

# TRANSFUSION MEDICINE REVIEWS

Vol 17, No 2

April 2003

## The Application of the Precautionary Principle to the Blood System: The Canadian Blood System's vCJD Donor Deferral Policy

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The precautionary principle is an influential concept that has been widely used in international treaties and declarations involving the protection of the environment. The principle is now being applied to the development of transfusion policy. In this article, we examine the application of the precautionary principle in the policy process leading to Canada's decision to defer donations from individuals who had traveled to the United Kingdom because of concerns over variant Creutzfeldt-Jakob disease. We found that, although the principle

prominently influenced the decision-making process, problems existed with its interpretation. In particular, there was difficulty in balancing the risk prevented by applying a precautionary measure against the risk introduced by the same measure; in this case, the potential for shortages of blood. This dilemma is somewhat unique to the public health sector and will likely recur in future applications of the principle to transfusion policy. Copyright 2003, Elsevier Inc. All rights reserved.

**T**HE PRECAUTIONARY PRINCIPLE has played an important role in environmental policy making over the past several decades, enhancing the ability of governments and public policy decision makers to take steps to mitigate potential risks to the environment in the absence of conclusive proof of the nature or extent of the risk.<sup>1</sup> Despite coming under considerable criticism for its ambiguity and potential for abuse, the principle has been gaining wide acceptance as a tenant of international environmental law. The precautionary principle is now also playing an increasingly important role in health policy decision making. Recently, it has emerged as a guiding principle for managing infectious risks to nations' blood systems.

The application of the precautionary principle to the blood system has the potential to considerably impact the nature of blood policy decision making. In this article, we describe some of the implications for the adoption of this principle for transfusion policy. We specifically examine how the principle influenced Canada's decision to defer donations from individuals who had traveled to the United Kingdom for 6 months (later reduced to 3 months)

between the years 1980 and 1996 because of concerns about variant Creutzfeldt-Jakob disease (vCJD).<sup>2</sup> From this analysis, as well as from examples of the application of the principle to other health sector issues, we derive conclusions on the suitability of the use of the principle for developing transfusion policy.

### WHAT IS THE PRECAUTIONARY PRINCIPLE?

The precautionary principle emerged out of the European environmental movement of the 1970s and has its roots in the German concept of *vor-*

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*Supported by a grant from the Canadian Institutes for Health Research.*

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*0887-7963/03/1702-0001\$30.00/0*

*doi:10.1053/tmr.v.2003.50007*

*sorge* or foresight. The primary intention of early applications of the principle was to proactively prevent the introduction of measures that could theoretically cause environmental damage, as opposed to responding to the environmental damage after it has occurred. The principle reflects recognition of the limitations of scientific models to accurately describe complex issues pertaining to environmental harm or health risk.<sup>3</sup> Since its introduction, the precautionary principle has had a substantial impact on environmental policy. It has been incorporated into the 1992 Rio Declaration on Environment and Development and the Maastricht Treaty Establishing the European Community and has become a core concept in European environmental law.<sup>4,5</sup>

The precautionary principle essentially states that complete evidence of risk does not have to exist to institute measures to protect individuals and society from that risk. The Rio Declaration defined the principle as follows: "Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

Although this has been a widely cited definition, numerous interpretations of the principle exist in international treaties and declarations.<sup>6</sup> These interpretations vary in the degree to which the burden of responsibility is transferred from regulators, who must show harm, to proponents of potentially harmful measures, who must show safety. Some of the core concepts that applications of the principle share include (1) advocating anticipatory action to prevent harm, (2) shifting some of the burden of proof to the proponents of new technologies to show safety, (3) advocating a consideration of all alternatives to a new technology including doing nothing, and (4) incorporating all affected parties in the decision-making process concerning adopting a new technology.<sup>7</sup> There are various degrees of interpretation of the precautionary principle. Strong interpretations place the entire burden of responsibility on the proponents of potentially harmful measures to show that these measures are safe. Weak interpretations place more of the burden of proof on those arguing the possibility of harm, opening the door to cost-benefit analyses.

Although it has obtained widespread use, the precautionary principle has emerged as a highly controversial and politicized concept. Policy mak-

ers have had difficulty in agreeing on how much or how little evidence is required to trigger a precautionary action and on the role of the scientific process when the principle is used.<sup>8,9</sup> The variability in the interpretation of the principle has led to accusations that the principle has been used as a mechanism to introduce trade protectionism. The principle has also been accused of producing overregulation, denying the public the benefits of new technologies, arousing unnecessary fear in the public about theoretical risks, and making the scientific process irrelevant.<sup>10</sup> Decision-making bodies have attempted to overcome these problems by providing guidelines for the interpretation of the precautionary principle.<sup>11</sup>

#### THE PRECAUTIONARY PRINCIPLE IN THE BLOOD SYSTEM

Despite the controversies surrounding the use of the precautionary principle, the principle has remained a central component of environmental policy and is also playing an increasingly important role in health policy decision making, primarily in the fields of environmental health and public health. The precautionary principle gained particular prominence in Canadian health policy making after an investigation into the transfusion-associated transmission of human immunodeficiency virus (HIV) and hepatitis C.<sup>12</sup> An inquiry into the Canadian blood system's handling of these infectious risks determined that, in waiting for definitive evidence of blood transmission of hepatitis C and HIV, the blood system failed to act in a timely manner to address these emerging threats. The Commission advocated that a precautionary approach be taken in addressing potential future infectious risks stating that "the safety of the blood supply is an aspect of public health, and, therefore, the blood supply system must be governed by the public health philosophy, which rejects the view that complete knowledge of a public health hazard is a prerequisite for action."<sup>12</sup> This statement has had an important effect not only in the development of transfusion policy in Canada but in the development of all Canadian public health policy.

#### LESSONS LEARNED FROM CANADA'S vCJD EXPERIENCE

vCJD is the first major infectious threat to the Canadian blood system since the precautionary principle was advocated by Justice Krever. The

decision-making process addressing the theoretical threat of blood product transmission of vCJD provides an opportunity to gain insights into whether and how the precautionary principle was applied by policy makers. We have previously reported the results of a detailed policy analysis describing the decision-making process that led to the Canadian vCJD donor deferral policy.<sup>2</sup> This analysis was based on information provided from 32 semistructured interviews with key stake holders that included individuals from all major decision-making organizations. The interviews were audio taped and transcribed verbatim. We examined the role of the precautionary principle in this decision-making process by extracting statements from interviews that referred to the principle. We categorized these statements based on whether they referred to interpretations of the precautionary principle, its impact in decision making and problems surrounding the implementation of the principle.

#### *Summary of Decision-Making Process*

vCJD was first identified in 1996 in the United Kingdom and was believed to have occurred as a consequence of individuals ingesting beef from cows with bovine spongiform encephalopathy (BSE).<sup>13,14</sup> Concerns soon arose that this condition might also be transfusion transmitted, which led to a UK decision to import certain blood product requirements from other countries.<sup>15</sup> This decision prompted Canadian blood officials to embark on an examination as to whether Canada should accept donations from individuals who had lived in the United Kingdom.<sup>16</sup> In performing this analysis, Canadian blood officials conducted a systematic evaluation of the impact on supply of a donor deferral policy versus the potential health benefit of such a policy. Information on the potential threat of vCJD to the blood supply was obtained from expert reports who stated that although no definitive epidemiological evidence existed on the matter, potential blood transmission of vCJD should be considered theoretically possible and a donor deferral policy should be implemented.<sup>17</sup> Previous experience in the Canadian blood system had indicated that a 3% reduction in blood supply was sustainable. Based on surveys of donors conducted by the blood suppliers, this was found to correspond to a donor deferral policy of 6 months (ie, deferring donations from individuals who had spent 6 months in the United Kingdom during the

BSE outbreak, 1980 to 1996, would reduce the blood supply by 3%).<sup>18</sup> In August 1999, policy makers officially announced that individuals who had traveled to the United Kingdom for 6 months between the year 1980 and 1996 would be deferred from donating blood.<sup>19</sup>

#### *Role of the Precautionary Principle in the Decision-Making Process*

Our analysis identified that the precautionary principle significantly influenced the vCJD policy-making process. The decision to introduce a donor deferral policy, in the absence of any epidemiological evidence, and rely primarily on biological models was largely a consequence of the influence of the principle. In describing the vCJD decision-making process, one informant stated, “this was embarked upon as a balanced risk reduction recognizing that the precautionary principle would prevail to the extent that we would exercise restraint in allowing an uncertain risk to enter our blood supply system while at the same time wishing not to introduce other risks.”

The previous blood transmission of hepatitis C and HIV was cited as an important reason as to why the principle factored so prominently into the decision-making process. One policy maker commented, “this is not a scientific decision it is a risk management decision in the context of what we have lived through, what we went through in Canada (blood transmission of hepatitis C and HIV).”

Although the precautionary principle influenced the decision-making process, our analysis identified important problems with its application to the vCJD donor deferral policy. We found that policy makers in the blood system, like their counterparts in the environmental sector, struggled with the interpretation of the principle. In commenting on this difficulty, one decision maker stated, “where do you draw the cut off. . .you can say well don’t do anything that could possibly have adverse effects until you know everything . . . Obviously you can’t operate that way. There is no profession, no discipline that operates that way. After all there is always some degree of uncertainty when we think we know something.”

In general, we found that policy makers supported a weaker interpretation of the principle. This was evidenced by the decision to embark on a partial donor deferral policy based on a 6-month residency period, as opposed to a complete donor

deferral policy prohibiting donations for individuals who had spent any time in the United Kingdom, because of concerns about reductions in blood supply. The weaker interpretation is also evident in the following definitions of the precautionary principle provided by some of the individuals we interviewed: “when there are real unknowns you better assume that what is unknown could be a lot more dangerous than what you might speculate that it is, and act as if it were more dangerous than what you speculate it would be” and “in the absence of any clear knowledge of risk you are going to have to do something, but that something is going to have to balance the loss of supply versus potential (improvement) in safety.”

Importantly, our analysis found that policy makers encountered a further obstacle in applying the precautionary principle that was not faced by their counterparts in the environmental sector. In applying the principle to the environmental sector, policy makers have had to consider a trade-off between the economic costs of introducing the precautionary measure and the potential environment and health benefits the introduced measure will provide. In addressing the problem of potential transfusion transmission of vCJD, Canadian decision makers encountered a different form of trade off: the health benefit of introducing a precautionary measure versus the health risk of introducing the same measure. Specifically, they weighed the potential health benefit of protecting the blood supply from a theoretical infectious risk and the potential health impact of a reduction in blood supply. This challenge of balancing competing health risks changed the dynamic of the process from being purely precautionary to more of a risk management approach.<sup>20</sup> Examples of the difficulty in applying the precautionary principle in this setting are reflected in the following comments: “recognizing that in the application of the precautionary principle strictly to health, that there are some potential problems in exercising restraint . . . when it involves a therapeutic product, the absence of (which) may in itself have a risk consequence to a patient population” and “but if you prophesized about a pathogen in Canada (and) have the whole population dealing with it, do you apply the same precautionary principles? Obviously (you) then (have to) balance supply against safety as well. It is a very troublesome way to make policy decisions in the blood system.”

Overall, our analysis suggests that the precau-

tionary principle could be viewed as sensitizing decision makers to the theoretical possibility of harm from vCJD blood transmission and encouraging the introduction of anticipatory measures in the absence of conclusive evidence of risk. However, the dilemma of the institution of a precautionary measure potentially creating a blood shortage resulted in a weaker interpretation of the principle and the introduction of a partial precautionary measure based on a cost-benefit analysis.

#### THE CHALLENGE OF APPLYING THE PRECAUTIONARY PRINCIPLE TO THE HEALTH SECTOR

The vCJD donor deferral decision reveals the “double-edged” implications of applying the precautionary principle to health issues, specifically the potential of a precautionary measure introducing a similar harm to that which it was intended to prevent. The precautionary principle in its original formulations was not intended to be applied to primarily health sector issues, and thus such problems likely were not foreseen. A review of the handling of other theoretical health risks shows the difficulty policy makers have encountered when determining when and how to use the principle. Failing to apply the precautionary principle in the health sector has led to serious consequences. The Inquiry into BSE and variant CJD in the United Kingdom stated that government officials, while awaiting more definitive scientific evidence, delayed implementing recommended policies that were consistent with the precautionary principle. This delay potentially contributed to further spread of BSE to other cows and to humans in the form of vCJD.<sup>21</sup> In Canada, the blood transmission of hepatitis C and HIV infectious risks was also identified as a consequence of not having acted with precaution.<sup>12</sup> However, important examples also exist of how applying the precautionary principle has created health risks as opposed to alleviating them. The use of the principle has been attributed to prompting the government of Peru to stop chlorinating drinking water, which contributed to the spread of cholera in the region in the early 1990s.<sup>22,23</sup> Similarly, precautionary-based concerns about the health risks of DDT led to its removal from use in South Africa and a subsequent increase in malaria cases.<sup>24</sup> Both of these decisions were subsequently reversed.

A clear difficulty can be seen to exist with the application of the precautionary principle to health

**Table 1. Mechanisms for Implementing the Precautionary Principle in the Health Sector**

	Mechanism	Example
A	<b>Strong precaution</b> (full precautionary approach)	European Commission position on importing genetically modified foods <sup>26</sup>
B	<b>Intermediate precaution</b> (risk-management approach) Introduction of partial precautionary measure designed to balance risk prevented by implementation of precaution versus risk created by introduction of precaution	US and Canadian policy on blood donations from individuals at risk of vCJD <sup>19</sup>
C	<b>Weak precaution</b> (deferred-implementation approach) Delayed introduction of precautionary measure until mechanisms instituted to protect against health risk created by introducing precautionary measure	Stockholm Convention position on DDT <sup>27</sup>
D	<b>No precaution</b> (evidence-based approach) Deferral of precautionary measure until more definitive epidemiological evidence becomes available	US FDA position on phthalates in cosmetic products <sup>28</sup>

Abbreviations: DDT, dichlordiphenyltrichloroethane; FDA, Food and Drug Administration.

sector problems in general and to transfusion policy in particular. The principle has the potential to provide an important tool to policy makers in guiding their decision making and sensitizing them to issues of risk which scientific models are unable to quantify. However, applying the principle to health policy can be problematic and potentially lead to serious health consequences.

#### CAN THE PRECAUTIONARY PRINCIPLE BE EFFECTIVELY APPLIED TO THE BLOOD SYSTEM?

Infectious threats to the blood system are particularly challenging to evaluate through standard epidemiological models because of the potential for long time periods between infection and the manifestation of disease and the often rarity of the conditions. Waiting for definitive evidence of an infectious threat before introducing preventative measures can have serious consequences if the infectious threat is proven to exist. In this sense, the precautionary principle is a helpful and necessary guide to decision makers. However, the principle, in its strongest formulations, cannot be practically applied to the blood system. Complete absence of risk is difficult if not impossible to prove, and waiting for definitive epidemiological evidence of safety could have serious economic and blood supply implications. In considering how best to use the precautionary principle, blood policy makers have several options. In Table 1, we describe 4 mechanisms by which the precautionary principle has been applied to health sector problems in the past. It appears that the risk-manage-

ment approach (approach B), an intermediate interpretation of the principle, is well suited to the health sector and the development of transfusion policy because of the risks and benefits often being measured in similar units. Unfortunately, high levels of uncertainty often surround estimations of both risk and benefit creating difficulties for decision making. Moreover, risk-management approaches often underestimate the importance of public perception of risk, particularly for issues in which risks are unknown or delayed and that are uncontrollable and lethal.<sup>25</sup> The deferred-implementation approach (approach C), a weaker interpretation of the principle, is another option available to transfusion policy makers when the potential harm of a precautionary measure is of particular concern.

#### CONCLUSION

Countries around the world will encounter continuing challenges of theoretical risks to their blood supplies and will need to develop mechanisms to address these risks. The precautionary principle in its broadest context, advocating anticipatory action, a shifting of burden of proof, a consideration of all alternatives, and the involvement of the public in decision making have been and will continue to be a useful tool to policy makers. However, for it to be an effective policy guide further refinements to the precautionary principle will be needed and a precautionary principle specific for the blood system will need to be developed.

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