Office of the Auditor General of Ontario

Value-for-Money Audit

Blood Management and Safety

December 2020

Ministry of Health
Canadian Blood Services

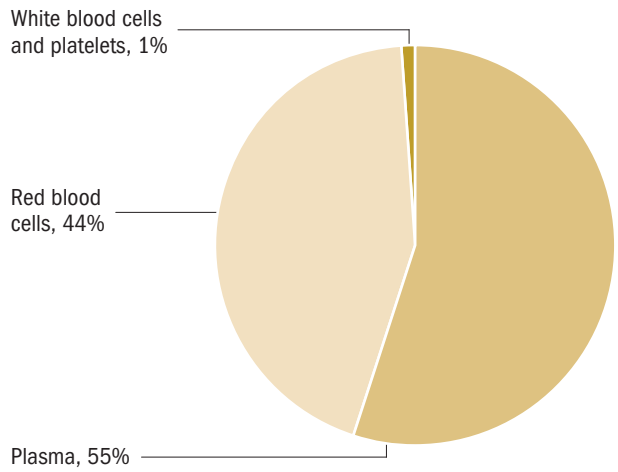
Blood Management and Safety

1.0 Summary

Blood is essential to human health because it delivers necessary nutrients and oxygen to all parts of the human body. When a person loses blood following an injury or has an emergency surgery, undergoes cancer treatment, or has certain health conditions that require regular blood transfusions, they rely on Ontario hospitals to have a safe supply of blood available to help treat them and sometimes save their life. Donated blood is either:

- broken down into its **component** parts (plasma, red blood cells, and platelets) for direct transfusion, as shown in **Figure 1**; or
- separated, or fractionated, into plasma protein products, hereafter called **blood products**, which are purified concentrations of certain combinations of proteins derived from plasma and also include recombinant products, which are not derived from plasma; a class of drugs derived from blood and used to treat specific conditions such as immune disorders and some neurological conditions.

Figure 1: Components in Whole Blood
Prepared by the Office of the Auditor General of Ontario



Hospitals in Ontario obtain their blood components and products from Canadian Blood Services, a national body that was established in 1998. All **blood components** used in Ontario 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. Canadian Blood Services informed us this is because there are no licensed Canadian drug manufacturers that have the capacity to fractionate plasma into these blood products. The Ontario Ministry of Health (Ministry) and all Canadian provinces and territories except Quebec (which has its own blood service) provide funding to Canadian Blood Services. It was created in response to a major blood system crisis in Canada when approximately 2,000 people contracted HIV and another 30,000 contracted hepatitis C from tainted blood and operates pursuant to a 1998

Memorandum of Understanding (MOU) between the federal government and provincial and territorial governments (except Quebec). It is responsible for providing a safe, secure and affordable supply of blood, blood products and their alternatives to its funding provinces and territories. Federal organizations are involved in blood management and oversight: Health Canada regulates blood according to federal regulations, which involves inspecting hospitals and blood donor clinics on 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; the Public Health Agency of Canada conducts public health surveillance of errors and adverse events related to blood transfusion.

In 2019/20, the Ministry of Health contributed $562 million to Canadian Blood Services—representing about 50% of total funding from all provinces and territories—to provide blood components and products to Ontario hospitals at no cost to them. About 40% of this funding went toward blood components; the other 60% went toward blood products.

Our 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 (Ig) blood product: Canadian Blood Services' self-sufficiency in collecting enough plasma to produce this blood product, at 13.7% in 2019/20, falls far short of its own goal of obtaining 50% of blood plasma needed for this product in Canada. Canadian Blood Services continues to rely primarily on US-based suppliers to provide blood products, though it also has some Europe-based suppliers to offset the risk. Given the significant lead time needed (up to a year) to fractionate plasma and produce immunoglobulins (Ig), the effect of the COVID-19 pandemic on the supply of Ig has not yet been realized. However, these US-based suppliers are at risk of becoming less dependable in supplying Canada, with early estimates indicating as much as a 15% decrease in plasma supply given increasing global demands and the potentially reduced donations during the COVID-19 pandemic. This makes effective Ig inventory management of blood products even more critical going forward in order to manage supply across the country. And effective inventory management requires a better understanding of how blood is used to treat patients in hospitals so that Canadian Blood Services can more accurately forecast and respond to shortages of any component.

We also 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 are relying on the clinical expertise in each hospital for appropriate blood use. While individual physicians have ultimate discretion to prescribe based on their patients' needs, the Ministry has indicated that it is responsible for promoting the appropriate use of blood and achieving better value for money.

Ontario hospitals use a variety of hospital information systems to record their blood inventories, blood use and related patient clinical data. These systems cannot be readily integrated so that relevant information on blood use can be shared and analyzed—for example, to inform decisions related to Canadian Blood Services' national blood supply plan and any potential implications on its expenditures. Hospitals are not required to report complete blood inventory data to Canadian Blood Services, which makes it difficult for either party to manage blood efficiently across Ontario hospitals and the overall province on an ongoing basis. Such reporting remains optional even though Canadian Blood Services continues to emphasize its importance. We found that in 2019/20, 43% of hospitals did not report their use of blood components by blood type; also, in the 2019 calendar year, 13% of hospitals did not report on their use of blood products. The lack of consolidated and complete information about blood component and product inventory and use makes it more difficult for the province to quickly address shortage situations and ensure

hospital physicians use blood only when necessary and according to provincial guidelines that were developed for one particular high-demand blood product called immunoglobulins.

Another challenge is that Canadian Blood Services provides blood components and products to Ontario hospitals at no cost to the hospitals. As such, there is less incentive for hospitals to invest time and resources into managing their use. Hospitals also have less incentive to use alternatives when available—such as using intravenous iron before a planned surgery to reduce the need for blood transfusions—as they must be paid for with their own budgets. In fact, hospital staff told us they usually required their patients to pay for this alternative treatment, which may further reduce uptake and thereby undermine efforts to minimize unnecessary blood transfusions. The 1997 Royal Commission of Inquiry on the Blood System in Canada recognized the inherent problem with blood being free to hospitals and recommended that hospital budgets be increased to pay for blood components and products. Some blood experts also informed us that blood is sometimes used inappropriately as a result of the current funding model.

A 2017 Ministry study of a sample of Ontario hospitals found that hospital physicians were overprescribing the highest-demand and highest-cost blood product, immunoglobulins (Ig), contrary to provincial usage guidelines—by about $2.2 million of Ig over eight months, which represents 1.5% of the total Ig expenditure. Almost one-quarter of what the Ministry paid Canadian Blood Services for blood in 2019/20 was for this blood product. Further, the demand for this product continues to increase in Ontario and overall in Canada, despite efforts by the Ministry that have helped reduce its use. However, the use per capita in Ontario is now lower than that in other provinces including British Columbia and Alberta.

In all, these circumstances increase the risk that not all blood components will be available when Ontarians need them in shortage situations and for those who rely on certain blood products to live or maintain their quality of life. Ontario has experienced actual short-term shortages of blood components and products in the five-year period ending in July 2020 on two different occasions. These shortages lasted from a few days to almost three months.

The following are some of our significant findings.

- **Ontario relies heavily on suppliers in the United States for essential and high-demand blood products including immunoglobulins (Ig), which is fractionated from plasma collected by these suppliers.** This reliance on US-based suppliers presents a risk to the health of people in Ontario who need these products, should the supply chain be disrupted. Both the Ministry and Canadian Blood Services first acknowledged this risk in 2013. However, the percentage of Ig made from plasma collected by Canadian Blood Services has steadily decreased since then, and is now down to 13.7% compared to 22.7% in 2013/14. This supply risk is particularly concerning now given COVID-19 restrictions have affected American plasma supplies; Canadian Blood Services indicated that plasma collections from its four major Ig suppliers, all of which are US-based, are projected to be 15%–20% lower in the current year. Also, recent US presidential orders have barred medical products from coming to Canada when supplies run low in the United States, regardless of any existing contracts with American suppliers. Blood products thus far have not yet been restricted.
- **Hospital 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 cannot effectively minimize waste from expired blood components and products using the information from Canadian Blood Services because Canadian Blood

Services has no way to confirm if the self-reporting from hospitals is accurate. The Ministry has introduced several programs to help redistribute blood components and products between hospitals in an attempt to reduce waste; however, without an electronic inventory system, their effectiveness is limited. Instead, these programs are manually driven, with hospitals having to contact each other to identify inventory that can be redistributed amongst them. Despite these redistribution efforts and recognizing that blood components and products have limited shelf life, over 5,000 units of red blood cells and over 5,000 units of platelets were still wasted annually in each of the last three years. The wasted red blood cells are equivalent to donations from about 15,000 donors. Ontario paid about $10.2 million to Canadian Blood Services for this wasted red blood cells and platelets in the three years ending December 31, 2019, which represents about 2% of total fresh blood component expenditures.

- **The Ministry-sponsored Ontario Regional Blood Coordinating Network (Network) cannot require hospital staff to change practices in blood use.** The Ministry has funded the Network around $1.6 million annually in recent years to identify and address issues in blood use in hospitals. The Ministry relies on the Network to improve hospital practices around the use of blood. However, the Network does not have any power to enforce best practices in blood management or even to require hospitals to open their records so that patterns of use can be reviewed. The Network's reviews still indicated that hospitals had overused one high-demand blood component—O-negative red blood cells, which are valuable because they are the most readily transfusable type of red blood cells—and only 14% of the hospitals that responded to a request from the Network in 2020 reported that they were meeting the single unit transfusion standard more than 80% of the time.
- **The Ministry has not conducted regular assessments of the Nurse Transfusion Coordinators program (Program).** The Program's 28 nurses in 23 hospitals counsel patients toward actions that reduce the need for blood transfusions in upcoming surgeries and improve patient outcomes. But the Ministry's assessments of the Program do not compare the performance of hospitals with and without nurse co-ordinators. This comparison could help assess the value added from a nurse co-ordinator. As well, there are no outcome measures to consistently track whether patients complied with nurses' recommendations to safely reduce blood use, or compare the frequency of transfusions occurring at hospitals without nurse co-ordinators. Our analysis on one type of surgery indicated that, overall, hospitals with nurse co-ordinators did have lower transfusions rates than those that do not have nurse co-ordinators. Despite these efforts, several such hospitals still conducted transfusions on 10% or more of the patients undergoing surgery, against a Program target of 3%. Nurses also track patient counselling statistics differently, resulting in significant variances in reported patients counselled, from a low of 63 to a high of 855 in 2019.
- **Ministry pays Canadian Blood Services over $500 million annually for blood without confirming that it only pays for blood components and products received.** The Ministry does not have processes and information to ensure that its payments for blood components and products are reasonable. The Ministry does not perform any reconciliations between what hospitals receive and what it pays. Canadian Blood Services informed us that its financial auditor also does not perform this reconciliation. On a sample basis, we compared the amount

of blood components that Canadian Blood Services billed to Ontario with data that Ontario hospitals reported to us. Although we did not find any significant discrepancies, this is a process that would allow the Ministry to confirm that it is only paying for supply Ontario receives. As part of this work, we did find that the record-keeping in some hospitals was incomplete. As well, we noted that 16% of hospitals that answered our survey did not retain records on shipments received and so they could not confirm the accuracy of shipment data provided to us by Canadian Blood Services.

Overall Conclusion

Ontarians have had a safe and largely reliable and secure supply of blood for many years. While sufficient safeguards are in place to ensure that blood remains safe, the Ministry should monitor hospital blood bank inspection results conducted by Health Canada to be aware of these results.

The impact of COVID-19 has led to growing concerns about the risk to, and insufficient supply of, global blood plasma—the main component required to manufacture immunoglobulins, a blood product that many Ontarians rely on for sometimes life-saving treatments. Ontario, in conjunction with other provincial counterparts and Canadian Blood Services need to continually monitor this situation.

Currently, the Ministry of Health does not gather information on which specific medical conditions drive the demand for the blood components and products hospitals use. As well, hospitals are not required to report the quantities of blood products they use to Canadian Blood Services, nor do they report information on what health conditions they use them for—for example, whether for preferred uses as defined in provincial guidelines or not. The collection of this information from hospitals would help better forecast future supply needs.

Furthermore, even though the Ministry provides annual funding to 28 nurses across 23 Ontario hospitals to counsel patients prior to certain elective surgeries to reduce the eventual need to transfuse blood during and after surgeries, it has not obtained current information to confirm that this program is cost-effective in managing blood use.

As well, the Ministry does not have a reconciliation process in place to confirm that it is only paying for blood Ontario hospitals receive. We noted that the Ministry does not reconcile the payments it makes to Canadian Blood Services for blood with blood inventory shipped to Ontario hospitals. We also found that there has been no dialogue between the Ministry and Canadian Blood Services on who should be responsible for identifying alternatives to blood, for example whether this should be a Canadian Blood Services responsibility. Such alternatives could offer a cost-effective way to better manage supply, especially in times of shortages and crisis.

This report contains 13 recommendations, with 30 action items, to address our audit findings.

OVERALL MINISTRY RESPONSE

The Ministry of Health (Ministry) appreciates the work of the Office of the Auditor General of Ontario (Auditor General) and supports the review of Ontario's blood programs to ensure that Ontarians have a safe and secure supply of blood and blood products, which are delivered in a cost-effective and evidence-based manner. The Ministry, in collaboration with all provinces and territories (except Quebec), continues to work with Canadian Blood Services (CBS)—an arm's length organization responsible for the safety and reliability of blood supply.

Building upon the successes of Ontario's Blood Utilization Strategy, the Ministry looks forward to continuing to advance evidence-based utilization of blood and blood products to achieve better clinical outcomes and value, in collaboration with hospitals and through consideration of new information and technology solutions. Ontario has benefited from promotion

and implementation of evidence-based blood utilization best practices through the Ontario Regional Blood Coordinating Network and the Ontario Nurse Transfusion Coordinators Program, which have helped achieve negative growth rates of red blood cell utilization and lower per capita use of O-negative red blood cells compared to other Canadian provinces. There are further opportunities to enhance data gathering and technology solutions to inform clinical decision making on better utilization management for blood where utilization is growing due to new clinical uses. As the Ministry considers further strategies for improvement, the need for information and data collection will be balanced with the responsibility to focus on delivery of front-line services.

Safety and surveillance of the blood system have always been a priority for Ontario. Ontario has continuously invested in safety and surveillance activities by CBS and hospitals, in support of national and local blood surveillance activities and welcomes further enhancements to this work. The Ministry is committed to ensuring that the Auditor General's recommendations are reflected in its actions to strengthen accountability and operational excellence, including continuing to leverage information technology in program delivery.

OVERALL RESPONSE FROM CANADIAN BLOOD SERVICES

Canadian Blood Services appreciates the Auditor General's report in support of the ongoing safety and security of the national blood system. While recommendations are directed at the Ontario Ministry of Health (Ministry), we note they are premised on the important partnership among provincial and territorial health systems and Canadian Blood Services to ensure Canadians have a safe, affordable and reliable supply of blood components and products. We will review and address with the Ministry those findings applicable to Canadian Blood Services. As Canadian Blood Services operates a nationally integrated system, consensus and collaboration on recommendations with all provincial/territorial ministries of health will be required to co-ordinate implementation across the country as appropriate.

More specifically, Canadian Blood Services welcomes recommendations regarding enhanced hospital information systems to assess how blood components and products are used. Currently, the type of data available to support demand and supply planning is limited to whether or not blood components and products were administered to the patient. Expanded data sets will assist in understanding how blood components and products are used and enhance Canadian Blood Services forecasting abilities to ensure that supply aligns with patient need.

We also agree with the finding that Canadian Blood Services must increase Canada's plasma supply for greater national sufficiency for immunoglobulin (Ig). COVID-19 impacts have exacerbated global Ig shortages and disrupted supply chains for years to come. Canadian Blood Services has taken steps to mitigate immediate Ig supply risks; the longer-term mitigation calls for a significant increase in domestic plasma supply by Canadian Blood Services for contract manufacturing into Ig exclusively for Canadian patients.

Further, the recommendations in this report echo those from a comprehensive performance review completed in 2020. Canadian Blood Services values the observations from this audit and looks forward to working with ministries of health towards meaningful system improvements.

2.0 Background

Ontario's 114 hospitals that collectively have 158 sites receive and transfuse blood and rely on an adequate supply of blood components and plasma protein products, hereafter referred to as blood products, to treat patients with a range of conditions. Blood components mainly consist of red blood cells, platelets and plasma that can be separated directly from donated blood, as shown in **Figure 1**; these components are transfused into patients with blood loss, anaemia, trauma or other conditions. The plasma component, in turn, can be manufactured into blood products, also called plasma protein products, which consist mostly of immunoglobulins (Ig) and factor concentrates, as shown in **Figure 2**. These products are used as drugs, or therapies, for a range of conditions that include immune disorders, bleeding conditions and neurological conditions. See **Appendix 1** for a glossary of terms.

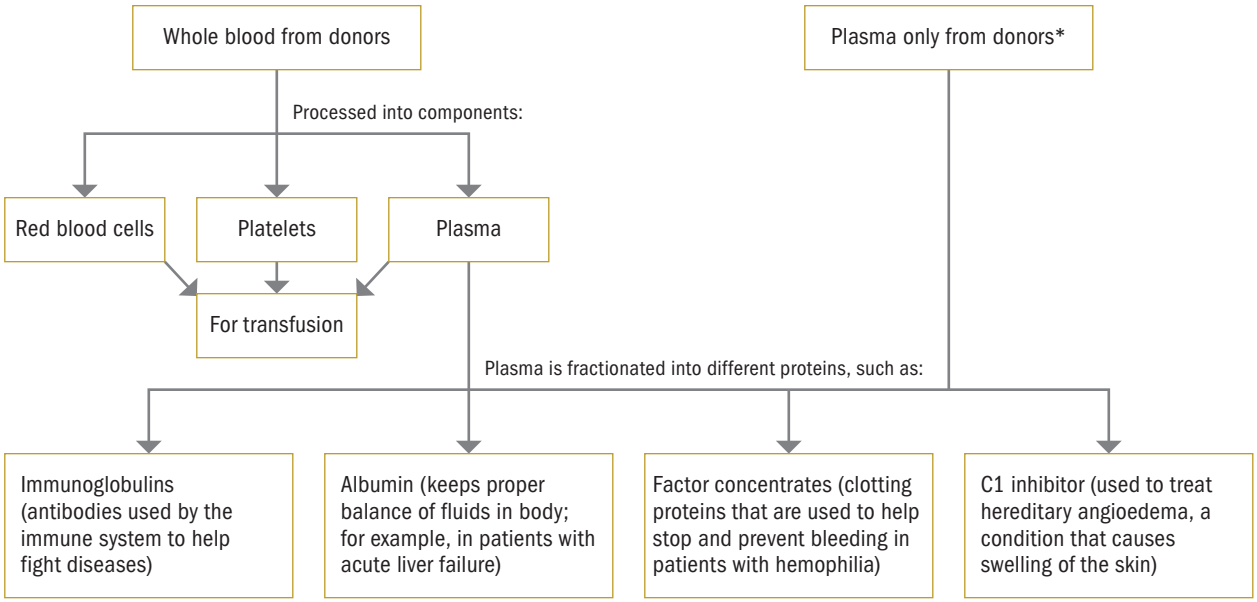
Before the COVID-19 pandemic, the blood supply had experienced only a few shortages of blood components and products, and none of them seriously affected Ontario hospitals' ability to provide patient care (see **Section 4.3.1** for more on shortages). When the pandemic was declared in mid-March 2020, elective surgeries were cancelled in Ontario hospitals, not because of a shortage in blood but to maintain hospital capacity to deal effectively with the COVID-19 pandemic and to reduce the risk of patients contracting COVID-19 in hospitals.

2.1 Responsibility for Planning and Managing Blood Demand and Supply

Responsibility for the planning and management of Ontario's demand and supply of blood components and products is shared among Canadian Blood Services, Ontario's Ministry of Health (Ministry) and Ontario hospitals. Canadian Blood Services is the national blood authority that is responsible

Figure 2: Process of Producing Plasma Protein Products (Blood Products)

Prepared by the Office of the Auditor General of Ontario



* Plasma can be donated on its own. Whole blood is extracted during the process of donation, plasma is collected and the remaining components are returned to the donor's body.

for providing a safe, secure and affordable supply of blood components and products and their alternatives to all provinces and territories except Quebec (which has its own blood authority).

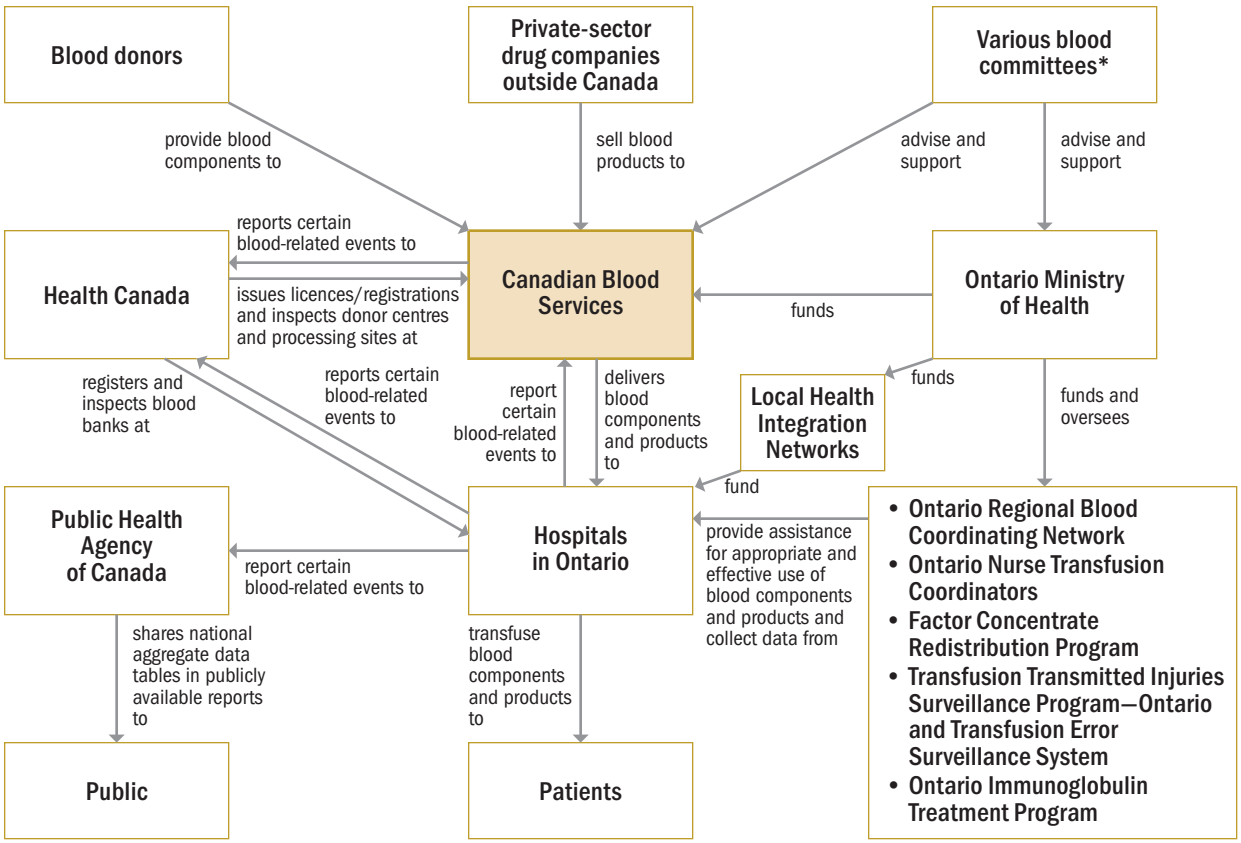
Regarding federal entities, Health Canada regulates blood as per the Blood Regulations, which involves inspecting hospitals and blood donor clinics on such activities as blood storage and processing, and collecting and reviewing data about investigations of adverse transfusion reactions related to the safety of the blood; the Public Health Agency of Canada conducts public health surveillance related to blood transfusion. **Figure 3** illustrates the relationship of the various organizations involved in the delivery of blood services in Ontario, and **Appendix 2** describes the responsibilities of each of these organizations.

The Ministry is responsible for paying Canadian Blood Services for the costs it incurs to collect, process and distribute blood components to hospital blood banks and the costs Canadian Blood Services pays manufacturers for the blood products ordered by Ontario hospitals. A blood bank is a unit within a hospital laboratory that stores and distributes blood components and products for use within the hospital. The Ministry's annual payment to Canadian Blood Services includes Ontario's share of the costs to operate Canadian Blood Services.

In 2019/20, the Ministry paid Canadian Blood Services about $562 million, consisting of $214 million for almost 495,000 units of blood components and $348 million for almost 700,000 units of blood products for use in Ontario hospitals. This payment is a 8% increase over the payment in 2015/16 to

Figure 3: Blood Management System in Ontario

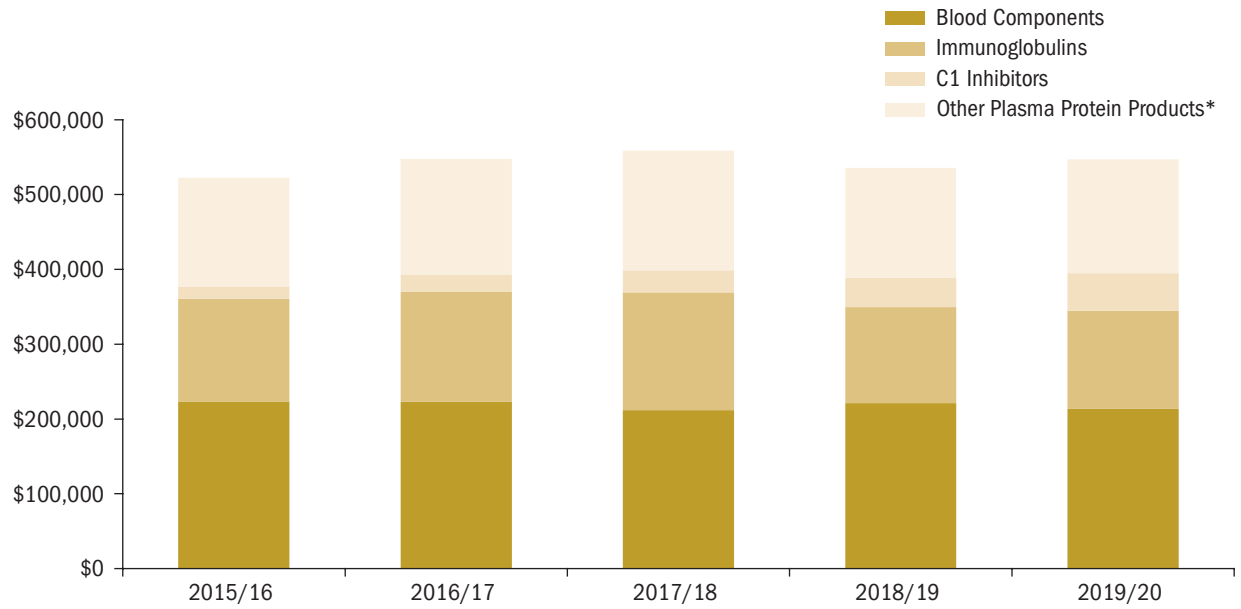
Prepared by the Office of the Auditor General of Ontario



* See **Appendix 2** for details on the following four committees: the National Advisory Committee for Blood and Blood Products, the National Emergency Blood Management Committee, the Provincial-Territorial Blood Liaison Committee, and the Ontario Emergency Blood Management Committee.

Figure 4: Ontario's Payments to Canadian Blood Services for Blood Components and Plasma Protein Products, 2015/16–2019/20 ($ 000)

Source of data: Canadian Blood Services



* Other plasma protein products include albumin, factor concentrates (such as recombinant factor VIII, factor VIII/VWF, recombinant factor IX, factor XIII and prothrombin complex), S/D plasma and other coagulation products.

Canadian Blood Services for blood components and products as shown in **Figure 4**. Our analysis of data submitted by Ontario hospitals to the Canadian Institute for Health Information on transfusion events indicated that in 2019/20, there were about 128,000 patient transfusions of blood components or products, about 20% of which involved more than one product or component. The basis of payments is further detailed in **Section 2.2**.

2.1.1 How Does Canada Get Its Blood Supply?

Canadian Blood Services collects whole blood as well as platelet and plasma on their own from donors across Canada, except in the territories and Quebec. Before blood is transfused into a patient, it must be separated into its components of red blood cells, plasma and platelets. The separation process takes place in two Canadian Blood Services processing centres in Ontario (located in Brampton and Ottawa) as well as six other centres across Canada. Platelet and plasma can also be donated on their own, referred to as apheresis, with the other components being returned to the donor's body during the process of donation. Canadian Blood Services distributes processed blood components to hospitals in Ontario and other provinces and territories. The majority of donated blood is distributed as finished blood components within the province collected; however, there is also a redistribution of blood across Canada to meet provincial and territorial demand to ensure optimal levels are being met in each province. According to Canadian Blood Services, Ontario imports from other provinces more blood than is locally donated.

To produce **blood products**, donated plasma goes through a technically demanding process called fractionation where plasma is separated ("fractionated") into different therapeutic products after removing any infectious agents in the plasma. Canadian Blood Services has contracted with manufacturers located in the United States and Europe to fractionate Canadian plasma donations.

It uses multiple suppliers to reduce dependency on one country for this fractionation service. Canadian Blood Services has also contracted with international pharmaceutical manufacturers to fractionate plasma mostly from paid American donors (with some from Canadian donors) into blood products—mostly immunoglobulins—for Canada.

Most countries rely on a system of voluntary, unpaid blood donations, in certain jurisdictions, particularly the United States, there are no laws preventing blood product manufacturers from paying plasma donors to supply the source material for their products. In Canada, Ontario, British Columbia and Alberta passed legislation that prohibits anyone other than Canadian Blood Services to pay an individual for blood. According to Canadian Blood Services, it can legally remunerate donors for any type of blood donation, including plasma donations, but it does not currently do so and has no future plans to do so.

2.1.2 What Role Does Canadian Blood Services Have in Ontario?

The federal government, the Ontario Ministry of Health and all other provinces and territories except Quebec signed a Memorandum of Understanding (MOU) in 1998 to establish Canadian Blood Services as Canada's national blood operator. This MOU also outlined the understandings of provincial and territorial ministers of health and the federal minister of health for a renewed blood system. Significant decisions at Canadian Blood Services—such as approving the budget or financing for major projects—are made by a majority vote, with each jurisdiction having one vote regardless of the level of funding contributions made towards the operation of Canadian Blood Services (Ontario is around 50%).

To help achieve Ontario's accountability standards and meet its funding requirements, the Ministry also entered into a transfer payment agreement with Canadian Blood Services in 2013. This agreement clarified how costs were allocated and laid out Canadian Blood Services' accountability to Ontario for the services provided, including recruitment of donors; collection, testing, production and distribution of blood and blood components; and purchase of blood products. This was later replaced by a national accountability agreement between Canadian Blood Services and all provinces and territories (except Quebec), which was finalized in August 2020. This agreement outlined the responsibility of Canadian Blood Services Board to report to all provincial and territorial ministers of health.

Every five to seven years, a third party has been engaged to conduct a performance review of Canadian Blood Services' operations. Both the 2013 review and the 2020 review focused on financial matters and operational performance, including blood safety and supply needs and corporate activities. The focus of each review was determined collaboratively between Canadian Blood Services and the provincial/territorial governments. The 2013 review primarily focused on governance and produced 79 recommendations; the 2020 review focused on quality management systems, enterprise risk management and the procurement of blood products, and produced 59 recommendations. See **Appendix 3** for a summary of the reports' recommendations. The expectation of holding such a review every five to seven years was formalized in the recent 2020 National Accountability Agreement.

2.1.3 What Are the Other Responsibilities of Canadian Blood Services?

While Canadian Blood Services' primary activities are blood services planning, and blood collection, processing, procurement and distribution, it also helps manage interprovincial organ sharing and the public stem cell registry, and conducts research and development to support the progression of transfusion activities in the health-care system. At the time of our audit, a new and significant research and development focus for Canadian Blood Services was collecting plasma from patients who had recovered from COVID-19 to help treat

other infected patients. The pandemic also presented a new challenge as well, as more people became reluctant to leave their homes and plasma donations declined internationally as a result. Additionally, a reduction in elective surgeries in Ontario hospitals that was put into effect to both reduce the risk of COVID-19 transmission to patients and physicians, and maintain hospital bed capacity to deal effectively with the pandemic.

2.2 Ontario's Payments to Canadian Blood Services for Blood

Ontario paid $214 million for blood components and $348 million for blood products in 2019/20. Canadian Blood Services charges the Ministry of Health as follows:

- **Blood components:** The cost of each component is allocated based on the amount of red blood cells used in Ontario as a percentage of the total amount used in Canada (excluding Quebec), including direct costs such as blood donor clinic staff and supplies and allocated overhead costs. This basis of allocation is set out in the negotiated provincial and territorial budget agreements. Between 2015/16 and 2019/20, Ontario's payment to Canadian Blood Services for blood components went down by 4%.
- **Blood products:** The cost for blood products is charged to Ontario at the cost that Canadian Blood Services pays for the products, as established through competitive procurement and negotiated contracts. Adjustments such as foreign exchange and program management overhead (an allocation related to Canadian Blood Services staffing and plasma collection) are included in these costs. Between 2015/16 and 2019/20, Ontario's payment to Canadian Blood Services for blood products went up by 16%, corresponding to an overall increase in blood products used.

From time to time, Canadian Blood Services incurs capital costs, such as for blood collection, which it allocates among funding provinces based on either population or utilization data.

2.3 Improving Safety of Patients Receiving Blood Transfusions

According to Canadian Blood Services, the safety of Canada's blood supply has improved significantly, with no recently reported instances of viral infections being transmitted through transfusions since the early 2000s. This is the result of disease-screening procedures, donor screening practices, and active surveillance and investigation by Canadian Blood Services to mitigate against new pathogens.

Because the risk of blood components and products contaminated with viruses cannot be completely eliminated, however, best practices recommend using alternatives to donated blood whenever possible. Blood components present a greater safety threat than blood products because the plasma fractionation process destroys viruses such as HIV and hepatitis C.

Following a recommendation by the 1997 Krever Inquiry (**Section 2.5**) to monitor the transfusion process from delivery of the donated blood to the hospital blood bank through to transfusion at bedside, and to follow up on adverse events, the Government of Canada introduced two surveillance systems to track and monitor patient outcomes. These are the Transfusion Transmitted Injuries Surveillance System (Injury Surveillance System) and the Transfusion Error Surveillance System (Error Surveillance System). They are intended to collect data on adverse events that occur during or after blood transfusion and on errors that occur during the transfusion chain. The Injury Surveillance System receives reports on adverse events—for example, skin rash and severe allergic reactions (see **Appendix 4** for details about the use, storage and shelf life of blood components). Errors (detected during or after transfusion) and "near-misses" (detected before transfusion) that

are reportable under the Error Surveillance System include transfusing the wrong blood type into a patient (see **Appendix 5** for more on blood type compatibility).

The Public Health Agency of Canada provides funding to and undertakes the national co-ordinating role for these two surveillance systems. Ontario's Ministry of Health provides supplementary funds to support all Ontario hospitals that report adverse events to the Injury Surveillance System on a voluntary basis and 28 hospitals that report all adverse events. **Figure 5** provides further details of the two surveillance systems.

In addition, provincial and territorial governments (except Quebec) created a risk financing vehicle, known as a captive insurance program, to insure the risks arising out of the Canadian blood supply system. The program provides $1 billion in insurance coverage for potential liability associated with the blood supply system (for example, patient injury due to issues with blood supply, or a new emerging blood-borne illness for which Canadian Blood Services does not currently test or a test does not currently exist). Between 1999 and 2010, Ontario paid $117.6 million related to insurance premiums and capital for its share of insurance coverage to be used in the event of any illness being transmitted through blood donations; Canadian Blood Services has not requested further payments from Ontario for this purpose since 2010.

2.4 Conserving Blood Used in Ontario Hospitals

Physicians in hospitals are ultimately responsible for making clinical judgments and decisions on when and how to use blood components and products in providing care to patients. To support blood conservation practices in Ontario, the Ministry of Health funds five programs to promote the appropriate use of blood components and products and improve patient safety. While sometimes blood transfusions are the best patient treatment option, blood transfusions still have associated risks of infection or allergic reactions for patients who are transfused. **Figure 6** shows the Ministry's costs for these programs from 2016/17 to 2019/20, as well as the lead organizations responsible for operating them. In 2019/20, the Ministry paid just under $6 million to three hospitals and a university to operate the five programs; the two highest-cost programs were the Ontario Regional Blood Coordinating Network (Network) and the Ontario Nurse Transfusion Coordinators; all five programs including these two are shown in **Appendix 2**.

The Network, which received almost $1.6 million in Ministry funding in 2019/20, helps support safe and effective transfusion services to patients. It identifies and makes recommendations to hospital staff regarding gaps and issues in blood use, and promotes evidence-based practices in transfusion medicine through educational events, annual hospital site visits with Canadian Blood Services to review hospital data on their use of blood components and products, and developing best practice guidelines and tools for hospitals. For example, it provides advice and recommendations to Ontario hospitals about the use of universal blood types, such as O-negative red blood cells and AB plasma; these blood components are considered "universal" because they can be transfused to anyone. The Ministry has provided funding to the Network for the last 14 years.

The Ministry began funding the Ontario Nurse Transfusion Coordinators program (Program) in 2002 to counsel patients, and improve patient outcomes by reducing their need for blood transfusions before, during and after surgery. In 2019/20, the Ministry provided about $3.5 million to fund 28 program-dedicated, full-time nurses stationed in 23 Ontario hospitals, which were chosen either because they had higher volumes of blood used in transfusions or they collectively represent all geographic areas of Ontario. Together, they provided care to and counselled 8,400 patients. They educate patients on the risks of blood transfusions and also educate physicians, nurses and hospital administrators about the benefits of

Figure 5: Differences between the Transfusion Transmitted Injury Surveillance System and the Transfusion Error Surveillance System

Prepared by the Office of the Auditor General of Ontario

	Type of Reaction/Error Recorded	Example(s) of Reaction/Error Recorded	# of Ontario Hospitals[1] that Reported in 2019	
			Mandatory Basis[2]	Voluntary Basis
Transfusion Transmitted Injury Surveillance System[3,4]	Serious, moderate and some minor adverse transfusion reactions related to the transfusion of blood components and blood products	• Lung injury	28	130
Transfusion Error Surveillance System[3]	Errors that occur at any point in the transfusion cycle from receipt of blood through to transfusion at the bedside. Errors are defined as any deviation from standard operating policies, processes and procedures. Information captured includes the process where the error was detected and actions taken as a result of the error.	• Sample collection errors, such as missing labels on samples • Unit transfusions errors, such as when a unit of blood is administered to the wrong patient or the wrong type of blood, or an incorrect dose of product was administered to a patient • Sample handling errors, such as requisition errors where patient paperwork and sample identification numbers do not match, or sample transportation errors within a hospital	0	3[5]

Note: A small number of events overlap between these two systems; for example, the Error Surveillance System may also capture details related to harm or injury to patients, such as respiratory complications following rapid transfusion of a large volume of blood, and fever but no destruction of red blood cells, that are also recorded in the Injury Surveillance System. But the two systems predominantly capture distinct events.

1. There is a total of 158 hospital sites in 114 hospitals in Ontario.
2. It is mandatory for these hospitals to report since they have been funded by the Ministry of Health (Ministry) to report all adverse transfusion events.
3. The Ministry has two funding agreements with the Public Health Agency of Canada and McMaster University, under which the two surveillance systems are managed.
4. The Ministry provides funding to all hospitals to report major adverse events into the system on a voluntary basis, but it provides additional funding to 28 hospitals to report all adverse events on a mandatory basis.
5. Hospital participation is voluntary; only 15 hospitals from four Canadian provinces/territories report data into the Error Surveillance system, three of which are Ontario hospitals. Program administrators informed us that other hospitals also sometimes report errors even though they have not been funded to do so.

Figure 6: Ministry of Health's Costs for Blood Utilization Strategy[1] Programs, 2016/17–2019/20 ($ 000)
Source of data: Ministry of Health

Product	Lead Organizations	2016/17	2017/18	2018/19	2019/20
Ontario Nurse Transfusion Coordinators	Unity Health Toronto—St. Michael's Hospital	3,457[2]	3,457[2]	3,544[2]	3,544[2]
Ontario Regional Blood Coordinating Network	McMaster University, The Ottawa Hospital, Sunnybrook Health Sciences Centre	1,555[2]	1,555[2]	1,555[2]	1,555[2]
Ontario Immunoglobin Treatment Program	The Ottawa Hospital	–	–	147	680
Transfusion Transmitted Injuries Surveillance System and Transfusion Error Surveillance System	McMaster University, Sunnybrook Health Sciences Centre	69[2]	69[2]	69[2]	69[2]
Factor Concentrate Redistribution Program	Unity Health Toronto—St. Michael's Hospital	19	19	50[3]	50
Total		**5,100**	**5,100**	**5,365**	**5,898**

1. The Strategy's purpose is to optimize the use of blood components and products to improve patient safety and achieve cost savings.
2. Ministry funding has not changed substantially or at all year over year.
3. Increase is due to increased number of hours for a program co-ordinator, from 30 hours a month in previous years to 90 hours a month in 2018/19. The program co-ordinator communicates with hospitals and arranges shipments of expiring clotting factor products for redistribution.

allowing time for patients to increase their blood iron and/or hemoglobin levels (blood iron and blood hemoglobin are inter-related) before certain elective surgeries, and counsel patients on how to raise their blood iron levels, for example, through iron supplements or a drug called erythropoietin (which also helps increase hemoglobin). They may also refer patients back to physicians, or to specialists, to treat other underlying disease, such as nutritional deficiency or anaemia, and may provide recommendations to patients on treating such conditions, and in some cases will make patient care recommendations to physicians. Program administrators, consisting of one full-time experienced nurse and a doctor with expertise in haematology (both based out of Unity Health Toronto—St. Michael's Hospital), provide advice to these nurses, conduct informal annual visits or meet with them (or their supervisors) to discuss areas for improvement in their performance, and perform administrative activities.

2.5 The Krever Inquiry and the Creation of Canadian Blood Services

In 1997, the Royal Commission of Inquiry on the Blood System in Canada, led by Justice Krever, issued its final report. The Canadian government launched the Krever Inquiry to investigate systemic weaknesses in the blood supply system, then operated by the Canadian Red Cross Society, that affected blood and blood product safety and resulted in about 2,000 people in Canada becoming infected with HIV and another 30,000 with hepatitis C through contaminated blood or blood products. The report's recommendations were primarily aimed at rectifying systemic issues to address and improve patient safety and the safety of the blood supply. The report had a lesser focus on how blood components and products were used and the sufficiency of the blood supply.

3.0 Audit Objective and Scope

Our audit 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.

In planning for our work, we identified the audit criteria (see **Appendix 6**) we would use to address our audit objective. These criteria were established based on a review of applicable legislation, policies and procedures, internal and external studies, and best practices. Senior management at the Ministry and Canadian Blood Services reviewed and agreed with the suitability of our objective and associated criteria.

We conducted our audit between January 2020 and August 2020. We obtained written representation from Ministry and Canadian Blood Services management that, effective November 13, 2020, they had provided us with all the information they were aware of that could significantly affect the findings or the conclusion of this report.

In conducting our work, we reviewed applicable legislation, agreements, reports, program guidelines and policies. We examined documents, analyzed data, reviewed information technology controls and assessed risks, and observed processes for ordering, receiving, shipping and storing blood components and products that are distributed by hospital blood banks. We also conducted a survey of around 90 transfusion medicine physicians who collectively provide services for all 158 hospital sites across Ontario. The survey allowed us to gain more perspectives from hospitals on their use of blood components and products as well as the processes through which they receive these from Canadian Blood Services, and to confirm the amounts of blood components and products the hospitals receive from Canadian Blood Services. A total of 75 transfusion medicine physicians (83% of total surveyed), representing 158 hospital sites (47% of total surveyed), responded to our survey.

Our audit was primarily conducted at the Ministry's head office in Toronto, Canadian Blood Services in Ottawa and selected hospitals.
At the Ministry, we performed the following work:

- interviewed program staff and obtained program data;
- obtained and analyzed transfusion data from the Health Data Branch; and
- obtained documents from the Legal Services Branch.

We visited Canadian Blood Services at its head office in Ottawa, interviewed relevant staff to learn about the organization and its operations, and obtained and analyzed shipment data on blood components and products. We also visited a Canadian Blood Services blood donor site in Toronto and the Brampton Operations facility that performs blood processing and testing to better understand the safety measures, controls and processes surrounding their operation.

To better understand how blood components and products are managed at hospitals and also to learn more about the programs the Ministry funds to promote safe and appropriate blood use, we visited Sunnybrook Health Sciences Centre, St. Michael's Hospital (part of Unity Health Toronto) and The Ottawa Hospital. We also interviewed Eastern Ontario Regional Laboratory Association staff regarding their work in reporting adverse transfusion events and McMaster University staff who are involved in Ministry-funded programs.

The programs we focused on were the Ontario Regional Blood Coordinating Network, the Ontario Nurse Transfusion Coordinators, the Transfusion Transmitted Injuries Surveillance System, the Factor Concentrate Redistribution Program and the Ontario Immunoglobulin Treatment Program.

At the hospitals we visited, we interviewed staff who administer the Ontario Nurse Transfusion

Coordinators program as well as several of the 28 nurse co-ordinators, and staff who administer the Transfusion Errors Surveillance System, the Factor Concentrate Redistribution Program, and the Ontario Immunoglobulin Treatment Program. We interviewed McMaster University staff who administer the Ontario Transfusion Transmitted Injuries Surveillance System, and data analytics staff at the McMaster Centre for Transfusion Research.

We reviewed and analyzed the following data: patient counselling data from the Ontario Nurse Transfusion Coordinators program, Ontario-specific adverse event transfusion data from the Transfusion Transmitted Injuries Surveillance System, data on transfusion error and "near-misses" from the Public Health Agency of Canada's Transfusion Error Surveillance System, and certain types of surgery data and transfusion data provided by the Ministry of Health with guidance provided by the Canadian Institute for Health Information.

We interviewed representatives from Health Canada to better understand federal legislative requirements, its inspection process for blood banks and Canadian Blood Services donor sites, and received data on these inspections. We also interviewed a representative of the Canadian Agency for Drugs and Technologies in Health to better understand its work in assessing the cost-effectiveness of blood components and products. As well, we contacted the Institute for Quality Management in Healthcare to obtain information about its inspection process and spoke with representatives from Choosing Wisely Canada (a campaign to help clinicians and patients engage in conversations about unnecessary tests, treatments and procedures) to obtain information about current blood use practices and transfusion guidelines.

We obtained information from representatives of Ontario Health and Local Health Integration Networks. Ontario Health manages the Ontario Laboratories Information System where lab test results from hospital and community laboratories across Ontario are stored, to understand what the system contains that is relevant to blood transfusions. Local Health Integration Networks fund and oversee Ontario hospitals. We researched how other Canadian provinces operate their blood programs and how other countries' blood agencies carry out their operations, and we contacted representatives of these organizations. We also reviewed the work of the Ministry's and Canadian Blood Services' internal audit groups and considered relevant work in conducting our audit.

We conducted our work and reported on the results of our examination in accordance with the applicable Canadian Standards on Assurance Engagements—Direct Engagements issued by the Auditing and Assurance Standards Board of the Chartered Professional Accountants of Canada. This included obtaining a reasonable level of assurance.

The Office of the Auditor General of Ontario applies the Canadian Standard on Quality Control and, as a result, maintains a comprehensive quality-control system that includes documented policies and procedures with respect to compliance with rules of professional conduct, professional standards and applicable legal and regulatory requirements.

We have complied with the independence and other ethical requirements of the Code of Professional Conduct of the Chartered Professional Accountants of Ontario, which are founded on fundamental principles of integrity, objectivity, professional competence and due care, confidentiality and professional behaviour.

4.0 Detailed Audit Observations

4.1 Risk of Transmitting Disease through Transfusion is Low

4.1.1 Disease Transmission Risk is Low

Canadian Blood Services is mandated to provide Canada with a safe supply of blood. We found that Canadian Blood Services has put additional

measures in place since the Krever Inquiry (explained in **Section 2.5**) that have improved the safety of supply. Canadian Blood Services publicly reports on all of its safety measures and publishes annual statistics on its surveillance of transmissible blood-borne infections. This includes results from its monitoring of transmissible disease, its investigations of possible transfusion transmission, and its research on potential new pathogens that may present a risk to the safety of the blood supply.

Canadian Blood Services reports its activities on these safety measures to Health Canada. Between January 1, 2016 and December 31, 2019, it investigated 244 look-backs and 217 trace-backs nationwide and completed 179 and 161, respectively, and reports this information publicly. The Ontario Ministry of Health (Ministry), along with the other provinces and territories (except Québec), relies on Canadian Blood Services as the national blood operator to ensure blood is safe from these types of threats. According to the results of investigations conducted by Canadian Blood Services and overseen by Health Canada, 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.

Canadian Blood Services monitors the safety of its blood supply through screening and testing for multiple pathogens. Canadian Blood Services tests all blood donations for certain pathogens and only selected donations for others, as shown in **Figure 7**. Canadian Blood Services will not distribute blood to Canadian hospitals until tests come back negative for these pathogens.

While Canadian Blood Services tests blood donations for the presence of these infectious diseases, some of these diseases have a window period where a donor may have the disease but acquired it so recently that it is not detected by testing. For example, HIV and Hepatitis C have a window period of one to two weeks, while Hepatitis B has a window period of one month. According to Canadian Blood Services, the risk of a unit of blood containing a transmissible disease is very low, at 1 in 12.9 million donations for HIV, 1 in 27.1 million for Hepatitis C and 1 in 1.4 million for Hepatitis B. For these diseases, Canadian Blood Services has two processes (trace-backs and look-backs) to investigate blood components associated with cases of possibly infected donations so that they can limit the potential damage from them. A trace-back involves retesting donors if a patient

Figure 7: Pathogens Screened by Canadian Blood Services

Source of data: Canadian Blood Services

	All Blood Donations	Blood Donations Screened Based on Risk Factors	
		Seasonal	Travel
Hepatitis B Virus (HBV)	✓		
Hepatitis C Virus (HCV)	✓		
Human Immunodeficiency Disease (HIV)	✓		
Human T-Cell Lymphotropic Virus (HTLV)	✓		
Syphilis	✓		
West Nile virus[1]		✓	✓
Chagas Disease[2]			✓
Bacteria[3]	✓		

Note: Canadian Blood Services also provides cytomegalovirus (CMV) testing on request for red cell or platelet products prescribed for intra-uterine transfusion.

1. Canadian Blood Services screens for West Nile virus in all blood donations made between June 1 and November 30, and in blood from donors who travelled between December 1 and May 31 (to countries where West Nile is active).
2. Canadian Blood Services screens for Chagas disease in all donors who travelled to Latin America, where the disease can be transmitted through certain insect bites.
3. Canadian Blood Services screens for bacterial growth in all platelet products.

who received their blood later tests positive for a possible transfusion-related infection. A look-back involves identifying patients who received blood from a donor who later tests positive for infection. Re-testing these potentially affected individuals is important because it is the only way to determine if a disease was transmitted via a transfusion and to identify and counsel individuals to get treatment and avoid behaviours that could result in the disease being transmitted to other people.

4.1.2 Ministry Does Not Use Health Canada Inspection Data to Identify Risk Areas in Hospital Labs That Handle Blood

The Ministry relies on Health Canada to inspect Ontario hospital blood banks (blood banks) and Canadian Blood Services donor sites (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 for the safety of blood donors and recipients alike. Health Canada indicated that these establishments are expected to comply with the legislative and regulatory requirements on their products, activities and processes.

We found that Health Canada did not identify significant blood safety risks in its inspections of blood banks. Since it began blood bank inspections in 2015, and up until July 2020, Health Canada had inspected all 14 registered blood banks and one out of 144 non-registered blood banks in Ontario. It prioritized registered blood banks for inspection because of the higher-risk activities performed at these sites, such as transforming blood or collecting autologous blood (that is, collecting blood from a single patient and re-transfusing it back to the same patient when required).

The Ministry was not aware that most unregistered blood banks were not inspected by Health Canada and does not obtain and review the data from Health Canada's inspections of blood banks and donor sites. The Ministry told us it believes that the federal government is responsible for overseeing these sites. Ministry oversight is still important because the Ministry has a legislated mandate to co-ordinate and maintain health services for Ontarians as well as to govern the care, treatment, and services and facilities provided by hospitals. In comparison, Saskatchewan informed us that it uses the results of Health Canada inspections to correct and improve transfusion practices; for example, to address Health Canada's concerns regarding one hospital that indicated more formal monitoring of documentation and review of transfusion errors was necessary, online transfusion error surveillance was implemented at this hospital (see **Section 4.2.4** for more on transfusion errors.)

We tried to assess the risk to the health of Ontarians from the 143 blood banks not being inspected by Health Canada for their compliance with the Blood Regulations under the federal *Food and Drugs Act*. However, we could not do so because of limited information available on whether adverse events are caused by activities in the blood bank or elsewhere in the hospitals.

The Institute for Quality Management in Healthcare, a controlled affiliate of Accreditation Canada/Health Standards Organization, is funded by the Ministry to operate quality management for licensed medical laboratories in Ontario. The quality management program also conducts accreditation assessments of hospital blood banks to compare practices to international, national, and provincial requirements, including industry-accepted standards. Similarly, the Ministry does not regularly review the results of these inspections. The Institute informed us that it has not had concerns that would require the suspension of services in any blood transfusion laboratory. We reviewed the results of their assessments, and found that the Institute identified at least one major non-conformance between 2015 and 2019 at each of 17 blood banks; these are blood banks that have never been inspected by Health Canada. Examples of these included a lack of ongoing training and competency assessments for staff that administer blood to patients as well as a lack of staff evalua-

tion records. The Institute informed us that these instances of non-conformance were all resolved to its satisfaction within 90 days of raising the issue with the hospital blood transfusion laboratory.

While Health Canada's inspections did not identify any significant safety risks with the 15 hospital blood banks, or with the 21 Canadian Blood Services' donor or blood processing sites, and none of the sites failed the inspections, it did identify certain deficiencies. For example, our review of Health Canada's 2019/20 data indicated that, in two of the six blood banks that it inspected, it identified risks associated with identifying and investigating adverse transfusion events, and ensuring the validation and cleanliness of critical equipment. Health Canada confirmed with us that it has followed up with these hospitals and the shortcomings have been resolved.

Also, we noted that Health Canada identified lower-level risks in record maintenance and retrieval in all blood banks and about 70% of 10 donor sites that it inspected in 2019/20 and lower-level risks in compliance with operating procedures in 70% of both blood banks and donor sites it inspected.

RECOMMENDATION 1

To better monitor compliance with federal regulations for the risk of unsafe blood storage and handling practices in Ontario hospitals and further reduce the potential risk of a negative health impact on patients, we recommend that the Ministry of Health:

- establish a mechanism to discuss and receive information from Health Canada on which Ontario hospital blood banks and Canadian Blood Services blood donor centres in Ontario will be inspected by Health Canada, and to obtain and share the results of the hospital inspections with Ontario Health; and
- regularly review Health Canada inspection reports to identify common risk areas and target these problem areas in future education initiatives for hospitals.

MINISTRY RESPONSE

Health Canada has responsibility for the inspection of blood banks in all Canadian jurisdictions for their compliance under the Blood Regulations in the federal Food and Drugs Act. The Ministry is pleased to note that there have been no non-compliance reports on Ontario hospitals since the initiation of Health Canada inspections in 2015. The Ministry supports a more systematic review of findings from Health Canada inspections of Ontario hospitals through enhanced communication. The findings will facilitate the identification of areas for improvement, which will enhance educational opportunities for Ontario hospitals.

4.2 Blood Data Stored in Multiple Systems Across Ontario Hospitals Limits Ministry's and Ontario Health's Ability to Monitor Real-Time Blood Inventory, Usage and Clinical Data

Blood inventory, usage and clinical data on patients are stored in different information systems across all Ontario hospitals, making it difficult to share and consolidate key data. Moreover, hospitals are not required to report their use and inventories of blood to Canadian Blood Services, leaving little information about how blood is used and how much is available for ongoing use. This fragmentation has potentially contributed to the use of immunoglobulins (Ig), a high-demand blood product, for conditions beyond those that provincial guidelines indicate are the primary preferred uses. It also limits the effectiveness of provincial initiatives aimed at reducing waste of blood components and products because of the significant manual efforts needed to gather and share information. Neither Canadian Blood Services nor the Ministry

Figure 8: Data Systems Used for Blood Management in Ontario

Prepared by the Office of the Auditor General of Ontario

Data System	Type of Data Collected/Stored
Canadian Blood Services	
Shipment Database	Amount of blood shipped to Canadian hospitals
Blood Component and Product Disposition Database	Blood use by Canadian hospitals
Ontario Hospitals	
Hospital Information Systems	Patient information, including diagnoses and medical history for patients that may have received a blood transfusion
Laboratory Information Systems	Laboratory information, including what is released from the blood bank
Ontario Health (to which eHealth Ontario joined)	
Ontario Laboratories Information System	Lab test orders and results from Ontario hospitals, including some data on adverse transfusion reactions
McMaster Centre for Transfusion Research	
Transfusion Registry for Utilization, Surveillance, and Tracking (TRUST)	Combines data from the hospitals' laboratories information systems and Discharge Abstract Database, along with pharmacy orders, diagnostic imaging, and other lab tests in four Hamilton hospitals to capture all information related to blood transfusions
Transfusion Transmitted Injuries Surveillance System – Ontario (TTISS-ON)	Moderate to severe transfusion reactions that occur as a result of blood transfusions in Ontario hospitals
Canadian Institute for Health Information	
Discharge Abstract Database	Clinical data on in-patient stays in Canadian hospitals, including if the patient received a blood transfusion
National Ambulatory Care Reporting System	Clinical data on out-patient visits to Canadian hospitals, including if the patient received a blood transfusion
Public Health Agency of Canada	
Transfusion Errors Surveillance System and TTISS	Information about transfusion errors at select Canadian hospitals, which is then shared nationally so that all hospitals have the opportunity to spot and prevent possible errors before they occur, and TTISS-ON data entered by program administrators

can assess on a real-time basis whether patients in hospitals are receiving the appropriate quantity and type of blood components or products that they need.

4.2.1 Lack of a Centralized Ontario Blood Information System Contributes to Inefficiencies, Waste and Data Challenges in Supply and Demand Forecasting

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. Instead, Ontario hospitals and Canadian Blood Services use multiple systems, as shown in **Figure 8**, to manage data such as blood ordered and shipped, quantity of blood used, patients' clinical conditions and adverse transfusion events (we discuss these in **Section 4.2.4**). The MOU between the federal government and the provinces and territories (except Quebec) states that Canadian Blood Services is responsible for maintaining "a capability to address inventory imbalances (shortages) to minimize waste and ensure adequate supply." Our audit found that, individually, these systems have various weaknesses that make it difficult for Canadian Blood Services to fulfill its responsibilities, as we detail

below. This limits the opportunity to enhance and integrate data to better manage system blood inventory and respond to changing blood demands more efficiently.

Ordering Blood Supplies

Hospitals still order blood by fax machine. As a result, Canadian Blood Services staff need to manually enter blood orders into its database to fill the orders, which allows for human errors. According to the hospitals we visited during the audit, each hospital generally determines how much blood it needs to order from Canadian Blood Services by referring to reports of previous use and through daily meetings within its blood bank to identify any low levels of components or products. Forty-six of the 75 hospital sites that responded to our survey reported to us that they did not receive what they ordered from Canadian Blood Services in at least one instance in the last 12 months. The 2020 performance review of Canadian Blood Services also recommended that Canadian Blood Services should "continue its efforts to automate the hospital ordering process for (fresh blood components) and (blood products) and develop strategies for strong adoption."

Reporting Blood Inventories and Blood Use

Not all hospitals report quantities of blood used. Canadian Blood Services encourages hospitals to report their usage data through its database, which is available to all hospitals, but it does not make reporting mandatory, nor does it confirm accuracy). We found that 13% of the 158 Ontario hospitals that transfuse blood, which were mainly smaller hospitals, did not report blood product use in 2019/20.

We reviewed the database and found that 43% did not report their use of blood by blood type in 2019/20, which is similar to the information provided to us by the Network. This has created challenges for Canadian Blood Services in quickly meeting the higher demand for certain blood components, such as universal blood types including O-negative red blood cells and AB plasma, which are needed for emergency situations. In 2018/19, Canadian Blood Services was able to meet hospitals' orders for O-negative red blood cells and AB plasma 97.7% and 98.6% of the time, respectively. An integrated system could help Canadian Blood Services obtain better information on where and how blood is being used in the national system and allow for improvements.

Furthermore, not all hospitals consistently report blood inventory, even though Canadian Blood Services asks hospitals to provide this data daily. Reporting inventory is especially important when managing potential shortages. Recently, in anticipation of possible blood shortages, Canadian Blood Services emphasized in its notices to hospitals that it is essential that they report inventory levels. For example, the National Emergency Blood Management Committee announced a national "green phase advisory" for all blood components and products in the spring of 2020 when it was anticipated that blood inventories might fall below normal levels, and an "amber phase" for a particular Ig product in the spring of 2019 when over a few months its demand went up by 50% and resulted in a shortage that lasted for months. During these times, as part of its daily interactions with hospitals, Canadian Blood Services phoned or emailed hospitals that did not comply and asked them to properly report, or it asked the Network to encourage reporting more actively.

Reporting Clinical Data

The Canadian Institute for Health Information collects clinical information on patients who receive blood transfusions in Canadian hospitals, but it does not always indicate the blood component or product transfused, or the number of units transfused. Our analysis of this data for 2019/20 indicated that in 11,638 (or 9%) of 128,282 transfusion events (representing 78,659 unique patients, some of whom had multiple transfusions),

hospitals did not record details on what component or product was transfused. As a result, both the Ministry and Canadian Blood Services are missing important insights into how much blood is used per patient and how many patients receive a particular blood product or component. The data also did not include patient condition, so there was no way to link clinical data with blood use data to help understand how hospitals use blood and whether they adhere to blood use guidelines. British Columbia informed us that it obtains complete information on hospital blood usage, including patient condition, through its Central Transfusion Registry.

Locating and Retrieving Potentially Compromised Blood

Canadian Blood Services does not have access to real-time information to assist it in locating and retrieving blood expediently from hospitals if it becomes concerned about its quality. In 2019/20, Canadian Blood Services data indicated that about 53% of 1,231 units of blood that it attempted to retrieve across the country was already transfused into a patient. Canadian Blood Services categorizes these transfusions as either "errors or accidents" because the units of blood were determined to have quality issues—such as unacceptable bacteria levels and labelling errors, or donors belatedly reported health and lifestyle concerns that could affect the quality of the blood—and may have manifested in adverse transfusions events, discussed more in **Section 4.2.4**.

Supply and Demand Forecasting

The 2020 performance review of Canadian Blood Services noted a variety of positive approaches used by Canadian Blood Services to forecast blood demand, but it also noted areas for improvement. For example, the review indicated that other countries collect data such as patient demographic information, patient diagnoses, and the relevant specialty (such as neurosurgery versus intensive care), but Canadian Blood Services does not collect data on prescribed dosages, intended frequencies of use, duration of treatments, and patient outcomes. Having this data could help Canadian Blood Services better forecast demand for blood products. The review also suggested a pilot study of two provinces or territories where data is incomplete, inaccurate or inconsistently available (which would include Ontario) to evaluate the costs and benefits of sharing data between hospitals and Canadian Blood Services.

Managing/Redistributing Inventory and Reducing Wastage

Given the fragmented and manual processes for managing hospital blood inventories, the Ministry currently funds the Network and the Factor Concentrate Redistribution Program (Program) to help redistribute blood components and products among hospitals as needed. Hospitals also work on their own to redistribute red blood cells and plasma. A more integrated inventory system would allow the Network, the Program and hospitals to more efficiently identify components or products that are nearing expiry and need to be redistributed, without having to contact individual hospitals to find out this information.

Currently, the Network and the Program contact hospitals to identify blood products that are approaching expiry and try to find a hospital that can use them. The Network has also developed inventory management tools such as formulas to help determine optimal inventory levels for hospitals; it encourages, but is not able to enforce, their use. As shown in **Figure 9**, in 2019/20, hospitals, the Network and the Program redistributed between 0.2% and 5.5% of blood components and products, helping hospitals reduce waste. Overall, the amount of blood components wasted has decreased between 2015 and 2019, as shown in **Figure 10**. The decline in quantity wasted ranged from 16% for red blood cells to 35% for platelets, and the proportion of wasted quantities of these blood components compared to quantities used

Figure 9: Percentage of Blood Components and Products Redistributed in Ontario, 2019

Prepared by the Office of the Auditor General of Ontario

Blood Component/Product	Entity Responsible for Redistributing	% Redistributed[1]
Red blood cells	Hospitals[2]	3.3
Platelets	Hospitals[3]	5.5
Plasma	Hospitals[2]	2.2
Factor concentrates	Factor Concentrates Redistribution Program	2.4
Immunoglobulins	Ontario Regional Blood Coordinating Network	0.2

1. Red blood cells, platelets and plasma are measured in units; factor concentrates are measured in corresponding dollar value based on 2018/19 data—the most recent data available; and immunoglobulins are measured in vials.
2. The Ontario Regional Blood Coordinating Network (Network) sometimes covers courier fees for some hospitals.
3. The Network created a web application in 2011 for hospitals to list and browse for expiring platelets for the purposes of redistribution.

also declined. Despite these redistribution efforts, over 5,000 units of red blood cells and over 5,000 units of platelets were still wasted annually in each of the last three years. The wasted red blood cells are equivalent to donations from about 15,000 donors. Ontario paid about $10.2 million to Canadian Blood Services for these wasted units of red blood cells and platelets in the three years ending December 31, 2019. Because these efforts are still manually driven, without a centralized inventory system that allows all inventories to be transparent to all hospitals, wastage will likely continue.

While at the time of our audit, Canadian Blood Services' inventory system allowed it to internally track its own inventories on a real-time basis, there was no capacity to track hospital inventories. Without complete data on hospitals' inventory of blood components and products, Canadian Blood Services is unable to determine the reason for shifts in demand, such as the increased demand for a particular Ig product that resulted in shortages in 2019. The 2013 performance review of Canadian Blood Services recommended it create a centralized function to manage inventory, and to work with hospitals to standardize the way they collect data related to blood demand and use.

Canadian Blood Services tracks its own blood component wastage that occurs before the blood is shipped to hospitals. In 2019/20, it discarded 5.7% of donated blood in Canada. Of the 30,523 units discarded by Canadian Blood Services within Ontario processing centres, 31% were underweight or low-weight donations that could not be used to provide one full unit of blood, and 8% had expired on Canadian Blood Services shelves. Other reasons for discarding included broken bags, labelling errors, and the detection of transmissible diseases during testing.

Representatives from Héma-Quebec informed us that, during the COVID-19 pandemic, they had gained access to Quebec hospitals' electronic blood inventory system, which helped inform the agency's distribution processes, ultimately allowing for better planning to respond to blood service needs.

Centralizing Blood Data Collection and Management

The Ministry was presented with proposed solutions to blood-management data systems in 2017 and 2018 to address gaps in the current assortment of decentralized databases and manual processes used in hospitals. The Ministry rejected both proposals based on their immediate costs, but did not factor in longer-term cost savings. The 2017 option was an unsolicited proposal submitted by McMaster University to the Ministry. It was expected to improve both demand forecasting and surveillance for appropriate blood use, product quality and safety. Specifically, it was designed to support real-time inventory monitoring and provide

Figure 10: Use and Waste[1] of Red Blood Cells, Platelets and Plasma at Hospitals, 2015–2019 (Units)
Source of data: Canadian Blood Services[2]

	2015	2016	2017	2018	2019	% Change Over 5 Years
Red blood cells						
Used	377,244	376,107	375,388	381,590	373,016	(1)
Wasted	6,565	5,009	5,007	5,491	5,502	(16)
% Wasted	1.6	1.2	1.3	1.4	1.4	n/a
Platelets[3]						
Used	49,219	53,190	54,405	56,471	56,058	14
Wasted	8,953	7,416	6,752	5,452	5,778	(35)
% Wasted	14.5	11.5	10.3	8.3	8.8	n/a
Plasma						
Used	53,254	54,154	49,717	53,357	45,787	(14)
Wasted	3,416	3,259	2,979	3,242	2,961	(6)
% Wasted	5.4	5.5	5.5	5.6	5.9	n/a

1. Waste refers to all outdated, broken or recalled blood components.
2. Based on data from Canadian Blood Services' hospital disposition database. This data is self-reported by hospitals.
3. Platelets have a short shelf life of only five to seven days from the date of collection.

comprehensive data on blood use to help determine optimal inventory levels for each hospital. In 2018, the Ministry requested Cancer Care Ontario's assistance to develop a request for proposal to assess the business requirements for an electronic ordering system for immunoglobulins. This system would help physicians order the correct quantities based on appropriate conditions, dosing, and frequency and duration of treatment. The Ministry informed us that while it approved proceeding with the business requirements assessment, other ministry projects and activities, including responding to the COVID-19 pandemic, had taken priority. It also informed us that, toward the end of our audit, in September 2020, it engaged with the Ministry's Health Services Information and Information Technology Cluster to take steps to advance the system's development.

In the absence of a provincial system to store and manage blood use data, two institutions have taken the initiative to develop their own systems:

- In 2001, McMaster University created a database on its own initiative to link all patient and transfusion (both blood components and products) data from 2002 to the present for four hospitals in Hamilton, Ontario. It collects and stores blood transfusion data from the four hospital databases and the Canadian Institute for Health Information's Discharge Abstract Database to produce comprehensive data on blood transfusions. The information contained in this integrated database includes both blood bank and clinical data and therefore helps inform transfusion practice, determine the optimal use of blood, and enhance the safety of transfusion for blood recipients and blood donors.
- One Ontario hospital introduced an electronic method of ordering Ig into its hospital information system in 2012, and plans to introduce controls, such as automatic dosage calculators that follow Ontario Ig guidelines, by spring 2021. This has allowed the Southwest Local Health Integration Network, where this hospital is located, to gain a better understanding of how Ig is being used, and to target its educational initiatives toward changing behaviours to improve overall usage.

We found that the Ministry has not used either project to identify lessons learned (for example by analyzing Ig usage patterns) that can be used by other Ontario hospitals. During our audit, Canadian Blood Services informed us that it was exploring the use of an online ordering system with hospitals in British Columbia that allows all parties to have more real-time access to blood inventory data. Once this work was complete, Canadian Blood Services informed us it would, together with provinces and territories, examine the feasibility of extending this to all hospitals in Canada.

RECOMMENDATION 2

To support data-driven decision-making in managing the supply of blood components and products, including redistributing them to patients who need them most, and to inform forecasting of demand, we recommend that the Ministry of Health, in conjunction with Ontario Health:

- as an interim solution in the absence of an integrated technology solution, request all hospitals report weekly to Canadian Blood Services their full inventory details for those blood components and products that are under a shortage advisory, and monitor hospitals' compliance;
- actively monitor Canadian Blood Services' exploration of an online ordering system for hospitals in British Columbia;
- assess and develop an appropriate information technology solution—leveraging existing initiatives such as the blood database at McMaster University—to extract relevant data, including the amount of blood used and conditions for which it was used to treat, from multiple hospital systems;
- work with Canadian Blood Services by providing Ontario data to further develop its forecasting approaches, including factors such as patient demographics.

MINISTRY RESPONSE

The Ontario Regional Blood Coordinating Network (Network), in collaboration with Canadian Blood Services, performs annual site visits in Ontario hospitals to discuss their performance in relation to best practices and utilization of blood components and products. The Network leverages the data that is currently available to facilitate informed decision-making and promote the adoption of best practices in blood management. As a result, many hospitals demonstrate improvements, year over year, with respect to their blood utilization. The Ministry acknowledges that further improvements to data collection in the management of blood components and plasma protein products would support decision-making and planning. The Ministry supports an interim step to improve hospital reporting of blood component and plasma protein product inventory when they are at risk or in shortage. This will better inform collaborative efforts with Canadian Blood Services in addressing shortages, with a longer-term goal of identifying resources for improved data collection and analysis. The Ministry will also consider the impacts of additional data collection on direct service provision within hospitals and seek to balance both activities.

4.2.2 Immunoglobulins Used for Conditions Not Included in the Provincial Guidelines

We found that neither Canadian Blood Services nor the Ministry of Health (Ministry) collects information on how immunoglobulins (Ig) are used in Ontario hospitals—for example, to what extent they are used to treat conditions for which there is no solid evidence to support their use. The Local Health Integration Networks (LHINs) that fund hospitals also do not collect this information. The lives of people with immune system disorders, who are unable to produce sufficient antibodies to fight infection, depend on access to a secure supply of

Ig. However, neither Canadian Blood Services nor the Ministry could tell us how many Ontarians have these disorders. 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 use of Ig to treat conditions not included in provincial guidelines is especially concerning because Ig demand could exceed supply if shortages of this product occur, such as if plasma donations fell in the United States. We discuss the risk of these shortages in more detail in **Section 4.3**.

Ontario pays more for immunoglobulins than all other blood products combined. The Canadian Agency for Drugs and Technologies in Health (Agency) provides research and analysis to healthcare decision makers in Canada. In a study published in 2018, it noted that each dose of Ig can cost between $550 and $2,200 per child and between $2,000 and $8,000 per adult. Ontario uses 45% of the total Ig distributed among the provinces and territories that Canadian Blood Services oversees. Almost one-quarter or $131 million of what the Ministry paid Canadian Blood Services for blood components and products in 2019/20 was for these products.

According to the 2018 final report by the Expert Panel on Immune Globulin Product Supply and Related Impacts in Canada (Expert Panel report), demand for Ig continues to increase in Canada and globally at 6% to 10% per year, with Canada being the second-highest global user per capita. The Panel report suggests that the reason for this higher use in Canada is that other jurisdictions such as Australia and the United Kingdom target Ig use on a smaller number of health conditions, "suggesting the need for more scrutiny over use of Ig" in Canada.

Immunoglobulins are used for a range of conditions, such as immune disorders, neurological conditions and other medical problems. Health Canada, the Ministry and Canadian Blood Services have raised concerns regarding whether Ig is being used in a consistent manner and according to medical guidance. According to Health Canada, patients with inherited immune disorders are completely dependent on Ig for survival; patients with neurological and acquired immune disorders may also benefit from them. Little is known about the prevalence of primary immune disorder in Canada, which Ig is used to treat, and what percentage of patients receiving Ig are receiving it for primary immune disorders versus other indications. In the United States, this disorder is estimated to affect between 1 in 4,000 and 1 in 10,000 people. In contrast, because British Columbia maintains a Central Transfusion Registry, it knows how many patients have primary immune deficiency (790 in total in 2018/19).

According to Canadian Blood Services, between 2010/11 and 2019/20, the demand for Ig across Canada has increased steadily from about 3.4 million grams to about 6.5 million grams, and the demand for Ig in Ontario has similarly increased from 1.6 million grams to 3.0 million grams. Furthermore, according to Canadian Blood Services, there is no indication that the pattern of growth in demand for these blood products will change significantly over the medium term.

We contacted Health Canada to obtain its perspective on the recommendations made by the Expert Panel given the current realities of the COVID-19 pandemic. It informed us that the recommendations "remain relevant but there are now additional pressures on global supplies of plasma and plasma-derived products given the impacts of the COVID-19 (pandemic)." It further explained: "The Federal Government is monitoring the situation in collaboration with CBS (Canadian Blood Services) and PTs (provinces and territories). We are currently reaching out to former Expert Panel members as well as our internal regulatory experts to understand the impact of COVID-19 on domestic and international plasma collection/prices into next year. We were informed that there have been significant impacts on plasma collections in the US, which were heavily hit at the start of the pandemic, and continue to be impacted despite considerable industry efforts aimed at convincing donors to

return to collection centres. For some products, there have also been production challenges in regions heavily hit by COVID-19 due to disease-related absenteeism."

To help manage the demand for this blood product, the Ministry, with support from the Ontario Regional Blood Coordinating Network that it funds, 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 and the Network together communicated these guidelines to senior hospital staff and the Network announced them through its newsletter and on its website as well as through site visits. The Ministry also included a paper-based order form along with the guidelines and asked hospital physicians to record conditions and dosages for patients using Ig, beginning in 2012. Each physician ordering these drugs is to submit the completed paper form to their hospital's blood bank. A transfusion medicine specialist who manages the blood bank is to review this form and ensure that the request follows appropriate guidelines, including proper dosing according to body weight and the condition the drugs would be treating. The Ministry also asked physicians who initially ordered the blood product to resubmit the form to blood bank staff every six months for reassessment in order to confirm the dose used was the lowest possible to be effective and that it was effective in improving patients' conditions. Staff from the Network informed us that the physician responsible for the blood bank may in some cases question the ordering physician about the appropriateness of the prescribed dose and patient condition. The Network further noted that blood bank physicians are sometimes reluctant to deny prescriptions because ordering physicians have more expertise in their patients' medical conditions.

However, we found that after creating the paper form, the Ministry left it to hospitals to comply with provincial guidelines on an ongoing basis, and has never confirmed that hospitals use this form or that physicians resubmit the form every six months as required. Also, the Ministry has not routinely collected the forms to consolidate the information contained within them and analyze how hospitals use Ig, including whether certain hospitals or physicians are more likely to prescribe incorrect doses of Ig. Without this type of analysis, neither the Ministry—as the funder of health services and blood products—nor the Local Health Integration Networks—as the funders and planners that oversee hospitals and other health-service providers across Ontario—can perform the following critical functions:

- **Detect Ig use for conditions that are not indicated as preferred in Ontario guidelines:** While the Ministry's paper order form contained an "other" category, where a prescribing physician can make a request to treat a health condition not listed in the Ontario guidelines, it does not gather or use the data. We surveyed hospitals and found that 57% of the responding hospital sites reported using Ig for purposes beyond preferred use. The Ministry informed us that determining proper use under the "other" category is the responsibility of the hospital. However, using Ig for conditions not identified as appropriate can deplete the supply of the products. The Ministry's responsibilities still include managing supply to avoid shortages; the strategy of having guidelines and order forms was to help ensure appropriate utilization of Ig and reduce overprescribing or wastage. The Ministry informed us that avoiding shortages was not an objective of this strategy. We surveyed 30 of the hospitals that informed us in our original survey that they used Ig for "other" conditions. They collectively informed us of about 20 such conditions, which we reviewed against research by the Canadian Agency for Drugs and Technologies in Health. While the Agency had no studies on the use of Ig in Ontario, its studies have indicated that Ig resulted in poorer outcomes (for two conditions) and was no different than other medications (for three conditions), and that

there was insufficient data to determine whether Ig was an effective treatment (for one condition).

- **Have an ongoing process to identify overprescribing practices that could lead to wasted Ig product:** In 2017, the Ministry conducted an eight-month study of Ig orders to confirm that the sampled 92 hospitals complied with the 2012 Ontario guidelines regarding appropriate patient conditions and dosage. The study did not identify any concerns with patients receiving less than medically indicated levels of the drugs, but found that the doses, frequency, or duration of prescriptions were generally higher than required. The study was conducted by hospital pharmacists at the Ministry's request on almost 1,100 physician orders for Ig. Pharmacists found most of the physician orders complied with the guidelines, but identified about $4.5 million of potential savings. Later in 2017, upon assessing the hospitals' compliance with the assessor's evaluations, the estimated cost savings were updated to $2.2 million. In contrast, the Ministry has an ongoing post-payment verification process under the Ontario Drug Benefit Program to review pharmacy claims and recover overpayments, including those for ineligible claims. Similarly, Cancer Care Ontario's eClaims is a web-based program that reviews patient claims, including their eligibility, to receive funding for cancer drugs.

The Expert Panel on Immune Globulin Product Supply and Related Impacts in Canada report, which was published prior to the onset of the COVID-19 pandemic, observed that work needs to be done in Canada to develop a national prioritized list of patient groups dependent on Ig, and a process for allocating these products appropriately during short-term or prolonged shortages. However, no progress on managing the use of Ig was made until the advent of the COVID-19 pandemic. We discuss the national guidelines in **Section 4.6.2**.

4.2.3 Funding Model May Not Be Encouraging Effective Management of Blood Supplies

Canadian Blood Services is funded directly by the Ministry of Health to provide blood components and products to Ontario hospitals. In contrast, hospitals are usually required to pay for drugs used in their hospitals from their own budgets, even though drugs are administered to patients in much the same way as blood products. As a result, payments for drugs are usually subject to more consideration of value for money and hospitals will have better systems for monitoring costs for the drugs they pay for from their hospital budgets. Given the Ministry covers the cost of blood, hospitals have less incentive to actively monitor the amount of blood they use or waste—and, as noted above, a limited ability to do so given the lack of an integrated information system. Some blood experts informed us that blood is sometimes managed less effectively as a consequence.

The Krever Inquiry also recognized this problem and recommended (Recommendation 16) "that the provinces and territories … increase the budgets of hospitals using blood components and blood products by amounts that will enable them to pay the national blood service for these components and products without affecting their other programs and services." It further stated that "the fee will act as an incentive for the appropriate use of blood components and blood products." The 2013 performance review of Canadian Blood Services, while not directly recommending a change to the funding model, observed the benefits of helping hospitals understand the costs associated with their use of blood products.

In recognition of and to address this concern, the Ministry established an Ig funding consultation group (with Canadian Blood Services as a participant) to explore opportunities to change the funding model for Ig and allocate blood costs among Ontario hospitals. However, this group has had no documented activity since February 2018.

Canadian Blood Services informed us that, in 2017, the Ontario Ministry of Health was considering changing the funding model to require hospitals pay for the Ig they use. However, the Ministry indicated the work on a funding model then transitioned to focus on an electronic ordering system for immunoglobulin because of the lack of reliable data to track its use.

We noted that Héma-Quebec is required by legislation to charge hospitals directly for blood components and products. While hospitals may be reimbursed by the government for these costs, Héma-Quebec informed us that its practice of directly billing hospitals, which flowed from recommendations made in the Krever report, had contributed to efficiencies in blood use at hospitals.

RECOMMENDATION 3

To better manage the demand and supply of immunoglobulins so that they are available for Ontarians who need them most and to avoid the costs of wasted product, we recommend that the Ministry of Health, in consultation with Ontario Health:

- collect more complete data from hospitals on how immunoglobulins are being used and identify emerging conditions that may warrant inclusion in provincial utilization guidelines;
- eliminate the option of prescribing immunoglobulin where the Ontario Immune Globulin Utilization Guidelines (Guidelines) state that the product is not recommended for use;
- educate physicians and monitor Ontario hospitals' adoption of the Guidelines; and
- assess potential tools, including updating the Guidelines as needed to prohibit uses where there is no credible evidence that they improve health outcomes, to achieve more appropriate use of blood products—particularly immunoglobulins—according to patient need.

MINISTRY RESPONSE

The Ministry regularly consults with experts in transfusion medicine and blood management to identify opportunities for improvement to Ontario's blood system. Based on past consultations, the Ministry has initiated work to implement an electronic immune globulin ordering system to manage utilization of immunoglobulins in Ontario hospitals, in alignment with the Ontario Immune Globulin Utilization guidelines. It is expected that this initiative will address the recommendations made by the Auditor General, as the proposed system. This will help in collecting more appropriate information such as the medical conditions being treated with immunoglobulin, and the volumes of immunoglobulin ordered to improve forecasting. Furthermore, the information obtained through the system will better inform the Ontario Immune Globulin Utilization Guidelines and educational efforts relating to the guidelines.

RECOMMENDATION 4

To better manage the demand and supply of immunoglobulins so that they are available for Ontarians who need them most and to avoid the costs of wasted product, we recommend that the Ministry of Health, in conjunction with Canadian Blood Services, monitor the international situation regarding the supply and demand of immunoglobulins given the impact of COVID-19 on supply.

MINISTRY RESPONSE

The Ministry will continue to seek leadership of Canadian Blood Services in monitoring the international situation regarding the supply and demand of immunoglobulins given the impact of COVID-19 on global supply. It is important to note that the actions taken to date by Canadian Blood Services and the Ministry have mitigated

against these impacts. Both organizations will continue to leverage lessons learned from these efforts and around the world to secure a better supply and manage demand based on appropriate use of the product.

4.2.4 Ontario Hospitals Not Required to Report to Patient-Care Systems that Track 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. This data is used to inform decision-making to improve patient safety, by providing a national platform for submitting data and issuing regular reports. 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**. Provincial program administrators of both systems informed us that the voluntary nature of the reporting developed because surveillance activities over blood transfusions were seen as a federal responsibility and the Ontario government has not sought to make such reporting mandatory. Similarly, the federal agency noted that surveillance is designed to be voluntary and is a shared responsibility that involves federal, provincial and territorial governments, hospitals and blood operators.

Our audit found that more complete tracking of adverse transfusion events and errors by all Ontario hospitals could yield more complete information in helping hospitals improve their transfusion practices.

In the case of the Injury Surveillance System, which tracks injuries incurred by patients during transfusions (as described in **Section 2.3**), Ontario hospitals are not subject to any regulatory requirement to report all adverse transfusion events. Reporting of these events is largely voluntary, with 130 or over 80% of hospitals in Ontario reporting some of their adverse events. The other 28 hospitals have entered into an agreement with the Ministry to report all adverse events; these 28 sites account for about one-third of all blood components transfused in Ontario. The Ministry provides a total of $69,400 a year that the Injury Surveillance System program administrator based out of McMaster University allocates across all hospitals, paying 28 hospital sites to report all adverse transfusion events and the other 130 to report major transfusion events to the Injury Surveillance System. While the System administrators release information on total adverse transfusion events broken down by different type of events, they do not compare the number of adverse events between hospitals and do not share information on lessons learned to help hospitals make necessary improvement to their blood management processes.

As shown in **Figure 11**, hospitals in Ontario reported a total of about 5,000 adverse transfusion events from 2015 to 2019, with each hospital reporting on average about eight events per year. The gradual increase of total events over that time largely corresponds to increased hospital participation, which grew from 95 hospitals in 2015 to 158 in 2019 following encouragement from Injury Surveillance System program staff. However, in 2019, 15 hospitals reported more than double the five-year average. In 2019, the highest number of adverse transfusion events reported by a single hospital was 170—both major adverse transfusion events such as severe allergic reactions and transfusion-associated circulatory overload (respiratory complications following rapid transfusion of a large volume of blood for certain patients with underlying health conditions) and minor adverse transfusion events such as minor allergic reactions and febrile non-hemolytic reactions (such as fever)—and on the low end, 36 hospitals reported no adverse events. Over these five years, 22 adverse events likely resulted in death and three definitely resulted in death.

Because hospital workers may be reluctant to report their own errors or those of their colleagues within the hospital, reported data and trends may

Figure 11: Number of Adverse Transfusion Reactions Reported by Ontario Hospitals, 2015–2019

Source of data: Transfusion Transmitted Injury Surveillance System

	2015	2016	2017	2018	2019	Average	Total
Minor reactions[1]	658	645	687	746	729	693	**3,465**
Major reactions[2]	260	313	272	358	384	317	**1,587**
Total reported	918	958	959	1,104	1,113	1,010	**5,052**
Number of hospitals reporting	95	96	123	158	158	126	n/a
Average number of adverse transfusion reactions reported per hospital	10	10	8	7	7	8	n/a

1. For example, a minor allergic reaction, a less severe delayed serological reaction (meaning the recipient develops new antibodies against red blood cells between 24 hours and 28 days after the transfusion without any symptoms or evidence of hemolysis) or a less severe febrile non-hemolytic reaction (a slight temperature increase without destruction of red blood cells).
2. Moderate to severe adverse transfusion events, such as acute hemolytic transfusion reactions (characterized by fever, chills, shortness of breath, low blood pressure, shock, nausea and/or vomiting) and transfusion-associated circulatory overload reactions (characterized by shortness of breath, fluid retention, swelling, rapid increase in blood pressure and/or findings of congestive heart failure).

not accurately reflect hospital safety. To determine whether hospitals were reporting all significant adverse transfusion events to the Injury Surveillance System, we analyzed relevant data from 2018 and 2019 in the Ontario Laboratories Information System, which includes data on investigations of adverse transfusion reactions. Our analysis indicated that the incidents related to investigations of 45 and potentially another 220 adverse events from 2018 and 74 and potentially another 222 adverse events from 2019 were not reported to the Injury Surveillance System. Furthermore, 18% of these unreported adverse events in each of these years were from the 28 sites that are required to report all adverse transfusion events to the Injury Surveillance System.

In the case of the Error Surveillance System that tracks transfusion errors (see **Section 2.3**), the Public Health Agency of Canada informed us that a limited network of carefully selected reporting sites—a concept known as sentinel sites—are used across Canada to identify the types of errors that occur so that they may be prevented. Information the program reported to the Ministry indicated that three Ontario hospital sites reported events in 2018 and 2019. Provincial program administrators informed us that only three hospital sites were funded to participate. The other 155 Ontario hospital sites have not been funded to participate as sentinel sites, though some have elected to submit data. The provincial program administrators informed us that hospital staff require training on how to properly report errors and no funding has been provided to train additional hospitals. We spoke to staff from one of the three hospital sites that contributed transfusion error data, who told us they would like to see other Ontario hospitals participate because, in their view, merely identifying such errors can have a direct impact on patient safety and can drive change and improvement. Specifically, they said that identifying errors is a necessary first step in determining the cause of an error, which can then lead to processes to fix the issues and therefore reduce harm to patients.

Hospitals' incomplete reporting of errors and injuries, in combination with a lack of root cause analysis in the Injury Surveillance System (see **Section 4.5.3**), means that it is not possible to assess, or effectively address where needed, the risk this represents for patients.

RECOMMENDATION 5

To improve the tracking of transfusion errors and injuries, we recommend that the Ministry of Health (Ministry), in consultation with Ontario Health:

- establish a plan to raise awareness and require all hospitals to report serious transfusion-related incident data to the Ministry; and
- monitor compliance with the plan on an annual basis.

MINISTRY RESPONSE

The Public Health Agency of Canada and Canadian Blood Services have complementary accountabilities in the surveillance of adverse transfusion events and transfusion errors by hospitals across Canada. The Ministry has continuously invested in programs led by these national organizations to help safeguard patients in Ontario. Specifically, the Ministry funds Ontario hospitals for their participation in national transfusion surveillance of adverse transfusion events and Canadian Blood Services for surveillance relating to infection through blood-borne pathogens via transfusion and severe adverse transfusion events. The Ministry will explore ways to complement these activities by requesting Ontario hospitals to report serious transfusion-related incidents to the Ministry, while raising awareness of their reporting requirements, in order to improve the safety of transfusion practices in the province.

4.3 Blood Supply Meeting Demand in Most Cases, But There Have Been Short-Term Shortages

Ontario and other provinces and territories that rely on Canadian Blood Services to supply blood experienced actual shortages of blood components and products on two occasions in the five-year period between August 2015 and July 2020. Even though O-negative blood is the highest in demand of red blood cell components, Canadian Blood Services' blood donor clinics were generally able to supply all that was requested by Ontario hospitals, with only one of 75 hospitals we surveyed indicating it did not receive this blood type when it requested it in the last 12 months. The longest realized shortage was for a form of manufactured blood product called immunoglobulins, or Ig, that patients can inject themselves. The shortage lasted for almost three months in mid-2019. This significantly affected new patients who were not able to begin using this treatment approach, which is less expensive to the health system and more convenient than the form of Ig that must be transfused in hospitals since patients do not use hospitals resources when obtaining treatment.

4.3.1 Blood System Experienced Two Episodes of Shortages and Prepared for Another Six Potential Shortages in Last Five Years

Over the past five years, hospitals in Canada have not had significant issues accessing blood for their patients, but on rare occasions when national inventory drops to below-normal levels, national and provincial blood-shortage plans are activated. Such shortages, even though not common, highlight the need to monitor and forecast supply and demand accurately since patients' outcomes may be impacted by a sudden unavailability of a blood component or product.

Canadian Blood Services and its funding provinces and territories have together established a national plan to support a consistent and co-ordinated response to blood shortages in Canada. At the provincial level, the Ontario Ministry of Health established the Ontario Emergency Blood Management Committee (described in **Appendix 2**) to develop a provincial response plan to minimize the impact of blood shortages on patient care.

Between August 1, 2015, and July 31, 2020, Ontario as well as the rest of Canada (except Quebec) experienced two blood shortages and six additional occasions where blood levels were lower than optimal levels, classified as "green phase advisory" (see **Figure 12**). The National Emergency Blood Management Committee, of which Canadian Blood Services is a member, announces these shortage advisories. The six green phase advisories lasted between 12 and 53 days, and

Figure 12: Phases of a Blood Shortage and Occurrences from August 2015 to July 2020

Source of data: Ministry of Health and Canadian Blood Services

Phase	Blood Levels	Hospitals' Responsibilities	# of Times this Phase was Announced, Aug 2015–Jul 2020
Green Phase Advisory	Blood components* inventory at Canadian Blood Services decrease below Canadian Blood Services' defined "green" levels for a particular blood type or component	• Report inventory to Canadian Blood Services by blood group and component within a specified time frame. • May be asked to reduce target inventory for the affected component by a percentage to aid recovery of supply or in anticipation of potential shortages. • Follow recommendations by the National and the Ontario Emergency Blood Management Committees, communicated by the Ministry of Health	6
Amber Phase	Blood levels are insufficient to continue with routine transfusions	• Report inventory to Canadian Blood Services and reduce inventory reordering to help improve overall access to inventory • Consider deferring or cancelling non-elective procedures that require the affected blood components • Initiate Hospital Emergency Blood Management Plan • Follow recommendations by the National and the Ontario Emergency Blood Management Committees, communicated by the Ministry of Health	2
Red Phase	Blood inventory levels are insufficient to ensure that patients with non-elective indications for transfusion will be able to receive required transfusions	• Continue Hospital Emergency Blood Management Plan • Collect inventory levels on a daily basis and report to Canadian Blood Services within the specified time frame determined by the National Emergency Blood Management Committee • Triage blood use • Document the deferral and cancellation of non-elective procedures that require blood • Follow recommendations by the National and the Ontario Emergency Blood Management Committees, communicated by the Ministry of Health • Transfer blood between hospitals to help hospitals that are short • Reduce amount of blood to be reordered	0
Recovery Phase	Blood inventory levels have begun to increase and are expected to be maintained at a level that would allow for gradually resuming normal transfusion activities	• Notify internal hospital personnel they are now in recovery phase • Blood use to be continuously monitored for 24 to 48 hours • Increase blood usage and activity slowly and increase inventory levels gradually • Review hospital's management of the blood shortage and debrief within the hospital • Follow recommendations by the National and the Ontario Emergency Blood Management Committees, communicated by the Ministry of Health	2

* Blood components include red blood cells, plasma, platelets and cryoprecipitates.

included various blood components and products, four of which were for the most commonly used blood component—red blood cells—and one of which was for cryoprecipitate. One of these green phase advisories for red blood cells also included all blood components and immunoglobulins (Ig). It started in March 2020 because of the uncertainties of the blood donation processes during the COVID-19 pandemic and was lifted in mid-July 2020 when Canadian Blood Services indicated that it had attained sufficient experience with the circumstances of the pandemic to ensure optimal inventory levels. The two shortages in this five-year period were classified as "amber phase", which means that inventory levels were insufficient to continue with routine transfusion practice. One of these shortages related to platelets, and lasted for two days in 2016 when demand unexpectedly rose during a holiday weekend; hospitals were advised to reduce elective surgeries. The second shortage related to the more convenient form of Ig that is often preferred because it may be self-administered at home. It lasted for 79 days in 2019 and resulted in patients continuing to go to hospitals to receive the intravenous form, and delaying their transition to the form they can self-administer at home.

4.3.2 Canada Supplies Only 13% of Plasma Needed to Manufacture Immunoglobulins

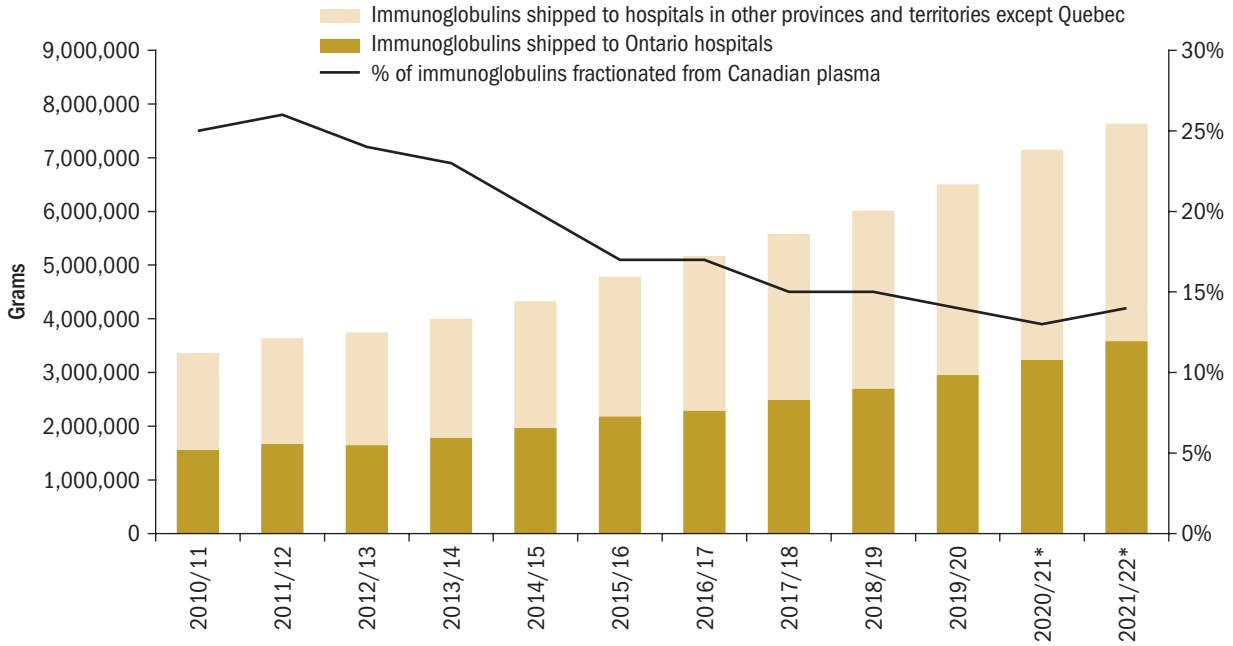
Canadian Blood Services currently relies on global vendors to produce blood products made from plasma obtained outside Canada to treat patients living with conditions such as angioedema, haemophilia and immune disorders; such plasma is purchased by foreign drug manufacturers from paid donors. Recognizing the risks of relying primarily on US supply for Canadian patients, Canadian Blood Services set a goal in 2017 to achieve 50% self-sufficiency in plasma to produce immunoglobulins or Ig by 2023/24. It concluded that complete self-sufficiency was inadvisable as it is prudent to minimize supply risk by diversifying suppliers over more than one source. However, progress toward the 50% goal has been slow. Not only has Canadian Blood Services not progressed toward its 50% goal, it has regressed since establishing it. Canadian Blood Services informed us this slow progress is due to the requirement to have provinces and territories approve major funding projects such as additional donor sites. This slow progress, combined with a 63% increase in demand for Ig between 2013/14 and 2019/20, increases the supply risk of Ontario hospitals not having access to sufficient blood products to meet the demand of patients, especially those who have immune disorders and rely on these products to live.

In 2014, both Canadian Blood Services and the Ministry recognized the risk of not having sufficient Ig to meet the needs of Canadians, and that this risk was increased by relying on foreign countries for these products. However, since 2013/14, the portion of plasma collected domestically for the purposes of Ig production, compared to all plasma required to meet the demand for immunoglobulin blood products, has been declining steadily, from 22.7% to 13.7% in 2019/20. Meanwhile, the quantity that must be shipped to hospitals across Canada to meet their demand has increased from about 4 million grams to 6.5 million grams, as shown in **Figure 13**. The 2020 performance review of Canadian Blood Services (which covered the period from April 2012 to March 2019) also recommended Canadian Blood Services continue to examine options for increasing plasma self-sufficiency within Canada and reduce dependency on other countries.

In 2017, Canadian Blood Services developed a plan to mitigate this risk that would include building 40 plasma collection clinics across the country. Most or 37 of these proposed sites would be located within existing blood donor sites to make it more convenient for Canadians to donate plasma, and a target was set to collect 617,000 litres of Canadian plasma by 2023/24 to achieve 50% self-sufficiency. Canadian Blood Services estimated this plan would cost $600 million, about 45% of which would have been Ontario's share based on Ig utilization.

Figure 13: Immunoglobulins Shipped to Hospitals in Ontario and across Canada and Immunoglobulins Fractionated from Canadian Plasma, 2010/11–2021/22

Source of data: Canadian Blood Services



* Projected data for 2020/21 and 2021/22. All other years' data are actual.

Provinces and territories, including Ontario, ultimately did not approve the 2017 plan. The Ministry informed us that it had not approved the plan because Canadian Blood Services presented only one option—to increase to 40 plasma collection clinics—and did not fully outline future costs. In addition, jurisdictions had concerns that Canadian Blood Services announced the proposal with a media release before allowing them to review it. At that time, the provinces and territories were anticipating the report from the federal government's Expert Panel on Immune Globulin Product Supply and Related Impacts in Canada (Expert Panel), and wanted to see its recommendations before they made any decisions on the 2017 proposal, including whether or not they should consider other options.

Two years after its initial plan was released, Canadian Blood Services proposed a smaller-scale plasma collection plan to the provinces and territories in 2019. This plan involved three proof-of-concept sites for plasma collection, which Canadian Blood Services originally planned to roll out by the end of 2020 at a cost of $35.8 million over the years 2019/20 to 2021/22, with projected costs for 2022/23 between $16.7 million and $20.9 million. The estimated total cost to Ontario, responsible for about 50% of these costs, will be approximately $27 million over these four years. The provinces and territories approved this plan in March 2019 by majority vote.

As of July 2020, only seven of the existing donor clinics across Canada (excluding Quebec)—including one in Ontario—had the specific equipment needed for plasma-only donation, though Canadian Blood Services continues to collect plasma by extracting it from the whole blood it collects, or by direct plasma donation using apheresis machines. In addition, only one of the three planned proof-of-concept sites was in operation; that site is in Ontario. Canadian Blood Services indicated that the other two sites, including one in Alberta and the other in British Columbia, will not be operational

until late 2020 and mid-2021. The volume of plasma that Canadian Blood Services has collected for Ig production declined from about 191,000 litres in 2012/13 to about 182,000 litres in 2019/20. Given the new realities of the pandemic (discussed in **Section 4.6.2**), Canadian Blood Services informed us that there is now a need to collect substantially more plasma within the next three to five years, above and beyond what was planned and approved prior to the pandemic since it is estimated that less plasma will be available from the United States.

Quebec negotiated an agreement with Green Cross, a South-Korean pharmaceutical company, in 2014 to establish a fractionation plant in Quebec. This plant was to be the first commercial-scale plasma fractionation plant in Canada. In July 2020, Grifols, a drug manufacturer with experience in plasma fractionation, purchased the fractionation plant from Green Cross. As of October 2020, the manufacturer publicly stated it was in the process of obtaining necessary licences and authorizations to launch operations in 2023. However, at the time of our audit, Canadian Blood Services had not evaluated whether the rest of Canada could either make use of this plant or whether another Canadian plant will be needed to mitigate the risk of relying on foreign supply for its blood products, particularly Ig. Canadian Blood Services informed us that the fractionation industry is very capital intensive, with a small number of large companies involved in it globally.

RECOMMENDATION 6

To protect the supply of blood products needed to meet the needs of patients who rely on them, in light of continuing lessons and experiences from the COVID-19 pandemic and its impact on plasma sufficiency in Canada, we recommend that the Ministry of Health request that Canadian Blood Services expediently update the plan to achieve the 50% national self-sufficiency goal, specifying actions and timelines to reach this goal, with monitoring and reporting back on the plan.

MINISTRY RESPONSE

The Ministry supports ongoing collaboration with other provincial and territorial governments through the existing Provincial/Territorial Blood Liaison Committee, and with Canadian Blood Services, on how best to address Canada's sufficiency in plasma used in producing immunoglobulins, and on addressing the potential shortage of immunoglobulin. In 2019, the Ministers of Health across all jurisdictions (excluding Quebec) approved a plan to introduce three proof-of-concept plasma collection sites in Canada. With the launch of these sites well under way, further addressing this situation will require continuous reliance on the expertise and experience of Canadian Blood Services in the collection of plasma, in addition to significant investments to better secure the supply chain for this product that is important in the treatment of people with rare health conditions.

4.4 Best Practice Guideline Helps Reduce Ontario Usage of Blood Components and Products—Greater Adoption and Cost Accountability by Hospitals Could Help Further Reduce Usage

Blood components and products supply are dependent upon human donations. While most transfusions occur without incident, a small portion of patients may show an adverse reaction, such as an allergic reaction or a fever. Processes to limit the use of transfusions are therefore important.

As noted in **Section 2.4**, the Ministry provides funding to the Ontario Regional Blood Coordinating Network (Network) to promote appropriate use of blood and improve patient safety. Through the Network, the Ministry provides Ig guidelines to help

hospital physicians decide when to prescribe Ig and to reduce unnecessary transfusions of red blood cells. In the case of certain other blood products, Canadian Blood Services has established even stricter measures, with approval from the Ministry, such as using the named-patient approach to limit the prescription of these products to only patients with confirmed medical conditions.

The positive impact of establishing appropriate use guidelines in 2009 (most recently updated in 2018) was significant: Ig use per 1,000 population in Ontario is, as of the 2019/20 fiscal year, lower than the usage rate in other provinces and territories. According to Canadian Blood Services, the rate in 2019/20 for intravenous Ig (transfused in hospitals) in Ontario was 155 grams, versus 219 grams in Alberta and 190 grams in British Columbia. For Ig injected by patients at home, the Ontario rate was 49 grams, versus 66 grams in Alberta and 31 grams in British Columbia.

Another way to manage blood use is to use safe alternatives where appropriate. Through the Ontario Nurse Transfusion Coordinators program (discussed further in **Section 4.5.1**), the Ministry provides funding for nurses in 23 Ontario hospitals that educate and provide alternatives to blood transfusion. For example, based on a patient's circumstances, they might advise oral and intravenous iron supplements to improve their blood iron level prior to elective surgeries, in order to avoid the potential need for a red blood cell transfusion during surgery. Also, at the time of our audit, the Ministry and other provincial ministries of health were discussing using another newly identified drug as an alternative to a blood product called C1 inhibitor. This blood product experienced a more than six-fold increase in demand between 2012/13 and 2019/20 across Canada according to Canadian Blood Services.

4.4.1 Risk that Not all Hospitals Following Best Practices in Transfusion Medicine Promoted by Ministry-Funded Network

The Ontario Regional Blood Coordinating Network (Network) receives funding—$1.55 million annually—from the Ministry to educate and improve hospital practices around blood transfusion. However, it cannot mandate the adoption of, or monitor compliance with, the best practices it recommends to hospitals for managing and using blood components and products. This inability to enforce or even properly evaluate whether best practices are being complied with reduces the value that can be realized from the payments made annually to the Network since 2006.

We found that not all hospitals adopt the best practices the Network promotes, and not all hospitals participate in its studies. While the Network's studies provide a snapshot of provincial use across Ontario, not having full hospital participation in these studies limits the Network's—and in turn the Ministry's—effectiveness and ability to fully understand how all hospitals in Ontario use blood and whether they are adhering to best practice guidelines.

The Network is made up of three regions; each region has staff with knowledge of, and access to clinical expertise in, blood management and use. Based out of McMaster University and two hospitals that are large users of blood (Sunnybrook Health Sciences Centre and The Ottawa Hospital), staff works with experts to provide guidance to hospitals on how to achieve best practices in blood management. Adoption of these best practices, however, is at the discretion of physicians, and participation in the Network's studies is at the discretion of hospitals. Some hospitals elected not to participate; those that did used about 90% of the components or products that were being studied. These studies included the use of AB plasma, compliance with standards on how blood is to be administered to a patient, and appropriateness of intravenous Ig use.

As shown in **Appendix 5**, O-negative red blood cells and AB plasma are considered universal blood donor types, and the Network has recommended best practices, developed by experts in the field of transfusion medicine, with respect to how they should be used in transfusions. The Network's studies found that Ontario hospitals did not always use these blood components appropriately:

- O-negative blood is used in emergency transfusions when the patient's blood type is not known. Otherwise, best practices indicate that it should be reserved for women of child-bearing years to avoid the risk of the blood transfusion causing a mother's immune system to react against her fetus, and to instead transfuse only O-positive blood to males in urgent situations (though a person's own blood type is always preferable if it is known). According to the 2015 study by the Network on the use of O-negative blood, 31% of hospitals reported that their policy was to transfuse O-positive (rather than O-negative) blood to males in urgent situations; these hospital policies are to help ensure that O-negative blood is available for the women of child-bearing years when needed. Best practice recommendations were released by the National Advisory Committee on Blood and Blood Products in 2016. We noted that the 2020 performance review of Canadian Blood Services recommended that provinces and territories facilitate agreements with hospitals that would allow Canadian Blood Services "to proactively monitor and influence O-negative hospital inventories with a national, system-wide lens." In addition, the review recommended that Canadian Blood Services and the provinces and territories should work together to "promote best practices to maintain the O-negative blood supply at appropriate levels." To better understand the way hospitals use O-negative blood, we calculated the percentage of O-negative red blood cells against all blood types ordered by hospitals in 2019/20 across Ontario and found that over the 140 hospital sites that ordered blood that year (many of which would have redistributed the blood to other sites), it ranged from 5% to 57% with a median of 14%. Moreover, for 20 hospitals, 30% or more of the red blood cells they ordered were O-negative; all of these were smaller hospitals in communities with a population of fewer than 10,000. Due to the lack of information on which conditions hospitals use blood to treat, it was not possible to determine whether O-negative blood was used appropriately. Saskatchewan informed us that it has conducted audits of hospitals and found over-stocking of O-negative blood led to the site often issuing this blood type on patients who were not O-negative, and that it did so to avoid an expiry of the blood. Following this discovery, the site was stocked with less O-negative blood to reduce such unnecessary use of the blood type.
- Best practices indicate that AB plasma can be used in non-AB patients in urgent situations where a patient's blood type is unknown. However, the Network also recommends limiting its use to specific emergency situations, and for hospitals to screen for blood type as soon as possible in urgent situations so that patients may receive group-specific plasma instead of AB. The Network found that, based on three months of data from 82 Ontario hospitals (which received almost 90% of all plasma shipped to Ontario hospitals by Canadian Blood Services), 75% of AB plasma was transfused to non-AB patients. But the Network did not indicate if any of these uses of AB plasma contravened best practices related to optimizing its use.

As well, the Network has recommended other best practice guidelines but its reviews have indicated a lack of compliance:

- Network guidelines to hospitals describe how to ensure the safe transfusion of platelets. The

Network's 2017 review that covered 90% of platelet use in Ontario concluded that they were used inappropriately about 40% of the time when evaluated against evidence-based criteria. The rates at which different types of adverse reactions are expected to occur when platelets are transfused inappropriately were then applied to the 40%. Its study estimated that had the guidelines been followed, over 800 adverse reactions could have been avoided. While most of these consisted of fever and minor allergic reactions, between three and four expected reactions consisted of symptomatic sepsis (an infection of the blood stream resulting in a cluster of symptoms such as drop in a blood pressure, increase in heart rate and fever) and anaphylaxis (severe and potentially life-altering allergic reaction). The Network estimated that this inappropriate use of platelets cost hospitals about $25 million in wasted blood component and additional hospital care costs.

- The Network has recommended that physicians use only one unit of blood and not transfuse at all if a patient has a high enough hemoglobin count; this standard was set both to conserve blood and improve patient outcomes. In 2020, the Network assessed compliance with these best practices by reviewing self-reported data from hospitals that elected to participate (only 45 of the 158 hospital sites participated). While improvements were noted over similar studies performed five years previously, even with the limited sample, and without the ability to confirm the accuracy of the self-reported data, the Network still found only 52% of responding hospitals reported that they were meeting the blood iron count standard more than 80% of the time; and only 14% of responding hospitals reported that they were meeting the target of 80% of their transfusions being single-unit transfusions.

RECOMMENDATION 7

To increase hospitals' adoption of, and compliance with, Ontario Regional Blood Coordinating Network (Network) guidelines on transfusion medicine best practices and better achieve value for the funds paid to the Network, we recommend that the Ministry of Health:

- consult with the Ontario Hospital Association to develop a plan to increase hospitals' participation in Network activities and adoption of its best practices and to make required information available to the Network; and
- monitor hospitals' participation in Network activities to ensure the adoption of best practices improve over time.

MINISTRY RESPONSE

The Ministry values the work of the Ontario Regional Blood Coordinating Network (Network), which saved $7.7 million in 2019/20 through reduced wastage of blood components by redistributing to hospitals where they can be used before expiry; and in collaboration with Canadian Blood Services, performing annual site visits in Ontario hospitals. This work has resulted in improvements to hospital performance in relation to best practices and utilization of blood components and products; the Network is recognized for as a leader in Canada for promoting and facilitating system-wide improvements. While the Ministry supports all of the work that the Network has done to date, the Ministry supports continued efforts—including consulting with the Ontario Hospital Association—to enhance the adoption of transfusion best practice and plasma protein product utilization guidelines in Ontario hospitals, and to monitor hospital participation in their adoption to help achieve better patient outcomes across the province.

4.4.2 Use of Blood Alternatives Instead of Donated Blood Not Fully Explored by Canadian Blood Services

Because the risk of contaminated blood components and products cannot be completely eliminated, best practices such as those endorsed by Choosing Wisely Canada (a group of medical professionals from the University of Toronto, the Canadian Medical Association and St. Michael's Hospital advocating to reduce unnecessary tests, treatments and procedures) recommend using alternatives to donated blood whenever possible. The report of the Krever Inquiry noted this issue and concluded: "The best way to reduce that risk is to reduce their use." Therefore, it stated (Recommendation 9): "It is recommended that the operator of the blood supply system promote appropriate use of, and alternatives to, blood components and blood products."

None of the contractual agreements between Canadian Blood Services and its funding provinces and territories clearly assign the responsibility for researching and promoting blood alternatives or define the different types of alternatives that are available. The MOU between the federal government and the provinces and territories (except Quebec) that established Canadian Blood Services states that the "mandate of [Canadian Blood Services] is to be responsible for a national blood supply system which assures access to a safe, secure and affordable supply of blood, blood products and their alternatives and supports their appropriate use."

The Ministry informed us 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.

Canadian Blood Services has interpreted alternatives to mean alternative products that are created in a laboratory and designed to function in the same way as products made from blood plasma—drugs that Canadian Blood Services currently procures and provides to provinces and territories. The Ministry also acknowledges that this is one type of blood alternative.

The Ministry further indicated that one alternative is a drug (available in both supplement form and intravenous form) that stimulates the production of red blood cells and iron; this drug is not funded through Canadian Blood Services. However, the alternative that is frequently cited by the blood experts we spoke to is intravenous iron, which studies show has been highly effective in raising blood iron levels and therefore reducing the need for blood transfusions both during surgeries and for treatment of iron deficiency anaemia. The cost of intravenous iron may be a barrier to its use. According to our survey of hospitals, all hospitals indicated they usually require patients to pay for this treatment except when a patient applies for financial assistance. We spoke to nurse co-ordinators at three hospitals and they informed us that, in their view, transfusions could be reduced if intravenous iron were paid for by the hospitals instead of patients.

As well, without Canadian Blood Services performing this function, no organization in Ontario has assumed central responsibility for assessing whether alternatives to blood can be used more cost-effectively. We found that while Canadian Blood Services has recommended and procured drugs not derived from blood—such as synthetic versions of factor concentrate blood products—for all provinces and territories, it has not had direction from the Ministry to establish any effective processes to identify possible alternatives to the most high-demand and expensive blood product, Ig. Meanwhile:

- The Canadian Agency for Drugs and Technologies in Health (Agency), a not-for-profit organization that is responsible for providing health-care decision-makers with objective evidence to help make informed decisions about the optimal use of health technologies including drugs, and which often performs cost-effectiveness reviews of drugs, informed us that its ability to study alternatives to the most common blood product, Ig, was hindered by a lack of publicly available information on the cost of this product. Canadian

Blood Services, however, has access to this information. It also indicated that provinces and territories (except Quebec) had not requested that it undertake such a review for other blood alternatives in at least five years. The Ministry indicated that it alone cannot request the Agency review alternatives, but that such requests should be made by all participating jurisdictions together.

- Canadian Blood Services does not have any processes to study blood alternatives to Ig, even though it has many resources devoted to research in the use of blood and is the only organization in Canada with ready access to the costs of Ig, which is an integral element to effectively studying cost-effective alternatives to blood. Canadian Blood Services informed us it does not have the authority to recommend medications and as such has not done so for blood components or Ig.

Our review of the Agency's research indicated that reviews done in Germany, the United Kingdom and Italy in 2015 and 2017 found that other drugs were as effective or more effective than Ig for conditions such as pediatric multiple sclerosis, Sydenham Chorea, Rasmussen Syndrome, and Stevens-Johnson Syndrome. The Agency's research did not indicate to what extent these or other conditions were treated with the drug alternatives compared with Ig in Ontario and, as noted in **Section 4.2.1**, this information is not readily available because the Ministry does not collect and analyze this clinical data from hospitals.

RECOMMENDATION 8

To encourage more effective, evidence-based use of blood components, blood products and alternatives to blood at hospitals, we recommend that the Ministry of Health:

- work with both the Canadian Agency for Drugs and Technologies in Health and Canadian Blood Services to periodically assess cost-effective alternatives to blood; and
- use data on the uses of immunoglobulins, obtained under **Recommendation 3**, to inform areas of focus for the Ministry's decision-making on alternatives.

MINISTRY RESPONSE

Recognizing that blood and its derivatives are biological products that always carry potential risks to patients, the Ministry supports a renewed effort in identifying alternatives that are either able to help avoid or reduce the need for blood transfusions as well as providing alternative cost-effective forms of treatment for plasma protein products such as immunoglobulin. The Ministry will require the expertise of the Canadian Agency for Drugs and Technologies in Health and Canadian Blood Services to provide the best advice on these alternatives. Given that these organizations are national service providers, the Ministry will work with its provincial and territorial partners to ensure this work is not duplicated in each jurisdiction.

4.5 Ministry Does Not Monitor Cost-Effectiveness of Blood Utilization Programs

4.5.1 Ministry Does Not Have Current Information to Confirm Nurse Co-ordinators Program is Effective

The Ministry has funded the Ontario Nurse Transfusion Coordinators program (Program) for 18 years. While the Ministry conducted a performance review of this program in 2009 and obtained certain evaluations of cost savings from the program, its assessments are limited because they do not compare the performance of hospitals with and without nurse co-ordinators. This comparison could help assess the value added from a nurse co-ordinator. The Ministry noted that there may be other differences across hospitals that cannot be quantitatively captured in such a comparison.

As discussed in **Section 2.4**, the Program funds the placement of specialized nurses in hospitals to provide care and counselling to patients before surgery aimed at reducing their need for blood transfusions during surgery and improving their outcomes; it is run by Program administrators that are based out of Unity Health Toronto—St. Michael's Hospital.

We found that the Ministry does not have information to compare the transfusion rates of hospitals that have this Program with those of hospitals that do not as a way to measure the effectiveness of the Program. The Program administrators measure the change in percentage of transfusion-related activities from year to year within the counselled patient population. While this measure assesses the effectiveness of the Program in reducing transfusion rates in Ontario, it does not identify how much other factors, such as changes in physician practice or new medication, could also impact the reductions in transfusion rates.

In order to evaluate whether hospitals with nurse co-ordinators were more effective in reducing transfusions, we obtained data on one common type of elective surgery for which nurse co-ordinators typically counsel patients at an early pre-operative stage—hip replacement surgeries. We analyzed data from the Canadian Institute for Health Information and the Ministry on procedures conducted in 2019 across Ontario hospitals; this data showed whether or not a transfusion was performed with a particular procedure (but not how many units of blood were transfused, which the nurse co-ordinators strive to reduce as appropriate). We could not evaluate the transfusion rate with the counselled patient population specifically because we had concerns about the inconsistency within nurse co-ordinators' data from their patient consultations (described below). Overall, we found that 3% of patients who had hip replacements in hospitals with nurse co-ordinators received a blood transfusion during surgery while the portion rose to 4% for patients that received their hip replacement at a hospital without a nurse co-ordinator. These results indicate that nurse co-ordinators are helping some of the patients they counsel and provide care to increase their blood iron levels prior to surgery and therefore avoid a transfusion. However, we also noted that 15 of the hospitals with nurse co-ordinators were transfusing at a rate that was higher than the 3% goal for these surgeries—with two of these hospitals transfusing 10% or more patients. In comparison, 39 other hospitals that did not have nurse co-ordinators were also transfusing at a rate higher than the 3% goal for hip replacements, with 10 of these transfusing more than 10% of their patients.

We also found that while the Program administrators collect other information to internally measure the activities of the Program nurses, the data was either of poor quality or the analysis was weak in supporting any decision-making. Specifically:

- Program administrators informed us that when nurses report on their activities (for example, the number of patients each nurse counselled), they do not all follow Program guidelines on what constitutes a counselling session. While some report every file review, whether or not they see a patient in person, others report only instances where they treat a patient (that is, for example, to advise them on or prescribe a medication to raise blood iron levels). Program administrators informed us that they have asked nurses to comply with standard reporting, but compliance has been unsatisfactory. Given this inconsistent reporting, we found a wide range in the annual number of patients counselled per full-time equivalent, from 65 to 974 with an average of 355 (a median of 230) in 2018, and from 63 to 855 with an average of 297 (and a median of 202) in 2019. For example, we noted that one nurse counselled 111 patients in 2018 and 68 patients in 2019; that was 68% and 80% below the average rates in each of those years. All program nurses are fully dedicated to the Program and do not have other nursing

responsibilities at the hospital where they are stationed. The Program administrators informed us that if the number of reported patients counselled by a nurse co-ordinator is much lower than average, they will contact the nurse co-ordinators to inquire about the issues and to develop a plan to address the deficiency, such as increasing the number counselled or treated. However, such communications are not always documented and so we could not assess which nurses were contacted or the nature of any conclusions reached in the discussions.

- Even though the primary purpose of the Program is for the nurses to provide care options and counselling to patients, and Program administrators analyze the patient data from nurses to determine how often recommended actions are followed, they have not assessed which nurse's recommended actions are followed more frequently. For example, while blood experts in Ontario hospitals have recommended intravenous iron as a safe and cost-effective alternative to blood transfusions for over 10 years, especially during elective surgeries such as hip or knee replacements, the Program administrators have not evaluated how often a nurse's recommendation to follow this course of treatment is complied with and how well it helped in reducing red blood cell transfusions.
- The Program administrators set internal targets and assessed the data reported by nurses to see if the number of transfusions has been decreasing at hospitals with nurse co-ordinators. For example, for patients planning hip replacements, they have set a maximum target of 3% of patients undergoing transfusions in surgery. They found that the percentage of hospitals that met this target increased from 17% in 2013 to 86% in 2019 and have reported this data to the Ministry. However, this measure does not consider whether hospitals that do not have nurse co-ordinators have experienced similar transfusion declines in patient groups.

A consulting firm the Ministry hired in 2009 to review the Program noted that Program administrators did not conduct performance reviews of nurses, and could not easily estimate cost savings per site. The consultant's recommendation did not indicate whether the Ministry or Program administrators should perform the cost savings review, but the Ministry informed us that this was the responsibility of the Program administrators. The administrators told us that they have not developed a cost-measurement tool to evaluate the savings at each hospital site because they do not know how to measure the costs at each hospital site, but that based on their knowledge of transfusion processes, a cost of about $1,200 per transfusion was a reasonable estimate according to an American study conducted in 2010 (no similar study has been conducted since). We compared the cost of each of the nurse co-ordinators with the cost savings each had potentially achieved through their counselling work. Specifically, we assumed that every patient the nurses recorded seeing that had not had a transfusion was owing to the actions of the nurse co-ordinator. While this analysis indicated that, in 2019/20, the vast majority of nurse co-ordinators had been instrumental in helping patients avoid transfusions, we found that the work of three nurse co-ordinators did not result in enough savings to justify the salaries paid. Specifically, these three nurses earned a combined salary of about $336,000, but were involved in reducing transfusions with an estimated cost of about $241,000.

One of the reasons the Program administrators do not formally evaluate nurses' performance is because nurses are selected by the hospitals they work out of, and paid under a transfer payment agreement between the hospital that administers the Program and the Ministry. Therefore, they are officially employees of the hospital at which they are stationed, and do not formally report to the Program administrators.

RECOMMENDATION 9

To evaluate the effectiveness of the Ontario Nurse Transfusion Coordinators in improving patient outcomes and reducing the cost of surgical procedures, we recommend that the Ministry of Health:

- collect and assess data on a representative selection of transfusion activities associated with specific surgical procedures, including data on the number of units of blood transfused, the estimated cost to transfuse and the number of patients transfused, in hospitals with program nurse co-ordinators compared to hospitals without program nurse co-ordinators; and
- request the Program administrators develop more comprehensive performance indicators and outcome measures that demonstrate the success of this program, establish targets, collect data from program nurses to measure against targets, and report this information annually to the Ministry.

MINISTRY RESPONSE

The Ontario Nurse Transfusion Coordinators program (program) is an example of Patient Blood Management that has garnered national and international recognition. Patient Blood Management, supported by the National Blood Advisory Committee on Blood and Blood Products and endorsed by the World Health Organization, is an evidence-based, multidisciplinary approach aimed at optimizing the care of patients to reduce their risk of requiring blood transfusion. Many jurisdictions have sought advice from the program's administrators to assist in the development of similar programs. Amongst other benefits, the program helps patients scheduled for elective surgeries to lower or eliminate the volume of blood transfused for those procedures, thereby improving their outcomes in comparison to patients whose surgeries do not include a patient blood management regimen. Ontario's per capita red blood cell utilization is lower than in most jurisdictions in Canada as a result of Ontario's commitment to Patient Blood Management, which is facilitated by this program. The benefits of the program were also highlighted in a peer-reviewed publication in 2014 with estimated cost savings of nearly $40 million annually, based primarily on data from 2011, to the broader health-care system. The Ministry would anticipate the savings achieved today would be even greater based on inflation and rising system costs over the last decade. To continue to improve best practices, the Ministry supports conducting an assessment of the program to evaluate its effectiveness in relation to patient outcomes and health system costs, and using findings from the assessment to better inform the current performance measures and reporting.

4.5.2 Ministry Does Not Confirm that its Payments for Blood are Reasonable Compared to Product Received by Ontario Hospitals

Though the Ministry pays Canadian Blood Services for blood following an annual review of the latter's budget, it does not perform other basic due diligence to ensure payments to Canadian Blood Services are reasonable. Specifically, 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. Canadian Blood Services informed us that its financial auditor also does not perform this reconciliation.

On a sample basis, we compared the amount of blood components that Canadian Blood Services billed to Ontario with data that Ontario hospitals reported to us. We found that 16% of hospitals that answered our survey did not retain records on shipments received and so they could not confirm the accuracy of shipment data provided to us by

Canadian Blood Services. As well, we found that of the responding hospitals, 5% reported a discrepancy for blood components and 7% reported a discrepancy for blood products between their inventory records of what was received and those of Canadian Blood Services of what was shipped to those hospitals.

RECOMMENDATION 10

To confirm its payments to Canadian Blood Services are reasonable and commensurate with blood shipped to Ontario hospitals, we recommend that the Ministry of Health put a process in place to verify that payments to Canadian Blood Services are for products shipped and received by Ontario hospitals, with underlying unit costs that are based on audited financial statements of Canadian Blood Services.

MINISTRY RESPONSE

The Ministry recognizes that blood and blood products are valuable health-care resources and has continuously sought to ensure that these resources are used appropriately by hospitals. Through Ontario's lower-than-average per capita utilization of blood and blood products, the Ministry is confident that Ontario's blood utilization programs have contributed to conservation and more appropriate use across Ontario hospitals. As utilization of blood and blood products continues to increase year over year due to the growing multitude of treatment modalities and their importance for emergency procedures, the Ministry also recognizes the value of audits to help identify opportunities for operational efficiencies and to monitor expenditure. As such, the Ministry will initiate an audit of a sampling of Ontario hospitals to verify that payments from the Ministry to Canadian Blood Services are for products both shipped to, and received by, Ontario hospitals, to assist in identifying any operational issues, if any, and to provide post-payment verification.

4.5.3 Ministry Does Not Use Data on Transfusion Injuries and Errors to Monitor Patient Outcomes

We 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. As a result, it has not done its due diligence to ensure that Ontarians are experiencing better health outcomes from blood transfusions.

In the case of transfusion injuries, as indicated in **Section 2.3**, both the Ministry and the Public Health Agency of Canada provide funding toward the Injury Surveillance System. While it is not the role of the Public Health Agency of Canada to establish provincial performance indicators, we found, however, that neither the Ministry nor the federal agency has established performance indicators to provide information on reducing patient injuries related to transfusions. The Ministry informed us that the purpose of the surveillance system is not to prevent or reduce adverse transfusion events, but to make data on adverse transfusion events available to hospitals to use for their own process improvement. The Agency informed us that its role is limited to ongoing collection of data on transfusion injuries and errors, and the dissemination of this data so that provinces and territories can use that information to prevent further injuries and errors.

Moreover, the federal agency informed us that it is not involved in any hospital operations and communicates with hospitals only to ensure data-quality requirements are being met. While the agreement between the Ministry and the Injury Surveillance System program lists activities that stakeholders must complete, such as education on adverse events, the only performance indicator tracked by the Ministry regarding the reporting of adverse events by hospitals is the number of hospital sites that report adverse events, which increased from 95 to 158 province-wide between 2015 and 2019, as discussed in **Section 4.2.4**.

We analyzed the major adverse transfusion events reported in the Injury Surveillance System in the last five years by the five hospitals that reported the most transfusion events, and found significant variations in trends by hospital. While some hospitals reported significant increases in major adverse events, others showed a decrease, as seen in **Figure 14**. These patterns provide information to investigate in order to identify root causes or best practices. The Ontario program administrators of the Injury Surveillance System annually report on overall trends, but they do not investigate variations among hospitals for root causes because it is not part of their mandate, and lack the authority and funding to do so (see discussion in **Section 4.1.2**). The Ministry obtains a summary of program activities—including the total number of adverse transfusion events and education provided to transfusion medicine staff to help prevent transfusion events—from the Injury Surveillance System twice annually, but does not perform further analysis because it considers blood surveillance activities to be a responsibility of the Public Health Agency of Canada. For example, neither the Ministry nor the Injury Surveillance System seek to determine how many adverse transfusion events originate from blood that Canadian Blood Services seeks to retrieve because of quality concerns, but is unable to before it is transfused into a patient, as discussed in **Section 4.2.1**.

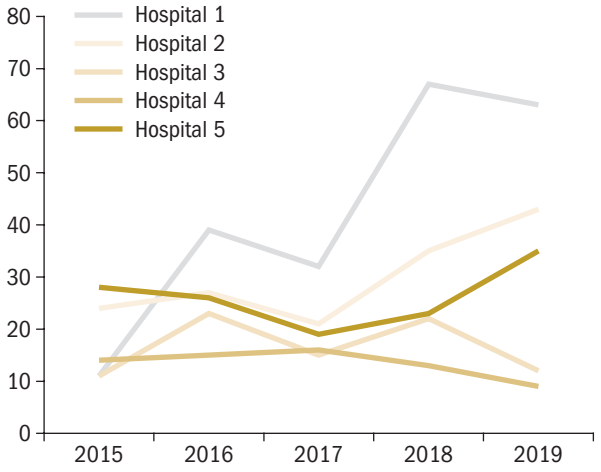
In the case of transfusion errors, the Ministry does not obtain data on patient transfusion injuries from the Error Surveillance System, which is funded by the federal government and co-ordinated by the Public Health Agency of Canada. This system contains only information from select hospitals across Canada that are funded to report their errors into this system; three of these hospitals are in Ontario. Personnel reporting error events are anonymized in the surveillance system to encourage more complete reporting.

We obtained the 2017/18 to 2019/20 error surveillance system data on the three funded Ontario hospitals. The Public Health Agency of Canada noted that it could not disclose the identities of these hospitals. We found that the three hospitals reported a total of about 12,000 errors over the three years, with about 5,700 reported in the 2019/20 fiscal year. These errors occurred at various stages, from the time blood was received in the hospital blood bank to the time it was administered to the patient. However, 96% of the errors were corrected before a patient was affected. Such errors included unnecessary collection of a blood samples and insufficient monitoring of blood storage devices such as fridges and freezers that had the potential to cause harm to patients, but was found not to have done so. For the remaining 4% or 530 events, 13 resulted in harm to the patient, though none resulted in death. Most of these cases of harm involved patients receiving a blood transfusion when it was not medically necessary.

Provincial program administrators at both surveillance systems informed us that, in their view, the mere existence of a process to encourage the reporting of incidents helps improve patient outcomes. This view is also confirmed by studies outside of Canada that have indicated that having

Figure 14: Number of Major Adverse Transfusion Reactions Reported by Five Ontario Hospitals that Reported the Most Reactions from 2015 to 2019

Source of data: Transfusion Transmitted Injury Surveillance System



Note: These five hospitals together reported 643 major adverse transfusion reactions from 2015 to 2019, representing about 41% of all such reactions reported by hospitals across Ontario over the same period.

transfusion surveillance systems can help improve patient safety. However, 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 has a legislated mandate under the *Ministry of Health and Long-Term Care Act* to develop, co-ordinate and maintain comprehensive health services for Ontarians as well as to govern the care, treatment, and services and facilities provided by hospitals. Even though the Ministry indicated that its role in managing the blood system includes achieving cost savings and improving patient safety, it has not assumed an active role in monitoring hospital activities related to blood use in patients, nor has it made any efforts to collect and analyze transfusion surveillance data.

We note that other provincial bodies, such as the Local Health Integration Networks (LHINs), also have certain responsibilities to improve patient care. The LHINs fund and oversee hospitals in the province. However, the Ministry told us that it believes the federal government alone is primarily responsible for monitoring adverse transfusion events in Ontario and the rest of the country, and for informing the provinces of any significant concerns arising from either of the surveillance systems.

RECOMMENDATION 11

To reduce the risk to Ontario patients from transfusion errors and injuries in Ontario hospitals, we recommend that the Ministry of Health, in consultation with Ontario Health:

- clarify where responsibility should reside for monitoring transfusion surveillance data reported by hospitals;
- monitor trends of serious transfusion incidents in Ontario; and
- establish a plan with Ontario hospitals for them to share the investigation reports of serious transfusion incidents on a timely basis, which includes communicating any lessons learned to other hospitals.

MINISTRY RESPONSE

While blood components used in hospital transfusions are biological products with the potential of risk to patients, they are used in the context of anticipated benefits to patient outcomes. Because of this, transfusion events and errors will always be a risk that needs continual vigilance. The Public Health Agency of Canada (PHAC) and Canadian Blood Services (CBS) have complementary accountabilities in the surveillance of adverse transfusion events and transfusion errors by hospitals to help safeguard patients in Ontario and across Canada. The Ministry recognizes the distinct, but important roles played by PHAC, CBS and individual hospitals. To help clarify where responsibility should reside for monitoring transfusion surveillance data reported by hospitals, the Ministry will take steps to establish a plan to promote awareness of those responsibilities, require all hospitals to report serious incident data and monitor trends of transfusion incidents to help assess whether action is needed based on the trend.

4.5.4 Canadian Blood Services' Public and Internal Reporting Does Not Provide Meaningful Information on Ontario Activities

Canadian Blood Services measures its performance in areas such as product demand, productivity, and quality and safety. However, it measures these indicators across all Canadian Blood Services overall; it does not break down performance by province. The agreements between the Ministry and Canadian Blood Services do not require Canadian Blood Services to report to the Ministry on performance indicators for Ontario alone and do not give Ontario the ability to require Ontario-only reporting. While Canadian Blood Services noted that there was nothing to prevent provinces from requesting provincial data, the Ministry has not requested provincial performance reporting in the past five years.

Figure 15: Targets and Actual Results of Performance Indicators Reported Publicly by Canadian Blood Services, 2017/18–2019/20

Source of data: Canadian Blood Services

Key Focus Areas	Performance Indicators	2017/18		2018/19		2019/20	
		Target	Result[1]	Target	Result[1]	Target	Result[1]
Product Demand	Order fill rate[2] (%)	98	99.2	98	99.3	98	99.1
	Order fill rate[3] for platelets (%)	98	98	98	98	98	98
	Immunoglobulin[4] Total Issued (in millions of grams)	5.38	5.58	5.94	6.01	6.5	6.51
	Recombinant Factor VIII[4] Total Issued (in millions of units)	210.77	199.53	223.49	210.27	218.72	236.77
	C1 Esterase Inhibitor[4] Total Issued (in millions of units)	32.50	39.03	42.95	48.30	57.97	59.70
Donor Focus	Active whole blood donor base	418,462	410,130	407,540	406,187	406,000	386,954
	Net promotor[5] score	n/a	76	75	69	78	85
Quality and Safety	Red cell discard rate[6] (%)	5.8	5.8	5.5	6.1	5.5	5.7
	# of adverse transfusion reactions[7]	80	56	80	51	80	63
	# of recalled fresh blood products[8]	1,600	1,048	1,200	970	1,200	825

1. Results shaded in grey indicate performance below target.
2. For red blood cells, excluding O-negative; number of total daily orders filled at 100% on the day a given customer submits an order.
3. Ability for Canadian Blood Services to deliver platelets to hospitals as a percentage of total fill requests for platelets.
4. Type of plasma protein product.
5. Donors' overall satisfaction with Canadian Blood Services' products or services and the donors' loyalty to the brand.
6. Number of discarded units as a percentage of units collected (produced in the case of manufactured product).
7. The unwanted and unintended response to the administration of blood or blood product as reported by hospitals.
8. Products already distributed to hospitals but recalled due to errors/accidents and post-donation information that could put patients at risk or do not meet Health Canada legislative requirements.

Canadian Blood Services reports publicly on performance indicators that relate to product demand, quality and safety, and customer satisfaction. For example, it measures its ability to deliver platelets and most blood types of red blood cells to hospitals as compared to hospitals' requests, as well as donors' overall satisfaction with its services. In the last three years for which data was available, Canadian Blood Services has met most of its targets. Overall, the rate at which Canadian Blood Services missed its targets has decreased in the last three years, as shown in **Figure 15**. It has been slightly under target in the areas of donor base and discard rates for red blood cells.

Canadian Blood Services also measures other areas as part of the performance review process. For example, it measures whether it has minimum inventory levels of certain blood products and the core operations cost associated with each unit of blood shipped. See **Figure 16** for these measures. Specifically, results showed that it met most targets in the most recent two years, with some misses in the 2017/18 year regarding financial and productivity—for example, labour hours spent per unit of blood produced. As well, its cost per unit has increased from 2018/19 to 2019/20.

We contacted a sample of other provinces, and found that they also do not obtain province-specific information from Canadian Blood Services. Some of these Canadian Blood Services-wide measures may not be readily presented to reflect Ontario-only performance, such as its core operations cost per unit of blood. However, the Ministry of Health has never asked to see any province-specific results, even though they could provide valuable insights into whether Ontario hospitals can efficiently obtain

red blood cells—as measured by fill rates—to help care for patients who require emergency surgeries; whether Canadian Blood Services is spending a reasonable amount to produce red blood cells; and how often Ontarians are potentially exposed to a transmissible disease from a blood transfusion.

Figure 16: Targets and Actual Results of Performance Indicators Reported Internally by Canadian Blood Services, 2017/18–2019/20

Source of data: Canadian Blood Services

Key Focus Areas	Performance Indicators	2017/18		2018/19		2019/20	
		Target	Result[1]	Target	Result[1]	Target	Result[1]
Financial and Productivity[2]	Immunoglobulin[3] inventory (weeks on hand)	6.5	8.1	6.0	6.9	5.5	6.2
	Recombinant Factor VIII[3] inventory (weeks on hand)	6.5	11.4	7.5	7.9	6.5	8.4
	Core operations labour hours per unit[4]	6.21	6.33	6.38	6.13	6.32	6.15
	Core operations cost per unit[5] ($)	335	350	352	347	357	364
	Units of blood collected over a 12-month period per full-time equivalent (FTE) collections staff (known as collections productivity)[6]	1,000	957	967	990	1,003	1,029
	Units of blood produced over a 12-month period per FTE processing staff (known as production productivity)	6,850	7,023	7,600	7,882	7,760	8,412
	Units of blood tested over a 12-month period per FTE testing staff (known as testing productivity)	13,750	14,923	16,300	18,715	19,100	19,267
	Units of blood collected over a 12-month period per FTE donor relations staff (known as recruitment productivity)[7]	3,530	3,520	3,470	3,570	n/a	n/a
	Recruitment cost for each unit of blood collected per FTE donor relations staff[7] ($)	n/a	n/a	n/a	n/a	42.79	42.57
Product Demand	Line fill rate[8] for AB plasma (%)	95	94	95	99	95	98
	Unit fill rate[9] (%)	95	95.3	95	97.7	95	97.8
Donor Focus	Donor retention rate (%)	81	70.3	82	70	74	70
Customer Satisfaction	Donor satisfaction rate (%)	92	95	90	93	75	82
	Hospital satisfaction rate (%)	95	99	90	96	95	98
	Public trust rate (%)	80	81	70	82	n/a	87

1. Results shaded in grey indicate performance below target.
2. Canadian Blood Services also tracks the performance of certain other aspects of its work, including C1 Esterase Inhibitor inventory levels, aggregate plasma protein product inventory levels, blood product pricing trends, estimated savings from procuring blood products, and blood product program management costs. However, Canadian Blood Services does not have targets in place to help evaluate the performance in these areas so they are not included in this figure.
3. Type of plasma protein product.
4. The gross productivity metric that links the inputs (staff, medical supplies, general and administrative expenses, amortization capital, and operational, project, and research and development expenses) and the outputs (shipments of fresh blood).
5. Total cost, including shipping cost to hospitals, to produce one unit of blood.
6. Effective 2019/20, this measure includes the donor service representative role.
7. In 2019/20, Canadian Blood Services changed the performance measure to a cost per collection measure to better align with cost drivers associated with donor recruitment.
8. Ability for Canadian Blood Services to deliver AB plasma to hospitals as a percentage of total fill requests for AB plasma.
9. For O-negative red blood cells; number of units issued as a percentage of the total number of O-negative units ordered in a given day.

RECOMMENDATION 12

To strengthen the Ministry of Health's ability to evaluate Canadian Blood Services' performance in providing safe blood to Ontario hospitals cost-effectively, we recommend that the Ministry of Health:

- request Canadian Blood Services break out Ontario results for national measures that can reflect Canadian Blood Services' performance relevant to Ontario;
- regularly review and assess the effectiveness of national performance measures and revise accordingly with Canadian Blood Services through mechanisms available; and
- request Canadian Blood Services provide at least annual feedback on trends of Ontario results.

MINISTRY RESPONSE

Canadian Blood Services performance is measured as a national system operator and not on behalf of any individual provincial or territorial funder. Ontario remains committed to the philosophy that Canadian Blood Services must ensure the quality, safety, value and efficacy of the blood system for all Canadians. In consultation with Canadian Blood Services, the Ministry will seek to clarify which national performance measures can be provided by provincial/territorial jurisdiction for Ontario.

4.6 COVID-19's Impact on Blood System

4.6.1 Blood Therapies for COVID-19 Under Development

Early research during the COVID-19 pandemic suggested that blood plasma from patients who recovered from COVID-19 might offer a potential treatment. Twenty-seven Ontario hospital sites are participating in a North American study that started in spring 2020 to test the safety and effectiveness of this treatment, and two of the three lead study investigators are Ontario physicians. While early reports of the effectiveness of the treatment have been mixed, at the time of the audit, the study was ongoing and expected to be complete by December 2020.

The rationale that blood holds a treatment option for COVID-19 is based on the science of viruses. When a person acquires a virus, their immune system produces antibodies to fight that virus. These antibodies remain in the plasma of a person's blood, and can protect them from later infection with the same virus. Plasma collected from a patient who has recovered from COVID-19 and has these antibodies is known as convalescent plasma, and it is hypothesized that transfusing convalescent plasma into patients that currently have COVID-19 may help them fight the disease.

In May 2020, Health Canada announced the approval of a major clinical trial to test the safety and effectiveness of convalescent plasma as a potential treatment option for patients with COVID-19. The North American study involves Canadian Blood Services, Héma-Quebec, and the New York Blood Center, along with 59 hospitals in Canada and New York. Canadian Blood Services and Héma-Quebec are collecting convalescent plasma from recovered COVID-19 patients in Canada, and are supplying it to Canadian clinical trial sites, including those located in Ontario, participating in this and other related studies.

Canadian Blood Services has also performed testing on donor blood to help determine whether the blood indicates that the donor has had COVID-19, a process referred to as seroprevalence testing. This is to help provide data on the prevalence of COVID-19 in Canada.

4.6.2 Impact of Pandemic Highlights Risks in Low Domestic Production of Plasma

Initial impacts of the COVID-19 pandemic on blood donation and collection resulted in the National Emergency Blood Management Committee (Com-

mittee) announcing a green phase advisory on all blood components and products in March 2020. The Committee lifted this advisory in July 2020. Canadian Blood Services informed us that during the first wave of the COVID-19 pandemic, it discarded on average 8% of blood between December 2019 and September 2020. The discard rate went up from 7% (4,410 units) in December 2019, peaking at 15.5% (8,243 units) in April 2020, and returned to 6% (3,702 units) by September 2020. This does not include additional blood discarded at hospitals during this period. According to data collected by the Ontario Regional Blood Coordinating Network, almost 1,400 units of blood were discarded between March 2020 and August 2020 at Ontario hospitals. The discard rate went up from 245 units in March 2020 to 552 units in April 2020, and steadily went down from May 2020 to August 2020, when 126 units were discarded. In comparison, the blood discard rates at Ontario hospitals were 29% higher in 2020 compared to 2019 during the three months from March to May.

While Canadian Blood Services surveys hospitals for anticipated uses of blood, it did not have any information on whether hospitals would require more blood to "catch up" on missed surgeries, such as elective hip or knee replacement surgeries. However, Canadian Blood Services has more direct control over the supply of blood components since they are domestically sourced. But it relies on its international contracts and contracts with companies in the United States for blood products, including Ig. The current contracts for Ig extend until March 2023. Canadian Blood Services informed us that the COVID-19 pandemic has contributed to unforeseen limitations in global plasma production. It indicated that plasma collections from its four major Ig suppliers, all of which are American, will be 15%–20% lower in 2020 than in 2019, which could cause a shortage of all forms of Ig by the fall of 2021 and adversely affect those Ontarians who rely on Ig to live. It highlighted that there is a risk that it may be unable to fulfill its mandate to its funding provinces and territories as set out in the MOU—to maintain an adequate supply of Ig. We noted that while certain pharmaceutical companies in Saskatchewan and Manitoba pay Canadians to donate plasma, Canadian Blood Services had not pursued this avenue to increase domestic plasma supply. It informed us that it "recognizes that considering the possibility of purchasing plasma collected from commercial plasma collectors for an appropriate portion of supply needs, should that plasma be available for sale and at a reasonable price (noting the commercial industry is largely vertically integrated and does not typically sell plasma), requires consensus among governments and Canadian Blood Services before pursuing further."

The Committee has developed guidelines that are to be distributed to physicians to guide their prescribing practices and manage Ig shortages. The guidelines include a list of more than 40 conditions for which Ig is commonly prescribed; these include immune conditions, such as primary immune deficiency, as well as various rheumatological, neurological, and haematological conditions. They also prioritize these conditions under amber and red phase advisories, and identify the patient conditions that will be treated using alternate means.

However, even with such guidance, no agreement between Ontario and Canadian Blood Services defines how the lower supply of Ig will be rationed among the funding provinces and territories.

In addition, in the event of shortages, the Committee's ability to effectively oversee and control Ig distribution to those who need it most is limited because:

- neither Canadian Blood Services nor the Committee has information on how many patients at each Canadian hospital require Ig to survive—information necessary to inform rationing decisions;
- the decision to distribute Ig to a patient remains with each individual physician; and
- the critical distribution decisions need to be made before Ig is sent to hospitals, and the

guidelines were produced without provincial or federal data on how many patients require Ig, for example, to maintain their health versus to survive (as discussed in **Section 4.2**).

Conversely, in times of severe shortages, there is a national guidance document that advises the provinces (excluding Quebec) how to direct Canadian Blood Services to issue high-demand components, such as O-negative blood or platelets, to ensure those who require them will receive them. In the absence of a red phase advisory, Canadian Blood Services does not have the ability to prioritize the distribution of these components.

Canadian Blood Services' blood continuity plan focuses on having enough contracts with international producers of blood products to mitigate the risk of any one producer discontinuing their supply. In addition, it has individual agreements with both Héma-Quebec and the American Red Cross to provide one another with blood if either is short in inventory because of an emergency and to maximize available blood when needed; this type of crisis has never occurred. The plan does not otherwise address how to continue to provide blood products in the event of a natural disaster that may disrupt the transportation of blood, or a human health emergency such as a pandemic that affects supplies across the board. Ontario has not developed a plan that includes alternative medications to deal with the largely unprecedented situation of patients being required to go without Ig.

Given the significant time—up to 12 months—required to fractionate plasma and manufacture it into blood products like Ig, the effect of the COVID-19 pandemic on the supply of blood products has not yet been realized. However, shortages are expected to affect supply through to the fall of 2021. The reasons for the shortages are as follows:

- **The pandemic has shifted donor behaviours:** COVID-19, and specifically the fear of transmitting the virus and physical distancing measures put into place to combat it, has reduced the amount of plasma being collected in the United States. For example, donors are likely more reluctant to leave their homes and visit a donation clinic. Also, according to Canadian Blood Services, United States federal financial pandemic relief programs may have reduced the financial incentive for Americans to donate plasma (blood product manufacturers commonly pay donors in the United States).
- **Prices for Ig are expected to increase:** Following our field work in October 2020, Canadian Blood Services informed us that vendors have advised that "additional Ig can only be offered at significantly higher unit prices and at lower volumes."
- **Presidential orders may halt products at the border:** The President of the United States can issue an executive order to ban export of medical supplies and drugs—and did so in April 2020 for medical masks. This order could extend to blood products manufactured in the United States. This leaves Canada at risk of a sudden disruption in the supply of Ig because Canada is heavily reliant on US-based Ig suppliers. In contrast, producing more plasma domestically reduces this risk: according to Canadian Blood Services, Ig produced in the United States with Canadian plasma is not vulnerable to US presidential orders; similarly, Ig produced in Europe is afforded this type of protection. However, this protected Ig represents only 13.7% of the source plasma used to produce Ig (as discussed in **Section 4.3.2**). Furthermore, American manufacturers charge Canadian Blood Services less for blood products if Canadian Blood Services provides them with the plasma.

RECOMMENDATION 13

To prepare for the event of limited supply of immunoglobulins and protect Ontarians who rely on these products to live, we recommend that the Ministry of Health:

- introduce any needed further measures across Ontario hospitals to ensure that immunoglobulins are provided to patients according to provincial utilization guidelines or guidelines within the National Immune Globulin Shortage Plan (Shortage Plan), and that alternatives are researched, identified and used to treat conditions that would otherwise be treated with immunoglobulins;
- 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 as recommended with the Shortage Plan; and
- clarify how Canadian Blood Services and all provincial and territorial governments will ensure equitable distribution of immunoglobulins to patients in most critical need in the event of a sudden shortage so that the treatment needs of Ontario patients are appropriately addressed.

MINISTRY RESPONSE

In August 2020, the Conference of Deputy Ministers approved the *National Plan for the Management of Shortages of Immunoglobulin (Ig)—Interim Guidance* to serve as a framework to directly inform the development of a full national Ig shortage management plan once this short-term supply risk is addressed. Work on the full plan is expected to be conducted over the next 24 months and work is currently being done to implement elements of the interim guidance plan to be prepared for, and mitigate against, a potential immunoglobulin shortage in 2021.

Given the National Immune Globulin Shortage Plan has been endorsed by all provincial and jurisdictional governments (excluding Quebec, which operates Héma-Quebec separately), Ontario is committed to working with the National Emergency Blood Committee, the Ontario Emergency Blood Committee, Canadian Blood Services and the Provincial/Territorial Blood Liaison Committee to participate in the national response, as recommended within the National Immune Globulin Shortages Plan. The Ministry supports introducing any needed further measures across Ontario hospitals to ensure that immunoglobulins are provided to patients according to provincial utilization guidelines, or guidelines within the National Immune Globulin Shortage Plan. The Ministry will continue to collaborate with all partners in the system to ensure that immunoglobulin is available to Ontarians most in need.

Appendix 1: Glossary of Terms

Prepared by the Office of the Auditor General of Ontario

albumin: A plasma protein product that keeps the proper balance of fluids in the body, and carries minerals, hormones and other substances through the blood.
Amber Phase: When national inventory levels of blood components and products are insufficient to ensure routine transfusion practices.
blood bank: Any unit within a hospital that stores and distributes, and may perform compatibility tests on, blood and blood components exclusively for use within hospital facilities, including hospital-based transfusion activities.
blood components: Whole blood is donated and processed into different components, including red blood cells, platelets, plasma and cryoprecipitate.
blood products: Purified concentrates of certain combinations of proteins derived from plasma and also include recombinant products, which are not derived from plasma. Also known as plasma protein products.
C1 inhibitor: A blood product used to treat a condition called hereditary angioedema, which causes swelling in the throat, arms, legs, face and intestinal tract. Also known as C1 esterase inhibitor.
Chagas disease: A transfusion-transmissible disease that is acquired through the bite of an insect in Latin America.
centrifuge: A machine used to separate whole blood into its components.
factor concentrate: A powder made by removing clotting factors from plasma and freeze-drying them. Clotting factors are blood products that help to stop bleeding in patients with hemophilia, and include fibrinogen and factors II, V, VII, VIII, IX, X, XI, XII and XIII.
fractionation: A highly complex process involving numerous technologies and specialized equipment, and is undertaken in large-scale biological manufacturing facilities known as “fractionation facilities”.
Green Phase: The baseline inventory level of blood components and products where supply is generally sufficient to meet demand.
Green Phase Advisory: A notification that may be issued to hospitals when Canadian Blood Services’ inventory levels are low with respect to a particular blood component or components. All hospitals need to report their inventories and be aware of the possibility of crossing into an Amber or Red Phase.
hematology: A medical science that deals with the blood and blood-forming organs.
hemoglobin: An iron-rich protein contained in red blood cells that carries oxygen from the lungs to tissue in the body.
hemophilia: A rare genetic disorder in which your blood does not clot normally because it lacks sufficient blood-clotting proteins (clotting factors), resulting in bleeding for a longer-than-normal time after an injury.
Human T-Cell Leukemia/Lymphoma Virus: A transfusion-transmissible disease that can cause leukemia and lymphoma.
immune disorder: These disorders weaken the immune system, allowing infections and other health problems to occur more easily. In the case of primary immune disorders, people are born with immune systems that do not work properly, leaving them more susceptible to illness. Also called immunodeficiency disorders.
immunoglobulins: Antibodies produced by white blood cells that are part of the immune system and help fight diseases.
plasma: A protein-rich liquid that makes up 55% of whole blood; aids in clotting and is a raw material used in the manufacturing of plasma protein products (blood products).
plasma protein products: Purified concentrates of certain combinations of proteins derived from plasma and also include recombinant products, which are not derived from plasma. See also **blood products**.
recombinant: An alternative to plasma-derived products, recombinant products are manufactured from genetically engineered proteins as opposed to human blood.
Red Phase: When national inventory levels of blood components and products are insufficient to ensure that patients with non-elective indications for transfusion will receive the required transfusion(s).
S/D plasma: A form of plasma made by collecting and combining plasma from multiple donors, and processing it with solvents to minimize potential viruses.

Appendix 2: Key Organizations in the Blood System and Their Roles and Responsibilities

Prepared by the Office of the Auditor General of Ontario

National	
Canadian Blood Services	• Funded by provincial and territorial governments (except Quebec) and the federal government • Recruits donors of whole blood and blood components and holds blood donor clinics • Processes donated blood into blood components and delivers these to hospitals in Ontario. Two of these processing sites are in Ontario (Brampton and Ottawa) • Tests blood to ensure its safety • Purchases manufactured plasma-derived products from mostly US manufacturers and delivers these to hospitals in Ontario • Delivers blood components and blood products directly to Ontario hospitals
Health Canada	• Administers the Blood regulations of the federal *Food and Drugs Act* • Maintains an arms-length relationship with Canadian Blood Services and Hema-Quebec that together operate Canada's blood transfusion system • Evaluates and authorizes changes submitted by the blood operators before they can be implemented based on scientific evidence • Inspects transfusion medicine labs in Ontario hospitals and blood donor clinics, as well as other operational areas within Canadian Blood Services for compliance with the requirements of the Blood Regulations, such as on storage, processing and reporting and investigation of adverse reactions, errors and accidents related to the safety of the blood, and their authorizations. Activities that fall outside the scope of the Blood Regulations, such as the practice of transfusion medicine, are not assessed during an inspection • Oversees the safety of blood products under the Food and Drugs Regulations
National Advisory Committee for Blood and Blood Products	• An interprovincial medical and technical advisory body to the provincial/territorial health ministries and Canadian Blood Services • Voting members include representatives from each province and territory (except Quebec); Canadian Blood Services; health-care professionals with experience in either transfusion medicine or a blood utilization management program; and provincial/territorial ministry of health personnel with primary responsibility for blood resource management. Non-voting members include co-chairs of the Provincial-Territorial Blood Liaison Committee and any member's delegate, a Quebec Comité Consultatif National de Médecine Transfusionnelle representative and additional experts invited on an ad hoc basis • Provides clinical leadership in assisting in identifying, designing and implementing blood utilization management initiatives throughout Canada
National Emergency Blood Management Committee	• Consists of Canadian Blood Services, National Advisory Committee for Blood and Blood Products and all provincial/territorial blood representatives • Develops recommendations and provides advice to the provincial/territorial ministries of health, hospitals and Canadian Blood Services to support a consistent and co-ordinated response to blood shortages in Canada by issuing blood advisories to hospitals
Provincial-Territorial Blood Liaison Committee	• Consists of a blood representative from each province and territory • Provides advice and support to the provincial and territorial deputy ministers and ministers of health on issues affecting the blood system

Public Health Agency of Canada	• Funds the Ontario Transfusion Transmitted Injuries Surveillance System and the Transfusion Error Surveillance System; the Ministry of Health provide supplementary funding to support Ontario's participation in both surveillance systems • Provides national public health surveillance related to blood safety • Conducts surveillance of the errors and adverse events associated with the clinical use of blood components and products • Provides data for national and international comparisons and trend analysis to inform clinical and public health decision-making
Provincial	
Ministry of Health	• Collaborates with other provinces and territories (except Quebec) to identify and discuss issues relating to the blood system and make (limited) decisions on the direction to be taken by Canadian Blood Services • Participates in provincial and national committees and working groups for co-ordination and collaboration with stakeholders in the blood system • Funds Canadian Blood Services based on a 1998 Memorandum of Understanding between the funding jurisdictions and the federal government, and a national accountability agreement between Canadian Blood Services and all funding provinces and territories that clarifies Canadian Blood Services' responsibilities in areas such as recruitment of donors and blood collection, testing, production and distribution of blood and blood components, and procurement of plasma protein products. The agreement also indicates when funding forecasts, shipment details and financial statements are to be submitted • Funds hospital-based initiatives[1] through transfer payments to make the best use of blood components and blood products to improve patient safety and achieve cost savings
Ontario Emergency Blood Management Committee	• Members include representatives from the Ministry of Health, the National Advisory Committee on Blood and Blood Products, Canadian Blood Services, Ontario Regional Blood Coordinating Network, Ontario hospitals, Ontario Nurse Transfusion Coordinators and the Nunavut Blood Office • Develops a provincial response plan with national and provincial stakeholders to minimize the impact of blood shortages
Organizations hosting the Ontario Regional Blood Coordinating Network.[1,2]	
McMaster University	• Site visits to hospitals in southwest Ontario • Focuses on blood management data such as extracting data from Canadian Blood Services' databases and generating reports from this data • Host organization of the Ontario Transfusion Transmitted Injuries Surveillance System (TTISS),[1] which collects adverse transfusion events from all hospitals in Ontario through an online database and submits the aggregate data to the national TTISS. While TTISS is primarily funded by the Public Health Agency of Canada, the Ontario Ministry of Health provides funding to TTISS and the Transfusion Error Surveillance System, which is used by some Ontario hospitals to report all adverse transfusion events, whereas other hospitals are only expected to report major events. • Houses the McMaster Centre for Transfusion Research, which provides scientific evidence that will inform transfusion practice, guide optimal use of blood and enhance the safety of transfusion for blood recipients and blood donors: • The Centre administers TRUST, a database created by McMaster University in 2001 that contains patient, blood product and transfusion data from 2002 to the present, for four hospitals in Hamilton (three Hamilton Health Sciences hospitals and St. Joseph's Healthcare). TRUST pulls data from the hospitals' Laboratory Information System, the Canadian Institute for Health Information's Discharge Abstract Database, the hospital pharmacy, radiology orders, 50 additional laboratory test results and physician roster information to produce comprehensive data on blood transfusions

The Ottawa Hospital	• Site visits to hospitals in Northern and eastern Ontario • Serves as the program leader for all three regional offices and is the lead on the redistribution of plasma-protein products (excluding factor concentrates) • Host organization for the Ontario Immunoglobulin Treatment Program,[1] an initiative that started mid-2019 to train patients on immunoglobulin self-administration to support improved patient outcomes while reducing the need for hospital beds and nursing resources
Sunnybrook Health Sciences Centre	• Site visits to hospitals in central Ontario • Specializes in quality improvement efforts and redistribution of blood components
Hospitals	

Unity Health Toronto – St. Michael's Hospital	• Host organization for the Ontario Nurse Transfusion Coordinators,[1] which funds 28 nurse co-ordinators across 25 hospitals in Ontario to:
	  ◦ implement the Patient Blood Management Strategy (alternatives to transfusion)
	  ◦ act as hospital-wide promoters
	  ◦ educate patients through counselling and also educate physicians, anesthesiologists and surgeons on patient blood management
	  ◦ collect hospital transfusion data
	• Host organization for Factor Concentrate Redistribution Program[1] to redistribute clotting factor concentrate (a blood product) near expiry throughout Ontario hospitals to ensure blood products are used before expiring. Factor concentrate is used to treat people living with hemophilia, which is a rare inherited bleeding disorder

All (approximately 160) hospitals in Ontario	• Order blood components and blood products directly from Canadian Blood Services and report utilization statistics to Canadian Blood Services • Provide direct health services to patients requiring blood components and blood products • Operate transfusion medicine labs that, among other things, test and match blood and blood products for patient transfusions across hospital specialties (such as surgery, hemophilia) and store delivered blood components and blood products from Canadian Blood Services • Report adverse transfusion events to the Ontario Transfusion Transmitted Injuries Surveillance System (TTISS) • Report transfusion errors to the Transfusion Error Surveillance System (TESS). Fifteen hospitals across Canada report into TESS; three of these hospitals are in Ontario

1. These funded transfer payment programs with several hospitals together comprise the Ministry of Health's blood utilization strategy.

2 As part of the Network, these organizations identify and address gaps and issues in blood use. They also promote evidence-based practices in transfusion medicine through educational events, annual site visits in their regions and developing best practice guidelines and tools for hospitals. McMaster University and The Ottawa Hospital have host responsibilities with other entities as indicated.

Appendix 3: Selected Recommendations from 2013 and 2020 Performance Reviews of Canadian Blood Services

Prepared by the Office of the Auditor General of Ontario

Recommendation	Recommendation # in Performance Review Report	Related Sections in This Report	Current Status as of Aug 31, 2020
2013 Performance Review			
Canadian Blood Services (CBS) and its Members should assess the opportunity to provide hospitals and health institutions with details on volumes and costs for the transfusable products they receive, similar to what exists for plasma protein products. Providing this information would partly meet the Krever Commission's recommendation on billing hospitals. It would help hospitals in understanding the costs associated with their use of blood products. Héma-Québec, the National Health Service Blood and Transplant (UK) and the Australia Red Cross Blood Service all provide this type of information, even when the payment comes from a central payer. Since there would be additional costs associated with this practice, a cost-benefit assessment should be completed prior to making a decision.	16	4.2.3	In progress
Members should develop guidelines and mechanisms to optimize usage of plasma products; CBS, using its unique expertise, should play a leadership role in exploring ways to achieve this objective.	31	4.4.1	• **Ontario Ministry of Health:** Little or no progress • **Canadian Blood Services:** In progress
CBS should create a centralized inventory management function. Inventory management of plasma protein products and medical supplies for Transfusable Products should be centralized in one group.	35	4.2.1	Implemented
CBS should work with hospitals to develop standardized data collection and reporting mechanisms for hospital demand and utilization to enable better monitoring and management of system-wide outdates and costs.	55	4.2.1	Implemented
CBS should continually improve reporting of safety incidents by modifying safety indicators and the corresponding quarterly targets to reflect the cause and impact of the event and, potentially, the impacts to the system.	56	4.1.2	Implemented
CBS should investigate opportunities to integrate and interface information systems within the organization as well as with those of its partners, particularly as the health-care system moves toward electronic information systems. These opportunities will require effective collaboration between CBS and the health-care system partners, as well as consideration of the legislative requirements to implement appropriate interfaces.	57	4.2.1	In progress

Recommendation	Recommendation # in Performance Review Report	Related Sections in This Report
2020 Performance Review*		
CBS should continue to examine options to increase plasma self-sufficiency within Canada to reduce dependency on US and global suppliers. This may require a discussion with Members at a strategic level to evaluate various options and should take into account the performance results for the plasma proof-of-concept collection sites (as they become available). CBS should also consider setting up a task force that looks at potential improvements within plasma collection processes and integrating them at a community level to drive higher volume and self-sufficiency in this area.	7	4.3.2
CBS and provinces and territories (PT) should work together to explore options for managing the increased use of C1 inhibitors. Consideration should be given to: • adding patients to a patient registry, such as the Named Patient Program, to better control and monitor the use of the product; • delisting the product form the CBS formulary and transferring it to PT drug formularies.	8	4.4
CBS should provide additional information to Members on: • foreign exchange fluctuations; • significant market trends for PPP over the last 3–5 years and future projections; • achievement of planned savings from new contracts on a year-over-year basis; and • impacts of variances in demand forecasts on Member funding.	9	4.3.2
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.	10	4.1.2 4.2.4 4.5.3
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. Treatment-related data would also inform utilization management for plasma protein products (PPP). Therefore, data requirements for forecasting and utilization management should be co-ordinated.	19	4.2.1
CBS should establish a working group to analyze and monitor PPP demand, including representation from PTs, suppliers, clinical experts and patient groups. • The group should look at ways of better predictability for PPP demand forecasting. • CBS should work with the PTs to improve the timeliness and consistency of hospital reporting with regards to PPP inventories.	21	4.2.1 4.3.2
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.	25	4.4.1

Recommendation	Recommendation # in Performance Review Report	Related Sections in This Report
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.	26	4.3.2
CBS and the PTs should explore opportunities for hospitals to share data supporting PPP use with CBS. A starting point for this recommendation could be: • Collaboratively agreeing on the desired utilization data and assessing the completeness, accuracy and availability of this data at a PT level. Data could include departments where PPP are being distributed, indications for which PPP are being prescribed, outcomes of the medication, prescribed dosage, intended frequency of use and duration of treatment. • Carrying out a pilot study with two jurisdictions and collecting utilization data where existing data is found to be incomplete, inaccurate or inconsistently available. Once this data has been collected, CBS and Members should weigh the costs and investment required to facilitate ongoing data sharing against the ancillary benefits mentioned above. This would help both parties determine if there is a valid business case for data sharing.	27	4.2.1 4.3.2
CBS should continue its efforts to automate the hospital ordering process for fresh blood components and PPP and develop strategies for strong adoption.	28	4.2.1
CBS and the PTs should complete a combined assessment of their utilization management activities for PPP and determine if these activities could be expanded further to improve utilization outcomes. Based on our comparative analysis, examples of utilization management approaches which should be considered, to the extent they are not already occurring within PT health systems, include: • Developing a simple web-based shared system to electronically manage PPP requests and check that these align with pre-established criteria (e.g., conditions where the use of PPP is considered clinically appropriate). • Implementing patient databases which would help the PTs collect data on treatments which have been administered, the outcomes and, if applicable, the side effects. This would enable PTs to evaluate the cost effectiveness and the results of different treatments and make improvements. • Determining whether certain higher-cost PPP should be limited to prescription by specialized doctors. Roles, responsibilities and expectations for utilization management should be clearly agreed upon and documented between CBS and the PTs. Once defined, CBS should evaluate the flow-on effect (e.g., resource levels, skills/expertise, etc.) on its existing utilization management activities and determine what changes need to be made. These should be discussed and agreed to with the PTs.	32	4.2.2 4.4.2

Recommendation	Recommendation # in Performance Review Report	Related Sections in This Report
CBS should review the processes which support the PPP Named Patient Program for any opportunities to strengthen utilization management. Given that PTs will also be undertaking utilization management initiatives within their health systems, any major changes to the Named Patient Program should first be agreed upon with PTs. The existing processes could be improved by: • Digitizing and creating a cloud-based application to replace the current process to submit request forms and supporting medical evidence to CBS via fax. Physicians could be provided with access to the cloud-based application as this would help introduce internal controls to verify physician authenticity. • Documenting and publishing CBS' process for the review and, where necessary, Medical Review of request forms. Determine if there are aspects of the Medical Review which could be simplified or performed by others (e.g., CBS pharmacists). • Formalizing and publishing the urgent/emergency ordering process. • Developing criteria to enable tiering/prioritization of orders and the associated timeframes for response from CBS. Consider reporting on process cycle times under the Named Patient Program. • Determining potential conditions which could prompt the auto-renewal of orders for an existing patient. These recommendations would also enable CBS to scale the Named Patient Program should there be a significant surge in demand for these products. Given the increasing cost pressure on PT health systems, CBS and the PTs should also identify the need to apply similar "exceptional access" principles when new products are approved for addition to the CBS formulary. By doing this up front, CBS and the PTs could more closely manage and monitor utilization of, for instance, high-cost PPP treatments.	33	4.2.2
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.	34	4.2.1
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 pan-Canadian Pharmaceutical Alliance "negotiation" approach which could be incorporated into its pricing strategies. CBS should also consider the feasibility of value-based pricing/procurement for PPP with the aim of developing strategies with manufacturers that can influence a reduction in total costs across the health system. Given there is increasing global demand for PPP and relatively constrained supply, this strategy could be conducive to CBS and PT health systems in ensuring that strategic manufacturers are more tightly integrated with health systems beyond just being suppliers of products. In this context, examples of outcome-based specifications for potential suppliers could include: • achieving economic efficiencies and better value for money for PT health systems by procuring not just cost effective PPP, but incorporating additional elements related to supply security and management, transition management, training where necessary or other downstream aspects that affect the Members and provide better overall economic outcomes for the health system; • further building on the innovation capacity and utilization reporting capability within PT health systems; and • ensuring patients have the best possible experience and have improved quality of care while at the same time, improving the clinical outcomes.	36	4.2.2

Recommendation	Recommendation # in Performance Review Report	Related Sections in This Report
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 errors and accidents and post-donation information per 10,000 collections, etc.) for the last 3 consecutive years.	55	4.1.2 4.5.3 4.5.4
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/Provincial-Territorial Blood Liaison Committee (PTBLC) representatives to: • Review the content of reports and materials provided to Members and PTBLC representatives to determine the extent to which these documents contain the data/information required by Members. • Develop a process to better support PTBLC representatives in their roles. The process should enable discussion of the nature of documentation/materials to be provided, timelines and any additional CBS support that may be required, to enable PTBLC representatives to support their respective Members with decision-making, approvals, etc. • 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.	56	4.5.4

* Canadian Blood Services had not determined the status of implementation of the recommendations made in this review when we completed our audit.

Appendix 4: Use, Storage and Shelf Life of Whole Blood and Its Components

Prepared by the Office of the Auditor General of Ontario

	Description	Primary Use and/or Patient Conditions	Storage Conditions and Shelf Life
Whole blood[1]	Consists of 55% blood plasma, 45% red cells, white cells,[2] and platelets	• Not transfused directly into patients • Is separated into component parts to obtain the blood components below	Refrigerated and anticoagulant applied (to prevent clotting): 21 to 35 days depending on the type of anticoagulant used
Red blood cells	Carries oxygen from the lungs to the body via a protein known as hemoglobin	• Acute blood loss • Chronic and acute anemia (low hemoglobin) • Surgery	Refrigerated: 42 days
Platelets	Key component for clotting	• Thrombocytopenia (low platelet count) • Cancer treatment • Organ transplants • Surgery	Room temperature with constant agitation to prevent clumping: five to seven days
Plasma[3]	• Protein-rich liquid component of whole blood • Maintains blood pressure and volume • Aids with clotting	• Trauma • Burns • Shock • Bleeding disorders	Frozen: up to one year Thawed: must be refrigerated and expires after five days
Cryoprecipitate[4]	Supplements low fibrinogen, a protein for clotting	• Hemophilia • Von Willebrand disease (a genetic disorder caused by missing clotting protein)	Frozen: up to one year Thawed: stored at room temperature and expires after four to six hours

1. Canadian Blood Services' most commonly donated product is whole blood; however, it also obtains blood components separately in some cases, such as the collection of only platelets or plasma through a process known as apheresis.
2. White blood cells are generally not used to treat medical conditions; if infused, they are likely to cause an adverse reaction.
3. Does not include plasma protein products that are derived from plasma, a raw material used to manufacture these products.
4. Cryoprecipitate is produced when frozen plasma is slowly thawed, centrifuged—a machine spins the substances to separate out the substances by their different densities—and the liquid portion is drained. It is collected and combined with cryoprecipitate from other donors until it reaches a sufficient volume for transfusion.

Appendix 5: Blood Type Compatibility

Source of data: Canadian Blood Services

Recipient Blood Type	% of Canadians with Blood Type	Compatible Donor Blood Type			
		Red Blood Cells	Platelets[1]	Plasma	Cryoprecipitate[2]
O+	39.0	O (+ or –)	O (+ or –)	Any Group	Any Group
O–	7.0	O (–)	O (–)	Any Group	Any Group
A+	36.0	A (+ or –) O (+ or –)	A (+ or –)	A AB	Any Group
A–	6.0	A (–) O (–)	A (–)	A AB	Any Group
B+	7.6	B (+ or –) O (+ or –)	B (+ or –)	B AB	Any Group
B–	1.4	B (–) O (–)	B (–)	B AB	Any Group
AB+	2.5	Any type (+ or –)	AB (+ or –)	AB	Any Group
AB–	0.5	Any type (–)	AB (–)	AB	Any Group
Unknown		O (–) if female <45[3] O (+) for all others		AB	Any Group

1. For platelets, it is preferred that the recipient receive the same type of platelets as their own blood type; however, if that is not possible, they are given the same blood types as listed here for plasma.
2. Cryoprecipitate is produced when frozen plasma is slowly thawed, centrifuged—a machine spins the substances to separate out the substances by their different densities—and the liquid portion is drained. It is collected and combined with cryoprecipitate from other donors until it reaches a sufficient volume for transfusion.
3. O-negative blood is given to women with child-bearing potential to reduce the risk of developing Rh sensitization—a process where the immune system of a person with a negative blood type will create antibodies to destroy positive-type blood. This can have serious implications when a pregnant woman with negative-type blood has a fetus with positive-type blood, as transfusing positive-type blood may create antibodies that attack the fetus's red blood cells, causing anemia, jaundice or other conditions.

Appendix 6: Audit Criteria

Prepared by the Office of the Auditor General of Ontario

Ministry of Health	
1.	The Ministry has processes in place to monitor that Canadian Blood Services meets its obligations to procure, ensure the safety and supply of, and provide blood components and products to Ontario hospitals, and to monitor that Canadian Blood Services does so in accordance with contractual agreements with the Ministry.
2.	The Ministry has processes in place to direct hospitals to use the most cost-effective and evidence-based treatment options to meet patient needs—for example, to use alternatives to blood components and products when available.
3.	The Ministry has processes in place to ensure that it pays for only those blood components and products that are requested and received by Ontario hospitals.
4.	The Ministry has processes and programs in place to minimize and track the waste of blood components and products.
5.	The Ministry has processes in place to collect sufficient, accurate and timely blood component and product inventories, as well as blood use and incident data, across all Ontario hospitals to improve cost management and patient outcomes; analyses exist to justify instances when data is not collected.
6.	The Ministry has processes and programs in place to prevent harm to patients from the use of blood components and products; when patients have been harmed, systems exist to detect the incidents in a timely manner and centrally track them to prevent recurrence.
7.	The Ministry identifies performance indicators for its role in blood component and product management, and processes to measure and report on them regularly.
Canadian Blood Services	
1.	Canadian Blood Services has processes in place to ensure a safe blood supply, including blood testing and surveillance to detect unsafe blood products, and such processes allow for blood tracking, through donor-specific identification, if blood components and products are found to cause harm.
2.	Canadian Blood Services has processes to obtain required blood components and products in the most cost-effective manner, with consideration given to national sustainability.
3.	Canadian Blood Services provides hospitals with needed blood components and products in a timely and effective manner.
4.	Canadian Blood Services identifies performance indicators for its role in blood component and product management, and processes to measure and report on them regularly.

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ISSN 1911-7078 (Online)
ISBN 978-1-4868-4888-1 (PDF, 2020 ed.)