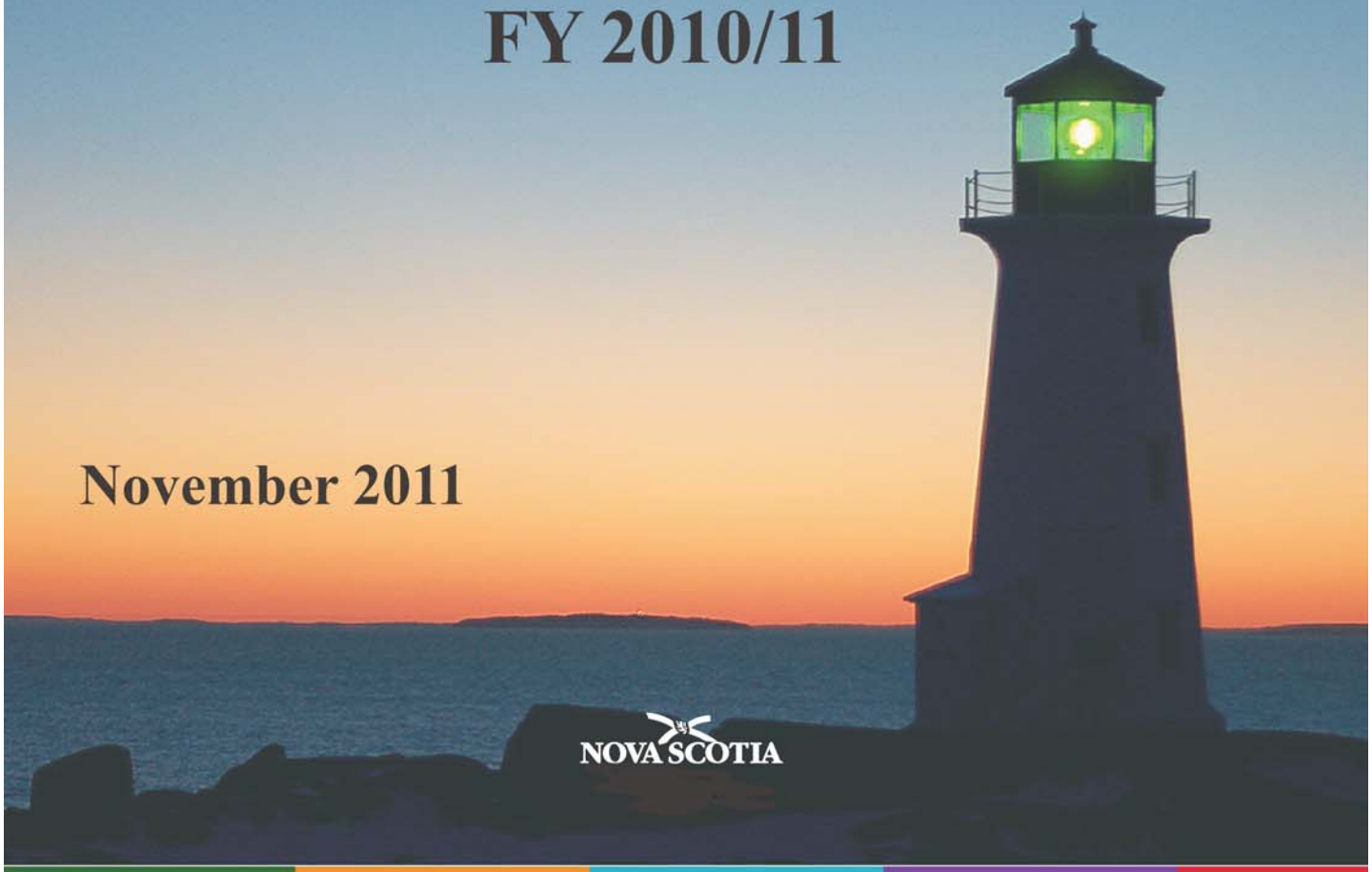
NOVA SCOTIA PROVINCIAL BLOOD COORDINATING PROGRAM

IVIG and SCIG Utilization in the Atlantic Provinces FY 2010/11



November 2011

NOVA SCOTIA

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1 Executive Summary

This report provides an overview of the distribution and utilization of intravenous immunoglobulin (IVIG) and subcutaneous immunoglobulin (SCIG) in the Atlantic Provinces for the 2010/11 fiscal year.

Canada has the highest per capita IVIG distribution when compared to six other developed countries using IVIG. Over the last decade IVIG distribution in Canada has increased by 7 to 10% each year. In 2010/11 the rise in IVIG distribution in Canada was by 8%. Canadian distribution of IVIG increased from 120g/1000pouplation in 2009/10 to 138 g/1000 population in 2010/11. Atlantic distribution only increased to 127g/1,000 in 2010/11 from 121g/1,000 populations in 2009/10. One of the four Atlantic Provinces showed a decrease in distribution. The distribution of IVIG in Nova Scotia decreased from 109g/1000 population in 2009/10 to 105 g/1000 in 2010/11. Newfoundland and Labrador, New Brunswick and Prince Edward Island showed a rise in the distribution of IVIG. Distribution of IVIG per thousand population in New Brunswick increased from 116g in 09/10 to 127g in 2010/11; in Prince Edward Island from 87g in 2009/10 to 150g in 2010/11; and increased in Newfoundland and Labrador from 160g in 2009/10 to161g in 2010/11.

NSPBCP continues to analyze data for elements introduced last year. Included in the list are the quantity of IVIG associated with inappropriate dosing; incidence and prevalence of the cases using IVIG in the Atlantic Provinces; and reporting Request approval pathway numbers for new adult cases in the Atlantic Provinces.

New to this year will be the provision of standardized province specific information. A template for this was unanimously agreed upon by the ACIUWG. Atlantic IVIG Clinical Experts-Primary immunodeficiency working group was convened as a subgroup of the Atlantic Collaborative in 2010/11 to ratify the Atlantic guidelines on the use of IVIG for Primary immunodeficiency conditions. The group decided to raise the target range of the serum IgG levels of the immunodeficiency to 7 to 10g/L instead of 5 to 10 g/L. The group also decided to decrease the rate of conversion from 1:1.37 to 1:1 when calculating the dose of SCIG in patients switching from IVIG.

The prevalence and incidence of the cases requiring IVIG in the Atlantic Provinces increased in New Brunswick, Prince Edward Island and Newfoundland and Labrador. The prevalence increased in New Brunswick from 35.8 last year to 39 in 10/11; in Prince Edward Island from 26.2 last year to 34 in 10/11; in Newfoundland and Labrador from 40 last year to 44 in 2010/11. The incidence increased in New Brunswick from 22 last year to 24 in 10/11; in Prince Edward Island from 13.5 last year to 21 in 10/11; in Newfoundland and Labrador from 22.6 last year to 24 in 2010/11. Nova Scotia is the only province in Atlantic Canada where both the prevalence and incidence of cases requiring IVIG declined in 2010/11.

In order to optimize the use of IVIG, the NSPBCP took an Atlantic initiative for the implementation of the IVIG Request approval process in 2009/10. The process was in place throughout 2010/11 in the Maritime Provinces and since January 2011in one of the regions

of Newfoundland and Labrador. This process serves as a guide for resolving issues of appropriateness and dosing of the most common indications in Neurology and Hematology. Two hundred and seventy eight cases underwent the request approval process during 2010/11. It is promising to note that 83% of the requests met the guidelines upon initial submission. 13% were for non Neurology non Hematology indications implying the need of the guideline document in disease categories other than Neurology and Hematology.

The Request approval process was activated in eleven cases that did not meet the guidelines for indication or dosing. Out of those consultation did not occur in one. Two requests were revised one after discussion with the BTS staff and one after discussion with MD. Expert opinions were sought but IVIG was granted for requests that did not meet the guidelines. Five requests were marked as "others". There are many options for this pathway such as, consultation pending but request Granted, consultation pending but request Withdrawn, consultation Unknown but request granted and consultation Unknown but request withdrawn.

The proportion of IVIG used in each of the major disease categories and the major indications for the use of IVIG remains largely unchanged in 2010/11.

Proportion of IVIG doses administered higher or more frequent than recommended improved from last year. Out of the total doses administered for the most common Neurology and Hematology indications 6.1% in Nova Scotia, 10.6% in New Brunswick, 2.58% in Newfoundland and Labrador and 3.3% in Prince Edward Island were higher or more frequent then recommended in 2010/11. It is an improvement from the 2009/10 figures of 9.2%, 12%, 6.5% and 4.2% in Nova Scotia, New Brunswick, Newfoundland and Labrador and Prince Edward Island respectively.

In the Atlantic Provinces 14,458 grams which equals to 4.8% of the total IVIG distributed of IVIG was used as higher or more frequent then recommended in 2010/11. This is an improvement from 17,011g or 6% of the total IVIG distributed last year. Out of the total 14,458g, ninety one percent was used as more frequent and nine percent as higher then recommended doses. In the absence of the clinical data there is no way of capturing whether the frequent dosing is due to lack of expected clinical response or a poor compliance with the guidelines.

An addition was made in the adult IVIG preprinted order form to capture if the repeat dose is due to lack of expected clinical response. This revised preprinted order form will be made available along with the IVIG dose calculator for the sites participating in the new method of dosing IVIG based on adjusted body weight.

The concept of dosing IVIG based on adjusted body weight instead of Actual body weight was introduced by NSPBCP in 2010/11. Hemolysis is associated with higher doses of IVIG. Dosing IVIG based on adjusted body weight is pharmacologically appropriate way of dose capping. The supporting documents and IVIG dose calculator is developed and available for use in the Adult patients of hematology, immunology and neurology (excluding Gullian Barre Syndrome). Data fields are revised for data submitters to accommodate the new data elements. Implementation is expected in Prince Edward Island and one of the District Health Authorities of Nova Scotia in 2011/12.

The use of IVIG for UL-I and labeled indications in the Atlantic Provinces improved during 2010/11 to 114g/1000 population from 107g/1000 last year. This is an improvement to 93.6% of the total use of IVIG during 2010/11 from 91% in 2009/10.

Atlantic Provinces have maintained their use of IVIG for unlabeled not indicated (UL-N) indications at 6.2% of the total use of IVIG or 7g/1000 population from 2009/10 to 2010/11 with an associated Atlantic cost savings of $4,176.68. There was an increase in the use of IVIG for UL-N indications in Nova Scotia from 2.6% in 09/10 to 3.3% in 10/11 and in New Brunswick from 6% in 09/10 to 7.9 % in 2010/11 respectively. There was a decrease in the use of IVIG for UL-N indications in Newfoundland & Labrador and Prince Edward Island from 10.3% and 7.6% in 2009/10 to 8.7% and 1.5% in 2010/11 respectively.

There was a cost savings of $122,288 and $45,447.8 with the declining UL-N use in Newfoundland & Labrador and Prince Edward Island respectively. Nova Scotia and New Brunswick have spent $37,097 and $115,726 more than last year for UL-N use.

Quarterly data analysis of IVIG data was introduced in 2010/11. This supported the timely identification and procurement of further information on the diagnosis of patients categorized as “insufficient information”. The process resulted in minimizing the Atlantic cases classified as “insufficient information” from 33 in 2009/10 to 3 in 2010/11.

Quarterly data analysis also supported the timely identification of serum IgG levels that had escaped reporting. This is reflected as an improvement in the proportion of immune deficiency patients with reported IgG levels in 2010/11in all but one Atlantic province. In Atlantic Provinces 79% of immune deficiency patients had serum IgG levels monitored and reported; it was 75% last year. Monitoring was improved to 93%, 80% and 86% during 2010/11 from 76%, 60% and 74% during 09/10 in Nova Scotia, Prince Edward Island and Newfoundland and Labrador respectively. It declined by 2% in New Brunswick.

With the rise in the target range of serum IgG levels, a higher proportion of patients had trough IgG levels below the target range of 7–10 g/L when compared with the last year’s proportions. Serum IgG levels were above the target of 10g/L in 13% of monitored cases in New Brunswick, 28% in Nova Scotia, 21% in Newfoundland and Labrador and 25% in Prince Edward Island. The dose in these cases may be adjusted to bring the serum IgG levels with in the recommended range.

The total discards of IVIG in Atlantic Provinces increased from 602g last year to 1408g in 2010/11. Discards in Nova Scotia declined from 269g in 09/10 to 213g in 10/11. Discard increased in New Brunswick to 830g in 10/11 from 158 in 09/10; in Prince Edward Island to 60g in 10/11 from zero in 09/10 and in Newfoundland and Labrador to 305g in 10/11 from 175g in 09/10.

An Atlantic SCIG Working Group developed guidelines and implemented the Subcutaneous Immunoglobulin Home Infusion Program for the Atlantic Provinces in 2009. Feed back was collected in October 2010 after a one year pilot. The feedback along with the recommendations from Atlantic IVIG Clinical Experts -Primary immune Deficiency subgroup was incorporated into the guidelines. Revised SCIG Home Administration guidelines will be disseminated along with the new patient education materials on Push as well as Pump method in 2011/12.

In 2010/11, 4813.2g of SCIG was distributed to Atlantic Canada. All reported use was for immunodeficiency patients and was within recommended dosing guidelines. No discards of SCIG were reported.

2 Introduction

This report is a summary of the utilization of IVIG and SCIG in the Atlantic Provinces for the fiscal year 2010/11. The purpose of this report is to describe the use of IVIG and SCIG in the Atlantic Provinces and to identify recommendations for improvements in data quality and/or strategies for optimizing appropriate use of these products and minimizing product wastage.

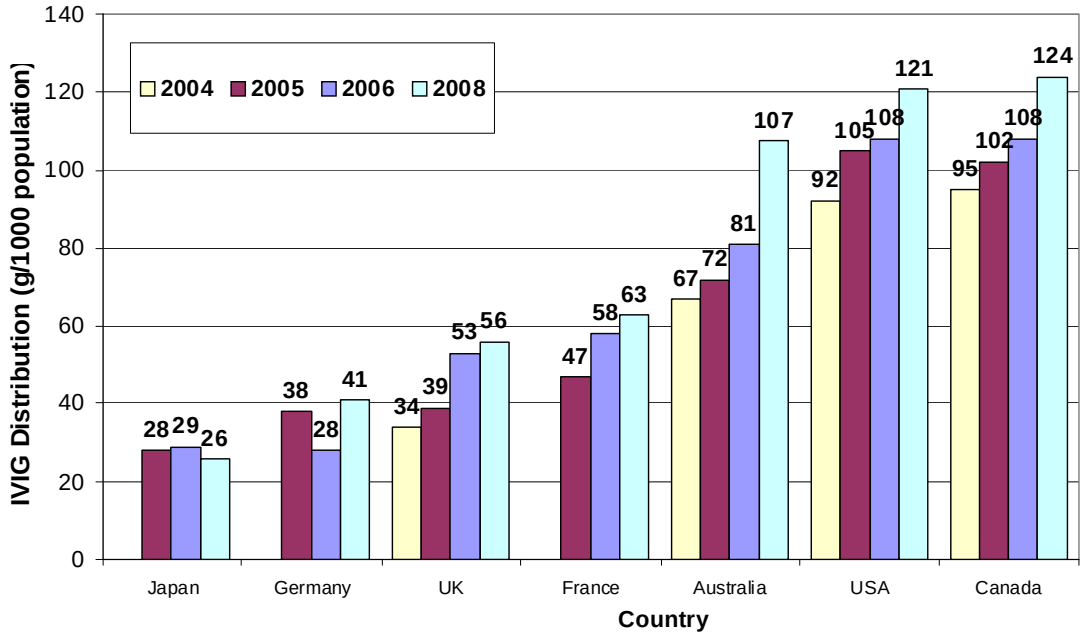
In this report we continue to publish the comparison of IVIG distribution data with the rest of Canada, as this serves as a benchmark for the Atlantic Provinces. In this report the Atlantic Provinces and the rest of Canada are examined separately.

In the Maritime Provinces and in one region of Newfoundland during fiscal year 2010/11, all new adult cases of Neurology and Hematology were subjected to the Request Approval Process and the details on the pathway that the request had undergone is reported in Section 7 of this report.

3 International and National Perspective

Figure 1 shows an international comparison of yearly per capita IVIG distribution for the past several years the most recent being 2008. In 2008, Canada had the highest use of IVIG in grams/1000 population with the United States of America (USA) and Canada using two to three times as much as other countries such as France, United Kingdom, Germany, and Japan. Figure 1 reveals the most recent available data at the time of this publication. The figure is titled 2004-2008 however 2007 data is not included.

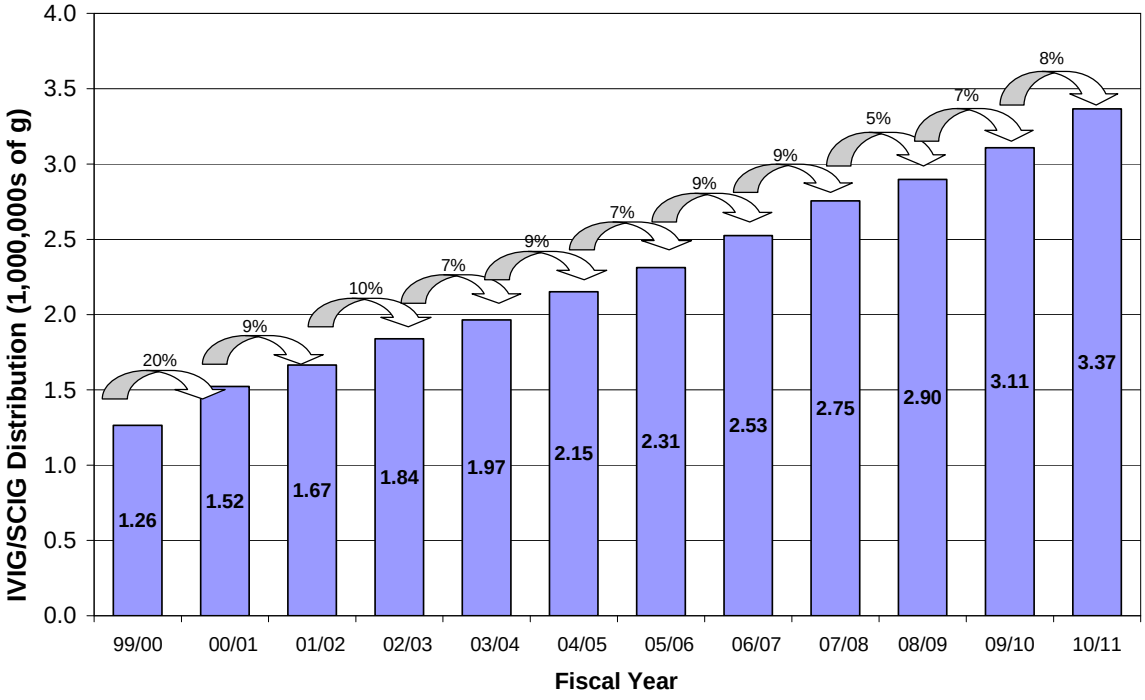
Figure 1: International Comparison of Yearly IVIG Distribution (2004-2008)



Source: International Blood/Plasma News; Australia National Blood Authority; Note: 2007 data not available.

Figure 2 shows the annual distribution of IVIG/SCIG in Canada since the turn of the millennium. The distribution regularly increases between 7–10 percent each year; the distribution of IVIG in Canada increased by 8 % in fiscal year 2010/11.

Figure 2: IVIG/SCIG Distribution in Canada



Note: does not include Quebec

4 Provincial Distribution Trends

Canadian Blood Services (CBS) distributes IVIG to facilities in all provinces except Quebec. This section summarizes the total amounts of IVIG shipped to facilities in the Atlantic Provinces in recent fiscal years. It should be noted that this is different from the amount of IVIG that is *utilized*, but it can be used as a very good estimate, especially when monitoring year-to-year trends.

Table 1 shows the total grams and the cost of IVIG distributed by CBS to each of the Atlantic Provinces for fiscal years 2004/05 to 2010/11.

The distribution of IVIG increased in New Brunswick, Prince Edward Island and Newfoundland and Labrador, during 2010/11. The distribution of IVIG increased in New Brunswick from 86,640g last year to 95,568g in 10/11; in Prince Edward Island from 12,255g last year to 21,355g in 10/11; in Newfoundland and Labrador from 81,650g last year to 82,115g in 2010/11. Nova Scotia is the only province in Atlantic Canada where the distribution of IVIG declined from102,148g in 2009/10 to 98,745g in 2010/11. This was associated with a decrease in the cost of IVIG for Nova Scotia in 2010/11.

Table 1: Total Grams and Cost* of IVIG Distributed to the Atlantic Provinces by Fiscal Year

Fiscal Year	New Brunswick		Nova Scotia		Prince Edward Island		Newfoundland & Labrador	
	Grams	Dollars	Grams	Dollars	Grams	Dollars	Grams	Dollars
2004/05	53,005	$3,263,330	67,338	$4,140,632	5,650	$344,400	59,328	$3,681,747
2005/06	62,828	$3,684,521	65,875	$3,878,469	7,550	$442,823	61,660	$3,639,135
2006/07	64,055	$3,540,739	88,108	$4,867,830	11,010	$597,763	67,800	$3,740,847
2007/08	68,370	$3,819,307	105,479	$5,602,758	15,235	$821,456	71,407	$4,065,703
2008/09	76,001	$4,350,852	104,502	$5,952,086	13,995	$814,328	66,179	$3,782,587
2009/10	86,640	$5,769,046	102,148	$6,825,891	12,255	$817,074	81,650	$5,451,493
2010/11	95,568	$6,011,384	98,745	$6,211,252	21,355	$1,343,266	82,115	$5,165,196

*** Costs** shown in this table reflect the actual amounts paid by each province and are not estimates.

Table 2 shows the total grams and the cost of SCIG distributed to each of the Atlantic Provinces for fiscal years 2008/09 to 2010/11. There was a rise in the distributed grams of SCIG during 2010/11 in New Brunswick, Nova Scotia and Newfoundland & Labrador.

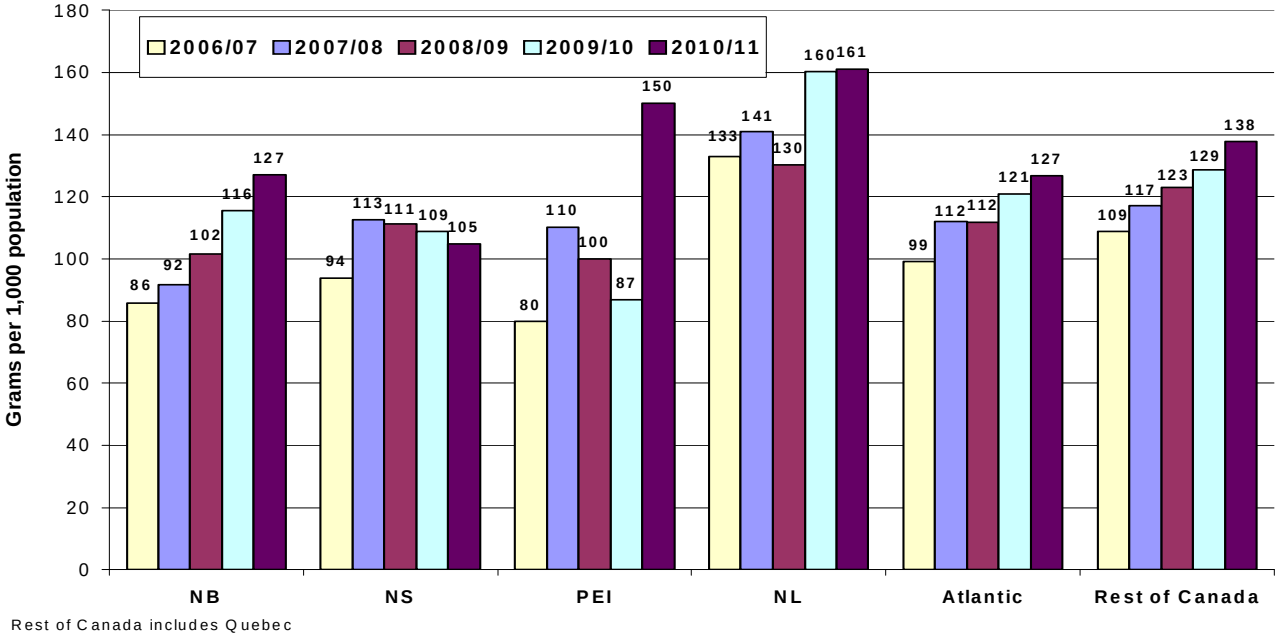
Table 2: Total Grams and Cost* of SCIG Distributed to the Atlantic Provinces by Fiscal Year

Fiscal Year	New Brunswick		Nova Scotia		Prince Edward Island		Newfoundland & Labrador	
	Grams	Dollars	Grams	Dollars	Grams	Dollars	Grams	Dollars
2008/09	115	$6,913	403	$24,195	0	0	77	$4,608
2009/10	346	$23,060	1205	$79,821	0	0	282	$18,141
2010/11	651	$40,960	3359	$211,293	0	0	803	$50,521

* Costs shown in this table reflect the actual amounts paid by each province and are not estimates.

The distribution of SCIG increased in New Brunswick from 346g last year to 651g in 10/11; in Nova Scotia from 1205g last year to 3359g in 10/11; in Newfoundland and Labrador from 282g last year to 803g in 2010/11. There was no SCIG distributed to Prince Edward Island.

Figure 3: IVIG Distribution in the Atlantic Provinces and the Rest of Canada Per 1000 Population



Rest of Canada includes Quebec

Figure 3 shows a comparison of the amount of IVIG distributed per thousand population in each of the Atlantic Provinces and combined as well as the amount of IVIG distributed to the rest of Canada including Quebec. The distribution of IVIG increased in Newfoundland & Labrador from 160g/1000 population in 09/10 to 161grams /1000 population in 2010/11; in New Brunswick from 116g/1000population to 127grams /1000 population in 2010/11; in Prince Edward Island from 87g/1000population to 150grams /1000 population in 2010/11. Nova Scotia demonstrated a decrease in distribution from 109grams/1000population in 09/10 to 105 grams/1000 population in 2010/11. The Atlantic Provinces combined show a rise from 121grams/1000 population to 127 grams/1000 population which is well below the distribution of 138grams/1000 population of IVIG in the rest of Canada (including Quebec). There was a rise in distribution of IVIG from 129 grams/1000 in 2009/10 to 138 grams/1000 population in Rest of Canada (including Quebec and excluding Atlantic provinces) during 2010/11.

Figure 4: Annual % Change of IVIG Plus SCIG Distibuted

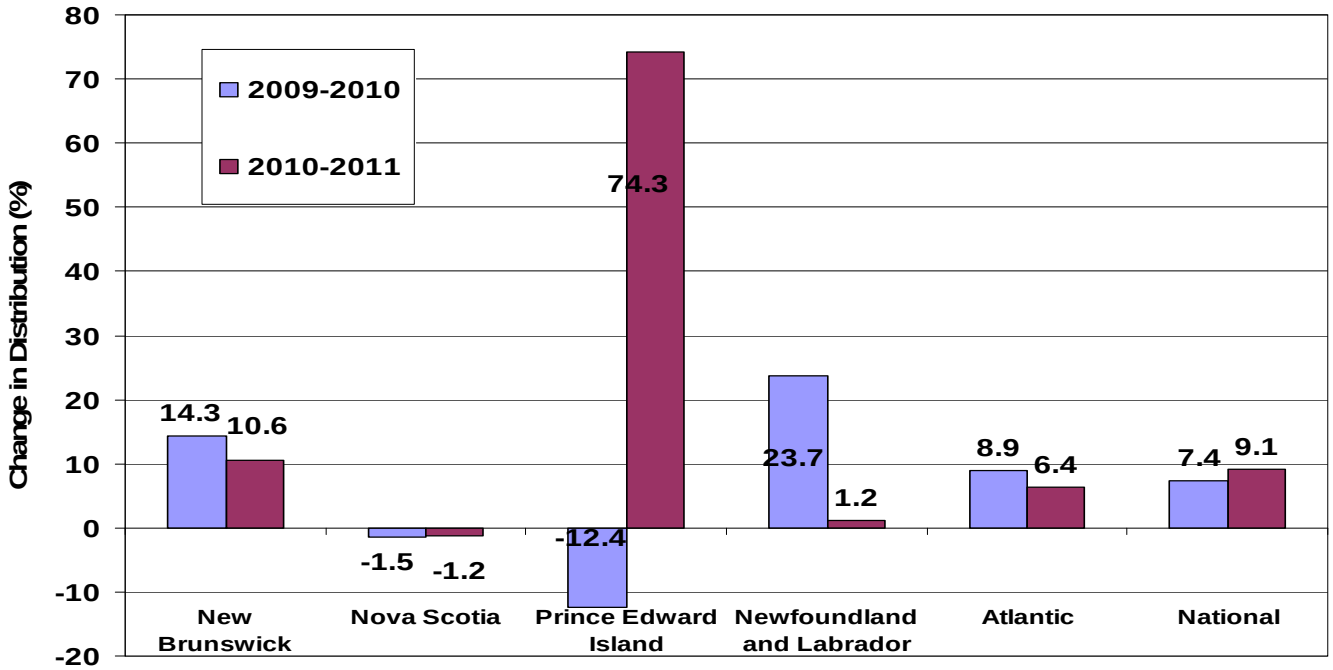


Figure 4 shows that the variance in distribution of IVIG and SCIG. The annual percent change in Newfoundland & Labrador, New Brunswick and Prince Edward Island increased by 1.2%, 10.6 % and 74.3% respectively in 10/11 from last year; distribution of IVIG and SCIG declined by 1.2% in Nova Scotia during 2010/11 from last year. Canada (including Quebec) experienced a 9.1% increase in distribution whereas; the Atlantic Provinces combined had an increase of 6.4% in distribution from last year.

Fig 5 shows the provincial comparison of national IVIG distribution per 1000 population.

Figure 5: National IVIG Distribution Per 1000 Population

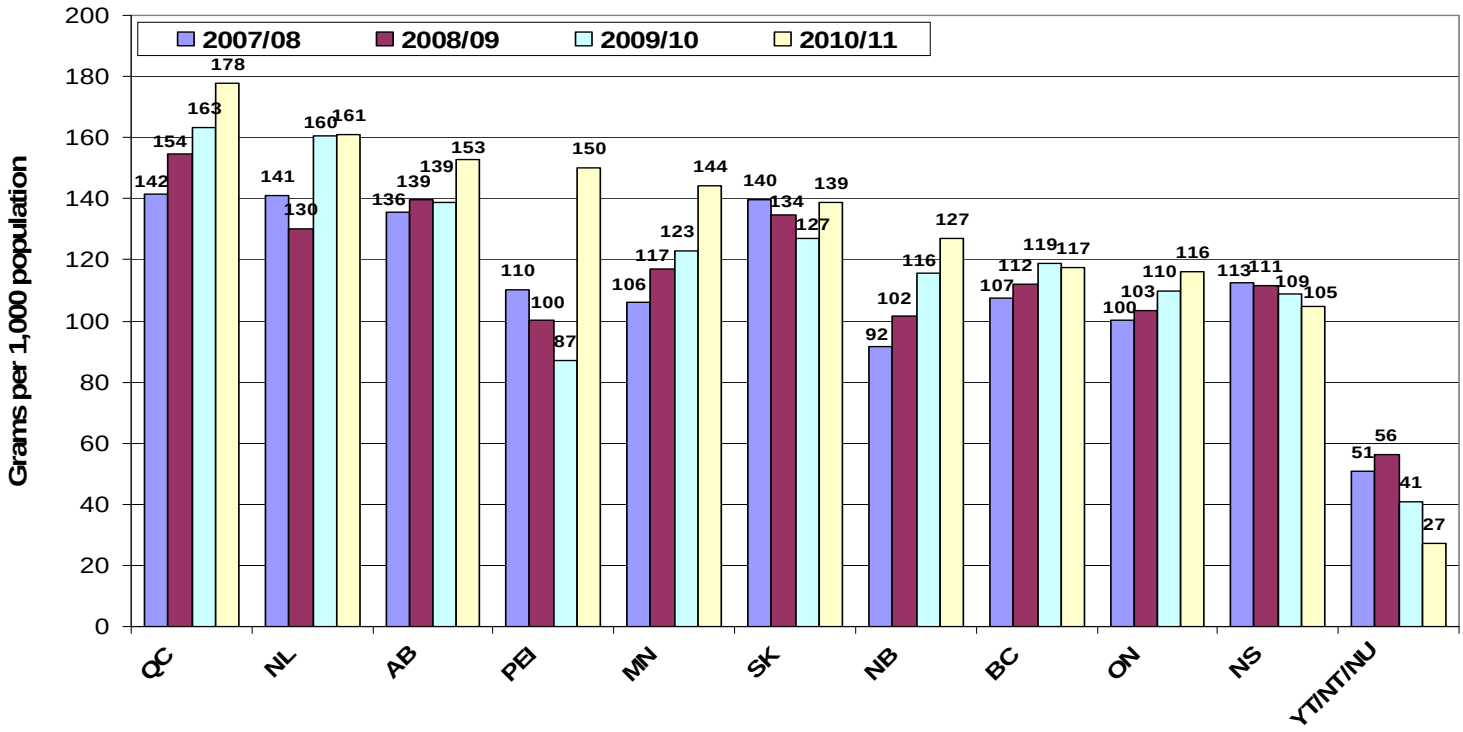
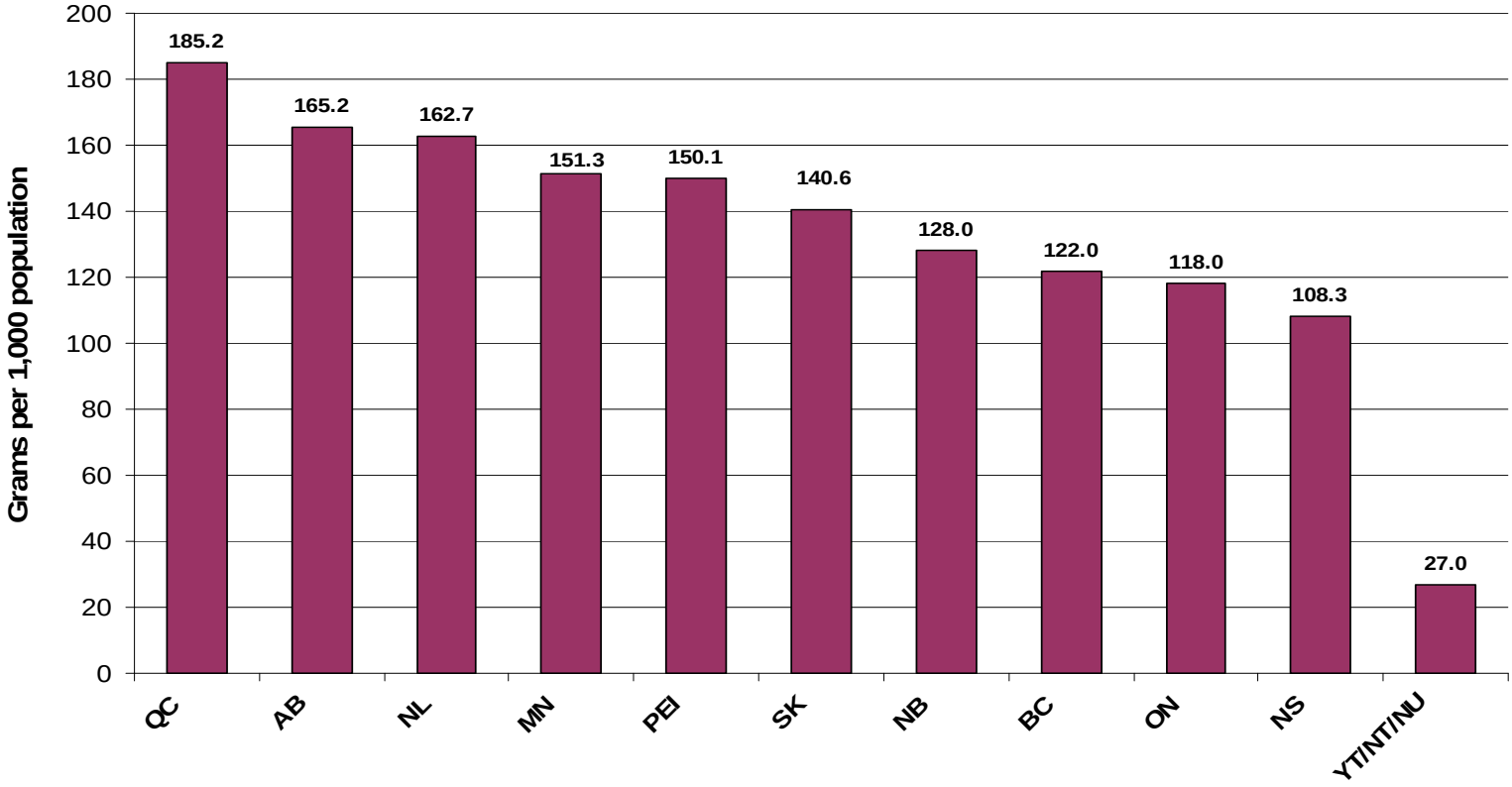


Figure 6: National IVIG+SCIG Distribution Per 1000 Population for 2010/11



Source: CBS (PT Portal)

Fig 6 shows the provincial comparison of national IVIG and SCIG combined distribution per 1000 population for fiscal year 2010/11.

5 Utilization Data

The information presented in the remainder of this report is derived from the IVIG utilization database housed at the Nova Scotia Provincial Blood Coordinating Program (NSPBCP). The following sections provide information regarding the data used to create the graphs and tables and should be considered in the interpretation of the utilization information in this report.

5.1 Data Collection

The population of reference for this report is all patients who received doses of IVIG for any indication. Percent capture of the distribution data for the Atlantic Provinces during the time period of this report was 96.5%. This is based on the amount of IVIG reported as *utilized (transfused +discarded)* divided by the total amount of IVIG *distributed.* The high percent capture supports the fact that the utilization data in this report is representative of the actual overall utilization and a result of a continuous evaluation, reminders, support and mutual effort between the NSPBCP and the data submitters throughout the Atlantic Provinces.

Percent capture of each Atlantic province is shown in Table 3. There is an improved percent capture in Nova Scotia for the last two years. An automated quarterly lab extract is now used to capture the utilization data in one of the DHAs of Nova Scotia; this has resulted in a timely and improved percentage capture of IVIG utilization data in Nova Scotia.

Table 3: Percent Capture for Each Province

Province	Percent Capture 2008-2009	Percent Capture 2009-2010	Percent Capture 2010-2011
New Brunswick	93.0%	97.1%	96.6%
Nova Scotia	89.3%	96.9%	96.9%
Prince Edward Island	99.1%	100%	89.3%
Newfoundland and Labrador	97.3%	100%	97.9%

Excludes SCIG
Includes (available) discard information

Table 4 provides the details of distributed and utilized IVIG data in the Atlantic Provinces. These are the figures used to generate the percent capture in each province.

To further improve the percent capture, it is recommended that a quarterly feedback be provided to the data submitters from NSPBCP. This will provide the opportunity to timely fill in the gaps of data submission.

Table 4: Percent Capture for Each Province 2010-11

Province	Distributed	Utilized	Discards	Diff of Distributed and Utilized	Percent Capture
New Brunswick	95567.5	91486.1	830.0	3251.4	96.6%
Nova Scotia	98745.0	95450.2	212.5	3082.3	96.9%
Prince Edward Island	21355.0	19015.0	60.0	2280.0	89.3%
Newfoundland & Labrador	82115.0	80075.4	305.0	1734.6	97.9%
Atlantic Provinces	297782.5	286026.7	1407.5	10348.3	96.5%

5.2 Data Quality

The NSPBCP strives to continuously improve the data obtained for analysis. One strategy is review of all submitted data for inconsistencies and incompleteness of the fields. Most of these checks are now completed using automated integrity queries. Any inconsistencies discovered by the queries are investigated and resolved. All cases with indications marked insufficiently or as “others” are identified and correct further information on diagnosis is sought. This is done to minimize the ambiguity in the categorization of the indications for the appropriateness of the use of IVIG. Clinical experts are consulted electronically to assign the appropriateness category when ever IVIG is used for any new indication.

This report includes data received by the NSPBCP for fiscal year 2010/11. The data is extracted from the database and that is the source used for generating the report. Data for fiscal year 2010/11 can continue to be entered into the database but it will not be part of the extract used for generating the report.

The NSPBCP continues to successfully liaise with one of the DHAs in Nova Scotia and the Lab Information System manager to obtain a quarterly data extract from the District’s Laboratory Information System (LIS). This approach has decreased human resource dependence as well as eliminated manual data entry errors. It is recommended that in order to minimize the human error, jurisdictions consider the option of exploring extracts of data from LIS systems into DaISI (flat files).

Currently there is a lag period of about one year between the end of the fiscal year and the dissemination of the annual IVIG and SCIG report. The NSPBCP aims to minimize this lag and provide timely feedback to the end users of the IVIG and SCIG data. Procurement of the Laboratory Information System (LIS) extract has supported this goal of NSPBCP. Last year the final analysis was performed in September whereas this year it was performed in July. Quarterly data submissions with review of missing data and data clean up contributed to the quality improvement and must be continued.

5.3 Data Elements

In 2010/11 data fields were added to DaISI related to the dosing of IVIG based on Adjusted Body Weight. This will be activated in sites implementing IVIG dosing calculation based on Adjusted body weight for data submission.

6 Disease Categories and Indications

When IVIG was first introduced in the early 1980s, it was used exclusively for immune deficiencies. Since that time the number of indications for its use has expanded across a wide range of specialties. Figure 7 shows the relative proportion of IVIG used by major disease categories. It is important to consider that the disease category is based on the categorization of the indication for use and does not necessarily reflect the specialty of the ordering physician.

Fig 7 shows an increase in the proportion of the utilization of IVIG in neurology and dermatology while the proportion of the IVIG used in hematology, immunology and rheumatology decreased in 2010/11.

Figure 7: Proportion of IVIG Use by Disease Category in the Atlantic Provinces for Recent Fiscal Years

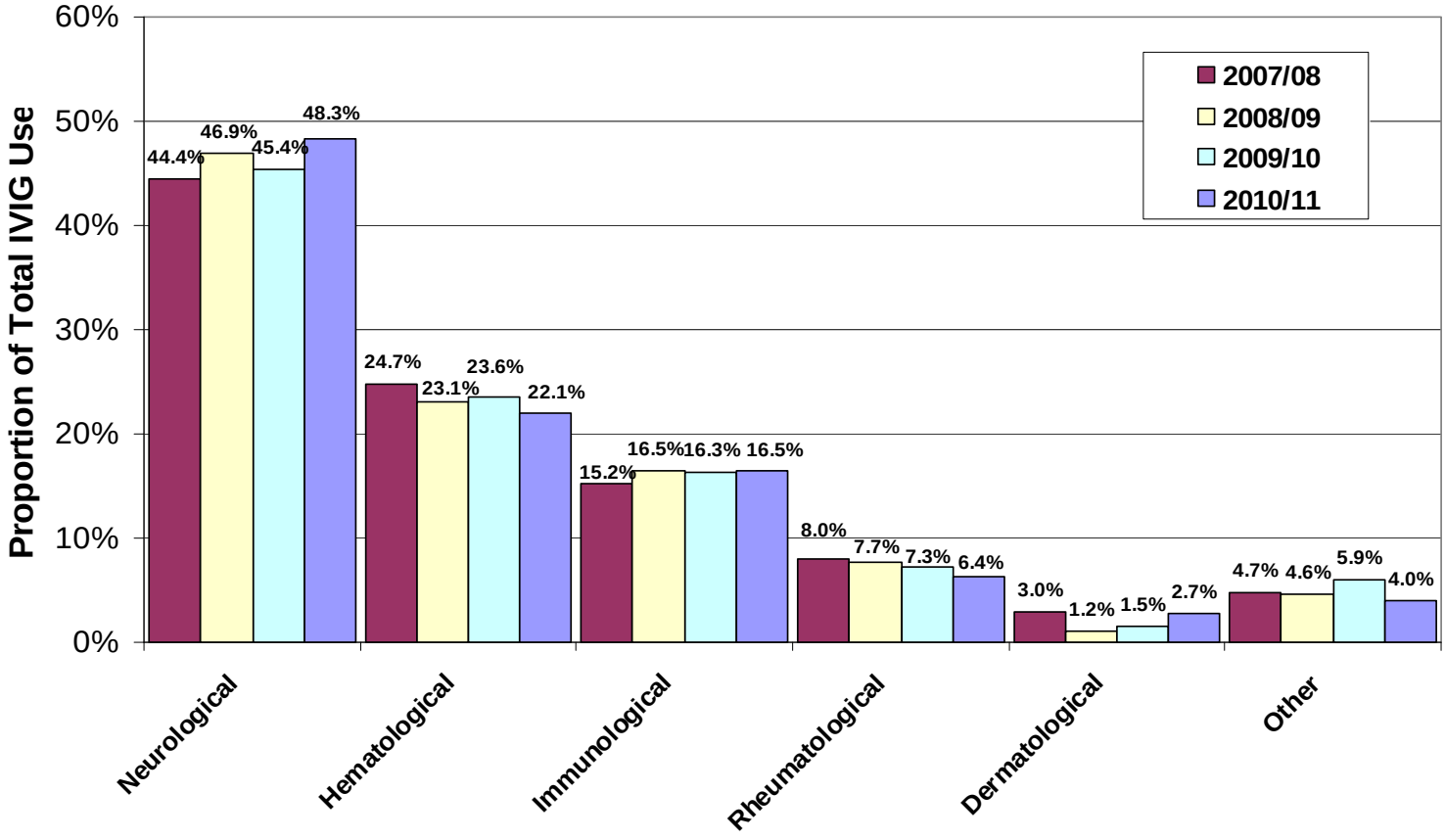
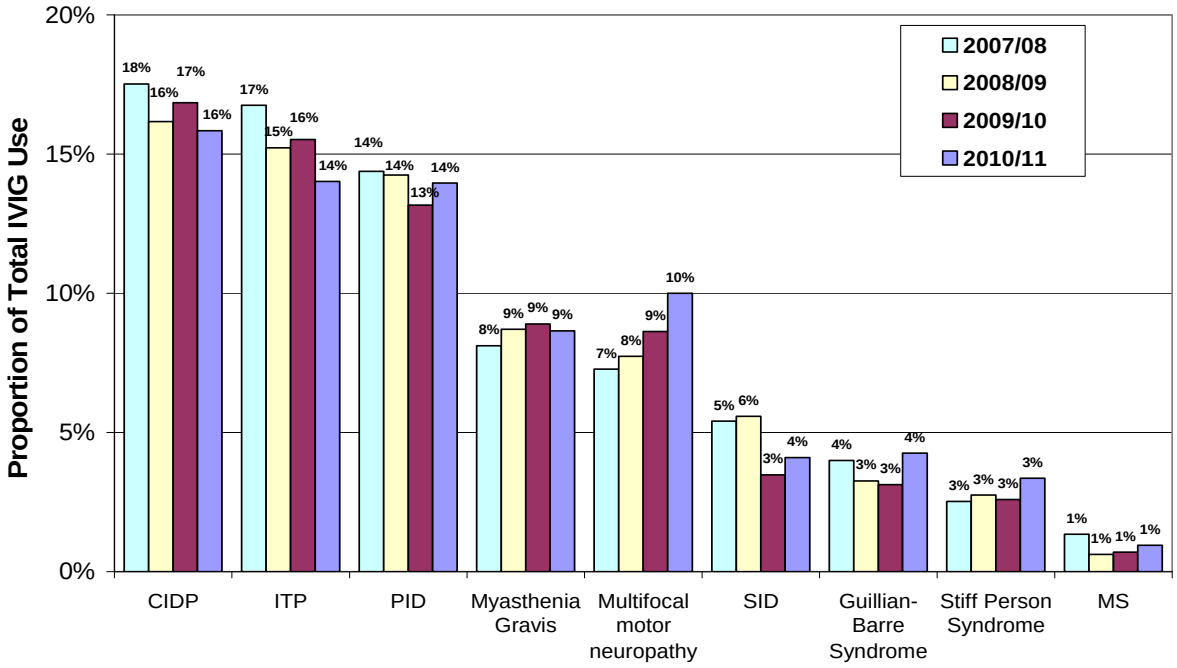


Figure 8 shows the relative proportion of total IVIG used in each of the most common indications. Again, each major indication maintained its rank from 2009/10 to 2010/11; there are other fluctuations. Common variable immunodeficiency is grouped under primary immune deficiency conditions and this is reflected as a rise in PID in Figure 8.

Figure 8: Proportion of IVIG Use by Indication in the Atlantic Provinces for Recent Fiscal Years



Graphs showing provincial-level per capita IVIG utilization for each of the indications shown in Figure 8 can be found in Appendix A.

7 Request Approval Process

In an effort to optimize the appropriate use of IVIG the Atlantic Collaborative IVIG Utilization Working Group (ACIUWG) developed an Atlantic-wide IVIG request approval system. Through this process, requests for IVIG are reviewed to determine if the indication, as well as the dosing, frequency and duration of treatment, meet the guidelines for its use. In the event of an incongruity, the ordering physician is contacted and discussion ensues regarding the variation. If the ordering physician continues to feel that a given case merits a change from the guidelines, he or she is asked to discuss the case with a consultant with the relevant clinical expertise. The pathway thus taken by the request is allocated a number representing the route it took for its approval. These pathway numbers are recorded and submitted for each and every new request of IVIG. A detailed guide of the request approval pathway numbers is attached as an appendix D at the end of the report.

Currently the project addresses the requests for IVIG for neurological and hematological indications, the two largest areas of adult use. The neurological and hematological guidelines have been developed by the Atlantic IVIG Clinical Experts Working Group and are based on those published by the National Advisory Committee on Blood and Blood Products in Transfusion Medicine Reviews in 2007. A comparable preprinted order form was developed for indications in the pediatric conditions.

The implementation of this process occurred in November 2009 in Nova Scotia, December 2009 in New Brunswick, March 2009 in Prince Edward Island and January 2011 in one region of Newfoundland Labrador. The data of 2010/11 in the Atlantic Provinces shows an improvement in dosing and appropriateness of use of IVIG when compared with the same of 2009/10.

Table 5 shows the distribution of request approval pathways taken by new adult IVIG cases in the Maritime Provinces during 2010/11 and in one region of Newfoundland Labrador during Q4 of 2010/11. Of the 278 requests that went through the approval process, 13 % were for indications not listed in the guidelines (non neurology and non hematology patients); and 83% met the guidelines for indication and dosage upon initial submission.

Request approval process was activated in eleven cases that did not meet the guidelines for indication or dosing. Out of those consultation did not occur in one. Two requests were revised one after discussion with the BTS staff and one after discussion with MD. Expert opinions were sought but IVIG was granted for requests that did not meet the guidelines. Consultation did not occur in one request. Five requests were marked as “other” or pathway number 9 which has many options like consultation pending but request Granted/ consultation pending but request withdrawn/ consultation unknown but request Granted/ consultation unknown but request withdrawn.

A strategy of incorporating UL-N indications into the existing IVIG request approval process was piloted in Nova Scotia effective April 1, 2010. The orders of IVIG for UL-N indications are subjected to the same process of review as are the existing appropriate

indications for neurology and hematology. Appendix C contains the list of UL-N indications for neurology and hematology.

Work is under progress for the expansion of this list in Disease categories other than neurology and hematology. It is recommended that the adult request approval process be expanded beyond neurological and hematological conditions to include immunological conditions and solid organ transplantation. It is also recommended that the Request Approval Process be implemented in the Pediatric cohort.

Table 5: Request Approval Pathways in Atlantic Provinces

Pathway #	Description	NB April 10– Mar 11	NS April 10 – Mar 11	PEI Apr 10-Mar 11	NL Jan 11- Mar 11
1	Request for an indication not listed in guidelines	25	9	1	1
2	Request met the guidelines upon initial submission	118	88	24	1
3	Request was revised after discussion with BTS staff				1
4	Request was withdrawn after discussion with BTS staff				
5	Request was revised to meet the guidelines after ordering MD consult	1			
6	Request was withdrawn after ordering MD consulted with the clinical expert				
7	Original request was granted even after the ordering MD consulted with the expert		3		
8	Consultation with the clinical expert did not occur	1			
9	Others	5	0		
Total		**150**	**100**	**25**	**3**

8 Appropriateness of Use

8.1 Appropriateness of Indications

When IVIG utilization data is received by the NSPBCP, the indications for the use of IVIG are categorized based on its appropriateness. The following describes the categories used:

- **L** (Labeled): the manufacturer can advertise the use of IVIG for these conditions
- **UL-I** (Unlabeled, Indicated): the manufacturer cannot advertise the use of IVIG for these conditions, but there is some evidence to support its use
- **UL-N** (Unlabeled, Not Indicated): there is no evidence to support the use of IVIG or
- **Insufficient Information**: the NSPBCP was unable to obtain sufficient information. Evidence exists that shows it to be ineffective that would lead to a definitive category assignment. In most cases the indication provided is only a symptom or overly general diagnosis rather than the specific indication for the use of IVIG. This category is addressed in the Data Collection section of this report.

Figure 9 shows a summary of the IVIG used per 1000 population for each of the appropriateness categories in the Atlantic Provinces. The Atlantic Provinces have maintained their use of IVIG for unlabeled not indicated (UL-N) indications at 6.2% of the total use of IVIG from 2009/10 to 2010/11. The overall Atlantic use for UL-N indications remained at 7g/1000 population in 2010/11 as in 2009/10. The use of IVIG for UL-I and labeled indications in the Atlantic Provinces improved during 2010/11 to 114g/1000 population from 107g/1000 last year. This is equal to 93.6% of the total use of IVIG during 2010/11 and an improvement from 91% of 2009/10.

Figure 9: Appropriateness of IVIg Use in the Atlantic Provinces

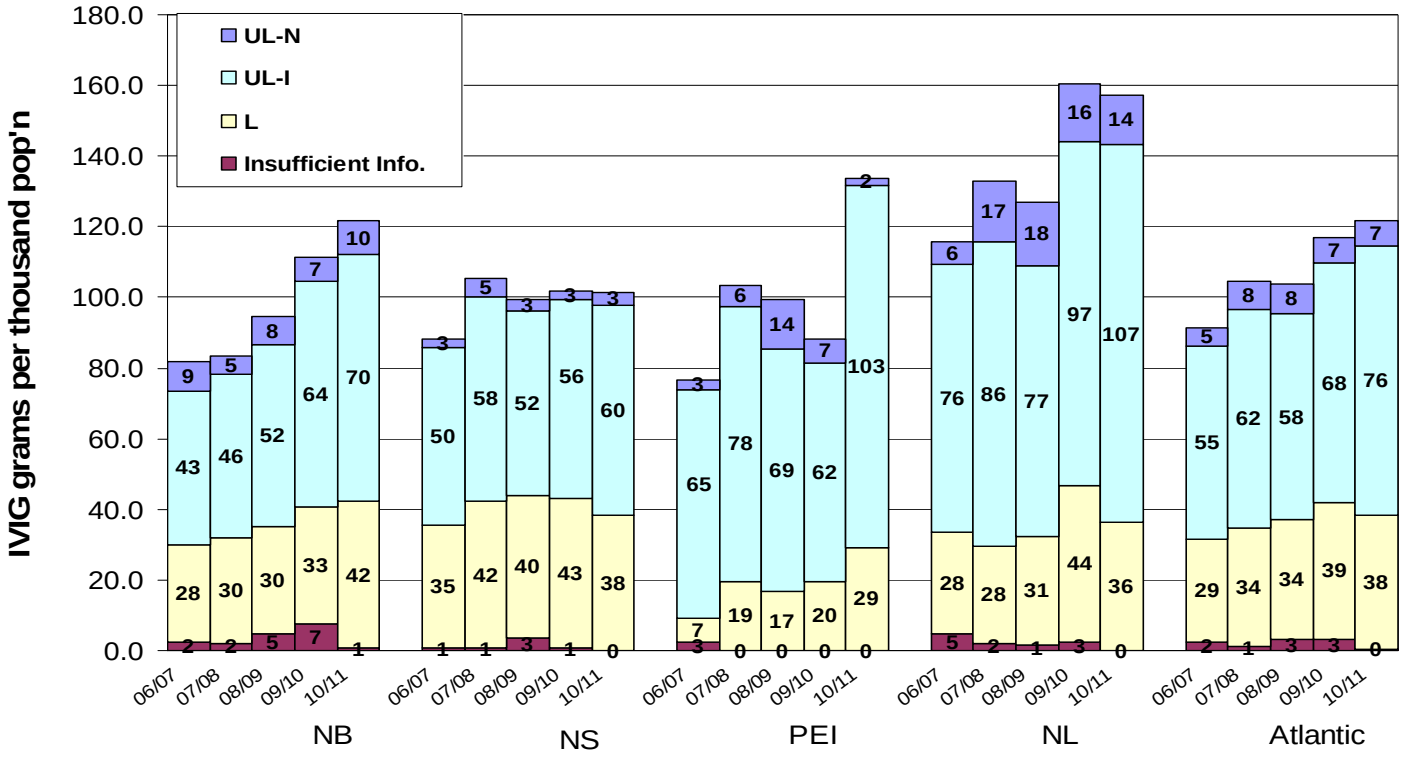


Figure 10 shows the proportion of IVIG for UL-N indications in the Atlantic Provinces. Nova Scotia and New Brunswick have increased their use of IVIG for the ULN indications from 2.6% and 6.1% of the total use of IVIG in 2009/10 to 3.3% and 7.9% in 2010/11 respectively. Newfoundland & Labrador and Prince Edward Island have improved in their utilization of IVIG for the UL-N indications from 10.3% and 7.6% in 2009/10 to 8.7% and 1.5% in 2010/11 respectively. The UL-N usage in the Atlantic Provinces continues to be at 6.2% of the total use in 2010/11.

Figure 10: Proportion of IVIG Use for ULN Indications

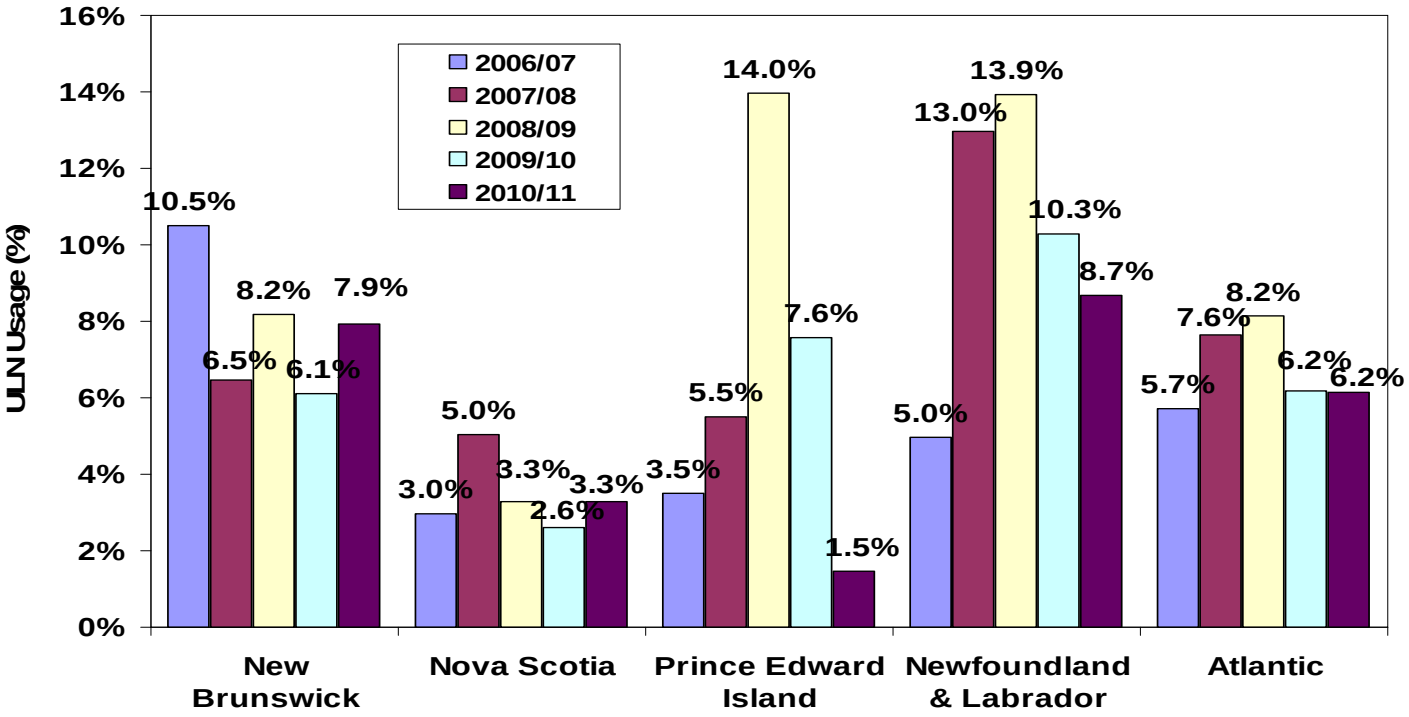


Table 6 reveals an estimated Atlantic cost savings of $4,176.68 in the use of IVIG for UL-N in 2010/11. This is partly due to a decline in the per gram cost of IVIG this year.

There was cost savings of $122,228.4 and $45,447.8 associated with the declining use of IVIG for the UL-N indications in Newfoundland & Labrador and Prince Edward Island respectively. Nova Scotia and New Brunswick have spent $37,097 and $115,726 respectively more than last year for UL-N use.

Table 6: Estimated Cost* of ULN IVIG Use in the Atlantic Provinces in Recent Fiscal Years

Fiscal Year	New Brunswick	Nova Scotia	Prince Edward Island	Newfoundland and Labrador
2005/06	$274,894.24	$71,401.10	$17,349.80	$149,808.85
2006/07	$427,038.64	$164,422.72	$24,690.10	$195,852.55
2007/08	$268,921.90	$332,181.94	$52,383.05	$583,820.77
2008/09	$384,898.64	$204,240.51	$129,456.20	$599,001.85
2009/10	$339,689.07	$159,151.05	$63,059.85	$559,697.88
2011/10	$455,414.87	$196,248.00	$17,612.00	$437,469.50

* Estimated cost is calculated by multiplying the total grams by an average price per gram of $62.90

8.2 Dosing

Clinical criteria and proper dosing have to be considered even if an indication is classified as appropriate. Data on clinical criteria are not collected, but enough information is collected on patient doses to make an assessment as to whether or not the dosing guidelines are being followed.

Table 7 provides an overview of the percent of doses that were either too high or too frequent for some of the top indications. The assessment was based on the guidelines adopted for the common request approval process in the Atlantic Provinces. The source for these was the 2007 National Advisory Committee on Blood and Blood Products guidelines for hematology and neurology. In completing the analysis, it could be seen that many variations in dosing exist. For consistency, a dosing pattern was considered appropriate if the total amount used in a given time period (usually four weeks) was within the recommended amount, even if the actual frequency of administration differed somewhat from the guidelines. In other words, weekly, biweekly, and monthly dosing regimes were all considered appropriate if the total amount in a four-week period was in line with the guidelines.

In 2010/11, all Atlantic Provinces revealed an improvement in the percent of doses administered that were appropriate for the nine most common indications in Neurology and Hematology. Percent of appropriate dosing in Nova Scotia improved from 9.2% in 2009/10 to 6.1% in 2010/11; New Brunswick from 12% 2009/10 to 10.59% in 2010/11; Newfoundland and Labrador from 6.5% 2009/10 to 2.58% in 2010/11 and Prince Edward Island decreased from 4% 2009/10 to 3.3% in 2010/11. It is important to note that this analysis does not consider clinical criteria; it only compares the reported dosing to the guidelines for dosing.

Table 7: Percent of Doses Administered Higher or More Frequent than Recommended for Selected Indications

Indication	NB			NS			PE			NL		
	08/09	09/10	10/11	07/08	08/09	10/11	08/09	09/10	10/11	08/09	09/10	10/11
CIDP*	35.0	27.0	5.2	26.0	19.0	1.4	0.0	0.0	0.0	18.0	7.0	0.4
Myasthenia Gravis	7.0	4.0	12.1	19.0	22.0	1.0	**	**	0.0	4.0	0.0	3.6
Guillain-Barré Syndrome	57.0	7.0	5.9	12.0	6.0	18.5	63.0	33.0	**	41.0	13.0	19.5
Multifocal Motor Neuropathy	40.0	41.0	21.4	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Multiple Sclerosis	0.0	0.0	0.0	31.0	0.0	6.1	**	**	0.0	0.0	15.0	**
Stiff Person Syndrome	78.0	**	0.0	0.0	3.0	0.0	**	**	0.0	0.0	0.0	0.0
ITP	24.0	24.0	10.9	14.0	9.0	22.4	14.0	0.0	21.3	7.0	24.0	6.1
Secondary Immuno-Deficiency	6.0	3.0	1.4	32.0	12.0	0.0	0.0	3.0	0.0	20.0	13.0	4.7
Primary Immuno-Deficiency	15.0	2.0	11.9	28.0	12.0	3.9	0.0	0.0	0.0	11.0	2.0	0.0

* chronic inflammatory demyelinating polyradiculoneuropathy
** IVIG was not used for this indication in the given time period.

In order to determine the grams associated with higher or more frequent doses in these most common indications, further analysis was performed. The same assessment guidelines that were described previously were applied and the extra grams associated with the higher doses were totaled as were the grams associated with doses administered more frequently than recommended dosing guidelines.

Table 8 shows the provincial comparison of the IVIG use as higher or more frequent then recommended in 09/10 and 2010/11**.** The grams of IVIG used as higher or more frequent then recommended has decreased in the Atlantic Provinces from 17, 011g in 09/10 to14,458g during 2010/11. This comprises approximately 5% of the IVIG used in Atlantic Canada during 10/11 and is lower than last year's 6%.

Table 8: Comparison of total use of IVIG where dosing is higher or more frequent then recommended by Fiscal Year

Fiscal Year	NB	NS	PEI	NL	Atlantic
2009-2010	6,650	6,234	190	3,937	17,011
2010-2011	8,123	4,674	520	1,141	14,458

Figure 11: Comparison of Total Use of IVIG Where Dosing is Higher or More Frequent than Recommended by Fiscal Year

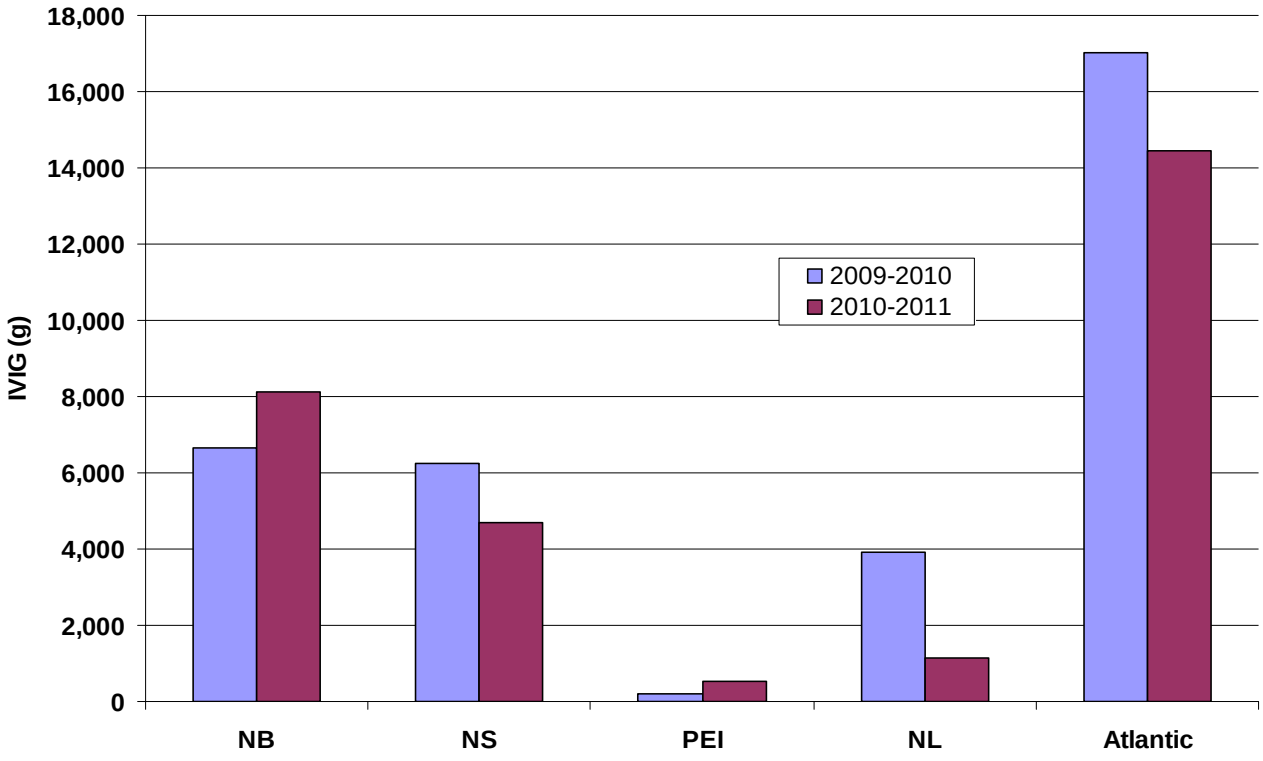


Table 9 reveals the provincial comparison of grams of IVIG given as higher and more frequent than recommended. Ninety one percent (13,162g out of 14,458g,) was used as more frequent doses; and 9% (1,296g) as higher than recommended doses in 2010/11. In 2009/10 seventy six percent of total 17,011g was given as more frequent doses then recommended and 24% was given as higher then recommended doses. NSPBCP does not collect clinical data to comment on the clinical requirement of the repeat doses. There is an inability to classify the 91% of more frequent then recommended doses as "clinically indicated or not". Some revisions are made requesting the Physicians to indicate if the IVIG dose is repeated due to lack of expected clinical outcome in the data collection tools. These are made available in the modified Adult Preprinted order form for the jurisdictions implementing the Dosing IVIG based on adjusted body weight.

Table 9: Comparison of Provincial use of IVIG as Higher than recommended and/or More Frequent than Recommended

IVIG	NB		NS		PEI		NL	
	09-10	10-11	09-10	10-11	09-10	10-11	09-10	10-11
More frequent than recommended IVIG grams (Percentage of total)	5290 (79.5)	7535 (92.8)	3942 (63.3)	4195 (89.7)	190g (100)	520 (100)	3545 (90.0)	912 (80.0)
Higher doses than recommended IVIG grams (Percentage of total)	1360 (20.5)	588 (7.2)	2292 (36.7)	479 (10.3)			392 (10.0)	229 (20.0)
Total grams	**6650**	**8123**	**6234**	**4674**	**190**	**520**	**3937**	**1141**

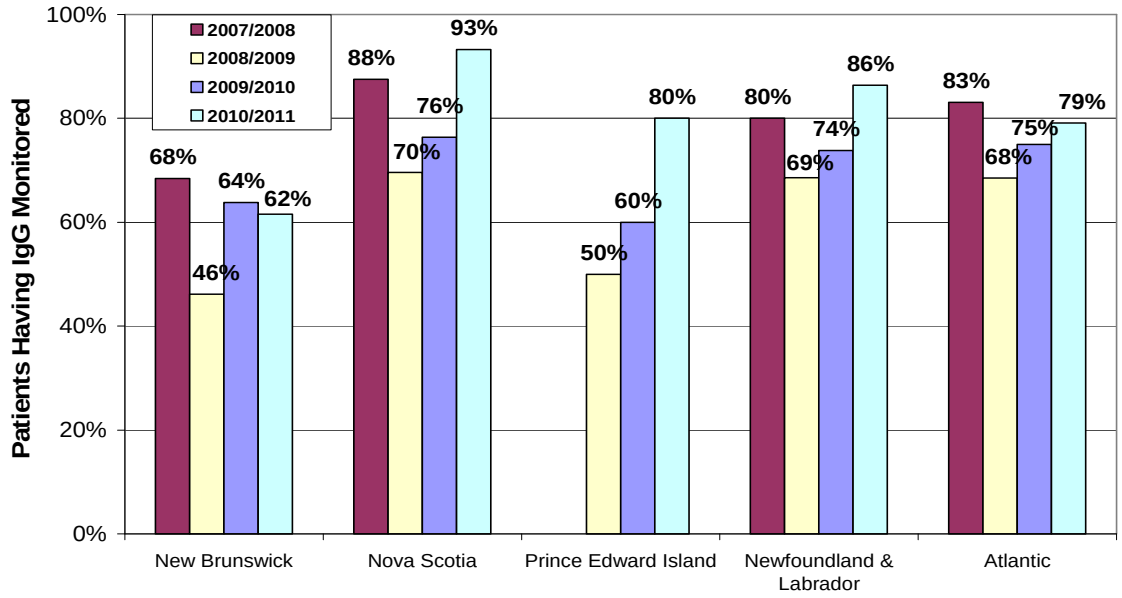
8.3 IgG Levels for Immune Deficiencies

When patients are receiving IVIG for the treatment of immune deficiencies, it is recommended that serum IgG levels be measured on a regular basis and the dose of IVIG be adjusted to keep the IgG level between 7 and 10g/L.

Figure 12 shows the proportion of patients with immune deficiencies who had their IgG levels monitored. The frequency of monitoring cannot be inferred from this graph. It can be seen that there was a marked improvement in the monitoring of IgG

levels in the Atlantic Provinces from 75% during 2009/10 to 79% 2010/11 in. This improvement was seen in Nova Scotia, Prince Edward Island and Newfoundland and Labrador. There was an improvement in monitoring serum IgG levels from 76%, 60% and 74% in 2009/10 to 93%, 80% and 86% during 2010/11 in Nova Scotia, Prince Edward Island and Newfoundland and Labrador respectively. New Brunswick declined in monitoring serum IgG levels from 64% in 2009/10 to 62% in 2010/11.

Figure 12: Proportion of Patients with Primary or Secondary Immune Deficiency who had IgG Levels Monitored



Note: PEI did not report IgG levels until 08/09

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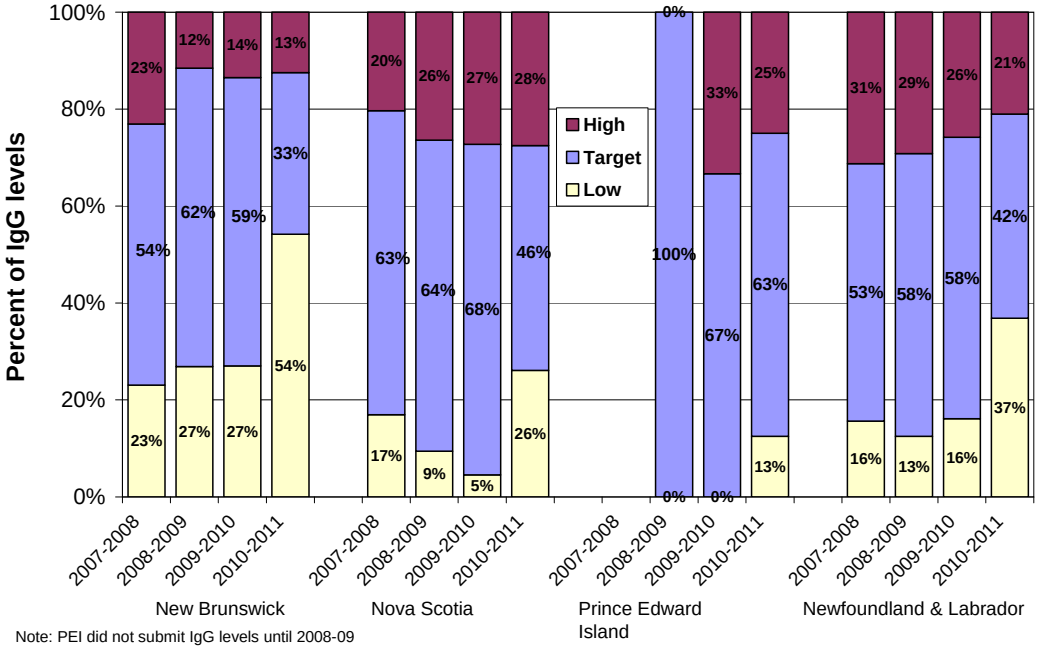
Figure 13 illustrates the proportions of patients whose most recent IgG levels were within the target range of 7 and 10 g/L. This is indicated by the size of the middle section of each bar. The top and bottom sections indicate the proportions of patients whose most recent IgG levels were above and below the target range respectively. This graph only includes the most recent IgG level within each given time period.

In 2010/11 fiscal year Atlantic IVIG Clinical expert working Group Primary immune deficiency sub group was convened and approved the Atlantic guidelines for the use of IVIG in primary immune deficiencies. These guidelines were based on the National Advisory Guidelines January 2010. The group decided to raise the target Serum IgG level from 5-10g/L to 7-10g/L. This is reflected as a rise in the "below the target range" of serum IgG levels seen among the patients who had IgG levels monitored in Atlantic Provinces during 2010/11 and a smaller proportion of patients with trough IgG levels in the target range during 2010/11 when compared with 2009/10.

This year, 74 % of the patients with immune deficiency in Nova Scotia had their IgG levels above 7g/L; out of these 46% were within target range and 28% were even higher than the target range. In Prince Edward Island 88% of patients had their IgG levels in and above the target range, out of these 63% were within the target range and 25%above the target range. Newfoundland and Labrador had 63% and New Brunswick had 46% of immune deficiency patients in and above the target range during 2010/11.

It is recommended that IgG levels continue to be collected and analyzed and monitored.

Figure 13: IgG Level Ranges



Note: PEI did not submit IgG levels until 2008-09

9 Discards

The goal of the utilization management of NSPBCP is to optimize appropriate use as well as to minimize wastage. Figure 14 shows a summary of the discarded IVIG during 2010/11 in the Atlantic Provinces. The total discard increased from 602g in 2009/10 to 1408g during 2010/11. There was a decrease in the discards in Nova Scotia from 269grams in 2009/10 to 213grams during 2010/11. Newfoundland & Labrador ,New Brunswick and Prince Edward Island reported higher discards of 305g, 830g, 60g during 2010/11 respectively which is a rise from last years 175g, 158g and zero grams in Newfoundland & Labrador ,New Brunswick and Prince Edward Island respectively.

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Figure 14: IVIG Discards in the Atlantic Provinces for Recent Fiscal Years

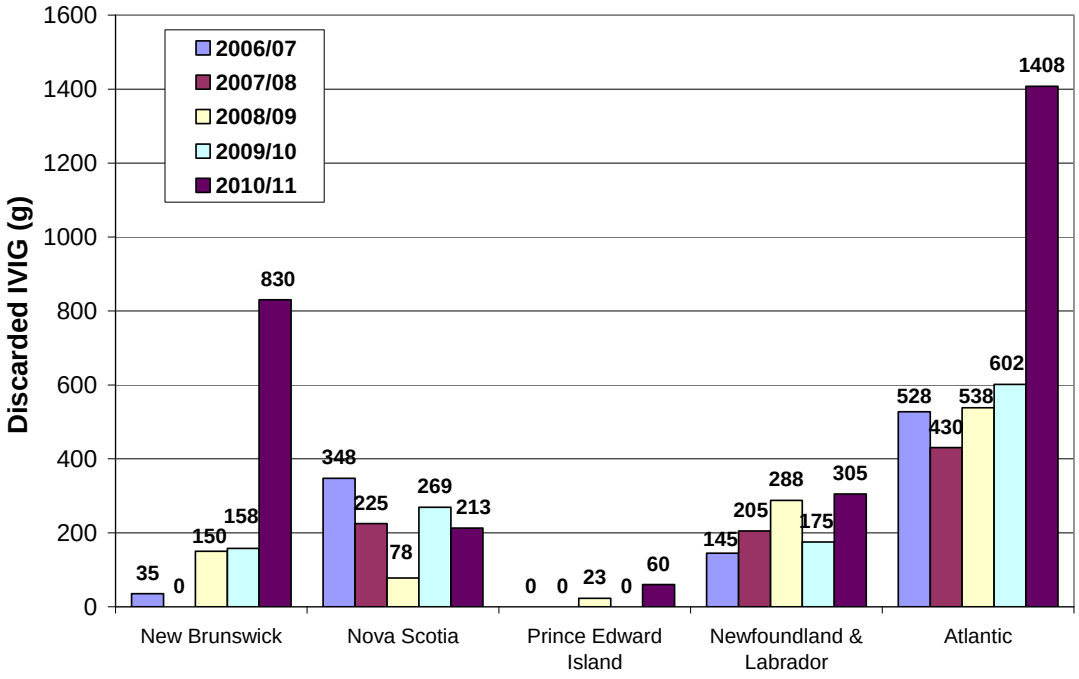


Table 10 shows the summary of estimated costs associated with IVIG discards in recent fiscal years. All but Nova Scotia have spent a greater amount of money on discards in Fiscal year 2010/11. The cost associated with the discard of IVIG in the Atlantic Provinces increased by $56,001 during 2010/11.

Table 10: Estimated Cost* of Reported IVIG Discards in the Atlantic Provinces in Recent Fiscal Years

Fiscal Year	New Brunswick	Nova Scotia	Prince Edward Island	Newfoundland and Labrador	Atlantic
2006/07	$1,878	$18,677	$0	$7,782	**$28,337**
2007/08	$0	$12,359	$0	$11,261	**$23,620**
2008/09	$8,574	$4,430	$1,315	$16,434	**$30,752**
2009/10	$10,510	$17,950	$0	$11,678	**$32,531**
2010/11	$52,207	$13,366	$3,774	$19,185	**$88,532**

* Estimated cost was calculated by multiplying the total grams by an average price per gram for that year.

Table 11 reveals the summary of the reasons of discards in the Atlantic Provinces. While discard of product is concerning it is important to note that the 1408 grams comprises 0.47% of the total IVIG distributed in Atlantic Canada.

It is recommended that the data on discard continues to be collected and monitored. Work needs to be done to develop a strategy for continuous education regarding the care for the use of IVIG and reminders for earlier return of the unused IVIG and other plasma products to the laboratory if not transfused. This is a preventable loss of money and precious plasma product. There is a need of environmental scan to explore successful practices and to identify innovative ideas on minimizing discards.

Table 11: Reasons for IVIG Discards in the Atlantic Provinces for Fiscal Year 2010/11

Reason for Discard	Amount (g)
In lab temperature/visually unacceptable	505
Returned to lab temperature/visually unacceptable	265
Broken	235
Expired	140
Spiked not transfused	110
Disposal required by CBS	100
Reconstituted, not used	25
Unknown	23
Incorrectly reconstituted	5
Total	**1408**

10 Prevalence and Incidence of the Use of IVIG in the Atlantic Provinces

Calculation of prevalence and incidence of the cases using IVIG in the Atlantic Provinces was introduced in 2009/10 to facilitate the understanding of a rise in distribution of IVIG in some areas of Atlantic Provinces. There is a marked rise in the distribution of IVIG in two of the four Atlantic Provinces in 2010/11. The study of prevalence and incidence may also be used to understand the variation in the trends of IVIG distribution over a period of time.

10.1 Prevalence

Prevalence is defined as the proportion of individuals in a population having a disease. In this case prevalence is used to describe the proportion of individuals in the population that are receiving IVIG.

Table 12 shows the yearly provincial comparison of the prevalence of patients requiring IVIG treatment in Atlantic Provinces over the last three years.

The prevalence of the cases requiring IVIG in the Atlantic Provinces increased in Newfoundland and Labrador, New Brunswick and Prince Edward Island. The prevalence increased in New Brunswick from 35.8 last year to 39 in 10/11; in Prince Edward Island from 26.2 last year to 34 in 10/11; in Newfoundland and Labrador from 40 last year to 44 in 2010/11. The prevalence in Nova Scotia decreased to 30 per 100,000 population in 20101/11 from 31.8 per 100,000 population in 2009/10.

Table 12: Prevalence of patients receiving IVIG /100,000 population in the Atlantic Provinces

FY	NB	NS	PEI	NL
2008/09	32.0	31.1	31.5	38.3
2009/10	35.8	31.8	26.2	40.0
2010/11	39.0	29.9	34.4	43.8

10.2 Incidence

Incidence refers to the rate at which new cases of a disease occur in a population during a specified period.

Table 13 shows the yearly provincial comparison of the incidence of patients requiring IVIG treatment in Atlantic Provinces over the last three years. The incidence of cases using IVIG has been rising in New Brunswick, Newfoundland over the last two years and in Prince Edward Island during 2010/11. The incidence increased in New Brunswick from 22 last year to 24 in 10/11; in Prince Edward Island from 13.5 last year to 21 in 10/11; in Newfoundland and Labrador from 22.6 last year to 24 in 2010/11.

The incidence in Nova Scotia decreased to 17.0 per 100,000 population in 2010/11 from 18.9 per 100,000 population in 2009/10.

Table 13: Incidence of patients on IVIG /100,000 Population in Atlantic Provinces:

FY	NB	NS	PEI	NL
2008/09	20.0	18.5	18.6	21.7
2009/10	22.0	18.9	13.5	22.6
2010/11	23.8	17.5	21.1	24.1

10.3 Utilization of IVIG by the Regions in New Brunswick and Prince Edward Island

The utilization of IVIG is localized to some regions in Prince Edward Island and New Brunswick in 2010/11 It will be worth while to probe the reasons for this uneven distribution.

Table 14 shows the summary of IVIG used and variance in utilization over years by the facility numbers of Prince Edward Island. There was a rise in the utilization of IVIG by 65.9% in facility 0002 and a rise by 52.6% in facility 0001 during 2010/11 of Prince Edward Island

Table 14: Utilization of IVIG in Prince Edward Island by Facility

Facility Number	IVIG(g) 08/09	IVIG (g) 09/10 (Variance %)	IVIG (g) 10/11 (Variance %)
0001	5850	9660 (65.1%)	14745 (52.6%)
0002	6900	2305 (-66.6%)	3825 (65.9%)
0003	765	440 (-42.5%)	445 (1.1%)
0006	360	40 (-88.9%)	0 (-100%)

Table 15 shows the comparison of IVIG utilized and variance in the use during 2009/10 and 2010/11 in New Brunswick. There is a rise from 17592g in 2009/10 to 23671g IVIG in 2010/11 in District A. This shows a variance of 34.6% in the use of IVIG in the District A of New Brunswick in 2010/11. The variance was higher in the other district last year

Table 15: Utilization of IVIG in NB by Districts

District	IVIG(g) 08/09	IVIG (g) 09/10 (Variance %)	IVIG (g) 10/11 (Variance %)
A	16617	17592 (5.8%)	23671 (34.6%)
B	54057	66366 (22.7%)	67816 (2.2%)

The use of IVIG is varied; in some cases it is the only treatment available while in others it may be adjuvant therapy. Currently, data is collected when IVIG is used. There is no record of those patients with the similar diagnosis but a different line of treatment. Lack of this denominator data limits the capacity to relate the rise to a changing practice or changing disease pattern. It is recommended that an attempt is made to identify the total cases of diseases relevant to immunoglobulin use. This may help in tracking many parameters in a statistical fashion.

11 Subcutaneous Immunoglobulin

In 2008, SCIG became a regular product within Canadian Blood Services' plasma protein products portfolio and the Atlantic Collaborative supported the addition of SCIG to its utilization management endeavors. Distribution data is provided by Canadian Blood Services. This section provides an overview of distribution and utilization.

11.1 Distribution

Figure 15 shows the amount of SCIG distributed to each of the Atlantic Provinces in the 2010/11 fiscal year. A total of 4,813.2 g of SCIG was distributed to the Atlantic Provinces in 2010/11.

Figure 15: SCIG Distributed to Atlantic Provinces by Fiscal Year

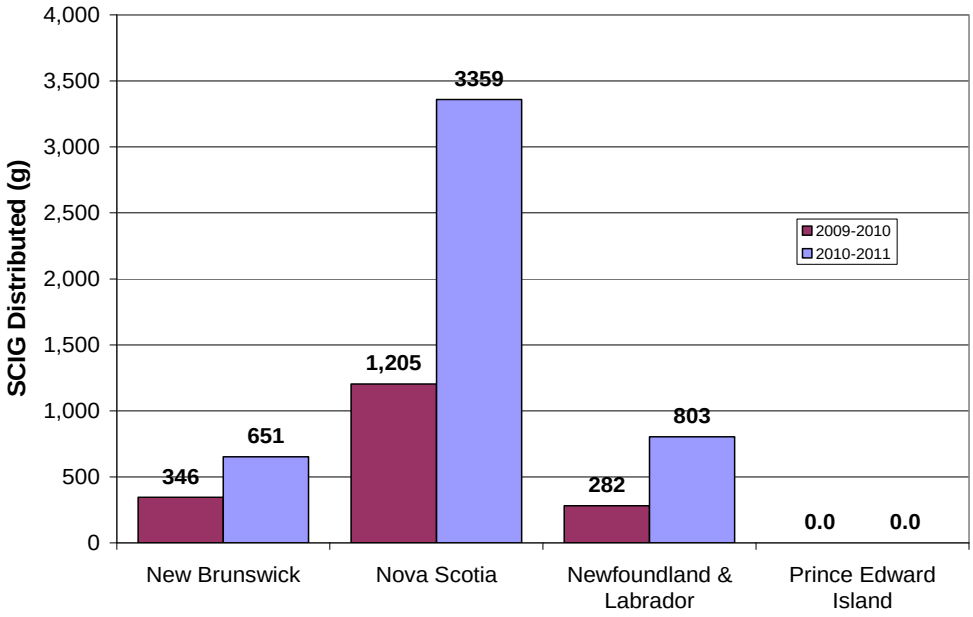


Table 16 reveals the percent capture of SCIG. This is calculated by dividing utilized SCIG by the distributed SCIG for that fiscal year. Low percent capture is due to the fact that SCIG follows a home infusion program and the utilization of SCIG is captured after a few weeks when patients bring in their log sheets for submission to the facilities. Vigilant follow up on log sheets is recommended to improve the percent capture and quality of data analyzed.

Table 16: Percent Capture for Each Province FY 2010-2011

Province	Percent Capture
Nova Scotia	81.0%
New Brunswick	97.7%
Newfoundland and Labrador	80.7%

Table 17 is the summary of the actual cost of SCIG for each of the Atlantic Provinces. A total of $302,775 was spent for SCIG in the Atlantic Provinces during 2010/11.

Table 17: Amount Distributed and Total Cost of SCIG for Fiscal Year 2010/11

Province	SCIG (g)	Cost of SCIG
New Brunswick	651	$40,960
Nova Scotia	3359	$211,293.35
Prince Edward Island	0	0
Newfoundland & Labrador	803	$50,521
Atlantic Total	**4,813**	**$302,775**

11.2 Utilization

11.2.1 Atlantic Guidelines

In an effort to ensure SCIG continues to be used according to the recommended guidelines an Atlantic SCIG Working Group was convened to develop guidelines for the implementation of SCIG home infusion programs in hospitals in the Atlantic Provinces during fiscal year 2009/10. These guidelines are in response to recommendations made in 2008 by the National Advisory Committee on Blood and Blood Products. The guideline document was completed in the summer of 2009 and after endorsement by the Atlantic Collaborative IVIG Utilization Working Group was disseminated for pilot use for a one year period ending September 2010. Feedback was collected and incorporated along with the recommendations proposed by the Atlantic IVIG Clinical Experts – Primary Immune deficiency sub group in the revised guidelines. These guidelines will be disseminated in future along with the patient education materials for the pump and the push method of Administration of SCIG. Current guidelines have instructions for the use of delivery Pump when administering SCIG at home. A decision was made by the Atlantic SCIG Working Group to include Push as an option for SCIG Home Administration Programs in

addition to the Pump method. Push is considered relatively easy and cost efficient method of administration. Patient education materials for the pump and the push method of SCIG Home Administration Programs are currently under development.

To date there are no major issues reported with SCIG. There were 4813.2g of the SCIG distributed in the Atlantic Provinces in 2010/11. There were 19 patients on SCIG in the Atlantic Provinces. Sixty eight percent of cases were in Nova Scotia. All use was for the appropriate indication and was within recommended dosing guidelines.

Table 18: SCIG Utilized doses in Atlantic Provinces during 2010/11

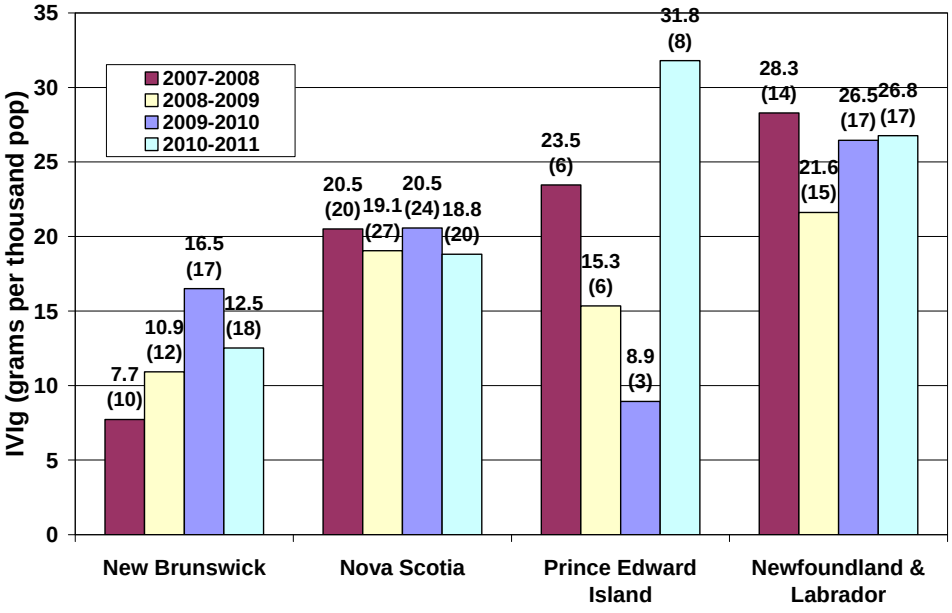
SCIG Utilization	NS	NB	PEI	NL
Number of cases on SCIG	13	2	0	4
Total number of doses for SCIG	421	53	0	183
Number of doses given higher than recommended	0	0	0	0

11.2.2 Discards

No discards of SCIG were reported in any of the Atlantic Provinces in 2010/11.

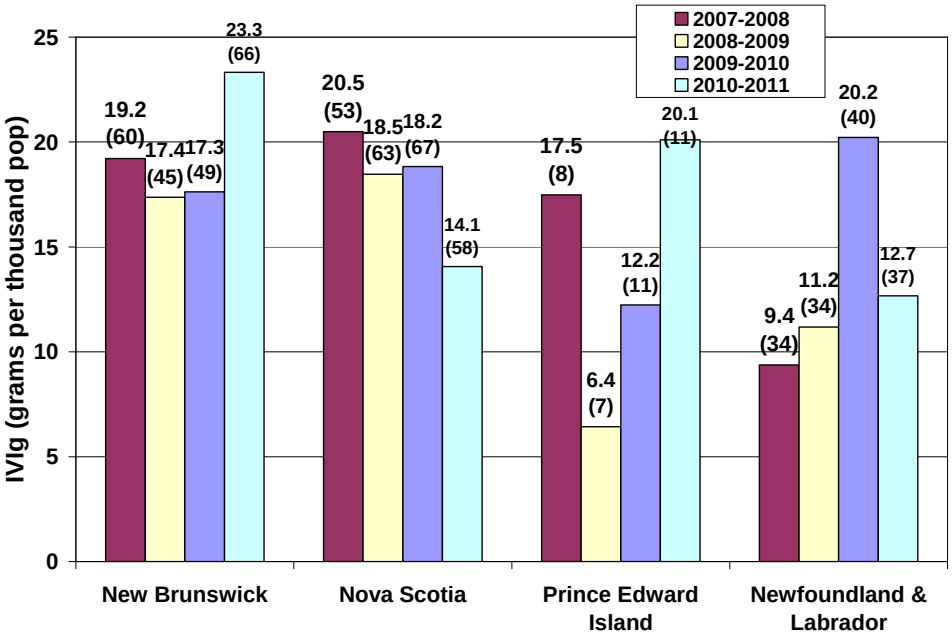
Appendix A Per Capita Utilization of IVIG for the Top Indications

Figure A1: Per Capita Utilization of IVIG for CIDP



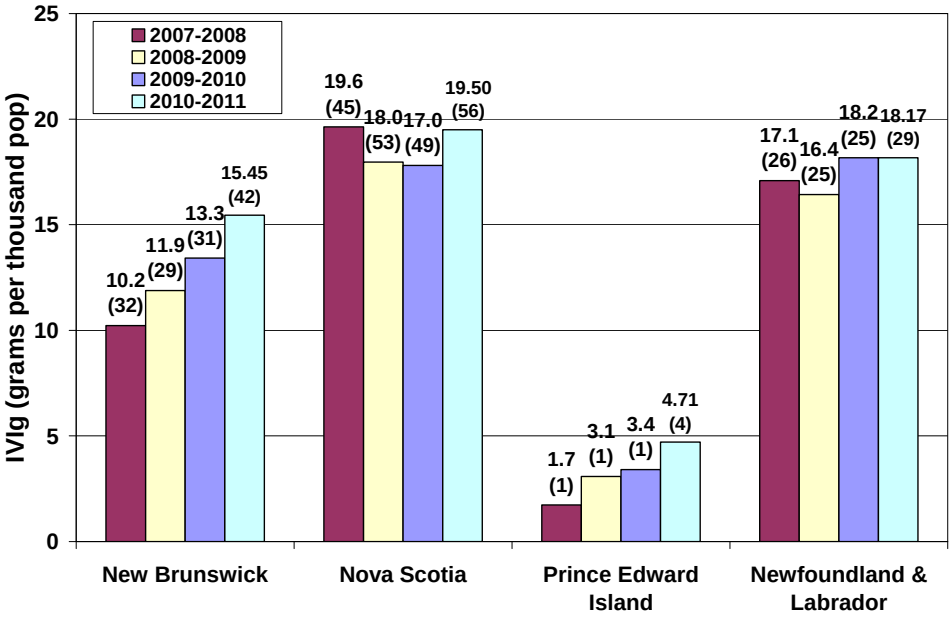
Parentheses indicate total number of patients

Figure A2: Per Capita Utilization of IVIG for Idiopathic Thrombocytopenic Purpura



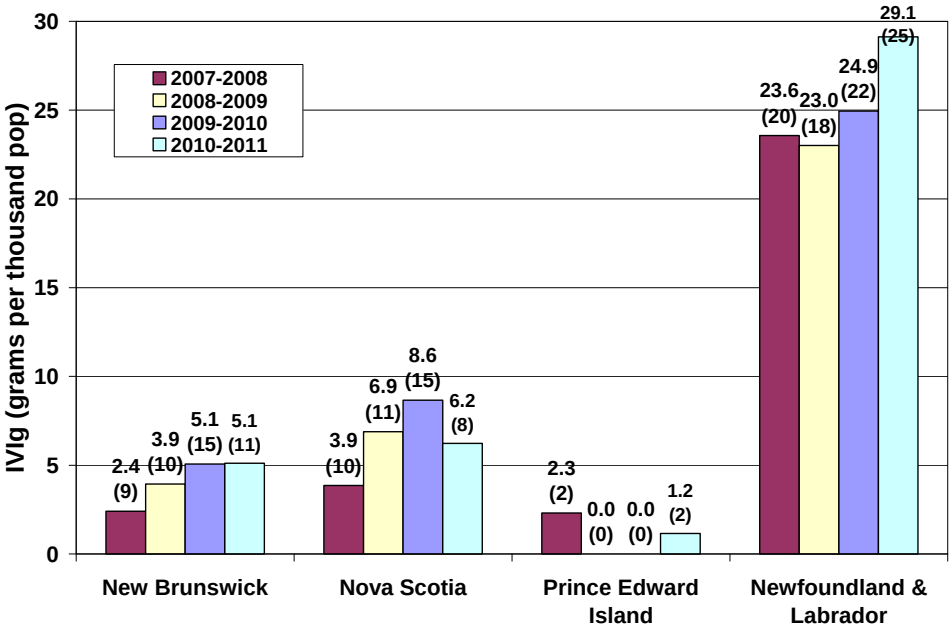
Parentheses indicate total number of patients

Figure A3: Per Capita Utilization of IVIG for Primary Immune Deficiencies



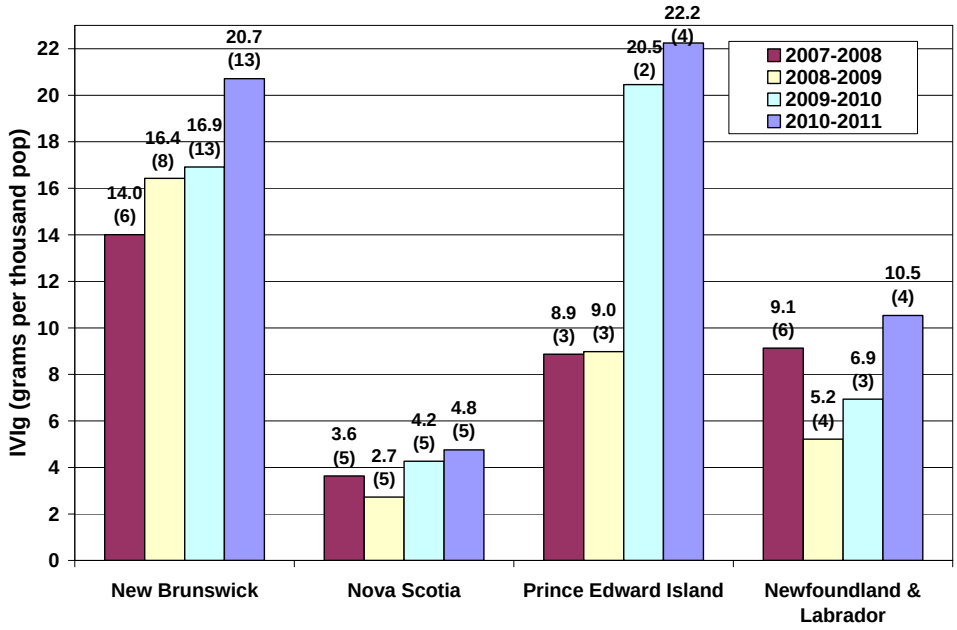
Parentheses indicate total number of patients

Figure A4: Per Capita Utilization of IVIG for Myasthenia Gravis



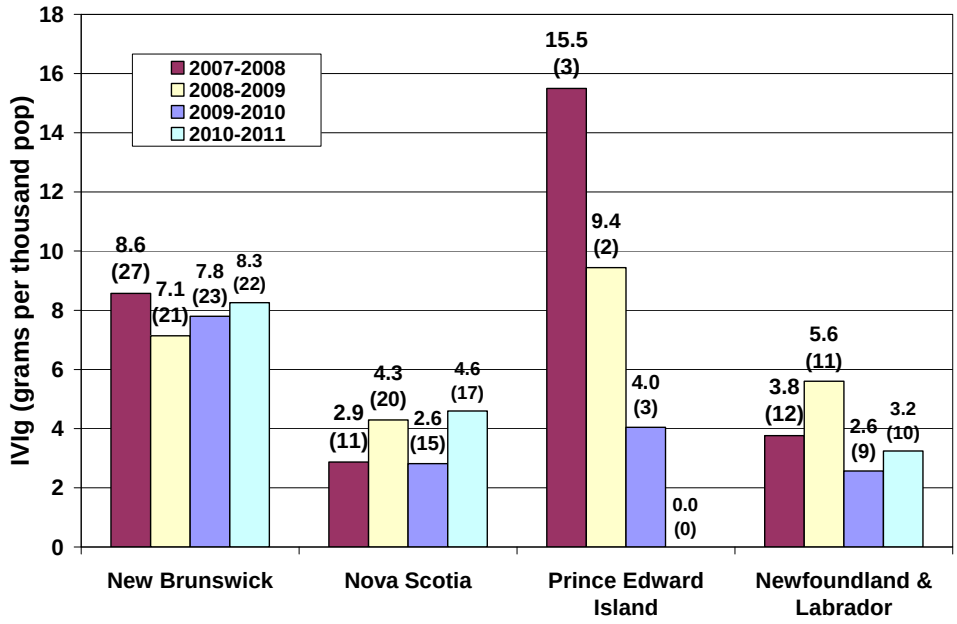
Parentheses indicate total number of patients

Figure A5: Per Capita Utilization of IVIG for Multifocal Motor Neuropathy



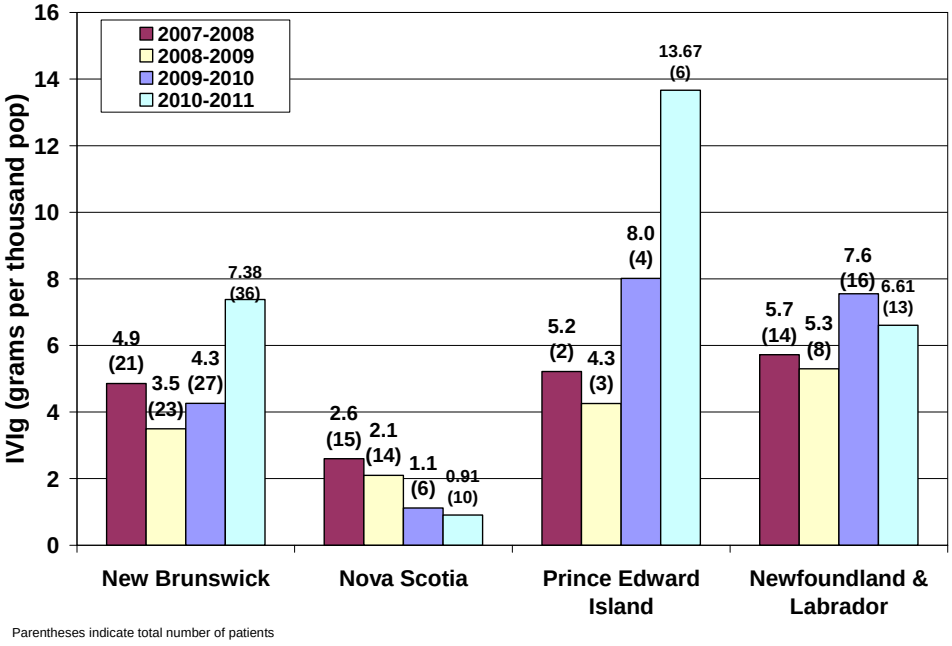
Parentheses indicate total number of patients

Figure A6: Per Capita Utilization of IVIG for Guillain-Barré Syndrome



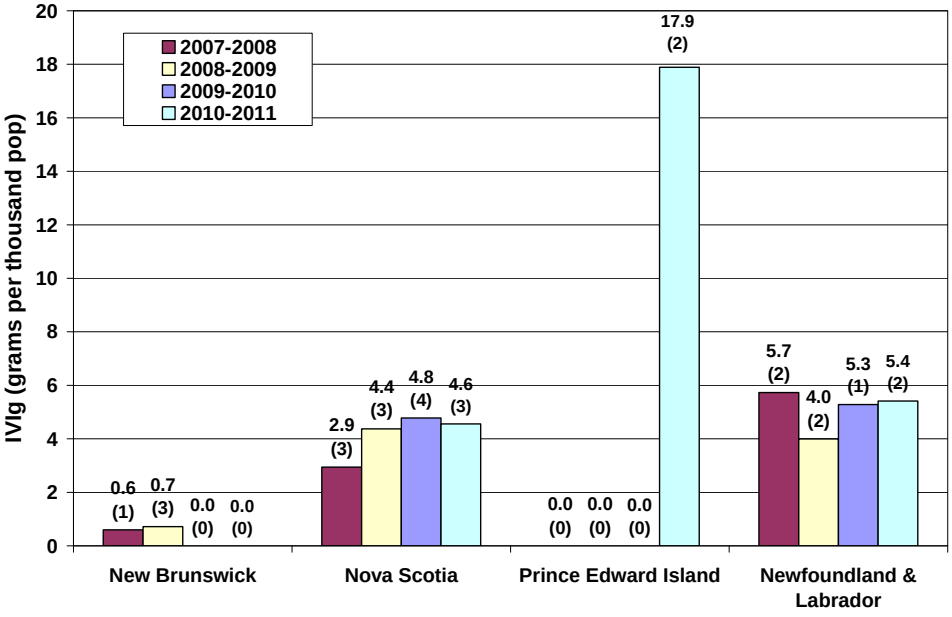
Parentheses indicate total number of patients

Figure A7: Per Capita Utilization of IVIG for Secondary Immune Deficiency



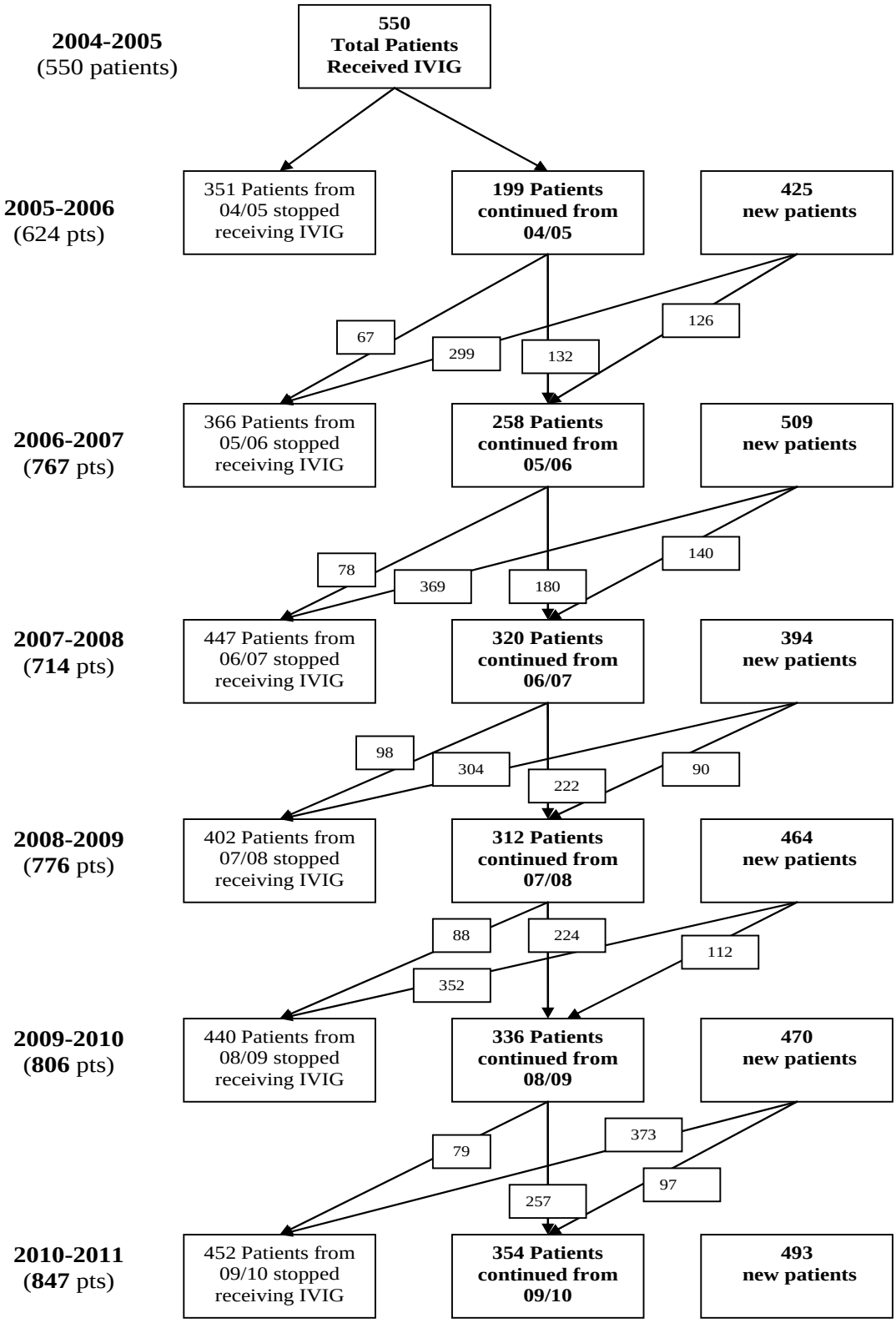
Parentheses indicate total number of patients

Figure A8: Per Capita Utilization of IVIG for Stiff Person Syndrome



Parentheses indicate total number of patients

Appendix B: Year to Year Carry-Through Patients



The Fig above shows the occurrence of new and carried over patients from last. There were 477 new patients in Atlantic Canada and 332 patients carried through from last year. This is a total of 809 patients in 2009/10.

Table B 1 reveals the distribution of initial and follow up patients in each Atlantic province from 2008/09 to 2010/11

Fiscal Year	Province	Number of IVIG Patients		
		Continued From Last FY	New For This FY	Total
2008-2009	1	89	150	239
	2	121	178	299
	3	18	26	44
	4	84	110	194
2009-2010	1	104	165	269
	2	123	173	296
	3	18	19	37
	4	91	113	204
2010-2011	1	114	179	293
	2	120	162	282
	3	19	30	49
	4	101	122	223

Appendix C List of UL-N Indications

Unlabeled and Not Indicated Indications for the Use of IVIG in Hematological and Neurological Conditions

Hematology	Neurology
• AML with Thrombocytopenia • Aplastic anemia • Aplastic Anemia with Pancytopenia • CD5 Leukemia • Disseminated intravascular coagulation • Hematopoeitic stem cell transplantation (unless patient is on a multinational protocol that recommends IVIG) • Heparin-induced thrombocytopenia • Leukemia • Mantle Cell Lymphoma • Myelodysplastic Syndrome with Thrombocytopenia • Non-Hodgkins Lymphoma with Sepsis Sickle Cell Anemia • Thrombocytopenia (unless patient has ITP)	• Adrenoluekodystrophy • Amyotrophic Lateral Sclerosis • Anti-NMDA receptor encephalitis • Autism • Bell's Palsy • Brainstem encephalitis • Critical Illness Neuropathy • Devics Disease • Diabetic Neuropathy • Encephalomyelitis • Hashimoto's Encephalopathy • IgM Paraproteinemic Neuropathy • Inclusion Body Myositis • Limbic encephalitis • Myelitis • Myelopathic Process • Nerve Impairment Similar to MS • Opsoclonus (involving eye movement) • Paraneoplastic Cerebellar Degeneration • Paraneoplastic Neuropathy • Paraneoplastic Subacute Cerebellar Degeneration • POEMS Syndrome • Post Polio Syndrome • Recurrent Demyelination of the Optic Nerve • Sensory Neuropathy • Transverse Myelitis

References:

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Feasby T, Banwell B, Benstead T, Bril V, Brouwers M, Freedman M, Hahn A, Hume H, Freedman J, Pi D, et al. Guidelines on the Use of Intravenous Immune Globulin for Neurologic Conditions. Transfusion Medicine Reviews 2007;Vol 21,No 2, Suppl 1(April 2007):S57-S107.

British Columbia Provincial Blood Coordinating Office. IVIG Utilization Management Handbook. 2002. First Edition.

Appendix D Request Path Numerical Code Guide

1 Request was for an indication not listed in the guidelines

2 Request met the guidelines upon initial submission

3 Request was revised to meet the guidelines after discussion with BTS staff

4 Request was withdrawn after discussion with BTS staff

5 Request was revised to meet the guidelines after ordering MD consulted with the clinical expert

6 Request was withdrawn after the ordering MD consulted with the clinical expert

7 The original request was granted even after the ordering MD consulted with the clinical expert

8 Consultation with the clinical expert was required but did not occur

9 Other