Immunoglobulin Database

Immunoglobulin Database Report 2015/16

mdsas
medical data solutions and services

1 Database Overview

Rob Hollingsworth

Introduction

I would firstly like to thank all Trusts and their staff that continue to support and provide data to the National Immunoglobulin Database. I would also like to thank the database steering group members for their input into the successful running of the database.

This report will provide a snapshot of the data from the database for the calendar year 2015-16. Also included is an update from NHS England and the Commercial Medicines Unit (CMU).

The database continues to evolve and there have been a number of updates since the last report in relation to the use of the database for the production of dashboard measures. Although still not perfect, considerable effort has been put in over the last two years to improve the dashboard measures and simplify their production from the database.

Increasing Use of Immunoglobulin

The annual increase in immunoglobulin sales continues at approximately 10%. In-line with predictions in last year's report. It is expected that within two years, national costs for immunoglobulin products will be around £190-200 million per annum.

Database Status

The database continues to grow, since its initiation the database has captured information on almost 60,000 patients and 71,000 separate treatment episodes. Trusts have entered over 750,000 treatment entries, accounting for over 25 million grams of immunoglobulin recorded on the database - this equates in value at an average price per gram of £34 to £850 million.

Database Developments

The database is now being used extensively by NHS England to support commissioning and therapy initiatives for immunoglobulins. This year some of these initiatives have related to investigating Immune Thrombocytopenic Purpura (ITP) dosing in accordance to guidelines and the validation of Trust financial re-imbursement for immunoglobulin use. It is envisaged in the coming year that the database will be used by NHS England to monitor individual Trust compliance with the entry of required outcome data.

The Commercial Medicines Unit (CMU) this year will also be making use of the database to support the development and introduction of a new framework for immunoglobulin procurement.

Home Therapy System Development

A home therapy system for Primary immunodeficiencies patients has been developed and a pilot of its use is currently underway. The system 'Haemtrack' enables Primary immunodeficiencies patients to record the details of their treatment through a smartphone or computer. Haemtrack has been used very successfully in Haemophilia with over 1 million treatments having been entered by patients. With this system clinicians can view real-time therapy entries made by patients via direct integration into the national immunoglobulin database. Following the pilot, it is planned to expand use of the system for other conditions treated with immunoglobulin.

Annual Database Meeting

The annual database meeting was held in December at Etc. Venues in Pimlico. The event was a great success with all available places for the meeting taken. A big thank you must go to all our speakers at the event, and to all attendees and sponsors who, with their feedback and support, helped make the meeting so successful. It is planned to hold the next annual meeting in December at the same venue. Further information will be available closer to the time of the meeting.

Annual Report

This report provides an analysis of immunoglobulin usage across England. Communications from key stakeholders are also included. Feedback on the annual report is very welcome from all stakeholders. If there is something additional that you would like to see in the report then please send your suggestions to support@mdsas.com.

2 Commissioning Update

Rob Coster

Intravenous and subcutaneous immunoglobulin is an expensive blood product used across a variety of clinical specialities. These treatments are a high-cost drug, entirely funded by specialised commissioners under the auspices of NHS England. In terms of cost, immunoglobulin is excluded from tariff and expenditure across England is £148 million per annum and increasing by about 10% per annum.

NHS England has finite resources and needs to make decisions to ensure the best possible outcome for all of the patients for whom it has commissioning responsibility. Decisions must be made in a systematic, consistent and transparent way, with the aim of fairly and rationally distributing these resources across different patient groups, and across competing demands.

NHS England has commenced a project focused on ensuring appropriate and cost-effective use of immunoglobulin. The project will be focusing on the following:

- Improved recording of outcome data on MDSAS database.
- Review of present DH Clinical Guidelines for Immunoglobulin Use.
- Audit and review of the effectiveness of Immunoglobulin Review Panels
- Appropriate dosing of intravenous immunoglobulin in various treatments, primarily Immune Thrombocytopenic Purpura (ITP)

Review of Guidelines

Immunoglobulin is commissioned by NHS England, at present in line with Department of Health Clinical Guidelines for Immunoglobulin Use. The guidelines state which conditions immunoglobulin is recommended for and these were developed originally according to priority, to inform demand management. The guidelines were last updated in 2011, so are due for review. As part of the project we are reviewing the current clinical guidelines with the aim of moving in line with NHS England's current commissioning decision making process. The review will concentrate on the indications in two groups:

Review of Blue and Grey Indications:

These indications will be reviewed in line with NHS England's policy and prioritisation process. We are seeking the views of expert clinicians in a range of specialities, for an initial review of the current indications, to feed into the policy development process and whether the use of immunoglobulin is still appropriate in each indication, alternative treatment options, any suggested changes to eligibility criteria and dose or efficacy outcomes that should be recorded on the database.

Red Indications:

We are reviewing the use of immunoglobulin in the red indications, with a view to transferring these into NHS England "routinely commissioned policies". A review of use of immunoglobulin in each indication will be carried out to ensure it is still appropriate and eligibility criteria, dose or efficacy outcomes should be recorded on the database.

Appropriate Dosing of Immunoglobulins

Although systematic data on treatment outcomes is not always recorded on the database, a substantial proportion of patients with ITP (~60%) are possibly being needlessly over-treated. Not only does this represent a clinically inappropriate drain on finite resources, estimated at greater than £2m per annum, but also exposes patients to potentially serious adverse effects associated with high dose immunoglobulin.

Based on the above, NHS England have been sharing information with acute Trusts and local NHS England commissioners to review use locally and to remind trusts of the need to adhere to the recommended dose; this would require the initial treatment dose to not exceed 1g/kg. Commissioners will reserve the right not to reimburse trusts for the cost of immunoglobulin exceeding 1g/kg unless verifiable justification for the use of a higher dose is recorded.

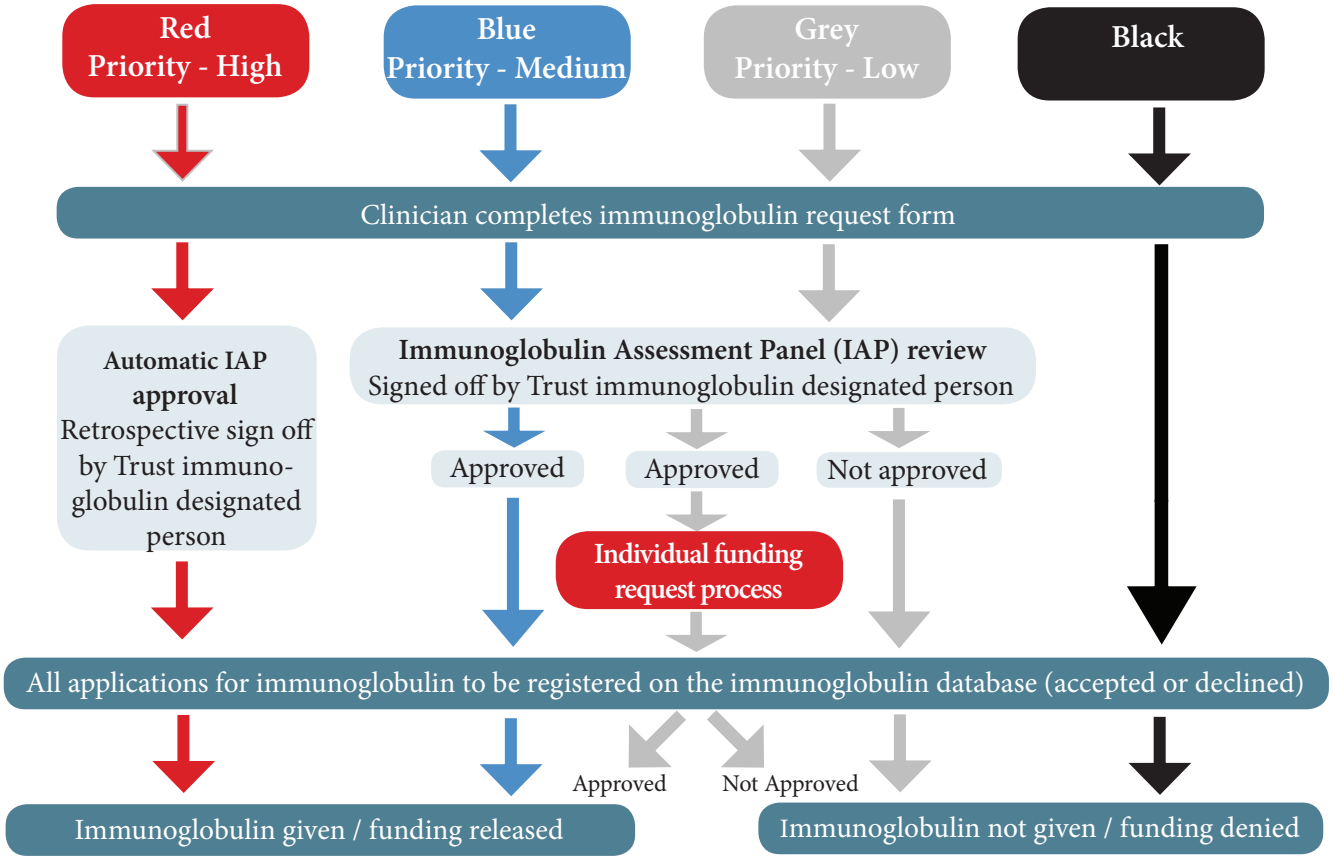
Audit and Review of the Effectiveness of Immunoglobulin Review Panels

An initial audit of Immunoglobulin Review Panels has been carried out and a good practice guide has been developed from the responses. This has been shared with commissioners and Trusts and a further audit will be carried out towards the end of 2017, looking for improvements in the way these panels run and the effective stewardship of immunoglobulin usage within Trusts.

Letters explaining the NHS England's position regards dosages and recording of outcomes on the database have been sent to trust Clinical Directors. There is also an expectation within the contract that providers do enter the required information, including outcome data on to databases and this will be monitored through the contracting process.

Commissioners, working with providers, must deliver improved outcomes, improve use of resources and be fair and consistent throughout the country, and ensure that all patients have equal access to services regardless of their location.

2.1.1 Immunoglobulin Approval process



3 NHS Procurement

David Ford

Contract Picture

All immunoglobulin purchased in England and Northern Ireland is covered by a national framework agreement tendered by the Commercial Medicines Unit (CMU), part of the Department of Health. The aim of the framework is to maintain security of supply and deliver value for money, whilst following EU tender procedures. There are separate agreements for Wales and Scotland managed in those countries.

The current spend on the Immunoglobulin framework is £165million per annum covering seventeen different products and just under five million grams of product through the six contracted suppliers of product. The current framework has seen a significant switching in products being used by the NHS and CMU has been working with trusts to capture forecasted product usage and ensure capability of suppliers to meet demand.

There has been a continued growth in IG sales over the previous and current contract of between 5 and 10% each year and a reduction in the average price paid per gram equating to 6.8% between 2011 and 2016 due to lower contract prices and product switching.

The framework has been extended up to the 31st May 2017 and work is underway to re-tender this agreement to have a new contract in place from 1st June 2017.

Tender Process / Stakeholder Engagement

As we plan the next tender process 2016, CMU will be seeking input from a wide range of stakeholders to review the strategy for the framework, review and update the specification, award criteria. Representation and views of pharmacists, commissioners, clinicians, IG database, patient groups and nursing staff are invaluable in ensuring requirements are met and that key requirements and considerations are included and evaluated accordingly within the process. This group are also critical in managing any issues that may arise during the contract period.

There are a number of considerations for the next tender including changes to market shares of contract sales, new IG products entering the UK market in 2016-17, the impact of the Brexit vote and its implications on product supply into the market, as well as proposed changes to the statutory scheme to control the prices of branded health services medicines.

The usage data from the database will also be used to inform and steer the strategy for the next agreement. A briefing document with all the award details for this framework will be circulated to the NHS in Spring 2017, we will be working with Trusts to monitor and manage the forecast demand as necessary.

Contacting CMU

For further information on the framework agreement, contracting process or if you wish to be formally engaged as part of the stakeholder group, please contact CMU at specialisedpharma@dh.gsi.gov.uk or Tel. 01928 755224.

Figure 3.1 Summary of total immunoglobulin sales 1/6/12 - 31/5/16 (England and N Ireland)

	1/6/12 - 31/5/13 (Grams)	1/6/13 - 31/5/14 (Grams)	1/6/14 - 31/5/15 (Grams)	1/6/15 - 31/5/16 (Grams)	Change Yr One to Two	Change Yr Two to Three	Change Yr Three to Four	Change Yr Four to Five
IVIG Products - Direct to Trust	3,398,996	3,651,702	4,031,709	4,361,790	6.3%	7.4%	10.4%	8.2%
IVIG Products - Home-care Companies	135,323	157,403	145,878	166,153	-23.9%	16.3%	-7.3%	13.9%
Subcut IG - Direct to Trust	127,004	119,495	135,702	173,349	0.4%	-5.9%	13.6%	27.7%
Subcut IG - Homecare Companies	425,754	537,998	610,290	705,018	15.7%	26.4%	13.4%	15.5%
Totals	4,087,077	4,466,598	4,923,579	5,406,310	5.6%	9.3%	10.2%	9.8%

4 Data Update

Mark Foster

The Sixth National Database Annual Report

This Data Update chapter in the sixth edition of the National Database Annual Report utilises 39 data sets to provide readers with an overview of immunoglobulin use in England for 2015/16. Data recorded on the database by the end of October 2016 is included in reporting. A full list of reports are provided on page 11.

Increasing Data Capture

The total volume of immunoglobulin recorded in England for 2015/16 was 4.6 million grams, this is the highest volume recorded by the database since its launch. Comparing volumes recorded with Commercial Medicines Unit (CMU) sales figures, it is estimated that the database captures around 90% of the volume purchased by CMU.

Usage in Specialisms

As highlighted in previous reports, neurological conditions use the most immunoglobulin (42%) by volume, then immunology (35%), haematology (9%). Conditions falling under other specialties as defined in the clinical guidelines make up the remaining 14%.

Usage in Top Conditions

Primary immunodeficiencies remain the number one condition for number of patients treated (3283) and volume of immunoglobulin recorded (1,196,375 grams). Idiopathic Thrombocytopenic Purpura is the second highest condition for number of patients treated (1475), third is Secondary Antibody Deficiencies (1334). Chronic Inflammatory Demyelinating Polyneuropathy is the second highest volume using condition (905,093 grams), third is MMN (450,687 grams).

Figure 1.1.1 Monthly patient registrations 2015/16

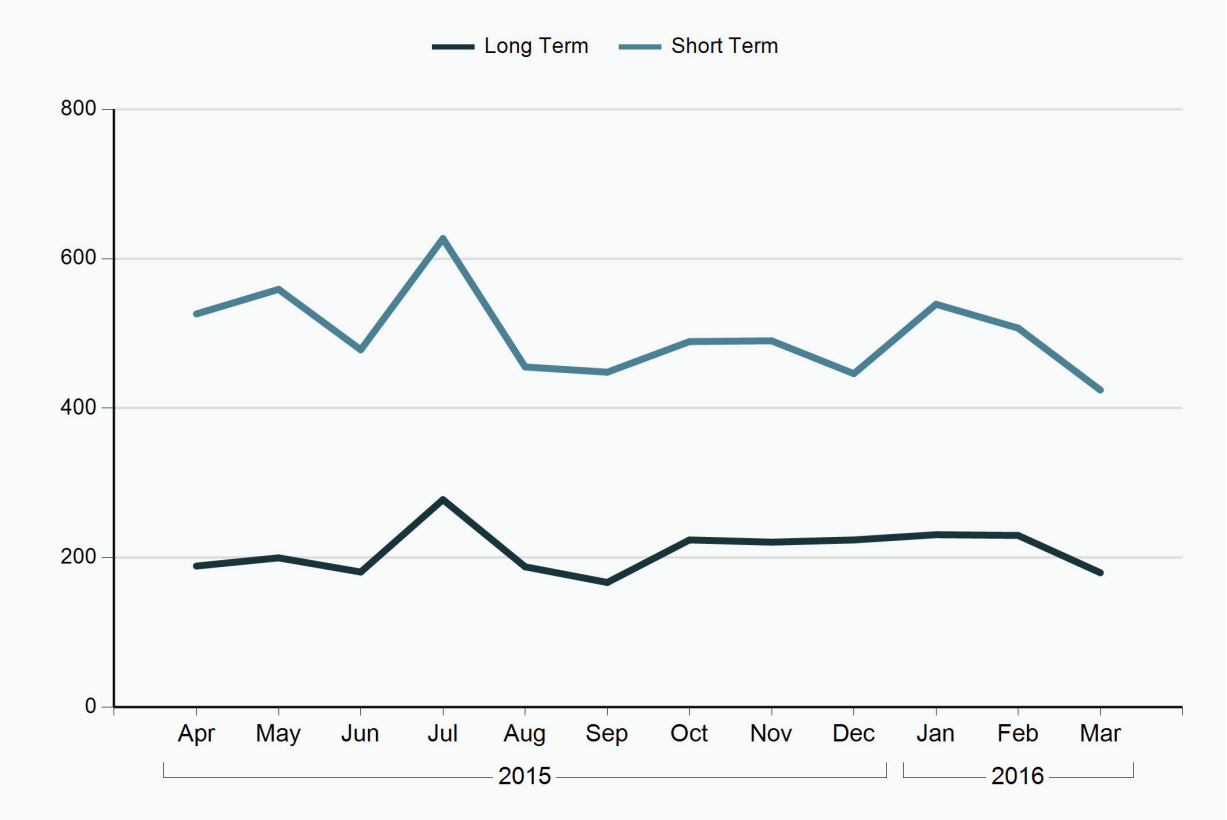


Figure 1.1.2 Yearly patient registrations 2011/12 - 2015/16

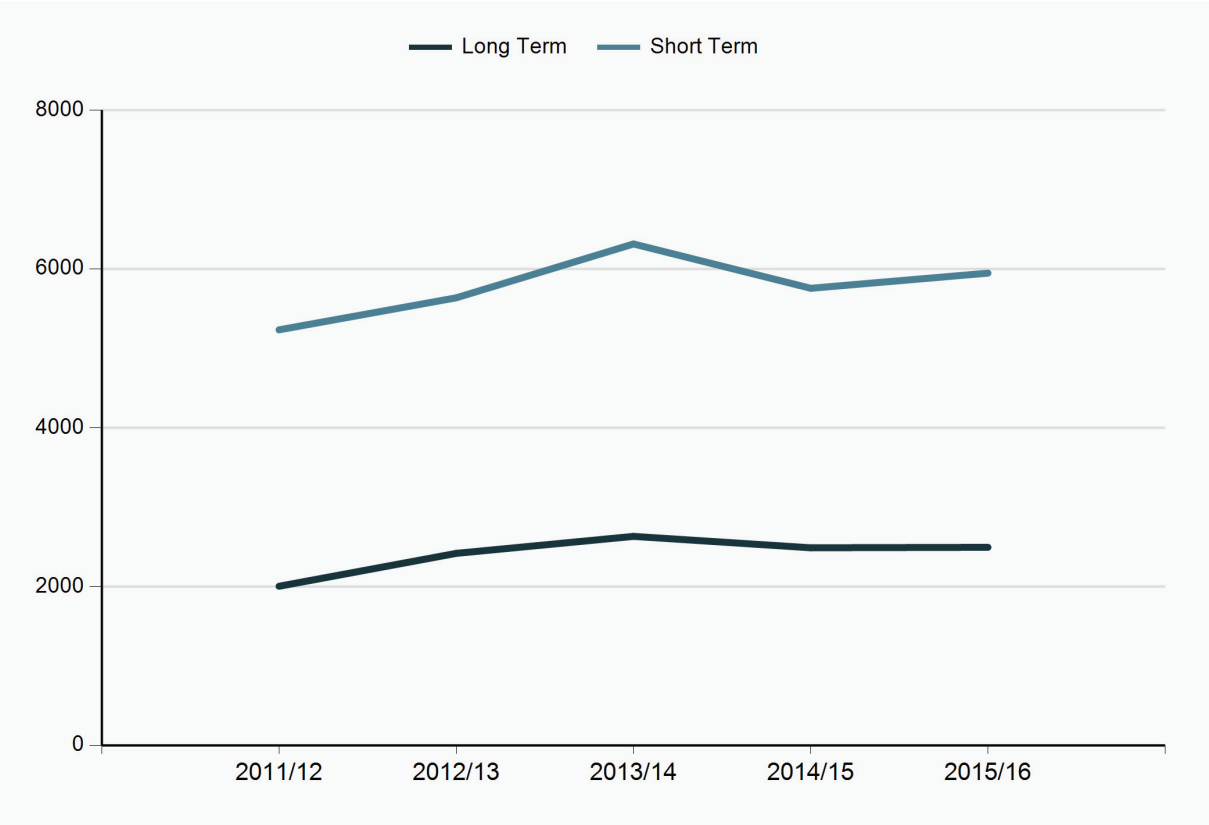


Figure 1.2 Yearly patient registrations by speciality 2011/12 - 2015/16

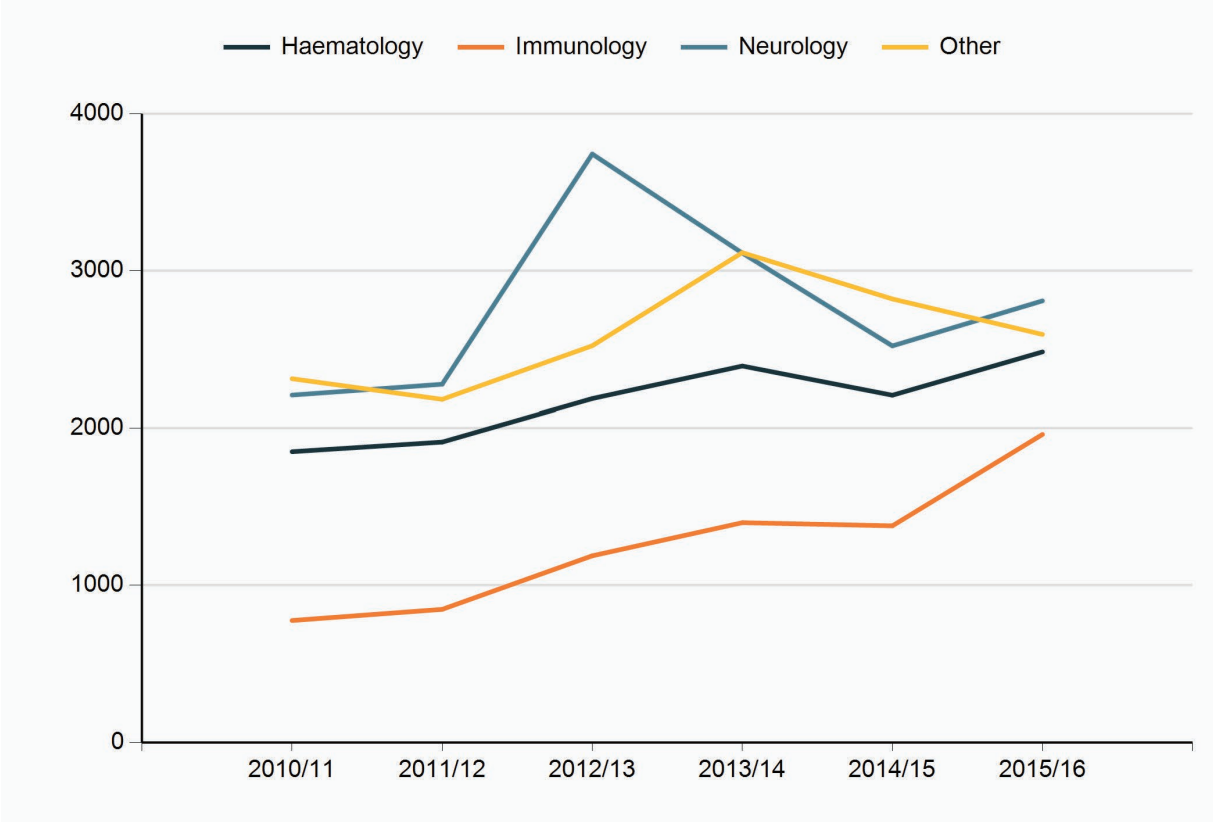


Figure 1.3 Patient registrations by region 2015/16

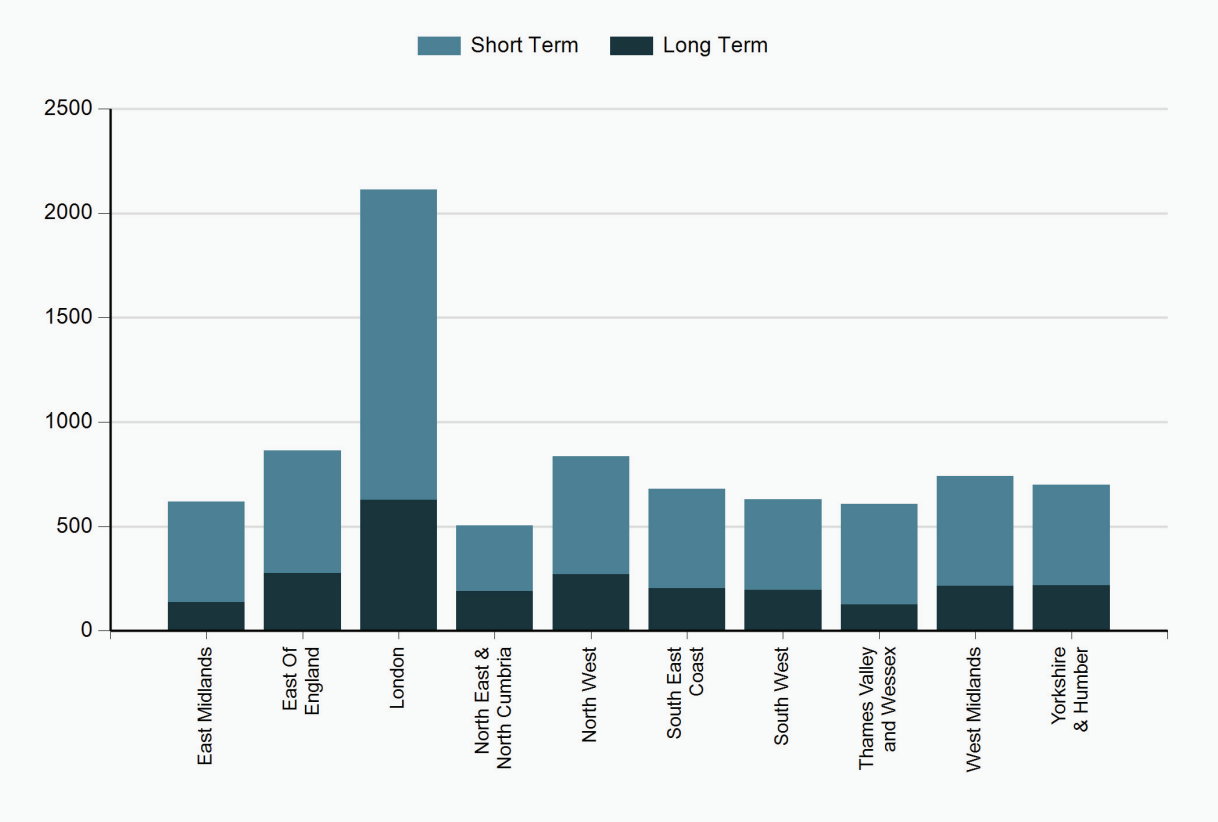


Figure 2.1.1 Monthly number of patients treated 2015/16

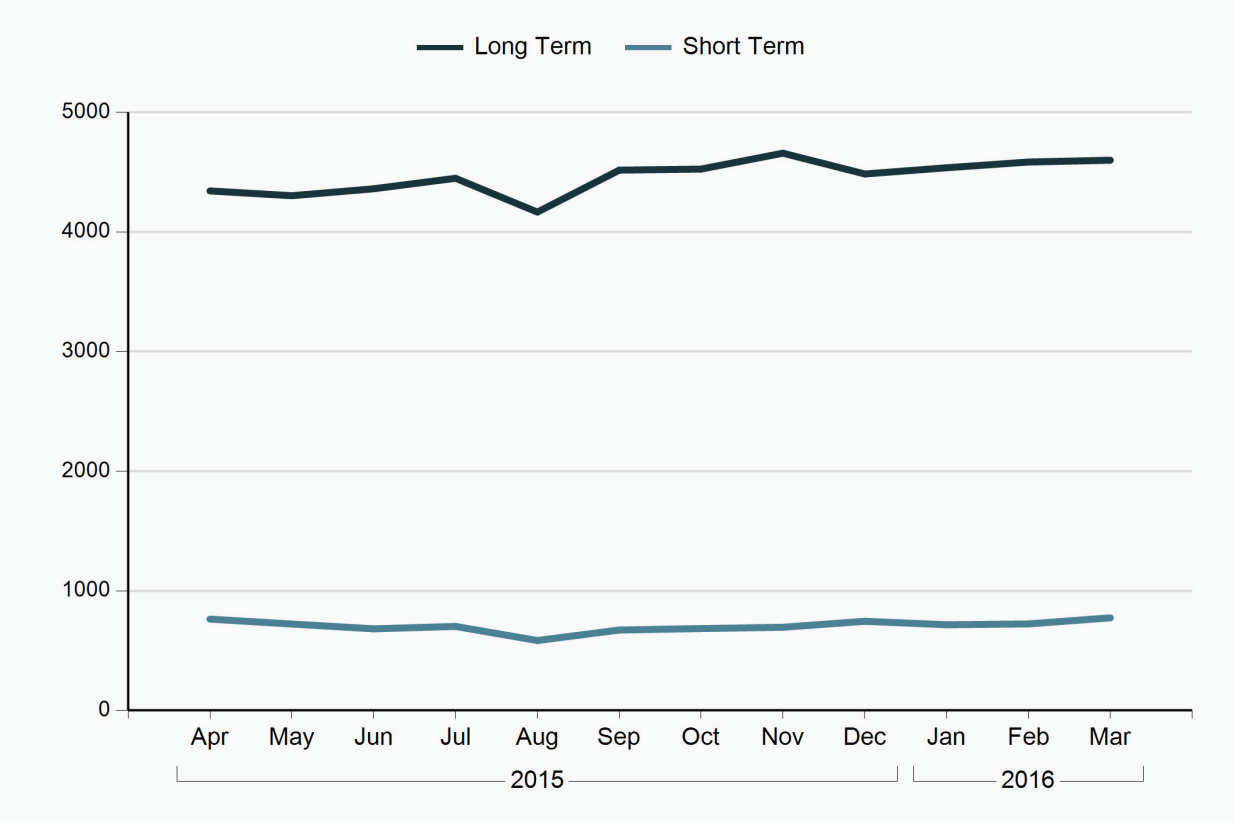


Figure 2.1.2 Yearly number of patients treated 2011/12 - 2015/16

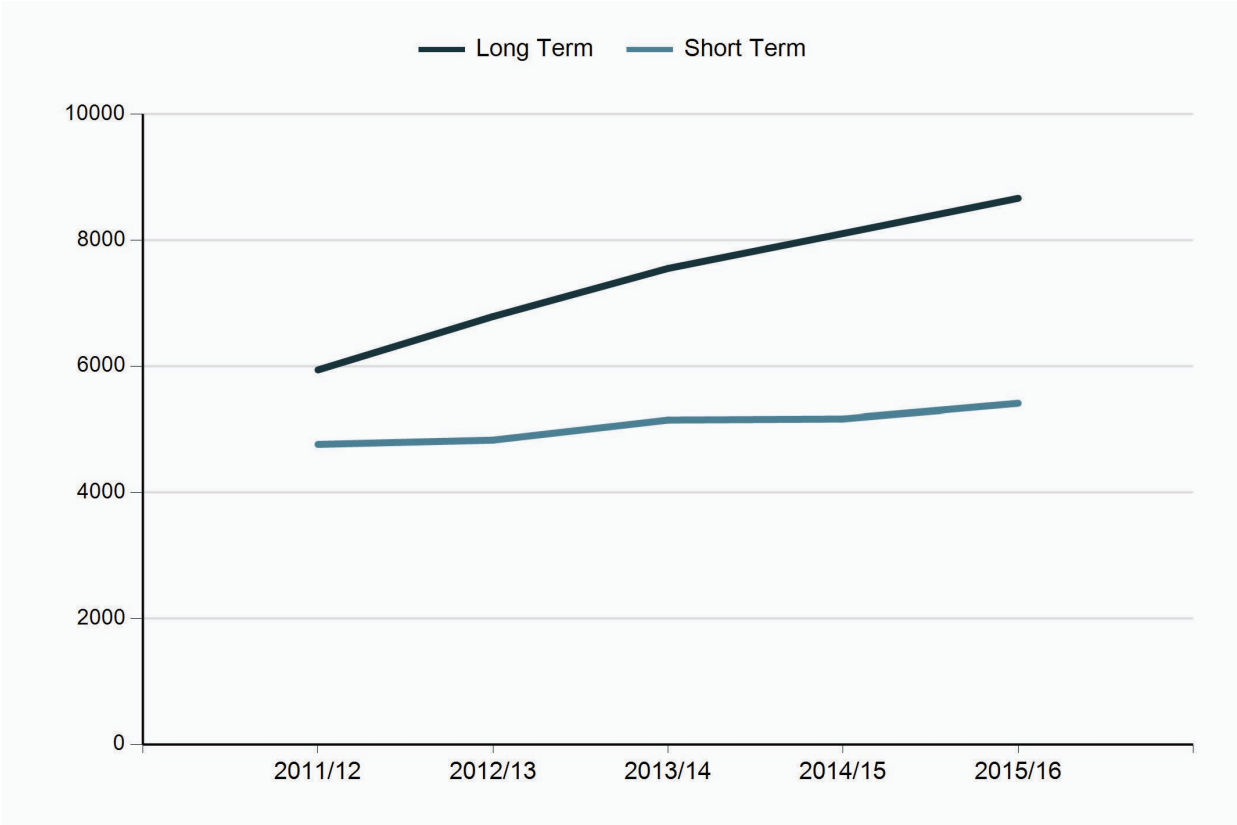


Figure 2.2.1 Monthly number of patients treated by speciality 2015/16

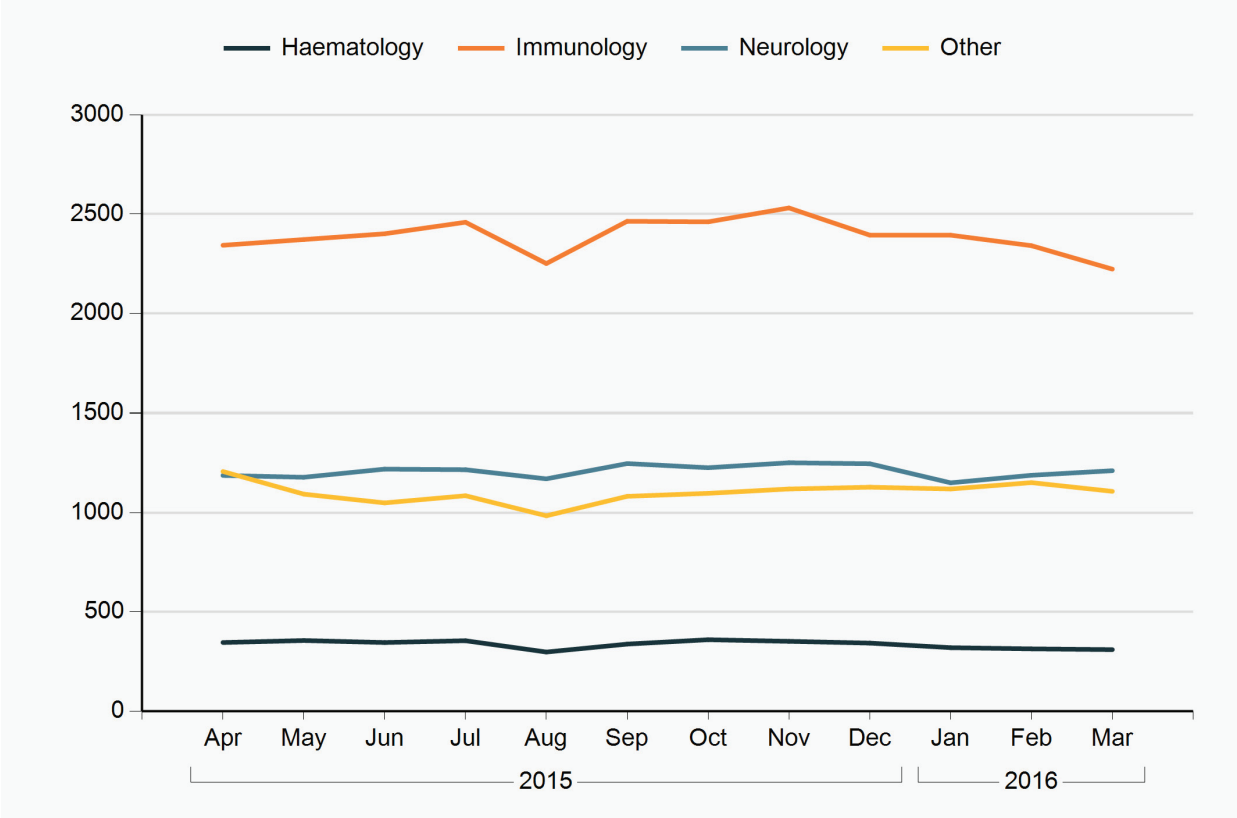


Figure 2.2.2 Yearly number of patients treated by speciality 2011/12 - 2015/16

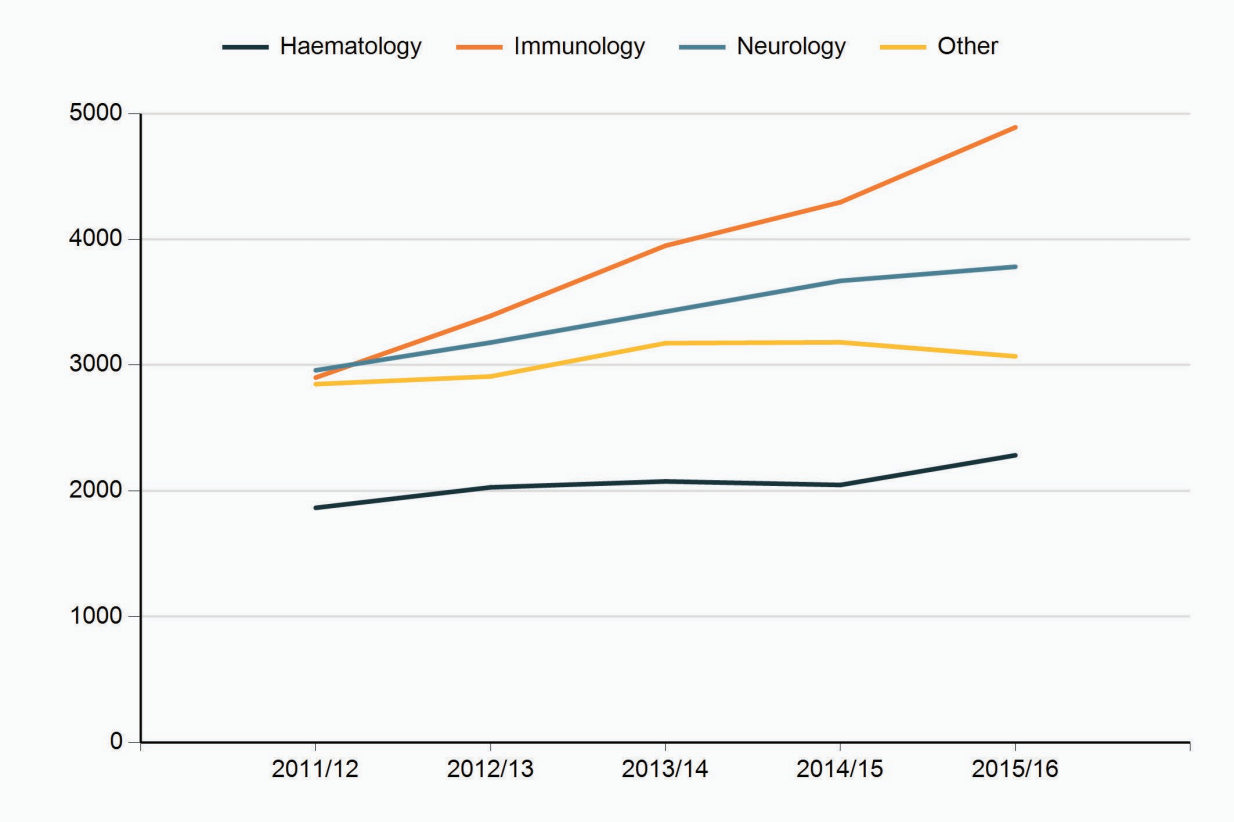


Figure 2.3 Yearly number of patients treated 2011/12 - 2015/16

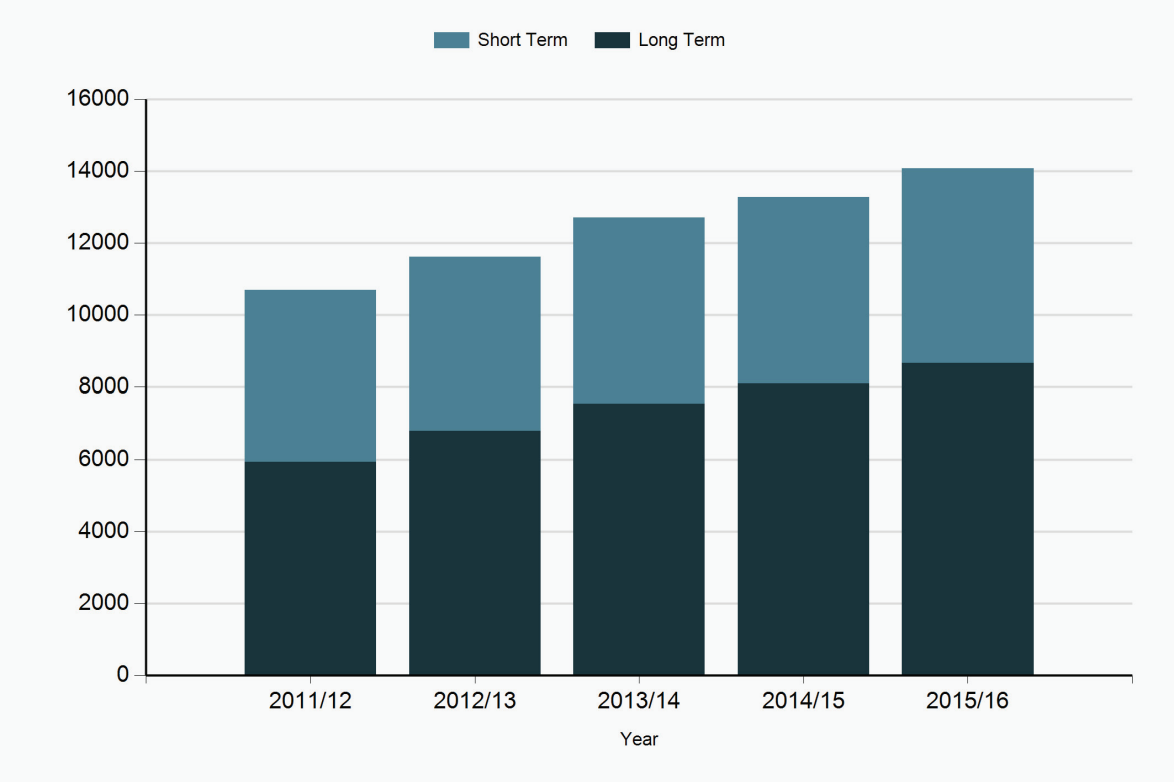


Figure 2.4.1 Number of patients treated by region 2015/16

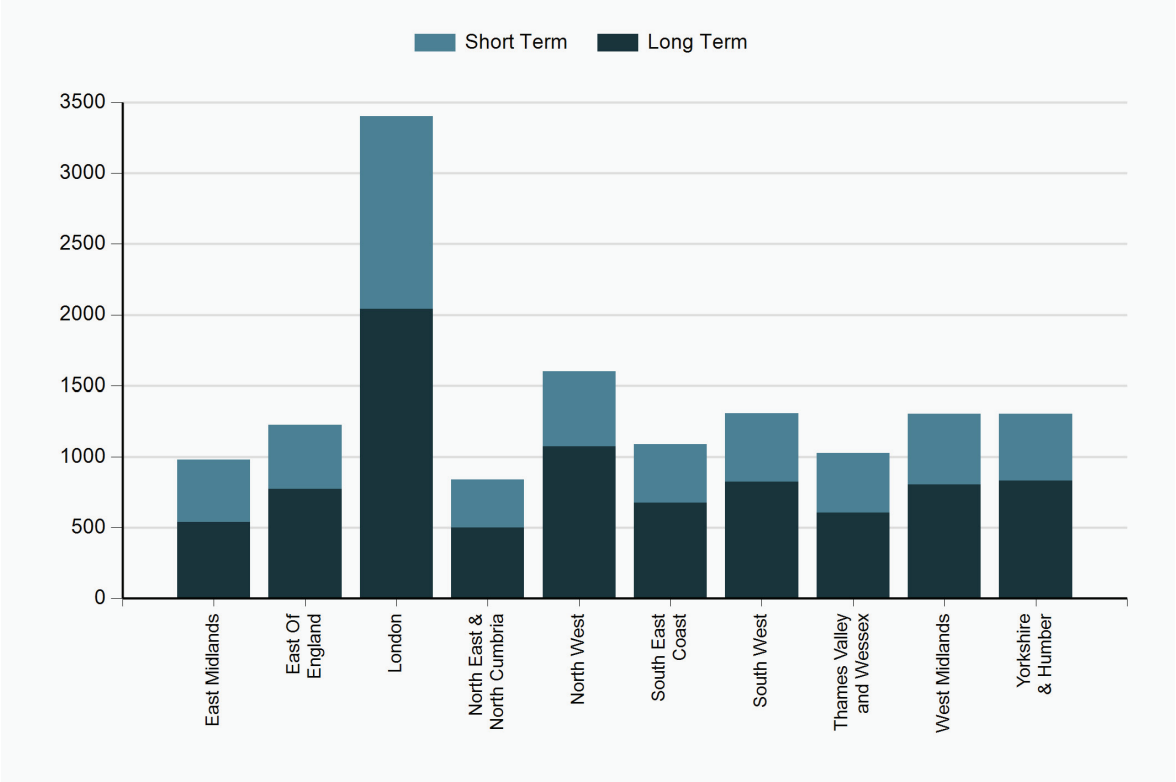


Figure 2.4.2 Yearly patients treated by region 2011/12 - 2015/16

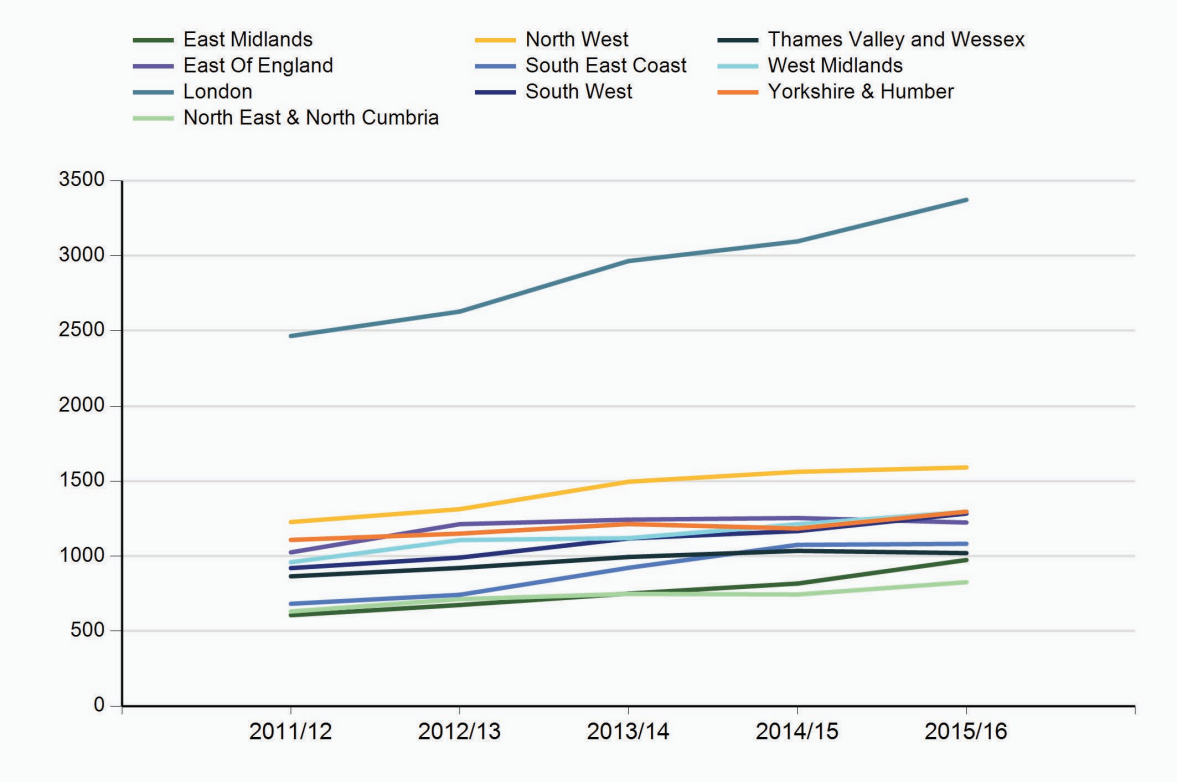


Figure 2.5 Yearly patients treated by treatment place 2011/12 - 2015/16

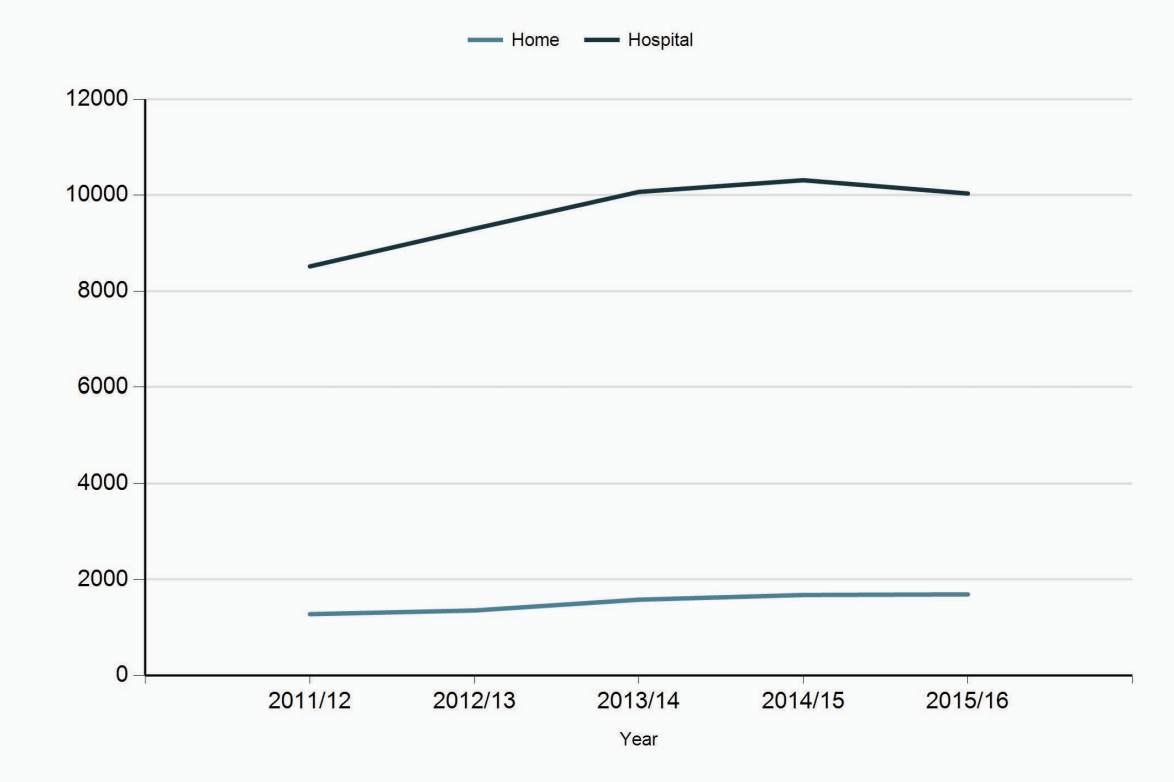


Figure 2.6 Number of patients treated for top 20 diagnoses 2015/16

Trust	2015/16	Change Last Year
Primary Immunodeficiencies	3283	+10%
Immune Thrombocytopenic Purpura - Acute	1475	+ 11%
Secondary Antibody Deficiencies	1334	+34%
Chronic Inflammatory Demyelinating Polyradiculoneuropathy	1289	+6%
Other Conditions	961	-4%
Chronic lymphocytic leukaemia	908	-
Guillain–Barré Syndrome	842	-2%
Myasthenia Gravis	604	+6%
Multifocal Motor Neuropathy	557	+6%
Kawasaki disease	304	+9%
Multiple Myeloma	269	-10%
Inflammatory myopathies	256	+19%
Immune thrombocytopenic purpura - Persistent	233	+14%
Transplantation (Solid Organ)	208	+33%
Staphylococcal toxic shock syndrome	191	-2%
Specific antibody deficiency	177	+ 18%
Low serum IgG levels following HSCT for malignancy	176	-8%
Haemolytic disease of the fetus and newborn	164	+27%
Autoimmune encephalitis	142	+19%
Autoimmune haemolytic anaemia	140	+12

Figure 2.7 Number of patients treated in top 20 trusts 2015/16

Trust	2015/16	Change
Royal Free NHS Trust	488	+6%
Barts And The London NHS Trust	457	+13%
Leeds Teaching Hospitals NHS Trust	368	+23%
The Newcastle Upon Tyne Hospitals NHS Foundation Trust	353	-4%
Imperial College Healthcare NHS Trust	343	+20%
Oxford Radcliffe Hospitals NHS Trust	331	-2%
University College London Hospitals NHS Foundation Trust	329	-1%
Sheffield Teaching Hospitals NHS Foundation Trust	323	-2%
Salford Royal NHS Foundation Trust	322	+7%
Nottingham University Hospitals NHS Trust	290	+7%
Heart Of England NHS Foundation Trust	280	+3%
Guy's And St Thomas' NHS Foundation Trust	278	+10%
University Hospitals Of Leicester NHS Trust	270	+26%
Southampton University Hospitals NHS Trust	244	+6%
Great Ormond Street Hospital for Children NHS Trust	235	+79%
Maidstone and Tunbridge Wells NHS Trust	190	+18%
Plymouth Hospitals NHS Trust	190	+4%
Central Manchester & Manchester Children's University Hospitals NHS Trust	186	-11%
North Bristol NHS Trust	181	+17%
Lancashire Teaching Hospitals NHS Foundation Trust	174	+10%

Figure 2.8 Number of grey patients treated and grey outcomes recorded 2011/12 - 2015/16

Year	2011/12	2012/13	2013/14	2014/15	2015/16
Grey Requests	812	911	908	831	849
Grey Requests with Outcome data	N/A	271	245	235	247
Percentage	N/A	30%	27%	28%	29%

Figure 2.9 Number of long term patients treated and Follow-Ups recorded 2011/12-2015/16

Year	2011/12	2012/13	2013/14	2014/15	2015/16
Long Term Patients	5212	5943	6797	7836	8397
Long Term Patients with Follow-Up	1054	1240	2147	3179	3726
Percentage	20%	21%	32%	41%	44%

Figure 3.1.1 Recorded monthly immunoglobulin use by regime 2015/16

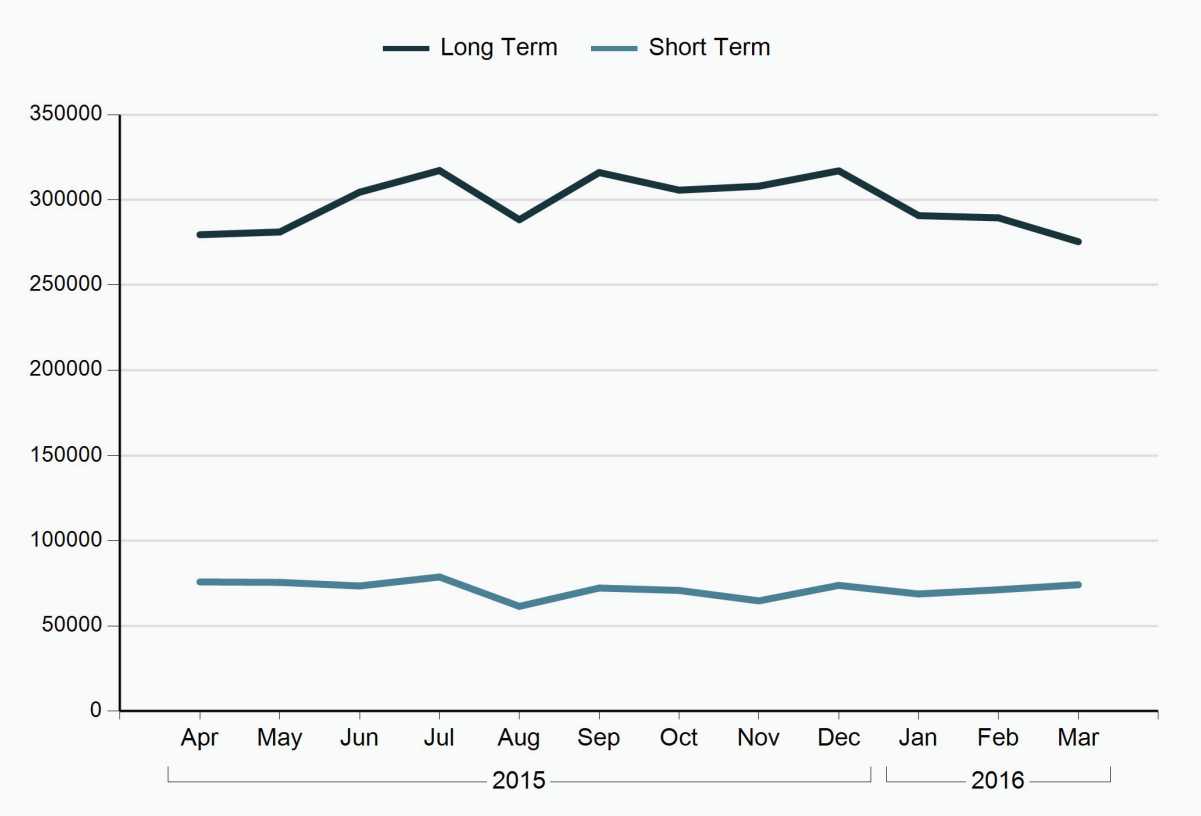


Figure 3.1.2 Recorded yearly immunoglobulin use by regime 2011/12 - 2015/16

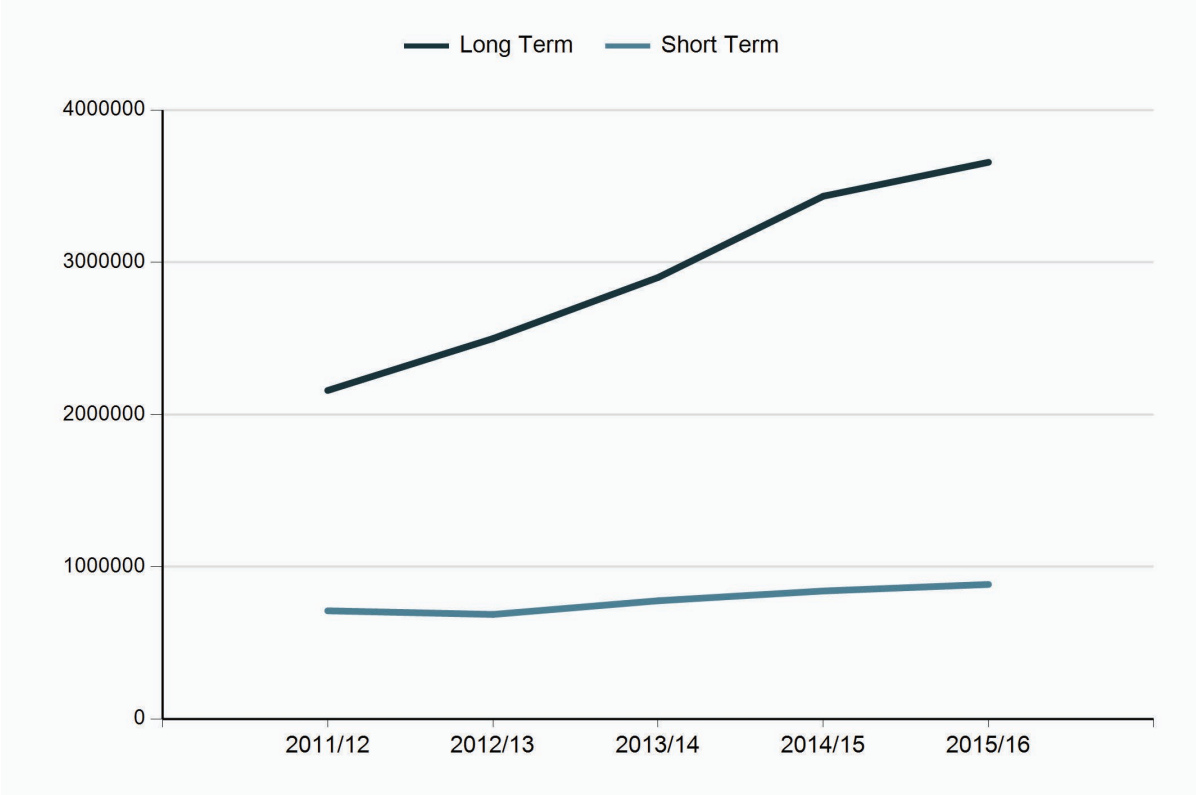
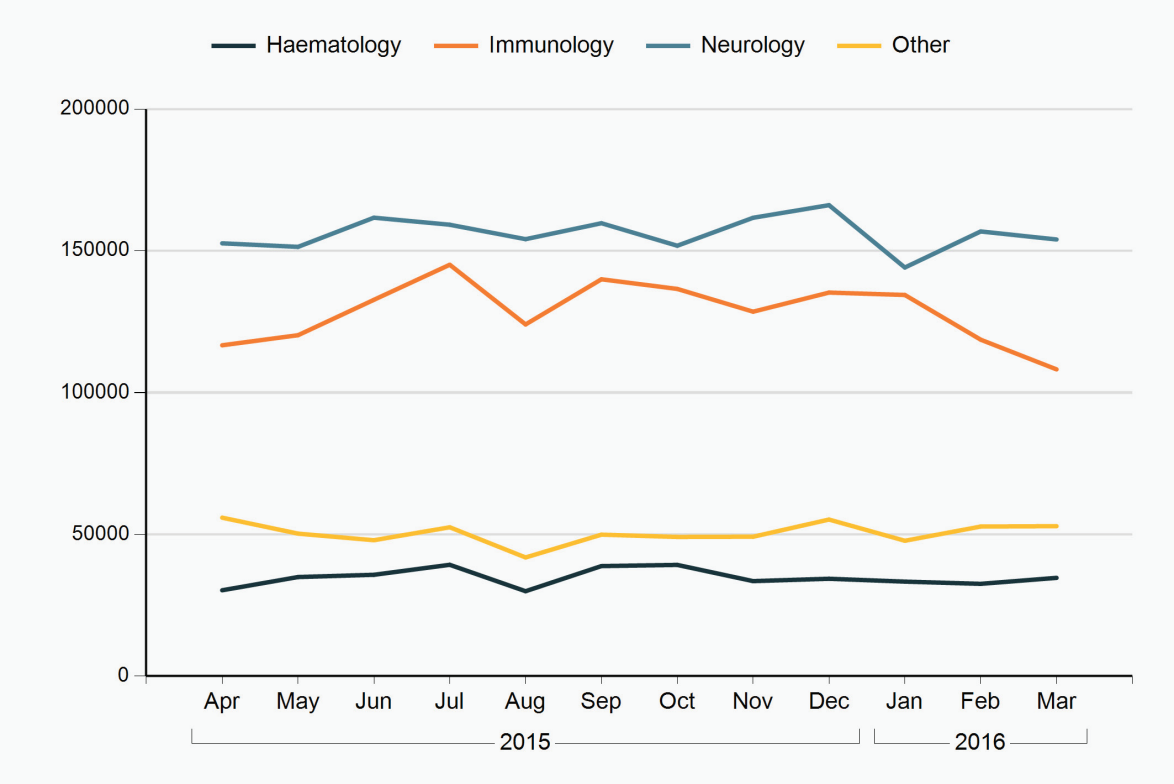


Figure 3.2.1 Recorded monthly immunoglobulin use by speciality 2015/16



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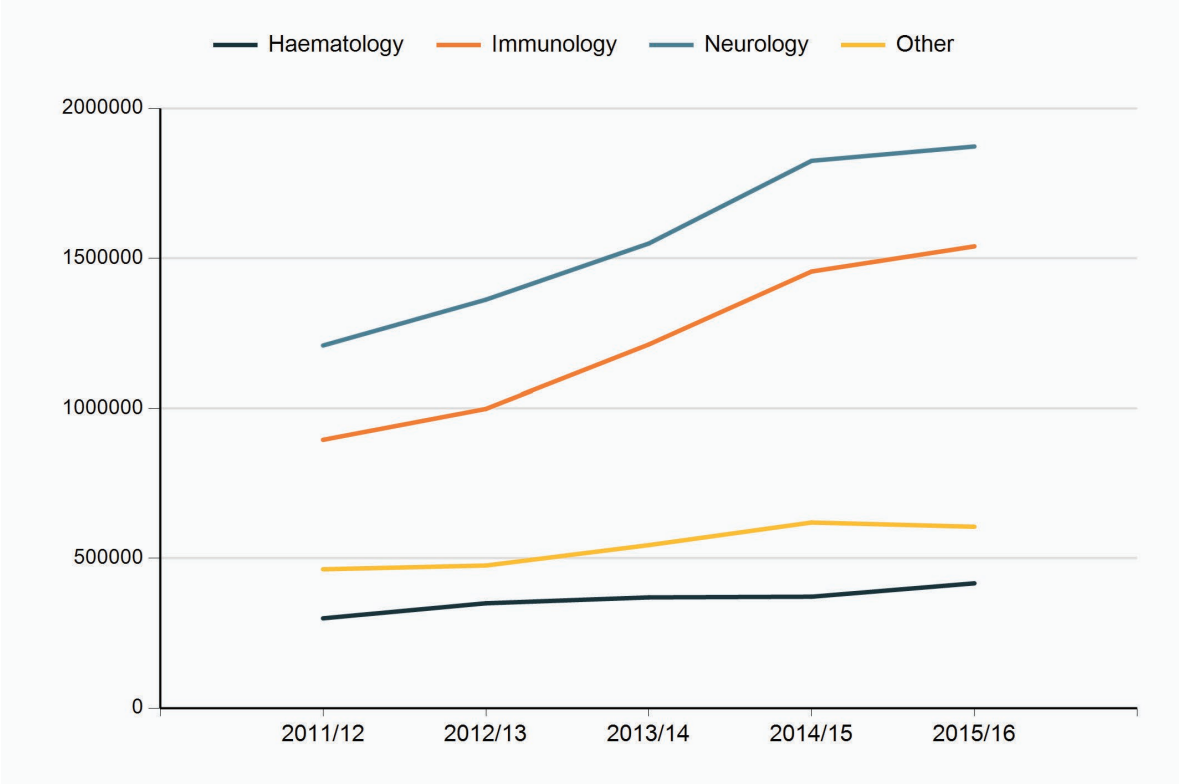


Figure 3.3.1 Recorded monthly immunoglobulin use by Indication 2015/16

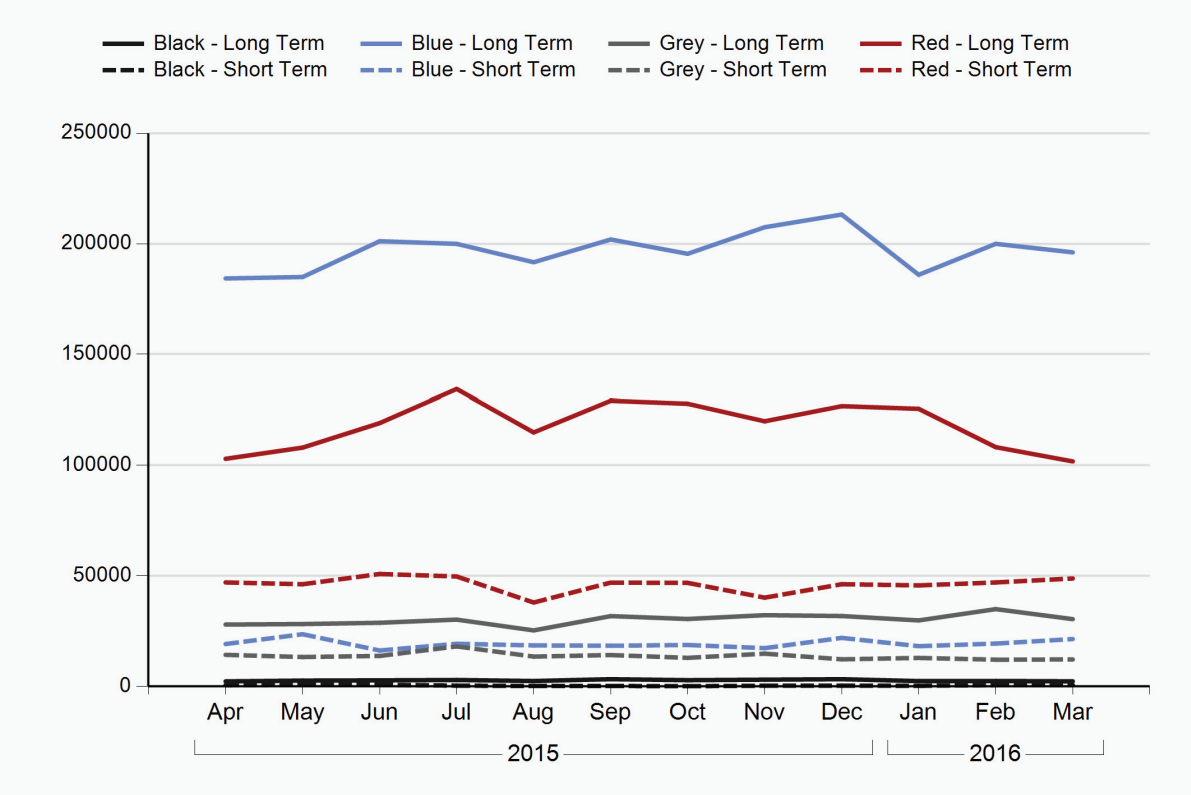


Figure 3.3.2 Recorded yearly immunoglobulin use by Indication 2011/12 - 2015/16

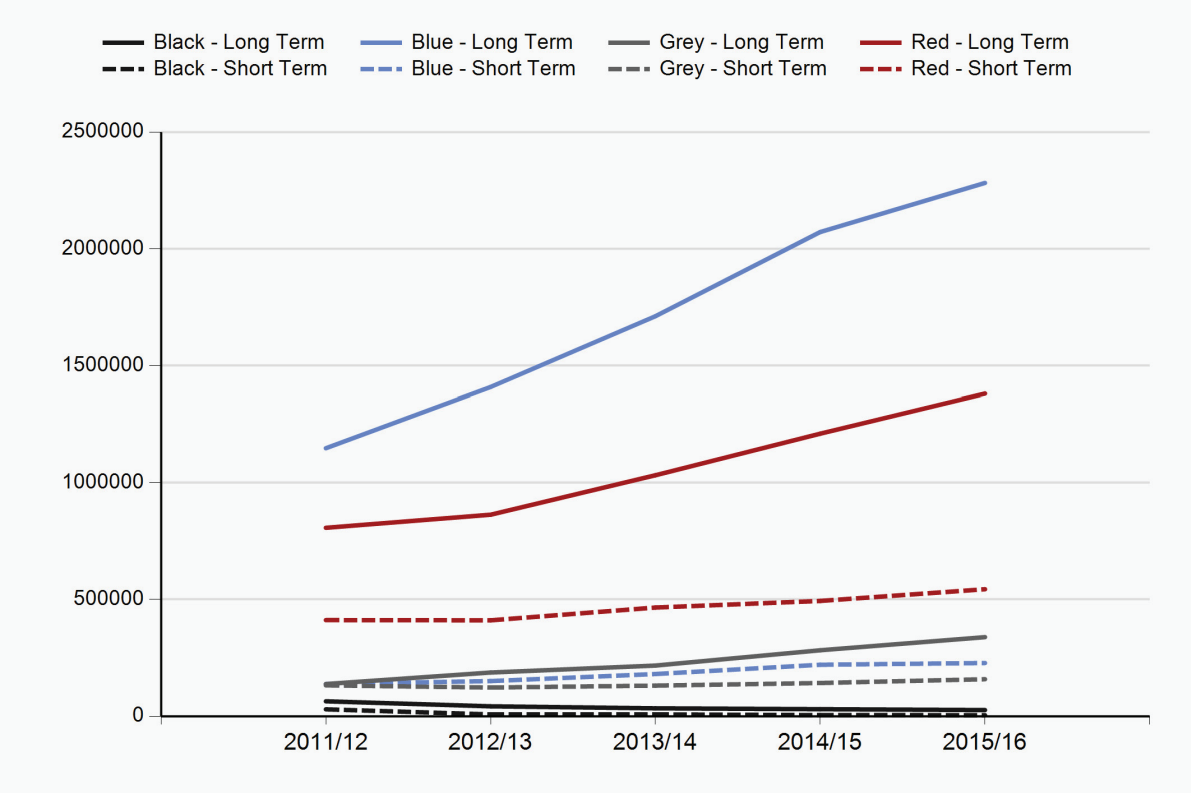


Figure 3.4.1 Recorded immunoglobulin use by region 2015/16

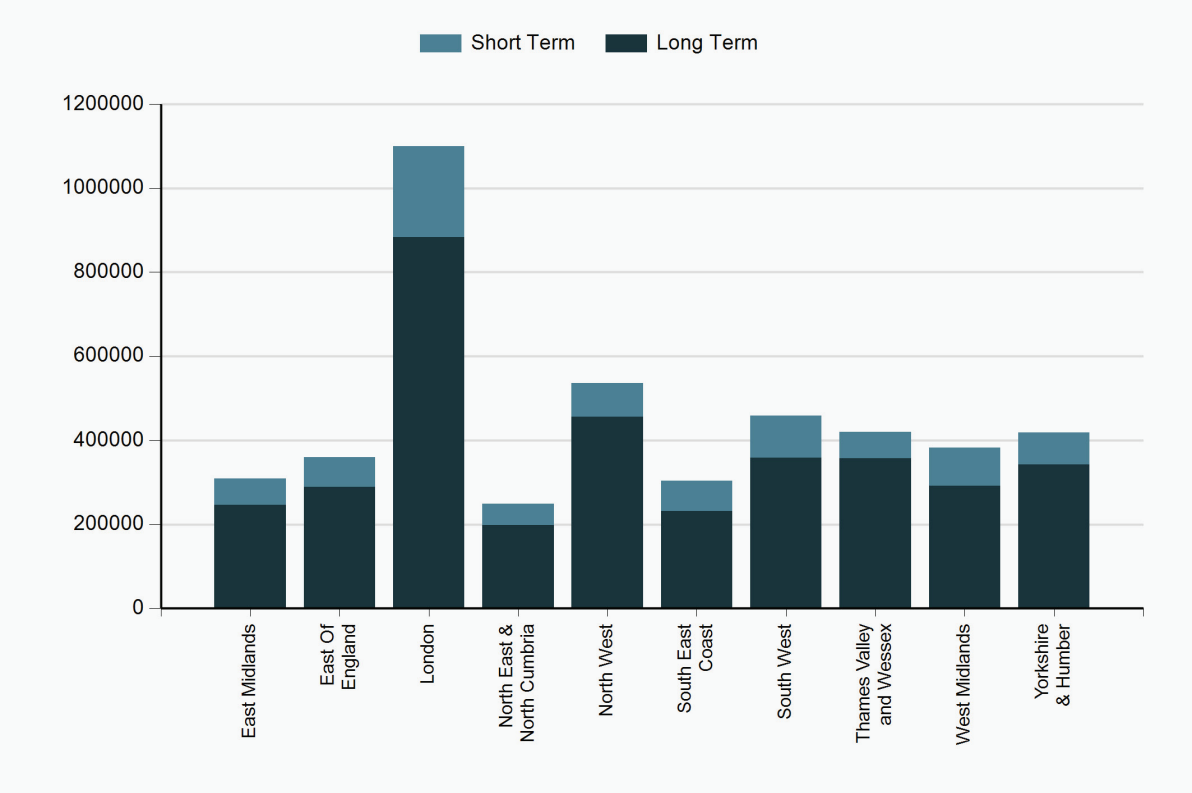


Figure 3.4.2 Recorded yearly immunoglobulin use by region 2011/12 - 2015/16

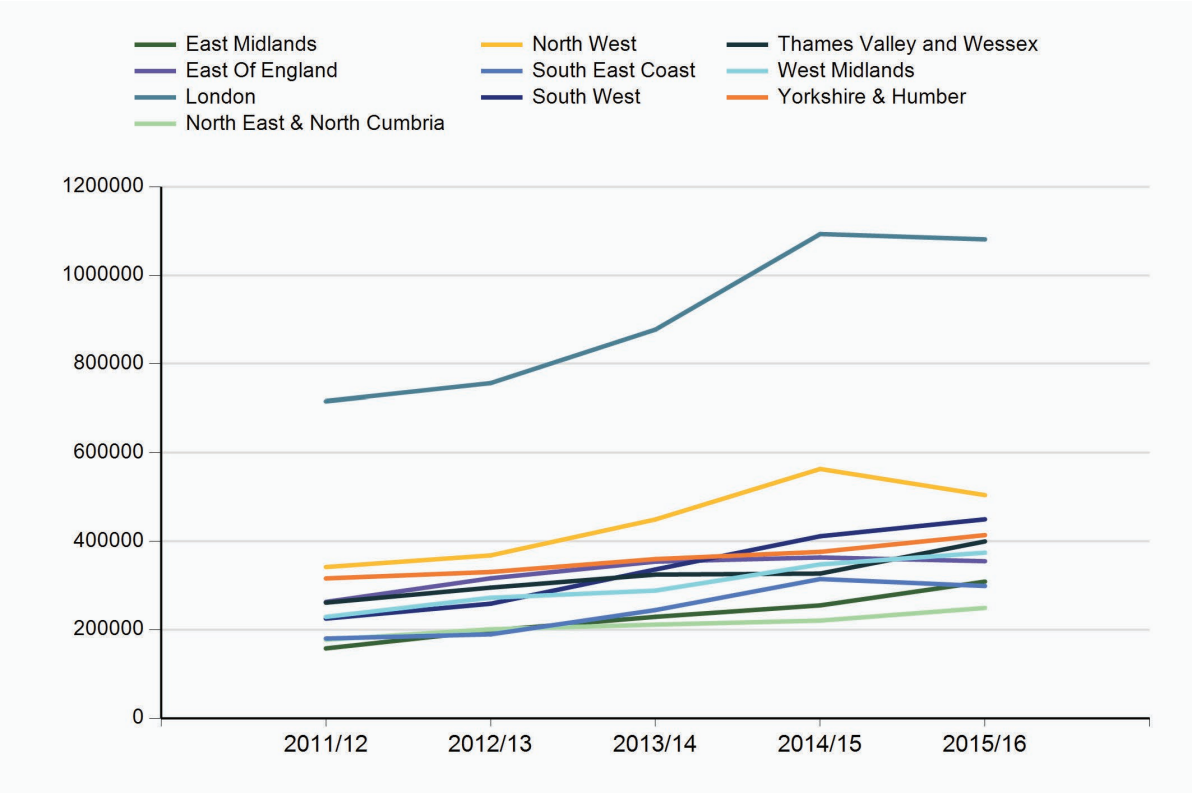


Figure 3.5.1 Volume of immunoglobulin used for the top 10 diagnoses 2015/16

Diagnosis	Usage (Grams)	Change Last Year
Primary Immunodeficiencies	1,196,375	+7%
Chronic Inflammatory Demyelinating Polyradiculoneuropathy	905,093	+4%
Multifocal Motor Neuropathy	450,687	+9%
Secondary antibody deficiencies	285,392	+24%
Other Conditions	268,984	-4%
Immune thrombocytopenic purpura - Acute	261,865	+17%
Chronic lymphocytic leukaemia	208,892	+2%
Myasthenia Gravis	172,558	-
Guillain–Barré Syndrome	137,080	-2%
Inflammatory Myopathies	107,448	+8%

Figure 3.5.2 Recorded yearly immunoglobulin use for the top 10 diagnoses 2011/12 - 2015/16

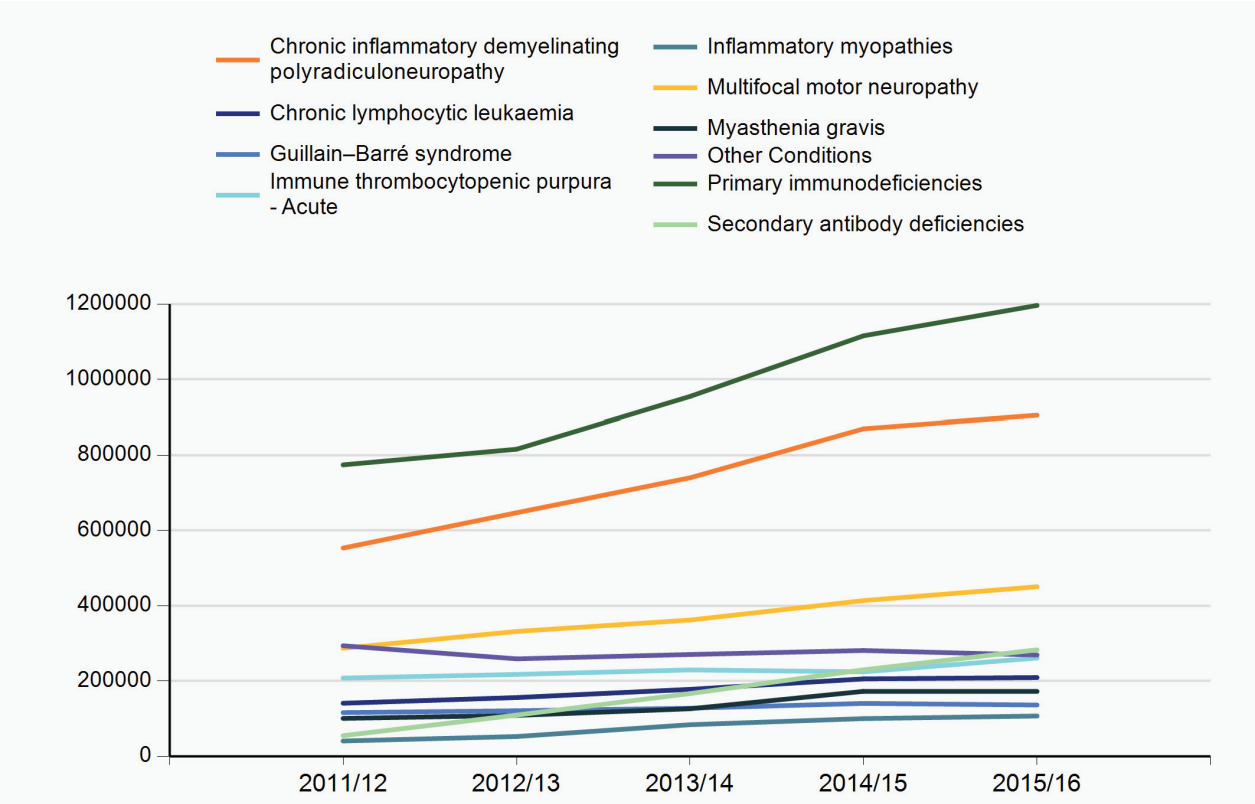


Figure 3.6 Volume of immunoglobulin used in top 20 trusts 2015/16

Trust	Usage (Grams)	Change Last Year
University College London Hospitals NHS Foundation Trust	233,066	+7%
Oxford Radcliffe Hospitals NHS Trust	231,947	+54%
Royal Free NHS Trust	193,359	-22%
Barts And The London NHS Trust	186,213	+6%
Salford Royal NHS Foundation Trust	158,723	-10%
Sheffield Teaching Hospitals NHS Foundation Trust	134,880	+9%
Leeds Teaching Hospitals NHS Trust	124,922	+5%
The Newcastle Upon Tyne Hospitals NHS Foundation Trust	113,583	-2%
University Hospitals Of Leicester NHS Trust	112,757	+32%
Heart Of England NHS Foundation Trust	107,771	+3%
Royal Cornwall Hospitals NHS Trust	97,740	+23%
Nottingham University Hospitals NHS Trust	93,260	+8%
Walton Centre for Neurology and Neurosurgery NHS Trust	89,685	-16%
Imperial College Healthcare NHS Trust	86,246	+3%
Lancashire Teaching Hospitals NHS Foundation Trust	84,826	+12%
Guy's And St Thomas' NHS Foundation Trust	80,275	+14%
Plymouth Hospitals NHS Trust	72,706	+2%
South Tees Hospitals NHS Trust	72,411	+6%
North Bristol NHS Trust	67,478	-1%
University Hospital Birmingham NHS Foundation Trust	61,294	-12%

Figure 3.7.1 Recorded monthly use of intravenous and subcutaneous immunoglobulin 2015/16

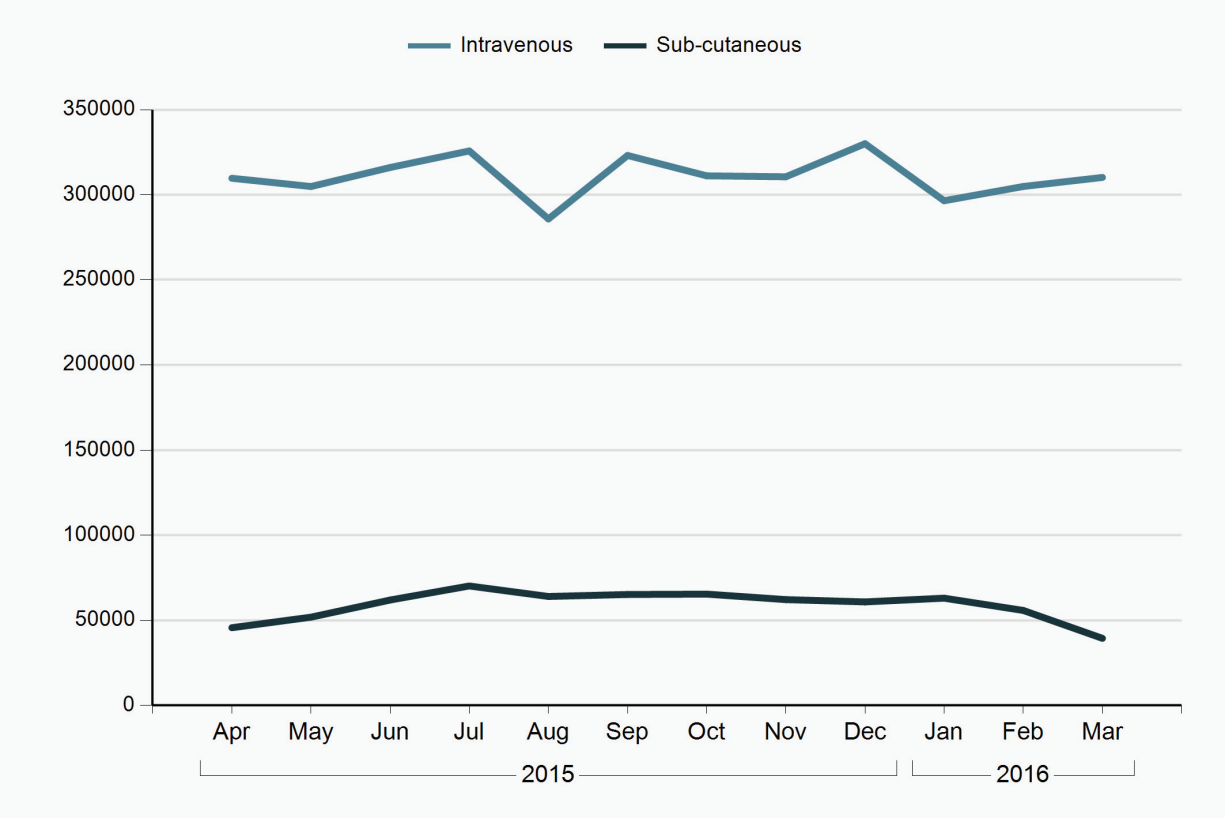


Figure 3.7.2 Recorded yearly use of intravenous and subcutaneous immunoglobulin 2011/12 - 2015/16

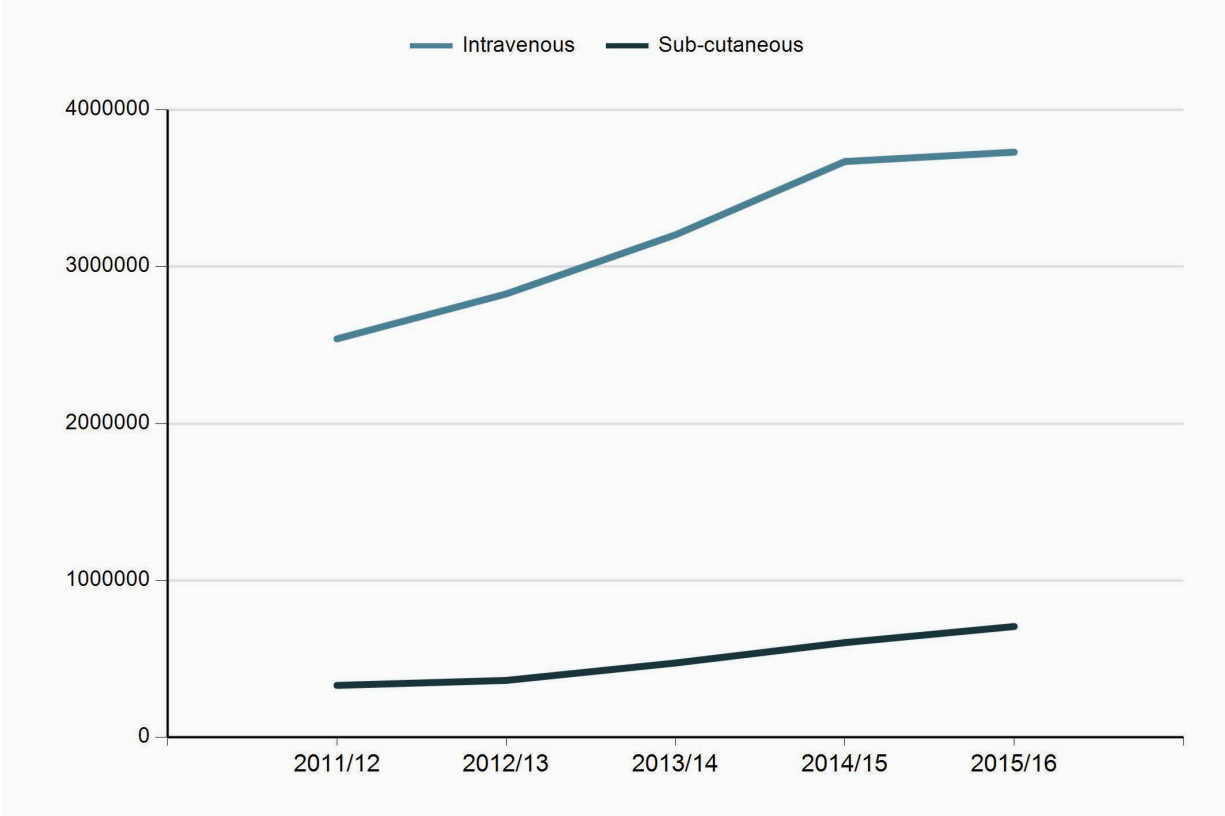


Figure 3.8.1 Recorded monthly use of intravenous immunoglobulin products 2015/16

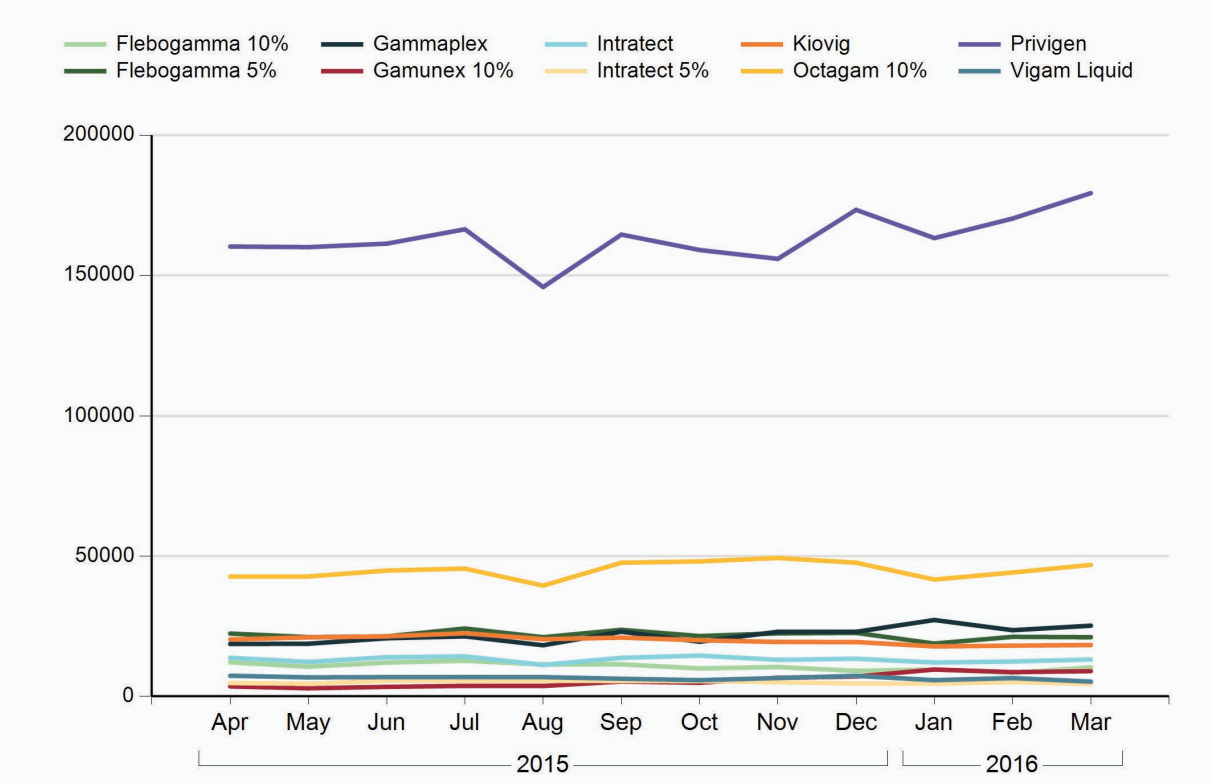


Figure 3.8.2 Recorded yearly use of intravenous immunoglobulin products 2011/12 - 2015/16

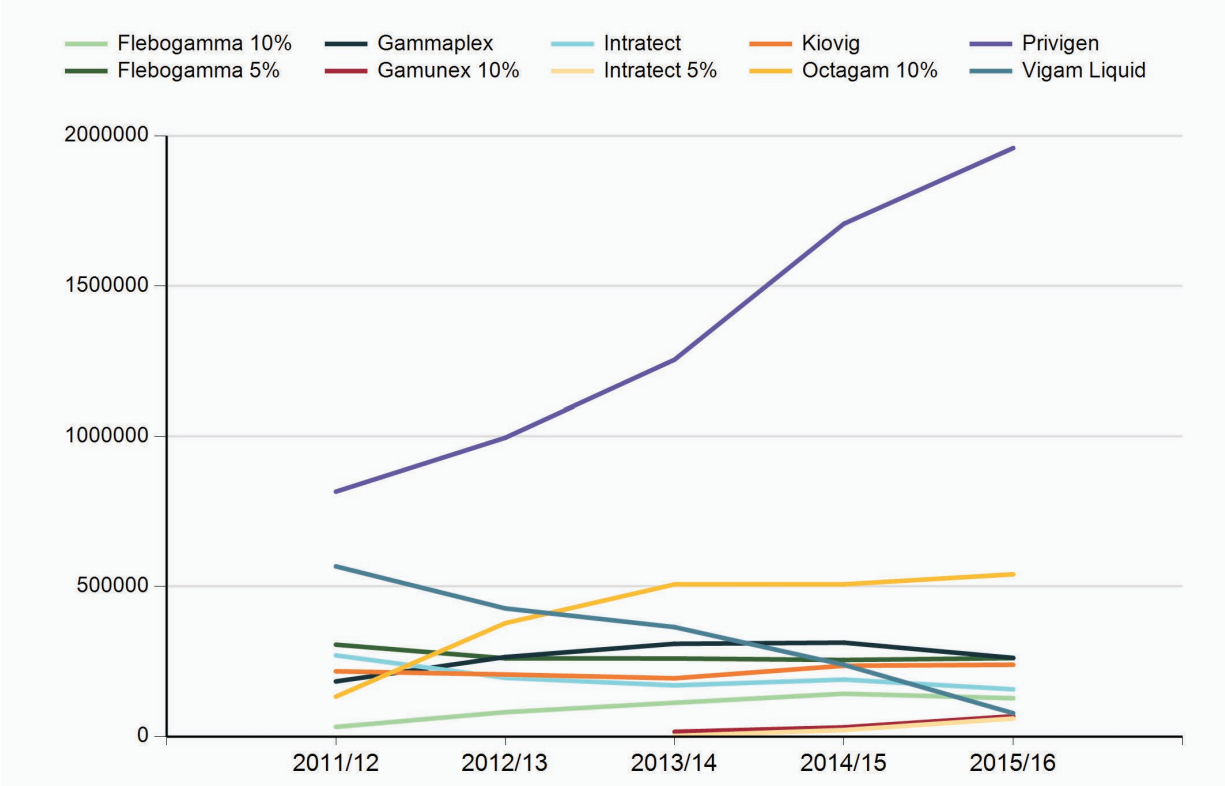


Figure 3.9.1 Recorded monthly use of subcutaneous immunoglobulin products 2015/16

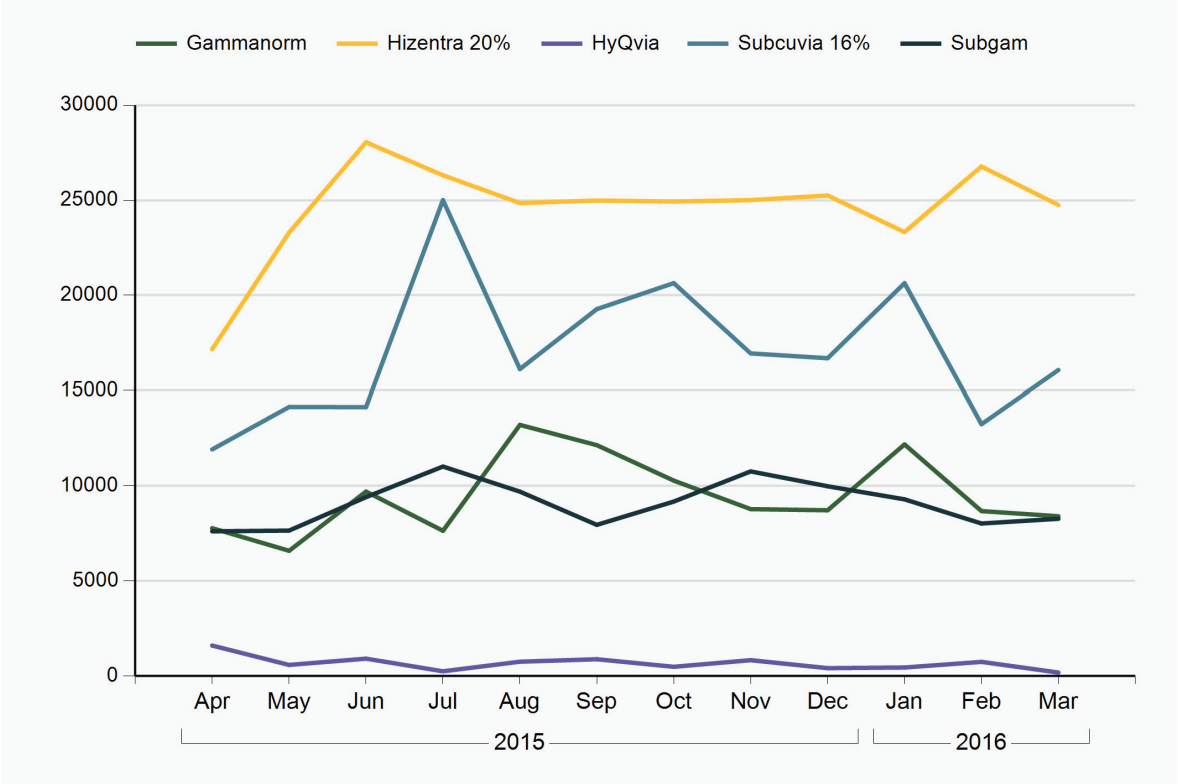


Figure 3.9.2 Recorded yearly use of subcutaneous immunoglobulin products 2015/16

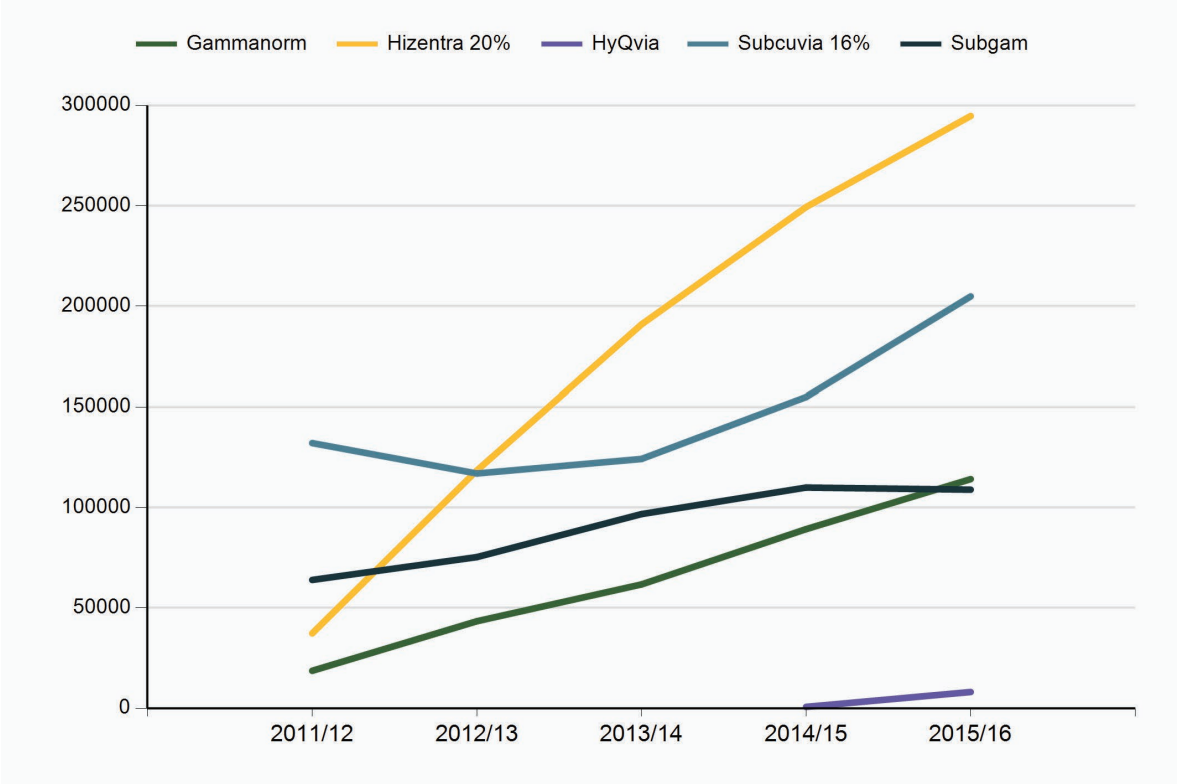


Figure 3.10.1 Recorded monthly use of immunoglobulin products by manufacturer 2015/16

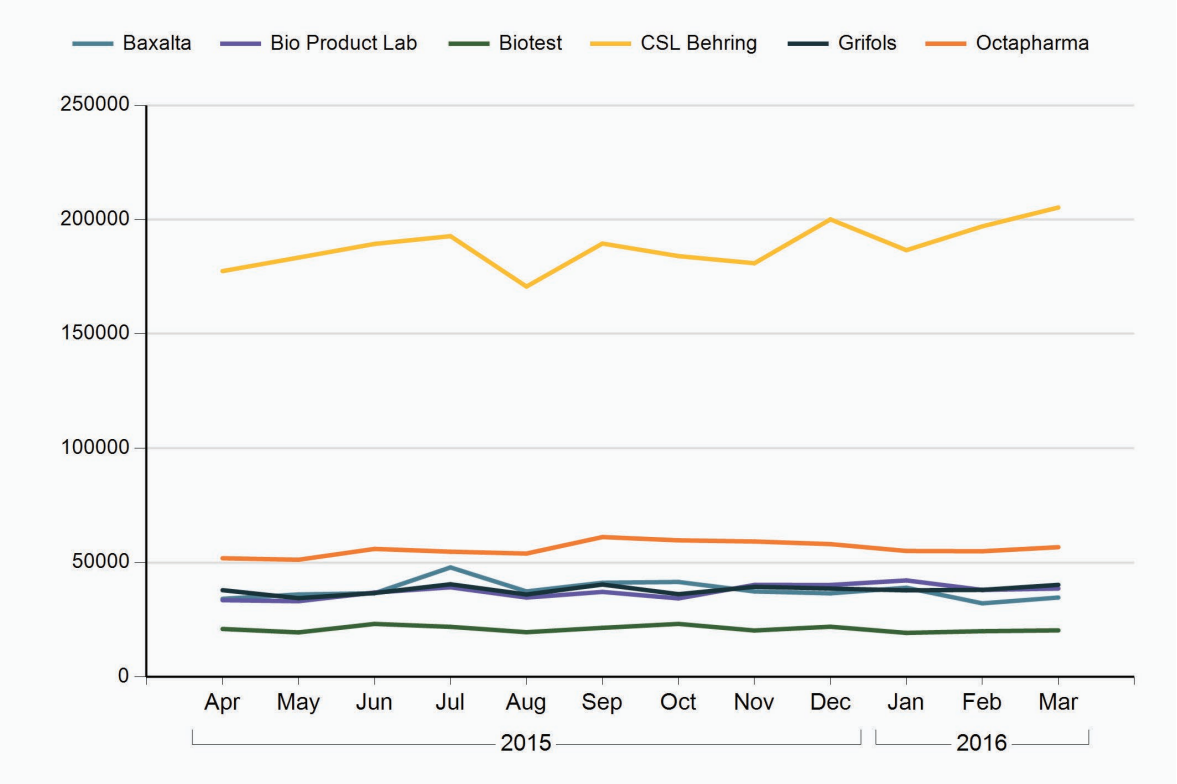


Figure 3.10.2 Recorded yearly use of immunoglobulin products by manufacturer 2011/12 - 2015/16

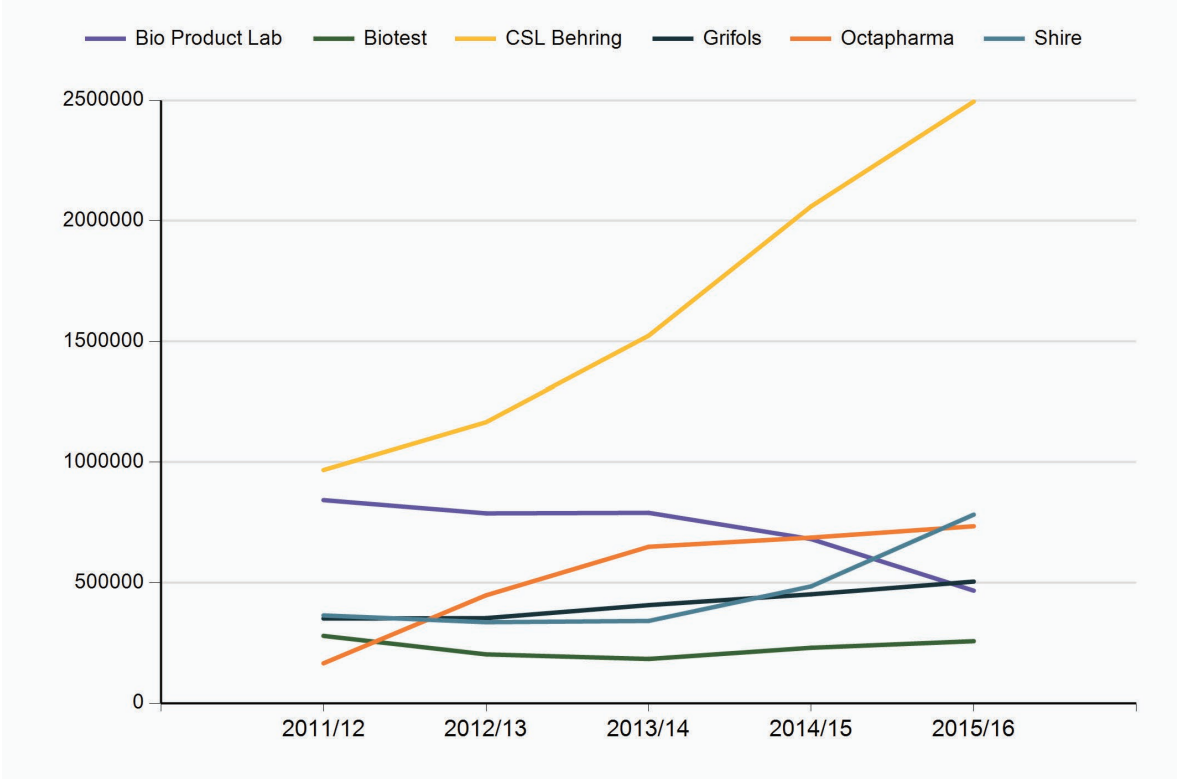


Figure 3.11.1 Average use of immunoglobulin per patient by speciality 2011/12 - 2015/16

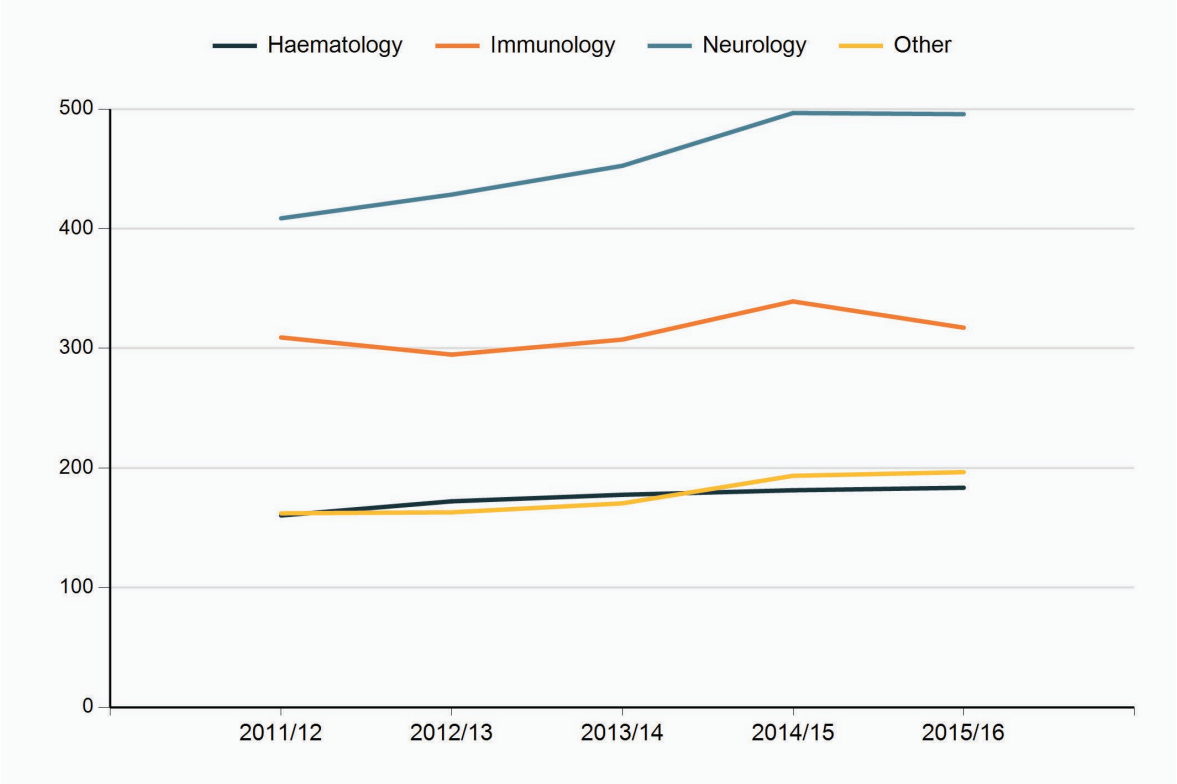


Figure 3.11.2 Average use of immunoglobulin per patient by indication & regime 2011/12 - 2015/16

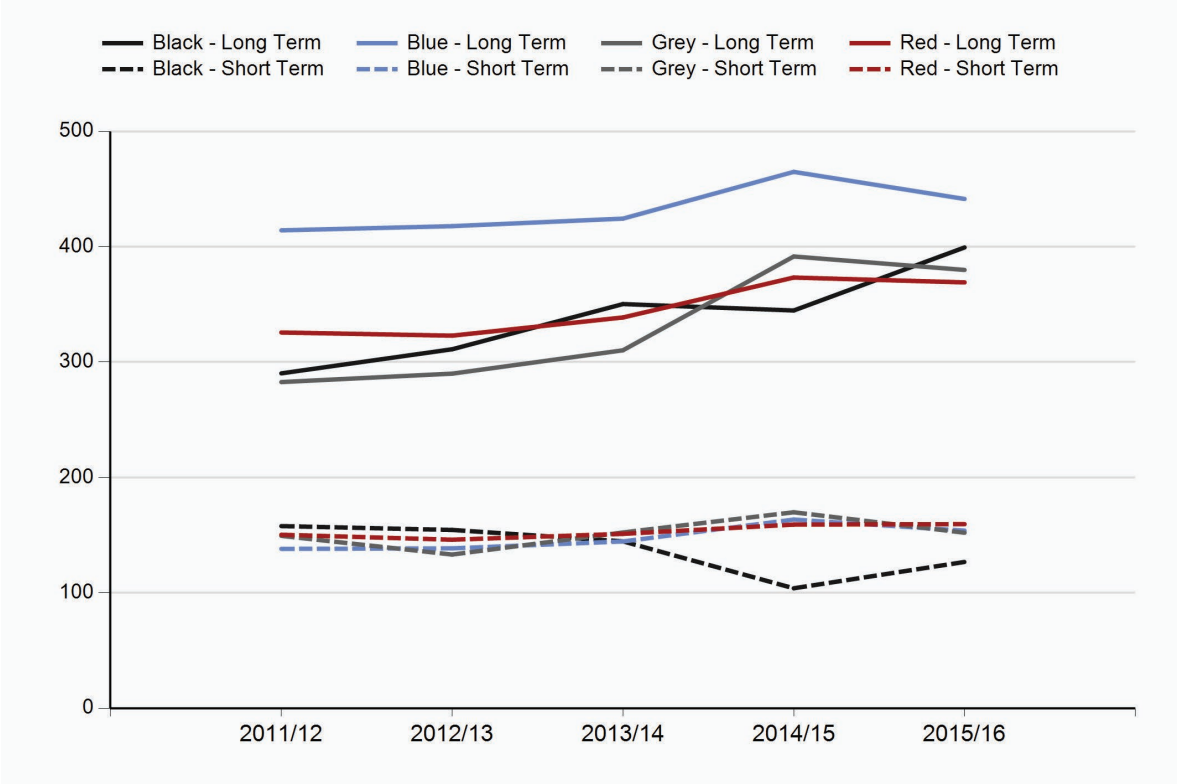


Figure 3.11.3 Average use of immunoglobulin per patient by region 2011/12 - 2015/16

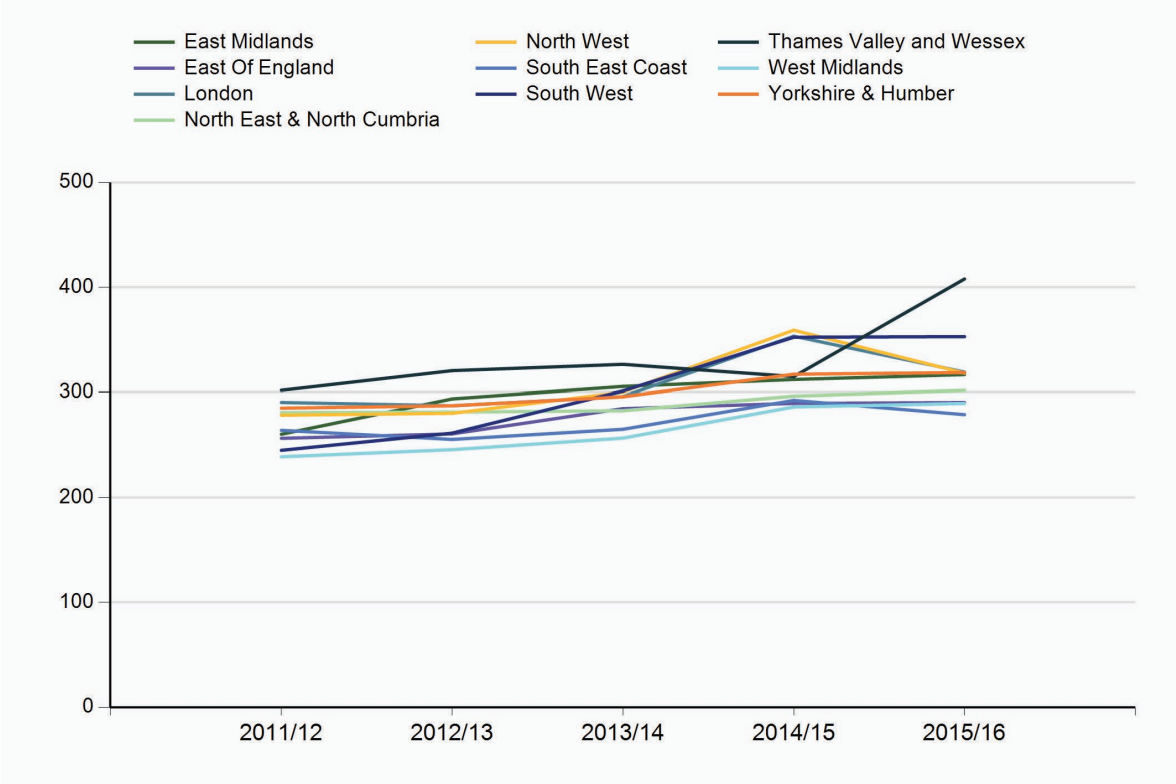
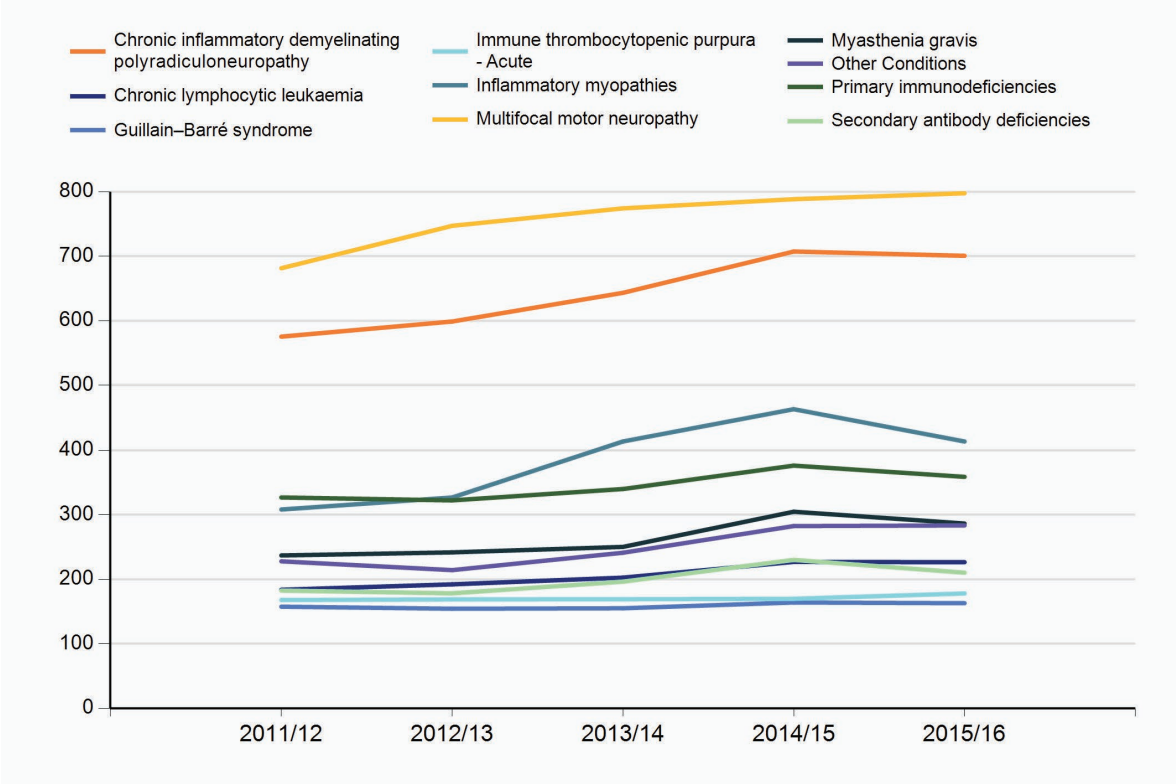


Figure 3.11.4 Average use of immunoglobulin per patient for top conditions 2011/12 - 2015/16



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