IMMUNE GLOBULIN QUALITY IMPROVEMENT PROJECT

PROJECT PROTOCOL

ORBCoN Ministry of Health IG Request Form Database

VERSION 3, DATE: SEPTEMBER 2023

Ontario Regional Blood Coordinating Network

Inspiring and facilitating best transfusion practices in Ontario.

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Background

The use of Immune Globulin (IG) products, specifically Intravenous Immune Globulin (IVIG) and Subcutaneous Immune Globulin (SCIG), continues to increase each year, at an average rate of 8% [1]. In the fiscal year 2019/20, the annual cost of IG products had exceeded $300 million in Canada (excluding Quebec), approximately 25% of the total expenditure on blood components and products.

IG products are used for a range of conditions, such as, replacement therapy for patients with hypogammaglobulinemia or as an immunomodulatory treatment in patients with autoimmune diseases. IVIG is a blood product prepared by several commercial manufacturers using plasma derived from donor blood, extracting IG subclass gamma, and infused via the vein in hospital or in outpatient clinic settings. SCIG is also made from plasma but is injected under the skin (subcutaneously) and can be easily infused at home. IG products (IVIG and SCIG) are supplied to hospital Transfusion Medicine Laboratories (TML) from Canadian Blood Services (CBS) to be issued to patients upon physician/prescriber request.

Paper request forms detailing the Ministry of Health (MOH) approved indications are available for physician/prescriber use when submitting requests for IG to TML. Although all paper request forms must be submitted to TML for review and approval [2,3] in Ontario, none of the stakeholders, including CBS, the MOH or the Ontario Regional Blood Coordinating Network (ORBCoN), collects comprehensive electronic data on how IG products are used in hospitals (e.g., labelled medical indication for use, assessment of appropriate dose, or to what extent utilization is being used to treat conditions for which there is limited/no evidence to support their use [4]). Without such data, it is difficult to investigate the expanding IG utilization and the rate of guideline compliance. Several provinces have undertaken annual audits to evaluate current practices and prepare formal reports to increase awareness of appropriate use [5-8]. ***In Ontario, to support continuous audit and feedback for IG stewardship, a centralized repository for IG utilization data is required.***

OAGO Audit Recommendation

In 2020, the Office of the Auditor General of Ontario (OAGO) released the findings of their Value-for-Money Audit of Blood Management and Safety (https://www.auditor.on.ca/en/content/annualreports/arreports/en20/20VFM_02bloodmgmt.pdf).

Recommendation three specifically stated the need:

> "***To better manage the demand and supply of immunoglobulins so that they are available for Ontarians who need them most and to avoid costs of wasted product, we recommend that the MOH, in consultation with Ontario Health: Collect more complete data from hospitals on how immunoglobulins are being used and identify***

emerging conditions that may warrant inclusion in provincial utilization guidelines……".

Ontario MOH IG Request Forms

The first version of the Ontario MOH IG request form was implemented in 2012 by hospitals throughout the province and was used during a 2012 audit performed by ORBCoN.

Currently, there are two MOH IG request forms available for use (https://transfusionontario.org/en/category/ivig-scig/ordering-ig-in-ontario/):

1) Neurology use (Appendix 1); and,
2) non-Neurology use (Appendix 2).

However, these paper request forms (MOH IG Request Form) for IG products are often stored in the TML. The valuable information captured on the MOH IG Request Forms are not readily captured electronically and forms are often partially or illegibly completed by the physician/prescriber. At this time, there is no strategy to capture provincial data in a usable format. This initiative provides a standardized collection of data on ordering practices and IG utilization in Ontario using a secure web platform data capture tool; Research Electronic Data Capture (REDCap) [9-10].

The purpose of this project is to record data collected via the official MOH IG request form (or electronic forms for hospitals with advanced computerized physician order entry [CPOE]) submitted to the hospital TML. The MOH is committed to ensuring the optimum utilization of blood products such as IG, and this project is part of an overall strategy to assure product is available to patients who need it the most.

Project Objectives and Aims

The aim of this Quality Improvement Project (QIP) is to enable better tracking of IG use in the province of Ontario – specifically with respect to dosing and indication.

The data repository will be available for sites that volunteer to participate in data collection. Standardized reports will support the goal of site-specific data that can be benchmarked against peer hospitals.

The QIP will allow the MOH, in collaboration with ORBCoN, to establish a means of monitoring IG utilization, generating reports, and the ability to trigger random audits if necessary for hospital sites utilizing IG outside the recommended guidelines.

Population to be Studied and Data Elements

All patients that receive IG products from Ontario hospitals are the population whose coded information is being captured in this data repository. Annual patient numbers and infusions will vary. Sites can decide to enter retrospective data from 2018-present date.

The source for data is the MOH IG Request Form (see Appendix 1 - Neurology & Appendix 2 - non-Neurology) showing the following data elements:

High level data elements include:

1. Hospital sites - ordering/receiving; multi-site institutions may enter data for more than one hospital site.
2. IVIG versus SCIG being requested.
3. Patient care area - in/outpatient setting to include: Inpatient, Outpatient (Clinic), Outpatient (Home Infusion), Outpatient (not specified), Emergency Department.
4. Date of infusion request (mandatory) and date infusion is required (optional).
5. Patient identification – will **not** be collected into REDCap but be replaced by a coded number (Prefix of the number will correspond to Data Access Group (DAG) number that is hospital site specific in REDCap, and the assigned subsequent sequential number to uniquely identify each patient); each site will document patient identifiers on a **Patient Tracking Log** (see Appendix 3) that will be maintained on site in the local TML or utilize a patient log already in place at their institution. This code, specific to the individual patient, will be used to enter a new instance each time an IG request form is received for this patient.
6. Patient height and weight - BMI will be calculated.
7. DOB is collected on the forms – data collected into REDCap will be categorized (i.e., Adult, Pediatric <18 years, or Neonate <4 months)
8. Sex - Male /Female. (*Please note:* the MOH form when developed, used the term 'gender' but sex is documented by physician/prescribers).
9. Indication for IG infusion - clinical indication from a list of Hematology, Neurology, Immunology, Dermatology, Infectious Diseases, Solid Organ Transplantation, or other indications.
10. Laboratory results and date as documented on the MOH IG form (for example, IgG level and platelet count) where applicable.
11. Dose of IG ordered and modified dose where applicable, including induction and maintenance dose requirements.
12. Indication of utilization of dosing calculator.
13. Ordering physician/prescriber specialty - from a list of Hematology, Neurology, Immunology, Dermatology, Infectious Diseases, Solid Organ Transplantation, Other.

14. Ordering physician/prescriber contact information - coded at the hospital level if required using the **Physician/Prescriber Contact Information Log** (See Appendix 4). Suggest using the first initial of your site name and number sequentially (i.e., K1).
15. Other treatment information – treatment/dose/duration/outcome.

There will be no interaction with patients to obtain information and no private health information will be collected.

Project Management Timelines

Data collection for this QIP is ongoing and at the discretion of the participating hospital sites, the MOH and ORBCoN.

Research Ethics Approval

All participating hospital sites will determine if they need to submit to their institution research ethic boards or quality improvement registration platform. This project is a quality improvement initiative. It is the responsibility of each hospital site to determine the necessary approvals are obtained for participation.

This information will be documented by ORBCoN with a pre-participation hospital site User Credential survey.

Design and Detail of Implementation Methodology

The pilot work for data capture was implemented in two (2) phases:

Phase 1: Pilot work

Phase 1 served as a pilot of the project, focusing on the data collection form and database build using REDCap. Pilot data was supplied by a volunteering single site in an Ontario hospital. Minor adjustments were made to the existing data capture system. The source of the data was anonymized information from MOH IG request forms submitted to the participating site TML. Accessibility to all data collected in REDCap was limited to staff members affiliated with the ORBCoN office and the staff designated by the southwest region sponsor site (Michael G. DeGroote Centre for Transfusion Research (MCTR), McMaster University). Designated MCTR staff may aid in data cleaning, data analysis and report development. In phase 1, the designated person(s) at the participating pilot hospital will also have access to only their own data.

The pilot hospital site entered their own information into REDCap. No identifiable data was collected, and a patient code was used as a unique patient identifier. The data entered could be modified to address any data discrepancies or if errors were corrected on the form after data entry occurred.

Phase 2: Role out Voluntary use to all Hospitals and Development of Reports

Phase 2 will include communication by ORBCoN with all appropriate TML personnel in Ontario hospitals, inviting them to participate and training materials will be circulated. The source of the data remains the same, it is anonymized information from MOH IG request forms submitted to hospital TML. Accessibility to all data collected in REDCap is limited to staff members affiliated with the ORBCoN office and the staff designated by the southwest region sponsor site, MCTR. Designated MCTR staff may aid in data cleaning, data analysis and report development. In phase 2, participating hospitals will have access to only their own data and templates of reports to help them summarize their data. Where appropriate, multi-site institutions will be able to enter, view and download data from all their designated hospital sites individually, based on the hospital site DAG. Aggregate/coded information will be summarized by site(s) for stakeholders at large, depending on the audience (i.e., MOH, CBS) the hospital sites may be identified.

As in phase 1, coded patient specific data will be entered using the **IG Recipient Patient Tracking Log** (Appendix 3). The data entered can be modified by the site staff assigned. This flexibility is required in the event of changes to the original orders, diagnostic information, or errors made in the initial request form completion.

Queries, reports, graphs, and an auditing process will be developed and revised with the stakeholders to include hospitals, MOH, and CBS.

Definition of Project End Points

- Data collection process established during a pilot phase with participating hospital.
- Access to information by hospitals, MOH, and ORBCoN during pilot phase was achieved and deemed acceptable.
- Adoption of the data collection process, established during the pilot phase, by participating Ontario hospitals.
- Determine IG utilization and compliance to Ontario IG guidelines, where applicable and feasible.

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those of the authors and of ORBCoN and do not necessarily reflect those of the Ontario Ministry of Health or the Government of Ontario.

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Appendices

Appendix 1: MOHLTC IG Request Form – Neurology Use

Ontario

MOHLTC IG Request Form

For Neurology Use Only

Patient Name:
Patient Hospital/Medical Record#:
Patient DOB (YYYY/MM/DD):
Gender M/F:
Location:
Ontario Health Insurance#:

ALL FIELDS BELOW ARE MANDATORY

SECTION A: Physician & Hospital Information

Date of Request (YYYY/MM/DD)	Date Required (YYYY/MM/DD)	Hospital Transfusion Service (HTS) Fax Number
Name of Ordering Physician	Physician's Contact Phone Number	Physician's Email
Is the patient being seen by a Neurologist/ Neuromuscular Specialist? ☐ Yes ☐ No	Is the request for a hospital inpatient? ☐ Yes ☐ No	Hospital where patient will receive IG

SECTION B: Request Type

☐ Initial Request: Maximum 6 month approval	☐ Renewal Request: A reassessment should be done to confirm IG treatment continues to be effective and that minimum effective dose is being applied. Maximum 12 month approval.

SECTION C: Clinical Indication **Refer to Ontario IG Management Utilization Guidelines for additional indications where IG may be appropriate**

Approved Condition	Guidelines for INITIAL Request	Guidelines for RENEWAL Request
☐ Guillain–Barré Syndrome (GBS) including Miller Fisher Syndrome and other variants	▪ IG recommended for Grade 3 severity (able to walk with aid) or greater; or less than Grade 3 severity that are progressing. ▪ IG should be given within 2 weeks of symptom onset. ▪ Adult: Total Dose of 2 g/kg divided over 2 to 5 days. ▪ Pediatric: Total Dose of 2 g/kg divided over 2 days.	▪ IG treatment for GBS is typically one-time/in the acute setting. ▪ Re-treatment for patients who do not respond may be considered. Repeat treatment with IVIG at 2g/kg divided over 2-5 days.
☐ Myasthenia Gravis (MG)	▪ IG is recommended as first-line treatment in moderate-severe MG or in myasthenic crisis. ▪ Induction Dose: 2g/kg divided over 2-5 days. ▪ Initial requests may be made for induction plus two maintenance doses; fill out Section D accordingly.	▪ IG in combinations with immunosuppressive therapy can be considered in refractory cases. If additional IG is required, dose should be adjusted depending upon response and titrated to the minimum effective dose. ▪ Maintenance Dose: 1g/kg
☐ Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)	▪ IG is recommended as first-line therapy in CIDP. ▪ Induction Dose: 2 g/kg divided over 2 to 5 days. ▪ All patients receiving IG for chronic treatment of CIDP should be followed by a neuromuscular specialist.	▪ Immunosuppressive therapy in combination with IG can be considered in refractory cases. Continued use should be based on objective measures of sustained effectiveness. Aim for minimum effective dose. ▪ Maintenance Dose: 1g/kg every 3 weeks.
☐ Multifocal Motor Neuropathy (MMN)	▪ IG is recommended as first-line treatment for MMN. ▪ Induction Dose: 2g/kg divided over 2-5 days.	▪ Maintenance Dose: Tailor to the lowest dose that maintains clinical efficacy, usually 1g/kg or less per treatment course. Some patients may require higher doses for efficacy, up to 2g/kg every 4 weeks.

Other (please specify the diagnosis): _____

These requests will require screening by Transfusion Service. Please include information regarding treatment to date and documentation to support IG treatment for an unapproved indication.

Has the patient used other therapies to treat this condition? ☐ Yes, specify other treatments below ☐ No

Treatment	Dose (if applicable)	Duration of treatment	What was the outcome?
			☐ No response ☐ Contraindications ☐ Intolerance
			☐ No response ☐ Contraindications ☐ Intolerance

Other Comments: (include notes regarding response to IG therapy)

SECTION D: Dosage Information **(Verification of dose using Dose Calculator tool is recommended. Refer to http://ivig.transfusionontario.org/dose/**

☐ Intravenous IG (IVIG) ☐ Subcutaneous IG (SCIG)

Patient Weight: kg Patient Height: cm BMI: **Dose must be adjusted for BMI greater than or equal to 30**

Induction/One-time dose g/kg = Total dose of g; divided over days

Maintenance dose g/kg = Total dose of g; divided over days; every weeks; Duration: months

Dose Calculator Used? ☐ Yes ☐ No If No, why was it not used?

SECTION E: For Transfusion Medicine Use Only

☐ Dose verified ☐ Dose adjusted to:	By (signature req'd):
☐ Confirmed with ordering physician	Date:
☐ Approved ☐ Denied	
Signature of Approving Physician or designate:	Date:

Please fax/send to :

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Appendix 2: MOHLTC IG Request Form – non-Neurology Use

Ontario
MOHLTC IG Request Form

For non-neurology use only

Patient Name
Patient Hospital/Medical Record#
D.O.B.
Gender
Location
Ontario Health Insurance#

ALL FIELDS BELOW ARE MANDATORY

Date Requested: (YYYY/MM/DD)	Treating Physician:
Date Required: (YYYY/MM/DD)	Physician Specialty:
Hospital where patient will receive IG.	Physician Phone #:

Dosage Information: (Verification of dose using Dose Calculator tool is recommended)

☐ Intravenous IG (IVIG) ☐ Subcutaneous IG (SCIG)						
Patient Weight: kg	Patient Height: cm	BMI:	**Dose must be adjusted for BMI greater than or equal to 30**			
☐ Induction/One-time dose	g/kg = Total dose of	g; divided over	days			
☐ Maintenance dose	g/kg = Total dose of	g; divided over	days; every	weeks; Duration:	months	
Dose Calculator Used? ☐ Yes ☐ No If No, why was it not used						
IgG level/Platelet count/other test results relevant to patient condition: Result: Date:						

Clinical indication for use: **Refer to Ontario IG Management Utilization Guidelines for additional indications where IG may be appropriate.**

Specialty	
Hematology	☐ Fetal/Neonatal Alloimmune Thrombocytopenia (F/NAIT)
	☐ Hemolytic Disease of the Fetus and Newborn (HDFN)
	☐ Immune Thrombocytopenia (ITP) ☐ Adult ☐ Pediatric
	☐ Post-transfusion Purpura
Dermatology	☐ Pemphigus Vulgaris (PV) and Variants
Rheumatology: Pediatric	☐ Juvenile Idiopathic Inflammatory Myopathy (J-IIM) (previously Juvenile Dermatomyositis)
	☐ Kawasaki Disease (KD)
Rheumatology: Adult	☐ Idiopathic Inflammatory Myopathy (IIM) Includes Dermatomyositis and Polymyositis
Immunology	☐ Primary Immune Deficiency (PID)
	☐ Secondary Immune Deficiency (SID)
	☐ Hematopoietic Stem Cell Transplant in primary immunodeficiencies
Solid Organ Transplant	☐ Kidney transplant from living donor to whom the patient is sensitized
	☐ Pre-transplant (Heart)
	☐ Peri-transplant (heart, lung, kidney, pancreas)
	☐ Post-transplant
Infectious Disease	☐ Invasive Group A streptococcal fasciitis with associated toxic shock
	☐ Staphylococcal Toxic Shock
***OTHER (requires approval)**	

For Transfusion Medicine Use Only

☐ **Dose verified** ☐ **Dose adjusted to:**	**By (signature req'd):**
☐ **Confirmed with ordering physician**	**Date:**
☐ **Approved** ☐ **Denied**	**Date:**
Signature of Approving Physician:	

Please fax/send to:

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Medical Condition	Suggested initial dose and duration
Fetal/Neonatal Alloimmune Thrombocytopenia (F/NAIT)	*Maternal*: Previous fetus with intracranial hemorrhage: Up to 2 g/kg/week starting as early as 12-16 weeks gestation. No previous fetus with intracranial hemorrhage: Up to 1 g/kg/week. Starting as early as 20 -26 weeks current gestation. *Infant*: Initial dose of 1 g/kg reassess following initial dose.
Hemolytic Disease of the Fetus and Newborn (HDFN)	0.5 g/kg over 4 hours
Immune Thrombocytopenia (ITP) Adult	*Acute*: 1 g/kg as a single dose. Repeat if PLT count does not respond I.e. still less than 30 x 10^9/L. *Chronic*: In consultation with a hematologist, as adjunctive therapy or where other therapies have failed or are not appropriate. Consider 1-2 g/kg. The use of regular IVIG as a treatment for chronic ITP should be considered as exceptional and alternative approaches (e .g. splenectomy, rituximab, thrombopoietin receptor agonists) should be considered.
Immune Thrombocytopenia (ITP) Pediatric	For patients who require treatment, a single dose of IVIG may be considered a front-line treatment (0 .8 to 1 g/kg). A second dose can be repeated if there is no clinical response. IVIG will result in a faster increment in platelet count compared with steroids. In emergent management, IVIG is recommended as part of multimodal therapy
Post-transfusion Purpura	Up to 2 g/kg divided over 2 to 5 consecutive days. Repeat if necessary; for short term use.
Pemphigus Vulgaris (PV) and variants	Total dose of 2 g/kg divided over 2 to 5 days every 4 weeks. Dose every 6 weeks after 6 months of therapy.
Juvenile Idiopathic Inflammatory Myopathy (J-IIM) (previously Juvenile Dermatomyositis)	*Initial dose*: Total dose of 2 g/kg divided over 2 days. *Maintenance dose*: A systematic approach should be taken to determine minimum effective dose.Continued use should be based on objective measures of sustained effectiveness. Maximum dose should not exceed 2 g/kg.
Kawasaki Disease (KD)	2 g/kg for 1 day (second dose can be given for patients that fail to respond to initial dose).
Idiopathic Inflammatory Myopathy (IIM) Includes Dermatomyositis and Polymyositis * does not include Inclusion Body Myositis	Maximum dose is 2 g/kg to be given over 2 days initially monthly for 3-6 months and if effective to be continued at decreasing frequency (determine minimum effective dose) over approximately 2 years.Survival of patients with IIM has been shown to be substantially improved in patients given IVIG.
Primary Immune Deficiency (PID) Secondary Immune Deficiency (SID)	*Adult*: 0.4-0.6 g/kg every 3-4 weeks *Pediatric*: 0.3-0.6 g/kg every 3-4 weeks Doses or frequency to be adjusted by experts according to desired trough level (more than 500 mg/dL and ideally 700 mg/dL) and according to individual patient clinical needs.
Hematopoietic Stem Cell Transplant in primary immunodeficiency	0.4-0.6 g/kg every 3-4 weeks; requirements may increase and should be based on clinical outcome.
Kidney transplant from living donor to whom the patient is sensitized	2 g/kg/month for 4 months.
Pre-transplant (Heart)	Suggested dose up to 1 g/kg/month until transplant.
Peri-transplant (heart, lung, kidney, pancreas)	Suggested dose 1 g/kg can give as divided doses if in association with a course of plasmapheresis.
Post-transplant	*Acute*: 1 g/kg/dose. Can be given as divided doses if in association with a course of plasmapheresis. *Chronic:* 1 g/kg/month.
Invasive Group A streptococcal fasciitis with associated toxic shock	1 g/kg on day one and 0 .5 g/kg per day on days 2 and 3 OR 0.15 g/kg per day for 5 days .
Staphylococcal Toxic Shock	

*** Refer to Ontario IG Management Utilization Guidelines for additional indications where IG may be appropriate.**

If you are unsure of the process for IG requests please refer to Ordering IG in Ontario

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Appendix 3: IG Recipient Patient Tracking Log

IG Recipient Patient Tracking Log

REDCap Record ID	Instance Number	Request Date (YYYY/MM/DD)	For Hospital Use ONLY		
			Last Name	First Name	Hospital Medical Record Number (MRN)

Appendix 4: Physician/Prescriber Contact Information Log

Physician / Prescriber Contact Information Log

Physician / Prescriber Specialty	Physician / Prescriber Identification Code	For Hospital Use ONLY		
		Physician / Prescriber Last Name	Physician / Prescriber First Name	Email Address / Phone #