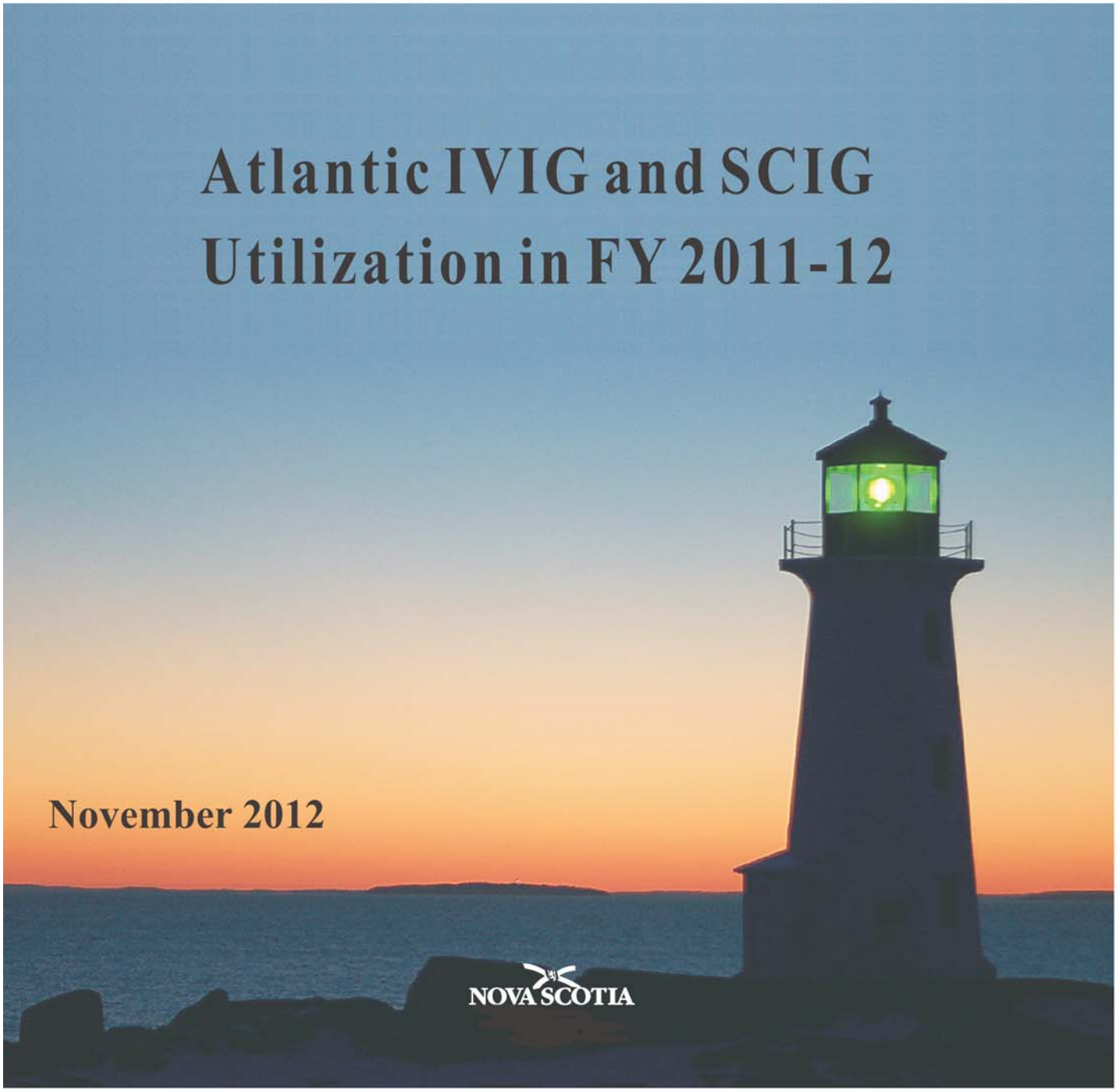
NOVA SCOTIA PROVINCIAL BLOOD COORDINATING PROGRAM

Atlantic IVIG and SCIG Utilization in FY 2011-12



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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 2011/12 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 2011/12 the rise in IVIG distribution in Canada was by 8%. Canadian distribution of IVIG increased from 137g/1000 population in 2010/11 to 145g/1000 population in 2011/12. Atlantic distribution increased to 135g/1,000 in 2011/12 from 127g/1,000 populations in 2010/11. Prince Edward Island is the only Atlantic Province that showed a decrease in distribution of combined IVIG and SCIG from 150g/1000 population in 2010/11 to 130g/1000 in 2011/12. The other three Atlantic Provinces showed a rise in the distribution of IVIG. The combined distribution of IVIG and SCIG per thousand population in New Brunswick increased from 128g in 2009/10 to 133g in 2011/12 and in Newfoundland and Labrador from 163g in 2010/11 to166g in 2011/12. The distribution of IVIG in Nova Scotia was 122g/1000 population in 2011/12, the second best among all Canadian Provinces and Territories. Whereas the combined distribution of IVIG and SCIG in Nova Scotia was 126g/1000 population, the third best in Canada. Although the IVIG distribution in Nova Scotia increased by 16.8% from last year, this was due to a rise of 77 patients requiring IVIG in Nova Scotia.

The Nova Scotia Provincial Blood Coordinating Program (NSPBCP) continues to analyze data for the data elements that were 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. The NSPBCP will also continue to provide the standardized province specific information.

The data used for generating annual reports is stored and is reproducible. On occasion, revisions, corrections and additions may be identified following the publication of the annual report. In the event that this occurs, the data in the database is adjusted and the amendments are documented. When conducting analyses on past years the amended data is used. This is a consideration when noting differences in numbers between previous year's reports and current report.

The prevalence and incidence of the cases requiring IVIG in the Atlantic Provinces which is calculated per 100,000 population, increased in Nova Scotia and decreased in New Brunswick and Prince Edward Island in 2011/12. The prevalence in Newfoundland and Labrador increased in 2011/12 but the incidence remained the same as 2010/11. In Nova Scotia the prevalence and incidence of cases requiring IVIG increased from 30 and 17 in 2010/11 to 37.7 and 24 respectively in 2011/12. The prevalence in Newfoundland and Labrador increased from 44 last year to 45 in 2011/12 but the incidence remained the same at 24. In New Brunswick, a decrease in prevalence and incidence were from 39 last year to 38 in 2011/12 and 24 to 20 in 2011/12 respectively. In Prince Edward Island a decrease in prevalence was from 36 last year to 34 in 2011/12 and decrease in incidence was from 22.5 last year to 14 in 2011/12.

The proportion of total IVIG used in each of the major disease categories remained the same in Hematology, Rheumatology and Dermatology; decreased by 1% in Neurology; and increased by 2% in Immunology during 2011/12 when compared with 2010/11. The amount of IVIG used increased in each disease category in 2011/12. The proportion of the total use of IVIG increased in Chronic

Inflammatory Demyelinating Polyradiculoneuropathy (CIDP) and primary and secondary immune deficiency, it decreased in all the other major indications from what is was in 2010/11.

The use of IVIG for unlabeled indicated (UL-I) and labeled (L) indications in the Atlantic Provinces improved from 115.5g/1000 last year to 126g/1000 during 2011/12. This is an improvement to 95.3% of the total use of IVIG in 2011/12 from 94.6% during 2010/11.

The Atlantic Provinces showed a decrease in their use of IVIG for unlabeled not indicated (UL-N) indications. In 2011/12, 6g/1000 population or 4.4% of the total IVIG use was for UL-N indications, a decrease from 5.4% (7g/1000) in 2010/11. There was a decrease in the use of IVIG for UL-N indications in Nova Scotia from 3% in 2010/11 to 2% in 2011/12; in New Brunswick from 8% in 2010/11 to 5.8% in 2011/12 and in Prince Edward Island from 1.4% in 2010/11 to zero in 2011/12. There was an increase in the use of IVIG for UL-N indications in Newfoundland & Labrador from 6% in 2010/11 to 7 % in 2011/12.

In the Atlantic Provinces 14,452 grams (4.6% of the total use) of IVIG was used as higher or more frequent than recommended which is almost the same as last year's 14,458 gram (5% of the total use). Ninety three percent of the total 14,452g was used as more frequent and seven percent as higher then recommended doses. It is possible that the higher/more frequent dosing was required to obtain the desired clinical response however currently a mechanism to capture clinical data is absent.

The IVIG request approval process is implemented throughout the Maritime Provinces and in two regions and two largest facilities of the third region of Newfoundland and Labrador. This process serves as a guide for resolving issues of appropriateness and dosing of the most common indications in neurology, immunology and hematology. Three hundred and seventy six requests passed through the approval process, 37 (9.8%) were for indications not listed in the guidelines (non-neurology, non-immunology and non-hematology). Of the remaining 339, 96.5% met the guidelines for indication and dosage upon initial submission. Five of the 12 cases that did not meet the guidelines were revised after discussion with the Blood Transfusion Service staff.

Introduction of quarterly data analysis of IVIG in 2010/11 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" to 8 in 2011/12. The same process also resulted in an improvement in reporting of serum IgG levels to 81% in 2011/12 from 77% in 2010/11.

Serum IgG levels were above the target of 10g/L in 12% of monitored cases in New Brunswick, 31% in Nova Scotia, 27% in Newfoundland and Labrador and 17% in Prince Edward Island. These patients will be followed up, if the levels remain high in the next reading, then the physicians will be requested to revise the dose while still achieving clinical effectiveness.

The total discards of IVIG in all Atlantic Provinces decreased from 1,423g last year to 668g in 2011/12. Discards decreased in Nova Scotia from 228g in 2010/11 to 129g in 2011/12; in New Brunswick from 830g in 2010/11 to 283g in 2011/12; in Prince Edward Island from 60g in 2010/11 to 51g in 2011/12 and in Newfoundland and Labrador from 305g in 2010/11 to 205g in 2011/12.

The dosing of IVIG based on adjusted body weight instead of actual body weight was introduced by the NSPBCP in 2010/11. It is applicable in adult patients of hematology, immunology and neurology (excluding Guillian Barré Syndrome). Dosing IVIG based on adjusted body weight was implemented

in Prince Edward Island effective July 1, 2011, in two facilities of Newfoundland and Labrador effective December 2011 and in the Capital District Health Authority effective March 1, 2012. The pilot implementation of dosing by adjusted body weight in Prince Edward Island, Newfoundland Labrador and Nova Scotia. This involved 131 patients and revealed an estimated average savings of 66g of IVIG per patient.

Revised Atlantic Subcutaneous Immunoglobulin (SCIG) Home Administration Guidelines 2012 were disseminated along with the patient education materials on a new method of self administration of SCIG. In 2011/12, 5,699g of SCIG was distributed to Atlantic Canada compared to 4,813g in 2010/11. All reported use of SCIG was within recommended dosing guidelines.

In conclusion, the per capita IVIG distribution increased in the Atlantic Provinces during 2011/12. Nova Scotia exhibited the highest variance in distribution related to a rise in incidence and prevalence of cases requiring IVIG. The percentage of IVIG used for appropriate (labeled and UL-I) indications increased, whereas the discards and the use of IVIG for UL-N indications decreased. The pilot implementation of dosing by adjusted body weight revealed an estimated average savings of 66g of IVIG per patient.

2 Introduction

This report is a summary of the utilization of IVIG and SCIG in the Atlantic Provinces for the fiscal year 2011/12. The purpose of this report is to describe the use of IVIG and SCIG in the Atlantic Provinces and to identify recommendations for improvement in data quality and strategies for optimizing appropriate use of these products and minimizing product wastage.

In this report the NSPBCP continues 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.

The data used for generating annual reports is stored and is reproducible. On occasion, revisions, corrections and additions may be identified following the publication of the annual report. In the event that this occurs, the data in the database is adjusted and the amendments are documented. When conducting analyses on past years the amended data is used. This is a consideration when noting differences in numbers between previous year's reports and current report.

The adult cases of Neurology (excluding GBS), Immunology and Hematology were dosed based on adjusted body weight instead of actual body weight in Prince Edward Island, two facilities in Newfoundland and Labrador, and one health district of Nova Scotia during fiscal year 2011/12. The detailed analysis of IVIG dosing based on this mode is reported in Section 11 of this report.

3 International and National Perspective

Figure 1 shows an international comparison of per capita IVIG consumption for 2005 and 2010 in select countries of the world. In 2010, 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 United Kingdom, Germany and Japan.

Figure 1: International comparison of per capita IVIG/SCIG consumption in select countries.
Source: Canadian Blood Services

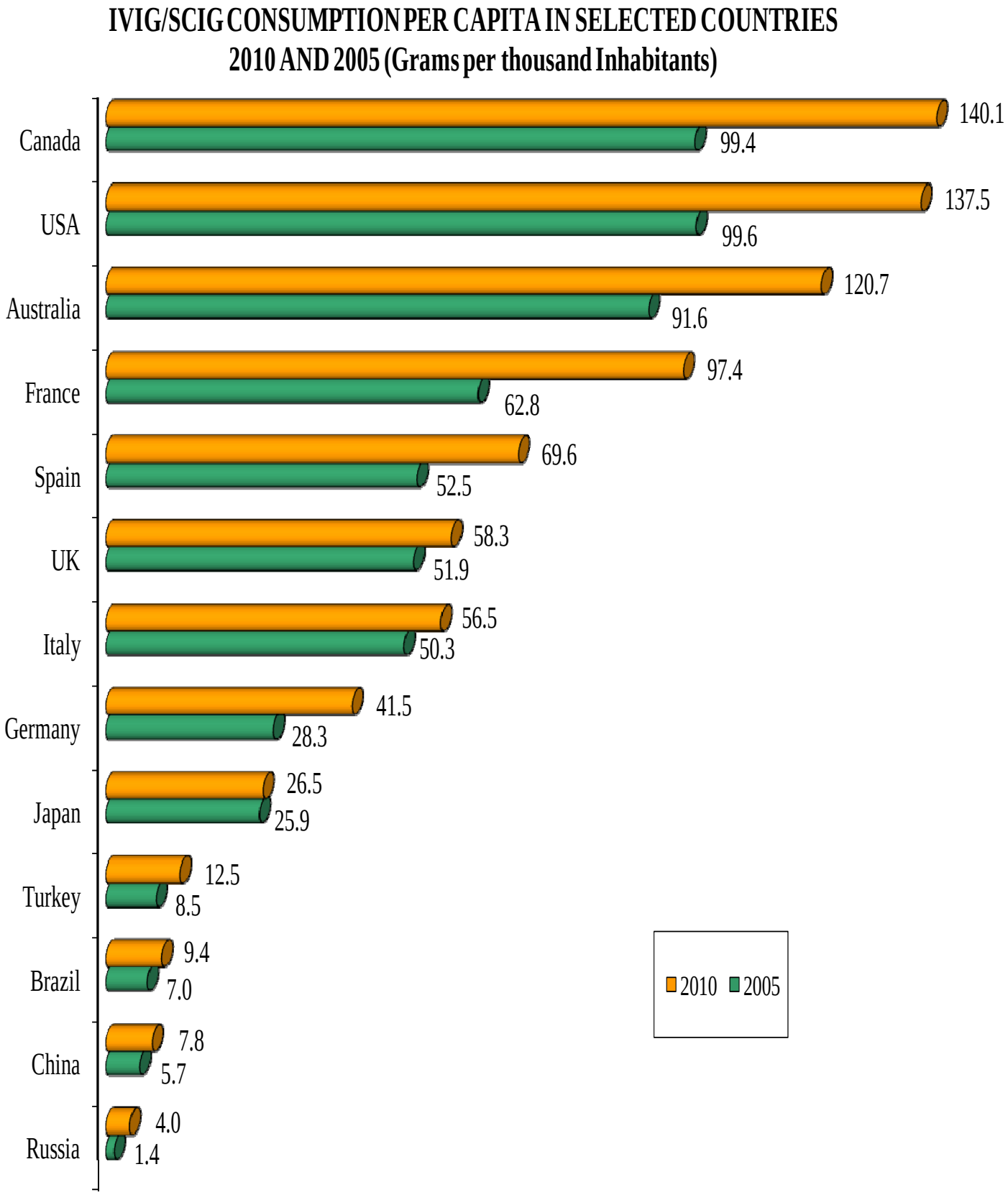
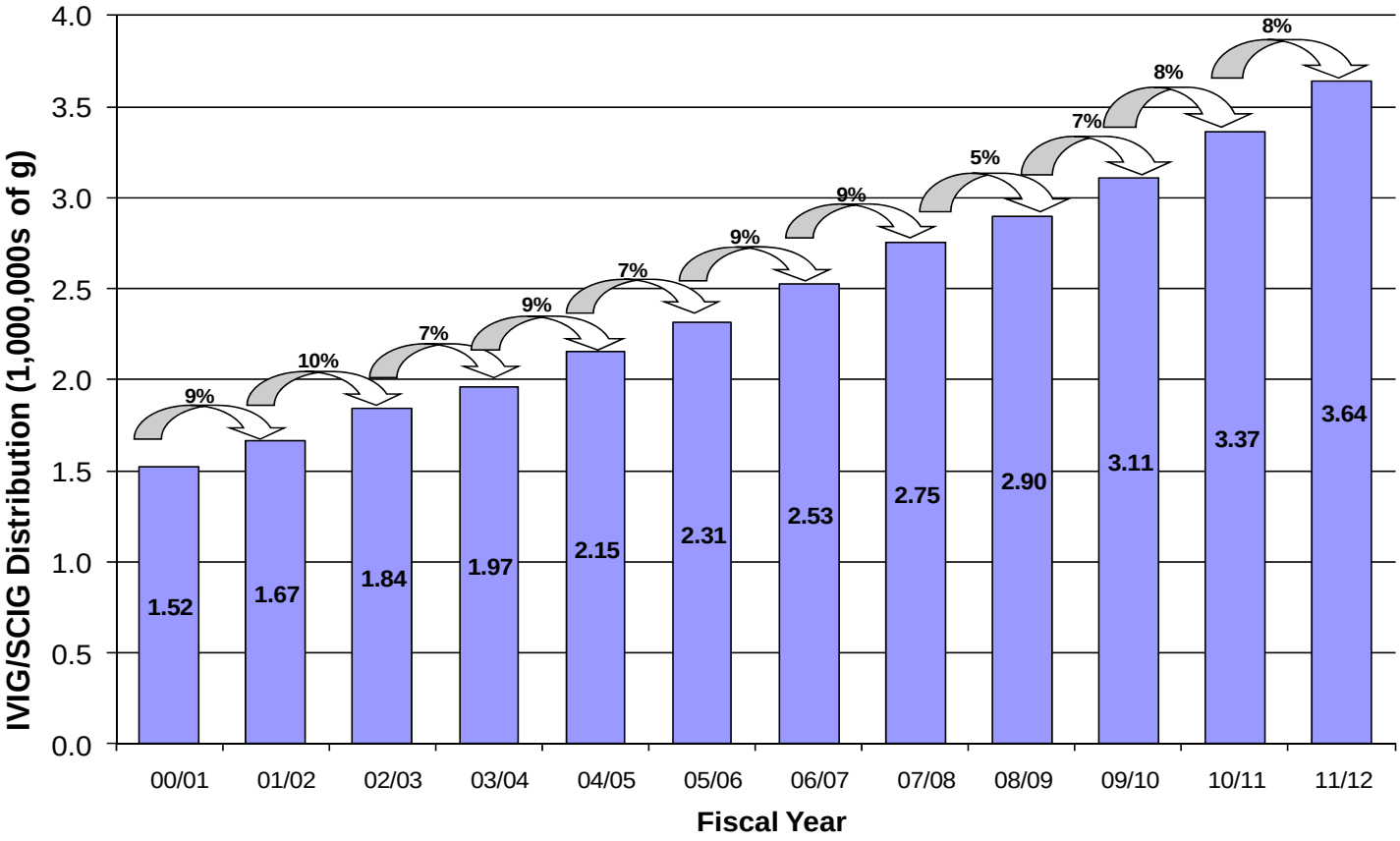


Figure 2 shows the annual distribution of IVIG/SCIG in Canada for the last twelve years. The distribution regularly increases between 7–10% each year; the distribution of IVIG in Canada increased by 8% in fiscal year 2011/12.

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. While different from the amount of IVIG *utilized*, it provides a good reference for 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 through to 2011/12.

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
2011/12	99,953	$5,894,638	115,355	$6,802,988	18,960	$1,118,155	83,813	$4,942,790

* 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 2011/12. There was a rise in the distributed grams of SCIG during 2011/12 in New Brunswick, Nova Scotia and Newfoundland & Labrador.

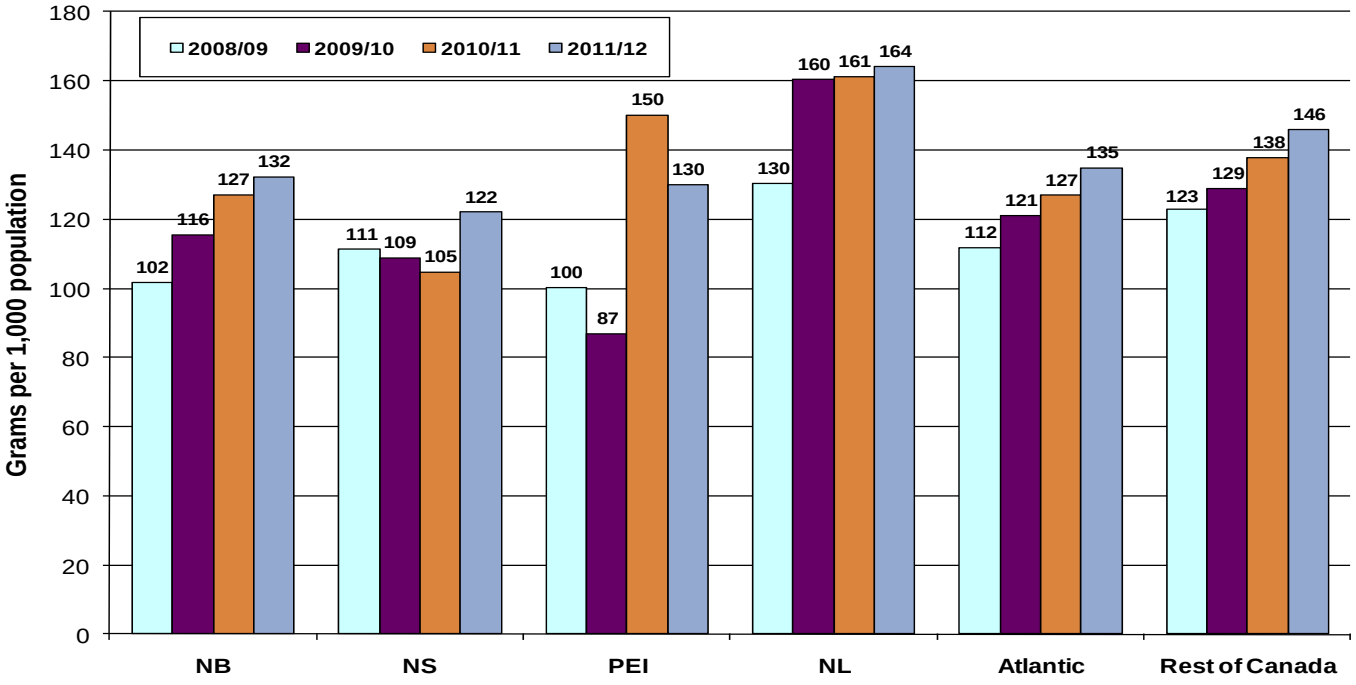
Table 2: Total Grams and Cost* of SCIG Distributed to the Atlantic Provinces by Fiscal Year

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
2011/12	774	$45,670	3,867	$228,054	0	0	1,058	$62,372

* 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 651g in 2010/11 to 774g in 2011/12; in Nova Scotia from 3,359g last year to 3,867g in 2011/12; in Newfoundland and Labrador from 803g last year to 1,058g in 2011/12. 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 individually and combined. The amount of IVIG distributed to the rest of Canada including Quebec is also shown here. The distribution of IVIG increased in New Brunswick from 127g/1000 population to 132g/1000 population in 2011/12; in Nova Scotia from 105g/1000 population in 2010/11 to 122g/1000 population in 2011/12; and in Newfoundland & Labrador from 161g/1000 population in 2010/11 to 164g/1000 population in 2011/12. Prince Edward Island demonstrated a decrease in distribution from 150g/1000 population to 130g/1000 population in 2011/12. The Atlantic Provinces combined show a rise from 127g/1000 population of 2010/11 to 136g/1000 population in 2011/12, whereas the IVIG distribution in Canada (including Quebec and excluding Atlantic provinces) was 146g/1000 population for fiscal year 2011/12 a rise from last year's 138g/1000.

Figure 4: Annual % Change of IVIG Plus SCIG Distibuted

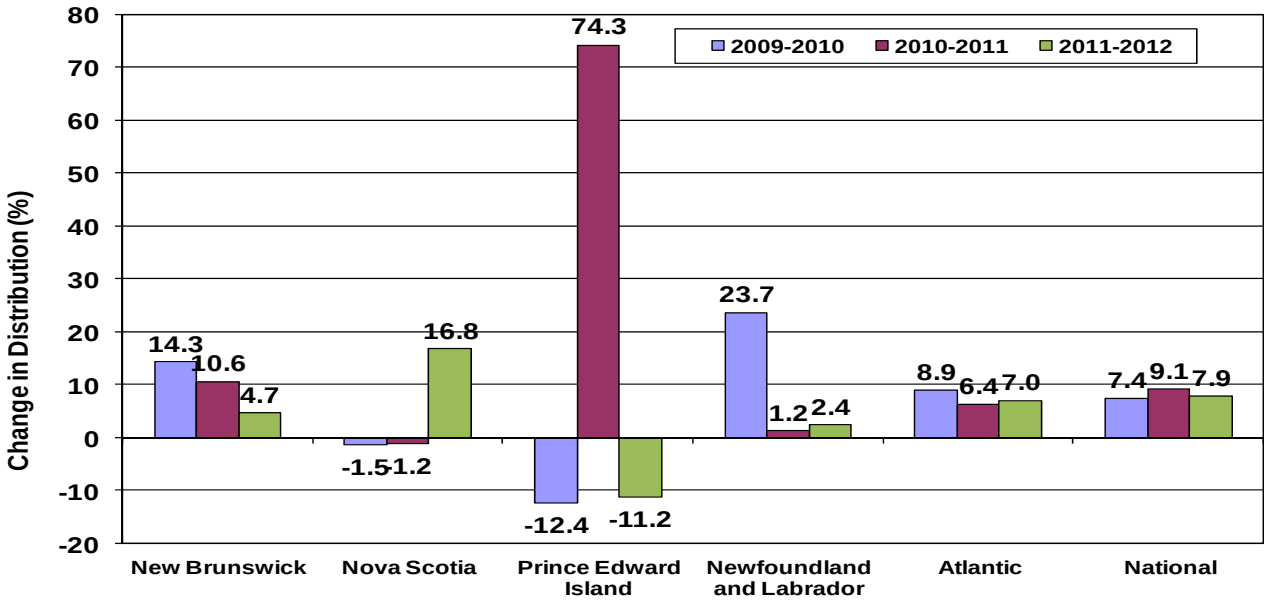


Figure 4 shows the National and Atlantic variance in the distribution of IVIG plus SCIG. The annual percent change in New Brunswick, Nova Scotia and Newfoundland & Labrador increased by 4.7%, 16.8% and 2.4% respectively in 2011/12 from last year; the distribution of IVIG and SCIG declined by 11.2% in Prince Edward Island in 2011/12. Canada (including Quebec) experienced a 7.9% increase in distribution whereas; the Atlantic Provinces combined had an increase of 7.0% in distribution.

Fig 5 shows the provincial comparison of national IVIG distribution per 1000 population. The IVIG distribution of Nova Scotia at 122g/1000 population in 2011/12 is the second lowest in the country. All provinces except Prince Edward Island have exhibited a rise in per capita IVIG distribution during 2011/12.

Figure 5: National IVIG Distribution Per 1000 Population

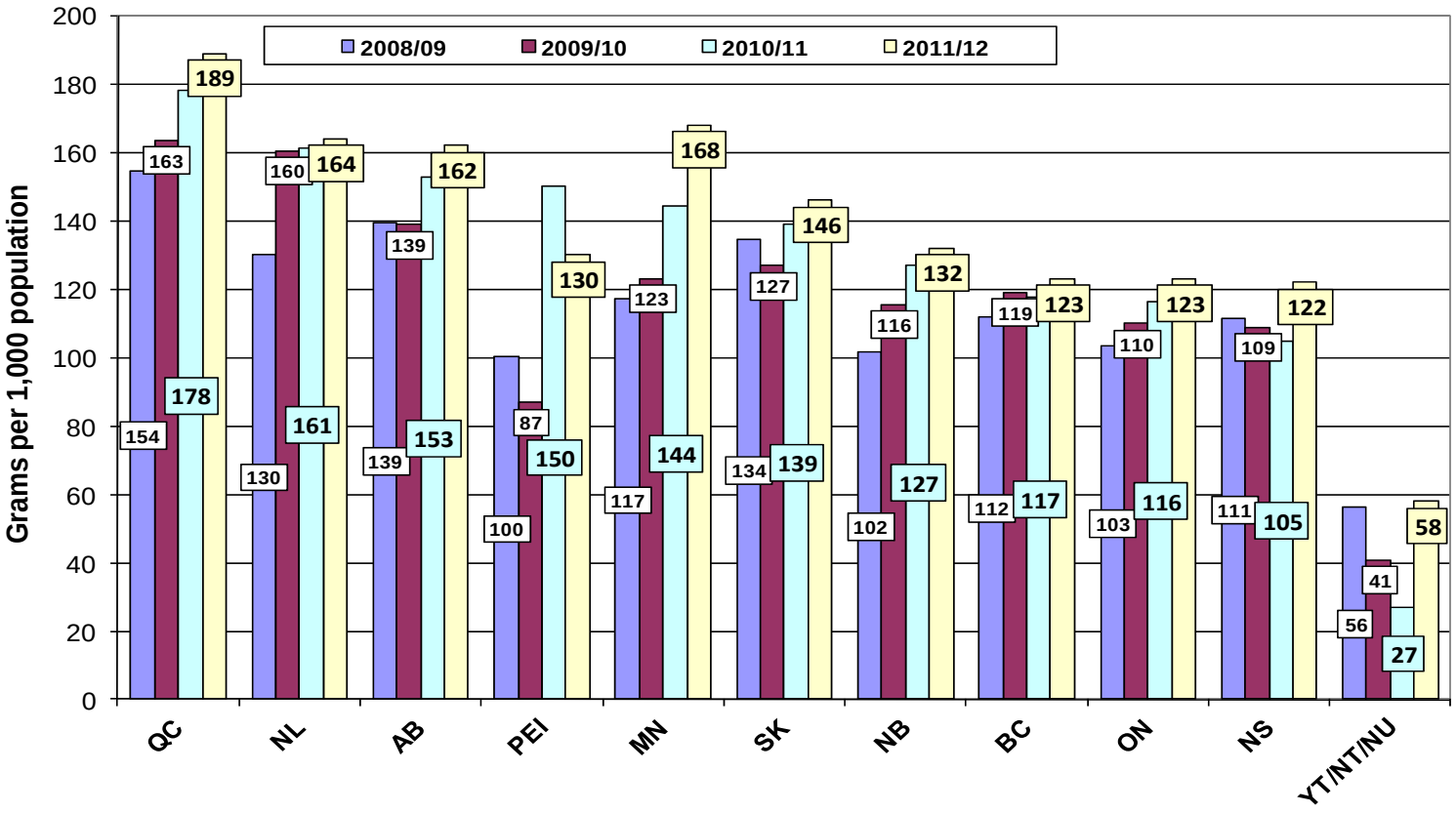
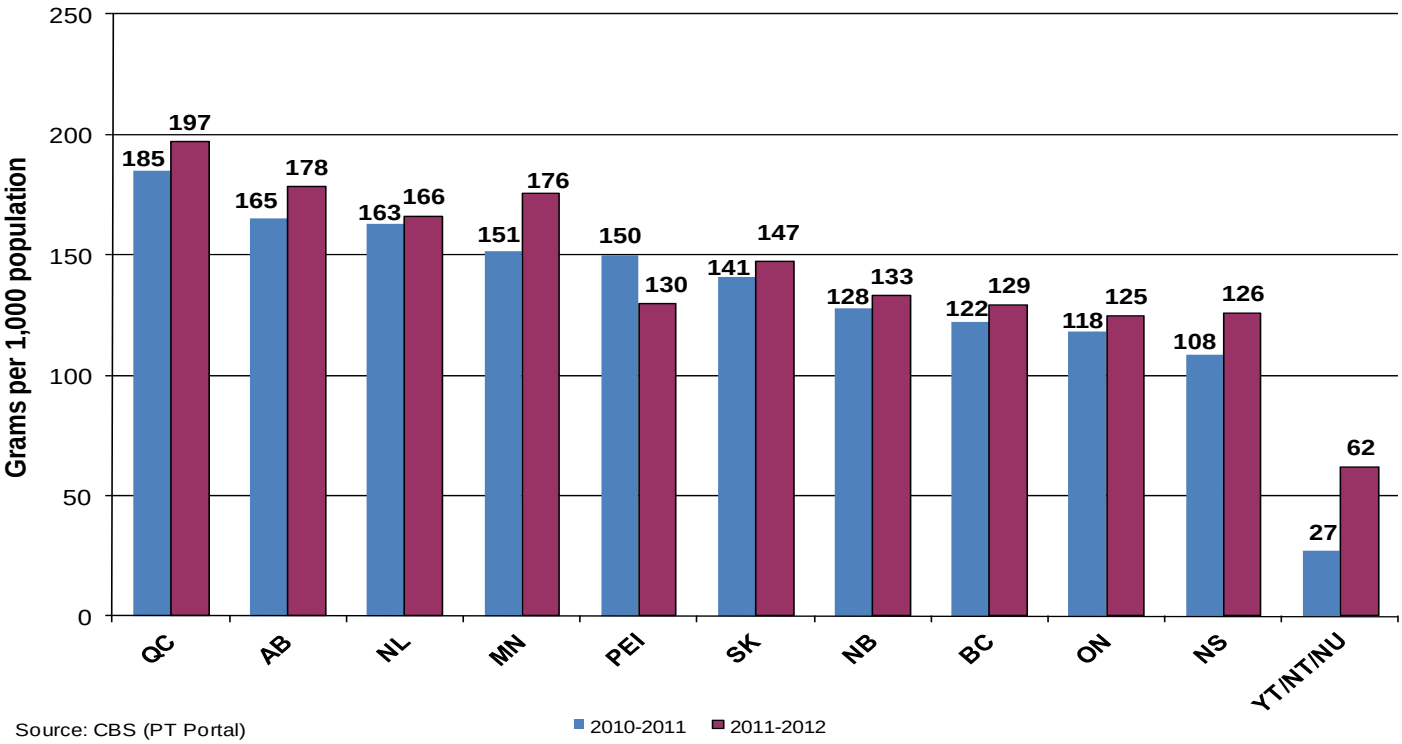


Fig 6 shows the provincial comparison of national IVIG and SCIG combined distribution per 1000 population for fiscal year 2011/12. The combined IVIG and SCIG distribution of Nova Scotia at 126g/1000 population in 2011/12 is the third lowest in the country. All provinces except Prince Edward Island have exhibited a rise in per capita IVIG and SCIG distribution during 2011/12.

Figure 6: National IVIG+SCIG Distribution Per 1000 Population



Source: CBS (PT Portal)

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 or SCIG for any indication. Percent capture of the distribution data for the Atlantic Provinces during the time period of this report was 98.2%. 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. The percent capture is above 95% for each of the Atlantic Provinces in 2011/12.

Table 3: Percent Capture for Atlantic Provinces

Province	Percent Capture 2009-2010	Percent Capture 2010-2011	Percent Capture 2011-2012
New Brunswick	97.1%	96.6%	95.8%
Nova Scotia	96.9%	96.9%	99.0%
Prince Edward Island	100%	89.3%	99.7%
Newfoundland and Labrador	100%	97.9%	99.5%
Atlantic Provinces	98.1%	96.7%	98.2%

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.

Table 4: Percent Capture for Each Province 2011-12

Province	Distributed	Utilized	Discards	Diff of Distributed and Utilized	Percent Capture
New Brunswick	99,952.5	95,502.5	282.5	4,167.5	95.8%
Nova Scotia	115,355.0	114,121.0	129.0	1,105.0	99.0%
Prince Edward Island	18,960.0	18,850.0	51.0	59.0	99.7%
Newfoundland & Labrador	83,812.5	83,188.5	205.0	419.0	99.5%
Atlantic Provinces	318,080.0	311,662.0	667.5	5,750.5	98.2%

5.2 Data Quality

The NSPBCP strives to continuously improve the data obtained for analysis. One strategy is the 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 insufficient or as “others” are identified and correct further information on diagnosis is sought on a quarterly basis. 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 whenever IVIG is used for any new indication.

This report includes data received by the NSPBCP for fiscal year 2011/12. The data is extracted from the database and that is the source used for generating the report. Data for fiscal year 2011/12 can continue to be entered into the database but it will not be part of the extract used for generating the report. However for previous fiscal years, an updated or live database is used for a true reflection of the revisions, corrections and submissions on data that were completed after the generation of previous annual reports. This may reflect as a variation

in the indications, utilized IVIG grams and overall appropriateness of use of IVIG from what was presented in the previous year's annual reports.

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 Laboratory Information System (LIS) into DaISI (flat files).

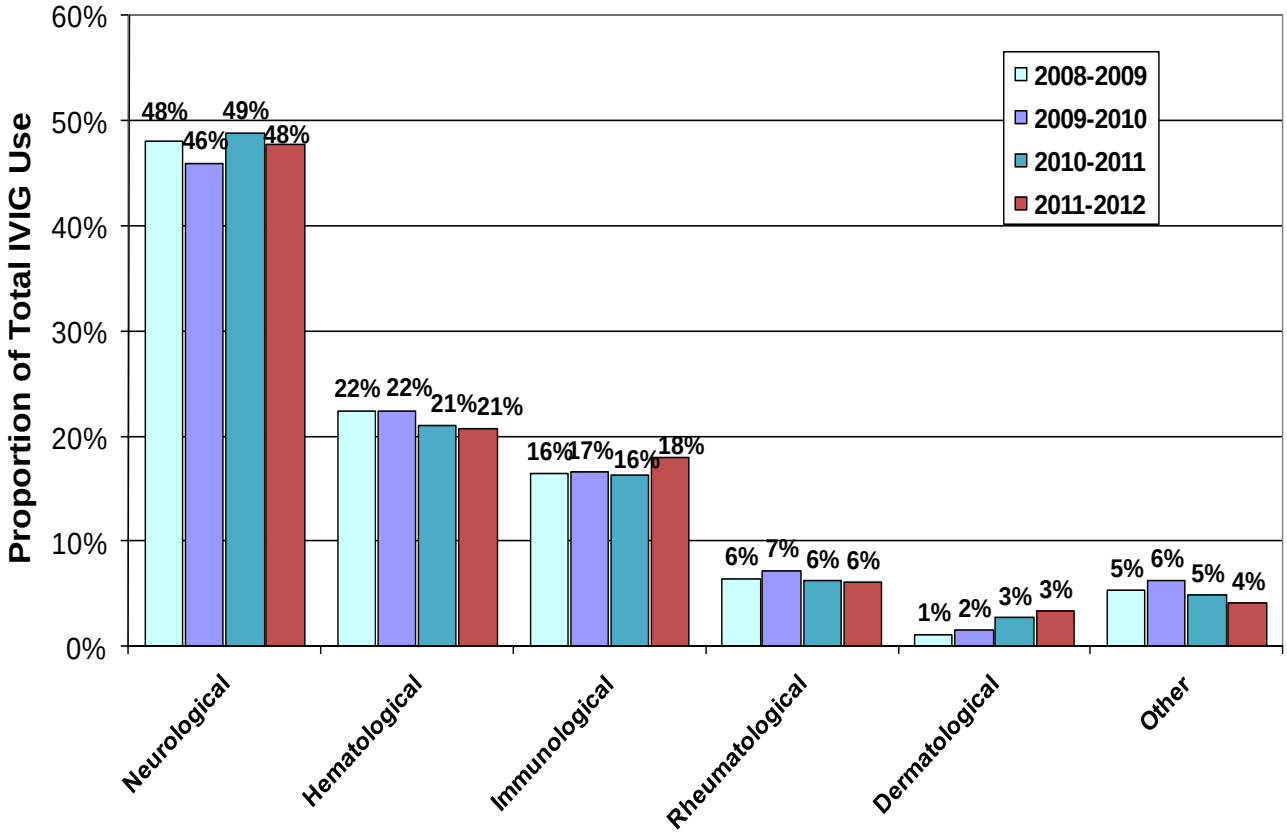
Quarterly data submissions which were reviewed for missing data and periodic data clean up contributed to quality improvement of the Atlantic IVIG/SCIG Utilization report and must be continued.

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.

Figure 7 shows a decrease in the proportion of IVIG utilized in neurology in 2011/12, while the

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



proportion of the IVIG used in hematology, rheumatology and dermatology remained the same as 2010/11. The proportion of the utilization of IVIG increased in immunology during 2011/12.

Figure 8a shows the proportion of total IVIG used in each of the most common indications. Higher proportion of the total utilized IVIG was used in Chronic Inflammatory Demyelinating Polyradiculoneuropathy, Primary Immune Deficiency and Secondary Immune Deficiency. All the other common indications in neurology and hematology have shown a decline in the proportion of total use of IVIG when compared with last year's proportionate use.

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

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

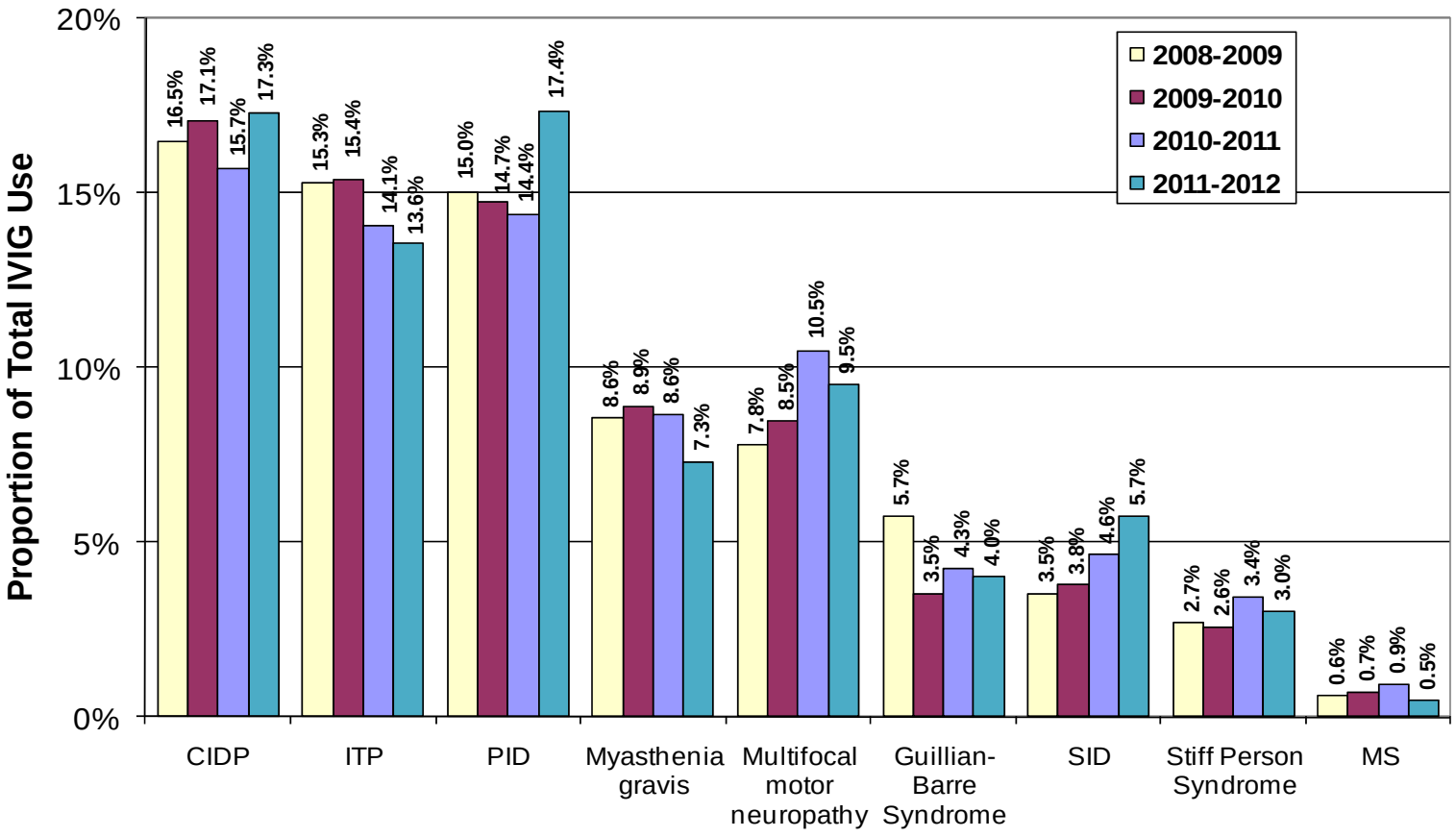


Figure 8b shows the total number of patients using IVIG in each of the most common indications. More patients were treated for Chronic Inflammatory Demyelinating Polyradiculoneuropathy, Primary Immune deficiency, Multifocal Motor Neuropathy, Myasthenia Gravis, Guillian Barré Syndrome and Secondary Immune Deficiency in 2011/12 when compared to 2010/11.

Figure 8b: Number of IVIG Patients by Indication in the Atlantic Provinces for Recent Fiscal Years

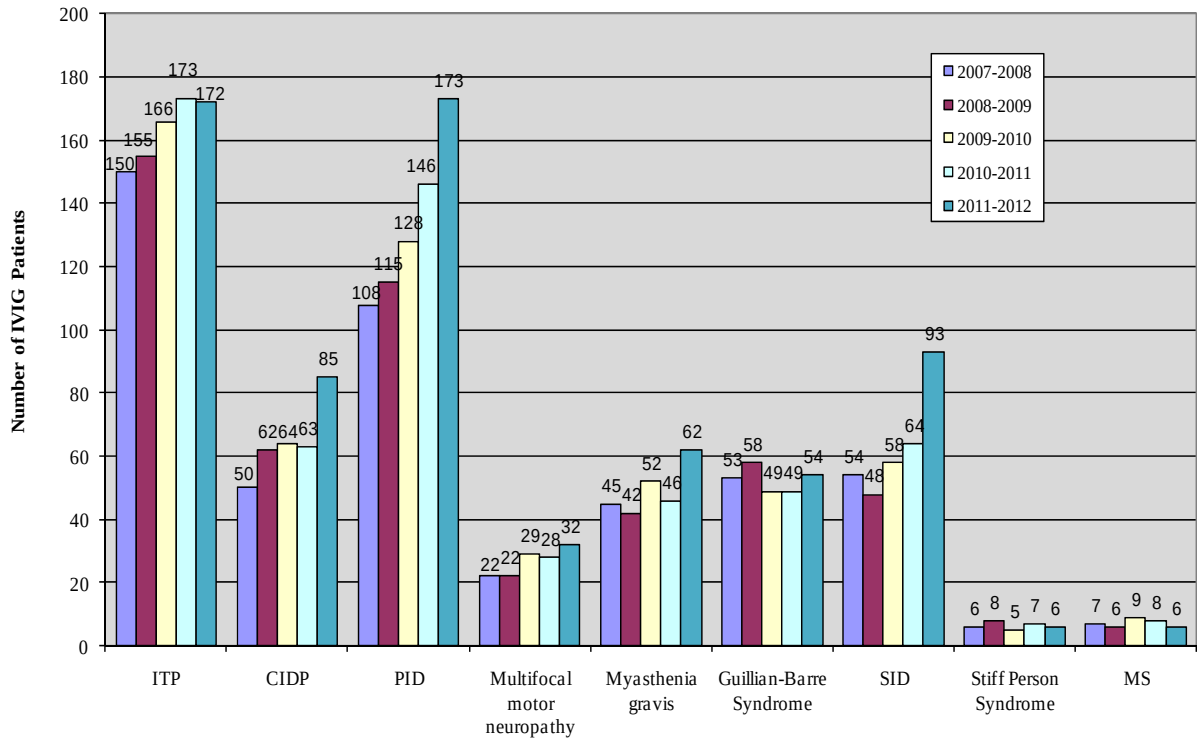


Table 5 shows the comparison of the top ten indications by usage of IVIG in each Atlantic province during 2011/12. It is interesting to note that the top indication in one province may not be the top indication of use in the other provinces.

Table 5: Top 10 Indications in the Atlantic Provinces based on usage in FY 2011-2012

NB		NS		PEI		NL	
Indication	**Usage**	**Indication**	**Usage**	**Indication**	**Usage**	**Indication**	**Usage**
ITP	18296	PID	27021.2	CIDP	5705	CIDP	16867.5
MMN	17473	CIDP	21129	MMN	4065	PID	11687
PID	14096	ITP	14754.5	Stiff Person	2010	MG	10414.5
CIDP	10149.5	MG	8615	Multiple Myeloma	1760	ITP	7854
SID	9006	Stiff Person	4580	ITP	1445	SID	5462.5
GBS	5698	GBS	4340	PID	1310	MMN	4090
MG	3777.5	MMN	4000	SID	880	PG	3190
Dermatomyositis	1730	Polymyositis	3843.5	Pregnancy ITP	550	Stiff Person	2795
Polymyositis	1520	SID	2534.5	CLL	510	GBS	2257.5
Nerve Impairement Similar to Ms	1170	Nemalin Myopathy	2480	Autoimmune Mediated Encephalopathy	255	Dermatomyositis	2225

7 Request Approval Process

In an effort to optimize the appropriate use of IVIG, the Atlantic Blood Utilization Strategy (ABUS) Working Group 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 IVIG requests for neurological, immunological and hematological indications are addressed. 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 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.

The process is implemented in all Maritime provinces. In Newfoundland and Labrador the request approval process is implemented in two regions and the two largest facilities of the third region. Table 6 shows the distribution of the request approval pathways taken by new adult IVIG cases during 2011/12. 376 requests passed through the approval process, 37 (9.8%) were for indications not listed in the guidelines (non neurology, non immunology and non hematology patients). Of the remaining 339, 96.5% met the guidelines for indication and dosage upon initial submission and the request

approval process was activated in 12 (3.5%) cases that did not meet the guidelines for indication or dosing. Out of those, five requests were revised to meet the guidelines, three after discussion with the Blood Transfusion Service staff and two after discussion with the Medical Director. Expert opinions were sought in five cases but IVIG was granted for all the requests.

The request approval process has improved the compliance with the guidelines. Five requests were revised to meet the guidelines after discussion with Blood Transfusion Service staff or the Medical Director. It is recommended that the adult request approval process be expanded beyond neurological and hematological conditions. It is also recommended that the request approval process be implemented in the Pediatric cohort.

Table 6: Request Approval pathways in the Atlantic Provinces Fiscal year 2011/12

Pathway	Description	NB	NS	PE	NL	Atlantic
1	Request for an indications not listed in the guidelines	28	8		1	37
2	Request met the guidelines for indication and dosage upon initial submission	131	141	19	36	327
3	Requests were revised to meet the guidelines after discussion with the Blood Transfusion Service staff	1	1	1		3
4	Requests was withdrawn after discussion with the Blood Transfusion Service staff					
5	Requests were revised to meet the guidelines after discussion with the Medical Director	1	1			2
6	Requests was withdrawn after the ordering MD consulted with the clinical expert					
7	Original request was granted even after the ordering MD consulted with the clinical expert	1	1	1	2	5
8	Consultation with the clinical expert did not occur					
9	Others		2			2
TOTAL		162	154	21	39	376

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 decreased their use of IVIG for unlabeled not indicated (UL-N) indications from 5.4% of the total use of IVIG in 2010/11 to 4.4% in 2011/12. The overall Atlantic use for UL-N indications decreased from 7g/1000 population in 2010/11 to 6g/1000 population in 2011/12. The use of IVIG for UL-I and labeled indications in the Atlantic Provinces improved during 2011/12 to 126g/1000 population from 115g/1000 last year. This is equal to 95.3% of the total use of IVIG during 2011/12 and an improvement from last year's 94.6%.

Figure 9: Appropriateness of IVIg Use in the Atlantic Provinces

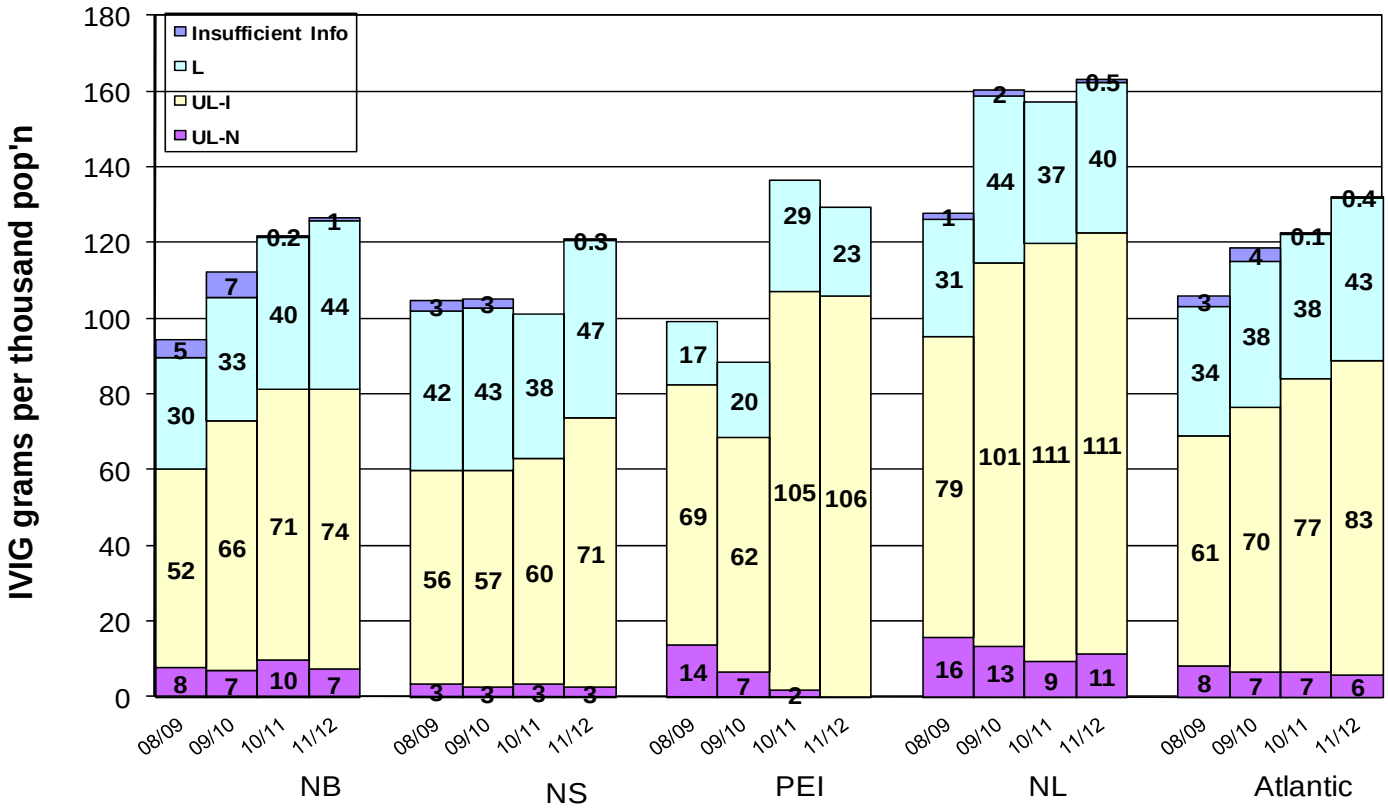


Figure 10 shows the proportion of IVIG for UL-N indications in the Atlantic Provinces. Newfoundland and Labrador increased their use of IVIG for UL-N indications from 5.9% of the total use of IVIG in 2010/11 to 7% in 2011/12.

New Brunswick, Nova Scotia and Prince Edward Island have decreased their use of IVIG for the unlabelled not indicated indications from 8.1%, 3.1% and 1.4% of the total use of IVIG in 2010/11 to 5.8%, 2.1% and zero in 2011/12 respectively. The UL-N usage in the Atlantic Provinces decreased from 5.4% of the total use in 2010/11 to 4.4% in 2011/12.

The indications for the UL-N use of IVIG are evaluated on a quarterly basis to minimize the coding issues resulting in the wrong categorization; the data base is updated to reflect these changes on an ongoing basis.

Figure 10: Proportion of IVIG Use for ULN Indications

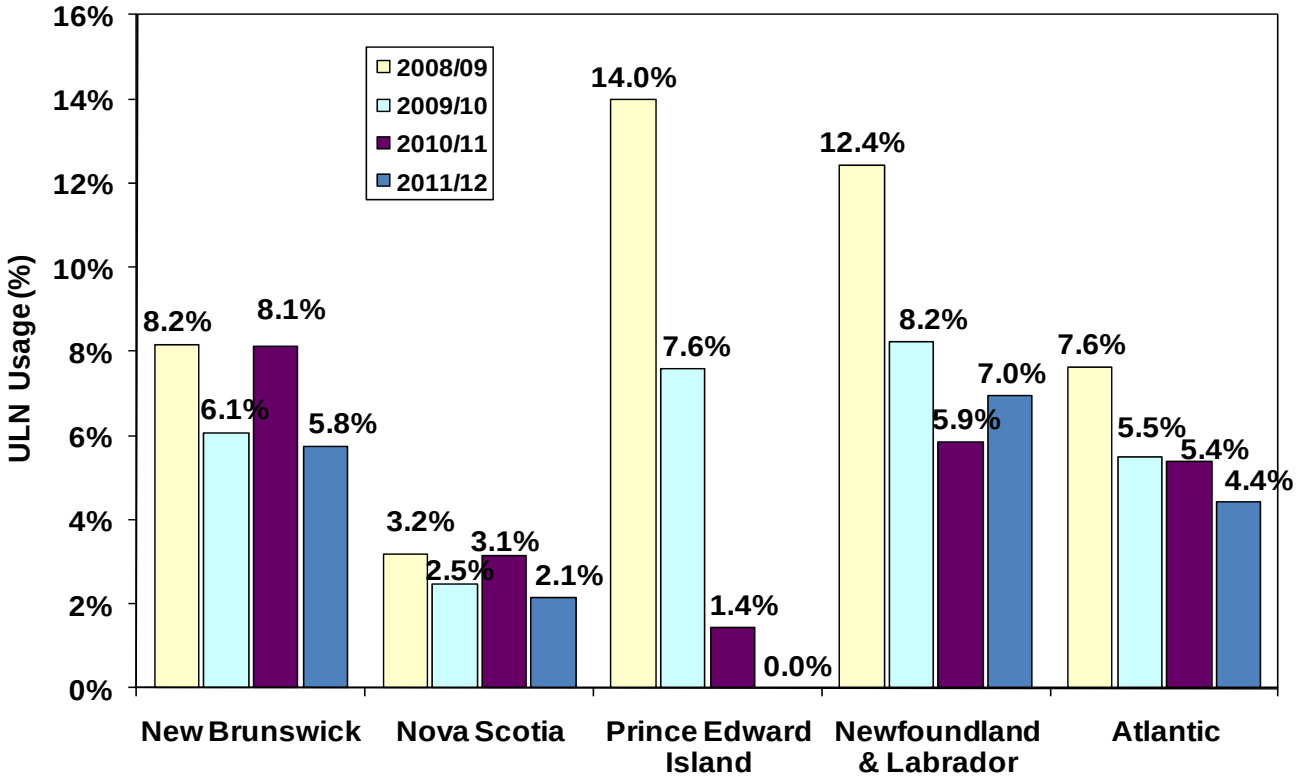


Table 7 reveals the cost of IVIG for UL-N use in 2011/12. The cost of IVIG associated with UL-N indications was $324,335 in New Brunswick; $144,653 in Nova Scotia; and $341,436 in Newfoundland and Labrador. IVIG was not used for any UL-N indications in Prince Edward Island.

Table 7: 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
2007/08	$221,367.90	$225,103.14	$43,120.05	$450,920.37
2008/09	$329,698.88	$179,522.41	$110,890.40	$459,937.94
2009/10	$340,356.37	$162,487.55	$63,059.85	$448,091.95
2010/11	$467,365.87	$188,700.00	$17,612.00	$295,315.50
2011/12	$324,335.00	$144,653.41	$0.00	$341,436.30

* Estimated cost is calculated by multiplying the total grams by an average price per gram of $58.97

8.2 Dosing

Prerequisite clinical criteria and appropriate dosing have to be considered even if an indication is classified as appropriate. Data on clinical criteria is 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 8 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 regimens were all considered appropriate if the total amount in a four-week period was in compliance with the guidelines.

There were 5,620 doses in the most common indications in the Atlantic Provinces for 2011/12, 5.5% of these doses were higher than recommended. In 2011/12 there was an improvement in the percent of doses administered that were appropriate for the nine most common indications in neurology and hematology in Nova Scotia from 6.1% in 2010/11 to 4.6% in 2011/12; in Newfoundland and Labrador from 2.58% in 2010/11 to 0.8% in 2011/12 and in New Brunswick from 10.6% in 2010/11 to10.2% in 2011/12. In Prince Edward Island higher than recommended doses increased from 3.3% in 2010/11 to 3.8% in 2011/12. 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 8: Percent of doses higher or more frequent than recommended for the most common indications.

Indication	**NB**			**NS**			**PEI**			**NL**		
	09/10	10/11	11/12	09/10	10/11	11/12	09/10	10/11	11/12	09/10	10/11	11/12
*CIDP	27.0	5.2	3.5	19.0	1.4	1.63	0.0	0.0	4.4	7.0	0.4	0.3
GBS	4.0	12.1	2.8	22.0	1.0	11	**	0.0	0	0.0	3.6	11.26
ITP	7.0	5.9	17.2	6.0	18.5	17.5	33.0	**	16.6	13.0	19.5	0.8
MMN	41.0	21.4	27.35	0.0	0.0	9.4	0.0	0.0	0	0.0	0.0	0
MS	0.0	0.0	0	0.0	6.1	2.6	**	0.0	0	15.0	**	NA
MG	**	0.0	0	3.0	0.0	0	**	0.0	NA	0.0	0.0	0.44
PID	24.0	10.9	10.3	9.0	22.4	3.2	0.0	21.3	7.2	24.0	6.1	0
SID	3.0	1.4	0	12.0	0.0	0	3.0	0.0	0	13.0	4.7	0
Stiff person syndrome	2.0	11.9	*	12.0	3.9	0	0.0	0.0	0	2.0	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.

Figure 11 shows the provincial comparison of the IVIG use as higher or more frequent then recommended in 2009/10, 2010/11 and 2011/12**.** The grams of IVIG used as higher or more frequent then recommended is almost the same in the last two years for the Atlantic Provinces. This equates to 4.6% of the IVIG used in Atlantic Canada during 2011/12 and 5% in 2010/11.

Figure 11: Annual Comparison of total use of IVIG where dosing is more frequent or higher than recommended

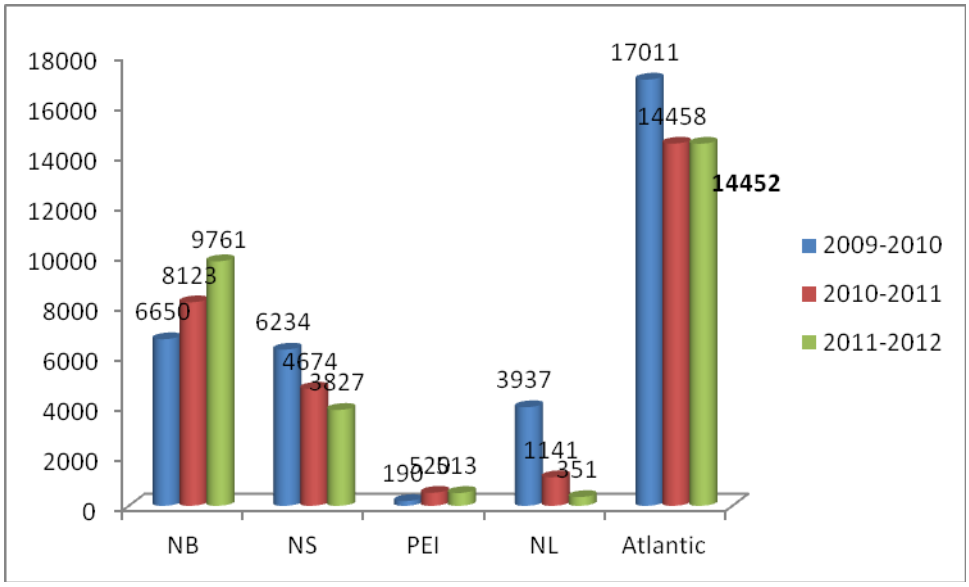


Table 9 reveals the provincial comparison of grams of IVIG given as higher and more frequent than recommended. Ninety three percent (13,389/14,452) was used as more frequent doses; and 7% (1,063g) as higher than recommended doses in 2011/12. In 2010/11, 91% of the total was given as more frequent doses then recommended and 9% was given as higher than recommended doses. The NSPBCP does not collect clinical data to comment on the clinical requirement of the repeat doses. There is currently an inability to classify the 93% of more frequent then recommended doses as "clinically indicated or not".

Table 9: Comparison of Provincial use of IVIG grams as higher or more frequent than recommended in fiscal year 2011/12

	NB	NS	PEI	NL	Atlantic
More frequent than recommended (IVIG g)	9,227	3,437	395	330	13,389
Higher than recommended (IVIG g)	534	390	118	21	1,063
Total	**9,761**	**3,827**	**513**	**351**	**14,452**

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 and reporting of serum IgG levels in the Atlantic Provinces from 77% in 2010/11 to 81% in 2011/12. Improvement in monitoring and reporting of serum IgG levels was observed in New Brunswick and Newfoundland and Labrador from 61% and 87% in 2010/11 to 72% and 95% in 2011/12 respectively.

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

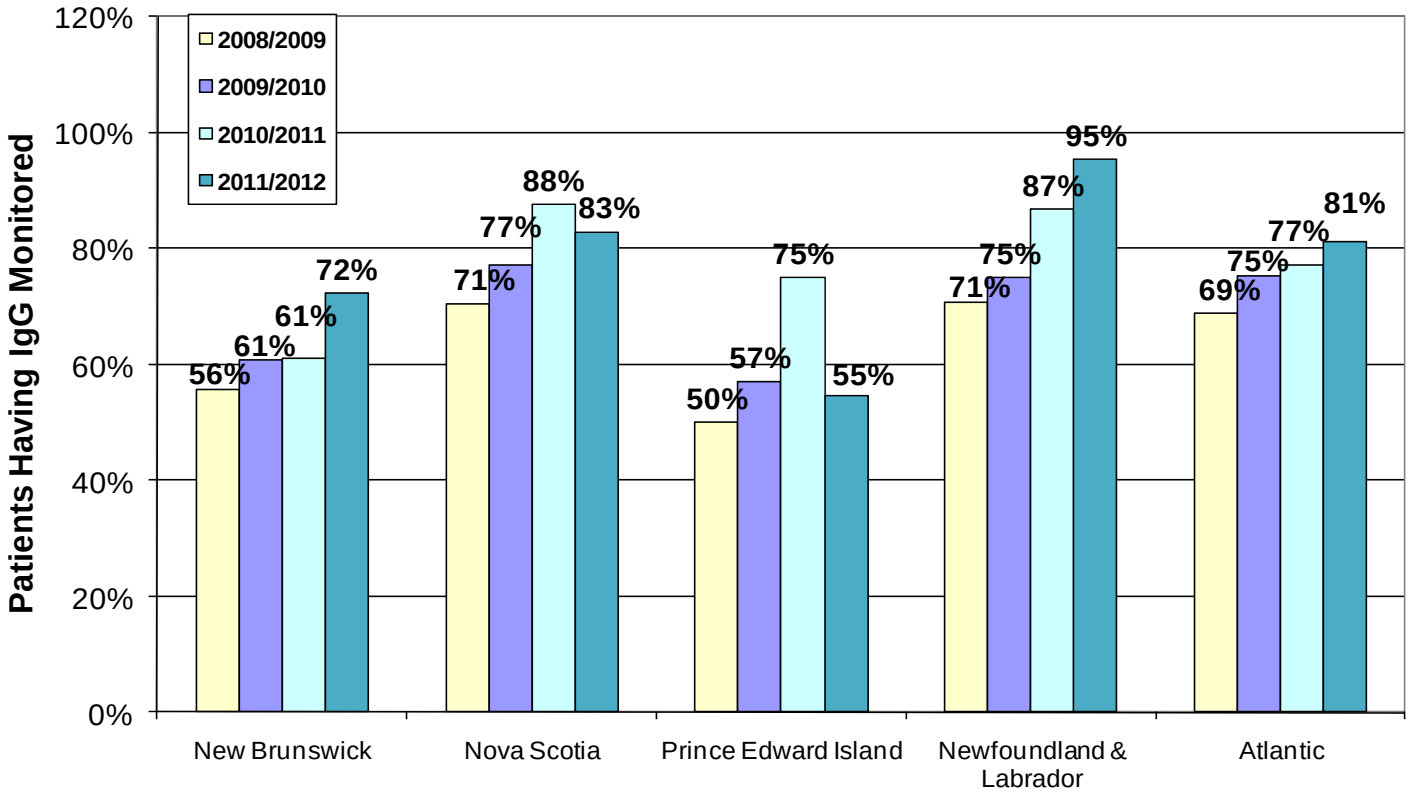
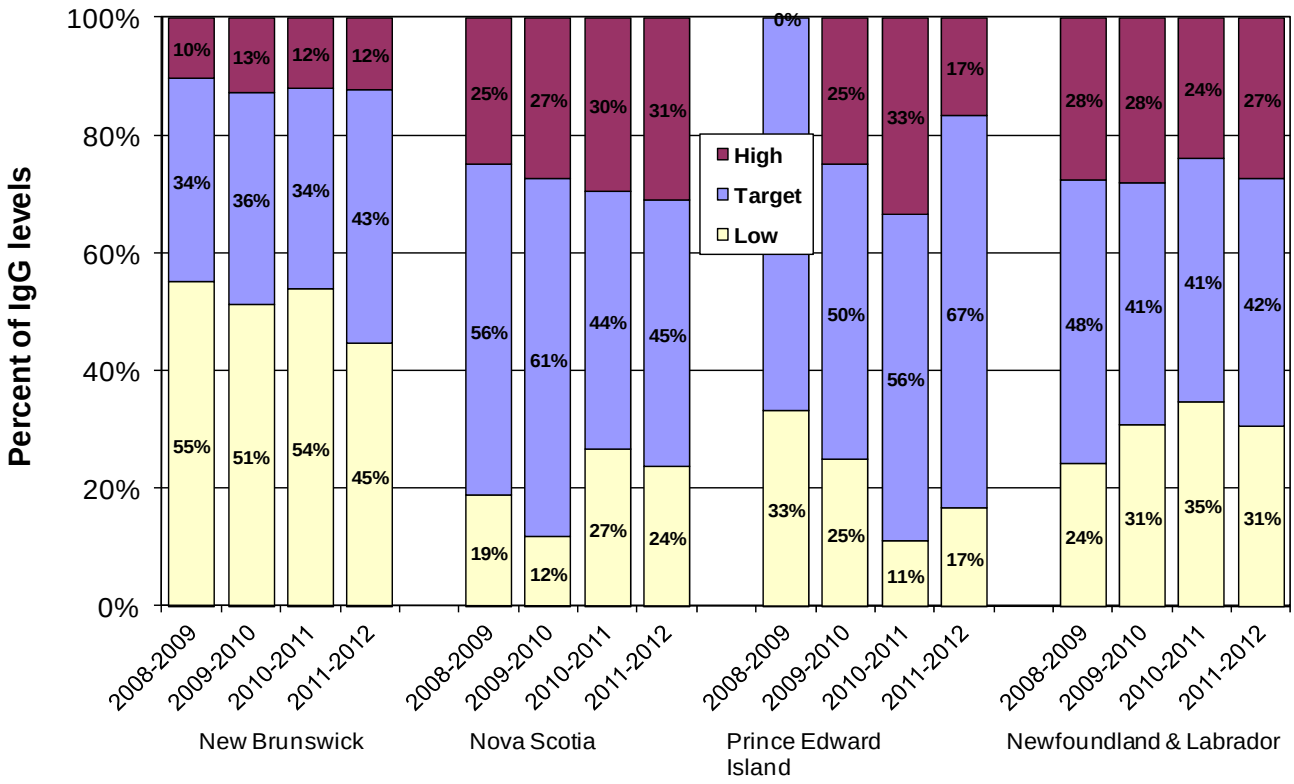


Figure 13 illustrates the percentage of patients whose most recent IgG levels were within the target range of 7 and 10 g/L. This is indicated by the size of the blue section of each bar. The top and bottom sections indicate the proportions of patients whose most recent IgG levels were above and below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

This year 55 % of the patients with immune deficiency in New Brunswick had their IgG levels above 7g/L; out of these 43% were within target range and 12% were even higher than the target range. In Nova Scotia 76% of patients had their IgG levels in and above the target range, out of these 45% were within the target range and 31% above the target range. In Prince Edward Island 83% of patients had their IgG levels in and above the target range, out of these 67% were within the target range and 17% above the target. In Newfoundland and Labrador 69% of immune deficiency patients had IgG levels in and above the target range, out of these 42% were within the target range and 27% above the target during 2010/11.

It is recommended that IVIG dosing in patients with IgG levels greater than 10 g/L be reviewed to consider providing a lower dose of IVIG/SCIG while still achieving clinical effectiveness.

Figure 13: IgG Level Ranges



9 Discards

The goal of the utilization management of the 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 decreased to 668g in 2011/12 from 1,423g in 2010/11. The decrease in discards was observed in all four provinces, in Nova Scotia from 228g during 2010/11 to 129g in 2011/12; in Newfoundland & Labrador, New Brunswick and Prince Edward Island from 305g, 830g and 60g during 2010/11 to 205g, 283g and 51g in 2011/12 respectively.

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

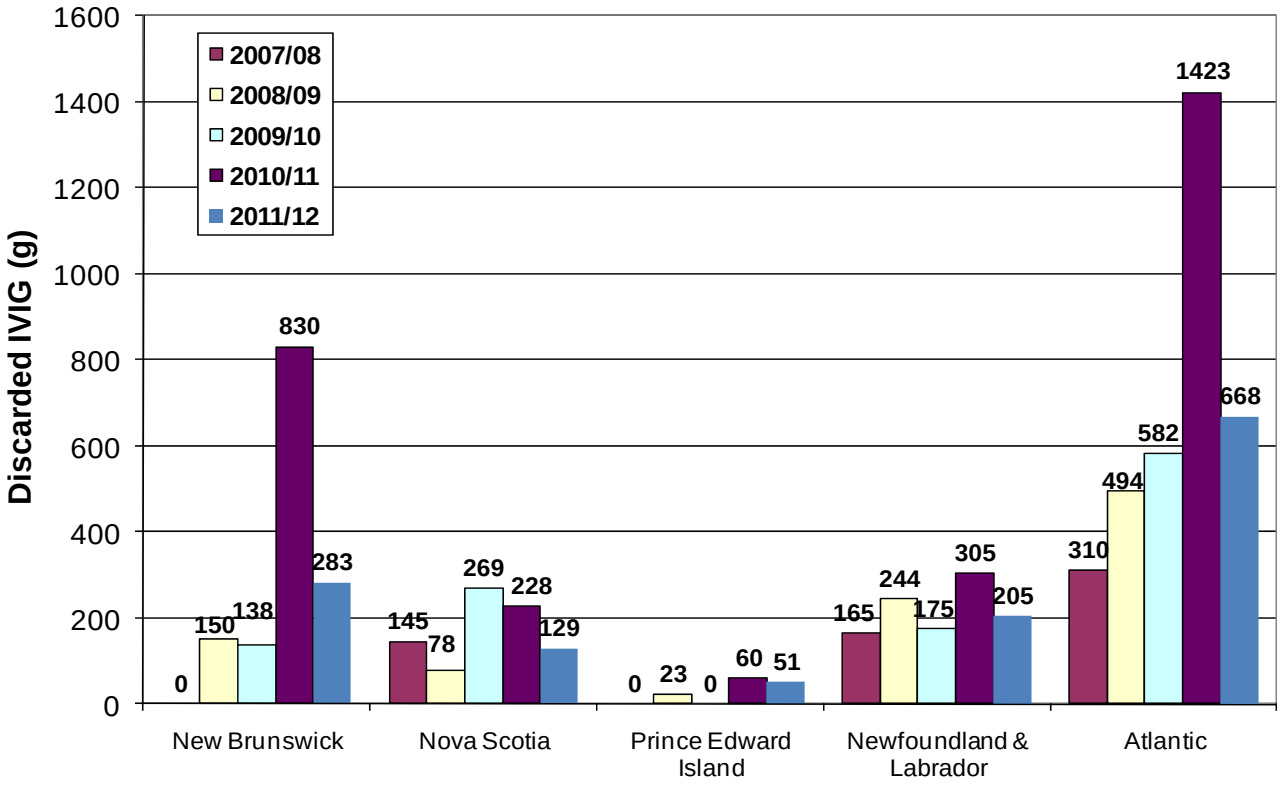


Table 10 shows the summary of estimated costs associated with IVIG discards in recent fiscal years in the Atlantic Provinces individually and combined.

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
2007/08	$0	$7,965	$0	$9,063	$17,028
2008/09	$8,574	$4,430	$1,315	$13,918	$28,237
2009/10	$9,175	$17,950	$0	$11,678	$38,803
2010/11	$52,207	$14,310	$3,774	$19,185	$89,475
2011/12	$16,659	$7,607	$3,007	$12,089	$39,362

* 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 for the discards in the Atlantic Provinces. The three main reasons of IVIG discards in the Atlantic Provinces are breakage, the lab temperature unacceptable /visually unacceptable and expiration.

Table 11: Reasons for IVIG discards in the Atlantic Provinces for fiscal year 2011-12

Reason for discard	Amount (g)
In lab temperature/visually unacceptable	170
Returned to lab temperature/visually unacceptable	40
Broken	236
Expired	152.5
Spiked not transfused	15
Reconstituted, not used	22
Incorrectly	30
Product failed to reconstitute properly	2
Total	**667.5**

Table 11a, 11b, 11c and 11d show the provincial level details of the reasons of discard by the facilities of the Atlantic Provinces. 170 grams were discarded in New Brunswick for in lab temperature/visually unacceptable where as the product discards related to expiration were 67.5 grams in New Brunswick, 20 grams in Nova Scotia, and 65 grams in Newfoundland and Labrador.

It is recommended that the data on discard continues to be collected and monitored. In order to minimize the discards due to expiration, work needs to be done to develop a strategy for redistribution and continuous education regarding the care for the use of IVIG and early return of the unused products to the laboratory if not transfused.

Table 11a: Reasons with grams of IVIG discard by facilities and districts of New Brunswick

District/ Region	Facility code	Reason for discard	Amount (g)
A	**848**	**expired**	**7.5**
B	**829**	**broken**	**35**
	829	**returned to lab temperature/visually unacceptable**	**5**
	801	**broken**	**5**
	823	**in lab temperature/visually unacceptable**	**170**
	846	**expired**	**60**

Table 11b: Reasons with grams of IVIG discard by facilities and districts of Nova Scotia

District/ Region	Facility	Reason for discard	Amount (g)
Annapolis Valley District Health Authority	Valley Regional Hospital	broken	20
		reconstituted, not used	5
Guysborough Antigonish Strait Health Authority	Guysborough Memorial	product failed to reconstitute properly	2
		reconstituted, not used	2
	St. Martha's Regional Hospital	broken	60
		reconstituted, not used	10
	Strait - Richmond Hospital	expired	20
Cape Breton District Health Authority	Cape Breton Regional Hospital (Sydney)	broken	10

Table 11c: Reasons with grams of IVIG discard by facilities in Prince Edward Island

District/ Region	Facility code	Reason for discard	Amount (g)
Provincial Health Services Authority	2	spiked not transfused/sterility/integrity of product compromised	10
	1	broken	11
		returned to lab temperature/visually unacceptable	30

Table 11d: Reasons with grams of IVIG discard by facilities and regions of Newfoundland and Labrador

District/ Region	Facility Code	Reason for Discard	Amount (g)
8901	1016	reconstituted, not used	5
		returned to lab temperature/visually unacceptable	5
	1017	broken	20
		expired	15
	1011	broken	10
		spiked not transfused/sterility/integrity of product compromised	5
	1013	broken	30
		expired	10
8902	1022	broken	10
	1001	broken	20
		expired	40
	1018	broken	5
8903	1025	incorrectly reconstituted	30

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 the Atlantic Provinces. There is a 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. It is calculated over 100,000 population.

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

The prevalence of the cases requiring IVIG in the Atlantic Provinces increased in Nova Scotia and Newfoundland and Labrador from 30 and 43.75 in 2010/11 to 37.66 and 45 in 2011/12 respectively. The prevalence decreased in New Brunswick from 39 last year to 38 in 2011/12 and in Prince Edward Island from 36 last year to 33.58 in 2011/12.

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

FY	NB	NS	PEI	NL	Atlantic
2008/09	32.00	31.92	31.54	38.32	33.31
2009/10	35.90	31.52	26.22	40.15	34.48
2010/11	38.97	30.03	35.84	43.75	36.23
2011/12	37.99	37.66	33.58	45.05	39.11

10.2 Incidence

Incidence refers to the rate at which new cases of a disease occur in a population during a specified period. It is calculated over 100,000 population.

Table 13 shows the yearly provincial comparison of the incidence of patients requiring IVIG treatment in the Atlantic Provinces over the last four years. The incidence of cases using IVIG decreased in New Brunswick and Prince Edward Island during 2011/12. The incidence increased in Nova Scotia from 17.3 last year to 24 in 2011/12. It remained unchanged in Newfoundland and Labrador.

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

FY	NB	NS	PEI	NL	Atlantic
2008/09	20.08	19.00	18.64	21.73	19.92
2009/10	22.02	18.42	13.47	22.24	20.11
2010/11	23.81	17.29	22.49	23.94	21.14
2011/12	20.25	24.01	14.39	23.89	22.19

10.3 Annual Variance in Grams of IVIG and SCIG per Patient

New to this year is the provincial calculation of annual variance in grams of combined IVIG and SCIG per patient using IVIG or SCIG. Table 14 below shows that although the number of patients increased in Nova Scotia by 77, the use of IVIG and SCIG per patient decreased in Nova Scotia during 2011/12 by 5.6% from what it was last year. The rise in per capita distribution of combined IVIG and SCIG in Nova Scotia may be attributed to the rise in incidence and prevalence of the use of IVIG in and not to a rise in inappropriate use per patient. This fact is also supported by a rise in the use of IVIG for appropriate indications and decline in the use for UL-N indications and discards in all Atlantic Provinces including Nova Scotia.

Table 14: Annual Variance in grams per patient for IVIG + SCIG

Province	FY	Grams of IVIG+SCIG	Total number of patients using IVIG+SCIG	Grams per patient	Annual Variance in grams per patient
NB	2009/10	84375.3	270	312.50	
NB	2010/11	92162.5	294	313.48	0.31%
NB	2011/12	95745.7	290	330.16	5.32%
NS	2009/10	99769.7	299	333.68	
NS	2010/11	98186	291	337.41	1.12%
NS	2011/12	117171.4	368	318.40	-5.63%
PEI	2009/10	12445	37	336.35	
PEI	2010/11	19420	51	380.78	13.21%
PEI	2011/12	18850	49	384.69	1.03%
NL	2009/10	81930.4	205	399.66	
NL	2010/11	80723.4	225	358.77	-10.23%
NL	2011/12	84225.3	235	358.41	-0.10%

10.4 Utilization of IVIG by the Regions in New Brunswick

The rise in distribution of IVIG was observed in New Brunswick, Nova Scotia and Newfoundland and Labrador during 2011/12. The highest variance was seen in Nova Scotia. A detailed analysis was completed at the level of District Health Authorities in order to identify the Districts exhibiting the highest use and variance in utilization with a view that this may support the root cause analysis at the District level. Table 15a shows the summary of IVIG used and variance in utilization over the years by the Districts of New Brunswick. In 2010/11 the variance in the utilization of IVIG was high in District A of New Brunswick whereas in 2011/12 the higher variance of 5.5% was seen in District B.

Table 15a: Utilization of IVIG in NB by Districts

District	IVIG(g) 09/10	IVIG (g) 10/11 (Variance %)	IVIG (g) 11/12 (Variance %)
A	17682.4	23670.6 (33.9%)	23897.7 (1.0%)
B	66366.5	67855.5 (2.2%)	71604.8 (5.5%)

Table 15b shows the summary of IVIG used and variance in utilization over years by the District Health Authorities of Nova Scotia. The highest variance was seen in DHA 3, 4, 8, 9 and IWK by 95.5%, 64.5%, 26.4%, 16% and 28.4% respectively.

Table 15b: Utilization of IVIG in NS by Districts

District	IVIG(g) 09/10	IVIG (g) 10/11 (Variance %)	IVIG (g) 11/12 (Variance %)
1	2660	3810 (43.2%)	2880 (-24.4%)
2	8334	8675 (4.1%)	8545 (-1.5%)
3	4887.5	3202.5 (-34.5%)	6260.56 (95.5%)
4	7213	7354.7 (2.0%)	12096 (64.5%)
5	1350	2040 (51.1%)	1390 (-31.9%)
6	3391.218	3955 (16.6%)	3727 (-5.8%)
7	1200	2010 (67.5%)	1941 (-3.4%)
8	14276.5	12827.5 (-10.1%)	16209 (26.4%)
9	47147.5	41575 (-11.8%)	48207.5 (16.0%)
IWK	8177.06	10015.5 (22.5%)	12864.9 (28.4%)

Table 15c shows the summary of IVIG used and variance in utilization over the years by the Regions of Newfoundland and Labrador. The highest variance of 5.3% and 4.4% were seen in the Eastern and Central Regional Authorities respectively.

Table 15c: Utilization of IVIG in NL by Districts

Regions	IVIG(g) 09/10	IVIG (g) 10/11 (Variance %)	IVIG (g) 11/12 (Variance %)
8901	64805	61212.3 (-5.5%)	64429.5 (5.3%)
8902	7234.8	7592.1 (4.9%)	7928.9 (4.4%)
8903	6170	8581 (39.1%)	8444 (-1.6%)
8904	3455	2690 (-22.1%)	2386 (-11.3%)

The use of IVIG is varied by indication, 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.

11 Dosing Intravenous Immune Globulin (IVIG) Based on Adjusted Body Weight

Adverse reactions like hemolysis are substantially more likely to happen when a high dose of IVIG is infused. Some Canadian jurisdictions have made recommendations to use adjusted weight based dosing instead of actual patient weight. Dosing weight, an intermediate between ideal body weight and actual body weight, was developed to more accurately dose IVIG. With most of the IVIG being used for appropriate indications and dosing, dosing IVIG based on adjusted body weight rather than actual weight may add to safety from hemolysis and may decrease the use of IVIG in patients with high deviation from ideal body weight.

ABUS recommended the implementation of dosing of IVIG based on adjusted body weight. Actual body weight (which includes the weight of adipose tissue of the patient) is used for calculating the dose of fat soluble drugs. As immunoglobulin is not lipid soluble an adjusted body weight is appropriate to use for dosing. The pilot implementation of dosing by adjusted body weight in Prince Edward Island, Newfoundland Labrador and Nova Scotia involved 131 patients and revealed an estimated average savings of 66 grams of IVIG per patient with an associated cost savings of $3,892/patient. An adjusted body weight calculator was developed and made available through the internet and as a smart phone application.

12 Subcutaneous Immunoglobulin

In 2008, SCIG became a regular product within Canadian Blood Services' plasma protein products portfolio and the Atlantic Blood Utilization Strategy Working Group 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.

12.1 Distribution

Figure 15 shows the amount of SCIG distributed to each of the Atlantic Provinces in the 2011/12 fiscal year. A total of 5,699g of SCIG was distributed to the Atlantic Provinces in 2011/12.

Figure 15: SCIG Distributed to Atlantic Provinces by Fiscal Year

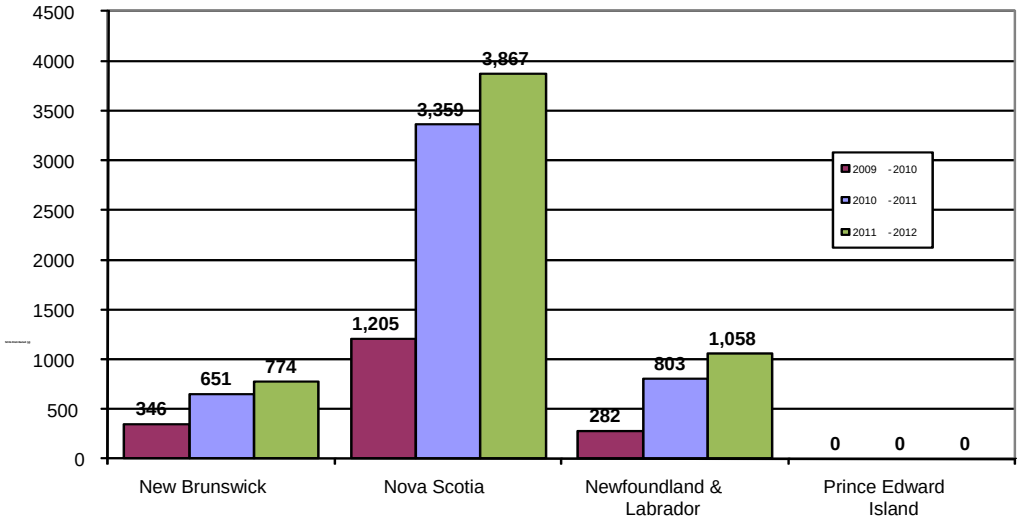


Table 16 reveals the percent capture of SCIG. This is calculated by dividing utilized SCIG by the distributed SCIG for that fiscal year. Low percent capture is due to the fact that SCIG follows a home infusion program and the utilization of SCIG is captured after a few weeks when patients bring in their 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 fiscal year 2011-12

Province	Percent Capture
Nova Scotia	78.9%
New Brunswick	31.4%
Newfoundland and Labrador	98.8%

Table 17 is the summary of the actual cost of SCIG for each of the Atlantic Provinces. The cost of SCIG in the Atlantic Provinces was $336,097 for fiscal year 2011/12.

Table 17: Amount Distributed and total cost of SCIG for fiscal year 2011-12

Province	SCIG (g)	Cost of SCIG
New Brunswick	774	$45,670
Nova Scotia	3867	$228,054
Prince Edward Island	0	0
Newfoundland & Labrador	1058	$62,372
Atlantic Total	**5699**	**$336,097**

12.2 Utilization

12.2.1 Atlantic Guidelines

In an effort to ensure SCIG continues to be used according to the recommended guidelines, an Atlantic Subcutaneous Immunoglobulin 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 Blood Utilization Strategy 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 in the revised guidelines. These guidelines were disseminated in February 2012. Guidelines also included the patient education material for a new method of self administration. A decision was made by the Atlantic SCIG Working Group to include a new method of self administration as an option for SCIG Home Administration Programs. This method is considered relatively easy and cost efficient.

To date there are no major issues reported with SCIG. There were 5,699g of SCIG distributed in the Atlantic Provinces in 2011/12. There were 19 patients on SCIG in the Atlantic Provinces. 68% of cases were in Nova Scotia. The use was for the appropriate indications and was within recommended dosing guidelines. One patient with Evan's Syndrome was also treated with SCIG. Subcutaneous Immune Globulin Home Administration Programs have transitioned 13.5% (27/199) of Primary Immune Deficiency patients in Atlantic Canada from receiving IVIG in hospital to self-administering SCIG in the comfort of their home.

Table 18: Utilization of SCIG in each Atlantic province during 2011/12

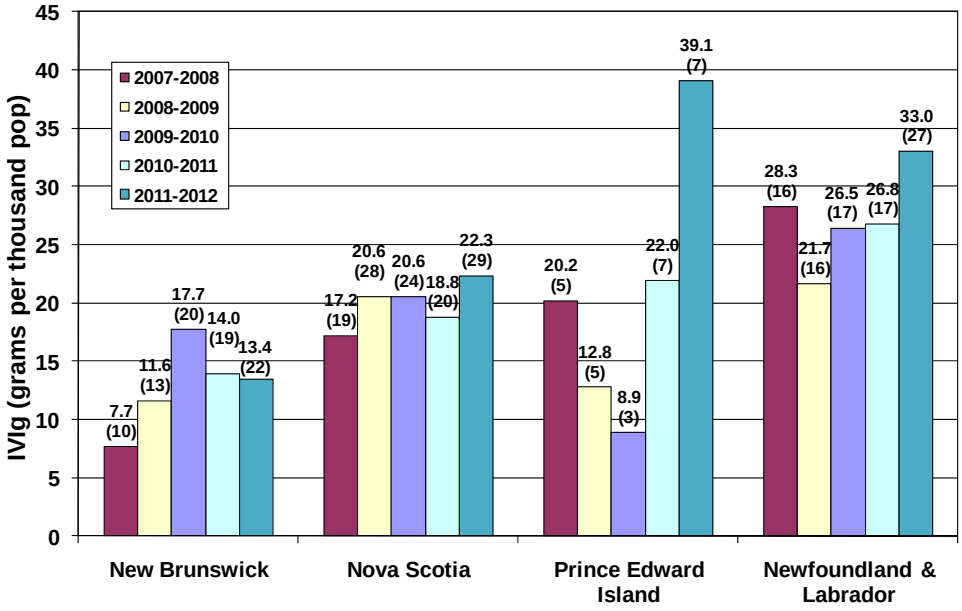
SCIG Utilization	NB	NS	PEI	NL
Number of cases on SCIG	3	19	0	5
Total number of doses for SCIG	84	536	0	235
Number of doses given as Higher than recommended	0	0	0	0
Number of doses given for indications other than PID	0	10 (Evan's Syndrome)	0	0
Grams of SCIG given for indications other than PID	0	30.3 grams	0	0

12.2.2 Discards

Eight grams of SCIG were discarded in the Atlantic Provinces in 2010/11.

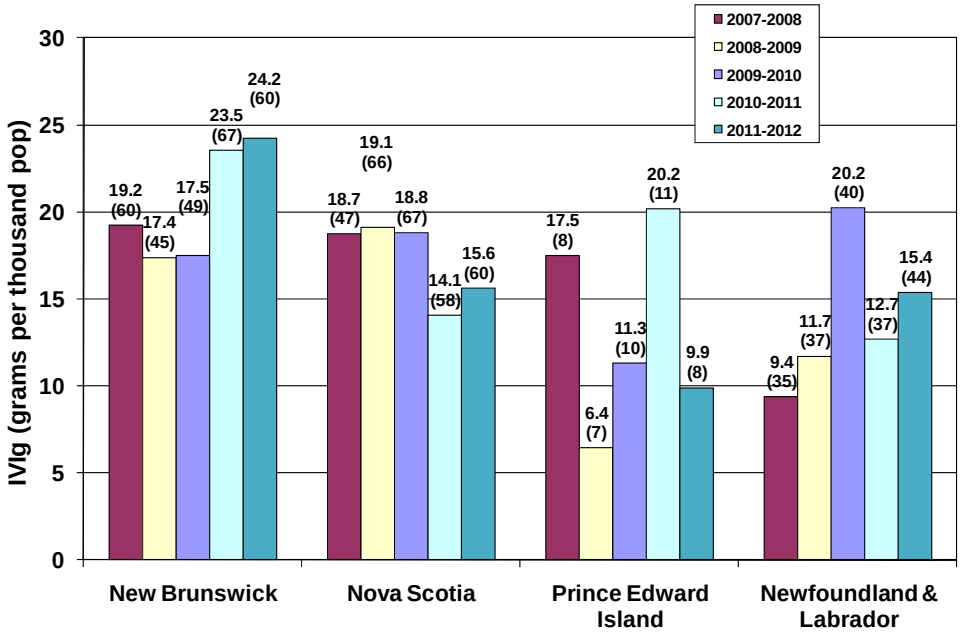
Appendix A per Capita Utilization of IVIG for the Top Indications

Figure A1: Per Capita Utilization of IVIG for CIDP



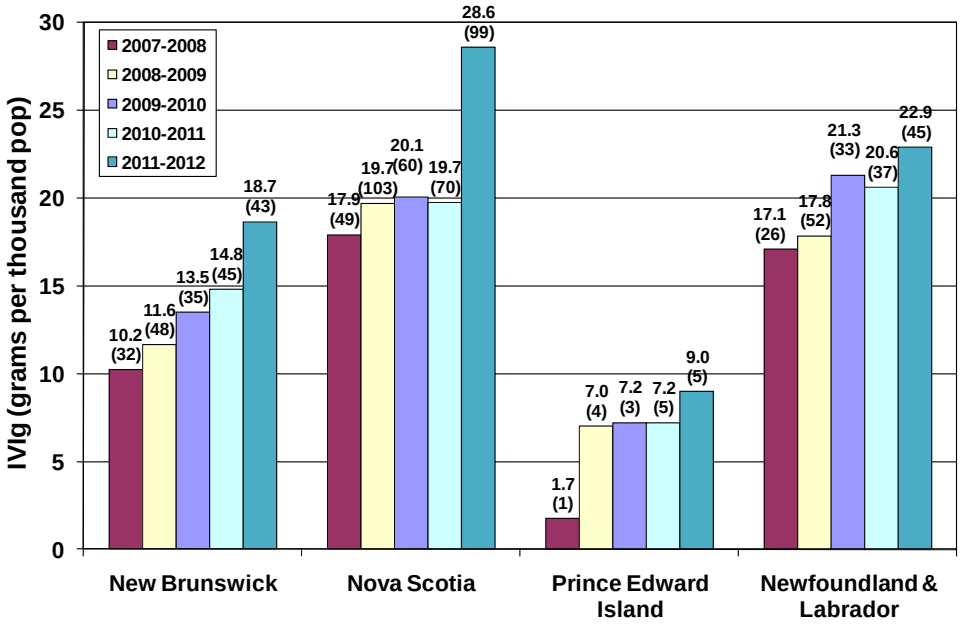
Parentheses indicate total number of patients

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



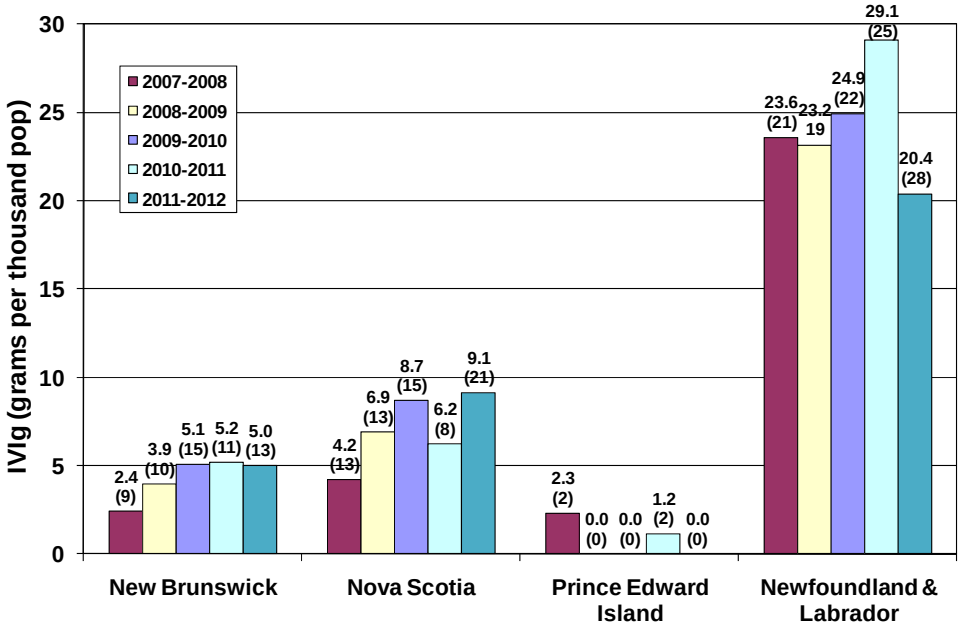
Parentheses indicate total number of patients

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



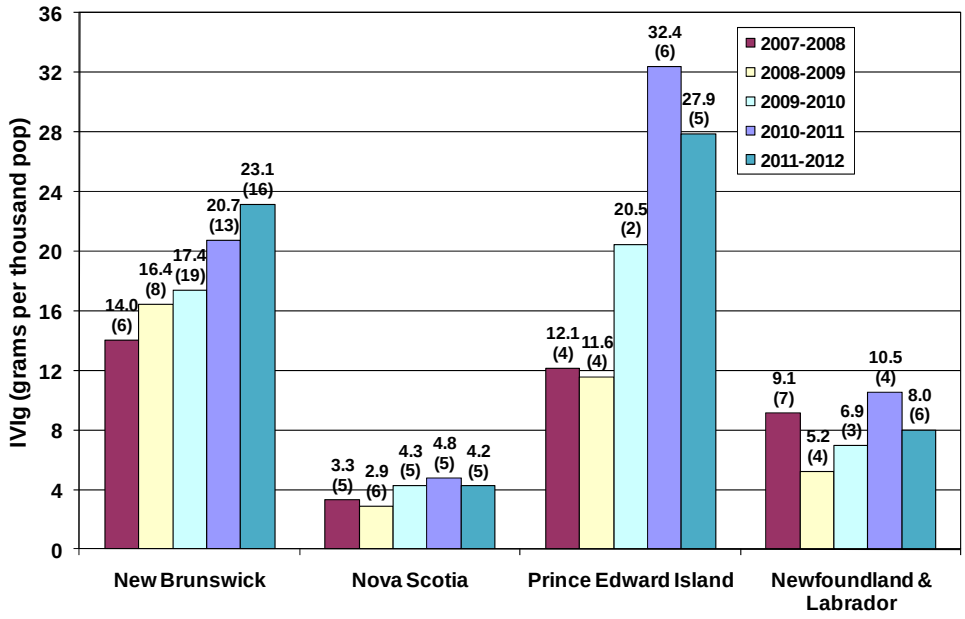
Parentheses indicate total number of patients

Figure A4: Per Capita Utilization of IVIG for Myasthenia Gravis



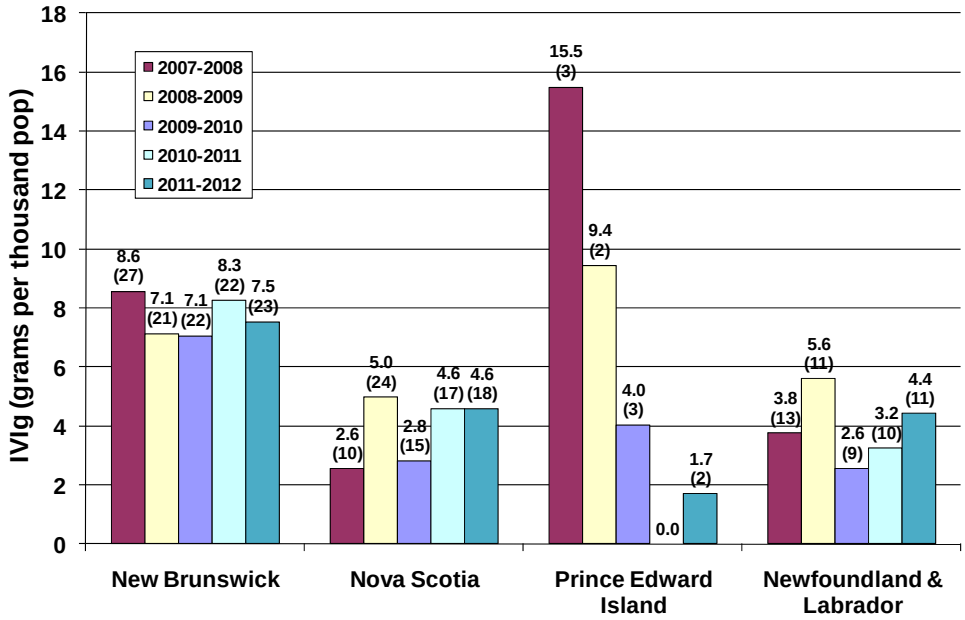
Parentheses indicate total number of patients

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



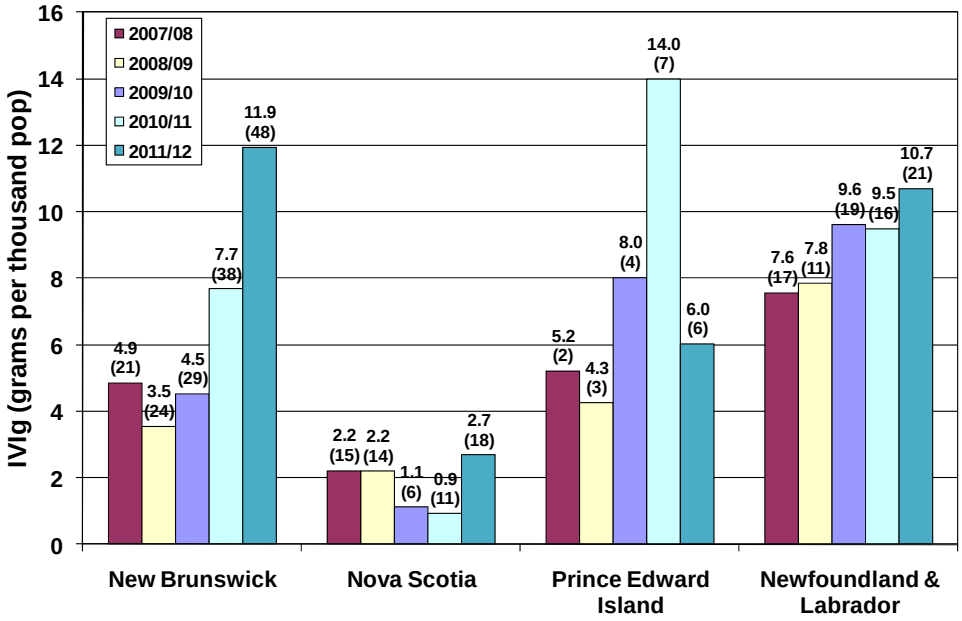
Parentheses indicate total number of patients

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



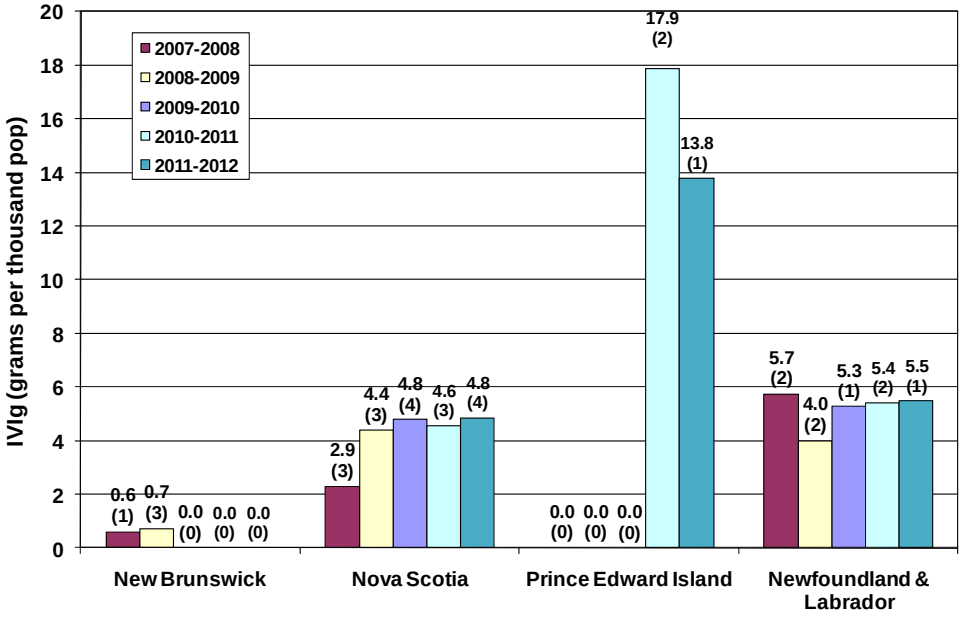
Parentheses indicate total number of patients

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



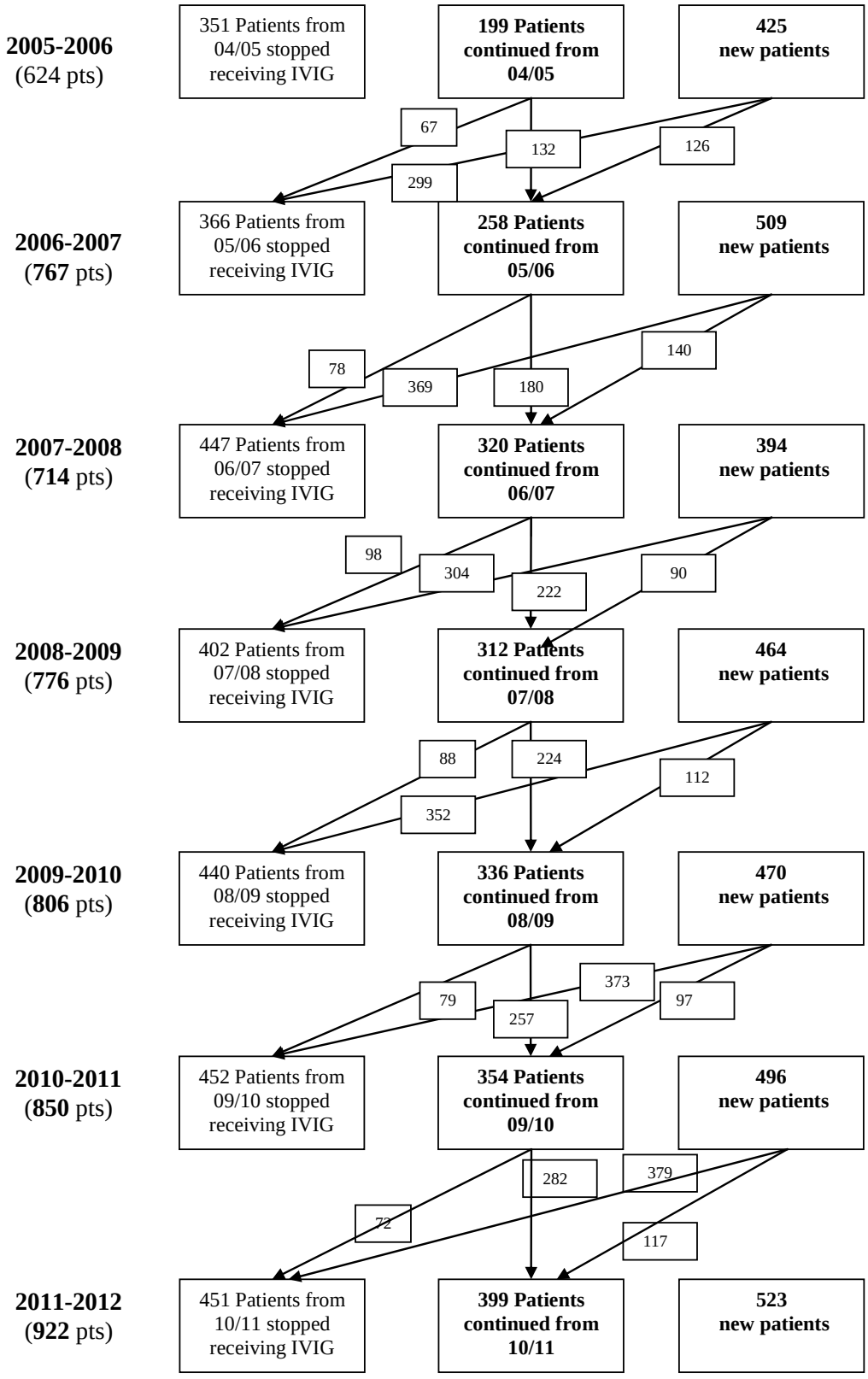
Parentheses indicate total number of patients

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 figure above shows the occurrence of new and carried over patients from last year. There were 523 new patients in Atlantic Canada and 399 patients carried through from last year. This is a total of 922 patients in 2011/12.

Table B 1 reveals the distribution of initial and follow up patients in each Atlantic province from 2008/09 to 2011/12

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	163	283
	3	19	32	51
	4	101	122	223
2011-2012	1	134	153	287
	2	129	227	356
	3	28	21	49
	4	108	122	230

Appendix C List of UL-N Indications

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