Immunoglobulin Database

Immunoglobulin Database Report 2014/15

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medical data solutions and services

1 Database Overview

Rob Hollingsworth

Introduction

Firstly, thanks to all Trusts that continue to provide data to the National Immunoglobulin Database. One hundred and sixty five Trusts across England and Scotland are now submitting their data to the database and it is now more complete than ever.

This report will provide a snapshot of the data from the database for the calendar year 2014-15. Also included is an update from NHS England Specialised Commissioning.

There have been a number of important updates in relation to the use of the database for the commissioning of immunoglobulin. These mainly relate to payment of Trusts related to infusions entered and requirement for outcomes entry to support continued treatment of specific conditions, particularly where evidence is lacking.

Increasing use of immunoglobulin

Annual usage of immunoglobulin continues to increase at a rate of around 10% per annum, thus even though there has been increased take-up of cheaper products, costs for NHS immunoglobulin therapy continue to increase. At the current rate of increase, it is expected that within three years' costs for immunoglobulin products will be around £190-200 million per annum. The annual increase in usage is illustrated in many of the reports included in this report.

Database Status

Since its initiation the database has captured information on over 53,000 patients and 70,000 separate treatment episodes, with 800,000 treatment infusions having been entered, accounting for over 4 million grams of immunoglobulin recorded on the database.

Database Developments

The services provided by the database have continued to evolve in-line with the changing requirements of the NHS. The database was initially setup to manage the supply of immunoglobulin in the event of a shortage, in accordance with the demand management programme. Since then the use of the database by commissioners and for procurement work has expanded significantly.

In the near future the database will be providing an integrated system for patients on home therapy to record the details of their treatment. This system 'Haemtrack' has been used very successfully in Haemophilia with over 800,000 treatments having been entered. Clinicians will be able to view in real-time therapy entries made by patients.

The database will also shortly be carrying out a pilot of pre-authorisation for the prescribing of immunoglobulin for a number of selected conditions. This would require Trusts to confirm that they have met each of the individual pre-conditions as specified in the guidelines before immunoglobulin can be prescribed to the patient. Initially the pilot will involve a small number of Trusts with a view to go-live across all trusts should the pilot prove to be successful.

Annual Report

Following on from previous Annual Reports, this report shall provide 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 do send your suggestions to support@mdsas.com.

Annual Database Meeting

The annual database meeting is held each year in December at Etc. Venues in Pimlico. The event is aimed at all users of the database and covers all specialities. Morning sessions feature guest speakers, with the afternoon being split into clinical and database focussed sessions. The afternoon database session offers valuable training and insight in to the workings of the database as well as offering the opportunity to provide feedback and suggestions. Numerous suggestions received from users at the annual meeting have been implemented into the current system, these suggestions play a vital role in the success of the database. The event also offers an invaluable opportunity for networking, attendance is highly recommended.

We're currently looking to improve the format of the clinical afternoon session. If you have an interest in the clinical processes involved with immunoglobulin and the database, please do get in touch. The next event will be in December 2016.

Database Updates

The year 2015 was very busy for the database with four version updates released. In August 2015 the database was migrated to new servers offering improved system performance and resilience.

The first version release v5.0 focussed largely on a new user interface update for the database. The new interface is compatible with multiple browsers. The update also extended the available screen resolution. System performance improvements were also incorporated as part of the update.

Throughout the following version releases multiple updates were made to add additional functionality and simplify the database. These updates included:-

- Additional flexibility with dates entered into the database
- Care Department field added in order to specify speciality where a patient was being treated
- Ability to select links from reports to go directly to patient records
- Treatment dosage entry added to follow-up screen
- Improved automated navigation
- Search function added in order search the list of 'other' diagnoses
- Ability to delete treatment episodes
- Trusts able to add new users and a new forgotten password function
- Performance increases e.g. automated infusion upload
- Mark treatment episodes as paediatric / adult care

Dashboard Updates

In addition to the above system updates a considerable amount of work has been put into improving the national dashboard measures. MDSAS have acted as an interface between Trusts, CRGs and Methods Insight Analytics in order to review and request changes to the national dashboard measures.

This has resulted in multiple changes to the dashboard measures and associated data books to make them more consistent and easier to understand. In conjunction with the dashboard measures the system has been updated to accurately reflect the updated measures.

A key functionality addition in the latest version update is the ability for patients to be excluded from specific dashboard measures (dashboard exclusions). This function is very useful in situations such as Patients receiving their therapy at other hospitals, or alternatively follow-up reviews carried out at other hospitals.

Recent dashboard measure updates have included:-

- Removal of the adverse event measures (PID 09 and IVIG 09)
- Rewording of PID 01 to "Number of patients in denominator who have immunoglobulin trough levels recorded and documented on the national database during the current reporting financial year"
- Private patients excluded from the dashboard measures

Conclusion

The database continues to be updated in response to Trust suggestions and NHS England requirements. Upcoming updates include the addition of a patient home therapy recording system to enable patients on home therapy to record their treatments, these are then viewable in real-time by clinicians.

2 Commissioning Update

Malcolm Qualie

Intravenous and subcutaneous immunoglobulin is an expensive blood product used across a variety of clinical specialities. The critical need as well as effectiveness of treatment varies; it is life-saving for some patients for whom no alternative treatment exists, while others do have clinically effective and often more cost-effective alternatives available to them.

Treatment with immunoglobulin represents a substantial financial commitment for the health service, with an annual cost of about £148 million. These treatments remain a high-cost drug entirely funded by specialised Commissioners under the auspices of NHS England.

2.1 Model Commissioning Policy for immunoglobulin

In 2009, the Model Commissioning Policy was published to target the scarce supply of immunoglobulin to those patients for whom this treatment is the preferred option and to ensure that immunoglobulin is used in a way that is both clinically effective and cost effective. Although there have been changes from regions to "Super Regions" the policy still requires in-hospital Immunoglobulin Assessment Panels (IAPs) for managing and prioritising access to immunoglobulin treatment (using the colour coding provided in the DH Demand Management Plan).

In addition, there was a requirement that all patient data be entered into the National Immunoglobulin Database, and funding for immunoglobulin is now related to accurate data entry with some centres having 100% compliance.

A National Immunoglobulin Working Group, which has Commissioner and clinician representatives will continue to provide advice to NHS England on further development of the service specification via the relevant National Clinical Reference Groups.

Four Factors determine whether NHS England commissions a service as a prescribed specialised service which are:

- The number of individuals who require provision of service;
- The cost of providing the service or facility;
- The number of persons able to provide the service or facility; and
- The financial implications for Clinical Commissioning Groups (CCGs) if they were required to arrange for the provision of the service or facility themselves.

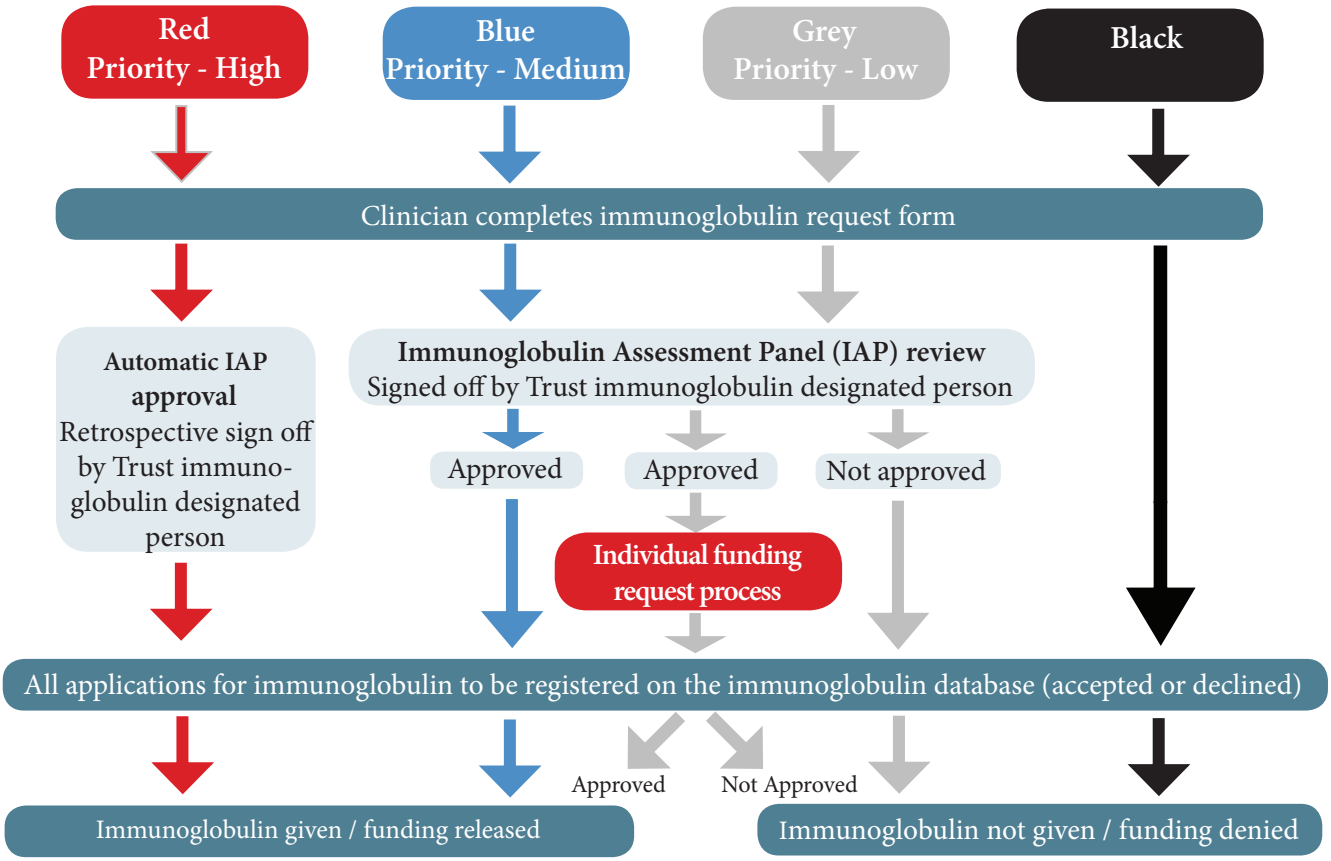
The ambition of NHS England is to bring equity and excellence to the provision of specialised care and treatment. This will be achieved through a commissioning process which is patient centered and outcome based, with the patient placed at the centre of planning and delivery.

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

A national consistent and coherent approach to specialised commissioning is built on universal support. Prior to NHS England there was wide variation in how each region discharged its commissioning responsibilities. This resulted in inconsistencies in the management of the commissioning cycle such as budget setting, contract negotiation, performance management and the development and application of service specifications, commissioning policies and quality standards. It also resulted in duplication of some activities and functions.

A consistent approach to central planning that is delivered locally has helped to tackle these variations. However, more can be done to improve data input and in particular increase the logging of outcome data which is particularly important for the grey indications.

2.1.1 The approval process



3 NHS Purchasing

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 £148million 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 2015 due to lower contract prices and product switching. The framework has been extended up to the 31st May 2016 and dialogue is taking place with stakeholders to discuss the possible further extension of this framework.

Managing Supply Issues

During the past year CMU have worked with suppliers, trusts and key stakeholders to manage a couple of supply issues affecting IVIg product. Available stocks of two products had to be rationed and prioritised for long-term critical patients utilising the IG database information. Dialogue also took place with the other framework suppliers to ensure that product could be made available during the affected period to meet the shortfall in supply. CMU have ensured that these issues are communicated to all trusts affected by this.

Stakeholder Engagement

As we plan the next tender process for later in 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.

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.

4 Data Update

Mark Foster

The Fifth National Database Annual Report

This fifth edition of the National Database Annual Report sees a new format introduced for the report. Clinical analysis by speciality has been removed in favour of a more data orientated approach. This report features 39 data sets which provide a valuable insight into immunoglobulin usage trends across England. Data recorded on the database by October 2015 is included in reporting. A full list of reports is provided on page 10. Communications from key stakeholders have also been included in this report.

Entries in the database

To Date (October 2015), over 55,000 patients have been registered with 75,000 treatments recorded from 156 trusts. A total of 13,300 patients were recorded as having received immunoglobulin for the financial year 2014/15 as shown in figure 2.3. This shows a significant increase from 9,700 patients in 2010/11 this increase will mainly be down to improving database completion rate. Total recorded immunoglobulin usage for 2014/15 stands at 4.2 million grams. Long term usage accounts for 3.4 million grams, with short term treatments using a total of 700,00 grams of immunoglobulin (figure 3.1.2). The total volume of immunoglobulin recorded since the launch of the database now exceeds 20 million grams.

Usage in Specialisms

As highlighted in previous reports, neurological conditions use the most immunoglobulin (43%) by volume, then immunology (34%), haematology (8%). Conditions falling under other specialties as defined in the clinical guidelines make up the remaining 15%.

Usage in top conditions

PIDs are the number one condition for number of patients treated (2944) and volume of immunoglobulin recorded (1,102,219 grams). ITP is the second highest condition for patients treated numbers (1313), third is CIDP (1218). CIDP is the second highest using condition (859,480 grams), third is MMN (411,494 grams).

Increasing data capture

The immunoglobulin database is now well established. Comparing volumes recorded with CMU sales figures, it is estimated that the database captures slightly over 90% of the volume purchased. This completion rate will increase as payment by database entries is enforced from April 2015. The total volume of immunoglobulin recorded has increased from 2.4 million grams in 2010/11 to 4.4 million grams in 2014/15.

Grey Outcomes

One of the main priorities for commissioners for the upcoming financial year is the recording of outcomes, particularly for grey conditions. Figure 2.8 details the percentage of grey treatments with recorded outcome data. For the financial year 2014/15 a total of 28% of treatments for grey conditions had outcome data entered. An immunoglobulin project group has been set up to review outcome data at trust level and to target trusts failing to enter outcome data.

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Figure 1.1.1 Monthly patient registrations 2014/15

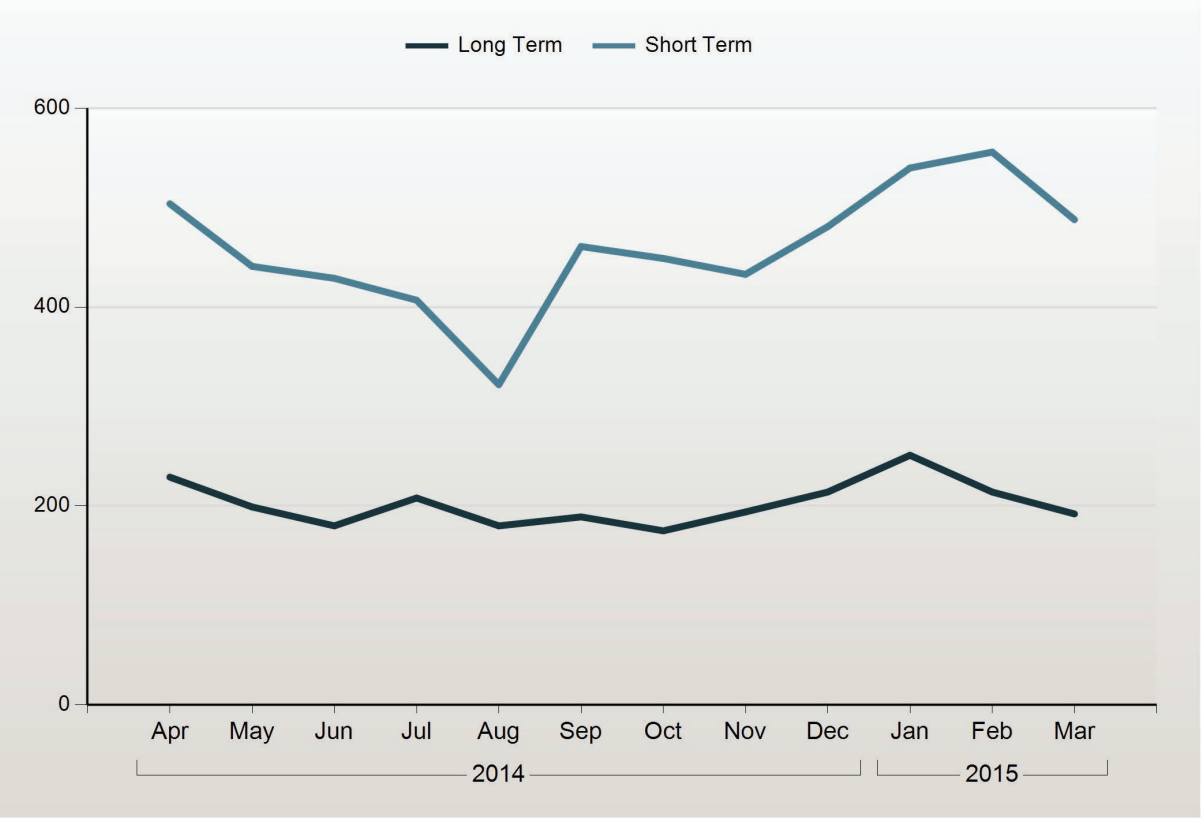

Figure 1.1.2 Yearly patient registrations 2010/11 - 2014/15

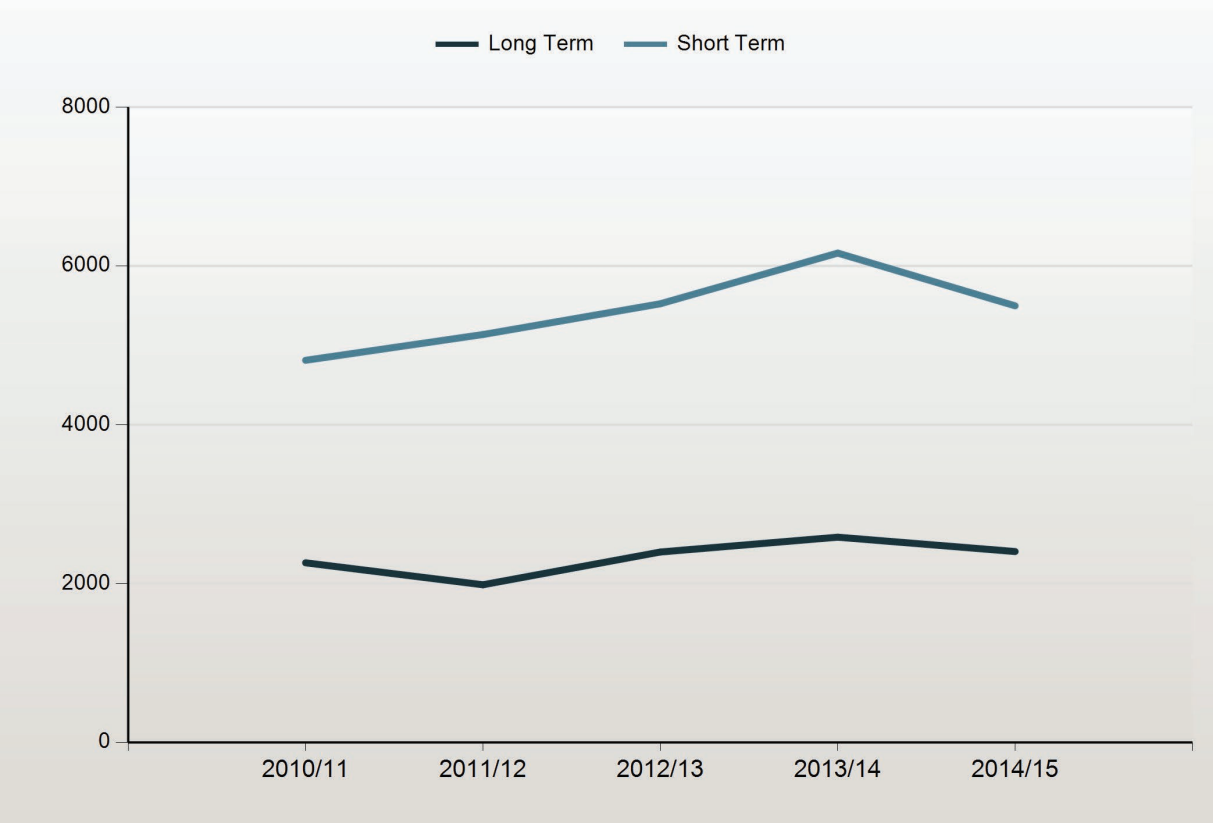

Figure 1.2 Monthly patient registrations by speciality 2014/15

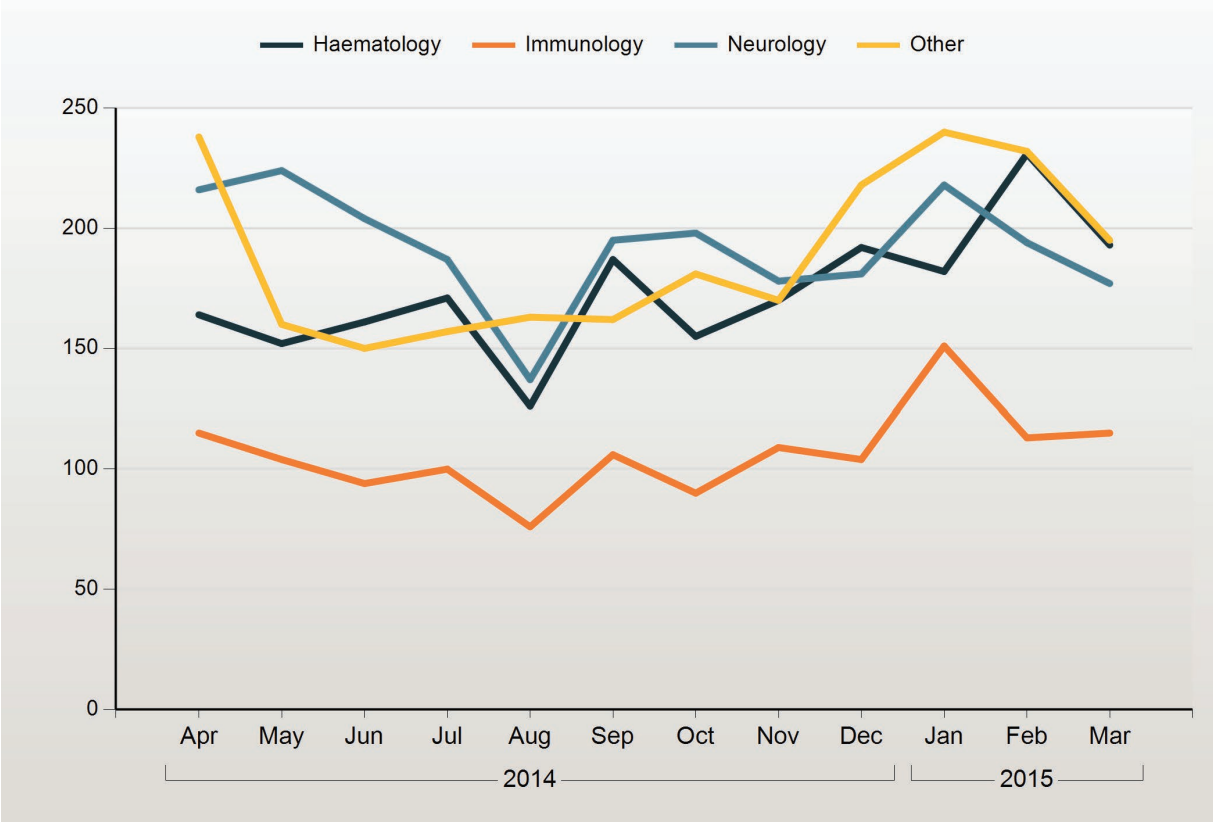

Figure 1.3 Patient registrations by region 2014/15

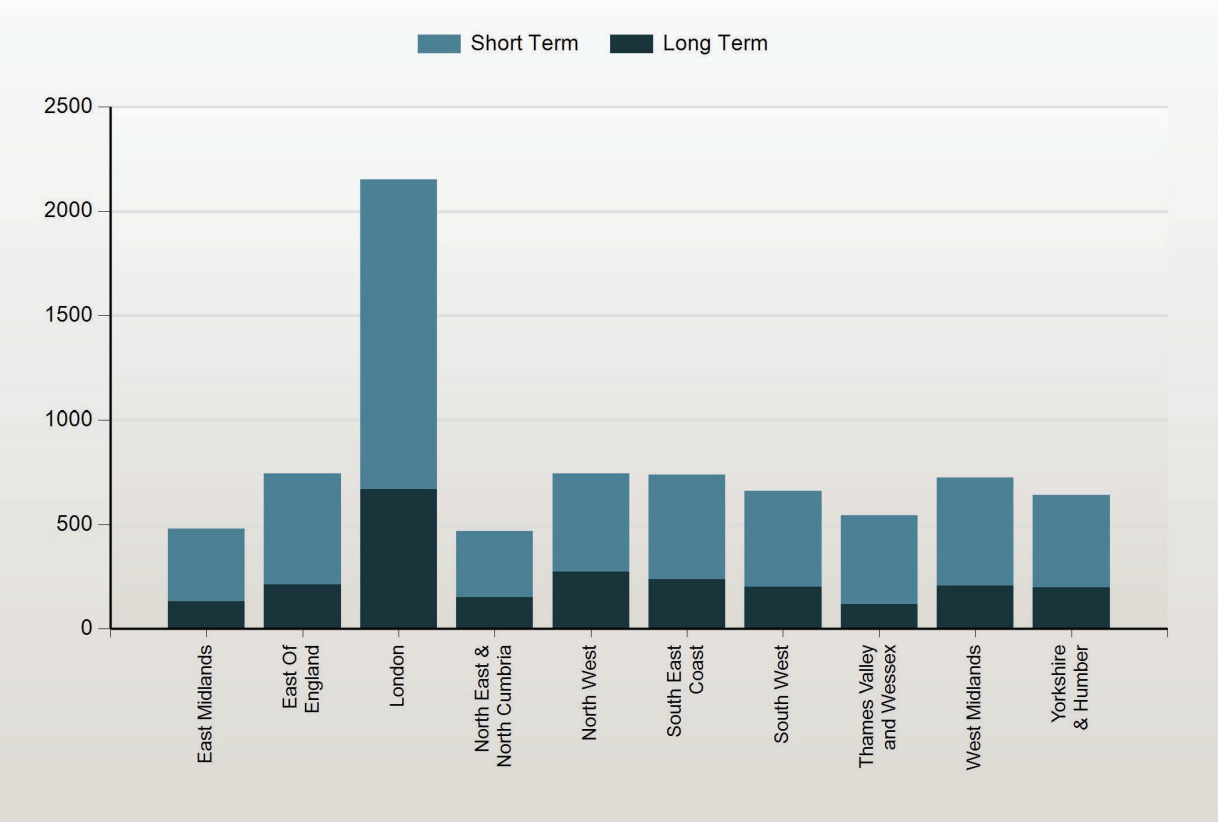

Figure 2.1.1 Monthly number of patients treated 2014/15

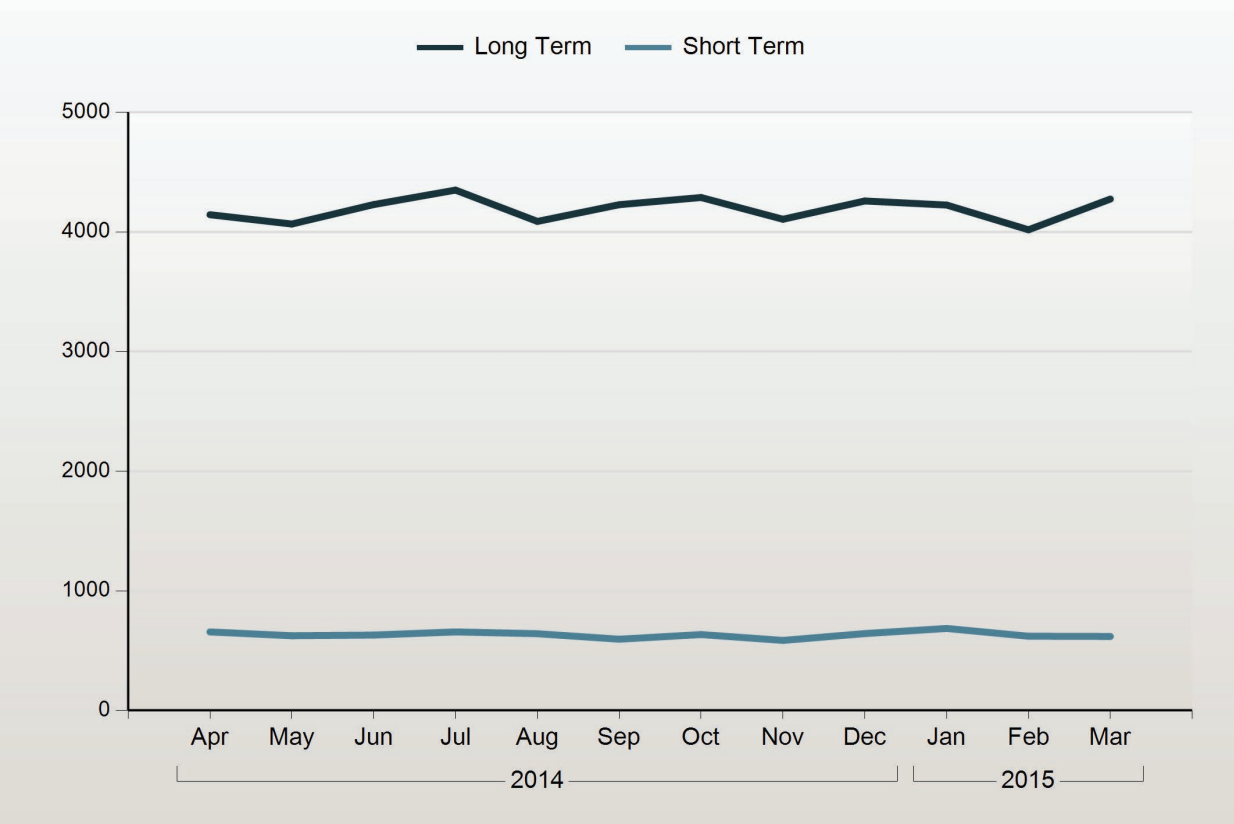

Figure 2.1.2 Yearly number of patients treated 2010/11 - 2014/15

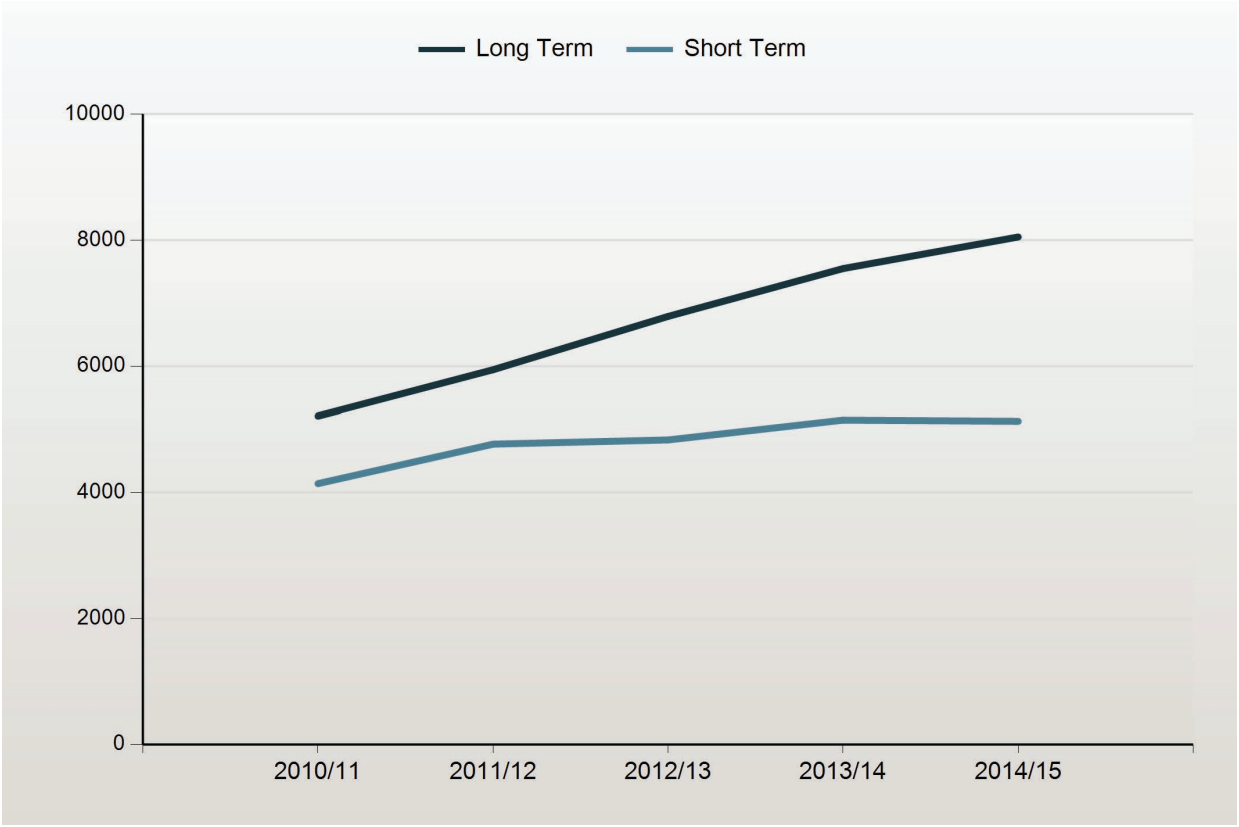

Figure 2.2.1 Monthly number of patients treated by speciality 2014/15

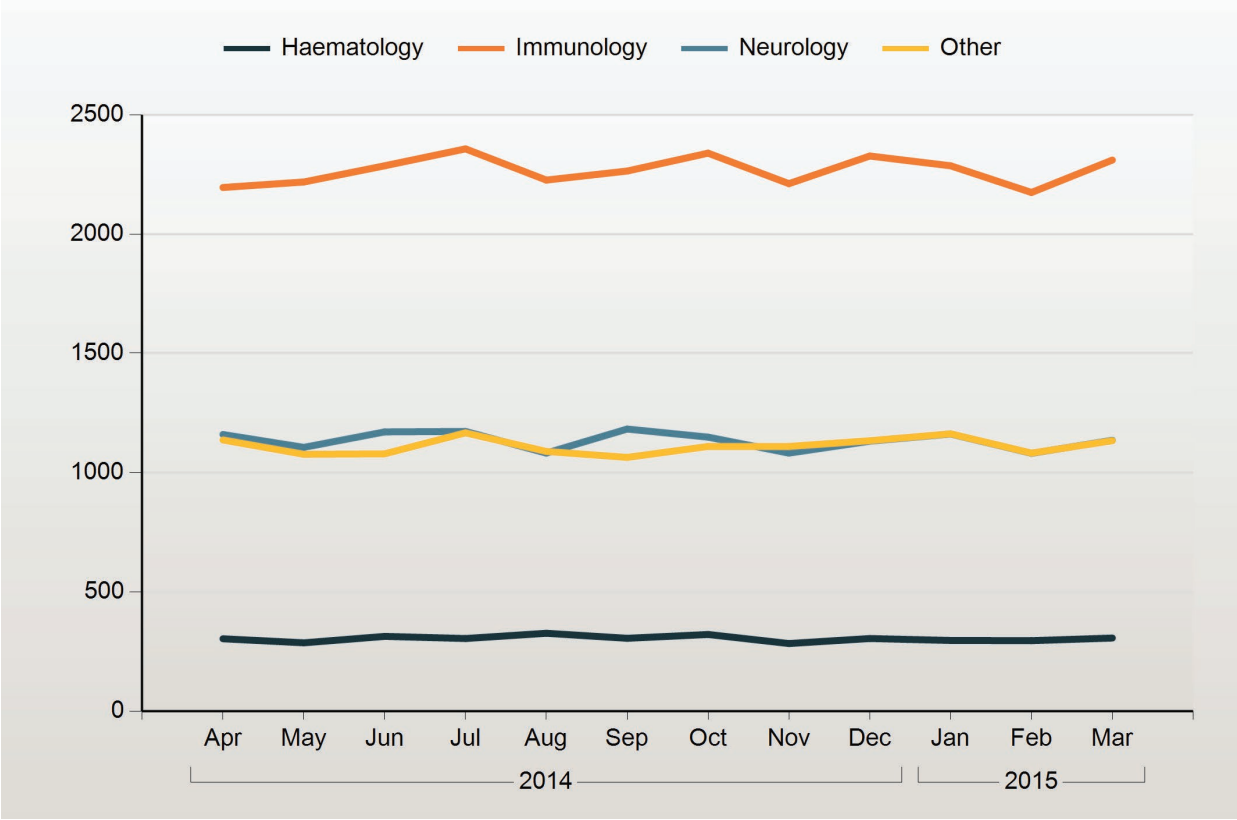

Figure 2.2.2 Yearly number of patients treated by speciality 2010/11 - 2014/15

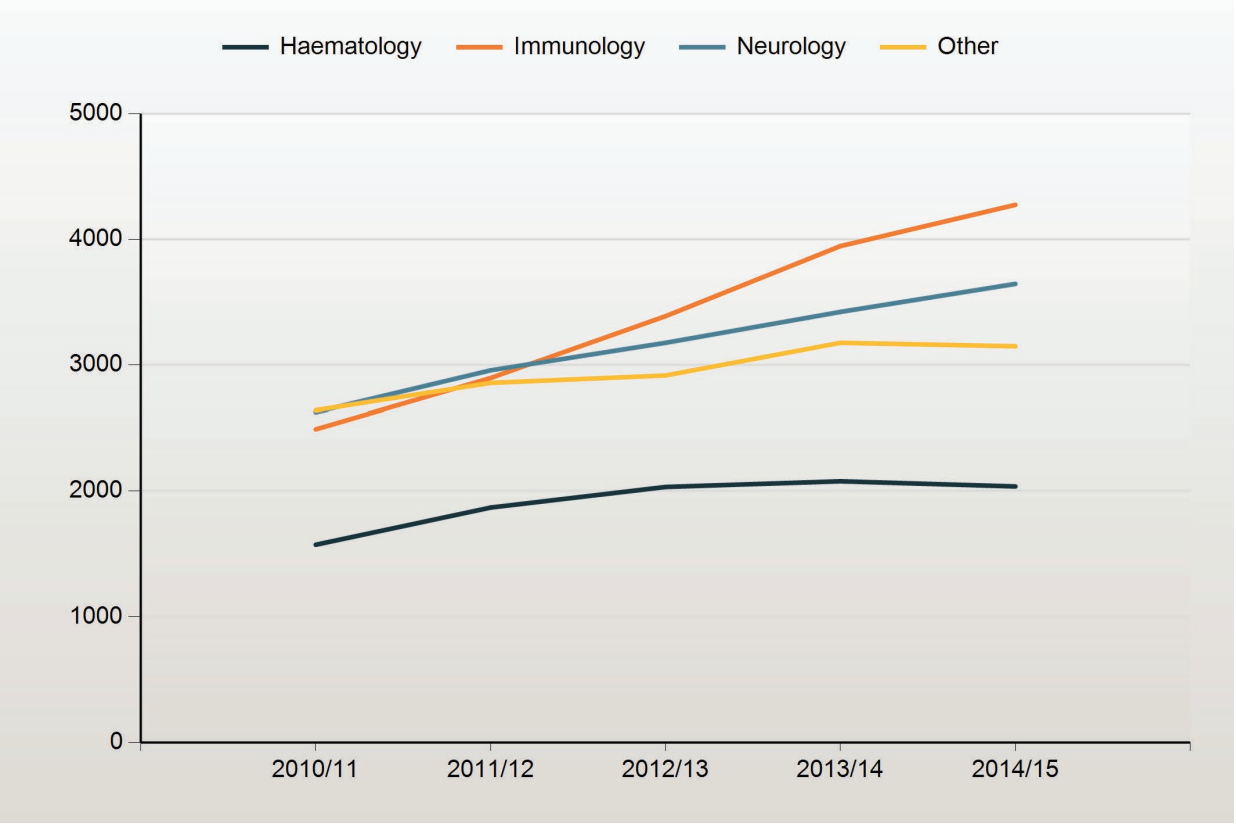

Figure 2.3 Yearly number of patients treated 2010/11 - 2014/15

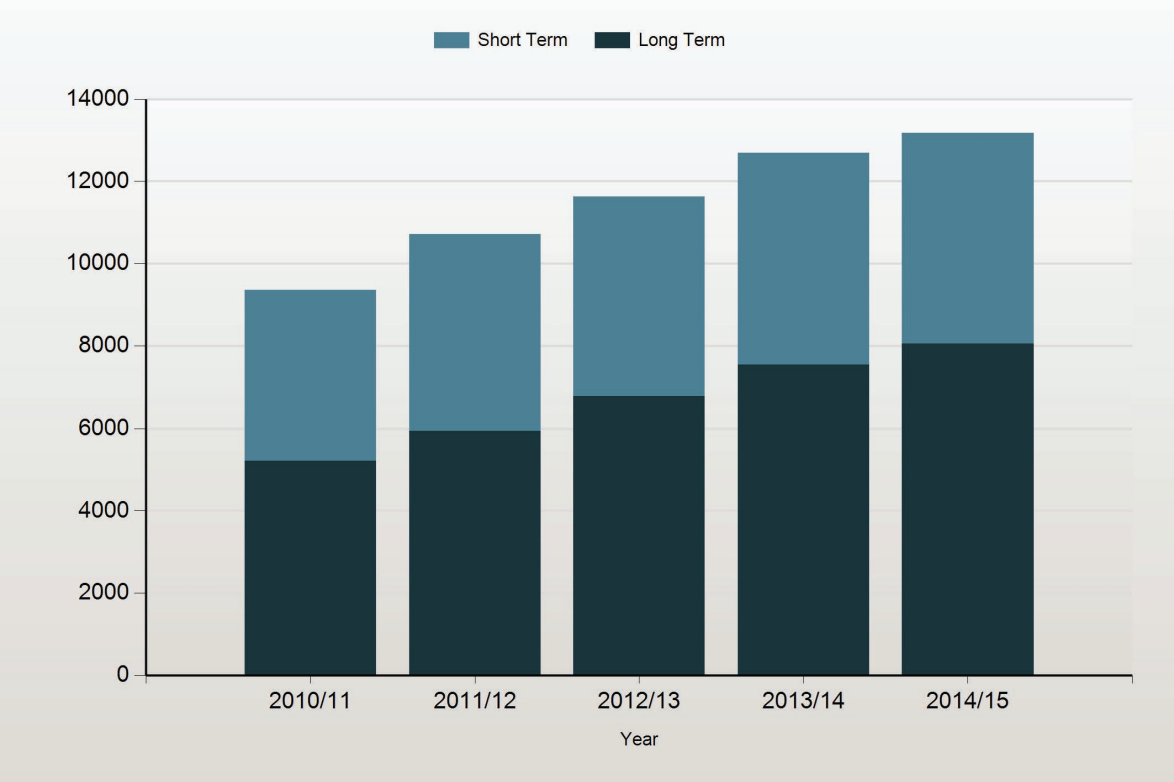

Figure 2.4.1 Number of patients treated by region 2014/15

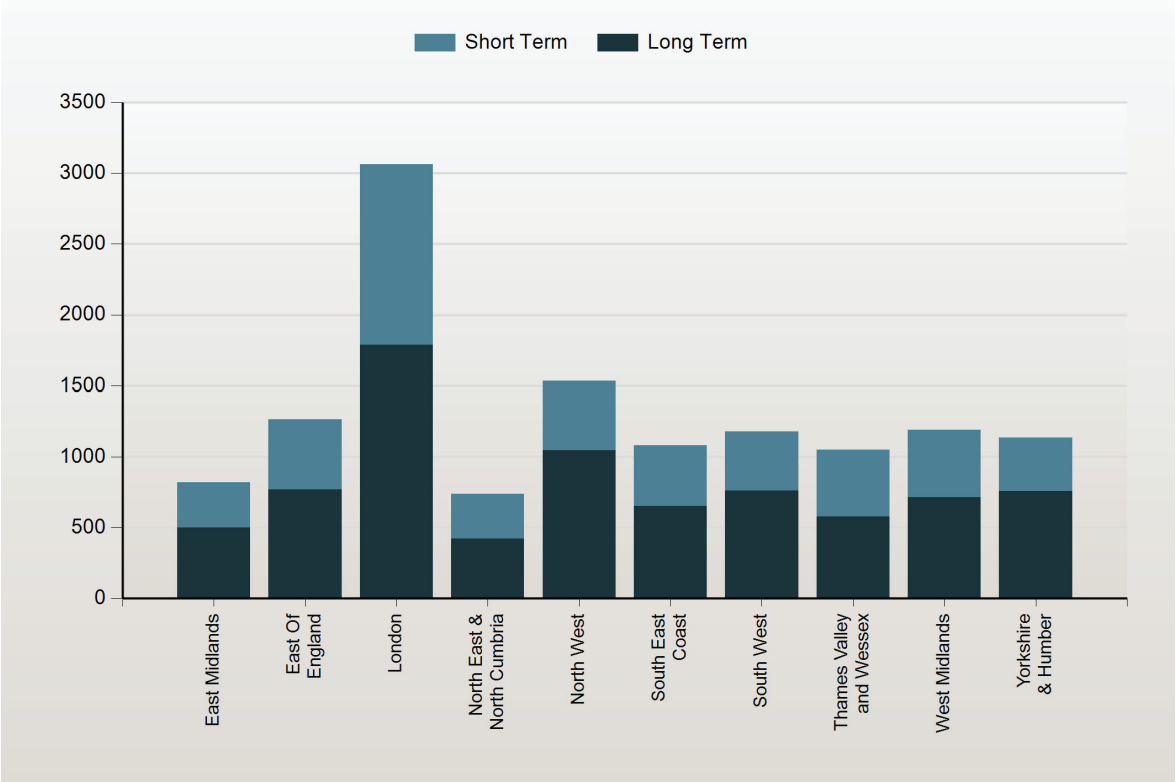

Figure 2.4.2 Yearly patients treated by region 2010/11 - 2014/15

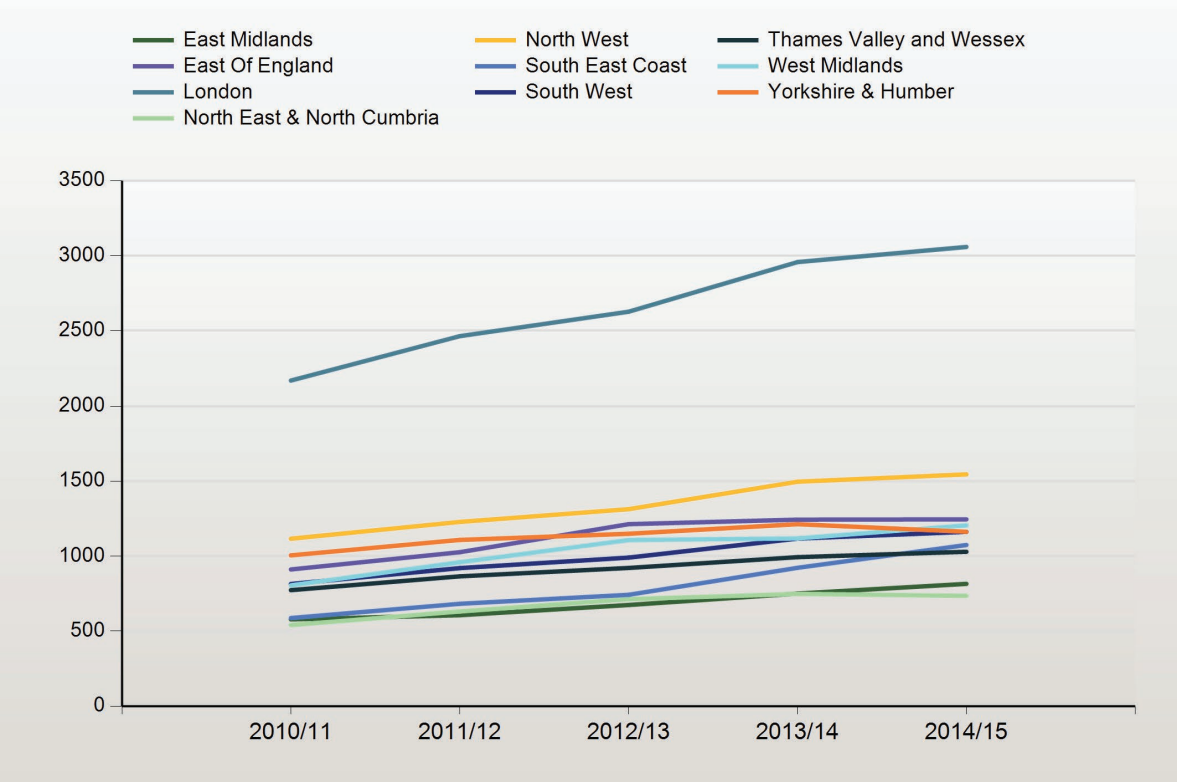

Figure 2.5 Yearly patients treated by treatment place 2010/11 - 2014/15

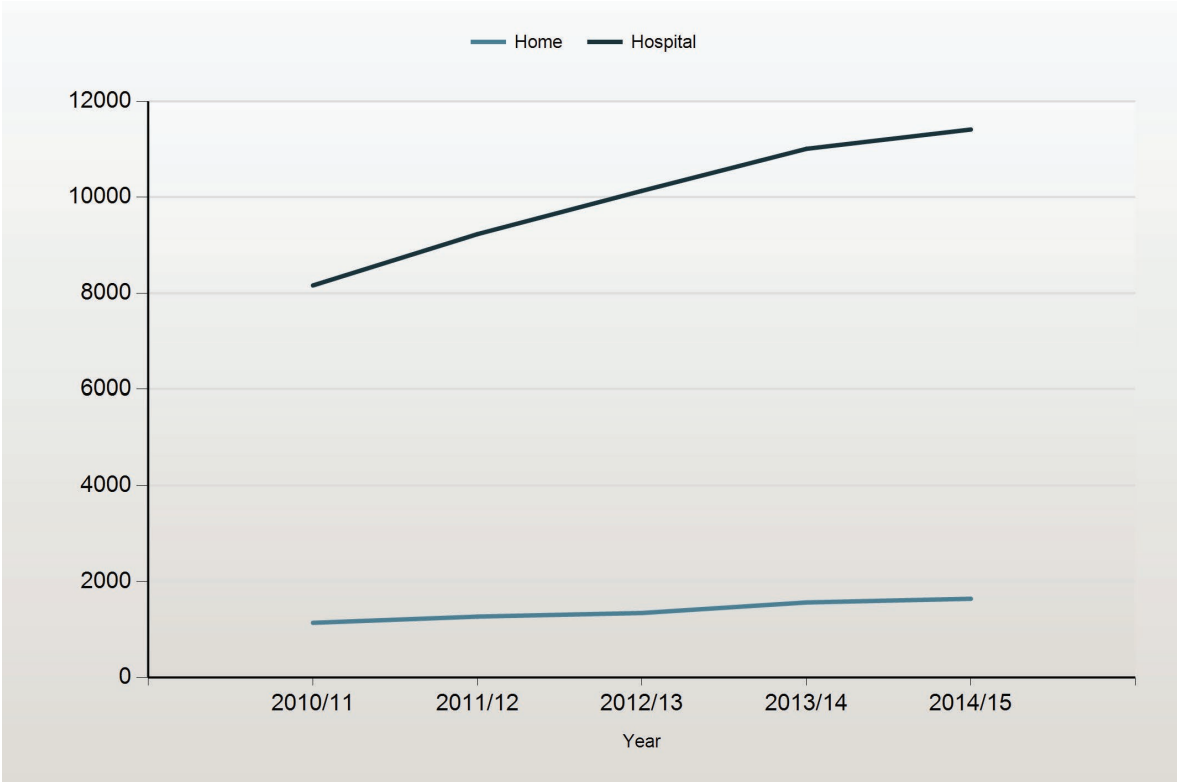

Figure 2.6 Number of patients treated for top 20 diagnoses 2014/15

Trust	Patients
Primary Immunodeficiencies	2944
Immune Thrombocytopenic Purpura - Acute	1313
Chronic Inflammatory Demyelinating Polyradiculoneuropathy	1218
Other Conditions	994
Secondary Antibody Deficiencies	982
Chronic lymphocytic leukaemia	901
Guillain–Barré Syndrome	851
Myasthenia Gravis	562
Multifocal Motor Neuropathy	525
Multiple Myeloma	297
Kawasaki disease	274
Inflammatory myopathies	212
Treatment of acute antibody-mediated rejection following solid organ transplantation	212
Immune thrombocytopenic purpura - Persistent	201
Low serum IgG levels following HSCT for malignancy	189
Staphylococcal toxic shock syndrome	184
Specific antibody deficiency	152
Transplantation (Solid Organ)	152
Impaired specific antibody production	129
Haemolytic disease of the fetus and newborn	128

Figure 2.7 Number of patients treated in top 20 trusts 2014/15

Trust	Patients
Royal Free NHS Trust	435
Barts And The London NHS Trust	405
The Newcastle Upon Tyne Hospitals NHS Foundation Trust	363
Oxford Radcliffe Hospitals NHS Trust	337
University College London Hospitals NHS Foundation Trust	332
Sheffield Teaching Hospitals NHS Foundation Trust	327
Leeds Teaching Hospitals NHS Trust	300
Salford Royal NHS Foundation Trust	300
Imperial College Healthcare NHS Trust	285
Heart Of England NHS Foundation Trust	271
Guy's And St Thomas' NHS Foundation Trust	270
Cambridge University Hospitals NHS Foundation Trust	252
Southampton University Hospitals NHS Trust	240
University Hospitals Of Leicester NHS Trust	229
Central Manchester And Manchester Children's University Hospitals NHS Trust	214
Plymouth Hospitals NHS Trust	205
Brighton And Sussex University Hospitals NHS Trust	182
East Kent Hospitals NHS Trust	179
University Hospital Birmingham NHS Foundation	176
Plymouth Hospitals NHS Trust	175

Figure 2.8 Number of grey requests and grey requests with outcomes recorded 2010 - 2014

Year	2010/11	2011/12	2012/13	2013/14	2014/15
Grey Requests	597	679	860	936	804
Grey Requests with Outcome data	N/A	N/A	274	244	227
Percentage	N/A	N/A	32%	26%	28%

Figure 2.9 Number of long term patients treated and Follow-Ups recorded

Year	2010/11	2011/12	2012/13	2013/14	2014/15
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 2014/15

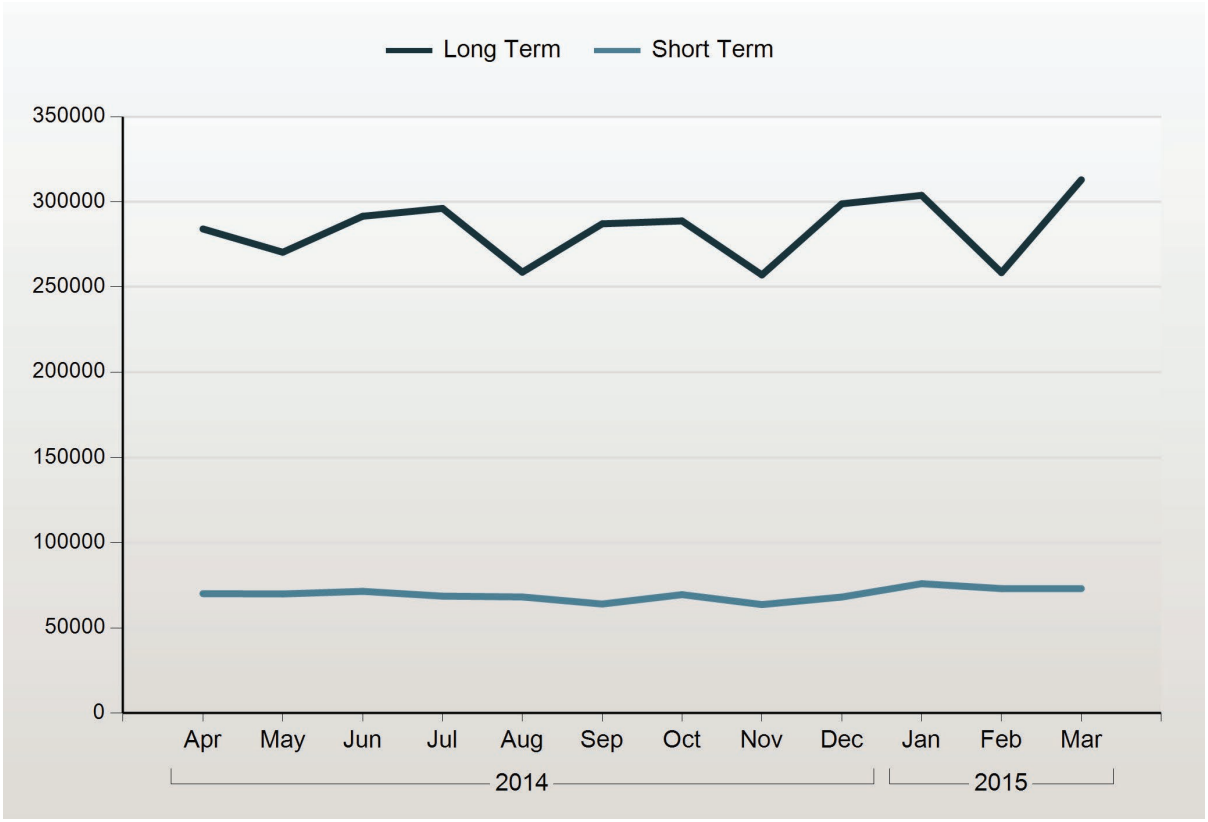

Figure 3.1.2 Recorded yearly immunoglobulin use by regime January 2011 - March 2014

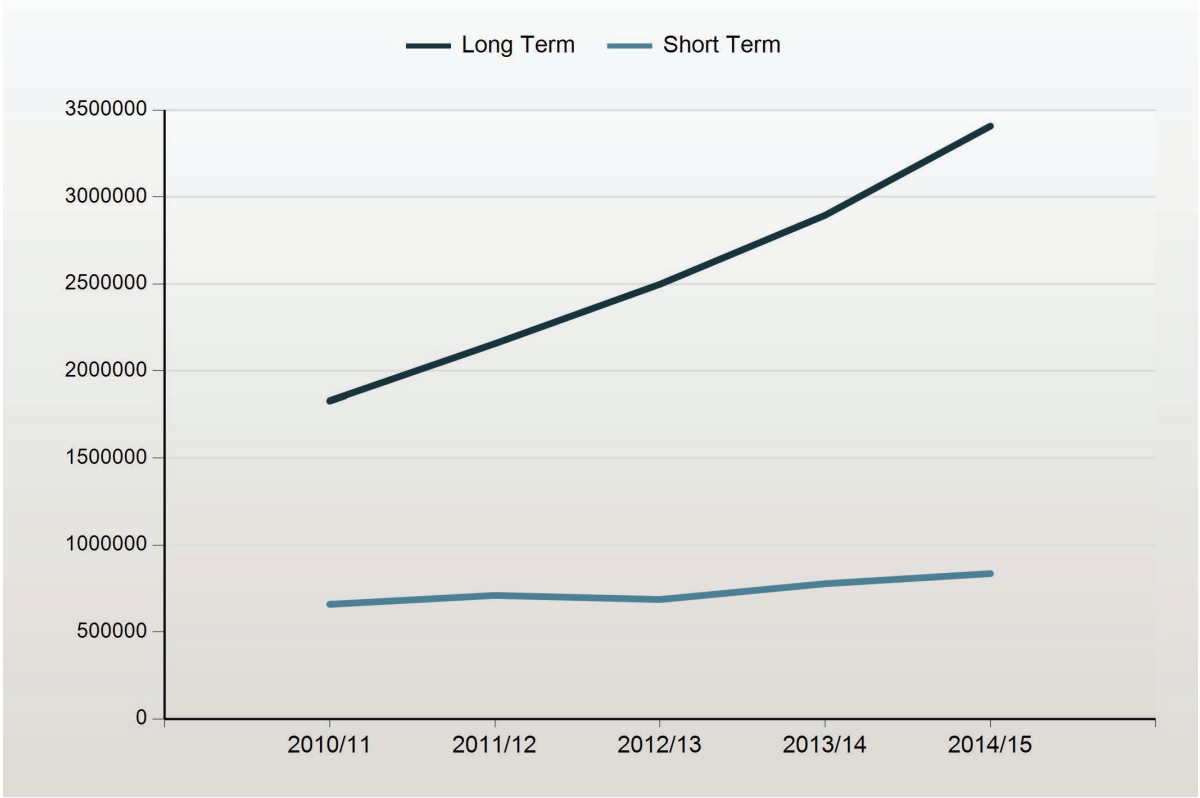

Figure 3.2.1 Recorded monthly immunoglobulin use by speciality 2014/15

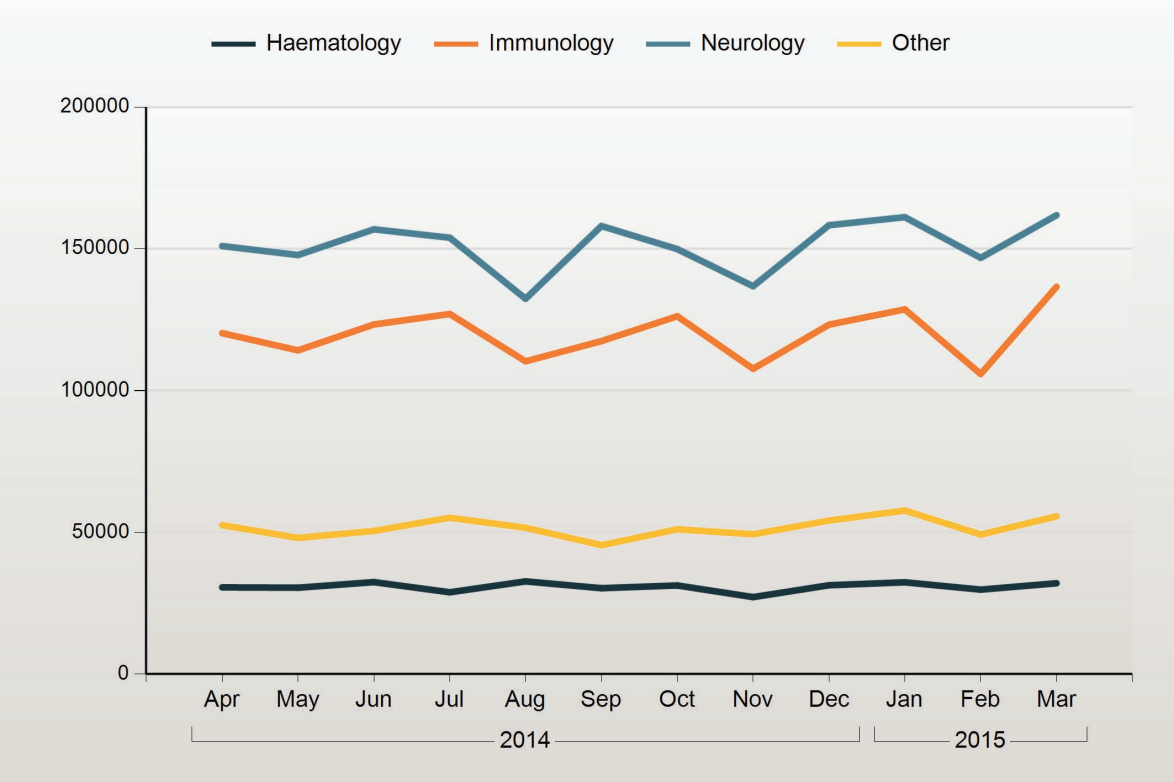

Figure 3.2.2 Recorded yearly immunoglobulin use by speciality 2010/11 - 2014/15

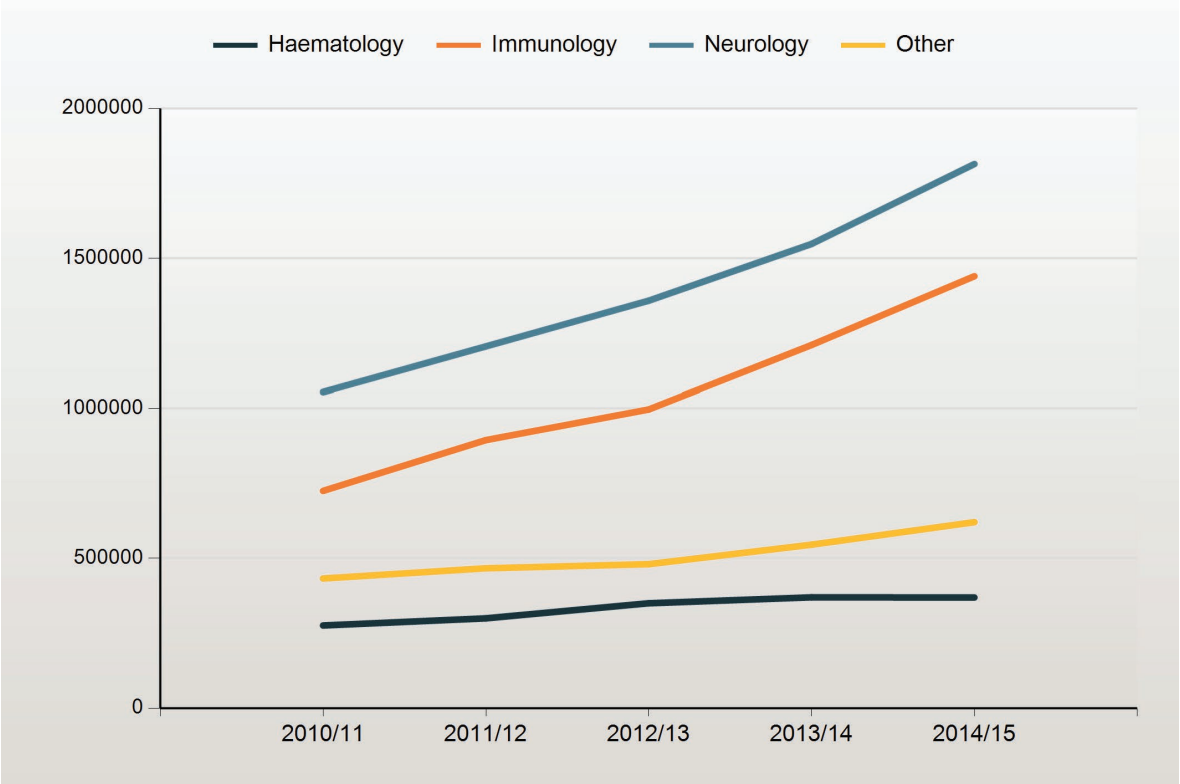

Figure 3.3.1 Recorded monthly immunoglobulin use by Indication 2014/15

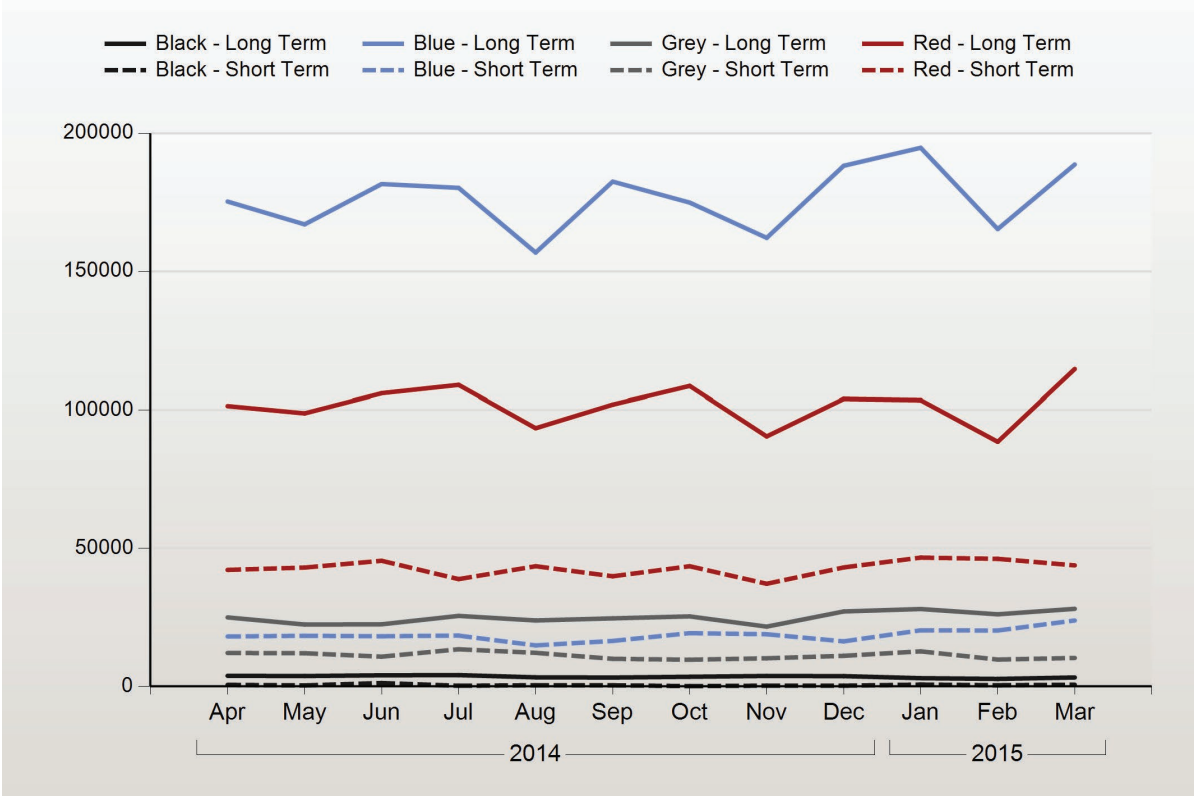

Figure 3.3.2 Recorded yearly immunoglobulin use by Indication 2011/12 - 2014/15

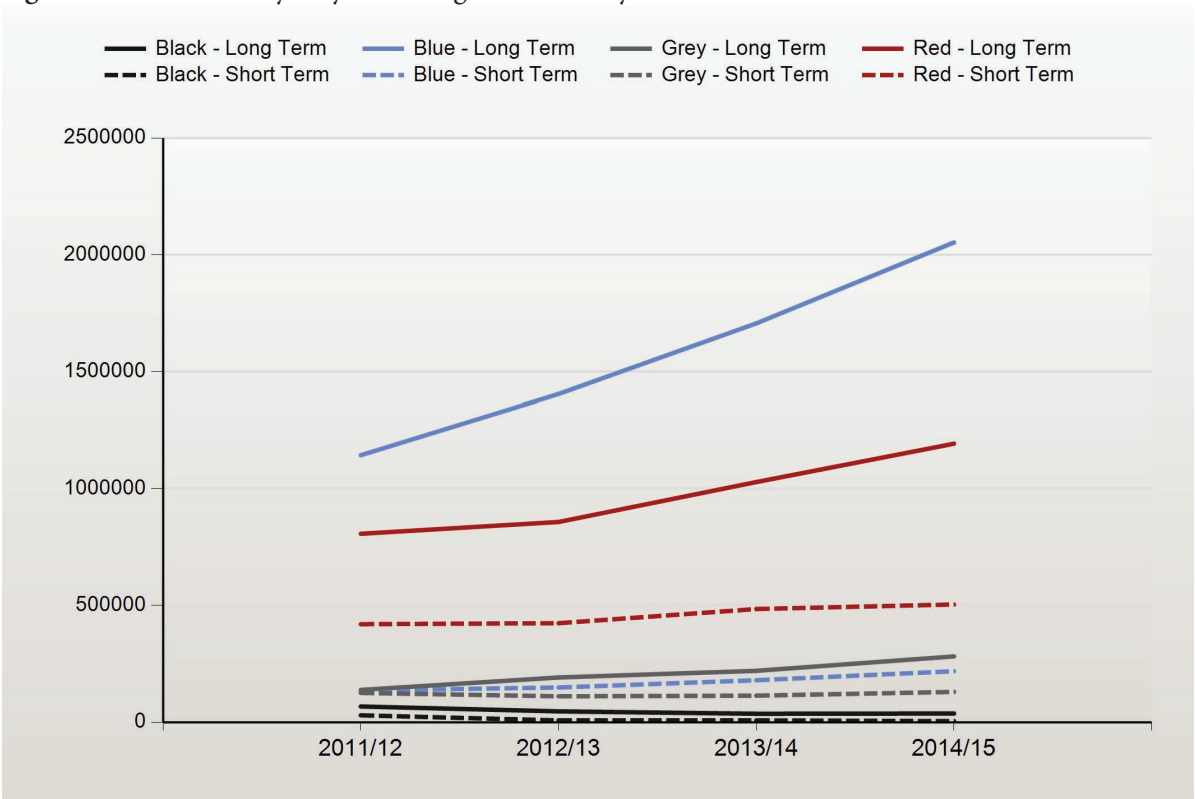

Figure 3.4.1 Recorded immunoglobulin use by region 2013/14

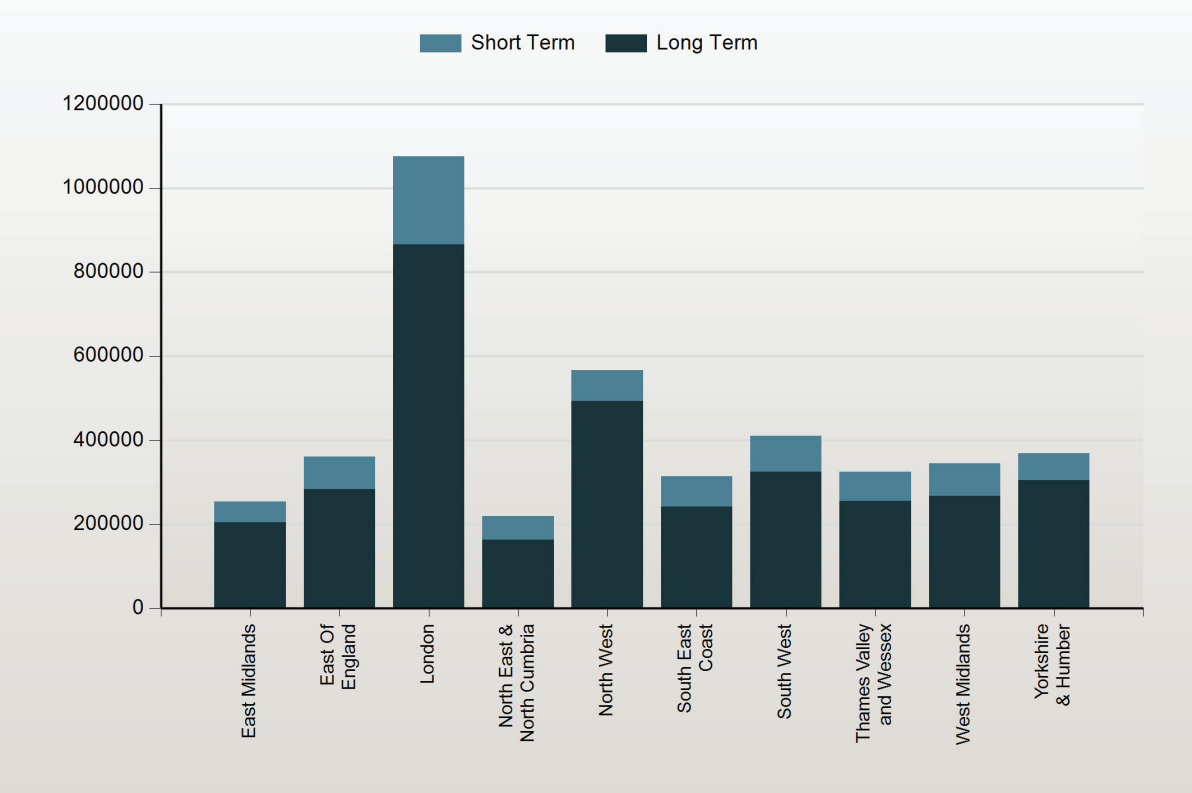

Figure 3.4.2 Recorded yearly immunoglobulin use by region 2010/11 - 2014/15

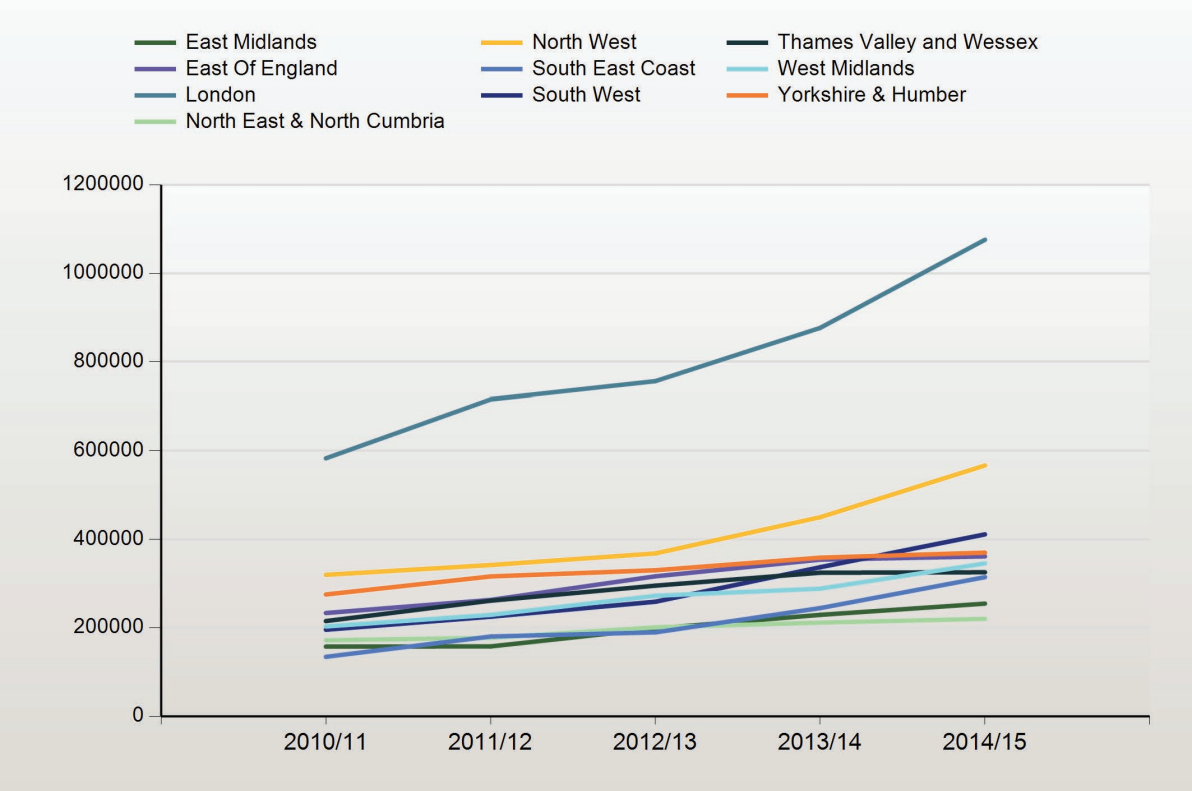

Figure 3.5.1 Volume of immunoglobulin used for the top 10 diagnoses 2014/15

Diagnosis	Usage (Grams)
Primary Immunodeficiencies	1,102,219
Chronic Inflammatory Demyelinating Polyradiculoneuropathy	859,480
Multifocal Motor Neuropathy	411,494
Other Conditions	289,681
Secondary antibody deficiencies	225,445
Immune thrombocytopenic purpura - Acute	222,817
Chronic lymphocytic leukaemia	204,527
Myasthenia Gravis	173,893
Guillain–Barré Syndrome	142,456
Inflammatory Myopathies	97,318

Figure 3.5.2 Recorded yearly immunoglobulin use for the top 10 diagnoses 2011/12 - 2014/15

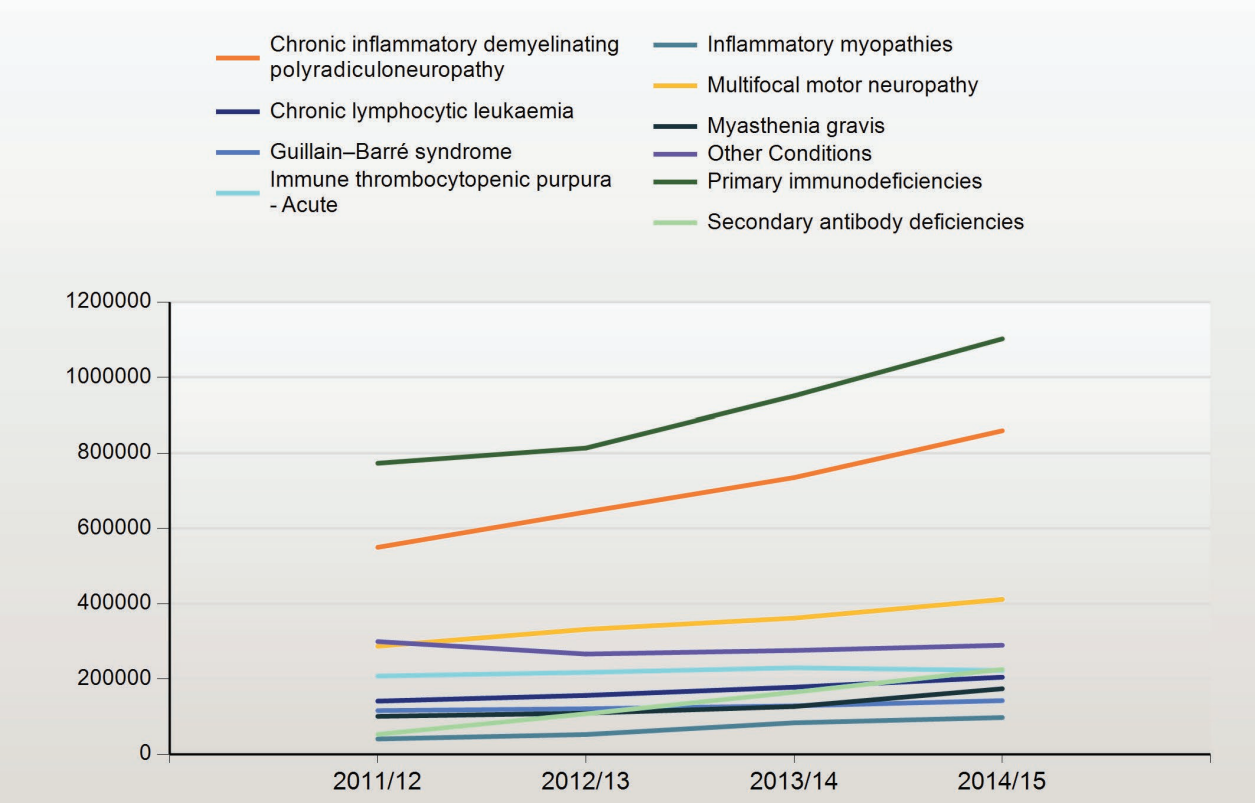

Figure 3.6 Volume of immunoglobulin used in top 20 trusts 2014/15

Trust	Usage (Grams)
Royal Free NHS Trust	242,542
University College London Hospitals NHS Foundation Trust	218,005
Salford Royal NHS Foundation Trust	175,947
Barts And The London NHS Trust	175,450
Oxford Radcliffe Hospitals NHS Trust	149,721
Sheffield Teaching Hospitals NHS Foundation Trust	123,171
Leeds Teaching Hospitals NHS Trust	118,991
The Newcastle Upon Tyne Hospitals NHS Foundation Trust	115,947
Walton Centre For Neurology And Neurosurgery NHS Trust	115,595
Heart Of England NHS Foundation Trust	104,304
Nottingham University Hospitals NHS Trust	86,121
University Hospitals Of Leicester NHS Trust	85,128
Imperial College Healthcare NHS Trust	83,927
Royal Cornwall Hospitals NHS Trust	79,190
Cambridge University Hospitals NHS Foundation Trust	76,062
Lancashire Teaching Hospitals NHS Foundation Trust	75,179
Plymouth Hospitals NHS Trust	71,475
Guy's And St Thomas' NHS Foundation Trust	69,959
University Hospital Birmingham NHS Foundation Trust	69,722
North Bristol NHS Trust	69,140

Figure 3.7.1 Recorded monthly use of intravenous and subcutaneous immunoglobulin 2014/15

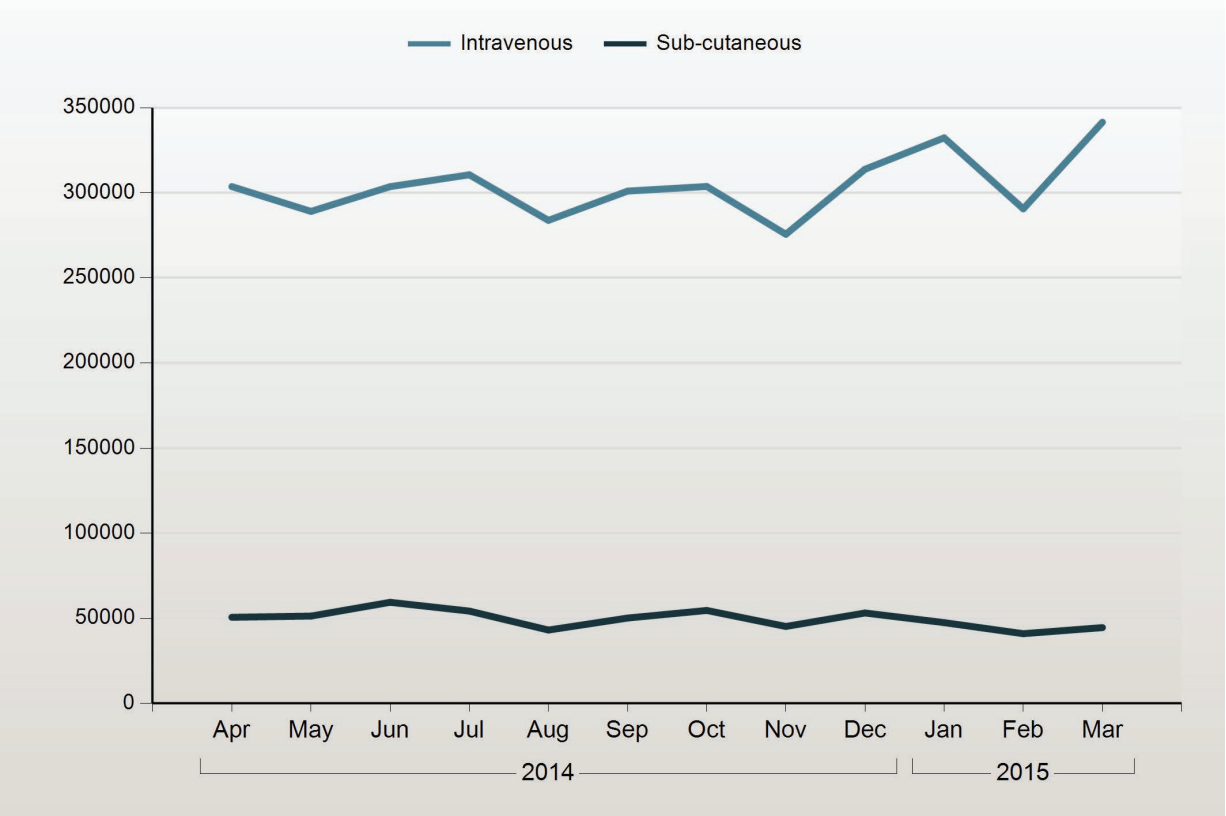

Figure 3.7.2 Recorded yearly use of intravenous and subcutaneous immunoglobulin 2011/12 - 2014/15

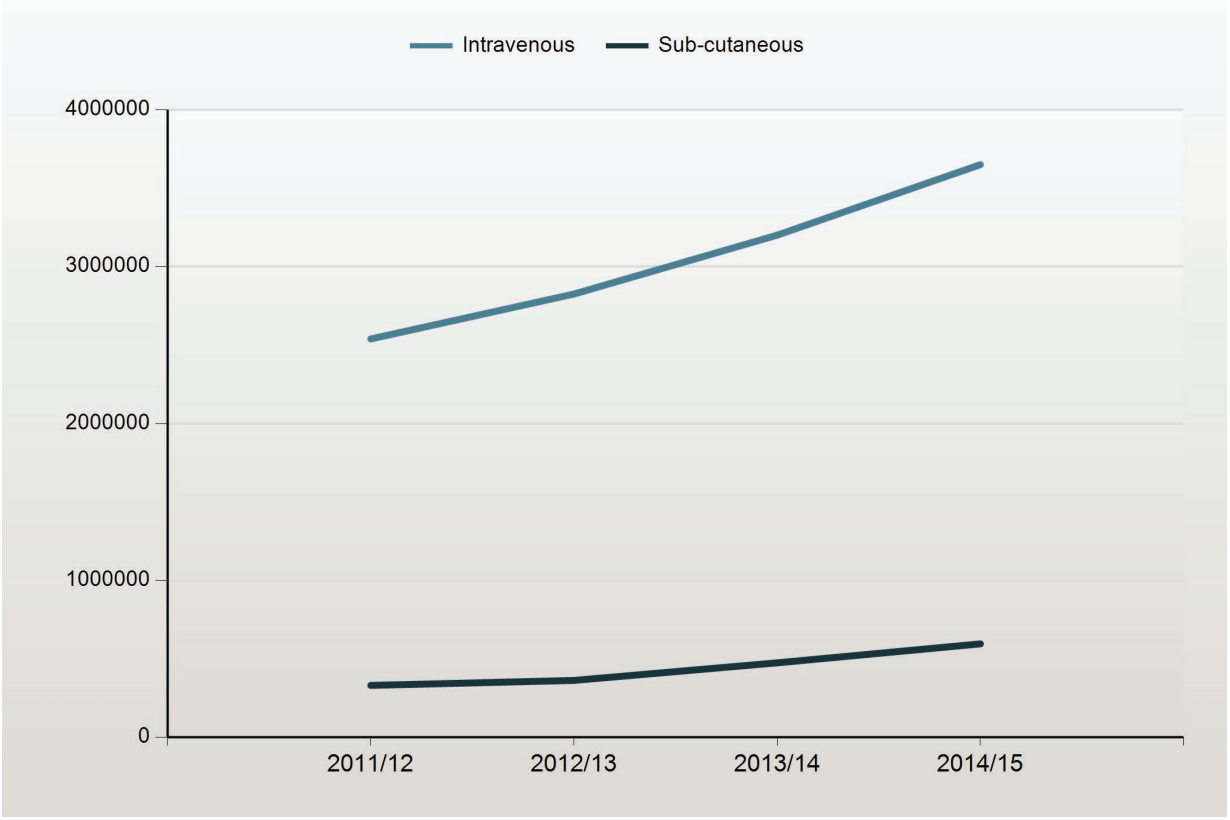

Figure 3.8.1 Recorded monthly use of intravenous immunoglobulin products

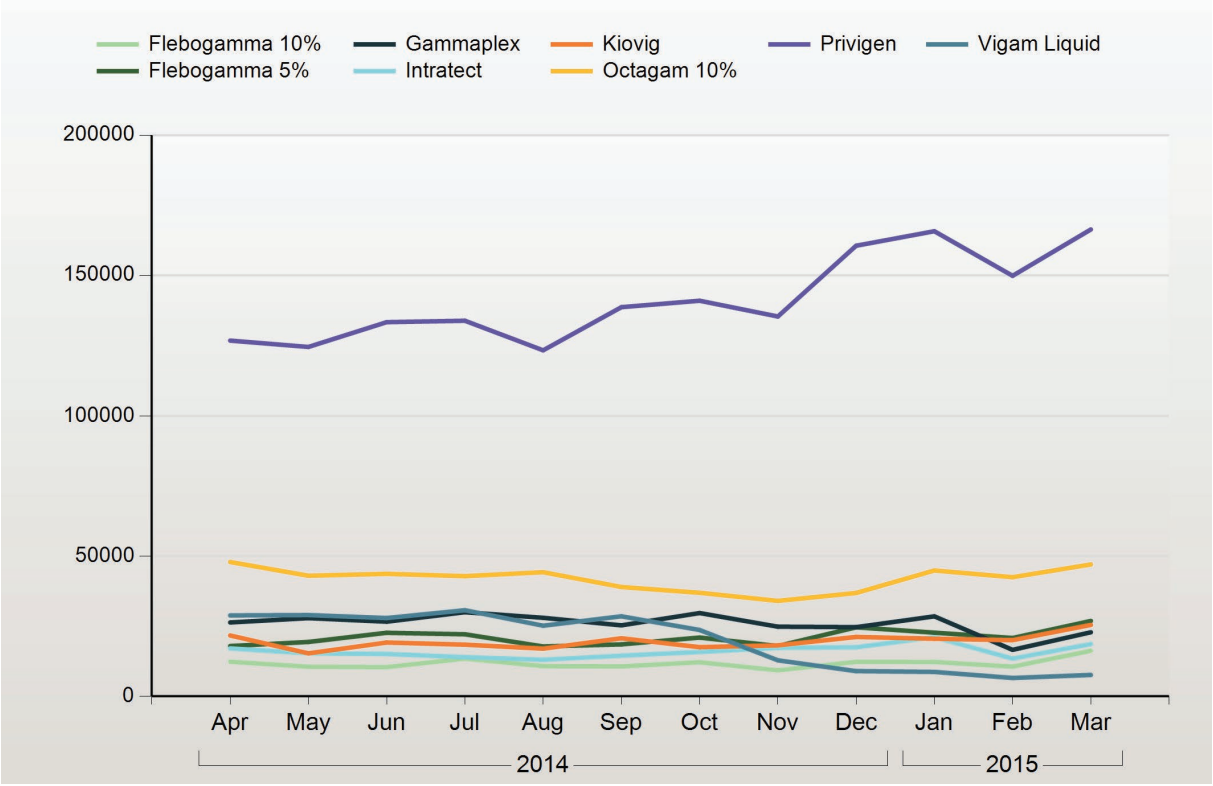

Figure 3.8.2 Recorded yearly use of intravenous immunoglobulin products

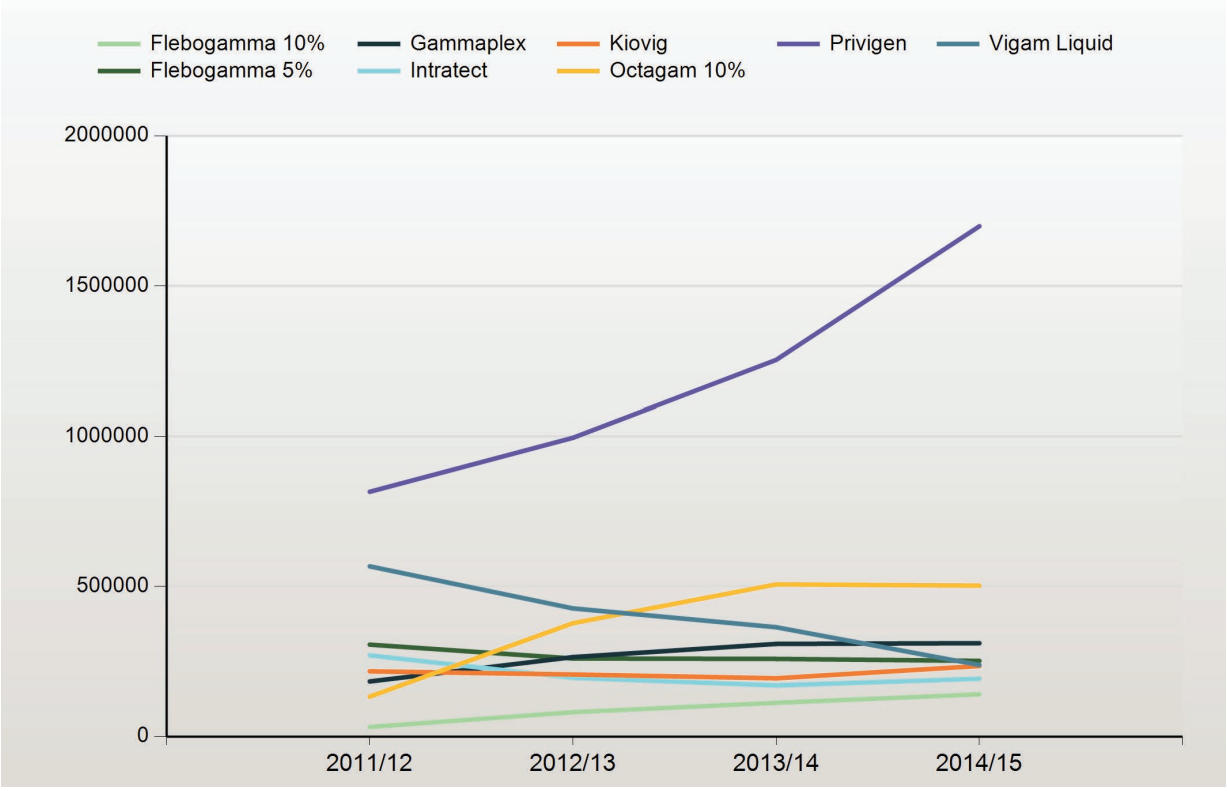

Figure 3.9.1 Recorded monthly use of subcutaneous immunoglobulin products 2014/15

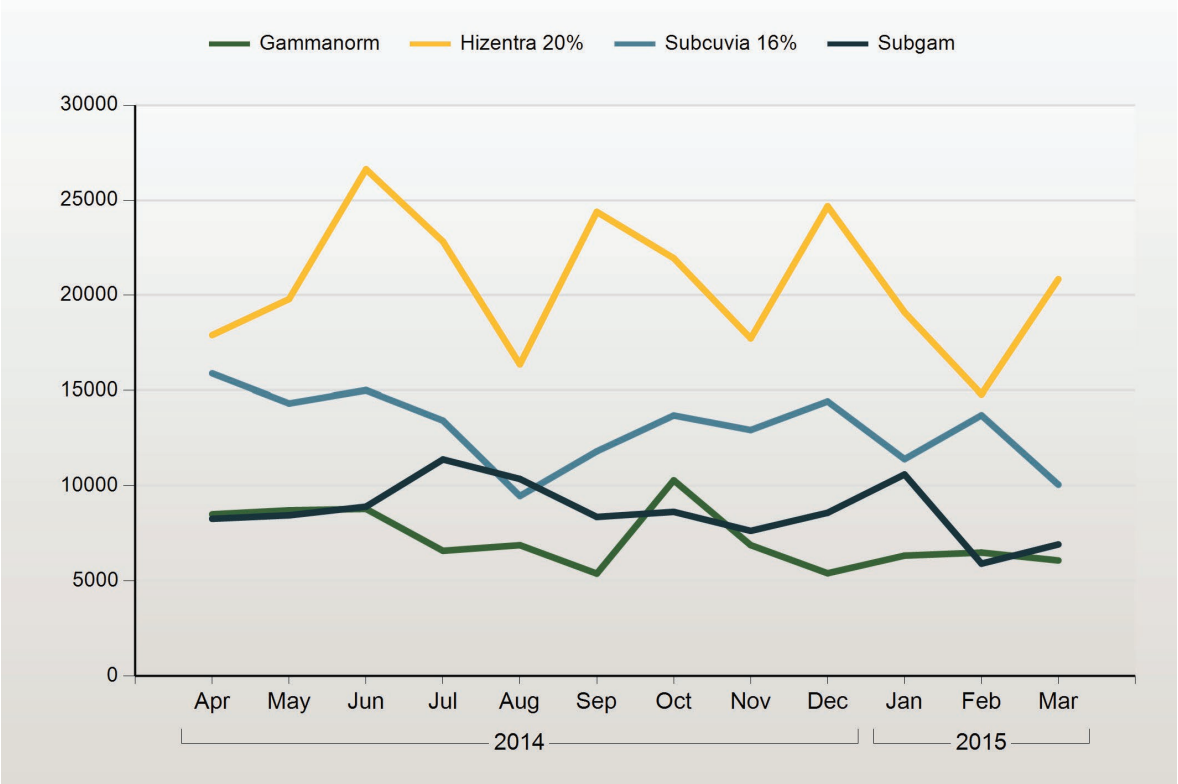

Figure 3.9.2 Recorded yearly use of subcutaneous immunoglobulin products 2014/15

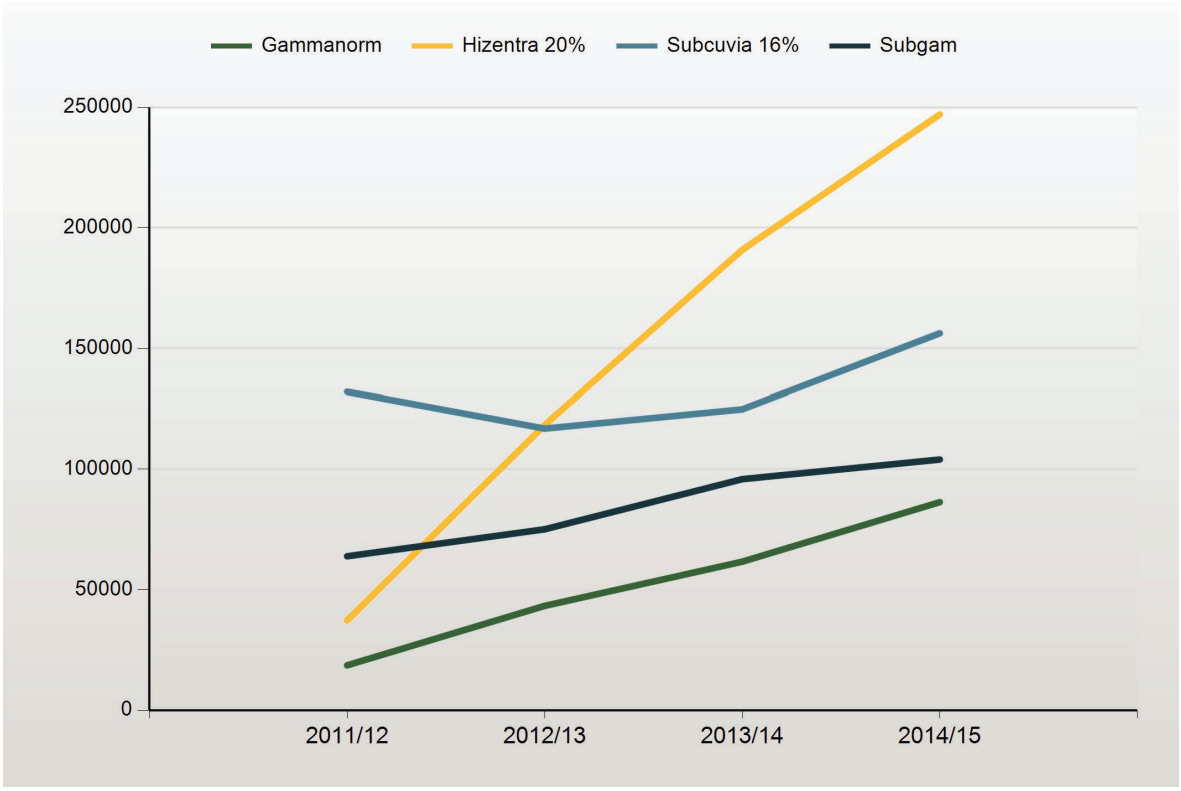

Figure 3.10.1 Recorded monthly use of immunoglobulin products by manufacturer 2014/15

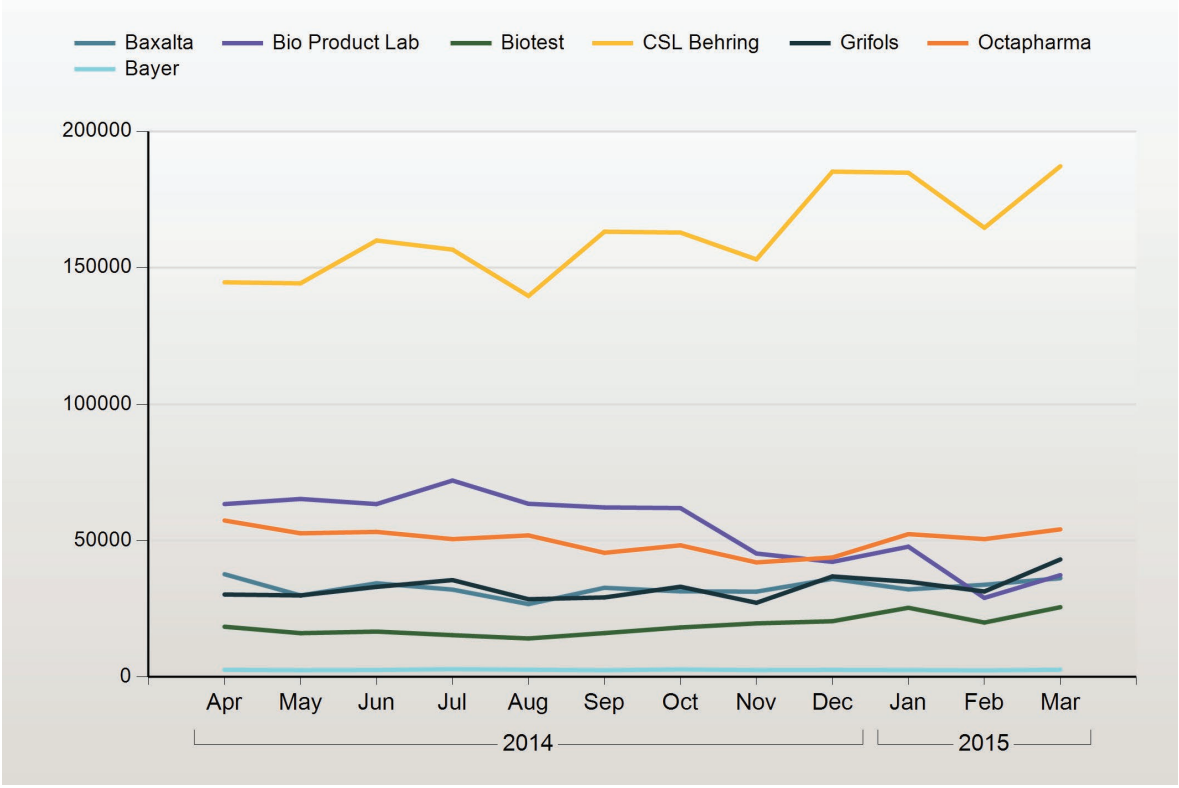

Figure 3.10.2 Recorded yearly use of immunoglobulin products by manufacturer 2010/11 - 2014/15

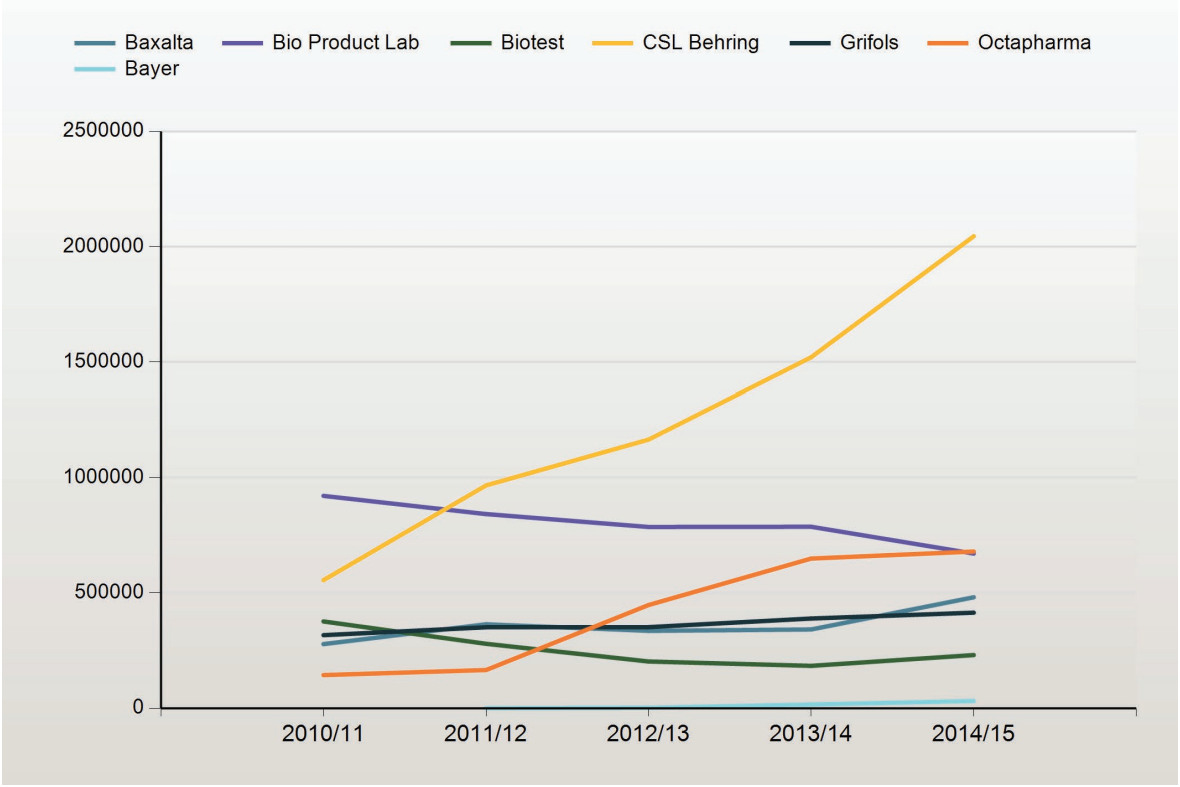

Figure 3.11.1 Average use of immunoglobulin per patient by speciality 2010/11 - 2014/15

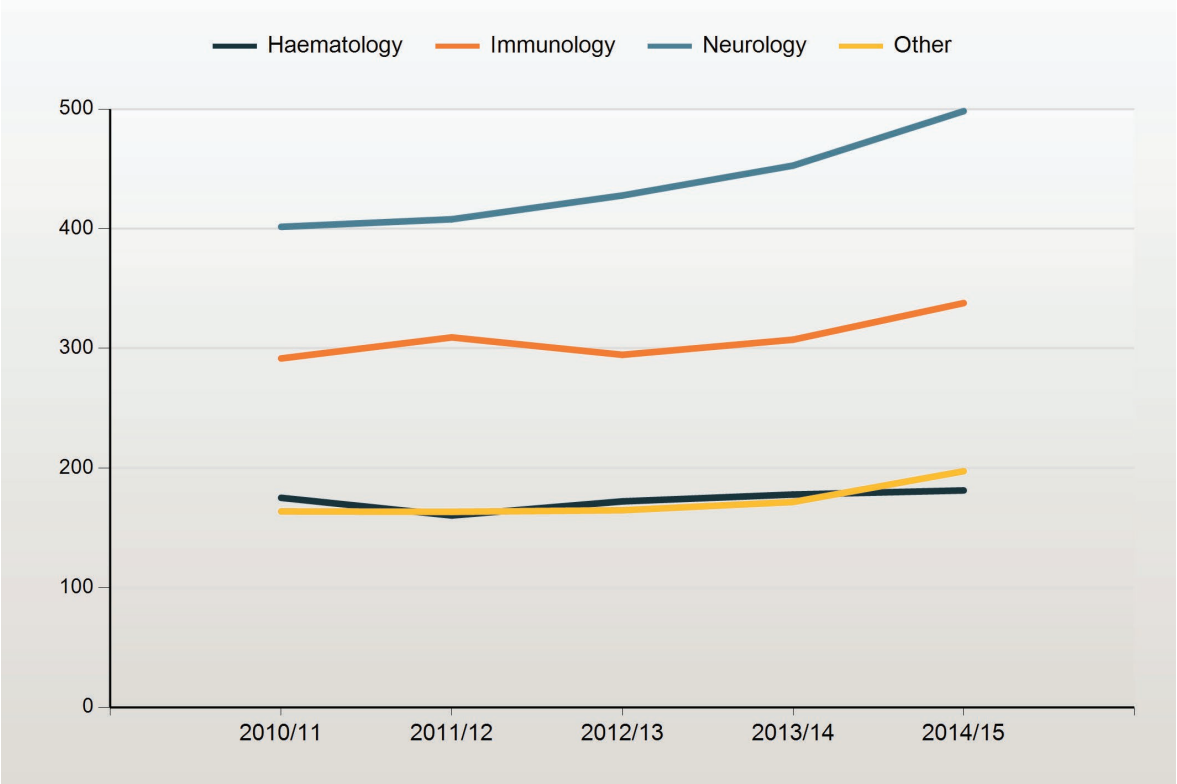

Figure 3.11.2 Average use of immunoglobulin per patient by indication & regime 2010/11 - 2014/15

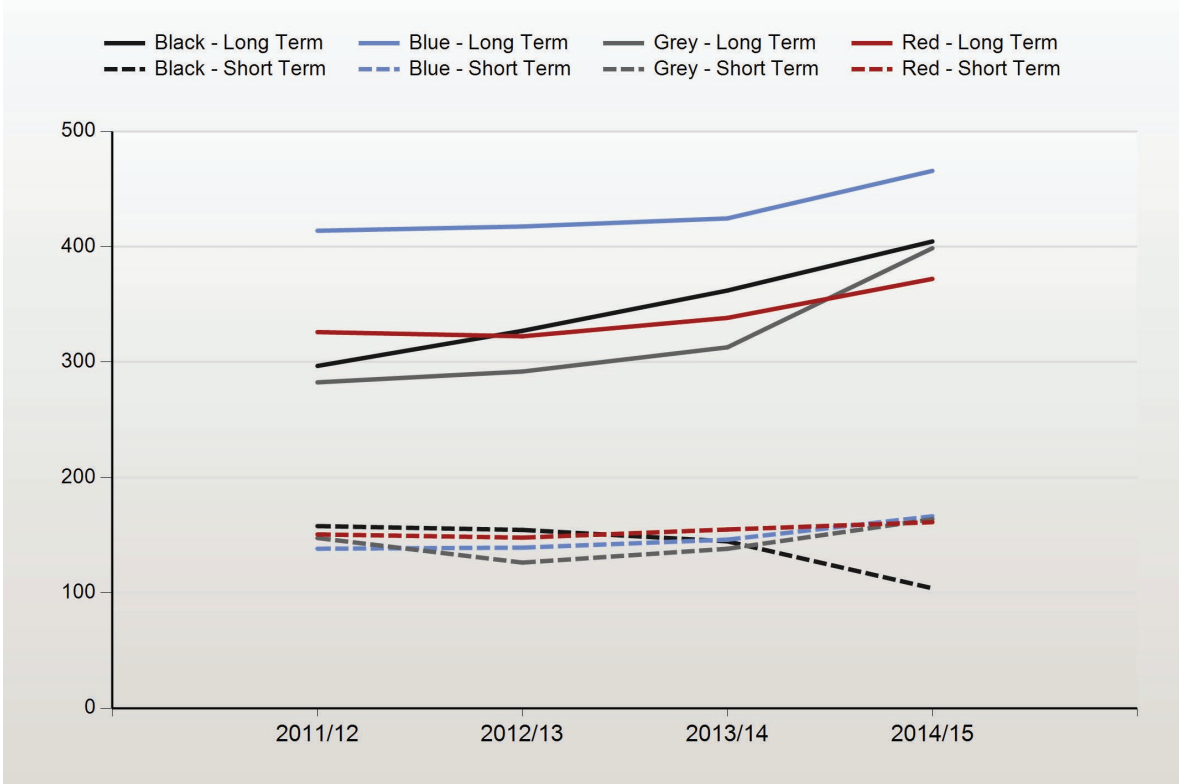

Figure 3.11.3 Average use of immunoglobulin per patient by region 2010/11 - 2014/15

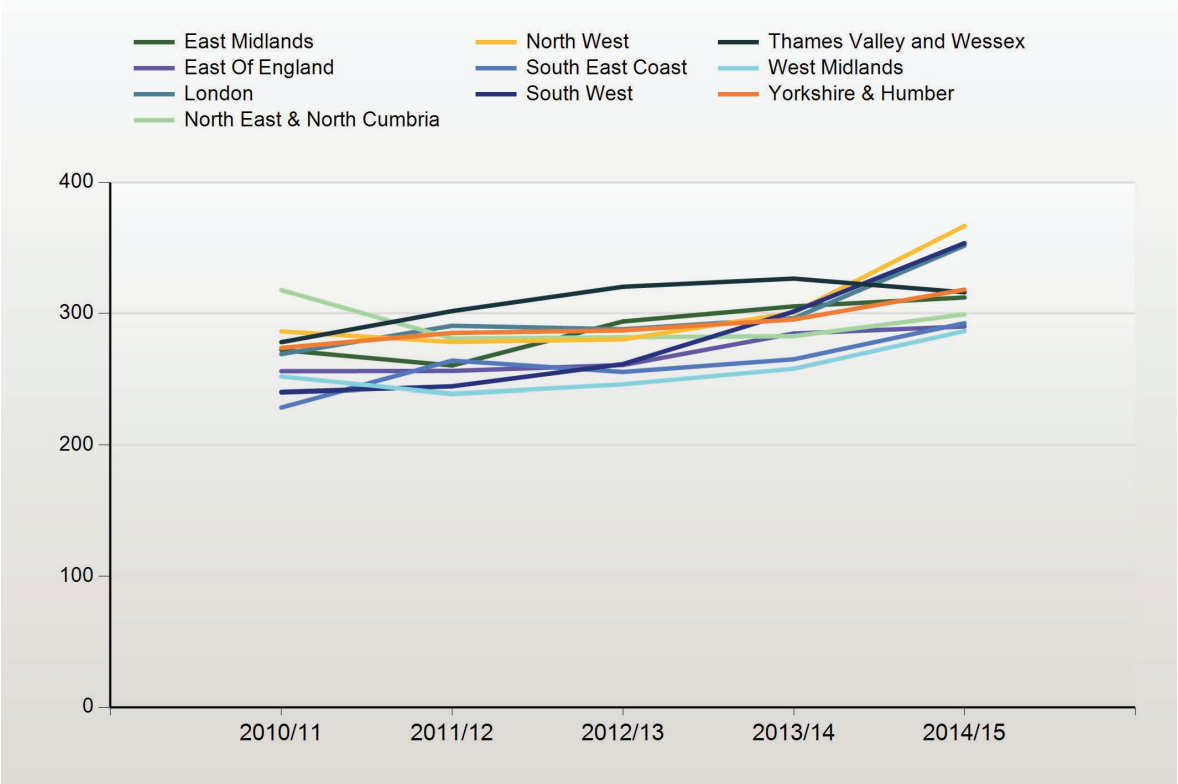

Figure 3.11.4 Average use of immunoglobulin per patient for top conditions 2010/11 - 2014/15