IRGM GLOBAL
Risk Management Consultants Limited

Canadian Blood Services
Société canadienne du sang

Summary of Risk Assessment for Blood Supply System Exposure

Background Information:

Canadian Blood Services has established two wholly-owned captive insurance corporations, CBS Insurance Company Limited (CBSI) and Canadian Blood Services Captive Insurance Company Limited (CBSE). CBSI was incorporated under the laws of Bermuda on September 15, 1998, and is licensed as a Class 3 reinsurer under the Insurance Act, 1978 of Bermuda and related regulations. CBSE was incorporated under the laws of British Columbia on May 4, 2006, and is registered under the Insurance (Captive Company) Act of British Columbia. The primary purpose of the insurance corporations is to provide Blood Risks Liability Insurance to Canadian Blood Services, which insurance cannot on a reliable basis be purchased from traditional commercial insurance markets[1], as well as to support Canadian Blood Services in fulfilling its responsibilities to establish and maintain an appropriate risk management regime and to maintain a timely response capability to deal with the sudden appearance of safety problems and emerging threats at any point in the blood supply. At present, through the captive insurance corporations, Canadian Blood Services has $1 billion of total coverage with respect to risks associated with the operation of the blood system.

[1] Traditional commercial liability insurance also prohibits any admission of fault, responsibility or liability except at the sole cost of the policyholder which, in the context of a blood supply system, precludes the system operator from taking any voluntary actions to prevent or mitigate loss, injury or liability which Canadian Blood Services as a responsible operator would elect to do in order to preserve confidence in the safety and security of the Canadian blood system.

As a part of the surveillance of blood borne pathogens and emerging threats at any point in the blood supply, the practice has been established of, at approximately five (5) year intervals[2], updating risk assessment for system exposure as a basis for, among other uses, reviewing appropriate insurance funding levels. Canadian Blood Services, through CBSI, engages an arm's-length risk management consulting and catastrophe risk modeling expert, IRGM GLOBAL Risk Management Consultants Limited (IRGM GLOBAL), to conduct and update sophisticated and comprehensive exposure modeling in consultation with a Blue Ribbon Medical Panel (comprising foremost blood, blood disease, infectious disease, transfusion research, organ and tissue transplantation and health economics experts: See Appendix "B" for details and credentials of the 2015 Blue Ribbon Medical Panel) and a Blue Ribbon Legal Panel (comprising foremost products liability, class action and blood system legal experts and an economic expert in the valuation of personal injury claims: See Appendix "C" for details and credentials of the Blue Ribbon Legal Panel).[3] The findings of the most recent risk assessment update, and relating recommendations, were presented to, and approved by, the Board of Directors of Canadian Blood Services on June 25, 2015. In keeping with the principle of transparency, the presentation was a part of open meeting No. 06-2015-126 of the Board of Directors.

Highlight Summary of the Updated Exposure Modeling and Risk Assessment:

The exposure modeling process is illustrated in Appendix "A"

Panel 1: Medical Panel Highlights:

- Members of the Medical Panel are of the unanimous opinion that it is reasonable to make the following assumptions and observations for the purpose of modeling a potential future blood catastrophe
    - History has shown the potential for catastrophic, transfusion transmittable blood risk events to occur:
        - HIV[4] in Canada and the global population
        - HCV[5] in Canada and the global population

[2] An initial risk assessment of system exposure was conducted as a part of the development and start-up of the new blood system in 1997-1998. Updated risk assessment of system exposure was conducted in 2003, 2008 and 2015, with an Exposure Models Risk Review conducted in 2013.

[3] The Blue Ribbon Panels are convened by IRGM GLOBAL as a part of each risk assessment update. The Blue Ribbon Panel process allows members of the respective Panels to each reach unanimous consensus regarding observations and assumptions used for the Exposure Model Update

[4] Human immunodeficiency virus (HIV) infection which over time leads to acquired immunodeficiency syndrome (AIDS)

[5] An infectious disease caused by the hepatitis C virus (HCV)

- The assessment process takes into consideration known and emerging infectious agents and pathogens to classify the types of agents and to develop disease scenarios in respect of which unique characteristics were generated based on disease penetrance, course, treatment and associated costs
- Underlying data[6] used in the assessment process includes, but is not limited to, historic and forecasted data on blood collections, transfused recipients by age, gender and blood component and product types, primary and secondary infection rates, hospitalization stays, recovery by age and diverse health conditions, and daily hospital and chronic care costs.
- Other model considerations include: time interval between transfusion recipient infection and development date of medical symptoms; time interval between transfusion recipient infection and diagnosis date of medical symptoms; time interval between transfusion recipient infections and date infection causally linked to transfusion; time interval between date transmittable harmful agent first enters blood supply system and date transmittable harmful agent is identified in the blood supply system; and time interval between identification of transmittable harmful agent in the blood supply system and date Canadian Blood Services is in a position to implement testing or other interventions
- The modeling approach takes into consideration all of the inputs of the Medical Panel, along with the underlying data and assumptions, to model the potential range of Medical System costs (including and excluding hospital costs)[7] should either an Acute or Chronic agent event occur, meaning:
    - An "Acute agent", WNV[8]-like, resulting in a brief period of infectivity and transmission risk
    - "Chronic agents" are those resulting in a prolonged asymptomatic latency period and a high transmission risk but variable disease outcomes in recipients, of which two types were identified and assumed:

[6] Data is sourced on an international basis from sources known to be credible and scientifically and medically recognized for data integrity and which includes data not in the public domain. Confidential patient information is not disclosed or shared.

[7] The gross system costs are used to understand the overall demand placed upon the health care system as a whole by a major blood event, whereas isolation of hospital costs are used to understand potential burdens or overloads on the hospital system due to the major blood event. The potential liability of Canadian Blood Services excludes amounts covered by the various provincial and territorial healthcare plans given that the corporate members funding Canadian Blood Services are the self-same provincial and territorial ministers of health (except Quebec) funding provincial and territorial healthcare plans with the result that the corporate members and their agencies have waived subrogation in favor of Canadian Blood Services and its captive insurance subsidiaries meaning that the corporate members will not seek to recover healthcare covered amounts from Canadian Blood Services.

[8] A mosquito-borne infection by the West Nile virus (WNV). Of WNV infections in humans, approximately 80% have few or no symptoms. In the cases where symptoms do occur, termed West Nile fever in cases without neurological disease, the time from infection to the appearance of symptoms is typically between 2 and 15 days. Less than 1% of the cases are severe and result in neurological disease when the central nervous system is affected.

        - "Pre-existing chronic agent", with HCV as an historical example, causing a chronic carrier state with a prolonged asymptomatic latent period; and
        - "New chronic agent", being HIV-like, newly introduced into the blood supply at a time when it is rapidly increasing in prevalence
- Part of the mandate of the Medical Panel is to review the health risk management and surveillance standards, improvements and protocols employed by Canadian Blood Services as reassurance that, on a benchmarked[9] basis, Canadian Blood Services continues to be ranked as a best in class blood operator. On every occasion, as a result of the diligent continuous improvement practice standards employed by Canadian Blood Services, the Medical Panel unanimously opined that Canadian Blood Services adhered to and met "best practices" and "world class" standards.

Panel 2: Legal Panel Highlights:

- Like the Medical Panel, the Legal Panel assists IRGM GLOBAL with the preparation of its Exposure Model Update and operates on a unanimous consensus basis including with respect to the opinion that it is reasonable to make and use the assumptions and observations set forth by the Legal Panel for the purpose of modeling a future potential blood catastrophe in Canada giving due consideration to the medical assumptions and to prevailing laws, legal environment and regulations in Canada
- Members of the Medical and Legal Panels maintained frequent contact to ensure consistency of medical and legal assumptions for modeling purposes
- Based upon population and transfusion volume by provinces and territories, the Legal Panel has made its assumptions based on Ontario law
- A claimant will only be entitled to damages for losses actually caused by a defendant's (Canadian Blood Services) negligent conduct
- The Legal Panel assumed the same patient categories and disease characteristics ("injuries", in legal terms) as those developed and assumed by the Medical Panel
- The Legal Model assumed that claims exerted against Canadian Blood Services would proceed as class actions given that all Provincial laws in Canada allow class actions

[9] Benchmarking is generally a comparative review with other like peers or peer groups, in the case of Canadian Blood Services other blood supply systems in the developed world, and against best practice health risk management standards across the healthcare sectors, including standards imposed by regulations or regulators and those voluntarily developed or adopted by operators or institutions renowned for using "cutting-edge" practices or technologies.

- Class actions will be settled on behalf of all recipients of blood and blood products who have been exposed to the pathogen, and:
    - Settlement will likely occur through negotiation without a hearing on the merits
    - Experience shows that the "opt-out" exposure of individual claims and settlements is negligible
- The Legal Model assumes that settlement will compensate infected recipients or their immediate family members for the following categories of damages:
    - General damages for pain and suffering, including loss of enjoyment of life
    - Loss of income
    - Loss of opportunity to form an interdependent relationship
    - Future care costs
    - Management fees
    - Dependants' claims
- The Model assumes that damages will be assessed at the following time intervals:
    - Acute: 18 months after infection
    - Chronic: 3 years after infection
- The Model assumes that class action prompts awareness that pathogen has been transmitted even if no symptoms have manifested
- Consistent with the Medical Model, certain recipients are considered able to work unless actually hospitalized or receiving home care
- Other Legal Model settlement assumptions were based upon relevant data and statistics, such as: marital status and retirement ages for males and females were based upon Statistics Canada data; ages and numbers of dependents were based upon Canadian data; "general damages" and "pecuniary damages" and probable ranges for each category of "damages" were based upon past awards by Canadian courts; pre-tax earnings and discounts by age group were simulated based upon Statistics Canada earnings tables, adjusted for inflation; legal costs, legal disbursements and third party administration costs were based upon proxy settlements like the HCV January 1, 1998 – July 1, 1990 class action settlement, the Walkerton tainted water class action settlement and the residential schools class action settlement; life expectancy was based upon Statistics Canada data on life expectancy at birth, by sex, by province[10] cross-referenced to the life expectancy tables for the life insurance industry in Canada

[10] The data provides life indicators describing the mortality within a population during a given period of time: death probabilities, survival probabilities, survivors at specific ages and years of life lived.

Exposure Estimates:

- The modeling approach takes into consideration all of the inputs of the Medical and Legal Panels, along with the underlying data and assumptions, to model the potential range of Medical System costs and corresponding Legal Liability Costs, to estimate the aggregate claim costs should either an Acute or Chronic event occur
- At this update, there were further model enhancements due to increased computing capacity, additional data sources, and greater granularity on those data sources including refined age, hospital length of stay, and post transfusion survival data specific to Canada allowing for more representative distributions to reflect the spread of risk based on the underlying data and assumptions
- The forecasted "expected losses", being the value of a possible loss taking into consideration the probability of that loss occurring, were estimated at[11]:
    - Acute event: $149 million (2008: $170 million; 2003: Acute and Chronic were combined and not separately modeled; 1998: an Acute agent event was not an identified threat)
    - Chronic event:
        - Pre-existing chronic agent: $1.273 million (2008: $1.448 million; 2003: $1.936 million; 1998: $2.119 million)[12]
        - New chronic agent: $1.172 million (not identified as a sub-category agent threat in previous models)
- Based on a weighted model assessment, the combined aggregate forecast should an event occur is $1.175 million at the 90th percentile, meaning the point at which there is a 90% chance that in any given year losses will be below this amount and a 20% chance that losses could be higher than this amount

Observations:

- Chronic agents lead to significantly larger costs than the acute agent

[11] Actual losses can vary and vary significantly from estimated losses due to external factors and statistical variations, such as material adverse changes in medical and legal inflation and changes in law or regulations, beyond precise measurement notwithstanding the employment of generally accepted actuarial or analytical principles and practices.

[12] Reductions over consecutive models are the consequence of risk profile reductions (such as reduced blood product utilization), enhancements in testing and pathogen reduction technologies (which reduce the prevalence of infections) and advances in treatment therapies, such as HIV antiretroviral therapy and other treatments (that prolong survivability, improve quality of life, reduce the risk of transmission and reduce overall treatment costs notwithstanding therapy costs)

- For catastrophe planning purposes, use of a chronic agent scenario would be prudent and customary for any catastrophe assessment
- Unlike other manufactured products, the inherent risks of biological products have rendered findings of strict liability and implied warranty unlikely in Canada
- Duty of Care legal review concluded that, based on current Canadian Law, Canadian Blood Services is unlikely to have significant exposure to liability for failing to provide an adequate supply of blood and blood products, especially given that Canadian Blood Services has rigid procedures and protocols in place for operational inventory and safety stock management

Conclusions:

- The Medical Panel ascribes a low likelihood of the next catastrophic event in the current five year period
- Should an event occur, the highest likelihood (80% chance) is that the event would be an Acute event scenario which is not catastrophic, with a 10% chance an event will be a catastrophic pre-existing chronic event and a 10% chance an event will be catastrophic due to new chronic agent
- While the likelihood of a catastrophe event is viewed to be unlikely, history has shown that the potential for such an event does exist. The potential for an adverse loss event, should an event occur, is a reality. As a proxy, as at April 30, 2015, compensation of $967.9 million has been issued to 14,735 approved claimants under the 1986-1990 Hepatitis C Settlement Agreement for the benefit of people infected with Hepatitis C through the blood system in Canada between January 1,1986 and July 1,1990, and as amended with Court approval to also apply to those infected with hepatitis C from the blood system prior to January 1,1986, and from July 1,1990, to September 28, 1998 (the Pre-1986/Post-1990 Hepatitis C Settlement Agreement)
- The “best in class” standards adhered to by Canadian Blood Services will minimize the legal risk of successful claims in negligence

Recommendations:

Based upon the technical and exposure analysis conducted by IRGM GLOBAL and upon the model results, and all other known and reasonably considered risk factors and risk controls, IRGM GLOBAL concluded that the current aggregate limit of $1 billion constitutes a reasonable and prudent funding level for the disposition of potential liability on the part of Canadian Blood Services ensuing to a blood risk liability claim event. Accordingly, IRGM GLOBAL recommended that the current liability insurance level of $1 billion be maintained

Summary:

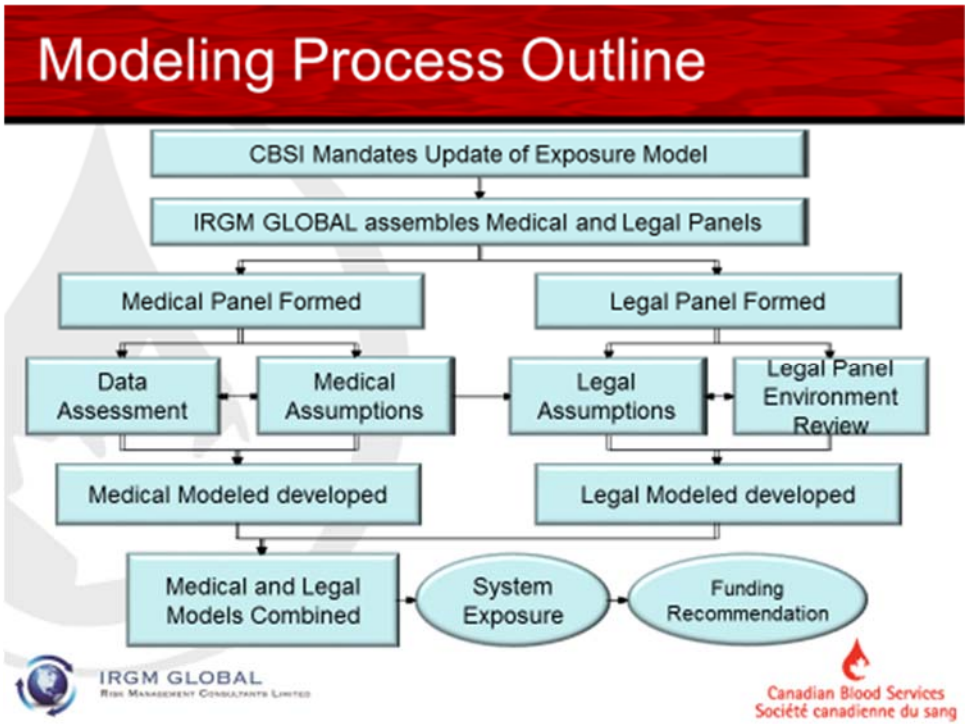
The practice of regularly updating risk assessment for system exposure derives multiple benefits for Canadian Blood Services and its corporate members, such as:

- The regular assembly of blue ribbon medical specialists to update and assess potential and emerging threats at any point in the blood supply and to review and benchmark the health risk management and surveillance standards employed by Canadian Blood Services
- The regular assembly of blue ribbon legal specialists to review and assess the implications of changes and emerging changes in regulations, laws and legal precedents
- Updating the trends and impacts of medical and legal inflation
- An independent assessment of current strategies to reduce the risk of transmissible, transfusion associated infections and the status of the most advanced pathogen reduction technologies
- An updated and independent analysis of potential liabilities associated with the ownership, management and operation of the blood system for relation to the status and standards of risk management, claims management, litigation management and liability management policies, practices and protocols to assure best practices and continuous improvements
- Quantifies the benefits of risk profile reductions[13] and affords a basis through analytics to substantiate the merits of funding support for new technologies such as pathogen reduction techniques to enhance blood safety within a health risk management framework which places on an equal footing the three critical elements of cost, benefit and risk[14]
- An independent assessment of the reasonableness and prudence of the liability insurance coverage provided to Canadian Blood Services

[13] The transfusion of blood and blood components has become an integral part of patient management in modern healthcare with the result that blood utilization rates are declining. Contributory factors include improved surgery techniques, product manufacturing enhancements and successful conservation strategies such as treatment plans aimed at minimising blood loss and utilization that have led to reduced blood demand in Canada (approximately a 7.6% demand decrease) and across the blood systems in the developed world.

[14] Annex B (Governance Model) of the Federal/Provincial/Territorial Memorandum of Understanding of 1997 that gave rise to the formation of Canadian Blood Services set forth these guiding principles with regard to decisions within the domain of management discretion including matters of health and safety with respect to the blood supply system.

Appendix “A”: Modeling Process Illustration



Appendix “B”: Blue Ribbon Medical Panel

Blue Ribbon Medical Panel

Panel Member	Credentials
Steven Kleinman, MD Committee Chair (also chaired prior three medical panels)	President, Kleinman Biomedical Research Clinical Professor of Pathology, University of British Columbia
Michael Busch, MD, PhD (also a member of the prior two medical panels)	Director, Blood Systems Research Institute Vice-President, Research and Scientific Affairs, Blood Systems, Inc. International expert in the fields of viral safety and transfusion medicine
Brian Custer, PhD, M.P.H. (also a member of the prior medical panel)	Associate Investigator, Blood Systems Research Institute. Specialist in Epidemiology and Health Outcomes Research
Louis Katz, MD (also a member of the prior medical panel)	Medical Director, CHC Regional Virology Center Executive Vice President, Medical Affairs, Mississippi Valley Regional Blood Center, Davenport, IA USA
Jutta Preiksaitis, MD (also a member of the prior two medical panels)	Professor, Division of Infectious Diseases, University of Alberta Infectious disease expert, specializing in the diagnosis of infections transmitted by organ transplantation and blood transfusion
Dr. Alan Tinmouth, MD, MSC (Clin Epi), FRCPC (new medical panel member)	Assistant Professor in Medicine (Hematology) at the University of Ottawa, Centre for Transfusion Research and Associate Staff at Ottawa Hospital
Boris Kralj, PhD (also a member of the prior two medical panels)	Executive Director, Economics & Chief Economist at Ontario Medical Association, and recognized Specialist in Health Economics
Dana Devine, PhD (Ex-Officio Member and CBS Liaison)	Vice President, Medical, Scientific & Research Affairs, Canadian Blood Services

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Appendix “C”: Blue Ribbon Legal Panel