

National Immune Globulin (IG) Shortage Simulation: Saskatchewan Participation Summary

February 13-14, 2025

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Saskatchewan IG Stewardship Program

Immune globulin (IG) is a human source blood product derived from the plasma of thousands of donors. Global supply of this product is limited due to the rising demand for this therapeutic treatment. Given the potential risk of supply disruptions, Canadian Blood Services has emphasized the need for responsible utilization of Ig products, including both intravenous Ig (IVIG) and subcutaneous Ig (SCIG).

Annual healthcare dollars spent on IG continues to rise. To better understand IG utilization trends and improve stewardship of IG, the provincial-territorial ministries of health from Alberta, Saskatchewan and Manitoba invested in the development of the '*Criteria for the Clinical Use of Immune Globulin*' recommendations document. First published in 2020, the purpose of this document was to ensure alignment of Ig use with best practices and endorsed dose adjustments based on adjusted body weight (ABW) for high body mass index adult patients to optimize dosing efficacy.

The Saskatchewan IG Stewardship Program was launched November 1, 2021, with the introduction of the **Adult 10% Intravenous Immune Globulin Pre-Printed Order Set (POS)**, incorporating the [Albert Health Services Adjusted Body Weight Calculator](#) and establishing a patient registry to monitor Ig use. The Program expanded in June 2023 to include the **Pediatric 10% Intravenous Immune Globulin POS**, further strengthening Ig stewardship efforts. The '*Criteria for the Clinical Use of Immune Globulin, 2nd Edition February 2022*' serves as the foundation for screening and approval of IVIG orders. The IG Nurse Navigators are essential team members, who are able to interpret clinical data, support evidence-based decision-making, and facilitate communication among care teams directly contributing to improved patient outcomes and optimized resource use. SCIG requests are not yet actively screened for appropriateness by the Program.

In recognition of the ongoing potential for national and global Ig supply challenges, the Canadian Blood Services – Provincial/Territorial Blood Liaison Committee (CBS-PTBLC) worked collaboratively with the National Advisory Committee on Blood and Blood Products (NAC) to develop the '*The National Plan for Management of Shortages of Immunoglobulin (Ig) Products*'. (The IG Shortages Plan) A project management team from Canadian Blood Services coordinated multidisciplinary stakeholder teams with national representation to participate in specialty-specific consultative sessions to prioritize Ig allocation in the event of varying degrees of product shortage. The final document was approved by the Council of Deputy Ministers and published on May 30, 2024.

National Ig Shortage Simulation Exercise

To assess national preparedness for a potential IG shortage, Canadian Blood Services coordinated a planned **IG Shortage Simulation Exercise**. Held on **February 13-14, 2025**, an “**Amber Phase**” IG shortage simulation was declared, indicating a hypothetical moderate supply constraint requiring conservation measures. Hospitals

Highlights

- IG products are costly and are limited in supply.
- CBS released the National IG Shortage Plan (May 2024) to manage potential supply risks.
- Mock Ig Shortage Simulation (Feb 13-14, 2025) declared an “Amber” shortage.
- Saskatchewan IG Stewardship Program contributed to leading a coordinated response with provincial labs during the Ig Shortage Simulation event.
- The robust IG Stewardship Program registry and proactive communication model place the province in a strong position to manage future IG shortages, ensuring patient safety and equitable distribution of resources.

were provided an Excel worksheet template to complete tracking IG requests (including IVIG and SCIG products) throughout a 32-hour period, recording the indication for IG, the dose requested, and the potential anticipated dose which may have been issued during an Amber Phase shortage in accordance with *The National Plan for Management of Shortages of IG Products*. These spreadsheets were then submitted to the IG shortage project coordinators for review and analysis.

This report details **Saskatchewan's Ig shortage response plan**, in the context of the planned Ig shortage simulation.

Saskatchewan Response

In preparation for the IG (IVIG and SCIG) shortage simulation exercise, the Nurse Navigators from the IG Stewardship Program, maintained an open communication with Saskatoon and Regina Transfusion Medicine technical and medical teams. Following an informational meeting with the provincial Transfusion Medicine Clinical Lead, the IG Nurse Navigators, Technical Supervisors from the Regina and Saskatoon Transfusion Medicine Lab (TML) sites, and Transfusion Safety Managers participated in the *National IG Shortages Simulation Exercise Overview Meeting* organized by the IG shortages project management team from Canadian Blood Services.

To enhance laboratory understanding of this exercise and participation expectations, the IG Stewardship Program created and disseminated a memo summarizing the Saskatchewan participation plan and a comprehensive FAQ document to Transfusion Medicine Laboratories within Saskatchewan. (Appendix A and B)

A plan was made for completion of the Excel worksheet template provided by the national IG shortage exercise shortages project management team: Regina and Saskatoon TML staff agreed to complete one Excel workbook each representing transfusing facilities within their urban sites; laboratories outside these cities were instructed to submit patient product request forms to the IG Stewardship Program for data collation. These three workbooks were then to be submitted directly to the Canadian Blood Services IG shortage exercise project management team; a copy of each was retained by the IG Stewardship Program for local analysis.

The IG shortage simulation exercise also provided an opportunity to trial convening our Saskatchewan Provincial Emergency Blood Management Team (PEBMC), which was convened the afternoon of February 13, 2025. This meeting was the first ever PEBMC meeting, in the context of a new provincial Transfusion Medicine Utilization and Interdisciplinary Committee (TUSIC) Steering Committee, which has a dual function to cover as a PEBMC. Key updates regarding the IG Stewardship Program and Saskatchewan's strategic position in the event of an IG shortage were provided to membership. The IG Stewardship Program maintains a registry of all patients who receive acute in-hospital IVIG therapy and outpatient urgent or maintenance IVIG infusions. Based upon existing information, the potential impact of an Ig shortage on patients receiving outpatient maintenance IVIG could be predicted.

Review of the IG Registry Data as of February 13, 2025 identified that since inception of the registry:

- 1214 individual patients have had IVIG prescribed with 3009 orders submitted
- 255 of these patients were receiving regular maintenance IVIG.

The potential impact of an actual Amber Phase IG Shortage event would impact patients from various specialties and require communication with physicians from specialties (Figure 1).

Potential Impact of Amber Shortage

Up to 127/255 (50%) patient IVIG doses impacted

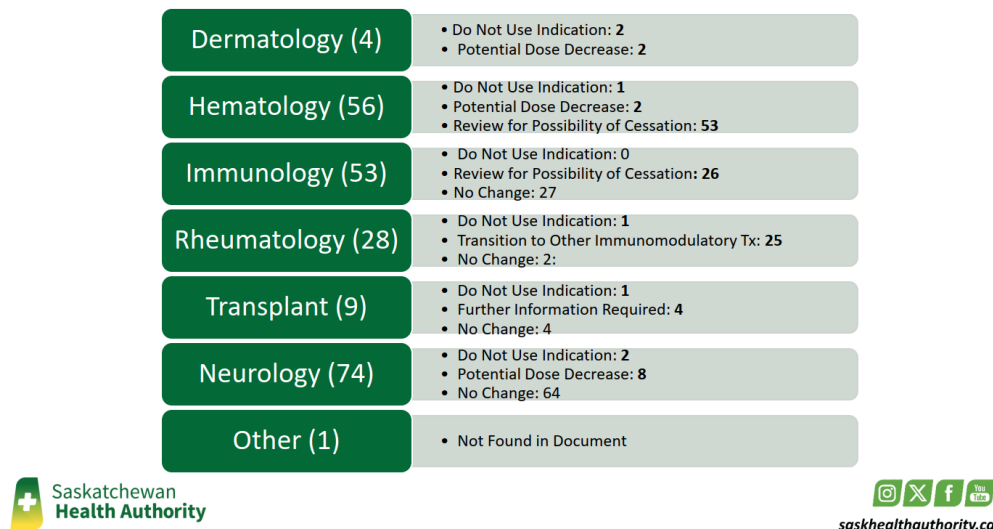


Figure 1: The potential impact of patients from various specialties (number denoted in parentheses) and how IVIG orders would need to be modified in the event of a real National IG Amber Phase Shortage. All physicians would need to be contacted to provide notification of a change in management (discontinuation due to a do not use indication or discussion to modify dosing) or reaffirm dosing would not undergo change.

Data from the three Excel workbooks where Saskatchewan data was collected and submitted during the IG shortages exercise was reviewed and analyzed. (Figure 2).

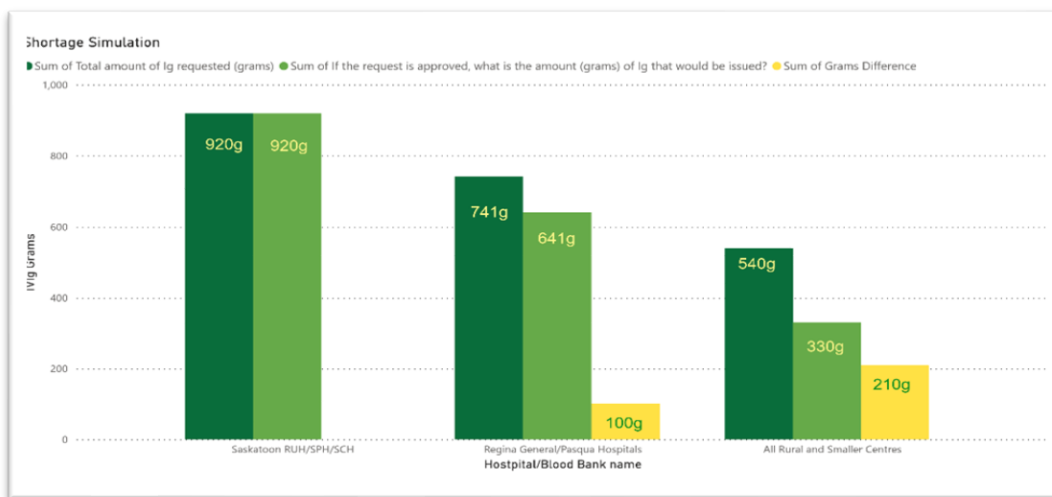


Figure 2: Summary of the potential reduction of IVIG utilization reduction in Saskatchewan, as documented in the setting of an Amber Phase Ig shortage simulation Feb 13-14, 2025.

In total, a potential 14.1% reduction in IVIG utilization was documented in the setting of an Amber Phase IG shortage. Among specific regions, there was no IVIG issue reduction observed in Saskatoon; a possible 13.5% reduction was observed in Regina; and a possible 38.9% reduction was observed in rural Saskatchewan.

Key Learnings

1. **Preparatory informational meetings facilitated planning for a successful event.**

Discussion between the IG Nurse Navigators, Transfusion Safety Managers, Transfusion Medicine Medical Leadership (with a connection to the National Emergency Blood Management Committee) and Transfusion Medicine Lab Supervisors helped ensure a plan was in place for communication of the shortage simulation exercise with transfusion medicine lab teams. This ensured an awareness of tasks or responsibilities regarding data collection in urban centers versus rural transfusing facilities.

2. **Data collection effectiveness by urban Transfusion Medicine Lab sites and Clinical Expertise of Nurse Navigators.**

Data collection by Saskatoon and Regina lab technologists, under the leadership of their supervisors, was important to ensure timely data collection for submission to the project coordinators. The IG Nurse Navigators bring a strong clinical background, which played a pivotal role in supporting rural teams during this paper-based simulation activity. During this exercise, the IG Stewardship Program Nurse Navigators were able to nimbly gather data from the IG registry maintained as a program to forecast potential impacts on recipients of IVIG maintenance therapy. Further, they provided consultative support to any lab sites with questions about the exercise. Following the paper-based event, they participated by collecting data from urban and rural sites, and reviewed and summarized data to evaluate our provincial performance within the activity.

3. **Benefit of convening a PEBMC Meeting.**

During the shortage simulation, it was confirmed that a PEBMC meeting could be convened in a relatively short time-frame. A meeting was scheduled with approximately 24 hours' notice, with nearly all members responding to the attendance request. Although not everyone was able to attend, they acknowledged the correspondence. This interdisciplinary representation is essential in the context of a real shortage event.

At the PEBMC meeting, membership was informed that up to 50% of patient IVIG treatments could be impacted in the setting of an Amber Phase IG shortage. The meeting further underscored the critical need for physician contact should an actual inventory shortage occur, ensuring timely communication and coordination to manage patient care effectively. During the meeting, it was also highlighted that the IG Stewardship Program's registry is one of the few in Canada with the capability to track and manage such shortages, providing a critical tool for maintaining patient care and inventory management during times of limited supply. This unique capability positions Saskatchewan at the forefront of responsive and proactive management in the event of a real IG shortage.

Successes

The IG Stewardship Program successfully and efficiently gathered necessary data during this exercise. Regina and Saskatoon labs successfully captured their own data, and the IG Stewardship Program Nurses coordinated data collection for all rural transfusing facilities. Clear, targeted communication ensured comprehensive details were collected in a timely manner. A reminder fax was sent to all IG holding laboratories within Saskatchewan at the outset of the exercise, prompting many facilities to respond promptly. Numerous laboratories

proactively faxed in their data, or called to inform the program that no IVIG had been issued, which contributed to the efficiency of the data collection process.

Challenges

Despite multiple communications issued about this shortage exercise, there was one rural laboratory that was incidentally discovered to have issued IVIG during the activity period without notifying the IG Stewardship Program. This highlighted that, despite messaging, communication misses may still occur. Fortunately, a Nurse Navigator was able to capture the necessary data prior to the submission of the form, mitigating the impact of this oversight.

Another challenge was that TML staff in urban centers without a clinical background may have inadvertently missed clinical details which could have led to possible IVIG dose reductions in an Amber Phase Shortage. Without activation or involvement of a medical triage team or specialist consultant to review orders where indicated by the IG Shortages Plan, a potential opportunity to decrease IVIG dosing may have been missed during this exercise. Thus, there may have been variability in data collected between all sites. This finding highlights the need for clarification as to when to engage the Transfusion Medicine Physician to review cases during a shortage exercise.

In the context of this paper-based exercise, a triage team was not convened. The establishment of a clinical triage team to review individual cases will be essential in the event of a real shortage to balance patient needs and IG utilization.

Summary

The Saskatchewan IG Stewardship Program foundation includes clinician completion of the IVIG POS and Nurse Navigator screening IVIG indication and dose appropriateness in according to the *Criteria for the Clinical Use of Immune Globulin 2nd Edition February 2022* (which incorporates the use of the Alberta Health Services Adjusted Body Weight Calculator.) The Program maintains a province-wide Intravenous Immune Globulin patient registry.

In response to the **National IG Shortage Simulation Exercise** held February 13-14, 2025, Saskatchewan demonstrated strong coordination and preparedness. The province participated fully in the simulation, with Regina and Saskatoon managing their own data while rural labs were represented by the IG Stewardship Program. A PEBMC meeting was successfully convened and underscored the importance of communication and highlighted that up to **50% of IVIG treatments** could be impacted in an actual shortage.

Key findings from the simulation data showed a potential 14.1% reduction in IVIG use, as documented in the setting of an Amber Phase Ig shortage. These outcomes emphasize the importance of a coordinated approach and open communication between the transfusion medicine laboratories and IG Nurse Navigators, and the value of maintaining an IG registry to better understand the potential impact of an IG shortage directly on patient care.

Successes included preparedness, comprehensive communication, transfusion medicine laboratory team participation with data collection and engagement, convening the PEBMC, and IG Nurse Navigator involvement with educational support and data analysis.

Saskatchewan's robust registry and proactive communication model place the province in a **strong position to manage future IG shortages**, ensuring patient safety and equitable distribution of resources.

Acknowledgement

The Saskatchewan IG Stewardship program would like to thank hospital and lab staff within the province who participated in the development of the provincial and regional plan and their participation in the simulation exercise. Appreciation is also expressed to CBS for their project management and coordination in the planning and execution of this Ig shortage simulation exercise.

Appendix A: Provincial memo disseminated to labs announcing the IG Shortage Simulation Activity.



MEMO

DATE: February 11, 2025

TO: All Saskatchewan Laboratory Directors and Managers

CC: Transfusion Utilization and Safety Interdisciplinary Committee (TUSIC) Steering Committee Membership

FROM: Dr. Oksana Prokopchuk-Gauk and Linda McPhee, Co-Chairs, TUSIC Steering Committee/Saskatchewan Provincial Emergency Blood Management Committee

RE: National Intravenous Immune Globulin (IVIG) Simulation Activity – February 13-14, 2025

The National Emergency Blood Management Committee (NEBMC) will be conducting a paper-based IVIG shortage simulation on February 13-14, 2025, to assess responsiveness in the event of a real shortage. This exercise will document potential modifications in IVIG distribution; however, there will be no actual impact on patient care.

Please refer to the attached NEBMC Communication and Saskatchewan IG Shortage Simulation FAQ for details.

Implications for provincial facilities:

- Facilities which do not stock or issue IVIG are exempt from participating in this exercise.
- Hospital-based transfusion medicine labs (TMLs) who do stock or issue IVIG must participate in this shortage activity. Staff from these sites will be expected to:
 - Review and familiarize themselves with the [National Ig Shortages Plan](#) (especially Appendix D).
 - Review the mock Ig shortage situation and excel worksheets with instructions which are provided from the NEBMC later this week.
 - Saskatoon and Regina hospital sites are to complete the excel spreadsheets accordingly and submit them to the IG shortage simulation project team. A copy of these spreadsheets and copies of any IG product request forms submitted to the TML are to be sent to the IG Stewardship Program.
 - All other sites are to send a copy of any IG product request forms to the IG Stewardship Program, where Nurse Navigators will complete spreadsheets for submission to the IG shortage simulation project team.

Inquiries and Feedback

- Questions may be directed to the IG Stewardship Program Nurse Navigators by phone at (306)-766-3135 or email at igstewardshipprogram@saskhealthauthority.ca

Thank you for your attention and participation.

Safety | Accountability | Respect | Collaboration | Compassion

With a commitment to a philosophy of Patient and Family Centred Care

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Frequently Asked Questions (FAQ) for the National IVIG Shortage Simulation Exercise

- **What is the purpose of this exercise?**

This exercise is meant to test the application of The National Plan for Management of Shortages of Immunoglobulin (Ig) Products

Note: This exercise applies only to IVIG and **does not include hyperimmunoglobulins** such as Hepatitis B Immunoglobulin or Tetanus Immunoglobulin.

- **Who is required to participate?**

Hospitals that stock Ig are strongly encouraged to participate in this simulation exercise. The primary participants will be urban laboratory staff and the IG Stewardship Program. Participation is crucial to accurately simulate decision-making and workflow adjustments during a potential Ig shortage.

- **What is the timeline for this exercise?**

On Feb 13th, hospitals that hold Ig inventory will be provided with an overview of the mock Ig shortage situation and two excel worksheets (one for Feb 13th and one for Feb 14th), with instructions.

- **How can we prepare for this simulation exercise?**

Review the [National Ig Shortages Plan](#), specifically the roles and responsibilities of all stakeholders and Appendix D: Inventory Phase Activity and Ig Allocation Criteria in advance of February 13th.

- **What are the key components of the exercise?**

During the exercise, all laboratories will continue issuing IVIG according to their usual processes. Transfusion Medicine Laboratories in Regina and Saskatoon will participate in the paper exercise, screening IVIG requests using the criteria outlined in Appendix D of [The National Plan for Management of Shortages of Immunoglobulin \(Ig\) Products](#). This does not need to be completed in real time.

Regina and Saskatoon labs will then complete the Excel worksheet, documenting the potential actions that would have been taken if this were an actual shortage. This may include adjustments such as dose reductions, treatment delays, or alternative therapies. The completed worksheet will serve as a record of decisions made during the simulation.

Laboratories outside of Regina and Saskatoon will submit the excel spreadsheets and any patient product request forms from any IVIG issued on February 13th and 14th to the IVIG Stewardship Program. The IVIG Stewardship Program will participate in the IG Shortage Simulation Exercise on their behalf.

Appendix B: Frequently Asked Questions (FAQ) for the National IVIG Shortage Simulation Activity, Page 2

- **Will there be any impact to patient care?**

No, this exercise is a simulation only. There will be no impact on patient care, and no changes will be made to IVIG dosing or administration during the exercise.

- **What tools or resources will be provided?**

The IG Stewardship Nurse Navigator will be available to provide support during the day from 08:00 to 16:30 and can be reached at 306-766-3135.

- **How will patient confidentiality be protected?**

The worksheets that are being submitted will not include patient identification information.

- **When do the worksheets need to be submitted?**

The spreadsheets shall be submitted at the end of each day. For laboratories in Saskatoon and Regina, submissions will be made by the laboratory staff. For sites outside of Saskatoon and Regina, the IG Stewardship Program will complete and submit the spreadsheet.

All worksheets must be submitted no later than **Monday, February 17th**, as the results from this simulation will be used for a second scenario with NEBMCs scheduled to take place on **Tuesday, February 18th**.

- **What if no IVIG is issued on these days?**

If your hospital does not issue any IG during the exercise days, please confirm this with the IG Stewardship Program. You can send your confirmation by email to igstewardshipprogram@saskhealthauthority.ca or by fax 306-766-3509.

- **Who can I contact for questions?**

For any additional questions, participants may contact the IG Stewardship Program by email at igstewardshipprogram@saskhealthauthority.ca or by phone at 306-766-3135.

Alternatively, you may reach out to:

Kim Goodwill, Manager of Transfusion Safety/PBM (South)
Email: kimberly.goodwill@saskhealthauthority.ca
Phone: 306-552-8584

Val Reddekopp, Manager of Transfusion Safety/PBM (North)
Email: val.reddekopp@saskhealthauthority.ca
Phone: 639-480-7929