

# Chapter 1

## Section 1.02

Ministry of Health

### Follow-Up on 2020 Value-for-Money Audit: Blood Management and Safety

#### RECOMMENDATION STATUS OVERVIEW

	# of Actions Recommended	Status of Actions Recommended				
		Fully Implemented	In the Process of Being Implemented	Little or No Progress	Will Not Be Implemented	No Longer Applicable
Recommendation 1	2			2		
Recommendation 2	4	2	2			
Recommendation 3	4		4			
Recommendation 4	1	1				
Recommendation 5	2		2			
Recommendation 6	1		1			
Recommendation 7	2		2			
Recommendation 8	2		2			
Recommendation 9	2		2			
Recommendation 10	1		1			
Recommendation 11	3	1	2			
Recommendation 12	3	2	1			
Recommendation 13	3		3			
<b>Total</b>	<b>30</b>	<b>6</b>	<b>22</b>	<b>2</b>	<b>0</b>	<b>0</b>
<b>%</b>	<b>100</b>	<b>20</b>	<b>73</b>	<b>7</b>	<b>0</b>	<b>0</b>

### Overall Conclusion

The Ministry of Health, as of October 31, 2022, has fully implemented 20% of actions we recommended in our *2020 Annual Report*. The Ministry has made progress in implementing an additional 73% of the recommendations, and made little or no progress in implementing two recommended actions.

The Ministry has fully implemented recommendations such as clarifying where responsibility should

reside for monitoring transfusion surveillance data reported by hospitals and requesting Canadian Blood Services provide at least annual feedback on trends of Ontario results.

The Ministry was in the process of implementing recommendations such as assessing and developing an appropriate information technology solution to extract relevant data from multiple hospital systems, such as the amount of blood used and conditions for which it was used to treat; establishing a plan to raise awareness and require all hospitals to report serious

transfusion-related incident data to the Ministry; and putting a process in place to verify that payments to Canadian Blood Services are for products shipped and received by Ontario hospitals.

The Ministry has made little progress on regularly reviewing Health Canada inspection reports to identify common risk areas and target these problem areas in future education initiatives for hospitals—primarily because Health Canada had not resumed its inspections of hospital blood banks since the COVID-19 pandemic began.

The status of actions taken on each of our recommendations is described in this report.

## Background

Hospitals in Ontario obtain their blood components and products from Canadian Blood Services, a national body that was established in 1998. Canadian Blood Services obtains blood components (such as plasma, red blood cells and platelets used for direct transfusion) from Canadian donors who voluntarily provided blood without compensation. In contrast, Canadian Blood Services purchases most processed blood products (a class of drugs derived from blood and used to treat specific conditions) 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 break down 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.

In 2021/22, the Ministry of Health contributed about \$616 million (\$562 million in 2019/20) to Canadian Blood Services—representing about 48% (50% in 2019/20) of total funding from all provinces and

territories—to provide blood components and products to Ontario hospitals at no cost to them. About 35% (40% in 2019/20) of this funding went toward blood components; the other 65% (60% in 2019/20) went toward blood products.

Our audit found that while the supply of blood components and products as of August 2020 was safe and had been reasonably reliable, the COVID-19 pandemic had magnified existing weaknesses in the reliability of the supply of the immunoglobulin blood product: Canadian Blood Services' self-sufficiency in collecting enough plasma to produce this blood product, at 13.7% in 2019/20 (15% in 2021/22), fell far short of its own goal of obtaining 50% of blood plasma needed for this product in Canada. Canadian Blood Services continued to rely primarily on US-based suppliers to provide blood products, though it also had some Europe-based suppliers to offset the risk. Given the significant lead time needed (up to a year) to fractionate plasma and produce immunoglobulins, the effect of the COVID-19 pandemic on the supply of immunoglobulins had not yet been realized. However, these US-based suppliers were 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.

The following were some of our significant findings:

- Ontario relied heavily on suppliers in the United States for essential and high-demand blood products including immunoglobulins, which is fractionated from plasma collected by these suppliers. This reliance on US-based suppliers presented 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 immunoglobulins made from plasma collected by Canadian Blood Services had steadily decreased since then, and

was down to 13.7% in 2019/20 compared with 22.7% in 2013/14. As of May 2022, it was 15%.

- Hospital use and waste of blood was not well reported and tracked. Although Canadian Blood Services encouraged hospitals to report their use through the Blood Component and Product Disposition Database, some hospitals either did not report or reported inconsistently. The Ministry could not effectively minimize waste from expired blood components and products using the information from Canadian Blood Services because Canadian Blood Services had no way to confirm if the self-reporting from hospitals was accurate. The Ministry had 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 was limited.

We made 13 recommendations, consisting of 30 action items, to address our audit findings.

We received commitment from the Ministry that it would take action to address our recommendations.

## Standing Committee on Public Accounts

On May 27, 2021, the Standing Committee on Public Accounts (Committee) held a public hearing on our 2020 audit. In February 2022, the Committee tabled a report in the Legislature resulting from this hearing. The Committee endorsed our findings and recommendations, and made two additional recommendations. The Ministry reported back to the Committee on June 21, 2022, and again on August 12, 2022. The Committee's recommendations and our follow-up on its recommendations are found in **Chapter 3, Section 3.02** of our *2022 Annual Report*.

## Status of Actions Taken on Recommendations

We conducted assurance work between April 2022 and August 2022. We obtained written representation from the Ministry of Health that effective October 31, 2022, it has provided us with a complete update of the status of the recommendations we made in the original audit two years ago.

### Risk of Transmitting Disease through Transfusion Is Low

#### 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;*

**Status:** Little or no progress.

#### Details

In our 2020 audit, we found that the Ministry was not aware that most unregistered blood banks were not inspected by Health Canada, and it did not obtain and review the data from Health Canada's inspections of blood banks and donor sites. Health Canada inspects these establishments for adherence to the federal Blood Regulations that specifically relate to protecting the blood supply in Canada for the safety of blood donors and recipients alike. While 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

This particular inventory advisory was resolved by the first week of August 2021.

- *actively monitor Canadian Blood Services' exploration of an online ordering system for hospitals in British Columbia;*

**Status: Fully implemented.**

### Details

In our 2020 audit, we found that Canadian Blood Services was exploring the use of an online ordering system with hospitals in British Columbia. Once this work was complete, Canadian Blood Services would examine the feasibility of extending this to all hospitals in Canada.

In our follow-up, the Ministry informed us that in November 2020 after our audit was completed, Canadian Blood Services launched the “Hospital Portal” to help establish a single location for all interactions between hospitals and Canadian Blood Services, and in January 2022, it launched a national online ordering solution within this portal. This solution allows hospitals to submit blood and blood product orders and monitor the progress of the order. Canadian Blood Services had onboarded all hospitals by August 2022.

- *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;*

**Status: In the process of being implemented by December 2024.**

### Details

In our 2020 audit, we found that there was no provincial system to store and manage blood use data. The Ministry was presented with two proposed solutions in 2017 and 2018—one from McMaster University and one from Cancer Care Ontario—to address gaps in the assortment of decentralized databases and manual processes used in hospitals at that time, but rejected them based on their immediate costs.

In our follow-up, we found that the Ministry and representatives from McMaster University met in December 2021 to consider the Transfusion Data Ontario proposal. As well, the Ministry was working with the Ontario Blood Consultation Group to establish a new data strategy subcommittee to review and analyze blood use information. In March 2022, the Ministry met with a small group of people within the Consultation Group to determine the approach and mandate of this new subcommittee, and in July 2022 it held a brainstorming session with all members of the Consultation Group to determine the type of work this subcommittee will undertake once formed. The Ministry expects to review recommendations from the data strategy subcommittee and fully implement our audit recommendation by December 2024.

- *work with Canadian Blood Services by providing Ontario data to further develop its forecasting approaches, including factors such as patient demographics.*

**Status: In the process of being implemented by December 2023.**

### Details

In our 2020 audit, we found that the 2020 performance review of Canadian Blood Services, conducted by an external party, noted that Canadian Blood Services did not collect data on prescribed dosages, intended frequencies of use, duration of treatment and patient outcomes. Having this data could help Canadian Blood Services better forecast demand for blood products. The review recommended a pilot study of Ontario and one other province/territory where data was incomplete, inaccurate or inconsistently available to evaluate the costs and benefits of sharing data between hospitals and Canadian Blood Services.

In our follow-up, we found that Canadian Blood Services meets with all ministries of health twice a year on forecasting, including meeting with the Ministry in October 2021. At that time, the Ministry provided information about hospital blood product usage to Canadian Blood Services to help it forecast

govern the care, treatment and services and facilities provided by hospitals.

In our follow-up, we found that Health Canada had suspended its inspections of hospital blood banks in Ontario in March 2020 because of the COVID-19 pandemic. In March 2021, the Ministry provided Health Canada with the names of program staff to whom it should share inspection documents directly, once it resumes inspections. In August 2021, Health Canada noted that it was exploring other ways to inspect facilities instead of traditional on-site inspections. The Ministry indicated that it will establish a mechanism to share blood bank inspection information with Ontario Health by March 2023, once Health Canada resumes its inspections.

- regularly review Health Canada inspection reports to identify common risk areas and target these problem areas in future education initiatives for hospitals;

**Status:** Little or no progress.

### Details

In our 2020 audit, we found that while Health Canada's inspections did not identify any significant safety risks, it did identify certain deficiencies. However, the Ministry did not obtain and review the data from Health Canada's inspections of blood banks and donor sites. In comparison, Saskatchewan used the results of Health Canada inspections to correct and improve transfusion practices in that province.

In our follow-up, we found that Health Canada had not conducted any inspections of Ontario hospital blood banks during the pandemic. In May 2022, Health Canada indicated it had resumed inspections of hospital blood banks using a hybrid model that involves remote inspections of certain sites, but it had not scheduled inspections of hospital blood banks up to August 2022. The Ministry expects that it will implement this recommendation by March 2023, once Health Canada resumes its inspections of Ontario hospital blood banks using a hybrid model.

## 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

### 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;

**Status:** Fully implemented.

### Details

In our 2020 audit, we found that there was no centralized hospital blood information system that allows Canadian Blood Services to see what blood components or products each Ontario hospital has on hand. Not all hospitals reported quantities of blood used and not all hospitals consistently reported blood inventory, even though Canadian Blood Services asks hospitals to provide this data daily. Reporting inventory was especially important when managing potential shortages.

In our follow-up, the Ministry indicated that during much of July 2021, the National Emergency Blood Management Committee (which consists of Canadian Blood Services, the National Advisory Committee on Blood and Blood Products, and government representatives) announced that there was a shortage of O negative red blood cells. The Ministry and the Committee made multiple requests to all Ontario hospitals that they report inventory daily to Canadian Blood Services. In addition, the Ministry engaged the Ontario Regional Blood Coordinating Network to monitor that hospitals report their inventories daily.

the use of plasma protein and related products up to 2024/25. In preparation for this, the Ministry gathered information including product use for patients living with haemophilia, factors impacting immunoglobulin use, and changes in use of C1 Esterase products that are on the product formulary. The Ministry continues to regularly review monthly forecasting data from Canadian Blood Services to inform its own forecasting on expenditures and utilization, both internally and with stakeholders such as those in the blood programs. The Ministry, together with Canadian Blood Services and blood program stakeholders, will explore ways to further develop forecasting to include factors such as patient demographics by December 2023.

### 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;*

**Status:** In the process of being implemented by December 2024.

### Details

In our 2020 audit, we found that neither Canadian Blood Services nor the Ministry of Health collected information on how immunoglobulins were used in Ontario hospitals. Without this information, the Ministry could not assure that immunoglobulins were used appropriately in accordance with the preferred conditions listed in the provincial utilization guidelines.

In our follow-up, we found that the Ministry, through the Ontario Regional Blood Coordinating Network, has taken steps to collect dosing and indication data when hospitals order immunoglobulins using the ordering form so that it can better track how

these products are being used. The Network has also created an online request order form for immunoglobulins to potentially replace the Ministry's current paper ordering process in the hospitals. The Ministry met with the Ontario Blood Consultation Group in November 2021 and the Ontario Immune Globulin Advisory Panel in January 2022 to review the business requirements for the online immunoglobulin ordering system. These requirements included, for example, which specific medical conditions should be available to select as specified indications on the order form. It plans to take the feedback from its meetings and the data it collects from order forms into consideration as part of its future work on updating the provincial utilization guidelines. The Ministry expects the online immunoglobulin ordering system to go live in hospitals by December 2024.

- *eliminate the option of prescribing immunoglobulin where the Ontario Immune Globulin Utilization Guidelines (Guidelines) state that the product is not recommended for use;*

**Status:** In the process of being implemented by December 2024.

### Details

In our 2020 audit, we found that the Ministry's paper order form contained an "other" category, where a prescribing physician could make a request to treat a health condition not listed in the Ontario guidelines. The Ministry informed us that determining proper use under the "other" category was the responsibility of the hospital.

In our follow-up, we found that the Ministry met with the Ontario Blood Consultation Group in November 2021 and the Ontario Immune Globulin Advisory Panel in January 2022 to review business requirements for an online immunoglobulin ordering system, which is expected to go live in December 2024. The new online ordering system will capture information such as the immunoglobulins being ordered, in what dosages and for what medical conditions. After this system is implemented, the Ministry can then

eliminate the option of prescribing immunoglobulin where the provincial guidelines do not recommend its use.

- *educate physicians and monitor Ontario hospitals' adoption of the Guidelines;*

**Status: In the process of being implemented by March 2023.**

### Details

In our 2020 audit, we found that the Ministry's study of immunoglobulin orders noted that the doses, frequency or duration of prescriptions were generally higher than required by the 2012 Ontario Guidelines.

In our follow-up, we found that the Ontario Regional Blood Coordinating Network, through the funding provided by the Ministry, has updated continuing education resources on blood-related products to highlight the importance of following the Guidelines. For example, it revised and relaunched the Bloody Easy Blood Administration eLearning program in November 2021. At the time of our follow-up, the Network was also redeveloping the Technologist Assessment Competency program, which it expected to launch in the Network's new online learning platform with annually updated tests. The Network was also updating the content of Bloody Easy 4 and expects to release Bloody Easy 5 in 2022/23 to keep it current with up-to-date best practices. As well, the Network has included the Guidelines in its online "Immunoglobulin Toolkit," which is intended to help hospital transfusion services manage immunoglobulins. In November 2021, the Network presented the results of its survey of immunoglobulin prescribers and transfusion service laboratories in Ontario to the Ontario Blood Consultation Group. This survey was designed to collect expert opinion on current practices related to the management of immunoglobulins in Ontario. The group discussed ways to better communicate with immunoglobulin prescribers to improve compliance with the Guidelines.

The Ministry expects that the Network will develop a mechanism for tracking hospital adoption of the Guidelines and physician education by March 2023.

- *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.*

**Status: In the process of being implemented by December 2024.**

### Details

In our 2020 audit, we found that the Ministry left it to hospitals to comply with provincial guidelines on an ongoing basis, and had never confirmed that hospitals used the paper form when ordering immunoglobulins. The Ministry had not routinely collected the forms to analyze how hospitals used immunoglobulins, and therefore it could not detect if and when these products were being used for conditions that were not indicated as preferred in Ontario guidelines.

In our follow-up, we found that the Ministry met with the Ontario Blood Consultation Group in November 2021 and the Ontario Immune Globulin Advisory Panel in January 2022 to review business requirements for an online immunoglobulin ordering system, which is expected to go live in December 2024. The new online ordering system will capture information such as the immunoglobulins being ordered, in what dosages and for what medical conditions. After this system is implemented, the Ministry can then assess potential tools to prohibit any uses of blood products where there is no credible evidence that they improve health outcomes.

### 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.*

**Status: Fully implemented.**

### Details

In our 2020 audit, we noted that plasma collection in the United States was heavily hit at the start of the COVID-19 pandemic, and continued to be affected despite considerable industry efforts aimed at convincing donors to return to collection centres. For some products, there had also been production challenges in regions heavily hit by COVID-19 because of disease-related absenteeism.

In our follow-up, we found that Canadian Blood Services informed the Ministry and other provinces in July 2021 that it had implemented various strategies to mitigate the immediate effects of the COVID-19 pandemic on immunoglobulin supply and, as a result, secured a healthy national inventory of immunoglobulin products to meet patient needs despite pandemic-related impacts to global supply chains and an ongoing global shortage that preceded the pandemic. The Ministry informed us that Canadian Blood Services, working closely with governments, will significantly increase plasma collection in Canada over the next three years and beyond. These updates followed several 2020 communications from Canadian Blood Services that indicated inventory risks from supply chain challenges arising from the COVID-19 pandemic.

### 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;*

**Status: In the process of being implemented by March 2023.**

### Details

In our 2020 audit, we found that surveillance activities over blood transfusions were seen as a federal responsibility and the Ontario government had not sought to make such reporting mandatory. Ontario hospitals were not subject to any regulatory requirement to report all adverse transfusion events.

In our follow-up, the Ministry informed us that the National Advisory Committee on Blood and Blood Products' Adverse Transfusion Reactions Reporting Subcommittee (Subcommittee) created and distributed a survey to Ontario and other provinces in late 2021 to better understand how each province collects and reports transfusion reactions to the Public Health Agency of Canada. At the time of our follow-up, the Subcommittee was analyzing the survey results and developing guidance for reporting adverse transfusion reactions. The Ministry expects this guidance will be finalized and posted on the National Advisory Committee's website by the end of 2022.

Furthermore, the Ontario Regional Blood Coordinating Network visited 162 hospitals to present transfusion reaction data for 2020, which was reported by hospitals that participated in the Ontario surveillance program. The presentation summarized the types of reactions seen according to blood component/product and their rates of incidence, which were extrapolated to suggest possible expected transfusion reactions. According to the Ministry, the comparison of the reported reactions to the potential expected reactions fostered discussions on the importance of educating hospitals on identifying and reporting reactions.

In addition, the Ministry indicated that McMaster University, which administers the Ontario surveillance program, has started work to raise awareness about reporting adverse transfusion events. At the time of our follow-up, it had developed an online training tool that includes videos and questions to show proof of training. Once answers are submitted, training will be automatically logged into the Ontario surveillance program database. The Ministry expects that all hospitals will begin reporting serious transfusion-related events by March 2023.

- *monitor compliance with the plan on an annual basis;*

**Status:** In the process of being implemented by March 2023.

### Details

In our 2020 audit, we 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. Reporting of these events was largely voluntary.

In our follow-up, the Ministry indicated that McMaster University, which administers the Ontario surveillance program, provided an annual educational and networking event in March 2022 to train hospital staff (primarily transfusion services laboratories staff responsible for reporting adverse transfusion events, managers and physicians) on standardizing the reporting of adverse transfusion events; more than 100 transfusion professionals registered for the event. The University has also developed an online training tool that includes videos and questions to show proof of training. Once answers are submitted, training will be automatically logged into the Ontario surveillance program database. The Ministry expects this training to be fully in use by March 2023, which could help monitor hospitals' compliance with incident reporting.

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

### 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.*

**Status:** In the process of being implemented by March 2023.

### Details

In our 2020 audit, we found that Canadian Blood Services set a goal to achieve 50% self-sufficiency in plasma to produce immunoglobulins by 2023/24. However, progress toward the 50% goal had been slow. Not only had Canadian Blood Services not progressed toward its 50% goal, it had regressed since establishing it.

In our follow-up, the Ministry noted that Canadian Blood Services requested Ontario and other provincial and territorial governments provide funding to establish additional collection centres and increase plasma collection capacity by 2023/24. Canadian Blood Services expects that its new collection centres, once fully operational, along with other activities, will help drive Canada's domestic sufficiency to about 25%, up from 13.7% in 2019/20. Ontario and other governments reviewed Canadian Blood Services' proposal and approved its funding for 2021/22 and 2022/23, and expect to review its 2023–2026 corporate plan and 2023/24 budget request by March 2023.

In addition, Ontario and other funding provinces and territories established a steering committee in October 2021 to recommend a national policy framework that supports Canadian Blood Services' mandate to source enough plasma from Canadians to produce immunoglobulins for Canadian patients. The Ministry expects the steering committee to finalize its report by March 2023.

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

### 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;*

**Status: In the process of being implemented by March 2023.**

### Details

In our 2020 audit, we found that the Ontario Regional Blood Coordinating Network could not mandate the adoption of the best practices it recommended to hospitals for managing and using blood components and products. Not all hospitals adopted the best practices the Network promoted and not all hospitals participated in its studies.

In our follow-up, the Ministry noted that the Ontario Regional Blood Coordinating Network surveyed hospitals in 2021 about their compliance with the provincial guidelines on immunoglobulin use. According to survey results, the compliance rate was high, but there was room for improvement in communicating and engaging with prescribers. The Network has included several other educational, engagement and communication activities in its 2022–23 business plan; the Ministry met with the Network in March 2022 to discuss these and expects the Network to work with the Ontario Hospital Association to develop a plan to increase hospitals' participation in these activities by March 2023.

- *monitor hospitals' participation in Network activities to ensure the adoption of best practices improve over time.*

**Status: In the process of being implemented by March 2023.**

### Details

In our 2020 audit, we found that the adoption of the Network's best practices for managing and using blood components and products was at the discretion of physicians, and participation in

the Network's studies—such as on the use of AB plasma, compliance with standards on how blood is to be administered to a patient, and appropriateness of intravenous immunoglobulin use—was at the discretion of hospitals.

In our follow-up, we found that the Ministry met with the Network in March 2022 to discuss its 2022–23 business plan. The plan includes audits of top hospital users of albumin, ongoing monitoring and evaluation of massive haemorrhage protocol quality metrics, and an analysis of immunoglobulin order requests. The Ministry will receive progress reports through the Network's mid-year and year-end reports and monitor how hospitals are participating in Network activities by March 2023.

### 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;*

**Status: In the process of being implemented by December 2024.**

### Details

In our 2020 audit, we found that no organization in Ontario had assumed central responsibility for assessing whether alternatives to blood could be used more cost-effectively. The Canadian Agency for Drugs and Technologies in Health's ability to study alternatives was hindered by a lack of publicly available information on the cost of immunoglobulins, the most common blood product. Canadian Blood Services, however, had 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 request should be made by all participating jurisdictions together.

In our follow-up, we found that Canadian Blood Services and provinces and territories have formed a working group to discuss this recommendation. The working group met in June 2021, October 2021 and January 2022 to consider collecting more patient-specific data such as age, diagnosis, treatment doses, frequency and duration as a way to assess cost-effective alternatives to blood. In addition, in October 2021, the National Advisory Committee on Blood and Blood Products proposed to work on a National Immunoglobulin Shortages Management Plan, including identifying alternatives to immunoglobulins. As part of this project, a literature review will be conducted, using funding approved by Health Canada, to examine alternative therapies for clinical conditions for which immunoglobulin is used, and to assess if and how other jurisdictions across Canada are using these alternatives. The work for the project will start in 2022/23 and will take a minimum of 18 months. The Ministry expects to finalize funding for this new plan with other provinces and territories, as well as Canadian Blood Services, by December 2024.

- use data on the uses of immunoglobulins, obtained under **Recommendation 3**, to inform areas of focus for the Ministry's decision-making on alternatives.

**Status:** In the process of being implemented by December 2024.

### Details

In our 2020 audit, we found that the Ministry did not collect and analyze clinical data from Ontario hospitals regarding conditions treated with drug alternatives compared with immunoglobulins. The Canadian Agency for Drugs and Technologies in Health's research had found that other drugs were as effective or more effective than immunoglobulins for certain health conditions.

In our follow-up, we found that the Ministry met with the Ontario Blood Consultation Group in November 2021 and the Ontario Immune Globulin Advisory

Panel in January 2022 to review business requirements for an online immunoglobulin ordering system, which is expected to go live in December 2024. The new online ordering system will capture information such as the immunoglobulins being ordered, in what dosages and for what medical conditions. The Ministry expects to use this data to inform its areas of focus for its decisions on using alternative therapies.

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

### Recommendation 9

*To evaluate the effectiveness of the Ontario Nurse Transfusion Co-ordinators 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;

**Status:** In the process of being implemented by December 2023.

### Details

In our 2020 audit, we found that the Ministry did not have information to compare transfusion rates of hospitals that had the Ontario Nurse Transfusion Coordinators program (Program) with those that did not as a way to measure the effectiveness of the Program.

In our follow-up, we found that the Ministry met with leads of the Program in January 2022 and April 2022 on how to collect data on and assess the Program. The Ministry was made aware that a number of nurse co-ordinators in the Program were reassigned to other areas of their hospitals to support the response to COVID-19 and a number of surgeries

were deferred or cancelled, making it difficult to collect data about the Program. The Ministry has determined that it is best to collect data and assess the Program when the impacts of COVID-19 on nurse deployment and surgeries are less significant.

Furthermore, the Ministry worked with the Ontario Blood Consultation Group to establish a new data strategy subcommittee to review and analyze blood use information. In March 2022, the Ministry met with a small group of people within the Consultation Group to determine the approach and mandate of this new subcommittee, and in July 2022 it held a brainstorming session with all members of the Consultation Group to determine the type of work this subcommittee will undertake once formed. The Ministry expects to request the subcommittee develop metrics that compare the results of hospitals with nurse co-ordinators to hospitals without nurse co-ordinators, and begin collecting and assessing this data by December 2023.

- *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.*

**Status:** In the process of being implemented by December 2023.

### Details

In our 2020 audit, we found that while the Program administrators collected 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. The Program administrators did not conduct performance reviews of nurses and could not easily estimate cost savings per site.

In our follow-up, we found that the Ministry has worked with the Ontario Blood Consultation Group to establish a new data strategy subcommittee to review and analyze blood use information. In March 2022, the Ministry met with a small group of people within

the Consultation Group to determine the approach and mandate of this new subcommittee, and in July 2022 it held a brainstorming session with all members of the Consultation Group to determine the type of work this subcommittee will undertake once formed. The Ministry expects to request the subcommittee develop metrics that compare the results of hospitals with nurse co-ordinators to hospitals without nurse co-ordinators, and begin collecting and assessing this data by December 2023.

### 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.*

**Status:** In the process of being implemented by December 2023.

### Details

In our 2020 audit, we found that the Ministry did not have processes to confirm that its payments for blood components and products were reasonable since it did not perform any reconciliations between what hospitals received and what the Ministry paid for. We surveyed hospitals and found some discrepancies between hospital records of what was received and Canadian Blood Services' records of what was shipped. Of the hospitals that responded to our survey, 5% reported a discrepancy in blood components and 7% reported a discrepancy in blood products.

In our follow-up, we found that the Ministry met with Canadian Blood Services and the Ontario Regional Blood Coordinating Network in March 2022 to discuss approaches to verify payments against products shipped. In June 2022, the Network was granted access to the disposition data hosted by Canadian Blood Services, which allows the Ministry to review a sample of data from different sources to

verify payments made to Canadian Blood Services. The Ministry, working with the Network, plans to establish a process to verify payments using existing data shared by Canadian Blood Services, and establish criteria to identify which hospital shipments to review, by December 2023.

### 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;*

**Status: Fully implemented.**

### Details

In our 2020 audit, we noted the Ministry did not use transfusion injuries and errors reported to the two national transfusion surveillance systems to monitor whether Ontario hospitals on the whole had fewer incidents year over year. It considered blood surveillance activities to be a responsibility of the Public Health Agency of Canada.

In our follow-up, the Ministry worked with the Public Health Agency of Canada and McMaster University to update the funding arrangement between parties involved in surveillance programs. In June 2022, the Ministry terminated its 2012 agreement with the Public Health Agency of Canada and confirmed with McMaster University that the Public Health Agency of Canada will be providing funding for the two transfusion surveillance programs directly to the University, and not through the Ministry, beginning 2021/22.

The Ministry noted that the Public Health Agency of Canada oversees the monitoring of transfusion errors. For transfusion injuries or reactions, the Adverse Transfusion Reactions Reporting Subcommittee (part of the National Advisory Committee on Blood and Blood Products) will review the 2021 survey responses from all provincial and territorial

surveillance system programs. It believes it can then use the survey responses to create a guidance document that will help provinces and territories, as well as the Public Health Agency of Canada, monitor transfusion surveillance data in the future and better assess accurate trends of serious transfusion incidents, including across Ontario.

- *monitor trends of serious transfusion incidents in Ontario;*

**Status: In the process of being implemented by March 2023.**

### Details

In our 2020 audit, we found that the Ministry obtained a summary of information from the Transfusion Transmitted Injuries Surveillance System (Injury Surveillance System) twice annually, but did not perform further analysis. The information included, for example, the total number of adverse transfusion events and education provided to transfusion medicine staff to help prevent transfusion events.

In our follow-up, we found that the Ministry had consulted with McMaster University, which administers the Injury Surveillance System in Ontario, in December 2020. Under the 2021–2024 funding agreement for the surveillance system with the Public Health Agency of Canada, McMaster also monitors trends of serious transfusion incidents in Ontario. The Ministry plans to review monthly and biannual reports on these incidents and share information with relevant stakeholders by March 2023.

- *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.*

**Status: In the process of being implemented by March 2023.**

### Details

In our 2020 audit, the Ministry had not assumed an active role in monitoring hospital activities related to

blood use in patients. It believed the federal government alone was responsible for monitoring adverse transfusion events in Ontario and the rest of the country.

In our follow-up, we found that the Ontario Regional Blood Coordinating Network visited hospitals to present transfusion injury data for 2020, which was reported by hospitals that participated in the Ontario surveillance program. It presented this information to 162 hospitals, including those that did not themselves participate in the surveillance program. The Ministry will work with the Network to establish a mechanism to share other information, such as transfusion errors that resulted in investigation reports, and communicate lessons learned to other hospitals by March 2023.

### 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;*

**Status: Fully implemented.**

### Details

In our 2020 audit, we noted that Canadian Blood Services did not break down its performance measures by province. This makes it difficult to gain insights specific to Ontario in areas such as product demand, productivity, and quality and safety.

In our follow-up, the Ministry noted that Canadian Blood Services created an annual report of performance metrics in October 2021. The report consolidates all performance indicators already provided to governments and presents them in the following format: actuals of each metric for the prior three years, current year actuals and targets, and targets for the next three fiscal years. As well, Canadian Blood Services reviewed all performance metrics to see

which ones could be broken down to show Ontario-specific results. It determined that it could only break down shipment data for red blood cell and platelets. In addition, Canadian Blood Services continues to provide Ontario-specific shipment data to the Ministry directly through an information-sharing portal on plasma protein and related products on a monthly basis.

- *regularly review and assess the effectiveness of national performance measures and revise accordingly with Canadian Blood Services through mechanisms available;*

**Status: In the process of being implemented by December 2023.**

### Details

In our 2020 audit, we found that some of the Canadian Blood Services-wide measures might not be readily presented to reflect Ontario-only performance, such as its core operations cost per unit of blood.

In our follow-up, we found that the Ministry established an internal process to regularly review reports from Canadian Blood Services and share updates with the Ministry's senior management. Dedicated ministry staff review the reports and prepare summary documents for filing and discussion purposes. The Ministry also shares these reports with other provinces and territories and addresses questions from them, if any, in meetings without Canadian Blood Services. The Ministry reviewed a draft of the annual performance report, provided input to Canadian Blood Services, which it incorporated. Canadian Blood Services will submit a completed 2023 annual report on performance metrics to ministries of health in 2023. The Ministry will share any additional feedback as part of its annual review of the final report by December 2023.

- *request Canadian Blood Services provide at least annual feedback on trends of Ontario results.*

**Status: Fully implemented.**

### Details

In our 2020 audit, we noted the Ministry of Health had never asked to see any province-specific results, even though they could provide valuable insights, such as whether Ontario hospitals could efficiently obtain red blood cells to help care for patients who required emergency surgeries and how often Ontarians were potentially exposed to a transmissible disease from a blood donation.

In our follow-up, the Ministry indicated that Canadian Blood Services has created an annual report of performance metrics in October 2021, which consolidates all Canadian Blood Services' performance indicators already provided to governments and presents them over a seven-year window including three prior years, current three-year actuals and targets, and targets for the next three fiscal years. Canadian Blood Services shares this with all provinces and territories via email and also through its information-sharing portal. Through this report, Ontario receives annual performance metrics, which includes Ontario-specific results on shipment data.

## COVID-19's Impact on Blood System

### 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;*

**Status:** In the process of being implemented by December 2024.

### Details

In our 2020 audit, we found that the National Emergency Blood Management Committee (Committee) had developed guidelines that were to be distributed to physicians to guide their prescribing practices and manage immunoglobulin shortages. However, in the event of shortages, the Committee's ability to effectively oversee and control distribution to those who needed it most was limited because the decision to distribute immunoglobulins to a patient remained with each individual physician. Ontario had not developed a plan that includes alternative medications to deal with the largely unprecedented situation of patients being required to go without immunoglobulins.

In our follow-up, we found that, in October 2020, the Ministry had instructed hospitals to comply with the Committee's directions by December 31, 2020, including following the Ontario Immune Globulin Utilization Guidelines and the Ontario Dosing Calculator for Immune Globulins. In addition, in October 2021, the National Advisory Committee on Blood and Blood Products developed a proposal for a National Immunoglobulin Shortages Management Plan, which would include identifying alternatives to immunoglobulins. As part of this project, a literature review will be conducted, using funding approved by Health Canada, to examine alternative therapies for clinical conditions for which immunoglobulin is used, and to assess if and how other jurisdictions across Canada are using these alternatives. The work for the project will start in 2022/23 and will take a minimum of 18 months. The Ministry expects to finalize funding for this new plan with other provinces and territories, as well as Canadian Blood Services, by December 2024.

- *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 within the Shortage Plan;*

Status: In the process of being implemented by December 2024.

### Details

In our 2020 audit, we found that Canadian Blood Services highlighted a risk that it might be unable to maintain an adequate supply of immunoglobulins as a result of the COVID-19 pandemic. As a result, the National Advisory Committee on Blood and Blood Products—which consists of health-care professionals with expertise in transfusion medicine and appointed by their respective provincial and territorial ministries, as well as Canadian Blood Services representatives—developed the National Immune Globulin Shortage Plan—Interim Guidance to serve as a framework to directly inform the development of a full national immunoglobulin shortage management plan once this short-term supply risk is addressed.

In our follow-up, we found that in October 2021, the National Advisory Committee on Blood and Blood Products developed a proposal for a new National Immunoglobulin Shortages Management Plan to address complex scenarios that could emerge in severe shortages. The Ministry expects to finalize a mechanism with other provinces and territories, as well as Canadian Blood Services, to fund this new plan by December 2024.

- *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.*

Status: In the process of being implemented by December 2024.

### Details

In our 2020 audit, we found that in the event of shortages, the ability to effectively oversee and control immunoglobulin distribution to those who need it most is limited. This was due to several factors; for example, Canadian Blood Services

and the National Emergency Blood Management Committee did not have information on how many patients at each Canadian hospital require immunoglobulins to survive, and the national immunoglobulin distribution guidelines were produced without provincial or federal data on how many patients required immunoglobulins to maintain their health versus to survive.

In our follow-up, we found that the Ministry had participated in discussions on the National Advisory Committee on Blood and Blood Products' proposal for a National Immunoglobulin Shortages Management Plan, and was working with other provinces and territories to determine a funding mechanism for the plan. The funding will support four key areas: ethical framework, triage and adjudication process, alternative therapies, and plan operationalization. If funding is received, the Ministry expects that, by December 2024, the National Advisory Committee will define a process by which to distribute immunoglobulins equitably in the event of a shortage, while taking into account ethical considerations.