

MANAGEMENT RESPONSE TO PERFORMANCE REVIEW 2019-2020

2020-10-08
(2021-01-28 Reformatted)

Public (P)

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Acknowledgements

Canadian Blood Services acknowledges PwC for their diligent effort in conducting the 2019-2020 collaborative performance review. We also extend our appreciation to the provincial/territorial representatives who participated on the performance review steering committee and working group, and the members of the expert panel.

Purpose

This document is written in response to the 2019-2020 collaborative performance review final report of May 2020. This response does not try to duplicate what is written in the report. For a full understanding of the findings, recommendations and Canadian Blood Services' response, readers are referred to the report noted above.

Introduction

Canadian Blood Services is responsible for ensuring Canadian patients have safe, reliable access to the high-quality blood, plasma, stem cells, and organs and tissues they need. To do this, we undertake a broad range of activities in four areas:

Blood for Life

We collect, test, manufacture and distribute blood and blood products, including red blood cells, platelets and plasma. We also provide diagnostic laboratory testing services in some provinces.

Plasma for Life

We collect plasma from unpaid volunteer donors in Canada, some of which is used 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 plasma protein products (PPPs). We then distribute approved PPPs to hospitals in Canada (excluding Quebec) for the treatment of immune disorders and diseases such as hemophilia.

Stem Cells for Life

We operate several programs that support better outcomes for patients living with the many diseases and disorders that can be treated with stem cell transplants. We collect umbilical cord blood to manufacture stem cells through our cord blood bank. We operate a robust national registry of adult stem cell donors and participate in an international network of donor registries.

Organs and Tissues for Life

We manage 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 (OTDT) community, we develop leading practices, support professional education and public awareness activities, and collaborate on new ways to share data on the performance of the OTDT system in Canada.

Governance

Canadian Blood Services was founded as a not-for-profit charitable organization through a memorandum of understanding between the federal, provincial and territorial governments (except Quebec). Our governance structure was designed to ensure vigilant oversight of the organization's management and operations while protecting the independence of Canada's blood system. We are empowered to make decisions based on the best available medical and scientific evidence.

The operations of Canadian Blood Services are funded by provincial and territorial governments, whose ministers of health collectively approve our annual budgets and three-year corporate plans. In addition to funding from these governments, we receive federal funding that supports our research and development activities, as well as our role in organ and tissue donation and transplantation. We are regulated by Health Canada through the federal Food and Drugs Act.

The provincial and territorial ministers of health act as members of the corporation under the Canada Not-for-profit Corporations Act, electing our board of directors. The board in turn is responsible and accountable for the overall stewardship of Canadian Blood Services. Directors are elected to oversee the management of the organization. The ultimate goal of this oversight is to ensure the long-term safety and effectiveness of Canada's system of blood, plasma, stem cells, and organs and tissues; the quality and the safety of the products and clinical services we deliver; and the relevance and efficacy of the various other activities undertaken by our organization.

The collaborative performance review of Canadian Blood Services completed in 2013 recommended that we continue working with provincial and territorial governments to develop a national accountability agreement (NAA) aligned with the legislative requirements of all jurisdictions. In 2018–2019, we reached an important milestone: a draft agreement between our organization and the provincial and territorial governments that fund our operations. Consistent with and complementary to the 1998 memorandum of understanding through which Canadian Blood Services was created, the NAA clarifies collective accountabilities and deliverables, and eliminates the need to negotiate bilateral agreements with individual provinces and territories.

At the same time, the NAA recognizes that Canadian Blood Services is the owner and operator of the national blood supply system, with authority and complete management discretion for operational decisions.

Background

Conducting regular performance reviews is consistent with our principles of transparency, accountability, continuous improvement and good governance. As agreed by Canadian Blood Services and the provinces and territories (PTs), the NAA stipulates that a performance review will be conducted every five to seven years. Canadian Blood Services was pleased to collaborate in the performance review, the purpose of which is to help bring about improvements in the system. As such, we welcome the resulting recommendations.

Method

A joint steering committee, comprising representatives from government and Canadian Blood Services, was formed to oversee the review. Chaired by the deputy minister of health from Prince Edward Island, the steering committee also included Ontario's deputy minister of health, the associate deputy minister from British Columbia, and Canadian Blood Services' chief executive officer, chief financial officer & vice president, corporate services and vice president, general counsel & corporate secretary. The steering committee created a joint working group to manage the review's day-to-day activity. Co-chaired by officials from Prince Edward Island and Canadian Blood Services, the working group also included officials from Ontario and British Columbia.

In the summer of 2019, the working group, in consultation with all PTs, created a request for proposals (RFP) and invited proposals to conduct the review. PwC was selected in November 2019. The review commenced in December 2019 and concluded in May 2020. An independent expert medical and industry advisory panel advised the PwC team on technical aspects such as system structure and delivery, quality and safety, supply and demand management, technology enablement, industry trends and future outlook.

The review covers the period from April 1, 2012 to March 31, 2019. Its scope focused on the two major product lines operated by Canadian Blood Services: fresh blood components and plasma protein products. Key to the effective operation of the product lines are four critical areas of activity that underpin the safety, sufficiency, and effectiveness of the products and services delivered: the quality management system; enterprise risk management; productivity and efficiency, and governance. These areas were also included in the scope of the review. Finally, two strategic initiatives were reviewed: 1) automated supply chain, which was introduced to achieve gains in quality, productivity and the overall donor experience; and 2) the donor experience/brand renewal initiative.

Although the final report covers the items described above, the review was not a financial audit of the organization, nor was it a safety inspection or regulatory audit. The review does not include Canadian Blood Services' captive insurance corporations, Canadian Blood Services Insurance and Canadian Blood Services Captive Insurance Company Limited, or research and development, all of which have been covered in separate reviews.

As part of our commitment to good governance and transparency, we will share the review—and our management response to the review—on www.blood.ca after both are tabled at the annual general meeting of members in the fall of 2020.

Overview of Recommendations

We believe the report's most important finding is that we have performed well, ensuring the safety of the national blood supply system and meeting the needs of a diverse group of stakeholders. As stewards of the blood system, we have maintained high levels of satisfaction amongst stakeholders. During the review period we strengthened our quality management culture, while significantly reducing costs to the system. We are proud of our accomplishments.

In total, PwC made 59 recommendations (note that four recommendations were duplicated in the report for ease of reading). Many of these are externally focused – for example, sharing of hospital and other relevant utilization data with Canadian Blood Services to enhance demand

forecasting. Fourteen of the recommendations are jointly directed at Canadian Blood Services and the provinces and territories. Such recommendations relate to collaboration to improve system performance, developing agreed upon processes to improve utilization management of plasma protein products, and devising a strategy to increase board diversity.

Internally focused recommendations pertain to increasing the effectiveness and efficiency of the organization, many of which are already underway or planned such as:

- front-end automation of the testing process;
- increasing Canadian plasma sufficiency;
- continuing to evolve the quality system;
- automation of hospital product ordering.

We are pleased that the review found the blood system and related activities to be safe and well run, and that Canadians continue to have trust and confidence in the system. At the same time, we acknowledge there are areas for improvement. We agree broadly with these findings and recommendations and are committed to continuing to work with governments to improve the entire system.

Approach to Our Management Response

In order to respond effectively to the report, we have grouped related recommendations into the following categories framed within our value proposition:

- i. Improving patient outcomes
 - Supply and demand forecasting
 - Utilization management
 - PPP formulary management, including PPP procurement
 - Plasma sufficiency
- ii. Enhancing system performance
 - Donor acquisition and retention
 - Quality and safety
 - Stakeholders
 - Technology
 - Project management
 - Governance
 - Enterprise risk management
- iii. Optimizing cost efficiency
 - Productivity and efficiency
 - Cost reduction
 - Organizational design

Appendix 1 offers a consolidated recommendation-by-recommendation response.

1. Improving Patient Outcomes

1.1 Supply and Demand Forecasting

RECOMMENDATIONS 19 & 20

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

Response: Canadian Blood Services currently has direct access to distribution data only. To improve both PPP demand forecasting and utilization management, the ideal data set would include specific patient information such as age, weight, and diagnosis; disease information such as severity or sub-type; treatment information such as dose, frequency, and duration; outcomes data such as hospitalizations, bleeds, and other acute events; and quality of life measures such as missed days of work or school. We are taking the first steps toward expanding our data set (see recommendation 33 as an example) but having direct access to comprehensive utilization data will be a multi-year process. Meanwhile, we are constantly scanning the environment and working with natural partners such as patient registries, provincial blood offices, and hospitals. Collaboration with the PTs is important as we move forward, particularly their support for Canadian Blood Services having access to patient-level data.

For fresh blood, forecasting accuracy is at an exceptionally high level for a biologics manufacturing company. This observation is less about “forecasting accuracy” and more about utilization “understanding” and, perhaps, management. Inappropriate utilization of fresh blood components is not occurring, by all the available measures. It is accepted that there can be marginal benefits to balancing supply / demand with improved demand sensing. This is particularly true within the current dynamic of the COVID-19 pandemic, a period not covered by this performance review.

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.

Response: The PPP forecasting process already includes consultation with the PTs to gather intelligence which is included in the forecast. Our forecast is shared with the vendors so they can develop their supply plan and vendors will comment if our forecast does not align with their own forecast. Access to clinicians and patient groups is more challenging and needs to be improved. Canadian Blood Services has undertaken various initiatives to improve access to this expertise, e.g. the hereditary angiodema (HAE) forum held in December 2019 and a planned Ig

forum for 2020. More work is required to explore who should be part of these advisory groups, the frequency of meetings and how they should be consulted.

1.2 Utilization Management

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.

Response: Canadian Blood Services' role has historically been focused on monitoring utilization and highlighting best practices. However, there are significant opportunities to positively impact blood product utilization in Canada. Canadian Blood Services is eager to jointly develop goals and initiatives with PTs to identify and address these opportunities, and to ensure collaboration and an increased commitment from our hospital partners.

These opportunities can include the potential to enable hospitals to more easily provide inventory visibility and utilization data. This would begin with extensive and broad stakeholder engagement. Inventory reporting on blood products by hospitals is currently voluntary and very manual. PT support for investing in technological solutions, that are known to exist, would be mutually beneficial in our shared goal of improving utilization management.

Canadian Blood Services will draft a proposed plan, focused on O-negative red cell units, to table with PTs for discussion by end of fiscal 2020-2021.

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.

Response: Customers have traditionally viewed Canadian Blood Services as a distributor of products and have therefore been reluctant to share patient-level data. However, as our additional role as a formulary manager has evolved, we have become part of the patient's circle of care, and we require access to patient-level data for activities such as adjudicating coverage criteria. We also require patient-level data to properly manage the PPP formulary, monitor demand, and predict utilization (see recommendation 19). Full implementation will be a multi-year process and the goal would be to partner with pilot sites as a first step. Depending on how

this strategy develops (stakeholder input, customers' needs, etc.), our implementation plan could include working with specific jurisdictions, or it could roll out with specific specialties or types of products, groups of hospitals that use the same data system, specific health professionals, or other options. As we continue to work towards having access to more data, we will continue to make the necessary connections with other initiatives (e.g. linking to hospital laboratory information systems) that can impact Canadian Blood Services.

RECOMMENDATION 32

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. 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 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.

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.

Response: Canadian Blood Services agrees with this recommendation and we note that it is complemented by recommendations 19, 25 and 33. Provincial and territorial governments have taken important steps towards implementing varying utilization management activities within their jurisdictions but there are opportunities for national coordination. Canadian Blood Services has been working with several provincial blood coordinating offices to share information on utilization management initiatives and best practices. We have presented and proposed initiatives for a coordinated and collaborative approach to utilization over the past several years and agree this remains an essential system need. Collaboration with PTs to complete a scan of PPP utilization management activities across the country would enable us to determine if these activities could be expanded further to improve utilization outcomes. While our role has traditionally been focused on monitoring utilization management, we believe our role as the national blood authority allows us to make important contributions to managing utilization as well.

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.

Response: A thorough review of the PPP named patient program (NPP) is required to strengthen utilization management. We are in the process of converting the NPP into an updated special authorization program (SAP) to ensure optimal use of products as well as assessing how this program can be supported through efforts to modernize the distribution system at Canadian Blood Services. The first steps of mapping the current NPP and developing an online formulary are underway. The updated SAP will support online ordering and streamline the adjudication process which will allow scalability while ensuring patients have timely access to the products they require. Both distribution modernization and an updated SAP will support the attainment of detailed data which will strengthen utilization management.

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.

Response: See response to Recommendation 27 (p.9).

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.

Response: Canadian Blood Services will explore ways to better track partial use of PPPs. As part of a refresh of the architecture of the current hospital disposition reporting for fresh blood components, we will consider how we could improve reporting on PPP use and partial use. Further, for products used in hospitals and medical day clinics, organizing scheduled clinics for patients would allow pooling of doses and reduced wastage. This is common practice in oncology and often coordinated through the pharmacy. Canadian Blood Services is looking to modernize its distribution of PPP to patients, which may include distribution through pharmacies.

1.3 Plasma Protein Products Formulary Management

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

Response: Several initiatives are already underway that are expected to help manage the ongoing increased utilization of C1-inhibitors including:

- Coordinating the listing of Haegarda with lanadelumab (Takhzyro)
- Modernization of the distribution system at Canadian Blood Services
- Updated special authorization program
- Creating a registry for HAE patients to track utilization

By taking a broader system view and coordinating the introduction of Haegarda on the Canadian Blood Services formulary with the listing of lanadelumab on the provincial/territorial formularies, we will provide better value to the healthcare system while balancing access to products for patients. Work on modernizing the distribution system and updating the special authorization program is underway. This will enable improved gatekeeping measures for all products, including C1-inhibitors. It is anticipated that these gatekeeping measures would include assessing product indication and dose, adjudicating special authorization criteria, and would result in the attainment of detailed data required to monitor utilization more effectively in the long-term.

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.

Response: Canadian Blood Services continues to work with PTs to update the current criteria which is used to determine what product categories are included on the PPP formulary, and we support the development of a collaborative process for periodic review of the criteria moving forward. Inconsistency in a common understanding or application of the existing criteria has resulted in delays in decision-making and confusion among stakeholders on when a review can be conducted for a new category. Further, the existing criteria is potentially inadequate to

address the emergence of new types of therapies, including those likely to be used in personalized medicine applications.

In 2019-20, Canadian Blood Services, PTs and the Canadian Agency for Drugs and Technologies in Health (CADTH) established an interim product selection process for the Canadian Blood Services formulary which builds on the strengths of both Canadian Blood Services and CADTH to provide stakeholders with an objective, transparent, evidence-based review process for plasma-related drugs. This interim process will be in place while Canadian Blood Services, CADTH and PTs continue to discuss and finalize the process for the review of plasma-related drugs into the future.

While the interim process is underway, the criteria at the front end remains to be determined. Canadian Blood Services has initiated discussions with the PT blood liaison committee seeking to update the criteria and has presented recommendations for revised criteria to the PTs and the national advisory committee for blood and blood products (NAC). Canadian Blood Services' recommended criteria has now incorporated input from both the PTs and NAC. We are committed to further collaborative discussions until consensus on the updated criteria can be reached.

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

Response: This recommendation addresses the value that can be brought to bear by Canadian Blood Services and public payers in assessing the impact of a new product listing on the patients, PPP formulary, and the overall health system. As part of the formulary modernization, we recently developed an interim plasma protein product review process, in partnership with CADTH, to review new categories. This process analyzes the health system cost from the Canadian public payer perspective each time a product is being reviewed. Further, it engages patient groups to understand their value for the treatment, experiences with the disease, and how access to new products impact them. The next step will be to modernize the brand review process to align both processes. As part of the modernization, we will incorporate the elements of the interim review process that will calculate feasible health system costs and assess the impact on patient experiences of new brand additions.

RECOMMENDATION 36

CBS should work with PTs to evaluate the broader use of alternative pricing strategies to determine if these 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.

Response: Canadian Blood Services has been working with an external consultant to determine how facets of value-based procurement can be used in the next PPP RFP, scheduled to be issued in 2021. Canadian Blood Services will review this with PTs.

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.

Response: Canadian Blood Services is committed to an RFP process which is fair and transparent to all, and which supports fairness, objectivity and integrity of process. Canadian Blood Services is interested in exploring options to further enhance this process with an independent fairness monitor in the next PPP RFP, scheduled to be issued in 2021.

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.

Response: Canadian Blood Services will include the documenting and publishing of the complaints process in the next PPP RFP, scheduled to be issued in 2021. In doing so, Canadian Blood Services it will include:

- the format in which complaints are to be communicated to Canadian Blood Services;
- points of escalation for the complaint;
- timeframes for a Canadian Blood Services response to the complaint and the format in which the response will be communicated; and
- options for redress should a supplier still feel dissatisfied.

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.

Response: Canadian Blood Services will discuss with PTs the appropriate process needed to obtain PT input on impacts of possible formulary changes and other factors that should be considered as part of the RFP decision making. Canadian Blood Services will include this input step in the next PPP RFP, scheduled to be issued in 2021.

1.4 Plasma Sufficiency

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.

Response: The long-standing global plasma supply challenges highlighted by PwC in the performance review report echo the warnings Canadian Blood Services has been alerting governments to over the past several years. Since 2018–2019, immune globulin (Ig) has been

in a shortage globally (the U.S Food and Drug Administration declared a severe shortage in 2019), as demand continues to outstrip supply and with no indication as to how long the situation will last. This tightening of Ig supply has now approached a critical level of urgency due to COVID-19, which has disrupted global supply chains, exposed domestic vulnerabilities, and caused ripple effects that will take years to address.

Most recently, vendors of Ig, the most widely used plasma-derived treatment, are struggling to “balance” international market demands and commitments. These vendors have advised that additional Ig can only be offered at significantly higher unit prices and at lower volumes moving forward. While Canadian Blood Services is implementing necessary short-term strategies to address and manage the immediate supply and price impacts due to COVID-19, the longer-term and more sustainable solution remains to reduce our reliance on the global market by substantially increasing Canada’s domestic plasma supply, above and beyond the three ‘proof of concept’ plasma centres that received funding approval prior to the pandemic.

While these three centres are an important step in the right direction, it was always known that they alone could not increase source plasma sufficiency for the country, given the continued annual growth of Ig usage. At best, they would hold the sufficiency rate steady.

At the end of the 2019-2020 fiscal year, the plasma sufficiency rate for Ig in Canada (excluding Québec, which is at approximately 22 per cent) sat at 13.7 per cent. Now, with pandemic related impacts and ongoing usage increases, the sufficiency rate has dropped further, below 13 per cent. This alarming trend is moving Canada further away from the 50 per cent minimum level that risk mitigation modelling is advising for the country. As an immediate risk response, Canadian Blood Services must begin collecting substantially more plasma. We must ensure Canada has enough domestically sourced and controlled supply of starting raw material (human plasma) to meet the needs of patients whose lives depend on Ig manufactured from this plasma. And given the long lead time (plasma collection centres take time to establish and bring to full operating capacity), the urgency of additional response in a post-pandemic environment is that much higher.

In summary, with COVID-19, the shortage scenario is no longer on the horizon; it is at a precipice. With the risk escalation articulated above, the long lead time to ramp up supply, and the continued uncertainty of these unprecedented times, Canadian Blood Services, as the accountable body responsible for security of Ig for Canadian patients and for risk consequences and mitigation measures, is planning to open eight additional plasma collection centres by 2023-2024 to increase sufficiency to approximately 22 per cent as soon as possible (this would align to Quebec’s level and current standard of care), on the way to bringing Canada closer to the overall target of 50 per cent self-sufficiency.

Further, in addition to securing and improving domestic supply, Canadian Blood Services’ increased plasma collection and manufacture of Ig is highly likely to be more financially favourable for the country, with Ig made from Canadian Blood Services’ collected plasma forecasted to be less costly than commercially sourced products, given the current price shocks on the global market which can be expected to last for years to come.

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.

Response: See response to Recommendation 7 (p.15).

2. Enhancing System Performance

2.1 Donor Acquisition and Retention

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.

Response: Healthcare agencies are part of an outward and forward-facing segment that we serve and do not have insight into donor relations and supply chain activities. We will continue to take the concerns and feedback of healthcare agencies into consideration as we develop our donor recruitment and retention plans and will continue to collaborate with other blood operators to understand and apply best practices in donor acquisition and retention. This represents a challenge facing all blood operators.

RECOMMENDATION 23

CBS should investigate the feasibility of adding new functionality to their 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.
- Enhance Customer Relationship Management capabilities to contact donors who do not complete their appointment bookings on the 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

Response: Providing deferral information to the donor at the time of appointment creation or upon completion of the donor questionnaire requires integration with our blood management system, eProgesa, which is the system of record for donor deferral information. Management acknowledges the benefit of providing donors with more information on deferral criteria prior to attending a collection event and this capability will be delivered in a future software release.

2.2 Quality and Safety

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.

Response: Work on benchmarking of safety and quality measures was started in 2018 with international partners through the Alliance of Blood Operators (ABO). The ABO benchmarking working group continues its work on quality performance metrics.

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.

Response: Canadian Blood Services is already in the process of assessing all the curricula in its quality education and training program (QETP) with regard to the relevance, currency, completeness and delivery of each course and of the program as a whole. This includes the need for refresher training on a yearly basis or other frequency. The QETP is intended to provide employees with an understanding of the importance of quality in all that we do and education on the quality management system and the role it plays in supporting the pursuit of quality and safety. The assessment and a plan forward are expected by the end of 2020-2021. The use of role personas will be utilized in the revised quality education and training program wherever feasible.

Additionally, a working group has been organized to identify and implement strategies to improve the effectiveness of training. As part of their work, the group will assess the opportunities to further embed the use of role personas.

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.).

Response: The working group organized to improve the effectiveness of training will be tasked with strengthening the incorporation of adult learning principles into training. Consideration will be given to introducing the requirement to perform learning needs assessments, the outcomes of which will influence training strategies and the use of training modalities that best satisfy the identified learning needs.

With regard to the use of coaches and mentors, this is an approach already in use by Canadian Blood Services. The organization currently has an instructional training program in place which includes the roles of coach and mentor and defines requirements that must be met by individuals who fulfill these roles. Within the program, coaches and mentors are referred to as “on the job trainers”. This program will be revamped in 2021-2022 including the requirements for coaches and mentors.

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.

Response: For many years, executives have had quality objectives in their direction letters and core quality measures in their performance plans. Some other senior leaders, depending on their role and accountability, also have quality objectives and measures in their performance plans. We have not systematically made this a requirement for all senior leaders, irrespective of role, and rather have been more selective about who needs to be held accountable for them. Quality objectives and measures are core to all operational and strategy discussions and are discussed routinely in a number of executive and leader forums (quality management system review meetings, executive business review meetings, divisional meetings, etc.). These discussions involve leaders from across the organization, including those that may not have specific objectives and measures in their performance plans.

This recommendation needs to be considered in the broader context of the individual’s role, e.g., their ability to influence the movement of these measures. We are currently in the process of revisiting our performance management process and this recommendation will be taken into account.

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.

Response: Canadian Blood Services will continue to administer the survey referenced in the report every one to two years to assess the organization’s culture of quality over time. The next survey will be conducted during 2020-2021, dependent of the impact of the COVID-19 outbreak

on organizational priorities. The survey contains questions, under the employee ownership section, about employee comfort in raising safety and quality issues.

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).

Response: The transformation of our quality management system has been ongoing for many years and continues to be a strategic objective for Canadian Blood Services. In 2014, the "Link program: strengthening and maturing our quality management system and culture" was launched with initial focus on activities related to product manufacturing and the provision of clinical services. The intent has always been to extend, in time, the scope of the quality management system to the rest of the organization. This scope expansion will be undertaken after the organization has addressed all the key quality management system improvements currently in scope areas.

Following the end of the review period, Canadian Blood Services automated quality event management and has started the implementation of a learning management system. This is planned to be completed in 2020-2021. Work has also started on automating change control and document management and implementation is scheduled for 2021-2022. Canadian Blood Services is also developing an approach to manage low risk non-conformances that should be implemented in 2021-2022 and a product lifecycle management process that includes sensing mechanisms and processes to understand customers' current and future/evolving needs and raise them to be addressed by the organization; this should be implemented in 2021-2022.

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.

Response: Canadian Blood Services believes the targets are reasonable, achievable and consistent with expectations of a biologics manufacturer. Discussions are ongoing to determine actions that will address root causes for the performance gaps.

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.

Response: Canadian Blood Services intends to conduct an assessment of its CAPA process now that it has been stabilized. This should be completed by end of 2020-2021. As part of the changes that might be made to the program, a requirement for "spot checks" will be introduced.

2.3 Stakeholders

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.

Response: Canadian Blood Services will proceed with current plans for a stakeholder strategy refresh including crossover with donor experience and hospital experience work.

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

Response: A cycle of review and action on hospital feedback (via the joint medical affairs & innovation, integrated supply chain, and quality & regulatory affairs divisions quarterly meetings) is in place; however, the follow-up mechanism and framework can be improved, including a prioritization mechanism. This will be installed once we exit the current pandemic crisis.

RECOMMENDATION 28

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

Response: Canadian Blood Services had two separate and interdependent pilots operating in this domain of our business – a vendor managed inventory program in Newfoundland with 13 hospitals and an on-line ordering program with four key hospitals in British Columbia. The latter program is being expanded to include additional hospitals that represent, in total, 80% of British Columbia’s volume. We are using this pilot to ensure that the ultimate on-line ordering process and portal is informed by hospital wants and needs. In addition, we are making internal

adjustments to ensure that the solution is scalable for Canadian Blood Services. Online ordering will evolve to apply primarily to “non-routine” orders in the order placement process, though the features and options of the system (order status updates, etc.) will continue to benefit all product orders. Capability to manage standing (“routine”) orders through vendor managed inventory processes will be developed. This will significantly decrease the administration process in the hospital blood banks.

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.

Response: Providing new PTBLC representatives with an orientation to familiarize themselves with Canadian Blood Services and the various roles and responsibilities within the national blood system as outlined in the national accountability agreement is important to ensure the effectiveness and efficiency of the committee.

In collaboration with the PTBLC, Canadian Blood Services will develop a formal orientation program for new PTBLC representatives which provides a thorough review of the national blood system and the specific role of the PTBLC.

2.4 Technology

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.

Response: Management will implement a more formal practice to ensure technology projects in excess of a material threshold will include a documented review of options (both technology and project delivery) to fulfill project requirements. These new practices will include external consultation (e.g. third party advisory firms, peer organizations, etc.) as appropriate.

2.5 Project Management

RECOMMENDATION 44

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

Response: This recommendation stems from a review of the automated supply chain (ASC) project which preceded establishment of the current enterprise project management office (ePMO) corporate standards. Since that time, the business case template has been adapted to include a robust risk section that includes rating risks as well as ongoing risk review processes.

All projects in the corporate portfolio subject to the Canadian Blood Services' project gating process contain detailed risks and associated ratings.

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.

Response: The enterprise project management office will examine a process by which the appropriate project benefits can be identified for integration into operational performance measures on a forward-looking basis.

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.

Response: This recommendation stems from a review of the ASC project which preceded the current enterprise project management office corporate standard. The business case under the current enterprise project management office not only identifies the benefits measures, but also the accountability. This is further reinforced through the benefit realization stage and documentation at project close out which delineates accountabilities for operationalization and benefit realization at a more detailed level.

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.

Response: This recommendation stems from a review of the ASC project which preceded the current enterprise project management office corporate standards. The enterprise project management office has a mechanism by which benefit realization is tracked on a project by project basis via the realization gate stage – the Canadian Blood Services project gating process contains an entire gate devoted to tracking benefit realization. This is augmented by the ongoing portfolio level tracking and reporting on benefits across the corporate portfolio.

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.

Response: The donor experience project was an important initiative for Canadian Blood Services as we worked to implement key activities to engage new and retain current donors throughout the national system. The project was successful in achieving targets, was on time and on budget, and will continue to inform our approach into the future. An outcomes report highlighting the benefits realized was provided to funding governments in March 2020. Donor retention is an area of continued focus and is addressed in recommendation 22 (p.16). Brand KPIs will be reported as part of a brand health index on a go forward basis.

2.6 Governance

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.

Response: Management currently provides information to members on foreign exchange risk, PPP market trends, PPP cost variances and the achievement of planned PPP contract savings through documents such as the corporate plan, the annual report to Canadians, and other formulary and financial updates to members via the provincial territorial blood liaison committee. Management will review how and where this information is reported to ensure clarity for members.

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 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.

Response: The national accountability agreement agreed upon by Canadian Blood Services and all PT ministers of health outlines our reporting requirements to PTs. Schedule B, Reports, Item 6 outlines reporting for major capital projects, more specifically *‘For major capital projects identified in the annual corporate plan, CBS and PT governments agree, that a performance reporting framework will be followed that informs the PT governments of significant performance measures, risks, issues and change requests in a timely manner. Monthly reports and quarterly financial forecasts will include sufficient information and analysis to: communicate risks, issues, strategic decisions and impacts; and assess performance relative to the approved funding (e.g.*

scope, schedule, budget, benefits and service quality levels). The reporting framework will include final budget reconciliation at project completion.'

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 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.

Response: Over the course of 2019-2020, Canadian Blood Services worked collaboratively with PTs to update and revise the board recruitment, nominations and elections framework which is the document that describes the principles and processes followed to recruit and elect directors to the board. The document was endorsed by Canadian Blood Services' board of directors and will be considered by the conference of deputy ministers in September. A key principle included in the refreshed framework is that "the board should reflect a diversity of identities, abilities, backgrounds, cultures, skills, perspectives and experiences that are representative of Canada's population" and that "limits be introduced to the number of terms a director can serve to support greater diversity on the board, including promoting new perspectives, talents and best practices." The principles articulated in the framework reflect the recommendations put forward in the performance review report and will be incorporated into the planning for the 2021 and 2022 board recruitment processes.

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

Response: The director selection advisory committee, co-chaired by the PT lead minister and the Canadian Blood Services' board chair, is responsible for determining the skills, qualifications, and attributes of director candidates to be recruited, with input from the board's

governance committee. While a skills/attributes matrix is completed in preparation for each director recruitment and election cycle, Canadian Blood Services acknowledges the value of ongoing board succession planning and will incorporate this suggestion into its board evaluation and effectiveness process. In addition, a board succession policy will be developed, to guide succession across various board leadership roles, including the chair roles for board committees and pension plan committees; representation on subsidiary boards; as well as the board vice-chair and chair roles. This work will of course be subject to the decision-making authority of the members regarding new director appointments, renewal or non-renewal of the terms of existing directors, and board chair selection.

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.

Response: Canadian Blood Services 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 shared with corporate members throughout the year in alignment with reporting requirements under the national accountability agreement.

Further, the development of Canadian Blood Services' 2019–2024 strategic plan, “Keeping the Promise”, involved a review of the organization’s performance measures. As a next step, Canadian Blood Services will engage with the PTs to review the various performance measures and identify relevant additions or adjustments that would be meaningful to members in terms of related outcomes.

Where applicable, Canadian Blood Services is considering the option of also making measures publicly available to ensure further transparency with all our various stakeholders.

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.

Response: The national accountability agreement agreed upon by Canadian Blood Services and all PT ministers of health outlines our reporting requirements to PTs. In accordance with this agreement, we submit quarterly reports to members and an annual corporate plan. Both reports provide quarterly and rolled-up annual data on key safety indicators. The rolling up of the reported indicators to members to provide year-over-year trends for the last three consecutive years will be provided through the annual corporate plan.

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.

Response: Canadian Blood Services will continue to provide the reporting and support to Members needed for enhanced decision-making, as outlined in our responses to Recommendations 53, 54 and 55 (pages 22 and 26 respectively).

2.7 Enterprise Risk Management

RECOMMENDATION 57

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.

Response: Canadian Blood Services accepts this recommendation related to developing operational risk views. An operational risk view for the fresh blood program was implemented on July 30, 2019, and an operational risk view for PPP was implemented on November 4, 2019. The organization will continue to refine and mature operational risk views across all product/service areas, in support of its integrated business planning process, in which operational performance and risk are analyzed, reported and discussed.

RECOMMENDATION 58

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.

Response: Canadian Blood Services agrees with this recommendation. Risk tolerance is currently reflected in detail in the organization's corporate risk exposure plot. However, Canadian Blood Services will develop an overarching risk appetite statement to serve as a "guidepost" for establishing and confirming risk tolerance thresholds. The organization will also look to leverage more broadly the risk tolerability tools in the Alliance of Blood Operators' risk-based decision-making framework for blood safety.

RECOMMENDATION 59

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.

Response: Canadian Blood Services agrees with this recommendation and will develop a master exercise plan as a tool to establish the complete population of elements which need to be tested periodically and the required frequency of such tests based on a risk assessment. In any given year, this tool will be used to inform the annual exercise plan which will include a minimum number of functional exercises in addition to walk-through and tabletop exercises.

Supply chain critical functions and support activities are standardized across each of our production and testing sites; therefore, separate recovery plans do not appear necessary or desirable. However, as part of our emergency preparedness, sites are guided by the first response program and site-specific guidance which includes emergency contacts and building safety equipment. The organization will review lessons learned from current and future recovery phases of the ongoing COVID-19 business continuity effort, including those related to recovery plans for a facility failure.

3. Optimizing Cost Efficiency

3.1 Productivity and Efficiency

RECOMMENDATION 1

CBS should build on its [collections] productivity gains and further improve its performance.

- 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.

Response: Canadian Blood Services has established a program of excellence within the process management function of the integrated supply chain. This program regularly examines process steps, supported by industrial engineering time studies, to target areas of opportunity. This program also leverages idea exchange and benchmarks with other blood operators around the world. In addition, we continue to leverage the partnership with Toyota production support system to drive continuous improvement across multiple supply chain dimensions, including collections.

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.

Response: Front-end automation continues to be an area of focus for Canadian Blood Services. It has already been installed in the Brampton donor testing site and will also be installed in Calgary after we have transitioned to the new site in 2020. We recognize the possibility of leveraging front end automation technology for diagnostic services and automation of anti-body testing in donor testing.

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.

Response: We are actively engaged in the evaluation of options to understand and legally define the structure and benefits of a group purchasing organization, as one approach to a "consortium".

RECOMMENDATION 4

CBS should build on its [production] productivity gains and further improve its performance.

- 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.

Response: We have established a program of excellence within the process management function of the integrated supply chain. This program regularly examines process steps, supported by industrial engineering time studies, to target areas of opportunity. This program also leverages idea exchange and benchmarks with other blood operators around the world. In addition, we continue to leverage the partnership with Toyota production support system to drive

continuous improvement across multiple supply chain dimensions; most particularly, the genesis of this program was in the realm of production and distribution.

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.

Response: Project costs within statutory financial statements will continue to be reported in the cost categories of staff, medical supplies and general and administrative costs. The national accountability agreement, which was executed subsequent to the performance review, outlines reporting for major capital projects, more specifically *'For major capital projects identified in the annual corporate plan, CBS and PT governments agree, that a performance reporting framework will be followed that informs the PT governments of significant performance measures, risks, issues and change requests in a timely manner. Monthly reports and quarterly financial forecasts will include sufficient information and analysis to: communicate risks, issues, strategic decisions and impacts; and assess performance relative to the approved funding (e.g. scope, schedule, budget, benefits and service quality levels). The reporting framework will include final budget reconciliation at project completion.'* This reporting framework will allow for the segregation of project expenses if required.

RECOMMENDATION 41

CBS should establish a portfolio management approach 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.

Response: The productivity and efficiency program (PEP) includes several elements: specific projects, benchmarking data and reviews, productivity target setting, and instilling a cost-conscious culture. Near the completion of the performance review, Canadian Blood Services implemented an enterprise project management office to provide oversight and improve the management of strategic projects throughout the organization. With these enhancements, a portfolio management approach to track the projects falling under PEP is now in place.

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.

Response: The CI program is a foundational aspect of building the “Canadian Blood Services way”, as defined in our strategic key focus areas for organizational excellence. The program is a total system of improved leadership behaviours, philosophical principles and tools and techniques rather than a series of discrete initiatives with specifically defined benefits. Its success is multi-dimensional and current KPIs for the business will capture its ultimate success (e.g. quality, service, cost, engagement, experience, etc.) We believe an additional framework is not necessary. The program already has a “kaizen strategy” framework that very specifically tracks anticipated benefits for efforts of particular focus at different operating sites over increments of time. In aggregate, these then also build into a complete organizational perspective as noted in the measures above.

RECOMMENDATION 48

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

Response: The productivity improvements associated with the automated supply chain project are well documented and are of a “one time” transformational nature. There is no extended set of benefits associated with ASC and, as such, there is no possibility to track additional benefits. Productivity improvements in the collections environment are numerous and span multiple dimensions.

3.2 Cost Reduction

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.

Response: As part of regular practice, management reviews value for money considerations in the general and administrative category. During the end of the performance review time period, management established an enterprise project management office to bolster in-house project management capabilities. Management is also assessing facility project and real estate management capabilities to ensure facility operations are efficient and effective.

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.

Response: Management has developed a more formal savings tracking application which is being used to track savings associated with contracts established April 1, 2018. This tracking application will be used to assess and track savings on a go forward basis.

3.3 Organizational Design

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.

Response: While Canadian Blood Services has always been responsible for plasma collection in Canada to meet patient need, the establishment of the plasma proof of concept program as a separate organizational unit inside Canadian Blood Services recognizes its status as a necessary and focused operation to increase Canada's plasma sufficiency level (not unlike Hema-Quebec's Plasmavie centres in Quebec). This operation has its own operational and financial targets and dedicated resources to ensure success in increasing domestic plasma supply in Canada. Canadian Blood Services will, however, take this recommendation under consideration, and acknowledges there may indeed be a time when an integration with blood operations is desirable.

Appendix 1

Summary of recommendations and responses

For the convenience of readers, the recommendations and their respective responses are provided in numerical order.

Recommendations and responses

#	Recommendation	Response
1	<p>CBS should build on its [collections] productivity gains and further improve its performance.</p> <ul style="list-style-type: none"> 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. 	<p>Canadian Blood Services has established a program of excellence within the process management function of the integrated supply chain. This program regularly examines process steps, supported by industrial engineering time studies, to target areas of opportunity. This program also leverages idea exchange and benchmarks with other blood operators around the world. In addition, we continue to leverage the partnership with Toyota production support system to drive continuous improvement across multiple supply chain dimensions, including collections.</p>
2	<p>CBS should continue to automate its front-end testing process to support improvements in testing productivity.</p> <ul style="list-style-type: none"> 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. 	<p>Front-end automation continues to be an area of focus for Canadian Blood Services. It has already been installed in the Brampton donor testing site and will also be installed in Calgary after we have transitioned to the new site in 2020. We recognize the possibility of leveraging front end automation technology for diagnostic services and automation of anti-body testing in donor testing.</p>
3	<p>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.</p>	<p>We are actively engaged in the evaluation of options to understand and legally define the structure and benefits of a group purchasing organization, as one approach to a "consortium".</p>
4	<p>CBS should build on its [production] productivity gains and further improve its performance.</p>	<p>We have established a program of excellence within the process management function of the integrated supply chain. This program</p>

#	Recommendation	Response
	<ul style="list-style-type: none"> 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. 	<p>regularly examines process steps, supported by industrial engineering time studies, to target areas of opportunity. This program also leverages idea exchange and benchmarks with other blood operators around the world. In addition, we continue to leverage the partnership with Toyota Production Support System to drive continuous improvement across multiple supply chain dimensions; most particularly, the genesis of this program was in the realm of production and distribution.</p>
5	<p>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.</p>	<p>Project costs within statutory financial statements will continue to be reported in the cost categories of staff, medical supplies and general and administrative costs. The national accountability agreement, which was executed subsequent to the performance review, outlines reporting for major capital projects, more specifically <i>'For major capital projects identified in the annual corporate plan, CBS and PT governments agree, that a performance reporting framework will be followed that informs the PT governments of significant performance measures, risks, issues and change requests in a timely manner. Monthly reports and quarterly financial forecasts will include sufficient information and analysis to: communicate risks, issues, strategic decisions and impacts; and assess performance relative to the approved funding (e.g. scope, schedule, budget, benefits and service quality levels). The reporting framework will include final budget reconciliation at project completion.'</i> This reporting framework will allow for the segregation of project expenses if required.</p>
6	<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"> 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. 	<p>As part of regular practice, management reviews value for money considerations in the general and administrative category. During the end of the performance review time period, management established an enterprise project management office to bolster in-house project management capabilities. Management is also assessing facility project and real estate management capabilities to ensure facility operations are efficient and effective.</p>
7	<p>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</p>	<p>The long-standing global plasma supply challenges highlighted by PwC in the performance review report echo the warnings Canadian Blood Services has been alerting governments to over the past several years. Since 2018–2019, immune globulin (Ig) has been in a shortage globally (the U.S Food and Drug Administration declared a severe shortage in 2019), as demand continues to outstrip supply and with no indication as to how long the situation will last. This tightening of Ig supply has now approached a critical level of urgency due to COVID-19, which has disrupted global</p>

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	<p>processes and integrating them at a community level to drive higher volume and self-sufficiency in this area.</p>	<p>supply chains, exposed domestic vulnerabilities, and caused ripple effects that will take years to address.</p> <p>Most recently, vendors of Ig, the most widely used plasma-derived treatment, are struggling to “balance” international market demands and commitments. These vendors have advised that additional Ig can only be offered at significantly higher unit prices and at lower volumes moving forward. While Canadian Blood Services is implementing necessary short-term strategies to address and manage the immediate supply and price impacts due to COVID-19, the longer-term and more sustainable solution remains to reduce our reliance on the global market by substantially increasing Canada’s domestic plasma supply, above and beyond the three ‘proof of concept’ plasma centres that received funding approval prior to the pandemic.</p> <p>While these three centres are an important step in the right direction, it was always known that they alone could not increase source plasma sufficiency for the country, given the continued annual growth of Ig usage. At best, they would hold the sufficiency rate steady.</p> <p>At the end of the 2019-2020 fiscal year, the plasma sufficiency rate for Ig in Canada (excluding Québec, which is at approximately 22 per cent) sat at 13.7 per cent. Now, with pandemic related impacts and ongoing usage increases, the sufficiency rate has dropped further, below 13 per cent. This alarming trend is moving Canada further away from the 50 per cent minimum level that risk mitigation modelling is advising for the country. As an immediate risk response, Canadian Blood Services must begin collecting substantially more plasma. We must ensure Canada has enough domestically sourced and controlled supply of starting raw material (human plasma) to meet the needs of patients whose lives depend on Ig manufactured from this plasma. And given the long lead time (plasma collection centres take time to establish and bring to full operating capacity), the urgency of additional response in a post-pandemic environment is that much higher.</p> <p>In summary, with COVID-19, the shortage scenario is no longer on the horizon; it is at a precipice. With the risk escalation articulated above, the long lead time to ramp up supply, and the continued uncertainty of these unprecedented times, Canadian Blood Services, as the accountable body responsible for security of Ig for Canadian patients and for risk consequences and mitigation measures, is planning to open eight additional plasma collection centres by 2023-2024 to increase sufficiency to approximately 22 per cent as soon as possible (this would align to Quebec’s level and current standard of care), on the way to bringing Canada closer to the overall target of 50 per cent self-sufficiency.</p> <p>Further, in addition to securing and improving domestic supply, Canadian Blood Services’ increased plasma collection and manufacture of Ig is highly likely to be more financially favourable for the country, with Ig made from Canadian Blood Services’ collected plasma forecasted to be less costly than commercially</p>

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		<p>sourced products, given the current price shocks on the global market which can be expected to last for years to come.</p>
8	<p>CBS and PTs should work together to explore options for managing the increased use of C1 inhibitors. Consideration should be given to:</p> <ul style="list-style-type: none"> • 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 	<p>Several initiatives are already underway that are expected to help manage the ongoing increased utilization of C1-inhibitors including:</p> <ul style="list-style-type: none"> • Coordinating the listing of Haegarda with lanadelumab (Takhzyro) • Modernization of the distribution system at Canadian Blood Services • Updated special authorization program • Creating a registry for HAE patients to track utilization <p>By taking a broader system view and coordinating the introduction of Haegarda on the Canadian Blood Services formulary with the listing of lanadelumab on the provincial/territorial formularies, we will provide better value to the healthcare system while balancing access to products for patients. Work on modernizing the distribution system and updating the special authorization program is underway. This will enable improved gatekeeping measures for all products, including C1-inhibitors. It is anticipated that these gatekeeping measures would include assessing product indication and dose, adjudicating special authorization criteria, and would result in the attainment of detailed data required to monitor utilization more effectively in the long-term.</p>
9	<p>CBS should provide additional information to Members on:</p> <ul style="list-style-type: none"> • 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. 	<p>Management currently provides information to members on foreign exchange risk, PPP market trends, PPP cost variances and the achievement of planned PPP contract savings through documents such as the corporate plan, the annual report to Canadians, and other formulary and financial updates to members via the provincial territorial blood liaison committee. Management will review how and where this information is reported to ensure clarity for members.</p>
10	<p>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.</p>	<p>Work on benchmarking of safety and quality measures was started in 2018 with international partners through the Alliance of Blood Operators (ABO). The ABO benchmarking working group continues its work on quality performance metrics.</p>
11	<p>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</p>	<p>Canadian Blood Services is already in the process of assessing all the curricula in its quality education and training program (QETP) with regard to the relevance, currency, completeness and delivery of each course and of the program as a whole. This includes the need for refresher training on a yearly basis or other frequency. The QETP is intended to provide employees with an understanding</p>

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	<p>both CBS' quality mandate / commitment and its strategic objectives.</p>	<p>of the importance of quality in all that we do and education on the quality management system and the role it plays in supporting the pursuit of quality and safety. The assessment and a plan forward are expected by the end of 2020-2021. The use of role personas will be utilized in the revised quality education and training program wherever feasible.</p> <p>Additionally, a working group has been organized to identify and implement strategies to improve the effectiveness of training. As part of their work, the group will assess the opportunities to further embed the use of role personas.</p>
12	<p>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>The working group organized to improve the effectiveness of training will be tasked with strengthening the incorporation of adult learning principles into training. Consideration will be given to introducing the requirement to perform learning needs assessments, the outcomes of which will influence training strategies and the use of training modalities that best satisfy the identified learning needs.</p> <p>With regard to the use of coaches and mentors, this is an approach already in use by Canadian Blood Services. The organization currently has an instructional training program in place which includes the roles of coach and mentor and defines requirements that must be met by individuals who fulfill these roles. Within the program, coaches and mentors are referred to as “on the job trainers”. This program will be revamped in 2021-2022 including the requirements for coaches and mentors.</p>
13	<p>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>For many years, executives have had quality objectives in their direction letters and core quality measures in their performance plans. Some other senior leaders, depending on their role and accountability, also have quality objectives and measures in their performance plans. We have not systematically made this a requirement for all senior leaders, irrespective of role, and rather have been more selective about who needs to be held accountable for them. Quality objectives and measures are core to all operational and strategy discussions and are discussed routinely in a number of executive and leader forums (quality management system review meetings, executive business review meetings, divisional meetings, etc.). These discussions involve leaders from across the organization, including those that may not have specific objectives and measures in their performance plans.</p> <p>This recommendation needs to be considered in the broader context of the individual's role, e.g., their ability to influence the movement of these measures. We are currently in the process of revisiting our performance management process and this recommendation will be taken into account.</p>
14	<p>CBS should survey employee safety awareness and comfort around raising safety and quality issues. CBS should survey employees annually to assess their</p>	<p>Canadian Blood Services will continue to administer the survey referenced in the report every one to two years to assess the organization's culture of quality over time. The next survey will be</p>

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	<p>overall safety awareness and comfort around raising safety or quality related issues.</p>	<p>conducted during 2020-2021, dependent of the impact of the COVID-19 outbreak on organizational priorities. The survey contains questions, under the employee ownership section, about employee comfort in raising safety and quality issues.</p>
15	<p>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"> • 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). 	<p>The transformation of our quality management system has been ongoing for many years and continues to be a strategic objective for Canadian Blood Services. In 2014, the "Link program: strengthening and maturing our quality management system and culture" was launched with initial focus on activities related to product manufacturing and the provision of clinical services. The intent has always been to extend, in time, the scope of the quality management system to the rest of the organization. This scope expansion will be undertaken after the organization has addressed all the key quality management system improvements currently in scope areas.</p> <p>Following the end of the review period, Canadian Blood Services automated quality event management and has started the implementation of a learning management system. This is planned to be completed in 2020-2021. Work has also started on automating change control and document management and implementation is scheduled for 2021-2022. Canadian Blood Services is also developing an approach to manage low risk non-conformances that should be implemented in 2021-2022 and a product lifecycle management process that includes sensing mechanisms and processes to understand customers' current and future/evolving needs and raise them to be addressed by the organization; this should be implemented in 2021-2022.</p>
16	<p>CBS should review CAPA completion targets. CBS should investigate approaches to better align targets to operational realities. This may include:</p> <ul style="list-style-type: none"> • 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. 	<p>Canadian Blood Services believes the targets are reasonable, achievable and consistent with expectations of a biologics manufacturer. Discussions are ongoing to determine actions that will address root causes for the performance gaps.</p>
17	<p>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.</p>	<p>Canadian Blood Services intends to conduct an assessment of its CAPA process now that it has been stabilized. This should be completed by end of 2020-2021. As part of the changes that might be made to the program, a requirement for "spot checks" will be introduced.</p>

#	Recommendation	Response
18	<p>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.</p>	<p>Canadian Blood Services will proceed with current plans for a stakeholder strategy refresh including crossover with donor experience and hospital experience work.</p>
19, 20	<p>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</p>	<p>Canadian Blood Services currently has direct access to distribution data only. To improve both PPP demand forecasting and utilization management, the ideal data set would include specific patient information such as age, weight, and diagnosis; disease information such as severity or sub-type; treatment information such as dose, frequency, and duration; outcomes data such as hospitalizations, bleeds, and other acute events; and quality of life measures such as missed days of work or school. We are taking the first steps toward expanding our data set (see recommendation 33 as an example) but having direct access to comprehensive utilization data will be a multi-year process. Meanwhile, we are constantly scanning the environment and working with natural partners such as patient registries, provincial blood offices, and hospitals. Collaboration with the PTs is important as we move forward, particularly their support for Canadian Blood Services having access to patient-level data.</p> <p>For fresh blood, forecasting accuracy is at an exceptionally high level for a biologics manufacturing company. This observation is less about “forecasting accuracy” and more about utilization “understanding” and, perhaps, management. Inappropriate utilization of fresh blood components is not occurring, by all the available measures. It is accepted that there can be marginal benefits to balancing supply / demand with improved demand sensing. This is particularly true within the current dynamic of the COVID-19 pandemic, a period not covered by this performance review.</p>
21	<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"> • 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. 	<p>The PPP forecasting process already includes consultation with the PTs to gather intelligence which is included in the forecast. Our forecast is shared with the vendors so they can develop their supply plan and vendors will comment if our forecast does not align with their own forecast. Access to clinicians and patient groups is more challenging and needs to be improved. Canadian Blood Services has undertaken various initiatives to improve access to this expertise, e.g. the hereditary angiodema [HAE] forum held in December 2019 and a planned Ig forum for 2020. More work is required to explore who should be part of these advisory groups, the frequency of meetings and how they should be consulted.</p>
22	<p>CBS should establish a task force consisting of representatives from CBS and healthcare agencies to</p>	<p>Healthcare agencies are part of an outward and forward-facing segment that we serve and do not have insight into donor relations</p>

#	Recommendation	Response
	<p>review existing processes, capabilities and technology and identify new opportunities for improving donor retention.</p>	<p>and supply chain activities. We will continue to take the concerns and feedback of healthcare agencies into consideration as we develop our donor recruitment and retention plans and will continue to collaborate with other blood operators to understand and apply best practices in donor acquisition and retention. This represents a challenge facing all blood operators.</p>
23	<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"> • Integrate the automated donor questionnaire with the online appointment booking process for donations. <ul style="list-style-type: none"> □ 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. • Enhance Customer Relationship Management capabilities to contact donors who do not complete their appointment bookings on the blood.ca website. <ul style="list-style-type: none"> □ 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 	<p>Providing deferral information to the donor at the time of appointment creation or upon completion of the donor questionnaire requires integration with our blood management system, eProgesa, which is the system of record for donor deferral information. Management acknowledges the benefit of providing donors with more information on deferral criteria prior to attending a collection event and this capability will be delivered in a future software release.</p>
24	<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>	<p>A cycle of review and action on hospital feedback (via the joint Medical Affairs & Innovation, Integrated Supply Chain, and Quality & Regulatory Affairs divisions quarterly meetings) is in place; however, the follow-up mechanism and framework can be improved, including a prioritization mechanism. This will be installed once we exit the current pandemic crisis.</p>
25	<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. 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>	<p>Canadian Blood Services' role has historically been focused on monitoring utilization and highlighting best practices. However, there are significant opportunities to positively impact blood product utilization in Canada. Canadian Blood Services is eager to jointly develop goals and initiatives with PTs to identify and address these opportunities, and to ensure collaboration and an increased commitment from our hospital partners.</p>

#	Recommendation	Response
		<p>These opportunities can include the potential to enable hospitals to more easily provide inventory visibility and utilization data. This would begin with extensive and broad stakeholder engagement. Inventory reporting on blood products by hospitals is currently voluntary and very manual. PT support for investing in technological solutions, that are known to exist, would be mutually beneficial in our shared goal of improving utilization management. Canadian Blood Services will draft a proposed plan, focused on O-negative red cell units, to table with PTs for discussion by end of fiscal 2020-2021.</p>
26	<p>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.</p>	<p>See response to Recommendation 7.</p>
27	<p>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"> • 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. <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>	<p>Customers have traditionally viewed Canadian Blood Services as a distributor of products and have therefore been reluctant to share patient-level data. However, as our additional role as a formulary manager has evolved, we have become part of the patient's circle of care, and we require access to patient-level data for activities such as adjudicating coverage criteria. We also require patient-level data to properly manage the PPP formulary, monitor demand, and predict utilization (see recommendation 19). Full implementation will be a multi-year process and the goal would be to partner with pilot sites as a first step. Depending on how this strategy develops (stakeholder input, customers' needs, etc.), our implementation plan could include working with specific jurisdictions, or it could roll out with specific specialties or types of products, groups of hospitals that use the same data system, specific health professionals, or other options. As we continue to work towards having access to more data, we will continue to make the necessary connections with other initiatives (e.g. linking to hospital laboratory information systems) that can impact Canadian Blood Services.</p>
28	<p>CBS should continue its efforts to automate the hospital ordering process for FBC and PPP and develop strategies for strong adoption.</p>	<p>Canadian Blood Services had two separate and interdependent pilots operating in this domain of our business – a vendor managed inventory program in Newfoundland with 13 hospitals and an on-line ordering program with four key hospitals in British Columbia. The latter program is being expanded to include additional hospitals that represent, in total, 80% of British Columbia's volume. We are using this pilot to ensure that the ultimate on-line ordering process and portal is informed by hospital wants and needs. In addition, we are making internal adjustments</p>

#	Recommendation	Response
29	<p>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:</p> <ul style="list-style-type: none"> • 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. <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>	<p>to ensure that the solution is scalable for Canadian Blood Services. Online ordering will evolve to apply primarily to "non-routine" orders in the order placement process, though the features and options of the system (order status updates, etc.) will continue to benefit all product orders. Capability to manage standing ("routine") orders through vendor managed inventory processes will be developed. This will significantly decrease the administration process in the hospital blood banks.</p> <p>While Canadian Blood Services has always been responsible for plasma collection in Canada to meet patient need, the establishment of the plasma proof of concept program as a separate organizational unit inside Canadian Blood Services recognizes its status as a necessary and focused operation to increase Canada's plasma sufficiency level (not unlike Hema-Quebec's Plasmavie centres in Quebec). This operation has its own operational and financial targets and dedicated resources to ensure success in increasing domestic plasma supply in Canada. Canadian Blood Services will, however, take this recommendation under consideration, and acknowledges there may indeed be a time when an integration with blood operations is desirable.</p>
30	<p>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>	<p>Canadian Blood Services continues to work with PTs to update the current criteria which is used to determine what product categories are included on the PPP formulary, and we support the development of a collaborative process for periodic review of the criteria moving forward. Inconsistency in a common understanding or application of the existing criteria has resulted in delays in decision-making and confusion among stakeholders on when a review can be conducted for a new category. Further, the existing criteria is potentially inadequate to address the emergence of new types of therapies, including those likely to be used in personalized medicine applications.</p> <p>In 2019-20, Canadian Blood Services, PTs and the Canadian Agency for Drugs and Technologies in Health (CADTH) established an interim product selection process for the Canadian Blood Services formulary which builds on the strengths of both Canadian Blood Services and CADTH to provide stakeholders with an objective, transparent, evidence-based review process for plasma-related drugs. This interim process will be in place while Canadian Blood Services, CADTH and PTs continue to discuss</p>

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		<p>and finalize the process for the review of plasma-related drugs into the future.</p> <p>While the interim process is underway, the criteria at the front end remains to be determined. Canadian Blood Services has initiated discussions with the PT blood liaison committee seeking to update the criteria and has presented recommendations for revised criteria to the PTs and the national advisory committee for blood and blood products (NAC). Canadian Blood Services' recommended criteria has now incorporated input from both the PTs and NAC. We are committed to further collaborative discussions until consensus on the updated criteria can be reached.</p>
<p>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:</p> <ul style="list-style-type: none"> • 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. <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 Transition Management section under PPP Procurement</p>	<p>This recommendation addresses the value that can be brought to bear by Canadian Blood Services and public payers in assessing the impact of a new product listing on the patients, PPP formulary, and the overall health system. As part of the formulary modernization, we recently developed an interim plasma protein product review process, in partnership with CADTH, to review new categories. This process analyzes the health system cost from the Canadian public payer perspective each time a product is being reviewed. Further, it engages patient groups to understand their value for the treatment, experiences with the disease, and how access to new products impact them. The next step will be to modernize the brand review process to align both processes. As part of the modernization, we will incorporate the elements of the interim review process that will calculate feasible health system costs and assess the impact on patient experiences of new brand additions.</p>	
<p>32 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. 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"> • 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). 	<p>Canadian Blood Services agrees with this recommendation and we note that it is complemented by recommendations 19, 25 and 33. Provincial and territorial governments have taken important steps towards implementing varying utilization management activities within their jurisdictions but there are opportunities for national coordination. Canadian Blood Services has been working with several provincial blood coordinating offices to share information on utilization management initiatives and best practices. We have presented and proposed initiatives for a coordinated and collaborative approach to utilization over the past several years and agree this remains an essential system need. Collaboration with PTs to complete a scan of PPP utilization management activities across the country would enable us to determine if these activities could be expanded further to improve utilization outcomes. While our role has traditionally been focused on</p>	

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	<ul style="list-style-type: none"> Implementing patient databases 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. <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>	<p>monitoring utilization management, we believe our role as the national blood authority allows us to make important contributions to managing utilization as well.</p>
33	<p>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:</p> <ul style="list-style-type: none"> 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. <p>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</p>	<p>A thorough review of the PPP named patient program (NPP) is required to strengthen utilization management. We are in the process of converting the NPP into an updated special authorization program (SP) to ensure optimal use of products as well as assessing how this program can be supported through efforts to modernize the distribution system at Canadian Blood Services. The first steps of mapping the current NPP and developing an online formulary are underway. The updated SAP will support online ordering and streamline the adjudication process which will allow scalability while ensuring patients have timely access to the products they require. Both distribution modernization and an updated SAP will support the attainment of detailed data which will strengthen utilization management.</p>

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	could more closely manage and monitor utilization of, for instance, high-cost PPP treatments.	
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.	See Recommendation 27.
35	<p>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:</p> <ul style="list-style-type: none"> • 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. 	<p>Canadian Blood Services will explore ways to better track partial use of PPPs. As part of a refresh of the architecture of the current hospital disposition reporting for fresh blood components, we will consider how we could improve reporting on PPP use and partial use. Further, for products used in hospitals and medical day clinics, organizing scheduled clinics for patients would allow pooling of doses and reduced wastage. This is common practice in oncology and often coordinated through the pharmacy. Canadian Blood Services is looking to modernize its distribution of PPP to patients, which may include distribution through pharmacies.</p>
36	<p>CBS should work with PTs to evaluate the broader use of alternative pricing strategies to determine if these 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.</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"> • 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. 	<p>Canadian Blood Services has been working with an external consultant to determine how facets of value-based procurement can be used in the next PPP RFP, scheduled to be issued in 2021. Canadian Blood Services will review this with PTs.</p>

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37	<p>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.</p>	<p>Canadian Blood Services is committed to an RFP process which is fair and transparent to all, and which supports fairness, objectivity and integrity of process. Canadian Blood Services is interested in exploring options to further enhance this process with an independent fairness monitor in the next PPP RFP, scheduled to be issued in 2021.</p>
38	<p>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:</p> <ul style="list-style-type: none"> • 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. 	<p>Canadian Blood Services will include the documenting and publishing of the complaints process in the next PPP RFP, scheduled to be issued in 2021. In doing so, Canadian Blood Services it will include:</p> <ul style="list-style-type: none"> • The format in which complaints are to be communicated to Canadian Blood Services; • Points of escalation for the complaint; • Timeframes for a Canadian Blood Services response to the complaint and the format in which the response will be communicated; and • Options for redress should a supplier still feel dissatisfied.
39	<p>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:</p> <ul style="list-style-type: none"> • 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. <p>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.</p>	<p>Management has developed a more formal savings tracking application which is being used to track savings associated with contracts established April 1, 2018. This tracking application will be used to assess and track savings on a go forward basis.</p>
40	<p>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:</p> <ul style="list-style-type: none"> • 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. <p>Once the RFP process is complete, CBS and the PTs should agree on:</p>	<p>Canadian Blood Services will discuss with PTs the appropriate process needed to obtain PT input on impacts of possible formulary changes and other factors that should be considered as part of the RFP decision making. Canadian Blood Services will include this input step in the next PPP RFP, scheduled to be issued in 2021.</p>

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	<ul style="list-style-type: none"> • The factors to consider from a transition management perspective. This could include: <ul style="list-style-type: none"> □ 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. 	
41	<p>CBS should establish a portfolio management approach for the PEP.</p> <ul style="list-style-type: none"> • 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. 	<p>The productivity and efficiency program (PEP) includes several elements: specific projects, benchmarking data and reviews, productivity target setting, and instilling a cost-conscious culture. Near the completion of the performance review, Canadian Blood Services implemented an enterprise project management office (ePMO) to provide oversight and improve the management of strategic projects throughout the organization. With these enhancements, a portfolio management approach to track the projects falling under PEP is now in place.</p>
42	<p>CBS should develop a benefits management framework for the CI Program to enable:</p> <ul style="list-style-type: none"> • 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. <p>The benefits management framework will help provide PTs with a better understanding of how the CI Program improves productivity and efficiency metrics.</p>	<p>The CI program is a foundational aspect of building the “Canadian Blood Services way”, as defined in our strategic key focus areas for organizational excellence. The program is a total system of improved leadership behaviours, philosophical principles and tools and techniques rather than a series of discrete initiatives with specifically defined benefits. Its success is multi-dimensional and current KPIs for the business will capture its ultimate success (e.g. quality, service, cost, engagement, experience, etc.) We believe an additional framework is not necessary. The program already has a “kaizen strategy” framework that very specifically tracks anticipated benefits for efforts of particular focus at different operating sites over increments of time. In aggregate, these then also build into a complete organizational perspective as noted in the measures above.</p>
43	<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>	<p>Management will implement a more formal practice to ensure technology projects in excess of a material threshold will include a documented review of options (both technology and project delivery) to fulfill project requirements. These new practices will include external consultation (e.g. third party advisory firms, peer organizations, etc.) as appropriate.</p>

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44	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.	This recommendation stems from a review of the automated supply chain (ASC) project which preceded establishment of the current enterprise project management office corporate standards. Since that time, the business case template has been adapted to include a robust risk section that includes rating risks as well as ongoing risk review processes. All projects in the corporate portfolio subject to the Canadian Blood Services' project gating process contain detailed risks and associated ratings.
45	As part of its reporting process on major projects to the Board and Members, CBS should: <ul style="list-style-type: none"> formally report on the financial benefits realization 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.	The national accountability agreement agreed upon by Canadian Blood Services and all PT ministers of health outlines our reporting requirements to PTs. Schedule B, Reports, Item 6 outlines reporting for major capital projects, more specifically <i>'For major capital projects identified in the annual corporate plan, CBS and PT governments agree, that a performance reporting framework will be followed that informs the PT governments of significant performance measures, risks, issues and change requests in a timely manner. Monthly reports and quarterly financial forecasts will include sufficient information and analysis to: communicate risks, issues, strategic decisions and impacts; and assess performance relative to the approved funding (e.g. scope, schedule, budget, benefits and service quality levels). The reporting framework will include final budget reconciliation at project completion.'</i>
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.	The enterprise project management office will examine a process by which the appropriate project benefits can be identified for integration into operational performance measures on a forward-looking basis.
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.	This recommendation stems from a review of the ASC project which preceded the current enterprise project management office corporate standard. The business case under the current enterprise project management office not only identifies the benefits measures, but also the accountability. This is further reinforced through the benefit realization stage and documentation at project close out which delineates accountabilities for operationalization and benefit realization at a more detailed level.
48	CBS should continue to monitor and report on the productivity results from process changes associated with the ASC project.	The productivity improvements associated with the automated supply chain project are well documented and are of a "one time" transformational nature. There is no extended set of benefits associated with ASC and, as such, there is no possibility to track additional benefits. Productivity improvements in the collections environment are numerous and span multiple dimensions.
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	This recommendation stems from a review of the ASC project which preceded the current enterprise project management office corporate standards. The enterprise project management office has a mechanism by which benefit realization is tracked on a

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	<p>required to report on benefits realization at project close-out.</p> <ul style="list-style-type: none"> • 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. <p>Consideration should be given to conducting a survey at the outset of the project and comparing the results against post project survey results.</p>	<p>project by project basis via the realization gate stage – the Canadian Blood Services project gating process contains an entire gate devoted to tracking benefit realization. This is augmented by the ongoing portfolio level tracking and reporting on benefits across the corporate portfolio.</p>
50	<p>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"> • 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. 	<p>The donor experience project was an important initiative for Canadian Blood Services as we worked to implement key activities to engage new and retain current donors throughout the national system. The project was successful in achieving targets, was on time and on budget, and will continue to inform our approach into the future. An outcomes report highlighting the benefits realized was provided to funding governments in March 2020. Donor retention is an area of continued focus and is addressed in recommendation 22. Brand KPIs will be reported as part of a brand health index on a go forward basis.</p>
51	<p>Develop a Board diversity strategy. Working with Members, the CBS' BoD should:</p> <ul style="list-style-type: none"> • 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. <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>	<p>Over the course of 2019-2020, Canadian Blood Services worked collaboratively with PTs to update and revise the board recruitment, nominations and elections framework which is the document that describes the principles and processes followed to recruit and elect directors to the board. The document was endorsed by Canadian Blood Services’ board of directors and the conference of deputy ministers. A key principle included in the refreshed framework is that “the board should reflect a diversity of identities, abilities, backgrounds, cultures, skills, perspectives and experiences that are representative of Canada’s population” and that “limits be introduced to the number of terms a director can serve to support greater diversity on the Board, including promoting new perspectives, talents and best practices.” The principles articulated in the framework reflect the recommendations put forward in the performance review report and will be incorporated into the planning for the 2021-2022 and 2022-2023 board recruitment processes.</p>

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52	<p>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 plan would be subject to Member decision-making regarding renewal of director terms and election of new directors.</p>	<p>The director selection advisory committee, co-chaired by the PT lead minister and the Canadian Blood Services’ board chair, is responsible for determining the skills, qualifications, and attributes of director candidates to be recruited, with input from the board’s governance committee. While a skills/attributes matrix is completed in preparation for each director recruitment and election cycle, Canadian Blood Services acknowledges the value of ongoing board succession planning and will incorporate this suggestion into its board evaluation and effectiveness process. In addition, a board succession policy will be developed, to guide succession across various board leadership roles, including the chair roles for board committees and pension plan committees; representation on subsidiary boards; as well as the board vice-chair and chair roles. This work will of course be subject to the decision-making authority of the members regarding new director appointments, renewal or non-renewal of the terms of existing directors, and board chair selection.</p>
53	<p>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.</p>	<p>Providing new PTBLC representatives with an orientation to familiarize themselves with Canadian Blood Services and the various roles and responsibilities within the national blood system as outlined in the national accountability agreement is important to ensure the effectiveness and efficiency of the committee. In collaboration with the PTBLC, Canadian Blood Services will develop a formal orientation program for new PTBLC representatives which provides a thorough review of the national blood system and the specific role of the PTBLC.</p>
54	<p>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.</p>	<p>Canadian Blood Services 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 shared with corporate members throughout the year in alignment with reporting requirements under the national accountability agreement. Further, the development of Canadian Blood Services’ 2019–2024 strategic plan, “Keeping the Promise”, involved a review of the organization’s performance measures. As a next step, Canadian Blood Services will engage with the PTs to review the various performance measures and identify relevant additions or adjustments that would be meaningful to members in terms of related outcomes. Where applicable, Canadian Blood Services is considering the option of also making measures publicly available to ensure further transparency with all our various stakeholders.</p>
55	<p>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</p>	<p>The national accountability agreement agreed upon by Canadian Blood Services and all PT ministers of health outlines our reporting requirements to PTs. In accordance with this agreement, we submit quarterly reports to members and an annual corporate plan.</p>

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	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.	Both reports provide quarterly and rolled-up annual data on key safety indicators. The rolling up of the reported indicators to members to provide year-over-year trends for the last three consecutive years will be provided through the annual corporate plan.
56	<p>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:</p> <ul style="list-style-type: none"> • 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. 	Canadian Blood Services will continue to provide the reporting and support to members needed for enhanced decision-making, as outlined in our responses to Recommendations 53, 54 and 55.
57	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.	Canadian Blood Services accepts this recommendation related to developing operational risk views. An operational risk view for the fresh blood program was implemented on July 30, 2019, and an operational risk view for PPP was implemented on November 4, 2019. The organization will continue to refine and mature operational risk views across all product/service areas, in support of its integrated business planning process, in which operational performance and risk are analyzed, reported and discussed.
58	<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.</p> <p>A formal risk statement will provide clarity across the organization as to the level of acceptable risk when making strategic and operational decisions.</p>	Canadian Blood Services agrees with this recommendation. Risk tolerance is currently reflected in detail in the organization's corporate risk exposure plot. However, Canadian Blood Services will develop an overarching risk appetite statement to serve as a "guidepost" for establishing and confirming risk tolerance thresholds. The organization will also look to leverage more broadly the risk tolerability tools in the Alliance of Blood Operators risk-based decision-making framework for blood safety.
59	<p>Develop a master BCM testing plan that identifies:</p> <ul style="list-style-type: none"> • entities/locations to be tested; • the nature of testing to be undertaken; • criteria for determining the test types; • frequency of testing; and 	Canadian Blood Services agrees with this recommendation and will develop a Master Exercise Plan as a tool to establish the complete population of elements which need to be tested periodically and the required frequency of such tests based on a risk assessment. In any given year, this tool will be used to inform the Annual Exercise Plan which will include a minimum number of

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•	<p>roles and responsibilities for getting the testing completed. Ask each site to customize the current generic Recovery Plan-Facility Failure to site specific plans.</p>	<p>functional exercises in addition to walk-through and tabletop exercises. Supply chain critical functions and support activities are standardized across each of our production and testing sites; therefore, separate recovery plans do not appear necessary or desirable. However, as part of our emergency preparedness, sites are guided by the First Response Program and site-specific guidance which includes emergency contacts and building safety equipment. The organization will review lessons learned from current and future recovery phases of the ongoing COVID-19 business continuity effort, including those related to recovery plans for a facility failure.</p>

Appendix 2 Acronyms

Abbreviation	Term
ABO	Alliance of Blood Operators
ASC	Automated supply chain
BCM	Business continuity management
BoD	Board of Directors
CADTH	Canadian Agency for Drugs and Technologies in Health
CAPA	Corrective action and preventive action
CBS	Canadian Blood Services
CI	Continuous improvement
CRM	Customer relationship management
EA	Error/accident
EMT	Executive Management Team
ePMO	Enterprise project management office
FBC	Fresh blood components
FTE	Full-time equivalent
G&A	General and administrative
HAE	Hereditary angioedema
KPI	Key performance indicator
NAA	National Accountability Agreement
NAC	National Advisory Committee for Blood & Blood Products
NPP	Named patient program

Abbreviation	Term
OTDT	Organ and tissue donation and transplant
pCPA	Pan-Canadian Pharmaceutical Alliance
PDI	Post donation information
PEP	Productivity and efficiency program
PPP	Plasma protein product
PTs	Provinces and Territories
PTBLC	Provincial Territorial Blood Liaison Committee
PwC	PricewaterhouseCoopers
QETP	Quality education and training program
RFP	Request for proposal
SAP	Special Authorization Program
US	United States