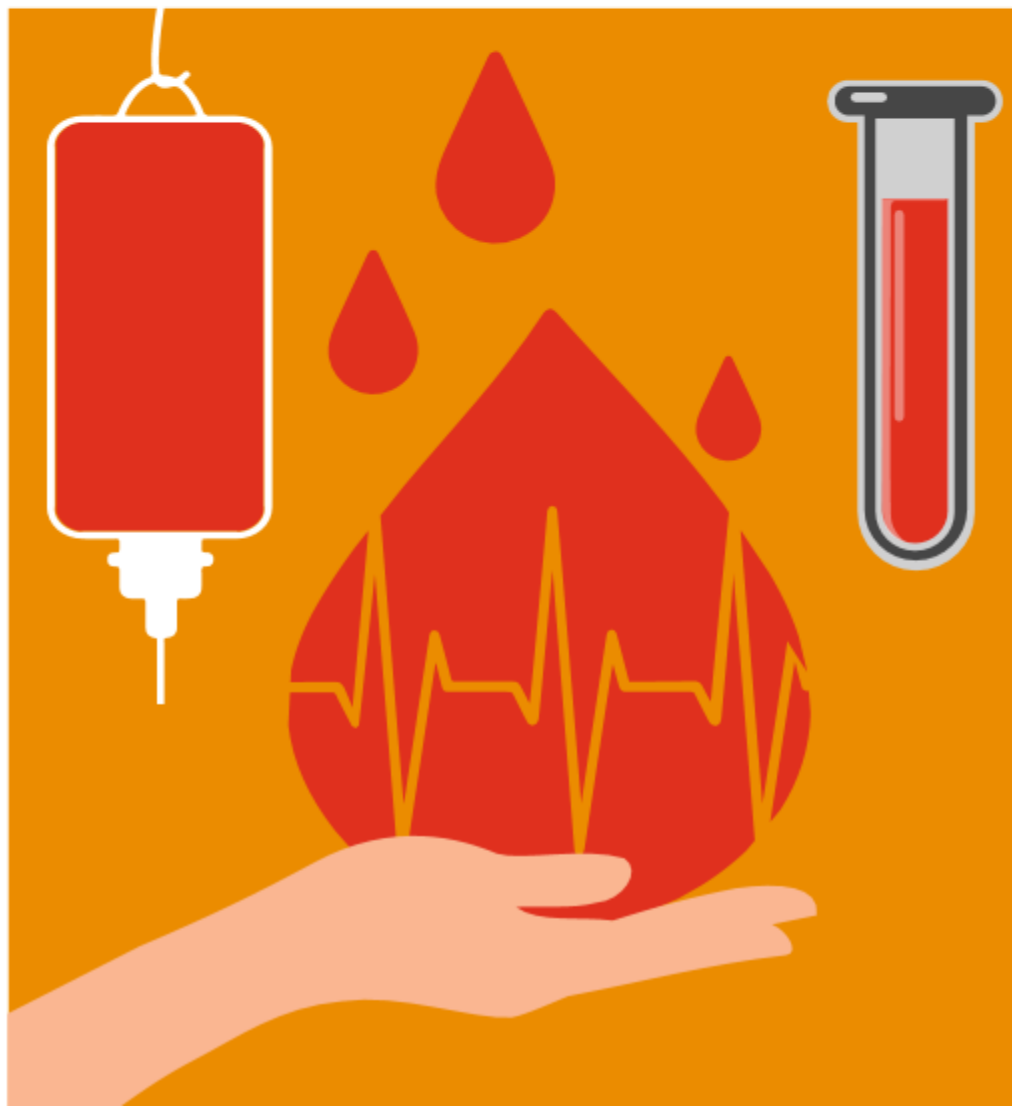


# 2019 Collaborative Performance Review

**Canadian Blood Services**

**Final Report**

May 2020





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May 22, 2020

Dear Corinne and Lindy:

**Subject: Report on the 2019 Collaborative Review of Canadian Blood Services (CBS)**

PricewaterhouseCoopers LLP (PwC) is pleased to present our final report on the results of the 2019 Collaborative Review of Canadian Blood Services. The review covered the seven year period from April 1, 2012 to March 31, 2019.

Our review covered the financial and operational performance of the organization, addressing the specific areas of scope that had been jointly identified by CBS and the Members. To present a balanced view of CBS' performance, we have included commentary on aspects that CBS performed well and also highlighted a number of areas where improvements can be made.

We do think reporting performance for seven years in one report was challenging and performing this review every 3-5 years might be a better approach for the future.

We also suggest that CBS and the Members consider expanding the scope of this review to a "system-wide" performance review and include sample visits to a few hospitals to truly incorporate aspects of patient needs, patient experience, utilization, etc., rather than only limit it to CBS operations. This will provide a holistic perspective of the performance of Canada's national blood supply system.

We would like to thank the Performance Review Working Group and the Canadian Blood Services leadership team and personnel for their assistance throughout the review.

If you have any questions or require clarification, please contact me directly at 416 687 8338, or via email, at [gupta.arun@pwc.com](mailto:gupta.arun@pwc.com).

Yours sincerely,

A handwritten signature in black ink, appearing to read "Arun Gupta", with a horizontal line drawn underneath.

**Arun Gupta**  
Transformation Assurance Leader  
PricewaterhouseCoopers LLP

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This Report was developed in accordance with the Agreement dated January 21, 2020 (and Amending Agreement No. 1 dated March 24, 2020) and is subject to the terms and conditions included therein.

Our work was limited to the specific procedures and analysis described herein and was based only on the information made available at the time we prepared the Report. Accordingly, changes in circumstances after the date of this Report could affect the findings outlined herein.

We are providing no opinion, attestation or other form of assurance with respect to our work and we did not verify or audit any information provided to us.

Our work did not include a detailed examination of CBS' processes, procedures, controls, and financial and non-financial information, since this was a performance review and not a detailed process review.

Financial information was reviewed for reasonableness and selective validation was performed against source documents, taking into account materiality/significance.

Financial and non-financial data was not audited/validated against CBS source systems for accuracy and completeness.

The collections, testing and productivity metrics analyzed in Section 3.1 (Financial Performance) were independently reviewed by a third-party professional services firm, which included verifying the accuracy of data against source systems for the last 3 years of this review. No major issues were noted.

The benchmarking data for Fresh Blood Components, presented in Section 3.1, and associated explanations have not been independently verified by PwC.

This information has been prepared solely for the use and benefit of and pursuant to a client relationship exclusively with the Government of PEI and Canadian Blood Services. PwC disclaims any responsibility to others based on its use and accordingly this information may not be relied upon by anyone other than the Government of PEI and Canadian Blood Services.

# List of Acronyms



<b>ABO</b>	Alliance of Blood Operators
<b>AIQ</b>	Analytical Instrument Qualification
<b>AR</b>	Adverse Reaction
<b>ASC</b>	Automated Supply Chain
<b>ATRs</b>	Adverse Transfusion Reactions
<b>BCY</b>	British Columbia and Yukon (region)
<b>BoD</b>	Board of Directors
<b>CAPA</b>	Corrective Action and Preventive Action
<b>CADTH</b>	Canadian Agency for Drugs and Technologies in Health
<b>CBS</b>	Canadian Blood Services
<b>CBSE</b>	Canadian Blood Services Insurance Company Limited-Excess
<b>CBSI</b>	Canadian Blood Services Insurance Company Limited
<b>CDM</b>	Conference of Deputy Ministers
<b>CEO</b>	Chief Executive Officer
<b>CFO</b>	Chief Financial Officer
<b>CIO</b>	Chief Information Officer
<b>CI</b>	Continuous Improvement
<b>CIPO</b>	Canadian Immunodeficiencies Patient Organization
<b>CMV</b>	Cytomegalovirus
<b>CMWG</b>	Cost Model Working Group
<b>COSO</b>	Committee of Sponsoring Organizations of the Treadway Commission
<b>CPI</b>	Consumer Price Index
<b>CPP</b>	Canada Pension Plan
<b>CRM</b>	Customer Relationship Management
<b>CSA</b>	Canadian Standards Association
<b>DCA</b>	Donor Care Associate
<b>DSR</b>	Donor Services Representative
<b>DTIS</b>	Donor Time in System
<b>EAs</b>	Errors and Accidents
<b>EAP</b>	Exceptional Access Program
<b>EDRD</b>	Expensive Drugs for Rare Diseases
<b>EI</b>	Employment Insurance

<b>EM</b>	Environmental Monitoring
<b>EMA</b>	European Medicines Agency
<b>EMT</b>	Executive Management Team
<b>ePMO</b>	Enterprise Program Management Office
<b>ERM</b>	Enterprise Risk Management
<b>ERP</b>	Enterprise Resource Planning
<b>FBC</b>	Fresh Blood Components
<b>FDA</b>	Food and Drug Administration
<b>FEX</b>	Foreign Exchange
<b>FTE</b>	Full-Time Equivalent
<b>GMPs</b>	Good Manufacturing Practices
<b>G&amp;A</b>	General and Administrative
<b>HC</b>	Health Canada
<b>HCV</b>	Hepatitis C Virus
<b>HEV</b>	Hepatitis E Virus
<b>HIV</b>	Human Immunodeficiency Virus
<b>HLA</b>	Human Leukocyte Antigen
<b>HPA</b>	Human Platelet Antigen
<b>HTAs</b>	Health Technology Assessments
<b>HTLV</b>	Human T-cell Lymphotropic Virus
<b>ICCBBA</b>	International Council for Commonality in Blood Banking Automation
<b>Ig</b>	Immunoglobulin
<b>KPIs</b>	Key Performance Indicators
<b>LHU</b>	Labour Hours per Unit
<b>LMS</b>	Learning Management System
<b>LVP</b>	Large Volume Platelet
<b>MAPE</b>	Mean Absolute Percentage Error
<b>MOU</b>	Memorandum of Understanding
<b>NAA</b>	National Accountability Agreement
<b>NAC</b>	National Advisory Committee on Blood and Blood Products
<b>NBA</b>	National Blood Authority
<b>NHD</b>	National Hemophilia Database (UK)
<b>NHS</b>	National Health Service (UK)
<b>NIRL</b>	The National Immunohematology Reference Laboratory

<b>NPS</b>	Net Promoter Score
<b>OECD</b>	Organization for Economic Co-operation and Development
<b>OTDT</b>	Organ and Tissue Donation and Transplantation
<b>pCPA</b>	pan-Canadian Pharmaceutical Alliance
<b>PDI</b>	Post Donation Information
<b>PEP</b>	Productivity and Efficiency Program
<b>PM</b>	Preventive Maintenance
<b>POs</b>	Purchase Orders
<b>POS</b>	Point of Sale
<b>PPP</b>	Plasma Protein Products
<b>PT</b>	Provinces and Territories
<b>PTBLC</b>	Provincial Territorial Blood Liaison Committee
<b>PRWG</b>	Performance Review Working Group
<b>RBC</b>	Red Blood Cell
<b>RBDM</b>	Risk Based Decision-Making
<b>RHA</b>	Regional Health Authorities
<b>rf</b>	Recombinant Factor
<b>RFP</b>	Request for Proposal
<b>QMS</b>	Quality Management System
<b>QMSR</b>	Quality Management System Review
<b>SCIg</b>	Subcutaneous Immunoglobulin
<b>SD</b>	Solvent Detergent
<b>SOPs</b>	Standard Operating Procedures
<b>Sr.</b>	Senior
<b>SRAC</b>	Scientific and Research Advisory Committee
<b>SREC</b>	Safety, Research and Ethics Committee
<b>TMC</b>	Talent Management Committee
<b>TRALI</b>	Transfusion-Related Acute Lung Injury
<b>TTISS</b>	Transfusion-Transmitted Injuries Surveillance System
<b>VP</b>	Vice-President

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# Executive summary

The independent inquiry into Canada's tainted blood scandal, led by Ontario Court of Appeal Justice Horace Krever, recommended the creation of a single, independent blood authority that would replace the Canadian Red Cross Society. This new blood authority would operate at arm's length from the provinces and territories and would be regulated by the federal government. In response, Canadian Blood Services (CBS) was established in 1998 as an independent, not-for-profit organization with responsibility for Canada's blood system. The Memorandum of Understanding (MOU) between the federal, provincial and territorial governments (excluding Quebec) is the governing document for Canada's blood system and CBS.

The MOU established the collaborative governance framework that guides the management and oversight of Canada's national blood supply system. Through this framework, governance of the system is assigned to three principle parties: the Provincial and Territorial Health Ministers (i.e., "Members"), a Board of Directors (BoD), and a Chief Executive Officer.

The Provincial and Territorial Health Ministers are responsible for:

- setting of CBS' mandate/mission;
- approving CBS' three-year corporate business plan, including performance objectives and funding requirements;
- selecting the members of CBS' Board of Directors; and
- oversight of the expenditure of public funds provided to CBS to execute its mandate.

The CBS BoD is responsible and accountable for the overall stewardship of CBS and directors are entrusted with overseeing the management of the organization. While the Members have overall accountability for the national blood supply system, the MOU specifically provides CBS with full management discretion over operational decisions.

The Provincial Territorial Blood Liaison Committee (PTBLC) supports Members in executing their responsibilities. PTBLC representatives interact with CBS on an ongoing basis and provide advice and support on issues to the Provincial and Territorial Deputy Ministers and Ministers of Health.

CBS' annual budget is negotiated with the Provinces and Territories (PT) through the PTBLC and approved by the Members. For Fresh Blood Components (FBC), each Member's budget allocation is determined based on its share of red blood cell shipments in relation to total red blood cell shipments. For Plasma Protein Products (PPP), Members pay for the actual costs of products consumed by hospitals in their respective provinces/territories and a portion of administrative expenses. Members are accountable within their jurisdictions for the appropriate use of the public funds provided to CBS to deliver on its mandate.

Consistent with and complementary to the MOU, CBS and the Members have developed a National Accountability Agreement (NAA) that clarifies collective accountabilities and deliverables, and eliminates the need to negotiate bilateral agreements with individual provinces and territories. It is expected that the draft NAA will be approved and implemented in fiscal year 2020-21.

CBS collects, tests, manufactures and distributes blood and blood products, including red blood cells, platelets and plasma. Some of the plasma collected by CBS is retained to meet the transfusion needs of Canadian patients who require treatment for trauma, burns, cancer and blood diseases. Plasma not used for transfusion is shipped to contract manufacturers of PPP retained by CBS to manufacture its plasma into fractionation products that are returned to Canada. CBS distributes approved PPP derived from the plasma that it has collected as well as those purchased from manufacturers, to hospitals in Canada (excluding Quebec) for the treatment of immune deficiencies and a multitude of other disorders.



In addition to its fresh blood and PPP business lines, CBS operates several programs that support better outcomes for patients living with the many diseases and disorders that can be treated with stem cell transplants, including collection of cord blood.

CBS manages a national transplant registry for interprovincial organ sharing, as well as related programs for donation and transplantation.

This performance review was initiated by the Members and CBS to evaluate the performance of CBS from April 1, 2012 to March 31, 2019 with regards to financial and operational performance, including safety and supply needs of customers, selected strategic initiatives and key corporate activities (i.e., governance and enterprise risk management).

The results of this performance review are founded on a combination of:

- qualitative and quantitative analysis;
- review of CBS' key performance indicators (KPIs);
- comparison of CBS' practices (e.g., PPP utilization management and procurement) to those of other jurisdictions as well as leading practices;
- input and perspectives from members of the expert panel assembled by CBS and PTs to support the review, by providing expertise in the areas of transfusion medicine, blood operator management, hemophilia and bleeding disorders, and PPP management; and
- benchmarking of selected CBS productivity metrics against other blood operators.

An overview of our performance review methodology is provided in Section 2.1.

**Over the review period, CBS performed well, ensuring the safety of the national blood supply system and meeting the needs of a diverse group of stakeholders.** Notable achievements that contributed to CBS' performance included:

- Maintained high levels of satisfaction amongst stakeholders regarding its ability to act as a steward of blood and the blood products system and its role in achieving patient outcomes
- Obtained Members' approval and funding to establish three proof-of-concept plasma donor centres to mitigate the risk of not being able to meet Canada's Immunoglobulin (Ig) demands, given the ever increasing global demand for Ig products and Canada's low level of plasma sufficiency
- Implemented several initiatives to improve the donor experience and retention, including the Donor Experience/Brand Renewal Project, aimed at building a strong and diverse donor base and the introduction of digital technologies to facilitate and speed up the donation process
- Established new PPP contracts that resulted in cost savings and avoidance of \$857 million over the review period
- Achieved close to \$60 million in productivity and efficiency savings over the review period
- Implemented a Continuous Improvement (CI) Program based on lean management techniques and the principles of the world renowned Toyota Production System
- Evolved its quality management system to align it with the standards of a biologics manufacturer
- Led an international committee of experts in developing a Risk Based Decision-Making (RBDM) Framework for blood operators. The Framework provides a new paradigm for blood safety decision-making with a health sector focus and a standardized approach supported by risk assessment tools.

A full listing of our findings and recommendations is provided in Appendix 1. Below we have provided a summary of the key observations<sup>1</sup>, findings and recommendations for each area covered in the performance review.

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<sup>1</sup> Observations are activities/ initiatives that CBS is doing well and have no associated recommendations.

The safety of the blood supply is paramount and safety considerations permeate every decision made by CBS. **Survey results over the review period indicated that the majority of hospitals, donors and the Canadian public viewed CBS' products as safe and CBS was assessed as being compliant with Health Canada (HC) and other third party safety requirements. Similarly, the majority of donors and the public viewed the process of donating blood as being safe.**

**CBS reduced its costs for Fresh Blood Components by \$28M (6%), mainly through the reduction of staff costs and medical supplies costs.** This was achieved through productivity improvements in the areas of collections, testing and production, combined with better contract pricing for medical supplies. While CBS improved the productivity of key FBC functions, it was less productive than some comparator blood organizations.

We recommend that CBS continue to build on its productivity gains and further improve its performance by learning from initiatives implemented by other blood operators and leverage its CI Program to identify and implement leading practices.

**CBS achieved \$59.7 million out of its \$62 million savings target.** These savings were attributed to the FBC business line and fell slightly below target due to incremental logistics expenses and additional donor relations expenses.

**Donor retention declined in six out of seven years, which presents a risk in meeting customer needs for FBC.** To address this risk, we recommend that CBS establish a task force consisting of representatives from CBS and healthcare agencies to review existing processes, capabilities and technology and identify new opportunities for improving donor retention.

**The PPP business line has become a significant focus area for the Members and CBS.** PPP constituted 46% of CBS' total spend in 2012-13 and 56% of CBS' total spend by 2018-2019. PPP spend increased by approximately \$185 million (39%) over the review period. While CBS negotiated several new contracts, which resulted in more favourable product prices and cost savings and avoidance of over \$800 million, the demand for PPP, coupled with a weakening Canadian dollar, outpaced the savings CBS achieved in per unit product costs.

**While work is underway to set-up three proof-of-concept plasma donor centres, CBS' ability to meet Canada's Immunoglobulin demand will be at risk if further action is not taken.** At the end of 2018-19, the plasma collected by CBS accounted for 15% of overall Ig demand. The global demand and pricing for PPP products are consistently increasing and will affect CBS' ability to meet the national demand.

CBS has been working with Provincial and Territorial governments to ensure an appropriate level of plasma sufficiency in Canada to support Ig use for life-saving treatment. Funding for three plasma proof-of-concept collection sites (Sudbury, Lethbridge, and Kelowna) was approved by Members in March 2019. The Plasma Proof-of Concept Collection Sites Reporting Framework outlines the performance metrics and reporting approach that will be used to assess the extent to which the plasma proof-of-concept collection sites are meeting the agreed upon performance metrics. Performance results will allow funders to make informed judgements and decisions regarding the overall performance success of the plasma proof-of-concept collection sites. These performance metrics will also provide key information that will guide strategic discussions on the issue of plasma self-sufficiency and may inform future funding requests.

We recommend that **CBS continue to examine options to increase plasma self-sufficiency within Canada to reduce dependency on US and global suppliers. This may require a discussion with the Members at a strategic level to evaluate various options and should be informed by the performance results of the three plasma proof-of-concept sites as they become available.**

**CBS has a formal product selection process for PPP which includes consideration of a range of factors (e.g., safety and efficacy of products, security of supply, competitive pricing) when evaluating products.** Further, CBS' approach to procuring PPP is similar to other countries and reflects broader public sector procurement principles and practices. Both processes incorporate value

for money principles.

Given the increasing demand and cost of PPP, we recommend that CBS and PTs jointly assess existing utilization management activities within health systems and develop ways to more effectively control PPP demand. Further, CBS and PTs should continue to collaborate on updating the eligibility criteria, which drives product selection, as part of the CBS Drug Formulary review process initiated after the end of the performance review period.

**CBS should improve its approach to transition management when existing PPP are replaced by new product categories or brands.** Resulting product changes can have a significant impact on PT health facilities and patients. An independent review of the 2017-18 PPP Request for Proposal (RFP) process highlighted the need to understand the financial and workload impacts on clinics/new providers and better manage the communication and implementation steps required for these changes.

We recommend that CBS consult more extensively with PTs to perform an analysis of the health system implications of product changes and develop an appropriate transition plan. CBS should also evaluate alternative strategies, beyond simply tendering, to derive additional value from future PPP procurement activities.

**CBS has made good progress in aligning its Quality Management System (QMS) with that of a biologics manufacturer and strengthening its quality culture.** We identified a number of opportunities for CBS to further enhance this initiative, including benchmarking CBS' safety performance against other comparable organizations and incorporating quality performance measures as part of senior management's annual performance reviews.

**CBS did not encounter any significant shortages in meeting the demands of customers for FBC and PPP, over the review period. We identified two areas of focus for the organization:**

- **Replenishing the stock of O-negative blood products has been challenging as the demand for O-negative blood is much higher than the proportional number of donors.** We recommend that CBS request that PT Ministries of Health facilitate agreements with hospitals that would allow CBS to proactively monitor and influence O-negative hospital inventories with a national, system-wide lens.
- **Enhanced data sets from hospitals would help support more accurate forecasting for PPP.** CBS gets limited data from patients, physicians and industry for forecasting and predicting future PPP demand. CBS requires an expanded data set to better inform its forecasting for PPP, especially for new products, brand changes, and new uses for existing products. We recommend that CBS and the PTs explore opportunities for hospitals to share data supporting PPP use with CBS.

**CBS established a CI Program, with the help of Toyota, in March 2015** to identify sources of waste and non-value add activities in CBS' supply chain. The CI Program was initially aimed at the production and distribution processes but progressed to target improvements in the quality and collection processes towards the latter stages of the review period. CBS attributed improvements in productivity across production and distribution to the CI Program.

**The absence of regular benefits tracking and reporting makes it difficult to monitor the success of the CI Program** and understand how improvements in productivity metrics are correlated to specific initiatives under the Program.

We recommend that CBS develop a benefits realization management framework for the CI Program to enable systematic tracking of benefits and increased visibility into the overall benefits.

**Our review of two strategic initiatives, Automated Supply Chain (ASC) and Donor Experience/Brand Renewal, found challenges with benefits realization.** While the ASC project was delivered ahead of schedule and on budget, there were a number of gaps with respect to delivery of core benefits. Some of these challenges were related to measurement and others to tracking and accountability. To address these issues, we recommend that:

- CBS ensure that benefits measures are clearly defined in project business cases along with clear

accountability for who should measure and who is expected to achieve them.

- As part of its major projects reporting process to the Board and Members, CBS should formally report on the financial benefits realization throughout the project.

The Donor Experience/Brand Renewal project was delivered on time and under budget. At the time of project close-out, some of the benefit realization measures related to donor retention and public perception of CBS were below target. We recommend that CBS prepare an action plan to support the tracking and realization of the benefits that have not met their targets.

**Over the current review period, CBS maintained a governance structure that was aligned with the requirements of the MOU and reflected elements of good governance based on leading practices.** There was consensus amongst stakeholders that CBS' governance model functioned well overall, and that CBS worked within the governance framework in an effective manner.

We recommend that CBS continue to support Members' efforts to enhance the diversity of its BoD, develop a Board succession plan that addresses, amongst other factors, the diversity of the BoD, and continue to improve the content and timeliness of reports/materials provided to the Members and PTBLC representatives.

We also recommend that CBS work with PTBLC representatives to create an orientation program for onboarding of new representatives to familiarize them with CBS and their new role.

**CBS evolved its Enterprise Risk Management (ERM) Program and took steps to strengthen its Business Continuity Management (BCM) practices.** While both areas have matured, there are opportunities for further improvement. Most notably, the opportunity exists to consolidate the operational risk view for FBC and PPP through separate risk registers with detail around existing and emerging risks.

**CBS used RBDM across the FBC and PPP business lines to support significant decisions that resulted in value for money within the health risk framework.** CBS applied RBDM to:

- guide decisions regarding the extent and type of testing required for emerging pathogens that could threaten the blood supply. The RBDM framework was used to undertake analyses that balanced cost, health risks, ethical considerations and patient benefits/outcomes and provided evidence-based recommendations to decision-makers.
- assess anticipated risks to the security of the plasma supply needed to manufacture Ig for Canadian patients, and to evaluate available risk management options. The analysis informed the business case for the three "proof of concept" plasma donor sites.

# 1

## Introduction

1.1 Background and context

1.2 Purpose of the review

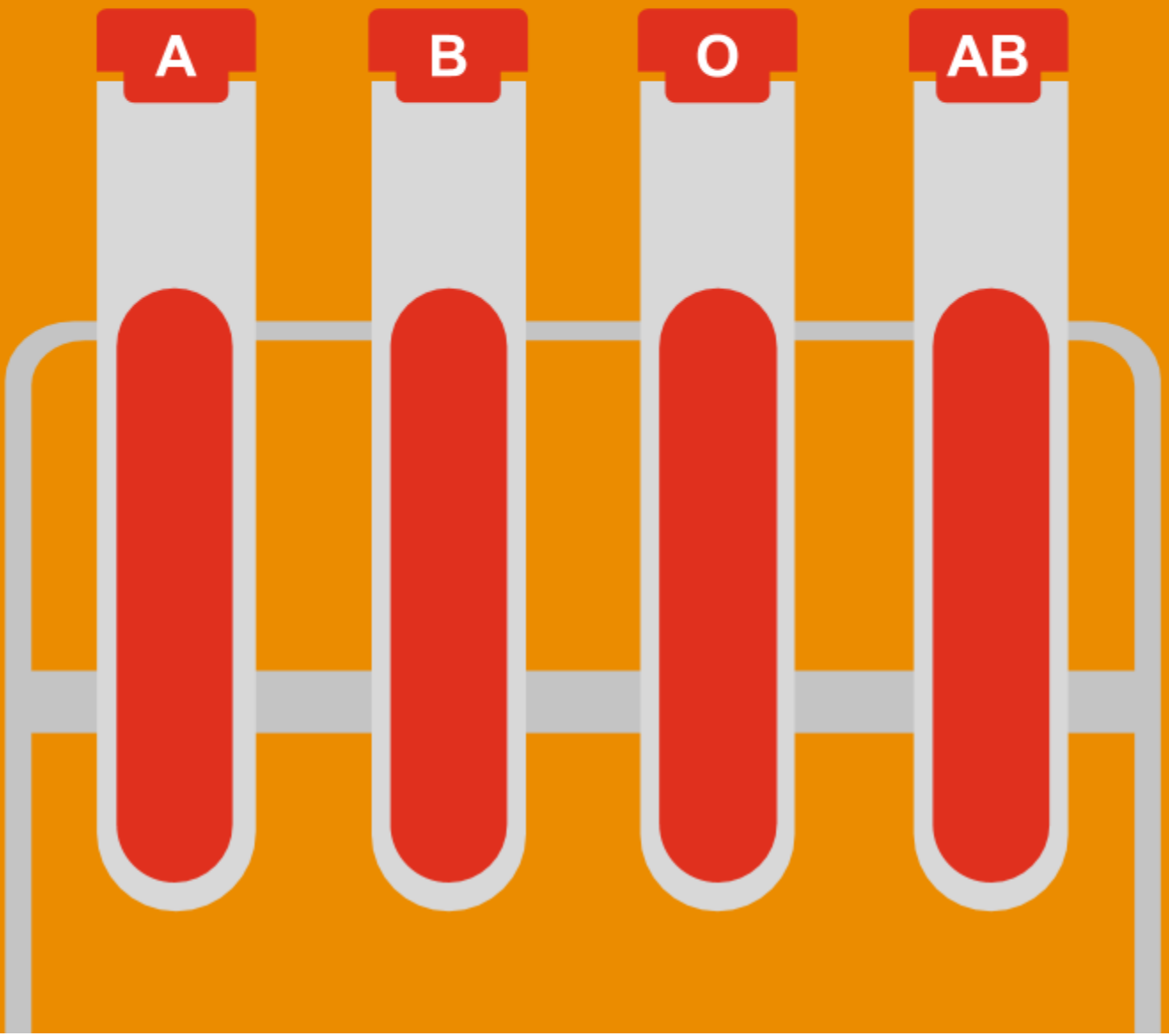
1.3 Report Structure

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B

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AB



# 1. Introduction

## 1.1 Background

Canadian Blood Services is the national, not-for-profit organization that manages the supply of blood and blood products in all provinces and territories outside of Québec. CBS was created in response to the Krever Commission's report on the contaminated blood crisis which called for a new blood services organization to replace the Canadian Red Cross Society and the Canadian Blood Agency and restore public trust in the safety and quality of Canada's blood system.

CBS was established in 1998 by a Federal/ Provincial/Territorial MOU and is the owner and operator of Canada's blood supply system. The MOU outlines the key principles for the national blood system:

- The safety of the blood supply is paramount;
- A fully integrated approach is essential;
- Accountabilities must be clear;
- The renewed blood supply system must be transparent;
- Voluntary donations should be maintained and protected;
- National self-sufficiency in blood and plasma collection should be encouraged;
- Adequacy and security of supply of all needed blood, components and plasma fractions for Canadians should be encouraged;
- The 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; and
- A national blood supply program should be maintained.

The MOU provides CBS with the ability to exercise full management discretion over all operational blood system decisions and assigns the following specific responsibilities to CBS:

- Recruiting blood donors and managing donations;
- Collecting whole blood, plasma and platelets;
- Testing and laboratory work;
- Processing, storage and distribution of blood products and alternatives and inventory management;
- Developing and implementing quality assurance/quality control standards;
- Coordinating a national research and development program for blood, blood products and transfusion medicine;
- Establishing educational programs for the appropriate utilization of blood and blood products; and
- Health risk management.

In response to a recommendation of the 2013 performance review of CBS, CBS and the Members developed a national accountability agreement. The NAA is a complementary document to the MOU that clarifies accountabilities and deliverables. It is expected that the draft agreement, once approved by all parties, will be formally adopted in 2020–21.

CBS' operations are organized across four business lines:

- **FBC:** CBS collects, tests and manufactures blood and blood products, including red blood cells, platelets and plasma. CBS also provides diagnostic laboratory testing services in some provinces.
- **Plasma:** CBS collects plasma from volunteer, unpaid donors in Canada. Some of this plasma is retained to meet the transfusion needs of Canadian patients, but most is shipped to contract manufacturers of PPP. CBS distributes approved PPP — derived from Canadian plasma, as well as products that are purchased from manufacturers — to hospitals in Canada (excluding Quebec) to treat immune disorders and other conditions, such as hemophilia.
- **Stem cells:** CBS operates several programs that support better outcomes for patients living with the many diseases and disorders that can be treated with stem cell transplants. CBS collects umbilical cord blood to manufacture stem cells through its cord blood bank. It also operates a national registry of adult stem cell donors and participates in an international network of donor registries. CBS provides human leukocyte antigen (HLA) typing services to ensure the best possible matches between stem cell donors and patients.
- **Organ and tissues:** CBS manages a national transplant registry for interprovincial organ sharing, as well as related programs for donation and transplantation. Working with partners across the organ and tissue donation and transplantation community, CBS contributes to the development of leading practices, supports professional education and public awareness activities, and collaborates on new ways to share data on the performance of the Organ and Tissue Donation and Transplantation (OTDT) system in Canada.

CBS is mainly funded by PT governments, whose ministers of health collectively approve its annual budgets and three-year corporate plans. In addition to funding from these governments, CBS receives federal funding that supports research and development activities, as well as its activities related to organ and tissue donation and transplantation. CBS is regulated by Health Canada through the federal Food and Drugs Act.

## 1.2 Purpose of review and scope

As a matter of good governance, and as initially contemplated in the 1998 MOU, CBS and the Members agreed on the need for a collaborative performance review of CBS. The last performance review of CBS was conducted in 2013.

The overarching objective of the 2019 collaborative performance review was to evaluate the effectiveness and efficiency of CBS in delivering on its mandate between April 1, 2012 and March 31, 2019.

The scope of the review covered CBS' national operations of its two primary product lines: FBC and PPP. In order to assess the safety, sufficiency and effectiveness of CBS' products and services and as directed by the Performance Review Working Group (PRWG), the review focused on four key areas:

- Fiscal and financial matters:
  - Evaluate cost drivers for the in-scope product lines to identify trends/significant variations.
  - For Fresh Blood Components, review productivity metrics and appropriate benchmarking and for PPP, review appropriate comparative analysis.
  - Analyze productivity and efficiency activities to identify changes over the review period and understand underlying causes.
  - Evaluate whether the two in-scope product lines are delivered with due regard for “value for money” based on four criteria: supply, cost, benefit and risk.

- Product supply and safety:
  - Evaluate CBS' ability to meet the blood safety and supply requirements of its customers.
  - Review effectiveness of forecasting methods (i.e. accuracy, completeness and reliability) based on analysis of historical data and demand drivers.
  - Review Plasma Protein Products with regards to effectiveness of structure, decision-making processes and procurement practices.
- Key Corporate Activities: Evaluate risk management practices and approaches, the maturity of the quality management system, and governance structures along with the related decision-making processes and accountabilities.
- Selected strategic initiatives: Evaluate the ASC and Donor Experience/ Brand Renewal Initiatives with regards to effectiveness of project management, deliverables and results achieved.

There are a number of additional areas that have been specifically identified as out of scope, including Canadian Blood Services Insurance Company Limited (CBSI), Canadian Blood Services Insurance Company Limited-Excess (CBSE), Centre for Innovation, Organ & Tissue Donations, Diagnostic Services and some other services such as travel, internal audit and fundraising.

## 1.3 Report structure

This report has been divided into 4 main sections which cover the scope areas described above. The table below provides a mapping of each section to the scope areas for ease of reference.

**Table 1: Mapping of report sections to the in-scope areas**

Report Section	Scope Areas Covered
<b>Financial Performance</b>	FBC- Cost drivers and benchmarking PPP- Cost drivers
<b>Operational Performance</b>	Customer Safety Needs Customer Supply Needs PPP Management, including comparative analysis Productivity and Efficiency Activities
<b>Strategic Initiatives Performance</b>	Automated Supply Chain Donor Experience/Brand Renewal
<b>Other Areas</b>	Governance Enterprise Risk Management

Value for money aspects have been considered within each of the scope areas listed in the above table. In the context of this performance review, value for money was defined as “*the use of public resources within a health risk framework which takes into consideration the four critical elements of supply, cost, benefit and risk*”. Value for money observations, findings and recommendations are delineated throughout the report with the icon shown on the right.



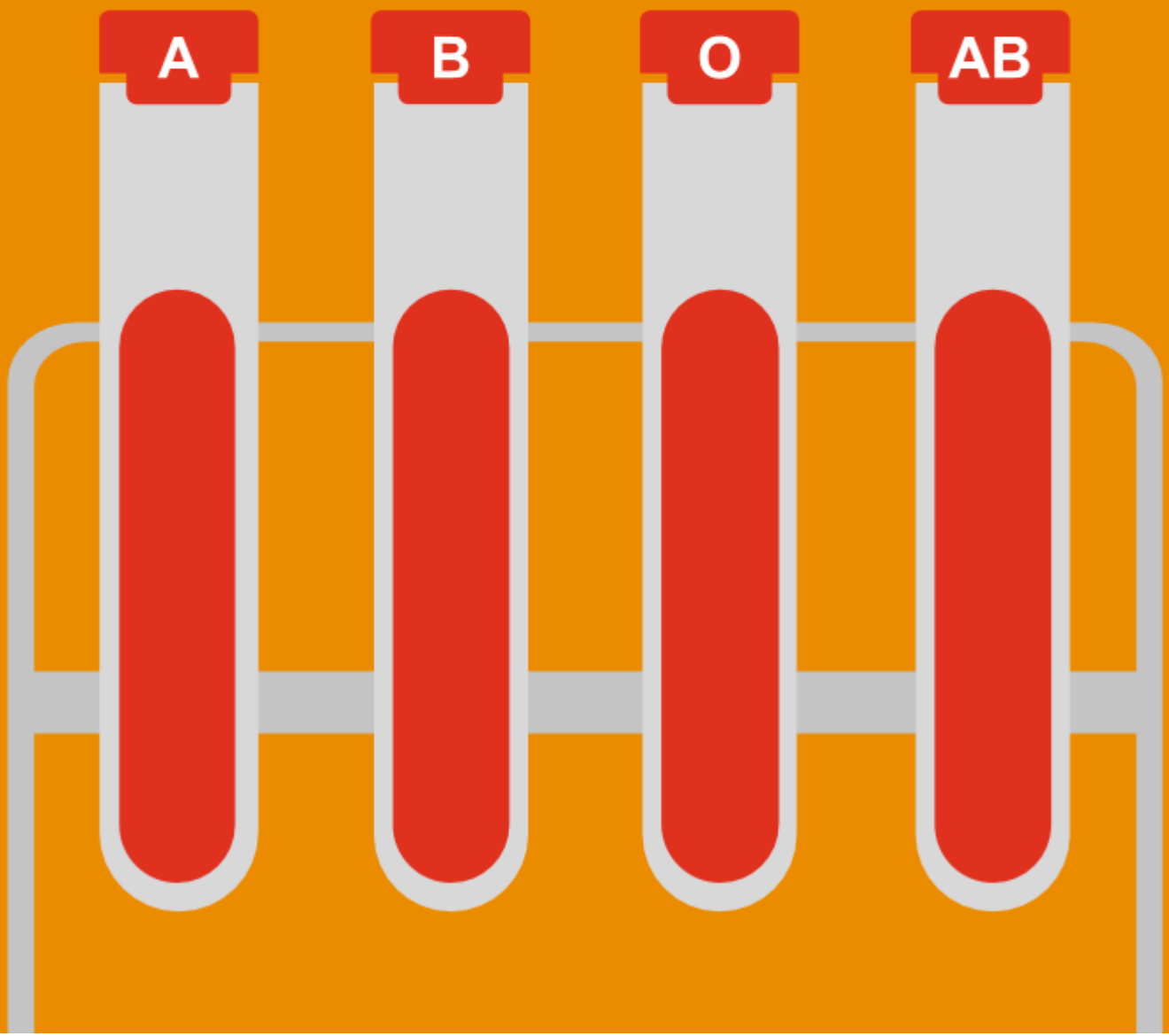
Within each report section, we have presented key observations and findings for each of the scope areas covered. “*Observations*” are intended to highlight those activities/initiatives that CBS is doing well and have no associated recommendations. “*Findings*” are opportunities for improvement and have one or more associated recommendations.



# 2

## Performance review methodology

2.1 Overview



## 2. Performance review methodology

### 2.1 Overview

PwC conducted the CBS performance review in four phases as shown in Figure 1 below.

**Figure 1: Overview of review approach**

Phase I	Phase II	Phase III	Phase IV
Planning	Discovery	Analysis	Reporting
<ul style="list-style-type: none"> <li>Kick-off meeting with PRWG</li> <li>Confirm objectives, scope, deliverables &amp; timeline</li> <li>Identify key stakeholders, participants, data sources, reports, information needed</li> <li>Review background documents</li> <li>Plan interviews</li> </ul>	<ul style="list-style-type: none"> <li>Conduct interviews with key CBS staff involved with the in-scope areas, Members' representatives and Expert Panel members</li> <li>Develop benchmarking/comparative analysis approach for FBC and PPP and obtain PRWG approval</li> <li>Obtain and review detailed performance and other data sets</li> <li>Develop and discuss preliminary observations with the PRWG and Expert Panel</li> </ul>	<ul style="list-style-type: none"> <li>Perform detailed qualitative and quantitative analyses.</li> <li>Conduct additional interviews</li> <li>Analyze benchmarking data</li> <li>Obtain input/advice from Expert Panel</li> <li>Review observations and recommendations with CBS staff</li> <li>Start preparing draft report</li> </ul>	<ul style="list-style-type: none"> <li>Deliver draft report</li> <li>Review draft report with CBS and PRWG</li> <li>Update draft report, as required</li> <li>Develop final report</li> </ul>

Key activities within our approach included:

- Member and CBS interviews** - We conducted initial and follow-up interviews with Members' representatives to obtain their views on CBS' performance over the review period, identify issues/concerns for analysis and to get an overall understanding of what has been working well and areas requiring improvement. We also conducted interviews with the CBS Executive Management Team (EMT) and selected directors and managers to inform our lines of inquiry during Planning and gather additional information during the Analysis Phase.
- Expert panel interviews** - CBS and PTs assembled a panel of experts with expertise in transfusion medicine, blood operator management, hemophilia and bleeding disorders and PPP (including clinical, management, industry expertise). PwC interviewed and obtained information from several expert panel members to inform our analysis and recommendations.
- Document review** - PwC conducted extensive document review consisting of CBS documents including, but not limited to, the MOU, annual reports, corporate plans, CBS Board of Directors' Quarterly Reports to Members, business cases, minutes of Board and EMT meetings, third-party audit reports, stakeholder surveys (e.g., public, hospitals, donors) and RBDM analyses. We also reviewed a number of publicly available documents to inform our analysis.
- Benchmarking/Comparative analysis** - PwC designed an approach for benchmarking FBC cost drivers against other blood operators. This approach consisted of benchmarking selected productivity metrics against benchmarking data available from the Alliance of Blood Operators (ABO) for three other blood operators to evaluate CBS' performance relative to peer organizations. For PPP, we conducted a comparative analysis of:
  - procurement practices against the *Procurement Guideline for Publicly Funded Organizations in Ontario* and selected international jurisdictions; and

- formulary management practices against provincial drug plans, provincial programs similar to CBS' Named patient Program, and selected international jurisdictions.
- **Review of third-party reports** - Our analysis was informed by a number of third-party reports. The following table provides an overview of the key third-party reports that we leveraged for our analysis along with the applicable sections.

**Table 2:** Third-party reports used for report analysis

Report	Description	Applicable report section
Third-party professional services firm report on CBS' key performance measures. (February 2020)	This report covered 29 CBS performance measures focused on financial and productivity, quality and safety, product demand, donor experience and customer experience. Each indicator was evaluated for consistency of methodology, use of best available data, accuracy of source data, alignment to objective (e.g. financial and efficiency, product quality and safety, donor experience) and extent to which the performance measure is easily interpreted. Accuracy of source data was tested for the last three years of the review period.	Section 3.0 - Financial Performance Section 4.1 - Customer Safety Needs Section 4.4 - Productivity and Efficiency
Accenture Consulting Report (December 2019)	Overview of Jurisdictional Oversight and Management of Supply and Distribution of PPP Across 8 Countries	Section 4.3 - PPP Management
CSL and Grifols (plasma fractionation companies) audit reports (Sample from 2012-13 to 2018-19)	Audit reports on CBS' compliance with standards related to plasma production processes and procedures	Section 4.1 - Customer Safety Needs
Health Canada Audit Reports (Sample from 2012-13 to 2018-19)	Results of inspections of Canadian Blood Services operations across the country, including the Head Office in Ottawa	Section 4.1 - Customer Safety Needs
Third-party professional services firm - Culture Diagnostic (May 2018)	Assessment of CBS' quality culture	Section 4.1 - Customer Safety Needs
Third-party health sciences/ pharma biotech professional services firm -Quality Management System Framework and Roadmap (September 2014)	Independent assessment of CBS' Quality Management System	Section 4.1 - Customer Safety Needs

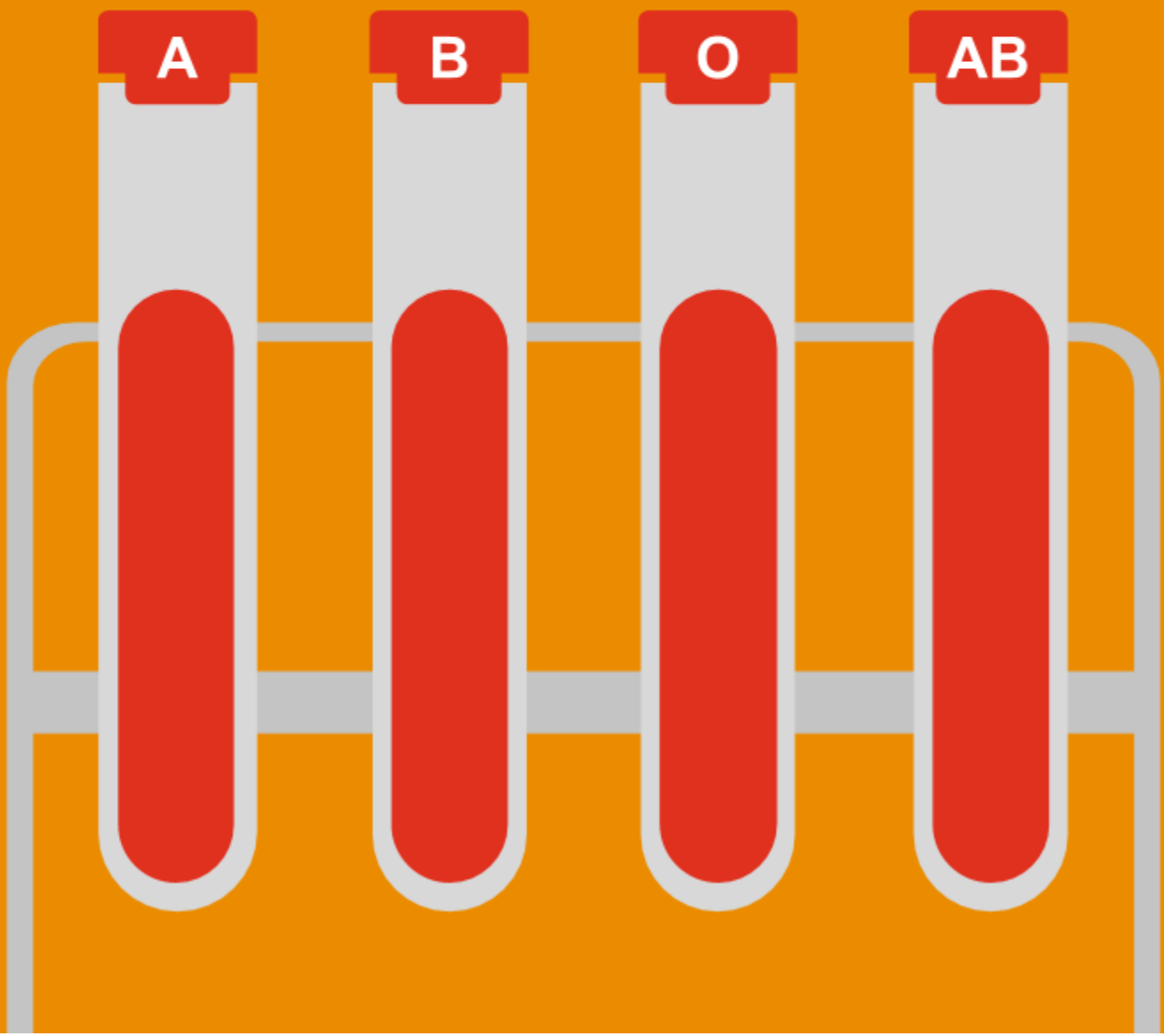
- **Analysis and validation** - Our work included detailed analyses and synthesis of quantitative and qualitative information obtained from internal CBS reports and analyses, third-party reports, and interviews to develop observations, findings and recommendations. We also conducted numerous validation sessions with CBS staff to confirm the factual accuracy of our observations and findings.

# 3

## Financial Performance

3.1 Fresh Blood Components

3.2 Plasma Protein Products



# 3. Financial Performance

## 3.0.1 Objective

The objective of the financial review is to evaluate how effective CBS has been in managing the funding received from Members over the review period with focus on two product lines: FBC and PPP.

## 3.0.2 Scope

The scope of the financial review consisted of two focus areas:

- **Focus Area 1:** Evaluation of FBC with respect to cost drivers, productivity metrics and benchmarking against ABO members; and
- **Focus Area 2:** Evaluation of PPP cost drivers.

The PPP section of financial performance should be read in conjunction with the PPP Management section of the report which provides deeper insights into PPP demand, utilization and some of the key challenges within that business line in more detail.

## 3.0.3 Context

CBS is mainly funded by the provincial and territorial governments. The level of funding is based on CBS' corporate planning process whereby budgets are reviewed and approved on an annual basis by Members. The funding requirements for FBC and PPP business lines accounted for 95% of CBS' budget for 2018-19.

For FBC, each Member's budget allocation is determined based on its share of red blood cell shipments in relation to total red blood cell shipments. For PPP, Members pay for the actual costs of products consumed by hospitals in their respective provinces/territories and a portion of administrative expenses.

In an effort to provide insights into CBS' financial performance, PwC has provided a summary analysis to support each of the findings in this section. This summary analysis does not provide details on all increases and decreases in financial or productivity metrics throughout the review period, but rather highlights material variances to support the observations.

## 3.0.4 Key Themes

CBS reduced its costs for FBC by \$28M (6%), mainly through the reduction of staff costs and medical supplies costs. This was achieved through productivity improvements in the areas of collections, testing and production, combined with better contract pricing for medical supplies. While CBS improved its productivity, it was less productive than comparator blood organizations at the end of the review period.

General and administration (G&A) costs increased over the seven years and accounted for 26% of overall operational expenses for FBC at the end of 2018-19.

PPP spend increased by approximately \$185 million (39%). There is a risk that costs associated with PPP will continue to rise due to the rising demand for PPP in Canada and globally and Canada's low level of plasma sufficiency. At the end of 2018-19, the plasma collected by CBS accounted for 15% of overall Ig demand. CBS needs to continue to explore options to further expand the collection of source plasma within Canada to reduce dependency on US and global suppliers.

While CBS negotiated a number of new contracts which resulted in more favourable product prices, the demand for PPP, coupled with a weakening Canadian dollar, outpaced the savings CBS achieved in PPP unit costs.

Below is an outline of our key themes for this area:

**Table 3: Summary of key themes**

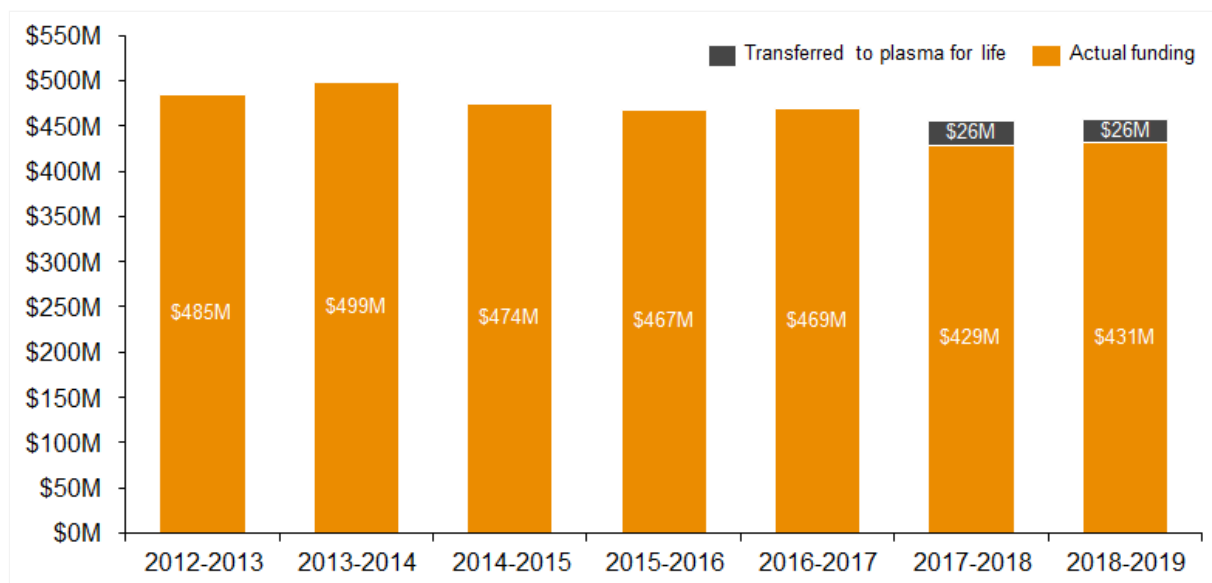
Area of Focus	Observation	Finding
<b>FBC Cost Drivers</b>		
<b>Staff Costs</b>	<ul style="list-style-type: none"> <li>Collections staff costs decreased by approximately \$13 million (18%) primarily due to changes in the collection network and implementation of the ASC project.</li> <li>Testing staff costs decreased by about \$5 million (26%) due to productivity increases resulting from rationalization and automation of the testing process.</li> <li>Production staff costs decreased by approximately \$4 million (14%), as a result of productivity gains from continuous improvement initiatives.</li> </ul>	<ul style="list-style-type: none"> <li>CBS was less productive than comparator organizations at the end of the review period.</li> <li>Staff costs for support services increased by approximately \$10 million (15%).</li> </ul>
<b>Medical Supplies</b>	<ul style="list-style-type: none"> <li>CBS achieved a reduction in medical supply costs for FBC of \$28 million (35%), primarily due to better contract pricing.</li> </ul>	
<b>General &amp; Administrative Costs</b>		<ul style="list-style-type: none"> <li>General and administrative costs increased by \$17 million (18%).</li> </ul>
<b>Benchmarking Analysis</b>		<ul style="list-style-type: none"> <li>CBS ranked third in collections and production productivity, and last in testing productivity, amongst the four comparator ABO members.</li> </ul>
<b>PPP Cost Drivers</b>		
<b>Product Demand</b>		<ul style="list-style-type: none"> <li>The plasma that CBS collected from donors accounted for 15% of the overall Ig demand at the end of 2018-19. Given the increase in demand for Ig products globally and the limited supply, there is a risk that CBS will experience higher costs as demand for these products increases over the next few years.</li> </ul>
<b>Foreign Exchange</b>	<ul style="list-style-type: none"> <li>Over 80% of PPP are purchased in US dollars and costs are sensitive to foreign exchange fluctuations. CBS' hedging strategy has helped reduce the costs associated with unfavourable exchange rate movements between the Canadian and US dollars.</li> </ul>	
<b>Product Costs</b>	<ul style="list-style-type: none"> <li>CBS achieved cost savings in PPP through new contracts that resulted in better product prices.</li> </ul>	

## 3.1 Fresh Blood Components

### 3.1.1 Overview

FBC expenses decreased by approximately \$28 million (6%), as shown in Figure 2 below. Expenses for 2017-18 and 2018-19 included a \$26 million transfer to PPP to account for the cost to collect plasma for fractionation. Further details on this cost transfer are provided in Appendix 2.

**Figure 2: CBS FBC Expenses 2012-19 (in millions)**



The decrease in CBS' expenses for FBC was mainly due to:

- Productivity improvements in collections, production and testing;
- Improved clinical practices;
- Reduction in medical supply costs; and
- 14% decline in collection volume for whole blood and plasma/platelet apheresis collections.

The main cost drivers for FBC are staff costs, medical supplies and general administration. These cost drivers are analyzed in more detail in the observations and findings section below, including benchmarking of productivity metrics against other blood operators. For purposes of the benchmarking analysis, PwC relied on comparative information collected from a set of blood operators who are members of the ABO. The benchmarking approach is outlined in Appendix 3.

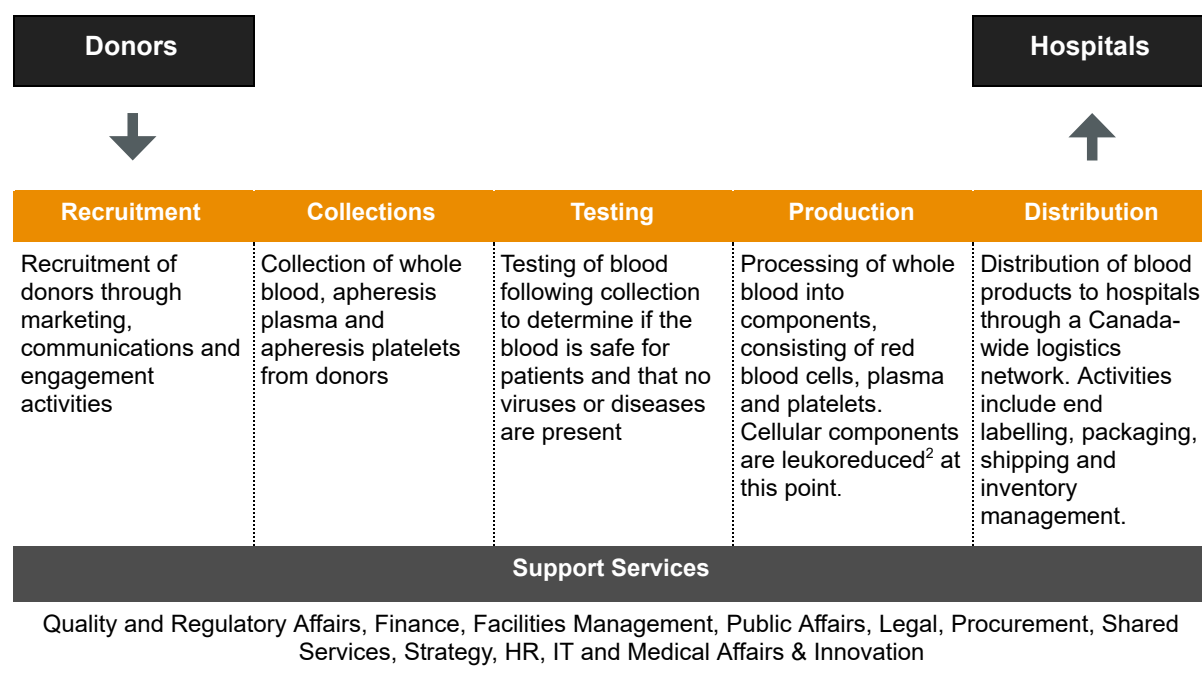
## 3.1.2 Key Observations and Findings

### 3.1.2.1 Staff Costs

Although CBS was behind comparator organizations for productivity measures at the end of 2018-19, overall staff costs decreased by \$10 million (3%).

Our analysis of staff costs and productivity metrics for FBC is based on the activities in CBS' supply chain shown in Figure 3 below.

**Figure 3: FBC Supply Chain Functions**



The collections, testing and production functions had the most significant reductions in staff costs while support services had a significant increase. Each of these areas is explained in more detail below with benchmarking analysis of productivity metrics, where applicable.

### Staff costs and productivity – Collections

**Observation: Staff costs for collections decreased by approximately \$13 million (18%). Several initiatives were implemented resulting in productivity improvements and a reduction of 248 Full-Time Equivalents (FTEs) (28%). The main initiatives contributing to the cost reduction included:**

- \$8 million cost reduction in 2018-19 due to changes to the collection network, which included moving from mobile to fixed donor collection sites.
- \$7 million in cost reduction as a result of the implementation of the ASC Project in 2016-17, which automated and streamlined the collection process. The project led to a reduction of approximately 90 FTEs.
- \$1.6 million in annual savings through implementation of the Donor Care Associate (DCA) Project in 2018-19, which resulted in replacing some nursing staff with flexible, multi-skilled donor care associates. This, in turn, led to a decrease in the number of nurses required by 16%.
- These decreases were partially offset by a \$3.3 million increase in other staff costs.

<sup>2</sup> Leukoreduction is the removal of white blood cells from blood or blood components.

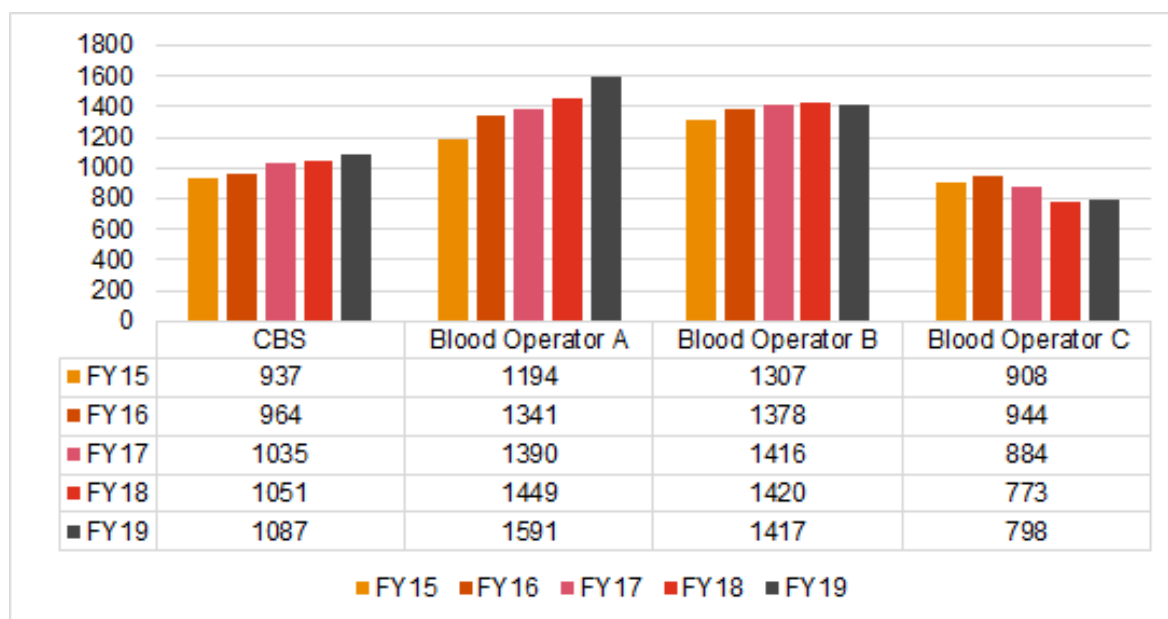


These initiatives also helped to increase collections productivity as detailed in the benchmarking analysis below.

## Benchmarking analysis – Collections productivity

**Finding: CBS ranked third, in collections productivity, amongst the four comparator ABO members, at the end of 2018-19.**

**Figure 4:** Weighted collection per standardised FTE for each ABO member<sup>3</sup>



**Source:** ABO Cost Model Report 2018–19

- Blood Operator A ranked first overall in per person collection productivity at the end of 2018-19 and had a 46% higher productivity than CBS. The practice of setting their collections budget based on productivity targets has enabled Operator A to drive higher efficiency and improvements within their collection process. They also continue to focus on improved donor flow at collection sites through optimized appointment templates and improved staff rostering to support their volumes.
- While CBS achieved a 16% increase in collections productivity over the benchmarking period, it lagged behind Blood operator A who surpassed CBS with a 33% increase in its collections productivity over the same period.



### **Recommendation 1: CBS should build on its productivity gains and further improve its performance by:**

- Assessing which of its existing initiatives are resulting in the greatest benefits and could be further enhanced (e.g., through automation).
- Continuing to leverage its CI Program to identify and implement leading practices to improve productivity on an ongoing basis.
- Learning from initiatives implemented by other blood operators who are outperforming CBS and identifying what can be further implemented to improve productivity.

<sup>3</sup> For the purposes of this review, benchmarking was conducted against three other members of the ABO. See Appendix 3 for additional details.

## Staff costs and productivity – Testing

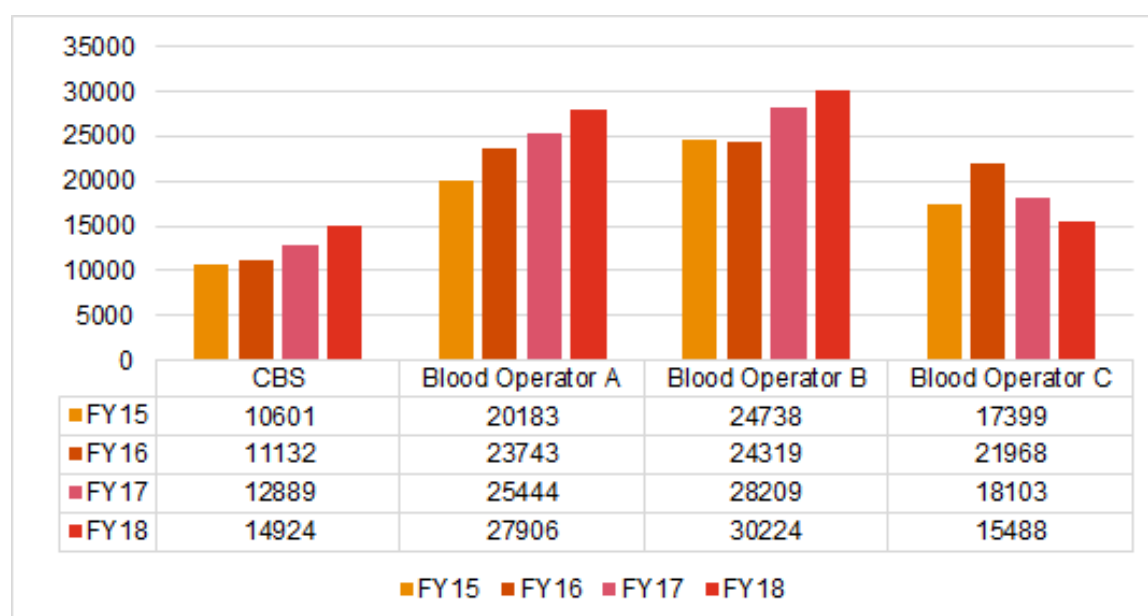
**Observation: Testing staff costs decreased by approximately \$5 million (26%) due to productivity increases resulting from rationalization and automation of the testing process, including:**

- \$4.8 million savings (over 2017-18 and 2018-19) and reduction of 18 FTEs by running two shifts instead of three shifts at Brampton and Calgary and quality control consolidation in 2017-18.
- \$700k in savings and reduction of 11 FTEs by automating front-end sample handling at Brampton.
- \$250k of savings and reduction of 3 FTEs by implementation of an automated testing platform for antibody screening and phenotyping.

## Benchmarking analysis – Testing productivity

**Finding: CBS ranked last in testing productivity, amongst the four comparator ABO members<sup>4</sup>, at the end of 2017-18<sup>5</sup>.**

**Figure 5: Mandatory testing productivity in units tested, per FTE, by ABO member**



**Source: ABO Cost Model Report 2018–19**

- While CBS achieved a 41% improvement in testing productivity over four years, its productivity remained behind the other operators.
- Blood Operator B ranked first overall in testing productivity and had more than double the productivity per FTE compared to CBS in 2017-2018.
- Blood Operator B achieved these increases through a staffing structure review of their testing sites and the application of lean principles to their testing process. Blood Operator B aims to increase testing productivity even further through the automation of front-end sample handling and implementing new analyzers for serological testing in the coming years (CBS is also currently implementing these).
- CBS may be lagging behind in testing productivity due to its overall lower testing volumes.

<sup>4</sup> In the context of these ABO testing measures, jurisdictional differences may influence the metrics. These differences include volume, testing regulations, geography and seasonality.

<sup>5</sup> See Appendix 3 for explanation regarding years covered in this analysis.



### Recommendation 2: CBS should continue to automate its front-end testing process to support improvements in testing productivity.

- The initial stage of the testing process, where blood vials are pooled and organized for testing, is an area that can benefit from the introduction of automation technology. The implementation of this technology would help reduce FTEs, increase testing productivity and potentially reduce the volume of quality incidents.
- PwC understands that CBS is implementing this technology in Brampton in 2019-20 and has plans to implement it in Calgary in 2020-21.
- CBS should undertake a time and motion study to compare its per FTE productivity with Blood Operator B to identify other factors that can be improved to drive higher productivity within its testing process.



### Recommendation 3: CBS should evaluate the feasibility of joining a consortium for testing to further improve productivity and reduce costs.

An expert panel member, currently working at a US blood operator, indicated that joining a consortium to obtain better pricing for equipment and reagents coupled with sharing of a testing platform has allowed them to achieve cost savings and productivity improvements. Under this scenario, testing would still be performed in Canada under CBS' control.

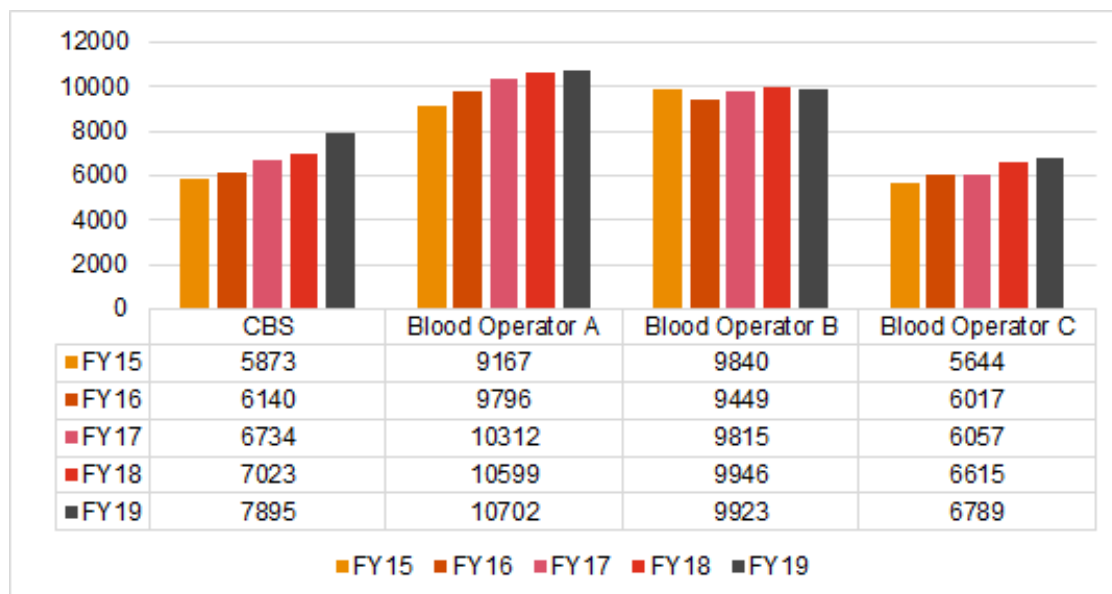
## Staff Costs and productivity – Production

**Observation:** Production staff costs decreased by approximately \$4 million (14%) due to a reduction of 110 FTEs. This was attributable to productivity gains from the CI Program initiatives, such as the standardization of production line processes, reduction in equipment downtime, and identifying and solving many small problems. Consolidation of production facilities was also a contributing factor.

## Benchmarking analysis – Production productivity<sup>6</sup>

**Finding:** CBS ranked third in per FTE production productivity, amongst the four comparator ABO members, at the end of 2018-19.

**Figure 6:** Weighted processed components per FTE by ABO member



**Source:** ABO Cost Model Report 2018–19

<sup>6</sup> Production productivity is the volume of weighted units of output per FTE. The units processed are weighted (units take varying time to process) based on an agreed to ABO standard.

- Blood Operator A ranked first overall in per FTE production productivity and had a 35% higher productivity than CBS in 2018-19. Operator A's higher productivity has been driven by workflow reviews which have delivered improvements in rostering.
- As represented in Figure 6, CBS' per FTE production productivity improved each year with an overall 34% productivity increase during the review period. However, as was the case for collections and testing, the overall per FTE production productivity lagged far behind two out of the three comparator organizations.



**Recommendation 4: CBS should build on its productivity gains and further improve its performance by:**

- Assessing which of its existing initiatives are resulting in the greatest benefits and could be further enhanced (e.g., through automation).
- Continuing to leverage its CI Program to identify and implement leading practices to improve productivity on an ongoing basis.
- Learning from initiatives implemented by other blood operators who are outperforming CBS and identifying what can be further implemented to improve productivity.

### Staff Costs – Support Services<sup>7</sup>

**Observation: Staff costs for support services increased by approximately \$10 million (15%).**

- The majority of this increase was due to a \$6.6million increase in 2015-16 due to the following:
  - \$4 million for 32 new FTEs including 20 FTEs within IT hired to support new technology for the ASC project and to support the new GiveBlood app. The other 12 FTEs were hired for Quality, Regulatory Affairs, People Culture & Performance and for fundraising.
  - \$1.5 million for other costs such as severance and retirement payments and monthly salary accruals which fluctuate from period to period.
- \$3.5 million was related to an increase in staff benefits over the review period (from 15.7% in 2012-13 to 18.3% in 2018-19), including CBS' portion of contributions to the Canada Pension Plan (CPP) and Employment Insurance (EI) benefits, long term disability costs and increases associated with mental health benefits.

#### 3.1.2.2 Medical Supplies



**Observation: CBS achieved a reduction in medical supply costs for FBC of \$28 million (35%), primarily due to better contract pricing.**

- Medical Supplies are used during the collection, production and testing processes. The majority of the savings in medical supply costs are attributable to the following:
  - \$12 million through renegotiation of the contract for collection bags in 2013-14 which resulted in a 53% decrease in unit costs.
  - \$8.7 million reduction in testing related medical supplies mainly as a result of a new contract for reagent testing in 2017-18 which led to savings of \$6.3 million.

#### 3.1.2.3 General and Administrative Costs

**Finding: General and administrative costs increased by \$17 million (18%) over the review period.**

- G&A expenses capture most of CBS' operating expenses with the exception of staff and medical supply costs. G&A includes expenses for donor relations, supply chain, IT, facilities and strategic projects.

<sup>7</sup> A proportion of FBC staff costs for support services supports other product and service lines.

- G&A expenses comprised 26% of overall FBC expenses in 2018-19 versus approximately 19% in 2012-13. We would normally expect G&A costs to be in the range of 15-17% of total costs. CBS' costs are above this range but are challenging to benchmark, given the inclusion of expenses such as strategic project costs in this category which would normally not be included as G&A costs.
- In 2018-19, costs associated with IT, strategic projects and facilities accounted for 54% of the G&A costs. These costs are mainly as a result of:
  - CBS operating two Enterprise Resource Planning (ERP) systems to meet its operational requirements;
  - Inclusion of strategic project costs related to the ASC, Donor Care Associate, Donor Experience and Data Centre projects, of which, a large proportion comprise professional services fees; and
  - Costs associated with leasing permanent donor centres and maintaining a network of facilities needed for production, testing and distribution of blood and blood products



**Recommendation 5: CBS should consider the removal of project expenses from the G&A cost category and tracking of these costs on their own.**

- Project expenses have been highly variable and make up a substantial portion of the G&A category. Their removal would help provide better visibility of G&A variability, while also isolating project expenses to understand the full cost of project implementations.

**Recommendation 6: CBS should conduct an analysis of its general and administrative expenses to identify opportunities for potential cost reductions. As part of this analysis, particular consideration should be given to:**

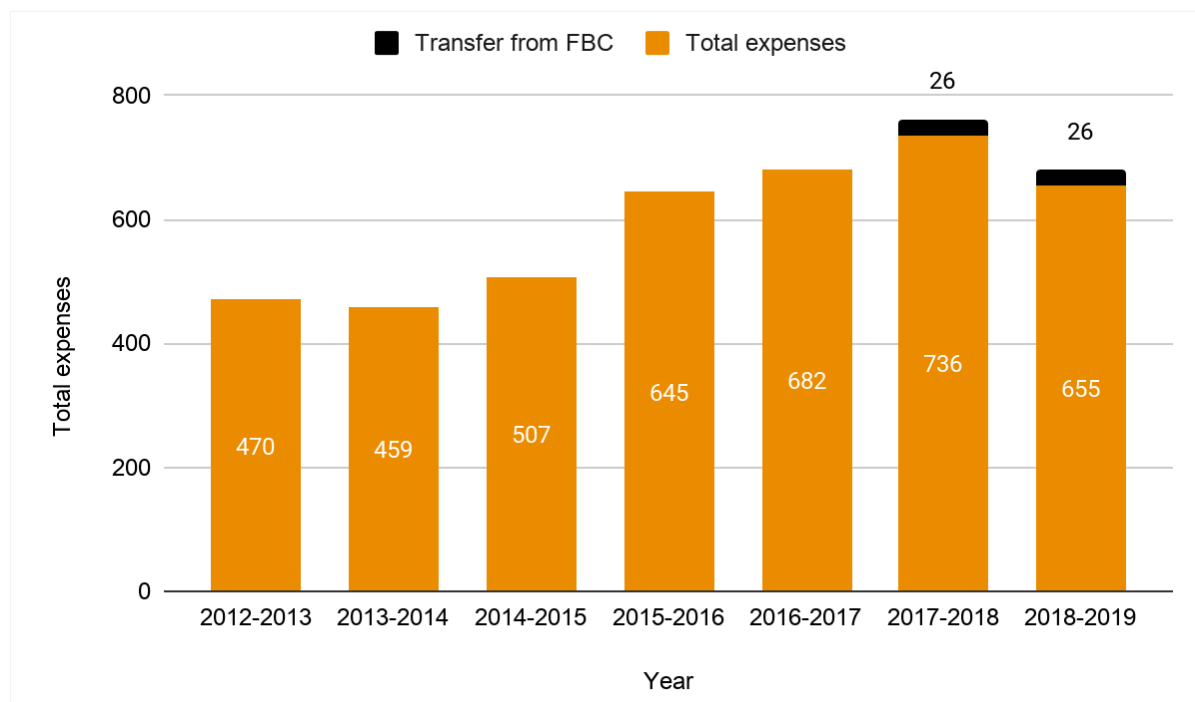
- Further developing in-house project management capabilities to support CBS' portfolio of projects and reduce reliance on more expensive external resources; and
- Evaluating costs relating to rent and utilities and identifying potential contractual opportunities to reduce them or manage them better. External vendors perform baseline benchmarking in this area on a contingent fee basis.

## 3.2 Plasma Protein Products

### 3.2.1 PPP Overview

PPP expenses increased by approximately \$185 million<sup>8</sup> (39%) over the review period, as seen from Figure 7 below.

**Figure 7: PPP Expenses by Year (in millions)**



This increase in PPP expenses is attributable to two main factors:

- **Product demand** - Increased PPP demand is the main cost driver for the increase in costs. The greatest driver for increased demand has been changing clinical practice with increased focus on prevention of diseases rather than treatment of acute attacks, bleeds or infections. Researchers are also discovering additional uses for the PPP, including highly specialized therapies for a wide range of rare diseases and conditions, beyond blood disorders.
- **Foreign Exchange (FEX) movements** - 80% of all PPP products are purchased in US dollars wherein the exchange rate has moved in an unfavourable direction over the review period. CBS has implemented a hedging program to try to mitigate against the FX risk.

The main cost drivers for PPP are product demand, foreign exchange changes, product costs and product mix. These are outlined in the key review findings section below in more detail.

### 3.2.2 Key Review Observations & Findings

#### 3.2.2.1 Product Demand

**Finding: The plasma that CBS collected from donors accounted for only 15% of the overall Ig demand at the end of 2018-19. Given the increase in demand for Ig products globally and the limited supply, there is a risk that CBS will experience higher costs as demand for these products increases over the next few years.**

One of the most critical PPP is Ig, which is used to treat a wide range of immunodeficiency, autoimmune, hematological and neurological disorders.

<sup>8</sup> Calculation excludes the \$26million cost transfer from FBC.

Over the review period, demand for Ig in Canada grew at an average rate of 8% annually, from 3.75 million units to 6.00 million units. At the same time, CBS' plasma sufficiency rate<sup>9</sup> decreased from 24% to 15%, resulting in more product purchased from global pharmaceutical companies at a higher cost.

CBS has been working with PT governments to ensure an appropriate level of plasma sufficiency in Canada to support Ig use for life-saving treatment. Funding for three plasma proof-of-concept collection sites (Sudbury, Lethbridge, and Kelowna) was approved by Members in March 2019.

The Plasma Proof-of Concept Collection Sites Reporting Framework outlines the performance reporting approach that will be used to assess the extent to which the plasma proof-of-concept collection sites are meeting the agreed upon performance metrics. Performance results will allow funders to make informed judgements and decisions regarding the overall performance success of the plasma proof-of-concept collection sites. Performance metrics will also provide key information that will guide strategic discussions on the issue of plasma self-sufficiency and may inform future funding requests.

**Recommendation 7: CBS should continue to examine options to increase plasma self-sufficiency within Canada to reduce dependency on US and global suppliers.**

This may require a discussion with Members at a strategic level to evaluate various options and should take into account the performance results for the plasma proof-of concept collection sites (as they become available).

CBS should also consider setting up a task force that looks at potential improvements within plasma collection processes and integrating them at a community level to drive higher volume and self-sufficiency in this area.

**Finding: The C1-inhibitor product had, on average, a year-over-year growth rate of 36% and the high demand for this product is expected to continue in the future.**

- The increase in demand for C1-inhibitors can be attributed to several reasons such as:
  - Changes in clinical practice to place patients on prophylactic (i.e. preventive) therapy rather than on-demand therapy;
  - An increase in new patients being diagnosed with Hereditary Angioedema and starting to use this therapy;
  - Patients previously treated with other therapies switching to C1-inhibitor products; and
  - Greater access to home therapy (i.e. an increased use of a specific C1-inhibitor product subcutaneously, which also requires more volume of product to be used than intravenously).



**Recommendation 8: CBS and PTs should work together to explore options for managing the increased use of C1 inhibitors.**

Consideration should be given to:

- adding patients to a patient registry, such as the Named Patient Program to better control and monitor the use of the product
- delisting the product from the CBS formulary and transferring it to PT drug formularies

### 3.2.2.2 Foreign exchange

**Observation: Over 80% of PPP are purchased in US dollars and costs are sensitive to foreign exchange fluctuations. CBS' hedging strategy has helped reduce the costs associated with unfavourable exchange rate movements between the Canadian and US dollar.**

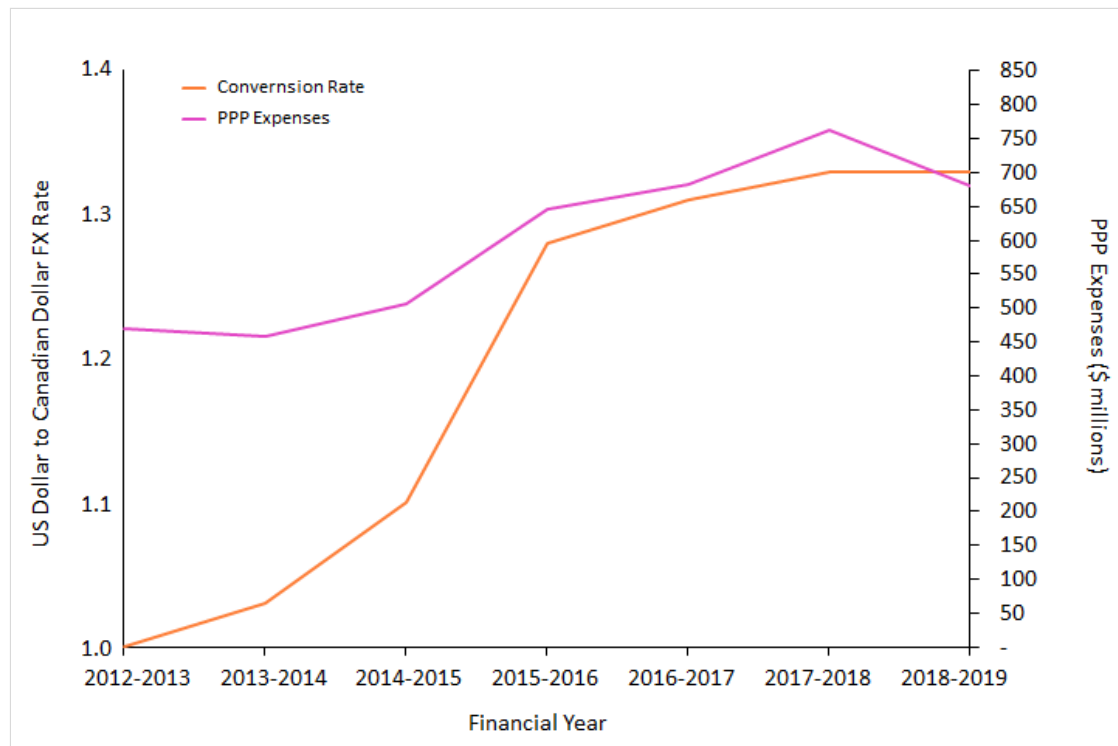
- Over the review period, the Canadian dollar to US dollar exchange rate increased from an

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<sup>9</sup> The sufficiency rate is the percentage amount of plasma CBS collects to satisfy its Ig demand.

average conversion rate of 1.00:1.00 to an average rate of 1.33:1.00, as can be seen in Figure 8.

**Figure 8: Total Expenses and Foreign Exchange by Year**



- CBS uses a hedging approach to help mitigate against the fluctuating exchange rate between the Canadian and US dollar. This consists of long-term forward agreements and short-term spot (current) exchange-rate purchases to manage foreign exchange rate risks. CBS was able to lock in future US dollar requirements at specified rates and participate in shorter-term movements in the spot market when required.

### 3.2.2.3 Product Costs



**Observation: CBS has achieved savings in PPP unit costs through more favourable pricing.**

CBS realized \$857 million in cost savings from PPP contracts between 2012-13 and 2018-19 which are outlined in table 4 below.

**Table 4: Cost savings and cost avoidance arising from PPP procurement activities during the review period**

#	Description	Fiscal Year of Tender	Cost Savings and Cost Avoidance
1	Contract Fractionation & Commercial Product	2012-2013	\$614 million in cumulative cost reductions and cost avoidance.
2	Recombinant Products [rFVIII and rFIX]	2012-2013	
3	Recombinant Products [rFVIII and rFIX]	2015-2016	\$90 million in cost reduction and avoidance.
4	Contract Fractionation & Commercial Product Recombinant Products [all]	2017-2018	\$141 million in cost reduction and avoidance.
5	Recombinant Product [rFVIII]	2018-2019	\$12 million in cost reduction



These savings are related to product unit cost reductions and do not include any costs associated with product changes that are incurred by the health service system.

Cost increases associated with growing utilization coupled with a weakening Canadian dollar offset these savings over the review period.

### 3.2.2.4 Product mix



**Observation: CBS introduced new brands to their PPP formulary to provide increased benefits to patients and achieve better value for money.**

- The procurement of subcutaneous Ig, as an alternative to intravenous Ig, has enabled patients to self administer the Ig product at home rather than having to visit a hospital.
  - The demand for subcutaneous Ig products as a percentage of overall Ig product demand rose from 6% to 18% over the review period. CBS introduced three additional subcutaneous Ig products to their formulary in response to the growing demand.
- Changes to the product mix have resulted in the following value for money benefits:
  - The switch to subcutaneous Ig helps reduce the time the patient needs to spend in a hospital, reduces the effort required by hospital staff and decreases the demands on Members' health care systems;
  - Although the costs for subcutaneous Ig are more expensive per unit than intravenous Ig, CBS has been able to obtain price reductions in 2017-18 resulting in an 82% decrease in unit price in 2018-19; and
  - CBS also introduced new product brands under the Ig and coagulation product categories as a result of a tendering process to achieve cost savings, which are noted in the product costs section above.

### 3.2.2.5 Other financial performance considerations for PPP

**Finding: While there is a regular and comprehensive process in place for CBS to report its financial performance to Members, there is an opportunity to provide more context to Members on the changes to their annual funding requirements for PPP.**

**Recommendation 9: CBS should provide additional information to Members on:**

- Foreign exchange fluctuations;
- Significant market trends for PPP over the last 3- 5 years and future projections;
- Achievement of planned savings from new contracts on a year over year basis; and
- Impacts of variances in demand forecasts on Member funding.

# 4

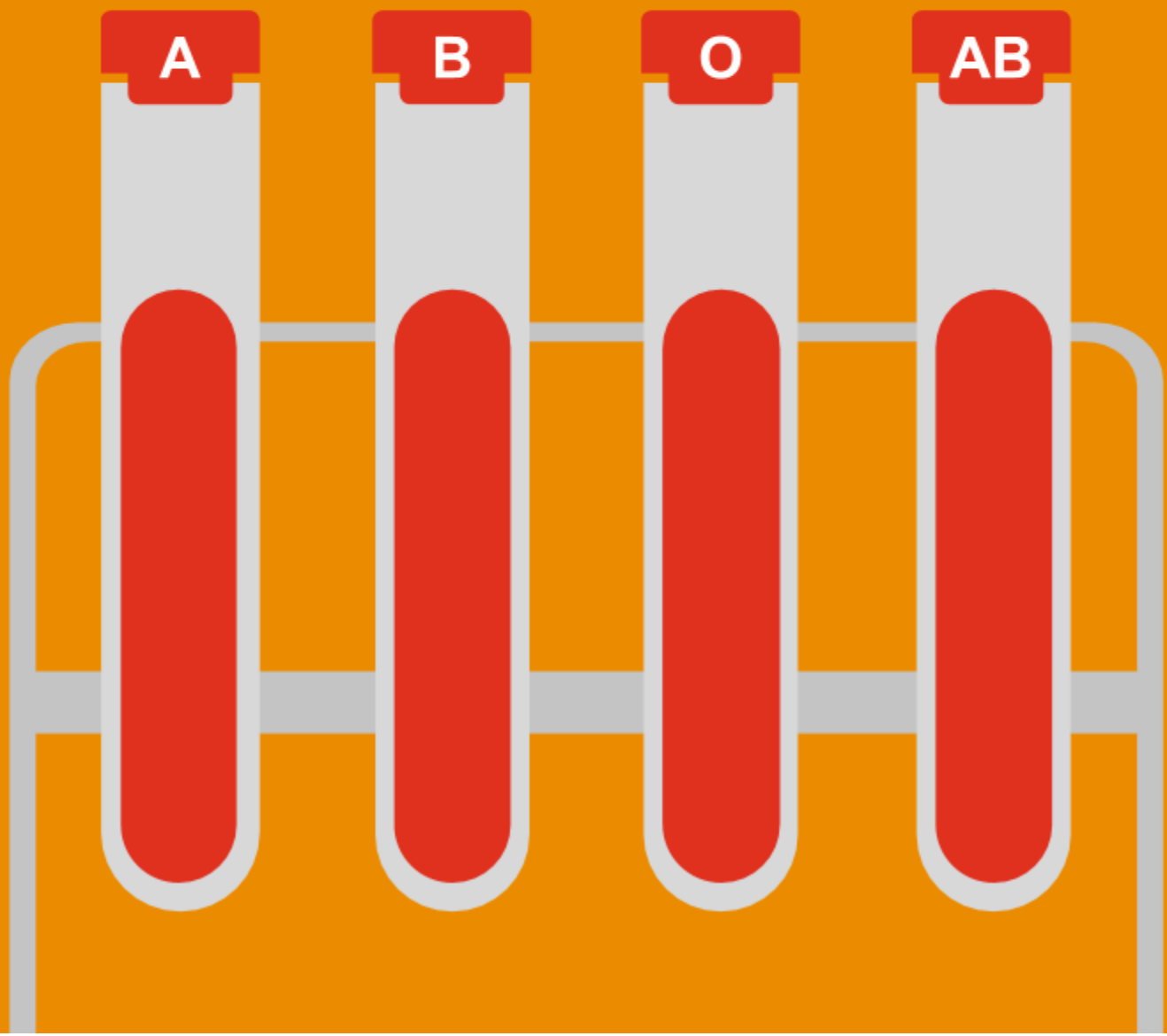
## Operational Performance

4.1 Customer Safety Needs

4.2 Customer Supply Needs

4.3 Plasma Protein Products Management

4.4 Productivity and Efficiency Activities



# 4. Operational Performance

## 4.1 Customer Safety Needs

### 4.1.1 Objective

This section includes findings, observations, and recommendations related to CBS' ability to meet the safety needs of customers and advance the maturity of CBS' QMS.

### 4.1.2 Scope

The focus of this section is on eight areas as follows:

- **Focus Area 1:** Regulatory and Third-Party Safety Requirements
- **Focus Area 2:** Safety Incidents
- **Focus Area 3:** Quality Management Structure & Decision-Making
- **Focus Area 4:** Quality Roles & Responsibilities
- **Focus Area 5:** Quality Culture
- **Focus Area 6:** Quality Processes
- **Focus Area 7:** Quality Metrics
- **Focus Area 8:** Stakeholder Satisfaction

Within each of these areas, we used the following criteria to evaluate CBS' effectiveness in meeting the safety needs of customers (i.e. hospitals, health centres, physicians, clinicians, patients, donors, and members of the public):

- Extent to which CBS complies with and consistently meets regulatory and third-party safety requirements;
- Extent to which safety processes have contributed to reduction in safety incidents; and
- Extent to which key stakeholders are satisfied with the safety of CBS' products and services.

The evaluation of safety consisted of:

- Review of CBS' safety-related documents (i.e., reports on CBS safety measures and performance, Health Canada audit reports, third party audit reports, reports tracking CBS' responses to audit findings, corporate reports, annual reports, corporate risk register, stakeholder satisfaction surveys, etc.);
- Tour of testing facility;
- Interviews with representatives from the BoD, representatives from CBS' Executive Management Team, representatives from Quality and Regulatory Affairs, representatives from a comparable organization; and
- Desktop research on safety and quality processes.

Outlined below are the key findings and observations in relation to the evaluation criteria.

### 4.1.3 Context

At CBS, safety policies and processes are guided by regional, national, and international legislation, regulations, and standards. Health Canada is the principal safety regulator and the *Health Canada, Food and Drugs Act*, is the key regulatory legislation. A sample of the legislations, regulations, and standards guiding the safety of FBC and PPP is provided in Appendix 4.

The overall governance of safety rests with the Board of Directors' Safety, Research and Ethics Committee (SREC) and the EMT. Among other activities, the SREC is tasked with overseeing product and clinical service safety and quality with a focus on:

- recipient safety;
- product security of supply;
- product and service regulatory and accreditation matters;
- donor safety and integrity;
- research activities; and
- ethics.

The EMT, through Quality Management System Review meetings, monitors the organization's performance on critical quality and safety measures<sup>10</sup> and makes decisions that address progress and advance the organization's safety agenda.

Operationally speaking, quality and safety at CBS is the responsibility of all business units across the organization and focuses on multiple areas: donor safety, patient safety, product safety, and employee health and safety (see Figure 9 below and Appendix 5 for detailed descriptions).

**Figure 9: Overview of Safety at CBS**

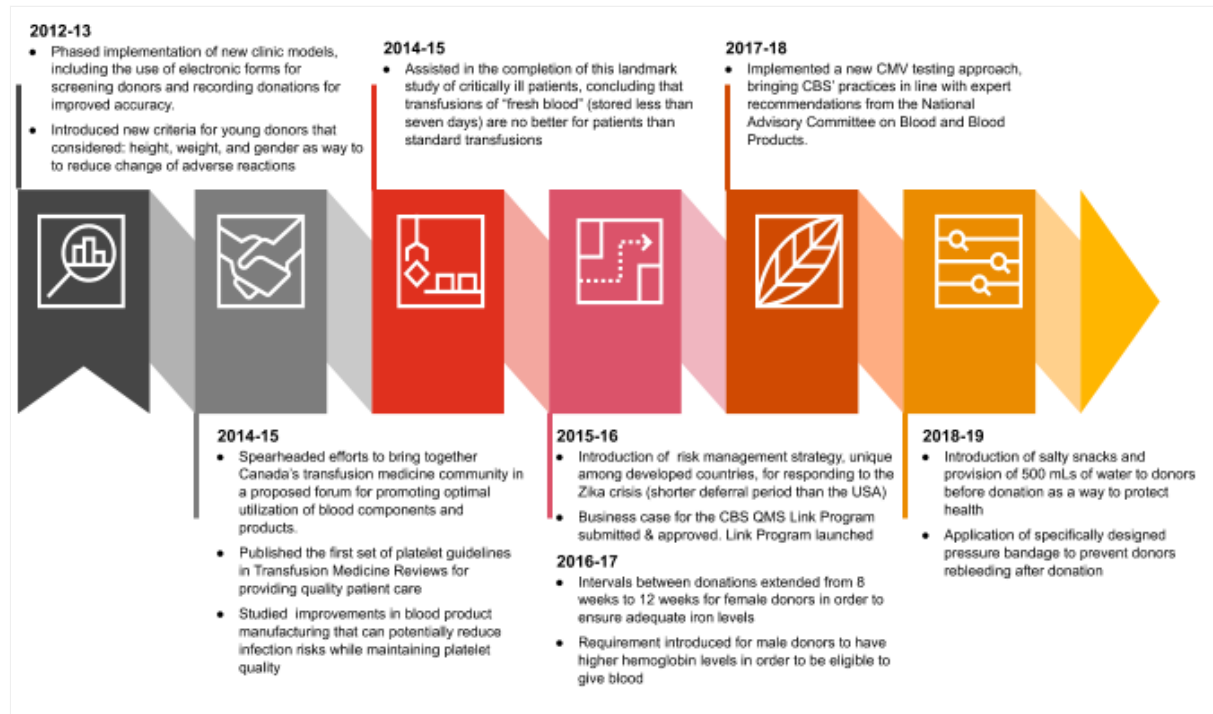


<sup>10</sup> **Note:** quality measures are discussed in the *Overview of the Quality Management System - A Mechanism Contributing to Enhanced Safety* section of this Performance Review Report.

### 4.1.3.1 Steps to Enhance Product, Donor, and Patient Safety at CBS over the Review Period

Over the review period, CBS implemented steps to help address donor, patient, and product safety as outlined in Figure 10 below:

**Figure 10: Steps Taken over Review Period to Enhance Product, Donor, and Patient Safety**



### 4.1.4 Key Themes

CBS has been meeting the safety needs of its customers over the review period. CBS has also made progress aligning its QMS with that of a biologics manufacturer and in strengthening its quality culture, but there is room for further improvement.

Below is a summary of our key themes:

**Table 5: Summary of key themes**

Area of focus	Observation	Finding
<b>Regulatory and Third-Party Safety Requirements</b>	<ul style="list-style-type: none"> <li>CBS was in compliance with regulatory and third-party safety requirements</li> </ul>	
<b>Safety Incidents</b>	<ul style="list-style-type: none"> <li>Overall, the rate of discards and the actual disparity between actual and target discard rates began to close</li> <li>Recalls of FBC and plasma units due to errors, accidents, and post-donation information have been declining</li> </ul>	<ul style="list-style-type: none"> <li>The quantity of Adverse Transfusion Reactions (ATR) has fluctuated over the review period. Though there are inherent risks with transfusions (e.g., allergic reactions), there is no data benchmarking CBS' performance relative to comparable organizations</li> </ul>

Area of focus	Observation	Finding
<b>Quality Management Structure &amp; Decision-Making</b>	<ul style="list-style-type: none"> <li>CBS has adopted the general structure required to bring the organization into alignment with a biologics manufacturer</li> <li>CBS has adopted and implemented an approach that enables evidence-based decision-making in relation to quality</li> </ul>	
<b>Quality Roles &amp; Responsibilities</b>		<ul style="list-style-type: none"> <li>While CBS has taken steps to describe and clarify roles and responsibilities as they relate to quality, there continues to be room for further enhancement</li> </ul>
<b>Quality Culture</b>	<ul style="list-style-type: none"> <li>CBS has made progress in establishing a quality culture in the organization</li> </ul>	
<b>Quality Processes</b>		<ul style="list-style-type: none"> <li>CBS took steps to standardize and automate its quality processes, but opportunities exist for further improvements</li> </ul>
<b>Quality Metrics</b>	<ul style="list-style-type: none"> <li>CBS achieved its performance targets for quality measures</li> </ul>	<ul style="list-style-type: none"> <li>While overall progress has been made on Corrective Action and Preventive Action (CAPA) improvements, the pace of progress has been slower than planned</li> <li>Approach to CAPA, including project management and target completion, should be reviewed</li> </ul>
<b>Stakeholder Satisfaction</b>	<ul style="list-style-type: none"> <li>Survey results indicated that the majority of hospitals, donors and the Canadian public viewed CBS' products as safe. Similarly, the majority of donors and the public viewed the process of donating blood also as being safe</li> </ul>	<ul style="list-style-type: none"> <li>CBS has not established tolerance levels for stakeholder satisfaction measures</li> </ul>

The section that follows contains detailed descriptions of all customer safety-related observations and findings emerging from this performance review along with applicable recommendations. A number of recommendations in this section have a direct impact on “value for money” when considered from a supply, benefit, cost or risk perspective.

#### 4.1.5 Regulatory & Third-Party Requirements

**Observation: CBS was in compliance with regulatory and third-party safety requirements, over the review period.**

Over the review period, there were no “critical” observations identified by Health Canada. “Critical” is defined by Health Canada as a finding that could lead to a severe issue causing an adverse impact on patients. Additionally, although Health Canada audits identified various findings over the review period, a review of a sample of Health Canada audit reports indicated that CBS received a rating of “Compliant”. CBS provided Health Canada with written action plans to address all findings and a process is in place for monitoring their completion.

CBS also met the safety requirements of third parties (i.e., CSL Behring and Grifols<sup>11</sup>) who carried-out audits of their production facilities and processes. Our review of a sample of audits conducted over

<sup>11</sup> These third parties are fractionators who use CBS products. They conduct audits to confirm that CBS' facilities, processes, etc. are in alignment with their safety and quality requirements.

the review period indicated that most of the findings were minor in nature.

## 4.1.6 Safety Incidents

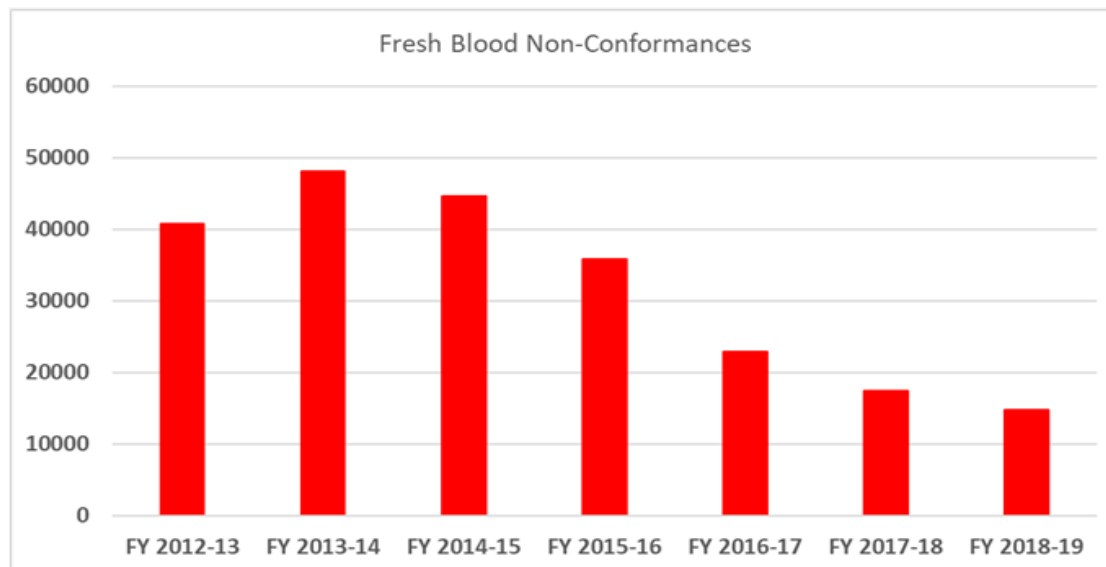
### 4.1.6.1 Discard Rates

**Observation: The rate of discards decreased and the disparity between the actual and target discard rates began to close over the review period.**

Discard rate is calculated as the percentage of whole blood collections discarded prior to distribution. Essentially, discards refer to the wastage of blood due to such things as non-conformances in donor selection and adherence to standard operating procedures.

There has been a reduction in non-conformances over the review period (see Figure 11).

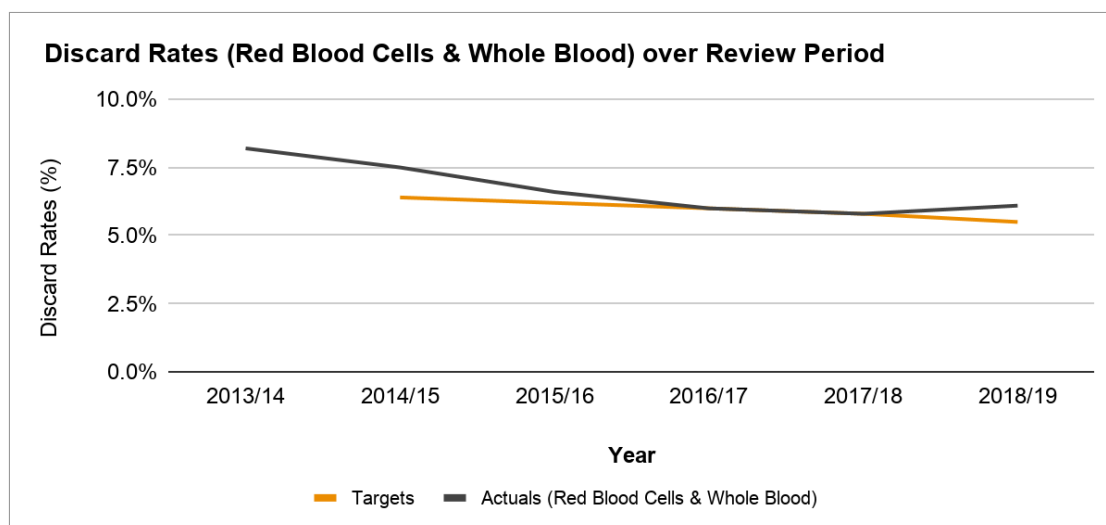
**Figure 11: Occurrence of Fresh Blood Non-Conformances over Review Period**



The reduction in non-conformances is likely a contributing factor to the general declining trend in discard rates over the review period. The highest rates of discards (see Figure 12) were reported in 2013-14 at 8.2% while the lowest rates were recorded in 2017-18 (5.8%).

Discard rates began to increase in 2018-19. CBS attributes this to the fact that they maintained a higher level of inventory throughout most of 2018-19 than in previous years. The excess inventory contributed to periods of increased outdated inventory and discards.

**Figure 12: Trends in Discard Rate over Review Period**



CBS indicated that a number of steps were taken to reduce discard rates which included:

- introduction of a phlebotomy retraining program to reduce low and underweight units collected
- introduction of a vein-marking tool to help situate the intended needle entry point and improve needle insertion success rate
- improved communication between staff, trainers, and managers about phlebotomy tips and advice and discussion to review success rates, better understand the causes of unexpected failure rates, and drive improvement
- implementation of a donor contact strategy that targets specific collections for in-demand blood groups (e.g., ONeg) and decreases donor contact for blood types that are usually part of excess inventory)

Along with an overall declining discard rate, the disparity between the actual discard rate and target discard rate began to close over the years.

#### 4.1.6.2 Recalls of Fresh Blood Components and Plasma Units Sent for Fractionation

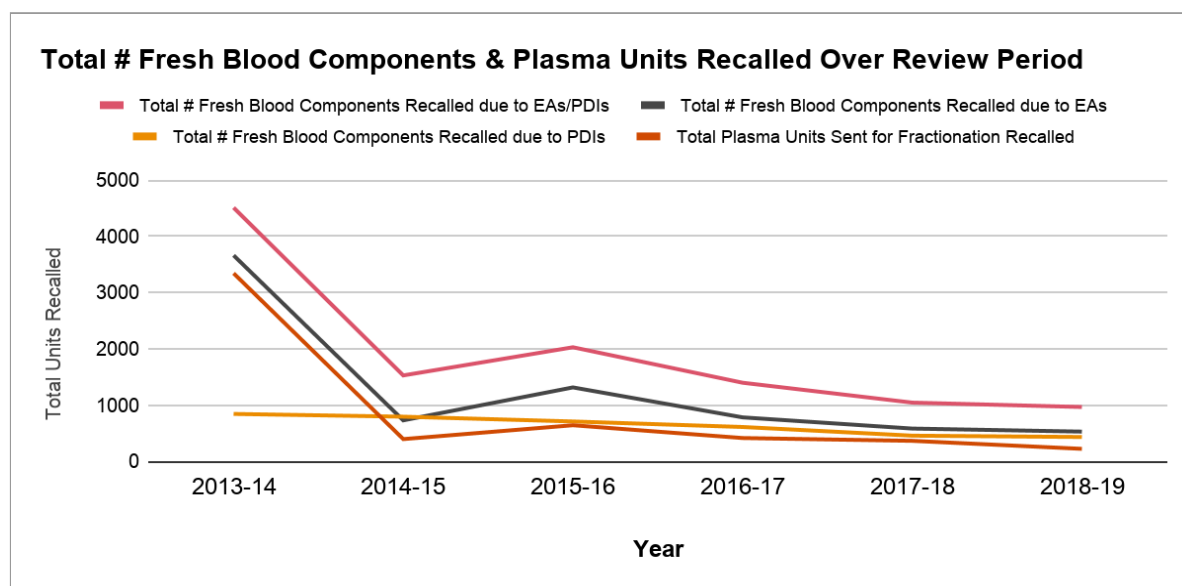
**Observation: Recalls of FBC and plasma units due to errors, accidents, and post-donation information have been declining over the review period.**

FBC and plasma units can be recalled, after distribution, due to:

- Errors and Accidents (EAs) in the process which surface concerns about product safety
- Post Donation Information (PDI) received from donors which call into question the safety of the donated blood product and plasma sent for fractionation

A review of year-over-year data, from 2013-14 to 2018-19, shows that recalls due to EAs and PDIs have been declining across both FBC and plasma units (see Figure 13).

**Figure 13: Trends in Total FBC & Plasma Units Recalled over Review Period<sup>12</sup>**



- Though there was a slight spike in 2018-19, EAs and PDIs for plasma units have declined from 207 in 2013-14 to 72 in 2018-19, representing a 65% decrease over the review period.
- Trends show that PDIs for FBC have been, on the whole, steadily declining from 847 cases in 2013-14 to 437 in 2018-19, representing a 48% decrease over the review period.
- The number of EAs have also decreased, on the whole, over the review period, from 3,663 in 2013-14 to 533 in 2018-19, representing an 85% decrease.

<sup>12</sup> Data was not available for 2012-13



#### 4.1.6.3 Adverse Transfusion Reactions Over the Review Period

**Finding: The quantity of adverse transfusion reactions has fluctuated over the review period. Though there are inherent risks with transfusions (e.g., allergic reactions), there is no data benchmarking CBS' performance relative to comparable organizations.**

In accordance with the blood regulations, sections 110-116, the hospital which is notified of an ATR must report to CBS if there is the possibility that adverse reaction (AR) is attributed to the safety of the blood product. If the ATR is assessed as a serious adverse reaction, and is attributed to an activity that occurred at the hospital, the hospital is required to report it to Health Canada (HC). CBS is required to report all serious ATRs which are assessed as related to the safety of the blood product to HC. Hospitals also voluntarily report all serious ARs to their provincial Transfusion-Transmitted Injuries Surveillance System (TTISS).

For PPP-related adverse reactions, reports are made from physicians directly to HC and the manufacturer. Examples of "serious" reactions include those resulting in death, hospitalization or prolongation of admission, congenital malformation, persistent or significant disability, requiring intervention to prevent any of aforementioned items.

Table 6 below provides an overview of ATRs over the review period. Transfusion reactions do not necessarily indicate a safety issue. There are elements of transfusion reactions that cannot be controlled despite best efforts (e.g., an allergic reaction<sup>13</sup>) and are part of the inherent risk for any transfusion.

**Table 6: Year-over-Year Adverse Transfusion Reactions over Review Period**

Adverse Transfusion Reactions	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18	2018-19
Number of adverse transfusion reactions reported to Health Canada	64	40	36	41	49	56	51

As seen in Table 6, the quantity of adverse transfusion reactions has fluctuated over the review period (with lows recorded in 2013-14 and 2014-15 at 40 and 36, respectively) but has been trending up starting towards the latter end of the review period.



#### **Recommendation 10: Introduce benchmarking of CBS' Safety & Quality performance.**

CBS should explore the feasibility of reporting on benchmark data for its critical safety and quality measures (e.g., adverse transfusion reactions) to situate CBS' safety performance relative to other comparable organizations. This will also help in identifying additional measures CBS can take to further improve its quality and safety related performance.

#### 4.1.7 Overview of the Quality Management System – A Mechanism Contributing to Enhanced Safety

In 2014, CBS commissioned a third-party health sciences / pharma biotech professional services firm to review its QMS and determine the level to which it aligned with the requirements of a biologics manufacturer. This assessment applied the six (6) elements of a Biologics QMS Model (see Figure 14 below) to CBS' quality system, as it existed at the time, to determine its level of maturity.

<sup>13</sup> Example: a donor may fail to report that they have consumed a certain product (e.g., peanuts) when going through the screening process which may in turn cause a reaction in a patient following transfusion

**Figure 14: Biologics QMS Model**



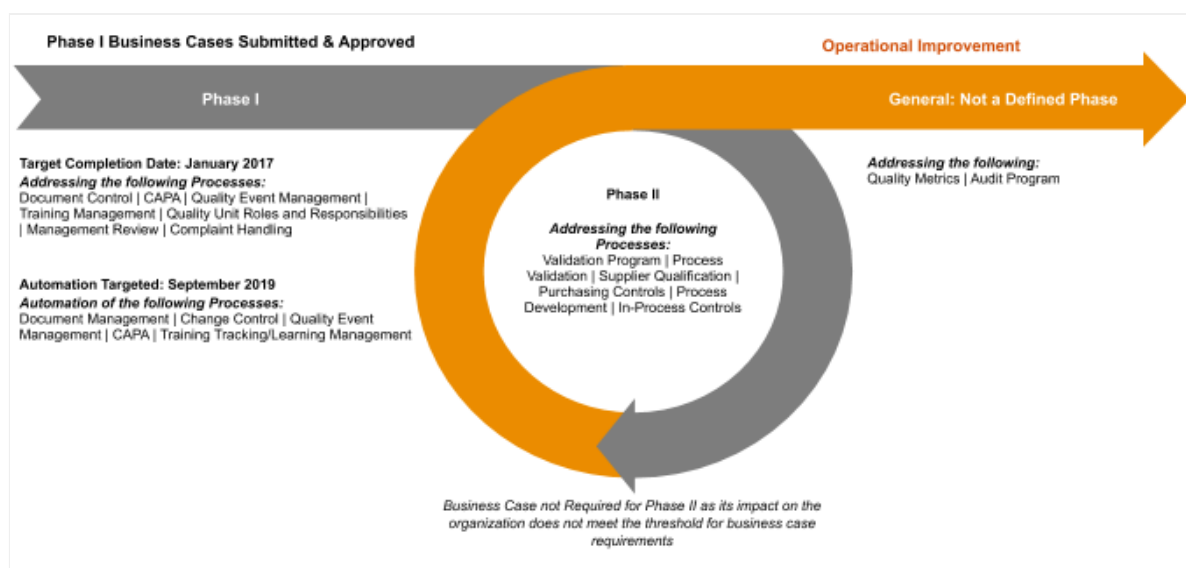
The assessment found that CBS had a QMS with the elements of a standard quality management system along with some elements of a biologics pharmaceutical manufacturer. However, it was determined that gaps existed both in CBS' system design and implementation which needed to be bridged to better achieve an effective, compliant, and sustainable QMS. Overall, the assessment identified:

- 11 high priority items requiring significant improvement;
- 16 medium priority items requiring improvement; and,
- 13 items with no significant issues.

The assessment also produced a recommended framework for the design of CBS' quality management system (see Appendix 6).

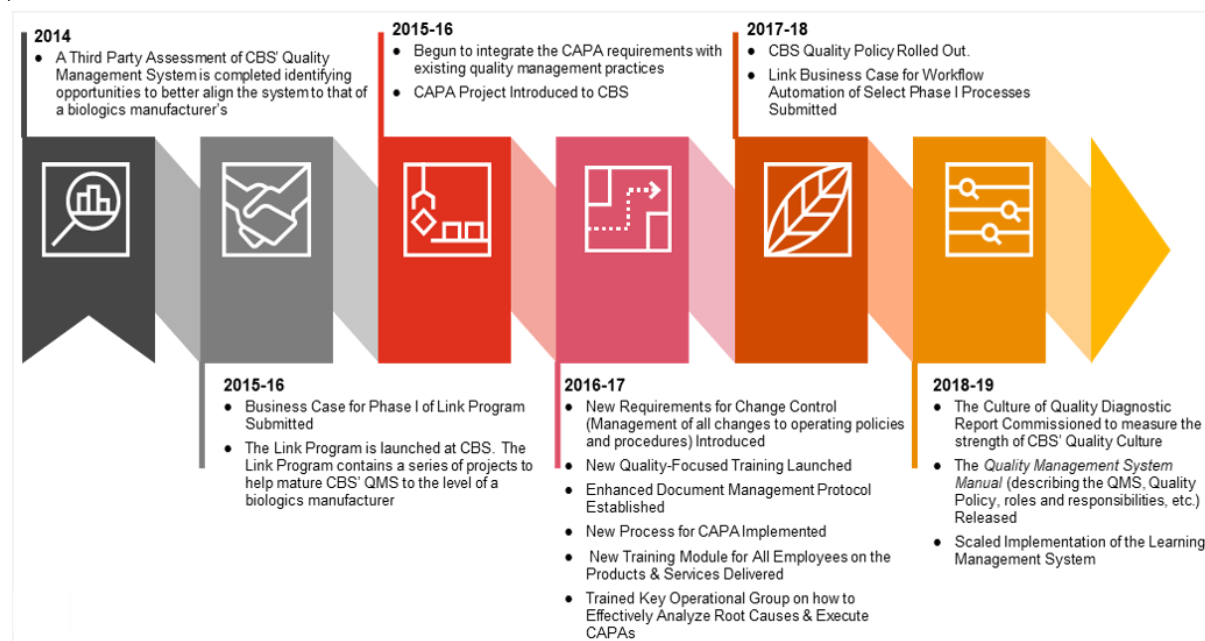
In 2015-16, CBS launched its Link Program which consisted of a series of projects to bring its QMS into alignment with that of a biologics manufacturer and address the gaps identified in the 2014 third-party assessment. A phased approach was adopted to address the priority items identified through the 2014 assessment. Each phase of this approach comprised a series of interrelated projects (see Figure 15 below). Two business cases were internally approved by CBS to support the Phase I projects.

**Figure 15: The Phased Approach to Align CBS' QMS to a Biologics Manufacturer's Model**



As of the completion of this performance review, much of Phase I had been completed (i.e., implementation of all process changes); however, there remain activities / projects that need to be actioned (these are discussed in Section 4.1.11.1- Standardized and Automated Processes below). Figure 16 provides an overview of the key activities that have occurred over the review period to mature CBS' QMS.

**Figure 16:** Overview of activities to align CBS' QMS to a Biologics Manufacturer's Mode



## 4.1.8 Quality Management Structure & Decision-Making

### 4.1.8.1 Extent to which Management Structure is Established

**Observation:** CBS has adopted the general structure required to bring the organization into alignment with a biologics manufacturer.

The proposed structure recommended (as part of the 2014 third-party assessment) for CBS' QMS included:

- Standing up of a dedicated sponsorship group overseeing the activities to mature the quality system and tracking progress on quality measures;
- Creation of a Quality Unit tasked with the management of the QMS and the requisite authority to make critical operational decisions related to the QMS.

Based on findings, over the review period, the QMS structure evolved to the following:

- The EMT sponsors both the initiative and any supporting projects to align CBS' quality management system to a biologics manufacturer's model. The initiative is overseen by the BoD by way of its *Safety, Research and Ethics Committee (SREC)*.
- Management and administration of the QMS is the responsibility of the Quality and Regulatory Affairs business unit. The business unit includes teams dedicated to:
  - quality management processes, including process design;
  - general solutions design;
  - quality assurance;
  - continuous improvement;
  - education and training;

- management of the Learning Management System (LMS);
- technical writing; and
- general QMS management.

Members of the Quality & Regulatory Affairs Team reported that each product line (e.g., FBC) assumed responsibility for quality in the context of their specific product. They monitor, track, and report on quality measures specific to their product line.

Responsibilities identified as critical for a biologics manufacturer's Quality unit. These responsibilities have been assumed by CBS' Quality and Regulatory Affairs business unit.

#### 4.1.8.2 Evidence-Based Decision-Making

**Observation: CBS has implemented an approach that enables evidence-based decision-making in relation to quality.**

The organization uses both a Quality Index and a CAPA<sup>14</sup> Index (both containing a series of quality measures / indicators) to track performance (these are discussed in greater detail in Section 4.1.12- Quality Measures below). These measures form inputs into operational and management meetings and enable evidence-based decision making. Specifically:

- Each Quarter the *Corporate Quality Management System Review (QMSR) and Balanced Scorecard* meeting is held at the national level with members of the EMT. At these meetings, matters such as national trends on key quality and safety measures (e.g., errors and accidents, non-conformances, customer complaints), CAPA performance issues / risks (e.g., open high risk CAPAs), and other quality and safety matters are discussed. These meetings produce a series of action items which are assigned to an owner and tracked.
- Each month a regional level meeting (the Regional QMSR) is held. At this meeting, participants review CAPAs, their status, and approaches to address any overdue CAPAs.

### 4.1.9 Quality Roles and Responsibilities

#### 4.1.9.1 Clarity of Roles and Responsibilities

**Finding: While CBS has taken steps to describe and clarify roles and responsibilities as they relate to quality, there continue to be opportunities for enhancement.**

CBS takes the view that quality and safety are the responsibility of all staff at CBS and should be the cornerstone of daily activities. Steps taken over the review period to clarify roles and responsibilities included:

- The release of the Quality Management Manual in 2018-19 with a focus on the governance aspects of quality. This Manual included:
  - an overview of the QMS and its components;
  - the organization's quality / safety expectations of all staff;
  - the responsibilities of management; and
  - listed the legislative and regulatory requirements to which CBS is held to account.

All managers completed an e-learn of the new manual.

- Rollout of training to staff. In 2016-17, the majority of CAPA investigators / approvers completed CAPA investigator / approver training.

<sup>14</sup> CAPAs are Plans created when a non-conformance has occurred. They are a tool developed to address the non-conformance and prevent it from recurring in the future.

In May 2018, CBS contracted a third-party professional services firm to conduct an assessment of its quality culture. As part of this assessment, the third-party contractor surveyed all CBS staff members on measures to assess clarity on roles and responsibilities and received 780 responses.

CBS' performance on these measures were found to be at or within the range of the Benchmark Company Average used (see Table 7 below); however, there was a larger gap when comparing CBS to Top Performing Companies in relation to some measures (# 2, 5 and 7 in Table 7). These findings indicate that while staff understand their roles and responsibilities, they require:

- greater clarification on how their responsibilities / duties contribute to creating and sustaining the organization's quality performance; and
- more targeted communication to help frame how leadership priorities support the organization's quality mandate / commitment.

**Table 7: Indicators of Role / Responsibility Clarity<sup>15</sup>**

Measures	Comparison of CBS' Performance <sup>16</sup>		
	Average of Top Performing Companies	Benchmark Company Average	CBS' Average
1. People clearly understand how quality expectations fit into their job requirements	7.1	6.7	<b>6.9</b>
2. My peers are directly involved in efforts to create and sustain quality performance	7.0	6.7	<b>6.6</b>
3. My peers are held accountable for quality performance	7.1	6.7	<b>7.0</b>
4. The message regarding quality's importance at my company is easy to understand	7.2	6.8	<b>7.0</b>
5. It can be difficult for people in my company to make sense of all the different leadership priorities*	5.6	5.8	<b>6.3</b>
6. People at my company are told that high quality performance is a leadership priority	7.3	7.0	<b>7.1</b>
7. My manager "walks the talk" when it comes to quality	7.5	7.3	<b>7.1</b>

\* Lower scores represent higher performance on this driver

### **Recommendation 11: CBS should develop role-based personas to strengthen the organizational culture mindset around quality.**

CBS should develop simple, easy-to-understand personas that showcase how the roles played by / duties performed by employee groups contribute to supporting both CBS' quality mandate / commitment and its strategic objectives. Once developed, these personas can be:

- introduced as part of training (e.g., onboarding training) to help provide staff with a clear view of how their duties are contributing to quality, and
- shared with staff (e.g., through posting on a bulletin board, in an email, etc.) as a way of illustrating how staff, as part of their daily duties, are contributing to quality at CBS.

<sup>15</sup> Source: Third Party Professional Services Firm. May 2018. Culture of Quality Diagnostic Report: Canadian Blood Services

<sup>16</sup> The numbers that follow represent the average rating based on a 9 point scale where "High" performance is represented by a score of 7 to 9. The Nine point agreement scale: 1 = Strongly Disagree, 5 = Neither Disagree Nor Agree, 9 = Strongly Agree



**Recommendation 12: CBS should explore opportunities to enhance the training approach for quality.**

CBS should explore strengthening the incorporation of adult learning principles into its Quality Management training. This would enable learning objectives to be met through “group learning events” that provide trainees with the opportunity to physically experience (through role plays, hands-on learning) and contextualize learning.

CBS should also consider introducing a formal coaching and mentorship program where knowledgeable and experienced staff work with other staff to help impart institutional knowledge (e.g., Standard Operating Procedures, approved ways of working / practices, etc.).

**Recommendation 13: CBS should include “performance on quality measures” as part of senior management’s annual performance assessments.**

CBS should introduce performance on quality measures to the list of criteria assessed during the annual performance reviews of senior management. This approach would further tie individual roles and responsibilities to the performance of each division.

**Recommendation 14: CBS should survey employee safety awareness and comfort around raising safety and quality issues.**

CBS should survey employees annually to assess their overall safety awareness and comfort around raising safety or quality related issues.

## 4.1.10 Quality Culture

### 4.1.10.1 Extent to which a Quality Culture has been Developed

**Observation: CBS has made progress in establishing a quality culture in the organization.**

The 2014 independent assessment recommended the creation of a clear (easy to understand) Quality Policy that reflected CBS’ role as a biologics manufacturer and the overall objective of the organization’s QMS. It also recommended that CBS introduce its revised Quality Policy and ensure that it is well-communicated across the organization.

The new Quality Policy was introduced to the organization in 2017-18 with an objective to build and sustain a quality culture at CBS. The organization’s QMS is framed by this Quality Policy which defines the organization’s overall approach to the matter of quality. To support quality, the Policy contains a requirement for all employees to live and uphold the safety culture and speak up if they see a safety infringement.

The third-party professional services firm that conducted a culture assessment of CBS in 2018, used 4 key measures (see Table 8 below) to determine the level to which quality had been embedded in the organization’s culture.

**Table 8: Measuring CBS’ Quality Culture**

Measure	Average of Top Performing Companies	Benchmark - All Companies	CBS’ Average
Hear Quality (i.e., staff hear other staff speak about Quality)	57%	52%	<b>52%</b>
Feel Quality (i.e., staff feels Quality all around)	71%	62%	<b>71%</b>
See Quality (i.e., staff sees others taking Quality Focused-Actions)	40%	35%	<b>43%</b>
Transfer Quality (i.e., staff transfers Quality to peers)	55%	48%	<b>54%</b>



A total 780 CBS employees participated in the quality survey and it was found that CBS was performing at about the level of or exceeding the level of high performing companies in three of the four measures tracked. The only measure where CBS was not performing to the level of high performing companies was *“Hear Quality (i.e., staff hear other staff speak about Quality)”* where CBS was performing at the average level of the 131 benchmark companies.

The quality culture assessment showed that CBS was performing within the first quintile of (i.e., with a high Culture of Quality Index Score) indicating that the organization is, from a Quality Culture perspective, within the spectrum of a biologics manufacturer and is closing the gaps identified in the 2014 Assessment.

## 4.1.11 Quality Processes

### 4.1.11.1 Standardized and Automated Processes

**Finding: CBS took steps to standardize and automate processes, but opportunities exist for further advancement.**

Progress has been made in automating the workflows of some processes (e.g., Document Management, Change Control, Quality Event Management, CAPA Training / Learning Management) that are a part of the QMS; however, the full scope CBS' goals has not been realized. Specifically:

- **Work Instructions.** The goal of Link was to standardize activities and move away from local work instructions. Additionally, CBS had set a goal to improve all work instructions by March 31, 2019. This was not achieved, due to the volume of work instructions. CBS is now targeting June 2020 for improving all work instructions.
- **LMS.** There was scaled implementation of the LMS with the system being rolled out to a few employees. Further, though training is underway, not all training is electronic or in the LMS. Some training remains paper-based and training automation is slated for future QMS maturity phases beyond the time covered as part of this performance review.
- **Electronic Containment.** The initial intent was to have “electronic containment” of products that have a quality event raised against them. This was not achieved because there is a reliance on ePROGESA (the regulated technical system used by CBS) to make this possible. As a result, there is a work-around in place that requires CBS to assess each product to determine risk / impact level and then take steps to disposition, as appropriate.
- **Automation.** Automation of some workflows has been achieved; however, broader automation (e.g., of CAPAs, change control, training, etc.) remains a goal. Automation has been slower than anticipated as variability in processes has required more time to achieve standardization.

Limited automation impacts the level to which CBS can achieve organization-wide consistency in the application of process steps.



#### **Recommendation 15: CBS should continue to evolve the Quality Management System.**

CBS should continue to align with industry best practices / standards with respect to its QMS. Consideration should be given to the following:

- expanding the scope of the QMS to include other processes (e.g., donor experience), and internal service business units (e.g., Finance, Human Capital / Human Resources);
- introducing approaches to address low risk non-conformances;
- continuing to expand system automation with a view to reducing manual / paper-based processes; and
- beginning to proactively inform the organization's strategy by exploring matters related to customers (e.g., understanding the customers' current and future / evolving needs and raising them, where relevant, as quality matters to be addressed by the organization).

## 4.1.12 Quality Metrics

### 4.1.12.1 Quality Measures

**Observation:** CBS took action to address the quality measures gaps identified as part of the 2014 assessment.

There is now:

- a clear process that identifies and systematically collects quality measures (indicators / metrics) from across the organization. These measures track CBS' progress towards achieving quality requirements be they legislative, regulatory, organizational "practices" and enable the organization to evaluate effectiveness and make evidence-based decisions
- quality measures are reported to and reviewed by the EMT on a quarterly basis
- quality events and their effectiveness are being tracked and reported on
- there is uniformity in the way that quality events (i.e., non-conformances, customer complaints, rejected units) are captured and reported

The assessment that follows looks at the extent to which established quality measures have been met over the review period as an indicator of the evolving maturity of the QMS.

### 4.1.12.2 Extent to which Quality Measures have been Met

**Observation:** CBS achieved its performance targets on quality measures.

CBS uses a Quality Index (supported by a series of measures) to track and report on quality performance. This index tracks and reports on six of the eight (8) principle measures (see Table 9 below).

**Table 9:** Year-over-Year Quality Index Measures Tracking

Quality Index Measures	2014-15 Baseline Year	2015-16	2016-17	2017-18	2018-19
Number of FBC recalled due to errors/accidents and post-donation information	1,531	2,031	1,401	1,048	970
Number extreme errors/accidents (FBC)	0	0	0	0	0
Number reported adverse transfusion reaction	36	41	49	56	51
Number Health Canada critical observations	0	0	0	0	0
Number plasma units sent for fractionation recalled due to errors/accidents and post-donation information	400	464	419	369	227
Number of supplier recalls / timely execution of supplier recalls (PPP)	0	0	4 Recalls	1	0

\* Prior to 2017-2018 the Quality Indicator was "number of supplier recalls"; the measure changed beginning in 2017-18 to "timely execution of supplier recalls"

Table 9 presents data on CBS' performance against each quality measure. The review found that the year-over-year targets have remained consistent over the review period.



#### 4.1.12.3 Corrective Action and Preventive Action Measures

**Finding: While overall progress has been made on CAPA improvements, the pace of progress has been slower than planned/expected. In particular, the pace at which open CAPAs are closed within 30 days is slower than anticipated; and has remained consistently below established targets.**

The 2014 third-party assessment of CBS' QMS found that there was a gap that needed to be bridged in relation to Corrective Action and Preventive Action (CAPA). The assessment found that:

- there was a need for a CAPA program that incorporates CBS' written procedures and is supported by implementation tools
- data collected on non-conformances needed to be meaningful, sufficiently detailed, and coded accurately to implement comprehensive CAPAs
- CAPAs were not addressing root causes
- the CAPA concept was not well understood and many employees were not aware of its purpose

The CAPA process (which includes root cause analysis, CAPA plans, and effectiveness checks) was introduced to CBS in 2015-16. The process targeted those non-conformances identified as "medium" and "high" risk. To achieve standardization across the organization in categorizing non-conformances and CAPAs, a non-conformance and CAPA categorization checklist was developed to assign risk ratings to both non-conformances and CAPAs.

Overall progress has been made on CAPA plans; however, not to the pace set by CBS. 2016-17 saw the highest percentage (36%) of CAPAs completed within 30 days of being opened; that said, the rate was well below the target of 95% (see Table 10 below) set by CBS. Though the targets decreased in 2017-18 (50%) and 2018-19 (35%); less than 30% of CAPAs were completed within 30 days of being opened in either year.

**Table 10: Year-over-Year CAPA Index Tracking**

Corrective Actions and Preventive Actions Measures	2016-17		2017-18		2018-19	
Target vs Actual	Target	Actual	Target	Actual	Target	Actual
Percent of CAPA plans completed in the quarter within 30 days of the CAPA being opened	95%	36%	50%	21%	35%	27%
Percent of CAPA solution(s) implemented within 4 months of CAPA being opened	80%	82%	80%	73%	60%	59%
Percent decrease in the rate of moderate and high-risk quality events from previous quarter	--	--	decrease	86% decrease	decrease	5% decrease

**Legend:** Red highlights indicate instances where Actuals were outside the range of established targets

Notwithstanding, once CAPA plans are completed, the approval timeline for those Plans was improving (i.e., 50% of CAPA plans were approved in less than 75 days in 2017–2018, while 50% of CAPA Plans were approved in less than 45 days in 2018-19).

Implementation of CAPA plans has been fluctuating over the years reviewed. Outside of a dip in 2017-18, the gap between the targeted performance and actual performance is closing.

CBS attributes the performance gap in the timelines to achieve CAPA targets to a combination of factors:

- the deferring of the implementation of solutions to later dates;
- an overestimation of the ability of the solutions to drive benefits within specified timelines (i.e. longer benefits realization period);
- chosen solutions not being sufficient or adequate to close gaps; or
- not having a sufficient volume and availability of staff (FTEs) to investigate and close CAPAs within established timelines.



**Recommendation 16: CBS should review CAPA completion targets.**

CBS should investigate approaches to better align targets to operational realities. This may include:

- engaging with comparable organizations to determine a reasonable rate of change that can be expected of a biologics manufacturer invested in maturing its quality system; and
- conducting a capacity and capability assessment to determine the staffing complement required to achieve targets and taking steps accordingly.



**Recommendation 17: CBS should confirm adoption of new behaviours/practices addressing non-conformances.**

To further enhance the effectiveness checks that are a part of the CAPA plan implementation process, CBS should introduce a formal approach to “spot check” for compliance following the implementation of a CAPA plan. This will enable the “spot checker” to determine the level to which the non-conformance behaviours/practices have been addressed, adopted by employees and embedded within standard day-to-day operating procedures.

## 4.1.13 Stakeholder Satisfaction

### 4.1.13.1 Products Meeting Specifications & Providing Benefit to Patients

**Observation: On the whole, CBS is meeting product specifications.**

There were no extreme<sup>17</sup> errors or accidents related to FBC over the years reviewed and there was a 43% decrease in the number of plasma units (sent for fractionation) that were recalled due to errors/accidents and post-donation information.

In August 2013, CBS issued a recall to hospitals for 1,500 units of blood. This was due to a failure of a Cytomegalovirus (CMV) test which was not performed according to specifications to identify the presence of CMV in platelet orders. This non-conformance was identified by CBS when the organization was conducting a routine safety audit. CMV is a common community-acquired infection that lies dormant in white blood cells and is harmless in the case of most individuals. That said, customers can request CMV-negative platelet orders.

### Providing Benefit to Patients

Despite the 2013 recall, overall satisfaction with CBS’ ability to meet the requirements of blood and blood components was ranked relatively highly among CBS’ customers (i.e., hospitals and healthcare centres) and its funders (i.e., Members).

<sup>17</sup> Extreme refers to an occurrence that meets the threshold to be reported to Health Canada and can result in adverse impact to patients.

In January 2019, CBS conducted an online survey with hospitals and healthcare centres across Canada (except Quebec) to assess how the organization was viewed in relation to blood and blood products. A total of 208 institutions responded to the survey. Results showed that:

- 98% of survey respondents trusted CBS to act in the best interest of the public
- 99% saw CBS playing an essential role in improving patient outcomes

This pattern is consistent with results from hospitals surveyed over the period of 2012-2018. During that time, 99% of participating hospitals indicated satisfaction with the safety of CBS' FBC and PPP.

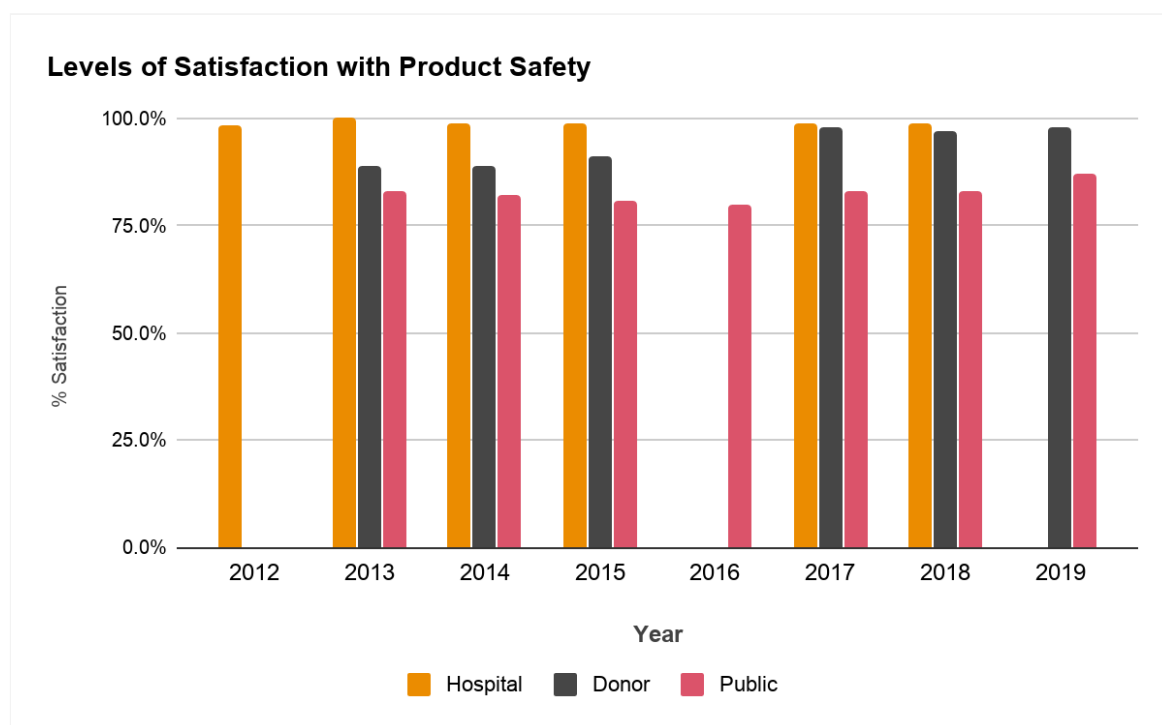
In addition to hospitals and healthcare centres, Member representatives were engaged (between the period of 2017-2019) and asked to provide feedback on the level to which CBS plays an "essential role in achieving improved patient outcomes". Results show that Members view CBS' role contributing to patient outcomes as growing in significance over the years (i.e., rating the organization at 7.0 out of 10 in 2017, and 8.9 out of 10 in 2019).

#### 4.1.13.2 Key Stakeholder Satisfaction with Safety of CBS' Products and Services

**Observation: Surveys results over the review period indicated that the majority of hospitals, donors and the Canadian public viewed CBS' products as safe. Similarly, the majority of donors and the public viewed the process of donating blood also as being safe.**

While there was some fluctuation in the public's view (see Figure 17), the year-over-year trends show that the levels of satisfaction with the safety of CBS' products have been increasing over the years with the highest levels of public and donor satisfaction registered in Spring 2019 (public satisfaction registered at 87% while donor satisfaction registered at 98%).

**Figure 17: Perceptions of Product Safety (Hospital, Donor, Public) over Review Period<sup>18</sup>**



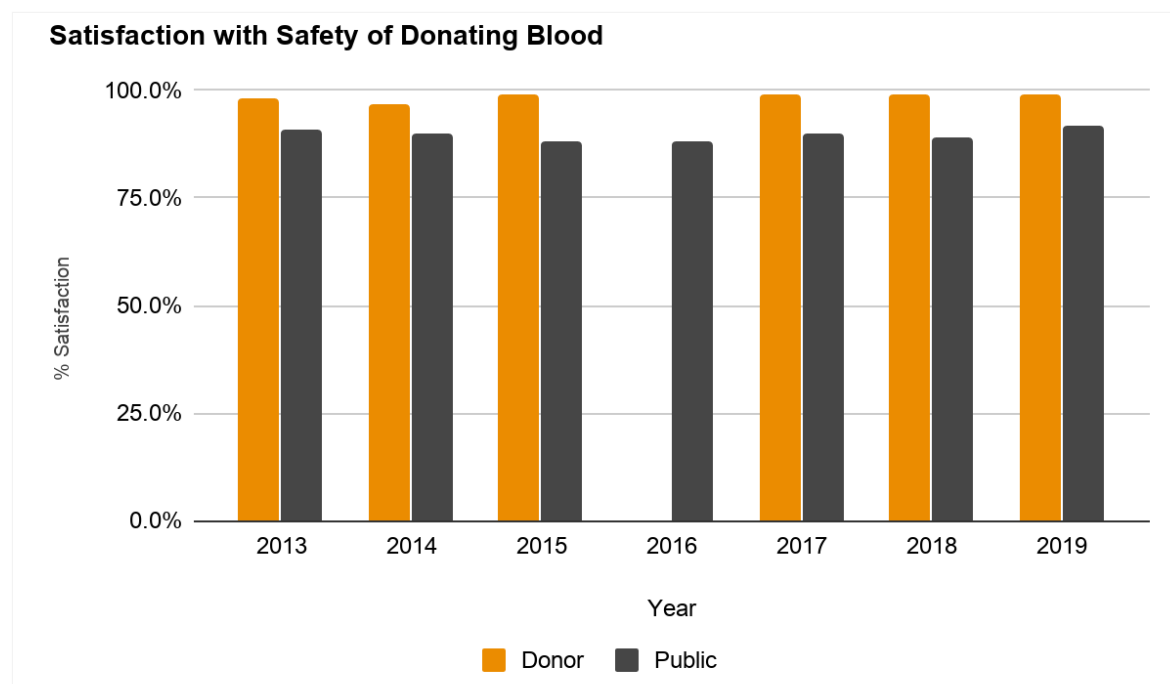
In addition to the public and donors, hospitals were also surveyed and asked to indicate their level of "satisfaction with safety of FBC and PPP". As seen in Figure 17, the level of hospital satisfaction has remained consistently high (between 98.5% and 100%) over the review period.

In addition to satisfaction with the safety of CBS products, donors and the public were also asked, in

<sup>18</sup> No data was available for donors and the public in 2012; and no data was available for hospitals and donors in 2016.

surveys conducted over the review period, if they believed that the process of donating blood met their definition of “safe”. As seen in Figure 18, donors have consistently registered high levels of satisfaction (between 97% - 99%) with the safety of the donation process.

**Figure 18: Donor and Public Perception of Safety of Donating Blood over the Review Period<sup>19</sup>**



The public also viewed the donation process as relatively safe. When surveyed on the matter of “*safety of donating blood*”, the public reported levels of satisfaction ranging between 88% to 92% (see Figure 18).

**Finding: CBS has not established tolerance levels for stakeholder satisfaction measures.**

As discussed above, CBS conducted several surveys, over the review period, with key stakeholders to determine levels of satisfaction with regards to product safety and safety of donating blood. However, CBS did not establish acceptable tolerance thresholds for its stakeholder/customer satisfaction measures.

**Recommendation 18: CBS should define tolerance levels for stakeholder satisfaction measures.**

Patient/stakeholder satisfaction tolerance levels should be informed by health industry practices and supported by a strategy (e.g., investigations, remediation steps, etc.) for dealing with situations when performance slips below established tolerance levels.

<sup>19</sup> No data was available for donors in 2016

## 4.2 Customer Supply Needs

### 4.2.1 Objectives

The objectives of this section are to evaluate:

- Forecasting methods, including:
  - Comparison of forecasts to actual results and review of forecasting models; and
  - Understanding of demand drivers.
- The effectiveness of meeting customer supply needs and expectations of customers.

### 4.2.2. Scope

There are three focus areas for this section:

- **Focus Area 1:** Effectiveness of meeting customer needs, including:
  - Product shortages over review period; and
  - Levels of satisfaction as indicated by survey results.
- **Focus Area 2:** Forecasting methods, including clinical inputs.
- **Focus Area 3:** Comparison of forecasts to actual results and analysis of the underlying root causes.

### 4.2.3 Context

CBS creates annual forecasts for different products to help prepare the future year's funding estimates. They also share this information with their supply chain team to manage the monthly demand. The forecast is provided for both the FBC and PPP business lines.

Team members from CBS' Supply Chain and Medical Affairs and Innovation function prepare statistical models based on historical utilization trends. The team then consults with key stakeholders to obtain additional demand information, such as emerging trends, to refine the model. The stakeholders that are consulted include:

- PT officials, physicians, ABO members and hospitals, patient groups for FBC; and
- PT officials, physicians, suppliers, hospitals, patient groups and the Canadian Agency for Drugs and Technologies in Health (CADTH) for PPP.

The forecasting team further compares the information with qualitative data to refine the model and issues it for input from the Medical Affairs and Innovation and Finance teams. CBS' forecasts for FBC and PPP includes review of information received from hospitals.

In May 2014, CBS upgraded the system to monitor and evaluate hospitals' disposition of blood product inventories. Hospital administrators can now use a web-based application to report their use of FBC and PPP products. In addition to capturing disposition data and generating daily inventory updates, the system compiles detailed monthly reports.

This new process provides insights around product management and enables hospitals to compare usage patterns. It is helpful to health-care providers in understanding and discussing transfusion related best practices and opportunities for improvement.

The forecasting process influences decisions regarding:

- Donor base requirements - size and type;
- Geographic distribution of collections - numbers and locations;
- The type of products - Red Blood Cell (RBC) and PPP components; and
- Donor centre schedule for staff.

The donor centre staff assignment occurs months in advance and it is difficult for CBS to alter its donor centre plan once the demand targets are set. Inaccurate forecasts may prevent CBS from reaching its order fill rate targets and can result in the need to supplement supply plans within the normal planning horizon. This can increase recruitment and other collection costs when additions are made with shorter notice.

The sub-sections below cover CBS' ability to meet customer needs and the associated level of customer satisfaction during the review period, including forecasting variances and product shortages.

## 4.2.4 Key Themes

Below is a summary of our key themes for this area:

**Table 11:** Summary of key themes

Area of Focus	Observation	Finding
<b>Forecasting Methods and Comparison of Forecast to Actual Demand</b>		
<b>Forecasting Methods</b>	<ul style="list-style-type: none"> <li>• CBS' forecasting methodology includes many of the attributes of a mature process</li> </ul>	<ul style="list-style-type: none"> <li>• CBS' forecasting approach could be further enhanced with expanded sets of patient and treatment data for FBC and PPP products</li> </ul>
<b>Comparison of FBC Forecasting to Actual Demand</b>	<ul style="list-style-type: none"> <li>• Red blood cells had the lowest variance among the three components of FBC</li> </ul>	<ul style="list-style-type: none"> <li>• Forecasting for plasma for transfusion and platelets ranged from -14% to +4%</li> </ul>
<b>Comparison of PPP Forecasting to Actual Demand</b>		<ul style="list-style-type: none"> <li>• Forecasting for PPP fluctuated, with over 90% variance within one product category (rFVIIa)</li> </ul>
<b>Customer Needs</b>		
<b>FBC Customer Needs</b>	<ul style="list-style-type: none"> <li>• CBS experienced some short-term and minor shortages for red blood cells and platelets but there were no critical shortages</li> </ul>	<ul style="list-style-type: none"> <li>• Donor retention has declined in six of the seven years which presents a significant risk to meet customer needs for FBC</li> <li>• With O-negative stocks in short supply, a pan-Canadian approach is needed to manage and protect the supply of O-negative blood</li> </ul>
<b>PPP Customer Needs</b>	<ul style="list-style-type: none"> <li>• CBS took action to improve its plasma sufficiency and reduce its reliance on foreign sources of Ig</li> <li>• Hospitals indicated that they were satisfied with the availability of the PPP brands and the different PPP vial sizes received from CBS</li> </ul>	<ul style="list-style-type: none"> <li>• While CBS did not experience any critical product shortages for PPP, enhanced datasets from hospitals would help support more accurate forecasting of PPP</li> </ul>

## 4.2.5 Key Review Observations and Findings

### Forecasting Methods and Comparison of Forecast to Actual Demand

#### 4.2.5.1 Forecasting Method

**Observation: Based on PwC's forecasting capability maturity profile, CBS' forecasting methodology exhibits many of the attributes of the advanced stage.**

Based on PwC's capability maturity profile for forecasting (see Appendix 7), CBS' forecasting capabilities are at an advanced stage (stage 3):

- Forecasts include multiple inputs such as market intelligence from suppliers, other ABO members and the PTs. These include planned product transitions and product pricing insights;
- Forecasts contain clinical inputs from hospitals, clinicians and CADTH;
- Forecasts include advanced forecasting methods, including time series analysis to develop the forecasts;
- Forecasts are developed by a designated and advanced statistical analysis team in CBS;
- Forecasting and demand planning processes are interconnected, and forecasts are developed using key inputs from demand planning teams; and
- Forecasting accuracy and bias are tracked, and the forecasting methods are continually refined.

**Finding: CBS' forecasting approach could be further enhanced with expanded sets of patient and treatment data for FBC and PPP products.**

Currently, the type of data available to support FBC and PPP forecasts is limited to whether the product was administered to the patient or not.

- If the product was used, a note is provided indicating whether it was used for an inpatient or outpatient.
- If the product was not used, data is captured on the nature of the discard or if the product was returned, redistributed or transferred to another hospital or region.

While this data is useful for hospitals, it does not support an overall understanding of hospital demand for CBS. Utilization data at the treatment level would provide CBS with better information on patient requirements. Examples of utilization data provided by hospitals in other countries<sup>20</sup> include:

- Utilization by diagnosis-related group
- Utilization by speciality (e.g. Neurosurgery, Intensive Care Unit, Orthopedics)
- Patient demographic information (e.g. age)

Specifically for PPP, treatment-related data such as the outcomes of the medication, prescribed dosage, intended frequency of use and duration of treatment would impact accuracy of forecasts.



**Recommendation 19: To support more accurate forecasting, CBS should work with hospitals and PTs to expand the data set to include greater detail around utilization and treatment-related information.**

As outlined in Section 4.3.7 (PPP Utilization Management), treatment-related data would also inform utilization management for PPP. Therefore, data requirements for forecasting and utilization management should be coordinated.

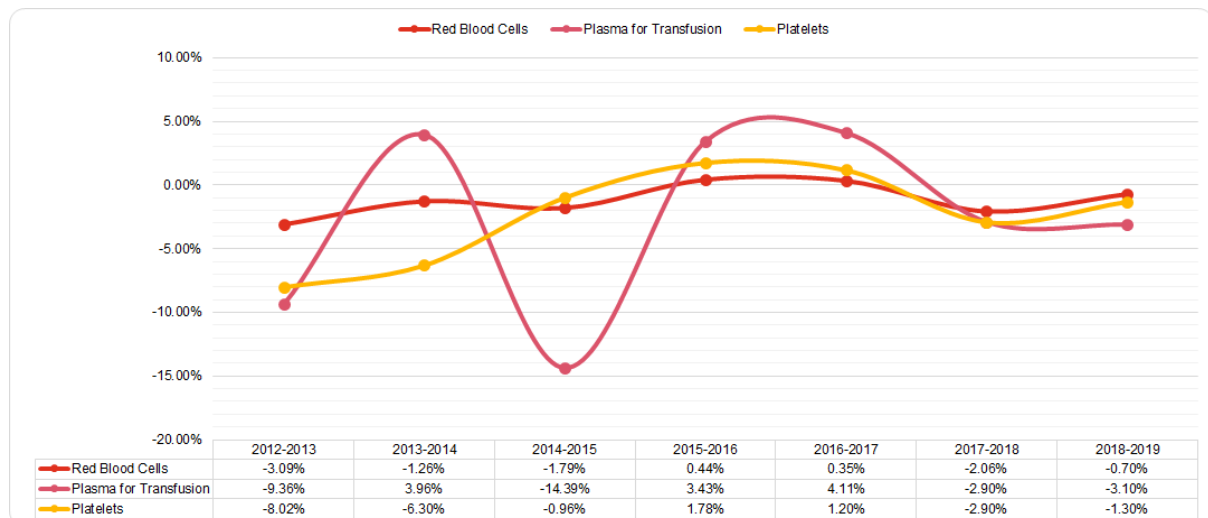
<sup>20</sup> WHO report "Estimate Blood Requirements - Search for a Global Standard"  
[https://www.who.int/bloodsafety/transfusion\\_services/estimation\\_presentations.pdf](https://www.who.int/bloodsafety/transfusion_services/estimation_presentations.pdf)

#### 4.2.5.2 Comparison of Forecast to Actual Demand - FBC

**Observation:** Forecasting for red blood cells (RBC) had the lowest variance among the three elements of FBC (RBC, plasma for transfusion and platelets).

- RBC make up the majority of FBC demand at approximately 80%.
- The demand forecast variance for RBC ranged from -3.0% to +0.4%, as seen in Figure 19 below, and was fairly stable.

**Figure 19:** CBS FBC budget to actual variance 2012-13 to 2018-19



**Finding:** The forecast variance for plasma for transfusion and platelets was higher than RBC.

- Forecast variances for plasma for transfusion ranged from -14.39% to +4.11% (see Figure 19 above) as demand declined due to the introduction of PPP substitutes, and more conservative transfusion practices.
- The forecast variance for platelets varied from -8.02% to +1.78%, though not as much as Plasma for Transfusion.



**Recommendation 20:** Refer to recommendation #19.

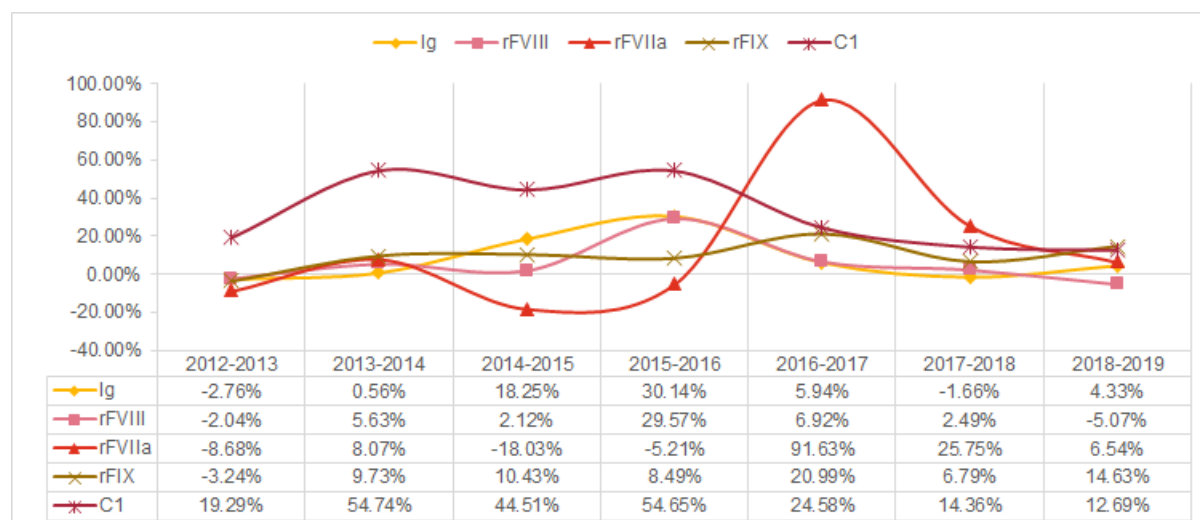


### 4.2.5.3 Comparison of Forecast to Actual Demand - PPP

**Finding: Forecasting for PPP fluctuated, with over 90% variance within one product category.**

- The five PPP product categories that make up an average of 86% of total spend have been challenging to forecast, with the most significant variances occurring for products rFVIIa, rFIX and C1 as shown in Figure 20 below.

**Figure 20: CBS budget to actual variances for the top 5 PPP product categories from 2012-13 to 2018-19.**



- In 2016-17, rFVIIa experienced an increase in demand that was not foreseen and caused a 92% variance and \$17.6 million impact in funding. The demand for rFVIIa has continued to fluctuate in subsequent years. rFVIIa is used as a treatment for a variety of blood disorders, including bleeding related to traumatic injury, major hemorrhage following surgery and bleeds for hemophilia patients with inhibitors. Its application can require a large amount of the product for one patient and is, therefore, challenging to forecast.
- Hospitals are requested to submit disposition data for the previous month for all PPP by the 10th working day of each month. Hospitals are also encouraged to provide inventory data on a daily basis via the inventory webpage. However, these requests are not consistently responded to across PTs. CBS experiences delays of up to two months from some PTs in receiving the data.
- CBS has a collaborative relationship with hospitals but has no authority to mandate them to submit data. As such, the percentage of hospitals reporting disposition data within each province varies from 41% to 100%.

**Recommendation 21: CBS should establish a working group to analyze and monitor PPP demand, including representation from PTs, suppliers, clinical experts and patient groups.**

- The group should look at ways of better predictability for PPP demand forecasting.
- CBS should work with the PTs to improve the timeliness and consistency of hospital reporting with regards to PPP inventories.

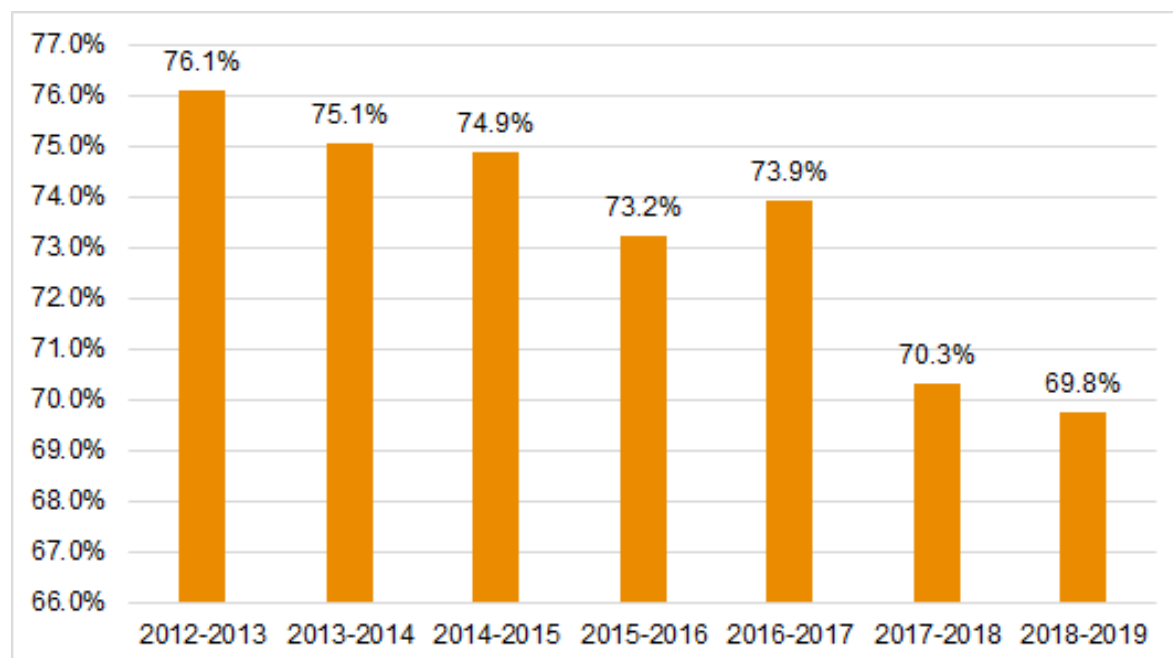
## 4.2.6 Customer Needs

### 4.2.6.1 FBC

**Finding: Donor retention declined in six out of seven years, which presents a risk in meeting customer needs for FBC.**

- Donor retention<sup>21</sup> decreased from 76.1% to 69.8%, as shown in Figure 21 below.

**Figure 21: CBS Donor Retention Rates 2012-13 to 2018-19**



- CBS has been proactive in addressing donor engagement and improving the donor experience. It has leveraged digital technologies to expedite the donation process and improve donor experience.
- To help support donor retention, CBS also launched the donor experience project (see Section 5.1.3) to increase its relevance to a new and diverse generation of Canadians and improve the donation journey.



**Recommendation 22: CBS should establish a task force consisting of representatives from CBS and healthcare agencies to review existing processes, capabilities and technology and identify new opportunities for improving donor retention.**

**Recommendation 23: CBS should investigate the feasibility of adding new functionality to its online donor booking system to help minimize donor deferrals and increase donor engagement.**

- Integrate the automated donor questionnaire with the online appointment booking process for donations.
  - The online donor booking process allows a member of the public to book an appointment and go to a collection site without knowing whether they are eligible to donate or not.
  - CBS should implement functionality that requires completion of eligibility criteria prior to an online booking. As part of this functionality, CBS should include an auto-deferral notice for a potential donor who's deemed to be ineligible to donate based on their answers to the pre-screening criteria. This would help:

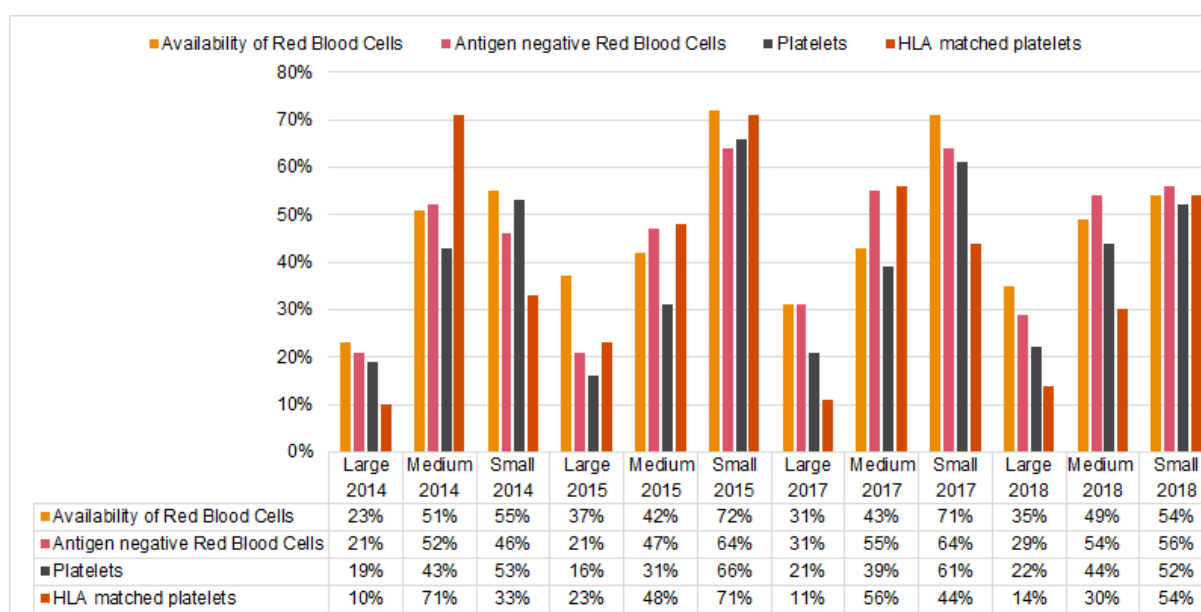
<sup>21</sup> Donor retention is defined as total whole blood donors donating 12 months prior, who have returned to donate in the next 12 months

- minimize the amount of ineligible donors visiting a donor centre;
  - reduce donor time in the donor centre to complete questionnaires; and
  - provide a source of data on potential donors.
- Enhance Customer Relationship Management (CRM) capabilities to contact donors who do not complete their appointment bookings on the [blood.ca](http://blood.ca) website.
    - For donors who do not complete the appointment booking process, an automated message should be issued via the CRM system to the donor's contact email address to offer support options for completion of their appointment booking and / or offer general support.
    - This would help attract donors who had the intent to donate but were frustrated by the booking process or had additional questions.

**Finding: While hospital satisfaction surveys on the availability of FBC indicate overall high satisfaction ratings, responses were less favourable amongst larger hospitals.**

- Based on online survey results from approximately 200 hospitals across Canada, the highest scores were provided by small and medium sized hospitals, with the larger hospitals providing the lowest scores. See Figure 22 below.

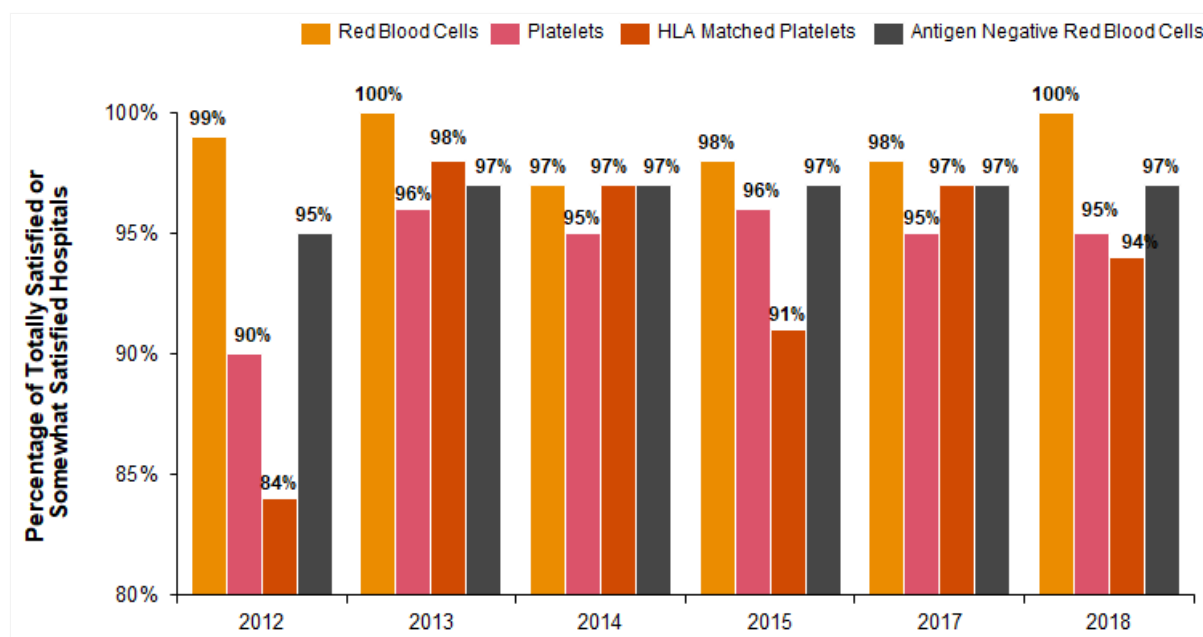
**Figure 22: Top Box (10/10) Hospital Satisfaction with Availability of FBCs (Small, Medium, Large Hospitals) for 2014, 2015, 2017, 2018<sup>22</sup>**



- The feedback from hospitals on the availability of FBCs has been positive.
  - Hospital satisfaction was consistently rated above 97% for RBC;
  - Hospital satisfaction increased from 90% in 2012 to 95% in 2018 for platelets; and
  - For HLA matched platelets, hospital satisfaction increased from 84% in 2012 to 94% in 2018. The improvement in satisfaction rates is the result of consolidation of the HLA platelet program into a national program with dedicated resources which has resulted in improved service delivery.

<sup>22</sup> The hospital surveys completed in 2012, 2013 and 2019 did not contain the breakdown of top box scores across small, medium and large hospitals. A hospital survey was not completed in 2016.

**Figure 23: Hospital Satisfaction with Availability of FBCs**



**Recommendation 24: CBS should implement a process to monitor and report on the progress of regional action plans to address hospital survey feedback. This includes the prioritization of feedback for each business line, to focus on areas requiring attention and the assignment of responsibility to business line leaders.**

**Observation: CBS experienced some short-term and minor shortages for RBC and platelets but there were no critical shortages.**

- There were five green phase advisories<sup>23</sup>, only one amber phase advisory and no red phase advisories. This implies that blood inventory levels did not reach a point where CBS were not able to meet the need of a patient with non-elective indications for transfusion.
- The amber advisory was related to higher than normal demand for platelets in January 2016 which was resolved in two days. The National Plan for the Management of Shortages of Labile Blood Components was rolled out to ensure continuity of product availability.
- The green advisories were mainly related to O-negative blood product shortages across the review period.
- CBS' annual order fill rate for platelets has ranged from 96.0% to 98.6% (see Figure 24 below). CBS missed its target of 98% in 2014-15 due to increased requests for cytomegalovirus negative units which are not as readily available.

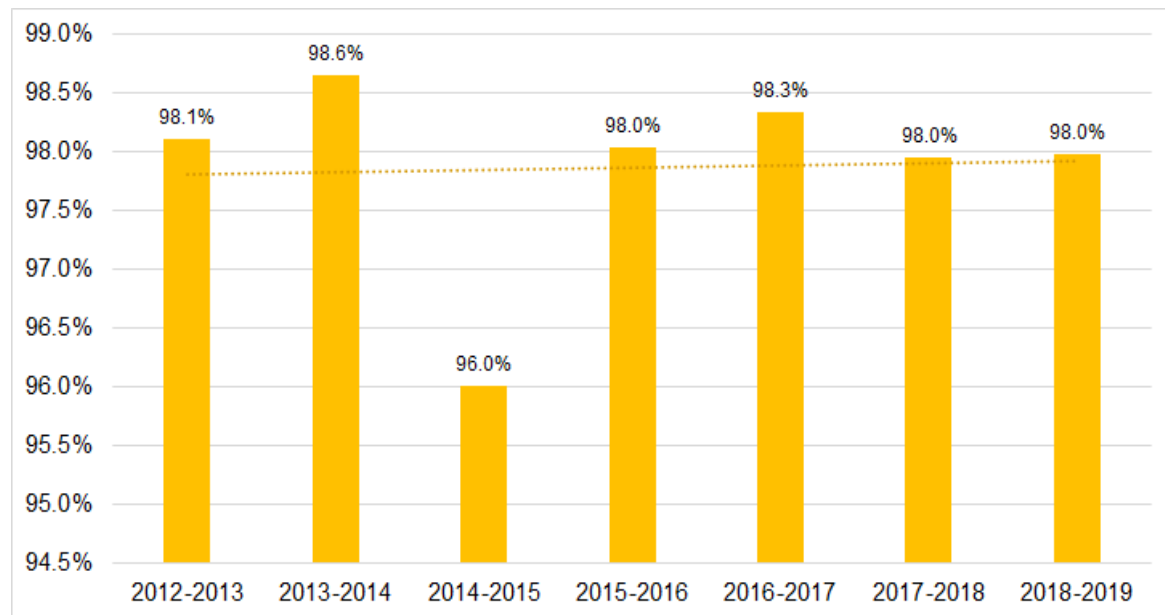
<sup>23</sup> A Green Phase Advisory implies that CBS inventory levels are low with respect to a particular blood component and that all hospitals need to determine their inventories and the likelihood of crossing into the Amber or Red Phase.

An Amber Phase implies that the national blood inventory is insufficient to continue with routine transfusion practices and hospitals/Regional Health Authorities (RHA) will be required to implement specific measures to reduce blood usage.

A Red Phase implies that blood inventory levels are insufficient to ensure that patients with non-elective indications for transfusion will receive the required transfusion(s).

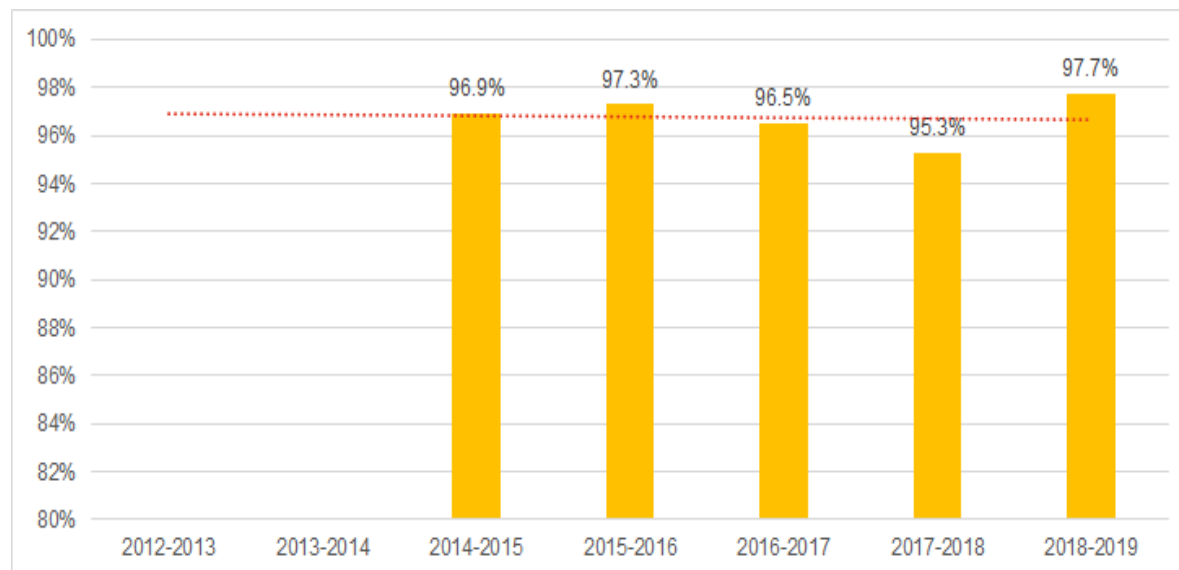
A Recovery Phase implies that blood component inventories have begun to increase and are expected to be maintained at a level which would enable the return from Red to Amber and subsequently to Green Phase.

**Figure 24: Unit Fill Rate for Platelets (2012-13 to 2018-19)**



- CBS has experienced low inventory of O-negative type red blood cells, where O-negative collections were below the target of 95%. As seen in Figure 25, the annual order fill rate for O-negative<sup>24</sup> red blood cells has ranged from 95.3% to 97.7%<sup>25</sup>. The unit fill rate reached a quarterly low of 92.8% in Q3 2017-18, when an inventory advisory was issued.

**Figure 25: Unit Fill Rate for O-negative Red Blood Cells (2014-15 to 2018-19)**



<sup>24</sup> Unit fill rate for O-negative RBCs reflects the number of units issued as a percentage of the total number of O-negative units ordered. CBS evaluates this measure as it relates to the percentage of O-negative RBC units issued compared to the total number of RBC units issued. This approach recognizes that there are limits on the number of O-negative units CBS can collect, despite increasing proportional demand for O-negative units relative to RBC demand as a whole

<sup>25</sup> Fill rates were not captured in CBS' performance measures for 2012-13 to 2014-15.

**Finding: Considering that O-negative stocks are challenging to replenish in a consistent manner, a pan-Canadian approach is needed to manage and protect the supply of O-negative blood.**

- Replenishing the stock of O-negative blood products is challenging. The inventory levels of O-negative cycled in and out of a “Red” inventory level<sup>26</sup> for 4% of the days in 2018-19.
- The demand for O-negative blood is much higher than the proportional number of donors for it. Approximately seven percent of the population in Canada has the O-negative blood type.
- CBS provides regular red cell utilization data and briefings to hospitals on transfusion best practices to mitigate against the over-utilization of O-negative blood. CBS also introduced some additional measures to help mitigate against O-negative shortages:
  - BloodBrief in 2013, which provides hospitals with red blood cell usage data to compare their usage data against peer hospitals and increases the awareness of potential issues. The data also provides hospitals an opportunity to share transfusion best practices in order to ensure the optimal utilization of blood products.
  - CBS publishes the *O Rh negative Red Blood Cell Utilization and Inventory Management Best Practices* to provide hospitals with guidance on how to reduce the use of O-negative blood.

**Recommendation 25: CBS should request that PT Ministries of Health facilitate agreements with hospitals that would allow CBS to proactively monitor and influence O-negative hospital inventories with a national, system-wide lens.**

Further, CBS and the PTs should work together on a national basis to promote best practices to maintain the O-negative blood supply at appropriate levels.

#### 4.2.6.2 PPP

**Finding: CBS took action to improve its plasma sufficiency and reduce its reliance on foreign sources of Ig.**

CBS’ plasma self-sufficiency rate gradually declined from 24% to 15%, over the review period. In 2015-16, CBS predicted that, without intervention, its rate of plasma self-sufficiency for Ig would decrease to 10% in 2020 and significantly increase its reliance on foreign markets for Ig products.

With growing global demand for Ig products, CBS recognized that it would face increasing risks in ensuring availability of Ig supply for Canadian patients and delivering an adequate supply of Ig products at an affordable cost to the Canadian health system.

In response to these risks, CBS developed a national plasma strategy and received funding approval from Members for a proof-of-concept program to establish three standalone plasma collection sites that will serve as models for a potential Canada-wide solution. Work is now underway to get donor centres up and running in Sudbury, Ontario; Lethbridge, Alberta; and Kelowna, British Columbia. Refer to section 3.2.2.1 for details on the Plasma Proof-of Concept Sites Reporting Framework which will be used to assess the success of this initiative.

**Recommendation 26: CBS should continue to examine options to increase plasma self-sufficiency within Canada to reduce dependency on US and global suppliers.**

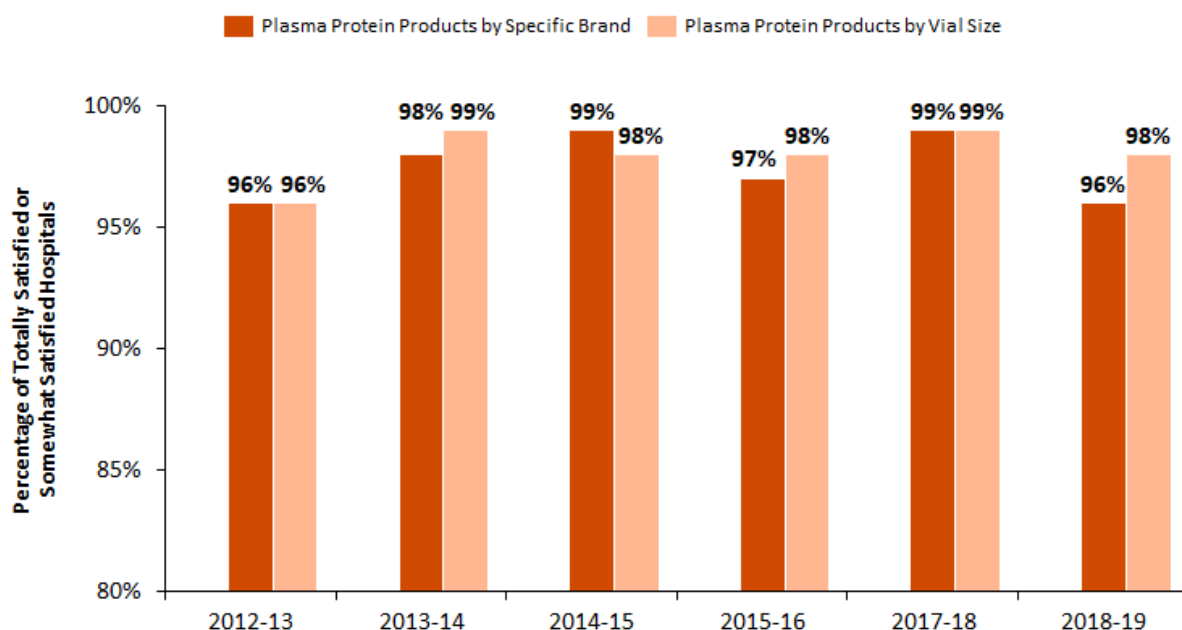
This may require a discussion with the Members at a strategic level to evaluate various options. CBS should also consider setting up a task force that looks at potential improvements within plasma collection processes and integrating them at a community level to drive higher volume and self-sufficiency in this area.

**Observation: Hospitals indicated that they were satisfied with the availability of the PPP brands and the different PPP vial sizes received from CBS.**

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<sup>26</sup> A “Red” inventory metric tracked is the percentage of daily site ABO RH inventory positions that are in <3 days on hand.

**Figure 26: Hospital Satisfaction with Availability of Plasma**



- CBS received an average satisfaction rate of 98% for both the availability of PPP brands and the PPP vial sizes. However, the satisfaction rates with the availability of PPP brands decreased from 99% to 96% in 2018-19. This decrease in satisfaction coincided with new contracts for recombinant PPP products.
- In its 2018-19 Q4 risk report, CBS noted ongoing requests for legacy PPP products and that it was working with manufacturers to mitigate challenges with the vial sizes of some products. The report also noted that clinicians were still expressing concerns, as reflected in the annual hospital physician survey results (see recommendation 40 regarding transition management in Section 4.3.9 - PPP Management).

**Finding: While CBS did not experience any critical product shortages for PPP, enhanced datasets from hospitals would help support more accurate forecasting of PPP.**

- As discussed previously, CBS requires an expanded data set to better inform its forecasting for PPP, especially for new products, brand changes, and new uses for existing products
- It is equally important for CBS to be aware of changes at the PT level driven by policy or other changes that may impact PPP demand by hospitals and clinics.

**Recommendation 27: CBS and the PTs should explore opportunities for hospitals to share data supporting PPP use with CBS. A starting point for this recommendation could be:**

- Collaboratively agreeing on the desired utilization data and assessing the completeness, accuracy and availability of this data at a PT level. Data could include departments where PPP are being distributed, indications for which PPP are being prescribed, outcomes of the medication, prescribed dosage, intended frequency of use and duration of treatment.
- Carrying out a pilot study with two jurisdictions and collecting utilization data where existing data is found to be incomplete, inaccurate or inconsistently available.

Once this data has been collected, CBS and Members should weigh the costs and investment required to facilitate ongoing data sharing against the ancillary benefits mentioned above. This would help both parties determine if there is a valid business case for data sharing.

#### 4.2.6.3 Other considerations

**Finding: Hospitals are using fax machines to order their FBC and PPP products from CBS.**

The hospital ordering process is fax based and has caused inefficiencies in CBS' management of hospital order requirements. This includes a lack of a standardized ordering process, additional steps

required in the records management process and the absence of alerts to process new orders efficiently.

CBS has developed a pilot program for hospital orders using an online hospital portal and this was implemented post the review period. The pilot was initially limited to four Vancouver area hospitals to gather more detailed information on hospital needs. It was then expanded to approximately 27 hospitals in British Columbia, which cover about 17% of national ordering, with the aim of a national roll-out.



**Recommendation 28: CBS should continue its efforts to automate the hospital ordering process for FBC and PPP and develop strategies for strong adoption.**

## 4.3 Plasma Protein Products Management

### 4.3.1 Objective

The objective of this section is to evaluate the structure, decision making and procurement practices for PPP. We have also considered patient needs as part of our evaluation.

### 4.3.2 Scope

The focus of this section is on five areas as follows:

- **Focus Area 1:** A management structure is established and effective for managing PPP.
- **Focus Area 2:** Processes and decision-making for PPP formulary are effective.
- **Focus Area 3:** Processes and decision-making for managing utilization<sup>27</sup> are effective.
- **Focus Area 4:** Processes for procurement of PPP have been developed and are effective.
- **Focus Area 5:** Processes for transition management have been developed and are effective.

For Focus Areas 2 to 5, we performed a comparative analysis to help determine the extent to which CBS' processes are aligned with practices used by other jurisdictions and comparable organizations. The comparative analysis approach was approved by the PRWG.

The sources for our comparative analysis are summarized in Appendix 8 and we have mapped these sources to the PPP Management Focus Areas (above) in Table 12. Information for the comparative analysis was obtained through publicly available sources, interviews (e.g., for the British Columbia Expensive Drugs for Rare Diseases (EDRD) Program and PharmaCare Biosimilar Transition Process) and an Accenture Consulting report provided by CBS.

<sup>27</sup> "Utilization management" refers to the practices which help ensure PPP products are used responsibly and appropriately.



**Table 12: Link between the sources for our comparative analysis and the CBS focus areas for PPP Management**

Link to PPP Management						
Ref	Comparative Jurisdiction	Comparison	Focus Area 2	Focus Area 3	Focus Area 4	Focus Area 5
1	8 Countries	PPP Overview in 8 Countries	Yes	Yes	Yes	-
2	British Columbia	EDRD Program	Yes	-	-	-
3	Government of Ontario	Provincial Drug Plan Exceptional Access Program	-	Yes	-	-
4	Government of British Columbia	Provincial Drug Plan Special Authority Request Process	-	Yes	-	-
5	Government of Ontario	Procurement Guideline for Public Sector Organizations	-	-	Yes	-
6	New Zealand	Government Procurement Rules	-	-	Yes	-
7	Canada	pan-Canadian Pharmaceutical Alliance (pCPA) Negotiation Process	-	-	Yes	-
8	British Columbia	PharmaCare Biosimilar Transition Process	-	-	-	Yes

### 4.3.3 Context

PPP are used to treat patients with a variety of inherited and acquired disorders, including some who require life-long therapy. They are prescribed for:

- hemophilia and other bleeding disorders;
- primary and secondary immune disorders, including neurological conditions;
- burns and traumas; and
- disorders related to inherited protein deficiencies and many other conditions.

While many of these drugs are administered in a hospital, they are being increasingly manufactured in formulations that permit in-home administration. The PPP formulary is managed by CBS on behalf of the funding provincial and territorial governments. Over the review period, the CBS formulary comprised human derived PPP and recombinant products which are made in a lab using recombinant DNA technology and are structurally and functionally similar to human plasma-derived products. At the end of 2018-19, the CBS formulary consisted of 54 human-derived and recombinant products in 26 different product categories. CBS delivers PPP to hospitals and clinics across Canada (excluding Quebec) using the distribution network funded as part of its national blood supply responsibilities.

Total PT funding for PPP increased from \$470 million in 2012-13 to \$681 million in 2018-19. Refer to the *Financial Performance - PPP* section for an analysis of PPP costs and cost drivers over the review period.

### 4.3.4 Key themes

The PPP program gradually became a significant focus area for the Members and CBS over the review period. While the medical use of PPP was limited at the beginning of the review period in 2012-13, it constituted 56% of CBS' total spend by the end of the review period.

CBS undertook several steps to evolve with the changing nature of demand and the overall PPP market during the review period. However, further change and improvement is needed to keep pace with PT expectations and evolving patient needs. Several recommendations within this section have a direct impact on "value for money" when considered from a supply, benefit, cost or risk perspective.

Below is a summary of our key themes:

**Table 13: Summary of key themes**

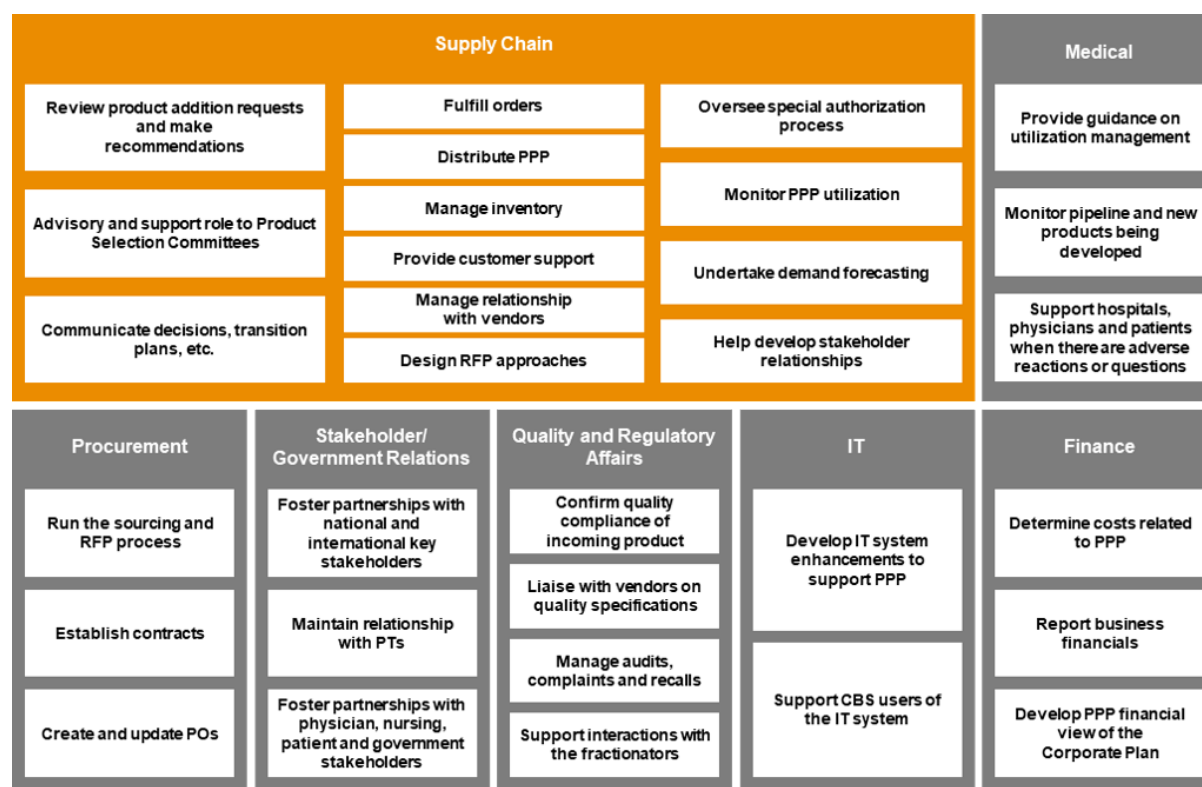
Area of focus	Observation	Finding
<b>Formulary management</b>	<ul style="list-style-type: none"> <li>CBS has a formal product selection process and the factors used to evaluate products for the formulary are generally aligned with global practices</li> <li>CBS' product selection process incorporates value for money principles</li> </ul>	<ul style="list-style-type: none"> <li>Formulary eligibility criteria for new product categories have not been updated</li> <li>PT approval is not required for new brands added to the formulary (unless there is a cost increase)</li> </ul>
<b>Utilization management</b>		<ul style="list-style-type: none"> <li>CBS and PTs have not undertaken a joint assessment of their utilization management activities for PPP in light of increased demand and costs over the review period</li> <li>CBS would benefit from additional PT data to inform PPP utilization management</li> </ul>
Area of focus	Observation	Finding
<b>Procurement</b>	<ul style="list-style-type: none"> <li>CBS procures new PPP via a tendering process. This procurement approach is similar to the purchasing of blood products in other countries</li> <li>CBS' procurement process is aligned with public sector practices in other jurisdictions and incorporates value for money principles</li> </ul>	<ul style="list-style-type: none"> <li>CBS has not explored the full range of procurement and pricing strategies which may help reduce product costs or improve health system outcomes</li> <li>There is no ongoing reporting to PTs on whether expected cost savings following PPP RFPs are being realized over time</li> </ul>
<b>Transition management</b>		<ul style="list-style-type: none"> <li>There are opportunities for CBS to work with PTs to enhance the transition management approach when introducing new PPP or changing existing PPP</li> </ul>

### 4.3.5 PPP Management Structure

**Observation: There is defined executive responsibility and a formal management structure for managing PPP.**

The CBS Board sets the vision and strategy for the PPP program. Between 2012 and 2017, when there were relatively few PPP treatments available, CBS was mainly focused on managing supply and executive responsibility for PPP was held by the Chief Supply Chain Officer. This helped CBS drive a higher focus on securing supply, logistics and distribution. The CBS structure for PPP between April 2012 and December 2017 is presented in Figure 27, along with examples of activities performed by various functional areas.

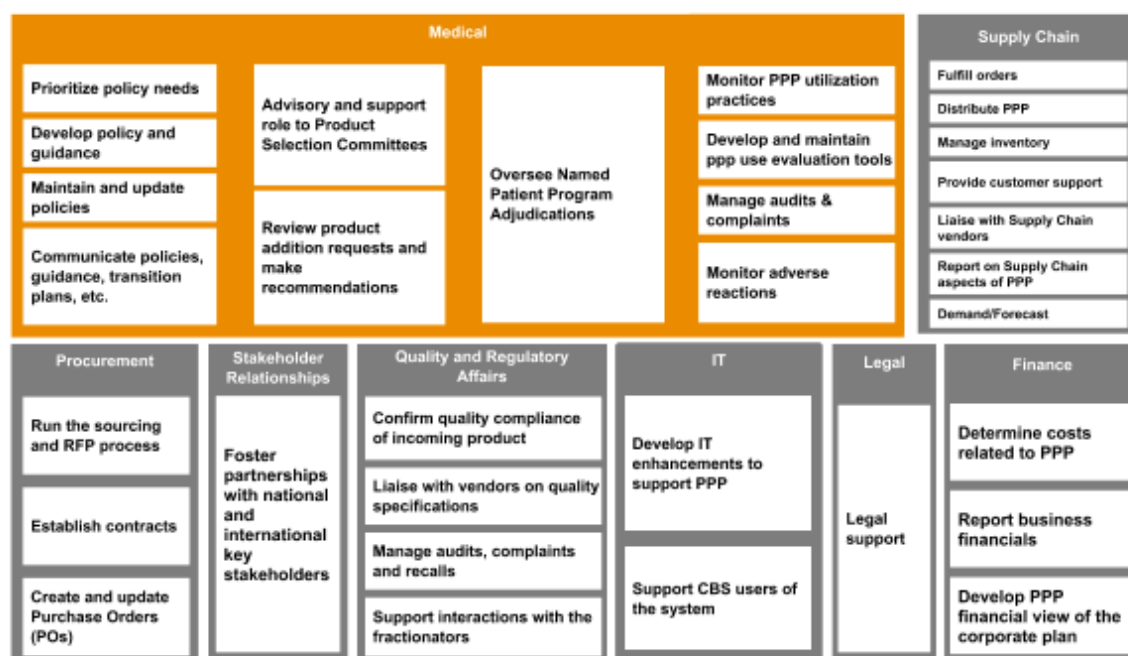
**Figure 27: PPP program structure between April 2012 and December 2017**



From January 2018 onwards, the Vice President (VP), Medical Affairs and Innovation became responsible for the PPP program. This ownership enabled a higher level of medical oversight over PPP and enabled CBS to provide a greater level of medical support to hospitals, particularly as the number and complexity of products used to treat various conditions was increasing.

The VP, Medical Affairs and Innovation is supported by two direct reports who are responsible for managing the PPP formulary and providing medical support - a *PPP Formulary Program Director* and *Medical Director & Special Advisor*. Managing other aspects of PPP requires a cross-divisional team which consists of staff in other CBS functional areas such as Supply Chain, Corporate Services, Quality and Regulatory Affairs, etc. The CBS teams and examples of activities performed are set out in Figure 28 below. Based on our interviews and analysis, we did not observe any issues with this structure.

**Figure 28: PPP program structure between January 2018 and the end of the review period**



**Finding: Separate Executive-level ownership for the three proof-of-concept sites for plasma collections is appropriate, but there may be economies of scale in integration with FBC operations.**

CBS announced the development of three proof-of-concept sites for plasma collections in August 2019. While the announcement of the sites was outside the review period, the decision making to assign executive responsibility (ahead of the announcement) occurred during the review period. We have therefore considered this executive ownership and responsibility as part of the performance review.

Ahead of the announcement, CBS appointed a separate executive - a VP, Plasma Operations - to own the development and opening of the sites. This separate ownership was assigned in August 2018 and is reasonable given the sites are new and of strategic importance to CBS. Notwithstanding, at the appropriate time in the future, CBS should evaluate whether the sites should continue to be under a separate VP, or, integrated with other aspects of CBS' ongoing blood operations.



**Recommendation 29: CBS should consider integrating the plasma proof-of-concept sites into its ongoing blood operations at the appropriate time.**

The benefits of integrating with other aspects of CBS' ongoing blood operations may include economies of scale from a cost and donor experience perspective. Examples of factors to consider in determining the "appropriate time" for integration include:

- The timelines for transitioning from "proof-of-concept" to "Business-as-Usual";
- Whether volumes (e.g. plasma collection metrics) are meeting or exceeding targets;
- Whether cost metrics (e.g. cost per collection) for operating the sites are meeting or exceeding targets; and
- Extent of readiness to scale and consider new proof-of-concept sites.

The decision regarding integration of the proof-of-concept sites should also be informed by the Plasma Proof-of Concept Sites Reporting Framework which will be used to assess the success of this initiative.

### 4.3.6 Formulary Management

**Observation: CBS has a formal product selection process and the factors used to evaluate products for the formulary are generally aligned with global practices.**

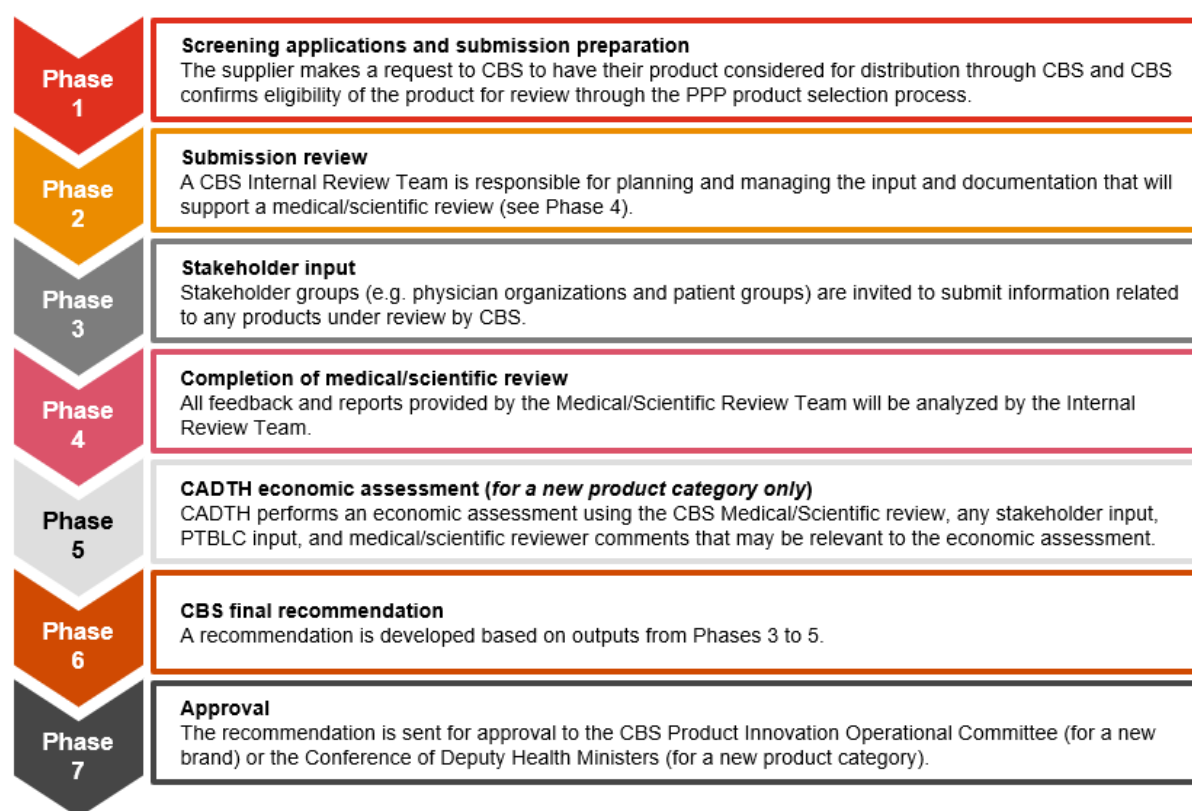
The CBS formulary is a national formulary consisting of PPP available for distribution to provinces and territories (except Quebec). In managing the formulary, CBS aims to take into account several factors, including the safety and efficacy of products, security of supply, appropriate range of choices for prescribers, competitive pricing and ensuring best possible health system outcomes.

CBS has a formal product selection process which is used to manage changes to the formulary. This is a documented process which is developed in collaboration with PTs. CBS made two updates to the product selection process in March 2015 and September 2016, respectively. These changes were made after consultation with Members and were intended to:

- Align CBS' product selection process with the equivalent process used by the CADTH<sup>28</sup> for pharmaceutical products; and
- Build more nimble timelines into the product selection process by carrying out certain process steps in parallel.

Following the process updates made in 2015 and 2016, the general product selection process is set out in Figure 29.

**Figure 29: Overview of the CBS product selection process**



### Comparison to other countries

From our comparative analysis, we have set out examples in Appendix 9 showing how PPP formularies are managed globally. This shows that five out of the seven countries in our analysis have a national formulary and all seven countries assess the therapeutic value and cost effectiveness of PPP (as part of a Health Technology Assessments (HTAs)) before making them available for

<sup>28</sup> CADTH is an independent, not-for-profit organization responsible for providing health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs.

distribution. This is similar to CBS' approach.

**Observation: CBS' product selection process incorporates value for money principles.**

There are several phases within the product selection process that enable CBS to consider value for money from the perspective of supply, cost, benefit and risk. Specifically:

- **Phase 1** – Suppliers are required to submit economic/cost information which is evaluated as part of the subsequent phases.
- **Phase 2-4** – An evaluation is undertaken of several product factors which includes clinical efficacy, safety profile, storage and shipping requirements and impact on patient quality of life.
- **Phase 5** – The independent economic assessment by CADTH supports the introduction of new PPP product categories. This includes a re-analysis of the supplier's economic/cost information which is then tested against independent inputs.
- **Phase 6** – Consideration is given to other aspects of CBS operations that were not captured in the CADTH economic assessment. These include:
  - Implications on existing contracts for other PPP;
  - CBS' ability to continue to provide blood products to patients where limited other treatment options are available; and
  - In the case of a new product brand, the existing available brands and the ability of the new product to improve security of supply.

While the factors considered by CBS are aligned with those of other countries and incorporate value for money principles, we describe two findings and recommendations for CBS' product selection process below.

**Finding: Formulary eligibility criteria for new product categories have not been updated.**

CBS receives requests from manufacturers to list new PPP categories or brands for inclusion on the formulary. CBS initiates a review after confirmation by the PTBLC on whether products meet the following eligibility criteria:

- *"product is a biological drug manufactured from human plasma or a biological drug whose active ingredient(s) are **functional equivalents** of the foregoing, used in the practice of **transfusion medicine**"; and*
- *"is not carried in the health system already."*

Eligibility criteria are important as they determine whether new treatments would be considered by CBS or by alternative parties in the health system such as provincial drug plans. Where the eligibility criteria are not fit for purpose or open to interpretation, there is risk that time and effort is expended debating whether a treatment should be evaluated by CBS and this may delay potential patients from accessing the treatment. With regards to the existing eligibility criteria:

- there is a potential for different interpretations of the eligibility criteria as there is no agreed upon definition of "transfusion medicine". With a narrow interpretation, "transfusion medicine" may be interpreted as only including blood products that are used to treat patients conventionally treated by hematologists. With a broader interpretation, it may be considered to include the practices in which blood or related products are used to treat clinical conditions other than blood disorders; and
- there are questions as to whether a recombinant product, or a product which is otherwise synthetically/genetically engineered, should be classified as a functional equivalent of a blood product, and, if so, under what circumstances.

Looking ahead, CBS and the PTs will also need to consider the implications of gene therapy on the formulary eligibility criteria. This is an emerging treatment which has the potential to replace PPP in certain situations and for certain diseases/disorders. As gene therapy evolves and matures, this will



raise a question as to where in Members' health systems these treatments should be considered for assessment.

Subsequent to the performance review period, CBS and PTs initiated a CBS Drug Formulary review process, including review of the eligibility criteria for future drug additions to the CBS formulary.

## Products not deemed to be eligible

It is worth noting that during the review period, two products (Lanadelumab and Alpha-1 antitrypsin) were deemed by CBS to have met the eligibility criteria, but were not approved by the Conference of Deputy Health Ministers (CDM) for further analysis, as they deemed that the products did not meet the above mentioned criteria. This difference of interpretation resulted in lost time and effort for both parties.



**Recommendation 30: CBS and the PTs should update the existing PPP eligibility criteria and develop a collaborative process for periodic review and timely approval of the criteria.**

Updating the PPP eligibility criteria is important to ensure that CBS and PT time is not unnecessarily expended on debating the eligibility of new products. Moreover, this helps improve patient outcomes by ensuring that new products can be considered by CBS (or elsewhere in PT health systems) in a quicker manner.

As part of the ongoing review of the CBS Drug Formulary, CBS and the PTs should update the PPP eligibility criteria for product selection taking into account the following factors:

- Definition of transfusion medicine given increasing indications for the use of PPP products and emerging trends; and
- Classification of synthetically and genetically engineered products.

CBS and the PTs should ensure that changes to the criteria are timely by agreeing on an appropriate interval/frequency for when the PPP eligibility criteria should be reviewed and approved.

**Finding: PT approval is not required for new brands added to the formulary (unless there is a cost increase).**

The number of product categories and brands on the CBS formulary increased over the review period as seen in Table 14. This was consistent with the increasing use of PPP for the treatment of various diseases and the increasing number of products brought to market by pharmaceutical companies.

**Table 14:** Number of product categories and brands on the CBS formulary (Source: CBS PPP Customer Tables of Information on blood.ca)

	2012/13	2013/14	2014/15	2015/16	2016/17	2017/18	2018/19
# of product categories on the formulary	18	18	15	24	24	24	26
# of brands on the formulary	38	38	35	48	49	49	54

Once a new PPP is considered eligible for CBS, consideration must then be given to whether the product is a new "product category" or a new "brand". For context:

- A new "product category" is a new product type which may or may not replace products already in the CBS formulary, and may result in additional Member budget requirements. Any proposal for a new category is discussed between CBS and the PTBLC for agreement and approval is under the authority of the CDM.
- A new "brand" is a product similar to an existing product already distributed by CBS and could replace an existing brand. New brands only require CBS approval, as long as there is no cost increase, and the PTBLC is notified of the decision to add a new brand once this is made by CBS.

Our interviews with PT officials highlighted that the health system implications arising from new brands were not always considered by CBS. While CBS analyzes the cost of new brands based on product price and recommended dosing impact, this approach does not sufficiently consider other implications such as the impact on patient experience or training costs which need to be incurred by

hospitals and clinics.



**Recommendation 31: CBS and the PTs should develop a process to analyze health system costs and patient experience implications for all brand additions.**

Doing this would enable both CBS and the PTs to consistently consider and quantify the health system cost implications of new brands. The analysis could be supported by a “business case”, which enables CBS and PTs to consider the following in a structured manner:

- PT health system cost and patient experience implications arising from a new brand;
- PT timelines and responsibilities for collating cost data; there needs to be a balance between providing sufficient time for the cost implications to be understood and ensuring the analysis does not unduly delay the product selection process; and
- A performance measurement strategy to subsequently compare actuals against expected savings.

Where there is a brand replacement arising from a PPP RFP, we have raised a separate finding and recommendation covering transition management in the *Transition Management* section under PPP Procurement.

### 4.3.7 Utilization Management

“Utilization management” refers to the practices which help ensure PPP are used effectively and in line with CBS/PT guidelines or for approved indications. PPP utilization is driven by several factors including the types of disorders that are treated, dosage, and frequency of use. PTs pay CBS for PPP on a cost recovery basis and this means that high utilization has a direct cost impact on the PTs.

Appendix 10 summarizes the utilization management activities performed by CBS and the PTs. The Appendix also includes the activities performed by the National Advisory Committee on Blood and Blood Products (NAC) which collaborates with the Members and provides advice on PPP utilization management.

There is limited publicly available data showing the extent of “ineffective” PPP use or the extent to which PPP are used outside of approved indications. This makes estimating the financial benefit of effective utilization management difficult to do. However, as a proxy, previous audits of Ig use in the four Atlantic provinces have identified that the proportion of Ig used for “non indicated” conditions ranged between 1.9% and 4.1% between 2013 and 2017. This means that tighter utilization management over Ig would present a cost saving opportunity of up to \$11 million in one product category assuming other provinces had similar proportions of “non-indicated” use.

In addition to Ig, there are other product categories in the formulary (see Table 14) and there is likely to be a financial benefit of tighter utilization for these categories. With this context considered, our utilization management findings and recommendations below provide an opportunity for CBS and the Members to lower overall health system costs, if implemented.

**Finding: CBS and the PTs have not undertaken a joint assessment of their utilization management activities for PPP in light of increased demand and costs over the review period.**

The MOU does not specify roles and responsibilities for CBS with regards to utilization management other than stating that CBS should be undertaking responsible and effective information and data management for utilization. In practice, while the PTs are ultimately responsible for managing utilization within their jurisdictions, their expectations for CBS' role in utilization management evolved due to the increased use of (and rising costs of) PPP. CBS has no enforcement power with regards to utilization management and plays varying roles ranging from “influencing” to “gatekeeping” for different products.

## Comparison to other countries



Globally, there are several approaches which other countries use to manage utilization for PPP. These are summarized in Table 15 below and compared to approaches used by CBS and the PTs. This comparison indicates that there are additional approaches which CBS and the PTs should consider. Additional details regarding these utilization management approaches are provided in Appendix 11.

**Table 15: Utilization management approaches in other countries**

Approach	Australia	Belgium	France	Germany	Netherlands	UK	US	CBS and PTs
1 Policies/Guidelines/Established medical criteria for the use of certain products	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
2 Patient registers and reporting on the number/volume of products administered	Yes	No	No	Yes	Yes	Yes	No	Yes
3 Volume allocations of products to geographic locations/dispensing restrictions	No	No	Yes	No	No	Yes	Yes	No
4 Practices to encourage the prescription of lower-cost alternatives (e.g. quotas, step therapy)	No	Yes	No	No	No	No	Yes	No
5 Insurer restrictions (e.g. prescription from certain doctors, prior authorization)	No	No	No	No	Yes	No	Yes	Yes <sup>29</sup>

Source: Accenture Consulting Report - An Overview of Jurisdictional Oversight and Management of PPP across 8 Countries

Between November 2013 and February 2015, CBS and the PTBLC worked collaboratively to identify utilization management improvement opportunities that could be coordinated across jurisdictions and that could demonstrate a cost-benefit to PT health systems. However, the momentum for this pan-Canadian approach was subsequently lost as jurisdictions instead opted to implement their own “localized” utilization management practices.



**Recommendation 32: CBS and PTs should complete a combined assessment of their utilization management activities for PPP and determine if these activities could be expanded further to improve utilization outcomes.**

- a. Based on our comparative analysis, examples of utilization management approaches which should be considered, to the extent they are not already occurring within PT health systems, include:
  - Developing a simple web-based shared system to electronically manage PPP requests and check that these align with pre-established criteria (e.g. conditions where the use of PPP is considered clinically appropriate).
  - Implementing patient databases<sup>30</sup> which would help the PTs collect data on treatments which have been administered, the outcomes and, if applicable, the side effects. This would enable PTs to evaluate the cost effectiveness and the results of different treatments and make improvements.
  - Determining whether certain higher cost PPP should be limited to prescription by specialized doctors.
- b. Roles, responsibilities and expectations for utilization management should be clearly agreed upon

<sup>29</sup> Prior authorization occurs via the CBS Named Patient Program. Refer below for further details.

<sup>30</sup> CBS has access to a patient register and information about products administered for the Bleeding Disorders population (but not for Ig and other PPP).

and documented between CBS and the PTs. Once defined, CBS should evaluate the flow-on effect (e.g. resource levels, skills/expertise, etc.) on its existing utilization management activities and determine what changes need to be made. These should be discussed and agreed to with the PTs.

**Finding: The processes which support the PPP Named Patient Program need to be strengthened for improved utilization management.**

During the review period, CBS introduced measures to control access and utilization for certain PPP in two main ways:

1. In May 2012, CBS introduced a process for Solvent Detergent (SD) Treated Plasma where the product was only released to patients meeting specific medical indications, following approval from a CBS Medical Director.
2. In September 2018, CBS introduced a “Named Patient Program” to provide continued access to two products which had been replaced following a RFP. The continued access was for patients unable to transition for medical reasons and where there was medical evidence demonstrating the patient’s eligibility.

Given the increasing utilization of PPP, there is potential for the Named Patient Program to be expanded and more widely used to manage access to, for instance, high cost drugs. Through a review of jurisdictional practices, our comparative analysis indicated that:

- Provincial drug plans have an Exceptional Access Program (EAP) to provide coverage for certain drugs (which would not otherwise be covered) where patients meet specific criteria. Similar to CBS, the EAP provides coverage once the patient’s application has been reviewed and recommended for coverage by the appropriate reviewers (e.g. physician committees).
- The Government of British Columbia has a process to manage access and patient funding for EDRD. The process provides coverage to extremely high-cost drugs where patients meet specific criteria and includes advice from an arm’s length independent advisory committee and several clinical subcommittees.

Our comparative analysis highlighted that the CBS Named Patient Program may not be sufficiently scalable should there be a desire to add products to the Program, or, should additional eligibility criteria be introduced. The analysis indicated the following differences:

- There is no electronic ordering and CBS requires physicians to complete manual request forms which must then be faxed to a CBS distribution site. This means that forms which have not been legibly completed, or, lacking all of the supporting medical documentation may be delayed in their review. Further, there is no verification of the authenticity of the physician.
- The CBS process for the review of the Named Patient request forms is not easily found or explained on blood.ca. This process is only outlined in customer letters published in August 2018 and June 2019. In practice, where a Medical Review is required for an order, this is performed by a CBS Review Panel which consists of three staff.
- There is no published urgent/emergency ordering process. Physicians phone CBS to inform them of urgency and CBS distributes the product without approval or via the Medical Review process.
- There are no criteria that drive the tiering/prioritization of orders and the associated timeframes for response from CBS. Further, the end-to-end process time from receipt of the request form to dispatch of the product is not published online or reported on. The request form states that requests are subject to a 30 day response time if a Medical Review is required.
- Approvals for access to PPP under the Program are typically for 12 months. However, there are no established conditions for “auto-renewal” and physicians must manually re-apply via the request form once a 12 month term is complete.



**Recommendation 33: CBS should review the processes which support the PPP Named Patient Program for any opportunities to strengthen utilization management.**

Given that PTs will also be undertaking utilization management initiatives within their health systems, any major changes to the Named Patient Program should first be agreed upon with PTs.

The existing processes could be improved by:

- Digitizing and creating a cloud-based application to replace the current process to submit request forms and supporting medical evidence to CBS via fax. Physicians could be provided with access to the cloud-based application as this would help introduce internal controls to verify physician authenticity.
- Documenting and publishing CBS' process for the review and, where necessary, Medical Review of request forms. Determine if there are aspects of the Medical Review which could be simplified or performed by others (e.g. CBS pharmacists).
- Formalizing and publishing the urgent/emergency ordering process.
- Developing criteria to enable tiering/prioritization of orders and the associated timeframes for response from CBS. Consider reporting on process cycle times under the Named Patient Program.
- Determining potential conditions which could prompt the auto-renewal of orders for an existing patient.

These recommendations would also enable CBS to scale the Named Patient Program should there be a significant surge in demand for these products.

Given the increasing cost pressure on PT health systems, CBS and the PTs should also identify the need to apply similar “exceptional access” principles when new products are approved for addition to the CBS formulary. By doing this up front, CBS and the PTs could more closely manage and monitor utilization of, for instance, high-cost PPP treatments.

**Finding: CBS would benefit from additional PT data to inform PPP utilization management.**

PPP utilization data is held in patient/lab management systems and in paper records within PT health systems. This data includes the departments where PPP are being distributed (e.g. neurology, oncology), indications for which PPP are being prescribed, outcomes of the medication, prescribed dosage, intended frequency of use and duration of treatment.

Given the disparate nature of these systems and the number of hospitals and clinics across Canada, this data is not readily accessible by CBS. Notwithstanding, there are additional benefits to PT health systems if there was a greater level of data sharing between CBS and the PTs. These benefits include more accurate forecasting of PPP demand, the ability to plan for any potential supply constraints, and tailored transition approaches when existing PPP are replaced with alternatives.

**Recommendation 34: CBS and PTs should explore opportunities for PTs to share better quality data supporting PPP use with CBS. Please refer to Recommendation 27 for details.**

**Finding: Partially consumed PPP are not currently tracked and reported on.**

CBS provides a web-based application for hospitals and clinics to input data on their PPP disposition (i.e. movement). CBS then uses this data to provide monthly reporting and comparative information enabling hospitals and clinics to heighten their awareness of PPP trends and compare between themselves.

CBS offers multiple vial sizes for several PPP that are listed on the formulary. However, where these vials are partially consumed (i.e. a patient is given their dosage and the remainder is discarded), this is currently recorded as a “used” product in the web-based application. CBS and the PTs cannot therefore reliably determine the cost of potential wasted product, and make informed decisions as to how this utilization could be better managed, or, determine whether there is enough demand for smaller vial sizes.



**Recommendation 35: Improve data collection and utilization reporting over partially consumed PPP.**

CBS should consider enhancing the web-based application to enable hospitals and clinics to record partial usage of PPP. Once this is complete, consideration should be given to:

- Reviewing the data collected on partially consumed PPP and reporting this data to PTs to help them better understand trends or practices which may help manage this utilization.
- Determining whether there is enough demand to justify procuring smaller vial sizes.

## 4.3.8 PPP Procurement

### 4.3.8.1 Procurement Approach

**Observation: CBS procures new PPP via a tendering process. This procurement approach is similar to the purchasing of blood products in other countries.**

CBS' procurement process for PPP is triggered for new brands and/or brand changes once the product selection process is complete, or, following contract renegotiation. CBS' approach to procuring PPP is via a competitive tendering process whereby a RFP is issued to manufacturers. We compared CBS' approach to other countries and found that the UK, Australia and France use a similar process. Specifically:

- In the UK, the National Health Service (NHS) undertakes national tenders allowing manufacturers of PPP to submit prices to be included in the national pricing framework. The NHS generally pays a fixed single price which is determined through negotiation with the manufacturer.
- In Australia, the National Blood Authority undertakes tendering and specific negotiation approaches for blood products.
- In France, drug prices are set through a combination of negotiation, regulation, and statutory rebates. Negotiations are governed by a five year framework agreement and consider a medicine's comparative therapeutic benefit, sales volumes, foreign prices, and local comparator prices.

Similarly, in Canada, the pCPA uses "negotiation" and, if required, RFPs from manufacturers when procuring drugs on behalf of provincial and territorial drug plans. However, there is limited publicly available information to be able to compare CBS' procurement approach to the pCPA.

**Finding: CBS has not considered the full range of procurement and pricing strategies which may help reduce product costs or improve health system outcomes.**

In addition to tendering and negotiation processes, our comparative analysis highlighted examples of other pricing strategies used globally. These are summarized in Table 16 and expanded on in Appendix 12. Of these pricing strategies, CBS leveraged external reference pricing in developing its 2015-2016 RFP strategy. Further, CBS negotiated a risk-share agreement for specific extended half-life products in 2015.

**Table 16: PPP pricing strategies in other countries**

PPP Pricing Strategy	Description	Countries Using Strategy
<b>External Reference Pricing</b>	Uses the price of a drug in other countries as a benchmark to inform or set the price.	Germany, Belgium
<b>Internal Reference Pricing</b>	Sets price based on a comparison with drugs within the country that are identical, similar, or therapeutically equivalent.	Australia, Germany
<b>Value-Based Pricing</b> <sup>31</sup>	Price is based on therapeutic value (versus cost). Contract features such as payment timing and the amount at risk can be customized depending on characteristics of the uncertainty and the needs of the participating parties. The manufacturer issues a rebate if anticipated benefits are not realized.	UK

Source: Accenture Consulting Report - An Overview of Jurisdictional Oversight and Management of PPP across 8 Countries

<sup>31</sup> Value-based pricing (procurement) is defined by the NHS as an "approach that delivers tangible, measurable financial benefit to the health system over and above a reduction in purchase price; and/or a tangible and measurable, improved patient outcome derived through the process of procurement (tendering, contracting, clinical engagement and supplier relationship management)."



**Recommendation 36: CBS should work with PTs to evaluate the broader use of alternative pricing strategies to determine if there are more advantageous models.**

CBS should determine whether there are aspects of the pCPA's "negotiation" approach which could be incorporated into its pricing strategies. CBS should also consider the feasibility of value-based pricing/procurement for PPP with the aim of developing strategies with manufacturers that can influence a reduction in total costs across the health system.

Given there is increasing global demand for PPP and relatively constrained supply, this strategy could be conducive to CBS and PT health systems in ensuring that strategic manufacturers are more tightly integrated with health systems beyond just being suppliers of products. In this context, examples of outcome-based specifications for potential suppliers could include:

- Achieving economic efficiencies and better value for money for PT health systems by procuring not just cost effective PPP, but incorporating additional elements related to supply security and management, transition management, training where necessary or other downstream aspects that affect the Members and provide better overall economic outcomes for the health system;
- Further building on the innovation capacity and utilization reporting capability within PT health systems; and
- Ensuring patients have the best possible experience and have improved quality of care while at the same time, improving the clinical outcomes.

#### **4.3.8.2 Procurement Process**

**Observation: CBS has a formal procurement policy and there is an established process for PPP RFPs which is being adhered to.**

CBS has a Purchasing Policy and a supporting Purchasing Policies and Procedures Manual which apply to the purchase of all goods and services, including PPP. CBS developed these documents with the objective of ensuring that procurement is objective, ethical and cost-efficient while meeting user requirements for quality, suitability and delivery. During the review period, CBS tendered five RFPs which are summarized in Appendix 13.

During the review period, there were two internal audits of procurement conducted by CBS Internal Audit which were finalized in May 2017 and February 2019, respectively. The scope of these internal audits included assessing management's adherence to the Purchasing Policy and Purchasing Policies and Procedures Manual, amongst other areas. The audits found that procurement was largely being performed in accordance with the Purchasing Policies and Procedures Manual. We also reviewed the 2017-2018 RFPs and found that established processes had been followed.

**Observation: CBS' procurement process is aligned with other public sector comparisons and incorporates value for money principles.**

The procurement process for RFPs is managed by CBS' Procurement function led by the Director, Procurement which reports to the Chief Financial Officer (CFO) and VP, Corporate Services. The RFP process is summarized in Figure 30 below.

**Figure 30: RFP process for the procurement of PPP**



## Comparison to public sector procurement processes

We performed a comparative analysis of CBS' procurement process against one example of a provincial public sector procurement process and one example of an international public sector procurement process. We selected the *Procurement Guideline for Publicly Funded Organizations in Ontario* and the *New Zealand Government Procurement Rules for Sustainable and Inclusive Procurement* (4th Edition, 2019). While CBS is independent from any government, its status as a not-for-profit charitable organization means that it is reasonable for its procurement processes to be compared with public sector comparisons.

The comparative analysis identified that CBS' procurement process and the aforementioned public sector examples are aligned. Appendices 14 and 15 provide further detail to support the similarities between CBS' RFP process and the comparisons.



## Value for money principles

The RFP process enables CBS to consider value for money from the perspective of supply, cost, benefit and risk. In particular, as part of:

- **Developing the RFP** - The criteria for selection are published as part of the RFP and consist of price and technical components (e.g. safety, quality, efficacy, integrity of supply). CBS also determines the most appropriate evaluators from the Selection Committee for each component.
- **Evaluation of bids (technical components and pricing)** - Bids are evaluated based on a combination of the technical components and pricing.

### **Finding: There are opportunities to provide a higher level of transparency into the PPP RFP process.**

For significant RFPs where there is wide stakeholder interest, not-for-profit and public sector organizations use an independent Fairness Monitor to provide a greater degree of transparency and independent oversight into the procurement process. Fairness Monitors are typically used for high-risk and/or high dollar value procurements where the circumstances warrant an additional level of transparency and prudence by the purchasing entity.

A Fairness Monitor attests to the neutrality, integrity, consistency, objectivity, transparency, and legitimacy of the procurement process. A Fairness Monitor for each PPP RFP would be independent of CBS and would give comfort to PTs that CBS' procurement policies and procedures were followed, that all parties were treated equally, and that any procedural problems were identified and addressed in a fair, open and transparent way.

### **Recommendation 37: CBS should consider using an independent Fairness Monitor for PPP procurement to provide greater transparency to PTs regarding the objectivity and integrity of the procurement process.**

### **Finding: The CBS complaints process for PPP RFPs is not published.**

Bidders must inform CBS if they have a concern or a complaint in relation to PPP RFPs. Where a bidder chooses to complain, they must inform CBS' Director, Procurement verbally or in writing. Should this occur, the complaint is recorded in CBS' Customer Feedback system and internally escalated to the CFO & VP, Corporate Services for awareness. During the review period, there were no complaints in relation to the PPP RFP process logged in CBS' Customer Feedback system. Notwithstanding, within the PPP RFP documents that were sent to bidders during the review period, CBS did not specify the complaint process for bidders to follow.

From our comparative analysis, the New Zealand Government:

- Provides a confidential Supplier Feedback Service for suppliers wanting to give feedback or raise a general concern about their procurement experience. This is a service within the Government's Procurement Office that then discusses the feedback/concern with the agency involved.
- Requests suppliers that want to make a formal complaint, to make the complaint in writing and address it to the agency's Chief Executive with a copy sent to Procurement.

### **Recommendation 38: Document and publish the complaints process for future PPP RFPs.**

For future RFP cycles, CBS should document and publish the complaints process in the RFP. In doing so, CBS should consider:

- The format in which complaints are to be communicated to CBS (e.g. written or verbal);
- CBS points of escalation for the complaint;
- Timeframes for a CBS response to the complaint and the format in which the response will be communicated; and
- Options for redress should the supplier still feel dissatisfied.

#### 4.3.8.3 RFP cost savings and cost avoidance

**Finding: There is no ongoing reporting to PTs on whether expected cost savings following PPP RFPs are being realized over time.**

As a result of the PPP RFPs that were completed during the review period, CBS realized cost savings and cost avoidance of \$857 million which are outlined in Table 4.

In practice, from a value for money perspective, the benefit of lowering PPP unit costs may be eroded by growing utilization and foreign exchange differences caused by a weakening Canadian dollar which could increase the overall cost of PPP. During our performance review, CBS management produced a retrospective analysis for the review period showing the reduction in PPP unit costs and how expected RFP savings and/or cost reduction estimates were influenced by higher utilization and foreign exchange differences (refer to the *Financial Performance - Plasma Protein Products* section for this analysis under the “Product Costs” heading).

However, this analysis was not in place during the review period and any reporting to PTs was done only via CBS’ budget and forecast processes. Further, the CBS cost savings/avoidance do not incorporate the cost impact on PT health systems related to transition. These costs can include laboratory costs, training and education costs for physicians and nurses, and costs for incremental patient visits and consultation.



**Recommendation 39: Develop an ongoing process to track and report on PPP RFP cost savings and/or cost avoidance to PTs.**

Develop and embed a process to systematically track and report on whether expected cost savings/avoidance from PPP RFPs are being actually realized. In doing so, CBS should consider:

- The expected frequency of tracking and reporting and the associated audience;
- Providing commentary/explanations to support differences in CBS’ original expectations versus results achieved; and
- Any unexpected additional costs that may have arisen.

In the long-term, CBS and the PTs should explore ways to identify and include the incremental cost impacts (e.g., increased workload at the hospital level) on PT health care systems, resulting from new PPP contracts, in the cost savings/cost avoidance estimates.

#### 4.3.9 Transition Management

**Finding: There are opportunities for CBS and PTs to collaboratively enhance the transition management approach when introducing new PPP or changing existing PPP.**

When existing PPP on the formulary are likely to be replaced following a RFP, CBS obtains feedback on the effort to transition via physician and patient representatives on the RFP Selection Committee. Further, once RFPs are complete and a decision is made, PTs and the general public are informed of changes to CBS’ formulary via Customer Letters and PPP Transition Newsletters published on the blood.ca website.

For the RFPs during the review period, the transition time set by CBS was between 6-9 months and extensions of transition time were granted by CBS on a case by case basis. PTs indicated that product changes can have a significant transition impact on PT health facilities, including transfusion medicine departments and other health care providers. This is a systemic issue in the health system and it is therefore challenging to ensure that any transition-related communication from CBS reaches the appropriate audience (e.g. prescribing doctors) and is both read and acted upon in a timely manner.



Following the 2017-2018 RFP process, CBS commissioned an external party to review how it conducted the RFP and report on how it could strengthen this process in the future. This review identified two main themes:

- **Confidentiality requirements** - Selection Committee members mentioned a need for broader stakeholder consultation prior to the initiation of the RFP to identify the biggest issues and main risks, the main considerations with potential switching of products, and possible scenarios which could arise in the selection process. This was not possible during the 2017-2018 RFP process due to confidentiality requirements.
- **Transition to new products** - Understanding the financial and workload impacts on clinics/new providers and the management of communication and implementation steps required for these changes.

## Comparative analysis

Each transition will vary depending on patient numbers, allowable timelines and the nature of products being transitioned and this means that “like-for-like” comparisons are therefore not always practicable. Notwithstanding, we compared CBS’ process to the Government of British Columbia’s process for transitioning approximately 20,000 patients from “biologics” to “biosimilars<sup>32</sup>” following a policy announcement made in May 2019. This comparison highlighted similarities and differences between the two transitions which are summarized in Appendix 16 and have informed our recommendation below.



**Recommendation 40: CBS should develop a process to seek information from PTs before the RFP process to better understand the impacts of potential changes on their health care systems.**

Pre-RFP, CBS and the PTs should agree on:

- How PT input and feedback will be gathered;
- The roles and responsibilities for coordinating this feedback; and
- Timelines so that this feedback can be gathered and considered in a timely manner ahead of issuing the RFP.

Once the RFP process is complete, CBS and the PTs should agree on:

- The factors to consider from a transition management perspective. This could include:
  - Impacted physician, nursing and patient groups and appropriate consultation timelines;
  - Incremental transition costs at the PT level;
  - Planned policy changes at a provincial level which may impact transition;
  - Potential physician, nurse and patient training needs; and
  - Length of transition time.
- A documented transition plan.
- Frequency and format of reporting to PTs on how the transition is progressing.

<sup>32</sup> The Government of Canada defines a “biosimilar” as a drug that is highly similar to a biologic drug that was already authorized for sale. There are no expected clinically meaningful differences in efficacy and safety between a biosimilar and the biologic drug that was already authorized for sale.

## 4.4 Productivity and Efficiency Activities

### 4.4.1 Objective

The objective of this section is to evaluate how CBS delivers value to its funders through its productivity and efficiency activities.

### 4.4.2 Scope

The focus of this section is on two areas as follows:

- **Focus Area 1:** Evaluate the Productivity and Efficiency Program (PEP), including the extent of achieving the target savings of \$100 million; and
- **Focus Area 2:** Evaluate the productivity and efficiency improvements implemented under the CI Program.

### 4.4.3 Context

The Federal, Provincial, Territorial MOU includes seven ministerial principles, one of which states that a *“cost-effective and cost efficient blood supply program for Canadians should be encouraged”*. The MOU also states that health and safety decisions regarding the blood supply system will need to be made with equal consideration of cost, benefit and risk. The scope of this review also includes supply as a fourth component for consideration, in accordance with the draft NAA.

Productivity and efficiency improvements are one way that CBS strives to achieve value for money in the use of public funding received from PTs. CBS drives productivity and efficiency in their business processes through two main programs: the PEP and the CI Program.

### Productivity and Efficiency Program

The PEP was established by CBS to provide management oversight, guidance and focus for the planning and execution of productivity related initiatives. The program consists of initiatives that focus primarily on improving productivity in the FBC business line. The PEP is funded from CBS' operational budget.

The PEP began in 2008 and consisted of two waves:

- The first wave resulted in \$70 million in cost savings between 2008-09 and 2011-12 (prior to the review period).
- The second wave, which is ongoing, targets an additional \$100 million of efficiencies by the end of 2020. The \$100 million in efficiencies is measured from the 2012-13 baseline and is adjusted for regular annual Consumer Price Index (CPI) and salary increases.

In 2012-13, CBS created an executive level PEP Steering Committee to provide oversight for the development, execution and monitoring of the PEP. Before a PEP initiative begins, it needs to go through an approval process with the EMT which includes ensuring the project represents value for money. This process includes:

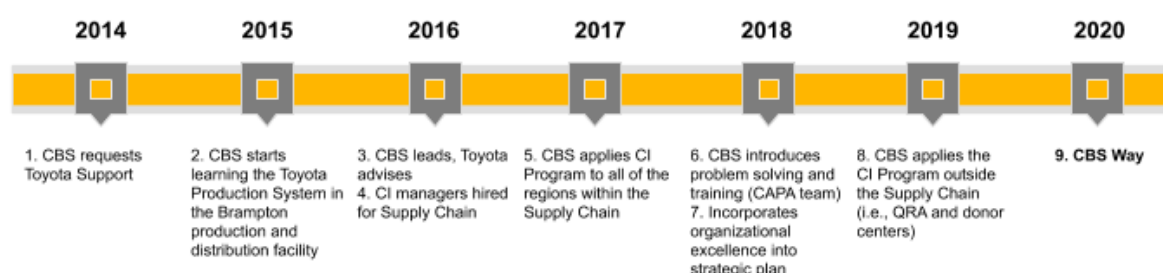
- A review of the initiative considering supply, cost, benefit and risk;
- Assessment of the investment required, including the potential return on investment; and
- Analysis of the impact and risk profile of the initiative and the impact on the risk profile of the wider portfolio of projects.

### Continuous Improvement Program

The CI Program was established, with the help of Toyota, in March 2015, to identify sources of waste and non-value add activities in CBS' supply chain. One of the main objectives of the CI Program is to develop a continuous improvement framework called the “CBS Way,” which CBS aims to achieve in

2020. The evolution of CBS' CI Program is detailed in Figure 31 below.

**Figure 31: CBS Continuous Improvement Progress Chart**



The CI Program was initially aimed at the production and distribution processes but progressed to target improvements in the testing and collection processes towards the latter stages of the review period.

To implement the CI Program, CBS worked with Toyota to identify sources of waste and opportunities for improvement at the CBS Brampton production facility. CBS adopted lean management techniques and began to align their decision-making in their production facilities with the principles of the Toyota Production System.

#### 4.4.4 Key Themes

Below is a summary of our key themes for this area:

**Table 17: Summary of key themes**

Area of Focus	Observation	Finding
<b>Productivity and Efficiency Program</b>		
<b>Achievement target savings</b>	<ul style="list-style-type: none"> <li>CBS achieved \$59.7 million out of its \$62 million savings target, at the end of the review period</li> </ul>	<ul style="list-style-type: none"> <li>CBS does not link its PEP savings targets to specific initiatives</li> </ul>
<b>Continuous Improvement Program</b>		
<b>Productivity and efficiency improvements</b>	<ul style="list-style-type: none"> <li>The implementation of CI Program initiatives helped improve productivity in production and distribution</li> </ul>	<ul style="list-style-type: none"> <li>The CI Program does not have a benefits management framework in place</li> </ul>

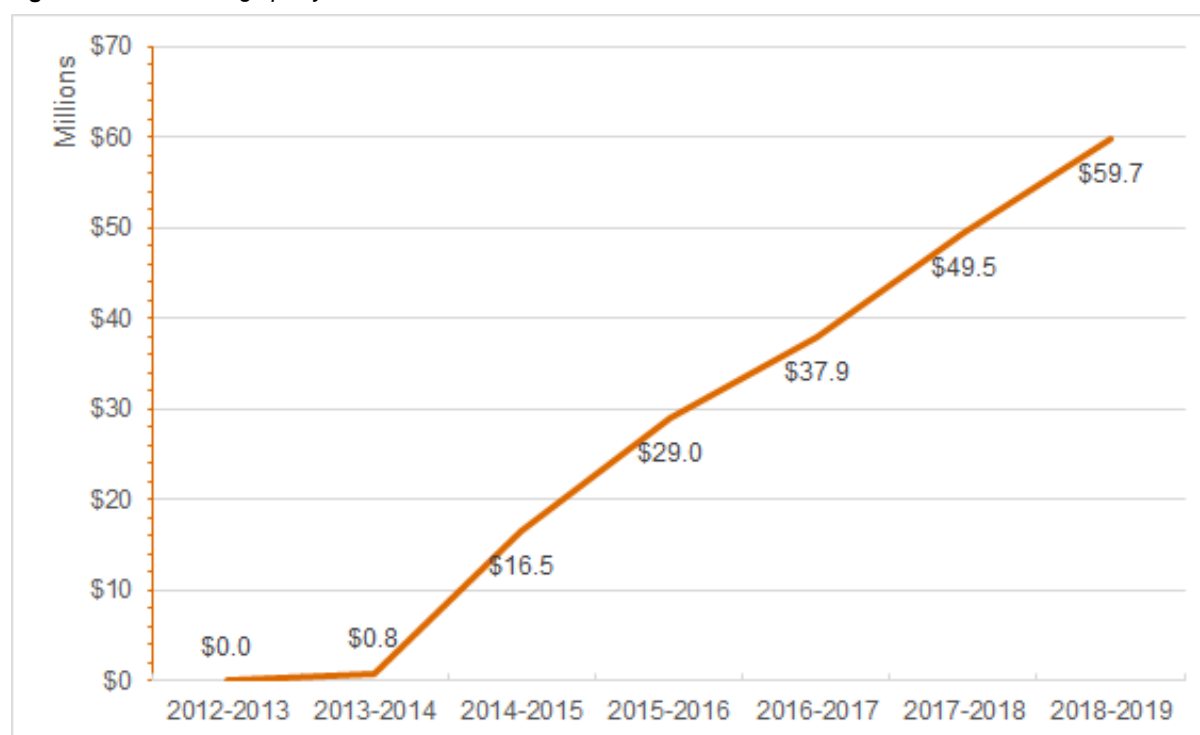
## 4.4.5 Key Review Observations & Findings

### 4.4.5.1 Productivity and Efficiency Program

**Observation:** CBS achieved \$59.7 million out of its \$62 million savings target, at the end of the review period.

- The cost savings of \$59.7 million were achieved incrementally between 2013-14 and 2018-19, as shown in Figure 32.

**Figure 32:** PEP savings per year 2012-13 to 2018-19



- Savings were calculated based on the annual change in FBC expenses, adjusted for annual demand and inflationary changes.
- We reviewed CBS' methodology and calculations for determining the cost savings and found them to be reasonable. However, as explained in the finding below, we could not attribute these savings to specific productivity and efficiency initiatives that CBS undertook over the review period.
- CBS fell short of its target savings by \$3.3 million due to:
  - \$2 million in incremental logistics expenses within the supply chain
  - \$1.3 million in incremental donor relations expenses to support recruitment efforts to shift the donor base to specific high-growth donor centres.

**Finding:** CBS does not link its PEP savings targets to specific initiatives.

- As explained in the observation above, CBS calculates efficiency savings using the changes in year over year FBC expenses, factoring in annual fresh blood demand and inflationary changes.
- This makes it challenging to understand the source of the efficiency gains and which initiatives have resulted in the best outcomes for Members and value for money.

**Recommendation 41: CBS should establish a portfolio management approach<sup>33</sup> for the PEP.**

- Consolidating the PEP initiatives under a portfolio management approach would enable CBS to track progress and monitor benefits realization for each initiative under the PEP. This approach would also help provide greater clarity to Members on the savings achieved as a result of implementing strategic initiatives such as the ASC.
- CBS should develop a formal methodology to estimate productivity and efficiency savings as part of this approach.
- Efficiency targets, including financial savings, should be included in the business case for each initiative submitted to the EMT for approval.

#### 4.4.5.2 Continuous Improvement Program

**Observation: The implementation of CI Program initiatives helped improve productivity in production and distribution.**

- The initial CI Program started in CBS' Brampton production facility and focused on key activities within distribution and production to help drive productivity improvements.
- Table 18 below shows the progressive improvements in production productivity.

**Table 18: CBS Production Productivity Metrics 2012-13 to 2018-19**

Financial Year	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18	2018-19
Production Productivity <sup>34</sup>	5,316	5,245	5,873	6,140	6,734	7,023	7,895

- The increase in productivity was due to:
  - standardization of production line processes;
  - reduction in equipment downtime; and
  - surfacing and solving many small problems.

**Finding: A benefits management framework for the CI Program is not in place.**

- The absence of regular benefits tracking and reporting makes it difficult to monitor the success of the CI Program and to understand how improvements in productivity metrics are correlated to specific initiatives under the Program.



**Recommendation 42: CBS should develop a benefits management framework for the CI Program to enable:**

- Identification of benefits for CI initiatives that are aligned with organizational goals
- Systematic tracking of benefits as project implementation progresses
- Increased visibility into the overall benefits provided by the CI program in relation to the investments made

The benefits management framework will help provide PTs with a better understanding of how the CI Program improves productivity and efficiency metrics.

<sup>33</sup> Portfolio management is the selection, prioritization and control of an organization's projects and programmes in line with its strategic objectives and capacity to deliver.

<sup>34</sup> Output per production FTE i.e. the # of weighted units processed per production FTE.

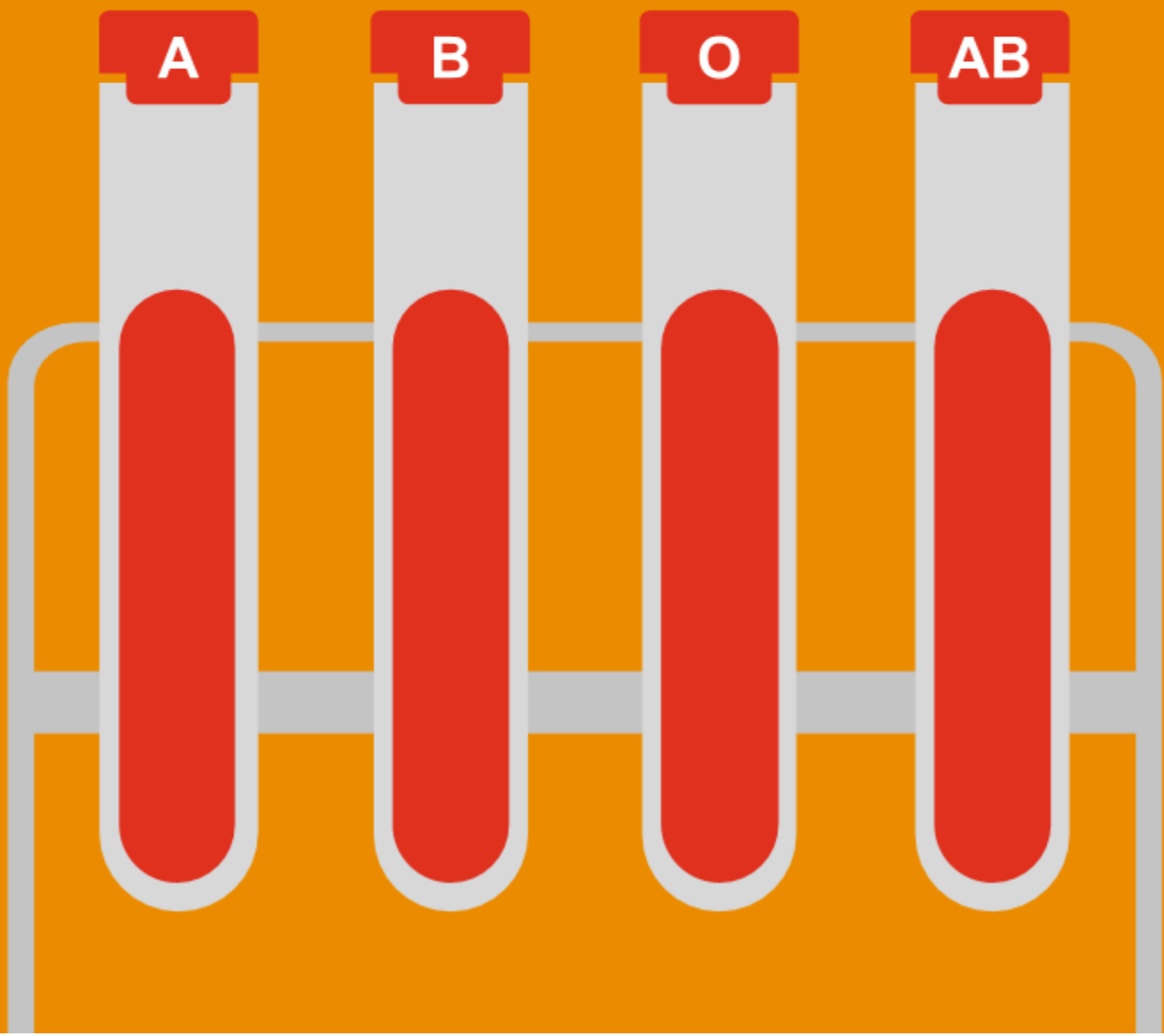
# 5

## Strategic Initiatives Performance

5.1.1 Project Management

5.1.2 ASC Project

5.1.3 Donor Experience  
Project



# 5. Strategic Initiatives Performance

## 5.0.1 Objective

Evaluate the ASC and Donor Experience projects for effectiveness of project management, deliverables and results.

## 5.0.2 Scope

The focus of this section is on two areas as follows:

**Focus Area 1:** Project Management, Governance and Reporting

- Effectiveness of governance, scope, schedule, change management and reporting processes

**Focus Area 2:** Benefits Realization

- Extent to which benefits as defined in the internal CBS project business case have been realized

## 5.0.3 Context

### ASC Project

The ASC project was implemented in July 2016 and was one of CBS' main PEP initiatives.

The objective of the project was to create a modern and efficient collections process through process improvements and greater investment in technology. Specifically, it focused on:

- Increasing safety and reducing potential errors in the collections process by reducing manual entry;
- Increasing productivity and efficiency resulting in FTE reductions;
- Enhancing donor experience through a seamless donation process;
- Enhancing staff experience through elimination of pain points in the process; and
- Providing data to make better business decisions.

Prior to this project, CBS gathered donor information through a manual, paper-based system that was susceptible to errors and expensive to operate.

CBS selected MAK Systems to implement ePROGESA, a software application for blood operators, to automate and simplify collections processes at all donor centres. The project involved collaboration across multiple CBS functions, including donor relations, collections, logistics, facilities and IT.

Work commenced in 2014 and the project was completed in 2016. CBS spent \$21.4 million on this initiative which included \$14.1 million of internal costs and \$7.3 million of external costs (professional services, other purchased services and equipment).

### Donor Experience Project

The Donor Experience project was launched to update CBS' business model to better meet future patient needs by building a strong and diverse donor base. It was recognized that the existing business model was inadequate to attract and retain the required donors to ensure a safe and secure blood supply for Canadians. The main objectives of this project were to:

- Implement a best-in-class donor experience feedback system providing real time feedback for deeper insights;
- Develop new "commitment to donors" and educate donor centre staff on commitments, and embed donor experience review into weekly huddles aided by the donor feedback technology;

- Modernize CBS' image to become more relevant to Canadians in a highly competitive non-profit environment. The last major brand renewal was undertaken in 2005 and the corporate statements (mission, vision, values) had not been updated since the organization was created in 1998; and
- Provide a design blueprint for donor centres that incorporated CBS' new branding.

Work commenced on the project in January 2018 and the renewed brand launched in September 2018. The Donor Experience Project was fully completed in February 2019. The total cost of implementation was \$5.9 million and included \$1.8 million of internal costs and \$4.1 million of external costs.

## 5.0.4 Key Themes

Both projects were implemented on time and adhered to CBS' project management stage gate methodology.

The ASC project had challenges with the realization of some of the benefits at project closeout and the financial benefits realization was not tracked. While the Labour Hour per Unit (LHU) was tracked, it did not provide a view of the extent of realization of the \$15 million of estimated project benefits.

For the Donor Experience project, the project outcomes related to donor retention and public perception of CBS were below target. Several recommendations in this section have a direct impact on value for money when considered from a benefits or cost perspective.

Below is a summary of our key themes for this area:

**Table 19: Summary of key themes**

Area of Focus	Observation	Finding
<b>Project Management, Governance and Reporting</b>	<ul style="list-style-type: none"> <li>• Both projects adhered to CBS' project management methodology at each stage gate</li> <li>• The level of oversight, governance and reporting was appropriate for both projects</li> </ul>	
<b>ASC Project</b>		
<b>Project Management - Budget and Schedule</b>	<ul style="list-style-type: none"> <li>• The project was completed ahead of schedule and on budget</li> </ul>	<ul style="list-style-type: none"> <li>• CBS chose a sole-source vendor to implement the technical solution</li> <li>• The business case for the ASC project did not articulate the overall risk associated with the project</li> </ul>
<b>Benefits Realization</b>		<ul style="list-style-type: none"> <li>• The ASC project's business case estimated a net benefit of \$15 million at the end of 2018-19 but the achievement of this benefit has not been tracked</li> <li>• Challenges were encountered in measuring the reduction of LHU and the target reduction for this benefit was not achieved</li> <li>• Operational targets within the project were not cascaded to accountable leadership at a local level</li> <li>• The reporting of benefits achievement at project close-out could be enhanced</li> </ul>
<b>Donor Experience Project</b>		
<b>Project Management - Budget and Schedule</b>	<ul style="list-style-type: none"> <li>• The project was completed on time and delivered under budget by \$1.2 million</li> </ul>	
<b>Benefits Realization</b>		<ul style="list-style-type: none"> <li>• The benefit realization measures related to donor retention and public perception of CBS were below target at the time of project close-out</li> </ul>



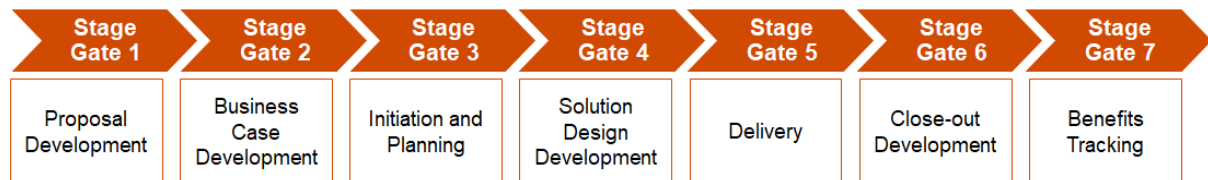
## 5.1 Key Review Findings

### 5.1.1 Project Management

**Observation: Both projects adhered to CBS' project management methodology.**

Both projects followed the CBS project management stage gate methodology consisting of seven stage gates as seen in Figure 33 below. The stage gates are aligned with what we typically expect to see for projects of this nature and scale. The stage gates relate to CBS' internal project governance.

*Figure 33 - Stage gates in the CBS project management methodology*



Project management artifacts for each stage gate were of high quality and consistent with CBS' project management methodology requirements.

**Observation: The level of oversight, governance and reporting was appropriate for both projects.**

- The ASC project was governed by the Clinical Environment Steering Committee and the PEP Board. There was evidence of the following practices throughout the project lifecycle:
  - Governance review and sign off of project decisions and documentation;
  - A change control process, where scope changes were reviewed and approved through the project governance framework; and
  - A deliverables register, where the progress of each project deliverable was tracked and then closed upon sign-off on the deliverable through governance.
- The Donor Experience project was governed by a Steering Committee which was represented by CBS executive team including leads from Supply Chain, IT and Public Affairs.
  - There was evidence of governance reviews and sign-off of project decisions and documentation throughout the project lifecycle.
- PTs were provided with updates on both projects at PTBLC meetings.
  - PTs were also apprised of the staff impacts and clinic changes related to the ASC project.

### 5.1.2 ASC Project

**Observation: The ASC project was completed ahead of schedule and on budget.**

- The ASC project was originally planned to be implemented in a phased manner starting with a go-live in one donor center in February 2016, followed by a gradual roll out to all other locations ending in August 2016. Due to technical limitations with the ePROGESA software, the project was undertaken through a nationwide roll-out, all at once, in July 2016.
- The original project budget of \$25.4 million was reduced over the course of the project to \$21.4 million, with proper approval, for a number of scope changes. The most significant scope change was the decision not to eliminate the Donor Services Representative (DSR) role from collection centres. This resulted in the removal of \$1.6 million from the originally approved budget. The project was ultimately completed at a cost of \$21.4 million.

It is important to see any large project/initiative with a lens of cost, timeline and benefits. While the ASC project did deliver on cost and timeline, there were a number of gaps with respect to delivery of core benefits. Some of these challenges were related to measurement and some related to tracking and accountability.

**Finding: CBS chose MAK systems on a sole source basis to implement ePROGESA as there were very few options in the market.**

- With limited vendor options for the ASC solution, CBS did not issue an open tender for the ASC functionality. CBS worked with ABO operators to explore what they had done and very few of them had implemented similar technologies.
- CBS experienced technical limitations with the ePROGESA software during the project and extensive configuration was required to ensure the product met CBS' requirements.



**Recommendation 43: For projects over a material threshold and within a new and emerging area, we recommend that CBS consider using a technology advisory firm to help them evaluate available technologies in the market and identify potential vendors to deliver the solution.**

**Finding: The CBS internal business case for the ASC project did not articulate the overall risk associated with the project.**

- The business case identified a total of 18 project and business risks. Each risk was rated with regards to probability and impact but an overall rating for each risk was not provided.
- In addition, an overall project risk rating (i.e., high, medium, low) was not provided to inform decision-making and approval of the business case by EMT.



**Recommendation 44: CBS' Enterprise Program Management Office (ePMO) should ensure that business cases for strategic initiatives provide a risk rating for all identified risks and clearly articulate the overall risk associated with each project.**

**Finding: The project business case estimated a net benefit of \$15 million at the end of 2018-19 but the extent to which this benefit has been achieved was not tracked.**

- The majority of the financial benefits outlined in the business case were predicated on the potential elimination of 130-183 FTEs (includes elimination of the 53 DSR positions). These FTE reductions were estimated to provide ongoing cost savings of approximately \$10-\$14 million annually.
- Over the course of the project, FTE reductions became a less relevant productivity measure as there were substantial staff reductions that occurred due to changes in collections targets that were unrelated to the ASC project.
- In January 2016, EMT agreed that the project should track productivity gains solely in terms of LHU as it is less prone to fluctuations as a result of ongoing business decisions.
- The project as part of its closeout report outlined the extent of achievement of LHU targets but did not provide a perspective on the achievement of financial benefits.

It is important to note that our "Benchmarking analysis" in the *Financial Performance* section of this report highlights that CBS is substantially behind its comparator organizations with respect to per FTE collection targets. While the ASC project resulted in some productivity improvements, it was not sufficient to enable CBS to catch up to other blood operators who had better collections productivity rates (see Figure 4).



**Recommendation 45: As part of its reporting process on major projects to the Board and Members, CBS should:**

- formally report on the financial benefits realization and project risks throughout the project as critical decisions are made and their potential impact on benefits realization; and
- explain the reasons for any variances from the benefits estimated within the original business case.

Project closeout reports should include an analysis of financial benefits realization and reasons for any shortfalls.

**Finding: Operational targets arising from the project were not cascaded to leadership at the local level resulting in lack of accountability to achieve them.**

- There was a gap between the identification of benefits targets, such as the LHU, and cascading the targets to operational budgets for realization. Early on in the project, local budgets were not impacted to reflect the LHU target and there was limited ability to influence this down the line.
- This accountability gap resulted in the LHU target being exceeded and the projected productivity gains not being achieved (see Appendix 17).



**Recommendation 46: CBS should establish a process for integration of project benefits targets with operational performance targets and budgets at the regional/local levels. This will drive higher probability for actual realization of benefit targets.**

**Finding: The ASC project had challenges measuring reduction in the LHU at project closeout.**

- A definition for the LHU metric was not established in the business case. However, it was evident from the project documentation that the project team found it challenging to measure the reductions against the LHU target. For example, there was debate as to whether supervisor backfill hours should be included in LHU and a finance review was initiated to better understand the issue.
- At project closeout, the LHU target of 1.26 had not been achieved due to an increase in non-clinical hours from 15.1% to 22.7%. CBS' LHU at the end of 2018-19 was 1.33.

**Recommendation 47: CBS should ensure that benefits measures are clearly defined in project business cases along with clear accountability for who should measure and who is expected to achieve them. This would help prevent downstream measurement and accountability challenges.**



**Recommendation 48: CBS should continue to monitor and report on the productivity results from process changes associated with the ASC project.**

CBS noted in the closeout report that targeted activities are planned to analyze and further reduce the LHU. These activities, which have been transitioned to the ownership of the Chief Supply Chain Officer, should continue to be reported to CBS governance forums, such as the EMT, with the aim of realizing this benefit.

**Finding: The reporting of benefits achievement at project close-out could be enhanced.**

- The ASC Realization Close-out Report (dated October 2018) indicated that the target for employee satisfaction had been achieved although there was no target specified in the business case and survey results referenced were two years old.
- Donors reporting a wait time of 1 hour or less could not be measured as part of the "enhanced donor experience" metric but the overall target was reported as having been achieved in the

Realization Close-out Report. The reason for not being able to measure the donor wait time was that the donor surveys no longer included the appropriate question.

**Recommendation 49: CBS' ePMO should review all business cases to ensure that targets are stated for all benefits metrics and that mechanisms are in place to collect the information required to report on benefits realization at project close-out.**

- Consideration should be given to the availability of data/information to enable benefits measurement in an efficient and cost-effective manner.
- For metrics tied to surveys such as employee satisfaction, a baseline measure should be included in the business case to measure against at the end of the project. Consideration should be given to conducting a survey at the outset of the project and comparing the results against post project survey results.

### 5.1.3 Donor Experience Project

**Observation: The Donor Experience project was completed on schedule and under budget by \$1.2 million.**

- The Donor Experience project had a total budget of approximately \$7.1 million. The actual spend for the project was approximately \$5.9 million.
- All unspent funds, which were mainly as a result of not requiring the budgeted contingency allowance, were reported as surplus to PT governments and returned to them.
- CBS launched their new brand in September 2018. CBS assets are being updated on an ongoing basis with the new brand and expected to finish in April 2020.

**Finding: The benefit realization related to donor retention and public perception was below target for this project (see Appendix 18).**

- The public's unaided awareness of whether Canadian Blood Services or the Red Cross manages the blood system has improved by 10% but remains 4% below target.
- Donor retention for both new and existing donors was 1% below target. This measure is anticipated to improve over time with introduction of the plasma proof-of-concept collection sites.
- The outcomes report notes that measures have been put in place to close the gap in the areas that have not met the realization targets. However, it does not contain an action plan to track progress coupled with business owners who are accountable for managing the remediation measures going forward.



**Recommendation 50: CBS should prepare an action plan to support the tracking and realization of the benefits that have not met their targets for the Donor Experience project.**

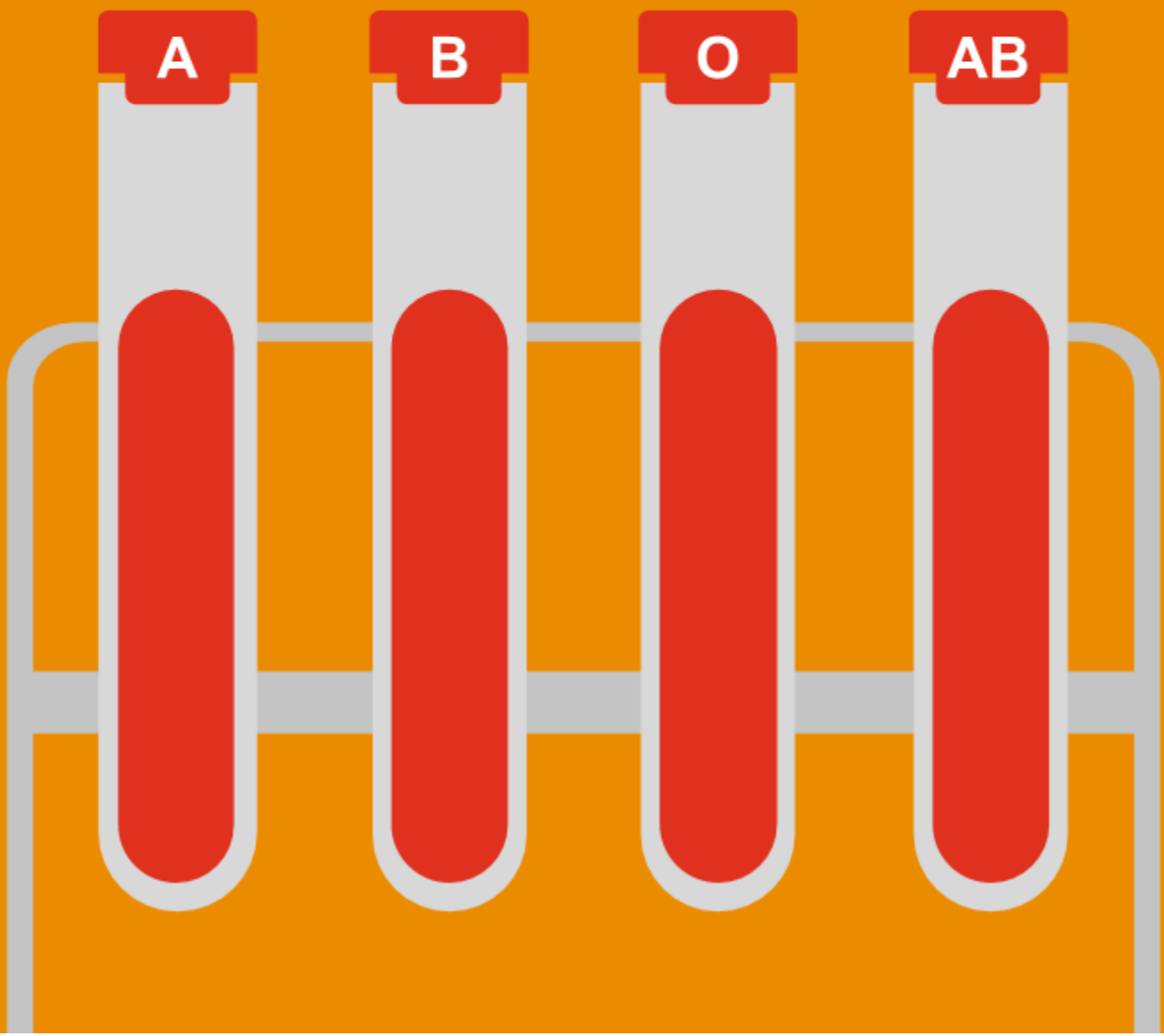
- The action plan should articulate the remediation activities for each measure that is below target, the accountable business owner and timelines for improvement.
- CBS should monitor progress and continue to measure against the targets outlined by the project to assess if the project is delivering value for money.

# 6

## Other Areas of Review

6.1 Governance

6.2 Enterprise Risk  
Management



# 6. Other Areas of Review

## 6.1 Governance

### 6.1.1 Objective

The objective of this section is to evaluate the level to which CBS governance model and structure, decision-making process, and accountabilities were relevant and functioning as intended with regards to FBC and PPP. It should be noted that CBS' overall governance structure applies to all of its business lines, though FBC and PPP account for 95% of the overall business. That said, the operational structure and decision-making processes for PPP are evaluated in Section 4.3 of our report.

### 6.1.3 Scope

The focus of this section is on three areas as follows:

- **Focus Area 1:** Governance Model and Structure;
- **Focus Area 2:** Accountabilities; and
- **Focus Area 3:** Decision-Making Processes.

The evaluation of the effectiveness of CBS' governance structure and model for each focus area was guided by the indicators outlined in Figure 34 below.

These indicators and the subsequent governance evaluation are informed by a series of leading practices set out by: the *Principles of Corporate Governance* developed by the Harvard Law & Harvard Business, the Organization for Economic Co-operation and Development's (OECD's) *Principles of Corporate Governance*, the Committee of Sponsoring Organizations of the Treadway Commission (COSO) *Internal Control - Integrated Framework*, and leading PwC practices established by PwC's Governance Insights Centre.

**Figure 34:** Criteria Used to Evaluate Governance Components

Functioning and Relevance of Governance Model and Structure	Functioning and Relevance of Accountabilities	Functioning and Relevance of Decision-Making Processes
<b>Criteria:</b> <ul style="list-style-type: none"><li>• Extent to which the governance model aligns to the principles enabling an effective corporate governance model and CBS' foundational documents</li><li>• Extent to which governance model/structure aligns with comparable organizations</li><li>• Extent to which Board of Directors' composition aligns with prevailing practices</li><li>• Extent to which succession planning has been undertaken to enable business continuity</li></ul>	<b>Criteria:</b> <ul style="list-style-type: none"><li>• Extent to which roles and responsibilities are clearly and consistently defined and codified</li><li>• Extent to which roles and responsibilities are appropriately assigned</li><li>• Extent to which reporting is timely and responsive</li></ul>	<b>Criteria:</b> <ul style="list-style-type: none"><li>• Extent to which decision-making is informed</li><li>• Extent to which responsibilities / duties are discharged and meeting the requirements of stakeholders</li></ul>

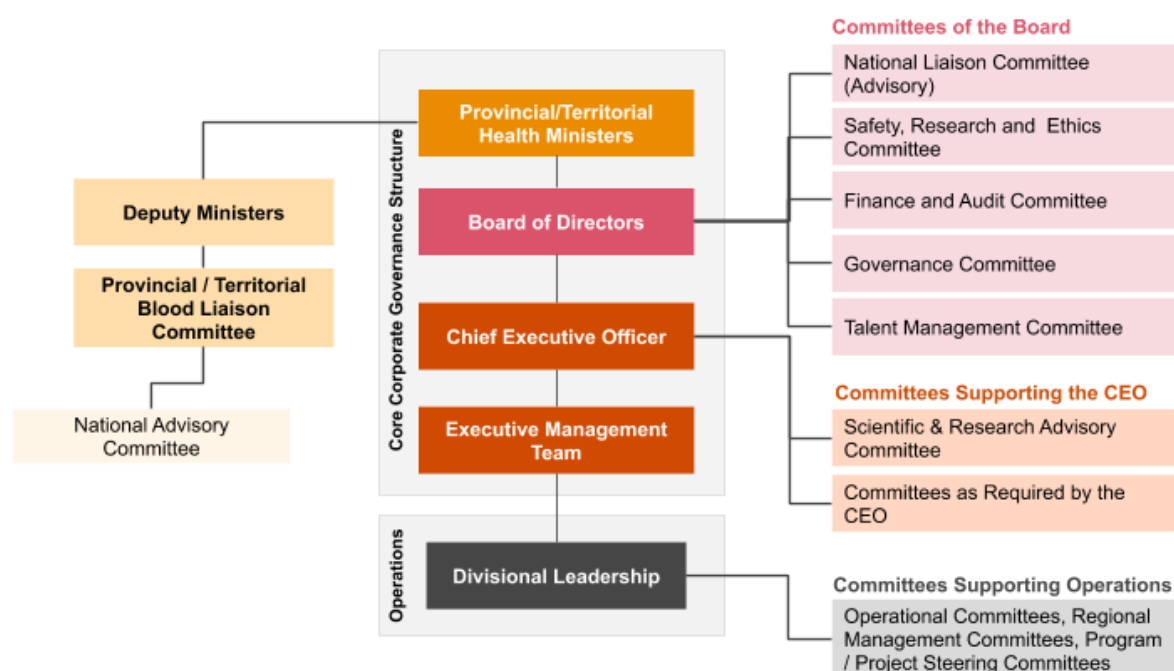
## 6.1.2 Context

The MOU establishing the CBS also established the collaborative governance framework that guides the management and oversight of Canada's national blood supply system. Through this framework:

- Governance of the system is assigned to three principle parties: the Provincial Territorial Health Ministers (i.e., "Members"), a Board of Directors, and a Chief Executive Officer;
- Responsibilities and accountabilities are assigned to each of these parties; and
- CBS, as the day-to-day operator of the system, is provided with management discretion over all operational decisions.

Figure 35 below provides an overview of CBS' governance model and structure.

**Figure 35: CBS Governance Model and Structure**



Within this model, governance responsibilities are assigned as follows:

- Provincial /Territorial Health Ministers are responsible for:
  - setting of CBS' mandate/mission;
  - approval of CBS' three-year corporate business plan, including performance objectives and funding requirements;
  - selecting the members of CBS' Board of Directors; and
  - oversight of the expenditure of public funds provided to CBS to execute its mandate.
- The PTBLC was established to support Members in executing their responsibilities. PTBLC representatives interact with CBS on an ongoing basis and provide advice and support on issues to the PT Deputy Ministers and Ministers of Health.
- An independent Board of Directors (where Directors are appointed by Members for four-year terms) is responsible for overseeing the overall direction, operational activities and budget of CBS. The BoD is also responsible for the appointment and dismissal of the Chief Executive Officer (CEO) and ensuring that CBS is operating and performing as intended.



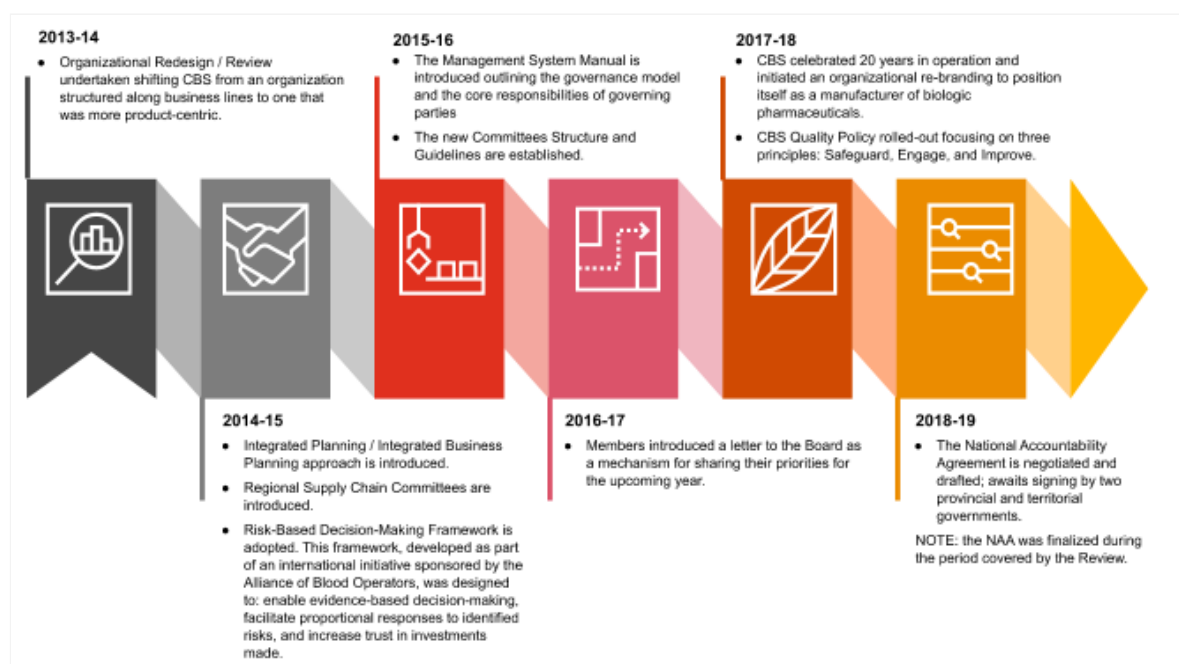
- A Leadership Team (including the CEO and an Executive Management Team) is responsible for managing CBS' day-to-day operations, implementing corporate and operational policies as directed by the BoD, and ultimately ensuring the organization achieves its business goals and delivers on its mandate.
- Divisional Leadership Teams (overseen by a member of the Executive Management Team) are accountable for operational decisions and driving performance at the divisional level.

A number of committees have been established to provide strategic and operational support to governing parties. A description of the scope of each committee is provided in Appendix 19.

### 6.1.2.1 Key Governance-Related Changes at CBS over the Review Period

CBS made a number of changes over the review period impacting its governance structure and processes; Figure 36 below provides an overview of the applicable activities.

**Figure 36: The Activities Impacting Corporate Governance at CBS**



### Organizational Redesign/Review

An organizational redesign was undertaken, in 2013-14, to align CBS with the elements of a biologics manufacturer's supply chain. The redesign resulted in CBS shifting from an organization structured along business lines to one that is more product-centric. The outcome was an organization with a matrix reporting structure:

- enabling a more integrated supply chain management model;
- allowing for greater collaboration and the sharing of common resources (i.e., systems, skill sets, etc.); and
- enabling greater consistency in the practices and standards followed by all groups and better sequencing of processes.

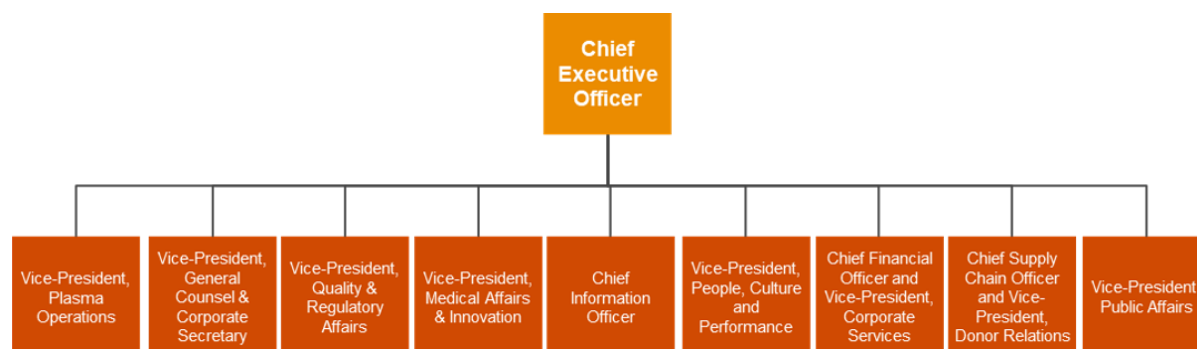
The redesign had no impact on the structure of the BoD or any of the committees supporting the BoD; however, it did impact the composition of the EMT.

The EMT is the senior management team leading CBS. Within this group, the CEO is the most senior member and is accountable to the BoD; all remaining members of the EMT report to the CEO. The EMT informs CBS' business goals, is accountable for the organization's performance, and provides operational oversight over its activities. Following the organizational redesign and subsequent changes such as the creation of the position of VP Plasma Operations and amalgamation of the Chief



Supply Officer and VP Donor Relations into one position, the EMT was structured to include 10 members (see Figure 37 below).

**Figure 37: Executive Management Team's Structure**



In addition to the above, other changes that resulted from the organizational redesign impacting governance, included:

- Introduction (in 2014-15) of an Integrated Planning/Integrated Business Planning approach to support the planning cycle. This approach included:
  - VP's Direction Letters (published annually) that outline the priorities/direction for the year ahead. These letters are cascaded down through each VP's team and inform the teams' individual performance plans for the year.
  - Quarterly meetings where the EMT reviews corporate performance (inclusive of the budget and forecasts) and strategic portfolios to ensure alignment with goals and expectations.
- Introduction (in 2014) of a new committee structure and supporting guidelines. The *Committee Management Guidelines* describe:
  - the conditions under which committees are created or closed;
  - the principles and rules enabling clarity and transparency around how committees work; and
  - the manner in which committees make recommendations or decisions.
- Introduction (in 2015-16) of a CBS decision inventory approach that can "be used as a tool to support conversations with divisions where areas of accountabilities are unclear"<sup>35</sup>. The decision inventory has primarily been used to identify and prioritize governance gaps for the PPP program team as the PPP area was evolving.

<sup>35</sup> CBS. (2015-16). Organization Design Benefits Realization Report (Q3 and Q4 2015-2016): EMT. (Internal document shared by CBS)

## 6.1.4 Key Themes

Over the review period, CBS maintained a governance structure that was aligned with the requirements of the MOU and reflected elements of good governance based on leading practices. There was consensus amongst stakeholders that CBS' governance model functioned well overall and that CBS worked within the governance framework in an effective manner.

Below is a summary of our key themes for this area:

**Table 20:** Summary of key themes

Area of focus	Observations	Findings
<b>Governance Model &amp; Structure</b>	<ul style="list-style-type: none"> <li>The governance model adopted by CBS is in alignment with the requirements of the MOU</li> <li>CBS' governance model contains the core components of an Effective Corporate Governance Model</li> </ul>	<ul style="list-style-type: none"> <li>The opportunity exists to enhance the diversity of CBS' Board of Directors</li> <li>A Board succession plan has not been developed</li> <li>An orientation program is not in place for new PTBLC representatives to familiarize them with CBS and their new role</li> </ul>
<b>Accountabilities</b>	<ul style="list-style-type: none"> <li>Governance roles and responsibilities are clearly defined</li> </ul>	<ul style="list-style-type: none"> <li>Opportunities exist for CBS to enhance the content and timeliness of reports / materials provided to Members</li> </ul>
<b>Decision-Making Processes</b>	<ul style="list-style-type: none"> <li>CBS has strengthened its decision-making processes over the review period through the introduction of a Risk-Based Decision-Making framework</li> <li>CBS stakeholders reported high levels of satisfaction with CBS' governance model</li> <li>CBS stakeholders also reported high levels of satisfaction with the organization's ability to act as a steward of the blood and blood products system and deliver on expected patient outcomes</li> </ul>	

The section that follows contains detailed descriptions of all governance-related observations and findings emerging from this performance review along with applicable recommendations. A selection of recommendations in this section have a direct impact on value for money when considered from a supply, benefit, cost or risk perspective.

## 6.1.5. Key Observations and Findings

### 6.1.5.1 Governance Model & Structure

#### Governance Model Alignment to Principles Supporting Effective Corporate Governance Model & Foundational Documents

**Observation: Governance model adopted by CBS is in alignment with the requirements of the Federal / Provincial / Territorial MOU.**

CBS' governance structure reflects the MOUs requirements (as outlined in *Annex B: NBA Governance Model*) calling for:

- A BoD that provides overall direction on CBS' affairs, operational activities, and budget;
- A CEO who is responsible for the management and day-to-day operation of CBS' programs and staff; and
- Members who are responsible for the mandate/mission of the organization, funding the organization, selecting the Board of Directors, and the overall expenditure of public funds. In accordance with the components of an effective governance model, the MOU does not afford Members the power to direct operational decisions.

**Observation: CBS' Governance Model contains the core components of an Effective Corporate Governance Model.**



In addition to alignment with the requirements of the MOU, the structure of CBS' Governance Model aligns, more broadly, to the requirements contributing to effective corporate governance. Though Corporate Governance leading practices highlight that there is no one-size-fits-all model, there are some key components that contribute to an "effective governance model". These include:

- a Board of Directors;
- a Chief Executive Officer;
- a funding entity; and
- a selection of critical committees.


Table 21 below illustrates the extent to which the CBS' governance model and the requirements of the MOU align to the components of an effective governance model.

**Table 21: CBS' Model & Components of an Effective Governance Model**

Component of an Effective Governance Model	MOU Alignment	CBS Governance Model Alignment
<b>Board of Directors</b> - responsible for overseeing the organization's management and business strategies to achieve long-term value creation	✓	✓
<b>Chief Executive Officer</b> - responsible for managing and executing the organization's strategies as approved by the BoD	✓	✓
<b>"Funding Body"</b> - not involved in the day-to-day management of the organization's operations, but has the right to elect representatives (directors) and to receive information/material to inform funding decisions	✓	✓
<b>Audit Committee</b> - responsible for selecting and retaining the external auditor, reviewing the financial statements, overseeing internal controls over financial reporting, compliance programs, and the internal audit function	✓	✓

Component of an Effective Governance Model	MOU Alignment	CBS Governance Model Alignment
<b>Corporate Governance Committee</b> - responsible for: establishing criteria for BoD membership (inclusive of considering knowledge, experience, independence, and diversity criteria); succession planning for the BoD and CEO; performing evaluations of the BoD's leadership; oversight to ensure effective functioning of the Board; reviewing corporate governance guidelines; managing stakeholder engagement efforts	N/A	
<b>Compensation Committee</b> - responsible for the organization's overall compensation philosophy, structure, policies and programs	N/A	

Legend ✓ met

 partially met

N/A not addressed in MOU

### 6.1.5.2 Alignment of CBS' Governance Model/Structure with Comparable Organizations

**Observation: CBS' Governance Model is consistent with the models of comparable organizations.**

To determine the extent to which the structure of CBS' Governance Model is "relevant", it was compared (at a high level) to the governance models of the Australian Red Cross Lifeblood and the American Red Cross. Findings indicated that CBS' Governance Model contained many of the same features as these comparable organizations. Each organization had a governance structure that included a Board, a chief executive officer, and committees to enable the Board to undertake its responsibilities (see Table 22).

**Table 22: Comparison of Governance Models - CBS, Australian Red Cross Lifeblood, & American Red Cross**

Canadian Blood Services	Australian Red Cross Lifeblood	American Red Cross
<ul style="list-style-type: none"> <li>Governed by a Board of Directors with overall responsibility for the organization and tasked with responsibility to hire and manage the performance of the CEO.</li> <li>A Chief Executive responsible for leading the management of the organization.</li> <li>The Board of Directors is supported by committees tasked with responsibility for: governance, finance and audit, talent management, executive compensation and benefits, BoD education, safety and risk management, and stakeholder engagement and relations.</li> </ul>	<ul style="list-style-type: none"> <li>Governed by a Board of Directors with overall responsibility for the organization and appointment of non-executive Board members</li> <li>A Chief Executive responsible for leading the management of the organization.</li> <li>The Board is supported by committees with responsibility for: governance, finance and audit, nomination and compensation/remuneration, risk management, and provision of expert advice on medical and scientific matters</li> </ul>	<ul style="list-style-type: none"> <li>Governed by a Board of Governors with responsibility for directing and overseeing management of organization</li> <li>Led by a President and CEO (one role) who executes the organization's strategy and leads its operations</li> <li>The Board of Governors is supported by a series of committees. Committees have responsibility for: governance, audit and risk management, management of an endowment fund, compensation and management development, exercising Board powers / authority in situations where critical decisions are required but it is not practicable to arrange a Board meeting</li> </ul>

### 6.1.5.3 Alignment of Board of Directors Composition to Prevailing Practices

#### Nomination of Directors

**Observation:** The process of nominating Directors to the BoD is in alignment with leading practices.

Leading practices highlight that while there is no mandatory structure for a Board of Directors, the look and structure of a BoD should be focused on the organization it serves. That said, there are practices that should be followed by organizations seeking an effective BoD. These practices include:

- an approach for nominating directors to and removing them from the BoD;
- BoD diversity;
- clearly articulated accountabilities and a BoD committed to executing its duties (discussed in Section 6.1.7.2: Discharging of Responsibilities & Meeting Stakeholder Expectations); and
- an approach to evaluate the performance of the BoD and its committees.

The process of nominating Directors to the CBS BoD is guided by the *PT Ministers of Health Nomination and Election of Canadian Blood Services' Board of Directors document*. This document sets out the core principles for Director recruitment, nomination, and election (e.g., transparency, gender balance and diversity, and selection of directors based on experience, expertise and qualifications related to the role).

The approach used by CBS aligns with the leading practices. In particular, the process is consultative, engaging a series of representatives (i.e., the BoD Chair, CBS BoD Committees), who help to inform the selection of potential candidates. Ultimately, the ideal candidate is selected, through a democratic voting process, by Members.

This process further aligns to the leading practices in its use of a skills matrix. A skills matrix is developed to support each nomination process which considers the key characteristics (skills, experience, etc.) that would be required to enable an effectively functioning BoD.

#### Board Diversity

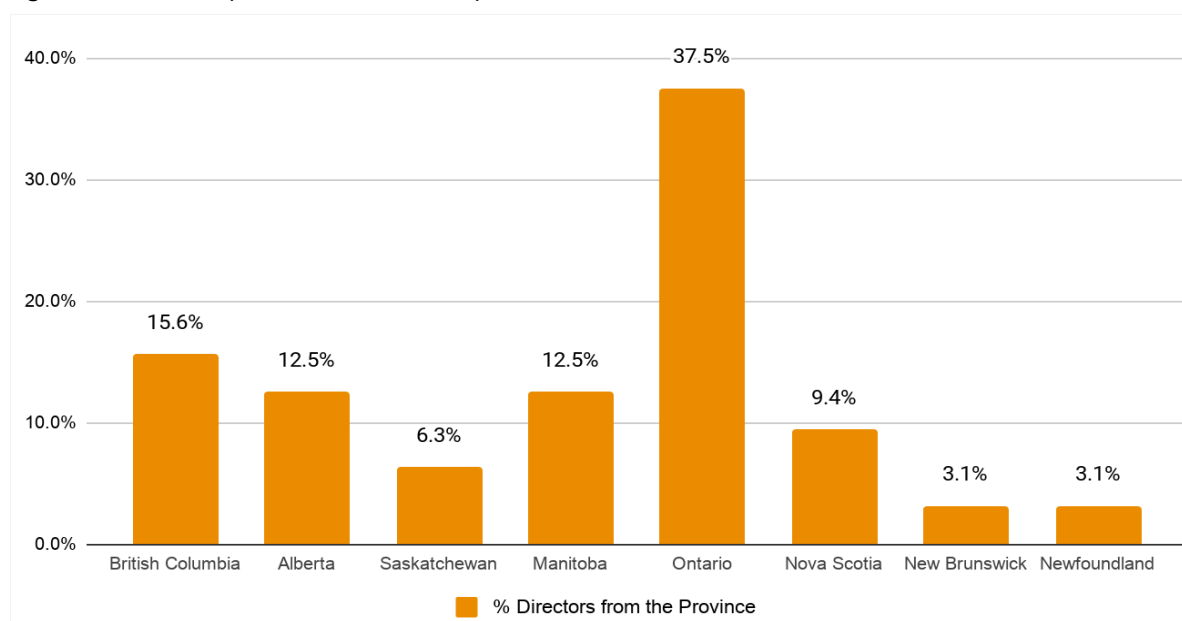
**Finding:** The opportunity exists to enhance the diversity of CBS' Board of Directors

The diversity of Directors contributes to an effectively functioning BoD. While CBS plays a key role in succession planning for the BoD, the recruitment, nomination and election of Directors to the CBS Board is the responsibility of Members.

With regards to diversity, we found that:

- though CBS had both male and female membership on the BoD, over the review period, male directors outnumbered females. Specifically, 67% of Directors were male. This is also true when looking at BoD leadership. Over the review period, CBS' BoD had five leaders (i.e., Chair or Vice-Chair) and, of those, two were female.
- the 2019 letter outlining Members' priorities for the year indicated the need to improve BoD diversity and the importance of future Boards reflecting diverse perspectives, experiences, cultural backgrounds and education levels. The matter of a more representative CBS BoD (i.e., a BoD that reflects Canada's and CBS' donor demographic) was also raised by the Director, Search Advisory Committee in 2018, and by the BoD in their 2019 BoD evaluations.
- there is an opportunity to enhance the regional representation of the BoD. Over the review period, the majority of BoD Directors resided in Ontario (see Figure 38 below). Further, the majority of Directors resided in Canada's urban centres with little rural or remote representation on the BoD.

**Figure 38: BoD Composition - Provincial Representation on the BoD**



**Recommendation 51: Develop a Board diversity strategy.**

Working with Members, the CBS' BoD should:

- Define “diversity” or, more specifically describe what a diverse BoD for CBS resembles. In defining “Board diversity”, attributes of status (e.g., Indigenous, First Nations, Metis), gender, race, ethnicity, culture, religion, age, sexual orientation, and regional location should be considered (i.e., in addition to urban and rural, consider “remote” locations).
- Outline the approach that the BoD and Members will take in the near and longer terms to enhance Board Diversity. Achieving “diversity” is likely to be an incremental process given that action can only be taken once the tenure of existing Directors comes to an end.
- Establish processes to track and report on the level to which the tenets of the BoD Diversity Strategy are being achieved, and periodically review and evolve the definition of “diversity”. We understand that CBS, the BoD, and Members are taking steps to enable a BoD composition that is reflective of the Canadian population and donor population.

The effective functioning of the BoD requires individuals with the necessary education, skills, and experience to effectively deliver on all aspects of the mandate assigned to CBS. As such, education, skills, and experience should remain the primary considerations when selecting a candidate for the BoD.

#### 6.1.5.4 Succession Planning / Governance Transitioning Enabling Effective Continuity

**Finding: While succession plans are in place for the CEO and senior management at CBS, a BoD succession plan has not been developed.**

According to leading practices, effective succession planning is a key role of the BoD. The approaches established by CBS and the BoD to address CEO and senior management succession planning align to leading practices. Specifically:

- **CEO Succession Planning:** It was confirmed, through interviews, that a CEO succession plan has been developed by the Talent Management Committee (TMC) and is reviewed annually by this Committee. The BoD views CEO succession planning as a top priority for the organization.
- **Senior Management Succession Planning:** CBS has a succession framework in place for its EMT. Each EMT position has two internal development candidates identified. These candidates are cultivated, through training and developmental experience, to enable them to, at some point, step into leadership positions.

- **Board Succession Planning:** CBS has processes in place for filling vacancies on its BoD; however, there is no formal BoD succession plan.

#### **Recommendation 52: Develop a BoD Succession Plan.**

While there is a process in place to fill vacancies on the BoD as they occur, it is recommended that a BoD succession plan be developed. This plan would be separate from the activities undertaken as part of recruitment; it would be a forward looking plan that proactively identifies the skills and requirements of an “effectively functioning” BoD that resembles Canada’s and CBS’ donor populations. It would also help inform the BoD Director training / education delivered through the Governance Committee.

The BoD succession plan would be subject to Member decision-making regarding renewal of director terms and election of new directors.

**Finding: An orientation program is not in place for new PTBLC representatives to familiarize them with CBS and their new role.**

CBS and PTs have not formally developed a joint orientation program, as part of the onboarding process, for new PTBLC representatives that provides formal orientation to the functioning of the PTBLC, roles and responsibilities, as well as an overview of CBS’ operational environment, products and services. Development of such a program will provide better support for new PT representatives as they assume their role on the Blood Liaison Committee.



#### **Recommendation 53: Develop a formal orientation program for new PTBLC representatives.**

CBS should work jointly with PTBLC representatives to create an orientation program for new representatives that provides an overview of the blood supply system; reviews the accountabilities, roles, and responsibilities of all parties involved in the system; describes the CBS operational environment, products, and services; and provides an overview of reports provided to Members / PTBLC representatives.

## **6.1.6 Accountabilities**

### **6.1.6.1 Definition of Governance Roles & Responsibilities**

**Observation: Governance roles and responsibilities are clearly defined.**

A review of CBS’ governance documents (i.e. MOU, by-laws, Management System Manual, Terms of Reference for key governance bodies, National Accountability Agreement) indicated that:

- Roles and responsibilities of parties within CBS’ Governance Model are consistently defined across all relevant governance documents.
- The details in these documents align with the responsibilities assigned to each party in the MOU. Corporate governance documentation, in addition to describing the specific accountabilities of each party, provides guidance on “how” responsibilities will be undertaken/executed.
- Governance documents identify where relationships exist amongst governing parties (e.g., identifying delegated authority, reporting relationships, etc.).

### **6.1.6.2 Assignment of Governance Responsibilities Enabling Effective Corporate Governance**

**Observation: Assignment and ownership of governance responsibilities is consistent with the principles of effective corporate governance**

In addition to having clearly defined roles and responsibilities, leading practices indicate that the actual assignment of those roles and responsibilities to the appropriate parties is also a critical enabler of effective corporate governance.



In the majority of cases, the assignment of responsibilities in CBS' Governance Model is consistent with recommendations set out in leading practices. Where deviations do exist, they can be attributed to CBS' unique three-party collaborative governance framework where responsibilities may reside with a different party within the Governance Model or are shared amongst multiple parties within the Model.

Table 23 identifies those instances where the assignment of governance responsibilities at CBS differs from leading practices (in this case, the recommendations put forward by the Forum of Corporate Governance). Appendix 20 contains a complete list of CBS' alignment with the assignment of governance responsibilities recommended by leading practices.

**Table 23: Assignment of Governance Responsibilities**

Governance Responsibility	Owner of Responsibility	
	Leading Governance Best Practices	CBS
Setting the organization's risk appetite, reviewing and understanding the major risks, overseeing risk management processes	BoD	BoD / CEO & EMT
Allocating capital: referring to the Board's provision of meaningful input and decision-making authority regarding the organization's process of allocating its financial resources (e.g., with a view to allocating resources to maximize results/outcomes)	BoD	BoD / CEO & EMT
Nominating the BoD Directors and committee members, overseeing effective corporate governance	BoD	Members & BoD
Identifying, evaluating and managing risks	Management	BoD & Management

### 6.1.6.3 Timely & Responsive Reporting

**Finding: Opportunities exist for CBS to enhance content and timeliness of reports / materials provided to PTs.**

The MOU requires CBS to produce and share reports including 3-Year Corporate Plans, Strategic Plans, annual reports, and audited financial statements. This performance review found that these requirements were met over the review period.

CBS also produces and shares, with its stakeholders, *Quarterly Reports* (a summary of year-to-date activities), *Monthly Reports* (i.e., Funding Forecasts, reports on Plasma Products / Fresh Blood, Monthly Provincial Receipts, summaries of year-to-date costing of Diagnostic Services), along with material to support ad-hoc and planned meetings with Members/PTBLC representatives (e.g., materials for monthly meetings with the PTBLC).

The reports produced by CBS are detailed and supported by various metrics. However, a review of reports identified that when changes were introduced to data being reported over the years (e.g., changes made to the inputs for the calculation of product discard rates), these changes were not clearly described in reports. Calling out changes to datasets helps to inform year-over-year comparison of data.

Additionally, changes were introduced to the level of data reported without a clear indication of why changes were being made. An example of this can be seen when looking at the fourth quarter reports from the BoD to the Members where the 2012-13 to 2014-15 reports included year-over-year trends reporting on key safety indicators (i.e., Health Canada Observations, Recalls due to EAs and PDIs per 10,000 collections, etc.) and the reports following 2014-15 contained only annual data.

The BoD Chair and Chairs of Board Sub-Committees engaged as part of this performance review, reported satisfaction with the depth and thoroughness of reports and decision-making materials produced by CBS.

PT governments and PTBLC representatives identified the following opportunities related to reports



and information provided by CBS:

- In the letter identifying their priorities for 2019 to the BoD, Members requested that the BoD review, re-evaluate, and update (as appropriate) CBS' performance measures to provide more robust comparative information on FBC and PPP.
- PTBLC representatives indicated the need to improve the timeliness of reports / materials. PTBLC representatives stated that reports/materials were not always received within a timeframe that would allow for reasonable and informed review. Additionally, some PTs noted they do not receive the level of detail required to explain how Members' funding is being used by CBS.
- PTBLC representatives requested that reports provide year-over-year trend analysis of data related to FBC and PPP and include explanations that help the reader understand the statistical significance of data being reported. Further, both Members and PTBLC representatives have requested more comparative data in the areas of FBC (including O-negative blood) and PPP (e.g., data on the number of days that the product inventory is below targets/inventory advisory is in place due to shortages, etc.).



#### **Recommendation 54: Review performance measures for FBC and PPP**

The BoD should establish a roadmap, including timelines, for reviewing and updating the performance measures for FBC and PPP in response to the letter shared by Members with the BoD outlining their priorities for 2019. In particular, consideration should be given to reporting on outcome-based measures.

#### **Recommendation 55: Introduce annual year-over-year trends reporting on key safety indicators.**

CBS should provide (each year in the fourth quarter report to Members) year-over-year trends for key safety indicators (e.g., Health Canada Inspections, Recalls due to EAs and PDIs per 10,000 Collections, etc.) for the last 3 consecutive years.

#### **Recommendation 56: Improve reporting and support to Members for enhanced decision-making.**

With due recognition of CBS' operational autonomy, it is recommended that CBS work with PTs/PTBLC representatives to:

- Review the content of reports and materials provided to Members and PTBLC representatives to determine the extent to which these documents contain the data/information required by Members;
- Develop a process to better support PTBLC representatives in their roles. The process should enable discussion of the nature of documentation/materials to be provided, timelines and any additional CBS support that may be required, to enable PTBLC representatives to support their respective Members with decision-making, approvals, etc.; and
- Review the PT Portal with a view to using it as a tool to house critical data, in a format that provides easy access to year-over-year performance data.

## **6.1.7 Decision-Making Processes**

### **6.1.7.1 Informed Decision-Making**

#### **Observation: CBS strengthened its decision-making processes over the review period through the introduction of a Risk-Based Decision-Making framework**

Between 2013 and 2015, CBS led an international committee of experts in developing the RBDM framework, a tool designed to help blood operators improve and standardize decision-making related to safety. This work was supported by the ABO, a collaborative network of organizations in North America and Europe, as well as Australia. The framework takes into account all risk factors associated with the complex medical and scientific missions of blood operators, including economic,

social and ethical concerns. Members of CBS' senior membership team (i.e., EMT) reported that CBS uses the framework as part of standard operating procedure for strategic and operational decisions related to blood safety and the CBS BoD has been briefed on how CBS has used the RBDM for a variety of blood safety and security of supply decisions (refer to Section 6.2-ERM for additional details).

CBS tracks and reports on an extensive suite of financial and productivity, quality and safety, product demand, donor and customer focused performance measures, that help to identify trends and highlight emerging risks/areas where action is needed. This list of performance measures is reported in full to the EMT on a quarterly basis and rolled-up versions are provided to the BoD and Members throughout the year.

### 6.1.7.2 Discharging of Responsibilities & Meeting Stakeholder Expectations

#### Board Governance Responsibilities

**Observation: The Board of Directors' governance responsibilities are effectively discharged.**

Leading practices indicate that a critical factor to enabling effective governance is the need for BoD Directors to spend the time required (e.g., meet as frequently as necessary) to appropriately and adequately discharge their responsibilities properly. Over the review period, CBS' BoD met seven (7) times each year (five closed-session meetings and two open-Board meetings). A year-over-year review of attendance showed that, starting in 2013/14<sup>36</sup>, attendance rates by the BoD Chair and Directors was and remained consistently high with the Chair attending all meetings, except one in that period, and the majority of BoD Directors attending all meetings.

In 2014 and 2019, a third-party professional services firm was contracted to conduct BoD evaluations. These evaluations involved gathering the views of the BoD Directors, committee members, and senior management on the BoD's performance. Results indicated the following:

- CBS' stakeholders consider its Governance Model as highly functioning and supported by a BoD with a strong performance;
- The BoD understood its responsibilities and mandate, including its role in providing stewardship to the organization;
- The BoD was comprised of strong Directors and Chairs with the ability to enable CBS to achieve its mandate; and
- The BoD was effective in holding itself accountable for performance.

#### Ability to Meet Stakeholder Requirements

**Observation: CBS stakeholders reported high levels of satisfaction with CBS' Governance Model.**

PT officials and Member representatives, members of the BoD (i.e., the Chair of the BoD), representatives from Committees supporting the BoD, and members of CBS' Executive Management Team were engaged throughout the course of this performance review and asked if they believed that the governance model/framework was effective, functioning as intended, and sufficiently enabling CBS to actively deliver on its mandate. Consistently, the feedback received from these groups was that the governance model was effective and was enabling CBS to deliver on its mandate.

**Observation: CBS stakeholders reported high levels of satisfaction with the organization's ability to act as a steward of the blood and blood products system and deliver on expected patient outcomes.**

CBS' stakeholders (i.e., Members, PTBLC representatives, hospitals, donors, volunteers, the public) indicated that the organization, over the review period, was able to deliver on its mandate and the

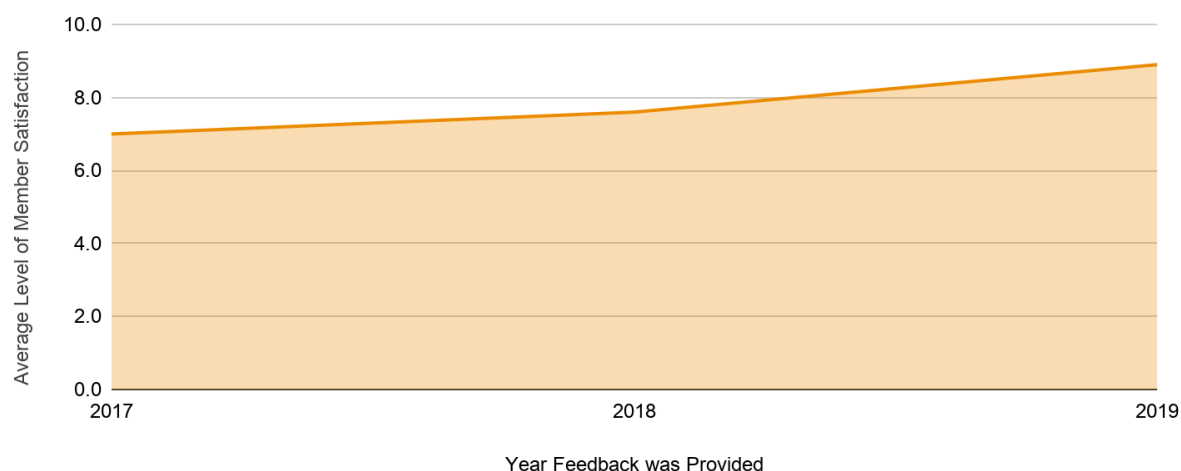
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<sup>36</sup> A complete dataset for 2012/13 was not available at the time of this performance review.

expectations assigned to it, particularly as it related to playing a role in achieving patient outcomes and the provision of a safe supply of blood and blood products.

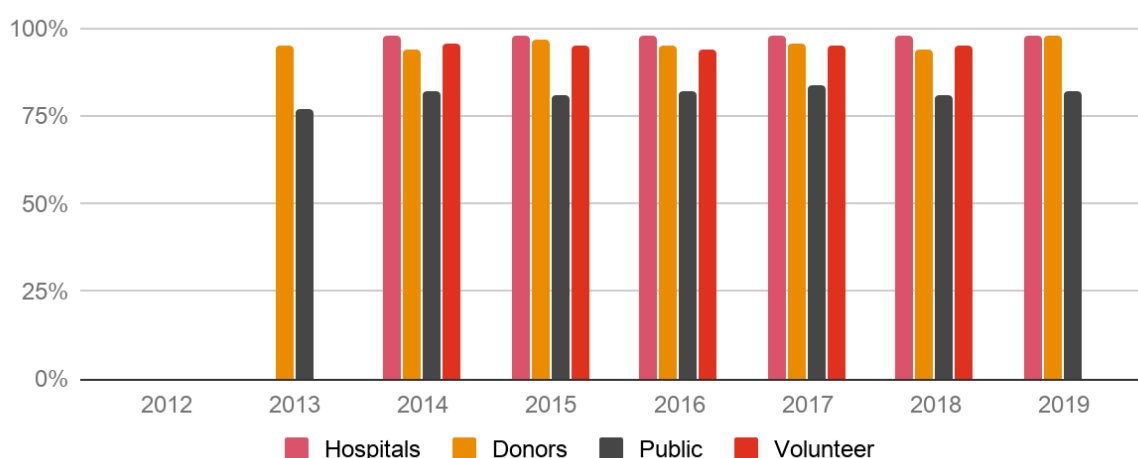
PTBLC representatives (representing the Members) indicated, when providing feedback on annual surveys, that “CBS *effectively delivers on its mandate as operator of the blood supply system in Canada through the provision of a safe supply of blood and blood products*”. This same group of stakeholders reported increasing levels of satisfaction with the role CBS plays in achieving patient outcomes (see Figure 39).

**Figure 39: CBS Plays an Essential Role in Achieving Patient Outcomes**



Further to this, as a marker of effective governance enabling the organization to achieve its mandated responsibilities, overall satisfaction with CBS and the role it plays in supporting the needs of stakeholders and the Canadian public has been consistently high and generally trending up over the review period. Trust in CBS to “*act in the best interest of the public*” ranked highly (see Figure 40) amongst all stakeholders engaged (i.e., hospitals, donors, volunteers, the public).

**Figure 40: Trust in CBS to Act in Public Interest**



Members/PTBLC representatives also indicated high levels of trust in CBS to act in the Public Interest over the review period. While their level of trust has dipped over the years (going from 9.2 in 2015 to 8.0 in 2019), it remained relatively high at the end of the review period.

It should be noted that the total number of Members/PTBLC representatives surveyed annually, over the review period, has not exceeded 13. Given the size of the pool of stakeholders engaged, large fluctuations in survey results are possible should one representative provide a higher/lower rating.

## 6.2 Enterprise Risk Management

### 6.2.1 Objective

The objective of this section is to evaluate CBS' enterprise risk management approaches and practices.

### 6.2.2 Scope

The focus of this section is on CBS' risk management program, with emphasis on the FBC and PPP business lines. Our review focused on the evaluation of the underlying aspects related to:

- Governance of the Risk Management Activities,
- Management of the Operational Risk within PPP and FBC
- Application of the RBDM Framework
- Addressing issues identified by prior reviews regarding ERM

### 6.2.3 Context

CBS' Enterprise ERM Program was established in 2007 and has been evolving since that time to embed ERM principles and processes throughout the organization.

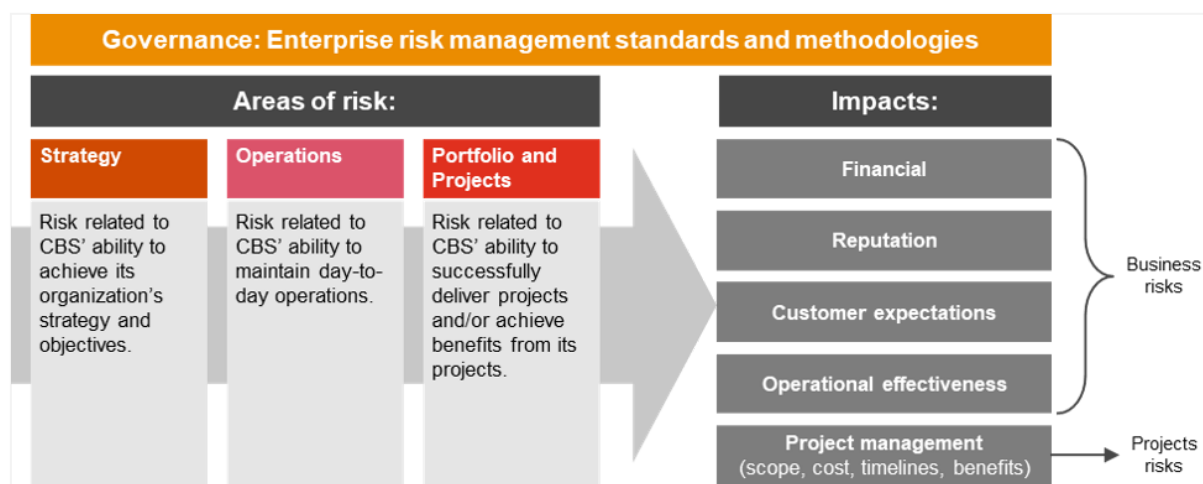
Over the review period, the ERM program was transferred from the People, Culture and Performance division to the legal division. This change was designed to support the alignment of ERM with other risk-related programs such as Risk and Insurance Management (captive insurance program, commercial insurance program, loss of control) and Risk-Based Decision Making. The ERM team also assumed oversight of the Business Continuity Program, which includes responsibility for conducting regular assessments of CBS' exposure to potential disruptions and determining protocols for maintaining or rapidly recovering critical business functions.

CBS' ERM Program has been designed to provide management and staff with the tools and guidance to identify and manage risks that could impede or otherwise negatively affect the achievement of the organization's strategic goals and operational objectives, and promote balanced and informed decision-making. More specifically, the Program is intended to provide the organization with:

- An enterprise-wide, integrated view of risk;
- A systematic approach to risk identification, planning and management;
- Consistent risk assessment criteria for management and staff to align with CBS' risk appetite;
- Monitoring and reporting mechanisms; and
- Avenues for communicating and escalating risk.

Figure 41 below provides an overview of CBS' ERM Framework which focuses on strategic, operational as well as portfolio and project risks. Impacts are assessed from the business (strategic and operational) and project perspectives.

**Figure 41: Overview of CBS' ERM Framework**



CBS has developed a risk management policy which articulates risk management principles and guides risk management activities. The policy, which is updated annually, also defines roles and responsibilities for the BoD, the executive, management, and staff, outlines reporting requirements, and details the risk universe and the organization's risk tolerance.

The BoD is responsible for governance of the ERM Program and oversight of management's actions for managing risk. The EMT is responsible for the maintenance and maturation of the ERM Program, establishing the corporate risk appetite and managing key risk exposures.

CBS has developed and maintains a Corporate Risk Profile that is updated annually by the EMT and approved by the BoD. During the review period, the CRP was reviewed through the quarterly strategy and risk review process by senior management and during BoD meetings.

In 2012, a maturity assessment of CBS' ERM Program conducted by CBS Internal Audit highlighted key areas improvement, including:

- cascading the ERM framework and principles throughout the organization;
- developing additional and more specific guidance relative to ERM;
- implementing an Integrated Risk and Control Framework;
- leveraging technology to analyze risk data and create reports;
- supporting the effectiveness of the board's oversight role;
- better supporting the ERM team by engaging internal and external subject-matter experts; and
- monitoring adequacy of ERM resources and resourcing of the ERM function (this includes the ERM team acting as facilitators to business areas).

## 6.2.4 Key Themes

CBS used RBDM across the FBC and PPP business lines to support significant decisions that reflected value for money within the health risk framework.

CBS evolved its ERM Program over the review period by addressing the areas identified for improvement in the 2012 maturity assessment. CBS also took steps to strengthen its BCM practices. While both areas have matured, there are further opportunities for improvement as detailed below.

Below is a summary of our key themes for this area:

**Table 24:** Summary of key themes

Area of Focus	Observations	Findings
<b>FBC and PPP Risk Management</b>	<ul style="list-style-type: none"> <li>CBS has demonstrated leadership in RBDM and leveraged RBDM to make decisions related to FBC and PPP that reflected value for money considerations</li> </ul>	<ul style="list-style-type: none"> <li>Separate operational risk registers have not been developed for FBC and PPP and a consolidated view of operational risks applicable to each business line is lacking</li> </ul>
<b>ERM Program</b>	<ul style="list-style-type: none"> <li>CBS evolved its ERM Program by addressing a number of the gaps identified in the 2012 ERM maturity assessment</li> </ul>	<ul style="list-style-type: none"> <li>A formal risk appetite statement was not in place over the review period</li> <li>The maturity of the Business Continuity Management Program could be advanced</li> </ul>

## 6.2.5 Key Observations and Findings

### 6.2.5.1 FBC and PPP Risk Management

**Finding: Separate operational risk registers have not been developed for FBC and PPP and a consolidated view of overall operational risks associated with each of these business lines is lacking.**

FBC and PPP constitute 95% of the overall spend for CBS. While the organization is structured across various functional units, it is quite critical to have a view of key risks from a business line perspective. This aligns with how leading organizations tend to approach risk management and the underlying mitigations.

CBS has identified high-level risks in its Corporate Risk Profile that are applicable to both FBC and PPP, such as:

- supply and demand;
- security of Ig supply;
- plasma related products formulary risk;
- non-conforming products and /or services;
- external factors such as those impacting safety;
- financial health and sustainability; and
- business disruption.

These risks are reported on along with associated controls in the quarterly risk reports. Additional, relevant risks are also captured within the Integrated Supply Chain Risk Register.

The current process for capturing risks related to PPP and FBC via the Integrated Risk Register does not drive a holistic view of and approach to managing the operational risks associated with FBC and PPP by the VP responsible for each of these business lines.



**Recommendation 57: CBS should develop operational risk views for FBC and PPP which detail the existing and emerging risks with input from relevant risk owners. These operational risk views per business line should be informed by divisional risk tools such as the Supply Chain Risk Register.**

**Observation: CBS has demonstrated leadership in RBDM and leveraged RBDM to make decisions related to FBC and PPP that reflected value for money considerations (i.e., supply, cost, benefit, risk).**

As described in the Governance section of this report, between 2013 and 2015, Canadian Blood Services led an international committee of experts in developing the RBDM Framework, a tool designed to help blood operators improve and standardize decision-making related to safety. The Framework sets out a clear methodology for ensuring that decisions are based on evidence, incorporate input of stakeholders and allow for resources to be effectively redirected proportionate to the risks at hand.

Since formally adopting the RBDM tool in 2015, Canadian Blood Services has used it to guide decisions such as the extent and type of testing required for emerging pathogens that could threaten the blood supply, including the Hepatitis E Virus (HEV), Babesia (a tick-borne parasite that infects red blood cells), cytomegalovirus<sup>37</sup> and Zika virus. Specifically:

- **HEV** - Based on a joint analysis with Héma-Québec, CBS decided not to implement testing for HEV, resulting in estimated cost avoidance of \$4 million-\$8 million annually. The RBDM process included extensive risk modelling and stakeholder consultation, and considered a range of scenarios including, no screening, testing all blood donations for HEV, testing selected blood donations for HEV and increasing physician awareness of HEV. The analysis indicated that a very small number of donors tend to be HEV positive and risk of transmission is very low. Accordingly, the recommended option was to increase physician awareness of HEV and improve adverse events and enhanced donor surveillance.
- **Babesia** – The RBDM analysis recommended a selective testing approach based on two risk scenarios. Under the first scenario where current risk was assessed as being very low, it was recommended that risk be managed through public health and tick surveillance, coupled with periodic blood donor seroprevalence<sup>38</sup> studies. In the second scenario, where the future risk of Babesia escalates and requires a more substantial mitigation response, it was recommended that CBS undertake selective testing of blood donors living in high risk areas and travelers to the US or Canadian risk areas. This testing approach would eliminate the need for universal testing which would result in higher costs for CBS. CBS did not undertake testing for Babesia as the risk was deemed to be very low.
- **CMV** – The RBDM analysis indicated that testing could be limited to pregnant women, neonates under the age of 28 days and intrauterine transfusion. Ultimately, CBS decided to limit testing to intrauterine transfusions which was also consistent with the recommendation of the National Advisory Committee on Blood Safety.
- **Zika Virus** – During the Zika outbreak, CBS worked with Héma-Québec to determine how to best mitigate risk to Canada's blood supply. Guided by the RBDM analysis, CBS decided not to implement testing for the Zika virus given that the number of people who might travel to Zika-afflicted areas and then donate blood within a few days of returning to Canada was extremely low. As a precaution, CBS instituted a deferral period of 21 days.

RBDM was also used to assess anticipated risks to the security of the plasma supply needed to manufacture Ig for Canadian patients, and to evaluate available risk management options according to many factors, including cost and health outcomes. The RBDM analysis was used to make recommendations regarding the appropriate level of sufficiency for Canada's supply of Ig and sourcing through new Canadian Collection Centres. The analysis informed the business case for the three standalone plasma proof-of-concept plasma donor sites which were approved by the Members in 2018-19.

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<sup>37</sup> CMV is the Human Herpes virus 5 and is commonly transferred to developing fetuses.

<sup>38</sup> The overall occurrence of a disease or condition within a defined population at one time, as measured by blood tests (serologic tests).



### 6.2.5.2 ERM Program

**Observation: CBS evolved its ERM Program by addressing a number of the gaps identified in the 2012 ERM maturity assessment. These included:**

- Updating the ERM Policy in 2012-13 to address areas such as ERM principles, processes, accountabilities, and risk tolerance levels (through the risk exposure plot);
- Formally publishing the ERM process and underlying guidance materials to support awareness and cascading of the ERM Program across the organization;
- Starting the integration of ERM into operations through the establishment of risk registers for Supply Chain and Information Technology to start integration of ERM into operations;
- Strengthening the role of the Board with regards to ERM, including delegation of the governance of the ERM Program to the Governance Committee of the Board and assignment of accountability for oversight of some risks to Board Committees at the discretion of the Board;
- Developing a control effectiveness assessment tool for integration of risk and controls;
- Making greater use of technology to facilitate risk reporting; and
- Integrating the risk management and project management processes.

**Finding: An overarching risk appetite statement was not in place over the review period.**

Risk tolerance is reflected in the corporate risk exposure plot that is included in CBS' ERM Policy. However, a risk appetite statement that describes the level and types of risk that are acceptable in order to achieve strategic and business objectives and defines risk tolerance thresholds for various parts of the organization had not been established during the review period. This is especially important for organizations in healthcare such as CBS that tend to be risk averse and opportunities may be foregone due to a lack of understanding of the acceptable level of risk.

**Recommendation 58: CBS should develop a formal risk appetite statement for core business functions to articulate the amount of risk that CBS is willing to take in the pursuit of its objectives and delivery of its mandate. A formal risk statement will provide clarity across the organization as to the level of acceptable risk when making strategic and operational decisions.**

**Finding: The maturity of the Business Continuity Management Program could be advanced.**

The 2016 internal audit of BCM recommended:

- implementation of governance processes;
- development of a master testing plan;
- maturing of facility BCM plans by including recovery sections; and
- creating more awareness amongst all staff regarding business continuity management.

These recommendations have been addressed with the exception of the master testing plan and addition of recovery sections to facility BCM plans.

While CBS has developed a generic Recovery Plan for facility failures, any site specific plans have not been developed. This is based on the rationale that the generic Recovery Plan articulates key recovery actions and considerations that would likely be applicable across each CBS collection and production facility. While a generic Recovery Plan is a good first step, site specific plans are needed to ensure that there are no missing critical elements and nothing is left to chance.

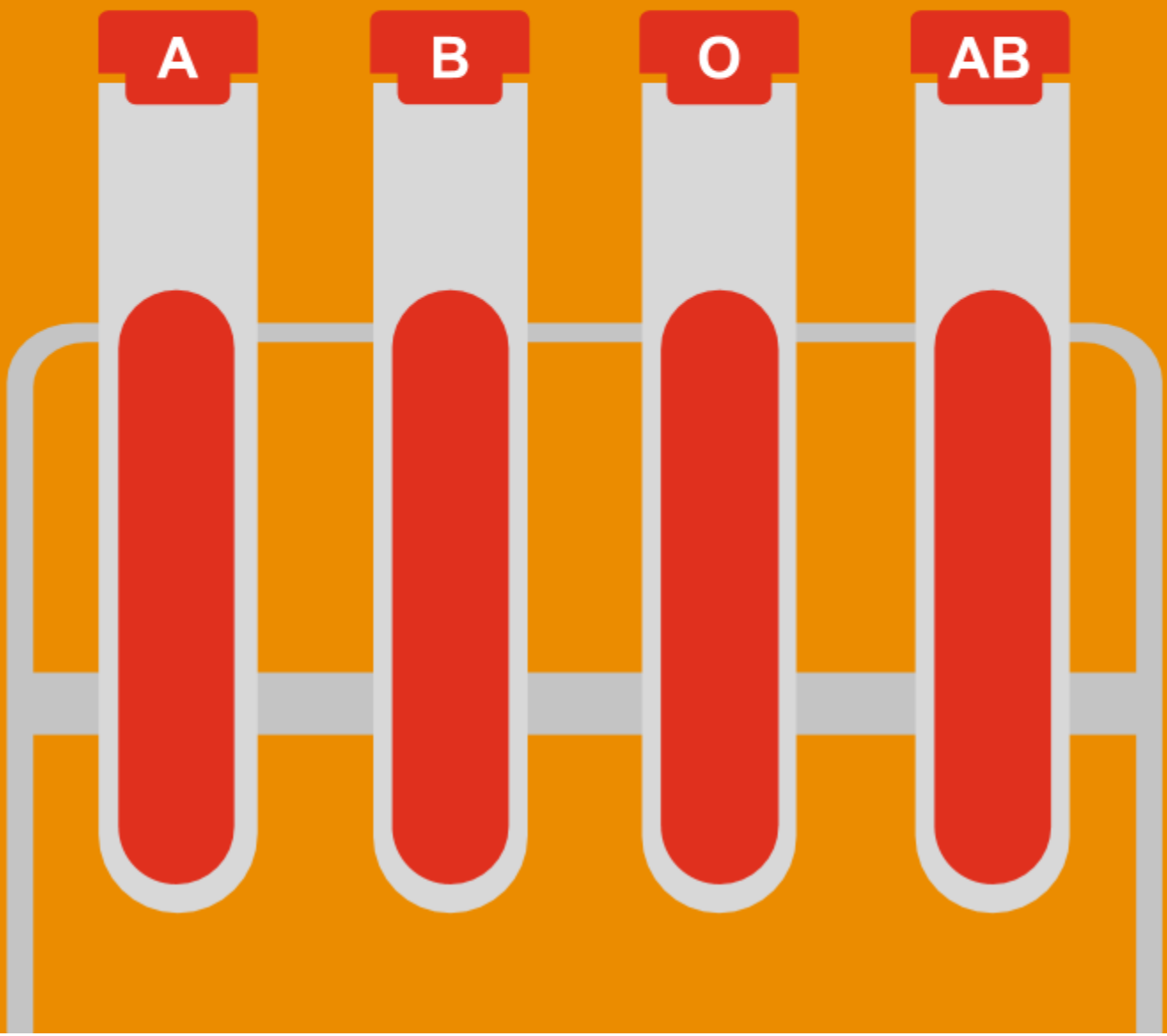


CBS also developed a business continuity testing strategy in 2018-19. This testing strategy outlines the criteria for developing an annual exercise plan, types of exercises and reporting requirements. This strategy informs the development of the Annual Exercise Plan. While an Annual Exercise Plan is in place, an overall master testing plan that identifies the locations/entities to be tested (using a risk-based approach), the frequency of testing, and the nature/types of testing to be executed has not yet been established.

**Recommendation 59: CBS should:**

- Develop a master BCM testing plan that identifies:
  - entities/locations to be tested;
  - the nature of testing to be undertaken;
  - criteria for determining the test types;
  - frequency of testing; and
  - roles and responsibilities for getting the testing completed.
- Ask each site to customize the current generic Recovery Plan-Facility Failure to site specific plans.

# Appendices



## Appendix 1- Summary of Findings and Recommendations

**Table 25:** Findings and Recommendations

Section	Finding	Recommendation
<b>3.0 Financial Performance</b>		
<b>3.1 Fresh Blood Components</b>		
<b>Benchmarking analysis – Collections productivity</b>	CBS ranked third in testing productivity, amongst the four comparator ABO members, at the end of 2018-19.	<p><b>Recommendation 1</b></p> <p>CBS should build on its productivity gains and further improve its performance.</p> <ul style="list-style-type: none"> <li>Assessing which of its existing initiatives are resulting in the greatest benefits and could be further enhanced (e.g., through automation).</li> <li>Continuing to leverage its CI Program to identify and implement leading practices to improve productivity on an ongoing basis.</li> <li>Learning from initiatives implemented by other blood operators who are outperforming CBS and identifying what can be further implemented to improve productivity.</li> </ul>
<b>Benchmarking analysis – Testing productivity</b>	CBS ranked last in testing productivity, amongst the four comparator ABO members, at the end of 2017-18.	<p><b>Recommendation 2</b></p> <p>CBS should continue to automate its front-end testing process to support improvements in testing productivity.</p> <ul style="list-style-type: none"> <li>The initial stage of the testing process, where blood vials are pooled and organized for testing, is an area that can benefit from the introduction of automation technology. The implementation of this technology would help reduce FTEs, increase testing productivity and potentially reduce the volume of quality incidents.</li> <li>PwC understands that CBS is implementing this technology in Brampton in 2019-20 and has plans to implement it in Calgary in 2020-21.</li> <li>CBS should undertake a time and motion study to compare its per FTE productivity with Blood Operator B to identify other factors that can be improved to drive higher productivity within its testing process.</li> </ul> <p><b>Recommendation 3</b></p> <p>CBS should evaluate the feasibility of joining a consortium for testing to further improve productivity and reduce costs.</p> <p>An expert panel member, currently working at a US blood operator, indicated that joining a consortium to obtain better pricing for equipment and reagents coupled with sharing of a testing platform has allowed them to achieve cost savings and productivity improvements. Under this scenario, testing would still be performed in Canada under CBS' control.</p>
<b>Benchmarking analysis – Production productivity</b>	CBS ranked third in per FTE production productivity, amongst the four comparator ABO members, at the end of 2018-19.	<p><b>Recommendation 4</b></p> <p>CBS should build on its productivity gains and further improve its performance.</p> <ul style="list-style-type: none"> <li>Assessing which of its existing initiatives are resulting in the greatest benefits and could be further enhanced (e.g., through automation).</li> <li>Continuing to leverage its CI Program to identify and implement leading practices to improve productivity on an ongoing basis.</li> <li>Learning from initiatives implemented by other blood operators who are outperforming CBS and identifying what can be further implemented to improve productivity.</li> </ul>

Section	Finding	Recommendation
<b>General and Administrative Costs</b>	General and administrative costs increased by \$17 million (18%) over the review period.	<p><b>Recommendation 5</b></p> <p>CBS should consider the removal of project expenses from the G&amp;A cost category and tracking of these costs on their own.</p> <p>Project expenses have been highly variable and make up a substantial portion of the G&amp;A category. Their removal would help provide better visibility of G&amp;A variability, while also isolating project expenses to understand the full cost of project implementations.</p> <p><b>Recommendation 6</b></p> <p>CBS should conduct an analysis of its general and administrative expenses to identify opportunities for potential cost reductions. As part of this analysis, particular consideration should be given to:</p> <ul style="list-style-type: none"> <li>• Further developing in-house project management capabilities to support CBS' portfolio of projects and reduce reliance on more expensive external resources; and</li> <li>• Evaluating costs relating to rent and utilities and identifying potential contractual opportunities to reduce them or manage them better. External vendors perform baseline benchmarking in this area on a contingent fee basis.</li> </ul>
<b>3.2 Plasma Protein Products</b>		
<b>Product Demand</b>	The plasma that CBS collected from donors accounted for only 15% of the overall Ig demand at the end of 2018-19. Given the increase in demand for Ig products globally and the limited supply, there is a risk that CBS will experience higher costs as demand for these products increases over the next few years.	<p><b>Recommendation 7</b></p> <p>CBS should continue to examine options to increase plasma self-sufficiency within Canada to reduce dependency on US and global suppliers.</p> <p>This may require a discussion with Members at a strategic level to evaluate various options and should take into account the performance results for the plasma proof-of concept collection sites (as they become available).</p> <p>CBS should also consider setting up a task force that looks at potential improvements within plasma collection processes and integrating them at a community level to drive higher volume and self-sufficiency in this area.</p>
<b>Product Demand</b>	The C1-inhibitor product had, on average, a year-over-year growth rate of 36% and the high demand for this product is expected to continue in the future.	<p><b>Recommendation 8</b></p> <p>CBS and PTs should work together to explore options for managing the increased use of C1 inhibitors.</p> <p>Consideration should be given to:</p> <ul style="list-style-type: none"> <li>• adding patients to a patient registry, such as the Named Patient Program to better control and monitor the use of the product</li> <li>• delisting the product from the CBS formulary and transferring it to PT drug formularies</li> </ul>
<b>Other financial performance considerations for PPP</b>	While there is a regular and comprehensive process in place for CBS to report its financial performance to Members, there is an opportunity to provide more context to Members on the changes to their annual funding requirements for PPP.	<p><b>Recommendation 9</b></p> <p>CBS should provide additional information to Members on:</p> <ul style="list-style-type: none"> <li>• Foreign exchange fluctuations;</li> <li>• Significant market trends for PPP over the last 3- 5 years and future projections;</li> <li>• Achievement of planned savings from new contracts on a year over year basis; and</li> <li>• Impacts of variances in demand forecasts on Member funding.</li> </ul>

Section	Finding	Recommendation
4.0 Operational Performance		
4.1 Customer Safety Needs		
<b>Adverse Transfusion Reactions Over the Review Period</b>	The quantity of adverse transfusion reactions has fluctuated over the review period. Though there are inherent risks with transfusions (e.g., allergic reactions), there is no data benchmarking CBS' performance relative to comparable organizations.	<p><b>Recommendation 10</b> Introduce benchmarking of CBS' Safety &amp; Quality performance.</p> <p>CBS should explore the feasibility of reporting on benchmark data for its critical safety and quality measures (e.g., adverse transfusion reactions) to situate CBS' safety performance relative to other comparable organizations. This will also help in identifying additional measures CBS can take to further improve its quality and safety related performance.</p>
<b>Clarity of Roles &amp; Responsibilities</b>	While CBS has taken steps to describe and clarify roles and responsibilities as they relate to quality, there continues to be opportunities for enhancement.	<p><b>Recommendation 11</b> CBS should develop role-based personas to strengthen the organizational culture mindset around quality. CBS should develop simple, easy-to-understand personas that showcase how the roles played by / duties performed by employee groups contribute to supporting both CBS' quality mandate / commitment and its strategic objectives.</p> <p><b>Recommendation 12</b> CBS should explore opportunities to enhance the training approach for quality. CBS should explore strengthening the incorporation of adult learning principles into its Quality Management training. This would enable learning objectives to be met through "group learning events" that provide trainees with the opportunity to physically experience (through role plays, hands-on learning) and contextualize learning.  CBS should also consider introducing a formal coaching and mentorship program where knowledgeable and experienced staff work with other staff to help impart institutional knowledge (e.g., Standard Operating Procedures, approved ways of working / practices, etc.).</p> <p><b>Recommendation 13</b> CBS should include "performance on quality measures" as part of senior management's annual performance assessments. CBS should introduce performance on quality measures to the list of criteria assessed during the annual performance reviews of senior management. This approach would further tie individual roles and responsibilities to the performance of each division.</p> <p><b>Recommendation 14</b> CBS should survey employee safety awareness and comfort around raising safety and quality issues.  CBS should survey employees annually to assess their overall safety awareness and comfort around raising safety or quality related issues.</p>
<b>Standardized &amp; Automated Processes</b>	CBS took steps to standardize and automate processes, but opportunities exist for further advancement.	<p><b>Recommendation 15</b> CBS should continue to evolve the Quality Management System.  CBS should continue to align with industry best practices / standards with respect to its QMS. Consideration should be given to the following:</p> <ul style="list-style-type: none"> <li>expanding the scope of the QMS to include other processes (e.g., donor experience), and internal service</li> </ul>

		<p>business units (e.g., Finance, Human Capital / Human Resources);</p> <ul style="list-style-type: none"> <li>• introducing approaches to address low risk non-conformances;</li> <li>• continuing to expand system automation with a view to reducing manual / paper-based processes; and</li> <li>• beginning to proactively inform the organization's strategy by exploring matters related to customers (e.g., understanding the customers' current and future / evolving needs and raising them, where relevant, as quality matters to be addressed by the organization).</li> </ul>
<b>Corrective Action and Preventive Action Measures</b>	<p>While overall progress has been made on CAPA improvements, the pace of progress has been slower than planned/expected. In particular, the pace at which open CAPAs are closed within 30 days is slower than anticipated; and has remained consistently below established targets.</p>	<p><b>Recommendation 16</b> CBS should review CAPA completion targets.</p> <p>CBS should investigate approaches to better align targets to operational realities. This may include:</p> <ul style="list-style-type: none"> <li>• engaging with comparable organizations to determine a reasonable rate of change that can be expected of a biologics manufacturer invested in maturing its quality system; and</li> <li>• conducting a capacity and capability assessment to determine the staffing complement required to achieve targets and taking steps accordingly.</li> </ul> <p><b>Recommendation 17</b> CBS should confirm adoption of new behaviours/ practices addressing non-conformances.</p> <p>To further enhance the effectiveness checks that are a part of the CAPA plan implementation process, CBS should introduce a formal approach to "spot check" for compliance following the implementation of a CAPA plan. This will enable the "spot checker" to determine the level to which the non-conformance behaviours/practices have been addressed, adopted by employees and embedded within standard day-to-day operating procedures.</p>
<b>Key Stakeholder Satisfaction with Safety of CBS' Products &amp; Services</b>	<p>CBS has not established tolerance levels for stakeholder satisfaction measures.</p>	<p><b>Recommendation 18</b> CBS should define tolerance levels for stakeholder satisfaction measures.</p> <p>Patient/stakeholder satisfaction tolerance levels should be informed by health industry practices and supported by a strategy (e.g., investigations, remediation steps, etc.) for dealing with situations when performance slips below established tolerance levels.</p>
<b>4.2 Customer Supply Needs</b>		
<b>Forecasting Method</b>	<p>CBS' forecasting approach could be further enhanced with expanded sets of patient and treatment data for FBC and PPP products.</p>	<p><b>Recommendation 19</b> To support more accurate forecasting, CBS should work with hospitals and PTs to expand the data set to include greater detail around utilization and treatment-related information.</p> <p>As outlined in Section 4.3.7 (PPP Utilization Management), treatment-related data would also inform utilization management for PPP. Therefore, data requirements for forecasting and utilization management should be coordinated.</p>
<b>Comparison of Forecast to Actual Demand - FBC</b>	<p>The forecast variance for Plasma for Transfusion and Platelets was higher than RBC.</p>	<p><b>Recommendation 20</b> Refer to recommendation 19.</p>

<b>Comparison of Forecast to Actual Demand - PPP</b>	Forecasting for PPP fluctuated, with over 90% variance within one product category.	<p><b>Recommendation 21</b></p> <p>CBS should establish a working group to analyze and monitor PPP demand, including representation from PTs, suppliers, clinical experts and patient groups.</p> <ul style="list-style-type: none"> <li>• The group should look at ways of better predictability for PPP demand forecasting.</li> <li>• CBS should work with the PTs to improve the timeliness and consistency of hospital reporting with regards to PPP inventories.</li> </ul>
<b>Customer Needs - FBC</b>	Donor retention declined in six out of seven years, which presents a significant risk in meeting customer needs for FBC.	<p><b>Recommendation 22</b></p> <p>CBS should establish a task force consisting of representatives from CBS and healthcare agencies to review existing processes, capabilities and technology and identify new opportunities for improving donor retention.</p> <p><b>Recommendation 23</b></p> <p>CBS should investigate the feasibility of adding new functionality to their online donor booking system to help minimize donor deferrals and increase donor engagement.</p> <ul style="list-style-type: none"> <li>• Integrate the automated donor questionnaire with the online appointment booking process for donations. <ul style="list-style-type: none"> <li>– The online donor booking process allows a member of the public to book an appointment and go to a collection site without knowing whether they are eligible to donate or not.</li> <li>– CBS should implement functionality that requires completion of eligibility criteria prior to an online booking. As part of this functionality, CBS should include an auto-deferral notice for a potential donor who's deemed to be ineligible to donate based on their answers to the pre-screening criteria.</li> </ul> </li> <li>• Enhance Customer Relationship Management capabilities to contact donors who do not complete their appointment bookings on the <a href="http://blood.ca">blood.ca</a> website. <ul style="list-style-type: none"> <li>– For donors who do not complete the appointment booking process, an automated message should be issued via the CRM system to the donor's contact email address to offer support options for completion of their appointment booking and / or offer general support.</li> <li>– This would help attract donors who had the intent to donate but were frustrated by the booking process or had additional questions.</li> </ul> </li> </ul>
<b>Customer Needs - FBC</b>	While hospital satisfaction surveys on the availability of FBC indicate overall high satisfaction ratings, responses were less favourable amongst larger hospitals.	<p><b>Recommendation 24</b></p> <p>CBS should implement a process to monitor and report on the progress of regional action plans to address hospital survey feedback. This includes the prioritization of feedback for each business line, to focus on areas requiring attention and the assignment of responsibility to business line leaders</p>
<b>Customer Needs - FBC</b>	Considering that O-negative stocks are challenging to replenish in a consistent manner, a pan-Canadian approach is needed to manage and protect the supply of O-negative blood.	<p><b>Recommendation 25</b></p> <p>CBS should request that PT Ministries of Health facilitate agreements with hospitals that would allow CBS to proactively monitor and influence O-negative hospital inventories with a national, system-wide lens.</p> <p>Further, CBS and the PTs should work together on a national basis to promote best practices to maintain the O-negative blood supply at appropriate levels.</p>
<b>Customer Needs - PPP</b>	CBS took action to improve its plasma sufficiency and reduce its reliance on foreign sources of plasma.	<p><b>Recommendation 26</b></p> <p>CBS should continue to examine options to increase plasma self-sufficiency within Canada to reduce dependency on US and global suppliers.</p>

		<p>This may require a discussion with the Members at a strategic level to evaluate various options. CBS should also consider setting up a task force that looks at potential improvements within plasma collection processes and integrating them at a community level to drive higher volume and self-sufficiency in this area.</p>
<b>Customer Needs - PPP</b>	<p>While CBS did not experience any critical product shortages for PPP, enhanced datasets from hospitals would help support more accurate forecasting of PPP.</p>	<p><b>Recommendation 27</b> CBS and the PTs should explore opportunities for hospitals to share data supporting PPP use with CBS. A starting point for this recommendation could be:</p> <ul style="list-style-type: none"> <li>• Collaboratively agreeing on the desired utilization data and assessing the completeness, accuracy and availability of this data at a PT level. Data could include departments where PPP are being distributed, indications for which PPP are being prescribed, outcomes of the medication, prescribed dosage, intended frequency of use and duration of treatment.</li> <li>• Carrying out a pilot study with two jurisdictions and collecting utilization data where existing data is found to be incomplete, inaccurate or inconsistently available.</li> </ul> <p>Once this data has been collected, CBS and Members should weigh the costs and investment required to facilitate ongoing data sharing against the ancillary benefits mentioned above. This would help both parties determine if there is a valid business case for data sharing.</p>
<b>Other considerations</b>	<p>Hospitals are using fax machines to order their FBC and PPP products from CBS.</p>	<p><b>Recommendation 28</b> CBS should continue its efforts to automate the hospital ordering process for FBC and PPP and develop strategies for strong adoption.</p>
<b>4.3 Plasma Protein Products Management</b>		
<b>PPP Management Structure</b>	<p>Separate Executive-level ownership for the three proof-of-concept sites for plasma collections is appropriate, but there may be economies of scale in integration with FBC operations.</p>	<p><b>Recommendation 29</b> CBS should consider integrating the plasma proof-of-concept sites into its ongoing blood operations at the appropriate time.</p> <p>The benefits of integrating with other aspects of CBS' ongoing blood operations may include economies of scale from a cost and donor experience perspective. Examples of factors to consider in determining the "appropriate time" for integration include:</p> <ul style="list-style-type: none"> <li>• The timelines for transitioning from "proof-of-concept" to "Business-as-Usual";</li> <li>• Whether volumes (e.g. plasma collection metrics) are meeting or exceeding targets;</li> <li>• Whether cost metrics (e.g. cost per collection) for operating the sites are meeting or exceeding targets; and</li> <li>• Extent of readiness to scale and consider new proof-of-concept sites.</li> </ul> <p>The decision regarding integration of the proof-of-concept sites should also be informed by the Plasma Proof-of Concept Sites Reporting Framework which will be used to assess the success of this initiative.</p>
<b>Formulary Management</b>	<p>Formulary eligibility criteria for new product categories or brands have not been updated.</p>	<p><b>Recommendation 30</b> CBS and the PTs should update the existing PPP eligibility criteria and develop a collaborative process for periodic review and timely approval of the criteria.</p>
<b>Formulary Management</b>	<p>PT approval is not required for new brands added to the formulary (unless there is a cost increase).</p>	<p><b>Recommendation 31</b> CBS and the PTs should develop a process to analyze health system costs and patient experience implications for all brand additions.</p>



		<p>Doing this would enable both CBS and the PTs to consistently consider and quantify the health system cost implications of new brands. The analysis could be supported by a “business case”, which enables CBS and PTs to consider the following in a structured manner:</p> <ul style="list-style-type: none"> <li>• PT health system cost and patient experience implications arising from a new brand;</li> <li>• PT timelines and responsibilities for collating cost data; there needs to be a balance between providing sufficient time for the cost implications to be understood and ensuring the analysis does not unduly delay the product selection process; and</li> <li>• A performance measurement strategy to subsequently compare actuals against expected savings.</li> </ul> <p>Where there is a brand replacement arising from a PPP RFP, we have raised a separate finding and recommendation covering transition management in the <i>Transition Management</i> section under PPP Procurement.</p>
<b>Utilization Management</b>	<p>CBS and the PTs have not undertaken a joint assessment of their utilization management activities for PPP in light of increased demand and costs over the review period.</p>	<p><b>Recommendation 32</b></p> <p>CBS and the PTs should complete a combined assessment of their utilization management activities for PPP and determine if these activities could be expanded further to improve utilization outcomes.</p> <p>Based on our comparative analysis, examples of utilization management approaches which should be considered, to the extent they are not already occurring within PT health systems, include:</p> <ul style="list-style-type: none"> <li>• Developing a simple web-based shared system to electronically manage PPP requests and check that these align with pre-established criteria (e.g. conditions where the use of PPP is considered clinically appropriate).</li> <li>• Implementing patient databases<sup>39</sup> which would help the PTs collect data on treatments which have been administered, the outcomes and, if applicable, the side effects. This would enable PTs to evaluate the cost effectiveness and the results of different treatments and make improvements.</li> <li>• Determining whether certain higher cost PPP should be limited to prescription by specialized doctors.</li> </ul> <p>Roles, responsibilities and expectations for utilization management should be clearly agreed upon and documented between CBS and the PTs. Once defined, CBS should evaluate the flow-on effect (e.g. resource levels, skills/expertise, etc.) on its existing utilization management activities and determine what changes need to be made. These should be discussed and agreed to with the PTs.</p>
<b>Utilization Management</b>	<p>The processes which support the PPP Named Patient Program need to be strengthened for improved utilization management.</p>	<p><b>Recommendation 33</b></p> <p>CBS should review the processes which support the PPP Named Patient Program for any opportunities to strengthen utilization management.</p> <p>Given that PTs will also be undertaking utilization management initiatives within their health systems, any major changes to the Named Patient Program should first be agreed upon with PTs.</p> <p>The existing processes could be improved by:</p> <ul style="list-style-type: none"> <li>• Digitizing and creating a cloud-based application to replace the current process to submit request forms and</li> </ul>

<sup>39</sup> CBS has access to a patient register and information about products administered for the Bleeding Disorders population (but not for Ig and other PPP).

		<p>supporting medical evidence to CBS via fax. Physicians could be provided with access to the cloud-based application as this would help introduce internal controls to verify physician authenticity.</p> <ul style="list-style-type: none"> <li>• Documenting and publishing CBS' process for the review and, where necessary, Medical Review of request forms. Determine if there are aspects of the Medical Review which could be simplified or performed by others (e.g. CBS pharmacists).</li> <li>• Formalizing and publishing the urgent/emergency ordering process.</li> <li>• Developing criteria to enable tiering/prioritization of orders and the associated timeframes for response from CBS. Consider reporting on process cycle times under the Named Patient Program.</li> <li>• Determining potential conditions which could prompt the auto-renewal of orders for an existing patient.</li> </ul> <p>These recommendations would also enable CBS to scale the Named Patient Program should there be a significant surge in demand for these products.</p> <p>Given the increasing cost pressure on PT health systems, CBS and the PTs should also identify the need to apply similar "exceptional access" principles when new products are approved for addition to the CBS formulary. By doing this up front, CBS and the PTs could more closely manage and monitor utilization of, for instance, high-cost PPP treatments.</p>
<b>Utilization Management</b>	CBS would benefit from additional PT data to inform PPP utilization management.	<p><b>Recommendation 34</b></p> <p>CBS and PTs should explore opportunities for PTs to share better quality data supporting PPP use with CBS. Please refer to recommendation 27 for details.</p>
<b>Utilization Management</b>	Partially consumed PPP are not currently tracked and reported on.	<p><b>Recommendation 35</b></p> <p>Improve data collection and utilization reporting over partially consumed PPP.</p> <p>CBS should consider enhancing the web-based application to enable hospitals and clinics to record partial usage of PPP. Once this is complete, consideration should be given to:</p> <ul style="list-style-type: none"> <li>• Reviewing the data collected on partially consumed PPP and reporting this data to PTs to help them better understand trends or practices which may help manage this utilization.</li> <li>• Determining whether there is enough demand to justify procuring smaller vial sizes.</li> </ul>
<b>PPP Procurement Approach</b>	CBS has not fully considered the full range of procurement and pricing strategies which may help reduce product costs and improve health system outcomes.	<p><b>Recommendation 36</b></p> <p>CBS should work with PTs to evaluate the broader use of alternative pricing strategies to determine if these are more advantageous models.</p> <p>CBS should determine whether there are aspects of the pCPA's "negotiation" approach which could be incorporated into its pricing strategies. CBS should also consider the feasibility of value-based pricing/procurement for PPP with the aim of developing strategies with manufacturers that can influence a reduction in total costs across the health system.</p> <p>Given there is increasing global demand for PPP and relatively constrained supply, this strategy could be conducive to CBS and PT health systems in ensuring that strategic manufacturers are more tightly integrated with health systems beyond just being suppliers of products. In this context, examples of outcome-based specifications for potential suppliers could include:</p>

		<ul style="list-style-type: none"> <li>• Achieving economic efficiencies and better value for money for PT health systems by procuring not just cost effective PPP, but incorporating additional elements related to supply security and management, transition management, training where necessary or other downstream aspects that affect the Members and provide better overall economic outcomes for the health system;</li> <li>• Further building on the innovation capacity and utilization reporting capability within PT health systems; and</li> <li>• Ensuring patients have the best possible experience and have improved quality of care while at the same time, improving the clinical outcomes.</li> </ul>
<b>Procurement Process</b>	There are opportunities to provide a higher level of transparency into the PPP RFP process.	<b>Recommendation 37</b> CBS should consider using an independent Fairness Monitor for PPP procurement to provide greater transparency to PTs regarding the objectivity and integrity of the procurement process.
<b>Procurement Process</b>	The CBS complaints process for PPP RFPs is not published.	<b>Recommendation 38</b> Document and publish the complaints process for future PPP RFPs.  For future RFP cycles, CBS should document and publish the complaints process in the RFP. In doing so, CBS should consider: <ul style="list-style-type: none"> <li>• The format in which complaints are to be communicated to CBS (e.g. written or verbal);</li> <li>• CBS points of escalation for the complaint;</li> <li>• Timeframes for a CBS response to the complaint and the format in which the response will be communicated; and</li> <li>• Options for redress should the supplier still feel dissatisfied.</li> </ul>
<b>RFP cost savings and cost avoidance</b>	There is no ongoing reporting to PTs on whether expected cost savings following PPP RFPs are being realized over time.	<b>Recommendation 39</b> Develop an ongoing process to track and report on PPP RFP cost savings and/or cost avoidance to PTs.  Develop and embed a process to systematically track and report on whether expected cost savings/avoidance from PPP RFPs are being actually realized. In doing so, CBS should consider: <ul style="list-style-type: none"> <li>• The expected frequency of tracking and reporting and the associated audience;</li> <li>• Providing commentary/explanations to support differences in CBS' original expectations versus results achieved; and</li> <li>• Any unexpected additional costs that may have arisen.</li> </ul> In the long-term, CBS and the PTs should explore ways to identify and include the incremental cost impacts (e.g., increased workload at the hospital level) on PT health care systems, resulting from new PPP contracts, in the cost savings/cost avoidance estimates.
<b>Transition Management</b>	There are opportunities for CBS and PTs to collaboratively enhance the transition management approach when introducing new PPP or changing existing PPP.	<b>Recommendation 40</b> CBS should develop a process to seek information from PTs before the RFP process to better understand the impacts of potential changes on their health care systems.  Pre-RFP, CBS and the PTs should agree on: <ul style="list-style-type: none"> <li>• How PT input and feedback will be gathered;</li> <li>• The roles and responsibilities for coordinating this feedback; and</li> <li>• Timelines so that this feedback can be gathered and</li> </ul>

		<p>considered in a timely manner ahead of issuing the RFP.</p> <p>Once the RFP process is complete, CBS and the PTs should agree on:</p> <ul style="list-style-type: none"> <li>• The factors to consider from a transition management perspective. This could include: <ul style="list-style-type: none"> <li>– Impacted physician, nursing and patient groups and appropriate consultation timelines;</li> <li>– Incremental transition costs at the PT level;</li> <li>– Planned policy changes at a provincial level which may impact transition;</li> <li>– Potential physician, nurse and patient training needs; and</li> <li>– Length of transition time.</li> </ul> </li> <li>• A documented transition plan.</li> <li>• Frequency and format of reporting to PTs on how the transition is progressing.</li> </ul>
<b>4.4 Productivity and Efficiency Activities</b>		
<b>Productivity and Efficiency Program</b>	CBS does not link its PEP savings targets to specific initiatives.	<p><b>Recommendation 41</b></p> <p>CBS should establish a portfolio management approach for the PEP.</p> <ul style="list-style-type: none"> <li>• Consolidating the PEP initiatives under a portfolio management approach would enable CBS to track progress and monitor benefits realization for each initiative under the PEP. This approach would also help provide greater clarity to Members on the savings achieved as a result of implementing strategic initiatives such as the ASC.</li> <li>• CBS should develop a formal methodology to estimate productivity and efficiency savings as part of this approach.</li> <li>• Efficiency targets, including financial savings, should be included in the business case for each initiative submitted to the EMT for approval.</li> </ul>
<b>Continuous Improvement Program</b>	A benefits management framework for the CI Program is not in place.	<p><b>Recommendation 42</b></p> <p>CBS should develop a benefits management framework for the CI Program to enable:</p> <ul style="list-style-type: none"> <li>• Identification of benefits for CI initiatives that are aligned with organizational goals</li> <li>• Systematic tracking of benefits as project implementation progresses</li> <li>• Increased visibility into the overall benefits provided by the CI program in relation to the investments made</li> </ul> <p>The benefits management framework will help provide PTs with a better understanding of how the CI Program improves productivity and efficiency metrics.</p>
<b>5.0 Strategic Initiatives Performance</b>		
<b>ASC Project</b>	CBS chose MAK systems on a sole source basis to implement ePROGESA as there were very few options in the market.	<p><b>Recommendation 43</b></p> <p>For projects over a material threshold and within a new and emerging area, we recommend that CBS consider using a technology advisory firm to help them evaluate available technologies in the market and identify potential vendors to deliver the solution.</p>
<b>ASC Project</b>	The CBS internal business case for the ASC project did not articulate the overall risk associated with the project.	<p><b>Recommendation 44</b></p> <p>CBS' ePMO should ensure that business cases for strategic initiatives provide a risk rating for all identified risks and clearly articulate the overall risk associated with each project</p>

<b>ASC Project</b>	The project business case estimated a net benefit of \$15M at the end of 2018-19 but the extent to which this benefit has been achieved was not tracked.	<p><b>Recommendation 45</b> As part of its reporting process on major projects to the Board and Members, CBS should:</p> <ul style="list-style-type: none"> <li>formally report on the financial benefits realization throughout the project as critical decisions are made and their potential impact on benefits realization; and</li> <li>explain the reasons for any variances from the benefits estimated within the original business case.</li> </ul> <p>Project closeout reports should include an analysis of financial benefits realization and reasons for any shortfalls.</p>
<b>ASC Project</b>	Operational targets arising from the project were not cascaded to leadership at the local level resulting in lack of accountability to achieve them.	<p><b>Recommendation 46</b> CBS should establish a process for integration of project benefits targets with operational performance targets and budgets at the regional/local levels. This will drive higher probability for actual realization of benefit targets.</p>
<b>ASC Project</b>	The ASC project had challenges measuring reduction in the LHU at project closeout.	<p><b>Recommendation 47</b> CBS should ensure that benefits measures are clearly defined in project business cases along with clear accountability for who should measure and who is expected to achieve them. This would help prevent downstream measurement and accountability challenges.</p> <p><b>Recommendation 48</b> CBS should continue to monitor and report on the productivity results from process changes associated with the ASC project.</p>
<b>ASC Project</b>	The reporting of benefits achievement at project close-out could be enhanced.	<p><b>Recommendation 49</b> CBS' ePMO should review all business cases to ensure that targets are stated for all benefits metrics and that mechanisms are in place to collect the information required to report on benefits realization at project close-out.</p> <ul style="list-style-type: none"> <li>Consideration should be given to the availability of data/information to enable benefits measurement in an efficient and cost-effective manner.</li> <li>For metrics tied to surveys such as employee satisfaction, a baseline measure should be included in the business case to measure against at the end of the project. Consideration should be given to conducting a survey at the outset of the project and comparing the results against post project survey results.</li> </ul>
<b>Donor Experience Project</b>	The benefit realization related to donor retention and public perception was below target for this project.	<p><b>Recommendation 50</b> CBS should prepare an action plan to support the tracking and realization of the benefits that have not met their targets for the Donor Experience project.</p> <ul style="list-style-type: none"> <li>The action plan should articulate the remediation activities for each measure that is below target, the accountable business owner and timelines for improvement.</li> <li>CBS should monitor progress and continue to measure against the targets outlined by the project to assess if the project is delivering value for money.</li> </ul>
<b>6.0 Other Areas of Review</b>		
<b>6.1 Governance</b>		
<b>Board Diversity</b>	The opportunity exists to enhance the diversity of CBS' Board of Directors.	<p><b>Recommendation 51</b> Develop a Board diversity strategy.</p> <p>Working with Members, the CBS' BoD should:</p> <ul style="list-style-type: none"> <li>Define "diversity" or, more specifically describe what a diverse BoD for CBS resembles. In defining "Board diversity", attributes of status (e.g., Indigenous, First Nations, Metis), gender, race, ethnicity, culture, religion,</li> </ul>

		<p>age, sexual orientation, and regional location should be considered (i.e., in addition to urban and rural, consider “remote” locations).</p> <ul style="list-style-type: none"> <li>Outline the approach that the BoD and Members will take in the near and longer terms to enhance Board Diversity. Achieving “diversity” is likely to be an incremental process given that action can only be taken once the tenure of existing Directors comes to an end.</li> <li>Establish processes to track and report on the level to which the tenets of the BoD Diversity Strategy are being achieved, and periodically review and evolve the definition of “diversity”. We understand that CBS, the BoD, and Members are taking steps to enable a BoD composition that is reflective of the Canadian population and donor population.</li> </ul> <p>The effective functioning of the BoD requires individuals with the necessary education, skills, and experience to effectively deliver all aspects of the mandate assigned to CBS. As such, education skills, and experience should remain the primary considerations when selecting a candidate for the BoD.</p>
<b>Succession Planning / Governance Transitioning Enabling Effective Continuity</b>	While succession plans are in place for the CEO and senior management at CBS, a BoD succession plan has not been developed.	<p><b>Recommendation 52</b> Develop a BoD succession plan.</p> <p>While there is a process in place to fill vacancies on the BoD as they occur, it is recommended that a BoD succession plan be developed. This plan would be separate from the activities undertaken as part of recruitment; it would be a forward looking plan that proactively identifies the skills and requirements of an “effectively functioning” BoD that resembles Canada’s and CBS’ donor populations. It would also help inform the BoD Director training / education delivered through the Governance Committee. The plan would be subject to Member decision-making regarding renewal of director terms and election of new directors.</p>
<b>Succession Planning / Governance Transitioning Enabling Effective Continuity</b>	An orientation program is not in place for new PTBLC representatives to familiarize them with CBS and their new role.	<p><b>Recommendation 53</b> Develop a formal orientation program for new PTBLC representatives.</p> <p>CBS should work jointly with PTBLC representatives to create an orientation program for new representatives that provides an overview of the blood supply system; reviews the accountabilities, roles, and responsibilities of all parties involved in the system; describes the CBS operational environment, products, and services; and provides an overview of reports provided to Members/PTBLC representatives.</p>
<b>Timely &amp; Responsive Reporting</b>	Opportunities exist for CBS to enhance content and timeliness of reports / materials provided to Members	<p><b>Recommendation 54</b> Review performance measures for FBC and PPP.</p> <p>The BoD should establish a roadmap, including timelines, for reviewing and updating the performance measures for FBC and PPP in response to the letter shared by Members with the BoD outlining their priorities for 2019. In particular, consideration should be given to reporting on outcome-based measures.</p> <p><b>Recommendation 55</b> Introduce annual year-over-year trends reporting on key safety indicators.</p> <p>CBS should provide (each year in the fourth quarter report to Members) year-over-year trends for key safety indicators (e.g., Health Canada Inspections, Recalls due to EAs and PDIs per 10,000 Collections, etc.) for the last 3 consecutive years.</p> <p><b>Recommendation 56</b> Improve reporting and support to Members for enhanced decision-making.</p>

		<p>With due recognition of CBS' operational autonomy, it is recommended that CBS work with PTs/PTBLC representatives to:</p> <ul style="list-style-type: none"> <li>• Review the content of reports and materials provided to Members and PTBLC representatives to determine the extent to which these documents contain the data/information required by Members.</li> <li>• Develop a process to better support PTBLC representatives in their roles. The process should enable discussion of the nature of documentation/materials to be provided, timelines and any additional CBS support that may be required, to enable PTBLC representatives to support their respective Members with decision-making, approvals, etc.; and</li> <li>• Review the PT Portal with a view to using it as a tool to house critical data, in a format that provides easy access to year-over-year performance data.</li> </ul>
<b>6.2 Enterprise Risk Management</b>		
<b>FBC and PPP Risk Management</b>	Separate operational risk registers have not been developed for FBC and PPP and a consolidated view of overall operational risks associated with each of these business lines is lacking.	<p><b>Recommendation 57</b></p> <p>Develop operational risk views for FBC and PPP which detail the existing and emerging risks with input from relevant risk owners. These operational risk views per business line should be informed by divisional risk tools such as the Supply Chain Risk Register.</p>
<b>ERM Program</b>	An overarching risk appetite statement was not in place over the review period.	<p><b>Recommendation 58</b></p> <p>Develop a formal risk appetite statement for core business functions to articulate the amount of risk that CBS is willing to take in the pursuit of its objectives and delivery of its mandate. A formal risk statement will provide clarity across the organization as to the level of acceptable risk when making strategic and operational decisions.</p>
<b>ERM Program</b>	The maturity of the Business Continuity Management Program could be advanced.	<p><b>Recommendation 59</b></p> <p>Develop a master BCM testing plan that identifies:</p> <ul style="list-style-type: none"> <li>• entities/locations to be tested;</li> <li>• the nature of testing to be undertaken;</li> <li>• criteria for determining the test types;</li> <li>• frequency of testing; and</li> <li>• roles and responsibilities for getting the testing completed.</li> </ul> <p>Ask each site to customize the current generic Recovery Plan-Facility Failure to site specific plans.</p>

## Appendix 2: Cost Transfer to PPP Business Line

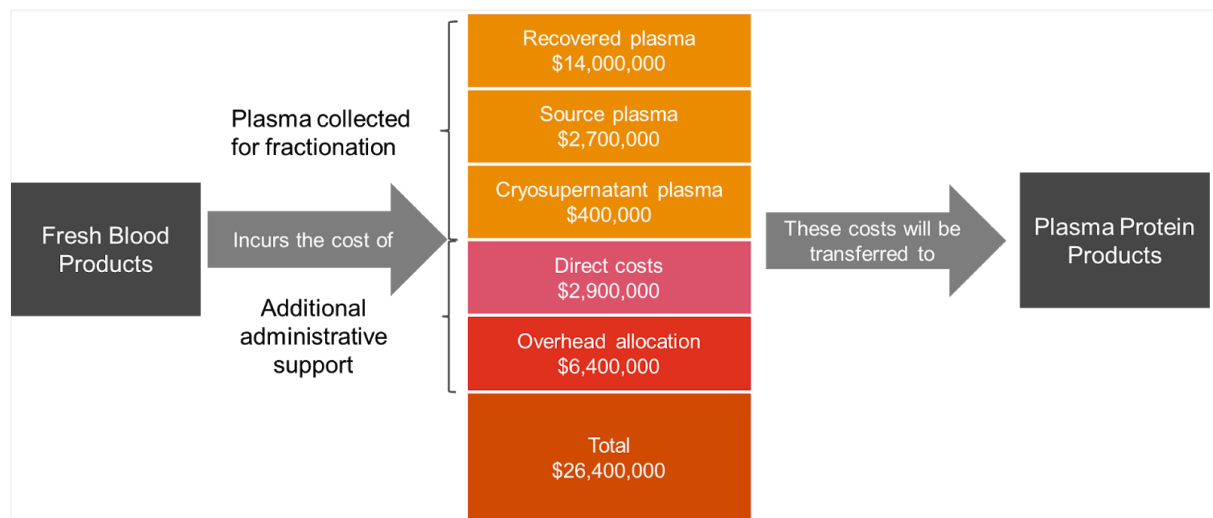
A cost transfer of \$26.4 million associated with plasma for fractionation was introduced in CBS' 2017-2020 Corporate Plan. The aim of the transfer was to account for the cross-subsidy that exists for the cost of collecting plasma shipped for fractionation (recovered plasma, source plasma and cryosupernatant plasma) and administrative support. Of this total, \$17.1 million represents the direct product cost transfer for recovered plasma, source plasma and cryosupernatant plasma shipped for fractionation; \$6.4 million represents the overhead transfer; and \$2.9 million represents the direct cost transfer.

There was no change in the total net funding that CBS received due to the introduction of the transfer, as funding for the blood program decreased in the same amount as the increase in the PPP program.

The introduction of the cost transfer changed the amount of funding due from the individual provinces and territories, as the allocation base for the \$26.4 million from red blood cells was applied to the Ig costs.

The calculation is based on data from CBS' internal product costing model. The initial calculation uses the actual cost from the 2015-2016 fiscal year for product shipments along with a charge for administrative support. Following the price transfer introduction, the estimated price transfer has been updated for changes in inputs (i.e. volumes and costs) but the calculation remains unchanged. For both 2017–2018 and 2018–2019 the transfer was \$26.4 million. A summary of the calculation can be seen in the Figure 42 below.

**Figure 42: PPP Transfer Breakdown for 2018-19**





## Appendix 3: Benchmarking Approach

Benchmarking information for blood operators is challenging to obtain as it is not readily available from public sources. For purposes of the benchmarking analysis as part of this review, PwC relied on comparative information collected from a set of blood operators, under strict confidentiality agreements, by the ABO. This information was made available by CBS to PwC, in redacted form, to enable the benchmarking analysis of FBC cost drivers. Our overall approach for this was reviewed with and approved by the PRWG.

The ABO prepares an annual benchmarking report through the collation of data obtained from their members. The annual benchmarking report is accompanied by an ABO Cost Model Report which contains more detail on cost and productivity metrics for the five countries that participate.

The ABO members which provide data for the ABO Benchmarking Report include:

- National Health Service Blood and Transplant (UK);
- American Red Cross;
- Australian Red Cross Lifeblood;
- The European Blood Alliance (not-for-profit European Blood Establishments from 26 countries); and
- Vitalant (non-profit transfusion medicine organization).

The ABO Cost Model Report contains information from a subset of these ABO members.

CBS primarily uses these two ABO reports to compare its performance against other ABO members and to identify potential areas for improvement.

For the purposes of the performance review, redacted data from the ABO Cost Model Reports for 2016-17 and 2018-19 were used to complete the benchmarking analysis across collections, testing and production. The ABO Benchmark 2018-19 Report was used to complete the benchmarking analysis on the whole blood donations deferred. The detail provided in the extracted information on collections from new donors did not contain sufficient commentary or volume information to include the data in our analysis.

In keeping with requirements outlined in the CBS Performance Review scope, PwC focused the benchmarking analysis on productivity metrics outlined in the following table.

**Table 26:** ABO benchmarking dataset used for FBC benchmarking analysis

Report	ABO Cost Model Reports 2016-17 & 2018-19 (contains data from 2014-15 to 2018-19)	ABO Benchmark 2018-19 Report (contains data from 2015-16 to 2018-19)
<b>Dataset used</b>	<ul style="list-style-type: none"><li>• Percentage change in collection productivity</li><li>• Percentage change in production productivity</li><li>• Percentage change in routine testing productivity</li><li>• Worked labour hours per unit</li><li>• Staff cost per labour hour</li></ul>	<ul style="list-style-type: none"><li>• Percentage of whole blood donations deferred</li><li>• Percentage of collection from new donors</li></ul>

## **Benchmarking data set**

This dataset, which is outlined in Table 26 above, was used to benchmark CBS against three other blood service operators (out of four). The fourth blood operator that provides data for the ABO cost model is not large enough to provide reasonable comparison.

The three comparator blood operators are operating in developed countries but have varying demographics, when compared with CBS. While the data is useful to draw comparisons, there are differences such as population served, population density, geography and diversity that will influence the metrics.

For purposes of this analysis, the names of the blood operators have been anonymized. They are referred to as Blood Operator A, Blood Operator B and Blood Operator C throughout the analysis.

The ABO Cost Model Report data 2018–19, which PwC received from CBS for benchmarking purposes, was heavily redacted and the commentary to support the metrics for the three operators was not comprehensive. This is due to the limitations imposed by the confidentiality requirements between the blood operators. The data provided for worked labour hours per unit and staff cost per labour hour did not have associated commentary to enable PwC to provide informed observations and, as a result, have been excluded from the analysis.

Due to confidentiality concerns, PwC was required to omit the 2018-19 metrics from the testing benchmarking analysis, as the absence of data for one operator in that year would potentially reveal its identity. Accordingly, we were only able to benchmark testing productivity metrics for four years from 2014-15 to 2017-18.

It should be noted that the commentary provided in the ABO benchmarking data, that PwC received, was not sufficient to provide specific recommendations with regards to collections, testing and production.

## Appendix 4: Sample of Legislative, Regulatory, and Standard Requirements for FBC and PPP

Product or Service	Legislative, Regulatory or Standard Requirements
<b>FBC</b>	<ul style="list-style-type: none"> <li>• Food and Drugs Act</li> <li>• Health Products &amp; Food Branch, Blood Regulations, SOR/2013-178</li> <li>• Regulatory Requirements for Blood Establishment Information Technology Submissions</li> <li>• Canadian Nuclear Safety and Control Act</li> <li>• Institute for Quality Management in Health Care</li> <li>• CAN/CSA-Z902-15, Blood and blood components, Canadian Standards Association (CSA)</li> <li>• Transportation of Dangerous Goods Act</li> <li>• Transportation of Dangerous Goods Regulations, SOR/2001-286</li> <li>• International Council for Commonality in Blood Banking Automation (ICCBBA) ST-001, Technical Specification, ICCBBA ST-005, Labeling of Blood Components, Version Number 1.1.0, (November 2016)</li> <li>• ICCBBA ST-002, Standard Terminology for Medical Products of Human Origin - For Use with Product Description Code Database, Version 7.11 (February 2018)</li> </ul>
<b>PPP</b>	<ul style="list-style-type: none"> <li>• Food and Drugs Act</li> <li>• Food and Drug Regulations, Part C (Drugs)</li> <li>• Health Canada GUI-0001. Good Manufacturing Practices (GMPs) Guidelines, February 28, 2018</li> <li>• US FDA Import for Export Requirements (Federal Food, Drug, and Cosmetic Act, section 801) including 21 CFR 607.40, 610.62 and 640.70</li> </ul>

## Appendix 5: Overview of Safety Mechanisms & Activities at CBS

The table below provides a detailed description of the safety mechanisms and activities in place and operating at CBS.

Medical Affairs & Innovation	
<b>Pathogen Surveillance</b>	Microbiology monitors emerging infectious disease threats to the blood supply through close liaison with public health officials, public health laboratories, international authorities in infectious diseases and transfusion medicine. The team provides input into pandemic planning and other business continuity planning. They work closely with epidemiology and donor and transplantation services to ensure donor and recipient safety and contribute to research and risk assessments on transfusion transmitted diseases.
<b>Epidemiology</b>	Epidemiology conducts studies and undertakes risk modelling to understand the risk of transfusion transmitted infections. They assess the risk of emerging infectious diseases through surveillance, donor studies and a risk assessment process. The results of their work are key inputs into risk mitigation strategies.
<b>Donor Selection Criteria</b>	Donor and clinical services is responsible for blood donor criteria and screening surveillance and management of necessary blood donation criteria changes. They provide medical oversight for diagnostic services, national testing laboratory, donor testing laboratories and national platelet immunology laboratories, stem cells, as well as the management of certain programs, such as Transfusion-Related Acute Lung Injury (TRALI) donor management.
<b>Medical Consultation</b>	Medical services and hospital relations provides medical support to lookback-traceback activities and donor re-entry. They provide daily medical coverage for donor eligibility assessment on clinic, donor and recipient adverse event investigation and reporting, National Contact Centre, and the rare blood program. This group is responsible for the transmissible disease notification program and related donor counselling.
<b>Research</b>	<p>The Centre for Innovation works closely with the supply chain, developing and executing product and process development projects to enhance and advance Canadian Blood Services operations for the benefit of Canadian patients. Examples of its development research include:</p> <ul style="list-style-type: none"> <li>• Feasibility of implementing source plasma donation with alternative eligibility criteria for men who have sex with men</li> <li>• Evaluating the role of donor characteristics and blood component manufacturing on the quality of red cell concentrates</li> <li>• Applying educational tools of knowledge translation to reduce the inappropriate use of plasma in Ontario: a collaboration between Canadian Blood Services and Ontario hospitals.</li> </ul>
Supply Chain	
<b>Donor Screening</b>	For every whole blood donation, the donor is first screened to make sure they are healthy. This involves answering an extensive list of questions, ensuring the safety of both the donor and the patient who will receive the blood products.
<b>Donor Testing</b>	<p>Testing performs extensive testing on donated blood for infectious diseases and blood groups. Supply Chain is responsible for ten testing laboratories, which are under one management structure. This includes donor testing, diagnostic services, product quality control (QC) testing, three reference laboratories and HLA labs for stem cells and platelets.</p> <ul style="list-style-type: none"> <li>• Donor testing is located at two sites: Brampton and Calgary</li> <li>• Performs the mandatory testing for the release of blood products, which includes Syphilis, Serological TD (HBsAg, Hepatitis C Virus (HCV)), Human Immunodeficiency Virus (HIV), Chagas and Human T-cell Lymphotropic Virus (HTLV), Nucleic Acid Testing (HIV, HCV, HBV, WNV), ABO/Rh, antibody testing and selective CMV testing</li> <li>• Quality control testing of the products is performed at the Brampton site.</li> </ul>
<b>Diagnostic Services – Perinatal and Crossmatch Services</b>	<ul style="list-style-type: none"> <li>• The Winnipeg and Edmonton sites provide a provincial Perinatal Testing Program for their respective provinces of Manitoba and Alberta.</li> <li>• The British Columbia and Yukon (BCY) site provides a provincial Perinatal Testing Program and reference service for British Columbia and Yukon.</li> <li>• The Winnipeg site operates a provincial Transfusion Medicine Program that includes a centralized transfusion service laboratory (crossmatch services) and reference service</li> </ul>

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for the province of Manitoba.

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### Supply Chain

#### HLA Testing

- The HLA Laboratory provides large scale HLA genotype testing for Canada (except Quebec).
- Service is also provided for the stem cell program, including cord blood samples.

#### Reference Laboratories

- The Winnipeg site provides a national reference testing service for HLA and human platelet antigen (HPA) antibody investigations. This site supports the provision of donor HLA and HPA matched platelet apheresis products to highly sensitized patients.
- The National Immunohematology Reference Laboratory (NIRL) provides testing services for both patients and donors from hospitals across the country.

#### Bacterial Testing

Bacterial contamination of platelet products is a serious concern in transfusion practice because platelet storage conditions allow bacteria to replicate to potentially dangerous levels. All platelet products are screened for bacteria by removing 8-10 ml which are added to a BacT/ALERT culture bottle — an environment that promotes bacteria growth if bacteria is present — and it is monitored for bacteria growth over a few days. If bacteria is detected, then the platelet unit is discarded or recalled from the hospital. If additional products were made from the blood donation, then those products are also recalled and discarded.

### Quality & Regulatory Affairs

#### Quality Management System (QMS)

A QMS is a framework to enable the delivery of products and services that meet customer needs and expectations, are safe and effective, and are free of defects. A QMS consists of documented policies, processes and procedures that govern how quality is managed; a quality assurance program that provides confidence that quality requirements are being fulfilled; and quality metrics to monitor and evaluate the effectiveness of activities.

CBS, starting in 2014, began taking steps to implement a QMS that is more aligned to systems found in the biologics manufacturing industry. Phase I activities included strengthening the following processes: quality event management, CAPA, document management, change control, and training management. Phase II includes the strengthening of the supplier management process and introducing a quality-by-design process. Workflow automation is also being introduced.

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## Appendix 6: Recommended Framework for CBS' QMS Design

The framework illustrated below is consistent with the elements of a Biologics QMS Model with the exception of an additional element, "Management Responsibility". "Management Responsibility" is defined as the function that works to clarify and give visibility to the responsibilities associated with the design, implementation, and sustainability of an effective QMS. This framework informed CBS' action plan to mature its QMS over the review period.

### Framework for CBS' QMS Design

Quality System	Management Responsibility	Facilities & Equipment Controls
<ul style="list-style-type: none"> <li>• Change Control</li> <li>• Final Product Release</li> <li>• Document Control</li> <li>• CAPA System Nonconformances</li> <li>• Risk Management</li> <li>• Complaint Handling</li> <li>• Errors and Accidents</li> <li>• Recalls</li> <li>• Trace-backs and Look-back</li> <li>• Audit Program</li> <li>• Quality Manual</li> <li>• Quality Metrics</li> <li>• Training Program</li> </ul>	<ul style="list-style-type: none"> <li>• Resource Management</li> <li>• Quality Unit Role and Responsibilities</li> <li>• Management Review</li> <li>• Quality Policy</li> </ul>	<ul style="list-style-type: none"> <li>• Validation Program</li> <li>• Facility Design</li> <li>• Environmental Monitoring (EM)</li> <li>• Calibration</li> <li>• Preventive Maintenance (PM)</li> <li>• Cleaning</li> </ul>
	Laboratory Controls	Production Controls
	<ul style="list-style-type: none"> <li>• Method Validation (Licensed Test Kits)</li> <li>• Stability Programs</li> <li>• Analytical Instrument Qualification (AIQ)</li> <li>• Final Product Testing</li> </ul>	<ul style="list-style-type: none"> <li>• Production Batch Records</li> <li>• In-process Controls</li> <li>• Process Development</li> <li>• Process Validation</li> </ul>
Material Controls	Packaging & Labeling Controls	
<ul style="list-style-type: none"> <li>• Supplier Qualification</li> <li>• Purchasing Controls</li> <li>• Finished Product Traceability</li> <li>• Materials and Supply Traceability</li> <li>• Acceptance Activities</li> <li>• Quarantine and Release</li> <li>• Handling and Storage</li> </ul>	<ul style="list-style-type: none"> <li>• Receiving and Distribution (Finished Product)</li> <li>• Label Control</li> <li>• Process Controls – End Labeling</li> <li>• Process Controls – Shipping</li> </ul>	

## Appendix 7: Capability maturity profile – Forecasting

<b>Stage 1</b> Basic	<ul style="list-style-type: none"> <li>• Multiple forecasts developed for each business</li> <li>• Forecasts are derived from sales plans</li> <li>• Demand forecast is manually calculated using standalone spreadsheets, limited statistical analysis and less than three months of historical data</li> <li>• Planning levels for forecasts not determined through balancing data noise and getting the right product mix accuracy</li> <li>• Forecast accuracy and bias not measured. Forecast assumptions not tracked</li> <li>• Limited statistical analysis skills</li> </ul>
<b>Stage 2</b> Emerging	<ul style="list-style-type: none"> <li>• Forecasts are based on basic analysis of sales history, with limited and/or unregulated input of customer/market intelligence</li> <li>• Use of simple, statistical methods (moving average, moving median, etc.) that are selected by forecasting solutions</li> <li>• Some statistical methods (e.g., coefficient of variation, bias and forecast error) used to determine forecastability across different planning hierarchies</li> <li>• Non-forecastable products use min-max/reorder point techniques that are reviewed periodically</li> <li>• Forecast accuracy is measured, but not used to drive improvement</li> <li>• Increasing consistency in using Mean Absolute Percentage Error (MAPE), lag, and bias to calculate forecast accuracy</li> </ul>
<b>Stage 3</b> Advanced	<ul style="list-style-type: none"> <li>• Forecasts incorporate multiple inputs such as sales history, customer/market intelligence, customer forecasts, planned product/service transitions, pricing/promotions</li> <li>• Use of advanced statistical methods (smoothing, multiple regression, time series) to develop the forecast</li> <li>• Customer-generated forecasts are directly incorporated</li> <li>• Automated forecasting tools used to aggregate and analyze internal and external demand data</li> <li>• Forecast consumption patterns are analyzed to improve models and reforecasts conducted on a highly selective basis</li> <li>• Separate forecasting performed for new products and end-of-life products</li> <li>• Forecasts developed by a designated often centralized advanced statistical analysis group</li> <li>• Forecasting and demand planning processes are interconnected. Forecasts are developed with key input from demand planning</li> <li>• Forecast accuracy and bias are tracked, linked to incentives, and methods are continuously improved</li> </ul>
<b>Stage 4</b> Differentiated	<ul style="list-style-type: none"> <li>• Advanced forecasting analytics are used for demand sensing and to characterize the information quality of all forecast inputs and incorporate them into an optimized forecast model</li> <li>• Use of multiple advanced forecasting algorithms with frequent optimization and tuning</li> <li>• Forecast consumption patterns are continuously analyzed statistically to improve forecasting assumptions. Reforecasting performed even between planning cycles</li> <li>• Input data from internal and external sources (e.g., field sales, customer Point of Sale (POS) systems) have been harmonized to enable rapid modeling and analysis</li> <li>• Collaboratively developed forecasts are shared with customers and suppliers automatically</li> <li>• Forecasts rapidly incorporate specific customers demand patterns</li> <li>• Demand sensing capability in forecasting solutions used to recognize trends (e.g., POS data) and make adjustments</li> <li>• Comprehensive forecast accuracy analytics measure forecast performance at multiple levels and time lags and continuously refine and optimize the forecasting process</li> <li>• Data maintenance is automated with little manual intervention</li> </ul>

## Appendix 8: Sources for PPP comparative analysis

Ref	Source	Availability
1	Accenture Consulting - An Overview of Jurisdictional Oversight and Management of PPP across 8 Countries (Australia, Belgium, Canada, France, Germany, Netherlands, UK, US)	Not publicly available. However, the sources of information used to inform this report were publicly available (e.g. annual reports, research reports, organization websites, etc.).
2	Expensive Drugs for Rare Diseases Process in British Columbia	Not publicly available.
3	Government of Ontario - Provincial Drug Plan Exceptional Access Program	Publicly available.
4	Government of British Columbia - Provincial Drug Plan Special Authority Request Process	Publicly available.
5	Procurement Guideline for Publicly Funded Organizations in Ontario as of March 2020	Publicly available.
6	New Zealand Government Procurement Rules: Rules for Sustainable and Inclusive Procurement, 4th Edition 2019	Publicly available.
7	Pan-Canadian Pharmaceutical Alliance process for negotiating with drug manufacturers on behalf of provinces and territories	Publicly available.
8	Government of British Columbia process for managing the transition of patients to biosimilars - Policy announced on May 27, 2019 and expanded on September 7, 2019.	Not publicly available.



## Appendix 9: Types of formulary and HTAs in other countries

Country	Type of Formulary	HTA Performed	HTA Considerations
<b>Australia</b>	National Formulary	Yes	<ul style="list-style-type: none"> <li>• Clinical safety</li> <li>• Therapeutic effectiveness</li> <li>• Cost effectiveness</li> </ul>
<b>Belgium</b>	National Formulary	Yes	<ul style="list-style-type: none"> <li>• Therapeutic value (efficacy, safety, convenience of use and applicability)</li> <li>• Cost effectiveness</li> <li>• Unofficial factors, such as statements from key opinion leaders and patients</li> </ul>
<b>France</b>	National Formulary	Yes	<ul style="list-style-type: none"> <li>• Therapeutic effectiveness</li> <li>• Cost effectiveness</li> </ul>
<b>Germany</b>	No National Formulary	Yes	<ul style="list-style-type: none"> <li>• Therapeutic effectiveness compared with standard treatment and/or existing drugs</li> <li>• Cost effectiveness</li> </ul>
<b>Netherlands</b>	National Formulary	Yes	<ul style="list-style-type: none"> <li>• Therapeutic effectiveness</li> <li>• Cost effectiveness</li> </ul>
<b>UK</b>	National Formulary	Yes	<ul style="list-style-type: none"> <li>• Therapeutic effectiveness compared with current alternative treatments</li> <li>• Cost effectiveness compared to a cost effectiveness threshold</li> </ul>
<b>US</b>	No National Formulary	Yes	<ul style="list-style-type: none"> <li>• Not known - performed by insurers that conduct their own assessments</li> </ul>

Source: Accenture Consulting Report - An Overview of Jurisdictional Oversight and Management of PPP across 8 Countries

## Appendix 10: PPP utilization management activities performed by CBS, Members and the NAC

### CBS

#### Influencing Activities:

- Develop educational resources (e.g. clinical guidelines and best practice documents) which cover the provision of blood products
- Provide resources and links to external resources (e.g. the ABO) with best practices on transfusion-related medicine
- Organize courses and events (e.g. the LearnTransfusion series) for practitioners in the field of transfusion medicine
- Provide PPP distribution data and reporting to hospitals/clinics which helps heighten hospital awareness of PPP trends over time and enables a comparison to other hospitals/clinics

#### Gatekeeping Activities:

Administer processes for SD Treated Plasma and a “Named Patient Program” for certain PPP products. Both processes require CBS’ review and approval before the associated drugs can be distributed to hospitals (see below for additional details).

### Members *(the activities performed vary between each PT)*

- Set utilization management guidelines which apply to hospitals and clinics. These may vary from the CBS issued guidelines
- Review orders for PPP products to check for validity before they are submitted to CBS
- Perform audits of blood product use within hospitals and clinics
- Review and monitor blood product utilization data from hospitals

### National Advisory Committee on Blood and Blood Products

- Share information about PPP utilization and utilization management efforts undertaken by Members
- Play a supportive role in the development of guidelines and recommendations for PPP use
- Provide leadership in the identification, design and implementation of blood utilization management initiatives

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Source: Accenture Consulting Report - An Overview of Jurisdictional Oversight and Management of PPP across 8 Countries

## Appendix 11: Utilization management approaches in other countries

Country	Approach
<b>Australia</b>	<p>The Australian National Blood Authority implemented an Immunoglobulin Governance Program aimed at improving the management of publicly funded immunoglobulin use. This Program includes the following components:</p> <ul style="list-style-type: none"> <li>• Criteria for the clinical use of intravenous Ig</li> <li>• Policies and procedures for access to Ig products</li> <li>• Establishment and support of a national network of committees and working groups to provide advice and inform the development and implementation of measures to further strengthen Ig product use and governance</li> <li>• Implementation of a national ordering and outcomes database to inform the supply and demand of Ig</li> <li>• The development and implementation of a performance improvement program.</li> </ul>
<b>Belgium</b>	<p>There is a national formulary of reimbursable drugs, with indications specified for each type of drug. This acts as a gatekeeping mechanism to discourage off label prescribing.</p> <p>Biosimilars are part of quotas for prescribing low cost medicines; physicians are encouraged to prescribe at least 20% biosimilars for treatment-naïve<sup>40</sup> patients.</p> <p>The Belgian Superior Health Council also developed national guidelines for the Recommended Indications for Administering Immunoglobulins, with the goal of standardizing usage. The National Institute for Sickness and Disability Insurance has placed restrictions on the usage of certain PPP, such as immunoglobulins. .</p>
<b>France</b>	<p>France has established a Temporary Specialized Scientific Committee devoted to the review of the priority uses of immunoglobulins in 2018, due to supply shortages. An April 2019 update by the Committee showed that the measures implemented resulted in a decrease in the volume of Ig consumed.</p> <p>Only hospital pharmacies can dispense clotting factor concentrates to persons with hemophilia. This limits access to the treatment and the prevention of bleeding episodes.</p>
<b>Germany</b>	<p>Guidelines are in place to aid clinicians in the choice of treatment such as the German Medical Association Cross Sectional Guidelines for Therapy with Blood Components and Plasma Derivatives.</p> <p>Healthcare organizations that consume PPP are required to report the number/volume of PPP administered, to a federal agency, to the Ministry of Health.</p>
<b>Netherlands</b>	<p>Each registered Ig product has its indications approved by the European Medicines Agency (EMA). Some products may have extra indications which are approved by the EMA and based on the outcome of clinical trials.</p> <p>The Dutch Hemophilia Registry was established in 2017. This gives insight into the total number of people in the Netherlands with bleeding disorders, their diagnosis, the use of coagulation factors, bleedings, treatment results and side effects of the treatment.</p> <p>Health insurers may set additional conditions for reimbursement aimed at appropriate use of a medicinal product (e.g., limited to prescription of specialized doctors).</p>

<sup>40</sup> A person is considered to be treatment-naïve if they have never undergone treatment for a particular illness.

Country	Approach
UK	<p>A national demand management program is in place, allocating Trusts<sup>41</sup> an annual volume of Ig based on the previous year's usage and forecasted growth. A shortage of immunoglobulin prompted the development of this program to ensure supply is maintained.</p> <p>The National Hemophilia Database (NHD) is a registry that is managed by the UK Haemophilia Centre Doctors' Organisation. This database collects data from Haemophilia Centres, which is required by the NHS and which helps plan haemophilia services, inform purchasing decisions and learn more about management of the condition. Every three months, a report on treatment data is sent to NHS Commissioners.</p> <p>The UK also implemented criteria for the use of therapeutic immunoglobulin in immunology, haematology, neurology and infectious diseases provide detail around the role, dose and place of Ig in the treatment pathway for individual indications, alongside possible alternative treatment options.</p>
US	<p>Health and drug plans employ control tools in conjunction with formularies: prior authorization, step therapy<sup>42</sup>, site of care policies (i.e, medical criteria for the use of specialty drugs), and quantity limits. These tools state the stage at which a drug can be used or how much can be purchased on one prescription, or where it can be administered.</p> <p>Each plasma protein therapy is approved by the FDA for distinct clinical indications . Various organizations , foundations and societies publish guidelines for conditions treated with PPP. Examples include the National Hemophilia Foundation, Immunoglobulin National Society, American Academy of Allergy, Asthma and Immunology, and so on.</p>

Source: Accenture Consulting Report - An Overview of Jurisdictional Oversight and Management of PPP across 8 Countries

<sup>41</sup> Trusts serve geographical areas or are a specialized function (e.g. ambulance services).

<sup>42</sup> "Step therapy" requires patients to try one or more medications specified by the insurance company, typically a generic or lower cost medicine, to treat a health condition.

## Appendix 12: PPP pricing strategies in other countries

PPP Pricing Strategy	Description	Countries Using Strategy	Considerations
<b>External Reference Pricing</b>	Also known as International Reference Pricing. Uses the price of a drug in other countries as a benchmark to inform or set the price.	Germany, Belgium	<ul style="list-style-type: none"> <li>Enables blood organizations to access better commercial terms or pricing which may only be available by manufacturers in other markets.</li> <li>Reference pricing is not always published (or shared) and comparisons between countries may therefore not be feasible. Further, manufacturers typically have different pricing and marketing strategies for each country.</li> </ul>
<b>Internal Reference Pricing</b>	Sets price based on a comparison with drugs within the country that are identical, similar, or therapeutically equivalent.	Australia, Germany	<ul style="list-style-type: none"> <li>Where there are drugs that are identical, similar or therapeutically equivalent, this approach enables alignment of pricing with drugs that are similar.</li> <li>There may not always be drugs within the country that are identical, similar, or therapeutically equivalent.</li> <li>Drugs plans in Canada differ between provinces and territories; the use of this method may result in inconsistencies between Members.</li> </ul>
<b>Value-Based Pricing</b>	<p>Price is based on the therapeutic value (versus cost).</p> <p>The manufacturer issues a refund/rebate to the purchaser if anticipated real world benefits are not realized.</p> <p>Contract features, such as payment timing and the amount at risk, can be customized depending on characteristics of the uncertainty and the needs of the participating parties.</p>	UK	<ul style="list-style-type: none"> <li>This pricing model may provide outcome-based benefits and should be supported by appropriate payment incentives, if and when benefits materialize. Equally, rebates could be received where these therapeutic benefits do not eventuate.</li> <li>Requires robust outcome ("benefit") tracking processes to collect and analyze data supporting outcomes.</li> </ul>

Source: Accenture Consulting Report - An Overview of Jurisdictional Oversight and Management of PPP across 8 Countries

## Appendix 13: PPP RFPs issued during the review period

#	Description	Fiscal Year of Tender	Contract Effective Date	Contract End Date	Contract Duration
1	Contract Fractionation & Commercial Product	2012-2013	April 1, 2013	March 31, 2018	5 years, with two one year extension options
2	Recombinant Products: rFIX	2012-2013	April 1, 2013	March 31, 2016	2 years, with three one year extension options
	rFVIII		April 1, 2013	March 31, 2016	2 years, with three one year extension options
	rFVIII		April 1, 2013	March 31, 2016	3 years, with two one year extension options
	rFVIII		April 1, 2013	Contract ongoing at end of review period	7 years, with three one year extension options
3	Recombinant Products [rFVIII and rFIX]	2015-2016	April 1, 2016	March 31, 2018	2 years, with two one year extension options
4	Contract Fractionation & Commercial Product	2017-2018	April 1, 2018	Contract ongoing at end of review period	3 years, with two one year extension options
	Recombinant Products [all]		April 1, 2018	Contract ongoing at end of review period	2 years, with two one year extension options
5	Recombinant Product [rFVIII]	2018-2019	April 1, 2018	Contract ongoing at end of review period	2 years, with two one year extension options

## Appendix 14: Comparison between the Procurement Guideline for Publicly Funded Organizations in Ontario and the CBS RFP Process

Procurement Guideline for Publicly Funded Organizations in Ontario	CBS RFP Process
Establishing internal controls to help reduce exposure to unauthorized or inappropriate expenditures.	<p>CBS has a Purchasing Policy and Purchasing Policies and Procedures Manual. Given the significant/material nature of PPP RFPs, these all require EMT approval before the RFP outcomes can be finalized.</p> <p>Board approval is required prior to entering into contracts for fractionation of CBS plasma and for contracts over \$50 million, including PPP contracts.</p>
Planning the procurement process, including determining market availability of product/services, procurement method (e.g., competitive or non-competitive), timelines, approval requirements, contract duration, etc.	CBS forms a Selection Committee which works with Procurement to plan the RFP. This includes the procurement method, timelines, and contract duration, amongst other areas.
Developing evaluation criteria prior to the start of the competitive process.	The CBS Selection Committee determines the bid evaluation criteria upfront. The criteria are disclosed in the RFP and subsequently used as part of the bid evaluation process.
Canvassing the market to obtain information about potential vendors of products/services that the organization desires to purchase.	<p>There are 12 main suppliers for PPP globally and, given its size, CBS has working relationships with all of them. Through these relationships, CBS has visibility of product pipelines and is able to canvas the market, prior to the issuance of the RFP.</p> <p>CBS does not exclude any vendors from the RFP process.</p>
Determining the procurement method - the Guideline recommends using a competitive process for medium to high dollar value transactions.	The RFP is issued to multiple manufacturers and is therefore a competitive process. The bid evaluation criteria enables CBS to evaluate multiple bids in a structured manner.
Documenting the transaction and keeping records.	The decision matrix for each evaluator on the Selection Committee is documented and retained. Further, CBS gives bidders the opportunity for a formal debrief of the strengths and weaknesses of their bid; this debrief is documented by CBS Procurement.
Reviewing and improving - Monitor contracts, vendor performance and satisfaction with the procurement process regularly, and introduce improvements as necessary.	CBS formally monitors vendor contracts and performance via monthly operational meetings, quarterly scorecards and semi-annual meetings between a CBS EMT member and senior supplier personnel. This monitoring is in addition to regular/ongoing interaction that operational teams have with suppliers.

## Appendix 15: Comparison between the New Zealand Government Procurement Rules and the CBS RFP Process

New Zealand Government Procurement Rules	CBS RFP Process
Planning your procurement - where organizations must conduct appropriate planning based on the size, risk and complexity of each procurement.	Given the size, risk and complexity of PPP RFPs, CBS forms a Selection Committee which works with Procurement to plan the RFP. This includes the procurement method, timelines and contract duration, amongst other areas.
Approaching the market - where organizations are encouraged to engage with the market prior to the RFP and understand what is available.	There are 12 main suppliers for PPP globally and, given its size, CBS has working relationships with all of them. Through these relationships, CBS has visibility of product pipelines and is therefore able to canvas the market prior to the issuance of the RFP.  CBS does not exclude any vendors from the RFP process.
Approaching the market - When approaching the market as part of a formal RFP, it is important that there is a formal approach to how this occurs.  This includes providing notice of procurement, providing sufficient information that suppliers need to prepare and submit meaningful responses, determining the evaluation criteria, providing a process for suppliers to ask and receive responses to queries and having a process to evaluate supplier responses fairly.	The CBS RFP process considers each of the elements specified.
Awarding the contract - This consists of the rules and principles to inform suppliers of the RFP decision, provide notice of contract award, debrief suppliers, address supplier complaints and maintain records.	The decision matrix from each evaluator on the Selection Committee is documented and retained.  The outcomes of RFPs are communicated to Members and published on blood.ca.  CBS gives bidders the opportunity for a formal debrief of the strengths and weaknesses of their bid; this debrief is documented by CBS Procurement.  There is a supplier complaints process - we have made a recommendation for this to be strengthened further).



## Appendix 16: Comparison between the Government of British Columbia (B.C.) and CBS transition processes

Government of B.C process for transitioning patients to biosimilars	CBS process for transitioning patients following the 2017-2018 RFP
Transition occurred over a 6 month period.	Transition typically occurs over a 6-9 month period. In 2017/18, transition extended over a 12-15 month period since contract awards were announced 6 months prior to new contract start dates to give hospitals 6 months notice to prepare, and for transition meetings to take place with key clinics.
Using available prescription and utilization data to identify prescribing physicians, patient numbers and prescribing pharmacies.	See Finding under Formulary Management - <i>CBS would benefit from more Member utilization data to inform its transition planning and execution.</i>
Targeted consultations with physician and pharmacy associations and groups over a six week period.	CBS targets and consults with impacted physician and nursing organizations (as well as impacted Members). This targeting is largely through CBS' awareness of stakeholders that would be impacted by the transition.
Developing targeted mailing material and patient information sheets for physician, pharmacy and patient use, in addition to publishing materials online.	CBS published Customer Letters and PPP Transition Newsletters on the blood.ca website. CBS also held webcasts for impacted physician and nursing organizations.
Presentations to patient groups with opportunities for feedback and sessions to provide responses to this feedback.	CBS provided transition updates at PTBLC and NAC meetings. There were patient updates via Customer Letters and the PPP Transition newsletters mentioned above.  There were also transition meetings between CBS, the manufacturer, physicians, nurses, and patient groups to discuss all transition related concerns. CBS participated in cross-country Subcutaneous Immunoglobulin (SCIg) patient meetings in support of the Canadian Immunodeficiencies Patient Organization (CIPO) to address questions.
Published reporting and metrics online on physician visits and the number of patients that had been transitioned.	Customer Letters and PPP Transition newsletters included reporting on inventory levels for the products being replaced but not on the number of patients transitioned.

## Appendix 17: ASC project benefits tracking

#	Realization Measure	Baseline (where known)	Realization (Target)	Realization (Actual)	Status
1	Reduction in non-conformances	0.92%	0.90%	0.71%	Target Achieved
2	Reduction in Audit Observations / Post Audit Observation Retrievals	Health Canada 22 in the period November 2011 to November 2012	< 1 safety observations	2 <sup>43</sup>	Target Achieved
		Corporate audits Error rate for internal RD audits is 4-5% in December 2012. The critical error rate was 0.71%	Reduce the critical error rate to < 0.5%	0.09%	Target Achieved
		Associated product retrievals from these corporate audits would be < 24 units or 0.6%	Product Retrievals <24 units	4 Retrievals	Target Achieved
3	Labour Hours per Unit		Nationally 1.26 (reduction 0.29)	Budget 2018-19 LHU 1.33	Major deviation from target
4	Donor time in system (DTIS)	52 minutes average	< 48 minutes average DTIS by clinic (decrease by 4-6 mins)	39.6 minutes average	Target achieved
5	Reduce costs of paper records		\$136,000	\$136,000	Target achieved
6	Enhance donor experience	Donor satisfaction survey 1. Top box donor satisfaction score on wait time is currently 42% 2. Donor Satisfaction survey in Spring 2013 - 7% donors report a donation time of one hour or less. 3. Donor satisfaction survey Spring 2013 - 48% say donation time has not changed.	1. Top box donor satisfaction score on wait time 42% 2. Donors reporting a donation time of one hour or less were not measurable as this is no longer a question on the survey. 3. Donors indicating donation time has not changed 48% combined with perception of decrease in time.	1. Winter 2017 survey Top box donor satisfaction score on wait time was 49%. 3. Donors indicating donation time has not changed (was 30%); Decreased somewhat or a lot is 43%.	Target achieved
7	Staff Satisfaction for Clinic Staff	Implementing automation will enhance the user experience for employees	No target established	2016 Staff Engagement Survey which gathered survey input in October 2016. There was an increase in overall staff satisfaction of 3% to 75% from the previous year's measure.	Target achieved

<sup>43</sup> The measure Health Canada Safety observations was re-baselined to <2 in the project plan.

## Appendix 18: Donor Experience project benefits tracking

Benefit Description	Realization Measure	Baseline	Realization Target	Realized Benefit Measure (Jan 2020)
<b>Donor Experience</b>				
Improved donor satisfaction	Top 2 Box score (9,10 out of 10)	Average donor satisfaction at end of March 2019 for the previous 4 quarters	Consistently achieve 75%	81% <sup>44</sup>
Increased donor retention for both new and existing donors	Retained donors	Average donor satisfaction at end of March 2019 for the previous 4 quarters	74% <sup>45</sup>	73%
Improved Net Promoter Score (NPS)	NPS	Average NPS at end of March 2019 for the previous 4 quarters	75 points or more	85 points
Reduction of Net Promoter Score variances between regions	NPS	Average NPS at end of March 2019 for the previous 4 quarters	Variance of 6 or less	<4
<b>Brand Renewal</b>				
Attribution of all scope of activities	General public and donor perception of being active in blood and plasma	Blood Unaided: 33%	Blood Unaided: 36%	Blood Unaided: 38% <sup>46</sup>
		Plasma Aided: 41%	Plasma Aided: 46%	Plasma Aided: 40%
Be competitive, enhance differentiation perception from competition	General public unaided brand awareness (Increase general public perception to reduce historical knowledge of Red Cross's involvement with blood donations)	31% CBS 32% Red Cross Baseline (1%)	Change to > 15 % Red Cross.	11%

<sup>44</sup> The NPS and Donor Satisfaction results were obtained through the donor feedback system which sends surveys to all CBS donors.

<sup>45</sup> The donor retention target was adjusted from 82 per cent to 74 per cent to account for factors unrelated to donor experience, including donation interval changes and short-term impact due to moving donor centres to new markets.

<sup>46</sup> These measures were updated to reflect the average of the 12-month period prior to the launch of the renewed brand which aligns more closely with general brand management practices. The realization score represents a realization average in the table and is based on a 12-month rolling average which is reported quarterly. The most recent quarter's results, 2019-20 Q3, are included in the report as 2019-20 Q4 had not yet closed.

## Appendix 19: Overview of Committees Supporting the Governance Model

A description of the scope of each Committee supporting the Canadian Blood Services' governance model is provided below.

Safety, Research and Ethics Committee	Governance Committee
Oversees issues related to maintaining and improving Canadian Blood Services' operations with respect to the safety and quality of products and clinical services, donor safety, security of supply, research and ethical responsibility. Additionally, this Committee oversees the program of haemovigilance, the quality management system, matters related to third party regulatory and quality audits and accreditations, and matters arising from the Centre for Innovation.	Ensures the Board of Directors and its Committees are operating in ways that promote effectiveness, efficiency, and enable transparency; ensures the BoD is operating independently of Management; and oversees both CBS' risk management process and Board and Director performance evaluations.
Talent Management Committee	Finance and Audit Committee
Oversees CBS' talent management policies, along with CEO performance management and compensation and benefits. Oversees labour relations issues and occupational health and safety matters. Additionally, this Committee approves the Executive Management Team's compensation adjustments, reviews (annually) the CEO succession and the succession plans of the Executive Management Team and oversees the CEO's performance management of the Executive Management Team.	Reviews CBS' financial forecasts to ensure compliance with established budget; advises the BoD on CBS' financial affairs; and oversees CBS' relationship with their external auditor and matters related to its internal auditor.
National Liaison Committee	Scientific and Research Advisory Committee
Oversees CBS' relationship with the recipient and user stakeholder community; facilitates and promotes communication between CBS and pertinent external organizations; and engages the stakeholder community to gather input on the blood system, key policies, and areas of CBS' responsibility.	Provides advice and recommendations to the CEO on matters concerning the safety of the blood system in Canada (e.g., safety and efficacy of blood, blood products and their alternatives; emerging risks and issues impacting the integrity of the national blood supply system on research and development matters at CBS).
National Advisory Committee	
Collaborates with and provides advice on the utilization management of blood and blood products and transfusion medicine practice, to the provincial and territorial Ministries of Health and CBS.	

## Appendix 20: Assignment of Governance Responsibilities

The table below identifies the ideal core governance responsibilities and the recommended assignment thereof by leading practices to enable an effectively functioning corporate governance model. In addition, the table identifies the key CBS governing parties that own identified governing duties responsibilities.

Governance Responsibility	Owner of Responsibility	
	Leading Governance Best Practice	CBS
Selecting the CEO	BoD	BoD
Setting the “tone at the top” and laying the groundwork for the corporate culture	BoD	BoD
Approving the Corporate Strategy & monitoring implementation of Strategic Plans	BoD	BoD
Setting the organization's risk appetite, reviewing and understanding the major risks, and overseeing risk management processes	BoD	BoD / CEO & EMT
Focusing on integrity and the clarity of organization's financial reporting and performance disclosure	BoD	BoD
Allocating capital: referring to the Board's provision of meaningful input and decision-making authority regarding the organization's process of allocating its financial resources (e.g., with a view to allocating resources to maximize results/outcomes).	BoD	BoD / CEO & EMT
Overseeing annual operating plans and budgets	BoD	BoD
Nominating the BoD Directors and Board committee members; overseeing effective corporate governance	BoD	Members & BoD
Overseeing the compliance program	BoD	BoD
Business operations	CEO & Management	CEO & Management
Strategic planning	CEO & Sr. Management	CEO & Sr. Management
Capital allocation (referring to the provision of recommendations to the Board on the capital allocation of the organization's financial resources)	CEO & Sr. Management	CEO & Sr. Management
Identifying, evaluating and managing risks	Management	BoD & Management
Production of accurate and transparent financial reporting and disclosures	Management and CEO & CFO	Management and CEO & CFO
Development of annual operating plans and budgets	Sr. Management & BoD	CEO, EMT / Divisional Leaders, & BoD
Selecting qualified management, establishing an effective organizational structure, and ensuring effective succession planning	Sr. Management	EMT / Divisional Leaders
Business resiliency - part of risk management, this includes items such as business continuity, physical security, cybersecurity, crisis management	BoD & Management	BoD, EMT & Management



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