krever decision-making in Canada was the manner in which scientific information was utilized in the formulation of policy. This was perhaps most glaringly
demonstrated when considering the decision-making process concerning the adoption of surrogate testing for hepatitis C. The details of the Canadian decision regarding surrogate testing has been well described elsewhere (Krever, 1997c). In summary, blood officials in the 1980s were confronted with the threat of a new form of hepatitis referred to as nonA-nonB hepatitis, later discovered to be hepatitis C. This form of hepatitis was known to be transfusion transmissible, however, the virus had not been identified and thus no specific test existed to identify contaminated blood. Consideration was therefore given to the use of surrogate tests which could not only identify some infected donations but also would result in the discarding of some donations that were not infected (Aach et al., 1981; Alter, Purcell, Holland, Alling, & Koziol, 1981). Canadian officials awaited the results of a prospective trial that compared the rates of post transfusion hepatitis from individuals who received blood from donors who had surrogate testing compared to those who received blood from donors who had not undergone surrogate testing. Unfortunately, by the time evidence demonstrating the efficacy of the surrogate testing strategy become available, thousands of individuals had become infected by hepatitis C through blood transfusions, many of which could potentially have been prevented (Blajchman, Bull, & Feinman, 1995).

On reflection, it becomes apparent that a fundamental failing of the Canadian blood system’s management of hepatitis C was the adoption or perhaps misapplication of the evidence-based paradigm when developing policy concerning safety. The evidence-based paradigm is dominated with the belief in a hierarchy of evidence that asserts that randomized trials are the highest level of evidence (Upshur, 2003). In the tainted blood tragedy such an approach was found to be wanting in many respects, primarily related to the consequences of waiting for high quality evidence when the health of populations, as opposed to the health of individuals, is at risk. Reflecting this recognition, the “precautionary principle” has emerged as a new paradigm governing the use of scientific information. The precautionary principle essentially states that complete evidence of risk does not have to exist before action is taken to protect against the risk, particularly when the risk is potentially catastrophic (Wingspread conference participants, 1998). Although there are numerous interpretations of the principle, applications generally advocate anticipatory action to protect against harm, prioritize protection of public health and the environment and promote public participation in decision-making (Stoto, 2002). While the principle has become highly influential in risk decision-making in the environment and in health, it also has been heavily criticized. Opponents of the principle point to its lack of clarity, potential to create unnecessary fear and potentially denying the public the benefits of new technology (Morris, 2000).

In addressing the theoretical risk of vCJD, the Canadian blood system, and blood systems around the world, was guided by the precautionary principle. However, at the same time they also integrated components of evidence-based policy making in an attempt to find a middle ground between these potentially conflicting paradigms. Specifically, they chose to introduce a measured response that would not cripple the blood supply. This response was then calibrated as new evidence emerged on risk of transmission. In doing so they succeeded in accomplishing several policy objectives including reestablishing confidence in the blood system and demonstrating to the public that policy makers were acting proactively to protect the public. Most importantly, as evidence accumulated to demonstrate the probable transfusion transmissibility of vCJD, the policy decisions made by Canada and other countries appear to have been warranted and likely prevented further spread of vCJD through transfusion (Llewelyn et al., 2004; Peden, Head, Ritchie, Bell, & Ironside, 2004). In hindsight, the integration of precautionary policy making in the new blood system would have to be considered a major success (Wilson & Ricketts, 2004).

Risk aversion and increasing costs

While the new blood system’s precautionary approach to blood safety has received praise it also has not been without some criticism. In Canada, over a three-year period since the blood system underwent structural reform, expenditures in the blood system have increased by 50% (Wilson & Hebert, 2003). These rising blood system costs have been attributed to several factors including the increase in use of blood products, and the increase in cost of specific blood products such as intravenous immunoglobulin (Wilson, MacDougall et al., 2003). However, attention has particularly been focused on the introduction of new safety measures.
that have only marginally improved the safety of the blood supply. Some transfusion policy analysts have described the introduction of these safety measures as “irrational”. These individuals point to the normally prohibitive cost-effectiveness ratios of many of these measures (Bayer & Feldman, 1999). The cost-effectiveness ratios associated with several of the post–Krever safety measures has far exceeded the generally accepted cost-effectiveness ratios of $50,000 to $100,000 per QALY (Laupacis, Feeny, Detsky, & Tugwell, 1992). For example, the cost/quality adjusted life year of nucleic acid amplification testing for hepatitis C is $4 million/QALY and for solvent detergent plasma $8 million/QALY (AuBuchon & Petz, 2001). These tests have also impacted upon the cost of blood. Nucleic acid amplification testing for both hepatitis C and HIV has been estimated to contribute 13–20% of the cost of a unit of blood in the United States (Weinberg et al., 2002). Blood systems are also being confronted with the decision of adopting several expensive new safety measures, such as pathogen inactivation technologies (Council of Europe, 2001). In the United States (US) the Medicare Payment Advisory Committee identified that blood-related costs have been increasing more rapidly than other hospital costs placing strains on the current Diagnosis Related Group (DRG) payment system (Medicare Payment Advisory Committee, 2001). In Canada, provinces, which are responsible for funding the blood system, have expressed unease about rising blood costs and asked for a reconsideration of how policy decisions concerning the introduction of safety measures are being made (IBM Consulting, 2002).

The decision to introduce highly risk averse policies (i.e. the choice of policies with a high certainty of eliminating remote risks) does not appear to be driven by “public hysteria” but rather by incentive systems that act directly on the policymakers. Evidence for the lack of public demand driving the policy process is provided by the introduction of other similar protective policies. For example leukoreduction, a process by which white blood cells are removed, was introduced to protect against transfusion reactions and potentially other immune mediated effects. The policy met some controversy over its necessity and could not be expected to have been a high agenda issue for the public who would have little understanding of the process and for whom transfusion reactions would not be a major health concern (Goodnough, 2000). The other explanation for the lack of public influence on blood policy is the absence of well-defined advocacy coalitions representing the public and the interests of consumers of blood products (Orsini, 2002). The majority of recipients of blood products are members of the general population who cannot necessarily be identified in advance. The Canadian blood system has also explicitly involved representatives of various consumer groups in their policy making process which has reduced the need for public lobbying by these individuals.

In contrast to the relative lack of risk aversion amongst the public, our analyses suggest that risk aversion on the part of policy makers is likely responsible for the introduction of several of the safety policies. Canadian officials are eminently aware of the public health consequences of the transfusion transmission of hepatitis C and HIV. They also cannot help but be aware of the legal consequences of those who were involved in the decision-making processes at the time. The current incentive structure does little to protect against liability because the recommendation of the Justice Krever to introduce a no-fault compensation system for transfusion related injury was not implemented. Such systems have been found to be effective in controlling litigation in pediatric vaccination, an analogous policy area (Plotkin, 2001). Further contributing to risk-averse policy making is the separation of funding from decision-making in the blood system, with the federal government having the authority of introducing safety measures but not the responsibility for paying for them. The impact of this structural factor on blood system costs could have been mitigated if Justice Krever’s recommendation to have hospitals pay for blood products had been introduced since the budget restrictions of the hospitals would have limited their ability to pay for expensive products.

Policy making concerning blood safety—looking forward

Despite the growing cost pressures on the blood system, we would expect the Canadian blood system’s proactive response to threats to blood safety to continue, given the current set of operating principles and policy factors at play. Consequently, so will the trend towards the adoption of risk-averse safety measures with marginal cost-effectiveness ratios. If individuals in the blood system are interested in continuing the current practice of ensuring a safe
blood supply with cost being a secondary concern, little change needs to occur in the decision-making process. On the other hand, if blood system decision-makers or provincial officials responsible for funding the blood system desire a change to this approach, it is unlikely that additional studies demonstrating the comparatively poor cost-effectiveness of safety measures alone will have much impact. The current set of institutional arrangements, in which the regulator can introduce safety regulations and not be held directly responsible for the costs of these regulations, will continue to encourage the implementation of safety measures to ensure a high level of blood safety. This is also encouraged by the arms-length relationship between the blood system operator and the provincial funders that permits the operator to independently introduce safety measures. To combat the impact of these factors provincial governments will have to make efforts to regain control of the policy making process in the blood system, or perhaps require federal regulators to pay a component of the costs associated with their safety regulations. The scenario of such federal unfunded mandates imposing cost burdens on other orders of government has been observed in the US where it was partially addressed through legislative means (Conlan, Riggle, & Schwartz, 1995). A risk-averse approach to blood safety is further encouraged as long as decision-makers are aware of their potential legal and public accountability and a no-fault compensation program for transfusion injured recipients that limits legal liability may help address this issue. Our analysis also suggests that as long as the Canadian blood supply is reliant upon importing plasma from the United States, Canadian blood policy will be heavily influenced by US blood policy. The continued goal of the Canadian blood system to achieve self-sufficiency may address this concern. Nevertheless, in an increasingly integrated world, decisions made in parallel policy subsystems of other nations’ will play a crucial role in determining policy. Standard of care may be defined as the international response to a threat and a decision-maker who disagrees with this response may still be left with little option but to meet the international standard.

Despite the presence of these factors, the adoption of highly risk-averse policies cannot continue endlessly and the opportunity costs of these policies will become increasingly evident. Eventually, policy-makers will have to decide at what level of uncertainty of risk or at what level of cost/QALY safety measures will not be introduced. The decision of whether to adopt pathogen inactivation technologies, which offer the promise to remove both known and unknown pathogens from transfusions although at a substantial cost, will present an interesting challenge to the continued adoption of new safety measures.

Conclusion

In many ways, the Canadian blood system serves as a model for a transformed system emerging from a crisis of confidence. vCJD represents the first infectious threat to this transformed system and important lessons can be learned from how this threat was managed. Decision-making related to vCJD is representative of the new blood system’s approach of aggressively addressing risk in a proactive manner and introducing policies in advance of clear evidence of risk. While this approach was essential in the first stages of reform, and has reestablished the confidence of the Canadian public, it has contributed to rising costs. The challenge the blood system now faces is to find the appropriate balance between maximizing safety and ensuring the system remains affordable.

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References

Aach, R. D., Szmuness, W., Mosley, J. W., Hollinger, F. B., Kahn, R. A., Stevens, C. E., et al. (1981). Serum alanine aminotransferase of donors in relation to the risk of non-A, non-B hepatitis in recipients: The transfusion-transmitted viruses study. New England Journal of Medicine, 304(17), 989–994.

Alter, H. J., Purcell, R. H., Holland, P. V., Alling, D. W., & Koziol, D. E. (1981). Donor transaminase and recipient hepatitis. Impact on blood transfusion services. Journal of The American Medical Association, 246(6), 630–634.

AuBuchon, J. P., & Petz, L. D. (2001). Making decisions to improve transfusion safety. In J. AuBuchon, L. Petz, & A. Fink (Eds.), Policy alternatives in transfusion medicine. Bethesda, MD: AABB Press.

Bayer Advisory Council on Bioethics. (1998). Creutzfeldt–Jakob disease, blood and blood products: A bioethics framework. Ottawa: Bayer Advisory Council on Bioethics.

Bayer, R., & Feldman, E.A. (1999). Understanding the blood feuds. In F. E. A., B. R. (Eds.), Blood feuds: AIDS, blood, and the politics of medical disaster. Oxford: Oxford University Press.
Will, R. G., Ironside, J. W., Zeidler, M., Cousens, S. N., Estibeiro, K., Alperovitch, A., et al. (1996). A new variant of Creutzfeldt-Jakob disease in the UK. *Lancet*, 347(9006), 921–925.

Wilson, K., Code, C., Dornan, C., Ahmad, N., Hebert, P., & Graham, I. (2004). The reporting of theoretical health risks by the media: Canadian newspaper reporting of potential blood transmission of Creutzfeldt-Jakob disease. *BMC Public Health*, 4(1), 1.

Wilson, K., Code, C., & Ricketts, M. N. (2000). Risk of acquiring Creutzfeldt-Jakob disease from blood transfusions: Systematic review of case-control studies. *British Medical Journal*, 321(7252), 17–19.

Wilson, K., & Hebert, P. C. (2003). The challenge of an increasingly expensive blood system. *Canadian Medical Association Journal*, 168(9), 1149–1150.

Wilson, K., Hebert, P. C., Laupacis, A., Dornan, C., Ricketts, M., Ahmad, N., et al. (2001). A policy analysis of major decisions relating to Creutzfeldt–Jakob disease and the blood supply. *Canadian Medical Association Journal*, 165(1), 59–65.

Wilson, K., MacDougall, L., Pinard, B., Amin, M. A., Fergusson, D., Graham, I., et al. (2003). How should Canada fund the blood system? An evaluation of the chargeback proposal. *Hospital Quarterly*, 6(3), 44–47.

Wilson, K., McCrea-Logie, J., & Lazar, H. (2004). Understanding the impact of intergovernmental relations on public health: Lessons from reform initiatives in the blood system and health surveillance. *Canadian Public Policy*, 30, 177–194.

Wilson, K., & Ricketts, M. N. (2004). The success of precaution? Managing the risk of transfusion transmission of variant Creutzfeldt–Jakob disease. *Transfusion*, 44(10), 1475–1478.

Wilson, K., Wilson, M., Hebert, P. C., & Graham, I. (2003). The application of the precautionary principle to the blood system: The Canadian blood system’s vCJD donor deferral policy. *Transfusion Medicine Review*, 17(2), 89–94.

Wingspread conference participants. (1998). *Wingspread statement on the precautionary principle*. Paper read at Wingspread Conference, January 23–25 1998, at Racine, Wisconsin.