Intravenous Immune Globulin (IVIG)
2012 Audit Report
Executive Summary

August 20, 2013

Executive Summary

IVIG is a blood product made from pooled human plasma, one of a group of products known collectively as Plasma Protein Products (PPPs). The product is administered to patients who either lack appropriate immunity due to immune deficiencies, or who have autoimmune disorders that can be improved by immune globulin infusion. IVIG is provided to hospitals across Canada (with the exception of Québec) by Canadian Blood Services (CBS), free of charge. Each province and territory is required to pay its share of the CBS budget based on units shipped to their respective jurisdiction.

The Ontario (ON) Regional Blood Coordinating Network (ORBCoN) was formed in 2006 by the Blood Programs Coordinating Office (BPCO) of the Ministry of Health and Long-term Care (MOHLTC). One of ORBCoN's goals is optimizing blood utilization management, with Intravenous Immune Globulin (IVIG) being a primary focus.

In 2007, a baseline provincial audit of IVIG utilization was conducted, over a 3-month period, involving 25 hospitals. In 2012, an audit capturing the same data points shown below was conducted, and results are presented in this report. Both audits involved the Ontario IVIG Advisory Panel (see Appendix 4 in full report), and were managed by ORBCoN.

The following data elements were collected in both audits:

- Hospital site (by code number)
- Patient care area (specialty)
- Date of infusion
- Patient identification by study code number
- Patient weight
- Primary Diagnosis
- Indication for IVIG infusion
- Dose of IVIG ordered
- Ordering physician specialty
- Volume of product issued
- Total volume infused yes/no
- If total volume not infused, indication of reason why not infused

Between 2007 and 2012, several milestones occurred regarding the use of IVIG in Canada and in Ontario.

- 2007: The National Advisory Committee on Blood and Blood Products published national guidelines for Hematology and Neurology indications
- 2008: ORBCoN submitted a report summarizing the 2007 audit results and made recommendations to the Ontario Blood Advisory Committee
- 2009: ORBCoN launched version 1 of the Ontario IVIG Utilization Management guidelines, using the national guidelines for Hematology, Neurology, Immunology and Solid Organ Transplant as primary references
- 2010: The National Advisory Committee on Blood and Blood Products published national guidelines for Immunology and Solid Organ Transplant indications *(an "in press" version of the latter was obtained in time to be included as references in version 1 of ON guidelines)*
- 2010: ORBCoN launched an IVIG toolkit which, in addition to the guidelines, contained a standard IVIG request form, standard infusion guidelines, adverse events chart and IVIG dose calculator

- 2011: ORBCoN surveyed Ontario hospitals; results suggested only a minority of hospitals had adopted the guidelines and request form
- 2012: MOHLTC launched the Ontario IVIG strategy, which included endorsing the request form

In 2012, an audit tool specifically designed to collect data for IVIG was used and accessed by hospital staff entering data directly into the software program. Sixty-one (61) hospitals, including small, community and teaching hospitals, participated in the 2012 audit. Data collection took place over a 3-month period between September 4, 2012 and November 30, 2012 inclusive. Data entry concluded January 15, 2013.

The audit captured data on 2,246 patients and 6,442 infusions. This corresponded to 301,298.4 grams infused. The increased participation and volume is due to the increased number of hospitals involved. Of the adult patients treated with IVIG, 1, 017 were female and 955 were male. Adult patients comprised 88% of the patients entered. For pediatric patients (17 years or lower), 257 were pediatric patients and 17 were neonates (0 to 28 days).

Data analysis and specialist review allowed the authors to report on usage for 120 clinical indications. The results are similar to the 2007 audit where over 80 clinical indications were included. Results are analyzed by comparing 2012 to 2007 audit results, and also categorized into labeled vs. unlabeled utilization. The following highlights are included in detail in the body of the report:

- 929 patients received infusions under Immunology specialty clinical conditions; this is the highest number of patients by specialty, which is consistent with the 2007 results
- 125,290 grams of IVIG were used for patients with Neurology specialty clinical conditions; this specialty is where the highest volume of product was used, consistent with the 2007 results
- Results for labeled vs. unlabeled use categories is very similar to 2007
    - Labeled use comprised 54.7% of the utilization (2007 49.7%)
    - Unlabeled, potentially indicated use is 33.2% (2007, 37.8%)
    - Unlabeled, not indicated use is 11.4% (2007, 10.5%)
- Utilization assessed using the Ontario IVIG Utilization Management Guidelines (version 2, March 31 2012) demonstrated use for:
    - Approved clinical conditions 85.4%
    - Recommended option clinical conditions 1.8%
    - Not approved clinical conditions 12.8%
- Numerical data to establish the precise impact of the dose calculator is not available through data analysis; however anecdotal evidence shared with the Ontario IVIG Advisory Panel indicates that dosing errors are being detected by verifying doses using the calculator

Subsequent to the 2012 audit, a practice survey was circulated to Ontario hospitals to assess aspects of the implementation of the Ontario IVIG strategy. The survey was circulated December 15, 2012 and was closed January 15, 2013.

The response rate was 59%. Ninety (90) % of respondents were from hospitals using IVIG. Small, community and teaching hospitals were represented.

In this survey, 93% of hospitals responding reported that they have implemented the form for IVIG requests, as mandated by the MOHLTC. Another 4% indicated implementation of the form was in progress. Eighty-eight (88) % of respondents reported using the dose calculator. Most use it not only for

obese patients as required by the strategy, but for all requests to verify dose accuracy. Seven (7) respondents indicate their hospital is not using any dose adjustment. Summary details on the survey appear in section 8 of the full report.

Upon reviewing a preliminary analysis of audit results, the following recommendations were made by the Ontario IVIG Advisory Panel:

Recommendation 1
Continue to support adherence to Ontario IVIG Utilization Management Guidelines (version 2 March 31 2012).

Recommendation 2
Implement detailed changes to the MOHLTC IVIG request form over 2013-14 and 2014-15.

Recommendation 3
Review or adjudication of requests outside the guidelines need to be further investigated for future phases of the IVIG strategy.

Recommendation 4
Continue to support the practice of dose adjustment using the ideal body weight calculation and provide information to hospital transfusion services, through targeted education and site visits, emphasizing the increased safety realized by identifying errors in dosing.

Recommendation 5
Roll out education based on audit results to identified hospitals over the 2013/14 and 2014/15 fiscal years.

Recommendation 6
Identify best practices for implementation of the evaluation of clinical outcome and need for reassessment strategies.

Recommendation 7
Perform an environmental scan regarding use of subcutaneous immune globulin (SCIG) to assess whether to implement a standard for a provincial home infusion programs.

Recommendation 8
Develop strategies to triage the use of IVIG during IVIG shortages to be included in the provincial contingency plan.

Recommendation 9
Accessibility to alternate therapies should be optimized due to evidence of potential significant improvements to patient care married with more cost effective treatments.

Recommendation 10
Investigate a means to avoid losing data that is being recorded daily on IVIG request forms.

Detailed rationale for the recommendations is included in detail in Section 9.0 of the full report.
The recommendations that are approved by the BPCO will inform the next phase of the Ontario IVIG strategy.