1. Study Background

1.1 Origin of Canada’s Blood System

Canadian Blood Services (CBS) was established in 1998 but the history of Canada’s blood system dates back over 50 years. An understanding of the evolution of the blood system is helpful to understanding why CBS exists and the challenges it faces today.

Throughout the two World Wars, the Canadian Red Cross functioned as an auxiliary to the medical services of the Canadian Armed Forces; they collected blood from volunteers and shipped the whole blood to the University of Toronto’s Connaught Laboratories for processing. Over time and as the number of volunteer donations began increasing, the Red Cross took on some of the blood processing functions. By 1947, the Red Cross had established a national blood transfusion service that was providing whole blood free of charge to hospitals. With advances that were being made in Transfusion Medicine and transfusion technologies, these previously simple donor and transfusion services became increasingly complex and expensive to maintain. The Red Cross needed capital funding to continue operating their Centres.

In 1958, the Red Cross began to receive some financial support from the federal and provincial governments for their blood transfusion service, while the Red Cross retained responsibility for full funding of their blood donor programs. By 1973, the financial support from both levels of government for blood transfusion services reached 90 per cent; and in 1977, the provincial governments took over full financial support for transfusion services and 80% of blood donor recruitment services within their respective provinces.

The Red Cross budgets then became subject to review by government representatives. In 1976, the federal Minister of National Health set out three governing principles for the Red Cross blood supply system:

- voluntary donation,
- national self-sufficiency, and
- gratuity of blood products to recipients.

In 1979, the provincial Ministers of Health endorsed these principles and added a fourth:

- desirability of non-profit domestic fractionation.

By 1979, the Red Cross was operating 17 blood services Centres across the country.
What was not included with these principles were definitions of the respective roles of the Red Cross, as the operator of the system, and of the provinces and territories, as the funders of the system and the users of blood products.

During the 1980s, the federal, provincial and territorial funding for the Red Cross was administered by the Canadian Blood Committee (CBC). Because the CBC had no corporate existence of its own and was not independent of governments, it was unable to make decisions that would bind the governments it represented or grant approval for annual budgets. New safety measures required the approval of every province and territory. Further complicating the speed and appropriateness of decision making was the lack of clarity regarding where the respective authority of Red Cross and CBC began and ended and communication issues.

In 1991, the Canadian Blood Agency (CBA) was formed as a federal, not for profit corporation through which the provinces and territories would fund and direct the blood system. Throughout this time, the Red Cross was also undergoing major organizational change.

A May 13, 1993 report entitled “Tragedy and Challenge: Canada’s Blood System and HIV” said that the Canadian blood system “did not respond to the HIV/AIDS challenge as quickly as it might have” but was unable to determine the reasons for this delay. The Standing Committee on Health & Welfare, Social Affairs, Seniors, and the Status of Women recommended a comprehensive review into the Canadian blood system and on September 16, 1993, the federal, provincial and territorial governments (excluding Quebec) recommended a public inquiry be held. On October 4, 1993, Justice Krever was appointed to carry out this review.

In February 1995, the Krever Commission presented an Interim Report on the safety of the blood system which reported a need for the blood system to be restructured to eliminate conflicts among the participants and to define clearly the responsibilities for the safety of the blood supply. In September 1996, Canada's Health Ministers met and deliberated on the complex issue of blood system reform and agreed to put in place a new national authority to operate Canada's blood system based on four principles:

1. Safety of blood is paramount;
2. A fully-integrated approach is essential;
3. Accountabilities must be clear;
4. The renewed blood supply system must be transparent.

In addition, the seven ministerial principles defined by the provincial and territorial Ministers of Health in 1989 were added to complement the above principles:

1. Voluntary donations should be protected;
2. National self sufficiency in blood and plasma collections should be encouraged;
3. Adequacy and security of supply of all needed blood, components and plasma fractions for Canadians should be encouraged;
4. Safety of all blood, components and plasma fractions should be paramount;
5. Gratuity of all blood, components and plasma fractions to recipients within the insured health services of Canada should be maintained;
6. A cost effective and cost efficient blood supply program for Canadians should be encouraged; and
7. A national blood supply program should be maintained.

These principles were to guide the provincial and territorial governments throughout the period of planning and transition to the new system that would ensure the safety of the Canadian blood supply.

1.1.1 The Creation of the Current National Blood System

On September 10, 1996 the federal, provincial and territorial governments created a national blood authority that was to operate at arm’s length from all governments and would be responsible for managing all aspects of an accountable blood system. The province of Quebec had already chosen to opt out of a national blood system and establish its own blood system called Hema-Quebec. October 15, 1997 saw the appointment of Canadian Blood Services Transition Bureau whose mandate was managing the safe and effective transfer of the Canadian Red Cross Blood Program to the new national blood authority, Canadian Blood Services (CBS). CBS was incorporated in February 1998 and CBS’ Board of Directors assumed responsibility for the transition in April 1998. CBS assumed full responsibility for the operation of the blood system on September 28, 1998.

The scope of services (core functions, key functions and responsibilities) of this national blood authority were set out in the 1997 Federal / Provincial / Territorial Memorandum of Understanding (MOU):

Core Operational Functions:

- Donor recruitment and management
- Whole blood and plasma collection
- Testing and lab work
- Processing
- Storage and distribution
- Inventory management.

Key functions to support these core operational functions, were to include:

- Standard, policy and guideline setting supplementary to any regulatory standards of the federal, provincial or territorial governments
- Coordinating a national program in research and development for blood, blood products and transfusion medicine
• Surveillance and monitoring
• Professional and public education and information
• Health risk management.

In addition, CBS is under the regulatory purview of the *Food and Drugs Act*.

The MOU also includes a provision for a review of the national blood authority within five years of its creation to determine if it has “adequately fulfilled its functions and responsibilities and to consider such modifications to the present Memorandum as they may deem necessary to remedy any possible deficiencies.” This statement is the foundation for the review that is the subject of this report.

### 1.2 Project Overview

#### 1.2.1 Study Purpose and Objectives

Acting as the lead province on behalf of the provinces and territories (excluding Quebec), the British Columbia Ministry of Health Services issued a Request for Proposal (RFP) for a “full and comprehensive review of the current and projected activity of Canadian Blood Services (CBS) as it relates to the Memorandum of Understanding between CBS and the Provinces and Territories” (the Members). The purpose of the review was to provide the Members and the CBS with options and recommendations for action and direction in relation to the current budget submission process.

The RFP required the following matters to be reviewed:

1. **Financial review and review of the scope of operations:**
   a) Analyze the current status of CBS financial performance, with reference to the level of services provided.
   b) Review scope and definition of core operations including:
      i. Core services indicated in Annex A of the MOU including their importance to the provision of blood supply on a national basis.
      ii. Provision of key support functions as indicated in Annex A of the MOU, and
      iii. The relevance and costs of the current non-core functions and services.
   c) Identify opportunities for operational efficiencies that would result in cost savings.

2. **Performance review:**
   a) Undertake a comparative performance review
      i. Assess the comparative standings of CBS financial and operational performance, as compared to Héma-Québec and blood suppliers in other countries with a similar service level, using a set of financial and operational performance indicators.
ii. Review performance indicators
   01. Identify current performance indicators and review them for completeness and relevance.
   02. Recommend additional performance indicators.

b) Review risk management functions
   i. Identify and assess risk management mechanisms as they relate to the safety, affordability and adequacy of the blood system.
   ii. Provide recommendations for improvement based on the assessment of the mechanisms identified.

3. Based on the above analysis, examine the current content, format and process of the multi-year budget submissions and make recommendations for improvements that will ensure timely, adequate and appropriate information is provided to the Members and CBS.

4. Identify regulatory and manufacturing industry cost drivers and their impact on the blood system.

1.2.2 Study Approach and Methodology

In planning the approach and methodology for this study, the goal was to ensure that the review is successful, practical and provides meaningful information to support decision-making.

Accessing blood system expertise was considered critical to the review. Dr. Thomas Zuck was engaged to be part of the consulting team and provided ongoing advice and input throughout the project. In addition, the BC Ministry of Health assembled an international Expert Panel to provide advice on the project methodology, the international benchmarking survey, the study findings and the draft recommendations. The members of this panel were Dr. David Pi, Ann Hoppe and Dr. Richard Counts. Dr. Zuck also participated in all Expert Panel meetings.

It was important that the review be more than a report card on the past. To be most valuable, the review recommendations should prepare CBS and the provincial/territorial governments not only for the current environment but also for the future.

The project methodology was divided into four phases:
Given the number and diversity of stakeholders of CBS, it was important that a comprehensive data collection approach be established early on in the project. A project evaluation plan was developed to guide the review. The following diagram highlights the variety of data collection sources and tools used to conduct the review. A brief description of the major information collection strategies follows.
Financial Review

The objective of the financial review was to understand the financial components of CBS’s core operations, key support functions and non-core functions and services. This consisted of analyzing CBS’s external and internal financial statements, interviewing personnel in the finance departments as well as personnel outside of the finance departments who have direct or indirect influence on the budget.

Document analysis involved developing an understanding of the trends observed in the financial statements. Interviews were conducted with senior finance staff to further understand the implications and the justifications for the major changes in the financial statements. Document requests were made to further breakdown the different expenses by category, thereby allowing key cost drivers to be identified, and understanding the impact of those cost drivers.

An analysis was produced and the preliminary findings and recommendations were discussed with the Chief Financial Officer to help explain any inaccuracies or inconsistencies in the report to ensure that there were no misunderstandings in the financial analysis prior to the finalization of this report.

Key documents reviewed are listed in Appendix A.

IT Assessment

A very high-level assessment of information technology capabilities at CBS was conducted. This task was a late addition to the initial project scope and therefore did not commence until mid-July. The assessment was based on interviews with senior IT staff, a visit to the Ottawa Centre for user input and documentation review. A list of the documents reviewed for the IT Assessment is included in Appendix A. A list of the staff interviewed is included in Appendix B.

The preliminary observations and recommendations from the IT Assessment were discussed with the Chief Information Officer prior to finalization of this report.

Documentation Review

To support our review activities, we identified and requested information that would best help our team quickly understand the scope and functions of CBS. A list of the documents reviewed is provided in Appendix A.
Stakeholder Interviews

Interviews were used as one method for identifying information and gathering opinions, perceptions and attitudes. Our team conducted approximately 70 interviews with representatives of the following stakeholder groups:

Current and Past CBS Representatives:
- CBS Board members
- Current CBS executive and management staff
- CBS Regional Centre Directors and Managers
- Past CBS Chief Executive Officer
- First CBS Board Chair

Federal and Provincial Government Representatives:
- Provincial/Territorial Contacts
- Federal and Provincial Deputy Ministers or delegates

Hospitals:
- Vice-Presidents of Medicine and Laboratory Directors

Medical / Transfusion Specialists:
- National Technical Working Group on Utilization Management
- National Blood Safety Council

Consumer Groups:
- Canadian Haemophilia Association
- Canadian AIDS Society
- Hepatitis C Society
- Canadian Medical Association

An interview guide was prepared for each group of stakeholder interviews and provided to participants in advance. The overall objectives of the individual interviews was to obtain information that will allow an assessment of the performance of CBS and opportunities for improvement. A list of stakeholders interviewed is provided in Appendix B.

International Benchmarking Survey

As specified in the RFP, an international benchmarking survey was conducted to assess the comparative standings of CBS financial and operational performance, as compared to Hema-Quebec and blood suppliers in other countries with a similar service level, using a set of financial and operational performance indicators.
The international agencies were selected based on selection criteria agreed upon by the Ministry and the Consultants with input from CBS. The Consulting team’s recommendation on the countries to participate in the survey was reviewed by an international Expert Panel selected by the BC Ministry of Health.

The survey was designed to collect the following types of information:

- Profile information about the country’s health care system and the blood agency in order to understand similarities and differences to CBS that should be taken into account in the analysis
- Types of standards used
- Financial indicators (i.e. cost by activity level)
- Operational performance indicators

The Consultants developed the survey questionnaire with input from CBS and the Expert Panel. Detailed instructions and definitions for calculating financial and operational performance indicators were also prepared in conjunction with CBS and provided to the participating countries. A copy of the questionnaire is included in Appendix C. The questionnaire was distributed via e-mail to a designated contact person in each country selected. The Expert Panel assisted the consultants in identifying contact persons in the selected countries.

The criteria considered in selecting the international cohort were:

**Similarity to the Canadian Blood System**
- The blood system is voluntary
- The volume of blood collected is comparable to CBS volumes
- The size and nature of the geographic area covered by the blood service is similar to the area covered by CBS (e.g. land area, rural/urban, transportation issues)

**Similarity to the Canadian Health Care System**
- A significant public health insurance program is in place
- The size of the adult population is similar to the Canadian population

**Assurance of Quality Standard**
- The blood service is accredited by a recognized program

**Ease of Information Collection**
- The extent to which individuals involved in the review have contacts in the country that can facilitate information collection

The above criteria reflect the ideal. However, it quickly became apparent that there is no other blood system exactly like CBS and this would be an unrealistic expectation. There was also a recognition that valuable learnings can result from studying blood systems that have taken different approaches to organizing and operating their system.
Based on the selection criteria, the decision was made to send the survey to Hema-Quebec and the following five international blood agencies:

- American Red Cross
- Australia
- France
- Sweden
- United Kingdom (England and North Wales)

Survey responses were received from:

- Canadian Blood Service
- Hema-Quebec
- Sweden - Uppsala and Örør county
- United Kingdom (England and North Wales)
- The American Red Cross

CBS and Hema-Quebec completed the full survey whereas the other countries provided partial responses only. A follow-up telephone conversation was conducted with a Hema-Quebec representative to better understand some of the responses submitted. The survey results were also supplemented to a limited extent with publicly available information on other blood service agencies. (However, it is important to note that a literature review was not within the scope of this study.) A brief summary of the blood systems in the participating countries is provided in Appendix D.

**Hospital Survey**

A hospital self-administered survey was developed to achieve the following objectives:

- To give hospitals an opportunity to provide input into the review
- To understand hospital requirements for blood components
- To assess hospital satisfaction levels with the provision of blood components
- To identify opportunities for improvement

The survey addressed issues related to: demand planning, order and inventory management, performance measurement and customer service. A copy of the survey tool is provided in Appendix E and detailed results are provided in Appendix F. The survey was developed by the Consultants. A CBS Centre Laboratory Director with hospital blood bank experience and a member of the Expert Panel reviewed the draft survey before it was finalized.

The survey was distributed to hospitals between June 20 and June 24 by means of e-mail or fax. Using mailing lists supplied by CBS, surveys were sent to the identified hospitals’ laboratory/blood bank managers for completion. The deadline for return of the surveys was July 10.
A total population of 556 hospitals in all provinces and territories excluding Quebec, were identified as receiving red blood cell shipments from CBS in 2001/02. Small and remote hospitals that receive their blood components from larger hospitals with no direct shipments from the CBS were excluded from the sample.

Sampling quotas were established to ensure representation from each province and territory based on the number of hospitals directly serviced by CBS. For the smaller provinces and territories (Nova Scotia, New Brunswick, Newfoundland, P.E.I., Yukon, Northwest Territories, Nunavut), all hospitals receiving CBS products were surveyed. A sample of approximately 60% was drawn from the remaining larger provinces with special attention paid to including the hospitals that receive the largest volumes of blood shipments.

A total of 387 hospitals were sampled. This represents 70% of all hospitals that receive CBS shipments. Assuming an expected 40% response rate, this sample size would ensure 95% statistical validity with a 5 to 7% confidence interval.

221 completed surveys were returned - a response rate of 57%. The table below shows the number of surveys distributed and returned by province. Some hospitals did not answer every question on the survey. The findings presented in this report include the number of responses on which the results for each question are based.

### Exhibit 1-3: Hospital Survey Sample and Returns

<table>
<thead>
<tr>
<th>Province</th>
<th>Hospitals That Receive CBS Shipments</th>
<th>Hospitals Surveyed</th>
<th>Hospitals That Returned Surveys</th>
<th>Survey Response Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>British Columbia</td>
<td>88</td>
<td>66</td>
<td>43</td>
<td>65%</td>
</tr>
<tr>
<td>Alberta</td>
<td>67</td>
<td>43</td>
<td>33</td>
<td>77%</td>
</tr>
<tr>
<td>Saskatchewan</td>
<td>76</td>
<td>52</td>
<td>27</td>
<td>52%</td>
</tr>
<tr>
<td>Manitoba</td>
<td>72</td>
<td>40</td>
<td>27</td>
<td>68%</td>
</tr>
<tr>
<td>Ontario</td>
<td>166</td>
<td>106</td>
<td>46</td>
<td>43%</td>
</tr>
<tr>
<td>New Brunswick</td>
<td>22</td>
<td>22</td>
<td>15</td>
<td>68%</td>
</tr>
<tr>
<td>Newfoundland</td>
<td>28</td>
<td>20</td>
<td>8</td>
<td>40%</td>
</tr>
<tr>
<td>Nova Scotia</td>
<td>22</td>
<td>22</td>
<td>14</td>
<td>63%</td>
</tr>
<tr>
<td>PEI</td>
<td>8</td>
<td>7</td>
<td>2</td>
<td>29%</td>
</tr>
<tr>
<td>Yukon</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>100%</td>
</tr>
<tr>
<td>Northwest Territories</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>75%</td>
</tr>
<tr>
<td>Nunavut</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>50%</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>556</strong></td>
<td><strong>387</strong></td>
<td><strong>221</strong></td>
<td><strong>57%</strong></td>
</tr>
</tbody>
</table>

*Note: One survey received was anonymous, accordingly the numbers in the column headed “hospitals that returned surveys” do not add up to 221.*
Validation Process

Once all of the information collected had been analyzed, an important part of the methodology was validation of the findings and preliminary recommendations. Two validation sessions were held to confirm the accuracy and interpretation of the findings and to get feedback on the preliminary recommendations prior to submission of a first draft of the report.

The first validation session was held on July 23, 2002 with the senior leadership team at CBS. Participants in the all-day (9 a.m. to 3 p.m.) validation session were:

- Gary Chatfield, Board Chair
- Graham Sher, Chief Executive Officer
- Ian Mumford, Executive Vice-President Operations
- Wesley Rees, Executive Vice-President Safety and Performance Management
- Dana Devine, Executive Vice-President P. Medical, Scientific and Clinical Management
- Watson Gale, Vice-President and Corporate Legal Counsel
- Darren Praznik, Executive Director Government Relations
- Pauline Port, Vice-President Corporate Services and Chief Financial Officer
- John Johnston, Vice-President Human Resources and Organizational Development
- Jeff Moran, Chief Information Officer
- Craig Ivany, Executive Director, Centre Operations
- Sophie deVillers, Executive Director, Policy and Planning
- IBM Business Consulting Services Team Members: Rik Ganderton, Michele Jordan, Gail Peterson, Kelly Shum and Dr. Thomas Zuck

A second full-day validation session was held on July 26th with members of the International Expert Panel. Participants in this session included:

- Dr. Richard Counts, President, Puget Sound Blood Centre, Seattle, Washington
- Ann Hoppe, Regulatory Consultant, Decatur, Georgia
- Dr. David Pi, Director of the Provincial Blood Co-ordinating Office, B.C. Ministry of Health Services
- Wendy Trotter, Manager, Blood Services, B.C. Ministry of Health Services
- IBM Business Consulting Services Team Members: Rik Ganderton, Michele Jordan, Gail Peterson, Michael Matthews and Dr. Thomas Zuck

Two draft reports were submitted for review by various provincial/territorial representatives and CBS. The feedback received has been incorporated into the final report.
1.2.3 Study Limitations

A number of factors had an impact on the methodology and/or outcomes of the study. It is important to describe these factors upfront so that they can be taken into account when interpreting the study results.

Study Scope and Objectives. The study was a performance review aimed at assessing the financial and operational performance of CBS. It is also important to clarify what the study was not.

- The study was not an accreditation or inspection of CBS from a safety, regulatory, clinical or technical point of view.
- The study was not a financial audit.
- The study was not a detailed examination of each service delivery and administrative function.

Study Timeframe. The timelines for the study were established at the outset by the BC Ministry of Health. The study commenced at the end of April and had a firm date of August 1 for submission of the draft final report. This allowed three months for project start-up, data collection, analysis, recommendation development and report writing. The tight study timelines placed limitations on the type and number of data collection activities that could be conducted. It was extremely important to clarify the project scope in terms of what could be done within the timelines (see above) and what the focus would be. It also necessitated a sufficiently large team to get the job done within the required timeframe.

Another important aspect of the study timeframe was that it included the summer months. This posed a challenge for scheduling interviews with stakeholders and conducting surveys.

The project timelines had a significant impact on the international benchmark survey. A number of countries noted that they would have preferred more time to answer the questions (e.g. three months was suggested by one country) and that vacation schedules (particularly in European countries) limited the availability of staff to gather the data.

Financial Data. At the time of the data collection phase of the review, the final audited financial statements were not available. Therefore, some of the statistics contained in the report for fiscal year 2001/02 were from unaudited sources. Also, for many areas, it was only possible to examine changes over the last two fiscal years. This is due to a number of organizational changes and modifications to the accounting methodology at CBS.

Risk Management Assessment. The terms of reference for the project called for the Consultants to:
“Review risk management functions
• Identify and assess risk management mechanisms as they relate to the safety, affordability and adequacy of the blood system.
• Provide recommendations for improvement based on the assessment of the mechanisms identified.”

It is important to stress that the project scope did not include an assessment of the risks faced by CBS or the adequacy of the risk management function. The review of risk management functions focused on the structure and process of risk management mechanisms. There was no attempt to identify and assess actual risks or to comment on the outcome of specific risk issues.

Impact of Transformation. While the performance review was being conducted the CBS was in the midst of a major Transformation project which includes several initiatives touching almost all aspects of the organization. For the most part, the initiatives are in the early phases of implementation and are not yet in place. This posed a challenge for the review team because the organization under review was clearly in a state of evolution. Also, a number of the areas identified for improvement were reportedly to be addressed in the future by the Transformation project, potentially rendering some of the review recommendations redundant. Without the ability to assess the success of the Transformation initiatives, the review was limited to assessing the extent of due diligence to support the transformation projects (e.g. existence of business cases, cost analysis, prioritization criteria, project plans, etc.).