

Performance Review of Canadian Blood Services

Final Report

October 15, 2002

i. Executive Summary

In 1998, [Canadian Blood Services \(CBS\)](#) assumed management responsibility of the national blood system from the Canadian Red Cross. The initial challenge facing this organization was to ensure a safe and secure blood supply and to restore public confidence in the blood system. The mandate of CBS is described in a Memorandum of Understanding (MOU) that was signed by representatives of all of the provinces/territories (except Quebec). The MOU established the roles and responsibilities for the key stakeholders in the national blood system: the federal government, the provincial/territorial governments and CBS. The MOU outlines the functions to be provided by CBS and a set of principles to guide operations and decision-making.

Core Operational Functions
<ul style="list-style-type: none"> • Donor recruitment and management • Whole blood and plasma collection • Testing and lab work • Processing • Storage and distribution • Inventory management
Key Support Functions
<ul style="list-style-type: none"> • Standard, policy and guideline setting supplementary to any regulatory standards of the federal, provincial or territorial governments • Coordinating a national program in research and development for blood, blood products and transfusion medicine • Surveillance and monitoring • Professional and public education and information • Health risk management.
Guiding Principles
<ul style="list-style-type: none"> • 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.

The MOU also includes a provision for a review of the national blood authority within five years of its creation to determine if it has “adequately fulfilled its functions and responsibilities...” The review was commissioned by the provincial/territorial ministries of health (with BC Ministry of Health as the lead Ministry) and was conducted from April to August 2002. The terms of reference for the review include a financial review, an operational performance review and a risk management review. Key components of the review methodology were:

- Stakeholder interviews
- An international benchmarking survey
- A hospital survey
- An analysis of financial statements
- An information technology assessment
- Documentation review

Input from a panel of internationally recognized experts in blood operations was utilized throughout the review. Findings and preliminary recommendations were presented to CBS and the expert panel for validation and feedback prior to inclusion in this report.

A summary of the key findings and key recommendations is provided below:

Achievements

Four years after its creation, CBS has evolved from the crisis phase through a stabilization phase and is now in the midst of a major organizational transformation process. The crisis is over. Stakeholders and the general public feel that the blood supply is safe. A Winter 2002 public survey found that 81% of respondents agree that “the blood system in Canada is safer today than it was five years ago”. Other important accomplishments CBS has achieved include:

- Transforming a fragmented, decentralized blood supply program into a functional, national, blood system
- 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 various infrastructure systems.

Governance

CBS has a two-tiered governance structure consisting of the CBS Board of Directors and the Corporate Members who are the Provincial/Territorial Ministers of Health. The MOU sets out the mandate, roles and responsibilities for the Board and the Members.

The Board of CBS is committed and brings a wide variety of important skill sets to their role. They are evolving from the very hands-on role that was required when CBS was created to a more strategic mode of operation. Mission, vision, value and quality statements have been developed for the organization. Appropriate standing committees are in place including a National Liaison Committee with representation from several consumer associations. Attendance at Board and Committee meetings is excellent. Steps that would strengthen the board even further include:

- Implementation of a formal board evaluation process
- Clarification of the role of regional directors
- Development of a stakeholder communications strategy; including protocols for communication with provincial/territorial/federal officials
- Recruitment of board members with expertise in information technology, corporate law and haematology.

Two important responsibilities of the Corporate Members as set out in the MOU are to provide a policy framework for CBS planning and decision-making and to provide funding for CBS operations. There are concerns related to both of these roles. First, the policy framework has never been developed. As a result, there is a lack of guidance and context for CBS decision-making on policy issues. Also, the Corporate Members do not have a reference point against which to measure and assess CBS decisions. Progress on some important issues has been hindered by the lack of a policy framework. Some of the issues that would benefit the most from a national policy framework are:

- How to balance safety and affordability including what level of safety is appropriate for Canadians and at what costs
- The respective roles of the provincial/territorial ministries of health and CBS with respect to utilization management strategies for hospitals and physicians; this is required to control costs
- Plasma self-sufficiency

Corporate Members should develop a policy framework for the national blood supply system. The Members should also initiate a process for ongoing policy forums involving provincial/territorial governments, federal government, CBS, hospitals, physicians, consumer associations and researchers. There is also a need to review the MOU and improve its clarity in order to provide additional guidance.

The Corporate Members make the decision about how much funding to provide to CBS based on information supplied by CBS in their multi-year budget submission. The multiyear budget process has been time consuming, frustrating and ineffective. This is discussed in more detail in the financial review section. A contributor to the problems with the multiyear budget process is the fact that the relationship between CBS and the Corporate Members has been strained throughout most of CBS' four-year history.

Also, Members and CBS spend very little time in direct, face-to-face dialogue. While there is unanimous agreement that the relationship is improving, there is also agreement that there is a long way to go. These tensions have inhibited good, clear communication. Members do not always feel they get the information they need to make budget decisions and sometimes there is a lack of confidence in the information that is provided. CBS does not always feel they get appropriate policy direction.

There is a need for a vision for CBS that is shared between CBS and the Corporate Members. Although CBS has a vision statement and a transformation plan, there is a lack of a common understanding of where the organization is going, particularly as it relates to CBS' Transformation project and emerging trends and issues such as utilization and plasma self-sufficiency.

Regulatory Framework

In Canada, blood has been considered a drug since 1988 and is subject to regulations under the *Food and Drug Act*. Since the Krever Commission, Health Canada has strengthened its regulatory role in relation to the blood system. CBS is regulated by the Blood Establishment Regulation Division (BERD) of Health Canada. Each blood centre and CBS head office is audited by Health Canada once per year. Standard operating procedures (SOPs) must be documented in detail. New and revised SOPs must be approved by Health Canada. This process can be time consuming. Health Canada can also direct that certain safety procedures be adopted by CBS. Failure to comply with Health Canada regulations can result in loss of CBS' operating license.

A concern is that compliance with Health Canada regulations often has cost implications that must be absorbed by the provinces/territories. Some costs are direct costs such as the \$35 per bag increase in the cost of blood bags when universal leukoreduction was mandated. Other costs are indirect such as the staff time involved in writing and revising SOPs and dealing with Health Canada on SOP changes. As CBS and the Corporate Members strive to predict and control rising costs, they must find a way to take the impact of the regulatory environment into account. Each party has a role to play in this. When the regulator dictates operational changes, CBS should produce an analysis that describes the costs, benefits and risks of the change, identifies the fit with international best practices, identifies alternatives, and highlights the implications for CBS. This analysis should be shared with the Members and the Provincial/Territorial Contacts. If the Members have concerns about implementing the change from either a cost, benefit or risk perspective, they should initiate a dialogue with the regulator to address these concerns.

There are some changes currently underway with respect to the regulatory environment. Health Canada is developing a new regulatory framework that will improve efficiency, speed and adequacy of the regulatory process. The purpose is to ensure the safety of the blood system without placing an undue burden on either the regulator or CBS. CBS is also in discussion with the regulator about ways to minimize the number of SOPs and

to ensure that approval of new SOPs occurs in a timely manner. CBS must ensure that the Members are kept abreast of these changes.

Management Structure, Staffing and Service Delivery

As of March 2002, CBS employed 4,756 people across the country and had a volunteer base of 17,000. Leadership is provided by an Executive Management Team (EMT) that includes a Chief Executive Officer, three executive vice-presidents, three vice-presidents and an executive director of policy and planning.

The majority of CBS staff are affiliated with the 14 regional centres across the country. Each regional centre is headed by a “Centre Director” and a management team. Each Centre also has a Medical Director (part time) that provides medical leadership. Reports suggest that in the past each of the centres functioned quite autonomously. CBS is attempting to improve standardization. It is critical that these strategies continue expeditiously. A major concern in this regard is the existence of thousands of Centre Operating Procedures (COPs). COPs must be consistent with the Standard Operating Procedures developed by Head Office and approved by Health Canada and must be approved by both the Centre Director and the Centre’s Quality Systems Associate that reports to Head Office. However, they are specific to each Centre and Head Office has no consolidated information on how many COPs there are and for what subjects. This situation does not provide assurance that, in keeping with being a national system, the same procedures are in fact followed consistently across the country.

Another issue that should be addressed from a service delivery perspective is patient services. Some Centres provide a variety of services to hospital patients but there is no consistency across the country in terms of what patient services are provided. This is a concern because CBS reports that the full costs of providing patient services are not recovered (direct costs are identified and recovered but the associated administrative and overhead costs are not identified) and therefore these services are partially subsidized by Blood Operations.

Transformation

CBS is an organization in transition. From the time CBS took over the operations of the Red Cross the need for substantial organizational and service delivery improvements was identified. The “Transformation Project” is now underway. It consists of several initiatives that touch upon all of the core functions. The initiatives are aimed at increasing donations, improving quality, improving automation and improving efficiency and cost-effectiveness. Initially, 28 different projects were identified by CBS. The following seven projects have been highlighted by CBS as priorities:

- Implementation of the MAK Progesa system

- Creation of a National Donor Contact Centre
- Consolidation of Testing Centres
- Consolidation and Specialization of Production
- Implementation of a Change Control System
- Unrelated Bone Marrow Donor Registry
- Implementation of SAP HR/Payroll (this project went live July 1, 2002)

A description of each of the seven priority projects is included in the report.

Managing a restructuring initiative of this nature is a challenge for a new organization. CBS needs to improve the management of the transformation project including:

- Improving the communications related to the project, particularly for the provincial/territorial representatives many of whom lack a solid understanding of what is being done, when, why and at what cost
- Implementation of a rigorous program management methodology, including an integrated project plan
- Ensuring that comprehensive business cases are developed for each initiative
- Implementation of an organization-wide change management program for staff and volunteers.

Financial Cost Analysis

The total operating cost for CBS in 2001/02 was approximately \$687 million. (This does not include approximately \$103 million for fractionated products purchased for Hema-Quebec. These costs are fully recoverable from Hema-Quebec.) The operating budget for CBS has increased significantly each year since the organization was established. The increases are described as significant because they are much higher than the increases experienced in other parts of the health care system. From 2000/01 to 2001/02, total CBS operating costs increased by 13%. By comparison, Canada's health care sector experienced growth of 4.3% in 2001 however, other blood systems experienced similar growth rates to that of CBS.

The financial component of this review aims to provide a detailed description of the cost variances, identify the reasons for the variances and offer some commentary on the reasonableness of the cost variances. The detailed analysis is included in Chapter 2 of the report.

The review looked at each of the following business areas separately because they have different cost drivers: Blood Operations, Patient Services, Fractionated Products, Unrelated Bone Marrow Donor Registry.

Blood Operations expenditures have increased each year. In 2001/02, Blood Operations expenditures were \$351 million, a 14.7% increase over the previous year. The main cost drivers for Blood Operations are:

- The demand for blood products (the volume of blood components shipped to hospitals increased by 5.3% from 2000/01 to 2001/02; the units of blood (all components) collected by CBS increased by 7.1%)
- Salary costs, which reflect provincial collective bargaining agreements (CBS reports that the average annual salary increase is approximately 4% per year but can range from 1% to 10%)
- The regulatory environment that can impact labour hours and/or medical supply costs (e.g. manual expiry date labelling resulted in an increase of 32 FTEs; leukoreduction increased the cost of blood bags by approximately \$35 each which had a direct impact on the cost per unit of blood collected)

Expenditures increased in all areas of Blood Operations. The largest dollar increases were in whole blood collections, quality assurance and quality control and administration/overhead.

Expenditures for whole blood collections increased by \$8.9 million or 10%. This is a reasonable reflection of the 7.1% increase in the volume of collections and salary cost increases.

Donor recruitment costs increased by 16% and recruitment costs per unit of whole blood collected increased by 7%. To ensure cost-effectiveness, donor recruitment should be monitored closely from the perspective of costs versus outcomes/benefits.

Expenditures for quality assurance and quality control (QA/QC) increased by \$6.3 million or 62%. CBS attributes the cost variance to two initiatives – the Change Control Initiative and the System Wide Validation Initiative. For the Change Control Initiative, professional fees and travel costs were \$2.3 million and \$284,000 respectively. For the System Wide Validation Initiative, professional fees and travel costs were \$1.3 million and \$293,000 respectively. These costs are relatively high and should be monitored for cost-effectiveness and because once these projects have been completed a reduction in QA/QC should be observed. Labour costs for quality assurance and quality control increased by \$1.8 million or 21%.

From 2000/01 to 2001/02, total administration/overhead expenses increased by \$6.6 million. Combined administration/overhead for the national level and the regional centres was \$85.4 million in 2001/02. This represents 24% of Blood Operations expenditures. This is a high proportion of administrative/overhead expenses and steps should be taken to reduce these expenses to the 10 to 15% range.

From the perspective of the total Blood Operations budget, there has been little variance between the budget and the actual results for Blood Operations. In 2001/02, CBS was under budget by \$10.4 million and in 2000/01 they were over budget by \$1.3 million. However, closer examination shows an opportunity for improved demand forecasting and budget management at the regional centre level. For 2001/02, the

regional centres and the plasma centres had a combined negative budget variance of \$8.6 million. Thirteen out of fourteen regional centres and both plasma centres were over budget in 2001/02, despite the fact that they used fewer FTEs than was budgeted and some reported efficiency gains.

Blood Operations is the core business of CBS and as such a better understanding of the cost of producing each type of blood product is required. At present, CBS reports a crude estimate of cost per unit of red blood cells but this indicator does not reflect the true costs. Also, cost per unit indicators are not reported for the other blood products such as platelets and plasma.

Patient Services accounted for \$11.3 million or one percent of the total CBS budget in 2001/02. Patient Services includes a range of tests performed for hospital patients rather than blood donors. Each service is priced according to a fee schedule for billing purposes however, the fee schedule does not capture indirect overhead costs (e.g. administrative support in the centres, facility charges, finance and IT support from head office) or capital costs. CBS is encouraged to continue the examination of its role in the provision of patient services and analyzing the costs of providing these services.

Fractionated Products include a range of products derived from the various proteins found in plasma. The process of fractionation isolates and extracts specific proteins from pools of plasma. There are also some fractionated products that can be manufactured and are not derived from human plasma. These are called “recombinant” products. There has been a high demand for recombinant products because of the perception that they are safer than plasma-derived products.

Canada does not have a fractionation plant. Therefore, most fractionated products are purchased from American suppliers. The supplier ships the product from the U.S. to the CBS fractionated product warehouse in Ottawa. The warehouse then ships the products to each of the 14 Centres. The Centres ship the products to the hospitals along with their order of blood components.

CBS purchases Fractionated Products for Hema-Quebec and other customers. These costs are fully recoverable.

In 2001/02, CBS expenditures on Fractionated Products were \$313 million. This represents an increase of 11% or \$31.5 million over the previous year. The three main cost drivers for fractionated products are: the US/Canadian exchange rate, the cost per unit of fractionated products that is driven by market forces and the demand for fractionated products which is driven by hospitals, physicians, consumers and health care policy. Overhead costs account for \$5.2 million or approximately 1.6% of total fractionated costs (including Hema-Quebec costs).

Management of the Fractionated Products part of the organization poses a number of challenges for CBS. First, product prices have been increasing at a significant rate.

Second, product utilization by the provinces/territories has been increasing. Both of these factors contribute to overall cost increases and CBS feels they have little or no control over the cost drivers. However, CBS should explore opportunities to influence prices through contract management and to influence demand through utilization guidelines and education.

A second issue is that actual expenditures on Fractionated Products have exceeded budget for the past couple of years. The variance was \$16.5 million in 2001/02 and \$34.2 million in 2000/01. However, when CBS original forecasts are compared to the member-approved budget and the actual expenditures, the analysis demonstrates that the CBS forecasts of fractionation expenditures are a relatively good predictor of actual fractionation expenditures. Original CBS forecasts come within less than \$10 million (approximately 3%) of actual expenditures. However, due to funding constraints, the provinces and territories typically approve a budget that is less than the amount requested by CBS based on their forecast. The variances between the Member approved budget and the actual expenditures is much greater than the variance between the CBS forecast and the actual expenditures. These results underscore the importance of the provinces/territories and CBS working collaboratively to set realistic and evidence-based budget goals.

A third, and extremely important, concern related to Fractionated Products is working capital. A significant proportion of CBS's cash is tied up in inventory. At the time of this review, CBS reported inventory of \$78 million. Of that \$78 million, \$64 million consists of fractionated products and approximately \$10 million consists of medical supplies. Approximately \$3 million of the inventory is Whole Blood.

When CBS was created in September 1998, a total of \$27 million was provided to cover the cost of inventory for fractionated products. This figure has not changed over the last four years. The levels of inventory (i.e. number of weeks supply of product) that CBS maintains also has not changed in four years. Because the demand and cost of fractionated products has increased significantly, there is an inventory coverage shortfall. CBS must use \$37 million from its cash reserves to finance the unfunded portion of the fractionated inventory. Recently, CBS has resorted to the use of "Restricted Funds" to fund this \$37 million dollar shortfall.

The current working capital situation is a serious issue and it should be the number one priority addressed by CBS and its funders at this time.

The Unrelated Bone Marrow Donor Registry (UBMDR) accounted for \$9.4 million in expenses in 2001/02. This represents a budget variance of \$1.9 million and an increase of \$1.1 million over the previous year's actual. It should be noted that UBMDR revenue is also above plan by \$1.4 million, which partially offsets the \$1.9 million variance. Approximately \$4.9 million revenue is generated under the UBMDR program. UBMDR revenues are obtained by charging other blood organizations for performing donor searches. UBMDR expenses are all of the expenses incurred for

managing the registry. This includes all labour, medical supply and other costs. Under the current funding model, any variance between the revenue and the expenses must be funded from Blood Operations.

UBMDR expenses have been steadily increasing over the past few years. Based on this trend alone a continued increase into 2002/03 would be projected. However, this trend may be offset (in whole or in part) by the impact of a new bone marrow registry system that was implemented in June 2002. The new system is expected to reduce the effort and costs of the search process. CBS has initiated a UBMDR Audit to understand and match their costs against the sources of revenue. They are currently in Phase I of the audit and are working towards allocating costs in the most appropriate manner as well as providing a detailed price analysis.

Multiyear Budget Submission

CBS is required to submit a three year corporate plan and a one year budget to its Members. CBS budgeting begins with forecasts of the units of blood to be issued to hospitals served by each Centre. The SAP system is used for development of the budget except for the salary information. Preparing the multi-year budget submission is a long process which takes CBS approximately ten months. The process has been affected by the strained relationship between CBS and the Corporate Members, particularly when it comes to financial issues. Corporate Members and P/T Contacts feel that CBS has not always provided them with the information they need to support decision-making on the budget and corporate plan. CBS feels that the information needs have not always been clearly spelled out but that they have responded appropriately to specific information requests.

There is no mutually agreed upon template for submission of the multi-year budget submission and CBS would develop the format for submission. A review of the most recent corporate plan suggests many areas for improvement. The plan was not particularly user-friendly. The narrative component was lengthy and information was provided without a context in terms of Member decision-making needs. Financial data was included in an appendix at the end with minimal explanation of the financial figures which were often confusing. In the past, the information needs of the Members were communicated in a reactive fashion. That is, a set of questions and requests for clarification would be prepared after the initial submission had been presented. In June 2001, the Provincial/Territorial Blood Liaison Committee prepared a "Checklist for Consideration in Ongoing Budget/Business Planning Processes" that provides very specific guidance for the content of the multi-year budget submission. This report includes a suggested template for the multi-year budget submission as well as several specific recommendations to improve the process.

Information Services

The Information Services (IS) department is a centralized support function operating out of CBS' Lancaster Road location in Ottawa. The IS department is managed by a Chief Information Office (CIO) who reports up through the Vice President of Corporate Services/CFO. IS employs approximately 133 staff which are a combination of CBS staff and contracted consultants. The total operating budget for IS is \$14 million with an additional \$28 million being allocated to four transformational initiatives (e.g. MAK implementation, Centralized Contact Centre, Consolidated Testing, and UBMDR)

CBS has aggressively moved to centralize the management of technology infrastructure from the IS location. The IS department has adopted an agile approach to Information Technology strategy which allows it to update its plan annually. CBS' IS department has also successfully employed technology portfolio management as a planning and budgeting tool. CBS' IT strategic approach allows for a better focus on CBS operational drivers as its projected time horizon is not excessively distant, and the portfolio management approach allows it to align IT spending with overall CBS business drivers.

The information technology systems at CBS are not leading edge. This has been recognized by CBS and that is why a number of Transformation initiatives focus on improving technology and automation. In particular, the introduction of MAK Progesa is expected to address many of the shortfalls in the current systems. Some additional opportunities for improvement include:

- Review PC platform financing options and explore staggering its capital purchase or leasing with its current hardware vendor
- Implementation of a chargeback or cost allocation mechanism for telecom and office equipment costs incurred by various departments.
- Consider the creation of a central IS project management office to centrally manage the multiple issues and dependencies that the many proposed initiatives are expected to create; this would include a review of the change management and training plan.
- The current burden of five and seven part regulatory approvals for all changes to the BLIS and FPMS systems is burdensome. CBS and Health Canada should explore the creation of a pre-approved procedure for break, fix and maintenance procedures.
- Consider eliminating the PDSI system and include the donor scheduling and call list generation capabilities into the ESS system until the Central Contact Centre and CRM initiatives are complete.
- Revise the resource scheduling model to reflect actual clinic capability.
- Explore the use of mobile technologies or the expansion of remote access capabilities as part of the replacement of PDSI.
- Explore a system that would allow telemarketers to solicit potential donors if a clinic is closer to their home than one they have used in the past.

- Review the SAP licensing agreement and continue to benchmark per seat costs against other Ottawa companies and government organizations.
- Continue to explore aggressive enterprise re-pricing contracts that allow for tiering of user types as additional modules are considered.
- Consider the implementation of employee time-entry as a next-stage project for SAP.

Operational Performance

CBS has made substantial progress in implementing performance indicators that focus on the four priority areas for the organization: enhance customer service, improve quality and safety, increase cost-effectiveness and greater employee satisfaction. There are two levels of performance measures: corporate measures and operational measures. Corporate measures were introduced by CBS in September 2001 and the operational measures in April 2002. However, at this stage, it appears that the implementation of the operational performance measures is further ahead than implementation of the corporate measures. Targets have been established for the operational performance measures but not for all of the corporate performance measures.

The performance measurement process was too new to support an adequate assessment of its effectiveness but there was evidence that the performance measurement program has been disseminated widely throughout the organization, is being used by the Centres and has been well-received.

This review assessed CBS performance relative to the ten guiding principles set out in the MOU. A summary of this assessment is provided in the table below:

Guiding Principle	Achievements	Areas for Improvement
The safety of the blood supply is paramount.	<ul style="list-style-type: none"> • New donor screening questions have been added • Donor deferral policy for vCJD has been implemented • Universal leukoreduction has been introduced • Two new tests (NAT-HCV and NAT-HIV) have been introduced to detect Hepatitis C and HIV earlier than with traditional testing • Manual expiry date labelling has been introduced • Quality Systems Department is in place • Most stakeholders and the general public feel that safety has improved 	Need to review the cost-effectiveness of NAT testing in light of the actual number of “window” cases detected and recently introduced royalty costs.
Adequacy and security of supply of all needed blood, components and plasma fractions	<ul style="list-style-type: none"> • Volume of blood collected has increased every year since 1998 • 83% of hospitals reported that order lead times meet their requirements 	<ul style="list-style-type: none"> • Hospital issues have not kept pace with the volume of collections; CBS has not met its target in terms of

Guiding Principle	Achievements	Areas for Improvement
for Canadians should be encouraged. A national blood supply program should be maintained.	<ul style="list-style-type: none"> • Bi-weekly fractionated products update is issued to all Centres, hospitals and Health Canada • 80% of hospitals reported their satisfaction with acquisition of fractionated products to be “very good” or “good” • Each Centre has a Service Interruption Recovery Plan • A contingency fund is in place for emergencies 	<p>meeting hospital demand</p> <ul style="list-style-type: none"> • The target for meeting hospital demand should be more ambitious • Elective surgeries have been cancelled as a direct result of a blood product shortage; this indicator should be tracked by all hospitals and reported to CBS
A national blood supply program should be maintained.	<ul style="list-style-type: none"> • Blood is regularly imported/exported to different provinces based on need • Standard Operating Procedures are developed at the national level • A number of support functions have been centralized nationally (IT, payroll, purchasing, marketing, communications) • Some national strategies have been developed by Head Office • Plans are in place for consolidation of a number of core functions including testing, manufacturing and telerecruitment 	<ul style="list-style-type: none"> • Degree of variation among Centres should be addressed (e.g. variations in services provided, existence of a large number of Centre-specific operating procedures)
A fully integrated approach is essential.	There is a need to clarify the definition of this principle.	
National self-sufficiency in blood and plasma collections should be encouraged.	<ul style="list-style-type: none"> • Canada is self-sufficient in red blood cell collections and platelet collections 	<ul style="list-style-type: none"> • Plasma collections are less than 30% of the nation’s requirements • The location of the two plasma centres should be reviewed in terms of critical mass and viability • A clear policy on plasma self-sufficiency is required
Accountabilities must be clear.	<ul style="list-style-type: none"> • CBS demonstrates accountability to Members through annual submission of a 3 year corporate plan and budget • CBS complies with Health Canada regulations 	<ul style="list-style-type: none"> • There are ambiguities in the MOU • There is a lack of consistent understanding of the roles of the Corporate Members and CBS
The system must be transparent.	<ul style="list-style-type: none"> • CBS has a National Liaison Committee with consumer representation that reports to the Board • Two open board meetings are held each year • Board minutes and audit results are 	<ul style="list-style-type: none"> • Information sharing is based on a “public relations” model whereby the decision about which information to share publicly is still largely made by CBS.

Guiding Principle	Achievements	Areas for Improvement
	<p>posted on the CBS website</p> <ul style="list-style-type: none"> • Consumer associations have been consulted on relevant policy issues • CBS meets with the National Blood Safety Council and participates in their forums. 	
<p>A cost-effective and cost-efficient blood supply program for Canadians should be encouraged.</p>	<ul style="list-style-type: none"> • Mandatory appointment booking for donors so that clinic activity is more predictable • A standardized clinic model • Centralization of key support functions such as information technology, finance, payroll and purchasing • Tracking of operational performance measures and comparing these metrics across the various Centres • Bloodmobile pilot underway • Plans developed for: MAK Progesa system to automate many information management functions that are currently done manually; PRISM technology to replace traditional testing for enzyme linked immuno-assay with a less labour intensive process; Consolidation of testing from 11 laboratories to three laboratories; a National Contact Centre to replace the decentralized donor telerecruitment function 	<ul style="list-style-type: none"> • Costs per unit should be calculated for all blood components not just red blood cells • CBS has not met its target to reduce the cost per unit by 5% • Labour hours per unit varies significantly across Centres • Administrative overhead costs represent a relatively high proportion of total expenditures • The wastage rate for blood bags is approximately 5% • Discard rates are high for all blood components (based on both expert opinion and CBS' own targets) • Consideration should be given to CBS' role in facilitating inter-hospital transfer of blood products to minimize hospital discard rates for outdated blood products • Sole supplier contracts should be re-examined • Utilization management guidelines for fractionated products are required
<p>Voluntary donations should be maintained and protected.</p>	<ul style="list-style-type: none"> • All donations are voluntary • Donations have increased over the years • Donor satisfaction is monitored regularly and a Donor Advisory Panel is in place 	<ul style="list-style-type: none"> • There is a need to increase the percentage of the eligible population that are donors (current rate is 3.6%)
<p>Gratuity of all blood, components and plasma fractions to recipients within the insured health services of Canada should be maintained.</p>	<p>Currently blood is free to all recipients that are covered by Canada's health insurance program</p>	

Risk Management

Risk Management mechanisms are systems within CBS that control risk, provide monitoring, feed information back to management, and allow for change within the risk management architecture. They include:

- Member reviews
- Board oversight
- Management oversight
- Regulatory oversight
- Insurance
- Emergency Response
- Competency profiles of employees
- External accreditation
- Courses and training
- Change Control Operating Procedure

While the organization has had informal risk management capacity for some time (as described above), the capacity for formal, structured risk management is still being put in place. As the first of four phases of implementing risk management, a plan for roll-out has been developed. Recent changes include the development of the framework, dedicating staff to risk management, separating Quality Assurance from manufacturing, and planning for risk management training of key staff. The second phase, “Development”, is in progress. A number of initiatives are under development, including the completion of a Risk Management Manual. It is noted that implementation is behind the schedule set in the Risk Management Program Update in February of 2002. This is an area of concern. Although the delay may simply be attributed to ambitious planning that did not factor delays into the timelines, it may also suggest that risk management is having difficulty competing for resources within the organization.

As mandated by the MOU, the Board of CBS has approved a framework to guide risk management at CBS.¹ It sets out the objects of the corporation as set out in the Letters Patent. It also provides references to materials and literature used to develop the framework. This framework is structured, comprehensive and focused on the needs of the particular organization. It follows a logical sequence. A number of specific suggestions to further improve the framework are included in the report. It must be noted that the Risk Management Framework does not specifically resolve the governance issue concerning the importance of safety.

As part of the assessment, documentation of a few recent and significant CBS decisions was reviewed to determine if risk management was integrated into the decision making

¹ It is understood that this policy is currently under revision.

process. The decision regarding consolidation of testing to three existing laboratories was reviewed most comprehensively. Overall, the review showed that risks were comprehensively considered, analyzed, and factored strongly in these decisions.

Opportunities for improvement to the risk management function include:

- Provide clarity in governance (i.e. the MOU)
- Rationalize Risk Management Policies
- Rationalize Risk Management Tools and Framework
- Apply the Framework Early and Often
- Exercise Discipline in Applying Frameworks and Tools
- Develop a Common Risk Management Language
- Provide leadership and change management support for implementation
- Build Risk Management into continuous learning
- Improve the systems to support the processes
- Continually improve the Risk Management Framework.

CBS has come along way in its short, four-year history. Many board members and staff commented that the situation they inherited was worse than they thought. There were lots of bridges to build and fences to mend but more importantly there was a great deal of work for the new leaders to do. What did not take long however, was the process for the leadership to understand the mandate of the organization and to embrace the concept of “safety is paramount” that has come to characterize CBS in the eyes of many stakeholders.

This review found an organization in which board members and executive leaders are committed to the success of the organization. Although the review did not include many opportunities for contact with frontline workers, when board and management were asked to identify the strengths of the organization, the frontline staff was the most common response. Clearly, CBS is evolving and will soon be “transforming” as it attempts to keep pace with international best practices in blood operations.

CBS’ ability to achieve its Transformation objectives and to continue to satisfy the terms set out in the Memorandum of Understanding will depend on its ability to address a number of issues.

In the coming months, it will be important for CBS and the Members to develop an action plan for moving forward with the suggestions emanating from this review. It is suggested that once the urgent financial matters have been resolved that role clarification, visioning and cost saving opportunities take precedence. This should be followed by a review of the MOU with a view to updating the MOU to reflect the current realities and future directions.

A summary of all of the review recommendations is provided in section 7 of the report.