National Blood Authority Australia

# Report on the use of Intravenous Immunoglobulin (IVIg) for 2009–2010

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# 2. Executive Summary

Growth in demand for Intravenous Immunoglobulin (IVIg) continues to increase, although the rate of increase appears to be slowing. The average annual growth from 2005-06 to 2009-10 is 12.3 per cent per annum and the growth from 2008-09 to 2009-10 financial year is 11.6 per cent.

In 2009-10, 2,655,184 gms (total) IVIg was issued representing a cost of $163.3 million nationally (excluding cost of plasma collections). 76 per cent of domestic IVIg and 24 per cent of imported IVIg was issued equating to 2,024,422 gms of domestic IVIg and 630,761 gms of imported. Excluding IVIg issued under DO, a total of 9,840 patients were issued IVIg nationally and there were 77,212 patient episodes.

Despite the introduction and sound promotion and explanation of the Criteria for the Clinical Use of IVIg in Australia (*the Criteria)* in 2008, there remains considerable variation in the grams issued per treatment episode across the jurisdictions for some conditions.

Neurology remains the discipline using the greatest amount of IVIg and demand is still increasing. Haematology is the next largest but growth has slowed within this discipline, whilst growth has declined in immunology, the third largest user of IVIg. The top three indications for which IVIg is issued most frequently are Chronic inflammatory demyelinating polyneuropathy (CIDP), Common variable immunodeficiency disease (CVID) and Chronic lymphocytic leukaemia (CLL).

# 3. Purpose

The purpose of this report is to document the trends in the use of IVIg and provide insights into the drivers of the use at the micro level. It draws on records held in the National Blood Authority (NBA) on issues and purchases, and on data provided by the Australian Red Cross Blood Service (the Blood Service) on its application to clinical indications.

# 4. Introduction and Caveats

This report provides an overview of IVIg issued in Australia. The report summarises product issued over time and provides detail on issues within 2009-10 financial year. The report focuses mostly on IVIg which has been funded by the Commonwealth, State and Territory governments under the National Blood Agreement, but also provides limited data concerning IVIg supplied under Direct Orders (DOs). It provides information at a national, and where appropriate state level, about patients receiving IVIg, the grams issued, the grams per 1000 population issued, average dose and treatment episodes. It should be noted that *the Criteria for the Clinical Use of Intravenous Immunoglobulin in Australia* (the Criteria) was introduced in March 2008 with a transition period extending to the end of September 2008, or in some particular cases, longer. A mapping program was conducted to ensure that diagnoses and indications captured prior to the implementation of the Criteria were meaningfully represented, however, it should be noted that, for this reason, information from previous years may not be directly comparable to 2008-09 forward.

Sections of data used in this report were collected by Blood Service using STARS and provided to the NBA. The reporting period covers Quarter one 2008-09 to Quarter four of the 2009-10 financial year.

# 5. Trends 2004-05 to 2009-10

Growth in the total issues of IVIg continued to increase for 2009-10 (Figure 1). However, the increase in growth nationally is lower than the average of the past few years. The increases were:

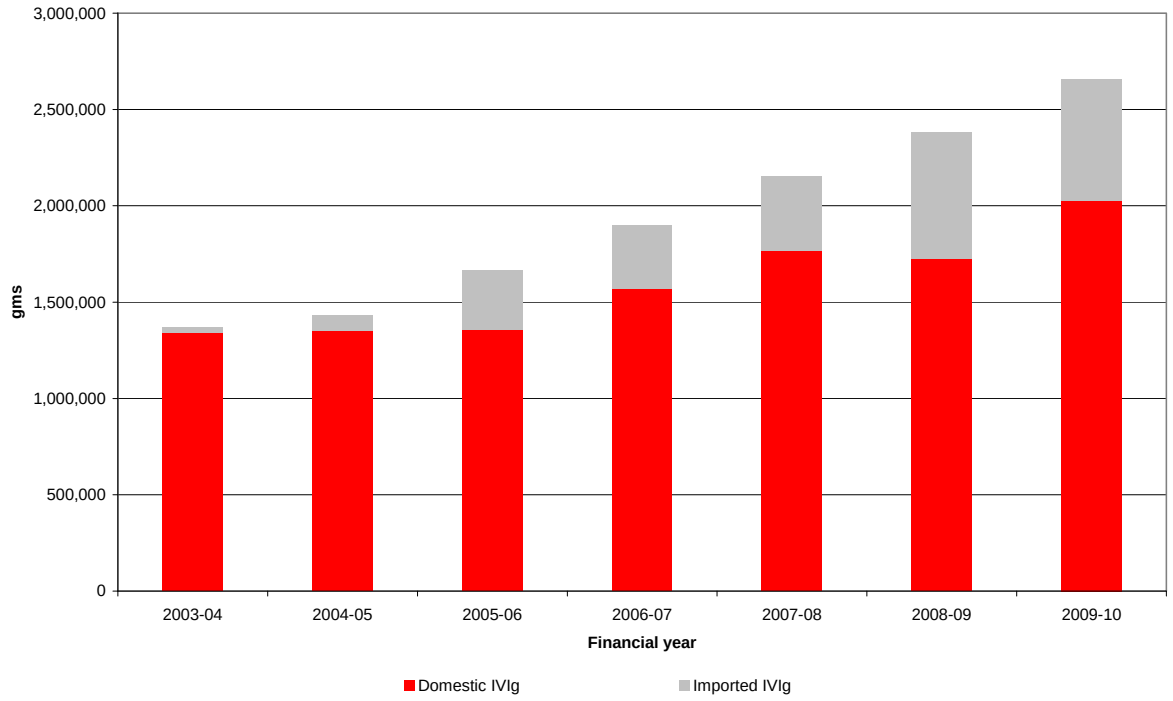
- 11.3 per cent for 2009-10, 10.6 per cent for 2008-09,
- 13.4 per cent for 2007-08 and
- 13.9 per cent for 2006-07.

This equates to an average increase of 12.3 per cent over the last 4 years.

A total of 2,655,184 grams was issued in 2009-10 – an increase of 275,035 grams from 2008/09. Of this total, 24% was imported, following government decisions on the domestic production that would be most appropriate.

The amount of domestically produced IVIg issued differs from the amount produced by CSL during any year when the level of required reserve inventory is changed. These changes reflect changes in the assessment of the needs to maintain supply security. With most long term IVIg users on Intragam P, an adequate reserve is an essential component of supply change management.

***Figure 1 Total grams of IVIg issued nationally over time***

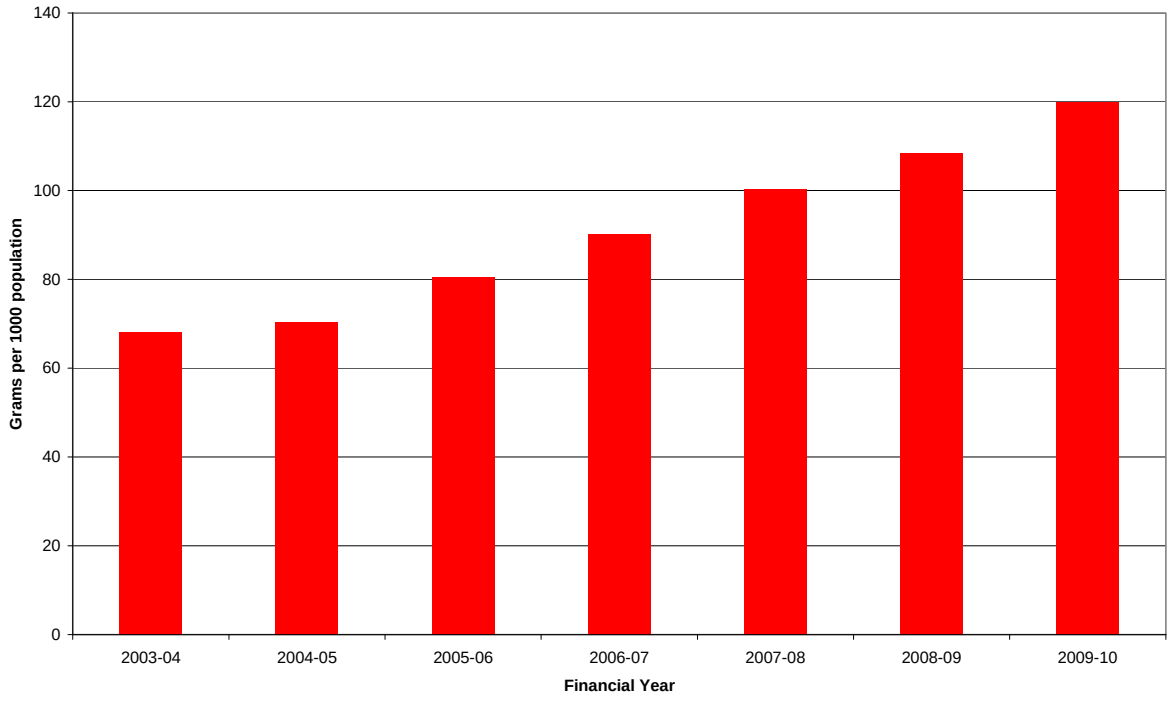



Source: IDMS database of issues via Big Red

Figure 2 and Table 1 below show issues of total IVIg and growth presented by 1000 head of population, with the calculated rate going from 108.42 gms per 1000 head of population in 2008-09 to 119.86 gms in 2009-10. The increase in issues per head of population means that the growth in issues is far outstripping population growth.

Some of the growth in per capita terms of IVIg use relates to the ageing of the Australian population and the strong correlation between ageing and conditions that can be treated by IVIg.

***Figure 2 The grams of IVIg issued per 1000 head of population nationally***




Source: IDMS database of issues via Big Red and ABS estimated resident population

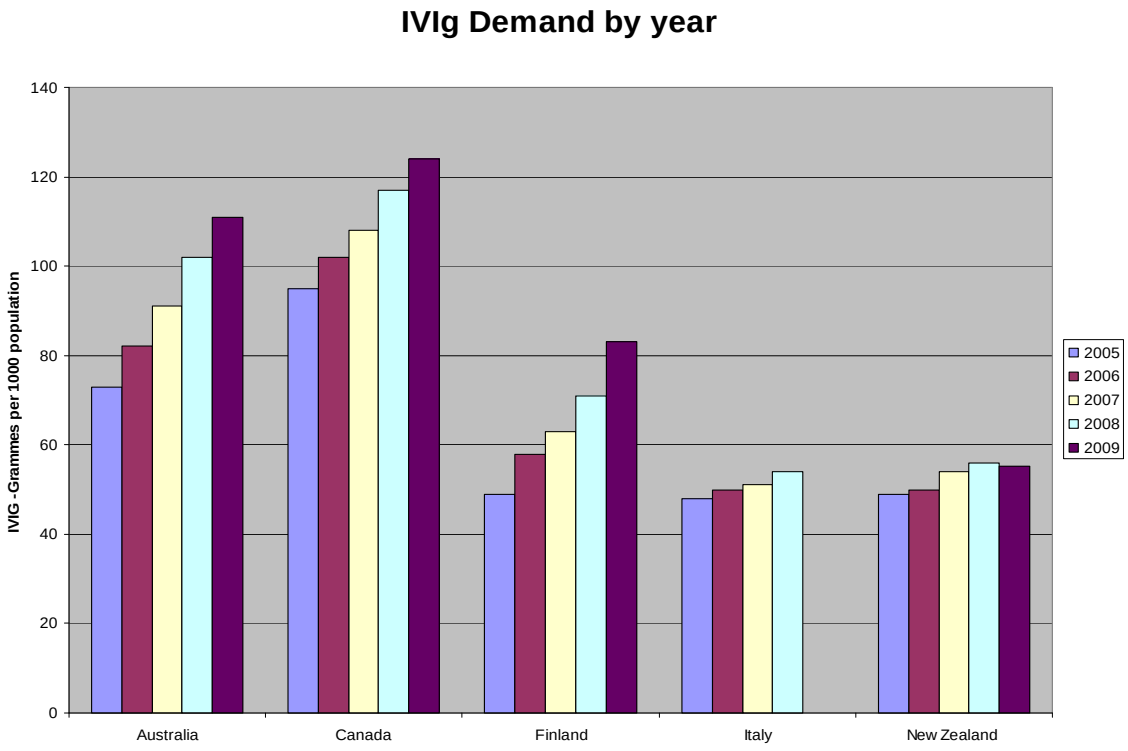
***Table 1 Issues of IVIg per 1000 head of population nationally and percentage change from previous year***

| Year of issue | 2003-04 | 2004-05 | 2005-06 | 2006-07 | 2007-08 | 2008-09 | 2009-10 |
|---|---|---|---|---|---|---|---|
| **Issue of IVIg (gm/1000 pop)** | 68.06 | 70.34 | 80.54 | 90.11 | 100.21 | 108.42 | 119.86 |
| **Increase by year** | | 3.3% | 14.5% | 11.9% | 11.2% | 8.2% | 10.5% |

Source: IDMS database of issues via Big Red

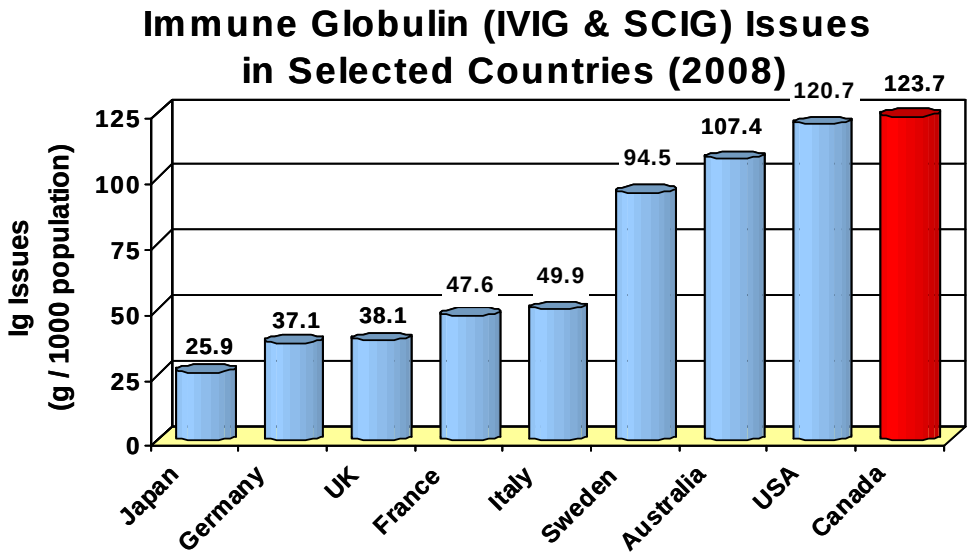
Australia's use for per capita continues however to be high in international terms as illustrated in Figure 3Figure 3 and Figure 4Figure 4, below which shows the use per capita compares only with Canada, the USA, Austria and Sweden.

***Figure 3 International IVIg use per 1000 population***




Source: Data prepared and presented at NPPSpa, 2010

***Figure 4 International IVIg use per capita***



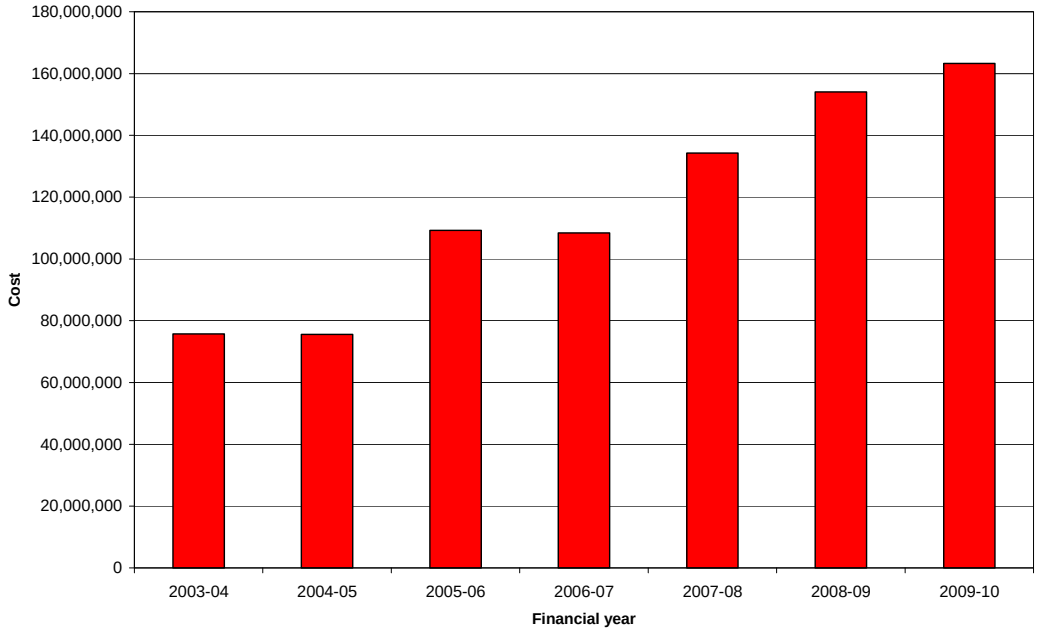

Data Sources: *The Plasma Fractions Market in the United States 2008* by The Marketing Research Bureau Inc., the National Blood Authority of Australia and Héma-Québec.

### *Questions for consideration*

- Why is Australia's use per 1000 population higher than many other countries ?
- Are patient outcomes in those countries that use less equivalent to those in Australia ?

Figure 5**Error! Not a valid bookmark self-reference.** shows the increased cost of the provision of IVIg under the national blood arrangements over time, associated with the increased growth. Total expenditure in 2009/10 was $163 million – an increase of $87½ million from 2003–04.

***Figure 5 Cost of IVIg from 2003-04 to 2009-10***




Source: IDMS database of purchases via Big Red
Note: These costs do not include the cost of plasma provided to the fractionator

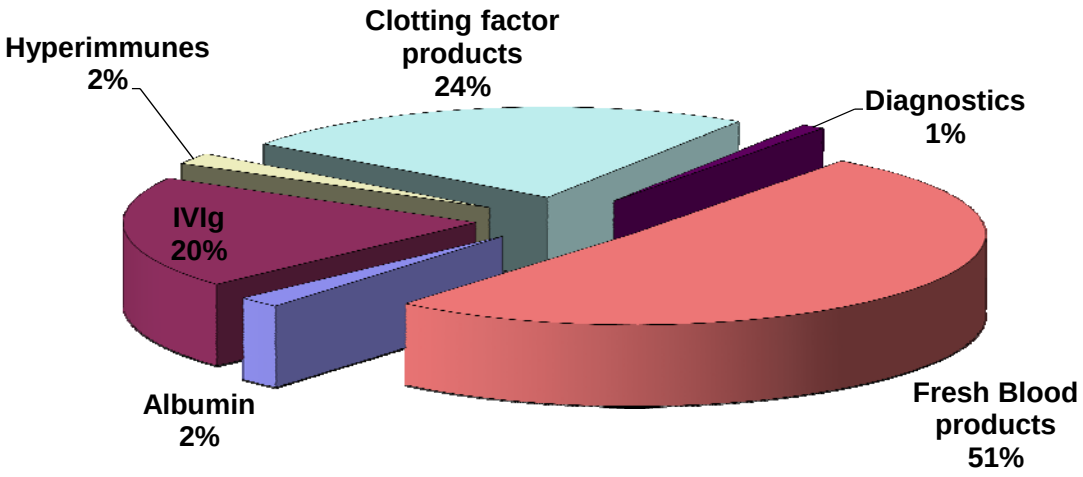
***Table 2 Cost of IVIg issued compared to National Supply Plan and Budget (NSP&B)and mid year review of plan $ million***

| | 2008-09 Actuals | 2009-10 NSP&B | 2009-10 Mid-year review | 2009-10 Actuals |
|---|---|---|---|---|
| **Domestic** | 107.1 | 136.3 | 128.3 | 114.4 |
| **Imported** | 47.0 | 45.1 | 49.6 | 48.8 |
| **Total invoiced cost** | 154.1 | 176.1 | 178.0 | 163.0 |

Source: IDMS database of purchases via Big Red and NBA National supply planning and budgeting processes.

Figure 6 is provided to illustrate the proportional cost of IVIg within the blood budget overall. IVIg makes up the third largest budget item within the overall blood and blood product budget and represents approximately 20 per cent of the total budget for blood and blood products.

***Figure 6 Share of total expense 2009-10***




Source: NBA Annual Report 2009-10

# 6. Plasma Costs

In 2009-10, the NBA provided $97.8 million to the Blood Service to collect 452,422 tonnes of plasma for fractionation. The majority (95 per cent) of this is used to produce Intragam P, with the balance (5 per cent) used for other hyperimmunes.

The fractionation process means that other products may also be produced from the plasma. Factor VIII is obtained from cryoprecipitate. Factor IX and Prothombin are next precipitated from residual plasma after the removal of the cryoprecipitate. The next group of products precipitated are the immunoglobulins (IVIg and hyperimmunes). Finally albumin is extracted from the residual plasma. This means that not all the above plasma collection costs should be allocated to IVIg.

We estimate that plasma collection costs allocated to IVIg are $81.7 million. These plasma costs are paid separately by jurisdictions based on their use of the domestic IVIg.

# 7. Criteria for use of IVIg

Since the introductions of *the Criteria*, IVIg data is often summarized by chapter. The chapters are described in the Criteria as:

- Chapter 5 being conditions for which IVIg has an established therapeutic role;
- Chapter 6 being conditions for which IVIg has an emerging therapeutic role;
- Chapter 7 being conditions for which IVIg is in exceptional circumstances only; and
- Chapter 8 being conditions for which IVIg use is not indicated.

Table 3 outlines the grams of IVIg issued per chapter. It should be noted that prior to 2008, data has been mapped to the current chapters and therefore may not be directly comparable. As would be expected, the highest issues are found for indications within chapter 5.

***Table 3 IVIg used showing use by chapters in the Criteria***

| Chapter | 2004-05 | 2005-06 | 2006-07 | 2007-08 | 2008-09 | 2009-10 |
|---|---|---|---|---|---|---|
| Chapter 5 | 1,005,594 | 1,172,728 | 1,363,847 | 1,625,246 | 1,990,586 | 2,212,914 |
| Chapter 6 | 402,416 | 400,682 | 368,458 | 417,939 | 345,176 | 371,832 |
| Chapter 7 | 17,820 | 19,518 | 33,970 | 45,130 | 47,275 | 61,924 |
| Chapter 8 | 13,110 | 16,259 | 15,351 | 8,888 | 0 | 2,550 |
| Not in current classification | 43,056 | 47,730 | 76,426 | 37,743 | 0 | 0 |

Source: IVIg Stars database maintained by the Blood Service.

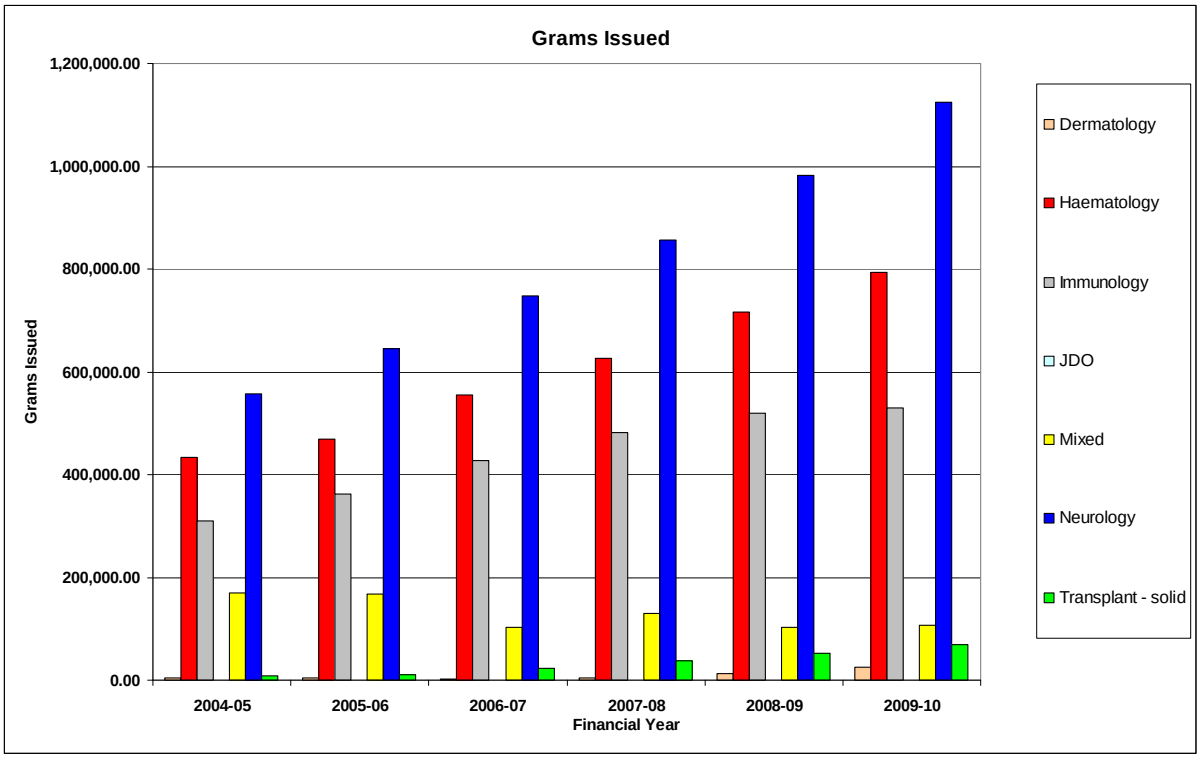
***Table 4 IVIg used showing use by chapters in the Criteria – per cent total***

| Chapter | 2004-05 | 2005-06 | 2006-07 | 2007-08 | 2008-09 | 2009-10 |
|---|---|---|---|---|---|---|
| Chapter 5 | 68% | 71% | 73% | 76% | 84% | 84% |
| Chapter 6 | 27% | 24% | 20% | 20% | 14% | 14% |
| Chapter 7 | 1% | 1% | 2% | 2% | 2% | 2% |
| Chapter 8 | 1% | 1% | 1% | 0% | 0% | 0% |
| Not in current classification | 3% | 3% | 4% | 2% | 0% | 0% |

Source: IVIg Stars database maintained by the Blood Service.

In line with previous years, the disciplines ordering IVIg and to which it is issued most commonly continued to be neurology, haematology and immunology (Figure 7). There was a small percentage increase in issue for neurology and haematology, whilst issues to immunology were flat. This should be taken with some caution however, as issues to the category of "mixed" discipline may represent any combination of the named disciplines. The numbers are presented in Table 5.

***Figure 7*** **IVIg by discipline over time**




Source: IVIg Stars database maintained by the Blood Service.
Note: Mixed indicates where a treatment has commenced in one discipline before being re categorised as a further discipline.

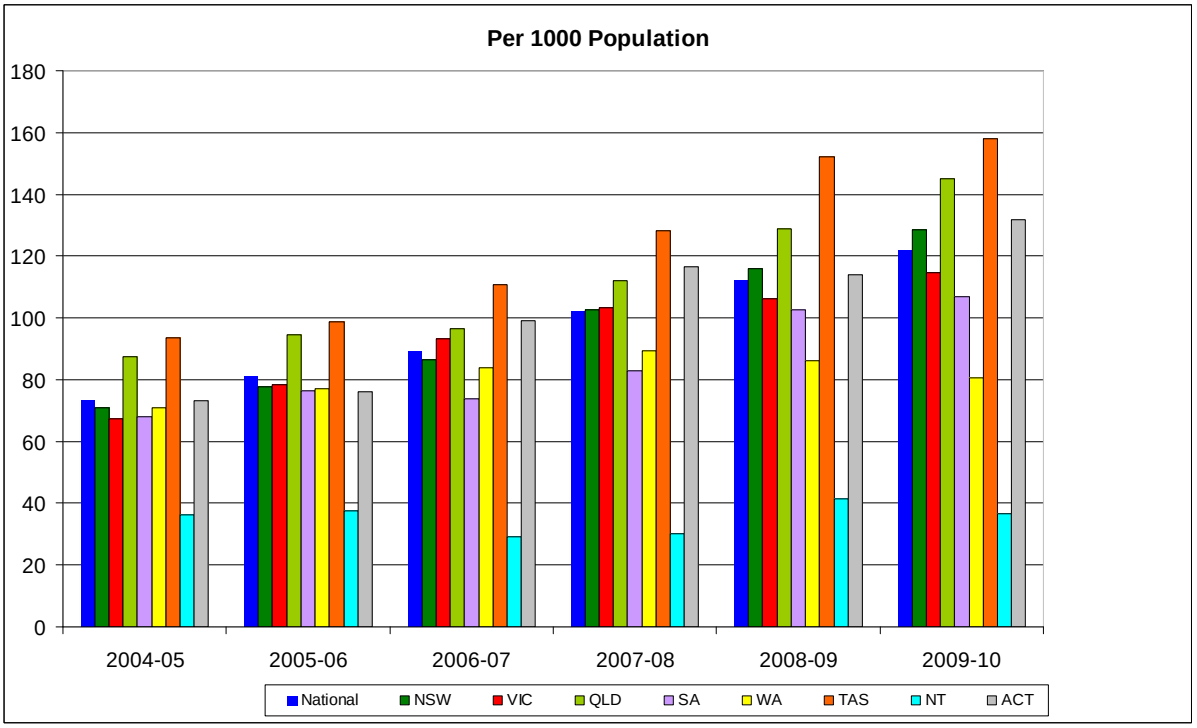
***Table 5*** ***Grams issued by discipline by year***

| Disease Category | 2004-05 | 2005-06 | 2006-07 | 2007-08 | 2008-09 | 2009-10 |
|---|---|---|---|---|---|---|
| Dermatology | 4,857 | 3,933 | 2,909 | 3,774 | 13,083 | 24,943 |
| Haematology | 434,237 | 469,082 | 554,711 | 626,294 | 716,767 | 794,098 |
| Immunology | 308,999 | 361,821 | 426,837 | 481,401 | 520,264 | 529,132 |
| DO | 0 | 0 | 0 | 280 | 0 | 243 |
| Mixed | 168,898 | 166,959 | 101,698 | 129,079 | 102,937 | 106,884 |
| Neurology | 556,974 | 644,329 | 748,109 | 855,874 | 981,372 | 1,124,604 |

Source: IVIg Stars database maintained by the Blood Service.

National and by jurisdiction IVIg issues per 1000 for the last three years are presented in Figure 8. Tasmania and the ACT continue to have rates which are well above national issue, whilst Western Australia and the Northern Territory continue to be below the national average. It should be noted that, to some extent, findings related to the smaller population jurisdictions must be viewed with some caution. WA and Victoria have remained reasonable stable in terms of the issues per 1000 population. With the exception of the NT, all other jurisdictions have seen a continued strong increase in the issues per 1000 population.

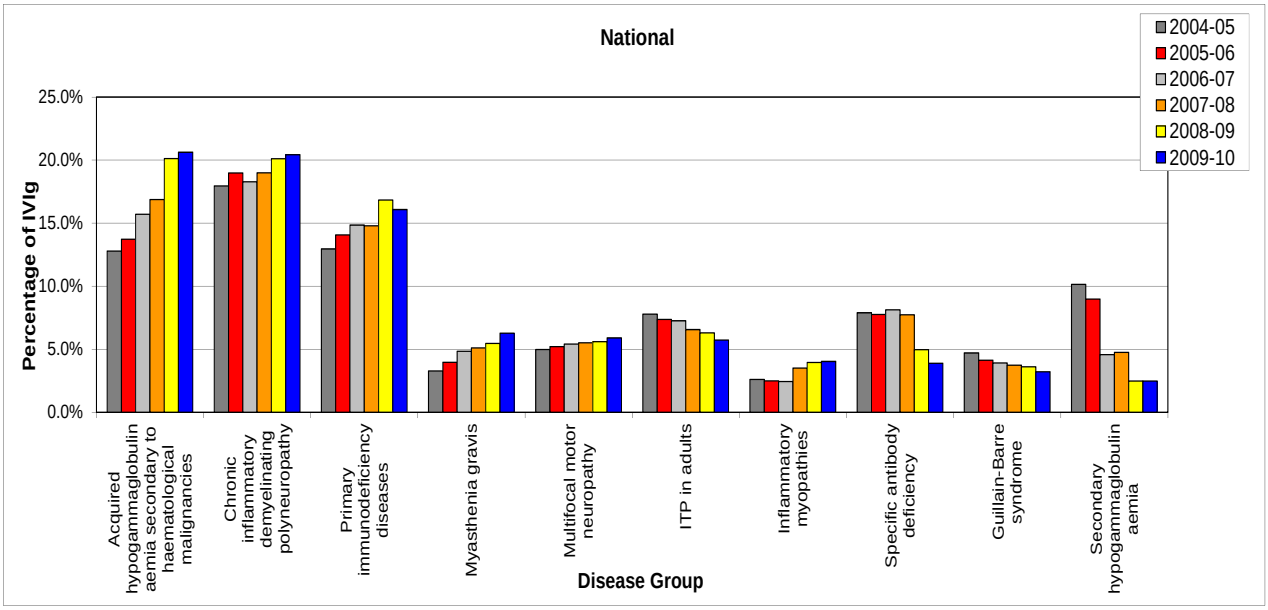
***Figure 8 IVIg issues by state by head of 1000 population over time***




Source: NBA IDMS issues data.

The largest group of primary diagnoses for which IVIg was issued has changed over time and is presented in Figure 9. Acquired hypogammaglobulinaemia secondary to haematological malignancies is the primary diagnoses to which the greatest percentage of IVIg was issued in 2009-10 (approx. 21 per cent) closely followed by CIDP (approx. 20 per cent). Since the implementation of the Criteria, IgG Subclass presents as a condition for which approximately 2.5 per cent IVIg is issued.

***Figure 9 Primary diagnosis to which the highest percentages of IVIg was issued nationally***




Source: IVIg Stars database maintained by the Blood Service.

***Questions for consideration***

- What impact do the management arrangements in each state have on the use per head ?
- Are there known geographical factors that make particular jurisdictions more attractive for patients with specific conditions (to the extent that it distorts the per-cent of these conditions per 1000 population) nationally, and if so, are they high cost patients and if so should there be a form of high cost patient pool for IVIg?

# 8. 2009-10 in review

The following sections in the report provides more detailed information on IVIg demand and issues for 2009-10.

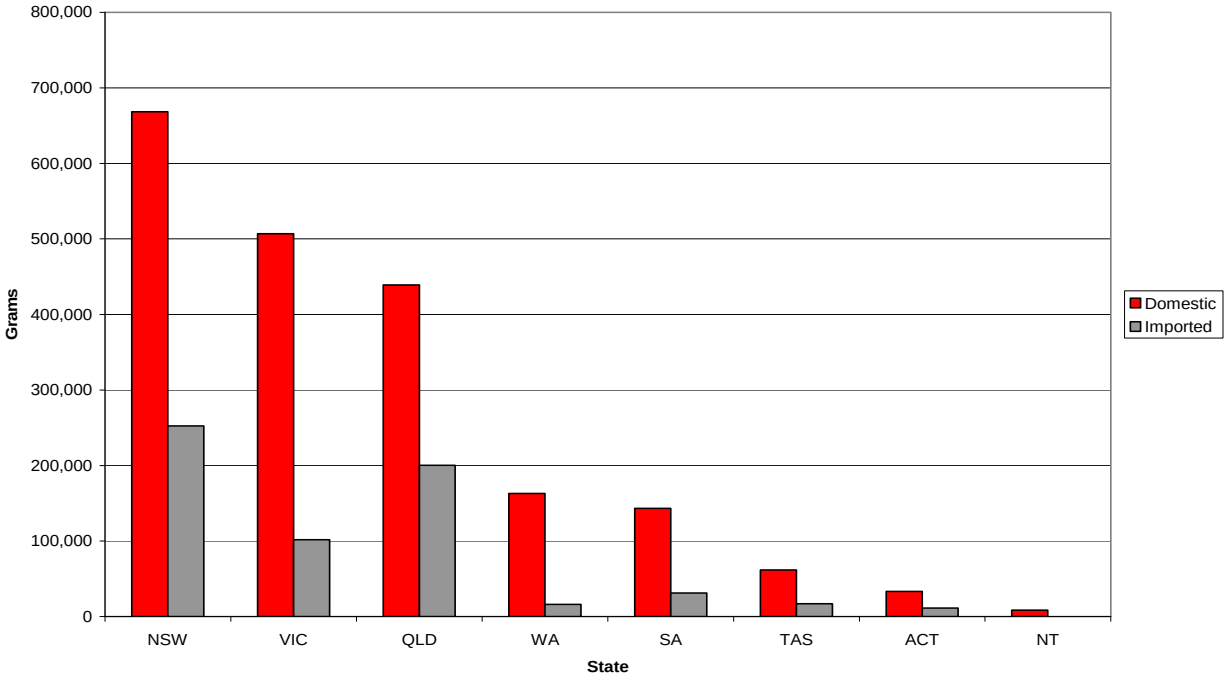
## *8.1. Summary information*

In 2009-10, 2,655,184 gms (total) IVIg was issued representing a cost of $163.3 million nationally. 76 per cent of domestic IVIg and 24 per cent of imported IVIg was issued equating to 2,024,422 gms of domestic IVIg and 630,761 gms of imported. Excluding IVIg issued under DO, a total of 9,840 patients were issued IVIg nationally and there were 77,212 patient episodes.

## 8.2. Total Issues and $

Table 6 show the total grams of IVIg issued in 2009-10 nationally and by jurisdiction, while Figure 10 depicts the jurisdictional figures in a graphical form. Nationally, the total amount was 2,655,184 gms with issues increasing with population size of the jurisdiction, as expected. These figures are total IVIg issued for the year and includes that issued by Blood Service, DO and NexGen trials. The amount captured in STARS is presented in Table 7.

***Figure 10 Total gms IVIg issued by jurisdiction 2009-10***




Source: IDMS database of issues via Big Red.

***Table 6 Grams IVIg issued by state and source 2003-04 to 2009-10***

| | | NSW | VIC | QLD | WA | SA | TAS | ACT | NT |
|---|---|---|---|---|---|---|---|---|---|
| **2003-04** | Domestic | 410,505 | 318,762 | 306,639 | 125,094 | 110,031 | 40,353 | 23,895 | 6,321 |
| | Imported | 0 | 22,200 | 3,000 | 144 | 2,856 | 0 | 0 | 0 |
| **2004-05** | Domestic | 420,858 | 326,130 | 284,043 | 148,200 | 95,403 | 46,065 | 24,615 | 7,806 |
| | Imported | 41,376 | 13,860 | 19,992 | 144 | 5,922 | 0 | 0 | 0 |
| **2005-06** | Domestic | 452,565 | 361,665 | 219,633 | 152,127 | 109,515 | 33,837 | 21,774 | 8,004 |
| | Imported | 76,368 | 52,097 | 134,475 | 7,765 | 15,300 | 13,608 | 8,165 | 0 |
| **2006-07** | Domestic | 493,172 | 407,244 | 337,301 | 155,821 | 92,958 | 50,583 | 26,470 | 6,732 |
| | Imported | 103,270 | 88,398 | 79,393 | 20,577 | 18,375 | 11,065 | 7,170 | 0 |
| **2007-08** | Domestic | 599,126 | 423,170 | 400,144 | 148,986 | 108,596 | 52,755 | 27,393 | 6,825 |
| | Imported | 105,633 | 111,010 | 85,055 | 38,445 | 18,416 | 11,740 | 16,875 | 0 |
| **2008-09** | Domestic | 562,320 | 417,574 | 383,865 | 143,628 | 128,511 | 53,745 | 22,841 | 10,503 |
| | Imported | 249,905 | 131,228 | 171,367 | 42,895 | 27,604 | 19,965 | 14,200 | 0 |
| **2009-10** | Domestic | 668,526 | 507,038 | 439,089 | 162,963 | 143,285 | 61,686 | 33,225 | 8,610 |
| | Imported | 252,416 | 101,930 | 200,264 | 16,248 | 31,244 | 17,110 | 11,550 | 0 |

Source: IDMS database of issues via Big Red.

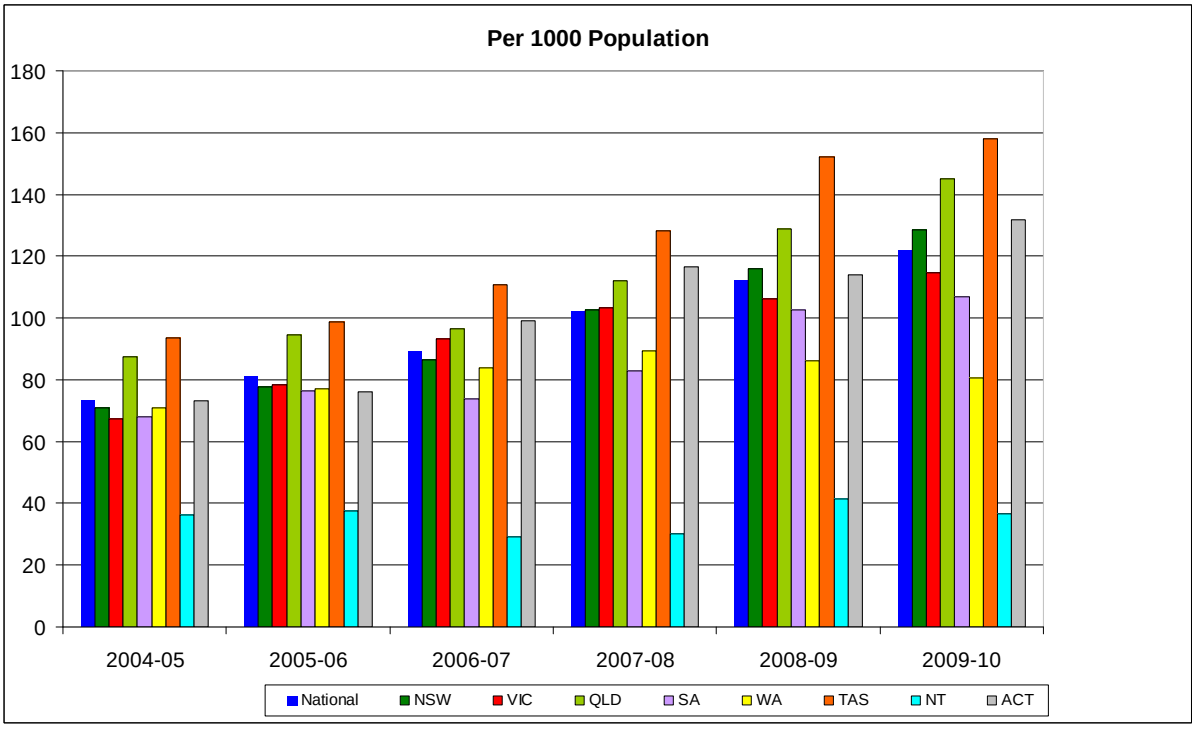
***Table 7 Grams IVIg issued as recorded in STARS for 2009-10***

| State | Kilograms issued | Proportion of total issues | Proportion of Australian population | Grams per 1000 population |
|---|---|---|---|---|
| **NSW** | 909 | 34.3% | 32.4% | 125.54 |
| **QLD** | 636 | 24.0% | 24.8% | 114.59 |
| **VIC** | 620 | 23.4% | 20.2% | 137.19 |
| **WA** | 179 | 6.8% | 10.3% | 78.01 |
| **SA** | 173 | 6.5% | 7.4% | 105.03 |
| **TAS** | 79 | 3.0% | 2.3% | 156.15 |
| **ACT** | 46 | 1.7% | 1.6% | 128.53 |
| **NT** | 8 | 0.3% | 1.0% | 35.53 |
| **Total** | 2,649 | 100.0% | 100.0% | 118.58 |

Source: IVIg Stars database maintained by the Blood Service. ABS population statistics.

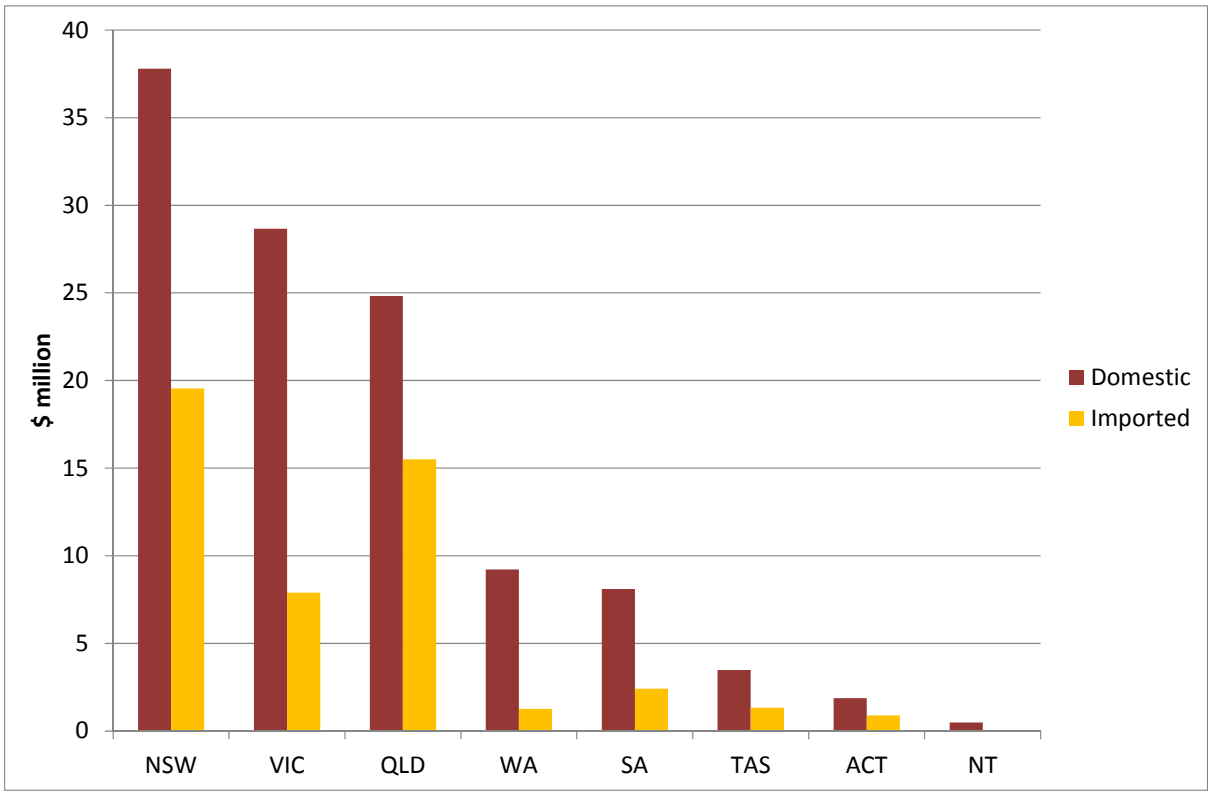
The total grams of IVIg issued per 1000 head of population is 118.6 gms nationally. Figure 11 presents this information by jurisdiction. As can be seen New South Wales, Queensland, Tasmania and the Australian Capital Territory received issues at a greater than national trend. Clearly, different patient populations within the jurisdictions will impact these figures significantly, however, it remains unclear as to what is causing the greater rate, particularly in Tasmania and the ACT (although, the smaller patient numbers will mean that specific patient needs will strongly impact these figures). ACT may also be affected by cross border issues.

***Figure 11 Total gms IVIg issued per 1000 population by jurisdiction by year***




Source: IVIg Stars database maintained by the Blood Service.

***Figure 12 2009-10 year costs of IVIg by jurisdiction***




Source: IDMS database of purchases via Big Red

***Table 8 Annual growth from previous year –Total issues of IVIg by jurisdiction between 2007-08 to 2009-10***

| | NSW | VIC | QLD | WA | SA | TAS | ACT | NT | Total |
|---|---|---|---|---|---|---|---|---|---|
| 2007-08 | 18.2% | 7.8% | 16.4% | 6.3% | 14.1% | 4.6% | 31.6% | 1.4% | 13.5% |
| 2008-09 | 15.2% | 2.7% | 14.4% | -0.5% | 22.9% | 14.3% | -16.3% | 53.9% | 10.5% |
| 2009-10 | 13.4% | 11.0% | 15.2% | -3.9% | 11.8% | 6.9% | 20.9% | -18.0% | 11.6% |

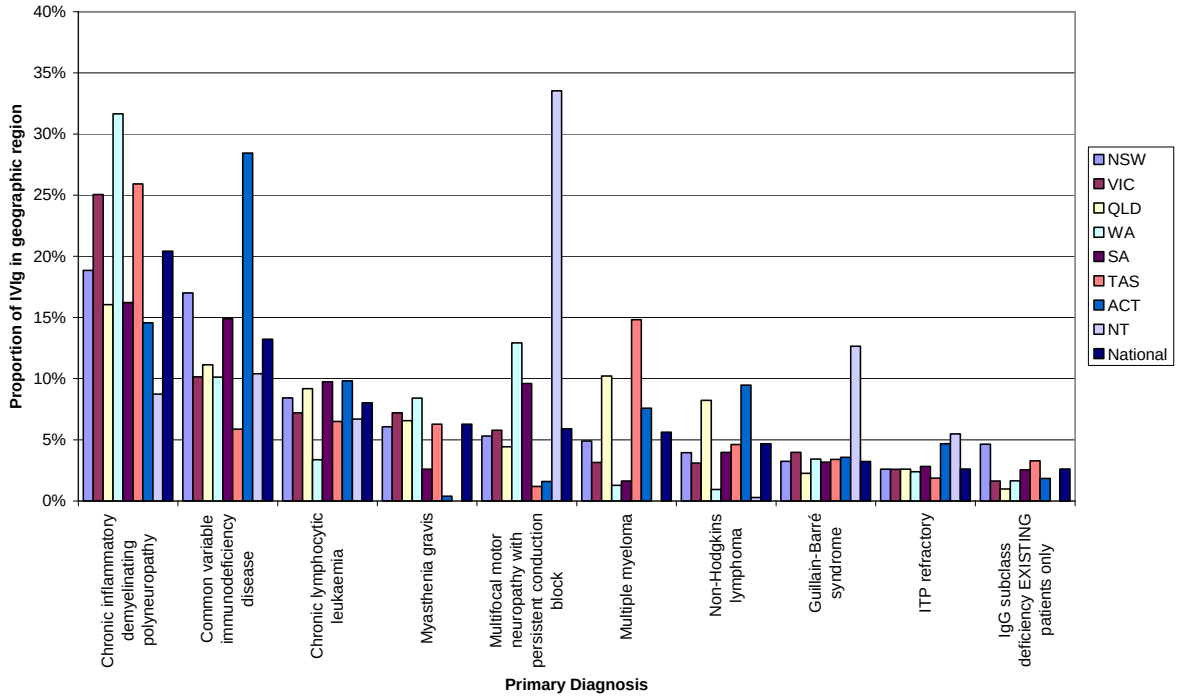
Source: IDMS database of issues via Big Red.

These variable growth rates across jurisdictions have generated an interest in better understanding the overall management arrangements for IVIg in each state. These were documented by the IVIG Criteria Review Group during 2009 and the information has been used to inform an analysis sought by the management committees of options for managing overall growth.

## 8.3. Grams Issued Nationally by Top 10 Primary Diagnosis

The top 10 primary diagnosis conditions nationally and by jurisdiction for the four quarters in 2009-10 are highlighted in Figure 13. There are some differences in the top 10 diagnoses between jurisdictions and it is accepted that there are other ways of presenting this information. For example, it is understood that both Tasmania and the Northern Territory are jurisdictions with very small patient numbers but it is interesting to note that specific patients can impact the jurisdictional proportion of IVIg (e.g. in inclusion body myositis). Nationally, CIDP continues to be the indication for which the greatest proportion of IVIg is issued.

***Figure 13 Top 10 diagnoses proportion of IVIg by jurisdiction***




Source: IVIg Stars database maintained by the Blood Service.

## 8.4. Grams/1000 population by Jurisdiction

The grams per 1000 population for Q1 to Q4 for each indication varies considerable between jurisdictions and complete data for each jurisdiction can be found at Appendix A. Some of the more notable differences in average dose per patient by indication are shown in Table 9.

***Table 9 Major differences between grams of IVIg issued per 1000 head of population by indication and by jurisdiction***

| | NSW | VIC | QLD | WA | SA | TAS | NT | ACT | Aust |
|---|---|---|---|---|---|---|---|---|---|
| **Chapter 5** | | | | | | | | | |
| Chronic inflammatory demyelinating polyneuropathy | 20.63 | 26.59 | 19.86 | 25.52 | 16.97 | 46.35 | 3.28 | 18.02 | 22.18 |
| Common variable immunodeficiency disease | 20.74 | 10.77 | 15.01 | 8.87 | 14.35 | 6.85 | 2.66 | 32.3 | 14.87 |
| Guillain-Barré syndrome | 4.15 | 4.31 | 4.07 | 3.21 | 3.32 | 7.42 | 1.24 | 2.94 | 3.97 |
| Inclusion body myositis | 1.23 | 0.91 | 1.27 | 0.5 | 0.14 | 5.62 | 0 | 0.42 | 1.06 |
| ITP in Specific circumstances (surgery, corticosteroids contraindicated, chronic ITP) | 2.64 | 1.37 | 1.9 | 0.7 | 4.43 | 1.6 | 13.28 | 1.39 | 2.14 |
| Multifocal motor neuropathy with persistent conduction block | 5.69 | 5.69 | 5.58 | 9.89 | 9.58 | 2.69 | 11.43 | 0 | 6.17 |
| Multiple myeloma | 5.61 | 3.43 | 13.91 | 0.76 | 1.77 | 15.43 | 0.55 | 7.54 | 6.05 |
| Myasthenia gravis | 6.23 | 5.77 | 7 | 7.13 | 3.28 | 11.96 | 0 | 0.64 | 6.02 |
| **Subtotal** | **100.29** | **86.94** | **104.5** | **69.22** | **84.79** | **127.45** | **39.88** | **100.68** | **91.98** |
| **Chapter 6** | | | | | | | | | |
| IgG subclass deficiency EXISTING patients only | 4.9 | 1.65 | 1.42 | 2.16 | 2.76 | 3.84 | 0 | 2.06 | 2.79 |
| Secondary hypogammaglobulinaemia (excludes haem malignancies) | 1.56 | 1.58 | 7.01 | 2.07 | 0.7 | 8.25 | 0 | 1.39 | 2.73 |
| **Subtotal** | **13.76** | **16.63** | **21.91** | **14.26** | **15.25** | **19.11** | **1.58** | **11.02** | **15.95** |

Source: IVIg Stars database maintained by the Blood Service.

Understanding the differences in the per population issue between jurisdiction for the more common indications would be beneficial. For example:

- CIDP – Whilst only a small patient population state, Tasmania was more than twice the national trend for this indication and the larger population jurisdictions were relatively close to the national trend
- CVID – NSW issued far more than the national trend and more than double most of the other jurisdictions
- Guillain-Barré syndrome – As an acute condition, it would be useful to more fully understand why Tasmania issued more than double the per 1000 population amount of the other jurisdictions
- Inclusion body myositis – again, it would be beneficial to understand why the demand is significantly greater in Tasmania over the other jurisdictions
- Multifocal motor neuropathy with persistent conduction block – whilst the three larger population jurisdictions have very similar issues, the other jurisdictions vary considerably and are much higher than those states

It is recognised that many factors will influence the figures in Table 9 and these figures are simply intended to generate thought and discussion between the jurisdictions and the NBA.

## *8.5. Patient Counts*

Excluding IVIg issued under DO, a total of 9,840 patients were issued IVIg nationally over 2009-10 and there were 77,212 patient episodes. Patient numbers by quarter are shown in Table 10. Note these are numbers of the unique patients receiving IVIg in the quarter. However, a particular patient may appear in a number of quarters.

***Table 10 Number of unique patients for whom IVIg was issued by jurisdiction by Quarter***

| | Quarter ending | NSW | VIC | QLD | SA | WA | TAS | NT | ACT | TOTAL |
|---|---|---|---|---|---|---|---|---|---|---|
| 2008-09 | Sep | 2216 | 1296 | 1448 | 331 | 402 | 145 | 13 | 105 | 5956 |
| | Dec | 2255 | 1327 | 1466 | 364 | 399 | 151 | 19 | 105 | 6086 |
| | Mar | 2261 | 1313 | 1470 | 362 | 357 | 170 | 17 | 99 | 6049 |
| | Jun | 2383 | 1356 | 1544 | 395 | 373 | 177 | 31 | 98 | 6357 |
| 2009-10 | Sep | 2447 | 1377 | 1652 | 400 | 385 | 184 | 24 | 112 | 6581 |
| | Dec | 2499 | 1388 | 1670 | 440 | 357 | 177 | 20 | 109 | 6660 |
| | Mar | 2556 | 1394 | 1682 | 395 | 354 | 183 | 15 | 102 | 6681 |
| | Jun | 2607 | 1460 | 1755 | 413 | 373 | 189 | 22 | 121 | 6940 |

Source: IVIg Stars database maintained by the Blood Service.

## *8.6. Average Doses by Jurisdiction*

The average dose issued is calculated by dividing the grams used by the treatment episodes or by the number of unique patients. The average dose issued for Q1 to Q4 of 2009-10 by jurisdiction varies across and between many indications and complete data for each jurisdiction can be found at Appendix B. Clearly, the average issue per 1000 head of population calculated for the jurisdictions with smaller populations should be viewed with caution owing to the small patient numbers.

Table 11Table 11 presents some of the more noteworthy differences. In general, such variance in average per patient issue from national average and between jurisdictions warrants further consideration. In particular, it would be informative to understand the reasons for the variation in issue for some of the more common indications such as CIDP, Multifocal motor neuropathy with persistent conduction block, Polymyositis, and Severe combined Immunodeficiency. For example, in Severe Combined Immunodeficiency, there is more than a two fold variation in issue per patient between even the large patient population jurisdictions.

***Table 11 Average grams IVIg issued to patient by indication and by jurisdiction 2009-10***

| Indication | Chapter | NSW | Vic | Qld | WA | SA | TAS | NT | ACT | National |
|---|---|---|---|---|---|---|---|---|---|---|
| Chronic inflammatory demyelinating polyneuropathy | 5 | 106.96 | 155.04 | 124.67 | 203.96 | 145.90 | 160.51 | 143.02 | 142.80 | 132.94 |
| Common variable immunodeficiency disease | 5 | 83.06 | 86.45 | 80.64 | 77.23 | 73.34 | 78.98 | 100.13 | 94.33 | 82.51 |
| Chronic lymphocytic leukaemia | 5 | 74.24 | 70.48 | 71.49 | 65.73 | 68.73 | 62.82 | 85.28 | 60.67 | 71.80 |
| Myasthenia gravis | 5 | 108.19 | 162.60 | 127.69 | 175.19 | 97.35 | 130.88 | 90.00 | | 129.55 |
| Multifocal motor neuropathy with persistent conduction block | 5 | 113.01 | 165.50 | 135.99 | 231.41 | 251.11 | 104.67 | 122.83 | 273.60 | 150.13 |
| Multiple myeloma | 5 | 65.21 | 64.79 | 74.20 | 56.93 | 53.34 | 78.89 | 94.57 | | 69.84 |
| IgG subclass deficiency EXISTING patients only | 6 | 76.97 | 80.52 | 55.14 | 77.53 | 82.87 | 92.68 | 106.13 | | 75.86 |
| Non-Hodgkins lymphoma | 5 | 70.59 | 74.53 | 72.60 | 69.88 | 65.37 | 76.06 | 84.00 | 24.00 | 72.23 |
| Guillain-Barré syndrome | 5 | 165.29 | 149.95 | 155.64 | 161.50 | 161.66 | 158.91 | 182.67 | 147.43 | 158.34 |
| Polymyositis | 5 | 95.05 | 147.42 | 122.05 | 75.00 | 193.12 | 96.64 | 113.50 | 107.00 | 116.99 |
| Other relevant haematological malignancies | 5 | 61.16 | 75.66 | 66.15 | 49.62 | 48.44 | 77.68 | 72.27 | | 65.87 |
| ITP Refractory | 5 | 144.16 | 108.54 | 116.54 | 87.22 | 151.94 | 87.00 | 239.44 | 149.00 | 123.20 |
| Other primary immunodeficiency | 5 | 71.14 | 83.77 | 72.88 | 75.36 | 95.39 | 72.00 | 18.00 | 43.50 | 75.56 |
| ITP in specific circumstances (surgery, corticosteroids contraindicated, chronic ITP) | 5 | 124.53 | 99.73 | 146.22 | 73.36 | 132.36 | 85.78 | 156.00 | | 121.31 |
| Secondary hypogammaglobulinaemia (excludes haem malignancies) | 6 | 56.58 | 64.46 | 71.20 | 56.96 | 51.15 | 99.13 | 87.43 | 21.00 | 65.58 |
| Specific antibody deficiency | 6 | 62.93 | 75.13 | 57.28 | 68.80 | 70.30 | | 74.91 | 24.60 | 64.97 |
| Inclusion body myositis | 5 | 102.71 | 150.05 | 186.88 | | 107.88 | 145.64 | | | 131.76 |
| ITP with life-threatening haemorrhage | 5 | 137.42 | 134.50 | 113.60 | 110.00 | 128.50 | 207.50 | 288.00 | 84.00 | 135.75 |
| Dermatomyositis | 5 | 88.86 | 167.05 | 101.83 | 147.38 | 120.00 | 225.00 | 159.75 | | 119.93 |
| Chronic inflammatory demyelinating polyneuropathy | 6 | 106.96 | 155.04 | 124.67 | 203.96 | 145.90 | 160.51 | 143.02 | 142.80 | 132.94 |

Source: IVIg Stars database maintained by the Blood Service.

## *8.7. Issued and reported as 'Criteria Not Met'*

The Blood Service were asked to indicate circumstances where IVIg was issued to patients who did not meet the criteria in Chapters 5, 6 or 7 of *the Criteria*. This may happen in emergency situations prior to diagnosis or in situations where the Clarification Process has not published a 'resolution' and the Jurisdictional Blood Committee (JBC) has decided to allow continued access to IVIg until such time as a resolution is published.

Table 12 lists the requests that did not meet the criteria but for which product was issued by Blood Service. A total of 69,120 grams were issued for a total of 880 unique patients, representing 2,307 treatment episodes.

***Table 12 Issues of IVIg under the National Blood Arrangements which did not meet the Criteria***

| | 2008-09 | | | 2009-10 | | |
|---|---|---|---|---|---|---|
| | **No of Patient IDs** | **No of Treatment Episodes** | **Total Grams issued** | **No of Patient IDs** | **No of Treatment Episodes** | **Total Grams issued** |
| Q Crit Not Met | 852 | 2,325 | 69,094 | 60 | 139 | 4,569 |
| DO Advised | | | | 13 | 0 | 0 |
| DO Issued | 2 | 1 | 140 | 7 | 9 | 378 |
| Indefinite | 1 | 2 | 48 | | | |
| Pending | 28 | 94 | 2,603 | 9 | 17 | 474 |
| Single | 1 | 1 | 27 | 1 | 13 | 507 |
| Not approved | 39 | 0 | 0 | 61 | 0 | 0 |
| **Total** | **923** | **2,423** | **71,912** | **151** | **178** | **5,928** |
| **Proportion of total issues** | | | **3.0%** | | | **0.2%** |
| **Total cost** | | | **$5.2 mil** | | | **$0.4 mil** |

Source: IVIg Stars database maintained by the Blood Service.

The application of the Criteria means that the number of patients receiving IVIg who do not meet the Criteria has fallen from 852 on 2008-09 to 60 patients in 2009-10. Some further investigation of why any who did not satisfy the Criteria received IVIg under the arrangements. Clearly, the Blood Service, as the gate-keeper in most jurisdictions, feels a responsibility to issue IVIg in emergency circumstances and this is not questioned.

## 8.8. Reconciliation

A reconciliation of STARS quarterly data with Blood Service clinical issue reports that the NBA receives on a monthly basis indicates variances identified are, overall, small (Table 13). Nationally reconciliation indicated that nationally, Blood Service issues were within half a percent of the data recorded in STARS. In the Northern Territory, approximately 14 per cent more IVIg was issued than is recorded in STARS, whilst in South Australia and the ACT there were more issues recorded in STARS than actual issues in that time period (approximately 5 per cent and 4 per cent respectively). In some cases these differences can be explained by product being ordered and recorded in STARS the month prior to product actually being issued.

***Table 13 Reconciliation of STARS (STARS less NBA issues – grams) quarterly data with Blood Service monthly clinical issue reports by jurisdiction and Nationally***

| | 2004-05 | 2005-06 | 2006-07 | 2007-08 | 2008-09 | 2009-10 |
|---|---|---|---|---|---|---|
| NSW | 3.6% | -0.1% | -0.5% | 0.0% | -1.0% | -1.3% |
| VIC | -6.1% | -4.3% | -2.9% | 0.4% | 2.2% | 1.7% |
| QLD | 11.7% | 6.7% | -4.3% | -3.8% | -1.2% | -0.6% |
| SA | 0.6% | -5.4% | 4.6% | 3.3% | 5.1% | -1.0% |
| WA | -4.4% | -2.3% | -1.2% | -0.1% | -0.6% | 0.0% |
| TAS | -1.8% | 1.3% | -11.7% | -2.2% | 2.6% | 0.6% |
| NT | -6.4% | -4.0% | -7.9% | -5.5% | -13.7% | -5.2% |
| ACT | -3.7% | -17.0% | -1.1% | -9.2% | 4.5% | 3.0% |
| Total | 1.5% | -0.6% | -2.1% | -0.8% | 0.3% | -0.2% |

Source: NBA IDMS issues data and IVIg Stars database maintained by the Blood Service.
Note: The proportion the STARS data is in excess of the NBA issues data for the same period.

# 9. Demographics of IVIg patients

This section provides demographics information on IVIg patients based on the entries in the STARS database between September quarter 2008 and June quarter 2010. It is assumed that the Patient IDs are unique and sequential or increasing over time. Table 14 shows the basic count information for the patient IDs.

***Table 14 Basic numbers***

| | **Number** |
|---|---|
| Total unique patient Ids | 14856 |
| Total unique patient Ids with some weigh data | 9534 |
| Total unique patient Ids with an age | 10537 |
| Total unique patient Ids with a weight change | 829 |
| Total unique patient Ids with more than one state | 264 |
| Total unique patient Ids with two states | 247 |
| Total unique patient Ids with three states | 17 |
| Total unique patient Ids with more than one diagnosis | 1106 |
| Total unique patient Ids with two diagnoses | 1015 |
| Total unique patient Ids with three diagnoses | 87 |
| Total unique patient Ids with four diagnoses | 4 |
| Earliest estimated birth year | 1900 |
| Total unique patient Ids born 1920 or earlier | 111 |

Source: IVIg Stars database maintained by the Blood Service.

***Table 15 Recruitment to the database – number of Patient IDs added in quarter***

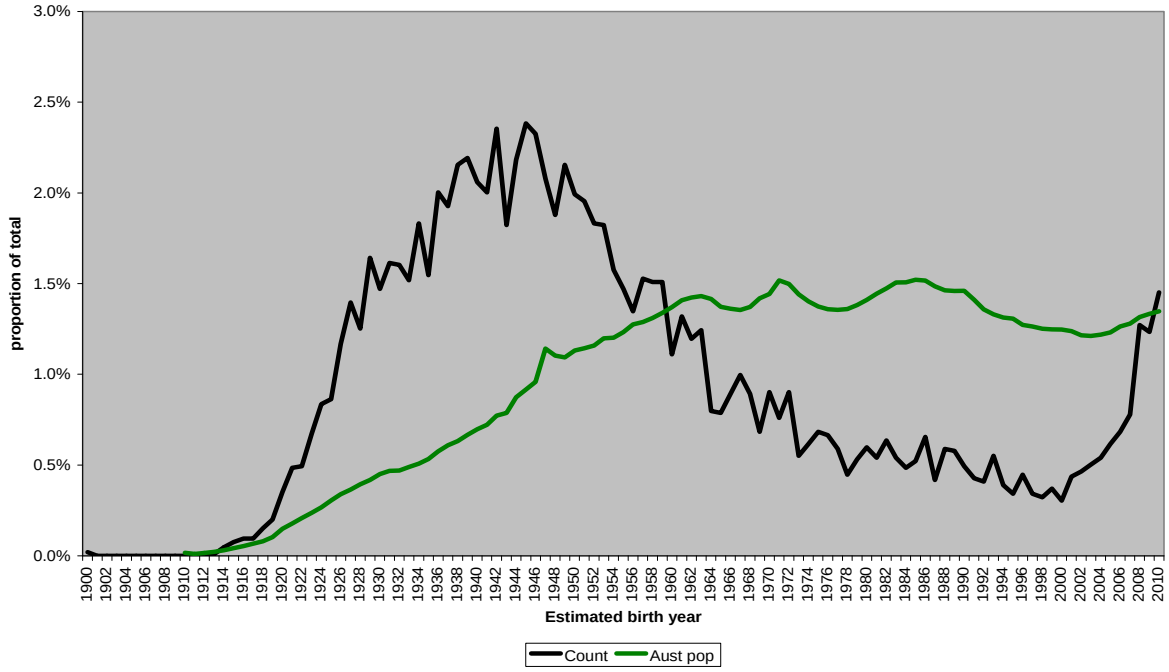
| Sep Q 08 | Dec Q 08 | Mar Q 09 | Jun Q 09 | Sep Q 09 | Dec Q 09 | Mar Q 10 | Jun Q 10 |
|---|---|---|---|---|---|---|---|
| 7068 | 1110 | 1045 | 1095 | 1386 | 1275 | 981 | 896 |

Source: IVIg Stars database maintained by the Blood Service.

Table 15 shows that the average number of new patients is around 1000 in each quarter. September quarter 2008 is a larger number because of the approximately 6000 existing patients who had their first IVIg prior to 2008-09 and received some in that quarter. Under that assumption that Patient IDs are almost sequential new recruits in a quarter will have a Patient ID greater than any patients in the previous quarter and less than any new patients in the next quarter.

As the age and weight data may be in every record of a particular patient ID we estimated the year of birth from when the age data existed and applied that to all of the patient's treatments. The distribution of estimated birth years is shown in Figure 14 where it is compared with the age distribution of the Australian Population from the ABS.

***Figure 14 Proportion of IVIg Patient IDs by estimated birth year***

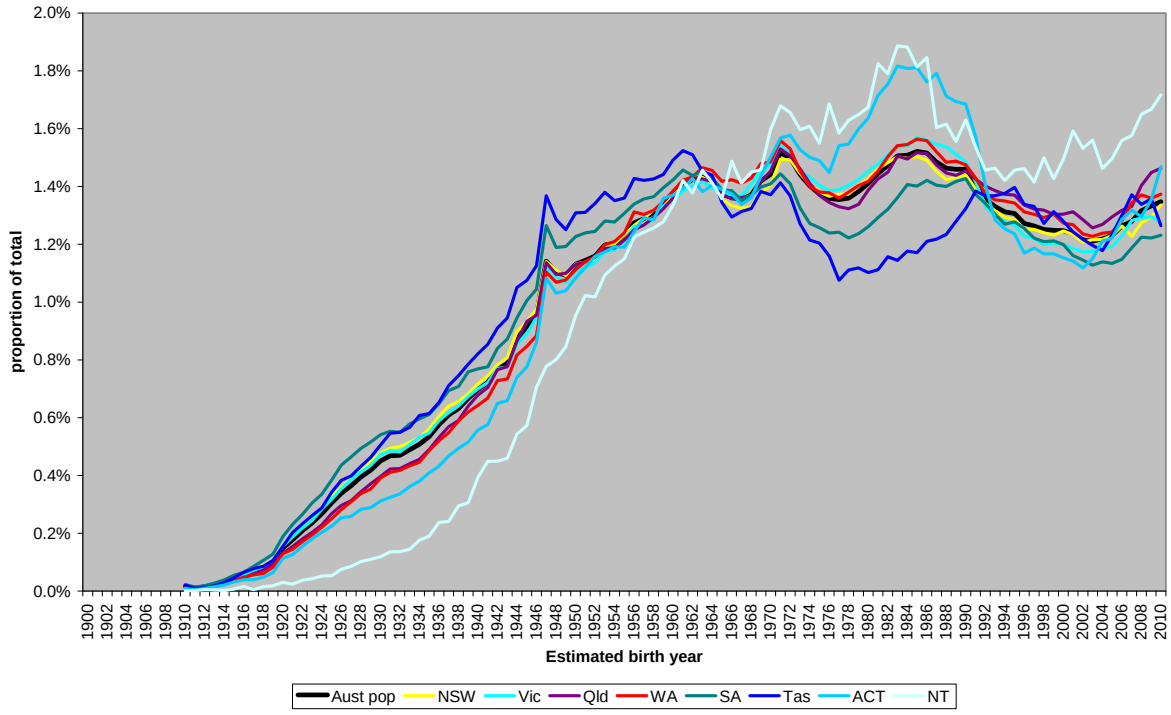



Source: IVIg Stars database maintained by the Blood Service.
ABS 3201.0 Population by Age and Sex, Australian States and Territories

Figure 14Figure 14 shows that there is a spike of use for the very young but the median birth year is 1950. This means half the IVIg patients are over 60. The median birth year for the Australian population is 1973 (i.e. age 37).

The age profiles of the different states vary as shown inFigure 15. The Northern Territory has a very young profile with a bulge in the early working age. The ACT also has a bulge in the working ages reflecting it being and education and administrative centre with many people migrating there for education and public service work opportunities. South Australia and Tasmania have more aged populations and seem lower proportions of working age people. This deficiency is more pronounced in Tasmania. Queensland and Western Australia have somewhat younger distribution than the average.

***Figure 15 Proportion of population 2010 by approximate birth year***




Source: ABS 3201.0 Population by Age and Sex, Australian States and Territories

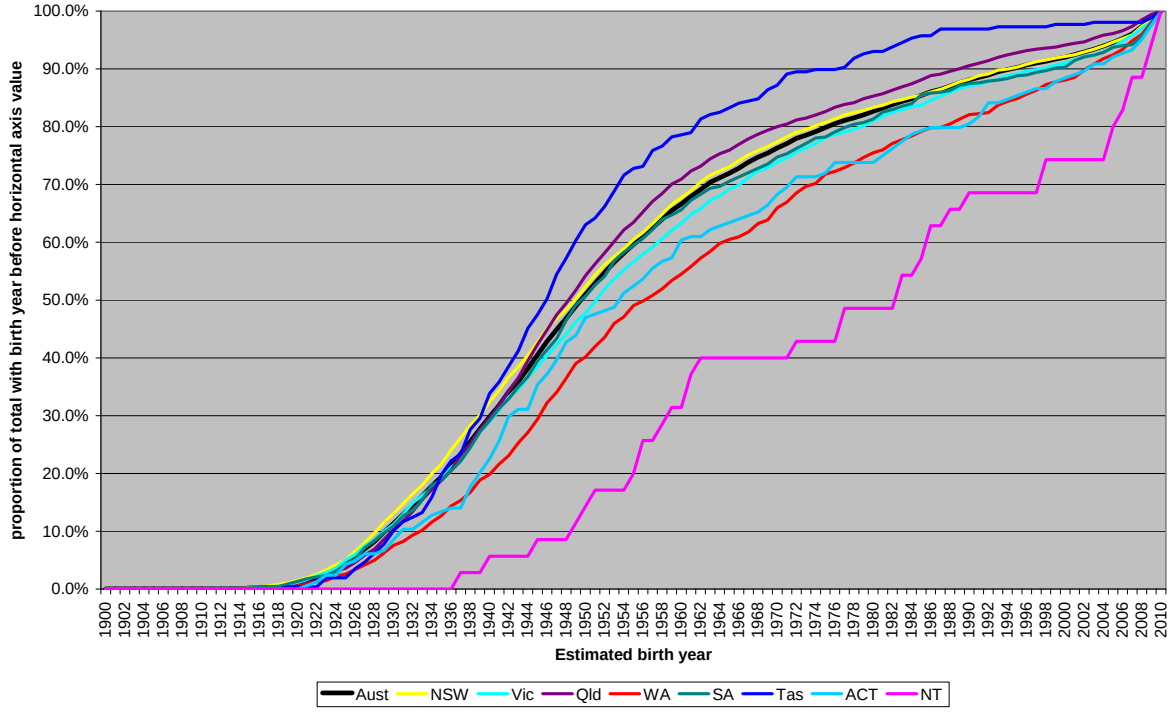
***Table 16 Median estimated year of birth for IVIg patients***

| Aust | NSW | Vic | Qld | WA | SA | Tas | ACT | NT |
|---|---|---|---|---|---|---|---|---|
| 1950 | 1949 | 1951 | 1948 | 1957 | 1950 | 1946 | 1954 | 1982 |

Source: IVIg Stars database maintained by the Blood Service.

From Table 16, Western Australia, ACT and Northern Territory have median estimated birth years significantly later and Tasmania is significantly earlier than the Australian median. This is consistent with the first three mentioned states having younger aged profiles and Tasmania having an older age profile. This is also demonstrated in Figure 16which shows the cumulative distribution of estimated birth years. States with lines to the left have generally older age profiles than states with lines to the right.

***Figure 16 Cumulative distribution of estimated birth year of IVIg patients by state***




Source: IVIg Stars database maintained by the Blood Service.

***Table 17 Median estimated year of birth for IVIg patients for the top 40 primary diagnoses by grams used***

| Primary Diagnosis | Total number of patients | No with age | % with age data | Median estimated year birth | Total grams for the two years |
|---|---|---|---|---|---|
| Chronic inflammatory demyelinating polyneuropathy | 1634 | 1351 | 83% | 1945.0 | 1,021,174 |
| Common variable immunodeficiency disease | 1312 | 1212 | 92% | 1957.0 | 672,269 |
| Chronic lymphocytic leukaemia | 1243 | 1007 | 81% | 1938.0 | 405,648 |
| Myasthenia gravis | 592 | 462 | 78% | 1948.0 | 296,600 |
| Multifocal motor neuropathy with persistent conduction block | 391 | 337 | 86% | 1952.0 | 289,918 |
| Multiple myeloma | 1032 | 775 | 75% | 1940.0 | 280,287 |
| Non-Hodgkins lymphoma | 735 | 606 | 82% | 1943.0 | 219,717 |
| Guillain-Barré syndrome | 1024 | 548 | 54% | 1956.0 | 171,349 |
| ITP refractory | 882 | 476 | 54% | 1948.0 | 146,847 |
| IgG subclass deficiency EXISTING patients only | 332 | 277 | 83% | 1949.0 | 129,709 |
| Secondary hypogammaglobulinaemia (excludes haem malignancies) | 568 | 424 | 75% | 1957.5 | 124,720 |
| Other relevant haematological malignancies | 619 | 434 | 70% | 1953.0 | 120,944 |
| Polymyositis | 228 | 181 | 79% | 1950.0 | 114,228 |
| ITP in specific circumstances (surgery, corticosteroids contraindicated, chronic ITP) | 674 | 390 | 58% | 1950.0 | 102,099 |
| Specific antibody deficiency | 590 | 486 | 82% | 1951.5 | 91,871 |
| Kidney transplantation post-transplant | 360 | 224 | 62% | 1962.5 | 89,700 |
| Other primary immunodeficiency | 265 | 214 | 81% | 1955.0 | 84,061 |
| HSCT (for prevention of GvHD in high risk Allogeneic HSCT). | 284 | 202 | 71% | 1960.0 | 75,930 |
| X linked agammaglobulinaemia | 122 | 113 | 93% | 1986.0 | 58487 |
| Inclusion body myositis | 97 | 72 | 74% | 1938.0 | 48,152 |
| Dermatomyositis | 83 | 57 | 69% | 1962.0 | 38,903 |
| Foeto-maternal /neonatal alloimmune thrombocytopenia (Antenatal) | 33 | 19 | 58% | 1976.0 | 32,570 |
| Stiff person syndrome | 31 | 25 | 81% | 1957.0 | 31,073 |
| ITP with life-threatening haemorrhage | 185 | 101 | 55% | 1945.0 | 27,992 |
| Autoimmune haemolytic anaemia | 190 | 113 | 59% | 1944.0 | 27,063 |
| ITP in pregnancy | 122 | 73 | 60% | 1979.0 | 21,606 |
| Kawasaki disease | 535 | 257 | 48% | 2006.0 | 20,962 |
| IgM para-proteinaemic neuropathy | 42 | 28 | 67% | 1932.0 | 17,873 |
| TSS - streptococcal | 118 | 60 | 51% | 1958.0 | 15,587 |
| Solid organ - lung | 83 | 60 | 72% | 1962.0 | 14,971 |
| Toxic epidermal necrolysis/Steven Johnson syndrome | 91 | 49 | 54% | 1967.0 | 13,016 |
| Kidney transplantation pre-transplant | 132 | 72 | 55% | 1959.5 | 12,853 |

| Primary Diagnosis | Total number of patients | No with age | % with age data | Median estimated year birth | Total grams for the two years |
|---|---|---|---|---|---|
| Epilepsy (rare childhood cases) | 26 | 19 | 73% | 1998.0 | 12,287 |
| ITP in children | 264 | 145 | 55% | 2004.0 | 12,051 |
| Acute disseminated encephalomyelitis | 57 | 35 | 61% | 1989.0 | 10,694 |
| Bullous pemphigoid | 11 | 9 | 82% | 1957.0 | 10,441 |
| Pemphigus vulgaris | 17 | 16 | 94% | 1955.0 | 9,939 |
| Paraneoplastic syndromes | 45 | 28 | 62% | 1954.0 | 9,904 |
| Susac syndrome | 9 | 8 | 89% | 1962.0 | 9,877 |
| Severe combined Immunodeficiency | 37 | 36 | 97% | 1961.0 | 9,380 |

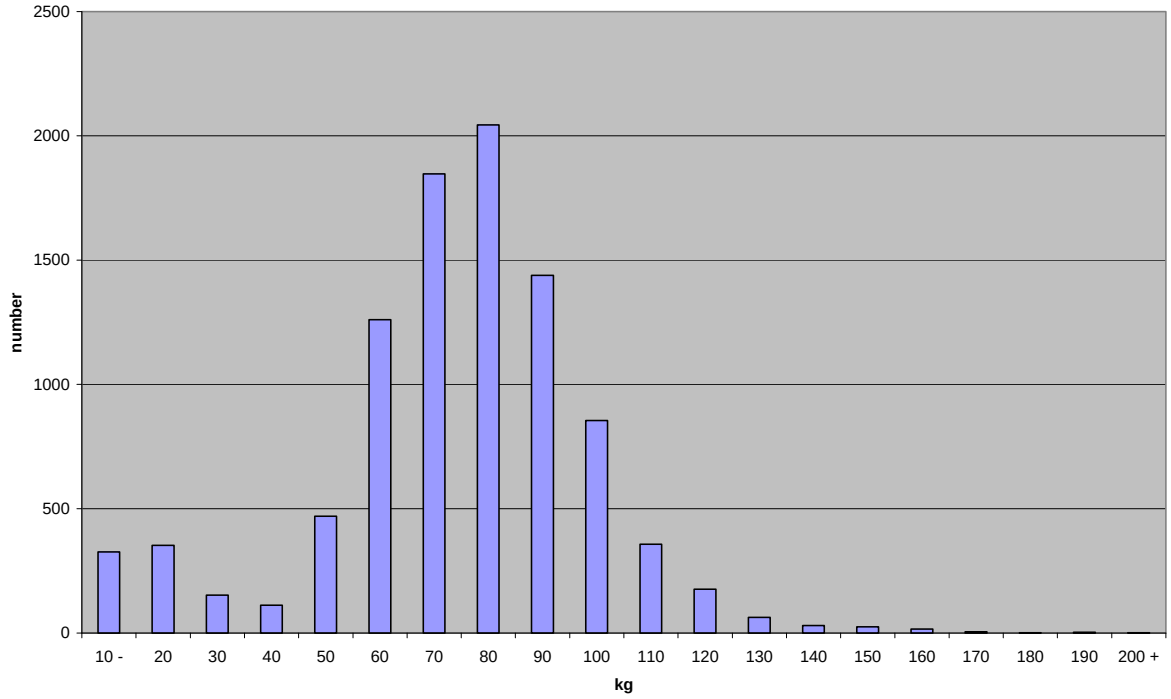
Source: IVIg Stars database maintained by the Blood Service.

In Table 17 we see that for a number of indications the proportion of patients with some age data is lower than others. The highlighted cells have a proportion less than or equal to 60 per cent. Kawasaki disease has the lowest proportion at 48 per cent.

### *Questions for further investigation*

- Given the ageing of the Australian population and the age profile of IVIg patients what will be the pressures on IVIg demand into the future?
- Will there be enough plasma donors to supply the future demand?
- Why do some diagnoses have proportionally less age data?
- Can patients with these conditions expect to have a standard life expectancy and if so what are the implications for demand over time from existing patients?

***Figure 17 Distribution of reported weight of IVIg patients***



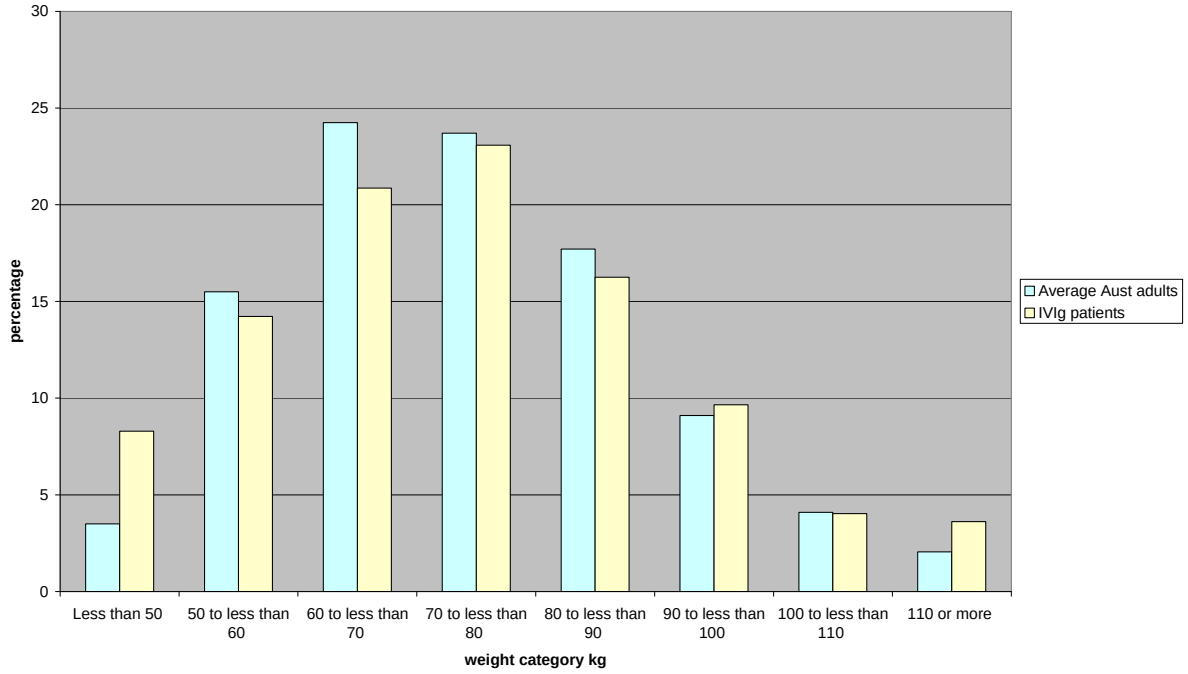

Source: IVIg Stars database maintained by the Blood Service.

The distribution shown in Figure 17 is affected by age and the relative weight of the patients. In Figure 18 we make a comparison with ABS survey data from 1995. As the ABS data is for adults only we did not include IVIg patients with weight 20kg or less in the distribution. The STARS data does not have gender so the comparison is crude. It appears that IVIg have slightly more obese people proportionally than the Australia population, although average weights would appear to be slightly lower than the general Australian population.

### *Questions for further investigation*

- Given many clinicians dose on weight, would it be cost effective to have a more comprehensive care model (as per pwbd's through the HTC's) to drive a healthy lifestyle commitment?

***Figure 18 The weight distribution of IVIg patients compared with adult Australia population***




Source: IVIg Stars database maintained by the Blood Service.
ABS 4359.0 - How Australians Measure Up, 1995: Average of male and female as no total average published.

## *9.1. New patients compared with existing patients selected diagnoses*

It is of interest whether the dosage received by new patients is different to the dosage for existing patients. Clinical practice is, in some cases, to give and initial loading dose and then continue with a maintenance dose. This loading dose may be achieved by an initial higher dose or initial more frequent doses.

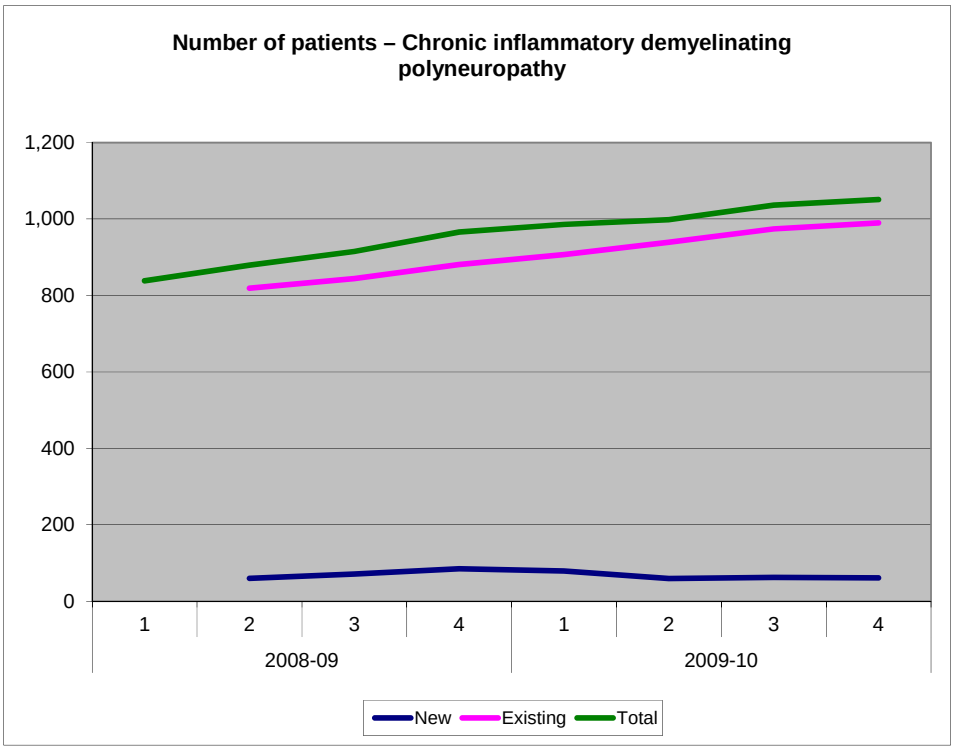
We have classified patients as new in a quarter if they appear for the first time in that quarter for a diagnosis. As the database starts in the first quarter of 2008-09 all patients in that quarter are classified as new.

The following analysis is for the five primary diagnoses that have the highest use of IVIg.

### 9.1.1. Chronic inflammatory demyelinating polyneuropathy (CIDP)

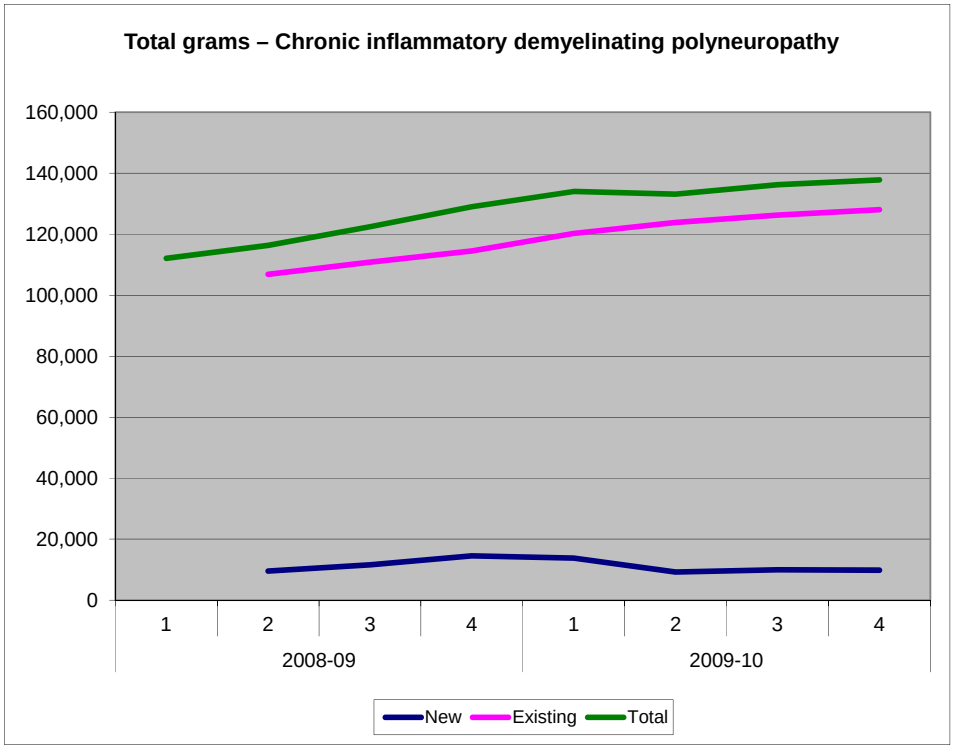
The following series of charts (Figure 19, Figure 20, Figure 21 and Figure 22) shows numbers and amounts of IVIg for patients with CIDP. Figure 19 and Figure 20 show that the numbers of patients and total grams are increasing at a reasonably steady rate. The increase over the eight quarters is 25 per cent for numbers and 23 per cent for total grams. In Figure 21 the combined effect of is shown. New patients are receiving between twenty ant thirty per cent more than existing patients. This may reflect loading doses. When the data is considered in terms of the amount per episode in Figure 22, the trend appears to be a declining dose per episode and new patient episodes doses are 10 to 15 per cent lower than those of existing patients.

***Figure 19 CIDP – new and existing – number of patients***



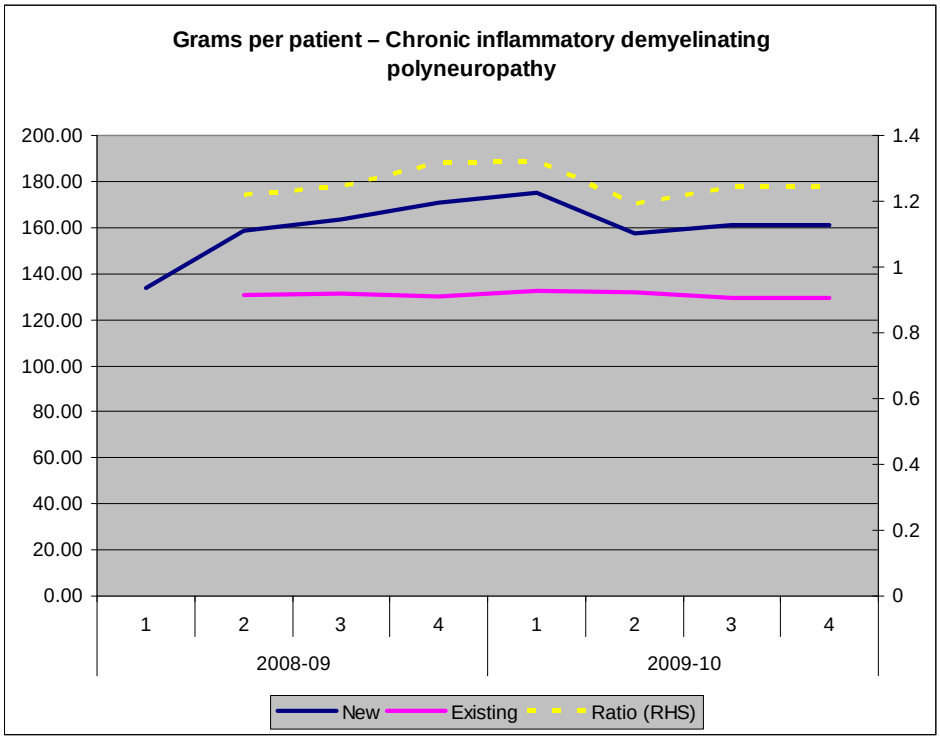

Source: IVIg Stars database maintained by the Blood Service.

***Figure 20 CIDP – new and existing – total grams***



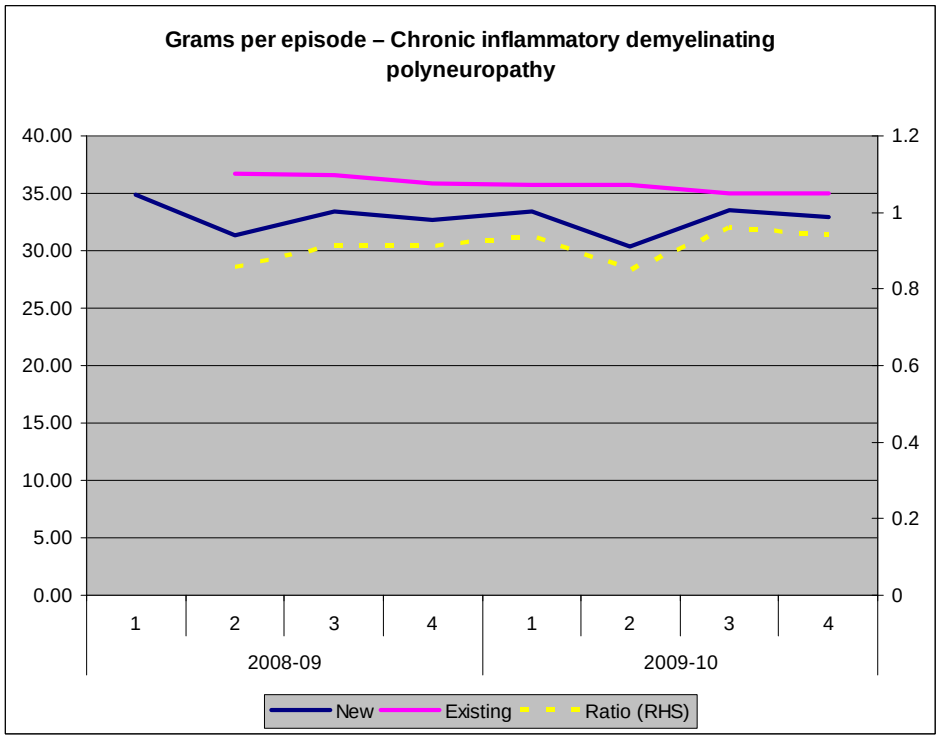

Source: IVIg Stars database maintained by the Blood Service.

***Figure 21 CIDP – new and existing – grams per patient***




Source: IVIg Stars database maintained by the Blood Service.

***Figure 22 CIDP – new and existing – grams per episode***

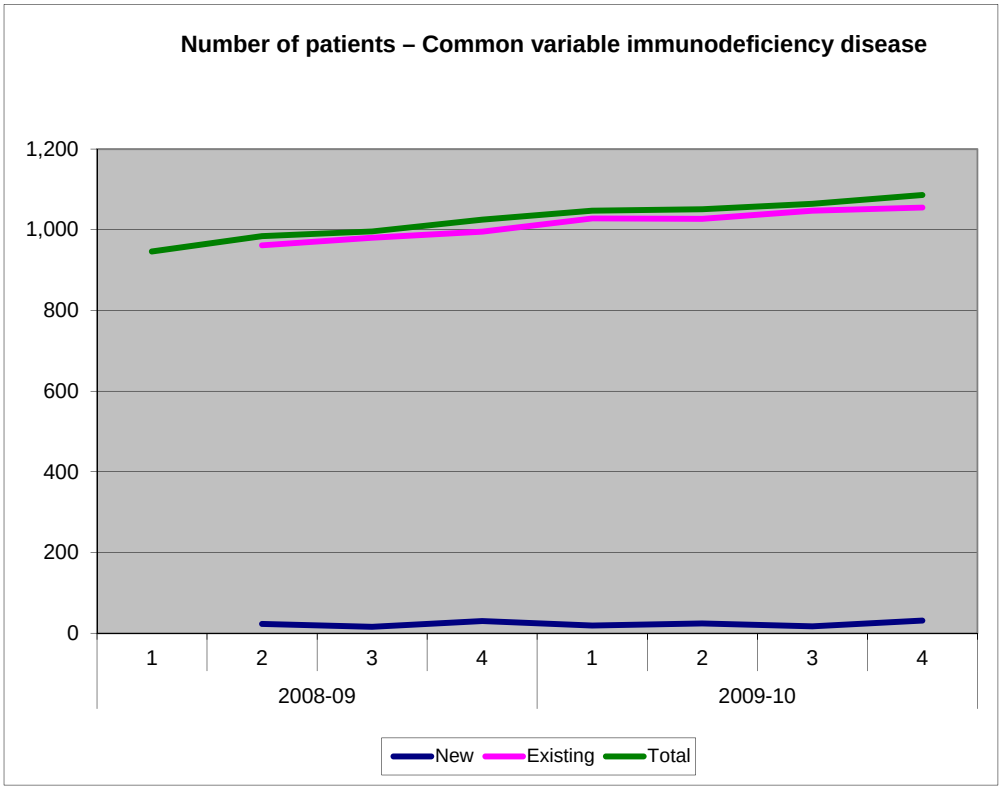



Source: IVIg Stars database maintained by the Blood Service.

### 9.1.2. Common variable immunodeficiency disease (CVID)

The following charts (Figure 23 and Figure 24) show the numbers and grams per episode for CVID.

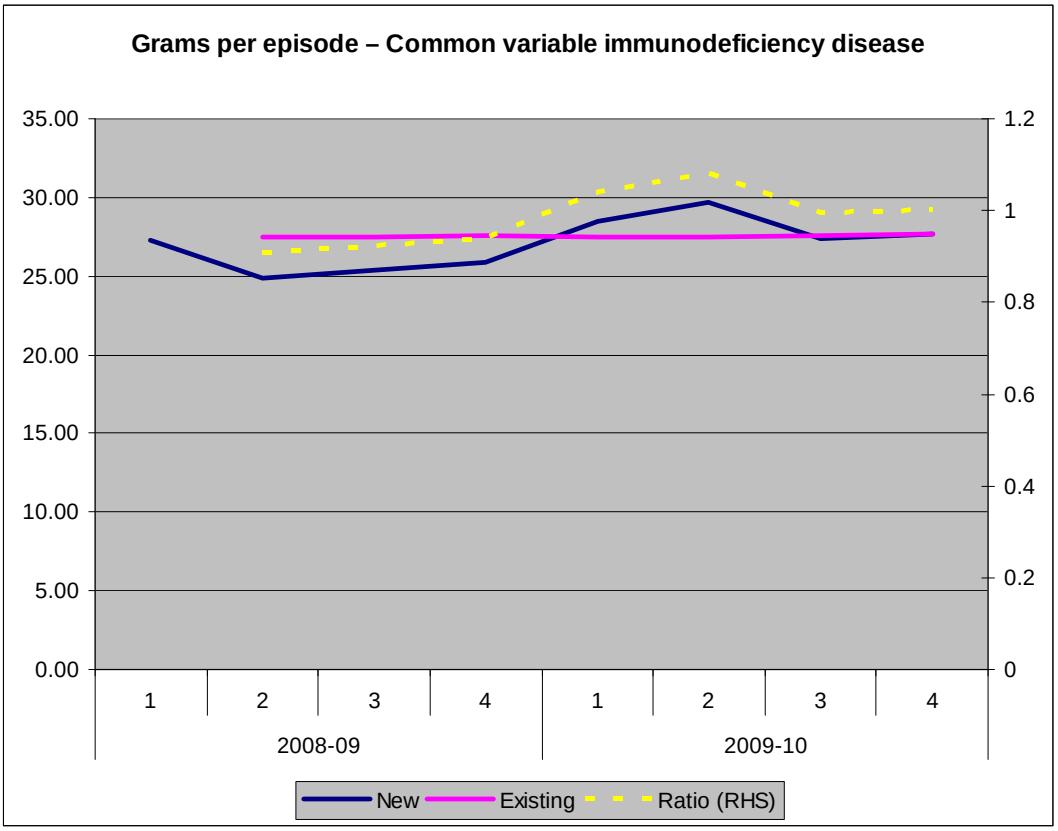
***Figure 23 CVID – new and existing – number of patients***




Source: IVIg Stars database maintained by the Blood Service.

Here growth in the number of patients is proportionally smaller than with CIDP. The largest number of new patients appear in the June quarter in both years. The increase over the eight quarters for CVID is 15 per cent for numbers and 19 per cent for total grams. The grams per episode is generally stable for existing patients. The grams per episode for new patients is more volatile reflecting their low absolute numbers.

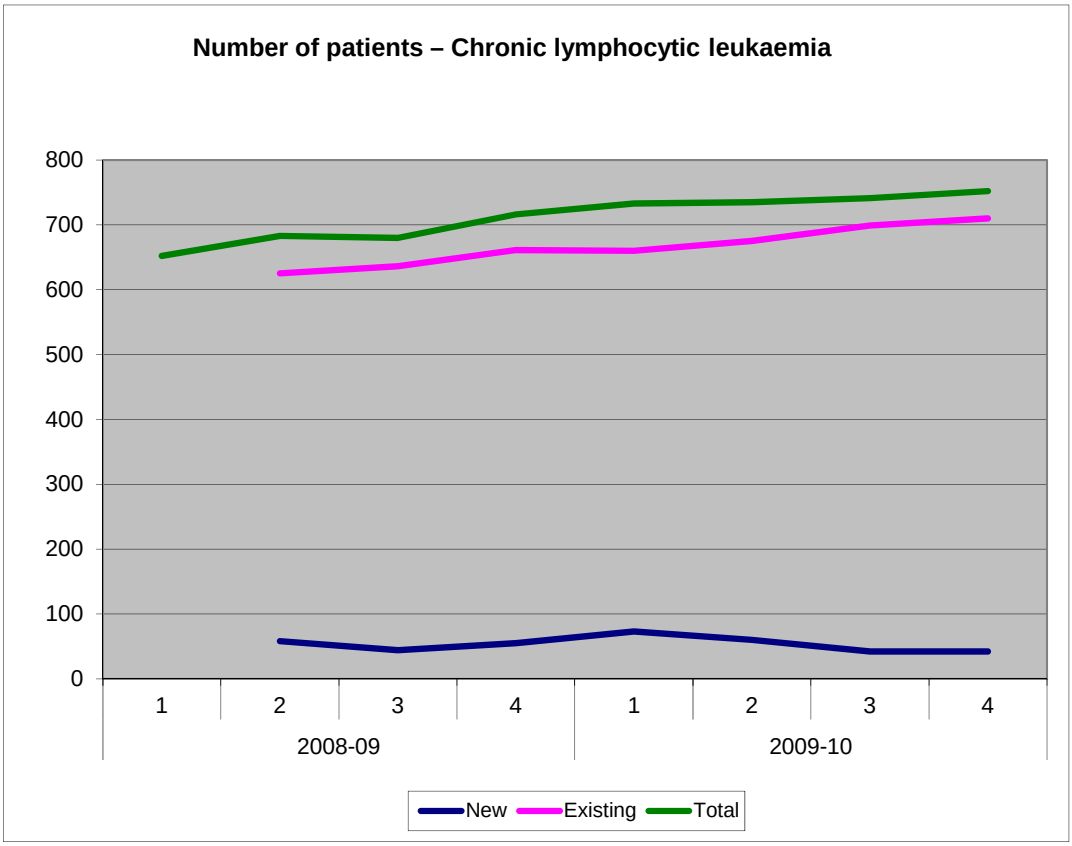
Figure 24 CVID – new and existing – grams per episode




Source: IVIg Stars database maintained by the Blood Service.

### 9.1.3. Chronic lymphocytic leukaemia

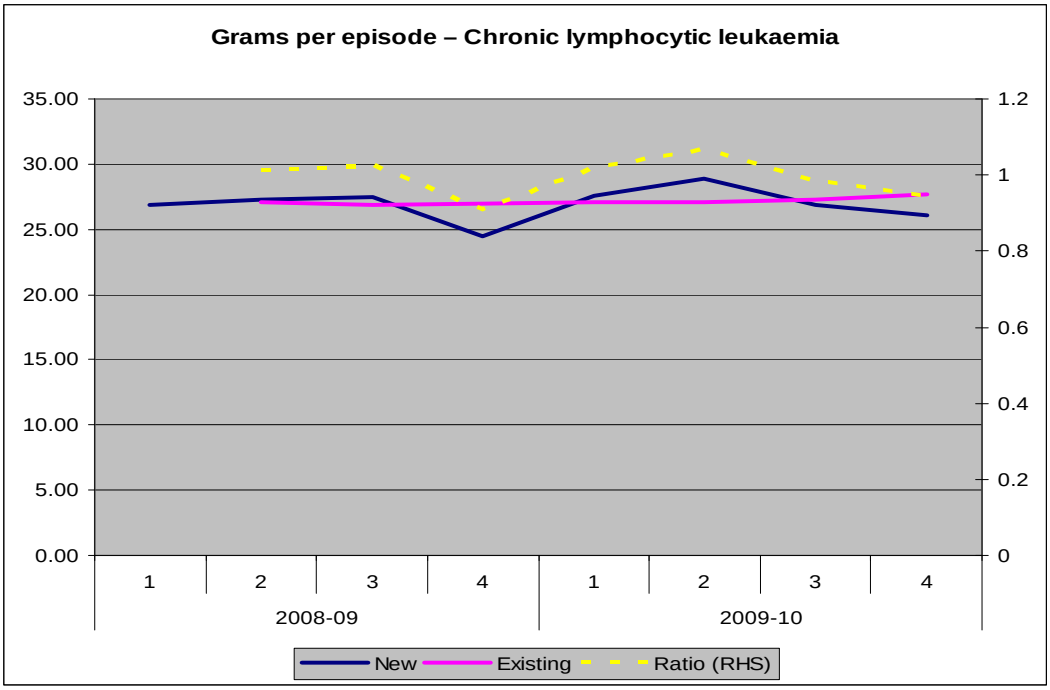
***Figure 25 Chronic lymphocytic leukaemia – new and existing – number of patients***




Source: IVIg Stars database maintained by the Blood Service.

The increase over the eight quarters is 15 per cent for numbers and 19 per cent for total grams. There is a very slight increase in the dosage per episode for Chronic lymphocytic leukaemia.

***Figure 26 Chronic lymphocytic leukaemia – new and existing – grams per episode***

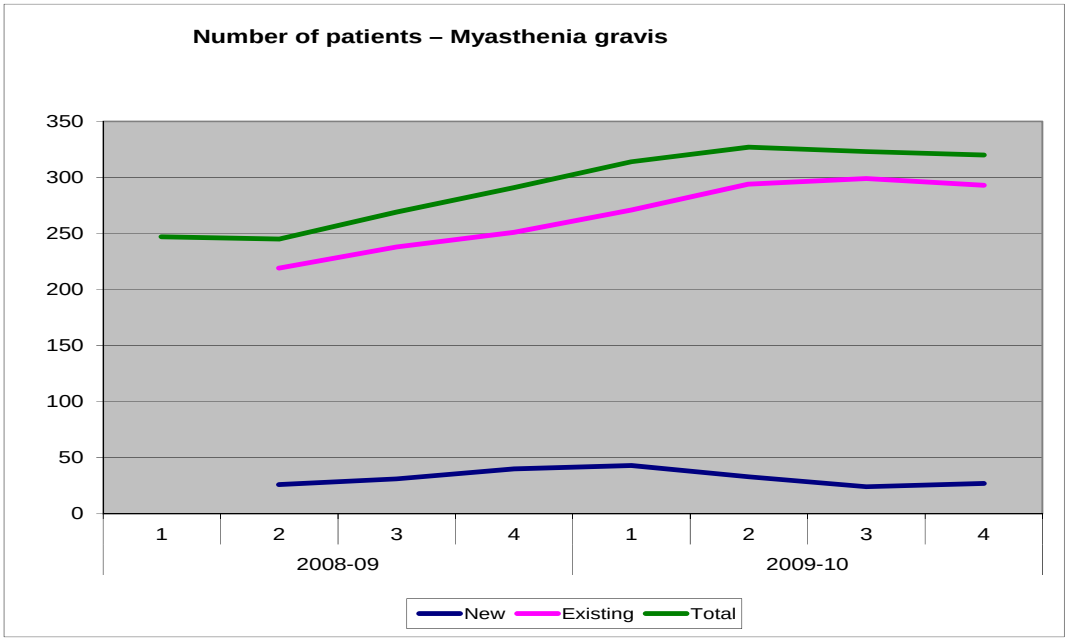



Source: IVIg Stars database maintained by the Blood Service.

### 9.1.4. Myasthenia gravis

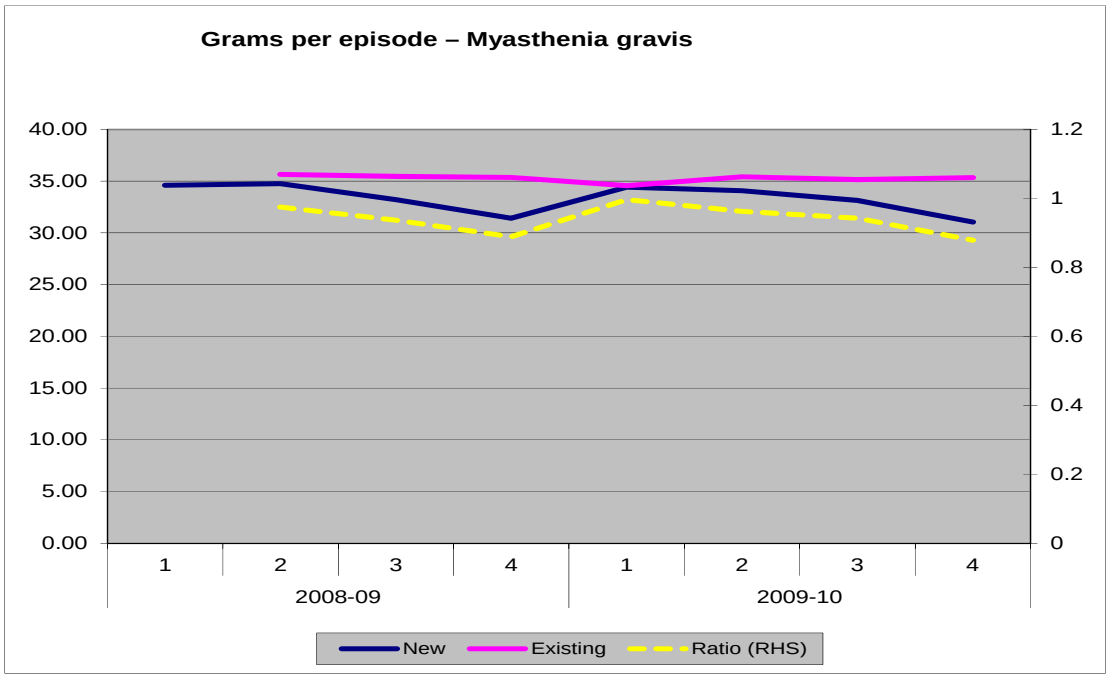
The increase over the eight quarters is 30 per cent for numbers and 43 per cent for total grams for this condition. The latter reflects a slight increase in the dose per episode interacting with the strong growth in numbers.

***Figure 27 Myasthenia gravis – new and existing – number of patients***




Source: IVIg Stars database maintained by the Blood Service.

***Figure 28 Myasthenia gravis – new and existing – grams per episode***

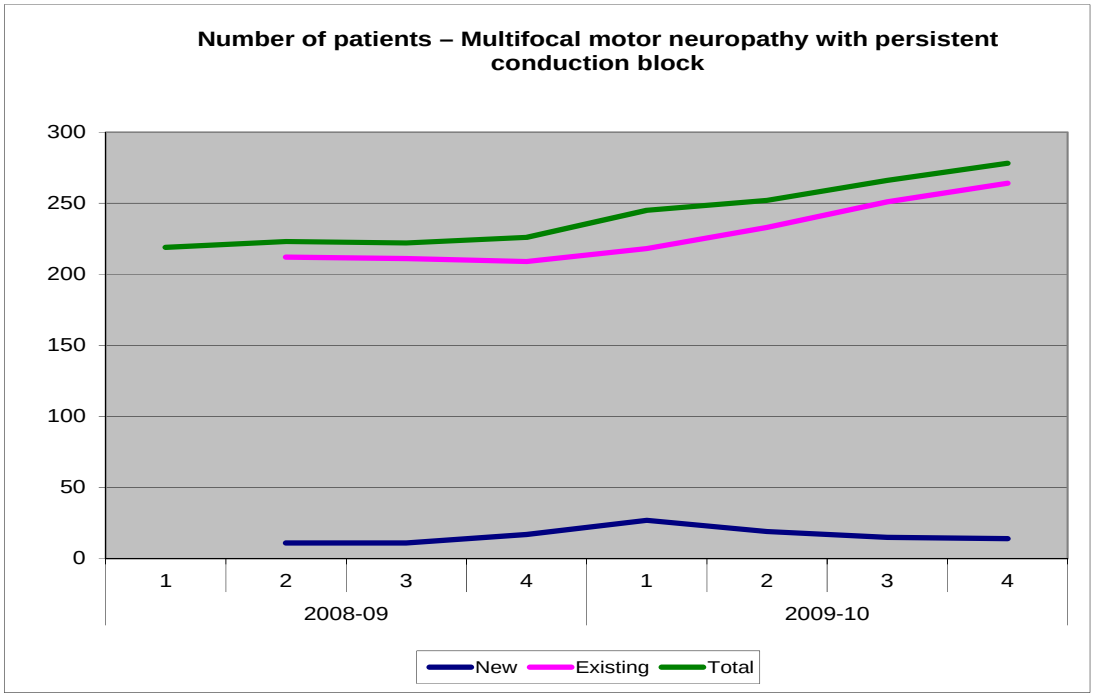



Source: IVIg Stars database maintained by the Blood Service.

### 9.1.5. Multifocal motor neuropathy with persistent conduction block

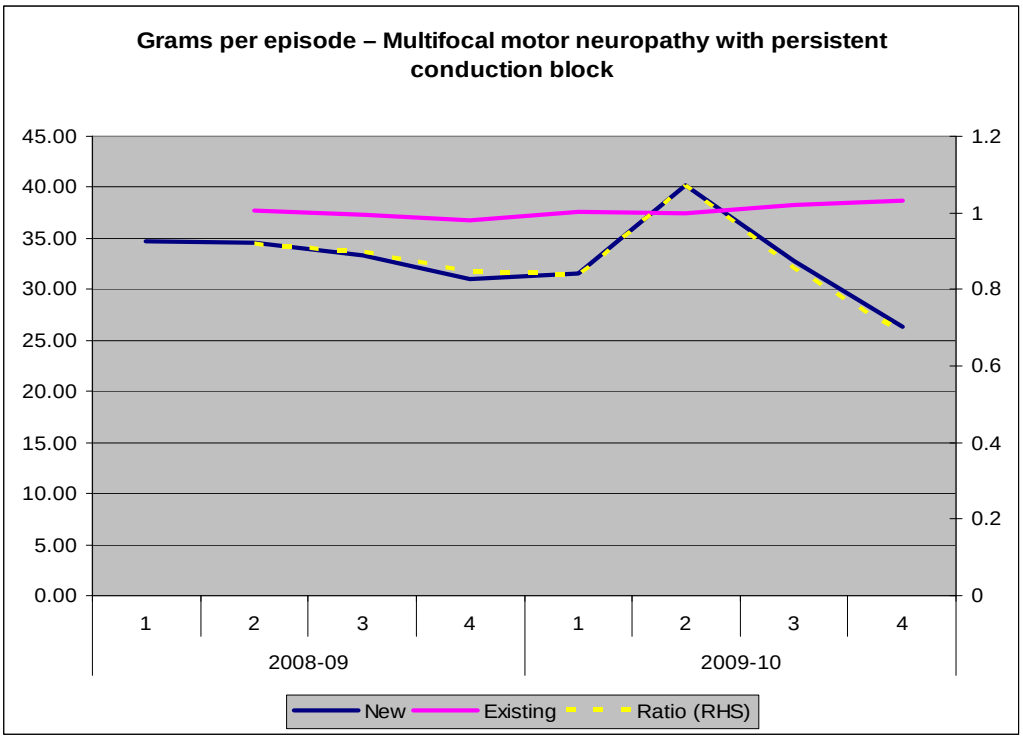
The increase over the eight quarters is 27 per cent for numbers and 30 per cent for total grams for this condition. The latter reflects a slight increase in the dose per episode.

***Figure 29 Multifocal motor neuropathy with persistent conduction block – new and existing – number of patients***




Source: IVIg Stars database maintained by the Blood Service.

***Figure 30 Multifocal motor neuropathy with persistent conduction block – new and existing – grams per episode***




Source: IVIg Stars database maintained by the Blood Service.

## *Questions for further investigation*

- Are the apparent differences between the dosing for new and existing patients reasonable?
- What are the clinical reasons for any changes in dose (i.e. increase of decrease) for a particular condition? (For example is the increase in dose per episode for CLL because of changes in patient weight or length between treatment episodes or change in overall dosing arrangement (adjusted body weight dosing) being used in a particular state or territory )
- Have improvements or changes in diagnosis of a condition contributed in any to the amount of IVIg that is being used?
- Do the grams per episode being used by a condition align with the dose information included in the Criteria?

## 9.2. *Difference in use between states – selected indications*

In this section we compare the grams per episode for some selected indications. The indications are those five that use the greatest amount of IVIg over the two financial years.

### 9.2.1. Chronic inflammatory demyelinating polyneuropathy

Figure 31 shows the grams per episode for the different states for Chronic inflammatory demyelinating polyneuropathy. The small states have very small numbers of patients so should be given very little weight. There are differences between the apparent dosing behaviour of the different states. New South Wales and Queensland appear to dose at about 10 per cent below the Australian average whereas South Australia and Western Australia appear to dose about 20 per cent above. Victoria seems to dose at the average rate.

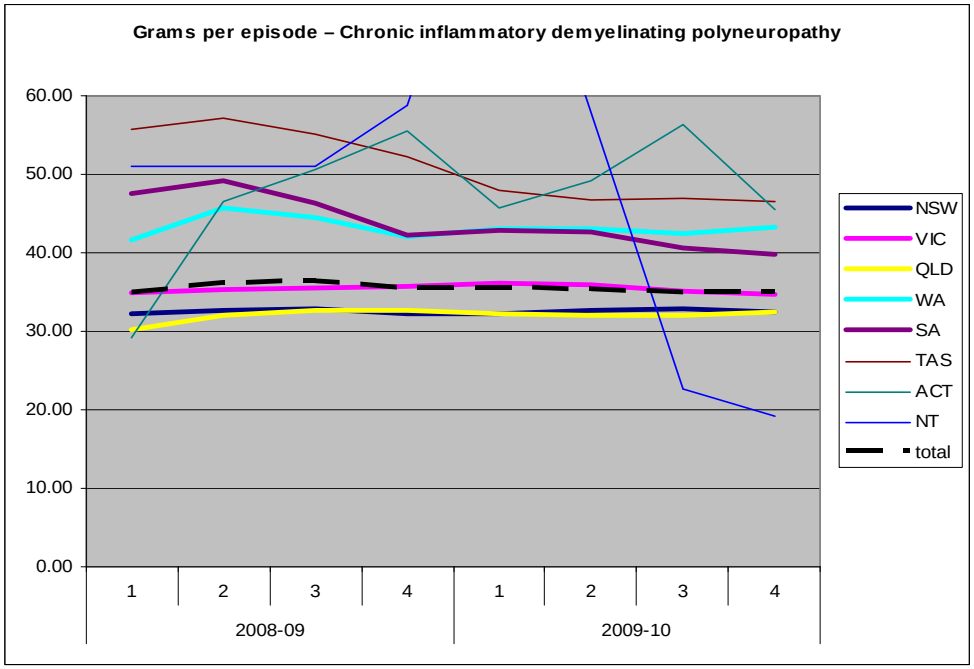
***Table 18 Total national numbers Chronic inflammatory demyelinating polyneuropathy***

| | 2008-09 | | | | 2009-10 | | | |
|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| Total | 838 | 879 | 915 | 966 | 986 | 998 | 1,036 | 1,051 |

Source: IVIg Stars database maintained by the Blood Service.

Some of these differences may relate to different interpretations of what is a treatment episode. The differences should, nevertheless, be explained and the Blood Service should be encouraged to ensure that nationally consistent definitions are used.

***Figure 31 Chronic inflammatory demyelinating polyneuropathy – grams per episode***

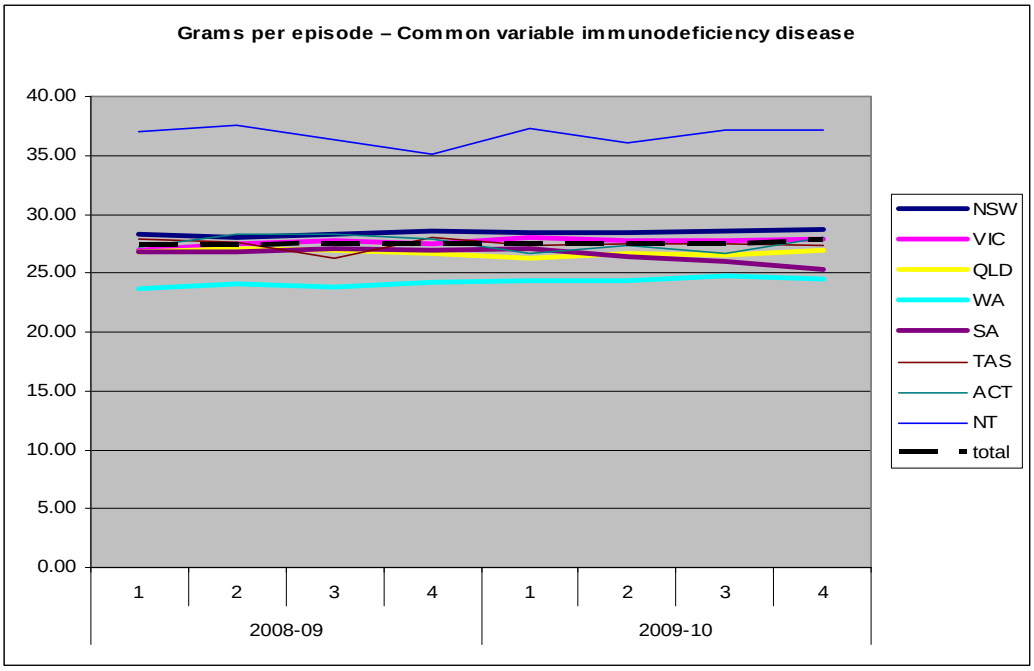



Source: IVIg Stars database maintained by the Blood Service.

### 9.2.2. Common variable immunodeficiency disease

For Common variable immunodeficiency disease Figure 32 shows most of the larger states are clustered around the Australian average. Western Australia appears to be a bit of an outlier about 10 to15 per cent below the average. This may reflects a trial of reduced dose in Western Australia for CVID. The Northern territory is somewhat of an outlier in the opposite direction. As the maximum number of patients in the Northern Territory is only two not a lot of weight can be put on these numbers.

***Figure 32 Common variable immunodeficiency disease – grams per episode***




Source: IVIg Stars database maintained by the Blood Service.

***Table 19 Total national numbers Common variable immunodeficiency disease***

| | 2008-09 | | | | 2009-10 | | | |
|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| Total | 946 | 984 | 996 | 1,025 | 1,047 | 1,051 | 1,064 | 1,086 |

Source: IVIg Stars database maintained by the Blood Service.

### 9.2.3. Chronic lymphocytic leukaemia

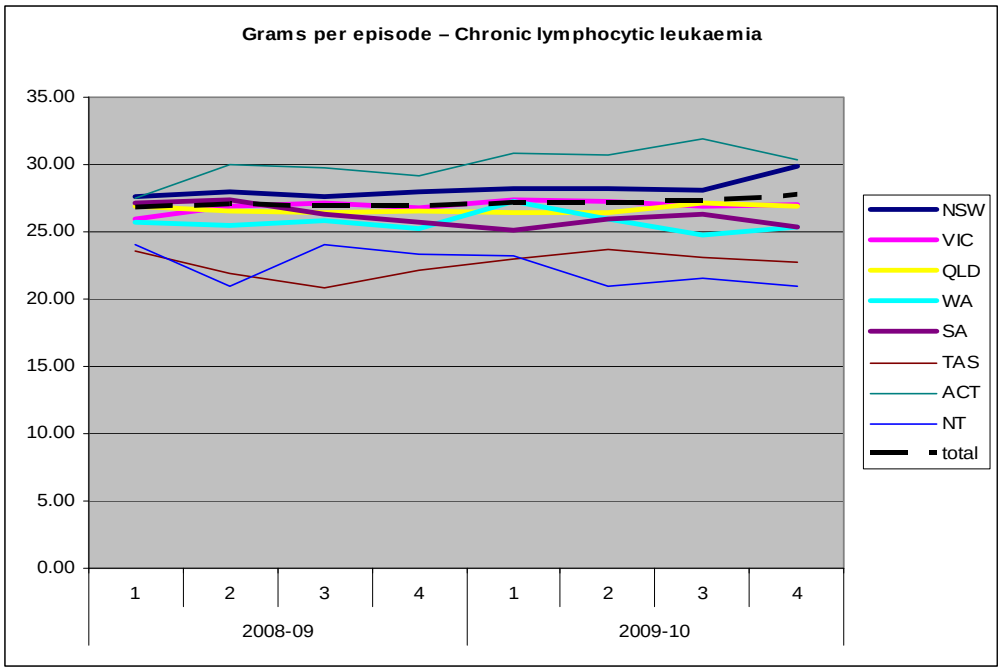
For Chronic lymphocytic leukaemia Figure 33 shows most of the larger states are clustered around the Australian average.

***Table 20 Total national numbers Chronic lymphocytic leukaemia***

| | 2008-09 | | | | 2009-10 | | | |
|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| Total | 652 | 683 | 680 | 716 | 733 | 735 | 741 | 752 |

Source: IVIg Stars database maintained by the Blood Service.

***Figure 33 Chronic lymphocytic leukaemia – grams per episode***




Source: IVIg Stars database maintained by the Blood Service.

### 9.2.4. Myasthenia gravis

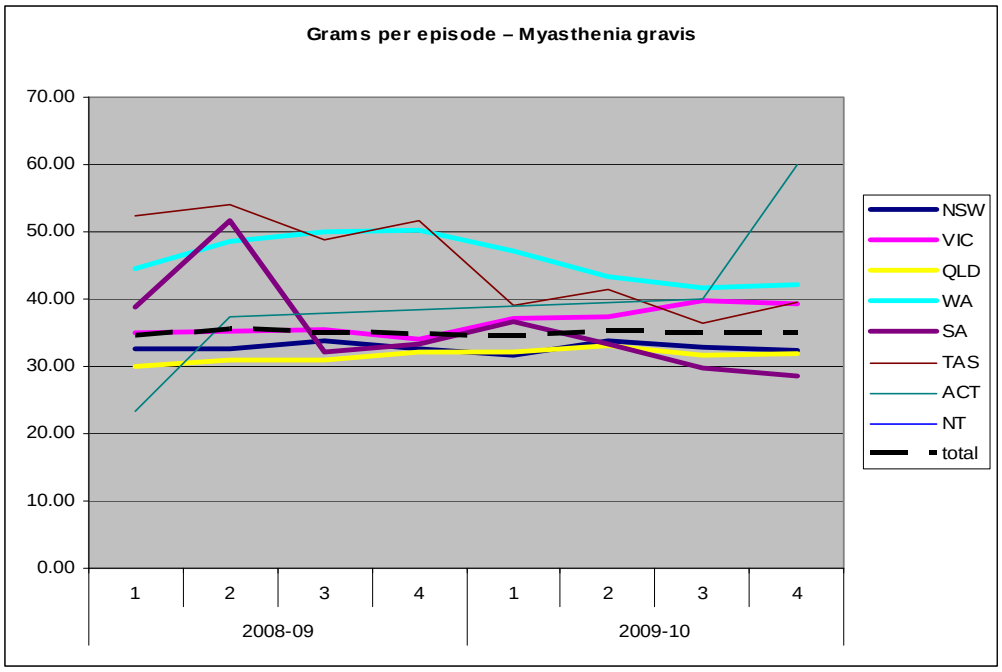
The picture for Myasthenia gravis show in Figure 34 appears more spread out. The numbers of patients for this condition are quite small and this may explain the divergence.

***Table 21 Total national numbers Myasthenia gravis***

| | 2008-09 | | | | 2009-10 | | | |
|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| Total | 247 | 245 | 269 | 291 | 314 | 327 | 323 | 320 |

Source: IVIg Stars database maintained by the Blood Service.

***Figure 34 Myasthenia gravis – grams per episode***




Source: IVIg Stars database maintained by the Blood Service.

### 9.2.5. Multifocal motor neuropathy with persistent conduction block

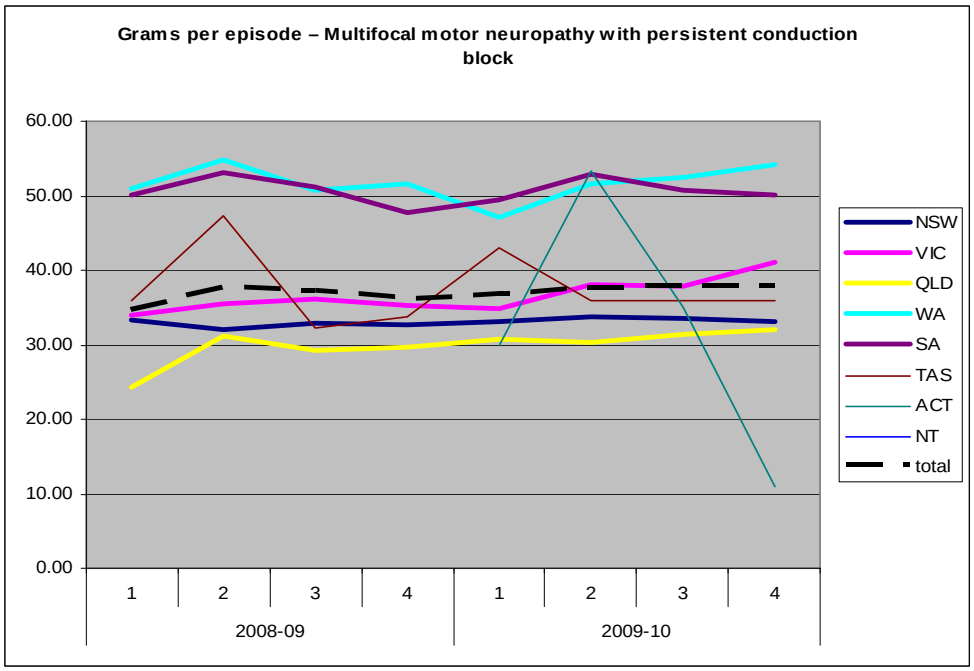
Figure 35 shows a quite dispersed picture. Western Australia and South Australia are more than 30 per cent above and New South Wales and Queensland more than 10 per cent below the average.

***Table 22 Total national numbers Multifocal motor neuropathy with persistent conduction block***

| | 2008-09 | | | | 2009-10 | | | |
|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| Total | 219 | 223 | 222 | 226 | 245 | 252 | 266 | 278 |

Source: IVIg Stars database maintained by the Blood Service.

***Figure 35 Multifocal motor neuropathy with persistent conduction block – grams per episode***




Source: IVIg Stars database maintained by the Blood Service.

***Questions for further investigation***

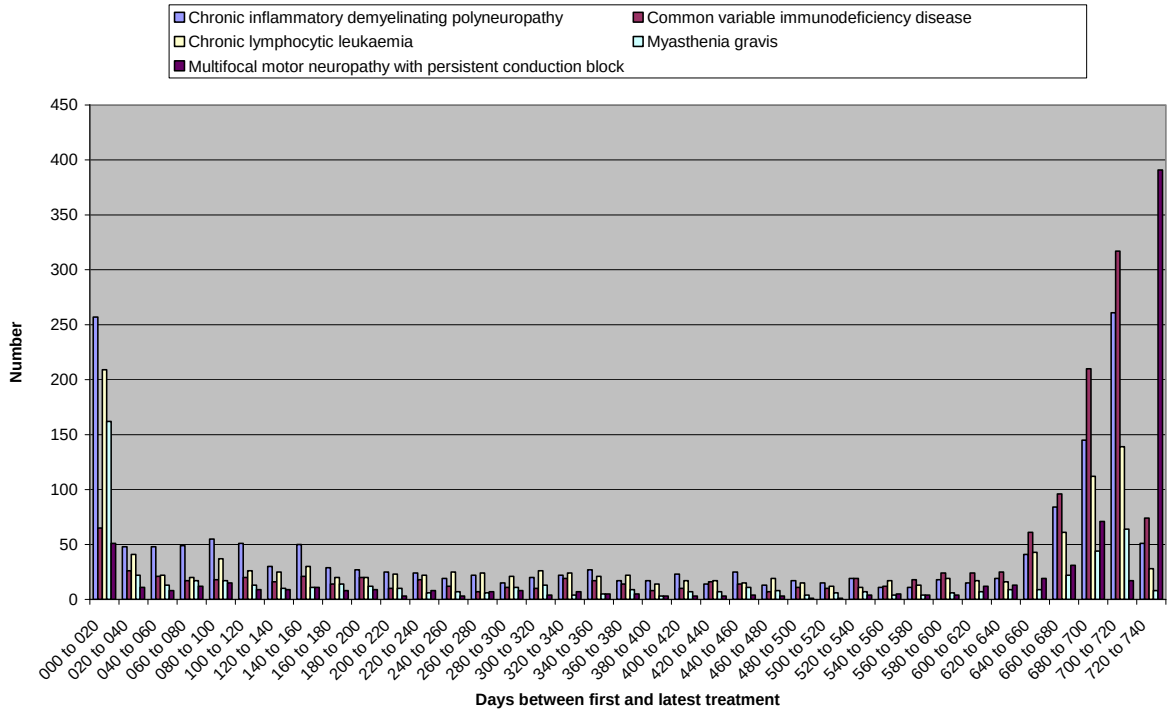
- Why are there apparent differences between the clinical practice between states?
- Are there differences in the way 'grams per episode' are captured in each state?
- What is an 'espisode'? Does this definition differ between states?

## 9.3. Time in treatment

For each unique patient and diagnosis we have estimated the time in treatment as the number of days between the recorded first date required and last date required for that patient. Obviously, a patient that joins in the last quarter will have a maximum possible difference of about 90 days. Someone who has a chronic condition receiving IVIg since the first quarter of 2008-09 could have a days in treatment of up to 730 days.

We have looked at the five conditions that use the largest amount of IVIg for each those conditions classified as short term and not short term.

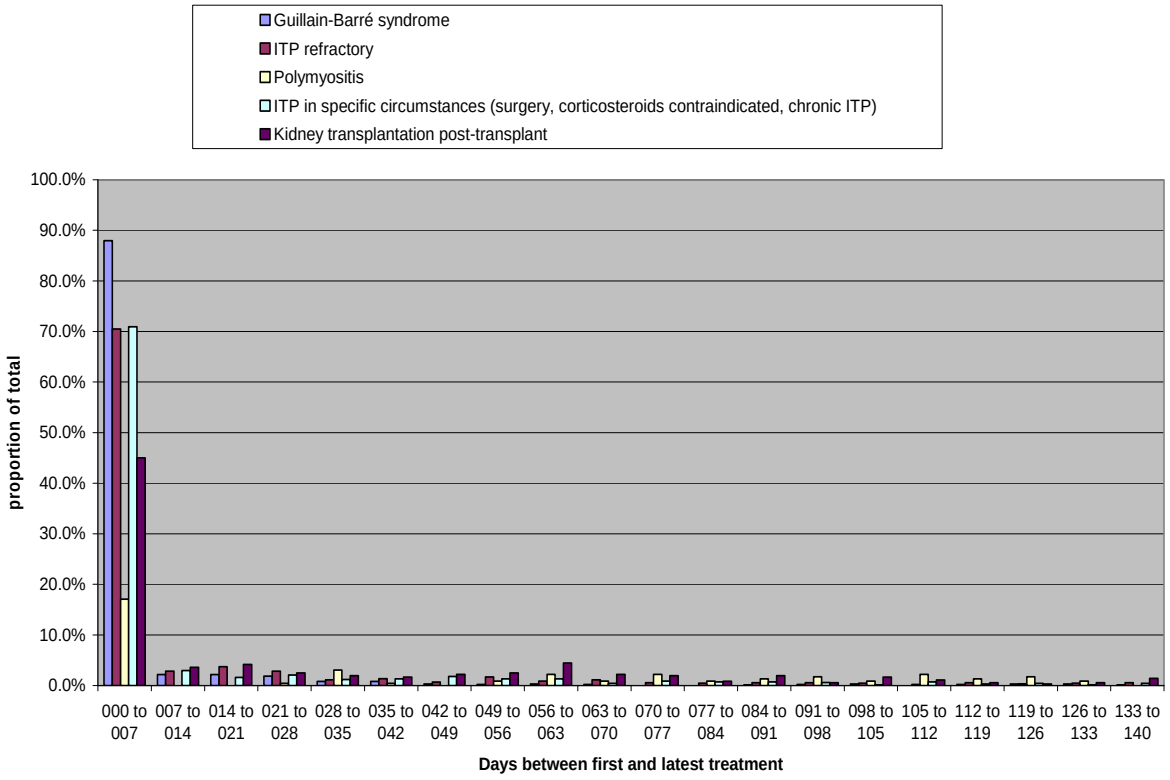
***Figure 36 Days in treatment selected long term conditions***




Source: IVIg Stars database maintained by the Blood Service.

The distributions shown in Figure 36 seem to have a U-shape. This reflects a large number of patients that had IVIg throughout the period, the new patients joining in each quarter (most of whom continue to receive IVIg) and some patients that receive IVIg for a short period only despite their condition being of a longer term nature. No data exists to inform whether these patients ceased because the treatment was successful or whether it did not achieve the desired improvements.

***Figure 37 Days in treatment selected short term conditions***

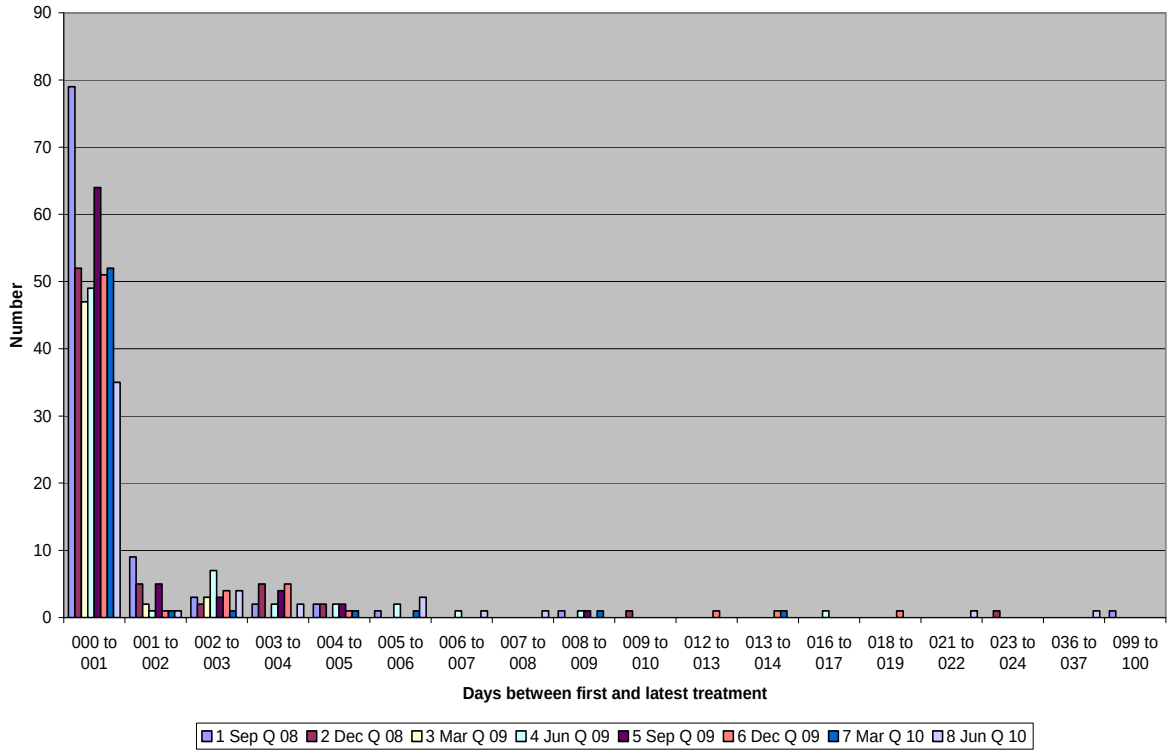



Source: IVIg Stars database maintained by the Blood Service.

Most of these distribution show high concentration of patients that receive treatment for less than a week. Treatments for kidney transplants post-transplant have about 45 per cent of patients with treatments less than one week but there is a majority of patients receiving longer term treatments. Although Polymyositis has the flag short term it does not appear to have short term treatment profile with less than 20 per cent of patients' treatment courses being less than a week. This raises questions about whether reviews have been undertaken for these patients and whether non-responding patients were taken off IVIg.

Figure 38 shows the treatment periods for Kawasaki disease. The vast majority receive treatment for one day and a few receiving additional treatments.

***Figure 38 Days in treatment for Kawasaki disease by quarter of first joining***




## *Questions for further investigation*

- Why are apparent long courses of IVIg for illnesses classified as short term?
- It would be interesting to find out how many patients in this group were reviewed after 3 to 6 months to determine if IVIg therapy is of benefit?

# 10. Conclusions

The data in the IVIg STARS database is a rich source of information about IVIg use and the patients using IVIg. Gaps in the data need to be improved. For example:

- The recording of each IVIg event in the database would provide a basis for better analysis of IVIg use.
- The inclusion of high quality demographic (such as weight and age) data for all patients would be valuable for analysis purposes.
- The database could provide better assurance that the reviews of patient outcomes were occurring by recording these reviews of the patient outcome.

Jurisdictions may wish to give consideration to the extent to which management structures at a local level may assist in driving this.

Such a rich source of data should be made available to researchers at the (non-identified) unit record level and to clinicians as feedback the on the current usage variations and as a possible mechanism for answering some of the clinical questions that have been raised by considering the data available.

The recording of each IVIg event in the database would provide a basis for better analysis of IVIg use. The inclusion of high quality demographic (such as weight and age) data for all patients would also be valuable for analysis purposes. The database could provide better assurance that the reviews of patient outcomes were occurring by recording these reviews of the patient outcome.

# Appendix A
# IVIg by Grams per 1000 Population – 2009-10 by state and indication

| Disease Category | Primary Diagnosis | NSW | Vic | Qld | WA | SA | Tas | ACT | NT | Grand total |
|---|---|---|---|---|---|---|---|---|---|---|
| Chapter 5 | Chronic inflammatory demyelinating polyneuropathy | 23.67 | 27.98 | 22.58 | 24.69 | 17.03 | 40.47 | 18.73 | 3.11 | 24.22 |
| | Chronic lymphocytic leukaemia | 10.56 | 8.06 | 12.92 | 2.63 | 10.24 | 10.15 | 12.59 | 2.38 | 9.52 |
| | Common variable immunodeficiency disease | 21.33 | 11.33 | 15.66 | 7.90 | 15.65 | 9.18 | 36.55 | 3.70 | 15.69 |
| | Dermatomyositis | 1.04 | 1.39 | 0.41 | 0.51 | 0.58 | 1.77 | 1.78 | 0.00 | 0.93 |
| | Guillain-Barré syndrome | 4.06 | 4.43 | 3.17 | 2.67 | 3.34 | 5.32 | 4.58 | 4.49 | 3.82 |
| | Idiopathic thrombocytopenic purpura - Adult | 0.00 | 0.00 | 0.02 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| | Inclusion body myositis | 1.42 | 0.54 | 1.86 | 0.00 | 0.52 | 5.16 | 0.00 | 0.00 | 1.13 |
| | ITP associated with HIV | 0.15 | 0.10 | 0.02 | 0.03 | 0.00 | 0.00 | 0.00 | 0.00 | 0.08 |
| | ITP in pregnancy | 0.55 | 0.26 | 0.28 | 0.85 | 0.99 | 0.14 | 0.00 | 0.00 | 0.46 |
| | ITP in specific circumstances (surgery, corticosteroids contraindicated, chronic ITP) | 2.34 | 1.98 | 3.76 | 0.89 | 4.67 | 1.52 | 0.87 | 0.00 | 2.49 |
| | ITP refractory | 3.27 | 2.88 | 3.66 | 1.86 | 2.96 | 2.91 | 6.00 | 1.95 | 3.10 |
| | ITP with life-threatening haemorrhage | 1.31 | 0.24 | 0.38 | 0.10 | 0.47 | 0.41 | 1.60 | 0.37 | 0.64 |
| | Kawasaki disease | 0.57 | 0.62 | 0.34 | 0.15 | 0.23 | 0.17 | 0.52 | 0.34 | 0.45 |
| | Lambert-Eaton myasthenic syndrome | 0.21 | 0.05 | 0.16 | 0.05 | 0.00 | 0.00 | 0.00 | 0.68 | 0.13 |
| | Multifocal motor neuropathy with persistent conduction block | 6.67 | 6.44 | 6.23 | 10.08 | 10.08 | 1.86 | 2.05 | 11.91 | 6.99 |
| | Multiple myeloma | 6.15 | 3.50 | 14.37 | 0.99 | 1.72 | 23.15 | 9.75 | 0.00 | 6.68 |
| | Myasthenia gravis | 7.62 | 8.06 | 9.24 | 6.56 | 2.72 | 9.80 | 0.50 | 0.00 | 7.45 |
| | Neonatal haemochromatosis | 0.26 | 0.00 | 0.25 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.14 |
| | Non-Hodgkins lymphoma | 4.95 | 3.45 | 11.57 | 0.73 | 4.17 | 7.19 | 12.17 | 0.10 | 5.54 |
| | Other primary immunodeficiency | 2.35 | 2.14 | 0.55 | 1.08 | 1.62 | 0.43 | 0.15 | 2.27 | 1.67 |
| | Other relevant haematological malignancies | 3.53 | 2.97 | 3.12 | 0.56 | 0.27 | 3.37 | 3.02 | 0.00 | 2.72 |
| | Polymyositis | 3.77 | 2.21 | 2.19 | 0.13 | 5.75 | 1.33 | 2.53 | 1.40 | 2.73 |
| | Severe combined Immunodeficiency | 0.04 | 0.33 | 1.24 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.35 |
| | Stiff person syndrome | 0.55 | 0.44 | 1.96 | 0.23 | 0.00 | 1.03 | 0.00 | 1.10 | 0.74 |
| | Wiskott-Aldrich syndrome | 0.02 | 0.01 | 0.07 | 0.26 | 0.12 | 0.85 | 0.00 | 0.00 | 0.08 |
| | X linked agammaglobulinaemia | 0.70 | 2.55 | 1.15 | 0.98 | 1.20 | 0.00 | 0.35 | 0.00 | 1.29 |

| Disease Category | Primary Diagnosis | NSW | Vic | Qld | WA | SA | Tas | ACT | NT | Grand total |
|---|---|---|---|---|---|---|---|---|---|---|
| Chapter 6 | Acute disseminated encephalomyelitis | 0.46 | 0.21 | 0.12 | 0.36 | 0.16 | 0.38 | 0.00 | 0.00 | 0.28 |
| | ANCA (PR3 or MPO)-positive idiopathic rapidly progressive glomerulonephritis | 0.02 | 0.02 | 0.01 | 0.03 | 0.00 | 0.00 | 0.00 | 0.00 | 0.02 |
| | Autoimmune haemolytic anaemia | 0.76 | 0.62 | 0.86 | 0.20 | 0.69 | 1.81 | 0.81 | 0.00 | 0.70 |
| | Bullous pemphigoid | 0.29 | 0.62 | 0.16 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.28 |
| | Churg-Strauss syndrome | 0.01 | 0.00 | 0.00 | 0.06 | 0.00 | 0.00 | 0.00 | 0.00 | 0.01 |
| | Cicatricial pemphigoid | 0.00 | 0.40 | 0.21 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.14 |
| | Evans syndrome | 0.14 | 0.01 | 0.09 | 0.02 | 0.00 | 0.00 | 0.00 | 0.00 | 0.07 |
| | Foeto-maternal /neonatal alloimmune thrombocytopenia (Antenatal) | 0.89 | 0.44 | 0.80 | 1.39 | 1.10 | 1.65 | 0.00 | 0.00 | 0.82 |
| | Foeto-maternal /neonatal alloimmune thrombocytopenia (Neonatal) | 0.01 | 0.00 | 0.00 | 0.01 | 0.60 | 0.01 | 0.00 | 0.12 | 0.05 |
| | Haemophagocytic syndrome | 0.17 | 0.28 | 0.09 | 0.00 | 0.09 | 1.29 | 0.00 | 0.00 | 0.18 |
| | HSCT (for prevention of GvHD in high risk Allogeneic HSCT). | 0.32 | 1.30 | 5.81 | 0.00 | 2.99 | 0.00 | 0.00 | 0.00 | 1.82 |
| | IgG subclass deficiency EXISTING patients only | 5.83 | 1.81 | 1.38 | 1.28 | 2.67 | 5.11 | 2.37 | 0.00 | 3.10 |
| | IgM para-proteinaemic neuropathy | 0.44 | 0.12 | 0.29 | 0.83 | 0.36 | 0.47 | 0.00 | 0.00 | 0.35 |
| | ITP in children | 0.10 | 0.25 | 0.67 | 0.21 | 0.27 | 0.08 | 0.48 | 0.37 | 0.29 |
| | Kidney transplantation post-transplant | 0.83 | 6.30 | 0.54 | 1.57 | 1.19 | 1.99 | 0.31 | 0.00 | 2.24 |
| | Kidney transplantation pre-transplant | 0.40 | 0.41 | 0.08 | 0.02 | 0.71 | 0.00 | 0.00 | 0.00 | 0.30 |
| | Microscopic polyangiitis | 0.02 | 0.00 | 0.08 | 0.07 | 0.00 | 0.00 | 0.00 | 0.00 | 0.03 |
| | Multiple scelorosis - severe relapse with no response to high dose methylprednisolone | 0.09 | 0.13 | 0.30 | 0.00 | 0.00 | 0.59 | 0.00 | 0.00 | 0.13 |
| | Multiple sclerosis in pregnancy | 0.02 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.01 |
| | Multiple sclerosis in young patients severe/relapsing/remitting in whom other therapies have failed | 0.02 | 0.00 | 0.13 | 0.00 | 0.00 | 0.23 | 0.00 | 0.00 | 0.04 |
| | Opsoclonus myoclonus ataxia | 0.07 | 0.07 | 0.08 | 0.19 | 0.01 | 0.27 | 0.00 | 0.00 | 0.08 |
| | Pemphigus vulgaris | 0.32 | 0.20 | 0.52 | 0.00 | 1.28 | 0.00 | 0.00 | 0.00 | 0.35 |
| | Post transfusion purpura | 0.09 | 0.01 | 0.00 | 0.00 | 0.05 | 0.00 | 0.00 | 0.00 | 0.04 |
| | Secondary hypogammaglobulinaemia (excludes haem malignancies) | 2.26 | 1.77 | 6.23 | 1.66 | 1.28 | 9.37 | 1.71 | 0.09 | 2.94 |
| | Specific antibody deficiency | 1.55 | 0.65 | 1.37 | 3.18 | 2.27 | 0.00 | 4.59 | 0.54 | 1.51 |

| Disease Category | Primary Diagnosis | NSW | Vic | Qld | WA | SA | Tas | ACT | NT | Grand total |
|---|---|---|---|---|---|---|---|---|---|---|
| | Toxic epidermal necrolysis/Steven Johnson syndrome | 0.34 | 0.56 | 0.00 | 0.21 | 0.55 | 0.39 | 0.00 | 0.00 | 0.32 |
| | TSS - staphylococcal | 0.11 | 0.14 | 0.16 | 0.26 | 0.05 | 0.14 | 0.55 | 0.63 | 0.15 |
| | TSS - streptococcal | 0.15 | 0.51 | 0.57 | 0.24 | 0.26 | 0.60 | 0.55 | 0.00 | 0.36 |
| | Wegeners granulomatosis | 0.02 | 0.00 | 0.04 | 0.00 | 0.16 | 0.00 | 0.00 | 0.00 | 0.03 |
| Chapter 7 | Acute leukaemia in children | 0.00 | 0.01 | 0.02 | 0.00 | 0.01 | 0.01 | 0.00 | 0.00 | 0.01 |
| | Autoimmune congenital heart block | 0.00 | 0.00 | 0.12 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.03 |
| | Autoimmune diabetic neuropathy | 0.08 | 0.22 | 0.00 | 0.00 | 0.00 | 2.68 | 0.00 | 0.00 | 0.14 |
| | Autoimmune neutropenia | 0.00 | 0.00 | 0.08 | 0.02 | 0.00 | 0.00 | 0.00 | 0.00 | 0.02 |
| | Catastrophic antiphospholipid syndrome | 0.20 | 0.06 | 0.27 | 0.00 | 0.60 | 0.00 | 1.34 | 0.00 | 0.20 |
| | Coagulation factor inhibitors | 0.02 | 0.04 | 0.10 | 0.03 | 0.54 | 0.00 | 0.00 | 0.00 | 0.08 |
| | Devic disease (neuromyelitis optica) | 0.12 | 0.13 | 0.06 | 0.05 | 0.00 | 0.00 | 0.00 | 0.00 | 0.09 |
| | Epidermolysis bullosa acquisita | 0.00 | 0.00 | 0.00 | 0.19 | 0.00 | 0.00 | 0.00 | 0.00 | 0.02 |
| | Epilepsy (rare childhood cases) | 0.09 | 0.61 | 0.27 | 0.42 | 0.00 | 0.00 | 0.00 | 0.00 | 0.28 |
| | Graves ophthalmopathy | 0.03 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.01 |
| | Haemolytic disease of the newborn | 0.02 | 0.02 | 0.00 | 0.01 | 0.03 | 0.01 | 0.10 | 0.00 | 0.02 |
| | Haemolytic transfusion reaction | 0.00 | 0.03 | 0.00 | 0.00 | 0.00 | 0.00 | 0.02 | 0.00 | 0.01 |
| | Myocarditis in children | 0.00 | 0.03 | 0.06 | 0.04 | 0.00 | 0.00 | 0.00 | 0.00 | 0.02 |
| | PANDAS/tic disorders | 0.00 | 0.01 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| | Paraneoplastic syndromes | 0.12 | 0.27 | 0.16 | 0.55 | 0.56 | 0.00 | 0.00 | 0.00 | 0.23 |
| | Potassium channel antibody-associated encephalopathy | 0.33 | 0.10 | 0.09 | 0.21 | 0.81 | 0.00 | 0.00 | 0.00 | 0.23 |
| | Pure red cell aplasia | 0.07 | 0.03 | 0.37 | 0.19 | 0.06 | 2.84 | 0.00 | 0.00 | 0.19 |
| | Pure white cell aplasia | 0.00 | 0.00 | 0.08 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.02 |
| | Scleromyxedema | 0.04 | 0.17 | 0.04 | 0.05 | 0.00 | 0.00 | 0.40 | 0.00 | 0.07 |
| | Sepsis - neonatal | 0.02 | 0.02 | 0.01 | 0.00 | 0.01 | 0.00 | 0.00 | 0.00 | 0.01 |
| | Sjogren's Syndrome | 0.17 | 0.01 | 0.13 | 0.26 | 0.93 | 0.00 | 1.56 | 0.00 | 0.20 |
| | Solid organ - heart | 0.04 | 0.04 | 0.00 | 0.07 | 0.09 | 0.00 | 0.00 | 0.00 | 0.03 |
| | Solid organ - heart/lung | 0.08 | 0.00 | 0.07 | 0.00 | 0.05 | 0.00 | 0.00 | 0.00 | 0.04 |
| | Solid organ - liver | 0.00 | 0.02 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.01 |
| | Solid organ - lung | 0.85 | 0.41 | 0.43 | 0.00 | 0.26 | 0.00 | 0.00 | 0.00 | 0.48 |
| | Solid organ - pancreas | 0.00 | 0.02 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| | Susac syndrome | 0.40 | 0.21 | 0.65 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.31 |

| Disease Category | Primary Diagnosis | NSW | Vic | Qld | WA | SA | Tas | ACT | NT | Grand total |
|---|---|---|---|---|---|---|---|---|---|---|
| Chapter 8 | Asthma | 0.00 | 0.35 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.09 |
| | Sepsis (other than neonatal sepsis) | 0.00 | 0.04 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.01 |
| | Systemic lupus erythematosus | 0.00 | 0.00 | 0.00 | 0.17 | 0.00 | 0.00 | 0.00 | 0.00 | 0.02 |
| Chapter DO | DO issue | 0.00 | 0.03 | 0.00 | 0.02 | 0.00 | 0.00 | 0.00 | 0.00 | 0.01 |
| Grand Total | | 125.54 | 111.69 | 140.75 | 78.01 | 105.03 | 156.15 | 128.53 | 35.53 | 118.58 |

# Appendix B
# IVIg Average Dose issued for 2009-10 by state and indication

| Disease Category | Primary Diagnosis | NSW | VIC | QLD | WA | SA | TAS | ACT | NT | Total |
|---|---|---|---|---|---|---|---|---|---|---|
| Chapter 5 | Chronic inflammatory demyelinating polyneuropathy | 32.54 | 35.48 | 32.22 | 43.02 | 41.50 | 47.01 | 48.71 | 23.03 | 35.14 |
| | Chronic lymphocytic leukaemia | 28.59 | 27.13 | 26.72 | 25.84 | 25.71 | 23.10 | 30.96 | 21.84 | 27.30 |
| | Common variable immunodeficiency disease | 28.57 | 27.87 | 26.61 | 24.49 | 26.19 | 27.41 | 27.16 | 36.91 | 27.56 |
| | Dermatomyositis | 29.85 | 41.76 | 30.55 | 56.14 | 50.53 | 150.00 | 45.64 | | 37.25 |
| | Guillain-Barré syndrome | 31.13 | 30.74 | 29.28 | 62.62 | 35.46 | 44.29 | 36.53 | 103.20 | 32.79 |
| | Idiopathic thrombocytopenic purpura - Adult | | | 25.00 | | | | | | 25.00 |
| | Inclusion body myositis | 33.68 | 37.99 | 36.40 | | 37.52 | 37.45 | | | 35.55 |
| | ITP associated with HIV | 28.83 | 62.22 | 25.00 | 80.00 | | | | | 35.50 |
| | ITP in pregnancy | 37.57 | 54.67 | 28.93 | 72.00 | 45.19 | 69.00 | | | 42.99 |
| | ITP in specific circumstances (surgery, corticosteroids contraindicated, chronic ITP) | 36.66 | 47.29 | 31.53 | 62.24 | 53.31 | 59.38 | 78.00 | | 39.05 |
| | ITP refractory | 37.53 | 56.99 | 33.63 | 56.24 | 61.54 | 51.00 | 79.81 | 74.50 | 42.84 |
| | ITP with life-threatening haemorrhage | 35.92 | 74.72 | 35.50 | 73.33 | 70.09 | 103.75 | 82.29 | 42.00 | 40.53 |
| | Kawasaki disease | 29.84 | 31.60 | 31.04 | 24.64 | 30.96 | 17.40 | 26.43 | 26.00 | 30.11 |
| | Lambert-Eaton myasthenic syndrome | 32.40 | 37.88 | 24.40 | 63.00 | | | | 39.00 | 31.22 |
| | Multifocal motor neuropathy with persistent conduction block | 33.44 | 38.03 | 31.07 | 51.20 | 50.84 | 39.25 | 19.39 | 85.50 | 37.56 |
| | Multiple myeloma | 28.19 | 26.74 | 25.05 | 25.58 | 23.56 | 28.19 | 29.91 | | 26.45 |
| | Myasthenia gravis | 32.65 | 38.42 | 32.22 | 43.42 | 32.69 | 39.16 | 45.00 | | 34.91 |
| | Neonatal haemochromatosis | 76.32 | | 57.45 | | | | | | 67.93 |
| | Non-Hodgkins lymphoma | 28.39 | 28.59 | 25.36 | 28.42 | 26.20 | 27.04 | 27.30 | 24.00 | 26.86 |
| | Other primary immunodeficiency | 25.68 | 28.39 | 24.06 | 22.82 | 35.61 | 24.00 | 7.71 | 20.08 | 26.47 |
| | Other relevant haematological malignancies | 28.56 | 27.08 | 24.72 | 23.45 | 19.82 | 27.13 | 30.11 | | 26.96 |
| | Polymyositis | 30.89 | 41.34 | 32.31 | 30.00 | 50.88 | 56.38 | 39.48 | 40.13 | 35.42 |
| | Severe combined Immunodeficiency | 19.60 | 22.06 | 25.05 | | | | | | 24.03 |
| | Stiff person syndrome | 40.77 | 44.89 | 68.19 | 66.00 | | 35.00 | | 21.00 | 52.33 |
| | Wiskott-Aldrich syndrome | 17.50 | 6.00 | 21.40 | 24.00 | 15.00 | 33.00 | | | 20.70 |
| | X linked agammaglobulinaemia | 22.70 | 26.48 | 24.42 | 22.64 | 25.31 | | 9.69 | | 24.78 |

| Disease Category | Primary Diagnosis | NSW | VIC | QLD | WA | SA | TAS | ACT | NT | Total |
|---|---|---|---|---|---|---|---|---|---|---|
| Chapter 6 | Acute disseminated encephalomyelitis | 31.92 | 30.21 | 37.71 | 51.38 | 33.38 | 39.00 | | | 33.92 |
| | ANCA (PR3 or MPO)-positive idiopathic rapidly progressive glomerulonephritis | 41.00 | 22.50 | 9.00 | 72.00 | | | | | 27.46 |
| | Autoimmune haemolytic anaemia | 33.15 | 56.90 | 35.87 | 77.17 | 51.32 | 76.67 | 97.00 | | 41.34 |
| | Bullous pemphigoid | 50.94 | 57.27 | 27.00 | | | | | | 48.86 |
| | Churg-Strauss syndrome | 21.00 | | | 144.00 | | | | | 41.50 |
| | Cicatricial pemphigoid | | 160.00 | 36.00 | | | | | | 79.40 |
| | Evans syndrome | 34.28 | 51.00 | 22.32 | 39.00 | | | | | 30.16 |
| | Foeto-maternal /neonatal alloimmune thrombocytopenia (Antenatal) | 73.57 | 60.53 | 65.73 | 67.91 | 58.26 | 3.44 | | | 36.33 |
| | Foeto-maternal /neonatal alloimmune thrombocytopenia (Neonatal) | 3.43 | 3.00 | 3.00 | 3.60 | 61.50 | 3.00 | | 5.40 | 22.14 |
| | Haemophagocytic syndrome | 31.79 | 52.70 | 32.08 | 6.00 | 24.83 | 43.67 | | | 38.99 |
| | HSCT (for prevention of GvHD in high risk Allogeneic HSCT). | 27.93 | 27.79 | 23.56 | | 32.52 | | | | 25.31 |
| | IgG subclass deficiency EXISTING patients only | 26.87 | 27.13 | 20.70 | 26.07 | 30.08 | 26.21 | 21.77 | | 26.24 |
| | IgM para-proteinaemic neuropathy | 29.37 | 31.50 | 32.27 | 45.21 | 22.62 | 120.00 | | | 32.84 |
| | ITP in children | 26.94 | 19.91 | 29.52 | 32.20 | 22.53 | 10.50 | 24.43 | 28.00 | 25.67 |
| | Kidney transplantation post-transplant | 27.15 | 31.81 | 12.22 | 55.34 | 23.51 | 50.45 | 55.00 | | 29.65 |
| | Kidney transplantation pre-transplant | 40.65 | 26.54 | 11.44 | 42.00 | 20.07 | | | | 27.23 |
| | Microscopic polyangiitis | 30.00 | | 25.20 | 30.00 | | | | | 27.12 |
| | Multiple scelorosis - severe relapse with no response to high dose methylprednisolone | 29.40 | 21.44 | 38.31 | | | 30.00 | | | 29.88 |
| | Multiple sclerosis in pregnancy | 32.50 | | | | | | | | 32.50 |
| | Multiple sclerosis in young patients severe/relapsing/remitting in whom other therapies have failed | 16.83 | | 24.88 | | | 39.00 | | | 24.04 |
| | Opsoclonus myoclonus ataxia | 33.44 | 24.00 | 36.00 | 19.64 | 15.00 | 27.50 | | | 26.62 |
| | Pemphigus vulgaris | 47.05 | 48.04 | 34.76 | | 124.06 | | | | 50.21 |
| | Post transfusion purpura | 45.40 | 48.00 | | | 30.00 | | | | 43.11 |
| | Secondary hypogammaglobulinaemia (excludes haem malignancies) | 25.79 | 26.55 | 23.77 | 20.63 | 20.56 | 36.05 | 34.00 | 21.00 | 24.99 |
| | Specific antibody deficiency | 22.58 | 27.95 | 19.83 | 23.01 | 26.06 | | 21.40 | 8.20 | 22.69 |

| Disease Category | Primary Diagnosis | NSW | VIC | QLD | WA | SA | TAS | ACT | NT | Total |
|---|---|---|---|---|---|---|---|---|---|---|
| | Toxic epidermal necrolysis/Steven Johnson syndrome | 55.24 | 69.14 | | 98.40 | 82.55 | 100.00 | | | 66.64 |
| | TSS - staphylococcal | 57.71 | 65.50 | 54.00 | 84.43 | 90.00 | 70.00 | 99.00 | 144.00 | 66.45 |
| | TSS - streptococcal | 88.42 | 83.24 | 65.77 | 137.00 | 72.17 | 151.50 | 99.00 | | 80.18 |
| | Wegeners granulomatosis | 36.00 | | 37.80 | | 24.00 | | | | 30.14 |
| Chapter 7 | Acute leukaemia in children | 3.00 | 13.20 | 12.67 | | 12.00 | 5.00 | | | 11.60 |
| | Autoimmune congenital heart block | | 25.00 | 60.00 | | | | | | 56.50 |
| | Autoimmune diabetic neuropathy | 23.46 | 51.10 | | | | 80.00 | | | 47.71 |
| | Autoimmune neutropenia | | | 29.75 | 54.00 | | | | | 31.62 |
| | Catastrophic antiphospholipid syndrome | 46.45 | 90.00 | 36.52 | | 82.00 | | 120.00 | | 53.20 |
| | Coagulation factor inhibitors | 33.00 | 73.00 | 38.75 | 72.00 | 49.78 | | | | 46.59 |
| | Devic disease (neuromyelitis optica) | 32.31 | 32.89 | 21.00 | 105.00 | | | | | 31.31 |
| | Epidermolysis bullosa acquisita | | | | 72.00 | | | | | 72.00 |
| | Epilepsy (rare childhood cases) | 31.00 | 34.66 | 21.00 | 22.16 | | | | | 28.21 |
| | Graves ophthalmopathy | 35.00 | | | | | | | | 35.00 |
| | Haemolytic disease of the newborn | 3.37 | 3.08 | 3.00 | 3.00 | 3.00 | 3.00 | 3.00 | | 3.16 |
| | Haemolytic transfusion reaction | | 50.00 | | | | | 3.00 | | 31.20 |
| | Myocarditis in children | | 18.83 | 51.60 | 48.00 | | | | | 32.72 |
| | PANDAS/tic disorders | | 24.00 | | | | | | | 24.00 |
| | Paraneoplastic syndromes | 25.00 | 30.65 | 25.39 | 52.63 | 29.71 | | | | 31.61 |
| | Potassium channel antibody-associated encephalopathy | 26.84 | 43.54 | 29.14 | 60.38 | 39.03 | | | | 32.74 |
| | Pure red cell aplasia | 47.80 | 72.50 | 31.28 | 35.79 | 50.00 | 40.00 | | | 36.96 |
| | Pure white cell aplasia | | | 25.93 | | | | | | 25.93 |
| | Scleromyxedema | 36.00 | 21.00 | 35.40 | 117.00 | | | 36.00 | | 26.52 |
| | Sepsis - neonatal | 3.07 | 3.14 | 4.88 | | 3.00 | | | | 3.26 |
| | Sjogren's Syndrome | 29.18 | 36.00 | 26.14 | 50.00 | 118.15 | | 31.11 | | 41.91 |
| | Solid organ - heart | 24.00 | 21.67 | 10.00 | 150.00 | 18.00 | | | | 25.43 |
| | Solid organ - heart/lung | 49.13 | | 27.00 | | 45.00 | | | | 39.06 |
| | Solid organ - liver | | 32.50 | | | | | | | 32.50 |
| | Solid organ - lung | 43.44 | 30.51 | 25.92 | | 47.67 | | | | 36.00 |
| | Solid organ - pancreas | | 7.50 | | | | | | | 7.50 |
| | Susac syndrome | 35.86 | 39.20 | 65.13 | | | | | | 44.95 |

| Disease Category | Primary Diagnosis | NSW | VIC | QLD | WA | SA | TAS | ACT | NT | Total |
|---|---|---|---|---|---|---|---|---|---|---|
| Chapter 8 | Asthma | | 39.49 | | | | | | | 39.49 |
| | Sepsis (other than neonatal sepsis) | | 75.00 | | | | | | | 75.00 |
| | Systemic lupus erythematosus | | | | 39.00 | | | | | 39.00 |
| Chapter DO | DO issue | | 32.08 | | 25.00 | | | | | 30.31 |

# Appendix C
# IVIg Data by Category and condition 2008-09 and 2009-10

## *10.1. Purpose*

To provide jurisdictions with information provided to the National Blood Authority (NBA) by the Australian Red Cross Blood Service (Blood Service) on IVIg issuage from their STARS system.

## *10.2. Background*

The Blood Service provides the NBA with data on IVIg issued under the National Blood Agreement.

The data is categorised by

- IVIg Criteria for Use Chapters
- Individual Conditions.

Data prior to March 2008 was recorded under the Australian Health Ministers Advisory Council (AHMAC) category I or II or III, these were mapped to the new IVIg Criteria for Use as per the Mapping Sheet.

Since 2006-07 the Blood Service has provided this information in Excel from their STARS system, to avoid re-keying errors.

The values for 'grams' and 'treatment episodes' for each condition were entered for each product where available for each jurisdiction, and calculations were made to include average dose, percent of dose, percent of total IVIg grams and per 1000 population.

Charts were then created in Excel to visually compare national and state/territory figures by financial years, total IVIg issuage and total treatment episodes, chapters, discipline, conditions and products.

## *10.3. Definitions*

The Blood Service have defined 'treatment episodes' to be the full dose for a specified treatment. The dose can be split into doses administered over a number of days.

Blood Service advise that this could be complicated by:

- Front loading doses;
- Ceasing treatment if demonstrating response after only part of the planned total dose;
- Hospitals ordering part doses even if they intend to administer a total dose;

Blood Service staff query orders, especially for initial treatments for conditions where large doses might be anticipated, to ascertain overall intention. Where it is clear that the hospital is ordering step by step, STARS does have the capacity to bundle these orders into one overall treatment dose.

## *10.4. Caveats and Assumptions*

Assumes that the provided datasets for each state/territory and time period are complete.

Inconsistencies in summation for 2004-05 and 2005-06 were calculated and corrected.

State/territory totals did not add up to the national totals, and so a separate national total was calculated by summing the states usage for each condition.

Inconsistencies with wording/naming: When analysing the data, the naming of conditions differed from year to year which resulted in conditions being inaccurately reported.

### 10.4.1. Issues include:

There were small spelling errors, slight differences in lettering (capital letters were not consistent), additional words included (i.e. Primary Immunological and Immunological) or words being replaced by acronyms (i.e. CVID and Common Variable Immunodeficiency). These differences were rectified and a consistent set of condition names were produced.

The 'miscellaneous' condition has appeared as a condition

Cross border usage has not been adjusted for in the data provided. This could impact on the grams per 1000 population calculations for States and territories such as ACT.

# Appendix D List of Figures

# Appendix E List of tables