

Legislative
Assembly
of Ontario



Assemblée
législative
de l'Ontario

STANDING COMMITTEE ON PUBLIC ACCOUNTS

VALUE-FOR-MONEY AUDIT: BLOOD MANAGEMENT AND SAFETY

(2020 ANNUAL REPORT OF THE OFFICE OF THE AUDITOR GENERAL OF
ONTARIO)

2nd Session, 42nd Parliament
71 Elizabeth II

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The Honourable Ted Arnott, MPP
Speaker of the Legislative Assembly

Sir,

Your Standing Committee on Public Accounts has the honour to present its Report and commands it to the House.



Taras Natyshak, MPP
Chair of the Committee

Queen's Park
February 2022

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2nd Session, 42nd Parliament

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(September 22, 2020 - October 20, 2021)

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INTRODUCTION

On May 27, 2021, the Standing Committee on Public Accounts held public hearings on the audit of Blood Management and Safety (*2020 Annual Report of the Auditor General of Ontario*), administered by Canadian Blood Services and the Ministry of Health.

The Committee endorses the Auditor's findings and recommendations, and presents its own findings, views, and recommendations in this report. The Committee requests that the Ministry of Health provide the Clerk of the Committee with written responses to the recommendations within 120 calendar days of the tabling of this report with the Speaker of the Legislative Assembly, unless otherwise specified.

ACKNOWLEDGEMENTS

The Committee extends its appreciation to officials from the Ministry of Health and Canadian Blood Services. The Committee also acknowledges the assistance provided during the hearings and report writing deliberations by the Office of the Auditor General, the Clerk of the Committee, and staff in Legislative Research.

OVERVIEW

Canadian Blood Services (CBS) is responsible for providing a safe, secure and affordable supply of blood, blood products and their alternatives to the provinces and territories.

Blood Components and Products

Donated blood is either:

- broken down into its **component parts** (plasma, red blood cells, and platelets) for direct transfusion; or
- separated, or fractionated, into **blood products**, which are purified concentrations of a certain combination of proteins derived from plasma and also include recombinant products, which are not derived from plasma; blood products are used to treat specific conditions such as neurological and immune disorders.

Hospitals in Ontario obtain their blood components and products from Canadian Blood Services. Blood components used in hospitals are obtained from Canadian donors who voluntarily provided blood without compensation to Canadian Blood Services. In contrast, Canadian Blood Services purchases most processed blood products it supplies to Ontario hospitals from foreign countries, primarily through the United States and others in Europe.

Immunoglobulins (Igs) are a type of blood product, used for a range of conditions, such as immune disorders, neurological conditions and other medical problems. Ontario pays more for immunoglobulins than all other blood products combined.

Federal-Provincial Relationship

The federal and provincial/territorial governments (except Quebec) signed a Memorandum of Understanding (MOU) in 1998 to establish Canadian Blood Services as Canada's national blood operator.

Two federal organizations are involved in blood management and oversight: Health Canada and the Public Health Agency of Canada.

- Health Canada regulates blood according to federal regulations, which involves inspecting hospitals and blood donor clinics for such activities as blood storage and processing, and collecting and reviewing data about investigations of adverse transfusion reactions related to the safety of the blood. Ontario relies on Health Canada to inspect Ontario hospital blood banks and Canadian Blood Services donor sites for adherence to the federal Blood Regulations, which are regulations under the federal *Food and Drug Act* that specifically relate to protecting the blood supply in Canada.
- The Public Health Agency of Canada conducts public health surveillance of errors and adverse events related to blood transfusion.

AUDIT OBJECTIVE AND SCOPE

The audit's objective was to assess whether the Ministry of Health (Ministry), in conjunction with Canadian Blood Services, had effective systems and procedures in place to provide Ontarians access to a safe and sufficient supply of blood components and products that meets their health-care needs in a cost-effective manner and complies with contractual agreements and relevant policies and procedures.

The audit criteria were established based on a review of applicable legislation, policies and procedures, internal and external studies, and best practices.

MAIN POINTS OF AUDIT

The audit found that while the supply of blood components and products as of August 2020 was safe and has been reasonably reliable, the COVID-19 pandemic has magnified existing weaknesses in the reliability of the supply of the immunoglobulin blood product. Canadian Blood Services fell short of its own goal of obtaining 50% of blood plasma needed for this product in Canada (it obtained 13.7% in 2019/20). The audit noted that the effect of the pandemic on Ig has not yet been realized because of the significant lead time to fractionate plasma and produce Ig.

Further, the audit found that neither the Ministry nor Canadian Blood Services had systems to assess how hospitals are using blood to treat patients or whether they are using it appropriately since they rely on the clinical expertise in each hospital for appropriate blood use (which is not well reported or tracked). The Ministry has acknowledged that it is responsible for promoting the appropriate use of blood and achieving better value for money.

Other audit findings include:

- Ontario relies heavily on suppliers in the United States for essential and high-demand blood products including immunoglobulins, which are fractionated from plasma collected by these suppliers.
- Hospitals' use and waste of blood is not well reported and tracked. Although Canadian Blood Services encourages hospitals to report their use through the Blood Component and Product Disposition Database, some hospitals either do not report or report inconsistently.
- The Ministry-sponsored Ontario Regional Blood Coordinating Network (Network) cannot require hospital staff to change practices in blood use; the Network is funded to identify and address issues in blood use in Ontario hospitals.
- The Ministry has not conducted regular assessments of the Nurse Transfusion Coordinators program (Program). The Program funded 28 nurses in 23 hospitals to counsel patients toward actions that reduce the need for blood transfusions in upcoming surgeries and improve patient outcomes.
- The Ministry pays Canadian Blood Services over \$500 million annually for blood without confirming that it only pays for blood components and products hospitals received.

ISSUES RAISED IN THE AUDIT AND BEFORE THE COMMITTEE

A number of issues were raised in the audit report and before the Committee. The Committee considers the following issues to be of particular importance.

The Ministry of Health informed the Committee it is making progress on addressing the audit report's recommendations, noting that the safety and surveillance of the blood system have always been a priority in Ontario. Canadian Blood Services works closely with the health systems across the country to deliver value by improving patient outcomes, enhancing system performance, and optimizing cost efficiency. CBS stated that Ontario is a major contributor to the national blood system, in terms of infrastructure, human capital, and technology.

The Committee heard that blood safety is a multi-tiered process spanning collection and production. The blood safety process starts by identifying optimal blood donors who go through strict screening criteria and a regulated blood collection process. During production, the blood is separated into different components (red blood cells, platelets, and plasma) and tested. Once a hospital receives blood there are a series of steps to verify its suitability, including additional testing.

The Ministry told the Committee the factors which contribute to the successful management of the blood system are twofold – the unique role of Canadian Blood Services and blood donors as well as Ontario's investments in provincial programs focused on optimizing the use of blood (totalling just under \$6 million annually). Ontario's investments promote the appropriate use of blood and blood products, develop and implement tools for Ontario hospitals to adopt evidence-

based best practice for transfusion services and medicine, and deliver cost efficiencies within the provincial health care system.

The provincial Blood Utilization Strategy which optimizes the use of blood and blood products includes five programs. The Committee heard about several, including: the Ontario Regional Blood Coordinating Network (ORBCoN), which develops best practice guidelines and tools for hospitals; the Ontario Nurse Transfusion Coordinators Program, which uses and promotes treatment strategies in hospitals to avoid unnecessary blood transfusion for surgical patients; and the Ontario Immunoglobulin Treatment Program, which monitors and trains patients living with immunodeficiency diseases on how to self-administer treatment at home. The Committee heard that these provincial programs have resulted in savings by reducing waste, lowering infection rates, and shortening hospital stays.

The Ministry explained it is focused on working with Canadian Blood Services and its provincial and territorial partners to continually monitor the supply of global blood plasma. It explained that actions taken thus far, such as requesting hospitals to follow best practices for immunoglobulin administration, have helped to mitigate risks. The Committee heard that the Ministry, Canadian Blood Services, and provincial and territorial partners will participate in a national policy discussion in 2021 convened by Health Canada to achieve consensus on the best legislative and regulatory framework for achieving plasma self-sufficiency. Progress is also underway to implement an electronic immune globulin ordering system to increase the availability of high-quality data and help to improve how blood product is used.

Risk of Transmitting Disease through Transfusion is Low

According to Canadian Blood Services, there have been no confirmed cases of blood-borne infections of HIV, Hepatitis B or Hepatitis C resulting from a blood transfusion since the early 2000s.

The audit found that Health Canada did not identify significant blood safety risks in its inspections of blood banks. A blood bank is a unit within a hospital laboratory that stores and distributes blood components and products for use within the hospital. From 2015 until July 2020, Health Canada had inspected all 14 registered blood banks that perform higher-risk activities and one out of 144 non-registered blood banks in Ontario. The Auditor noted that the Ministry was not aware that most unregistered blood banks were not inspected by Health Canada and the Ministry did not obtain and review the data from Health Canada's inspections of blood banks and donor sites.

The Committee asked about the apparent lack of oversight for blood banks in Ontario hospitals. The Ministry explained that there are 144 hospitals in Ontario that are not required to register with Health Canada since they do not perform activities that require registration. Under the Blood Regulations in the federal *Food and Drugs Act*, a requirement for registration is manufacturing and transforming blood and making changes to blood products; only 14 hospitals perform these activities. However, non-registered hospitals still need to meet certain requirements and standards for labelling and storing blood. Accreditation Canada accredits all hospital transfusion labs, including the 144 non-registered hospital transfusion labs, for the safety of transfusion services. The Ministry

expects that the Ontario Regional Blood Coordinating Network will be able to monitor and assess the results and share common issues and concerns with hospitals by December 2022.

Health Canada has agreed to share the hospital inspection results with the Ministry of Health. The Ministry stated it will work with the Ontario Regional Blood Coordinating Network to incorporate Health Canada's hospital inspection report findings within the joint annual Canadian Blood Services/ ORBCoN hospital site visits.

Committee Recommendation

The Standing Committee on Public Accounts recommends that

1. The Ministry of Health should

- a. establish a process to regularly receive information from Health Canada regarding which hospital blood banks and Canadian Blood Services donor centres are inspected and share the results with Ontario Health; and
- b. better monitor compliance with federal regulations regarding blood storage by regularly reviewing Health Canada's hospital inspection reports to identify common risks and target these areas through education initiatives with hospitals.

Blood Data Stored in Multiple Systems Limiting Real-time Data

Blood inventory, usage and clinical data on patients are stored in different information systems across all Ontario hospitals. There is no centralized hospital blood information system that allows Canadian Blood Services to see what components or products each Ontario hospital has on hand.

The Committee expressed concern that many of the blood tracking systems are based on outdated technologies, such as fax machines, and asked why it will take three to four years to update the technology. Canadian Blood Services explained that it will take several years to implement electronic ordering because it has to integrate its online system with all hospitals in Canada, many of which have very different IT systems in their blood banks or laboratory systems. CBS stated it is working closely with the provinces to implement a fully integrated vendor management system with real time inventory.

The Ministry explained that the Ontario Contingency Plan for Blood Shortages requires all hospitals to report their inventory to Canadian Blood Services through their Blood Component and Disposition System during a shortage advisory. The Ministry acknowledged that additional improvements to data collection in the management of blood components and products would support decision-making and planning. It supports an interim step to improve hospital reporting when hospitals are at risk or in shortage to better inform collaborative efforts with Canadian Blood Services. Further, it will explore McMaster University's proposal to expand its blood database province-wide as a solution to the blood-management data systems issue.

Committee Recommendation

The Standing Committee on Public Accounts recommends that

2. **The Ministry of Health and Ontario Health should work together to improve data-driven decision-making to manage the supply of blood components and products by**
 - a. **regularly reminding hospitals of the requirement to report inventory to Canadian Blood Services;**
 - b. **regularly assessing potential information technology solutions for blood management across multiple hospital systems, including Canadian Blood Services' plans to expand electronic ordering and McMaster University's blood-management data system; and**
 - c. **sharing Ontario data with Canadian Blood Services to improve insights and strengthen analysis.**

Immunoglobulins Used for Conditions Not Included in the Provincial Guidelines

The audit found that neither Canadian Blood Services nor the Ministry collects information on how immunoglobulins are used in Ontario hospitals. The audit report stated that without information on the conditions that Ig is used to treat, the Ministry cannot assure that it is used appropriately in accordance with the preferred conditions listed in the provincial utilization guidelines. The Ministry developed Ontario-specific utilization guidelines in 2009 to inform hospitals on Ig's common and clinically appropriate uses, dosages, and frequency of administration.

The Ministry stated it has started work to implement an electronic immunoglobulin ordering system to manage their use in Ontario hospitals. It expects this to improve information gathering in areas, such as understanding which medical conditions are being treated with Ig.

Committee Recommendation

The Standing Committee on Public Accounts recommends that

3. **The Ministry of Health, working together with Ontario Health, should better manage the demand and supply of immunoglobulins by**
 - a. **supporting the implementation of an electronic hospital ordering system for immunoglobulins;**
 - b. **eliminating the option of prescribing immunoglobulin where the Ontario Immune Globulin Utilization Guidelines do not recommend its use;**
 - c. **updating the Ontario Immune Globulin Utilization Guidelines to ensure immunoglobulins are only recommended for use where there is evidence to prove their effectiveness;**

-
- d. working with the Ontario Regional Blood Coordinating Network to regularly educate physicians on the use of the Ontario Immune Globulin Utilization Guidelines; and
 - e. developing a system to monitor hospitals' adoption of the Ontario Immune Globulin Utilization Guidelines.

Ontario Hospitals Not Required to Report Transfusion Errors and Injuries

The Public Health Agency of Canada co-ordinates two blood transfusion surveillance systems that collect transfusion adverse event and error data: the Transfusion Transmitted Injuries Surveillance System (TTISS) and the Transfusion Error Surveillance System (TESS). This data is used to inform decision-making to improve patient safety, by providing a national platform; however, reporting is largely voluntary. The audit found that in 2019, all 158 hospital sites in Ontario reported some—but not all—transfusion injury data to the Injury Surveillance System, and only three formally reported transfusion errors to the Error Surveillance System.

The Committee heard that even with voluntary reporting Ontario provides a large amount of data for the federal health agency to analyze in order to identify and address risks associated with the use of blood, blood components, and blood products. CBS noted it is not uncommon to have effective and voluntary reporting systems from which large amounts of data can be gleaned to improve practice across the system.

The Committee asked why reporting for the blood transfusion surveillance systems is voluntary rather than mandatory. Canadian Blood Services explained that when TTISS and TESS were established, no country had a mandatory reporting system for hospital-based adverse transfusion events. Canadian Blood Services told the Committee that as a manufacturer licensed by Health Canada, it does have a mandatory reporting system to the federal regulator but only past a certain threshold (i.e., not minor deviations). The Ministry explained the decision to make reporting mandatory falls to government.

Committee Recommendation

The Standing Committee on Public Accounts recommends that

- 4. The Ministry of Health should improve the tracking of transfusion errors and injuries by requesting that all hospitals report serious transfusion-related events.**

Blood Supply Meeting Demand in Most Cases, but Short-Term Shortages Occur

The audit report noted that blood shortages are not common but do occur. Canadian Blood Services experienced actual shortages of blood components and products on two occasions in the five-year period between August 2015 and July 2020. Canadian Blood Services set a goal to achieve 50% self-sufficiency in plasma collection by 2023/24. However, the audit found that since 2013/14, the portion of plasma collected domestically for the purposes of Ig production has been declining steadily, from 22.7% to 13.7% in 2019/20.

The Committee asked if a goal of 50% self-sufficiency in plasma is possible without paid collection. The Ministry told the Committee that provincial and territorial governments have been working to support Canadian Blood Services to establish more plasma collection capacity and funded three dedicated plasma collection centres, one each in Ontario, Alberta, and British Columbia. By 2023-24, Canadian Blood Services will have 11 dedicated plasma centres which will help increase plasma collection self-sufficiency from 13% to 25%. CBS stated it is evaluating how to achieve 50% self-sufficiency by collecting more plasma and comparing other models of collection to a non-remunerated model to determine how quickly it can scale from 25% to 50% in plasma collection self-sufficiency.

Committee Recommendation

The Standing Committee on Public Accounts recommends that

5. **The Ministry of Health should request that Canadian Blood Services accelerate the plan to achieve 50% national plasma collection self-sufficiency, with clear timelines and provisions to monitor the plan's implementation.**

Best Practice Guideline Helps Reduce Ontario Usage of Blood Components and Products

The Ontario Regional Blood Coordinating Network (Network), led by two hospitals and one university, promotes appropriate use of blood and improves patient safety. The audit found that not all hospitals adopt the best practices the Ontario Regional Blood Coordinating Network promotes, and not all hospitals participate in its studies.

The Ministry told the Auditor that provinces and territories are responsible for making blood alternatives available to reduce the need for transfusion, but this responsibility has not been formalized in any documents. The Ministry acknowledged the need for better coordination and alignment between the Ministry and Canadian Blood Services. It noted the Ontario government's responsibility to identify where a pharmaceutical product can be a good and safe alternative to blood.

The Committee asked why hospitals fail to adopt the Ontario Regional Blood Coordinating Network's best practices. The Ministry explained that the translation of best practices into implementation in the health care sector is a continual effort. To ensure that best practices are implemented systematically, the Ministry relies on permanent structures, clinical leadership, and performance measurement. The Ministry has met with the Network to determine how to measure hospitals' participation and adoption of its clinical best practice guidelines.

Committee Recommendations

The Standing Committee on Public Accounts recommends that

- 6. The Ministry of Health, in order to increase the effectiveness of the Ontario Regional Blood Coordinating Network (Network) guidelines on transfusion medicine best practices, should**
 - a. work with the Ontario Hospital Association to develop a plan to increase hospitals' participation in the Network; and**
 - b. monitor hospitals' adoption of the Network's best practices to help achieve better patient outcomes.**
- 7. The Ministry of Health, in order to encourage more effective, evidence-based use of blood components, blood products, and alternatives to blood, should**
 - a. work with the Canadian Agency for Drugs and Technologies in Health and Canadian Blood Services to periodically assess cost-effective alternatives to blood; and**
 - b. use data on the uses of immunoglobulins to inform areas of focus for the Ministry's decision-making on alternatives to blood.**

Ministry Does Not Monitor Cost-Effectiveness of Blood Utilization Programs

Nurse Co-ordinators Program

The audit found that the Ministry does not have information to compare the transfusion rates of hospitals with the Ontario Nurse Transfusion Coordinators Program (Program) to hospitals without the Program. Further, the audit found that not all Nurse Co-ordinators in the Program report program activities following program guidelines.

The Ministry explained that as the Program grows and scales there are always consistency challenges. The Ministry supports conducting an assessment of the Program to evaluate its effectiveness in relation to patient outcomes and health system costs to better inform performance measures and reporting. The Ministry has consulted with the Ontario Blood Consultation Group regarding implementing the audit's recommendation and plans to discuss the recommendation with the Ontario Nurse Transfusion Coordinators Program.

Payments for Blood

The audit also noted that the Ministry does not have processes to confirm that its payments for blood components and products are reasonable since it does not perform any reconciliations between what hospitals receive and what the Ministry pays for.

The Committee asked about the 5% discrepancy between what is ordered and delivered and what is paid for. The Ministry stated it will audit a sample of Ontario hospitals to verify that payments from the Ministry to Canadian Blood Services are for products shipped to and received by Ontario hospitals to identify any operational issues and provide post-payment verification.

Data on Transfusion Injuries and Errors to Monitor Patient Outcomes

The audit found that the Ministry does not use transfusion injuries and errors reported to the two national transfusion surveillance systems to monitor whether Ontario hospitals on the whole have fewer incidents year over year. Further, Ontario's Injury Surveillance System program administrators still did not have any evidence that the Injury Surveillance System in Ontario had helped improve patient safety.

The Ministry noted it has met with the Ontario Regional Blood Coordinating Network and discussed developing a mechanism for monitoring transfusion surveillance data by hospitals and had exploratory discussions for the Network to potentially assume this oversight role.

Public and Internal Reporting Does Not Provide Meaningful Information on Ontario Activities

The audit found that Canadian Blood Services does not break down performance (such as product demand, productivity, quality and safety performance) by province. The Auditor noted that the Ministry had not requested provincial performance reporting in the five years prior to the audit (and there was nothing to prevent provinces from requesting provincial data).

The Ministry stated it is consulting with other provincial and territorial health ministries regarding the audit's recommendation to improve its evaluation of Canadian Blood Services' performance. It will establish a provincial-territorial and Canadian Blood Services working group and determine which national performance measures can be provided for Ontario.

Committee Recommendations

The Standing Committee on Public Accounts recommends that:

- 8. The Ministry of Health, in order to better evaluate and improve the effectiveness of the Ontario Nurse Transfusion Coordinators Program (Program), should**

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- a. collect and analyze data on transfusion activities in hospitals with and without the Program including the number of units of blood transfused, costs, and the number of patients transfused to determine value-for-money;
 - b. request that the Program administrators establish performance indicators and outcome measures to demonstrate the effectiveness of the Program, and report this information on an annual basis; and
 - c. explore mechanisms to require hospitals with the Program to follow best practices.
9. The Ministry of Health should establish a process to ensure its payments to Canadian Blood Services are for products shipped and received by Ontario hospitals on a regular basis, with underlying unit costs based on audited financial statements of Canadian Blood Services.
10. The Ministry of Health and Ontario Health should work together to:
- a. clarify responsibilities for monitoring transfusion surveillance data reported by hospitals;
 - b. monitor trends of serious transfusion incidents; and,
 - c. establish a plan for hospitals to share investigation reports of serious transfusion incidents on a timely basis.
11. The Ministry of Health should improve its ability to evaluate Canadian Blood Services' performance to provide safe blood to hospitals in a cost-efficient manner by
- a. requesting that Canadian Blood Services provide Ontario-specific results for national performance measures;
 - b. regularly reviewing and assessing Canadian Blood Services' performance through national performance measures; and
 - c. requesting that Canadian Blood Services provide information on Ontario's trends on an annual basis.

COVID-19's Impact on Blood System

The audit report highlighted concerns of disruption to the immunoglobulin supply in Ontario given supply chain issues due to the pandemic, particularly regarding global plasma production. The audit noted shortages are expected to affect the supply to the fall of 2021 due to shifting donor behaviour, prices for Ig, and Canada's reliance on the United States.

The Committee heard that in the early months of the pandemic Canadian Blood Services increased its inventory holdings of immunoglobulin (estimating it had collected approximately a two-year supply). Canadian Blood Services told the Committee it has robust contracts with suppliers that guarantee holdings in their

warehouses in Canada and deliveries to Canadian Blood Services to meet hospitals' needs. Further, it worked with the National Advisory Committee on Blood and Blood Products to establish specific guidelines to optimize the use of Ig during the pandemic. In the long term, Canadian Blood Services emphasized the need to collect more plasma and fractionate it within Canada, which will eliminate concerns around dependence on the US manufacturing supply chain and global borders. It noted that it had raised concerns to its provincial and territorial partners regarding potential global shortages of immunoglobulin prior to the pandemic.

The Committee asked why there are no manufacturing (i.e., fractionation) capabilities within Canada. Canadian Blood Services explained that a fractionation facility is being built in Quebec by one of the largest global plasma collectors and fractionators (Grifols) and it will serve all of Canada, not just Quebec. Canadian Blood Services shared that it considered building its own fractionation facility several times but decided against this, citing costs and a lack of expertise. The Ministry told the Committee that provincial and territorial governments have been working to support Canadian Blood Services to establish more plasma collection capacity in the country. As previously mentioned, CBS is building three additional dedicated plasma collection centres.

The Committee asked about what other measures have been implemented to ensure the security of the blood supply. The Ministry emphasized that there have been no actual shortages of any blood components or products throughout the pandemic. Blood shortages are classified by four different stages of advisories: green phase, amber phase, red phase, and recovery phase. The various phases indicate blood inventory levels as well as hospitals' responsibilities. Canadian Blood Services has issued 13 advisories in the green and recovery phases since the start of the pandemic.

In March 2020 the national and provincial emergency blood committees (National Emergency Blood Management Committee and Ontario Emergency Blood Management Committee) were convened to address the impact of the pandemic on the blood supply system and provincial-territorial utilization. The Ontario Emergency Blood Management Committee met weekly to ensure recommendations would be appropriately communicated within the health care system and provide advice to the national committee. The Ministry increased its communication with Ontario hospitals and encouraged initiatives and the issuance of advisories consistent with the issuance of the 13 advisories noted above. It also increased the frequency of ad hoc meetings with stakeholders to discuss the impact of COVID-19 on the blood supply.

Canadian Blood Services relied on its previously established business continuity management program, leveraging supply chain resilience and business continuity capabilities. It worked closely with all the provinces and territories to identify investments to avoid supply disruptions, including investments for personal protective equipment, redesigning workflow in collection environments, and creating physical barriers.

The audit report noted that 27 Ontario hospital sites are participating in a North American study to test the safety and effectiveness of using a recovered COVID-19 patient's antibodies to help treat current COVID-19 patients. The Committee heard that the clinical trial showed that convalescent plasma was not an effective therapy for patients admitted to hospitals with COVID-19 for those waiting for ICU admission or in the ICU.

Committee Recommendations

The Standing Committee on Public Accounts recommends that:

- 12. The Ministry of Health should prepare for a limited supply of immunoglobulins (Igs) and protect Ontarians by**
 - a. ensuring Ontario hospitals comply with the National Emergency Blood Management Committee's action items, including developing shortage management plans, following Ig best practices and utilization guidelines, and updating laboratory information systems to accept all Ig brands and vial sizes carried by Canadian Blood Services;**
 - b. exploring additional measures, if necessary, and consider enforcement mechanisms to ensure hospitals follow provincial utilization guidelines or guidelines within the National Immune Globulin Shortage Plan (Shortage Plan);**
 - c. continuing to work with the National Emergency Blood Committee, the Ontario Emergency Blood Committee, Canadian Blood Services and the Provincial/Territorial Blood Liaison Committee to participate in a national response; and**
 - d. regularly updating calculations to estimate the number of patients in most critical need of Ig in the event of an amber or red advisory to ensure the equitable distribution of Ig across Ontario.**
- 13. The Ministry of Health should confirm that the production of the immunoglobulin manufacturing facility being built in Quebec will be in a position to serve all of Canada and ensure the facility has national outreach.**

CONSOLIDATED LIST OF COMMITTEE RECOMMENDATIONS

The Standing Committee on Public Accounts recommends that:

- 1. The Ministry of Health should**
 - a. establish a process to regularly receive information from Health Canada regarding which hospital blood banks and Canadian Blood Services donor centres are inspected and share the results with Ontario Health; and**
 - b. better monitor compliance with federal regulations regarding blood storage by regularly reviewing Health Canada's hospital inspection reports to identify common risks and target these areas through education initiatives with hospitals.**
- 2. The Ministry of Health and Ontario Health should work together to improve data-driven decision-making to manage the supply of blood components and products by**
 - a. regularly reminding hospitals of the requirement to report inventory to Canadian Blood Services;**
 - b. regularly assessing potential information technology solutions for blood management across multiple hospital systems, including Canadian Blood Services' plans to expand electronic ordering and McMaster University's blood-management data system; and**
 - c. sharing Ontario data with Canadian Blood Services to improve insights and strengthen analysis.**
- 3. The Ministry of Health, working together with Ontario Health, should better manage the demand and supply of immunoglobulins by**
 - a. supporting the implementation of an electronic hospital ordering system for immunoglobulins;**
 - b. eliminating the option of prescribing immunoglobulin where the Ontario Immune Globulin Utilization Guidelines do not recommend its use;**
 - c. updating the Ontario Immune Globulin Utilization Guidelines to ensure immunoglobulins are only recommended for use where there is evidence to prove their effectiveness;**
 - d. working with the Ontario Regional Blood Coordinating Network to regularly educate physicians on the use of the Ontario Immune Globulin Utilization Guidelines; and**
 - e. developing a system to monitor hospitals' adoption of the Ontario Immune Globulin Utilization Guidelines.**

4. The Ministry of Health should improve the tracking of transfusion errors and injuries by requesting that all hospitals report serious transfusion-related events.
5. The Ministry of Health should request that Canadian Blood Services accelerate the plan to achieve 50% national plasma collection self-sufficiency, with clear timelines and provisions to monitor the plan's implementation.
6. The Ministry of Health, in order to increase the effectiveness of the Ontario Regional Blood Coordinating Network (Network) guidelines on transfusion medicine best practices, should
 - a. work with the Ontario Hospital Association to develop a plan to increase hospitals' participation in the Network; and
 - b. monitor hospitals' adoption of the Network's best practices to help achieve better patient outcomes.
7. The Ministry of Health, in order to encourage more effective, evidence-based use of blood components, blood products, and alternatives to blood, should
 - a. work with the Canadian Agency for Drugs and Technologies in Health and Canadian Blood Services to periodically assess cost-effective alternatives to blood; and
 - b. use data on the uses of immunoglobulins to inform areas of focus for the Ministry's decision-making on alternatives to blood.
8. The Ministry of Health, in order to better evaluate and improve the effectiveness of the Ontario Nurse Transfusion Coordinators Program (Program), should
 - a. collect and analyze data on transfusion activities in hospitals with and without the Program including the number of units of blood transfused, costs, and the number of patients transfused to determine value-for-money;
 - b. request that the Program administrators establish performance indicators and outcome measures to demonstrate the effectiveness of the Program, and report this information on an annual basis; and
 - c. explore mechanisms to require hospitals with the Program to follow best practices.
9. The Ministry of Health should establish a process to ensure its payments to Canadian Blood Services are for products shipped and received by Ontario hospitals on a regular basis, with underlying unit costs based on audited financial statements of Canadian Blood Services.

10. The Ministry of Health and Ontario Health should work together to:

- a. clarify responsibilities for monitoring transfusion surveillance data reported by hospitals;
- b. monitor trends of serious transfusion incidents; and,
- c. establish a plan for hospitals to share investigation reports of serious transfusion incidents on a timely basis.

11. The Ministry of Health should improve its ability to evaluate Canadian Blood Services' performance to provide safe blood to hospitals in a cost-efficient manner by

- a. requesting that Canadian Blood Services provide Ontario-specific results for national performance measures;
- b. regularly reviewing and assessing Canadian Blood Services' performance through national performance measures; and
- c. requesting that Canadian Blood Services provide information on Ontario's trends on an annual basis.

12. The Ministry of Health should prepare for a limited supply of immunoglobulins (Igs) and protect Ontarians by

- a. ensuring Ontario hospitals comply with the National Emergency Blood Management Committee's action items, including developing shortage management plans, following Ig best practices and utilization guidelines, and updating laboratory information systems to accept all Ig brands and vial sizes carried by Canadian Blood Services;
- b. exploring additional measures, if necessary, and consider enforcement mechanisms to ensure hospitals follow provincial utilization guidelines or guidelines within the National Immune Globulin Shortage Plan (Shortage Plan);
- c. continuing to work with the National Emergency Blood Committee, the Ontario Emergency Blood Committee, Canadian Blood Services and the Provincial/Territorial Blood Liaison Committee to participate in a national response; and
- d. regularly updating calculations to estimate the number of patients in most critical need of Ig in the event of an amber or red advisory to ensure the equitable distribution of Ig across Ontario.

13. The Ministry of Health should confirm that the production of the immunoglobulin manufacturing facility being built in Quebec will be in a position to serve all of Canada and ensure the facility has national outreach.