

Canadian Assessments and Policies Concerning Deferral of Blood Donors Who Resided or Traveled in BSE/vCJD Countries

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ORGANIZATION OF BLOOD SAFETY AND BLOOD PRODUCT OUTCOME

Blood Safety and Blood Product Outcome Blood-Borne Pathogens

Transfusion Transmitted Injuries (Surveillance and Research)

Surveillance of High Risk Patients
A. Bone Marrow and Stem Cell Patients
B. Apheresis Patients
C. Hemophilia Patients

National Blood Transfusion Surveillance System
Four Pilot Provinces

Community Acquired Blood-Borne Infections (Surveillance and Laboratory)

Passive Surveillance Hepatitis
Provincial Public Health

Active Surveillance
Enhanced Hepatitis Surveillance
Center of Excellence in Hepatitis

PROGRAM INFLUENCES ON HEALTH POLICIES

PROGRAM LINKS WITH OTHER PROGRAMS AND ORGANIZATIONS

CJD Surveillance and Research

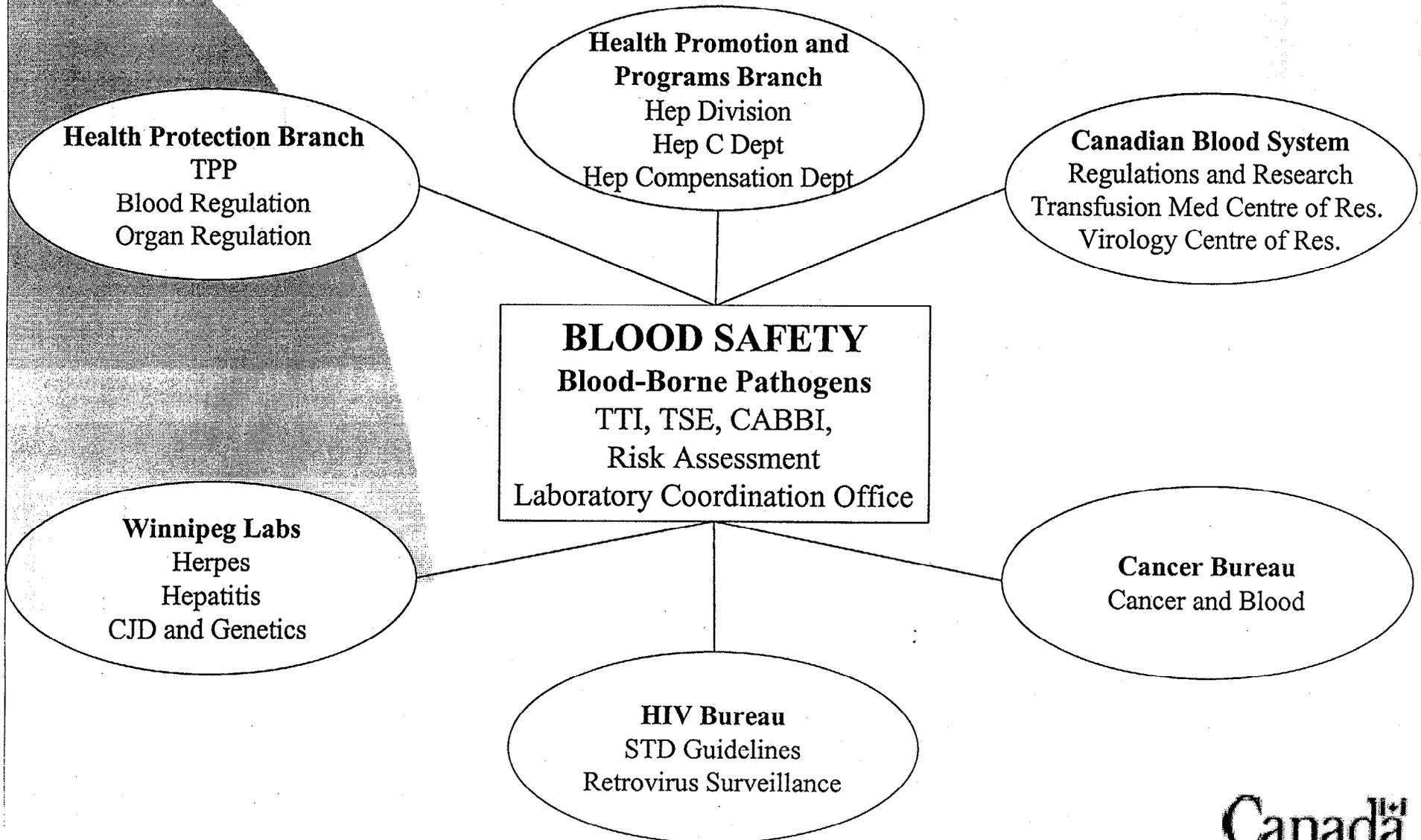
Blood-Borne Pathogens
TTI
Risk Assessment

Regulations
Food Directorate
TPP
CFIA

Interactions with Winnipeg Labs
CJD and Genetics

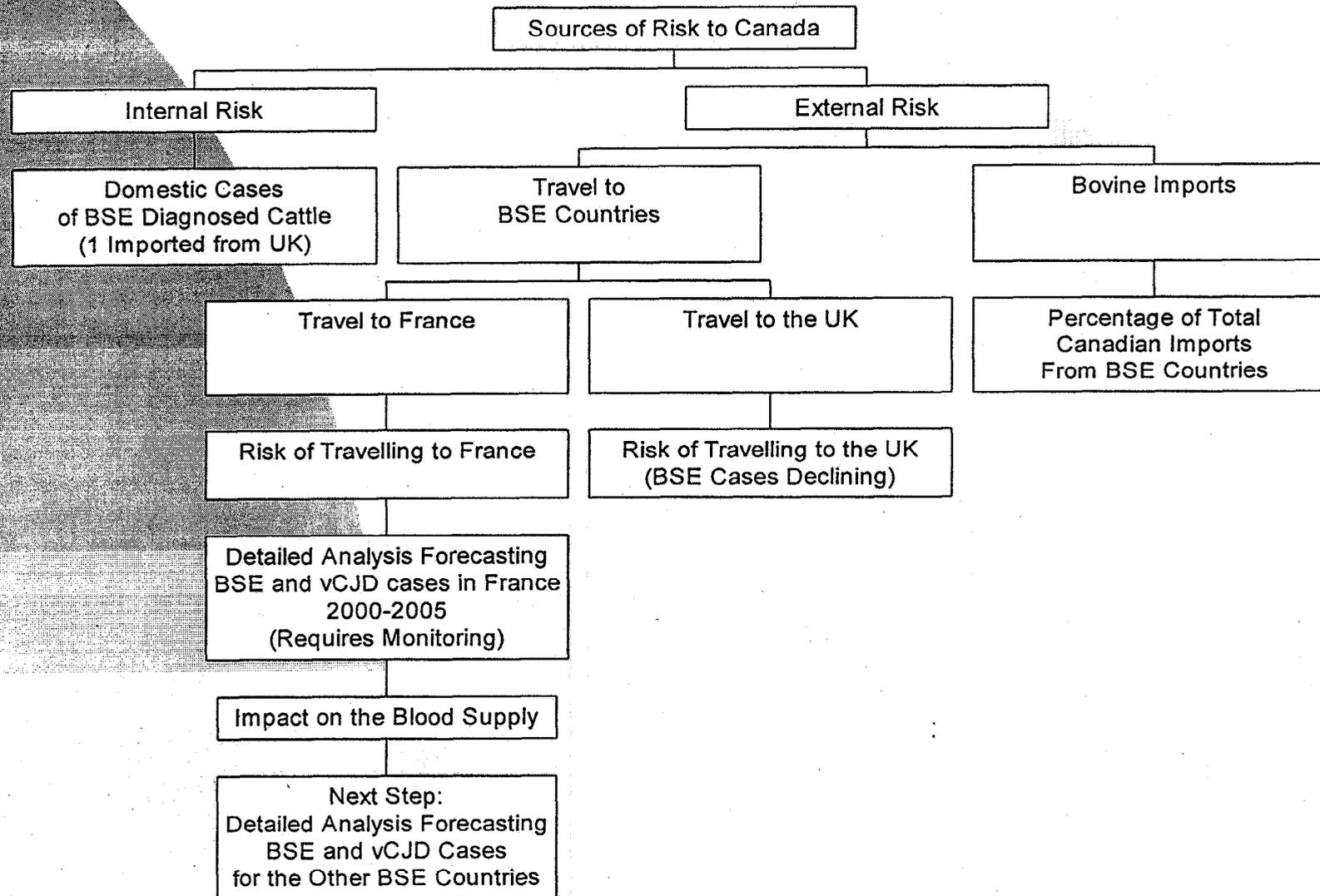
Canadian Blood System
Héma-Québec

PROGRAM LINKS - INFLUENCES ON HEALTH POLICIES

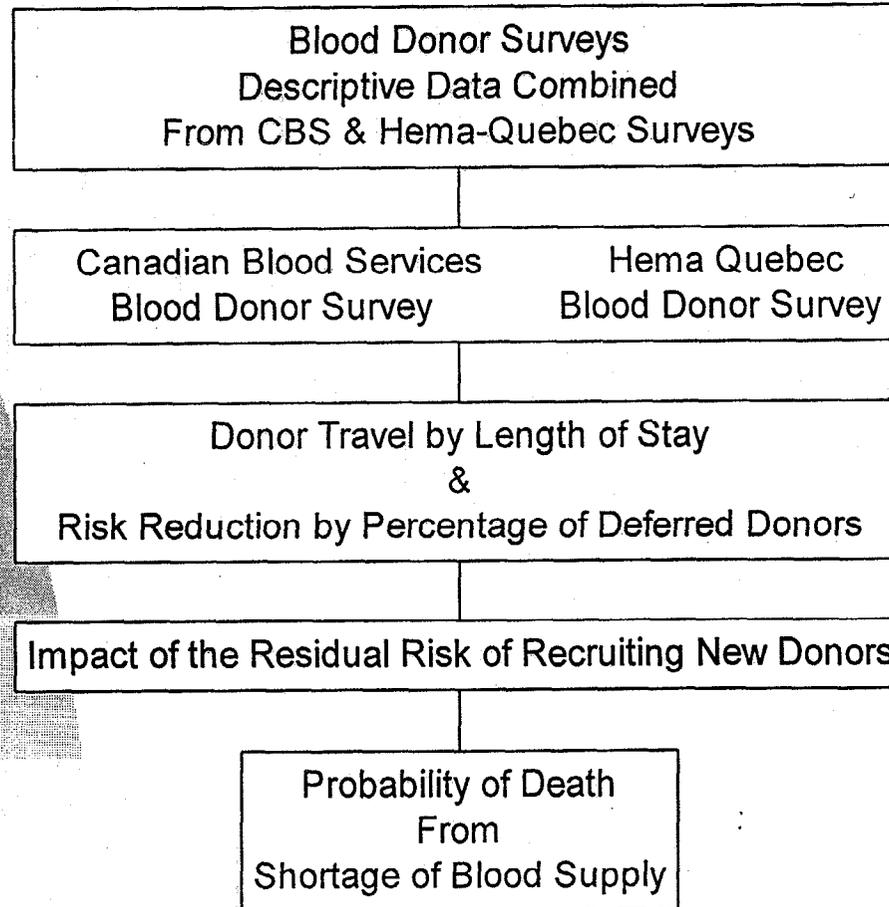


Risk Assessment Overview: BSE and vCJD

Risk to Canadians



Impact on the Blood Supply



Methodological Approach to Calculating vCJD Risk Among Canadians

Previous Analysis Method 1

Part 1 of the Analysis Estimates the Risk in France
Based on External Risk (Bovine Imports from the UK, French Risk is 10% of UK Risk).
Internal Risk is Calculated Based on:
The BSE infected cattle proportionate to the total size of the French herd, comparable to the BSE infected cattle in the UK, proportionate to the total size of the UK herd.

The rate of vCJD to the total population in France and the UK was used as a proxy of the exposure rate over time (1 month, 6 months, 1 year, 2 years), to estimate the number of Canadian travellers to France the UK who might potentially acquire vCJD.

Current Analysis Method 2

Part 1 of the Analysis Estimates the Risk in France
Based on External Risk (Bovine Imports from the UK, French Risk is 10% of UK Risk).
Internal Risk is Calculated Based on:
The BSE infected cattle proportionate to the total size of the French herd, comparable to the BSE infected cattle in the UK, proportionate to the total size of the UK herd.

The Estimated Number of infected, slaughtered BSE cattle, 766,000 (C.I. 745,000-799,000) and the infectious agent, 0.01 (C.I. 0-1000): based on the Wellcome Trust Epidemiology Group, over 16 years, used to estimate the probability of Canadians travelling to the UK and France potentially acquiring vCJD

BACKGROUND

- ▶ vCJD poses a theoretical risk of transmission through blood & blood products
- ▶ Precautionary measures were prescribed in relation to "U.K. risk" August 1999
- ▶ Defer donors
- ▶ Withdraw components and derivatives

BACKGROUND (2)

- ▶ Donors deferred on basis of:
 - residence in the U.K.
 - in period of 1980 - 1996
 - if cumulative residence was 6 months or longer



What's New

► Currently:

- 3 cases of vCJD acknowledged in France
- additional case(s) awaiting confirmation?
- it is considered necessary to re-evaluate the risk reduction strategy

Bases for Considering Risk

- ▶ Occurrence of BSE
- ▶ Consumption of U.K. beef
- ▶ Occurrence of vCJD

Options for Risk Mitigation

- ▶ 1. Maintain existing measures.
- ▶ 2. Defer/withdraw product on basis of 10 years residence in France, 1980-1996.
- ▶ 3. Defer/withdraw on basis of reduced residence in U.K. and corresponding period for France ("20" factor).
- ▶ 4. Aggressively reduce "French risk" [6 months; 75% reduction; $\leq 3\%$ donor loss].

Current Thinking

- ▶ Quantitative risk assessments may inform decision making, but in this situation:
 - based upon small numbers
 - require unverifiable assumptions
 - the epidemics in the UK and France are unpredictable

- ▶ Therefore, reduce to essence:
 - There is risk in the UK and there is risk in France

- ▶ Conclude:
 - apply same criterion to France as was applied to UK
 - 6 months residence (cumulative)
 - during period 1980-1996

International Harmonization (1)

- ▶ 1999: U.S. and Canada applied same deferrals
 - components for transfusion
 - plasma for manufacture

- ▶ 2000: Canada acting alone
 - Canadian institutions will comply
 - U.S. plasma derivative manufacturers not mandated by their regulator



International Harmonization (2)

- ▶ If Canada requires compliance U.S. manufacturers may withdraw from Canadian market.
 - reduced choice
 - shortages of products

- ▶ If Canada requests compliance, manufacturers may not comply
 - two classes of drug, compliant and non-compliant
 - 70% IGIV derives from U.S. manufacture
 - other biologics

- ▶ Good communications necessary.

CONCLUSIONS

1. vCJD Transmission through Blood Transfusions
Hypothetical but Animal Studies may show this Risk
2. True Risk is the Blood Supply Availability
3. Relative Risk and True Risk of the Blood Supply must
be balanced with Hypothetical Risk of vCJD Blood
Transfusion Transmission in Humans
4. Management of Hypothetical Risk points to Risk
Reduction



Blood Borne Pathogens Division

Centre for Infectious Disease Prevention and Control

Therapeutics Product Program
(regulatory body)



CABBI
Economic Burden of Hepatitis C (micro-simulation program)

Mathematical Modeling for predicting the incidence and prevalence of Hepatitis C

Student Programs
Co-op program, Internship courses in applied statistics and quantitative risk analysis with universities

Statistics and Risk Assessment UNIT

Partners
Universities, Hospitals, Provinces and territories and CIDPC, international institutions (academic and government)

TTI
Xenotransplantation surveillance

Apherisis surveillance

Blood Borne Pathogens Monitoring Surveillance System (Hep C,B,A, CJD, HTLV I & II)

PRIONS
Ongoing quantitative vCJD Risk Assessment

vCJD and vaccine risk

CJD death certificate review

Targeted Research
Autologous Blood Utilization and Optimization Study

Development of Mathematical Modeling of rare diseases

Blood Transfusion and Cancer Risk