

MANAGEMENT RESPONSE TO PERFORMANCE REVIEW

Close-out Report (2024–2025)

PUBLIC (P)

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Purpose

In May 2020, PricewaterhouseCoopers LLP (PwC) presented its final report on the results of the [2019 Collaborative Review of Canadian Blood Services](#). The review covered the seven-year period from April 1, 2012, to March 31, 2019.

While the analysis brought forward areas for improvement—both within Canadian Blood Services’ operations and at a system-wide level requiring ongoing collaboration with provincial and territorial governments (PT governments)—it ultimately found the organization had “performed well, ensuring the safety of the national blood supply system and meeting the needs of a diverse group of stakeholders”.

Canadian Blood Services agreed broadly with PwC’s findings and recommendations and published a management response in October 2020, providing information on the direction the organization planned to take or was already implementing to address each recommendation. This report closes each of the recommendations that were not fully addressed by the earlier management response.

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 provincial and territorial governments, a collaborative performance review is conducted every five to seven years.

A joint steering committee, comprising of representatives from PT governments 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 the deputy minister of health from Ontario, the associate deputy minister from British Columbia, Canadian Blood Services’ chief executive officer, Canadian Blood Services’ chief financial officer and vice president, corporate services, and Canadian Blood Services’ vice president, general counsel and corporate secretary. The steering committee created a joint working group to manage the day-to-day activities of the review. 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 PT governments, 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 covered 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.

About us

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 and manufacture blood and blood products, including red blood cells, platelets and plasma for transfusion. We distribute these blood products to health care providers for the treatment of patients across Canada. We also provide diagnostic laboratory testing services in some provinces.

Plasma for Life: Of the plasma we collect and test in Canada, some goes to patients for transfusion, while most is shipped to pharmaceutical manufacturers contracted by Canadian Blood Services to produce medications for use by patients in this country. These medications — primarily immunoglobulins — form part of a national formulary of plasma protein and related products (PPRP) that we bulk-purchase from global providers and manage on behalf of all provinces and territories except Quebec.

Stem Cells for Life: We collect, test and manufacture stem cells obtained from cord blood. We also operate a national registry of adult stem cell donors and participate in an international network of donor registries to identify potential matches for patients requiring stem cell transplants. Together, these programs support better outcomes for people living with the many diseases and disorders that can be treated with transplanted stem cells.

Organs and Tissues for Life: We serve as the country's coordinating agency for organ and tissue donation and transplantation (OTDT). We manage a national transplant registry for interprovincial organ sharing, as well as related programs for donation and transplantation. With our partners across the OTDT community, we also develop leading practices, support professional education and public awareness activities, and share data on the performance of the OTDT system in Canada.

To support our operations and advance transfusion and transplantation science and medicine, Canadian Blood Services also conducts wide-ranging research and development activities. Our

core research programs promote advances in the fields of transfusion, cellular therapies and transplantation medicine. We also participate in clinical trials and research led by others. Through these efforts, we help to introduce innovative products, important knowledge, enhanced safety and quality measures, and refined processes and technologies. Our work also facilitates problem-solving in the supply chain, contributing to optimal patient outcomes. We support professional education and public awareness initiatives related to transfusion and transplantation. And we regularly share insights and expertise with our health system partners, other stakeholders, governments and international blood service organizations.

Our governance

Established in 1998, Canadian Blood Services is a charitable organization that was created through a memorandum of understanding among Canada's federal, provincial and territorial governments (except Quebec). While we operate independently from government, we are regulated by Health Canada through the federal Food and Drugs Act. Most of our financial support is provided by provincial and territorial governments, but we do receive federal financial support primarily for our research and development activities, as well as for our role in organ and tissue donation and transplantation.

Current health ministers of the provinces and territories (except Quebec) serve as corporate members of Canadian Blood Services and appoint our board of directors under bylaws as governed by the Canada Not-for-profit Corporations Act. Accountability relationships between Canadian Blood Services and the corporate members are set out in the National Accountability Agreement, which was finalized in 2019–2020. A lead province is designated every two years. The provincial and territorial health ministers collectively approve our annual budgets and corporate plans.

Acronyms

| Abbreviation | Term |
|--------------|---|
| ABO | Alliance of Blood Operators |
| AHCDC | Association of Hemophilia Clinic Directors of Canada |
| ASC | Automated supply chain |
| BCM | Business continuity management |
| BIA | Budget impact assessment |
| BoD | Board of Directors |
| CADTH | Canadian Agency for Drugs and Technologies in Health (as of May 2024, Canada's Drug Agency) |
| CAPA | Corrective action and preventive action |
| CBDR | Canadian Bleeding Disorders Registry |
| CBS | Canadian Blood Services |
| CI | Continuous improvement |
| CRM | Customer relationship management |
| CSR | Corporate social responsibility |
| 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 and Blood Products |
| NPP | Named patient program |
| OTDT | Organ and tissue donation and transplantation |
| pCPA | Pan-Canadian Pharmaceutical Alliance |
| PDI | Post donation information |
| PEP | Productivity and efficiency program |

| Abbreviation | Term |
|--------------|--|
| PPP | Plasma protein products |
| PPRP | Plasma protein and related products |
| PTs | Provinces and territories |
| PTBLC | Provincial Territorial Blood Liaison Committee |
| PwC | PricewaterhouseCoopers |
| QETP | Quality education and training program |
| QMS | Quality management system |
| RFP | Request for proposal |
| SAP | Special Authorization Program |

Recommendations and responses

The following chart reproduces the PwC recommendations of May 2020 and Canadian Blood Services’ October 2020 management responses (columns one and two, respectively). Column three provides the organization’s final and concluding management response for each recommendation.

| # | Recommendation (May 2020) | Management Response (October 2020) | Final Management 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> | <p>This recommendation is considered addressed, as outlined in the October 2020 management response. Canadian Blood Services continues to advance improvement efforts across all dimensions of the integrated supply chain, including leveraging best practices in process management and learnings from other blood operators.</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 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> | <p>This recommendation is considered addressed. Front-end automation has been enabled in Canadian Blood Services’ donor testing sites in Brampton and Calgary, resulting in increased testing productivity. In addition, as a member of the Alliance of Blood Operators, Canadian Blood Services engages in regular discussions with our counterparts in other countries to stay up to date with international efficiency journeys and to compare our internal processes to find opportunities for continuous improvement.</p> |

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| 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. | 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". | This recommendation is considered addressed. The option of a collaborative purchasing arrangement was assessed and is no longer being pursued due to improvements that have permitted further optimization of our testing operations. We will, however, continue to actively identify and leverage opportunities to increase our testing productivity and reduce costs where appropriate. |
| 4 | <p>CBS should build on its [production] 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. | 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. | This recommendation is considered addressed. Canadian Blood Services continues to mature our program of operational excellence within the process management and supply chain operation functions. This program regularly examines process steps, supported by industrial engineering time studies, to target areas of opportunity. We also leverage idea exchange and benchmark data 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. |
| 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. | 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 | This recommendation is considered addressed, as outlined in the October 2020 management response. Canadian Blood Services has also increased the level of detail in our annual budget approvals process to provide PT governments as funders with better visibility of the organization's funding needs and planned expenses. |

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| | | 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. | |
| 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. | 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>This recommendation is considered addressed. Canadian Blood Services continues to ensure general and administrative expenses are reviewed on a quarterly and annual basis. We have also:</p> <ul style="list-style-type: none"> • Developed our own in-house project management capabilities and only use external project management resources when capacity or a certain specialized expertise is required. • Established a Project Management Community of Practice to further develop and align project management skills and capabilities inside the organization and lessen the dependency on outside resources. • Continued to mature our real estate capabilities with all leases managed through a formal competitive tendering process. Regarding utilities costs, Canadian Blood Services focuses on the implementation of technologies to monitor and reduce these costs. Energy and water use is benchmarked in Energy Star Portfolio Manager, and the organization belongs to a Strategic Energy Management Cohort and the Alliance of Blood Operators' Environmental Sustainability and Corporate Social Responsibility Community of Practice that places us amongst peers in our industry. |
| 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 | 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– | This recommendation is considered addressed. Beyond what was articulated in the management response of October 2020, in 2022, Canadian Blood Services announced a blueprint for action to further secure the |

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| | 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. | <p>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</p> | <p>domestic plasma supply and ensure patients in Canada continue to have long-term access to immunoglobulins. As discussed with and supported by corporate members, key actions flowing from the blueprint include:</p> <ul style="list-style-type: none">• Collecting significantly more plasma under Canadian Blood Services’ non-remunerated model;• Signing an agreement with Grifols, a global healthcare company and leader in producing plasma medicines, where Grifols will collect plasma in Canada as Canadian Blood Services’ agent; and,• Via the same agreement, enabling the country’s first domestic end-to-end supply chain to meet patients’ critical needs for immunoglobulins, an important lesson of the COVID 19 pandemic. |

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| | | 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. | |
| 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 | <p>This recommendation is considered addressed by Canadian Blood Services to the current extent possible. Subsequent to the performance report, utilization of Haegarda on Canadian Blood Services’ formulary has significantly decreased primarily due to the listing of lanadelumab, a comparator product, on PT drug plans. Having the two products listed on different formularies has created challenges in leveraging opportunities to manage their utilization. Additionally, the registry under development</p> |

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| | | <ul style="list-style-type: none"> • 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> | <p>for patients with hereditary angioedema is independent of Canadian Blood Services and PT governments.</p> <p>Canadian Blood Services is undertaking a Distribution Modernization program as a pilot in Alberta for Hemlibra and Glassia. This provides Canadian Blood Services with valuable and detailed dispensing data for these products which can be leveraged to support utilization management activities. Distribution Modernization could be expanded to other provinces and products to achieve similar aims, with agreement from other PT governments.</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> | <p>This recommendation is considered addressed, as articulated in the October 2020 management response. All necessary and relevant information on foreign exchange risk, PPRP market trends, PPRP savings and demand variances are regularly provided to corporate members through documents such as the corporate plan, the Annual Report to Canadians, and other formulary and financial updates to corporate members via the Provincial Territorial Blood Liaison Committee.</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. The Alliance of Blood Operators benchmarking working group continues its work on quality performance metrics.</p> | <p>This recommendation is considered addressed. Canadian Blood Services now regularly reports safety and quality benchmarking data to the Alliance of Blood Operators to situate our safety and quality performance relative to other comparable organizations. The safety and quality data focuses on post donation information, errors and accidents, hospital complaints and hospital returns.</p> |

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| 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. | Canadian Blood Services is already in the process of assessing all the curricula in its quality education and training program 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 quality education and training program 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. | This recommendation is considered addressed, as articulated in the October 2020 management response. Canadian Blood Services implemented a refreshed training program for all employees related to the importance of quality that utilizes role-based personas where appropriate. Among other objectives, this refresh ensures the program is relevant for different roles across the organization. |
| 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.). | 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. | This recommendation is considered addressed. Canadian Blood Services has defined a framework for enhancing its training program that brings greater focus on improving the effectiveness of training and the learner experience. The framework builds on five key elements: learner aptitude and suitability; training design and delivery; the learner experience; learner application of learning; and leadership engagement. For example, a redesigned instructional staff training program has been implemented and incorporates the application of adult learning principles during training delivery. The program also requires that new instructors observe the successful delivery of training as the final requirement of achieving qualification as an instructor. Similarly, guidance has been implemented for training developers regarding the use of adult learning principles during the creation of training materials. |

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| 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. | 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. | Canadian Blood Services has completed the review of our performance management processes and considers this recommendation addressed. Further to the October 2020 management response, senior management continues to have quality objectives in their annual direction letters and core quality measures in their performance plans, which are shared with their respective teams. |
| 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. | 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. | This recommendation is considered addressed. Canadian Blood Services re-ran its employee survey in 2022 and found improvement in employee ownership of quality, including increased comfort by employees to raise concerns. In addition, a refreshed quality training program was introduced for all new employees which focuses heavily on Canadian Blood Services’ quality policy and the behaviours, actions and thinking associated with developing and sustaining a strong quality mindset. |
| 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: | 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 | This recommendation is considered addressed. Canadian Blood Services has made significant progress in strengthening key quality management processes and increasing the level of automation for greater process |

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| | <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 nonconformances; 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>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 nonconformances 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> | <p>control and greater operational efficiency. For example, and as referenced in the recommendation:</p> <ul style="list-style-type: none"> Our Quality Management System has been expanded to include other processes and internal service business units such as the control of materials on blood.ca. A process has been implemented to manage low-risk non-conformances. The work to automate change control and document management has been completed and work is underway to automate adverse transfusion reaction and adverse donor event management. A quality-by-design process to manage the introduction of new products and services for customers is in the process of being implemented. <p>Results from employee surveys have demonstrated a growing focus on quality throughout the organization. Further, the quality training program was refreshed to make it more relevant to all employees.</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> | <p>This recommendation is considered addressed. Canadian Blood Services continues to confirm that the CAPA targets are reasonable, achievable and consistent with expectations of a biologics manufacturer. Increased executive sponsorship and oversight over corrective and preventive action events were put in place and have resulted in the CAPA targets being met more frequently.</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</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</p> | <p>This recommendation is considered addressed. Canadian Blood Services has formalized the introduction of quality management system reviews in all relevant areas of the organization, where cross-functional teams, made up of</p> |

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| | 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. | changes that might be made to the program, a requirement for "spot checks" will be introduced. | quality representatives and process/functional managers, review various quality indicators such as quality event/non-conformance trends, training completion rates, and CAPA progress. These reviews are intended to identify where management intervention might be required to maintain progress or correct/influence adverse trends. |
| 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. | Canadian Blood Services will proceed with current plans for a stakeholder strategy refresh, including crossover with donor experience and hospital experience work. | This recommendation is considered addressed. A renewed strategy has been completed, including implementation of an annual stakeholder satisfaction survey. Further, should survey results indicate a notable decline in stakeholder satisfaction, action would be taken in the form of an independent stakeholder perception audit to understand the results and identify steps to address causes. |
| 19/20 | 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. | 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 | This recommendation can be considered addressed to the current extent possible, recognizing overall utilization efforts are a perennial and shared focus for both Canadian Blood Services and PT governments. To date, Canadian Blood Services has completed a review of hospital disposition data to identify the current state of the data’s quality. The primary gaps relate to improving hospital reporting cadence, timing, and blood type data granularity. As noted in the Oct. 2020 response, it is expected that having direct access to comprehensive utilization data will be a multi-year process, and that the minimum viable outcome will initially not be able to include treatment-related information. Canadian Blood Services has taken the preliminary actions required to streamline and automate the collection and reporting of the disposition data. Continued work is planned over the next number of years to further buildout and strengthen this capability. Canadian Blood Services continues to evaluate opportunities to improve demand planning methodology within the current data quality constraints. |

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| | | 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. | For PPRPs, Canadian Blood Services currently collects patient-level information for products which require criteria to be met to be accessed (i.e., through Special Authorization and Exceptional Access processes). The modernizations made to the Special Authorization program allow Canadian Blood Services to capture patient-level data to inform decisions. See recommendation 32 for more details. |
| 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. | 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>This recommendation can be considered addressed to the current extent possible, recognizing PPRP utilization efforts are a perennial and shared focus for both Canadian Blood Services and PT governments. Of note, mechanisms to collaborate with PT governments, suppliers, clinical experts and patient groups to share intelligence about PPRP demand forecasting are in place. At this time, the biggest challenge to PPRP demand planning is the lack of access to patient-level data, which would improve the ability to understand and anticipate future needs.</p> <p>Importantly, Canadian Blood Services meets with each PT government twice a year to discuss their respective provincial utilization practices and share intelligence collected from suppliers, clinical experts and patient groups. As part of these meetings, Canadian Blood Services provides PT governments with focused questions to align the type of intelligence received. The meetings result in a PPRP forecast that is agreed upon between Canadian Blood Services and PT governments.</p> |
| 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. | 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 | This recommendation is considered addressed, though the focus of donor recruitment is a perennial one for blood operators around the world. Canadian Blood Services continually leverages learnings from other blood operators, from industry sectors and from external agency advisors to make enhancements to donor experience and retention. This includes refreshing our donor retention, loyalty and |

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| | | donor acquisition and retention. This represents a challenge facing all blood operators. | recognition programs with aims to reduce the gap between new and active donor retention rates and to ease some pressure on acquisition. |
| 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. | <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> | <p>This recommendation is considered addressed, and a part of Canadian Blood Services' refreshed donor engagement strategy. We have integrated the donor questionnaire into our online booking process. As per Health Canada regulations, the questionnaire is automatically sent to donors via email the night before their appointment, to speed up the screening process and enhance the donor experience. A basic form of auto-deferral has also been added to the online booking process to address basic requirements.</p> <p>Canadian Blood Services has also modernized our customer relationship management capability, including roles, responsibilities, processes, and technology, to transform the way we recruit and manage donors. We developed a digital donor selection criteria manual, which replaces our current paper-based process for managing and distributing donor eligibility information with a front-end interface for use across the country, and a back-end solution to enable content editors with an efficient process for updating and distributing changes in eligibility requirements.</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</p> | <p>This recommendation is considered addressed. Canadian Blood Services gathers feedback via Hospital Liaison Specialists who work directly with hospitals. This provides more specific insights and allows for two-way dialogue, improving on previous third-party surveys. Additionally, Canadian Blood Services has gained valuable customer</p> |

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| | | mechanism. This will be installed once we exit the current pandemic crisis. | insights through a hospital engagement committee, further enhancing its ability to address hospital concerns effectively. The use of a centralized reporting system and further review operations continue to enhance our monitoring capability and identify improvement opportunities. |
| 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. | 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 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. | This recommendation can be considered addressed to the current extent possible, recognizing utilization is a perennial focus for Canadian Blood Services and PT governments. Further, Canadian Blood Services welcomes the development of goals and initiatives with PT governments to identify and address utilization management, and to ensure collaboration and an increased commitment from our hospital partners. We have taken the preliminary actions required to streamline and automate the collection and reporting of the available O-negative inventory data. Continued work is planned over the next number of years to further build out and strengthen this capability should PT governments seek to facilitate agreements that would improve access to hospital inventories and product disposition data. |
| 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. | See response to Recommendation 7. | This recommendation is considered addressed, as articulated in response to recommendation 7. |

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| 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. 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>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> | <p>This recommendation is considered addressed to the current extent possible. Canadian Blood Services currently collects patient-level information for products which require criteria to be met to be accessed (e.g., through Special Authorization and Exceptional Access processes). The changes made to the Special Authorization program allow Canadian Blood Services to capture patient-level data to inform decisions. See recommendation 32 for more details.</p> <p>Canadian Blood Services also launched the Distribution Modernization project for patients in Alberta for Hemlibra (emicizumab) and Glassia (alpha-1 proteinase inhibitor). Through this project, a specialized pharmacy coordinates with patients' medical providers, patient support programs, and Canadian Blood Services to dispense and deliver these medications to patients (most often to their homes). The project provides valuable information about how these medications are being used. This distribution model can be expanded to other provinces or other products.</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 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</p> | <p>This recommendation is considered addressed. Canadian Blood Services has replaced the paper-based hospital ordering process with an online ordering system for both fresh blood components and PPRPs. The online solution has been rolled out across the country and has enhanced the experience of both Canadian Blood Services' staff and our hospital customers while enabling supply chain efficiencies. An online ordering system for patient specific requests has also been implemented across the country.</p> |

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| | | (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. | |
| 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. 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>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 Héma-Québec’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> | <p>This recommendation is considered addressed. Canadian Blood Services’ strategic plan published in 2024 outlines our continued commitment to match products and services to patients and health system needs. To deliver on this strategic priority, we are intentionally shifting from a distinct product-based approach whereby donor centres are dedicated to the collection of one product to an approach where donor centres can collect multiple types of products. This will enable participation in Canada’s Lifeline from a larger number of donors from more parts of the country while optimizing collections to meet system and patient needs.</p> <p>Further, Canadian Blood Services’ plasma collections program has reached the stage of maturity where it no longer needs to stand alone and can be integrated into our blood collections program. The first “proof of concept” plasma donor centre has been open for over four years, and there are now a total of nine plasma donor centres nationally, with the tenth centre opening in March 2025 and an eleventh centre planned for 2025–2026.</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</p> | <p>This recommendation is considered addressed through discussions between PT governments and Canadian Blood Services, which are expected to conclude in early 2025–2026.</p> |

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| | | <p>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 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> | |
| 31 | <p>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; | <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</p> | <p>This recommendation is considered addressed through discussions between PT governments and Canadian Blood Services, which are expected to conclude in early 2025–2026.</p> <p>As background, when a new PPRP is reviewed, Canadian Blood Services prepares a Budget Impact Assessment (BIA) which is shared with PT governments when a recommendation is made regarding whether to list or not list the product on Canadian Blood Services' formulary. The</p> |

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| | <ul style="list-style-type: none"> 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. | <p>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>BIAs include direct savings and costs for Canadian Blood Services' budget as well as indirect savings and costs for the broader healthcare system (e.g., shifts in utilization from a product carried by Canadian Blood Services to provincial drug plans, impact of patients transitioning from one product to another, etc.).</p> <p>Canada's Drug Agency (CDA) also conducts a BIA when reviewing a new product. However, CDA's BIA only considers the potential cost of introducing the new product on the drug plan budget. Canadian Blood Services' BIA process goes further in that it considers the impact on all product use, regardless of what formulary the product is listed on. This provides a broader view of the impact of adding the new product.</p> |
| 32 | <p>CBS and the PTs should complete a combined assessment of their utilization management activities for PPP and determine if these activities could be expanded further to improve utilization outcomes. 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). 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>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> | <p>This recommendation can be considered addressed to the current extent possible, recognizing utilization is a perennial focus for Canadian Blood Services and PT governments.</p> <p>Of note, significant changes have been made to the Special Authorization Process, which now includes collection of patient identifiers and data. This information is required to evaluate if the patient meets the criteria for use established through the review process and approved by PT governments. These changes support enforcing criteria to control the use of the PPRPs that are introduced with listing criteria (e.g., gatekeeping).</p> <p>In addition, an Exceptional Access Process has been developed which allows Canadian Blood Services to review patient-specific requests for products that do not meet the approved listing criteria.</p> <p>Through Canadian Blood Services' Distribution Modernization project in Alberta, we are gathering more detailed, transaction-level data for Hemlibra (emicizumab)</p> |

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| | 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. | | and Glassia (alpha-1 proteinase inhibitor). The project could be expanded to include other provinces and other products. See recommendation 27 for additional details. |
| 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</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 (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.</p> | <p>This recommendation is considered addressed. As mentioned in recommendation 32, significant changes have been made to the Special Authorization Process. The addition of patient identifiers has improved communications between Canadian Blood Services and hospitals.</p> <p>This process was also digitized, using a centralized case-management system, removing duplication of data, streamlining the process, improving visibility and capturing the data in a centralized database. This process is now integrated into Canadian Blood Services' online ordering portal, which will further increase efficiencies, as this will remove the need for transcription of the requests and will streamline the process for prescribers/blood banks (e.g., replacing need to fax, improving visibility on contracts and renewals).</p> <p>In parallel, Canadian Blood Services has created an e-Formulary, which allows users to search the formulary for information on listed products. The e-formulary serves as a central location for customers to find all information pertaining to a product and its ordering (e.g., links to request forms and associated policy documents).</p> <p>To formalize and publish the urgent/emergency ordering process, the Special Authorization request forms now include a field to note the urgency of the request.</p> |

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| | 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. | | |
| 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. | 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> | <p>This recommendation is considered addressed. Canadian Blood Services has explored and subsequently put in place ways to better track partial use of PPRPs, recognizing that this work is relevant only to certain products and that Canadian Blood Services has no control over marketed vial sizes which is the domain of the manufacturer. The patient-specific data being captured through the updated Special Authorization request forms has enabled Canadian Blood Services to review dosing and guide manufacturers on vial sizes for addition to the formulary.</p> <p>Canadian Blood Services partnered with three hospitals in Ontario to hire a pharmacist to work in their hemophilia treatment centers. The pharmacist’s expertise is leveraged to improve dose customization for patients and remove wastage. During the research phase of this project, the pharmacist was able to save approximately 2.5 times their salary, by adjusting rFVIII and rFIX doses. When looking at emicizumab, between all three sites, the pharmacists saved approximately \$2M annually by optimizing dosing for patients.</p> <p>Two pharmacists continue to work in three hemophilia treatment centres in Ontario and Canadian Blood Services looks forward to continued discussions with governments on expanding the project to other parts of the country (there are 22 hemophilia treatment centres across the country).</p> |

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| 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. 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> | <p>This recommendation is considered addressed. Canadian Blood Services completed work with an external expert to determine how facets of value-based procurement could be integrated into future plasma protein and related product RFPs. The 2021 PPRP RFP included value-based procurement concepts, which allowed vendors to demonstrate additional value in addition to price. While this new approach delivered limited value, Canadian Blood Services will continue to include value-based procurement concepts in future plasma protein and related product RFPs.</p> |
| 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> | <p>This recommendation is considered addressed. An independent Fairness Monitor was incorporated into the 2021 PPRP RFP for recombinant formulary products and has been used in other subsequent RFPs since that time, including the competitive procurement process that was applied to establish a corporate partner for plasma collections to secure Canada's plasma supply for patients in the country and establish a domestic supply chain for immunoglobulins.</p> |

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| 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 | <p>This recommendation is considered addressed. The escalation process outlined in the October 2020 management response continues to be in place for PPRP RFPs.</p> |
| 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. 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>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> | <p>This recommendation is considered addressed. With global inflationary pressures, it is expected that future PPRP contracts will include price increases rather than cost savings and/or cost avoidance. The savings tracker has therefore become less meaningful as product and brand mixes have changed over time from those used as a baseline to calculate savings five years ago. Canadian Blood Services continues to work closely with Canada's Drug Agency (formerly CADTH) to identify system impacts of PPRPs.</p> |

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| 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. 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: <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. | <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> | <p>This recommendation is considered addressed. Canadian Blood Services and PT governments agreed on a process for notifying PT governments and obtaining their input before and after Canadian Blood Services' PPRP RFPs.</p> |
| 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. | <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</p> | <p>This recommendation is considered addressed. It is important to consider the impacts of COVID-19 which required the organization to appropriately focus on maintaining operations. The productivity and efficiency program was a point-in-time program and its principles are now embedded into Canadian Blood Services' Strategic Plan. The ePMO project management framework includes the identification of potential benefits as part of its gating processes.</p> |

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| | <ul style="list-style-type: none"> 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. | management approach to track the projects falling under PEP is now in place. | |
| 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> | 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. | This recommendation is considered addressed, as articulated in the October 2020 management response. This work is embedded into daily operations, and the continuous improvement framework evolves and matures with the needs of the business. |
| 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. | 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. | This recommendation is considered addressed. Canadian Blood Services uses a "Request for Proposal" process which requires that technology investments in excess of the established threshold value undergo a competitive tender process. This ensures that a formal, documented review of multiple options is completed before systems or services are purchased. |
| 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 | This recommendation is considered addressed, as articulated in the October 2020 management response. In addition to risk ratings and ongoing risk reviews, there is also a concurrent step in the business case approval process which requires a risk assessment to review |

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| | | projects in the corporate portfolio subject to the Canadian Blood Services’ project gating process contain detailed risks and associated ratings. | medium and complex business cases to ensure all risks are sufficiently captured. |
| 45 | <p>As part of its reporting process on major projects to the Board and Members, CBS should:</p> <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. <p>Project closeout reports should include an analysis of financial benefits realization and reasons for any shortfalls.</p> | 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.’ | This recommendation is considered addressed, as articulated in the October 2020 management response. |
| 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. | This recommendation is considered addressed. Internal processes are in place to ensure a clearer connection of project benefits with targeted benefits and the organization’s key focus areas. The alignment of benefits targets to performance targets is established within a project business case by using the organizational measures in place. 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. |

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| 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. | This recommendation is considered addressed, as articulated in the October 2020 management response. |
| 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. | This recommendation is considered addressed, as articulated in the October 2020 management response. Productivity results from the ASC project have been operationalized into supply chain collections activity. |
| 49 | <p>CBS’ ePMO should review all business cases to ensure that targets are stated for all benefits metrics and that mechanisms are in place to collect the information required to report on benefits realization at project close-out.</p> <ul style="list-style-type: none"> • 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> | 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. | This recommendation is considered addressed. Canadian Blood Services’ ePMO continues to effectively track benefit realization for all business cases on a project-by-project basis, as well as through portfolio level tracking and reporting. The business cases are reviewed to ensure alignment to these measures so they can be tracked and reported on. In some cases, this requires establishing an initial baseline. |
| 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 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 | This recommendation is considered addressed, as articulated in the October 2020 management response. |

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| | <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. | 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. | |
| 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> | 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>This recommendation is considered addressed, with the Canadian Blood Services Board of Directors' diversity strategy updated as follows:</p> <ul style="list-style-type: none"> Diverse characteristics sought for directors on the board are described in a board diversity statement. A diversity, equity and inclusion policy, which includes a definition of diversity, has been implemented and is reviewed bi-annually. The board has formally expressed support for the goals of the federal 50-30 Challenge, recognizing that the decision-making for director selection ultimately rests with PT governments. Diversity has been identified as a principle in the formal framework for recruiting, nominating and electing directors which has been reviewed by Canadian Blood Services and PT governments. The recruitment of directors follows best practice including, for each recruitment cycle: <ul style="list-style-type: none"> Development of a skills matrix that identifies gaps that currently exist or will exist as directors depart the board and a priority list of skills and attributes for potential candidates which includes diversity. |

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| | | | <ul style="list-style-type: none"> ○ Engagement of a professional recruitment firm to identify, screen and assess potential candidates. ○ Outreach / targeted recruitment to organizations representing equity deserving potential candidates. • A matrix will track the matching of the identified skills and diversity attributes to the candidates nominated and the new board composition. |
| 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. | 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 vicechair 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. | This recommendation is considered addressed. The key components of a successful succession planning program are individually in place at Canadian Blood Services. An overarching policy document has been prepared to describe the program in composite. Relevant learnings from the director recruitment, nomination and election process are incorporated into the plan. |
| 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. | 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 | This recommendation is considered addressed. An orientation program was developed in collaboration with PT governments for onboarding new PTBLC representatives and orientation materials are updated on a periodic basis to ensure they remain accurate and comprehensive. |

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| | | program for new PTBLC representatives which provides a thorough review of the national blood system and the specific role of the PTBLC. | |
| 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. | 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 | This recommendation is considered addressed. Canadian Blood Services and PT governments worked together to review the various performance measures and to identify relevant adjustments, with recognition that these measures will need to be periodically reassessed to align with Canadian Blood Services’ strategic priorities. |
| 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. | 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. | This recommendation is considered addressed, as articulated in the response to recommendation 54. |
| 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: | Canadian Blood Services will continue to provide the reporting and support to members needed for enhanced | This recommendation is considered addressed, as articulated in the response to recommendation 54. |

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| | <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 CB S 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. | 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. | This recommendation is considered addressed. Integrated risk views across products and services are summarized as part of the quarterly enterprise risk reporting process, with an operational risk summary report provided to the Executive Management Team and key leaders. When appropriate, operational risk information is included in the analysis of relevant corporate risks as part of the Enterprise Risk Report. |
| 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. | 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. | This recommendation is considered addressed. Canadian Blood Services has developed an organizational 'Corporate Risk Appetite' framework which contains risk appetite statements and management direction. The risk appetite has been leveraged in supporting complex organizational decisions, including the prioritization and selection of key projects, and in the development and execution of our strategic plan. |
| 59 | Develop a master BCM testing plan that identifies: | Canadian Blood Services agrees with this recommendation and will develop a Master Exercise Plan as a tool to | This recommendation is considered addressed. Canadian Blood Services has a master exercise and testing plan, |

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| | <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• roles and responsibilities for getting the testing completed. <p>Ask each site to customize the current generic Recovery Plan-Facility Failure to site specific plans.</p> | <p>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.</p> <p>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> | <p>which is refreshed each year. Numerous organizational exercises have been completed, both at the process level, and for significant events/hazards.</p> |