

# A policy analysis of major decisions relating to Creutzfeldt–Jakob disease and the blood supply

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## Abstract

CREUTZFELDT–JAKOB DISEASE (CJD) IS THE FIRST major challenge that the blood system has faced since the completion of the Krever inquiry in 1997. We report the results of a detailed policy analysis comparing 2 CJD-related decisions: a 1995 recall of blood from a donor with classic CJD and the 1999 decision to defer donations from individuals with a 6-month travel history to the UK between 1980 and 1996 due to concerns related to variant CJD. Overall, we observed that decision-making improved significantly from 1995 to 1999. In 1998/99 the potential threat of variant CJD was identified at an early stage, and a systematic risk assessment process was initiated. Decision-making was consultative and involved consumers. However, the perception existed that further improvement could take place in the areas of transparency of process and interaction of organizations. We observed that the presence of a second operator had an important impact on decision-making in 1998/99.

The potential transmission by blood of Creutzfeldt–Jakob disease (CJD) has presented the Canadian blood system with several challenges. The response to these challenges provides insight into the blood system's decision-making process and its evolution since the Krever inquiry. We report the results of a detailed policy analysis that compares 2 CJD-related decisions: a 1995 recall of blood from a donor with classic CJD and the 1999 decision to defer donations from individuals with a 6-month travel history to the United Kingdom between 1980 and 1996 because of concerns related to variant CJD (vCJD). CJD is the first major challenge the blood system has faced since the completion of the Krever inquiry in 1997. We examined examples of the decision-making process before and after the blood system was changed in response to the inquiry's recommendations.

## Methods

Our policy analysis consisted of 2 components: a literature review and semi-structured interviews with key informants. The literature review consisted of a systematic survey of the medical literature concerning the risk of transmission,<sup>1</sup> a content analysis of newspaper articles reporting stories about CJD and blood transfusion, and a review of minutes of meetings of major decision-making organizations and of government documents obtained through access to information requests. We conducted 32 interviews with key informants, which were audiotaped and transcribed verbatim. Information from the interviews was coded to identify important concepts related to the policy process. Coding was verified, and the information was entered into a qualitative software program. The codes were collapsed into categories and the categories compared to develop themes to explain the decision-making process and identify the key policy determinants. We focused on the following domains of the policy process while developing themes: the organizational structure for decision-making, the information available to the decision-makers, the value systems of decision-makers and the key external factors that influ-

## Review

## Synthèse

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CMAJ 2001;165(1):59-65

See related article page 51

[Return to July 10, 2001  
Table of Contents](#)

enced decision-making. These domains are based on the components of the Sabatier-Lomas policy analysis framework.<sup>2</sup> We also conducted sessions with the major stakeholders to obtain feedback on our findings.

## Structure of the blood system (1995–1999)

In 1995, the Drugs Directorate of Health Canada (part of the then Health Protection Branch), through its Bureau of Biologics, was the federal regulator of blood and set blood policy. The Red Cross, which was the national operator of the blood system, was responsible for collecting and distributing blood. The Red Cross received funding from the Canadian Blood Agency, whose responsibility was to direct, coordinate and finance aspects of the blood system consistent with the objectives of the provinces and territories. Bayer Inc. was the primary manufacturer of blood products for Canada and supplied blood products to the Red Cross.

Between 1995 and 1999, the Canadian blood system experienced considerable change. Based on the Krever inquiry's interim report, federal, provincial and territorial ministers proceeded to develop a plan to reform the blood system. Quebec opted out of these discussions.<sup>3</sup> The new national blood authority became Canadian Blood Services (CBS), which began operations in September 1998. CBS received funding from the provinces and territories and, in turn, collected, tested and distributed blood products for all territories and provinces except Quebec. It combined the operating and financing roles of the Red Cross and the former Canadian Blood Agency. Quebec developed its own plan for a blood system following the recommendations of the Géliveau Committee. Its new provincial blood operator, Héma-Québec, also began operations in September 1998.<sup>4</sup>

Between 1995 and 1999, there were also important changes within the regulatory authority. In 1999, the Drugs Directorate was renamed the Therapeutic Products Programme. The Bureau of Biologics, which was now called the Bureau of Biologics and Radiopharmaceuticals (referred to as Bureau of Biologics in this article), continued to be responsible for the regulation of blood products. Both CBS and Héma-Québec were required to follow Health Canada regulations. The National Blood Safety Council was created in 1997, based on a recommendation of the Krever Commission. Its responsibilities were to oversee the decision-making process in the blood system and report directly to the Minister of Health. Bayer Inc. continued to be the national manufacturer of fractionated blood products (Table 1).

## Review of decisions

### 1995 recall of blood from a Vancouver donor

The issue of blood that was potentially infected with CJD became a public health concern on this continent in the United States in 1994. In that year, the American Red Cross and US blood manufacturers initiated 3 voluntary with-

drawals of blood from donors who had subsequently developed CJD.<sup>5</sup> In response to these withdrawals, the US Food and Drug Administration developed a policy on June 1995 to withdraw cellular product donations from individuals with CJD. One month later, on July 11, the issue of blood transmission of CJD came to the Canadian public's attention. On this date, a Canadian Press story was published in several papers recounting testimony by a US hematologist, Dr. Nathan Koblinsky, at the Krever inquiry that CJD could be the next major threat to the blood supply.<sup>6</sup> 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.<sup>7</sup> 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 (for further information regarding knowledge about the risk of transmission of CJD by blood transfusion in 1995 and 1999, see the Appendix on the *CMAJ* Web site at [www.cma.ca/cmaj/vol-165/issue-1](http://www.cma.ca/cmaj/vol-165/issue-1)

**Table 1: Organizations involved in decision-making in 1995 and 1999**

1995	1999
<b>Policy-makers</b>	
Minister of Health's office <i>Regulator</i>	Minister of Health's office <i>Regulator</i>
Health Protection Branch → Drugs Directorate → Bureau of Biologics	Health Protection Branch → Therapeutic Products Programme → Bureau of Biologics and Radiopharmaceuticals
<b>Operators</b>	
Canadian Red Cross	Canadian Blood Services Héma-Québec
<b>Funder</b>	
Provincial and territorial governments through the Canadian Blood Agency	Provincial and territorial governments directly to respective operator
<b>Manufacturer of blood products</b>	
Bayer Inc.	Bayer Inc.
<b>Consumer groups</b>	
Canadian Hemophilia Society had highest profile	Canadian Hemophilia Society had highest profile
<b>Other</b>	
Laboratory Centre for Disease Control (scientific arm of the Health Protection Branch — limited role in 1995)	Laboratory Centre for Disease Control (scientific arm of the Health Protection Branch — important role in 1999)
No equivalent organization	National Blood Safety Council (oversaw blood system for the Minister of Health)
No equivalent organization	Bayer Advisory Council on Bioethics (independent agency provided evaluation of blood policy issues)

/jakobappendix.htm).<sup>8</sup> The immediate consequences of the recall were shortages of certain blood products.<sup>9</sup> The total cost of the recall, the largest in Canadian history, was estimated at \$11 million.<sup>10</sup> On Oct. 20, 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.<sup>11</sup>

### **Discovery of vCJD**

In 1996, investigators in the UK published the first case series describing a variant form of CJD.<sup>12</sup> The investigators believed, and subsequent studies supported the fact, that this condition was related to bovine spongiform encephalopathy (BSE) or mad cow disease.<sup>13</sup> Almost immediately, concerns arose that this condition could potentially be transmitted through blood transfusion. In February 1998, the UK decided to import plasma products due to a concern that an unknown portion of the British population could be harbouring vCJD.<sup>14</sup> This decision stimulated discussion in the US and Canada about whether these countries should accept blood from individuals who had travelled to regions where BSE was occurring.

On Oct. 15, 1998, the potential threat of vCJD to the blood supply increased in public profile in Canada because of the release of the Bayer Advisory Council on Bioethics report on CJD, which received widespread media attention. One of the recommendations of this report was to not accept donations from individuals who had travelled to areas where BSE was occurring.<sup>15</sup> On Oct. 27, 1998, an important scientific meeting at Health Canada discussed the Advisory Council's report and a separate report by Dr. Neil Cashman, which also recommended a deferral policy. There was a lack of agreement on the benefits of donor deferral, however, the potential risk to the blood supply was recognized. At the meeting, the Bureau of Biologics asked the operators to evaluate the impact a donor deferral would have on their respective supplies.<sup>16</sup>

### **1998 holding of blood from a Utah donor**

As the blood system was determining how to address the issue of vCJD, it was also considering reversing its policy on classic CJD. During this time, the issue arose of a US blood donor from Utah who had developed CJD (Dec. 8, 1998). Some blood products manufactured from this donor's plasma were identified as being in the Canadian blood supply. Due to the young age of the donor, there was concern that he may have been suffering from a variant form of the condition, perhaps related to chronic wasting syndrome of elk (a transmissible spongiform encephalopathy similar to BSE and CJD). On Dec. 17, 1998, the blood products derived from this individual were placed on hold and were not to be issued for use.<sup>17</sup> The regulator eventually obtained confirmation that the donor did not have a variant form of the condition and on Dec. 24, 1998, it removed the hold on his blood.<sup>18</sup>

### **1999 ban on blood from donors who had visited the UK**

In March 1999, both operators had obtained the results of their surveys of the impact of donor deferral on the blood supply. Héma-Québec determined that excluding individuals who had spent 1 month in the UK between 1980 and 1996, the peak years of the BSE outbreak (a 1-month deferral policy), would reduce their blood supply by about 3%. The previous experience of the Red Cross had led the operators to believe that this was the maximum reduction of supply that the blood system could tolerate. Héma-Québec, in April, passed a resolution supporting a 1-month deferral policy.<sup>19</sup> CBS was not prepared to proceed with a similar policy at that time, which would have reduced their blood supply by 10%, and was considering deferring donations based on a longer time spent in the UK. CBS also emphasized the potential impact a donor deferral policy would have on deterring future donors and decided to obtain further consultations on the issue. The Bureau of Biologics notified both agencies that they needed to work together to develop a unified proposal. It was the opinion of the federal Minister of Health's office that a single national standard would be in the best interests of the blood system, a position shared by the National Blood Safety Council. However, CBS and Héma-Québec were unable to present a unified proposal by the deadline of June 10, 1999.<sup>20</sup> Health Canada developed its own regulation and presented a draft proposal to the operators that stated that individuals who had spent 6 months in the UK between 1980 and 1996 should be deferred from donating (a 6-month deferral policy). This proposal was based on a risk assessment model developed by the Laboratory Centre for Disease Control (LCDC) and the knowledge that the US would proceed with a similar policy.<sup>21</sup> On August 17, Health Canada announced its policy regarding donor deferral.<sup>22</sup> As operators can exceed the standard of the regulator on these matters, Héma-Québec chose to proceed with a 1-month policy.

### **Events following the 1999 blood ban**

Both CBS and Héma-Québec implemented their respective donation deferral policies in advance of the regulator's deadline of February 2000.<sup>23</sup> Due to concerns about reduced supply as a consequence of the deferral policy, both agencies introduced aggressive blood donor recruitment programs.<sup>24</sup> In the year 2000, 2 new cases of vCJD were identified in France.<sup>25</sup> Based on the LCDC risk assessment model, donor deferral was recommended. On Aug. 31, 2000, Health Canada announced that it would defer donations from individuals who had travelled to France for a period of 6 months between 1980 and 1996.<sup>26</sup> Both Héma-Québec and CBS indicated they would follow this directive. The US did not implement a similar deferral policy at that time.

## Comparison of decision-making leading to the 1995 recall and the 1999 donor deferral policy

We observed that the 1999 decision to defer donations from individuals who had travelled to the UK demonstrated a significant improvement in decision-making over the 1995 recall of blood connected with a Vancouver donor and the 1998 holding of blood connected with a Utah donor. The potential threat of vCJD was identified at an early stage by the Bureau of Biologics, and a systematic risk assessment process was initiated by the LCDC. Decision-making was consultative and involved consumers. However, the perception exists that further improvement could take place in the areas of transparency of process and interaction of organizations (Table 2).

### Areas where there has been improvement in decision-making

#### *Reactive versus proactive decision-making and the evaluation of risks and benefits of policy*

According to interviews and documents, one of the main criticisms of the 1995 recall decision was that it was reactive. The Red Cross was forced to respond urgently to concerns that a donor had been diagnosed with CJD, due to the lack of a policy governing decision-making on the issue. In 1999, decision-making was proactive. The potential threat of vCJD to the blood supply was addressed by the Bureau of Biologics soon after the condition was described, and a policy development process was initiated.<sup>27</sup> The proactive nature of decision-making contributed to another

important improvement in the policy process in 1999. In 1995, the operator, the Canadian Red Cross, had to make the decision to withdraw blood products in the absence of a careful examination of the risk of transmission and the impact on the blood supply. In making the decision, the Red Cross primarily relied upon information on risk of transmission obtained from US decision-making bodies.<sup>28</sup> The regulator, the Bureau of Biologics, did conduct a detailed evaluation of the issue of blood transmission of CJD; however, the results of this evaluation were not available until well after the recall decision had been made.<sup>29</sup> In contrast, in 1999, the regulator and operators conducted a detailed, systematic assessment of the risk of transmission of vCJD and the potential impact of a donor deferral policy on the blood supply. This information was entered into a risk assessment model that guided the decision to choose a 6-month length of stay criterion. The information from this assessment and the model was also used to guide the decision to defer donors who had visited France.<sup>21</sup>

#### *Consultative decision-making process*

In 1995, prior to the decision to recall blood connected with a Vancouver donor, the important decision-making organizations examined the risk of CJD to the blood supply independently with little communication among them. In contrast, in 1999, the regulator involved the operators at an early stage in the decision-making process. In addition, the working relationship between the Bureau of Biologics and the LCDC was considerably more effective in 1999 than in 1995.

#### *Involvement of consumers*

There have been significant improvements in the involvement of groups representing consumers of blood products in the policy process from 1995 to 1999. In 1995, consumers were not involved in the decision-making process to any extent before the recall decision, although they were kept informed once the decision had been made. There was also no formal mechanism to involve consumers in decision-making. In contrast, in 1999, consumers were involved in several stages of decision-making by both the operators and the regulators. The operators also developed mechanisms to consult with blood donors.

### Areas of uncertain impact on decision-making

#### *The 2-operator system*

One of the most significant differences in decision-making between the 1995 and 1999 decisions was the existence of a second operator. The presence of Héma-Québec introduced an important dynamic into the policy process that led to the donor deferral decision.

Héma-Québec significantly affected the policy process when it announced in April 1999 that it was prepared to in-

**Table 2: Comparison of 1995 and 1999 decisions**

1995	1999
<b>Areas in which decision-making improved</b>	
Reactive decision-making	Proactive decision-making
No formal evaluation of risks and benefits prior to recall decision	Thorough assessment of risks and benefits prior to policy being introduced
Limited communication among organizations prior to decision	Consultative decision-making process throughout
Consumer groups not involved in decision-making	Consumer groups involved in decision-making
<b>Areas of uncertain impact</b>	
Single operator	2 operators
<b>Areas in which problems are still perceived to exist</b>	
Limited interaction between stakeholders	Interaction between stakeholders was at times less than ideal
Lack of transparency of decision-making process	Improved transparency of decision-making process, however, some deficits may still exist
Susceptibility to events in the United States	Susceptibility to events in the United States



roduce a 1-month donor deferral policy. CBS, at this time, had not completed its evaluation of the impact of a donor deferral. However, it recognized that it could not have as strict a donor deferral policy because a higher percentage of its donors had travelled to the UK. The possibility of having 2 different standards of safety for blood in Canada created concern on the part of the regulator and the federal Minister of Health's office. The regulator asked the 2 organizations to work together to develop a uniform policy. However, this initiative was unsuccessful.

It is important to recognize that CBS and Héma-Québec started the policy process on donor deferral from different positions. Both were newly created organizations; however, the initial development and management of CBS would be more challenging than for Héma-Québec due to CBS's considerably larger jurisdiction. CBS also had more concerns than Héma-Québec regarding the adequacy of its blood supply when the discussions about donor deferral began. Perhaps most importantly, CBS was aware that any decision on donor deferral would have a larger impact on its supply base than was the case for Héma-Québec.

Individuals whom we interviewed expressed differing views on the advantages and disadvantages of having Héma-Québec as a second operator in the policy process. Several of our informants indicated that they believed that Héma-Québec's rapid response and development of policy regarding donor deferral drove decision-making on this issue. The informants attributed Héma-Québec's speed and efficiency to both the structural advantage it had due to its smaller size as well as to the expertise of its personnel. However, other informants believed that there were political motivations for the introduction of what could be perceived as a "higher" standard by Héma-Québec, perhaps associated with an attempt to establish the autonomy of its organization. These informants also stated that this may have unnecessarily complicated the policy process. Héma-Québec asserted that it had no choice but to proceed with the policy it chose, because the agency had an obligation to provide the maximum protection to its recipients that its supply could withstand. Consumer representatives whom we interviewed believed that the second operator acted as an important check and balance in the system. Some stated that while they had initially supported a single operator system, following the donor deferral decision they now saw value in, and supported, the 2-operator system.

The 2-operator system serves as a useful case study of the strengths and weaknesses of decentralization of the blood system. One of the arguments in favour of decentralization of health and social policy sectors is that it allows for competition between regions to develop. This competition can lead to innovation and experimentation as competing systems attempt to produce "better" policy.<sup>30</sup> The dynamic of Quebec and the rest of Canada produces a unique form of competition given the underlying political tension between these 2 regions. Social policy researchers have argued that this unique competitive environment has con-

tributed to Canada's greater progress in social policy since the 1960s compared with the US.<sup>31</sup> The primary disadvantage of decentralization of social policy areas is the potential for conflict between regions and difficulties in establishing national standards.<sup>32</sup> From our analysis, it appears that a 2-operator system created a competitive environment that stimulated policy-oriented learning. However, at the same time, it also resulted in the development of conflict between the operators and, arguably, did not produce a single national standard.

Our evaluation of the 2-operator system took place soon after both operators had begun operations. As the operators become more familiar with each other, the impact on the policy process of a second operator could change.

## Areas in which problems are still perceived to exist

### *Interaction of organizations*

Although our analysis demonstrates that communication between organizations had improved since 1995, some difficulties may still exist. Many of our informants stated that, in the early stages of the decision-making process, there was a certain tension between the 2 operators as they learned to work with each other. The unfamiliarity of the working relationship led to problems of communication between the boards of the 2 organizations. Our informants also identified some difficulties in the relationship between the operators and the regulator. The failure of the operators to present a coordinated proposal on donor deferral to the regulator demonstrated some of the early communication difficulties. A lack of understanding of the roles and responsibilities of the National Blood Safety Council was also identified as being a problem early in the decision-making process. Many of these interactions have improved since the early stages of the policy to defer donors who had visited the UK. According to some of our informants, the key organizations interacted effectively to develop the policy to defer donors who had visited France.

### *Transparency and public consultation*

Lack of transparency was one of the major criticisms of the blood system at the time when the blood supply was confronted with hepatitis C and HIV.<sup>33</sup> Improving transparency has been a particularly important concern of the new blood system to re-establish public confidence. Although considerable progress has been made in this area, our analysis suggests that the perception continues to exist that the decision-making process may benefit from greater transparency. The blood system, in particular, came under criticism for transparency issues in 1998 surrounding the Utah donor issue. The regulator and the operators made an attempt at greater transparency of process in developing the policy to defer donors who had visited the UK by in-

volving consumer groups throughout the policy process. Although some informants stated that these changes had improved transparency, we found that some consumers and members of the media thought that further progress could be made in this area.

One issue relating to transparency that emerged was whether consultation should take place with the general public and, if so, by what mechanism. The US Food and Drug Administration holds advisory board meetings, which are open to the public and at which voting on recommendations takes place. Our informants have both praised these meetings for their openness and education of the public and criticized them for leaving the blood system susceptible to having its agenda driven by interest groups. In Canada, the National Blood Safety Council periodically holds public forums on blood issues, however, no voting takes place at these meetings. CBS is currently responding to a task force's recommendations on how the operator can enhance public participation.<sup>34</sup>

### **The influence of events in the US on Canadian decision-making**

Events in the US were a key factor that influenced the decision-making process in all 3 CJD-related decisions that we examined. One of the main reasons why Canadian policy on blood is so heavily influenced by US policy is that Canada is not self-sufficient in fractionated products. Consequently, Canada must rely upon plasma products derived from US donors, emphasizing the importance of the 2 countries' sharing similar safety standards. It should be noted, however, that in 2000 the US and Canada did not share the same policy on how to handle the issue of donations from individuals who had travelled to France, with Canada choosing to proceed with a donor deferral policy and the US initially deciding not to. The American Red Cross has since instituted a similar policy to Canada's.

### **Conclusion**

Our analysis demonstrates a significant evolution in the mechanism by which decision-making in the blood system occurs, and we have outlined some of the important aspects of the current state of decision-making. The blood system will continue to face difficult challenges from CJD as BSE emerges in other European countries and new information becomes available on the risk of transmission of vCJD by blood. To handle these challenges effectively, the blood system will have to continue to develop its approach to policy-making.

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*Contributors:* Dr. Wilson contributed to the study design, conducted interviews, analyzed data and wrote various drafts of the manuscript. Dr. Hébert contributed to the study design, facilitated contacts with key organizations, provided feedback on findings at regular intervals through the study and reviewed the final manuscripts. Dr. Laupacis contributed to the study design, provided feedback on find-

ings at regular intervals through the study and reviewed the final manuscripts. Dr. Dornan provided content expertise on the role of the media in the policy process, provided feedback on findings at regular intervals through the study and reviewed the final manuscripts. Dr. Ricketts provided content expertise on the risk of transmission of Creutzfeldt-Jakob disease via blood products, provided feedback on findings at regular intervals through the study and reviewed the final manuscripts. Ms. Ahmad acted as study coordinator, obtained documents, arranged and attended interviews, coded manuscripts and contributed to revisions of the manuscript. Dr. Graham contributed to the study design with a focus on qualitative methodology, provided feedback on findings at regular intervals through the study and reviewed the final manuscripts.

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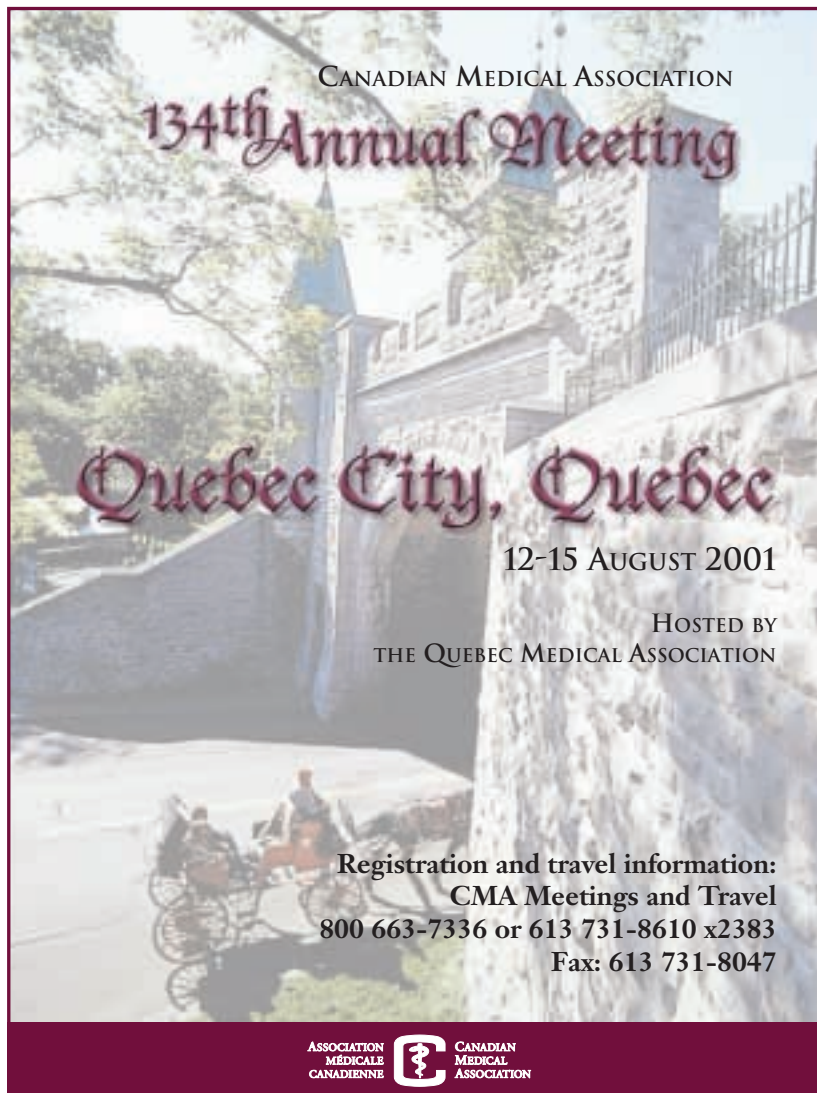
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