

Chapter 5

Section 5.02

Blood Management and Safety

Standing Committee on Public Accounts Follow-Up on Value-for-Money Audit, 2020 Annual Report

On May 27, 2021, the Standing Committee on Public Accounts (Committee) held a public hearing on our 2020 audit of Blood Management and Safety. The Committee tabled a report on this hearing in the Legislature in February 2022. A link to the full report can be found at auditor.on.ca/en/content/standingcommittee/standingcommittee.html.

The Committee made 13 recommendations and asked the Ministry of Health (Ministry) to report back by June 2022. The Ministry formally responded

to the Committee on June 21, 2022, and again on August 12, 2022. The status of each of the Committee's recommended actions is shown in **Figure 1**.

We conducted assurance work between April 2022 and August 2022, and obtained written representation from the Ministry that effective October 31, 2022, it has provided us with a complete date of the status of the recommendations made by the Committee.

Figure 1: Summary Status of Actions Recommended in February 2022 Committee Report

Prepared by the Office of the Auditor General of Ontario

| 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| | | Fully Implemented | In the Process of Being Implemented | Little or No Progress | Will Not Be Implemented | No Longer Applicable |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 | 3 | 3 | | | | |
| Recommendation 3 | 5 | | 5 | | | |
| Recommendation 4 | 1 | | 1 | | | |
| Recommendation 5 | 1 | | 1 | | | |
| Recommendation 6 | 2 | | 2 | | | |
| Recommendation 7 | 2 | | 2 | | | |
| Recommendation 8 | 3 | | 3 | | | |
| Recommendation 9 | 1 | | 1 | | | |
| Recommendation 10 | 3 | 1 | 2 | | | |
| Recommendation 11 | 3 | 2 | 1 | | | |
| Recommendation 12 | 4 | | 4 | | | |
| Recommendation 13 | 1 | 1 | | | | |
| Total | 31 | 7 | 22 | 2 | 0 | 0 |
| % | 100 | 23 | 71 | 6 | 0 | 0 |

Overall Conclusion

As of October 31, 2022, 23% of the Committee's recommended actions had been fully implemented, and 71% of the recommended actions were in the process of being implemented. There has been little or no progress on two recommended actions.

Detailed Status of Recommendations

Figure 2 shows the recommendations and status details that are based on responses from the Ministry of Health, and our review of the information provided.

Figure 2: Committee Recommendations and Detailed Status of Actions Taken

Prepared by the Office of the Auditor General of Ontario

| Committee Recommendation | Status Details |
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| <p>Recommendation 1</p> <p>The Ministry of Health should:</p> <ul style="list-style-type: none"> establish a process to regularly receive information from Health Canada regarding which hospital blood banks and Canadian Blood Services donor centres are inspected and share the results with Ontario Health; <p>Status: Little or no progress.</p> <ul style="list-style-type: none"> better monitor compliance with federal regulations regarding blood storage by regularly reviewing Health Canada's hospital inspection reports to identify common risks and target these areas through education initiatives with hospitals. <p>Status: Little or no progress.</p> | <p>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.</p> <p>The Ministry had not been able to review any Health Canada inspection reports to identify common risk areas and target these problem areas in future education initiatives for hospitals because 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.</p> |
| <p>Recommendation 2</p> <p>The Ministry of Health and Ontario Health should work together to improve data-driven decision-making to manage the supply of blood components and products by:</p> <ul style="list-style-type: none"> regularly reminding hospitals of the requirement to report inventory to Canadian Blood Services; <p>Status: Fully implemented.</p> | <p>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. This particular inventory advisory was resolved by the first week of August 2021.</p> |

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| <ul style="list-style-type: none"> regularly assessing potential information technology solutions for blood management across multiple hospital systems, including Canadian Blood Services' plans to expand electronic ordering and McMaster University's blood-management data system; <p>Status: Fully implemented.</p> <ul style="list-style-type: none"> sharing Ontario data with Canadian Blood Services to improve insights and strengthen analysis. <p>Status: Fully implemented.</p> | <p>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. Also, 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.</p> <p>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 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.</p> |
| <p>Recommendation 3</p> <p>The Ministry of Health, working together with Ontario Health, should better manage the demand and supply of immunoglobulins by:</p> <ul style="list-style-type: none"> supporting the implementation of an electronic hospital ordering system for immunoglobulins; <p>Status: In the process of being implemented by December 2024.</p> <ul style="list-style-type: none"> eliminating the option of prescribing immunoglobulin where the Ontario Immune Globulin Utilization Guidelines do not recommend its use; <p>Status: In the process of being implemented by December 2024.</p> | <p>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 an 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. The Ministry expects the online immunoglobulin ordering system to go live by December 2024.</p> <p>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, it will aid in physicians not prescribing immunoglobulin where the provincial guidelines do not recommend its use.</p> |

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| <ul style="list-style-type: none"> • updating the Ontario Immune Globulin Utilization Guidelines to ensure immunoglobulins are only recommended for use where there is evidence to prove their effectiveness; Status: In the process of being implemented by December 2024. • working with the Ontario Regional Blood Coordinating Network to regularly educate physicians on the use of the Ontario Immune Globulin Utilization Guidelines; Status: In the process of being implemented by March 2023. • developing a system to monitor hospitals' adoption of the Ontario Immune Globulin Utilization Guidelines. Status: In the process of being implemented by March 2023. | <p>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, prescribing of immunoglobulins by physicians will align with the provincial guidelines. This ensures immunoglobulins are only recommended for use where there is evidence to prove their effectiveness.</p> <p>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. 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.</p> <p>The Ministry expects that the Network will develop a mechanism for tracking hospital adoption of the Guidelines and physician education by March 2023.</p> |
| <p>Recommendation 4</p> <p>The Ministry of Health should improve the tracking of transfusion errors and injuries by requesting that all hospitals report serious transfusion-related events. Status: In the process of being implemented by March 2023.</p> | <p>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.</p> <p>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.</p> <p>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. Also, the university has 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.</p> <p>The Ministry expects that all hospitals will begin reporting serious transfusion-related events by March 2023.</p> |

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| <p>Recommendation 5</p> <p>The Ministry of Health should request that Canadian Blood Services accelerate the plan to achieve 50% national plasma collection self-sufficiency, with clear timelines and provisions to monitor the plan's implementation.</p> <p>Status: In the process of being implemented by March 2023.</p> | <p>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. The Canadian Blood Services proposal outlined a plan for establishing eight additional plasma collection centres by 2023/24, in addition to three existing proof-of-concept sites, one of which is located in Ontario. Ontario and other provincial and territorial governments reviewed Canadian Blood Services' proposal and through the annual budget process 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.</p> <p>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.</p> |
| <p>Recommendation 6</p> <p>The Ministry of Health, in order to increase the effectiveness of the Ontario Regional Blood Coordinating Network (Network) guidelines on transfusion medicine best practices, should:</p> <ul style="list-style-type: none"> work with the Ontario Hospital Association to develop a plan to increase hospitals' participation in the Network; <p>Status: In the process of being implemented by March 2023.</p> <ul style="list-style-type: none"> monitor hospitals' adoption of the Network's best practices to help achieve better patient outcomes. <p>Status: In the process of being implemented by March 2023.</p> | <p>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.</p> <p>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.</p> |

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| <p>Recommendation 7</p> <p>The Ministry of Health, in order to encourage more effective, evidence-based use of blood components, blood products, and alternatives to blood, should:</p> <ul style="list-style-type: none"> work with the Canadian Agency for Drugs and Technologies in Health and Canadian Blood Services to periodically assess cost-effective alternatives to blood; <p>Status: In the process of being implemented by December 2024.</p> <ul style="list-style-type: none"> use data on the uses of immunoglobulins to inform areas of focus for the Ministry's decision-making on alternatives to blood. <p>Status: In the process of being implemented by December 2024.</p> | <p>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.</p> <p>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.</p> |
| <p>Recommendation 8</p> <p>The Ministry of Health, in order to better evaluate and improve the effectiveness of the Ontario Nurse Transfusion Coordinators Program (Program), should:</p> <ul style="list-style-type: none"> collect and analyze data on transfusion activities in hospitals with and without the Program, including the number of units of blood transfused, costs, and the number of patients transfused to determine value-for-money; <p>Status: In the process of being implemented by December 2023.</p> | <p>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.</p> <p>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.</p> |

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| <ul style="list-style-type: none"> request that the Program administrators establish performance indicators and outcome measures to demonstrate the effectiveness of the Program, and report this information on an annual basis; Status: In the process of being implemented by December 2023. explore mechanisms to require hospitals with the Program to follow best practices. Status: In the process of being implemented by December 2024. | <p>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.</p> <p>The Ministry noted that the Program is already an evidence-based program that supports best practices and improves outcomes of patients at participating hospitals by reducing exposure to transfusion when appropriate. As noted above, the Ministry has worked with the Ontario Blood Consultation Group to establish a new data strategy subcommittee to review and analyze blood use information. The Ministry expects to request the data strategy subcommittee develop metrics that compare the results of hospitals with nurse co-ordinators to hospitals without nurse co-ordinators, and discuss approaches that have supported best practices in hospitals with the Program. Based on this work, the Ministry will work with the Program leads and the data strategy subcommittee to establish mechanisms to require hospitals with the Program to follow best practices by December 2024.</p> |
| <p>Recommendation 9</p> <p>The Ministry of Health should establish a process to ensure its payments to Canadian Blood Services are for products shipped and received by Ontario hospitals on a regular basis, with underlying unit costs based on audited financial statements of Canadian Blood Services. Status: In the process of being implemented by December 2023.</p> | <p>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.</p> |
| <p>Recommendation 10</p> <p>The Ministry of Health and Ontario Health should work together to:</p> <ul style="list-style-type: none"> clarify responsibilities for monitoring transfusion surveillance data reported by hospitals; Status: Fully implemented. | <p>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.</p> <p>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.</p> |

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| <ul style="list-style-type: none"> monitor trends of serious transfusion incidents; Status: In the process of being implemented by March 2023. establish a plan for hospitals to share investigation reports of serious transfusion incidents on a timely basis. Status: In the process of being implemented by March 2023. | <p>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.</p> <p>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.</p> |
| <p>Recommendation 11</p> <p>The Ministry of Health should improve its ability to evaluate Canadian Blood Services' performance to provide safe blood to hospitals in a cost-efficient manner by:</p> <ul style="list-style-type: none"> requesting that Canadian Blood Services provide Ontario-specific results for national performance measures; Status: Fully implemented. regularly reviewing and assessing Canadian Blood Services' performance through national performance measures; Status: In the process of being implemented by December 2023. requesting that Canadian Blood Services provide information on Ontario's trends on an annual basis. Status: Fully implemented. | <p>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.</p> <p>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.</p> <p>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.</p> |

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| <p>Recommendation 12</p> <p>The Ministry of Health should prepare for a limited supply of immunoglobulins (Igs) and protect Ontarians by:</p> <ul style="list-style-type: none"> ensuring Ontario hospitals comply with the National Emergency Blood Management Committee’s action items, including developing shortage management plans, following Ig best practices and utilization guidelines, and updating laboratory information systems to accept all Ig brands and vial sizes carried by Canadian Blood Services; <p>Status: In the process of being implemented by December 2024.</p> <ul style="list-style-type: none"> exploring additional measures, if necessary, and consider enforcement mechanisms to ensure hospitals follow provincial utilization guidelines or guidelines within the National Immune Globulin Shortage Plan (Shortage Plan); <p>Status: In the process of being implemented by December 2024.</p> <ul style="list-style-type: none"> continuing to work with the National Emergency Blood Committee, the Ontario Emergency Blood Committee, Canadian Blood Services and the Provincial/Territorial Blood Liaison Committee to participate in a national response; <p>Status: In the process of being implemented by December 2024.</p> | <p>In October 2020, the Ministry had instructed hospitals to comply with the National Emergency Blood Management Committee’s directions by December 31, 2020, including following immunoglobulin best practices and utilization guidelines, and updating laboratory information systems to accept all immunoglobulin brands and vial sizes carried by Canadian Blood Services. 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 this 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.</p> <p>In October 2021, 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 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.</p> |

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| <ul style="list-style-type: none"> regularly updating calculations to estimate the number of patients in most critical need of Ig in the event of an amber or red advisory to ensure the equitable distribution of Ig across Ontario. <p>Status: In the process of being implemented by December 2024.</p> | <p>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.</p> |
| <p>Recommendation 13</p> <p>The Ministry of Health should confirm that the production of the immunoglobulin manufacturing facility being built in Quebec will be in a position to serve all of Canada and ensure the facility has national outreach.</p> <p>Status: Fully implemented.</p> | <p>The Ministry noted that according to Grifols' press release in October 2020, Grifols will become the only large-scale commercial manufacturer of plasma products in Canada and will begin operating in 2023 once it obtains the necessary licences and authorizations. As an independent corporation, Grifols has full control of the strategic direction of its Montreal facility. The Ministry will continue to engage with Canadian Blood Services on any developments regarding Grifols' Montreal facility. The Ministry further noted that Canadian Blood Services will actively monitor Grifols' progress in operationalizing its Montreal facility. Any future contractual relationship, including the purchase of fractionation services at Grifols' Montreal facility, must be a result of a market-competitive process led by Canadian Blood Services.</p> |