

SCOPA Summary Status Table in Response to the Report of the Auditor General of Ontario on Blood Management and Safety Audit

Date: March 10, 2021

Auditor's Recommendation	Completed undertaking	Outstanding undertaking (including timeline)
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: 1.1 establish a mechanism to discuss and receive information from Health Canada to define which Ontario hospital blood banks and Canadian Blood Services blood donor centres in Ontario will be inspected by Health Canada, and to obtain and share the results of the hospital inspections with Ontario Health; and 1.2 regularly review Health Canada inspection reports to identify common risk areas and target these problematic areas in their future education initiatives for hospitals.	Ministry response in the Office of the Auditor General of Ontario (OAGO) audit report in December 2020: Health Canada has responsibility for the inspection of blood banks in all Canadian jurisdictions for their compliance under the Blood Regulations in federal Food and Drugs Act. The Ministry is pleased to note that there have been no non-compliance reports on Ontario hospitals since the initiation of Health Canada inspections in 2015. The Ministry supports a more systematic review of findings from Health Canada inspections of Ontario hospitals through enhanced communication. The findings will facilitate the identification of areas for improvement, which will enhance educational opportunities for Ontario hospitals. 1.1 – Completed to date: Health Canada has confirmed to the Ministry there is federal policy in place they use to select the hospitals and Canadian Blood Services facilities for inspection under the federal blood regulations. Relevant individuals within the Ministry of Health were identified and their names were provided to Health Canada to receive the results of hospital inspections. Health Canada agreed to begin communicating the result. 1.2 – Completed to date: The Ministry met with the Ontario Regional Blood Coordinating Network (ORBCoN) and discussed mechanisms for them to incorporate hospital inspection report findings from Health Canada within the joint annual Canadian Blood Services / ORBCoN hospital site visits, and the anticipated resource needs to support this activity.	1.1 – Outstanding <u>Timeline for completion – December 2022 (On track)</u> The Ministry will establish communication between Health Canada and Ontario Health (OH) for OH to receive inspection results of Ontario hospital blood banks. 1.2 – Outstanding <u>Timeline for completion – December 2022 (On track)</u> The Ministry will work with ORBCoN on: 1) incorporating hospital inspection report findings from Health Canada within the joint annual Canadian Blood Services / ORBCoN hospital site visits for those hospitals that have been inspected; and 2) how ORBCoN might begin identifying themes of risk identified through Health Canada inspection reports to incorporate within their future educational events with hospitals.

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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: 2.1 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; 2.2 actively monitor Canadian Blood Services' exploration of an online ordering system for hospitals in British Columbia; 2.3 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; and 2.4 work with Canadian Blood Services by providing Ontario data to further develop its forecasting approaches, including factors such as patient demographics.	Ministry response in the OAGO audit report in December 2020: The Ontario Regional Blood Coordinating Network (Network), in collaboration with Canadian Blood Services, performs annual site visits in Ontario hospitals to discuss their performance in relation to best practices and utilization of blood components and products. The Network leverages the data that is currently available to facilitate informed decision-making and promote the adoption of best practices in blood management. As a result, many hospitals demonstrate improvements, year over year, with respect to their blood utilization. The Ministry acknowledges that further improvements to data collection in the management of blood components and plasma protein products would support decision-making and planning. The Ministry supports an interim step to improve hospital reporting of blood component and plasma protein product inventory when they are at risk or in shortage. This will better inform collaborative efforts with Canadian Blood Services in addressing shortages, with a longer-term goal of identifying resources for improved data collection and analysis. The Ministry will also consider the impacts of additional data collection on direct service provision within hospitals and seek to balance both activities. 2.1 – Completed to date: For blood and blood components, the Ontario Contingency Plan for Blood Shortages requires all hospitals to report their inventory to Canadian Blood Services through their Blood Component and Disposition System during a shortage advisory. During a shortage, Canadian Blood Services reports to the Ministry hospital compliance for reporting inventories. Hospitals are now able to report inventories to Canadian Blood Services according to the terms of an immune globulin shortage advisory. Currently there are no shortages in blood components or blood products. 2.2 – Completed to date: Canadian Blood Services has reported to the Ministry, and other Provincial and Territorial (PT) jurisdictions, that it plans to expand the BC piloted online	2.1 - Outstanding <u>Timeline for completion – December 2021</u> The ministry is planning to send a communication to hospitals reminding of the requirements under the Ontario Contingency Plan to report weekly during a shortage advisory. 2.2 – Outstanding <u>Timeline for completion – December 2023</u> <u>(On track)</u> The Ministry continues to monitor Canadian Blood Services plans to expand the BC piloted online ordering system to confirm when it will be available in all hospitals across the country that order blood and blood products from Canadian Blood Services. 2.3 – Outstanding <u>Timeline for completion – December 2024</u> <u>(On track)</u> The Ministry will discuss with the McMaster University about their previously submitted proposal to expand their blood database province-wide, from which the appropriate data can be made available. Funding options will need to be explored which will influence the direction and the timeline of this recommendation. 2.4 – Outstanding <u>Timeline for completion –December 2025+</u> <u>(On track)</u>

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	ordering system to make it available in all hospitals across the country that order blood and blood products from Canadian Blood Services. 2.3 – Completed to date: In January 2021, the Ontario Blood Consultation Group (comprised of experts in transfusion medicine and Ontario's blood utilization programs) was provided an overview by the Ministry on the audit recommendations and to solicit feedback on their priorities for implementing the audit recommendations, including this one. 2.4 – Completed to date: The Ministry has planned for initial meetings with Canadian Blood Services to determine whether an Ontario data approach for patient-level data or a broader provincial / territorial approach should be taken.	Timelines for implementation depend on whether a multi-provincial / territorial data approach for collecting patient-level data or an Ontario approach is taken. A Canadian Blood Services - PT Working Group is being discussed.

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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: 3.1 collect more complete data from hospitals on how immunoglobulins are being used and identify emerging conditions that may warrant inclusion in provincial utilization guidelines; 3.2 eliminate the option of prescribing immunoglobulin where the Ontario Immune Globulin Utilization Guidelines (Guidelines) state that the product is not recommended for use. 3.3 educate physicians and monitor Ontario hospitals' adoption of the Guidelines; and 3.4 assess potential tools, including updating the Guidelines as needed to prohibit uses where there is no credible evidence that they improve health outcomes, to achieve more appropriate use of blood products – particularly immunoglobulins – according to patient need.	Ministry response in the OAGO audit report in December 2020: The Ministry regularly consults with experts in transfusion medicine and blood management to identify opportunities for improvement to Ontario's blood system. Based on past consultations, the Ministry has initiated work to implement an electronic immune globulin ordering system to manage utilization of immune globulins in Ontario hospitals, in alignment with the Ontario Immune Globulin Utilization guidelines. It is expected that this initiative will address the recommendations made by the Auditor General, as the proposed system. This will help in collecting more appropriate information such as the medical conditions being treated with immune globulin, and the volumes of immune globulin ordered to improve forecasting. Furthermore, the information obtained through the system will better inform the Ontario Immune Globulin Utilization Guidelines and educational efforts relating to the guidelines. 3.1 – Completed to date: Prior to the release of the OAGO audit report in December 2020, the Ministry prepared a draft business change proposal outlining the high-level business requirements for such a hospital electronic immune globulin ordering system, which could be expanded for use with other plasma protein products and would provide patient-level information on medical condition and dosing. 3.2 – Completed to date: Please refer to update for 3.1. An electronic immune globulin ordering system would be needed to fully eliminate the option of prescribing immunoglobulin where the Ontario Immune Globulin Utilization Guidelines (Guidelines) state that the product is not recommended for use. As recently as October 2020, the Ministry has communicated the requirement for hospitals to follow the Ontario Immune Globulin Utilization Guidelines. 3.3 – Completed to date:	3.1 – Outstanding <u>Timeline for completion – December 2024 (On track)</u> The Ministry continues to develop the fulsome requirements for hospital electronic immune globulin ordering system. The requirements will determine whether an existing system could be adapted for this use, or whether a new system is required. This information will determine timelines for implementation and the funding requirements for a system. 3.2 – Outstanding <u>Timeline for completion - December 2024 (On track)</u> Please refer to update for 3.1 for implementation considerations. 3.3 – Outstanding <u>Timeline for completion - December 2022 (On track)</u> The Ministry will work with ORBCoN on: 1) incorporating physician education on the use of the Ontario Immune Globulin Utilization Guidelines into their workplan; and 2) developing/confirming a mechanism for tracking hospital adoption of the Guidelines. 3.4 – Outstanding

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	The Ministry met with the Ontario Regional Blood Coordinating Network (ORBCoN) and discussed the need to develop a mechanism for hospitals' adoption of the Ontario Immune Globulin Utilization Guidelines and the anticipated resource needs to support this activity. 3.4 – Completed to date: The Ministry has reviewed this recommendation and determined that it would be best to bring this item forward for discussion and consideration by other PT health ministries.	<u>Timeline for completion - December 2023 (On track)</u> The Ministry will raise in April 2021 with PT health ministries whether a national approach to updating evidence-based reviews of immune globulins would be best done on behalf of all jurisdictions to avoid duplication of efforts and determine next steps.

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4.0 To better manage the demand and supply of immunoglobulins so that they are available for Ontarians who need them most and to avoid the costs of wasted product, we recommend that the Ministry of Health, in conjunction with Canadian Blood Services, monitor the international situation regarding the supply and demand of immunoglobulins given the impact of COVID-19 on supply.	Ministry response in the OAGO audit report in December 2020: The Ministry will continue to seek leadership of Canadian Blood Services in monitoring the international situation regarding the supply and demand of immunoglobulins given the impact of COVID-19 on global supply. It is important to note that the actions taken to date by Canadian Blood Services and the Ministry have mitigated against these impacts. Both organizations will continue to leverage lessons learned from these efforts and around the world to secure a better supply and manage demand based on appropriate use of the product. 4.0 – Completed to date: Canadian Blood Services regularly provides updates PT health ministries on the national and international situation regarding the supply and demand of immunoglobulins, including through updates provided to the PT health ministries and the National Emergency Blood Management Committee. More recently, Canadian Blood Services provided updates to Provincial and Territorial Ministries of Health on immunoglobulin demand and supply in October 2020 to highlight the potential for an immunoglobulin supply shortage and global price shocks. The existing forums and processes have been reviewed in light of the OAGO recommendation, and it has been determined by Canadian Blood Services and the Ministry that this recommendation has been appropriately addressed.	

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To improve the tracking of transfusion errors and injuries, we recommend that the Ministry of Health (Ministry), in consultation with Ontario Health: 5.1 establish a plan to raise awareness and require all hospitals to report serious transfusion-related incident data to the Ministry; and 5.2 monitor compliance with the plan on an annual basis.	Ministry response in the OAGO audit report in December 2020: The Public Health Agency of Canada and Canadian Blood Services have complementary accountabilities in the surveillance of adverse transfusion events and transfusion errors by hospitals across Canada. The Ministry has continuously invested in programs led by these national organizations to help safeguard patients in Ontario. Specifically, the Ministry funds Ontario hospitals for their participation in national transfusion surveillance of adverse transfusion events and Canadian Blood Services for surveillance relating to infection through blood-borne pathogens via transfusion and severe adverse transfusion events. The Ministry will explore ways to complement these activities by requesting Ontario hospitals to report serious transfusion-related incidents to the Ministry, while raising awareness of their reporting requirements, in order to improve the safety of transfusion practices in the province. 5.1 – Completed to date: The Ministry met with the Ontario Regional Blood Coordinating Network (ORBCoN) and discussed the need to develop a mechanism for raising awareness of both the Transfusion Transmitted Injuries Surveillance System (TTISS) and the Transfusion Errors Surveillance System (TESS). As a result, a meeting between ORBCoN, TTISS and TESS, and clinical experts has been scheduled to discuss data collection beyond what is currently being collected, and to determine an appropriate approach for reporting. 5.2 – Completed to date: Please refer to update for 5.1.	5.1 – Outstanding <u>Timeline for completion - December 2022 (On track)</u> Plans will be developed to address this recommendation following consultations with stakeholders. 5.2 – Outstanding <u>Timeline for completion - December 2022 (On track)</u> Monitoring compliance will require implementation plan to be developed under 5.1 which is on track.

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6.0 To protect the supply of blood products needed to meet the needs of patients who rely on them, in light of continuing lessons and experiences from the COVID-19 pandemic and its impact on plasma sufficiency in Canada, we recommend that the Ministry of Health request that Canadian Blood Services expediently update the plan to achieve the 50% national self-sufficiency goal, specifying actions and timelines to reach this goal, with monitoring and reporting back on the plan.	Ministry response in the OAGO audit report in December 2020: The Ministry supports ongoing collaboration with other provincial and territorial governments through the existing Provincial/Territorial Blood Liaison Committee, and with Canadian Blood Services, on how best to address Canada's sufficiency in plasma used in producing immune globulins, and on addressing the potential shortage of immune globulin. In 2019, the Ministers of Health across all jurisdictions (excluding Quebec) approved a plan to introduce three proof of concept plasma collection sites in Canada. With the launch of these sites well underway, further addressing this situation will require continuous reliance on the expertise and experience of Canadian Blood Services in the collection of plasma, in addition to significant investments to better secure the supply chain for this product that is important in the treatment of people with rare health conditions. 6.0 – Completed to date: As per its mandate and accountability to Canadians, Canadian Blood Services is committed to increasing Canada's sufficiency in plasma for immunoglobulin. Discussion and formal approval of funding for additional plasma collection beyond the three proof of concept sites approved in 2019 is ongoing as per Canadian Blood Services' annual budget process. In November 2020, Canadian Blood Services and provinces and territories also supported having a national policy discussion, convened by Health Canada, on plasma self-sufficiency.	6.0 – Outstanding <u>Timeline for completion – December 2022 (On Track)</u> Provincial/Territorial Ministers of Health are expected to approve Canadian Blood Services' 2021-22 budget in March 2021 which includes funding of Canadian Blood Services' plan for further plasma collection in 2021-2022. Further, it is anticipated that Canadian Blood Services and provinces and territories will engage in a national policy discussion, convened by Health Canada, on plasma self-sufficiency, including a discussion on commercial plasma collections, by December 2021.

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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: 7.1 consult with the Ontario Hospital Association to develop a plan to increase hospitals' participation in Network activities and adoption of its best practices and to make required information available to the Network; and 7.2 monitor hospitals' participation in Network activities to ensure the adoption of best practices improve over time.	Ministry response in the OAGO audit report in December 2020: The Ministry values the work of the Ontario Regional Blood Coordinating Network (Network) which saved \$7.7 million in 2019/20 through reduced wastage of blood components by redistributing to hospitals where they can be used before expiry; and in collaboration with Canadian Blood Services, performing annual site visits in Ontario hospitals. This work has resulted in improvements to hospital performance in relation to best practices and utilization of blood components and products; the Network is recognized for as a leader in Canada for promoting and facilitating system-wide improvements. While the Ministry supports all of the work that the Network has done to date, the Ministry supports continued efforts – including consulting with the Ontario Hospital Association – to enhance the adoption of transfusion best practice and plasma protein product utilization guidelines in Ontario hospitals, and to monitor hospital participation in their adoption to help achieve better patient outcomes across the province. 7.1 – Completed to date: The Ministry met with the Ontario Regional Blood Coordinating Network (ORBCoN) to start an ongoing discussion to determine how to measure hospital's participation and adoption of their posted clinical best practice guidelines. Consultation with the Ontario Hospital Association (OHA) as recommended by the OAGO will also be considered as part of this discussion. 7.2 – Completed to date: Please refer to update for 7.1.	7.1 – Outstanding <u>Timeline for completion – December 2022 (On Track)</u> Outcome of discussions with ORBCoN and OHA will determine the implementation timeline of this recommendation. 7.2 – Outstanding <u>Timeline for completion – December 2022 (On Track)</u> Development of a plan under 7.1 will determine how to monitor hospital participation and adoption of ORBCoN's posted best practices.

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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: 8.1 work with both the Canadian Agency for Drugs and Technologies in Health and Canadian Blood Services to periodically assess cost-effective alternatives to blood; and 8.2 use data on the uses of immunoglobulins, obtained under Recommendation 3, to inform areas of focus for the Ministry's decision-making on alternatives.	Ministry response in the OAGO audit report in December 2020: Recognizing that blood and its derivatives are biological products that always carry potential risks to patients, the Ministry supports a renewed effort in identifying alternatives that are either able to help avoid or reduce the need for blood transfusions as well as providing alternative cost-effective forms of treatment for plasma protein products such as immune globulin. The Ministry will require the expertise of the Canadian Agency for Drugs and Technologies in Health and Canadian Blood Services to provide the best advice on these alternatives. Given that these organizations are national service providers, the Ministry will work with its provincial and territorial partners to ensure this work is not duplicated in each jurisdiction. 8.1 – Completed to date: The Ministry has had initial discussion with Canadian Blood Services on this work and plans to raise the recommendation with PT health ministries to seek initial feedback on whether this effort can be coordinated nationally. 8.2 – Completed to date: Please refer to update for 3.1.	8.1 – Outstanding <u>Timeline for completion – December 2022 (On Track)</u> Once Canadian Blood Services and PT health ministries have come to consensus on whether this effort will be managed nationally, CADTH will be engaged by the Ministry to determine next steps. 8.2 – Outstanding <u>Timeline for completion – December 2025 (On Track)</u> Please refer to update for 3.1. The areas of focus for the Ministry will be determined after the implementation of 3.1.

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To evaluate the effectiveness of the Ontario Nurse Transfusion Coordinators in improving patient outcomes and reducing the cost of surgical procedures, we recommend that the Ministry of Health: 9.1 collect and assess data on a representative selection of transfusion activities, associated with specific surgical procedures, including data on the number of units of blood transfused, the estimated cost to transfuse and the number of patients transfused, in hospitals with program nurse co-ordinators compared to hospitals without program nurse co-ordinators; and 9.2 request the Program administrators develop more comprehensive performance indicators and outcome measures that demonstrate the success of this program, establish targets, collect data from program nurses to measure against targets, and report this information annually to the Ministry.	Ministry response in the OAGO audit report in December 2020: A peer-reviewed publication in 2014 with estimated cost savings of nearly \$40 million annually, based primarily on data from 2011, has highlighted the benefits of the Ontario Nurse Transfusion Coordinators program to the broader health care system. The Ministry would anticipate the savings achieved today would be even greater based on inflation and rising system costs over the last decade. To continue to improve best practices, the Ministry supports conducting an assessment of the program to evaluate its effectiveness in relation to patient outcomes and health system costs, and using findings from the assessment to better inform the current performance measures and reporting. 9.1 – Completed to date: In January 2021, the Ontario Blood Consultation Group (comprised of experts in transfusion medicine and Ontario's blood utilization programs) was provided an overview by the Ministry on the audit recommendations and to solicit feedback on their priorities for implementing the audit recommendations, including this one. 9.2 – Completed to date: Please refer to update for 9.1.	9.1 – Outstanding <u>Timeline for completion – December 2023 (On Track)</u> The Ministry will discuss with Ontario Nurse Transfusion Coordinators program their proposal to address the audit recommendation. Outcome of this discussion will influence the direction and the timeline of this recommendation. 9.2 – Outstanding <u>Timeline for completion – December 2023 (On Track)</u> Outcome of this discussion will influence the direction and the timeline of this recommendation.

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10.0 To confirm its payments to Canadian Blood Services are reasonable and commensurate with blood shipped to Ontario hospitals, we recommend that the Ministry of Health put a process in place to verify that payments to Canadian Blood Services are for products shipped and received by Ontario hospitals, with underlying unit costs that are based on audited financial statements of Canadian Blood Services.	Ministry response in the OAGO audit report in December 2020: The Ministry recognizes that blood and blood products are valuable healthcare resources and has continuously sought to ensure that these resources are used appropriately by hospitals. Through Ontario's lower-than-average per capita utilization of blood and blood products, the Ministry is confident that Ontario's blood utilization programs have contributed to conservation and more appropriate use across Ontario hospitals. As utilization of blood and blood products continues to increase year over year due to the growing multitude of treatment modalities and their importance for emergency procedures, the Ministry also recognizes the value of audits to help identify opportunities for operational efficiencies and to monitor expenditure. As such, the Ministry will initiate an audit of a sampling of Ontario hospitals to verify that payments from the Ministry to Canadian Blood Services are for products both shipped to, and received by, Ontario hospitals, to assist in identifying any operational issues, if any, and to provide post-payment verification. 10.0– Completed to date: In January 2021, the Ontario Blood Consultation Group (comprised of experts in transfusion medicine and Ontario's blood utilization programs) was provided an overview by the Ministry on the audit recommendations and the Ministry solicited feedback on their priorities for implementing the audit recommendations, including this one.	10.0 – Outstanding <u>Timeline for completion – December 2022 (On Track)</u> The Ministry will initiate discussions with Canadian Blood Services on a mechanism for verifying blood and blood product orders from hospitals against actual shipments.

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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: 11.1 clarify where responsibility should reside for monitoring transfusion surveillance data reported by hospitals; 11.2 monitor trends of serious transfusion incidents in Ontario; and 11.3 establish a plan with Ontario hospitals for them to share the investigation reports of serious transfusion incidents on a timely basis, which includes communicating any lessons learned to other hospitals	Ministry response in the OAGO audit report in December 2020: While blood components used in hospital transfusions are biological products with the potential of risk to patients, they are used in the context of anticipated benefits to patient outcomes. Because of this, transfusion events and errors will always be a risk that needs continual vigilance. The Public Health Agency of Canada (PHAC) and Canadian Blood Services have complementary accountabilities in the surveillance of adverse transfusion events and transfusion errors by hospitals to help safeguard patients in Ontario and across Canada. The Ministry recognizes the distinct, but important roles played by PHAC, Canadian Blood Services and individual hospitals. To help clarify where responsibility should reside for monitoring transfusion surveillance data reported by hospitals, the Ministry will take steps to establish a plan to promote awareness of those responsibilities, require all hospitals to report serious incident data and monitor trends of transfusion incidents to help assess whether action is needed based on the trend. 11.1 – Completed to date: The Ministry met with the Ontario Regional Blood Coordinating Network (ORBCoN) and discussed the need to develop a mechanism for monitoring transfusion surveillance data by hospitals, with ORBCoN potentially taking this role. 11.2 – Completed to date: Please refer to update for 11.1. 11.3 – Completed to date: As per 11.1, after the role of ORBCoN in monitoring transfusion surveillance data is determined, a plan will be established 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.	11.1 – Outstanding <u>Timeline for completion - December 2022 (On Track)</u> ORBCoN's workplan and resource needs will be examined further with the Ministry to determine if they will take on the role for monitoring transfusion surveillance data. 11.2 – Outstanding <u>Timeline for completion - December 2022 (On Track)</u> Should ORBCoN take on the role outlined in 11.1, the monitoring of trends, reporting of trends to the Ministry and hospitals, and using the trend information to inform their educational activities will be included in their workplan. 11.3 – Outstanding <u>Timeline for completion - December 2022 (On Track)</u> As per 11.1, after the role of ORBCoN in monitoring transfusion surveillance data is determined, a plan will be established 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.

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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: 12.1 request Canadian Blood Services break out Ontario results for national measures that can reflect Canadian Blood Services' performance relevant to Ontario; 12.2 regularly review and assess the effectiveness of national performance measures and revise accordingly with Canadian Blood Services through mechanisms available; and 12.3 request Canadian Blood Services provide at least annual feedback on trends of Ontario results.	Ministry response in the OAGO audit report in December 2020: Canadian Blood Services performance is measured as a national system operator and not on behalf of any individual provincial or territorial funder. Ontario remains committed to the philosophy that Canadian Blood Services must ensure the quality, safety, value and efficacy of the blood system for all Canadians. In consultation with Canadian Blood Services, the Ministry will seek to clarify which national performance measures can be provided by provincial/territorial jurisdiction for Ontario. 12.1 – Completed to date: In February 2021, the Ministry presented this audit recommendation to the PT health ministries for consultation to review the various performance measures. 12.2 – Completed to date: Please refer to update for 12.1 12.3 – Completed to date: Please refer to update for 12.1.	12.1 – Outstanding <u>Timeline for completion - December 2022 (On Track)</u> Following consultation with PT health ministries to review the various performance measures, a Canadian Blood Services -PT working group will be established to identify relevant additions or adjustments that would be meaningful to governments, including establishing a process for regular review, assessment, and at least annual feedback on trends of results. The Ministry will seek to clarify which national performance measures can be provided by provincial/territorial jurisdiction for Ontario. 12.2 – Outstanding <u>Timeline for completion - December 2022 (On Track)</u> Please refer to update for 12.1 12.3 – Outstanding <u>Timeline for completion - December 2022 (On Track)</u> Please refer to update for 12.1

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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: 13.1 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; 13.2 work with the National Emergency Blood Committee, the Ontario Emergency Blood Committee, Canadian Blood Services and the Provincial/Territorial Blood Liaison Committee to participate in a national response as recommended with the Shortage Plan; and 13.3 clarify how Canadian Blood Services and all provincial and territorial governments will ensure equitable distribution of immunoglobulins to patients in most critical need in the event of a sudden shortage so that the treatment needs of Ontario patients are appropriately addressed.	Ministry response in the OAGO audit report in December 2020: In August 2020, the Conference of Deputy Ministers approved the National Plan for the Management of Shortages of Immunoglobulin (Ig)—Interim Guidance to serve as a framework to directly inform the development of a full national Ig shortage management plan once this short-term supply risk is addressed. Work on the full plan is expected to be conducted over the next 24 months and work is currently being done to implement elements of the interim guidance plan to be prepared for, and mitigate against, a potential immunoglobulin shortage in 2021. Given the National Immune Globulin Shortage Plan has been endorsed by all provincial and jurisdictional governments (excluding Quebec, which operates Héma-Quebec separately), Ontario is committed to working with the National Emergency Blood Committee, the Ontario Emergency Blood Committee, Canadian Blood Services and the Provincial/Territorial Blood Liaison Committee to participate in the national response, as recommended within the National Immune Globulin Shortages Plan. The Ministry supports introducing any needed further measures across Ontario hospitals to ensure that immunoglobulins are provided to patients according to provincial utilization guidelines, or guidelines within the National Immune Globulin Shortage Plan. The Ministry will continue to collaborate with all partners in the system to ensure that immunoglobulin is available to Ontarians most in need. 13.1 – Completed to date: In October 2020, the National Emergency Blood Management Committee (NEBMC) released a communication to all hospitals in Canada requesting that they take a number of actions to prepare for a potential shortage of specific vial sizes and brands of immunoglobulins. These steps included: Reviewing the <i>National Plan for Management of Shortages of Immunoglobulin Products</i>;	13.1 – Outstanding <u>Timeline for completion – December 2025 (On Track)</u> The Ministry will continue to attend NEBMC and host OEBMC meetings to address any changes in immune globulin supply and demand through its other committees. As for the electronic immune globulin ordering system for hospitals, please refer to update for 3.1. 13.2 – Outstanding <u>Timeline for completion – December 2021 (On Track)</u> The Ministry continues working with Canadian Blood Services, OEBMC, the Ontario Regional Blood Coordinating Network (ORBCoN), the Immune Globulin Advisory Panel, and the Ontario Contingency Planning Working Group to address participation in a national response, as well as addressing Ontario-specific actions needed in contributing to the national effort. 13.3 – Outstanding <u>Timeline for completion – December 2022 (On Track)</u> The data approach proposed by the Ministry will be shared with the National Advisory Committee on Blood and Blood Products for verification and will serve as a mechanism for ensuring equitable distribution through a

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	- Working with their provincial emergency blood management committee to develop shortage management plans; - Ensuring the utilization of Ig products follows best practices and PT guidelines; and - Confirming hospitals' laboratory information systems are configured to accept all Ig brands and vial sizes carried by Canadian Blood Services The Ministry subsequently, in conjunction with the Ontario Emergency Blood Management Committee, issued a communication to all Ontario hospitals directing them to comply with these directions by December 31, 2021 including that all hospitals following the Ontario Immune Globulin Utilization Guidelines and the Ontario Dosing Calculator for Immune Globulins. 13.2 – Completed to date: Prior to, and following, the release of the OAGO report in December 2020, Ontario's chair of the OEBMC and other clinical representatives from Ontario have been attending NEBMC meetings since October 2020 to mitigate against an anticipated shortage of immune globulin. OEBMC has had several calls following NEBMC meetings to determine if there is any Ontario-specific response needed based on the NEBMC direction. The Ministry has been working with Canadian Blood Services, OEBMC, the Ontario Regional Blood Coordinating Network (ORBCoN), the Immune Globulin Advisory Panel, and the Ontario Contingency Planning Working Group to address participation in a national response, as well as addressing Ontario-specific actions needed in contributing to the national effort. 13.3 – Completed to date: The Ministry has developed an approach for estimating the volumes of immune globulin and number of patients by medical condition in Ontario to determine the number of patients who would receive immunoglobulins during an amber or red phase shortage declaration by NEBMC.	national adjudication body during a red phase shortage declaration.

SCOPA Summary Status Table in Response to the Report of the Auditor General of Ontario on Blood Management and Safety Audit

Date: March 10, 2021

Auditor's Recommendation	Completed undertaking	Outstanding undertaking (including timeline)
	As part of this approach, the Ministry has requested BC and Atlantic Canada provide their respective provincial data as these jurisdictions have systems in place for information collection. Further, ORBCoN has requested data from a number of Ontario hospitals to determine whether patient mix and volume of immune globulin use by medical condition vary with the BC and Atlantic Canada data that has been requested.	