NATIONAL BLOOD AUTHORITY
AUSTRALIA

NATIONAL REPORT ON THE ISSUE AND USE OF IMMUNOGLOBULIN (Ig)

Annual Report 2014-15

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NATIONAL BLOOD AUTHORITY
AUSTRALIA

Locked Bag 8430
Canberra ACT 2601
Phone: 13 000 BLOOD (13000 25663)
Email: data@blood.gov.au
www.blood.gov.au

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Introduction

Immunoglobulins products analysed in this report include intravenous immunoglobulin (IVIg) and subcutaneous immunoglobulin (SCIg). These are referred to as immunoglobulin (Ig). Ig is a blood product derived from donated human blood. It is used to treat a broad range of conditions, with applications in immunoglobulin replacement and immune modulation therapy. This report provides an analysis of national data on national Ig supply in Australia in 2014-15, also considering trends in supply over the last ten years.

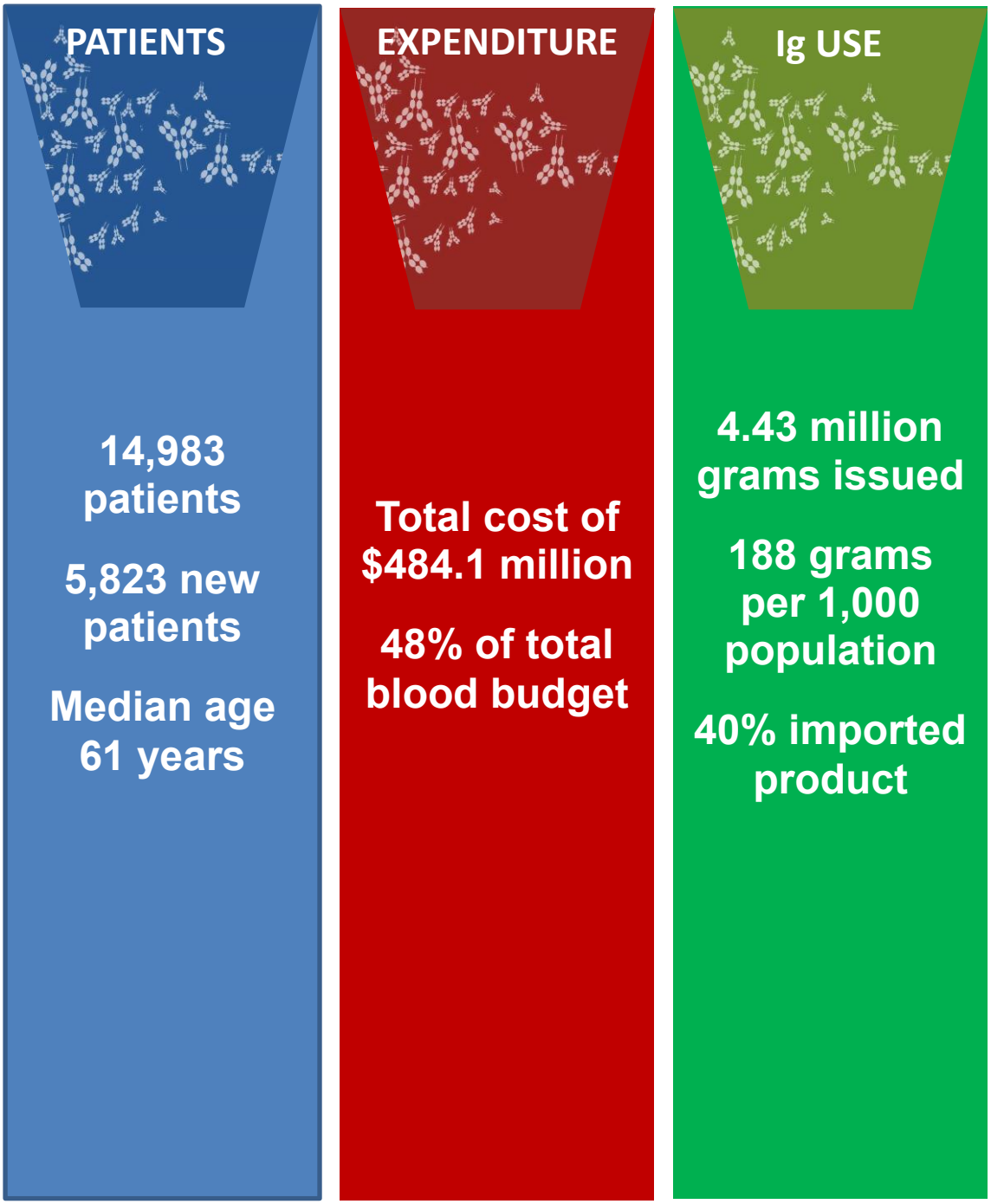
In Australia it is estimated that over 99% of all Ig is supplied under national blood arrangements through contracts administered by the National Blood Authority (NBA). The NBA's role is to coordinate national supply and demand planning for blood and blood products including supply risk management; purchasing blood and blood products on behalf of all Australian governments; developing and implementing national strategies to encourage better governance, promoting appropriate use of blood and blood products; and providing expert advice to support government policy development. Further background is at **Appendix A.**

The *Criteria for the Clinical Use of Intravenous Immunoglobulin (IVIg) in Australia* (*Criteria*) identifies the conditions and circumstances for which the use of intravenous immunoglobulin (IVIg) is funded under national blood arrangements. The *Criteria* was first published in 2008, and was updated in 2012. It classifies the 93 diagnostic groups described in the *Criteria* into those for which IVIg has an established therapeutic role (Chapter 5), has an emerging therapeutic role (Chapter 6) and those where IVIg has application in exceptional circumstances only (Chapter 7). IVIg is only supplied for these diagnostic groups unless purchased by a single state, hospital or individual (a Direct Order). Chapter 8 of the *Criteria* outlines those conditions for which IVIg should not be supplied, as there is no evidence to support its use in these conditions.

Ig comprises a large proportion of blood expenditure each year. Demand for Ig continues to rise steadily, and Australian per capita use of this product is one of the highest among western countries. Demand for Ig is met through local manufacture of Ig by CSL Behring using plasma collected from voluntary, non-remunerated Australian donors and is supplemented by importation of Ig from overseas manufacturers. Both the domestic and imported Ig are distributed by the Australian Red Cross Blood Service (Blood Service), with the Blood Service also being responsible for collection of data on behalf of governments for product funded under the national blood arrangements.

Australia is in a unique position to provide analysis and commentary on the use of Ig due to national supply arrangements. This report begins with an analysis of Ig supply over the last ten years, then considers patient demographics, expenditure on Ig, clinical indications for which Ig was supplied and finally analyses the dose prescribed for various conditions. The top ten diagnostic groups account for 88.1% of all Ig supplied in 2014-15, and for this reason specific analysis focuses on these groups.

Report Snapshot



Methodology

The report uses data from two primary sources, as follows:

1. Data collected by the Blood Service under contractual arrangements with the NBA on behalf of all Australian governments. This data is collected either when an order is placed for Ig, or is collected following the treatment where product is issued as imprest stock. The data is collected into the Blood Service's Supply Tracking Analysis Recording System (STARS) database.
2. Data collected by the NBA on the units Ig issued to Australian Health Providers (AHPs) and purchases from suppliers. This data is held in the NBA Integrated Data Management System (IDMS).

Over the seven years between 2008-09 and 2014-15, data has been captured on 42,245 patients. Caveats relating to the quality of this data are outlined below.

This report does not include data on supply of Normal Immunoglobulin (NIg). It includes data on Subcutaneous Immunoglobulin (SCIg) for 2013-15 only as no SCIg product was available in Australia before 2013-14.

The report includes some language that may be unique to the Australian environment. A list of acronyms and definitions used in this report is at **Appendix B.**

The *Criteria* groups together a number of conditions into one diagnostic group. For example, primary immunodeficiency disease is a diagnostic group in the *Criteria,* with this group incorporating the numerous separate conditions. In some cases the analysis will focus on the diagnostic group, while in other areas it will focus on the condition.

Each condition has been classified according to clinical discipline. It is acknowledged that for some conditions this classification is somewhat arbitrary. For example, there are immunological conditions affecting the blood that could potentially be mapped to either immunology or haematology. Where there appeared to be significant overlap between clinical disciplines, the condition was mapped as mixed. In the majority of cases, the condition was mapped to the speciality most likely to be responsible for patients with that condition, noting that this can vary. **Appendix C** provides the mapping of condition to discipline.

The summary of key items from the data file is provided for each condition at the state and territory level. The summary includes patient numbers, grams of Ig used for the condition, grams per treatment episode and grams per 1,000 population (**Appendix D).** The source used for each figure and table is provided at **Appendix G.**

DATA QUALITY

There are some factors relating to data quality, which need to be considered when reading this report, as follows:

- The reconciliation of data held in STARS and IDMS indicates minor variances at a national level. In some cases these differences can be explained by product being ordered and recorded in STARS the month prior to product actually being issued to a patient.
- Not all data fields are completed for all patients. For example, of the total patients recorded since 2008 37,209 patients (88%) had weight data entered, but only 7,184 (17%) had their weight data change in a treatment following the first entry.
- The ABS population series 3201.0 (Population by Age and Sex, Australian States and Territories) ended in June 2010 and was replaced by Australian Demographic Statistics (cat. No 3101.0). Series 3201.0 was utilised as the denominator for population statistics for Ig annual reports before 2011-12.
- Care should be taken when interpreting the data relating to the smaller states and territories as one or two patients can overly influence the use compared to larger states. The five largest Australian states are New South Wales (NSW), Victoria (VIC), Queensland (QLD), South Australia (SA) and Western Australia (WA).
- There has been no adjustment for Ig used in one state or territory for patients residing in a different state or territory.
- A total of 958 (2%) patients received product in more than one state and territory. For example, if a patient relocated from New South Wales to Victoria, they will be counted as a patient in both states. The national patient count only includes one count for each patient. This may result in the sum of the state and territory totals being greater than the national total.
- Patient numbers were first reported in 2008-09. A small number of patients who did not receive product funded under national blood arrangements have been excluded from the total patient count.
- A total of 3,860 (9%) patients had more than one condition over time. In these cases, a patient may be counted more than once in the data in this report, that is, the patient will be counted in the totals for each condition.
- The STARS data has age and weight data recorded at treatment dates (first reported in 2009-10). This data changes over time. Age data is based on the patient's age at 1 January each year.
- Diagnosis group and conditions captured prior to the implementation of the Criteria were mapped to ensure that they were meaningfully represented, however information from previous years may not be directly comparable from 2008-09 forward. There is a small variance between disciplines by year due to mapping methodology.

10 Year Trends

DEMAND TRENDS

In 2014-15 a total of 4,433,146 grams of Ig was issued, representing an increase of 411,284 grams (10.2%) over 2013-14. Since 2005-06 there has been an on average 12.0% increase in Ig use, with the greatest proportion of that increase comprising imported products (Figure 1).

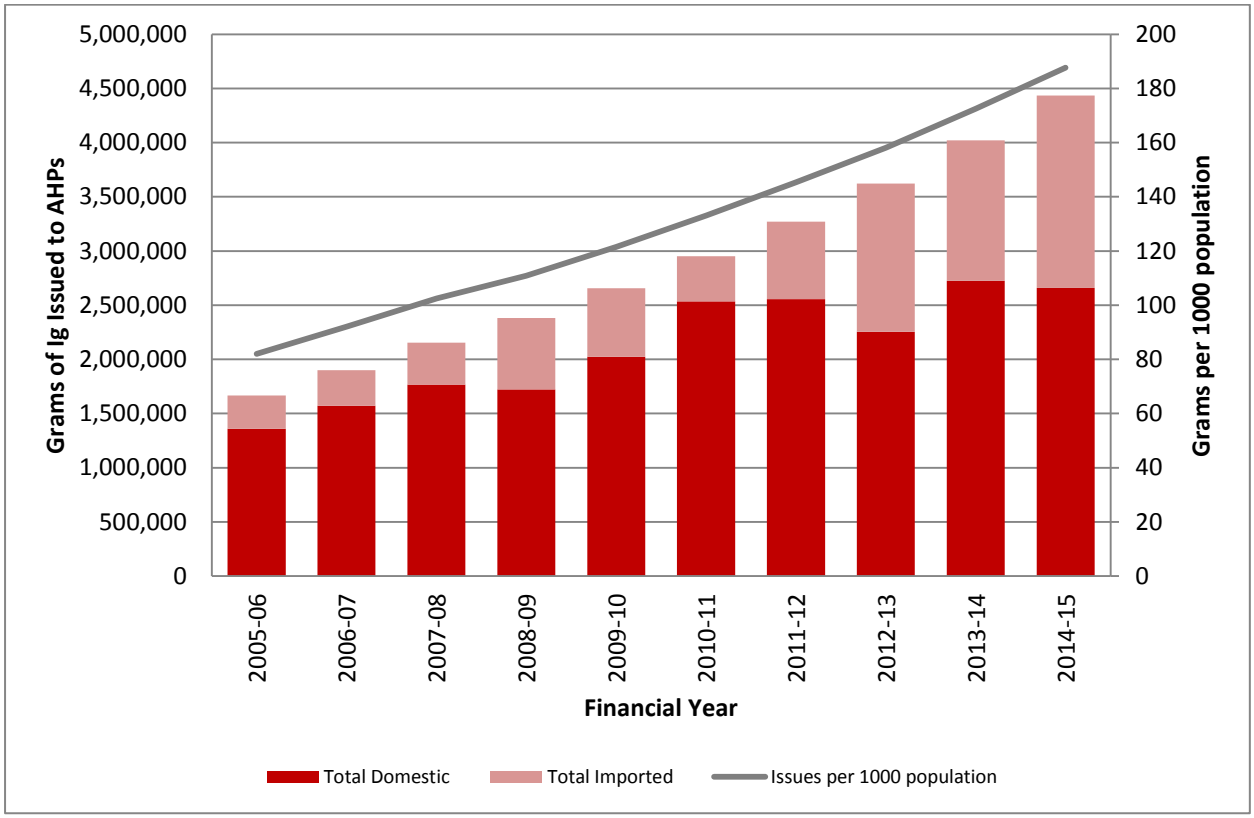


Figure 1 Ten year trends in issues of Ig

Table 1 Growth in Ig grams issued since 2005

	2005-06	2006-07	2007-08	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15
Growth from previous year	16%	14%	13%	11%	12%	11%	11%	11%	11%	10%
Average Growth from 2005-06		14%	15%	14%	15%	15%	16%	17%	18%	18%
Total grams per 1,000 population	82	92	102	111	121	133	145	158	172	188
Increase in grams per 1,000 population over previous year	15%	12%	11%	8%	10%	10%	9%	9%	9%	9%

There has been a steady increase in demand for Ig over the last ten years, with increases of 10-11% per annum for the last five years. While a small proportion of this increase may be attributable to population increases, there has also been a steady increase of 8-10% per annum in the use of Ig per

capita (Table 1) since the introduction of the *Criteria* in 2008. A breakdown of the year on year change in grams issued by state and territory has been provided in Table 2. Queensland has been growing at the fastest rate, closely followed by Victoria and New South Wales. Further information about the breakdown of domestic and imported Ig by state over time can be found in **Appendix E**.

Table 2 Percentage change in grams issued over time by state and territory

	NSW	VIC	QLD	WA	SA	TAS	NT	ACT
2005-06	14%	15%	15%	8%	20%	3%	3%	22%
2006-07	13%	20%	18%	10%	-11%	30%	-16%	12%
2007-08	18%	8%	16%	6%	14%	5%	1%	29%
2008-09	15%	3%	14%	0%	23%	14%	54%	-14%
2009-10	13%	11%	15%	-4%	12%	7%	-18%	20%
2010-11	11%	10%	16%	10%	-4%	8%	7%	28%
2011-12	11%	7%	16%	6%	9%	1%	47%	17%
2012-13	11%	13%	11%	7%	9%	-6%	21%	12%
2013-14	10%	11%	12%	15%	6%	14%	12%	1%
2014-15	9%	11%	12%	7%	12%	8%	8%	8%

FINANCIAL TRENDS

The increase in demand for Ig places a financial burden on the Australian health system. In Australia, the total cost of domestic Ig supply comprises the cost of the plasma collected by the Blood Service, plus the cost of purchase of the finished Ig product from the supplier (CSL Behring). Imported plasma is purchased at a total product cost only.

Total expenditure on Ig (excluding plasma for fractionation) in 2014-15 was $273.1 million, an increase of $28.7 million (11.7%) over 2013-14 (Figure 2). The increased expenditure predominately represents increases in demand.

There has also been an increase in the price of plasma for fractionation due to the increased ratio of apheresis to whole blood plasma for fractionation being supplied, resulting in an increase in the cost of domestic Ig. Combined with expenditure for plasma for fractionation, Ig accounts for a total expenditure of $484.1 million (excluding hyperimmune plasma for fractionation).

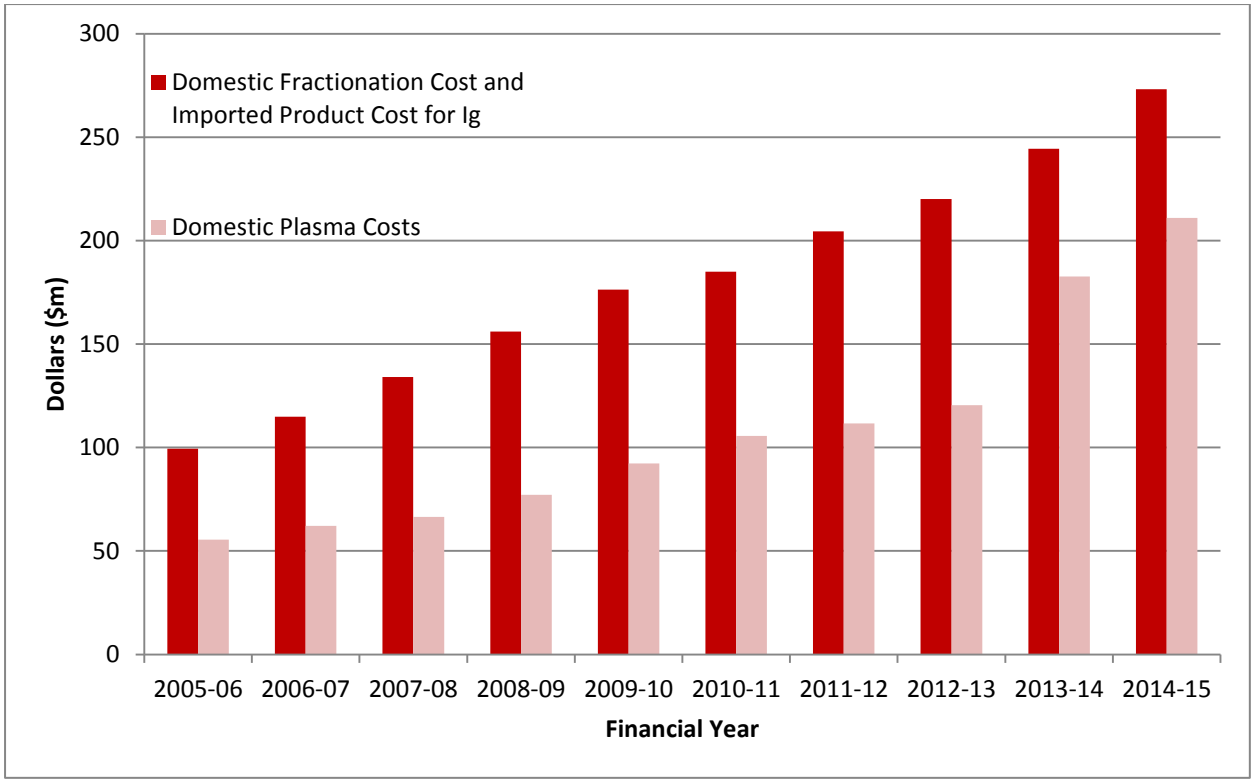


Figure 2 **Ten year trends in expenditure on Ig**

Demographics

PATIENT NUMBERS

A total of 14,983 patients were issued Ig under national blood arrangements during 2014-15 for 140,855 treatment episodes. This represents a 7.2% increase in the number of patients since 2013-14. A summary of some patient numbers is provided in Table 4. A breakdown of unique patients by state and territory and quarter is provided in **Appendix F**.

Table 3 Annual numbers of patients, treatment episodes and grams

Year	Patients	Treatment Episodes	Total Grams Issued
2008-09	9,870	77,212	2,380,257
2009-10	10,537	85,299	2,655,184
2010-11	11,492	93,893	2,950,371
2011-12	12,127	101,388	3,271,309
2012-13	13,102	110,183	3,622,433
2013-14	13,981	122,791	4,021,861
2014-15	14,983	140,855	4,433,146

Table 4 Basic numbers

	2014-15
Total unique patient IDs with some weight data	14,658
Total unique patient IDs with an age recorded	14,983
Total unique patient IDs with a weight change	781
Total unique patient IDs with more than one state or territory	180
Total unique patient IDs with two states or territories	170
Total unique patient IDs with three or more states or territories	10
Total unique patient IDs with more than one condition	377
Total unique patient IDs with two conditions	367
Total unique patient IDs with three conditions	9
Total unique patient IDs with four or more conditions	1
Total unique patient IDs aged 93 or older	45

Note: The above table calculations relate to only 2014-15 patients unlike previous reports where it included multiple years of data

GEOGRAPHIC DISTRIBUTION

Nationally, 0.6 patients per 1,000 population received Ig in 2014-15. This varied between states and territories, ranging from 0.3 in Western Australia to 0.8 in Queensland (Figure 3). All states and territories other than the Australian Capital Territory show an increase in the number of patients per 1,000 population over the previous year.

Details on the number of patients by condition are at **Appendix D.**

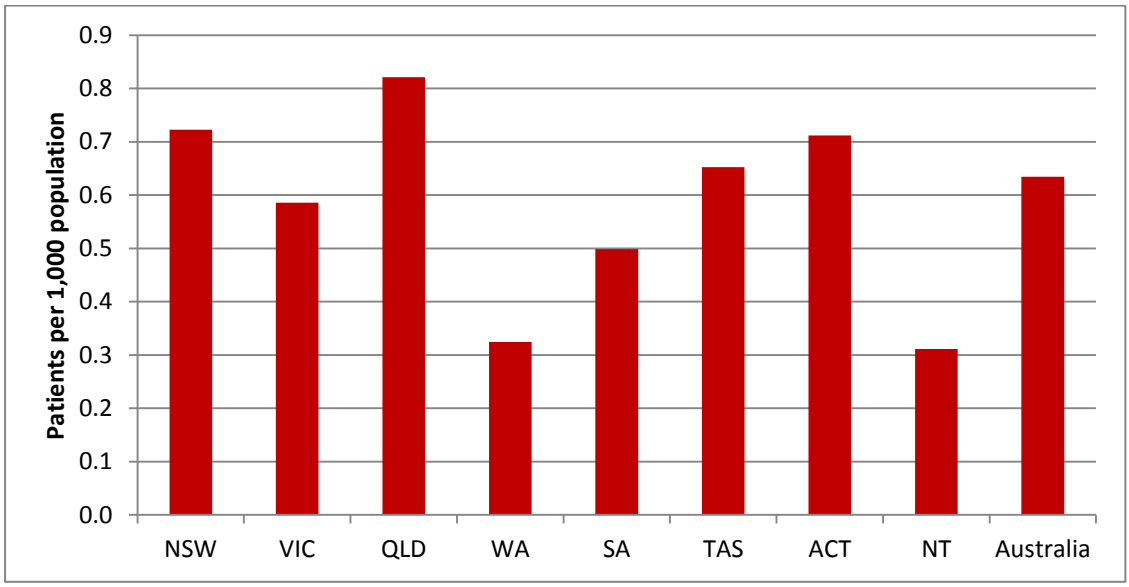


Figure 3 Patients per 1,000 population 2014-15

There is significant variation between jurisdictions in Ig use in grams per 1,000 population, ranging from 72.6 in the Northern Territory to 251.3 in Queensland (**Figure 4**). Rates for the smaller population states and territories must be viewed with some caution as there are many factors that could contribute to their different use patterns, such as patients travelling to larger states for specialist treatment. Comparing only the five largest Australian states, the variation in Ig use is 2.4 fold, ranging from 103.7 grams per 1,000 population in Western Australia to 251.3 grams per 1,000 population in Queensland. The reason for this inter-state and territory variation is unknown. The lower use may represent appropriate management and prescribing practices, or may represent a level of under-diagnosis.

Over time, Western Australia has shown only slight increases in the number of grams issued per 1,000 population, while most states and territories have seen a continued strong increase in Ig issued per 1,000 population.

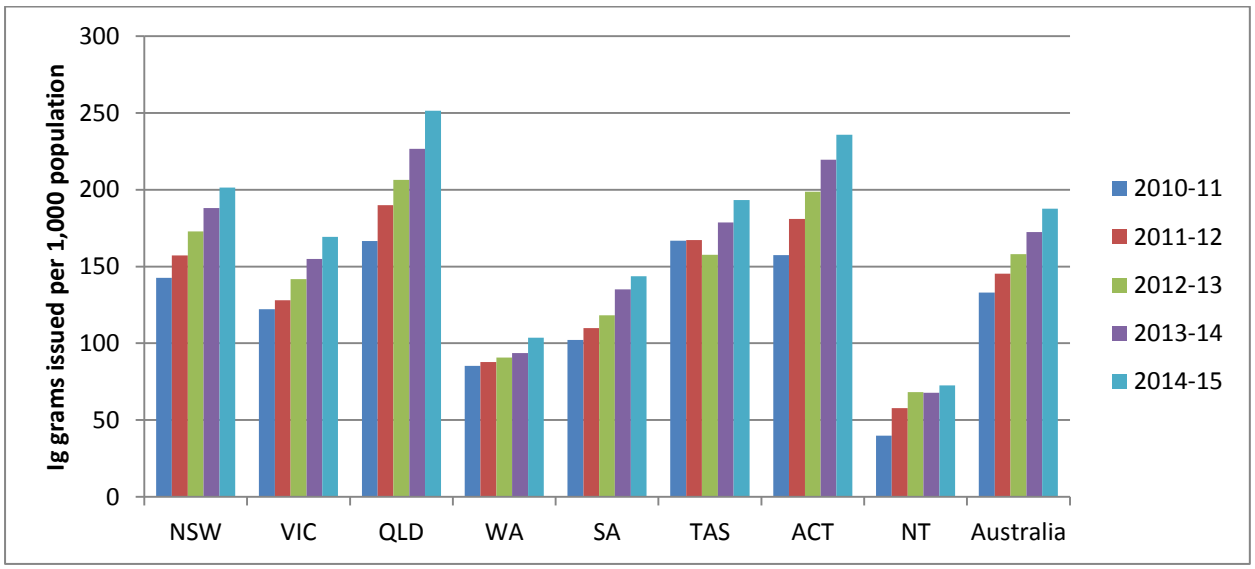


Figure 4 Grams of Ig per 1,000 population by state and territory over time

AGE

The distribution of estimated age is shown in Figure 5 where it is compared with the age distribution of the Australian population at June 2013[1]. A bimodal peak can be seen in the Ig population, with the majority of recipients either being very young, or over 55. The ageing population is expected to place a greater burden on Ig demand into the future, with the proportion of the world's population over 60 years expected to double between 2000 and 2050[2].

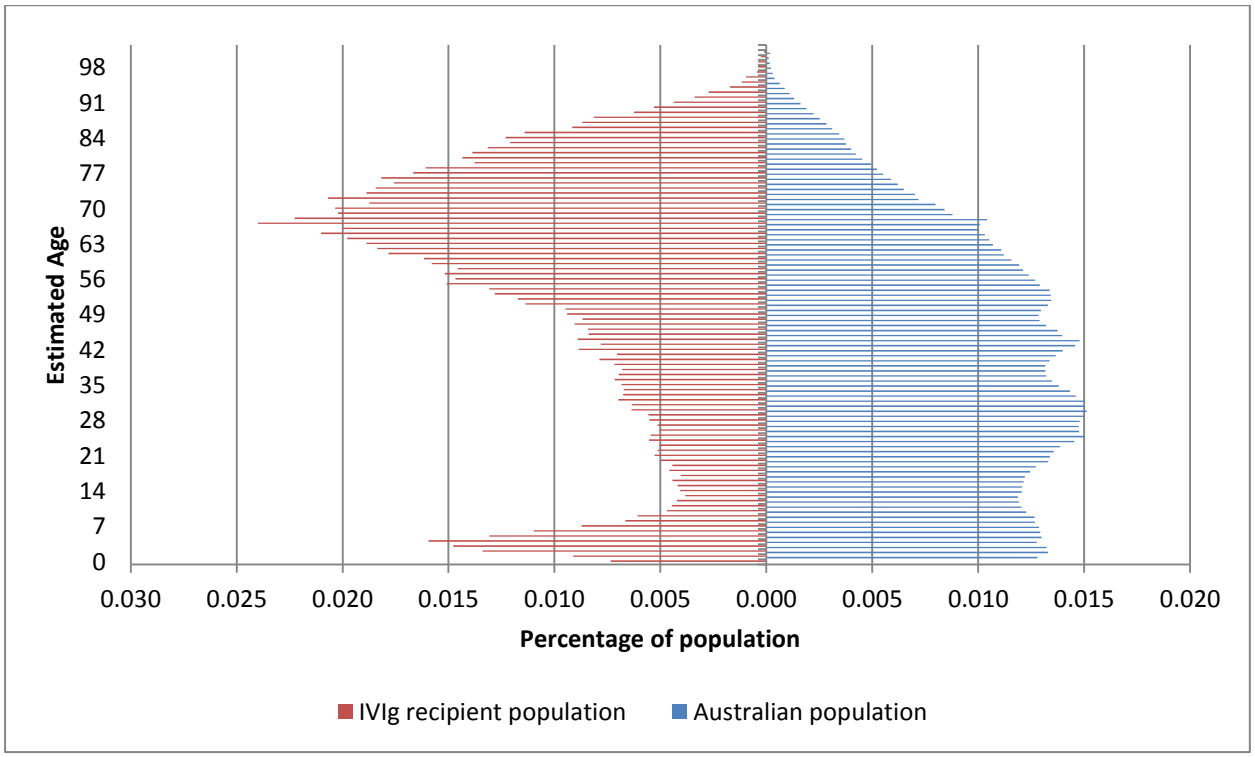


Figure 5 Patient age compared to average Australian age

WEIGHT

Ig dosing is dependent on the weight of the patient. For immune replacement conditions, the patient weight determines the initial dosing, with maintenance therapy titrated against IgG levels and the patient's clinical response to therapy. However, for conditions where Ig is used for its immunomodulatory properties, the *Criteria* limits the dose that can be prescribed based on the patient weight alone.

[1] ABS 3101.0

[2] World Health Organisation, http://www.who.int/ageing/en/ (Accessed 26 Feb 2014)

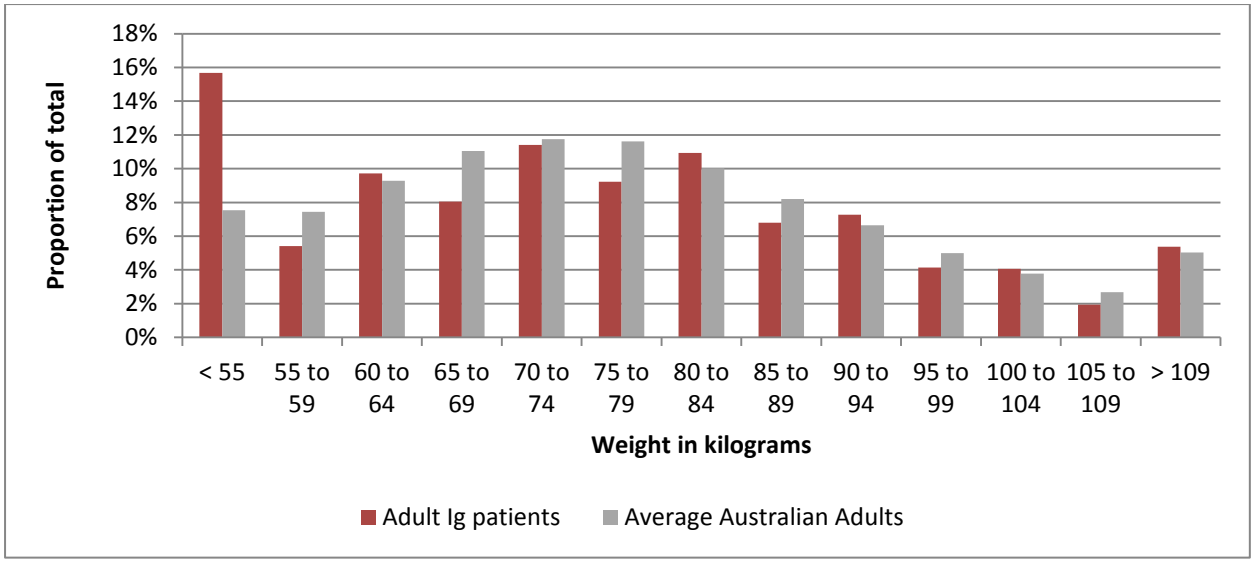


Figure 6 Patient weights relative to Australian average

Note: The above figure calculations relate to only 2014-15 patients unlike previous reports where it included multiple years of data

Figure 6 compares the weight of Ig recipients in Australia and the Australian population[3]. There is a higher proportion of patients treated with Ig less than 55kg relative to the proportion in the Australian population. The average weight of adult Ig patients (77.6 kg) is slightly lower than the average weight of an Australian adult (77.7 kg[4]). Given that studies suggest that 63% of Australians are overweight or obese[5], the similarity in weight profiles between Ig recipients and the Australian population suggests that a large proportion of Ig recipients may also be overweight. While the current *Criteria* provides for dosing based on body weight, some limited studies suggest that dosing on lean body weight (ideal body weight) may be more appropriate. A small pilot study in Western Australia focussing on a narrow range of conditions suggested reductions of Ig dose of between 2.4% and 4.2% were achieved using a lean body dosing methodology[6]. However, this has not been published in peer review literature, was not a randomised controlled trial, and did not discuss whether there were differences in clinical outcomes between the two groups. With an increasingly obese population, we can expect increases in demand if total (rather than lean) body weight dosing is continued and review of the literature relating to lean body mass dosing should be considered for future iterations of the *Criteria.*

It should be noted that care should be taken when analysing the weights, not all patients have weight recorded and for those that do the weight recorded may not be recent.

[3] ABS 4841.0
[4] ABS 4841.0 (average of male and female)
[5] ABS 4364.0.55.001
[6] Aston, L 2012, *The effect of ideal body weight (IBW) adjusted dosing on the use of intravenous immunoglobulin (IVIg) in Western Australia*, Australian Red Cross Blood Service, Australia.

Expenditure

In 2014-15, Australian expenditure on Ig products was $273.1 million, with additional expenditure of $211.0 million on plasma for fractionation (excluding hyperimmune plasma for fractionation) collected by the Blood Service.

The cost of Ig as a proportion of the national blood budget is shown at Figure 7. Ig is the second largest budget item, representing 26% of the total budget for blood and blood products. Combined with expenditure for plasma for fractionation, Ig accounts for 47.9% of the total blood budget, at a total expenditure of $498.9 million (including hyperimmune plasma for fractionation).

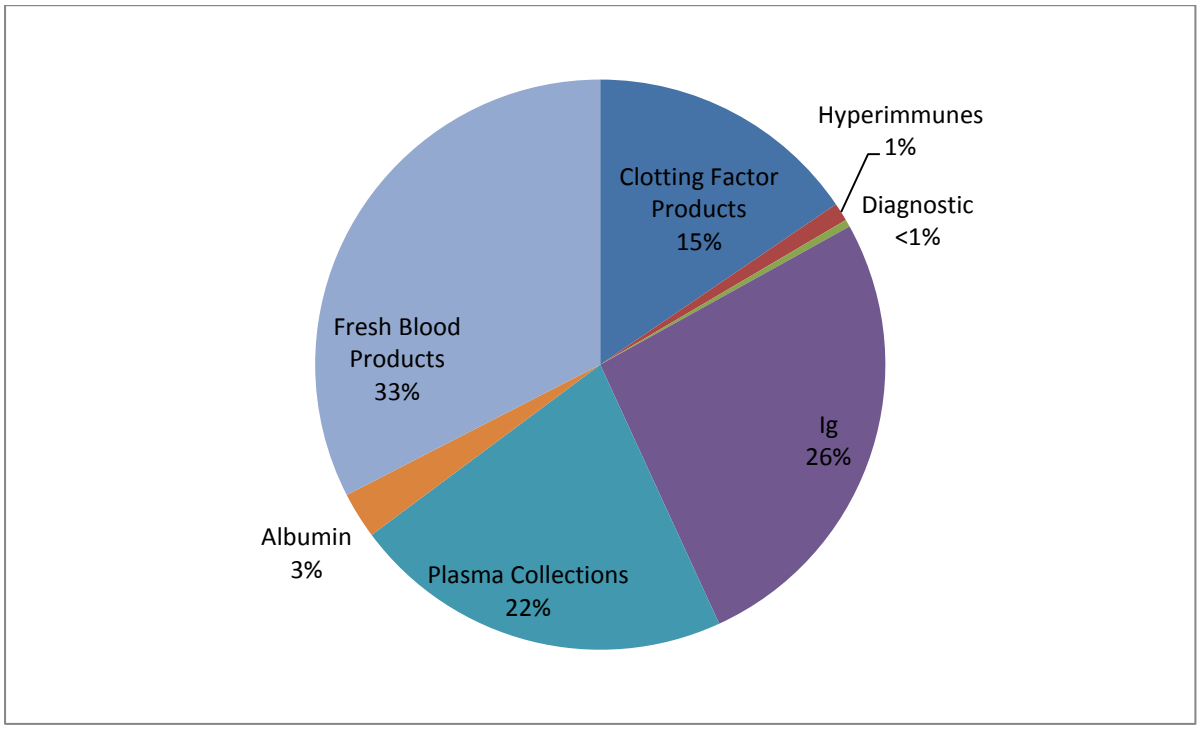


Figure 7 Ig expenditure as a proportion of the national blood budget

Of the Ig supplied under national blood arrangements in Australia, 60% (2,659,462 grams) was manufactured domestically and 40% (1,773,683 grams) was imported from overseas. This represents a 36.7% increase in product importation since 2013-14 (476,604 grams) (Table 5). Domestic supply is driven by the amount of plasma for fractionation collected in Australia and this increased by 4.9% in 2014-15 over 2013-14. Intragam P (IVIg) and Evogam (SCIg) are Ig products manufactured domestically in 2014-15. The imported products available were Kiovig (IVIg but can be administered subcutaneously) and Octagam (IVIg) and Gammanorm (SCIg). When a patient is allocated to receive one of the imported products it is the clinician's choice as to which product they order. Supply of Octagam constituted 62% of the supply of imported Ig.

Table 5 Issues of domestic Ig compared with imported Ig

			NSW	VIC	QLD	WA	SA	TAS	ACT	NT	AUS
Domestic Ig	Intragam P	g	919,806	573,195	724,434	150,903	130,551	57,453	59,178	4,863	2,620,383
		$(m)	$58	$36	$46	$10	$8	$4	$4	$0	$166
	Evogam	g	10,606	6,365	11,224	5,074	5,244	534	32	0	39,079
		$(m)	$1	$0	$1	$0	$0	$0	$0	$0	$2
	Total Domestic	g	930,412	579,560	735,658	155,977	135,795	57,987	59,210	4,863	2,659,462
		$(m)	$59	$37	$47	$10	$9	$4	$4	$0	$168
Imported Ig	Kiovig	g	164,798	144,581	162,867	40,370	103,877	3,920	22,770	12,671	655,853
		$(m)	$10	$9	$10	$2	$6	$0	$1	$1	$39
	Octagam	g	415,970	272,222	292,752	70,229	75	37,139	6,384	190	1,094,958
		$(m)	$25	$16	$17	$4	$0	$2	$0	$0	$65
	Gammanorm	g	12,278	66	2,571	972	3,391	549	3,046	0	22,872
		$(m)	$1	$0	$0	$0	$0	$0	$0	$0	$1
	Total Imported	g	593,045	416,868	458,189	111,570	107,343	41,608	32,199	12,861	1,773,683
		$(m)	$35	$25	$27	$7	$6	$2	$2	$1	$105
Proportion of domestic to imported Ig		g %	61%	58%	62%	58%	56%	58%	65%	27%	60%
		$(m) %	63%	60%	63%	60%	58%	60%	66%	29%	62%

Note: $(m) excludes the costs for plasma for fractionation.

Clinical Indications

IG ISSUES BY CRITERIA CHAPTER

The *Criteria* classifies conditions into four chapters based on the level of evidence supporting the use of Ig, as follows:

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

Ig was predominately issued for conditions within Chapter 5 (Table 6). The relative distribution by chapter has remained relatively stable since 2008, with a decrease in Ig issues for Chapter 8 conditions (Table 7).

Table 6 Ig issues (g) by Criteria chapter

	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15
Chapter 5	1,990,586	2,212,914	2,505,332	2,724,809	3,025,452	3,409,100	3,785,615
Chapter 6	345,176	371,832	397,231	444,605	453,352	463,361	494,489
Chapter 7	47,275	61,924	76,033	101,287	120,979	148,581	178,221
Chapter 8	3,326	2,550	2,574	1,909	39	0	0
Total	**2,386,361**	**2,649,462**	**2,981,385**	**3,272,930**	**3,599,831**	**4,021,042**	**4,458,326**

Table 7 Ig issues by Criteria chapter (percentage)

	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15
Chapter 5	83%	84%	84%	83%	84%	85%	85%
Chapter 6	14%	14%	13%	14%	13%	11%	11%
Chapter 7	2%	2%	3%	3%	3%	4%	4%
Chapter 8	<1%	<1%	<1%	<1%	<1%	0%	0%

For conditions where Ig is used only in exceptional circumstances (Chapter 7), four diagnostic groups accounted for 57.5% of those issues. These conditions were Limbic Encephalitis – nonparaneoplastic (36,076g), Solid organ transplant – lung (16,311g), Pyoderma gangrenosum (13,256g) and Sjogren's Syndrome (9,761g). While use in these conditions represents a small proportion of total Ig use, closer examination may be warranted. For example, approximately 140 lung transplants are performed in Australia every year[7], and 94 patients received Ig for this indication, meaning that more than half of these patients received Ig.

Both Limbic Encephalitis – nonparaneoplastic and Pyoderma gangrenosum have tripled in grams issued since 2012-13 and doubled in patient count.

While Ig may be issued in life threatening situations prior to diagnosis or in situations where the diagnosis is unclear at the time of treatment, in 2014-15 there were no cases where Ig was supplied for a condition not in the *Criteria* (excluding Direct Orders where alignment with the *Criteria* is not required as it is not funded under the national blood arrangements). However, data to support compliance with all aspects of qualifying criteria for each condition is not always collected.

IG ISSUES BY DIAGNOSTIC GROUPS

The top ten diagnostic groups account for 88.1% of all Ig supplied, with the top three diagnostic groups accounting for 57.7%.

Acquired hypogammaglobulinaemia secondary to haematological malignancies is the diagnostic group for which the greatest percentage of Ig was issued in 2014-15 (22.0%), closely followed by chronic inflammatory demyelinating polyneuropathy (21.9%). Primary immunodeficiency diseases accounted for 13.8% of total Ig use (Figure 8, Table 8).

Since 2009 there has been a 1.6 fold increase in Ig issues for both acquired hypogammaglobulinaemia secondary to haematological malignancies and chronic inflammatory demyelinating polyneuropathy, and a 1.3 fold increase in issues for primary immunodeficiency diseases. This is compared with the 1.5 fold increase in Ig over this period for all conditions.

[7] 2013, *Lung Transplantation Fact Sheet*, Lung Foundation, Australia.

Secondary hypogammaglobulinaemia falls into the top ten diagnostic groups, in spite of being a condition where the evidence for use is emerging (Chapter 6). Further iterations of the *Criteria* will need to consider whether the recent literature supports continued issues for this diagnostic group. The increase in issues of secondary hypogammaglobulinaemia is largely in New South Wales, where there has been a 361% increase between 2008-09 and 2014-15, associated with a concurrent increase in patient numbers (increase of 153%). The grams issued per patient has increased by 82%. However there has been a large increase in grams per 1,000 population from 1.5 to 6.6. Other states and territories have not had changes as large as New South Wales.

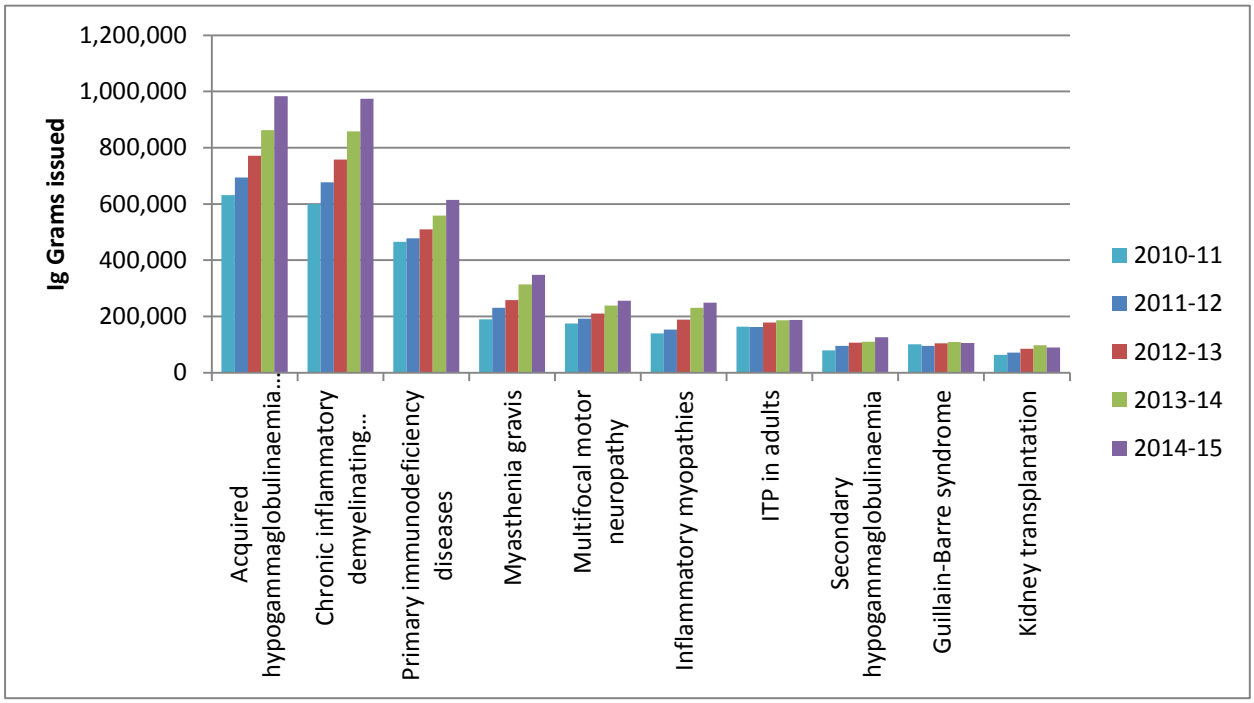


Figure 8 **Ig grams issued by diagnostic group**

Table 8 Ig grams issued for top 10 diagnostic groups over time

	2010-11	2011-12	2012-13	2013-14	2014-15
Acquired hypogammaglobulinaemia secondary to haematological malignancies	631,689	694,640	771,071	862,898	982,773
Chronic inflammatory demyelinating polyneuropathy	599,181	677,458	758,271	857,533	974,258
Primary immunodeficiency diseases	465,424	477,461	509,364	558,617	614,781
Myasthenia gravis	189,771	231,064	257,966	313,940	348,336
Multifocal motor neuropathy	175,176	192,109	209,791	239,314	256,041
Inflammatory myopathies	139,195	153,931	188,362	230,473	249,229
ITP in adults	163,905	162,098	178,738	186,640	187,621
Secondary hypogammaglobulinaemia	79,151	95,183	106,484	110,024	126,561
Guillain-Barre syndrome	101,014	95,359	104,360	108,929	105,567
Kidney transplantation	63,480	71,922	84,931	97,070	90,031

IG ISSUES BY CONDITION

Table 9 provides an overview of the conditions that use the most Ig, including data on total Ig use, patient numbers and median birth year. These conditions account for 88.4% of all Ig supplied, with the top ten conditions accounting for 75.0%. This data is also replicated in Figure 9 for the top 10 conditions.

Table 9 Patient numbers and age for the top 20 conditions

Conditions (Top 20)	Ig g (% of total)	Patients n (% of total)	Median Age
Chronic inflammatory demyelinating polyneuropathy	974,258 (22%)	2,054 (14%)	64
Common variable immunodeficiency disease	537,584 (12%)	1,656 (11%)	54
Myasthenia gravis	348,336 (8%)	818 (5%)	63
Chronic lymphocytic leukaemia	315,205 (7%)	1,283 (9%)	72
Non-Hodgkins lymphoma	287,900 (6%)	1,208 (8%)	68
Multifocal motor neuropathy	256,041 (6%)	444 (3%)	57
Multiple myeloma	255,962 (6%)	1,100 (7%)	71
Polymyositis	135,102 (3%)	341 (2%)	64
Secondary hypogammaglobulinaemia (excludes haem malignancies)	126,561 (3%)	580 (4%)	60
Guillain-Barré syndrome	105,567 (2%)	628 (4%)	55
Kidney transplantation post-transplant	83,131 (2%)	335 (2%)	50
Other relevant haematological malignancies	80,969 (2%)	428 (3%)	64
ITP refractory	74,228 (2%)	468 (3%)	64
Specific antibody deficiency	63,646 (1%)	252 (2%)	57
ITP in specific circumstances (surgery, corticosteroids contraindicated, chronic ITP)	58,430 (1%)	372 (2%)	59
Dermatomyositis	57,451 (1%)	161 (1%)	57
Inclusion body myositis	56,676 (1%)	140 (1%)	70
HSCT - post	42,738 (1%)	307 (2%)	52
ITP with life-threatening haemorrhage	42,394 (1%)	297 (2%)	66
X linked agammaglobulinaemia	36,945 (1%)	113 (1%)	24

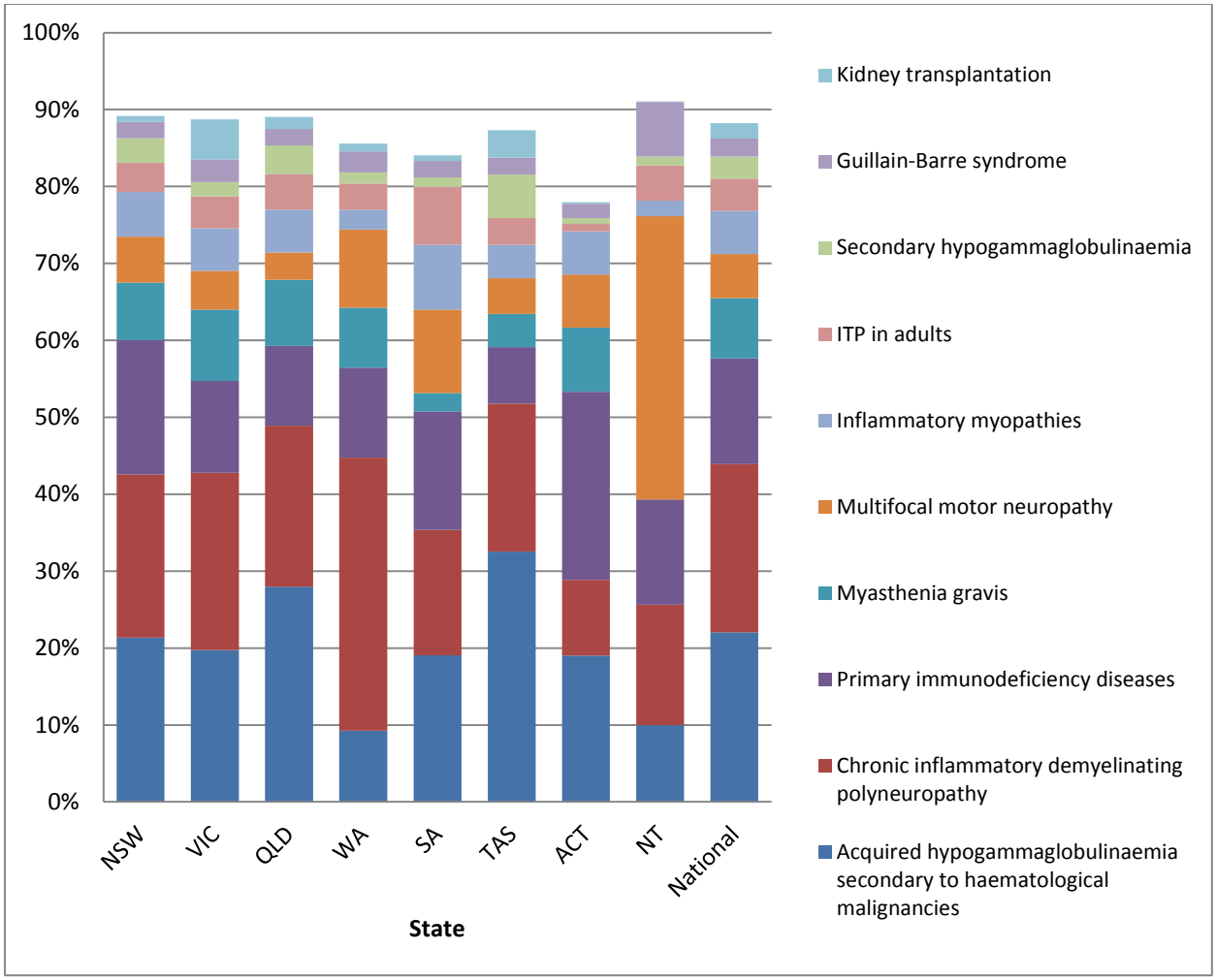


Figure 9 **Proportion of Ig used for top 10 conditions**

Population based data on Ig issues is particularly interesting for conditions where the majority of patients receive Ig as it can provide an estimation of disease prevalence. One condition for which Ig would be prescribed for the vast majority of diagnosed patients is common variable immunodeficiency disease.

Ig was supplied for 1,656 patients with common variable immunodeficiency disease. The estimated prevalence of common variable immunodeficiency disease as measured by patients treated with Ig for this indication is 6.6 per 100,000 population (ranging from 1.2 to 17.0 per 100,000 population across Australian states and territories and 4.7 to 10.5 if ACT, NT, TAS and WA are excluded).

For common variable immunodeficiency disease, this estimate is higher than other studies suggest with estimates between 2 and 4 people per 100,000 population[8]. The ability to calculate accurate prevalence estimates is important for health service planning. It should be noted that the prevalence estimate is for diagnosed and treated patients only, and studies suggest that for common variable immunodeficiency disease there is likely to be a large population of undiagnosed patients who would benefit from treatment with Ig.

[8] Cunningham-Rundles, C 2012, *The many faces of common variable immunodeficiency*, American Society of Hematology, USA.

IG ISSUES BY CLINICAL DISCIPLINE

The number of grams of Ig issued categorised according to clinical discipline is shown in Figure 10. Some conditions are classified as mixed, in that they fall across more than one clinical discipline. Other conditions fall within a clinical discipline other than neurology, haematology or immunology, such as use in transplants or dermatology. These are considered under 'Other' in Figure 10. Table 10 replicates this data.

Since 2009, there has been a 1.7 fold increase in Ig issues for neurological conditions, compared with a 1.4 fold increase for haematological conditions and a 1.3 fold increase for immunological conditions.

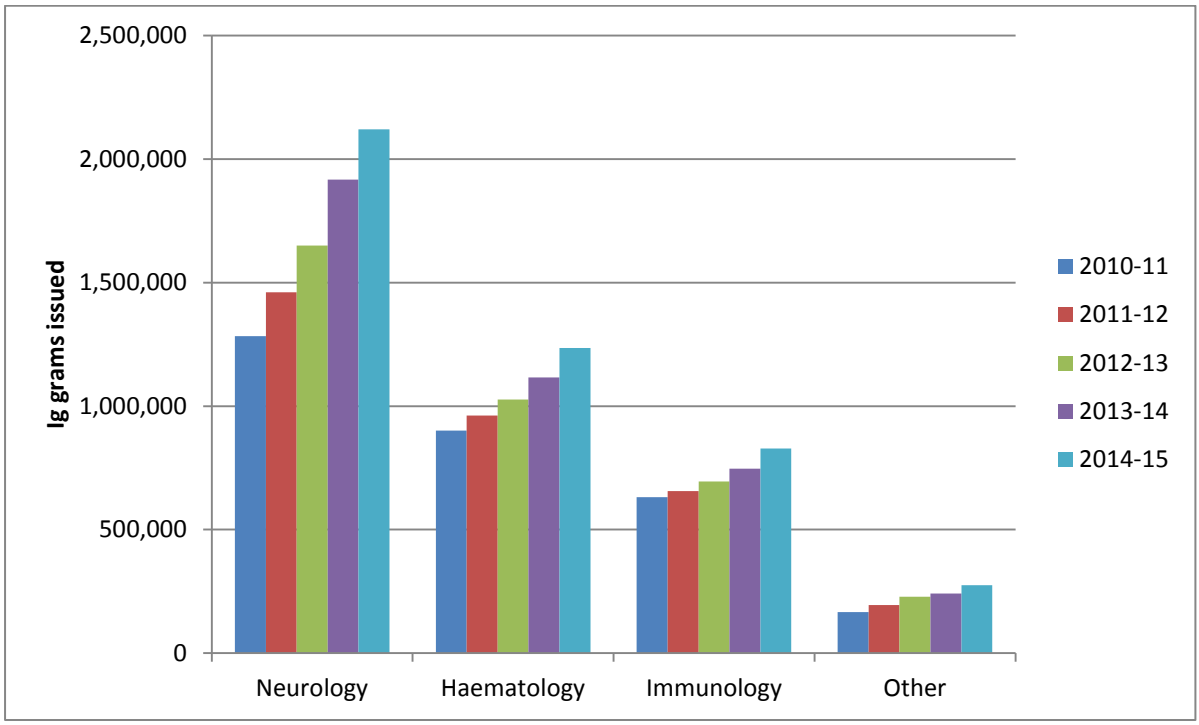


Figure 10 Ig issues by clinical discipline

Table 10 Ig grams issued by clinical discipline

	2010-11	2011-12	2012-13	2013-14	2014-15
Neurology	1,283,190	1,460,702	1,649,358	1,916,792	2,120,111
Haematology	900,826	961,366	1,026,219	1,116,037	1,234,816
Immunology	631,076	656,179	695,298	746,828	828,735
Other	166,079	194,363	228,947	241,386	274,664

There is significant variation across Australia in Ig use for each clinical discipline. Figure 11 shows that in Western Australia issues for neurological conditions represent a greater proportion of total issues than for other states. The proportional use for immunological conditions is much lower in Queensland and Tasmania than other states, with use of Ig for haematological conditions prevailing in these two states. The reason for this inter-state and territory variation is unknown, but it may represent differences in

clinician practice, different patient populations or may indicate differences due to availability of specialist services across Australia.

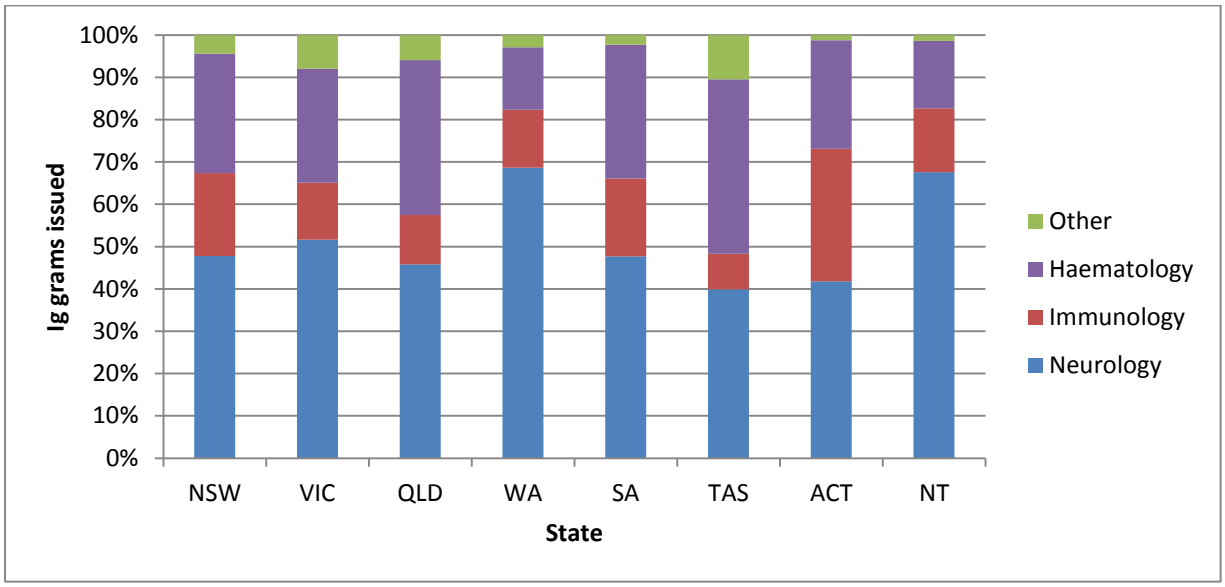


Figure 11 Ig issues by clinical discipline for top 10 conditions by state and territory

IG GRAMS ISSUED PER 1,000 POPULATION

The amount of Ig issued per 1,000 population for each indication varies between state and territory. Complete data for conditions for each state and territory can be found at **Appendix D** and is summarised in for the conditions using the most Ig. Table 11 shows a breakdown of the proportion of Ig issued in each state and territory with a comparison to the proportion of the population in each state and territory.

The highest variation between states and territories in Ig use per capita is seen in Chronic Inflammatory Demyelinating Polyneuropathy followed by Non-Hodgkin's lymphoma. There were a low number of Ig issues per capita in South Australia and Western Australia respectively, and high use in Queensland. The reason for the significant variation between these states is unknown, and further studies may be required to ascertain the significance of this finding. Interestingly, the difference appears to be attributed to a greater number of patients, rather than higher dosing, with the dosing in South Australia being higher than Queensland for Chronic Inflammatory Demyelinating Polyneuropathy (**Appendix D)**.

Table 11 Grams of Ig issued by state and territory

2013-14	Ig issued (g)	Proportion of total Ig issued	Proportion of Australian population	Grams per 1,000 population
NSW	1,523,456	34%	32.0%	201
VIC	996,428	22%	24.9%	169
QLD	1,193,847	27%	20.1%	251
WA	267,548	6%	10.9%	104
SA	243,138	5%	7.2%	144
TAS	99,595	2%	2.2%	193
ACT	91,409	2%	1.6%	236
NT	17,724	0%	1.0%	73
Total	**4,433,146**	**100%**	**100%**	**188**

The following tables (Table 12, Table 13, Table 14, Table 15 and Table 16) show the patient numbers for states and territories over time for specific conditions.

Table 12 Patient numbers by state and territory: chronic inflammatory demyelinating polyneuropathy

Chronic inflammatory demyelinating polyneuropathy	2010-11	2011-12	2012-13	2013-14	2014-15
NSW	539	598	652	704	772
VIC	339	372	421	447	464
QLD	312	386	485	529	580
WA	90	99	105	108	123
SA	70	73	80	81	81
TAS	33	30	33	37	32
ACT	14	17	22	28	27
NT	<5	5	7	4	8
Australia	**1,372**	**1,551**	**1,753**	**1,903**	**2,054**

Table 13 Patient numbers by state and territory: common variable immunodeficiency disease

Common variable immunodeficiency disease	2010-11	2011-12	2012-13	2013-14	2014-15
NSW	562	617	650	721	793
VIC	225	232	241	265	276
QLD	251	276	311	317	338
WA	58	61	67	78	88
SA	107	102	101	110	110
TAS	18	20	21	25	25
ACT	50	54	58	60	66
NT	5	5	<5	<5	<5
Australia	**1,247**	**1,323**	**1,406**	**1,543**	**1,656**

Table 14 Patient numbers by state and territory: myasthenia gravis

Myasthenia gravis	2010-11	2011-12	2012-13	2013-14	2014-15
NSW	179	219	235	267	297
VIC	122	141	177	186	199
QLD	142	181	199	212	245
WA	40	36	39	51	41
SA	24	19	17	14	17
TAS	15	17	10	10	11
ACT	5	10	13	14	16
NT					
Australia	**521**	**609**	**671**	**747**	**818**

Table 15 Patient numbers by state and territory: chronic lymphocytic leukaemia

Chronic lymphocytic leukaemia	2010-11	2011-12	2012-13	2013-14	2014-15
NSW	368	381	394	431	483
VIC	233	230	225	271	290
QLD	265	283	297	292	318
WA	35	48	41	45	64
SA	85	79	79	86	77
TAS	32	31	31	34	34
ACT	21	25	29	30	31
NT	<5	5	5	6	9
Australia	**1,024**	**1,060**	**1,078**	**1,179**	**1,283**

Table 16 Patient numbers by state and territory: multiple myeloma

Multiple myeloma	2010-11	2011-12	2012-13	2013-14	2014-15
NSW	304	324	378	389	425
VIC	161	153	157	176	215
QLD	307	330	346	360	365
WA	16	15	16	20	23
SA	16	17	22	24	25
TAS	58	51	47	42	39
ACT	21	14	10	10	14
NT	<5	<5	<5	<5	
Australia	**878**	**901**	**969**	**1,012**	**1,100**

Table 17 Ig issued per 1,000 population by state and territory for top 10 conditions

Condition	NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National	Fold Variation*
Chronic inflammatory demyelinating polyneuropathy	44	39	52	37	24	38	23	11	41	2
Common variable immunodeficiency disease	33	15	23	11	20	14	56	1	23	3
Myasthenia gravis	16	12	16	4	12	16	20	5	13	4
Chronic lymphocytic leukaemia	15	16	21	8	3	8	19	0	15	6
Non-Hodgkins lymphoma	10	10	26	2	8	16	13	0	12	11
Multifocal motor neuropathy	12	9	9	11	16	9	16	27	11	2
Multiple myeloma	12	8	21	1	3	25	8	0	11	16
Polymyositis	7	4	9	1	6	2	3	0	6	8
Secondary hypogammaglobulinaemia (excludes haem malignancies)	7	3	9	2	2	11	2	1	5	6
Guillain-Barré syndrome	4	5	5	3	3	4	4	5	4	2

*The Fold Variation in Table 17 is a measure describing difference in the Ig grams per 1,000 population between the state being issued the least to the state being issued the most, using only data from the five largest states. For example, a low value of 30 and a high value of 60 correspond to a fold variation of 2, or in common terms, a two-fold increase.

Dosing

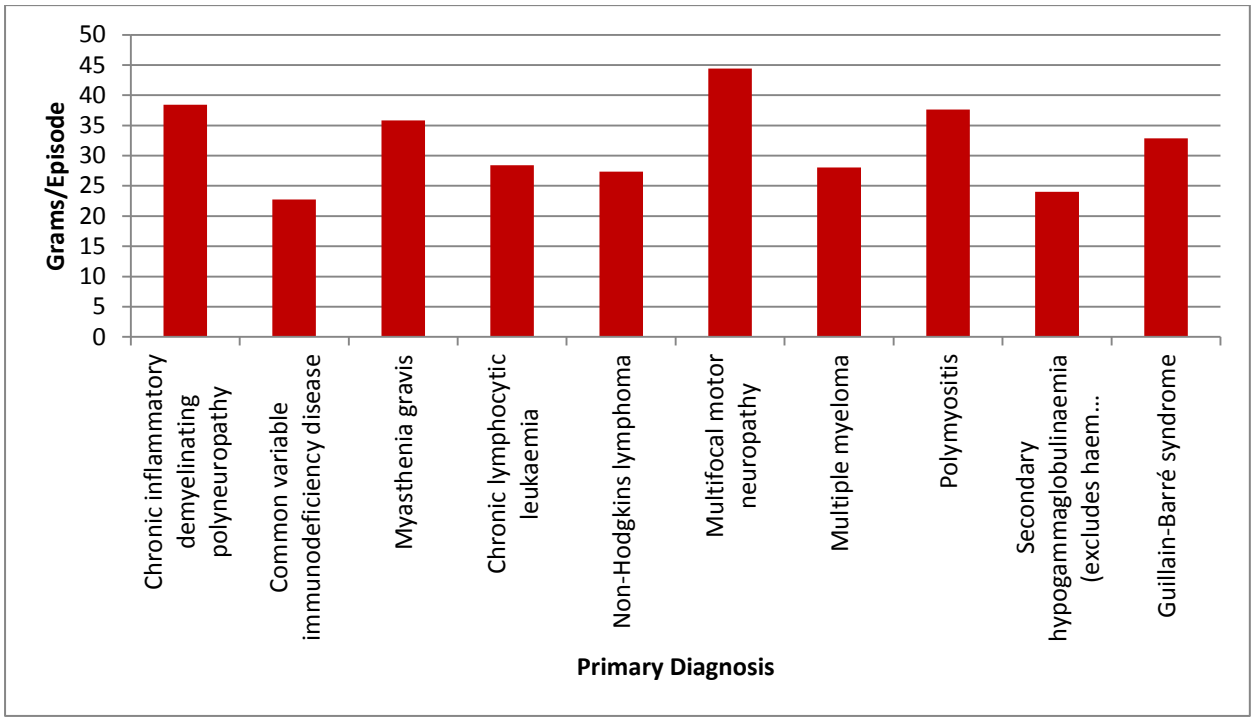


Figure 12 Grams per episode by condition

The data shows that there is significant variance in the dosing of the top 10 conditions; where dosing is calculated as number of grams administered in each episode (Figure 12). The definition of episode in the data is not uniform and therefore this data should be interpreted with caution. Variations are expected as the doses and frequency of dose varies as the underlying method for calculating the dose also varies. Also note that the *Criteria* requires the lowest possible dose to achieve the desired clinical outcome, so the 'dose' is not 'mandated' but rather suggested and guided to the lower end to achieve efficacy which may contribute to the differences in dosing between conditions. The dosing is stable compared to the 2013-14 year.

Dosing in the neurological conditions is higher than for other conditions, as provided for in the *Criteria.* For dosing information for other conditions refer to **Appendix D.**

The grams per kilogram were calculated for each infusion episode (Table 18). From this data it is difficult to assess whether the dosing strategy utilised was in accordance with that provided for under the *Criteria.* This is particularly difficult as the patient weight data is not updated for every episode and may change over time.

Table 18 Ig grams per episode

Condition	<=0.4 g/kg/episode n (%)	0.4 – 0.99 g/kg/episode n (%)	1 – 2 g/kg/episode n (%)	>2 g/kg/episode n (%)	No weight Data n(%)
Chronic inflammatory demyelinating polyneuropathy	8,198 (38%)	11,791 (55%)	906 (4%)	20 (0%)	501 (2%)
Common variable immunodeficiency disease	8,352 (46%)	8,178 (45%)	64 (0%)	1 (0%)	1,697 (9%)
Myasthenia gravis	3,394 (42%)	4,312 (53%)	235 (3%)	5 (0%)	120 (1%)
Chronic lymphocytic leukaemia	6,272 (58%)	4,312 (40%)	8 (0%)	0 (0%)	253 (2%)
Non-Hodgkin lymphoma	6,406 (63%)	3,580 (35%)	6 (0%)	0 (0%)	182 (2%)
Multiple myeloma	5,600 (62%)	3,219 (36%)	2 (0%)	0 (0%)	150 (2%)
Multifocal motor neuropathy	1,341 (28%)	2,837 (59%)	452 (9%)	3 (0%)	138 (3%)
Polymyositis	1,195 (38%)	1,749 (56%)	150 (5%)	2 (0%)	38 (1%)
Secondary hypogammaglobulinaemia (excludes haem malignancies)	2,699 (57%)	1,842 (39%)	68 (1%)	5 (0%)	99 (2%)
Guillain-Barré syndrome	356 (44%)	370 (46%)	74 (9%)	13 (2%)	0 (0%)

Products and Use

In March 2013, the JBC approved the introduction of SCIg under the national blood arrangements. The first phase of implementation was through hospital-based management arrangements, with no additional cost to patients, and further work will be undertaken to support supply of SCIg for other pathways of care. In 2013-14 the NBA established arrangements for supply of the following SCIg products:

- Evogam 16% vial size 0.8g/5ml and 3.2g/20ml supplied by CSL Behring (Australia) Pty Ltd (domestic)
- Gammanorm 16% 1650mg/10ml and 3300mg/20ml supplied by Octapharma Australia Pty Ltd (imported)
- Kiovig 10% 1g/10ml, 2.5g/25ml, 5gm/50ml, 10g/100ml and 20g/200ml supplied by Baxter Healthcare (imported)

These products are authorised and distributed by the Blood Service in the same manner as IVIg.

The following tables show the patient numbers, grams issued by states and territories or by condition for IVIg and SCIg products in 2014-15.

Table 19 Patient numbers for products issued by state and territory in 2014-15

	IVIg				SCIg			
State	**Intragam P**	**Kiovig 10%**	**Octagam 5%**	**Octagam 10%**	**Evogam**	**Gammanorm**	**Kiovig 10%**	**Total**
NSW	3,730	527	758	544	49	60		5,480
VIC	2,002	461	717	346	44	<5		3,447
QLD	2,334	555	510	607	37	15	<5	<3,905
WA	550	130	116	61	32	6		844
SA	512	319	<5		27	9		<845
TAS	182	13	11	136	<5	5		<340
ACT	210	46	6	8	<5	9		<280
NT	40	39		<5				<80
AUS	**9,422**	**2,071**	**<2,210**	**<1,695**	**<190**	**<105**	**<5**	**<15,010**

Table 20 Grams of product issued by state and territory in 2014-15

	IVIg				SCIg			
State	Intragam P	Kiovig 10%	Octagam 5%	Octagam 10%	Evogam	Gammanorm	Kiovig 10%	Total
NSW	940,329	168,172	265,945	158,492	10,598	11,788	0	1,555,324
VIC	569,970	145,379	194,366	81,424	6,491	66	0	997,695
QLD	716,892	161,495	151,785	137,498	10,220	2,162	180	1,180,232
WA	153,162	40,767	54,349	16,634	4,973	1,011	0	270,895
SA	132,627	104,153	75	0	5,398	3,493	0	245,746
TAS	58,425	3,909	3,675	33,812	282	574	0	100,676
ACT	58,212	22,453	1,475	5,050	51	2,686	0	89,927
NT	4,905	12,786	0	139	0	0	0	17,830
AUS	**2,634,522**	**659,113**	**671,669**	**433,049**	**38,014**	**21,780**	**180**	**4,458,326**

Table 21 Patient numbers for products issued by diagnostic group in 2014-15

	IVIg				SCIg			
Diagnostic Group	Intragam P	Kiovig 10%	Octagam 5%	Octagam 10%	Evogam	Gammanorm	Kiovig 10%	Total
Acquired hypogammaglobulinaemia secondary to haematological malignancies	3,625	282	220	243	12	12		4,307
Chronic inflammatory demyelinating polyneuropathy	895	456	529	308				2,056
Primary immunodeficiency diseases	1,715	53	34	31	146	73	<5	<1,935
Myasthenia gravis	234	193	262	166				818
Multifocal motor neuropathy	170	125	125	46				444
Inflammatory myopathies	284	145	141	84				638
ITP in adults	466	285	217	230				1,150
Secondary hypogammaglobulinaemia	468	39	35	35	11	<5		<585
Guillain-Barré syndrome	143	169	178	149				628
Kidney transplantation	77	58	117	148				384
Specific antibody deficiency	264	10	14	5	16	13		309

Table 22 Grams of product issued by diagnostic group in 2014-15

	IVIg				SCIg			
Diagnostic Group	**Intragam P**	**Kiovig 10%**	**Octagam 5%**	**Octagam 10%**	**Evogam**	**Gammanorm**	**Kiovig 10%**	**Total**
Acquired hypogammaglobulinaemia secondary to haematological malignancies	857,700	50,759	34,282	36,189	2,158	1,686		982,773
Chronic inflammatory demyelinating polyneuropathy	441,324	185,068	235,047	112,819				974,258
Primary immunodeficiency diseases	533,871	14,490	8,903	8,812	31,909	16,617	180	614,781
Myasthenia gravis	102,399	79,827	105,593	60,517				348,336
Multifocal motor neuropathy	91,581	74,888	67,131	22,441				256,041
Inflammatory myopathies	113,055	59,362	51,366	25,446				249,229
ITP in adults	68,289	48,402	34,740	36,190				187,621
Secondary hypogammaglobulinaemia	102,942	8,040	8,346	4,537	1,261	1,436		126,561
Guillain-Barré syndrome	19,281	28,287	31,309	26,690				105,567
Kidney transplantation	15,372	11,671	28,840	34,149				90,031
Specific antibody deficiency	73,248	1,662	2,720	1,025	2,686	2,041		83,381

Appendix A – Background

Funding for Ig

Ig supplied under national blood arrangements is funded 63% by the Commonwealth government, with the remaining 37% being funded by the state and territory to which the product is supplied.

The Criteria

A process to review the Australian Health Ministers' Advisory Council (AHMAC) (2000) guidelines commenced in 2004. A result was the approval of the first edition of the *Criteria* by Health Ministers in December 2007. The first edition of the Criteria was made available to clinicians on 3 March 2008 and applied to all new patients from that date. For patients already receiving Ig for an indication not listed as being funded under national blood arrangements, a six month transition period was allowed to enable treatment strategies to be reviewed, with the exception of IgG subclass deficiency, where grandfathering of the use of Ig was permitted under defined circumstances.

The *Criteria* is a publication that describes the criteria that patients must meet to receive Ig that is funded by all Australian governments. Product is provided free of charge to all patients who have a condition meeting qualifying criteria for supply as outlined in the *Criteria*. The *Criteria* helps to ensure that Ig is accessed consistently across Australia for the treatment of patients whose health is likely to be improved with Ig therapy. The *Criteria* was developed using the best available medical evidence and expertise.

As part of the process to implement the new *Criteria*, the NBA established a clarification process in November 2008. A consultation group was consulted on specific queries that arose in relation to interpretation of the *Criteria.* Consideration of the queries and comments resulted in some amendments to specific indications in the *Criteria*. The revisions were published on the NBA's website in February 2009.

A review of the *Criteria* commenced in 2010. A National Ig Criteria Review Working Group was established to oversee the 2010–11 *Criteria* review process. The *Criteria* second edition was made available to clinicians on 10 August 2012 and applied to all new patients from that date. For patients already receiving Ig for an indication where the specific criteria have changed, a six month transition period was been allowed to enable treatment strategies to be reviewed, with the exception of IgG subclass deficiency patients, as described above.

Supply of Product

Immunoglobulin is made from donated human plasma. Australia has not been able to make enough Ig from Australian blood donations for a number of years. While NBA makes sure there is enough Ig by importing this product, there is a finite international supply.

There are two main ways Ig is available in Australia:

1. Supply under national blood arrangements

If the Ig is ordered to treat a medical condition which is funded under the *Criteria* then the product is supplied and funded under national blood arrangements. In this case the cost of the product is shared between the Commonwealth and the relevant state or territory.

Orders for Ig under national blood arrangements are made to the Blood Service, which is contracted by the NBA as the authoriser and distributor of all Ig funded under these arrangements. In seeking authorisation, the requesting clinician will be asked to provide information to the Blood Service to

establish that the request meets the *Criteria*. For ongoing conditions, the *Criteria* may specify review criteria to be applied in reviewing the patient to determine whether access to funded Ig will continue.

In the role as authoriser of requests for Ig, the Blood Service maintains a database of requests, and provides data to the NBA which is used as a basis for reporting on the annual use of Ig in Australia.

2. Direct order and other supply arrangements

If the Ig is to treat a medical condition that is not funded under the *Criteria*, then the individual state or territory may approve the accessing of product under the Direct Order arrangements established by the NBA, or the product may be ordered directly from a commercial supplier of Ig. In this case the supply of the product is not funded under national blood arrangements, and the cost must be met in some other way.

History

In **2003-04** the NBA coordinated demand management activities for two products in short supply; Biostate (plasma-derived Factor VIII) and Intragam P (plasma-derived Ig). At all times, the NBA successfully met the blood and blood product needs of all Australian states and territories through intensive management of the product, via its contracts with the Blood Service and CSL Limited and the importation of substitutable products from overseas. The NBA arranged for an imported product to be purchased to make up for the shortfall, and this product was made available to patients in March 2004.

In **2004-05** the NBA successfully negotiated a new Plasma Products Agreement with CSL Limited, which came into effect from 1 January 2005.

In December 2004 the NBA also signed a Standing Offer contract with CSL Limited (for the supply of Sandoglobulin), as well as with Octapharma Australia Pty Ltd (for the supply of Octagam) for a two-year period in order to allow access to imported Ig as a contingency supply if and when needed to supplement shortfalls in the domestic Ig supply. The Ig Standing Offer comprised two components, a National Blood Supply component whereby imported Ig was procured by the NBA for use under the National Blood Agreement (i.e. for those conditions covered under the nationally agreed cost sharing arrangements) and a Jurisdictional Direct Order component which allowed approved recipients to access imported Ig for all other conditions.

Ig had to be intensively managed again in 2004–05 due to ongoing increases in demand and indications for its clinical use for over 60 clinical syndromes and conditions.

As part of a strategic solution to the shortage of Ig, governments purchased imported Ig (Sandoglobulin®) in 2003 and placed it in the National Reserve of Plasma Products. In order to optimise the use of the stocks in the National Reserve, the NBA in conjunction with states and territories, the Blood Service and CSL Limited, developed and implemented a plan to rotate the Sandoglobulin® stocks out of the National Reserve. This rotation commenced in October 2004.

In **2005–06**, the challenges in supply of domestic Ig required the NBA to adopt the same intensive product management arrangements as it had in 2004-05 with the continued rotation of Sandoglobulin®.

In **2006-07** in order to ensure Ig remained available to all Australians, the NBA negotiated a further 12-month extension to the Ig Standing Offer in December 2006. A procurement process for the renewal of the standing offer arrangements commenced in early 2007.

Intensive product management was successfully undertaken in 2006–07 to avert a number of temporary and longer-term potential shortages, including shortages of Ig and plasma-derived Factor VIII.

In **2007-08** the NBA commenced a procurement process for new contracts in mid-2007. The outcome of the procurement was the finalisation of a new fixed price contract with Octapharma Australia Pty Ltd for the supply of Octagam for three years under the National Blood Supply arrangement. Octagam and a CSL Ltd imported product, Sandoglobulin Liquid, were also supplied under Direct Order arrangements negotiated by the NBA.

In **2008-09** the NBA continued imports of intravenous immunoglobulin to be able to meet domestic clinical demand.

During **2009–10** the plasma fractionation arrangements were governed by the five-year Plasma Products Agreement between the NBA and CSL Limited, which expired on 31 December 2009, and a new CSL Australian Fractionation Agreement which took effect on 1 January 2010.

The contract with Octapharma Australia Pty Ltd for the supply of Octagam was due to expire on 31 December 2010, with the NBA having an option to extend the contract by one year. In May 2010 the NBA moved to exercise the option to extend the current contract with Octapharma Australia Pty Ltd, with improved value for money, for a further 12 months.

A contract with CSL Limited for the supply of Sandoglobulin NF (nanofiltration) Liquid under the Direct Order arrangement expired at the end of December 2009.

The NBA entered into a three-year contract with Lateral Grifols Pty Ltd for the supply of Flebogamma 5% DIF (dual inactivation plus nanofiltration) under Direct Orders, which commenced on 1 January 2010.

During **2010-11** imported intravenous immunoglobulin continued to supplement domestic Ig production to meet clinical demand in Australia. In September 2010, Octapharma issued a nationwide voluntary recall of Octagam due to production concerns. To enable domestic demand to be met, the NBA invoked relevant clauses that had been included in the contract with Lateral Diagnostics to allow supply of Flebogamma through national blood arrangements (in addition to the Direct Orders supply). Lateral Diagnostics, working with the Spanish-based manufacturer of Flebogamma, Grifols S.A., responded rapidly and fully to the NBA's additional requirements and this arrangement continued for the remainder of the year. The voluntary recall of Octagam was still in place in Australia at 30 June 2011.

In **2011-12** CSL Limited experienced a decline in its immunoglobulin (IgG) yield. As a result of the reduction in yield, and other logistical factors, CSL Limited was unable to supply Intragam P 200ml from its working inventory against the full annual supply estimate amounts. The NBA also gave approval for CSL Limited to access the Minimum Product Inventory and the National CSL Reserve to augment supply. By the end of June 2012 CSL Limited had fully restocked the Minimum Product Inventory and the National CSL Reserve, although the NBA continued to carefully manage the planned supply of Intragam P in 2012-13.

The Therapeutic Goods Administration (TGA), Australia's national regulator for drugs and regulatory devices, approved the re-introduction of Octagam 5% in October 2011 following the voluntary recall of product in September 2010. The NBA worked with the Blood Service, Octapharma Australia Pty Ltd and Grifols Australia Pty Ltd to manage the transition of patients from Flebogamma 5 % DIF under the national supply arrangements; this was achieved by March 2012.

In October 2011 the NBA signed contracts for the supply of imported Ig with Octapharma Australia Pty Ltd for the supply of Octagam 5%. The new contract took effect on 1 January 2012. A 10% formulation of this product became available in July 2012; Baxter Healthcare Pty Ltd for the supply of Kiovig 10 % from 1 January 2012 and with Grifols Australia Pty Ltd for a direct order contract operating until 31 December 2012 for the supply of Flebogamma 5% DIF. A new direct order contract for continued supply of Flebogamma 5% commenced on 1 January 2012.

In **2012-13** two contracts were place for supply of imported Ig under the national blood arrangements. The contracts commenced on 1 January 2012 for a period of three years and have provision for a one year extension. The suppliers are Baxter Healthcare Pty Ltd and Octapharma Australia Pty Ltd.

The NBA, on behalf of all Australian governments, completed a review of the adequacy of the current Ig authorisation and clinical governance arrangements. The aim of the review was to identify options for improvements in the management of Ig. The review also analysed the issues, benefits and risks of potentially including NIg and subcutaneous immunoglobulin (SCIg) in the Ig management framework.

The review identified that there are significant variations in Ig management processes nationally, with process inefficiencies, under investment in integrated data systems and limited evidence of alternative therapies being considered before prescription. It also found variation in dosing, high prescription rates in some conditions compared to international rates of use, limited transparency of price implications and no accountability for cost with the prescriber.

In March 2013, the Jurisdictional Blood Committee (JBC) considered the final report of the review and endorsed the NBA commencing work to implement five short term improvement projects recommended by the review. The five projects are to:

- describe the functional model for the current authorisation and clinical governance arrangements, and formally allocate responsibility in each jurisdiction
- introduce new management processes to include NIg and SCIg in the Ig authorisation process
- improve patient information to ensure patients are aware of the Criteria requirements for eligibility and ongoing therapy
- centralise hospital ordering and product management at the blood bank or pharmacy for improved management, and define when and how emergency stock should be managed
- define and deliver a package of information concerning current Ig products and arrangements, particularly for junior medical and nursing staff.

Key longer term strategic projects recommended by the review will be considered in 2013-14 for establishing an improved framework for strengthening the clinical governance and authorisation of immunoglobulin in Australia.

In March 2013, the JBC approved the introduction of SCIg under the national blood arrangements. The first phase of implementation will be through hospital-based management arrangements, with no additional cost to patients, and further work will be undertaken to support supply of SCIg for other pathways of care. Supply of SCIg commenced in September 2013, including both domestically manufactured and imported SCIg products.

In 2013-14 the NBA established arrangements for supply of the following SCIg products:

- Evogam 16% vial size 0.8g/5ml and 3.2g/20ml supplied by CSL Behring (Australia) Pty Ltd (domestic)
- Gammanorm 16% 1650mg/10ml and 3300mg/20ml supplied by Octapharma Australia Pty Ltd (imported)
- Kiovig 10% 1g/10ml, 2.5g/25ml, 5gm/50ml, 10g/100ml and 20g/200ml supplied by Baxter Healthcare (imported)

Appendix B – Acronyms and Glossary

ACRONYMS

ACT	Australian Capital Territory
AHMAC	Australian Health Ministers' Advisory Council
AHMC	See SCoH
AHP	Australian Health Providers
ANCA	Anti-neutrophil cytoplasmic antibody
AUS	Australia
DO	Direct Order
HIV	Human immunodeficiency virus
HSCT	Hematopoietic stem cell transplantation
IDMS	Integrated Data Management System
Ig	Immunoglobulin products including IVIg and SCIg
ITP	Idiopathic thrombocytopenic purpura
IVIg	Intravenous immunoglobulin
JBC	Jurisdictional Blood Committee
JDO	Jurisdictional Direct Order
NBA	National Blood Authority
NIg	Normal immunoglobulin
NSW	New South Wales
NT	Northern Territory
PANDAS	Paediatric autoimmune neuropsychiatric disorder associated with streptococcal infections
QLD	Queensland
SA	South Australia
SCIg	Subcutaneous Immunoglobulin
SCoH	Standing Council of Health
STARS	Supply Tracking Analysis Recording System
TAS	Tasmania
TGA	Therapeutic Goods Administration
TSS	Toxic shock syndrome
VIC	Victoria
WA	Western Australia

GLOSSARY OF TERMS

Term	Description
Blood products	Products manufactured from donated blood
Blood Service	The Australian Red Cross Blood Service
Clinical Discipline	Classification of the conditions according to the clinical discipline
Condition	Specific diagnoses within a diagnostic group. Also known as the primary diagnosis. In some instances the diagnostic group may be the same as the condition, For example – Myasthenia gravis is the condition and Diagnostic Group.
Criteria for the clinical use of intravenous immunoglobulin in Australia (*the *Criteria)	A document describing the indications for which IVIg is funded under national blood arrangements by all Australian governments
Criteria Met	Circumstances, based on evidence and clinical experience, under which the clinical use of Ig is considered appropriate to be funded in Australia
Criteria Not Met or Qualifying (Q) Criteria Not Met	Circumstances, based on evidence and clinical experience, under which the clinical use of Ig is not considered appropriate to be funded in Australia
Direct Orders (DO)	Previously known as Jurisdictional Direct Orders (JDO). Arrangements implemented by the NBA with suppliers to facilitate the purchase of Ig for the treatment of conditions not satisfying the *Criteria for the clinical use of IVIg in Australia*
Diagnostic Group	A grouping of clinical/medical conditions, as outlined in the *Criteria.* Also known as disease group
Disease Group	See diagnostic group
Fractionation	A manufacturing process that separates blood plasma into components
Imprest stock	Health provider orders of product for stock that is maintained at a certain level
Intravenous immunoglobulin	A blood product derived from donated human plasma that is administered intravenously

Term	Description
Jurisdiction	The parties to the Australian National Blood Agreement, being the Australian Government and all state and territory governments
Minimum Product Inventory	The minimum inventory of Ig held by CSL to meet contract obligations
National Blood Agreement	The Agreement signed by all governments in 2003 that sets out the objectives for governments for the management of the Australian blood sector
National blood arrangements	Arrangements, including funding arrangements, established under the National Blood Agreement
National CSL Reserve	The reserve of inventory of Ig that CSL Behring manages on behalf of the NBA for contingency purposes.
Normal immunoglobulin	A blood product derived from donated human plasma that is administered by intramuscular injection (as opposed to intravenous or sub-cutaneous injection)
Plasma	The liquid part of the blood containing antibodies and other proteins
Primary diagnosis	See 'condition'
Subcutaneous immunoglobulin	A blood product derived from donated human plasma that is administered subcutaneously
Treatment episode	One instance or episode of a treatment plan, for example a treatment plan may be made up of 4 episodes over 4 months with each episode occurring every 4 weeks. For example; 1 dose of transfused product every two weeks for 6 months would be 13 treatment episodes

Appendix C – Clinical Discipline mapping table

Condition	Chapter	Diagnostic Group	Clinical Discipline
Chronic lymphocytic leukaemia	Chapter 5	Acquired hypogammaglobulinaemia secondary to haematological malignancies	Haematology
Multiple myeloma	Chapter 5	Acquired hypogammaglobulinaemia secondary to haematological malignancies	Haematology
Non-Hodgkin's lymphoma	Chapter 5	Acquired hypogammaglobulinaemia secondary to haematological malignancies	Haematology
Other relevant haematological malignancies	Chapter 5	Acquired hypogammaglobulinaemia secondary to haematological malignancies	Haematology
Post-haemopoietic stem cell transplantation (HSCT)	Chapter 5	Acquired hypogammaglobulinaemia secondary to haematological malignancies	Haematology
Chronic inflammatory demyelinating polyneuropathy	Chapter 5	Chronic inflammatory demyelinating polyneuropathy	Neurology
Guillain-Barré syndrome	Chapter 5	Guillain-Barré syndrome	Neurology
Dermatomyositis	Chapter 5	Inflammatory myopathies	Neurology
Inclusion body myositis	Chapter 5	Inflammatory myopathies	Neurology
Polymyositis	Chapter 5	Inflammatory myopathies	Neurology
Idiopathic thrombocytopenic purpura - Adult	Chapter 5	ITP in adults	Haematology
ITP associated with HIV	Chapter 5	ITP in adults	Haematology
ITP in pregnancy	Chapter 5	ITP in adults	Haematology
ITP in Specific circumstances (surgery, corticosteroids contraindicated, chronic ITP)	Chapter 5	ITP in adults	Haematology
ITP Refractory	Chapter 5	ITP in adults	Haematology
ITP with life-threatening haemorrhage	Chapter 5	ITP in adults	Haematology
Kawasaki disease	Chapter 5	Kawasaki disease	Immunology
Lambert-Eaton myasthenic syndrome	Chapter 5	Lambert-Eaton myasthenic syndrome	Neurology
Multifocal motor neuropathy	Chapter 5	Multifocal motor neuropathy	Neurology
Multifocal motor neuropathy with persistent conduction block	Chapter 5	Multifocal motor neuropathy	Neurology
Myasthenia gravis	Chapter 5	Myasthenia gravis	Neurology
Neonatal haemochromatosis	Chapter 5	Neonatal haemochromatosis	Mixed - Haem/Immun
Common variable immunodeficiency disease	Chapter 5	Primary immunodeficiency diseases	Immunology
Other Primary	Chapter 5	Primary immunodeficiency diseases	Immunology

Condition	Chapter	Diagnostic Group	Clinical Discipline
Immunodeficiency			
Severe combined Immunodeficiency	Chapter 5	Primary immunodeficiency diseases	Immunology
Transient hypogammaglobulinaemia of infancy	Chapter 5	Primary immunodeficiency diseases	Immunology
Wiskott-Aldrich Syndrome	Chapter 5	Primary immunodeficiency diseases	Immunology
X linked agammaglobulinaemia	Chapter 5	Primary immunodeficiency diseases	Immunology
Stiff person syndrome	Chapter 5	Stiff person syndrome	Neurology
Acute disseminated encephalomyelitis	Chapter 6	Acute disseminated encephalomyelitis	Neurology
ANCA (PR3 or MPO)-positive idiopathic rapidly progressive glomerulonephritis	Chapter 6	ANCA-positive necrotising vasculitis	Immunology
Churg-Strauss Syndrome	Chapter 6	ANCA-positive necrotising vasculitis	Immunology
Microscopic polyangiitis	Chapter 6	ANCA-positive necrotising vasculitis	Immunology
Wegener's granulomatosis	Chapter 6	ANCA-positive necrotising vasculitis	Immunology
Autoimmune haemolytic anaemia	Chapter 6	Autoimmune haemolytic anaemia	Haematology
Evans syndrome	Chapter 6	Evans syndrome	Haematology
Foeto-maternal /neonatal alloimmune thrombocytopenia (Antenatal)	Chapter 6	Foeto-maternal /neonatal alloimmune thrombocytopenia	Haematology
Foeto-maternal /neonatal alloimmune thrombocytopenia (Neonatal)	Chapter 6	Foeto-maternal /neonatal alloimmune thrombocytopenia	Haematology
Haemophagocytic syndrome	Chapter 6	Haemophagocytic syndrome	Haematology
HSCT (for prevention of GvHD in high risk Allogeneic HSCT).	Chapter 6	HSCT (for prevention of GvHD in high risk Allogeneic HSCT).	Haematology
IgM para-proteinaemic neuropathy	Chapter 6	IgM para-proteinaemic neuropathy	Neurology
ITP in children	Chapter 6	ITP in children	Haematology
Kidney transplantation – post-transplant	Chapter 6	Kidney transplantation	Renal specialist
Kidney transplantation – pre-transplant	Chapter 6	Kidney transplantation	Renal specialist
Kidney transplantation post-transplant	Chapter 6	Kidney transplantation	Renal specialist
Kidney transplantation pre-transplant	Chapter 6	Kidney transplantation	Renal specialist
Multiple sclerosis - Severe relapse with no response to high dose methylprednisolone	Chapter 6	Multiple sclerosis	Neurology
Multiple Sclerosis in Pregnancy	Chapter 6	Multiple sclerosis	Neurology
Multiple Sclerosis in young patients	Chapter 6	Multiple sclerosis	Neurology

Condition	Chapter	Diagnostic Group	Clinical Discipline
severe/relapsing/remitting in whom other therapies have failed			
Opsoclonus myoclonus ataxia	Chapter 6	Opsoclonus myoclonus ataxia	Neurology
Bullous pemphigoid	Chapter 6	Pemphigoid	Immunology
Cicatricial pemphigoid	Chapter 6	Pemphigoid	Immunology
Pemphigus foliaceus	Chapter 6	Pemphigus	Immunology
Pemphigus vulgaris	Chapter 6	Pemphigus	Immunology
Post transfusion purpura	Chapter 6	Post transfusion purpura	Haematology
Secondary hypogammaglobulinaemia (excludes haem malignancies)	Chapter 6	Secondary hypogammaglobulinaemia	Mixed
IgG subclass deficiency EXISTING patients only	Chapter 6	Specific antibody deficiency	Immunology
Specific antibody deficiency	Chapter 6	Specific antibody deficiency	Immunology
IgG subclass deficiency. Existing patient with suppurative lung disease	Chapter 6	Specific antibody deficiency	Immunology
Toxic epidermal necrolysis/Steven Johnson Syndrome	Chapter 6	Toxic epidermal necrolysis/Steven Johnson Syndrome	Immunology
Toxic Shock Syndrome (TSS) - Staphylococcal	Chapter 6	Toxic shock syndrome	Immunology
Toxic Shock Syndrome (TSS) - Streptococcal	Chapter 6	Toxic shock syndrome	Immunology
Acute leukaemia in children	Chapter 7	Acute leukaemia in children	Haematology
Autoimmune congenital heart block	Chapter 7	Autoimmune congenital heart block	Immunology
Autoimmune diabetic neuropathy	Chapter 7	Autoimmune diabetic neuropathy	Neurology
Autoimmune neutropenia	Chapter 7	Autoimmune neutropenia	Haematology
Autoimmune uveitis	Chapter 7	Autoimmune uveitis	Immunology
Catastrophic antiphospholipid syndrome	Chapter 7	Catastrophic antiphospholipid syndrome	Immunology
Coagulation factor inhibitors	Chapter 7	Coagulation factor inhibitors	Haematology
Devic disease (neuromyelitis optica)	Chapter 7	Devic disease (neuromyelitis optica)	Neurology
Diabetic Amyotrophy	Chapter 7	Diabetic Amytrophy	Neurology
Epidermolysis bullosa acquisita	Chapter 7	Epidermolysis bullosa acquisita	Dermatology
Epilepsy (rare childhood cases)	Chapter 7	Epilepsy (rare childhood cases)	Neurology
Graves ophthalmopathy	Chapter 7	Graves ophthalmopathy	Immunology
Haemolytic disease of the newborn	Chapter 7	Haemolytic disease of the newborn	Haematology
Haemolytic transfusion reaction	Chapter 7	Haemolytic transfusion reaction	Haematology
Hashimoto encephalopathy	Chapter 7	Hashimoto enecephalopathy	Neurology

Condition	Chapter	Diagnostic Group	Clinical Discipline
HIV in children	Chapter 7	HIV in children	Immunology
Limbic encephalitis-nonparaneoplastic	Chapter 7	Limbic encephalitis-nonparaneoplastic	Neurology
Myocarditis in children	Chapter 7	Myocarditis in children	Mixed
PANDAS/tic disorders	Chapter 7	PANDAS/tic disorders	Neurology
Limbic encephalitis-paraneoplastic	Chapter 7	Paraneoplastic syndromes	Neurology
Paraneoplastic cerebellar degeneration (Yo antibodies)	Chapter 7	Paraneoplastic syndromes	Neurology
Paraneoplastic Subacute Sensory Neuropathy	Chapter 7	Paraneoplastic syndromes	Neurology
Paraneoplastic syndromes	Chapter 7	Paraneoplastic syndromes	Neurology
Potassium channel antibody-associated encephalopathy	Chapter 7	Potassium channel antibody-associated encephalopathy	Neurology
Pure red cell aplasia	Chapter 7	Pure red cell aplasia	Haematology
Pure white cell aplasia	Chapter 7	Pure white cell aplasia	Haematology
Pyoderma gangrenosum	Chapter 7	Pyoderma gangrenosum	Dermatology
Rasmussen Syndrome	Chapter 7	Rasmussen Syndrome	Neurology
Scleromyxedema	Chapter 7	Scleromyxedema	Mixed
Sepsis - neonatal	Chapter 7	Sepsis - neonatal	Paediatrician
Sjogren’s syndrome	Chapter 7	Sjogren’s syndrome	Immunology
Sjogren's Syndrome	Chapter 7	Sjogren’s syndrome	Immunology
Solid Organ - Heart	Chapter 7	Solid organ transplantation (other than kidney)- total	Organ specialist
Solid Organ - Heart/Lung	Chapter 7	Solid organ transplantation (other than kidney)- total	Organ specialist
Solid Organ - Liver	Chapter 7	Solid organ transplantation (other than kidney)- total	Organ specialist
Solid Organ - Lung	Chapter 7	Solid organ transplantation (other than kidney)- total	Organ specialist
Solid Organ - Other	Chapter 7	Solid organ transplantation (other than kidney)- total	Organ specialist
Solid Organ - Pancreas	Chapter 7	Solid organ transplantation (other than kidney)- total	Organ specialist
Transplant - Solid Organ	Chapter 7	Solid organ transplantation (other than kidney)- total	Organ specialist
Transplants - Allogeneic stem cell or bone marrow	Chapter 7	Solid organ transplantation (other than kidney)- total	Organ specialist
Susac syndrome	Chapter 7	Susac syndrome	Neurology
Systemic Capillary Leak Syndrome	Chapter 7	Systemic Capillary Leak Syndrome	Immunology
Acute optic neuritis	Chapter 8	Acute optic neuritis	Neurology
Acute rheumatic fever	Chapter 8	Acute rheumatic fever	Mixed
Adrenoleukodystrophy	Chapter 8	Adrenoleukodystrophy	Neurology
Amegakaryocytic	Chapter 8	Amegakaryocytic thrombocytopenia	Haematology

Condition	Chapter	Diagnostic Group	Clinical Discipline
thrombocytopenia			
Antiphospholipid syndrome (non obstetric)	Chapter 8	Antiphospholipid syndrome (non obstetric)	Mixed
Aplastic anaemia/pancytopenia	Chapter 8	Aplastic anaemia/pancytopenia	Haematology
Asthma	Chapter 8	Asthma	Mixed
Atopic dermatitis/eczema	Chapter 8	Atopic dermatitis/eczema	Dermatology
Autism – young adults	Chapter 8	Autism – young adults	Mixed
Autologous haemopoietic stem cell transplantation	Chapter 8	Autologous haemopoietic stem cell transplantation	Haematology
Behcet's disease	Chapter 8	Behcet's disease	Immunology
Cardiac surgery with bypass – prophylaxis	Chapter 8	Cardiac surgery with bypass – prophylaxis	Mixed
Congestive cardiac failure	Chapter 8	Congestive cardiac failure	Mixed
Crohn's disease	Chapter 8	Crohn's disease	Mixed
Diamond Blackfan syndrome	Chapter 8	Diamond Blackfan syndrome	Haematology
Female infertility	Chapter 8	Female infertility	Mixed
Glomerulonephritis – IgA nephritis	Chapter 8	Glomerulonephritis – IgA nephritis	Mixed
Haemolytic uraemic syndrome	Chapter 8	Haemolytic uraemic syndrome	Haematology
Henoch-Schonlein purpura	Chapter 8	Henoch-Schonlein purpura	Mixed
HIV/AIDS – adult	Chapter 8	HIV/AIDS – adult	Mixed
Idiopathic dilated cardiomyopathy	Chapter 8	Idiopathic dilated cardiomyopathy	Mixed
Linear IgA disease	Chapter 8	Linear IgA disease	Dermatology
Lupus cerebritis	Chapter 8	Lupus cerebritis	Mixed
Lupus nephritis	Chapter 8	Lupus nephritis	Mixed
Motor neuron disease/amyotrophic lateral sclerosis	Chapter 8	Motor neuron disease/amyotrophic lateral sclerosis	Neurology
Myalgic encephalomyelitis	Chapter 8	Myalgic encephalomyelitis	Neurology
Narcolepsy/cataplexy	Chapter 8	Narcolepsy/cataplexy	Neurology
Nephrotic syndrome	Chapter 8	Nephrotic syndrome	Mixed
Obsessive compulsive disorders	Chapter 8	Obsessive compulsive disorders	Mixed
Polyneuropathy of critical illness	Chapter 8	Polyneuropathy of critical illness	Neurology
Recurrent foetal loss (with or without antiphospholipid syndrome)	Chapter 8	Recurrent foetal loss (with or without antiphospholipid syndrome)	Mixed
Rheumatoid arthritis	Chapter 8	Rheumatoid arthritis	Mixed
Sepsis (other than neonatal sepsis)	Chapter 8	Sepsis (other than neonatal sepsis)	Mixed
Sickle cell disease	Chapter 8	Sickle cell disease	Haematology
Systemic lupus erythematosus	Chapter 8	Systemic lupus erythematosus	Mixed
Ulcerative colitis	Chapter 8	Ulcerative colitis	Mixed

Condition	Chapter	Diagnostic Group	Clinical Discipline
JDO issue	JDO Chapter	JDO	JDO
Acute Idiopathic Dysautomia	NA	Pre 2008 *Criteria*	Neurology
Alloimmune Neutropenia In Infancy	NA	Pre 2008 *Criteria*	Haematology
Alloimmune Thrombocytopenia Neonatal	NA	Pre 2008 *Criteria*	Haematology
Autoimmune Thrombocytopenic	NA	Pre 2008 *Criteria*	Haematology
Cutaneous Vasculitis	NA	Pre 2008 *Criteria*	Mixed
Hypogammaglobulinaemia	NA	Pre 2008 *Criteria*	Immunology
Hypogammaglobulinaemia Unclassified	NA	Pre 2008 *Criteria*	Immunology
Immunological Miscellaneous, No diagnosis recorded	NA	Pre 2008 *Criteria*	Immunology
Miscellaneous	NA	Pre 2008 *Criteria*	Mixed
Myelopathy due to HTLV-1	NA	Pre 2008 *Criteria*	Immunology
Necrotising Myelitis	NA	Pre 2008 *Criteria*	Mixed
Other Lymphoproliferative / Hypogammaglobulinaemia	NA	Pre 2008 *Criteria*	Haematology
Paediatric Myocarditis	NA	Pre 2008 *Criteria*	Mixed
Sensory neuropathy associated with anti-Hu antibodies	NA	Pre 2008 *Criteria*	Neurology
Septic thrombocytopenia	NA	Pre 2008 *Criteria*	Haematology
Stills Disease - Adults	NA	Pre 2008 *Criteria*	Immunology
Trauma - Burns	NA	Pre 2008 *Criteria*	Mixed

Appendix D – Dataset of Ig supply by state/territory 2014-15

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
Chapter 5										
Chronic inflammatory demyelinating polyneuropathy	Patients	772	464	580	123	81	32	27	8	2,054
	Grams	330,311	229,623	247,123	96,161	39,999	19,387	8,866	2,790	974,258
	Grams/Episode	38	38	34	59	45	39	33	50	38
	Grams per 1,000	44	39	52	37	24	38	23	11	41
Chronic lymphocytic leukaemia	Patients	483	290	318	64	77	34	31	9	1,283
	Grams	118,762	70,932	76,671	10,616	20,659	8,452	7,791	1,324	315,205
	Grams/Episode	30	28	26	26	31	30	31	33	28
	Grams per 1,000	16	12	16	4	12	16	20	5	13
Common variable immunodeficiency disease	Patients	793	276	338	88	110	25	66	<5	1,656
	Grams	246,707	89,346	110,887	27,399	34,270	7,052	21,588	336	537,584
	Grams/Episode	22	25	24	18	21	26	19	24	23
	Grams per 1,000	33	15	23	11	20	14	56	1	23
Dermatomyositis	Patients	66	39	28	11	10	<5	6	0	161
	Grams	21,564	11,075	12,448	4,225	2,745	1,959	3,435	0	57,451
	Grams/Episode	35	37	41	43	27	65	61	0	38
	Grams per 1,000	3	2	3	2	2	4	9	0	2
Guillain-Barré syndrome	Patients	193	163	154	50	35	14	11	9	628
	Grams	33,094	29,377	25,209	7,424	5,266	2,260	1,677	1,262	105,567
	Grams/Episode	31	35	31	37	34	38	32	35	33
	Grams per 1,000	4	5	5	3	3	4	4	5	4
HSCT - post	Patients	173	62	53	9	5	6	0	<5	307
	Grams	19,977	9,265	9,954	578	1,107	1,596	0	261	42,738
	Grams/Episode	27	28	29	19	41	30	0	29	28

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
	Grams per 1,000	3	2	2	<1	<1	3	0	1	2
Inclusion body myositis	Patients	49	40	26	<5	19	<5	<5	<5	140
	Grams	16,270	18,024	12,690	227	7,616	1,242	252	357	56,676
	Grams/Episode	34	38	34	38	44	31	36	119	36
	Grams per 1,000	2	3	3	<1	5	2	<1	1	2
ITP in pregnancy	Patients	21	24	28	6	7	<5	0	<5	89
	Grams	2,490	2,496	5,214	640	1,089	546	0	60	12,534
	Grams/Episode	46	66	31	64	84	68	0	60	43
	Grams per 1,000	<1	<1	1	<1	<1	1	0	<1	<1
ITP in specific circumstances (surgery, corticosteroids contraindicated, chronic ITP)	Patients	91	92	122	28	29	9	0	<5	373
	Grams	14,422	10,775	24,626	3,341	3,946	1,081	0	275	58,465
	Grams/Episode	44	55	34	56	60	77	0	92	42
	Grams per 1,000	2	2	5	1	2	2	0	1	2
ITP refractory	Patients	50	163	143	36	59	14	0	<5	468
	Grams	12,468	24,718	20,532	3,909	10,827	1,458	0	318	74,228
	Grams/Episode	40	58	33	69	50	73	0	80	45
	Grams per 1,000	2	4	4	2	6	3	0	1	3
ITP with life-threatening haemorrhage	Patients	200	36	24	11	16	<5	6	<5	297
	Grams	29,551	3,481	4,094	1,264	2,559	417	869	160	42,394
	Grams/Episode	43	51	39	63	64	52	72	80	45
	Grams per 1,000	4	<1	<1	<1	2	<1	2	<1	2
Kawasaki disease	Patients	108	116	58	29	17	12	5	5	350
	Grams	4,737	4,964	2,436	1,023	834	630	264	222	15,110
	Grams/Episode	35	31	34	31	44	42	44	32	34
	Grams per 1,000	<1	<1	<1	<1	<1	1	<1	<1	<1
Lambert-Eaton myasthenic syndrome	Patients	5	<5	13	<5	0	0	<5	0	24
	Grams	2,054	2,087	6,262	845	0	0	290	0	11,538
	Grams/Episode	33	43	34	44	0	0	22	0	35

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
	Grams per 1,000	<1	<1	1	<1	0	0	<1	0	<1
Multifocal motor neuropathy	Patients	179	84	90	32	35	12	10	6	444
	Grams	92,731	50,260	41,519	27,479	26,615	4,643	6,222	6,573	256,041
	Grams/Episode	43	43	35	66	57	31	51	58	44
	Grams per 1,000	12	9	9	11	16	9	16	27	11
Multiple myeloma	Patients	425	215	365	23	25	39	14	0	1,100
	Grams	89,334	44,289	97,480	3,417	5,325	13,040	3,078	0	255,962
	Grams/Episode	30	29	26	28	33	31	28	0	28
	Grams per 1,000	12	8	21	1	3	25	8	0	11
Myasthenia gravis	Patients	297	199	245	41	17	11	16	0	818
	Grams	115,692	92,293	101,497	21,105	5,891	4,367	7,491	0	348,336
	Grams/Episode	36	37	33	48	36	30	42	0	36
	Grams per 1,000	15	16	21	8	3	8	19	0	15
Neonatal haemochromatosis	Patients	<5	<5	7	<5	0	0	<5	0	15
	Grams	1,569	6,213	3,810	1,080	0	0	3	0	12,675
	Grams/Episode	65	70	59	83	0	0	3	0	66
	Grams per 1,000	<1	1	<1	<1	0	0	<1	0	<1
Non-Hodgkins lymphoma	Patients	345	247	488	31	64	30	18	<5	1,208
	Grams	73,136	56,685	124,770	6,010	14,079	8,177	4,973	69	287,900
	Grams/Episode	29	30	25	26	30	27	31	35	27
	Grams per 1,000	10	10	26	2	8	16	13	<1	12
Other Lymphoproliferative / Hypogammaglobulinaemia	Patients	0	<5	0	0	0	0	0	0	<5
	Grams	0	189	0	0	0	0	0	0	189
	Grams/Episode	0	21	0	0	0	0	0	0	21
	Grams per 1,000	0	<1	0	0	0	0	0	0	<1
Other primary immunodeficiency	Patients	54	39	12	7	12	<5	<5	6	130
	Grams	13,269	10,469	1,977	2,073	1,402	318	141	1,497	31,146
	Grams/Episode	17	20	16	27	6	6	12	25	16

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
	Grams per 1,000	2	2	<1	<1	<1	<1	<1	6	1
Other relevant haematological malignancies	Patients	149	70	113	40	48	7	<5	<5	428
	Grams	30,674	15,972	21,316	4,468	5,680	1,488	1,245	126	80,969
	Grams/Episode	29	29	25	19	27	26	29	18	27
	Grams per 1,000	4	3	4	2	3	3	3	<1	3
Polymyositis	Patients	154	50	97	9	27	7	<5	0	341
	Grams	52,597	26,355	40,559	2,611	10,432	1,197	1,352	0	135,102
	Grams/Episode	34	47	37	40	46	36	52	0	38
	Grams per 1,000	7	4	9	1	6	2	3	0	6
Severe combined Immunodeficiency	Patients	11	8	14	<5	<5	0	0	<5	36
	Grams	1,378	2,334	3,804	120	47	0	0	3	7,686
	Grams/Episode	12	15	26	40	2	0	0	3	17
	Grams per 1,000	<1	<1	<1	<1	<1	0	0	<1	<1
Stiff person syndrome	Patients	20	11	14	0	0	<5	0	<5	46
	Grams	11,768	5,312	9,352	0	0	918	0	150	27,500
	Grams/Episode	48	44	41	0	0	54	0	30	45
	Grams per 1,000	2	<1	2	0	0	2	0	<1	1
Wiskott-Aldrich syndrome	Patients	0	<5	<5	<5	0	0	0	0	6
	Grams	0	580	432	408	0	0	0	0	1,420
	Grams/Episode	0	19	36	24	0	0	0	0	24
	Grams per 1,000	0	<1	<1	<1	0	0	0	0	<1
X linked agammaglobulinaemia	Patients	32	52	16	5	6	0	<5	<5	113
	Grams	10,543	16,538	5,154	1,698	2,154	0	257	600	36,945
	Grams/Episode	24	21	26	13	30	0	5	24	22
	Grams per 1,000	1	3	1	<1	1	0	<1	2	2
Chapter 5 Total	Patients	4,589	2,707	3275	638	677	263	220	61	12,268
	Grams	1,345,094	833,649	1,009,814	228,118	202,538	80,227	69,793	16,383	3,785,615
	Grams/Episode	31	34	29	39	33	32	28	42	32

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
	Grams per 1,000	178	142	213	88	120	156	180	67	160
Chapter 6										
Acute disseminated encephalomyelitis	Patients	22	10	12	<5	0	0	<5	<5	50
	Grams	3,416	2,108	2,883	410	0	0	395	36	9,248
	Grams/Episode	31	38	42	46	0	0	26	9	35
	Grams per 1,000	<1	<1	<1	<1	0	0	1	<1	<1
ANCA (PR3 or MPO)-positive idiopathic rapidly progressive glomerulonephritis	Patients	<5	0	7	0	0	0	0	0	10
	Grams	512	0	885	0	0	0	0	0	1,397
	Grams/Episode	34	0	37	0	0	0	0	0	36
	Grams per 1,000	<1	0	<1	0	0	0	0	0	<1
Autoimmune haemolytic anaemia	Patients	24	23	35	9	16	6	<5	0	115
	Grams	4,580	1,952	7,536	1,427	3,762	1,008	24	0	20,288
	Grams/Episode	47	46	42	49	68	67	8	0	48
	Grams per 1,000	<1	<1	2	<1	2	2	<1	0	<1
Bullous pemphigoid	Patients	14	<5	5	<5	0	0	0	<5	26
	Grams	7,860	1,290	2,193	420	0	0	0	198	11,961
	Grams/Episode	59	76	35	30	0	0	0	66	52
	Grams per 1,000	1	<1	<1	<1	0	0	0	<1	<1
Churg-Strauss syndrome	Patients	<5	0	0	0	0	<5	0	0	<5
	Grams	150	0	0	0	0	342	0	0	492
	Grams/Episode	30	0	0	0	0	114	0	0	62
	Grams per 1,000	<1	0	0	0	0	<1	0	0	<1
Cicatricial pemphigoid	Patients	<5	5	6	<5	<5	0	<5	0	18
	Grams	4,500	5,486	4,160	270	1,890	0	4,315	0	20,621
	Grams/Episode	83	69	50	135	57	0	117	0	71
	Grams per 1,000	<1	<1	<1	<1	1	0	11	0	<1
Evans syndrome	Patients	<5	<5	<5	0	0	0	0	0	6
	Grams	197	310	259	0	0	0	0	0	766

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
	Grams/Episode	22	78	37	0	0	0	0	0	38
	Grams per 1,000	<1	<1	<1	0	0	0	0	0	<1
Foeto-maternal /neonatal alloimmune thrombocytopenia (Antenatal)	Patients	<5	<5	<5	<5	<5	<5	0	0	16
	Grams	2,427	1,743	4,056	1,197	4,320	78	0	0	13,821
	Grams/Episode	62	70	97	67	105	39	0	0	83
	Grams per 1,000	<1	<1	<1	<1	3	<1	0	0	<1
Foeto-maternal /neonatal alloimmune thrombocytopenia (Neonatal)	Patients	7	8	<5	<5	0	<5	0	0	22
	Grams	30	33	12	6	0	12	0	0	93
	Grams/Episode	3	3	3	3	0	4	0	0	3
	Grams per 1,000	<1	<1	<1	<1	0	<1	0	0	<1
Haemophagocytic syndrome	Patients	21	16	5	<5	<5	<5	<5	0	48
	Grams	2,788	2,679	657	183	225	200	27	0	6,758
	Grams/Episode	53	52	31	46	56	200	9	0	49
	Grams per 1,000	<1	<1	<1	<1	<1	<1	<1	0	<1
IgG subclass deficiency EXISTING patients only	Patients	<5	24	<5	<5	5	5	0	0	36
	Grams	36	7,998	42	870	1,524	1,548	0	0	12,018
	Grams/Episode	36	28	21	23	29	25	0	0	27
	Grams per 1,000	<1	1	<1	<1	<1	3	0	0	<1
IgG subclass deficiency. Exisitng patient with suppurative lung disease	Patients	21	0	<5	0	0	0	0	0	23
	Grams	7,609	0	108	0	0	0	0	0	7,717
	Grams/Episode	29	0	27	0	0	0	0	0	29
	Grams per 1,000	1	0	<1	0	0	0	0	0	<1
IgM para-proteinaemic neuropathy	Patients	27	12	30	<5	5	0	0	0	77
	Grams	9,522	3,473	11,697	2,970	1,249	0	0	0	28,911
	Grams/Episode	36	41	34	68	46	0	0	0	38
	Grams per 1,000	1	<1	2	1	<1	0	0	0	1
ITP in children	Patients	24	22	48	10	24	0	<5	<5	133
	Grams	1,871	761	1,587	426	1,176	0	93	205	6,119

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
	Grams/Episode	32	20	24	22	24	0	47	51	26
	Grams per 1,000	<1	<1	<1	<1	<1	0	<1	<1	<1
Kidney transplantation post-transplant	Patients	66	172	57	16	11	10	<5	<5	335
	Grams	9,483	48,496	16,973	2,788	1,621	3,555	195	20	83,131
	Grams/Episode	23	32	22	50	19	55	14	10	29
	Grams per 1,000	1	8	4	1	<1	7	<1	<1	4
Kidney transplantation pre-transplant	Patients	24	28	<5	0	<5	0	0	0	58
	Grams	2,160	3,398	1,238	0	105	0	0	0	6,901
	Grams/Episode	30	17	34	0	35	0	0	0	22
	Grams per 1,000	<1	<1	<1	0	<1	0	0	0	<1
Microscopic polyangiitis	Patients	0	0	<5	<5	0	0	0	0	<5
	Grams	0	0	192	570	0	0	0	0	762
	Grams/Episode	0	0	24	34	0	0	0	0	30
	Grams per 1,000	0	0	<1	<1	0	0	0	0	<1
Multiple sclerosis - severe relapse with no response to high dose methylprednisolone	Patients	9	<5	8	0	0	0	0	0	20
	Grams	1,797	784	1,990	0	0	0	0	0	4,571
	Grams/Episode	27	25	26	0	0	0	0	0	26
	Grams per 1,000	<1	<1	<1	0	0	0	0	0	<1
Multiple sclerosis in pregnancy	Patients	<5	0	<5	0	0	0	0	0	5
	Grams	732	0	318	0	0	0	0	0	1,050
	Grams/Episode	27	0	23	0	0	0	0	0	26
	Grams per 1,000	<1	0	<1	0	0	0	0	0	<1
Multiple sclerosis in young patients severe/relapsing/remitting in whom other therapies have failed	Patients	14	<5	7	0	0	0	0	0	22
	Grams	4,399	156	1,110	0	0	0	0	0	5,665
	Grams/Episode	33	78	29	0	0	0	0	0	33
	Grams per 1,000	<1	<1	<1	0	0	0	0	0	<1
Opsoclonus myoclonus	Patients	13	9	<5	<5	<5	0	0	0	26
	Grams	2,721	1,311	100	261	1,533	0	0	0	5,925

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
ataxia	Grams/Episode	28	16	20	13	44	0	0	0	25
	Grams per 1,000	<1	<1	<1	<1	<1	0	0	0	<1
Pemphigus foliaceus	Patients	<5	0	<5	0	0	0	0	0	<5
	Grams	2,458	0	418	0	0	0	0	0	2,876
	Grams/Episode	42	0	28	0	0	0	0	0	39
	Grams per 1,000	<1	0	<1	0	0	0	0	0	<1
Pemphigus vulgaris	Patients	17	7	5	<5	<5	0	<5	0	33
	Grams	11,205	2,909	3,069	1,440	1,450	0	1,980	0	22,052
	Grams/Episode	51	69	40	120	145	0	180	0	59
	Grams per 1,000	1	<1	<1	<1	<1	0	5	0	<1
Post transfusion purpura	Patients	<5	<5	0	0	0	0	0	0	<5
	Grams	55	240	0	0	0	0	0	0	295
	Grams/Episode	28	80	0	0	0	0	0	0	59
	Grams per 1,000	<1	<1	0	0	0	0	0	0	<1
Secondary hypogammaglobulinaemia (excludes haem malignancies)	Patients	240	103	183	27	14	16	8	<5	580
	Grams	49,941	18,561	44,542	3,904	3,066	5,656	681	211	126,561
	Grams/Episode	26	26	24	15	10	33	18	42	24
	Grams per 1,000	7	3	9	2	2	11	2	<1	5
Specific antibody deficiency	Patients	94	33	57	46	21	<5	<5	<5	252
	Grams	22,260	8,553	14,168	11,065	5,387	746	1,359	109	63,646
	Grams/Episode	19	23	25	18	15	26	26	9	20
	Grams per 1,000	3	1	3	4	3	1	4	<1	3
Toxic epidermal necrolysis/Steven Johnson syndrome	Patients	16	20	<5	<5	<5	<5	<5	0	50
	Grams	2,137	3,421	718	449	390	790	237	0	8,142
	Grams/Episode	55	73	60	75	65	113	79	0	68
	Grams per 1,000	<1	<1	<1	<1	<1	2	<1	0	<1
TSS - staphylococcal	Patients	10	26	<5	6	<5	<5	<5	0	53
	Grams	1,508	4,142	509	795	57	395	464	0	7,869

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
	Grams/Episode	94	109	64	61	29	56	116	0	89
	Grams per 1,000	<1	<1	<1	<1	<1	<1	1	0	<1
TSS - streptococcal	Patients	28	32	12	12	9	6	<5	0	103
	Grams	4,402	4,281	1,151	1,645	1,095	890	563	0	14,027
	Grams/Episode	94	73	58	72	64	74	94	0	76
	Grams per 1,000	<1	<1	<1	<1	<1	2	1	0	<1
Wegeners granulomatosis	Patients	<5	<5	<5	0	<5	0	0	0	<5
	Grams	135	312	12	0	351	0	0	0	810
	Grams/Episode	27	24	12	0	27	0	0	0	25
	Grams per 1,000	<1	<1	<1	0	<1	0	0	0	<1
Chapter 6 Total	Patients	698	555	501	150	123	57	34	10	2,103
	Grams	160,886	124,394	122,582	31,094	29,201	15,220	10,333	779	494,489
	Grams/Episode	30	32	28	26	27	41	55	26	30
	Grams per 1,000	21	21	26	12	17	30	27	3	21
Chapter 7										
Acute leukaemia in children	Patients	0	5	0	0	0	0	0	0	5
	Grams	0	291	0	0	0	0	0	0	291
	Grams/Episode	0	24	0	0	0	0	0	0	24
	Grams per 1,000	0	<1	0	0	0	0	0	0	<1
Autoimmune neutropenia	Patients	5	<5	5	0	0	0	0	0	12
	Grams	2,103	155	685	0	0	0	0	0	2,943
	Grams/Episode	57	52	34	0	0	0	0	0	49
	Grams per 1,000	<1	<1	<1	0	0	0	0	0	<1
Autoimmune uveitis	Patients	<5	<5	0	0	<5	0	0	0	<5
	Grams	475	135	0	0	143	0	0	0	753
	Grams/Episode	48	45	0	0	48	0	0	0	47
	Grams per 1,000	<1	<1	0	0	<1	0	0	0	<1
Catastrophic	Patients	5	<5	11	<5	0	0	0	0	19

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
antiphospholipid syndrome	Grams	813	288	1,944	171	0	0	0	0	3,216
	Grams/Episode	68	96	29	29	0	0	0	0	37
	Grams per 1,000	<1	<1	<1	<1	0	0	0	0	<1
Coagulation factor inhibitors	Patients	<5	<5	<5	0	<5	0	0	0	10
	Grams	240	132	1,699	0	719	0	0	0	2,790
	Grams/Episode	60	66	94	0	42	0	0	0	68
	Grams per 1,000	<1	<1	<1	0	<1	0	0	0	<1
Devic disease (neuromyelitis optica)	Patients	16	<5	5	<5	<5	0	<5	0	29
	Grams	4,984	885	805	1,662	350	0	135	0	8,821
	Grams/Episode	34	33	28	128	35	0	27	0	38
	Grams per 1,000	<1	<1	<1	<1	<1	0	<1	0	<1
Diabetic Amyotrophy	Patients	<5	7	<5	0	0	0	<5	0	15
	Grams	1,647	1,338	705	0	0	0	36	0	3,726
	Grams/Episode	29	36	29	0	0	0	36	0	31
	Grams per 1,000	<1	<1	<1	0	0	0	<1	0	<1
Epidermolysis bullosa acquisita	Patients	0	0	0	<5	0	0	<5	0	<5
	Grams	0	0	0	1,461	0	0	1,170	0	2,631
	Grams/Episode	0	0	0	86	0	0	90	0	88
	Grams per 1,000	0	0	0	<1	0	0	3	0	<1
Epilepsy (rare childhood cases)	Patients	<5	8	6	7	<5	0	0	0	24
	Grams	360	2,480	1,217	1,324	126	0	0	0	5,507
	Grams/Episode	36	34	35	53	32	0	0	0	38
	Grams per 1,000	<1	<1	<1	<1	<1	0	0	0	<1
Graves ophthalmopathy	Patients	0	0	<5	0	0	0	0	0	<5
	Grams	0	0	2,490	0	0	0	0	0	2,490
	Grams/Episode	0	0	59	0	0	0	0	0	59
	Grams per 1,000	0	0	<1	0	0	0	0	0	<1
Haemolytic disease of the	Patients	19	20	9	11	9	<5	10	<5	82

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
newborn	Grams	78	183	1,035	609	45	11	45	7	2,013
	Grams/Episode	3	8	41	29	3	6	3	4	16
	Grams per 1,000	<1	<1	<1	<1	<1	<1	<1	<1	<1
Hashimoto encephalopathy	Patients	<5	<5	<5	<5	0	0	0	0	8
	Grams	627	973	660	1,270	0	0	0	0	3,530
	Grams/Episode	35	35	30	58	0	0	0	0	39
	Grams per 1,000	<1	<1	<1	<1	0	0	0	0	<1
Limbic Encephalitis (nonparaneoplastic)	Patients	37	34	55	7	6	<5	<5	<5	147
	Grams	7,850	6,646	15,559	1,027	861	410	3,438	287	36,076
	Grams/Episode	35	33	30	29	32	27	55	41	33
	Grams per 1,000	1	1	3	<1	<1	<1	9	1	2
Limbic Encephalitis (Paraneoplastic)	Patients	<5	9	6	<5	<5	<5	<5	0	26
	Grams	643	1,528	3,067	510	100	100	132	0	6,080
	Grams/Episode	27	28	34	30	20	20	26	0	31
	Grams per 1,000	<1	<1	<1	<1	<1	<1	<1	0	<1
Myocarditis in children	Patients	<5	17	6	0	<5	0	0	0	28
	Grams	99	273	349	0	57	0	0	0	778
	Grams/Episode	25	10	39	0	19	0	0	0	18
	Grams per 1,000	<1	<1	<1	0	<1	0	0	0	<1
PANDAS/tic disorders	Patients	<5	<5	0	<5	0	<5	<5	0	7
	Grams	718	864	0	288	0	204	87	0	2,161
	Grams/Episode	27	36	0	72	0	51	87	0	36
	Grams per 1,000	<1	<1	0	<1	0	<1	<1	0	<1
Paraneoplastic cerebellar degeneration (Yo antibodies)	Patients	<5	<5	<5	<5	<5	<5	0	0	10
	Grams	630	85	100	1,503	175	512	0	0	3,005
	Grams/Episode	42	17	20	72	35	32	0	0	45
	Grams per 1,000	<1	<1	<1	<1	<1	<1	0	0	<1
Paraneoplastic Subacute	Patients	<5	<5	<5	0	<5	<5	0	0	11

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
Sensory Neuropathy	Grams	630	812	400	0	208	200	0	0	2,249
	Grams/Episode	25	41	50	0	26	40	0	0	34
	Grams per 1,000	<1	<1	<1	0	<1	<1	0	0	<1
Paraneoplastic syndromes	Patients	0	0	<5	0	<5	0	0	0	<5
	Grams	0	0	1,195	0	363	0	0	0	1,558
	Grams/Episode	0	0	39	0	33	0	0	0	37
	Grams per 1,000	0	0	<1	0	<1	0	0	0	<1
Potassium channel antibody-associated encephalopathy	Patients	17	<5	<5	<5	5	<5	0	<5	29
	Grams	4,540	639	426	998	1,800	754	0	240	9,396
	Grams/Episode	29	34	39	111	44	29	0	24	35
	Grams per 1,000	<1	<1	<1	<1	1	1	0	<1	<1
Pure red cell aplasia	Patients	10	5	12	<5	<5	<5	0	0	31
	Grams	1,790	497	2,754	101	1,510	1,440	0	0	8,091
	Grams/Episode	35	38	44	51	84	40	0	0	44
	Grams per 1,000	<1	<1	<1	<1	<1	3	0	0	<1
Pyoderma gangrenosum	Patients	<5	17	<5	0	<5	0	0	<5	26
	Grams	1,703	7,627	1,200	0	2,592	0	0	135	13,256
	Grams/Episode	53	59	60	0	72	0	0	45	60
	Grams per 1,000	<1	1	<1	0	2	0	0	<1	<1
Rasmussen Syndrome	Patients	8	<5	<5	<5	<5	<5	<5	0	16
	Grams	2,451	486	549	90	800	510	363	0	5,249
	Grams/Episode	45	35	24	90	53	43	33	0	40
	Grams per 1,000	<1	<1	<1	<1	<1	<1	<1	0	<1
Scleromyxedema	Patients	<5	<5	0	0	<5	0	0	0	7
	Grams	4,285	1,161	0	0	980	0	0	0	6,426
	Grams/Episode	60	23	0	0	35	0	0	0	43
	Grams per 1,000	<1	<1	0	0	<1	0	0	0	<1
Sjogren's Syndrome	Patients	9	<5	<5	<5	<5	0	<5	0	20

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
	Grams	1,936	1,089	1,445	100	2,476	0	2,715	0	9,761
	Grams/Episode	29	29	41	20	118	0	58	0	46
	Grams per 1,000	<1	<1	<1	<1	1	0	7	0	<1
Solid organ - heart	Patients	5	7	<5	<5	0	<5	0	0	17
	Grams	461	1,340	800	140	0	396	0	0	3,137
	Grams/Episode	46	45	57	140	0	44	0	0	49
	Grams per 1,000	<1	<1	<1	<1	0	<1	0	0	<1
Solid organ - heart/lung	Patients	<5	6	<5	0	0	0	0	0	8
	Grams	96	838	324	0	0	0	0	0	1,258
	Grams/Episode	32	23	27	0	0	0	0	0	25
	Grams per 1,000	<1	<1	<1	0	0	0	0	0	<1
Solid organ - liver	Patients	6	<5	0	<5	<5	0	0	0	9
	Grams	733	93	0	24	65	0	0	0	915
	Grams/Episode	37	47	0	24	33	0	0	0	37
	Grams per 1,000	<1	<1	0	<1	<1	0	0	0	<1
Solid organ - lung	Patients	38	36	15	<5	<5	<5	0	0	94
	Grams	5,663	6,502	2,759	406	559	423	0	0	16,311
	Grams/Episode	48	29	23	31	29	33	0	0	32
	Grams per 1,000	<1	1	<1	<1	<1	<1	0	0	<1
Solid organ - other	Patients	0	0	0	0	<5	0	0	0	<5
	Grams	0	0	0	0	80	0	0	0	80
	Grams/Episode	0	0	0	0	10	0	0	0	10
	Grams per 1,000	0	0	0	0	<1	0	0	0	<1
Solid organ - pancreas	Patients	0	<5	0	0	0	0	0	0	<5
	Grams	0	335	0	0	0	0	0	0	335
	Grams/Episode	0	12	0	0	0	0	0	0	12
	Grams per 1,000	0	<1	0	0	0	0	0	0	<1
Susac syndrome	Patients	5	0	<5	0	0	0	0	0	9

Condition		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	National
	Grams	2,274	0	2,610	0	0	0	0	0	4,884
	Grams/Episode	37	0	47	0	0	0	0	0	42
	Grams per 1,000	<1	0	<1	0	0	0	0	0	<1
Systemic Capillary Leak syndrome	Patients	5	<5	<5	0	0	0	<5	0	9
	Grams	1,518	1,980	3,060	0	0	0	1,680	0	8,238
	Grams/Episode	45	104	113	0	0	0	80	0	82
	Grams per 1,000	<1	<1	<1	0	0	0	4	0	<1
Transplant - Solid Organ	Patients	0	0	0	0	0	<5	0	0	<5
	Grams	0	0	0	0	0	270	0	0	270
	Grams/Episode	0	0	0	0	0	15	0	0	15
	Grams per 1,000	0	0	0	0	0	<1	0	0	<1
Chapter 7 Total	Patients	218	200	163	51	48	16	24	6	716
	Grams	49,344	39,652	47,836	11,683	14,008	5,229	9,801	669	178,221
	Grams/Episode	38	35	36	55	47	32	55	30	38
	Grams per 1,000	7	7	10	5	8	10	25	3	8
Total	Patients	5,465	3,447	3901	837	843	336	276	76	14,983
	Grams	1,555,324	997,695	1,180,232	270,895	245,746	100,676	89,927	17,830	4,458,326
	Grams/Episode	31	33	30	37	33	33	31	40	32
	Grams per 1,000	206	169	248	105	145	195	232	73	189

Appendix E – Grams Ig Issued by State and Territory

		NSW	VIC	QLD	WA	SA	TAS	ACT	NT
2004-05	Imported Ig		22,200	3,000	144	2,856			
	Domestic Ig	410,505	318,762	306,639	125,094	110,031	40,353	23,895	6,321
2005-06	Imported Ig	41,376	13,860	19,992	144	5,922			
	Domestic Ig	420,858	326,130	284,043	148,200	95,403	46,065	24,615	7,806
2006-07	Imported Ig	76,368	52,097	134,475	7,765	15,300	13,608	8,165	
	Domestic Ig	452,565	361,665	219,633	152,127	109,515	33,837	21,774	8,004
2007-08	Imported Ig	103,270	88,398	79,393	20,577	18,375	11,065	7,170	
	Domestic Ig	493,172	407,244	337,301	155,821	92,958	50,583	26,470	6,732
2008-09	Imported Ig	105,633	111,010	85,055	38,445	18,416	11,740	16,875	
	Domestic Ig	599,126	423,170	400,144	148,986	108,596	52,755	27,393	6,825
2009-10	Imported Ig	249,905	131,228	171,367	42,895	27,604	19,965	14,200	
	Domestic Ig	562,320	417,574	383,865	143,628	128,511	53,745	22,841	10,503
2010-11	Imported Ig	252,416	101,930	200,264	16,248	31,244	17,110	11,550	
	Domestic Ig	668,526	507,038	439,089	162,963	143,285	61,686	33,225	8,610
2011-12	Imported Ig	136,728	93,835	107,798	30,108	27,383	8,843	11,900	80
	Domestic Ig	887,016	577,260	631,545	167,745	139,296	76,197	45,540	9,099
2012-13	Imported Ig	265,995	144,284	183,435	59,900	35,775	12,138	14,708	30
	Domestic Ig	874,995	570,969	674,277	150,294	145,134	73,491	52,446	13,440
2013-14	Imported Ig	467,371	321,085	361,654	92,914	72,613	16,436	26,648	9,551
	Domestic Ig	804,375	484,680	589,662	132,108	123,810	64,305	48,480	6,744
2014-15	Imported Ig	930,412	579,560	735,658	155,977	135,795	57,987	59,210	4,863
	Domestic Ig	593,045	416,868	458,189	111,570	107,343	41,608	32,199	12,861

Appendix F – Unique Patients by Quarter and State and Territory

Year	Quarter	NSW	VIC	QLD	WA	SA	TAS	ACT	NT	AUST
2009-10	Q1	2,434	1,367	1,644	380	400	183	112	23	6,508
	Q2	2,496	1,378	1,667	356	440	177	109	20	6,619
	Q3	2,554	1,386	1,682	353	395	183	102	15	6,640
	Q4	2,602	1,451	1,752	371	413	189	120	22	6,889
2010-11	Q1	2,692	1,492	1,839	376	420	197	143	22	7,148
	Q2	2,781	1,533	1,886	394	394	205	132	21	7,315
	Q3	2,752	1,532	1,884	376	396	211	130	15	7,262
	Q4	2,791	1,622	1,946	385	417	197	142	23	7,496
2011-12	Q1	2,921	1,658	2,047	407	419	199	142	27	7,794
	Q2	2,971	1,628	2,115	413	428	206	137	22	7,898
	Q3	2,949	1,590	2,150	401	430	203	150	23	7,860
	Q4	2,961	1,632	2,215	405	458	202	154	29	8,019
2012-13	Q1	3,107	1,751	2,391	449	449	205	168	32	8,494
	Q2	3,139	1,809	2,360	436	462	196	171	26	8,557
	Q3	3,211	1,753	2,298	410	454	183	164	33	8,465
	Q4	3,309	1,821	2,378	425	463	187	170	36	8,737
2013-14	Q1	3,406	1,890	2,472	435	506	204	181	36	9,081
	Q2	3,428	1,971	2,510	472	481	209	172	36	9,237
	Q3	3,440	1,952	2,583	454	502	213	188	30	9,317
	Q4	3,550	2,042	2,660	513	493	215	188	34	9,653
2014-15	Q1	3,713	2,150	2,763	518	545	238	189	41	10,099
	Q2	3,725	2,169	2,719	521	506	228	202	32	10,057
	Q3	3,733	2,161	2,772	510	530	215	191	25	10,096
	Q4	3,846	2,249	2,868	514	555	223	202	31	10,440

Appendix G – System Source for Tables and Figures