2. Organization and Service Review

2.1 Historical Context and Highlights

CBS is a not-for-profit, charitable organization whose mission is to manage the blood supply in all provinces and territories (excluding Quebec). It was incorporated in February 1998 and took on the responsibility for Canada’s blood system on September 28, 1998.

CBS has had to stabilize and operate the system, and is only now catching up to developments in international blood systems management.

CBS inherited an organization consisting of three levels of management: central, regional and local.

At the Central or Head Office level, corporate functions and services are offered such as developing national standards and support services. Functions such as payroll, human resources and accounts payable occurred at the regional level. Once the transition from the Red Cross to CBS took place, these regional services were targeted for transfer to the Head Office.

The local level is currently comprised of 14 Blood Centres and two Plasma Centres. The Blood Centres are located in Vancouver, Calgary, Edmonton, Regina, Saskatoon, Winnipeg, Toronto, London, Hamilton, Sudbury, Ottawa, Halifax, Saint John, Charlottetown, and St. John’s. The Plasma Centres are located in Thunder Bay and Charlottetown.

Each of these Centres performs many similar tasks: donor recruitment, blood collection, testing, production, storage and distribution of blood. In addition to these core services, some Centres offer specialized services such as stem cell extraction, prenatal testing, and transmissible disease testing.

At present, the organization has approximately 4,700 staff and 17,000 volunteers. Operating expenditures for the organization have risen steadily over the years and are now over $750 million. Donors and collections have also increased. There are over 465,000 active donors in CBS’ database. In 2001/02, over 803,000 units of whole blood were collected. CBS supplies blood to approximately 550 hospitals across the country.

The initial challenge facing this organization was to ensure a safe and secure blood supply and to restore public confidence. Fundamental to how CBS was to achieve this was how the new organization would be managed. Key aspects of the organizational structure include:
• An independent Board of Directors, appointed by the Members, and who represent stakeholder interests.

• Independent expert advisory committees whose role is to provide early and informed reviews to the CEO:
  o Research & Development Advisory Committee
  o Scientific Advisory Committee
  o Consumer Advisory Committee (later changed to the National Liaison Committee)

• Transparency with respect to CBS operations, including:
  o Two public Board meetings per year
  o Regulatory audit results posted to CBS’ web site
  o General information available on the web site
  o Stakeholder consultation and input for decision making

• A contingency fund that allows CBS to respond to unforeseen events in a timely and flexible manner

2.2 Achievements

CBS has come a long way in a short time. The organization that CBS inherited had a number of shortcomings. Several of these shortcomings are described in the Krever report:

The Red Cross, as the operator of the blood supply system during the 1980s, did not promptly introduce appropriate risk-reduction measures to enhance the safety of the blood supply. The internal structure of the Red Cross was not conducive to sound and timely decision making. The Red Cross adhered to principles that were not related to the blood supply system, and its board of governors supervised many programs that were not related to the blood program. The Red Cross’s blood transfusion service and its blood donor recruitment each had partial management of the blood program. The national office of the transfusion service did not create and enforce comprehensive national risk-reduction measures, nor did it allow local centres to exceed the national safety standards that did exist. There were no formal links to the provincial public health authorities.2

The many significant challenges facing the new CBS leadership included overcoming internal organizational deficiencies, improving the safety of the nation’s blood system,

enhancing employee and volunteer morale and restoring public confidence in the blood system.

This context is critical to setting realistic expectations for the performance of CBS less than four years after its inception. Some of the many accomplishments CBS has achieved in its four-year history include the following:

- Transforming a fragmented, decentralized blood supply program into a functional, national, blood system
- Restoring public confidence in the blood system following the tainted blood crisis
- Achieving high donor satisfaction
- Enhancing the regulatory environment and framework
- Meeting regulatory requirements
- Increasing collections significantly
- Introducing new safety measures (e.g. universal leukoreduction, NAT testing)
- Implementing or upgrading information management systems (e.g. SAP, BLIS 2000, ESS)
- Centralizing the accounting function in Ottawa. This includes the accounts payable, purchasing, accounts receivable, general accounting and reporting.
- Introducing an organization-wide performance measurement framework (“Strategy Map”)

The national crisis that precipitated the establishment of CBS was a public crisis. Therefore, the public’s views on the current blood system are of special interest. CBS routinely commissions public surveys. The most recent survey found that 81% of respondents agree that “the blood system in Canada is safer today than it was five years ago.”  

During the course of this review, many different stakeholders were consulted. When these stakeholders were asked to describe the strengths of the CBS there were several different responses but also some common themes.

Key strengths cited by the various stakeholder groups include:

- Dedicated staff on the frontline
- A strong senior management team (“They are enthusiastic, positive and are a good configuration of people and skills.”)
- A committed board of directors
- Safety measures that have been implemented (“They’ve got their eye on the ball on safety – they’ve done an exceptional job of implementing safety precautions”)
- A national system is now in place
- An approach that is proactive rather than reactive
- Public image and donor recruitment

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3 Winter 2002 General Public Research Program, Final Report, by Ipsos-Reid Corporation, April 2002
• Good local collaboration
• Sound understanding of the main issues in the blood system, from both an academic and an operational perspective
• Monitoring, reporting and follow-up on directives
• System is more open and interactive

CBS is to be commended for its many significant achievements particularly providing Canadians with a safer blood system. There is no longer a crisis.

But, like any other organization, there are always things that could be improved. The balance of this report describes findings and observations and offers suggestions for improvement moving forward.

2.3 Governance

2.3.1 The Governance Structure

CBS has a two-tiered governance structure consisting of 1) the Corporate Members and 2) the CBS Board of Directors. This is illustrated in the diagram below. The Members are the Ministers of Health in the provinces and territories. The Members appoint the CBS Board of Directors to oversee the organization. Each Member has identified a contact person from their Ministry to serve as the day-to-day liaison with CBS. These individuals are collectively referred to as the P/T Contacts.

Exhibit 2-1: CBS Governance and P/T Liaison Structure
The Federal/Provincial/Territorial Memorandum of Understanding

The mandate, roles and responsibilities for the Members and the Board are set out in a Memorandum of Understanding (MOU). The purpose of the Memorandum of Understanding “is to record the understandings and commitments of the Minister of Health (Canada) and the Provincial and Territorial Ministers of Health regarding their respective roles and responsibilities in a renewed national blood system, including their future relationships with the National Blood Authority [i.e. CBS] and its function and structure”.

The MOU came into force in 1997 almost one year before CBS was established. When the document was written, the term “National Blood Authority” or “NBA” was used to describe the yet to be formed new blood agency.

The MOU is a critical document because it sets out the roles and responsibilities of the various levels of government and describes the mandate of the CBS. There are a number of annexes to the MOU:

- Annex A sets out the functions and responsibilities of the CBS
- Annex B describes the governance model
- Annex C addresses transition issues

Recognizing the importance of the MOU as a guiding document, it is used as the frame of reference for this review. That is, CBS’ performance is assessed against the roles, functions and responsibilities described in the MOU.

The definition of the overall roles and responsibilities of the federal/provincial/territorial governments, as set out in the MOU, was to include:

- Funding
- Setting broad health policy objectives
- Serving as members of the national blood authority
- Ensuring the overall integrity of the blood system
- Exercising their on-going powers and responsibilities as Ministers under existing health legislation.

The roles and responsibilities of the federal government, as set out in the MOU, include:

- Responsibility for the administration of the Food and Drugs Act with respect to the national blood system
- Responsibility to ensure that Canada maintains an effective national blood system surveillance program
- Responsibility for regulating certain components of the national blood system
• Preparation of an annual report on regulatory policies and decisions in relation to blood
• Meet twice annually with the Members to discuss issues of mutual concern
• Provision of transition funding
• Provision of annual funding for research and development.

Overlaying these roles, responsibilities and functions, the MOU stated that the common policy objective for the new national blood authority would be based on the following principles:

• The safety of the blood supply is paramount
• A fully integrated approach is essential
• Accountabilities must be clear
• The renewed blood system must be transparent
• Voluntary donations should be maintained and protected
• National self-sufficiency in blood and plasma collections should be encouraged
• Adequacy and security of supply of all needed blood, components and plasma fractions for Canadians should be encouraged
• Gratuity of all blood, components and plasma fractions to recipients within the insured health services of Canada should be maintained
• A cost-effective and cost-efficient blood supply program for Canadians should be encouraged.
• A national blood supply program should be maintained.

While the MOU provides some direction in terms of mandates, there are several sections of the MOU which are ambiguous and open to multiple interpretations. The most notable example of this relates to safety and affordability.

• Section 3.0 of the MOU states: “the safety of the blood supply is paramount”.
• Annex B states: “The domain of management discretion will include matters of health and safety with respect to the blood supply system. Decisions in this regard will be made within a health risk management framework which places on an equal footing the three critical elements of cost, benefit and risk.”

Other examples of ambiguities in the MOU that warrant clarification include:

• The MOU states “national self-sufficiency in blood and plasma collections should be encouraged”. It is not clear what “encouraged” means and whether or not achievement of this principle is mandatory.
• Annex A lists a key function of CBS as “standard, policy and guideline setting supplementary to any regulatory standards of the federal, provincial or territorial governments”. This is reinforced in Annex B with the statement: “the Board is responsible for development and implementation of NBA standards supplementary to any regulatory standards of the federal, provincial and territorial governments”.

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As discussed later in this report, CBS is of the view that supplementary standards are not necessary in the current regulatory environment. This view was not shared by the review’s expert panel.

- Annex B states “NBA will own and operate the blood supply system”. Annex B also states “NBA is the vehicle by which the provincial and territorial governments can deliver a national blood supply program…”
- Annex B states “NBA must be able to exercise complete management discretion over all operational blood system decisions” and “the mandate of the NBA is to be responsible for a national blood supply system…” Annex B also states “Canada’s provincial and territorial Health Ministers will be responsible and accountable for the national blood supply program”.
- Annex B mentions a “contingency fund for emergencies” but does not define an emergency.

These ambiguities contribute to a lack of role clarification amongst CBS and the Corporate Members.

**Recommendation #1:** The MOU is a critical guiding document for the national blood supply system. Unfortunately, the document includes a number of ambiguities that have contributed to lack of clarity in terms of roles and expectations. It is recommended that the Provincial/Territorial Ministers of Health and Health Canada initiate a process to clarify the ambiguities in the MOU and ensure that the current and future realities are reflected. A desired outcome would be a set of uniform priorities regarding safety, benefits and costs. If the relative weights of these factors are to vary depending on circumstances, these should be clearly spelled out. Ideally, the MOU review process should follow the proposed development of a vision (see below) so that the MOU is reflective of future directions. There are a number of optional approaches that could be taken: 1) the Members could initiate a review of the MOU and open a dialogue to change the wording of the ambiguous sections, 2) the Members could execute an addendum to clarify the ambiguous issues, or 3) some other form of common agreement between the parties could be reached to address specific issues that are currently unclear (e.g. the policy framework might accomplish this). Reviewing and amending an inter-provincial MOU is a significant undertaking and the Members should seek legal advice on the most appropriate approach.

**The Corporate Members**

The Corporate Members are the Ministers of Health from each province/territory. As stated earlier, the Provincial and Territorial Health Ministers (excluding Quebec) are accountable for the national blood supply system. Their specific responsibilities were listed above.
The provincial/territorial Ministers are ultimately accountable for the national blood supply. The MOU describes the national blood authority as “the vehicle by which provincial and territorial governments can deliver a national blood supply program effectively and efficiently…”

The MOU recognizes that the Corporate Members wear two hats – they have responsibilities as Provincial and Territorial Health Ministers as Ministers and they have responsibilities as Members of the CBS. These dual responsibilities are described in the MOU as follows:

**Exhibit 2-2: Dual Roles of Provincial/Territorial Health Ministers**

<table>
<thead>
<tr>
<th>As Provincial and Territorial Health Ministers</th>
<th>As Members of the CBS</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Ministers are responsible for:</td>
<td>• Members establish and will remain responsible for the mission and mandate of the NBA</td>
</tr>
<tr>
<td>• the effectiveness of the blood supply</td>
<td>• Members will have the authority to approve the three year corporate business plan</td>
</tr>
<tr>
<td>system as an integral component of the P/T health care delivery systems</td>
<td>• Members will be responsible for selecting the Board of Directors</td>
</tr>
<tr>
<td>• funding requirements of the NBA as approved by its Members</td>
<td>• Members have the authority to require direct external comprehensive management audits and targeted special audits of the NBA at their discretion</td>
</tr>
<tr>
<td>• recommending to the Minister of Health (Canada) any proposed changes to the NBA legislation”</td>
<td>• Should objectives for the blood program not be met satisfactorily, Members will hold the Board accountable to take corrective action</td>
</tr>
</tbody>
</table>

The duality of the Member/Minister roles challenges the Members/Ministers to fairly and effectively balance the needs of their particular province with the needs of the national blood system. An example of where this situation might pose a serious challenge is when CBS wishes to shift the provision of a particular function from one province to another province in order to consolidate/centralize the function and achieve efficiencies. While the efficiencies gained benefit CBS and ultimately the entire
country, the consolidation process may result in loss of employment in the affected province.

The Provinces and Territories, through their Deputy Ministers, rotate the responsibility of the lead for the blood system every two years. Being the lead involves acting as a secretariat for all meetings and issues involving the blood system, and acting as the main liaison between the Provinces and Territories, and CBS.

**CBS Board of Directors**

The directors of CBS’ board are appointed by the Corporate Members. There are 13 directors, including the Chair.

*Composition.* Four directors are considered “regional directors”. Regional directors are elected on the basis of nominations from Members representing the regions of (1) British Columbia and Yukon, (2) Alberta, Saskatchewan, Manitoba, the Northwest Territories and Nunavut, (3) Ontario, and (4) New Brunswick, Prince Edward Island, Nova Scotia and Newfoundland.

Two Directors are elected from the general public on the basis of their relevant knowledge or experience with organizations representing persons consuming blood and blood products (i.e. consumers).

The remaining six Directors are elected on the basis of their knowledge or expertise with business, scientific, medical, technical or public health matters. Employees of the federal, provincial or territorial governments are not eligible for appointment.

The current Board members reflect a wide variety of important skill sets. However, interviews with Board members indicate that some Board members have identified a need for expertise in the following areas: corporate law, transfusion medicine and information technology.

**Recommendation #2:** Currently board members are selected based on geography as well as their expertise in business, scientific, medical, technical or public health matters. When filling future vacancies it is recommended that Members consider recruiting individuals with experience in corporate law, information technology and transfusion medicine.

One of the challenges facing the Board is their lack of clarity around the role of the regional directors. The MOU does not specify a particular role for the regional directors that is different from that of the other directors. However, one P/T Contact described the role of regional directors as “providing a voice on the Board that brings forward information about the interests, concerns and sensitivities of the Members of that region.” Some regional directors have agreed to provide their regional Ministers with...
regular updates on the progress of CBS. At present this type of communication is carried out outside of the context of a broader communications strategy.

The question has also been raised about the need for the regional director positions. To provide a context for discussing this issue, a brief examination of the board composition of selected other national, health-related organizations was carried out. The table below illustrates the extent to which selected organizations have regional directors. A brief description of the mandate and budget of each organization is also provided.

**Exhibit 2-3: Regional Directors – A Comparison of National Organizations**

<table>
<thead>
<tr>
<th>Organization</th>
<th>Regional Directors (yes/no)</th>
<th>% Regional Directors on the Board</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Canadian Blood Service (CBS)</strong></td>
<td>Yes</td>
<td>31%</td>
</tr>
<tr>
<td>Approximate budget - $750M</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Canadian Institute for Health Information (CIHI)</strong></td>
<td>Yes</td>
<td>75%</td>
</tr>
<tr>
<td>An independent, non-profit organization that coordinates the development and maintenance of a comprehensive and integrated approach to health information for Canada and provides/coordinates the provision of accurate and timely data and information. Approximate budget - $37M⁴</td>
<td>Yes</td>
<td>75%</td>
</tr>
<tr>
<td><strong>Canada Health Infoway</strong></td>
<td>Yes</td>
<td>45%</td>
</tr>
<tr>
<td>An independent, non-profit corporation formed to foster and accelerate the development and adoption of electronic health information systems with compatible standards and technologies on a pan-Canadian basis. Approximate budget - $500M⁵</td>
<td>Yes</td>
<td>45%</td>
</tr>
<tr>
<td><strong>Canadian Centre of Health Technology Assessment (CCOHTA)</strong></td>
<td>Board consists of one representative from each province/territory and one federal representative</td>
<td></td>
</tr>
<tr>
<td>A non-profit organization that reviews research that has been done on medical technologies. Approximate budget - $3M⁶</td>
<td>Yes</td>
<td>53%</td>
</tr>
</tbody>
</table>

The table above suggests that it is not unusual for national health-related organizations to have Board members that are appointed to represent a particular geographic region or a specific province. Clearly, national organizations find value in having Board members from various geographic regions. The issue for CBS is defining an appropriate role for regional directors and setting guidelines for Board member

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⁴ Canadian Institute for Health Information website (cihi.ca.)
⁵ Canada Health Infoway website (canadahealthinfoway.ca)
⁶ Canadian Centre of Health Technology Assessment website (ccohta.ca)
activities. CBS has struggled with this issue for a long time. For example, in 1999, the CBS Board required regional directors to submit written summaries of their interactions with their provincial ministers.\(^7\)

**Compensation.** Board members are compensated for their time. Reimbursement rates have been established for meeting time, preparatory time and travel time.

**Roles and Responsibilities.** The MOU describes the following responsibilities for the Board of Directors:

- Overall direction of the affairs, operational activities and budget of the NBA, including the appointment and dismissal of the Chief Executive Officer
- Translating the approved business plan into blood supply system operations
- Within the framework established by the Members, exercising broad discretion in establishing corporate and operational policies of the NBA, including setting and enforcing NBA standards
- Achieving the three-year corporate business plan
- Reporting on performance to Ministers as Members
- Developing and implementing NBA standards supplementary to any regulatory standards of the federal, provincial or territorial governments
- Developing corporate and operational policies
- Appointing committees as deemed necessary to help them in carrying out their duties
- The Finance Committee will be responsible for preparing NBA budgets for the approval of the Board

The Board of Directors of CBS was established before any staff were hired and before the organization was officially launched. At that time, there was a great deal of work to be done and even with the assistance provided by the “transition bureau”, Board members were required to play an intensive, hands-on role. The Board remained in this very operational mode for most of the organization’s short history with a focus on putting the required structures, systems and processes in place. In the past year, it appears that the Board’s role has evolved in keeping with the maturing of the organization. There is now a concerted effort to shift the board to a more strategic mode of operation.

**Committees.** The board has established the following standing committees:

- Executive Committee
- Finance and Audit Committee
- Human Resources Committee
- Safety, Science and Ethics Committee

\(^7\) CBS Board Minutes of May 19, 1999.
There is also a National Liaison Committee. The National Liaison Committee was initiated as a pilot. The committee is made up of members of the public, stakeholders and the medical community at the national level. The purpose is to provide input on blood system issues, ensure special interests are brought to the attention of CBS, and to build effective relationships with stakeholders. The summary notes from these meetings are posted on the CBS Web site. The Chair and Co-Chair of the National Liaison Committee are the two consumer representatives on the Board of Directors. Over a dozen consumer associations are represented on the National Liaison Committee.

**Attendance.** CBS posts the attendance record for each individual board member on its public website. The Board of Directors held 37 meetings (full Board and various Committees) during the period April 1, 2000 to February 19, 2001. The results for this period suggest a board that is dedicated and involved.

There were ten Board meetings held during the period. Board meetings typically last two to three days. Fifty-eight percent of Board members attended all ten of the Board Meetings and another 25% attended 9 out of 10 meetings. Only two board members missed two or more Board meetings.

The attendance rates for Board Committee meetings are also quite high. Seventy-five percent of Board members attended 20 or more Committee meetings. The other Board members attended between 8 and 19 Committee meetings. Forty-two percent of Board members had a perfect attendance record for all Board and Committee meetings. These are very impressive attendance records.

**Board Evaluation.** CBS’ Board has been carrying out informal evaluations since as early as 1998. The decision to carry out a formal Board evaluation process was made at the October 17, 2000 meeting of the Executive Committee of CBS Board of Directors. It was agreed that an existing Board evaluation tool would be used for the first evaluation. A questionnaire was administered and the results were tabulated and discussed at the Executive Committee meeting on December 13, 2000. The results were generally positive. The Board Evaluation results were also reported to the full Board and results relating to specific committees were sent to the respective Committees for discussion. At the meeting of CBS Board of Directors held on September 20, 2001 a motion was passed “that the Board of CBS establish and implement a formalized Board Evaluation process in order to assess effectively the ongoing performance of the Board and its ability to achieve excellence in governance”. At the time of this review, this “formalized” process had not yet been completed. However, in preparation for the last strategic retreat of the Board, one of the Board members developed a detailed questionnaire to gather information on the Board’s views of the strengths and weaknesses of the organization. The questionnaire achieved a high response rate and the results were presented and discussed at the Board Retreat.

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8 CBS Board Minutes, July 8, 1998.
Recommendation #3: It is recommended that CBS complete the proposed development and implementation of a “formalized” Board evaluation process.

CBS Corporate Statements

CBS has a number of corporate statements that provide parameters for its operation.

The Letters Patent was signed in February 1998 as part of the organization’s application for incorporation of a corporation without share capital under the Canada Corporations Act. There are also seven by-laws. CBS has articulated mission, vision and values statements as follows:

Exhibit 2-4: CBS Mission, Vision and Values

<table>
<thead>
<tr>
<th>Mission Statement</th>
</tr>
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<tbody>
<tr>
<td>Canadian Blood Services operates Canada's blood supply in a manner that gains the trust, commitment and confidence of all Canadians by providing a safe, secure, cost-effective, affordable and accessible supply of quality blood, blood products and their alternatives.</td>
</tr>
</tbody>
</table>
Vision Statement

Canadians have **confidence** in us.

Canadian Blood Services provides a safe, secure, cost-effective, affordable and accessible supply of **quality** blood, blood products and their alternatives. Canada is self-sufficient in blood and we are working to be self-reliant in plasma. Emerging risks and best practices are monitored continuously. Our blood and blood products are safe and of quality.

CBS has established and works to maintain **effective** relationships with all of our stakeholders.

Our arm's length relationship with Provincial/Territorial and Federal governments enables us to operate within our business plan and with **reliable** funding. We are known for our financial stewardship of public funds.

We work with consumer groups to address strategic issues and meet their needs. We monitor our environment and other key indicators that enable us to **anticipate** changes and prepare for them.

CBS continues to help hospitals **improve** blood utilization and surveillance. We have found that educating consumers, donors, physicians and other health professionals is key to managing utilization of blood and blood products.

Donors actively support us and our donor base is **strong**. Our volunteers continue to play a **critical** and meaningful role.

Through our work and support, the science of transfusion medicine is **advanced**. Our research program is leading to the development of alternative products in transfusion practices.

We are internationally recognized for our **excellence** and innovative programs and services.

Our employees view CBS as a great place to work. We have an environment that **rewards** creativity, teamwork and vision, and provides opportunities for personal and professional advancement.

We are **proud** of the contribution we make.
Value Statements

We are committed to delivering safe, quality blood, blood products and their alternatives to Canadians through a national not-for-profit organization that:

- accepts responsibility for ensuring the safety and quality of Canada's blood supply system;
- considers blood a national resource;
- values and celebrates the contributions of blood donors and volunteers;
- values employees within an environment that provides opportunities for personal and professional advancement;
- encourages and welcomes early and informed input into its activities and operations;
- promotes the appropriate use of blood, blood products and their alternatives;
- responds quickly to medical, technical, scientific and management advances and innovations;
- accepts responsibility for the financial stewardship of public funds;
- rewards creativity, teamwork and vision;
- is guided by a code of ethical conduct;
- is value-driven and focused on appropriate outcomes;
- is dedicated to achieving or exceeding world standards; and
- is dynamic, open and accountable.

Relationship between the Corporate Members and the CBS Board of Directors

The Corporate Members and CBS Board of Directors meet once per year as part of the Annual Meeting that is required by the Canada Corporations Act. The meeting is usually held in September and focuses on presentation of the budget and corporate business plan. The time period for these meetings is very limited – sometimes less than one hour.

To facilitate ongoing communication throughout the year, each province/territory has identified a staff contact person to serve as the liaison between CBS and the Corporate Members. These “P/T contacts” have fairly regular contact with CBS staff and meetings are held three or four times per year. They do most of the background work required to support effective decision-making by the Members. There is no common job description for the P/T Contacts and there are variations in their seniority, experience with blood issues, role and availability for CBS issues relative to other roles that they have within their Ministry. This leads to inconsistencies in the role performed. A basic job description should be developed which can be added to by each province/territory to reflect unique needs. The current P/T Contacts also bring a diverse range of skill sets (e.g. policy, finance, medicine) which is beneficial to the group as a whole and should be maintained.
The relationship between the Corporate Members and CBS’ Board of Directors has been strained and difficult over the years. Members and P/T Contacts do not always feel that CBS provides all of the information they require for decision-making. CBS Board and senior management feel that Member information needs are not always well-articulated and that clear policy direction is sometimes lacking. Meeting the diverse needs of 12 independent jurisdictions combined with frequent changes in individual Corporate Members have heightened the communication challenge for CBS.

However, there is currently a consensus among the Members and P/T Contacts that communication has greatly improved within the last year. Provinces and territories are becoming more comfortable with the information that is being provided and there are reports that the overall relationship between CBS and the Members is much better. Recently, a mechanism has been put in place to allow for regular contact between the CEO of CBS and the Deputy Ministers of the provinces. The new Deputy Minister’s Policy Committee on Blood is comprised of Deputy Ministers from British Columbia, Alberta, Manitoba, Ontario and Nova Scotia as well as the CEO of CBS. The Committee met once in June 2002 and are scheduled to meet again on October 30, 2002.

The limited amount of contact between CBS and the Corporate Members has meant a lack of opportunities for in-depth policy discussion. The MOU (Annex B) suggests that the Board of Directors must establish corporate and operational policies consistent with a policy framework established by the Members. Such a policy framework has not yet been developed. As a result, there are a number of outstanding policy issues that need to be addressed jointly by CBS, the Members and in some cases Health Canada. One example is plasma self-sufficiency which will be discussed later in this report.

Perhaps another symptom of the history of poor communication is the lack of a common understanding of roles and responsibilities. The MOU describes roles for the federal government, the provincial/territorial ministers and CBS but there are gaps in the descriptions and some statements are open to broad interpretation. Over the years, there has not been much progress in improving the clarity. As a result, the study found variations in how stakeholders perceive the roles of the various players. This includes the role of CBS, the Provincial/Territorial Ministers (as Ministers and as Members) and the P/T Contacts.

The issues described above in relation to role definition and a policy framework are critical to the effectiveness of the CBS. To demonstrate this point, one need only refer back to the Krever Commission Report which identified many of the same issues in relation to the Canadian Red Cross and the Canadian Blood Agency.

“In 1976, the federal and provincial ministers of health decided that the blood supply system was to be governed by three principles: voluntary donation, national self-sufficiency, and gratuity of blood products to recipients. The three principles did not begin to define the respective roles of the Red Cross, as the
operator of the system, and of the provinces, as the funders of the system. In 1981, when the Canadian Blood Committee, whose members were public servant representatives of the federal and provincial governments, was formed, one of its tasks was to create a comprehensive national blood policy that defined the respective functions of the Red Cross and the committee. The committee never created a national blood policy. As a result, no one was clearly in charge of, or accountable for, the safety of the blood supply. The roles of the Red Cross and the committee were blurred, and the continuing tensions between them interfered with efficient and effective decision-making. The blood supply was consequently not as safe as it could and should have been. If the functions had been clearly defined, many of the problems relating to safety that arose could have been more quickly and effectively solved.”

Clarification of roles and creation of a policy framework for CBS are priorities that the Members and CBS will need to address in a timely manner.

Recommendation #4: It is recommended that CBS develop a detailed Stakeholder Communications Plan that recognizes the Members as key stakeholders. The Stakeholder Communications Plan should include:

- A formal and ongoing government communication strategy that would include communications with the Ministers, Deputy Ministers, P/T Contacts, Federal officials and other key government stakeholder groups. This will be particularly important during implementation of the Transformation Project which will have varying degrees of impact on different provinces.
- Protocols for Board of Director communications with senior Provincial/Territorial officials. These protocols should take advantage of Regional Director reporting relationships and access to Ministers of Health. The communications protocols should also acknowledge that all CBS Directors should have access to Provincial/Territorial officials. The nature of the communication between regional directors and Ministers of Health should respond to the needs of the Ministers but would likely include updates on CBS issues and projects of interest to the Minister and solicitation of advice from the Minister on provincial factors to take into account in the corporate planning process. The protocols should also set expectations on the frequency of reporting to Ministers (e.g. twice per year).

Recommendation #5: The Annual Meeting between CBS and the Members is perhaps the single most important event for the CBS Board and EMT. Preparatory activities such as identification of coaches, intelligence gathering, identifying potential questions and hot spots, audience analysis, presentation skills, etc. are critical. The goal is for CBS to go to the Annual Meeting with a clear idea of the Members needs and armed with the specific information the Members require. Effective communication between

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CBS and the P/T Contacts will provide advance notice of the interests and likely receptivity of Members to what CBS wishes to present and or have approved.

**Recommendation #6:** To improve communication between CBS and the Members, it is recommended that Members identify ways to expand the length of the meeting time with CBS and/or increase the number of meetings held per year. The recent establishment of the Deputy Ministers Policy Committee on Blood is a good start to building a better relationship.

**Recommendation #7:** It is recommended that the CBS Board and Corporate Members engage in a process to clarify the respective roles and responsibilities of Corporate Members (both as Members of CBS and as Provincial/Territorial Health Ministers), Deputy Ministers, the lead Ministry, P/T Contacts (a generic job description should be created), the CBS Board and the CBS Chief Executive Officer. This review of roles and responsibilities should give special consideration to clarification of roles and expectations with respect to utilization management. The statement of roles should emphasize a partnership between the Provincial/Territorial Ministers and CBS that recognizes that is the responsibility of the Ministers, not CBS, to manage utilization at the hospital and physician level. CBS can however, play an important role in research, education, guideline development and evaluation of utilization practices.

**Recommendation #8:** Discussions with stakeholders revealed a lack of a common view of where the organization is and should be heading in the future. It is recommended that the CBS Board and Corporate Members engage in a facilitated process to renew the CBS vision and describe the future role and scope of CBS. Clearly, there are a number of directions that could be pursued. Some of the directions that have been suggested by stakeholders include:

- Reduce size and scope of CBS to be strictly a producer and distributor of blood and blood components. This direction would consider such strategies as divesting the distribution of fractionation products, divesting patient services, outsourcing certain infrastructure functions (e.g. payroll, IT), shifting research and development and public education roles to other players, and leaving utilization issues to the provinces/territories.
- Enhance the size and scope of CBS through growth and diversification. Strategies that would take prominence with this direction might include working towards goal of plasma self-sufficiency, enhancing CBS’ role in utilization management, increasing CBS’ role in research and development and increasing CBS’ technical leadership in transfusion medicine.

The vision must respond to the needs of the key stakeholders. It should reflect a customer-facing posture that places greater emphasis on utilization issues and hospital
linkages. The review team does not support a reduction in scope that is based on divestment of the fractionation business because the MOU defines blood as including alternatives and commercial products. Also, it is not evident that there is an organization better equipped to take this on or that setting up a stand-alone fractionation operation would improve effectiveness or efficiency. Internal operations however, should be as lean and efficient as possible. As emphasized throughout this report, the review team favours an enhanced role for CBS in development of utilization guidelines and education initiatives.

Recommendation #9: The MOU implies that it is the responsibility of the CBS Board to develop operational policies within a framework established by the Corporate Members. The policy framework has never been developed and there have been few opportunities for productive policy discussion. Therefore, it is recommended that the Corporate Members initiate a process to create a policy framework that would guide policy development by CBS. The framework should include direction to CBS on how to balance safety and affordability in the blood system and what level of safety/risk will be acceptable for Canadians. Development of the policy framework should be informed by public dialogue, research and comparisons with blood systems in other jurisdictions.

Recommendation #10: It is recommended that Members request CBS to use a portion of their Research and Development funds to conduct research of a policy nature. For example, research on how other countries have dealt with key policy challenges such as balancing safety and affordability and establishing a level of risk tolerance.

Recommendation #11: It is recommended that CBS continue to convene regular (e.g. annual or semi-annual) forums to gather stakeholder input that will assist CBS in developing strategic policies. CBS has conducted forums in the past. The difference here is the link to policy development. CBS would be accountable for identifying a clear policy goal for each forum, disseminating forum proceedings in a timely manner and following through with policy development. Key policies would be submitted to the Members. Some of the pressing policy issues that should be considered include plasma self-sufficiency and utilization of fractionated products (particularly IVIG and Recombinant Factor VIII). It is important to note that a policy discussion on plasma self-sufficiency should be informed by a thorough identification and analysis of plasma costs (both production and purchase) and fractionated product utilization guidelines that will help to determine the level of demand that should be forecasted.
2.4  Management Structure and Staffing

As described earlier, the Canadian Blood Services Transition Bureau was appointed on October 15, 1997. The first Board, led by Chairman, Ken Fyke, was appointed in April 1998. The Board hired the first CBS Chief Executive Office (Lynda Cranston) who then hired an executive management team.

With some exceptions, the executive management team has remained intact but there has been some restructuring of executive management roles in an effort to streamline the executive team functions. For example, the former Vice-President Marketing and Communications and Vice-President, Operations positions are now a single position. Also, the Vice-President, Human Resources position has gone through some revision and is now responsible for Organizational Development as well as Human Resources. Another change was the creation of the position of Vice-President Corporate Services and Chief Financial Officer.

Last year, an important change in senior leadership occurred at CBS. Following the resignation of the Chief Executive Officer in July 2001, Dr. Graham Sher (past Vice-President, Medicine, Scientific and Clinical Management) was appointed as the new Chief Executive Officer. Ken Fyke ended his tenure as Chair of the Board in October 2000. William Gleed served as interim Chair between October 2000 and September 2001. Gary Chatfield was appointed as the new Board Chair in September 2001.

The current senior management of CBS is comprised of the following people and positions:\textsuperscript{10}:

\textsuperscript{10} CBS Organizational Chart, dated February 14, 2002
Currently, CBS employs approximately 4,756 people and has a volunteer base of 17,000. The following diagrams describe the total national workforce by work function.
In their efforts to increase overall organizational effectiveness, initiatives are being implemented under the Transformation Project umbrella that will have an effect on staffing levels. As CBS automates and standardizes work processes, introduces more technologies to manage work processes, consolidates activities and redesigns work functions, there will be a need for a different mix of staff and staff numbers required to collect and process blood and blood components. April 24, 2002 saw the public announcement of the multi-faceted Transformation Project whose full impact on staffing is not yet known. The Transformation Project is discussed in more detail in section 2.6.
As with other health care organizations, CBS will likely have to compete for human resources skilled in different areas such as information technologies. In addition, there will be a need to look at creative, innovative ways of making a highly regulated work environment an attractive alternative to other health care organizations. Maintaining human resources in the health care sector is a global issue and there are numerous sources of information on best practices in recruitment and retention that might be of assistance to CBS.

2.5 Service Delivery and Functions

Before describing the various functions provided by CBS, a brief orientation to blood and blood components is provided below.

2.5.1 Blood and Blood Components

Blood is comprised of a liquid component (plasma) and protein substances (red blood cells, white blood cells and platelets) and it is this combination of substances that is referred to as whole blood. The role of these components includes:

- **Red Blood Cells** carry oxygen to tissues and are responsible for removal of carbon dioxide through the lungs.

- **White Blood Cells** protect the body from infection and often carry viruses and bacteria.

- **Plasma**, the liquid portion of the blood, is a protein-salt solution in which red and white blood cells and platelets are suspended. Plasma, which is 90 percent water, constitutes about 55 percent of blood volume. It contains **albumin** (the chief protein constituent), **fibrinogen** (responsible, in part, for the clotting of blood), **globulins** (including antibodies), and other clotting proteins. Plasma can be derived from whole blood collections using a centrifugation process. Or, it is possible to use a process called plasmapheresis to extract only the plasma from a donor. Plasmapheresis allows an individual donor to donate almost twice as much plasma as from a unit of whole blood. Plasma can be fractionated (separated) into specific products such as albumin, specific clotting factor concentrates and IVIG (intravenous immune globulin).

- **Platelets** provide the basis for clotting that helps control bleeding. Platelets can be extracted from plasma that is collected as part of a whole blood donation. Or it is possible to collect only platelets and return the other blood components to the donor using a process called plateletpheresis or cytapheresis.

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11 This information is taken from the CBS website (www.bloodservices.ca)
2.5.2 Key Functions of the Blood System

The major components of a blood system are illustrated in the following diagram. The role of CBS extends from donor recruitment to distribution. Transfusion and therapeutic interventions involving blood components are the responsibility of hospitals within each provincial/territorial health system.

Exhibit 2-7: Components of the Blood System

![Diagram of Blood System Components]

2.5.2.1 Donor Recruitment

Donor recruitment activities are a critical function for CBS as all subsequent activities are contingent on maintaining a large, regular donor pool. Over the last decade, prior to the establishment of CBS, the total number of blood donations had decreased. Therefore, CBS was faced with the challenge of increasing donations while building the organization. One of their first major campaigns was the launching of aggressive recruitment programs and the introduction of changes to make donor processes more ‘donor-friendly’. Public service announcements and advertising campaigns such as “Roll Up Your Sleeves Canada” are part of a multi year plan intended to recruit 160,000 new regular donors by December 31, 2005.

All donations are voluntary and donors must be between 17 and 70 years of age. Statistics collected by CBS indicate there are approximately 465,555 active donors today; yet of eligible Canadians (excluding Quebec), only 3% are regular donors. Of these donors, 85% are repeat and 15% are first-time donors.
As indicated in the following chart, there has been a 13% increase in new donors from fiscal year 2000/01 to 2001/02. The next diagram displays the percentage of eligible donors by province.

While CBS has seen an increase in donations since its inception, attracting and persuading Canadians to become regular and frequent blood donors will always be a major part of their operations.

**Exhibit 2-8: New Donors**
Exhibit 2-9: Proportion of Eligible Population that are Active Donors by Province

<table>
<thead>
<tr>
<th>Province</th>
<th>Proportion (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada</td>
<td>3.6%</td>
</tr>
<tr>
<td>BC</td>
<td>2.5%</td>
</tr>
<tr>
<td>Alberta</td>
<td>4.1%</td>
</tr>
<tr>
<td>Saskatchewan</td>
<td>5.3%</td>
</tr>
<tr>
<td>Manitoba</td>
<td>4.9%</td>
</tr>
<tr>
<td>Ontario</td>
<td>3.5%</td>
</tr>
<tr>
<td>New Scotia/PEI</td>
<td>4.4%</td>
</tr>
<tr>
<td>New Brunswick</td>
<td>4.6%</td>
</tr>
<tr>
<td>Newfoundland</td>
<td>5.3%</td>
</tr>
</tbody>
</table>

2.5.2.2 Blood Collections

Blood Collections is a core function of CBS. CBS maintains 42 permanent blood collection clinics and operates several mobile clinics each day. Mobile clinics are clinics that are held in different community locations each day. In 2001/02, CBS held 11,917 blood donor clinics, up from 11,189 for the previous year.

When a donation is made at a Centre, the donor must first answer a series of health and lifestyle related questions to determine their eligibility to donate. This extensive list of questions is to ensure the health of both the donor and ultimate recipient—a patient requiring a transfusion.

The process of blood collection requires the donor, a needle attached to a plastic tube and a sterile blood bag. The donor’s blood passes through the needle and tubing into the sterile bag which is then sent to the laboratory for processing. At the same time, some blood from within the bag is taken for purposes of typing and testing for infectious agents.

The following diagram indicates an increasing trend in the number of units of whole blood collected since 1998 when CBS was established. Beginning in 1999, CBS has had to place restrictions on donations from people who have spent time in Europe because of concern about transmission of variant Creutzfeldt-Jakob Disease (vCJD). The vCJD deferral policy does not seem to have negatively impacted the volume of whole blood collections because CBS has increased efforts in the area of donor recruitment.
Exhibit 2-10: Trend in Whole Blood Collections

Exhibit 2-11: Trend in Donor Deferrals due to Risk of vCJD

It is from whole blood that red cells, platelets and plasma are retrieved. Red cells and platelets are generally processed and distributed directly to hospitals. Most plasma is sent to the US for processing into fractionated products. The following graph
highlights the percentage increases in whole blood, plasma and platelets since the
inception of CBS.

**Exhibit 2-12: Trends in Collection of Blood Components**

<table>
<thead>
<tr>
<th>Year</th>
<th>Whole Blood</th>
<th>Plasma</th>
<th>Platelets</th>
</tr>
</thead>
<tbody>
<tr>
<td>98/99 to 99/00</td>
<td>5.0%</td>
<td>-1.0%</td>
<td>12.6%</td>
</tr>
<tr>
<td>99/00 to 00/01</td>
<td>2.5%</td>
<td>5.6%</td>
<td>15.0%</td>
</tr>
<tr>
<td>00/01 to 01/02</td>
<td>8.5%</td>
<td>1.0%</td>
<td>13.7%</td>
</tr>
</tbody>
</table>

### 2.5.2.3 Testing

When blood is collected, samples are taken for testing purposes. Before blood is issued
to hospitals for use in transfusion, the samples are tested for:

- **Infectious Diseases:** Syphilis, Hepatitis B and C, HIV 1 and 2 (the viruses that
cause AIDS) and Human T-Cell lymphotropic virus HTLV-I and II (the viruses that
can cause a rare form of leukemia in adults and chronic nervous system disease)
- **Blood Groups and Antibody Screening:** to determine ABO and Rh type, blood
group antibodies

Laboratory tests for infectious diseases, blood groups and antibody screening are
conducted on each unit of blood collected. If the blood or plasma tests positive for any
disease marker, it is destroyed and the donor is notified of the abnormal test results.
These donors are then permanently deferred and will not be permitted to donate blood
in the future. Blood samples that test positive at a Centre laboratory are sent to the
National Testing Laboratory (NTL) in Ottawa for confirmatory testing.

Nucleic Acid Amplification Testing (NAT) is a relatively new form of testing that is
done at four CBS laboratories. CBS uses NAT for Hepatitis C and HIV testing.
The following diagram identifies the number of NAT samples tested in each NAT laboratory (Vancouver, Halifax, National lab in Ottawa, and Toronto) for fiscal years 2000/01 and 2001/02. A total of 866,266 samples were tested in 2001/02. As noted above, the National lab in Ottawa re-tests samples that were tested at the Centres as required. This explains why the total number of samples tested is greater than the units of whole blood collected – some units are tested more than once.

NAT testing is discussed further in section 5.2.1.1.

Exhibit 2-13: Number of Samples NAT Tested

As part of efforts to achieve greater organizational efficiencies, CBS will be centralizing its testing at three laboratories located in Calgary, Toronto and Halifax. This is discussed in section 2.6.

2.5.2.4 Manufacturing

Once collected from a donor, each unit of whole blood is processed by a Component Production lab, assessed for suitability, and separated by centrifugation into the following components:

- Red blood cells
- Plasma
- Platelets
• Cryoprecipitate
• Cryosupernatant

Each unit of blood also undergoes ‘leukoreduction” a filtration process that removes the white blood cells to reduce the incidence and severity of transfusion reactions.

2.5.2.5 Label and Release

When the testing and production are complete, the components are then sent for Label and Release. All production and testing records are reviewed for suitability, completeness and accuracy, and each component is labelled with all applicable labels. The labelling is then verified for accuracy before the blood components are released to inventory, and available for distribution to hospital customers. Units are labelled to indicate:

• Donor Identification Number (DIN)
• Blood Type
• Blood Product
• Date of collection
• Date of expiration

At this time, the expiry date process mandated by Health Canada is done manually. It is anticipated the introduction of the new MAK Progesa computer system will negate the need for this manual process.

The automation of this process will also improve the ability to track inventory. For example, the current process of determining total inventory counts requires that an individual manually count each unit of blood component. Clearly, this is a labour intensive process subject to human error as are all manual processes.

Once products are labelled, they are committed to an inventory and thus, available for release to a hospital.

2.5.2.6 Fractionation

CBS operations are divided into two streams; blood operations, which deal with fresh blood and blood components, and fractionation, whereby plasma is frozen for shipment to a fractionation centre in the US.

As the volume of Canadian plasma shipped to the US is insufficient for national needs, American plasma is also used in the fractionation process. At the fractionation centre a number of different products are produced and shipped back to CBS for distribution to
CBS Centres and then hospitals. Factor VIII, albumin and intravenous immunoglobulin (IVIG) are the most common fractionation products produced.

CBS receives fractionated products processed in two ways; 1) the Canadian plasma sent to the fractionator is used specifically for Canadian fractionation products (referred to as custom fractionation) and 2) CBS purchases fractionated product manufactured from American plasma (referred to as commercial product).

2.5.2.7 Distribution

The Centres receive orders for blood products and fractionated products from their hospital customers by fax or by phone. CBS laboratory staff monitor inventory levels of all products and fill the hospital orders as they arrive. The appropriate components are then retrieved, checked, packed, and shipped to hospitals for patient transfusion.

2.5.2.8 Transfusion

A critical event in the blood collection and manufacturing process is the transfusion to a patient. Hospitals report adverse reactions to CBS as part of their overall surveillance function. CBS in turn communicates with Health Canada regarding adverse transfusion reactions. Beyond this reporting requirement, there are no other formal mechanisms in place to enable CBS to track a unit of blood from the vein of the donor to the vein of the recipient. To date, CBS has no authority regarding how blood products are used within the boundaries of the hospital system. This is the responsibility of hospitals, clinicians and, ultimately, provincial/territorial Ministries of Health.

2.5.2.9 Inventory Management

The entire blood collection and manufacturing processes are manually intensive. This makes for an unwieldy and inefficient process; for example, inventory counts must be conducted by hand as there is no other method of keeping track of ‘real time’ inventory levels. MAK Progesa will automate these currently manual processes, resulting in greater process efficiencies in areas such as:

- Storage of blood donor recruitment data
- Tracking of blood components
- Labelling
- Order management
- Inventory management
2.5.3 Challenges

In spite of a trend of increasing units of whole blood collection, CBS must contend with a declining donor base. The challenge that continues to face CBS is in creating a significant public awareness campaign aimed at increasing the percentage of eligible donors who are committed to a program of regular blood donations.

Another challenge will be in balancing the adoption of emerging best practices and cost efficiency. For example, since the implementation of NAT, several countries are reconsidering the ongoing use of this test based on the number of HIV and HCV cases uncovered.

While CBS is working hard toward developing and implementing efficient work processes based on nationally derived standards, there are still many inefficient and fragmented work processes. This will require integrated information systems and a more rapid move toward standard work processes.

2.6 The Transformation Project

2.6.1 History and Rationale for the Transformation Project

When CBS took over operations from the Red Cross, they inherited a system that can be described as:

- very manual and labour intensive
- highly duplicative
- paper based and error prone
- inflexible to shifts in demand
- reaching its limit in terms of capacity expansion
- increasingly expensive.

In 1999, the new management of CBS identified strategic directions required for an integrated blood system. The first step identified in achieving this was to design and implement:

“an Organizational Model and Service Delivery Systems to enable CBS to achieve its vision and mission as well as to identify and implement the services and support that CBS should provide to its customers.”\(^{12}\)

Various external consultant reports confirmed the need for improvement of many CBS systems.

\(^{12}\) CBS Report to Canadians 1999/2000
According to CBS, the initial design of their new organizational model and service delivery system was comprised of two phases: Phase 1 focused on obtaining information about the current organization, identifying issues and suggestions, and soliciting ideas for future direction, and Phase 2 was to establish overall directions to guide the development of the new model.

By Fall, 1999, the initiatives under consideration included:

- Development of a national donor recruitment and retention strategy to guide overall recruitment and management programs
- Redesign of clinic processes with a focus on donor needs that included consideration of issues such as clinic locations, appointment procedures, recognition programs and other opportunities to support donor convenience and enthusiasm
- Improvement of collections processes and increased focus on collections efforts in high yield areas
- Consolidation of specialized testing locations that consider cost-effectiveness, redundancy, geography and weather conditions on transportation
- Establishment of national inventory capabilities to ensure excess supply of blood and blood products are provided to areas with shortages/limited supply
- Encouragement in developing utilization management approaches through planning and education of their professional colleagues and in collaboration with Provincial and Territorial representatives
- Providing effective strategy and policy support from Head Office to local operations, the new model must incorporate a capability to locate support services in the field, where possible.

CBS reports this Organization Model / Service Delivery project was delayed in the Fall 1999 due to a number of more urgent and costly challenges:

- Health Canada had just introduced a directive for universal leukoreduction approximately one month after CBS took over the Red Cross blood operations
- There had been no consideration of, or preparation for, Y2K
- Implementation of HCV NAT was initiated
- Health Canada had introduced the first deferral policy for donors having traveled to the UK

At the same time, CBS recognized the need to structure their services and processes in the most cost effective way possible but without compromising safety. Winter 2000 saw the Organization Model / Service Delivery project re-launched as the Transformation Initiative.
Initially, there were 28 Transformation projects identified. CBS Executive Management Team (EMT) recognized the need to select the projects based on a set of prioritization criteria based on project interdependencies with other systems, potential cost savings and an understanding of what resources were available to carry out implementation. In the summer of 2001, the following projects were identified as priorities and the EMT gave instructions to proceed with the following projects:

- Implementation of the MAK Progesa system
- Creation of a National Contact Centre - Donor Contacts only
- Consolidation of Testing Centres
- Consolidation and Specialization of Production
- Implementation of a Change Control System
- UBMDR
- Implementation of SAP HR/Payroll (this project went live July 1, 2002)

These seven key projects are proceeding, but are at different stages of implementation and CBS is working to ensure that the projects are well coordinated and well aligned. A brief description of each priority project is provided below:

### 2.6.2 MAK Progesa

MAK Progesa is an information system linking donor recruitment, collections, blood component production, testing, labeling, hospital orders and inventory management. It will also replace the current non-integrated information systems, resulting in a truly national and integrated blood system. The MAK system will enable CBS to better track blood donations from the donor through to delivery to the hospital. At this time, the pilot site for this system is Halifax. CBS staff have been working with the Health Canada regulators for some time to ensure the right SOPs are developed, approved and ready for implementation at the ‘go live’ date in February, 2003. Full implementation across all Centres is anticipated for late 2003.

The specific objectives of MAK include:

- The creation of a single national database available to all CBS sites
- Enabling end-label practice to be implemented
- System component suitability and discard controls
- System reconciliation of component production
- Electronic transfer of all test results
- The ability for all components to be traced from collection to distribution
- On-line, real-time inventory of all components on a national basis
- Elimination of stand alone systems

The decision to pursue MAK implementation was actually made by the Canadian Blood Agency just prior to the creation of CBS because the existing systems were not Y2K compliant. It appears that
there was no business case developed at the time. CBS is currently developing a business case for MAK.

**Recommendation #12**: CBS does not have a completed business case for implementation of MAK Progesa because the decision to implement MAK was made by the Canadian Blood Agency before CBS was formed in 1998. It is recommended that CBS expeditiously complete the business case for MAK that is currently under development.

### 2.6.3 Donor Contact Centre

February 2002 saw the public announcement of Sudbury, Ontario as the site of the new National Contact Centre, estimated to be implemented by February 2003. The purpose is to create system-wide cost-efficiencies consolidating all donor recruitment and booking functions under a single roof. The new Centre will handle functions such as:

- Booking donor appointments
- Answering questions from the public
- Recruiting donors
- Supporting marketing campaigns
- Addressing eligibility inquiries

A business case for this project was completed on November 6, 2001.

### 2.6.4 Consolidation of Testing Centres

This project involves a two-phased approach to consolidation of testing. Initially, testing will be consolidated from 11 laboratories to three laboratories in existing facilities (Calgary, Toronto and Halifax). The rationale for this change is to enable CBS to focus on economies of scale, standardization and automation, and to move from manual to more technological work processes. An anticipated benefit is improvements to the safety and quality of the blood system.

This consolidation of testing will be made possible with the introduction of new technology called PRISM that will both increase capacity and reduce product losses and recalls. PRISM is expected to drastically reduce the staffing required for immunoassay testing. The PRISM equipment and the reagents required for testing have been approved by the Canadian regulator. However, since CBS also sends plasma to the U.S. for fractionation there is a requirement for the PRISM reagents that will be used to test the plasma to receive approval from the American regulator as well. CBS
is currently working on this approval. PRISM technology has been purchased and is in place, undergoing validation in Toronto.

In the second phase of consolidation, testing will be moved from the existing Centres to new, stand-alone, state-of-the-art testing facilities. A major reason offered by CBS for building the new testing facilities is to locate the facilities closer to transportation channels (e.g. airports) to expedite transport of samples for testing. The expert panel assembled for this review had concerns about this rationale and felt that the timing of the delivery of samples is unlikely to affect the critical path for the testing process given the length of time required for the tests to be completed (usually overnight).

While there is a document outlining the issues, risks and recommendations associated with this project, a comprehensive business plan was not available for review by the consulting team.

2.6.5 Consolidation and Specialization of Production

The purpose of this project is to streamline production functions. The current 14 production sites are all used to produce a range of blood products from whole blood. At present, each Centre also maintains an inventory of all frozen products (for example, fresh frozen plasma, cryoprecipitate, and cryosupernatent plasma)

The scope of this project is to evaluate CBS production locations and recommend a reduction in the number of locations that will be used to produce and issue frozen plasma components. The planning for Specialized Production is complete and implementation is scheduled for mid-August in London and mid-October in Regina. For Consolidated Production, the planning phase will be completed by September 2002, to be followed by implementation.

A business case was completed on February 2, 2002.

2.6.6 Implementation of a Change Control System

The Change Control System refers to the establishment of a policy that will assure all changes will be controlled by evaluating, approving and monitoring all changes that may impact CBS operations. The purpose is to ensure all changes are properly documented, evaluated and authorized by qualified personnel. Work is underway to design four critical elements:

- Document Management
- Validation
- Non-conformance System
- Training
These elements are anticipated to be presented to Health Canada by the end of September 2002. A business case for an automated solution was presented to the Executive Management Team in mid-August 2002.

### 2.6.7 Unrelated Bone Marrow Donor Registry

Due to scientific advances and improvements to information technologies, a plan (initially begun in 1988) was developed for the enhancement of the UBMDR information system. The objectives of this new registry are to enable:

- Integration of existing processes into a single centralized system
- Integration of HLA typing
- Automation of preliminary search requests
- Provision of rapid search results
- On-line search status
- Focused recruitment campaigns
- Attaining International accreditation

A business case was completed in November 27, 2001. This system was implemented on June 24, 2002.

### 2.6.8 Implementation of SAP HR/Pay

Until this project was implemented, each Centre was responsible for their own HR / Payroll functions. While staff are still adjusting to changes brought about by implementing a standard, national pay system, the specific benefits were identified as part of the ‘go forward’ decision:

- More consistent and efficient human resources, time and payroll processes across the country
- Enhanced ability to manage human resources more effectively
- Improved controls and accuracy of human resources, time and payroll functions

The first payroll was prepared by the new system in June 2002.

### 2.6.9 Challenges

The Transformation Initiative is a major undertaking that will substantially change the operations of the organization. However, a number of stakeholder groups raised some common concerns that must be addressed. These concerns include the timing, quality and regularity of communications to impacted staff and stakeholders. CBS Centre staff are too often unaware of what, when and how Transformation will affect them and this
hampers their ability to alleviate concerns or answer questions. Hospital representatives report frustration on two fronts; inadequate notice of CBS changes that impact hospital processes and the inability of CBS to meet timelines they set. For example, the implementation of MAK will have resource implications for hospitals. This makes effective communications with this stakeholder group a necessity. While some staff at CBS Head Office see this as a responsibility of the regional Centres, the Centres do not feel they are sufficiently aware of the status and impact of Transformation to initiate communications with their hospital stakeholders.

Another major challenge is in understanding what projects have been selected and what is their current progress status. There are many Transformation Initiative documents available but they do not always use the same project name. While discussions with CBS staff indicate a structured approach to the Transformation projects, communications and available documentation appear less so. This observation is consistent with feedback from both Centre staff and P/T Contact staff. In order to ensure a common understanding of decisions made regarding specific projects and timelines for implementation, a more comprehensive and systematic communication strategy is required.

Recommendation #13: It is recommended that CBS develop a Transformation Communication Strategy for Corporate Members and CBS staff/volunteers that uses consistent language and provides for regular updates on project status. This could be part of the Stakeholder Communications Plan referenced earlier. As part of the strategy, CBS would clarify and communicate to the Corporate Members and the P/T Contacts at the earliest opportunity, how each of the Transformation initiatives that is being planned will be financed. This must include a description of operational and capital cost requirements and the projected timing of both funding investments and cost savings.

Recommendation #14: The planning phase for Transformation has been long and many of the projects identified are intended to be organization-wide. Managing the complexity and project interdependencies of any national, large-scale initiative is a challenge. It is recommended that CBS implement a rigorous program management methodology for Transformation as soon as possible. The program management methodology should include development of an integrated project plan that shows how all of the projects fit together, costs, benefits, phasing and interdependencies.(see below)
Recommendation #15: CBS has undergone, and continues to undergo, a great deal of change in many areas. Staff are change weary and they will require a great deal of support, training, information and communication to make the Transformation Project a success. It is recommended that CBS implement an organization-wide Change Management strategy for the Transformation Initiative as soon as possible. Ideally, a dedicated staff position should be identified to lead the Change Management program. [It was noted that during this review, recruitment was underway for a Manager of Organizational Development at Head Office whose role will include Change Management, among other duties.]

Recommendation #16: While CBS has provided business cases for some of the Transformation Initiatives, it is recommended that business cases be developed in a timely manner for all projects that are being pursued. Each business case should include at least the following information:

- Full description of the initiative
- Timeframes for planning, implementation and evaluation
- Description of costing methodology and planning process
- Application of the cost, benefit, risk framework mentioned in the MOU
- All costs (planning, implementation, ongoing, capital)
- Timing of cost outlays and cost savings
- Expected benefits and how they are to be achieved and measured (e.g. cost savings, safety impact, supply impact, efficiency gains, automation improvements, staffing impact, donor impact)
- Performance measures and targets
- Implications/risks (e.g. product supply impact, staffing impact, donor impact, regulatory impact)
2.7 Regulatory Framework

Throughout the 1980s, the federal department with regulatory responsibility over food, drugs and the environment was the Health Protection Branch (HPB). The approach taken toward enforcement of regulations though, was one of “voluntary compliance”. Krever quotes the then HPB Assistant Deputy Minister:

“the branch promoted voluntary compliance throughout the 1980s. The flexibility it allowed was preferable to issuing regulations and learning that they were not necessary or had become outdated and then having to remove them. Voluntary compliance is a much more appropriate and efficient and effective way of doing it [regulating]. And by and large, I have to say that voluntary compliance permitted us to extend the purview, to extend the examination of a wider range of areas than would otherwise be possible because regulation and regulatory action is very expensive ...”

This statement reflects the history but, a different philosophy exists today.

2.7.1 Current Role of Health Canada

Today, the federal government, through Health Canada’s Blood Establishment Regulatory Division, is responsible for regulating the blood system. Health Canada’s regulatory framework is the laws, policies, standards, directives, guidelines and regulations outlining the legal requirements from collection to the distribution of blood and blood components.

Since 1988, blood and blood products have been regarded and regulated as drugs. The Food and Drug Regulations established the means by which the Minister of Health (Canada) might be satisfied that the premises, processes and conditions of manufacture “are suitable to ensure that the drug will not be unsafe for use.” Specifically, it is Divisions 1A (i.e. Establishment Licences), 2 (i.e. Good Manufacturing Practices) and 4 (i.e. Schedule D Drugs) of the Food and Drug Regulations that are the regulations applicable to blood and blood components.
Since Krever, Health Canada has strengthened its regulatory role in relation to the blood system; they have increased their inspection activities, issued guidelines based on current Good Manufacturing Practices, approved each Standard Operating Procedure and issued an annual license to both of Canada’s blood systems. Health Canada sets out the minimum requirements for acceptable performance as it relates to donor selection, blood collection, blood processing, testing, labeling, record keeping, lookback / traceback, recall and storage.

As part of the enhanced role of Health Canada, an Expert Advisory Committee (EAC) on Blood Regulation was appointed in 1995. Members of this committee include representatives from the medical and scientific communities as well as from within Health Canada. Their role is to provide timely advice on emerging issues and federal responsibilities within the blood system. In 1997, the Minister of Health Canada also appointed a National Blood Safety Council to provide advice on issues related to public health, ethics, and public policy related to the blood system.

Ultimately, the current role of Health Canada is to reduce the risk of transmission of a disease through blood components or products by ensuring there are procedures established and followed that will preclude or at least minimize the probability or extent of contamination of any pooled biological material.

### 2.7.2 Good Manufacturing Practices

Blood is defined as a bio-pharmaceutical product and must be manufactured following strict regulatory standards. The Good Manufacturing Practices (GMP) standards refer to Division 2, Part C of the *Food and Drug Regulations* and are the minimum legal requirement applicable to all regulated industries to ensure consistency when applying Health Canada’s regulatory requirements to their work processes. Associated with these legal requirements are associated ‘guidelines’ aimed at helping CBS and Hema-Quebec implement relevant GMP standards. These however, are not the only standards to which CBS can be held. For example, as the two plasma centres provide a biological product for shipping and processing in the US, they are also subject to all relevant US Food and Drug Administration regulations.

CBS and Health Canada independently track and monitor current and emerging international standards in blood safety through mechanisms such as participation in international advisory committees, the creation of safety advisory committees and / or by benchmarking practices against other blood agencies. For example, in November 1998, Health Canada issued a directive to CBS calling for implementation of pre-storage leukoreduction of red blood cells and platelets. On the other hand, CBS took the initiative to implement Nucleic Acid Amplification Testing (NAT) without being directed to do so by the regulator. However, the regulator did make NAT testing a condition of license for CBS. Therefore, while not a 'directive' per se, as in the case of leukoreduction, “condition to license” means that the license (to operate the blood
program) is in effect so long as CBS addresses NAT testing. These measures were based on evolving international standards aimed at proactively improving the safety of the blood system.

Health Canada does not regard the GMP standards as the only interpretation of the GMP regulations, nor were they intended to cover every conceivable case. For example, alternative means of complying with these regulations can be considered with the appropriate scientific justification and different approaches may be called for as new technologies emerge.

The guidance given in the Good Manufacturing Practices Guidelines has been written with a view to harmonization with GMP standards from other countries and those of the World Health Organization (WHO), the Pharmaceutical Inspection Cooperation/Scheme (PIC/S) and the International Conference on Harmonization (ICH).

The GMP standards therefore, are a ‘living’ set of standards intended to be flexible enough to apply as new medical and scientific information emerges. The application and regulation of GMP standards however, have a direct and ongoing impact on the operations of the CBS.

2.7.3 Organizational Impact

CBS must ensure that the manufacturing, packaging, labelling, distribution, testing and delivery of blood components complies with GMP requirements. The responsibility rests with the senior management (and ultimately the Board) and requires the participation and commitment by personnel in many different departments and at all levels within CBS and by its suppliers.

Good Manufacturing Practice standards are concerned with both production and quality control and Health Canada describes their basic requirements:

- Manufacturing processes are clearly defined and controlled. All critical processes are validated to ensure consistency and compliance with specifications
- Manufacturing processes are controlled and any changes to the process are evaluated

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14 http://www.hc-sc.gc.ca/hpfb-dgpsa/bgtg-dpbg
• Changes that have an impact on the quality of the drug are validated as necessary
• All necessary key elements for GMP are provided including:
  - qualified and trained personnel
  - adequate premises and space
  - suitable equipment and services
  - correct materials, containers and labels
  - approved procedures and instructions
  - suitable storage and transport.
• Instructions and procedures are written in clear and unambiguous language
• Operators are trained to carry out and document procedures
• Records are made, manually or by instruments, during manufacture which demonstrate that all the steps required by the defined procedures and instructions were in fact taken and that the quantity and quality of the drug was as expected. Deviations are investigated and documented
• Records of manufacture including distribution which enable the complete history of a batch to be traced are retained in a comprehensible and accessible form
• The distribution of the drugs minimizes any risk to their quality
• A system is available to recall any batch of drug, from sale or supply
• Complaints about marketed drugs are examined, the causes of quality defects investigated and appropriate measures taken in respect of the defective drugs and to prevent re-occurrence

How CBS translates these requirements into work processes for the organization is through the development of Standard Operating Procedures (SOPs). These documents must be approved by Health Canada before implementation and become the processes all staff must follow from donor recruitment through to the delivery of product to hospitals.

2.7.4 Compliance Performance of the CBS

CBS has worked hard at introducing the structures and processes required for working in a regulated environment. This is not always easy; staff do not always understand the rationale for the lack of professional autonomy a regulated work environment requires and staff are not always comfortable with their work being scrutinized rigorously by internal or Health Canada auditors.

At any time throughout the year, there is an audit underway in at least one Centre or at Head Office. It is important to remember to understand the challenges faced by CBS as they implement a manufacturing model into an organization that is manually driven and
therefore prone to errors. In spite of this, staff express a strong commitment to continual process improvement.

Health Canada states\(^\text{16}\) that over the last five years, they and CBS have worked to improve and maintain the level of confidence in the blood system. The overall compliance performance of CBS was described as “good”. The one area they identify needing improvement is in a consistently timely response to citations. The anticipated changes to Health Canada’s regulatory framework may also help provide CBS with clearer guidance with respect to regulatory requirements.

### 2.7.5 Controlled Documents and Standardization

A Standard Operating Procedure is a type of controlled document used for the procurement of materials, donor management and services, the processing, testing, disposition, release, distribution and outcomes reporting of blood products; or a procedure that is used by the supporting functions of CBS, not directly involved in the activities as defined above, (e.g., Payroll). SOPs precisely describe the tasks / activities required for work process and staff must adhere to the steps within the SOP; there is no leeway for individual interpretation of an SOP. For example, a phlebotomy performed in Vancouver must be performed precisely the same way and with the same equipment in Halifax. Failure to do so will result in a citation by the Health Canada or CBS Quality Systems audit staff. This precision in work processes can make it very challenging for staff unused to working in a regulated environment.

Because each SOP is a controlled document, each one must be assigned a unique identifier used to control, monitor and retrieve it. The administrative tasks and time required to maintain SOPs and other controlled documents is significant. The following table identifies the number and type of SOPs that have been identified by CBS. There are a total of 961 SOPs and CBS reports that 300 to 400 of them have been implemented.

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\(^{16}\) Interview questionnaire responses from Ms. J. Hill, Acting Director General, Biologics & Genetic Therapies Directorate, Health Canada. July 2002.
Exhibit 2-14: Standard Operating Procedures by Functional Category

<table>
<thead>
<tr>
<th>CANADIAN BLOOD SERVICES</th>
</tr>
</thead>
<tbody>
<tr>
<td>STANDARD OPERATING PROCEDURES (SOPs) as of March 2002</td>
</tr>
<tr>
<td>Source: SOP Business Process Flow Map, Version 15.0, 2002-03-04, CBS</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Functional Category</th>
<th>Number of SOPs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collections</td>
<td>88</td>
</tr>
<tr>
<td>Component Production</td>
<td>60</td>
</tr>
<tr>
<td>Testing</td>
<td>160</td>
</tr>
<tr>
<td>Labelling/Release of Finished Components</td>
<td>14</td>
</tr>
<tr>
<td>Product Management</td>
<td>40</td>
</tr>
<tr>
<td>Head Office Manufacturing</td>
<td>15</td>
</tr>
<tr>
<td>Information Management</td>
<td>72</td>
</tr>
<tr>
<td>Quality Assurance</td>
<td>103</td>
</tr>
<tr>
<td>Quality Management System</td>
<td>28</td>
</tr>
<tr>
<td>Administrative Systems</td>
<td>1</td>
</tr>
<tr>
<td>Research and Development</td>
<td>2</td>
</tr>
<tr>
<td>Plasma</td>
<td>26</td>
</tr>
<tr>
<td>Equipment Operation</td>
<td>105</td>
</tr>
<tr>
<td>Equipment Maintenance</td>
<td>99</td>
</tr>
<tr>
<td>Equipment Calibration</td>
<td>28</td>
</tr>
<tr>
<td>Equipment Verification</td>
<td>64</td>
</tr>
<tr>
<td>Reagents and Supplies - Preparation and Quality Control</td>
<td>53</td>
</tr>
<tr>
<td>Reagents and Supplies - Instructions for Use</td>
<td>3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>961</strong></td>
</tr>
</tbody>
</table>

At CBS, controlled documents include not only Standard Operating Procedures (SOPs), but also:

- Centre Operating Procedures (COPs) are written descriptions of Centre processes that define how to perform general tasks in place at the Centres. These are based on the SOPs but are tailored to meet the unique requirements of any of the 14 Centre sites
- Departmental Operating Procedures (DOPs) define the administrative management processes in place in the individual departments
- Centre Supplements are procedures that outline the specific information in an SOP permitted customization to address the differences for the following:
  - To document a site's choice between several approved procedural options
  - To adapt the SOP to constraints imposed by locally acknowledged authorities, as specified in the Operating Procedure
• Directives are a CBS Executive Management sanctioned, controlled document, used to convey an immediate notification of a new requirement or change to an operational process or procedure that is required to be implemented without delay. The Directive will be in effect only as long as is necessary to process the emergent change to the affected documentation describing the operational process.

• Information Bulletins are a CBS Executive Management sanctioned, controlled document, used to convey an immediate notification of a new requirement or change to general information, not directly related to operational procedures or processes. An example would be a supplier name or address change. These bulletins are in effect until such time as any documentation referencing the changed information has been updated through either a need for a procedural revision or the periodic review process.

• Manuals are large operational procedures or reference documents that may be divided into discrete instructional sections, or may be issued in their entirety. If divided, the individual sections will be revised, approved, distributed and controlled as separate entities.

• Forms are a paper or computer controlled document with blank areas for recording and organizing specific information items in a standardized manner.

• Labels are a form used for identification purposes, usually on materials or products.

• Training Documents are materials designed to aid in the training of CBS employees in the SOPs required to fulfill their assigned job functions, and

• Job Aids are an approved, controlled document that contains a section of information that has been extracted directly from an approved Operating Procedure, maintaining the integrity of the original wording. This document maintains a reference to both the document number and revision number of the source Operating Procedure.
2.7.6 Cost Drivers and Regulatory Pressures

To date, CBS reports there are approximately 29,000 controlled documents and each controlled document must be logged, maintained and tracked within the organization. There are three factors that increase the complexity in making changes to controlled documents: 1) the time required by CBS to write new or amended SOPs, 2) the number of manual processes required to manufacture blood and blood components and 3) the time it takes Health Canada to approve changes to SOPs.

Every manufacturing process requires an SOP and CBS staff report it can take up to 18 months from the time a SOP is written and approved by Health Canada. For every new or amended SOP, there is also the corresponding need to have written and approved training procedures outlining how CBS will ensure staff are trained to the new or amended SOP. This process is clearly burdensome, requiring significant investments of staff and management time.

The impact of inheriting a system where regional Centres functioned as separate entities can be seen in the duplicative and labour intensive processes of implementing national SOPs. SOPs are created by the Head Office to implement Health Canada regulations across all sites. SOPs tend to be very specific in how tasks are to be carried out, yet the Centre might be unable to implement them as written. This drives the need for developing Centre Operating Procedures.

COPs are developed in order to accommodate local differences. For example, the physical layout in a Centre, equipment, facilities or local union agreements may make a SOP from Head Office impossible to implement at the Centre level. In other situations, a COP may be the outcome or corrective action of audit observations specific to the Centre (both internal, corporate and Health Canada).

The creation of a COP however, is not an arbitrary event; there are broad guidelines set out in an SOP, (SOP CQ/1000 version 1, section 4) on when a COP can/should be considered:

"the decision to undertake development of a new Procedure or revision of an existing Procedure shall be the responsibility of.....the Quality Assurance Specialist for COPs..... The Quality Assurance Specialist shall be responsible for coordinating the development and revision of Centre COPs. Centre COPs shall be prepared to provide Centre staff with detailed instructions necessary to implement National SOPs. Note: Centre COPs cannot redefine limits or standards set in National Standards or National SOPs.

The challenge to CBS however, is in the sheer number of COPs that are currently in existence. To illustrate, the following diagram demonstrates how a single SOP can be turned into a different COP for each Centre.
Exhibit 2-15: Proliferation of Centre Operating Procedures

This potentially duplicative, unwieldy and manual process is a significant Process Control and administrative challenge that requires considerable time and energy to manage. CBS is well aware of the need to streamline this process. Given the current Regulatory-SOP process, their success in reworking this process will be somewhat hampered given the different physical layout and equipment in each of their Centres.

In spite of this challenge however, there is opportunity to standardize processes to reduce staff frustrations and minimize the volume of rework needed to perform common tasks. It is also anticipated that the integrated MAK system will reduce the unnecessary variation that exists across Centres and contributes to COP development. Another opportunity that was identified by Centre staff is to allow for more input from a broad range of Centres when SOPs are being developed so that local differences can be recognized upfront.

Recommendation #17: Although there has been improvement in the establishment of a national model, there is still significant variation across the regional Centres. This variation exists in the scope of services, operating procedures and the nature of equipment and facilities. It is recommended that CBS continue its efforts to increase the level of standardization in the Regional Centres. This should include:

- Reducing and standardizing patient services
- Developing and enforcing more rigid criteria under which Centre Operating Procedures should be developed
- Developing a standard template for demand forecasting for use by the regional
Centres
- Continuing to maximize consolidation opportunities over the long-term based on evidence-based assessments of costs, benefits and risks. A number of consolidation initiatives have been implemented or are planned; continued evaluation of the benefits and savings from these initiatives will help to identify additional opportunities (e.g. further reduction in consolidation sites or additional functions to consolidate).

Recommendation #18: According to CBS, many Centre Operating Procedures exist because of a lack of standardization of equipment and facilities. It is recommended that CBS develop a capital plan that includes a long-range strategy to standardize equipment and facilities as much as possible within capital cost constraints that may be imposed by the funders/Members.

2.7.7 Regulatory Approval Process: Anticipated Changes

Health Canada is currently conducting a review of regulatory requirements that include issues related to the efficiency, speed and adequacy of the current regulatory framework. The purpose of this review is to continue to ensure the regulatory process is sufficient to ensure the safety of the blood system without placing an undue burden on either the regulator or CBS. It is anticipated this review will also identify gaps in guidance documents which may help provide clearer instruction for regulators and CBS with respect to Health Canada’s requirements.

Health Canada states the current Food and Drug Regulations are difficult to follow, and do not contain provisions specific to blood collection and components manufacturing. The new regulations Health Canada will be proposing will stipulate requirements that must be met with respect to safety, efficacy and quality as well as surveillance, adverse event reporting and a compliance and enforcement strategy. The areas of potential impact include:

- Management responsibility
- Quality systems
- SOPs
- Document control
- Validation and
- Training.

17 Health Canada website:
These new regulations will apply to establishments involved in the collection, processing, packaging, labelling, storage, importation or distribution of blood or blood components intended for transfusion. While anticipated to be several years before completion, Health Canada, in conjunction with their Expert Panel Working Group and representatives of CBS and Hema-Quebec, is working on developing National Blood Standards.18

Recommendation #19: Health Canada is presently reviewing and revising its regulatory framework. In situations where a new regulatory requirement is in the works that will have major cost implications, CBS should routinely prepare a detailed briefing note for Members on the process, anticipated changes to the framework, the expected impact on CBS and any action that needs to be taken by CBS or the Members.

Recommendation #20: It is recommended that the Members convene a meeting with Health Canada for a presentation on the regulatory framework and discussion of how to minimize the burden of the regulatory process for CBS while respecting safety considerations.

2.7.8 Challenges

Annex A of the MOU provides that the national blood authority will provide “standard, policy and guideline setting supplementary to any regulatory standards of federal, provincial or territorial governments;” Annex B further provides that “the Board is responsible for the development and implementation of NBA standards supplementary to any regulatory standards of the federal, provincial or territorial governments.” Pursuant to these mandates, CBS maintains two separate types of procedure guidance documents or operating standards: Standard Operating Procedures (SOPs) and Centre Operating Procedures (COPs). As mentioned above, SOPs are said to number 961, of which about 300 to 400 have been implemented and guide current practice. Although an exact number of COPs systemwide is not available, it is believed to be in the many thousands. Whereas the former provide general guidance and are promulgated and approved by CBS, the latter are developed by the Centres to provide operational guidance at the bench level. They require no approval by Head Office.

The enabling documents cited do not specify which, if any, standards are to be applied to operations of CBS, although international best practices are expected by some. The review group could not identify which standards are applied operationally by CBS to

18 “Towards Renewed Regulatory Frameworks for Blood and Blood Components intended for Transfusion and Cells, Tissues and Organs Intended for Transplantation”, Health Canada
the various SOPs and COPs, although several are in widespread use internationally (e.g. ISO 9000, AABB standards, UK standards). The option to introduce some standards has, in some cases, been pre-empted by law, the implementation of universal leukoreduction, for example. This should not prevent the adoption of additional standards.

Recommendation #21: In order to further improve uniform best practices and predictability among Canada’s blood Centres, a national set of standards applied to all blood facilities would be desirable. They would be divided into two categories: 1) Laws defining required practices for regulated products and processes; and 2) Standards defining ideal or precatory best practices for products and processes not mandated by law. It is within the second of these categories that CBS should be proactive. Ideal and uniform standards should be implemented nation-wide and a voluntary inspection system established to assure uniform compliance. Such standards should be referenced regarding controlling authority.

2.8 Stakeholder Relationships

In carrying out its operations, CBS interacts with a variety of stakeholder groups. Effective stakeholder relationships are a critical success factor in high-performing organizations. This section describes CBS’ key stakeholder relationships.

Consumer Groups
Consumer groups include a variety of groups that represent blood donors, blood recipients, CBS volunteers, victims of tainted blood, and health care professionals.

Transparency is a key principle of CBS and there are many efforts made to keep these groups informed of direction and functioning of CBS. Some of CBS’ efforts at acknowledging the value of the input and support of these groups include:

- Federal audit results are posted to their web site
- Board minutes are posted to CBS’ web site
- Two Board meetings per year are open to the public and held in a variety of cities
- Hosting donor recognition programs
- Staff training sessions in Customer Training are being conducted for CBS staff

The National Liaison Committee

Another important way that CBS links with consumer groups is through its National Liaison Committee. This Committee of the CBS Board represents a variety of stakeholder groups that include:
• Anemia Institute
• Arthritis Society of Canada
• Canadian Association of Transplantation
• Canadian Blood and Bone Marrow Transplant Group
• Canadian Cancer Group
• Canadian Healthcare Association
• Canadian Hemophilia Society
• Canadian Immunodeficiency Patient Organization
• Thalassemia Foundation of Canada
• Canadian Society for Transfusion Medicine
• Neutropenia Support Association

The National Liaison Committee is an opportunity for these diverse groups to have input into CBS Board meetings and have replaced the original Consumer Advisory Committee.

**Hospitals**

Hospitals are CBS’ customers. In 2001/02, CBS shipped blood products to over 500 hospitals.

Regional Centres report more focused and frequent contacts with their hospital customers and are asking for their input and collaboration on joint issues. At some Centres, staff are providing education sessions for hospital laboratory staff, which are reported as well received, especially by smaller organizations. CBS staff do report that communications with larger hospitals can be strained and still require some work. The Vancouver and Edmonton Centres have implemented a Customer Feedback Process as a mechanism for receiving regular feedback from the hospitals.

The major issue reported by hospital representatives that were interviewed is the lack of timely information from CBS Head Office (they clearly distinguish between a Centre and Head Office) regarding changes such as the implementation of the MAK Progesa computer system. The most common complaint is too little lead time as this type of project has a significant impact on hospitals. In addition to the short lead time, concern was expressed in not knowing when MAK would be implemented nationally.

The hospital survey also revealed a number of other issues regarding the level of customer service to hospitals. Detailed survey results are included in Appendix E and in section 5.3.

**Medical Community**

The National Technical Working Group on Utilization Management was recently established to serve as a medical and technical working group on blood utilization...
management issues and supports the Policy Advisory Committee of the Blood and Blood Products Utilization Management Initiative. This working group also provides professional leadership in assisting in identifying, designing, and implementing cost-effective blood utilization management initiatives for the optimization of patient care.

The initial Chair of the Technical Working Group shall be an individual as determined by the Minister of Health of the Province of British Columbia acting as the lead Minister for the blood system. The Technical Working Group shall be made up of the following members:

- Medical and technical experts jointly appointed by the P/T Ministries of Health and CBS. Effort shall be taken to obtain expert representation from across Canada in accordance with the structure set out in the by-laws of CBS. This would include two representatives from the following four areas of the country: (i) Atlantic, (ii) Ontario, (iii) Alberta, Saskatchewan, Manitoba, Northwest Territories and Nunavut, and (iv) British Columbia and Yukon.

- Three representatives from CBS with one such representative focussing on the operational aspects of matters being discussed.

- The Chair of the Policy Advisory Committee.

The members meet formally on a quarterly basis but meetings may be held more often as required.

Of the members interviewed for this review, there was consistency in responses to the questions related to “what areas CBS exceeded and did not exceed expectations”. With regard to areas where expectations were not met, the comments related to:

- Communications (for example, there is no systematic communication mechanism with the provinces regarding changes planned by CBS);

- The perception there is an inconsistent application of Lookback / Traceback processes nationally;

- Lack of timely dissemination of results arising out of the Utilization Management Consensus Conference

Regarding areas of satisfaction, respondents indicated that CBS is generally able to supply blood products and that they meet international safety standards (e.g., leukoreduction).

One area most respondents would like to see a greater CBS presence in is physician education. This is consistent with results gathered through the hospital survey.

**Recommendation #22:** The MOU states that education/information programs for medical professionals is a key function of CBS. The hospital survey found that hospitals value the educational initiatives provided by CBS. It is recommended that the
CBS develop strategies to enhance its role in educating stakeholders, particularly hospitals and physicians, on blood use and transfusion medicine. These strategies should include consideration of:

- Establishment of a portal or a designated portion of the CBS website for health care professionals
- Development of standard hospital and stakeholder educational packages for use by Centres; these packages would be prepared on a regular basis such as quarterly or semi-annually
- Requiring Centres to host a minimum number of educational sessions per year
- Developing performance measures related to education such as the number of educational sessions, the number of participants or organizations represented at educational sessions, evaluation results from educational sessions.

Some provinces (e.g. Ontario) have a number of educational initiatives in place in relation to the blood system and transfusion medicine. In addressing this recommendation, CBS should work with these provinces to minimize duplication of activity.

**National Blood Safety Council**

The National Blood Safety Council is directly accountable to the federal Minister of Health. The Council was formed in 1997.

The purpose of the Council is to provide advice to the Minister of Health on public health, ethical, public policy, and other issues pertaining to blood safety within the responsibility of the federal government, particularly issues pertaining to blood regulation and surveillance. The Council will:

- Be vigilant over the blood system with a particular emphasis on the surveillance and regulation of blood safety. This will involve:
  
  - Reviewing and commenting on structure, organizational issues and relationships within the blood system and, when it is likely to affect safety of blood, the interrelations between the blood system and the broader health system.
  - Reviewing and commenting on the performance of the organizations and bodies within the blood system, with a focus on those departments in Health Canada that deal with regulation and surveillance of blood and blood products
  - Identifying any issues that may pose a risk to blood safety including emerging pathogens, chemical or physical properties of blood and failures, flaws or gaps in the risk management strategies throughout the process of recruiting donors to administration of blood and blood products, and monitoring for adverse reactions.
• Provide a forum for communication among all the stakeholders involved in the blood system, the users and public on issues pertaining to blood safety.

It is important to emphasize that the role of the Council is to be vigilant over the entire blood system, not just CBS. The span of vigilance includes Hema-Quebec, hospitals, the regulator (Health Canada) and other sectors.

The Council consists of a Chair and up to 20 members with a wide range of knowledge/skills.

Some of the issues that the Council has addressed over the years include:

• Implementation of Krever recommendations
• Solvent detergent plasma
• Nucleic Acid Amplification Testing (NAT)
• Variant CJD
• IVIG shortages
• Hospital issues
• Emergency preparedness

Current priority issues for the Council include new and emerging pathogens, inter-organizational gaps, donors, cost-containment and adequacy of supply.

Council representatives interviewed feel that progress has been made in addressing the issues it has examined because when the Council announces a forum the organizations involved start getting prepared.

There have been times over the past four years when the relationship between CBS and the NBSC was strained. The current relationship appears to be much improved. CBS is not mandated to provide information to the NBSC. However, when invited, CBS and Hema-Quebec will present information to the Council. This generally happens about twice per year. CBS also participates in forums organized by the NBSC. Recently, CBS requested a meeting with the Council to share information on the Transformation Project.