Royal College of Physicians

Inflammatory Bowel Disease Programme

Biological therapy

National clinical audit of biological therapies

UK inflammatory bowel disease (IBD) audit

Annual report
September 2016

Royal College of Physicians | Inflammatory Bowel Disease Programme

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In association with:

BDA The Association of UK Dietitians

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HQIP Healthcare Quality Improvement Partnership

Healthcare Improvement Scotland

National clinical audit of biological therapies. Annual report. September 2016. UK IDB audit

This report was prepared by the biological therapy audit subgroup on behalf of the UK inflammatory bowel disease (IBD) programme steering group. (For a complete list of steering group members please see Appendix 2.)

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Healthcare Quality Improvement Partnership

The national clinical audit of biological therapies is commissioned by the Healthcare Quality Improvement Partnership (HQIP) as part of the National Clinical Audit Programme (NCA). HQIP is led by a consortium of the Academy of Medical Royal Colleges, the Royal College of Nursing and National Voices. Its aim is to promote quality improvement, and in particular to increase the impact that clinical audit has on healthcare quality in England and Wales. HQIP holds the contract to manage and develop the NCA Programme, comprising more than 30 clinical audits that cover care provided to people with a wide range of medical, surgical and mental health conditions. The programme is funded by NHS England, the Welsh Government and, with some individual audits, also funded by the Health Department of the Scottish Government, DHSSPS Northern Ireland and the Channel Islands.

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UK inflammatory bowel disease (IBD) programme

The Clinical Effectiveness and Evaluation Unit (CEEU) of the RCP manages the national clinical audit of biological therapies as part of the UK inflammatory bowel disease (IBD) programme. The UK IBD programme aims to improve the delivery of care for people with IBD through effective measurements against standards and feedback to providers.

Citation for this document: Royal College of Physicians. *National clinical audit of biological therapies: annual report*. UK inflammatory bowel disease (IBD) audit. London: Royal College of Physicians, 2016.

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ISBN 978-1-86016-624-2| eISBN 978-1-86016-625-9

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Document purpose	To disseminate the results of the national inflammatory bowel disease (IBD) biological therapy audit and stimulate local improvement activity.
Title	National clinical audit of biological therapies. UK inflammatory bowel disease (IBD) audit. Annual report September 2016.
Author	On behalf of the IBD programme steering group
Publication date	22 September 2016
Audience	Healthcare professionals, NHS managers, service commissioners and policymakers
Description	This is the fifth biological therapy report published from the UK IBD audit. This report is for anyone who is interested in IBD. It publishes national- and hospital-level findings on the efficacy, safety and appropriate use of biological therapies for patients newly started on biologics since its inception on 12 September 2011 until 29 February 2016.
Supersedes	National clinical audit of biological therapies. UK inflammatory bowel disease (IBD) audit. Adult report. September 2015. National clinical audit of biological therapies. UK inflammatory bowel disease (IBD) audit. Paediatric report. September 2015.
Related publications	IBD Standards Group, 2013. *Standards for the healthcare of people who have inflammatory bowel disease, IBD standards, 2013 update*. **www.ibdstandards.org.uk** Mowat C, Cole A, Windsor A *et al*, on behalf of the IBD Section of the British Society of Gastroenterology. Guidelines for the management of inflammatory bowel disease in adults. *Gut* 2011;60:571–607. National Institute for Health and Care Excellence, 2008. Technology appraisal 163: *Infliximab for acute exacerbations of ulcerative colitis.* **www.nice.org.uk/guidance/TA163** National Institute for Health and Care Excellence, 2011. Technology appraisal 187: *Infliximab (review) and adalimumab for the treatment of Crohn's disease.* **www.nice.org.uk/guidance/TA187** National Institute for Health and Care Excellence, 2015. Technology appraisal 329: *Infliximab, adalimumab and golimumab for treating moderately to severely active ulcerative colitis after the failure of conventional therapy (including a review of TA140 and TA262)*. **www.nice.org.uk/guidance/TA329** National Institute for Health and Care Excellence, 2015. Quality standard 81: *Inflammatory bowel disease.* **www.nice.org.uk/guidance/QS81** Royal College of Physicians, 2014. *Experience of inpatients with ulcerative colitis throughout the UK*. Royal College of Physicians, 2014. *National audit of inflammatory bowel disease (IBD) service provision. Adult report.* Royal College of Physicians, 2014. *National audit of inflammatory bowel disease (IBD) service provision. Paediatric report* Royal College of Physicians, 2014. *National clinical audit of inpatient care for adults with ulcerative colitis*. Royal College of Physicians, 2014. *National clinical audit of inpatient care for young people with ulcerative colitis*. Scotland leading the way a national blueprint for inflammatory bowel disease in Scotland. **www.alliance-scotland.org.uk/download/library/lib_5773c0b293b3e/**
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Executive summary

Background

Over the last 10 years, biological therapies have transformed treatment for people with inflammatory bowel disease (IBD). Most of these drugs work by targeting a protein in the body called tumour necrosis factor alpha (TNFα). Overproduction of this protein is thought to be partly responsible for the chronic inflammation in people with IBD.

The purpose of this audit is to measure the efficacy, safety and appropriate use of biological therapies in patients with IBD in the UK. The audit also aims to capture patients' views on their quality of life at intervals during their treatment. This is the fifth report of the biological therapy element of the UK IBD audit; all analyses within this report include only those patients who were newly started on biological therapies between 12 September 2011 (the start of data collection) and 29 February 2016. The data contained within this report have **only** been taken from completed submissions within the biological therapy audit web tool (**www.ibdbiologicsaudit.org**).

The biological therapies audit provides IBD teams with the means to understand whether they achieve Standard A6 of the **IBD standards**;[1] specifically, regular review of patient outcomes and auditing of biological therapy. Participation in the audit also provides the opportunity to review compliance with National Institute for Health and Care Excellence (NICE) recommendations **technology appraisal 187**[2] and **technology appraisal 329**[3] and also fulfils NICE quality statement 4: monitoring drug treatment in **quality standard 81**.[4]

Key messages

This round of audit is of particular interest due to the emerging availability of biosimilar infliximab (Inflectra and Remsima), which became available in the UK from February 2015. There is little data available comparing infliximab (Remicade) to its biosimilar versions (Inflectra and Remsima). The analysis of short-term data conducted in this report shows that infliximab biosimilars are as effective as infliximab (Remicade). Given that they are far less expensive than Remicade, sites should adopt infliximab biosimilars to take advantage of significant cost savings. This report also gives important insights into the use of other biological therapies adalimumab (Humira), golimumab (Simponi) and vedolizumab (Entivyio).

Participation in the biological therapies audit remains consistent. Between 1 March 2015 and 29 February 2016, 138 (87%) of the 159 eligible adult trusts / health boards and 19 (76%) of the 25 IBD specialist paediatric sites in the UK participated in this audit or the Personalised Anti-TNF Therapy in Crohn's disease study (PANTs).[5] This equates to a total of 2722 adult and 278 paediatric patients entered to the audit. This is the largest number of patients entered to the audit in a single year since the audit began in 2011.

The data demonstrate other changes in practice with a greater proportion of patients with ulcerative colitis (UC) being treated, in line partly with the changes to the recommendations in NICE guidance. There has also been a reduction in the frequency of surgery prior to treatment and biological therapies being used earlier in the disease course. Data from this audit indicate that not all patients are being adequately screened prior to treatment. It is important that all patients are screened for opportunistic infections prior to starting biologics and that they are followed up appropriately to ensure the safe and effective use of these medicines. This report focuses primarily on new starters on biologics. However, continued monitoring of those patients switching to new biosimilars is also required.

This will be the final report produced by the UK IBD audit at the Royal College of Physicians (RCP). It is currently in the process of transitioning data collection to support audit and quality improvement to the IBD Registry. It is vitally important that sites continue to monitor and audit their patients on biologics locally and submit data to the IBD Registry for future national comparisons where possible.

Key findings

- Biological therapies are safe. Ten per cent of adult and 5% of paediatric patients audited over the last year experienced an adverse reaction at 3-month follow-up. The commonest adverse reaction was a rash; 3% in adult patients, 2% in paediatric patients, with infection seen in only 1% of adults. There were no reported malignancies. (**Adults – Section 2, p 23 / Paediatrics – Section 3, p 38**)

- Treatment rates for ulcerative colitis have increased substantially in the past year. In 2015, ulcerative colitis represented 17% (412/2396) of adult patients and 12% (32/277) of paediatric patients treated. This rose to 33% (903/2722) of adult patients and 17% (47/278) of paediatric patients in 2016. (**Adults – Section 2, p 21 / Paediatrics – Section 3, p 37**)

- The short-term efficacy of biosimilar infliximab (Inflectra and Remsima) is equivalent to Remicade. A response was seen at 3 months in 84% of adult and 86% of paediatric patients treated with Inflectra/Remsima and 85% of adult and paediatric patients treated with Remicade. (**Adults – Section 2, p 26 / Paediatrics – Section 3, p 41**)

- Biological treatments are being used earlier in the disease course in adult patients. The median time from diagnosis to treatment for adult patients has fallen from 4.5 years in 2012 to 3.8 years in 2016 (p=0.026). It has also fallen for paediatric patients from 1.2 years in 2012 to 0.9 years in 2016. (**Adults – Section 2, p 21 / Paediatrics – Section 3, p 37**)

- Only 60% of adult and 47% of paediatric patients audited in 2016 had complete pre-treatment screening for opportunistic infections. For example, 82% of adult and 81% of paediatric patients had either a Gamma interferon or Mantoux screen. (**Adults – Section 2, p 19 / Paediatrics – Section 3, p 35**)

- Only 31% of adult and 44% of paediatric patients audited in 2016 were recorded as having been followed up within 3 months of initial treatment. (For the follow-up time point, a 1-month window either side was used in order to best capture patients – eg for 3-month follow-up, data entered 61–121 days after initial treatment were included.) (**Adults – Section 2, p 18 / Paediatrics – Section 3, p 34**)

- The frequency of surgery prior to treatment has diminished over the rounds of this audit. Surgery recorded in 2012 was 36% for adult and 25% for paediatric patients, by 2016 this had reduced to 15% for adult and 8% for paediatric patients. In addition, surgery in the 6 months following treatment is less frequent than in the 6 months before treatment. (**Adults – Section 2, p 21 / Paediatrics – Section 3, p 37**)

- It is of some concern that treatment with concomitant steroids for adult patients has increased over the rounds of audit, rising from 28% in 2012 to 36% in 2016 at initial treatment. This use does, however, reduce by 3-month follow-up to 7% in 2012 and 21% in 2016. (**Adults – Section 2, p 21 / Paediatrics – Section 3, p 37**)

- Data from research studies can successfully be used for clinical audit purposes. The completion of the Personalised Anti-TNF Therapy in Crohn's disease study (PANTs) represents one of the largest anti-TNFα research studies performed and the data have been successfully incorporated into the biological therapies audit. (**Section 1, p 15**)

Recommendations

- Clinicians should use infliximab biosimilars as the first line anti-TNFα for appropriate patients with active IBD.
- Clinicians should completely screen all patients prior to treatment with biological therapies. Adult patients must have a chest X-ray and screening for TB (Gamma interferon or a Mantoux screen), as well as hepatitis B, hepatitis C and HIV. Paediatric patients must have a chest X-ray and screening for hepatitis B and TB (Gamma interferon or a Mantoux screen).
- Clinicians should document follow-up in all patients within 3 months and at 1 year following initial treatment with biologics. A disease activity index should also be recorded in all patients at baseline, 3 months and 1 year as a minimum. These steps will ensure that only appropriately responding patients continue to have treatment.
- Steroid use in all patients should be kept to a minimum. Infliximab has a steroid sparing effect and steroids should be stopped at the first opportunity.
- Clinicians should audit all patients on biological therapies to ensure their safe and appropriate use. Data can also be provided to studies such as PANTs[5] for research. The UK IBD Registry can be used as a mechanism to keep a register of this information, comparing local to national outcomes and supporting audit and quality improvement (**www.ibdregistry.org.uk**).
- Clinicians should share findings and recommendations of this report at relevant multidisciplinary team, clinical governance and audit meetings, with the aim of developing a local action plan for implementing improvement.

Implementing change: action plan

This action plan has been produced to enable you to take forward the recommendations of this national audit. It can be adapted through the addition of further actions that you feel are appropriate for your own service. You can download a copy of this action plan from **www.rcplondon.ac.uk/biologics**.

National recommendation	Action required	Staff responsible	Progress at your site (Include date of review, name of individual responsible for action)
1 Clinicians should use infliximab biosimilars as the first line anti-TNFα for appropriate patients with active IBD.	All new starters should commence treatment on infliximab biosimilars. Consideration should be given whether to switch those patients currently established on Remicade to infliximab biosimilars.	NHS managers Consultant gastroenterologists IBD nurses Infusion clinic staff Pharmacists	
2 Clinicians should completely screen all patients prior to treatment with biological therapies. Adult patients must have a chest X-ray and screening for TB (Gamma interferon or a Mantoux screen), as well as hepatitis B, hepatitis C and HIV. Paediatric patients must have a chest X-ray and screening for hepatitis B and TB (Gamma interferon or a Mantoux screen).	Clinicians should ensure that complete screening is included in patient pathways, using for example a checklist completed before a patient commences on anti-TNFα.	Consultant gastroenterologists IBD nurses Infusion clinic staff	
3 Clinicians should document follow-up in all patients within 3 months and at 1 year following initial treatment with biologics. A disease activity index should also be recorded in all patients at baseline, 3 months and 1 year as a minimum. These steps will ensure that only appropriately responding patients continue to have treatment.	At first infusion clear arrangement for follow-up within 3 months must be in place. This could be done by any suitably qualified professional of the IBD team. Arrangements should be in place to allow collection of disease activity score using a defined disease activity index. If treatment is continued, clear arrangements for an annual review must be in place.	Consultant gastroenterologists IBD nurses Infusion clinic staff Pharmacists	

National recommendation	Action required	Staff responsible	Progress at your site (Include date of review, name of individual responsible for action)
4 Steroid use in all patients should be kept to a minimum. Infliximab has a steroid sparing effect and steroids should be stopped at the first opportunity.	A defined reduction regime should be in place for all patients on steroids at first infusion.	Consultant gastroenterologists IBD nurses Infusion clinic staff	
5 Clinicians should audit all patients on biological therapies to ensure their safe and appropriate use. Data can also be provided to studies such as PANTs[5] for research. The UK IBD Registry can be used as a mechanism to keep a register of this information, comparing local to national outcomes and supporting audit and quality improvement (www.ibdregistry.org.uk).	Teams should decide which system of data collection best suits the needs of their service. An updated record should be kept on all patients on biologics and where possible this should be submitted to the IBD Registry for national analysis.	NHS managers Consultant gastroenterologists IBD nurses Infusion clinic staff	
6 Clinicians should share findings and recommendations of this report at relevant multidisciplinary team, clinical governance and audit meetings, with the aim of developing a local action plan for implementing improvement.	Identify an appropriate time to discuss the results of the audit and decide key priority areas for improvement. Present findings and recommendations at an appropriate meeting and ensure that action plans for implementing changes are devised.	NHS managers Consultant gastroenterologists IBD nurses Infusion clinic staff Members of the IBD team	
7 ENTER THE LOCAL ACTIONS YOU HAVE IDENTIFIED HERE			
8 ENTER THE LOCAL ACTIONS YOU HAVE IDENTIFIED HERE			

1: Introduction and methods

Introduction

Biological therapies have revolutionised the treatment of inflammatory bowel disease (IBD), with usage increasing rapidly in the UK over the past few years. They are effective treatments and relatively safe, however, they remain a significant cost burden for hospitals in the UK. The availability of biosimilar infliximab provides an opportunity for substantial cost savings, reducing the cost of treatment from approximately £10,000 per patient per year to less than £5,000. However, IBD data confirming equivalent efficacy of infliximab biosimilars compared with Remicade are currently relatively sparse. Golimumab and vedolizumab have seen more widespread use in 2016 and have been included in the biologics audit for the first time this year. Thus continued auditing of their effectiveness, safety and appropriateness remains a clinical priority. Further information about biological therapies and their licensing can be found in **section 5, pp 38–39**.

Aims of the biological therapies audit

To assess nationally:

1 the appropriate use/prescribing of biological therapies in the treatment of IBD
2 the efficacy of biological therapies in the treatment of IBD
3 the safety of biological therapies in the treatment of IBD
4 the views of patients with IBD on their quality of life at defined intervals throughout their use of biological therapies.

Methods

This is a prospective audit, with data collection taking place in 'real time' during the clinical appointment with the patient. Participating sites are asked to identify and enter data on patients newly started on biological therapies. Data entry takes place in the form of 'submissions' to a web-based data collection tool (**www.ibdbiologicsaudit.org**). A submission refers to data entered in any of the following categories: patient demographics, IBD disease details, initial anti-TNFα treatment, follow-up anti-TNFα treatment and IBD-related surgery. Further detail about each of the categories can be found in **section 6, pp 40–43** of this report.

Definition of a 'site'

Lead clinicians are asked to collect and submit data on the basis of a unified IBD service that would be registered as a named 'site'. This is typically a single hospital within a trust / health board, but where more than one hospital under a trust / health board offers independent IBD services, data are entered for separate 'sites'. Some organisations that run a coordinated IBD service across several hospitals with the same staff participate in the audit as one trust / health board-wide site.

Eligibility and participation

Sites are eligible to participate in the biological therapies audit if they prescribe and administer biological therapy to their patients with IBD. Of the 159 adult trusts / health boards eligible to participate in the UK, 138 are participating in the biological therapies element and/or in the Personalised Anti-TNF Therapy in Crohn's disease study (PANTs)[5] as well as 19 of the 25 specialist paediatric IBD sites; see below for further information. There are a further eight paediatric sites participating in addition to the specialist ones (27 in total). Paediatric patients may also be receiving biological therapies under adult gastroenterology services. Further information on participation and a list of participating and non-participating sites can be found in **section 7, pp 53–79** of this report.

PANTs

The PANTS[5] study started in March 2013 and finished patient recruitment in July 2016 with follow-up data still being collected. It is a prospective, uncontrolled, cohort study investigating primary non-response, loss of response and adverse drug reactions to infliximab and adalimumab in patients with severe active luminal Crohn's disease (CD). The collected clinical data are aligned with data collected by the biological therapy audit (and in due course with the UK IBD registry). Relevant anonymised data from PANTs have been included and analysed in this report. Sites submitting data to PANTs are indicated by an asterisk in the list of participating and non-participating sites in **section 7, pp 53–79** of this report.

Inclusion and exclusion criteria

Only patients with diagnosed IBD – that is, CD, ulcerative colitis (UC) and IBD unclassified (IBDU) – who have been started on biological therapy for the treatment of their IBD are included. Patients of all ages are included in the audit. Sites that do not provide any biological treatment to their patients with IBD are excluded from participation. The process of including and excluding data in national analyses is detailed in the initial treatment consort diagrams on **p 17** for adult patients and **p 33** for paediatric patients in this report.

Denominators

Denominators throughout the report vary depending on the number of submissions to which the analysed data relate. A submission refers to data entered in any of the following categories: patient demographics, IBD disease details, initial treatment, follow-up treatment and IBD-related surgery. For example, a single patient can have multiple initial or follow-up treatments and may have been treated with one or both drug types. The denominators can vary considerably, so readers should review all table notes and explanatory text provided within the report.

Data-collection tool

The web-based data collection tool was developed by Westcliff Solutions Ltd: **www.westcliffsolutions.co.uk.** Security and confidentiality are maintained during data collection by using unique usernames and passwords; only the lead clinician at each site can authorise local access. Data can be saved during and at the end of an input session, and online help – including definitions and clarifications of data items, internal logical data checks and instant feedback mechanisms – ensure that high-quality data are collected. For an explanation of the different submission types in the biological therapies audit, please see **section 6, pp 49–52** of this report.

Site-level data

The IBD programme steering group, having taken statistical advice, has identified a sample size of fewer than six patients as potentially compromising patient anonymity. Results in site reports that meet this criterion have therefore been replaced with 'n<6'.

Evidence

Guidance referred to within this report is taken from the following sources:

- IBD Standards Group, 2013. *Standards for the healthcare of people who have inflammatory bowel disease, IBD standards, 2013 update*. **www.ibdstandards.org.uk** [Accessed 16 July 2015].
- Mowat C, Cole A, Windsor A *et al*, on behalf of the IBD Section of the British Society of Gastroenterology. Guidelines for the management of inflammatory bowel disease in adults. *Gut* 2011;60:571–607.
- National Institute for Health and Care Excellence, 2008. Technology appraisal 163: *Infliximab for acute exacerbations of ulcerative colitis*. **www.nice.org.uk/guidance/TA163**. [Accessed 16 July 2015].
- National Institute for Health and Care Excellence, 2011. Technology appraisal 187: *Infliximab (review) and adalimumab for the treatment of Crohn's disease*. **www.nice.org.uk/guidance/TA187** [Accessed 16 July 2015].
- National Institute for Health and Care Excellence, 2015. Technology appraisal 329: *Infliximab, adalimumab and golimumab for treating moderately to severely active ulcerative colitis after the failure of conventional therapy (including a review of TA140 and TA262).* **www.nice.org.uk/guidance/TA329** [Accessed 16 July 2015].
- National Institute for Health and Care Excellence, 2015. Quality standard 81: Inflammatory bowel disease. **www.nice.org.uk/guidance/QS81** [Accessed 16 July 2015].
- Royal College of Physicians, 2014. *Experience of inpatients with ulcerative colitis throughout the UK.*
- Royal College of Physicians, 2014. *National clinical audit of inpatient care for adults with ulcerative colitis.*

Availability of audit results in the public domain

Full and executive summary copies of this report are available in the public domain via the Royal College of Physicians (RCP) website (**www.rcplondon.ac.uk/biologics**). The national report of results will be made available to NHS England; the Department of Health, Social Services and Public Safety in Northern Ireland; Healthcare Improvement Scotland; and the Department for Health and Social Services in Wales. A number of key indicators for each of the participating sites are published in the public domain in **section 7, pp 54–79** of this report; these findings are also available via **www.data.gov.uk**, in line with the government's transparency agenda.

Presentation of results

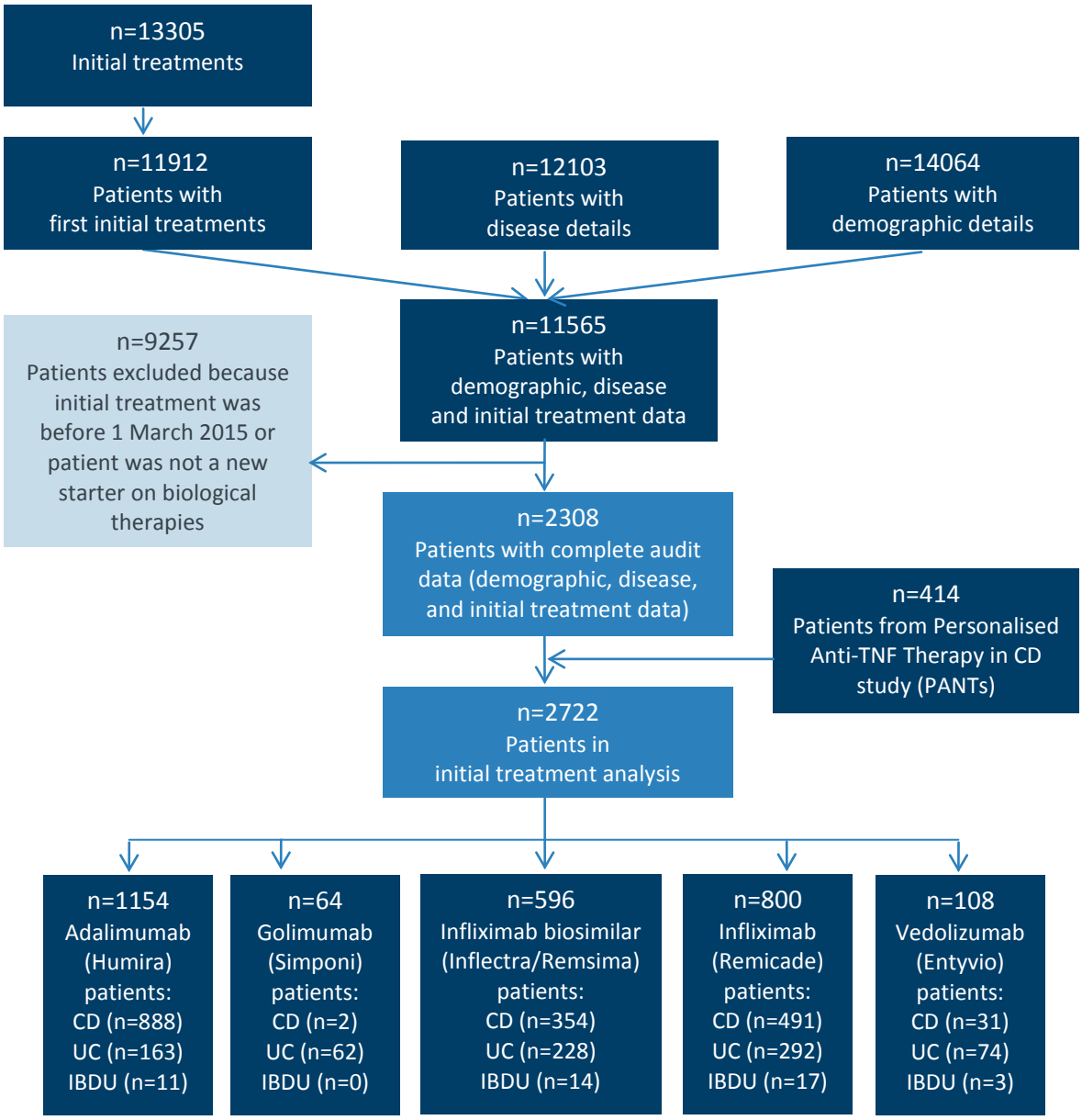
National results are presented as percentages for categorical data and as medians and interquartile ranges (IQRs) for numerical data. This report summarises data provided by sites that registered to participate in the audit and indicated that they provide their IBD service to adult patients or paediatric patients. Full national data results for both adult and paediatric patients can be found in online appendices 5 and 6 at **www.rcplondon.ac.uk/biologics**.

2: Key results – adult services

Consort diagram for initial treatment – adult patients

Between 1 March 2015 and 29 February 2016, 2722 individual adult patient demographic submissions had been entered on the web tool.

Fig 1 Consort diagram for initial treatment – adult patients



CD = Crohn's disease; IBDU = inflammatory bowel disease unclassified; UC = ulcerative colitis.

Fig 1 is integral to understanding the patient numbers and the reasons that patients were excluded from analysis when considering the results in this report. Readers are reminded that individual results are often a subset of this number and that the context and actual number of cases should be considered when interpreting findings. A consort diagram detailing patient numbers and reasons for exclusion from follow-up treatment data can be found in **Appendix 3, p 83**.

Understanding these results

The tables in this section use key data items to address the objectives of the biological therapies audit and provide an overall view of the main characteristics of the included patients. It is important to note that this report is patient focused rather than treatment based. All analysis in this section relates to data entered to the audit between 1 March 2015 and 29 February 2016, apart from Table 5 which includes over time analysis.

The results in this section should not be directly compared with any previous biological therapy audit report. This is due to sites being able to lock and unlock any case entered to the audit since its inception and amend data retrospectively.

The consort diagram in **Fig 1 (p 9)** shows that only those patients with at least one initial treatment were included in the analyses. Thereafter, the numbers reduce based on whether patients were recorded as having been followed up at 3 and 12 months after initial treatment. For the follow-up time point, a 1-month window either side was used in order to best capture patients – eg for 3-month follow-up, data entered 60–120 days after initial treatment were included.

Table 1 Adult patient summary

This table provides a summary of adult patients and their treatments included in the national analysis.

	Patient group, % (n)			
Treatment and biologic type	**CD**	**UC**	**IBDU**	**All IBD**
Initial treatment	**(n=1766)**	**(n=903)**	**(n=53)**	**(n=2722)**
Golimumab (Simponi)	0.1% (2)	7% (62)	-	2% (64)
Adalimumab (Humira)	50% (888)	27% (247)	36% (19)	42% (1154)
Infliximab biosimilar (Inflectra/Remsima)	20% (354)	25% (228)	26% (14)	22% (596)
Infliximab (Remicade)	28% (491)	32% (292)	32% (17)	29% (800)
Vedolizumab (Entyvio)	2% (31)	8% (74)	6% (3)	4% (108)
3-month follow-up	**(n=591)**	**(n=247)**	**(n=17)**	**(n=855)**
Golimumab (Simponi)	0.2% (1)	9% (22)	-	3% (23)
Adalimumab (Humira)	46% (273)	26% (64)	35% (6)	40% (343)
Infliximab biosimilar (Inflectra/Remsima)	17% (99)	19% (48)	35% (6)	18% (153)
Infliximab (Remicade)	35% (208)	37% (92)	29% (5)	36% (305)
Vedolizumab (Entyvio)	2% (10)	9% (21)	-	4% (31)
12-month follow-up	**(n=5)**	**(n=1)**	**(n=0)**	**(n=6)**
Golimumab (Simponi)	-	-	-	-
Adalimumab (Humira)	60% (3)	-	-	50% (3)
Infliximab biosimilar (Inflectra/Remsima)	-	-	-	-
Infliximab (Remicade)	40% (2)	100% (1)	-	50% (3)
Vedolizumab (Entyvio)	-	-	-	-

CD = Crohn's disease; IBD = inflammatory bowel disease; IBDU = inflammatory bowel disease unclassified; UC = ulcerative colitis.

Table 2 Key demographic items data – adult patients

Table 2 compares demographic data and disease distribution for audited adult patients treated with biologics. Denominators differ when questions were not answered.

General patient characteristics	CD	UC	IBDU
Total number of patients	**1766**	**903**	**53**
Gender: male, % (n/N)	46% (812/1759)	59% (529/903)	49% (26/53)
Age at diagnosis in years, median (IQR)	n=1715 27 (20, 40)	n=900 32 (24, 45)	n=53 32 (24, 45)
Age at initial treatment in years, median (IQR)	n=1766 36 (26, 49)	n=900 39 (28, 52)	n=53 34 (27, 51)
Time from diagnosis to treatment in years, median (IQR)	n=1715 4 (1, 11.3)	n=903 3.4 (1.3, 7.7)	n=53 2.2 (1.1, 6.8)
Disease distribution, % (n/N)			
Terminal ileum (L1)	31% (540/1761)	-	-
Colonic (L2)	25% (444/1761)	-	-
Ileocolonic (L3)	38% (677/1761)	-	-
None of these	6% (100/1761)	-	-
Any part of the gut proximal to the terminal ileum (L4)	30% (404/1366)	-	-
Perianal involvement	19% (342/1766)	-	-
Proctitis (E1)	-	11% (103/903)	2% (1/53)
Left sided (E2)	-	46% (412/903)	34% (18/53)
Extensive (E3)	-	43% (388/903)	64% (34/53)

CD = Crohn's disease; IBDU = inflammatory bowel disease unclassified; IQR = interquartile range; UC = ulcerative colitis.

Table 3 Pre-treatment screening – adult patients

The table below shows the percentage of adult patients that had adequate pre-treatment screening between 1 March 2015 and 29 February 2016. This analysis excludes data collected in PANTs.[5]

Patients with adequate screening prior to treatment*	CD	UC	IBDU	Total
Total number of patients	**1352**	**903**	**53**	**2308**
Screening completed, % (n)	60% (814)	61% (546)	53% (28)	60% (1388)
Incomplete screening, % (n)	39% (528)	39% (352)	47% (25)	39% (905)
No screening, % (n)	0.6% (10)	0.6% (5)	0% (0)	0.7% (15)

CD = Crohn's disease; IBDU = inflammatory bowel disease unclassified; UC = ulcerative colitis.

*Patients that had chest X-ray, either Gamma interferon or Mantoux screen, hepatitis B, hepatitis C and HIV screen.

Table 4 Pre-treatment screening by type – adult patients

The table below shows the percentage of adult patients that have had pre-treatment screening by type of screening performed. Data collected in PANTs[5] have not been included in this analysis.

	Screening undertaken , % (n/N)		
Screening type	**Yes**	**No**	**Not indicated**
Chest X-ray	**88% (2039/2308)**	**9% (199/2308)**	**3% (70/2308)**
CD	89% (1198/1352)	8% (110/1352)	3% (44/1352)
UC	88% (792/903)	9% (85/903)	3% (26/903)
IBDU	93% (49/53)	8% (4/53)	0% (0/53)
Gamma interferon / Mantoux screen	**82% (1886/2308)**	**10% (233/2308)**	**8% (189/2308)**
CD	82% (1114/1352)	10% (134/1352)	8% (104/1352)
UC	81% (731/903)	10% (93/903)	9% (79/903)
IBDU	77% (41/53)	11% (6/53)	11% (6/53)
Hepatitis B serology	**95% (2196/2308)**	**4% (81/2308)**	**1% (31/2308)**
CD	95% (1286/1352)	3% (45/1352)	2% (21/1352)
UC	95% (859/903)	4% (34/903)	1% (10/903)
IBDU	96% (51/53)	4% (2/53)	0% (0/53)
Hepatitis C serology	**94% (2164/2308)**	**5% (109/2308)**	**2% (34/2308)**
CD	94% (1266/1352)	5% (62/1352)	2% (23/1352)
UC	94% (848/903)	5% (45/903)	1% (10/903)
IBDU	94% (50/53)	4% (2/53)	2% (1/53)
HIV screen	**80% (1846/2308)**	**14% (322/2308)**	**6% (139/2308)**
CD	79% (1061/1352)	15% (199/1352)	7% (91/1352)
UC	82% (744/903)	12% (112/903)	5% (47/903)
IBDU	77% (41/53)	21% (11/53)	2% (1/53)
Varicella screen	**84% (1941/2308)**	**11% (251/2308)**	**5% (115/2308)**
CD	83% (1124/1352)	12% (161/1352)	5% (66/1352)
UC	86% (775/903)	9% (84/903)	5% (44/903)
IBDU	79% (42/53)	11% (6/53)	9% (5/53)
Stool cultures	**50% (1157/2308)**	**34% (793/2308)**	**16% (357/2308)**
CD	43% (580/1352)	39% (522/1352)	18% (249/1352)
UC	60% (544/903)	28% (256/903)	11% (103/903)
IBDU	62% (33/53)	28% (15/53)	9% (5/53)
C. difficile test	**42% (963/2308)**	**39% (890/2308)**	**20% (454/2308)**
CD	35% (477/1352)	42% (569/1352)	23% (306/1352)
UC	50% (455/903)	34% (305/903)	16% (142/903)
IBDU	59% (31/53)	30% (16/53)	11% (6/53)

CD = Crohn's disease; IBDU = inflammatory bowel disease unclassified; UC = ulcerative colitis.

Table 5 Analysis of results over time – adult results

This table compares some key results over time for adults with IBD included in the audit according to reporting timescales.

Result	Audit period				
	12 Sep 2011 – 29 Feb 2012	1 Mar 2012 – 28 Feb 2013	1 Mar 2013 – 28 Feb 2014	1 Mar 2014 – 28 Feb 2015	1 Mar 2015 – 29 Feb 2016
Participation in the biological therapy audit					
Adult sites with data included in analysis (n)	99	114	158	159	161
Adult patients audited initiating biological therapies					
Patients with CD (n)	426	1026	1509	1943	1766
Patients with UC (n)	62	184	281	412	903
Patients with IBDU (n)	22	33	33	41	53
Total (n)	510	1243	1823	2396	2722
Treatment time					
Time from diagnosis to initial treatment in years, median (IQR)	n= 510 4.5 (1.4, 11.5)	n=1243 4.3 (1.0, 10.3)	n=1819 4.2 (1.1, 11.2)	n=2387 3.6 (0.9, 10.5)	n=2671 3.8 (1.1, 9.6)*
Adverse reactions reported at initial treatment for adult patients					
Adverse reactions, % (n/N)	3% (17/510)	3% (32/1243)	2% (44/1823)	2% (54/2396)	4% (117/2722)
Disease activity reported at initial treatment for adult patients					
HBI score, median (IQR)	n=266 6 (0, 10)	n=498 9 (6, 11)	n=782 8 (4, 11)	n=1125 8 (4, 10)	n=927 7 (4, 10)
SCCAI score, median (IQR)	n=121 0 (0, 4)	n=105 9 (6, 11)	n=124 9 (6, 11)	n=178 9 (6, 11)	n=409 7 (5, 10)
Adult patients on concomitant therapies at initial treatment					
Immunosuppressants◆ % (n/N)	53% (271/510)	57% (712/1243)	52% (954/1823)	53% (1263/2396)	52% (1403/2722)
Steroids† % (n/N)	28% (140/510)	29% (365/1243)	31% (562/1823)	31% (745/2396)	36% (969/2722)
Adult patients on concomitant therapies at 3-month follow-up					
Immunosuppressants◆ % (n/N)	45% (83/184)	56% (253/456)	51% (387/753)	49% (501/1032)	45% (385/855)
Steroids† % (n/N)	7% (13/184)	5% (23/456)	16% (122/753)	18% (189/1032)	21% (176/855)
Surgery					
Surgery for IBD, % (n/N)	36% (184/510)	30% (376/1243)	27% (493/1823)	22% (514/2396)	15% (412/2722)
Surgery 6 months before starting biological therapies, % (n/N)	6% (29/510)	6% (74/1243)	5% (92/1823)	4% (85/2396)	3% (68/2722)
Surgery 6 months after starting biological therapies, % (n/N)	6% (32/510)	4% (55/1243)	3% (60/1823)	2% (54/2396)	2% (52/2722)

*p=0.026

◆Immunosuppressants include azathioprine, mercaptopurine and methotrexate. †Steroids include budesonide, hydrocortisone, methylprednisolone and prednisolone. CD = Crohn's disease; HBI = Harvey–Bradshaw index; IBDU = inflammatory bowel disease unclassified; IQR = interquartile range; SCCAI = Simple Clinical Colitis Activity Index; UC = ulcerative colitis.

Table 6 National comparison of key results – adult patients

This table depicts national variation in the results of the biological therapy audit between England, Northern Ireland, Scotland and Wales. It only includes sites that submitted enough data to be included in the national analysis. A full list of participating and non-participating sites can be found in **section 7, pp 53–79** of this report.

Result	Country			
	England	Northern Ireland	Scotland	Wales
Sites participating in the audit (n)	139	4	8	10
Patients audited (n)	2491	38	91	102
Time from diagnosis to initial treatment in years, median (IQR)	n=2442 3.8 (1.1, 9.9)	n=38 5.2 (2.6, 10.2)	n=89 4.1 (1.4, 9.4)	n=102 2.9 (0.8, 7.5)
Patients with an adverse reaction recorded during initial treatment % (n/N)	5% (115/2491)	8% (3/38)	3% (3/91)	6% (6/102)
Disease severity (HBI) at initial treatment, median (IQR)	n=868 7 (4, 10)	n=2	n=22 5 (3, 9)	n=35 8 (7, 13)
Patients with follow-up recorded at 3 months, % (n/N)	32% (796/2491)	24% (9/38)	18% (16/91)	33% (34/102)
Patients on biological therapy who were appropriately prescribed anti-TNFα in compliance with NICE technology appraisal 187[2] criterion 1.1, % (n/N)	46% (399/868)	50% (1/2)	36% (8/22)	63% (22/35)

HBI = Harvey–Bradshaw index; IQR = interquartile range; TNFα = tumour necrosis factor alpha.

Audit objective – safety

Table 7 Adverse reaction by biologic/biosimilar – adult patients

This table shows the percentage of all adult patients for whom an adverse reaction was recorded by type of biologic used as treatment.

Biologic/biosimilar	Adverse reaction recorded = Yes	
	Initial treatment	3-month follow-up
Adalimumab (Humira)	3% (38/1154)	12% (42/343)
Golimumab	9% (6/64)	9% (2/23)
Infliximab biosimilar (Inflectra/Remsima)	5% (27/596)	11% (17/153)
Infliximab (Remicade)	5% (40/800)	7% (21/305)
Vedolizumab	15% (16/108)	0% (0/31)

Table 8 Adverse reaction by type – adult patients

This table shows the percentage of all adult patients for whom an adverse reaction was recorded by type of reaction.

Adverse reactions % (n)	Initial treatment (n=2722)	3-month follow-up (n=855)
Adverse reaction recorded Yes=	5% (127)	10% (82)
Abdominal pain	0% (1)	0.1% (1)
Alopecia	0% (0)	0.1% (1)
Angioedema of upper airway	0% (0)	0.1% (1)
Arthralgia	0.1% (3)	1% (10)
Blood abnormality	0% (1)	0.4% (3)
Bronchospasm (cough/wheeze/dyspnoea)	0% (0)	0.2% (2)
Cardiac failure	0% (0)	0% (0)
Chest pain	0% (1)	0.2% (2)
Chills	0% (0)	0% (0)
Confirmed demyelination	0% (0)	0% (0)
Death	0% (0)	0% (0)
Difficulty breathing	0% (0)	0.2% (2)
Dizziness	0.1% (3)	0.1% (1)
Fatigue	0.1% (2)	0% (0)
Fever	0% (1)	0.1% (1)
Flushing	0.1% (3)	0.2% (2)
Headache	0.2% (5)	1% (9)
Hypotension	0% (1)	0% (0)
Infection	0.2% (5)	1% (9)
Injection site reaction	0% (1)	0.6% (5)
Itching	0.1% (3)	0.2% (2)
Limb weakness	0% (0)	0% (0)
Malignancy	0% (0)	0% (0)
Nausea	0.3% (7)	0.4% (3)
Panic attacks	0% (1)	0.1% (1)
Rash	0.4% (12)	3% (23)
Serum sickness-like reaction	0.1% (3)	0% (0)
Urticaria	0% (0)	0% (0)
Other	0.3% (9)	3% (24)

Audit objective – efficacy

Disease activity for adult patients at the time of initial treatment was compared with that at the follow-up nearest to 3 months from the date of the initial treatment. Follow-up data include only those patients who had an initial treatment.

Table 9 Disease activity CD – adult patients

When severity of CD in adult patients is classified by the Harvey–Bradshaw index (HBI), a score <5 is considered to be clinical remission and >16 is considered to be severe disease.

Biologic/biosimilar	HBI score – Median (IQR)	
	Initial treatment	3-month follow-up
Adalimumab (Humira), median (IQR)	n=442 8 (4, 10)	n=174 3 (1, 6)
Infliximab (Remicade), median (IQR)	n=269 6 (4, 10)	n=137 2 (1, 5)
Golimumab, median (IQR)	n=2	n=0
Infliximab biosimilar (Inflectra/Remsima), median (IQR)	n=199 7 (5, 10)	n=73 3 (1, 5)
Vedolizumab, median (IQR)	n=15 9 (6, 12)	n=3 3 (2, 5)
Total, median (IQR)	n=927 7 (4, 10)	n=387 3 (1, 5)

HBI = Harvey–Bradshaw index; IQR = interquartile range.

Table 10 Response to therapy and remission by biologic/biosimilar – adult patients

This table shows response* to therapy and remission† at 3-month follow-up in adult patients by biologic/biosimilar type.

Biologic/biosimilar	Response	Remission
Adalimumab (Humira)	76% (127/168)	61% (106/174)
Infliximab biosimilar (Inflectra/Remsima)	84% (59/70)	69% (50/73)
Infliximab (Remicade)	85% (114/134)	74% (103/139)
Vedolizumab (Entyvio)	67% (2/3)	67% (2/3)

*Response is defined as decrease of >3 in Harvey–Bradshaw index for adult patients
†Remission is defined as Harvey–Bradshaw index (HBI) score <4 for adult patients

Table 11 Response to therapy – adult patients

This table shows response* to therapy at 3-month follow-up in adult patients with CD who were treated with a biologic or biosimilar. The Harvey–Bradshaw index (HBI) is used to quantify disease activity for adult patients with CD. The denominators change when dates of diagnosis for patients are missing.

	Time from diagnosis to initial treatment in years					
Response to therapy	<1	1–2	3–5	6–10	>10	Total
CD National data % (n/N)	84% (76/91)	80% (53/66)	85% (50/59)	78% (45/58)	77% (63/82)	81% (287/356)

*Response is defined as decrease of >3 in Harvey–Bradshaw index for adult patients
CD = Crohn's disease.

Table 12 Remission achieved – adult patients

This table shows whether remission* was achieved at 3-month follow-up in adult patients with CD who were treated with a biologic or biosimilar. As before, the HBI was used to quantify disease activity in adults with CD. The denominators change when dates of diagnosis for patients are missing.

	Time from diagnosis to initial treatment in years					
Remission achieved	**<1**	**1–2**	**3–5**	**6–10**	**>10**	**Total**
CD National data % (n/N)	64% (61/95)	68% (46/68)	75% (45/60)	61% (37/61)	69% (59/86)	67% (248/370)

*Remission is defined as Harvey–Bradshaw index (HBI) score <4 for adult patients
CD = Crohn's disease.

Table 13 Disease activity UC – adult patients

When severity of UC in adult patients is classified by SCCAI, a score of <3 is considered to be remission and >13 is considered to be severe disease.

	SCCAI score – Median (IQR)	
Biologic/biosimilar	**Initial treatment**	**3-month follow-up**
Adalimumab (Humira), median (IQR)	n=103 6 (4, 8)	n=15 4 (2, 7)
Infliximab (Remicade), median (IQR)	n=106 9 (6, 11)	n=31 2 (1, 7)
Golimumab, median (IQR)	n=35 7 (5, 9)	n=5 7 (7, 10)
Infliximab biosimilar (Inflectra/Remsima), median (IQR)	n=115 8 (6, 10)	n=22 4 (2, 6)
Vedolizumab, median (IQR)	n=36 6 (5, 8)	n=9 5 (2, 6)
Total, median (IQR)	n=395 7 (5, 10)	n=82 4 (1, 7)

IQR = interquartile range; SCCAI = Simple Clinical Colitis Activity Index.

Table 14 Infliximab (Remicade) vs infliximab biosimilar (Inflectra/Remsima) – adult patients

This table compares data entered to the audit on adult patients being treated with either infliximab (Remicade) or its biosimilar (Inflectra/Remsima) between 1 March 2015 and 29 February 2016.

	Infliximab (Remicade)	Infliximab biosimilar (Inflectra/Remsima)
General patient characteristics		
Gender: male, **%** (n/N)	53% (421/799)	51% (300/593)
Age at diagnosis, years, median (IQR)	n=790 28 (20, 42)	n=579 30 (22, 43)
Age at initial treatment, years, median (IQR)	n=800 35 (26, 50)	n=595 37 (27, 52)
Time from diagnosis to treatment, years, median (IQR)	n=790 3.3 (0.9, 8.5)	n=580 3 (0.8, 9)
Disease severity, median (IQR)		
HBI at initial treatment	n=269 6 (4, 10)	n=199 7 (5, 10)
HBI at 3-month follow-up	n=137 2 (1, 5)	n=73 3 (1, 5)
Response and remission at 3-month follow-up, % (n/N)		
Response to treatment (Response is defined as decrease of >3 in HBI for adult patients)	85% (114/134)	84% (59/70)
Remission achieved (Remission is defined as HBI score <4 for adult patients)	74% (103/139)	69% (50/73)
Adverse reactions, % (n/N)		
At initial treatment	5% (40/800)	5% (27/596)
At 3-month follow-up	7% (21/305)	11% (17/153)
Concomitant therapy, % (n/N)		
Concomitant therapy for IBD at initial treatment	81% (651/800)	80% (474/596)
Immunosuppressants (Includes azathioprine, mercaptopurine and methotrexate)	54% (430/800)	49% (291/596)
Steroids (Includes budesonide, hydrocortisone, methylprednisolone and prednisolone)	38% (304/800)	43% (255/596)

HBI = Harvey–Bradshaw index; IBD = inflammatory bowel disease; IQR = interquartile range.

Audit objective – appropriateness of prescribing anti-TNFα

Detailed information about the NICE guidance and recommendations for use of biological therapies in patients with IBD in the UK can be found in **section 5, pp 47–48** of this report. In Tables 15 and 16, NICE criterion 1.1 from technology appraisal 187[2] and criterion 1.1 from technology appraisal 329[3] have been used to assess the appropriateness of prescribing biological therapy.

Table 15 Compliance with NICE technology appraisal 187 criterion 1.1

This table shows compliance with criterion 1.1 of NICE technology appraisal 187[2] in adult patients with CD. Patients with no recorded HBI were excluded from this analysis.

NICE technology appraisal 187	National CD data % (n/N)
Criterion 1.1 Infliximab and adalimumab are recommended as treatment options for adults with severe active CD if (a) the disease has not responded to conventional therapy or (b) the person is intolerant of or has contraindications to conventional therapy (mercaptopurine, azathioprine, methotrexate, prednisolone, budesonide, methylprednisolone or hydrocortisone)	
CD patients with HBI score ≥8 before starting anti-TNFα treatment, % (n/N)	48% (448/927)
CD patients with HBI scores who were treated with conventional therapy at time of or prior to starting anti-TNFα treatment, % (n/N)	93% (865/927)
CD patients who were appropriately prescribed anti-TNFα treatment in compliance with criterion 1.1 of NICE technology appraisal 187, % (n/N)	46% (430/927)

CD = Crohn's disease; HBI = Harvey–Bradshaw index; NICE = National Institute for Health and Care Excellence; TNFα = tumour necrosis factor alpha.

Table 16 Compliance with NICE technology appraisal 329 criterion 1.1

This table shows compliance with criterion 1.1 of NICE technology appraisal 329[3] in adult patients with UC. Patients with no recorded SCCAI were excluded from this analysis.

NICE technology appraisal 329	National UC data % (n/N)
Criterion 1.1 Infliximab, adalimumab and golimumab are recommended as treatment options for adults with moderate to severe active UC (a) whose disease has responded inadequately to conventional therapy or (b) who are intolerant of or have contraindications to conventional therapy (mercaptopurine, azathioprine, methotrexate, prednisolone, budesonide, methylprednisolone or hydrocortisone)	
UC patients with SCCAI score ≥5 before starting anti-TNFα treatment, % (n/N)	80% (314/395)
UC patients with SCCAI scores who were treated with conventional therapy at time of or prior to starting anti-TNFα treatment, % (n/N)	92% (364/395)
UC patients who were appropriately prescribed anti-TNFα therapy in compliance with criterion 1.1 of NICE technology appraisal 329, % (n/N)	74% (293/395)

SCCAI = Simple Clinical Colitis Activity Index; NICE = National Institute for Health and Care Excellence; TNFα = tumour necrosis factor alpha; UC = ulcerative colitis.

Table 17 Concomitant therapy for IBD – adult patients

This table shows the percentage of all adult patients on any immunosuppressants or steroids as concomitant therapy during their treatment with biological therapies.

Type of concomitant therapy	Initial treatment, % (n)	3-month follow-up, % (n)
CD patients	**1766**	**591**
Concomitant therapy for IBD = Yes	74% (1301)	65% (383)
Immunosuppressants*	53% (931)	48% (284)
Steroids†	29% (506)	21% (123)
UC patients	**903**	**247**
Concomitant therapy for IBD = Yes	87% (783)	70% (172)
Immunosuppressants*	49% (443)	38% (94)
Steroids†	48% (431)	21% (51)
IBDU patients	**53**	**17**
Concomitant therapy for IBD = Yes	83% (44)	65% (11)
Immunosuppressants*	55% (29)	41% (7)
Steroids†	60% (32)	12% (2)

*Immunosuppressants include azathioprine, mercaptopurine and methotrexate.
†Steroids include budesonide, hydrocortisone, methylprednisolone and prednisolone.
CD = Crohn's disease; IBD = inflammatory bowel disease; IBDU = inflammatory bowel disease unclassified; UC = ulcerative colitis.

Audit objective – patient-reported outcome measures

Outcome measures have traditionally relied on disease activity indexes, but these measures fail to assess the patient's subjective view of their experience. Patient-reported outcome measures therefore evaluate quality from the patient's perspective. Typically, they are short, self-completed questionnaires that measure the patient's health status or health-related quality of life at a single point in time. The health status information is collected from patients by way of PROMs questionnaires completed before, during and after an intervention (in this case, initiation of biological therapy) and provides an indication of the outcomes or quality of care delivered to patients.

EQ-5D

The EQ-5D[8] is a standardised instrument for use as a measure of health outcome. It provides a simple descriptive profile and a single index value for health status. It was primarily designed for self-completion by respondents and is ideally suited for use in clinics.

The EQ-5D is a descriptive system of health-related quality of life states consisting of five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression), each of which can take one of three responses depending on level of severity – no problems / some or moderate problems / extreme problems – within a particular EQ-5D dimension. Total EQ-5D scores range from 0 (worst health / death) to 1 (best health), with an increase in score denoting improved health. Scores from each domain are weighted and converted into a single weighted summary index. The data within this report are presented in the form of a median (IQR). The EQ-5D has been shown to be valid, reliable and responsive in patients with IBD.[9]

In total, 17% (471/2722) of patients completed an EQ-5D questionnaire at an initial treatment with a median (IQR) score of 0.76 (0.64, 0.8). At 3-month follow up 28% (242/855) of patients completed an EQ-5D questionnaire with a median (IQR) score of 0.8 (0.73, 1). The limited number of EQ-5D questionnaires completed at initial and follow-up treatment meant that a difference between these scores could not be calculated. However, the median scores at these two stages were calculated. A comparison of these scores showed an increase in the median EQ-5D score of 0.04 between initial and 3-month follow-up. This may suggest clinical improvement in quality of life after patients have begun biological therapies.

CUCQ-12

The Crohn's and ulcerative colitis questionnaire (CUCQ)-12[10] is a relatively new and shortened version of the 32-item Crohn's and Colitis questionnaire (CCQ-32) – a quality of life measurement tool developed specifically for use with patients with IBD to measure active disease and long-term monitoring of the condition.

The items in the CUCQ-12 questionnaire address the following 12 dimensions: sleeping, appetite, energy level, rushing to the toilet, being bloated, incomplete emptying of bowels, blood in stool, generally unwell, faecal incontinence, nocturnal diarrhoea, passing wind and effect on leisure activity. Each question is scored between 0 (best health) and 14 (poor health), corresponding to the number of days affected by a parameter in a fortnight, giving a total CUCQ-12 score ranging from 0 (best health) to 168 (poor health). Remission in patients with UC and CD is suggested by CUCQ-12 scores of <45 and <50, respectively. The minimum significant change in CUCQ-12 is 13 for both UC and CD. Early results have shown that the CUCQ-12 performs well in patients with IBD, with positive correlations compared with the EQ-5D and 12-item short-form (SF-12).

In total, 18% (483/2722) of patients completed a CUCQ-12 questionnaire at initial treatment. The median (IQR) score of 70 (38, 98) suggests active disease at this time point. At 3-month follow-up 29% (248/855) of patients completed a CUCQ-12 questionnaire with a median (IQR) score of 35 (15, 55). The limited number of CUCQ-12 questionnaires completed at initial and follow-up treatment meant that a difference between these scores could not be calculated. However, the median scores at these two stages were calculated. A comparison of these scores showed an increase in the median CUCQ-12 score of 35 between initial and follow-up treatment, which may suggest clinical improvement in quality of life following biological therapy.

Table 18 PROMs questionnaire for adult patients (IBD-PROM)

This table gives completion rates and results of the IBD-PROM questionnaires used in the biological therapies audit – the EQ-5D[8] and CUCQ-12[10] – for all adult patients calculated. Total EQ-5D scores range from 0 (worst health / death) to 1 (best health), with an increase in score denoting improved health. Total CUCQ-12 scores range from 0 (best health) to 168 (poor health), with each question scored between 0 (best) and 14 (poor).

IBD-PROM	Initial treatment	3-month follow-up
Patients with EQ-5D data completed, % (n/N)	17% (471/2722)	28% (242/855)
EQ-5D score, median (IQR)	**n=471** **0.76 (0.64, 0.8)**	**n=242** **0.8 (0.73, 1)**
Patients with CUCQ-12 data completed, % (n/N)	18% (483/2722)	29% (248/855)
CUCQ-12 score, median (IQR)	**n=483** **70 (38, 98)**	**n=248** **35 (15, 55)**

CUCQ = Crohn's and ulcerative colitis questionnaire; IBD = inflammatory bowel disease; IQR = interquartile range; PROMs = patient-reported outcome measures.

IBD-related surgery in adult patients

Table 19 IBD-related surgery in adult patients with CD

This table displays the surgical procedures in adult patients with CD by type of procedure and whether the surgery took place within the 6 months before or after starting biological therapies.

CD-related surgery	Adult patients with surgery recorded* (n=1827)	
	Surgery 6 months before starting biological therapies (n=333)	Surgery 6 months after starting biological therapies (n=176)
Surgical procedure by type (%, n)		
Anterior resection	0.3% (1)	-
Appendicectomy	0.3% (1)	-
Cholecystectomy	0.3% (1)	0.6% (1)
Colectomy and ileostomy	2% (8)	9% (15)
Drainage of abscess	0.9% (3)	3% (5)
Gastric surgery	-	0.6% (1)
Other surgical procedure	16% (54)	17% (30)
Partial colectomy	0.6% (2)	3% (5)
Perianal surgery	53% (177)	23% (40)
Right hemicolectomy / ileocaecal resection	7% (23)	14% (24)
Small bowel resection	7% (23)	23% (41)
Stoma formation	2% (8)	4% (7)
Stoma reversal	0.3% (1)	-
Stricturoplasty	2% (6)	3% (6)
Total proctocolectomy permanent ileostomy	0.3% (1)	3% (5)
Unknown procedure	14% (46)	2% (4)

*Patients may have one or more surgeries recorded.
CD = Crohn's disease.

Table 20 IBD-related surgery in adult patients with UC

This table displays the surgical procedures in adult patients with UC by type of procedure and whether the surgery took place within the 6 months before or after starting biological therapies.

UC-related surgery	Adult patients with surgery recorded* (n=133)	
	Surgery 6 months before starting biological therapies (n=12)	Surgery 6 months after starting biological therapies (n=68)
Surgical procedure by type (%, n)		
Appendicectomy	8% (1)	-
Colectomy and ileostomy	25% (3)	75% (51)
Other surgical procedure	42% (5)	4% (3)
Partial colectomy	-	9% (6)
Perianal surgery	17% (2)	3% (2)
Small bowel resection	8% (1)	-
Total proctocolectomy ileoanal pouch	-	2% (1)
Total proctocolectomy permanent ileostomy	-	7% (5)

*Patients may have one or more surgeries recorded.
UC = ulcerative colitis.

Table 21 IBD-related surgery in adult patients with IBDU

This table displays the surgical procedures in adult patients with IBDU by type of procedure and whether the surgery took place within the 6 months before or after starting biological therapies.

IBDU-related surgery	Adult patients with surgery recorded* (n=19)	
	Surgery 6 months before starting biological therapies (n=3)	Surgery 6 months after starting biological therapies (n=9)
Surgical procedure by type (%, n)		
Colectomy and ileostomy	-	78% (7)
Perianal surgery	100% (3)	22% (2)

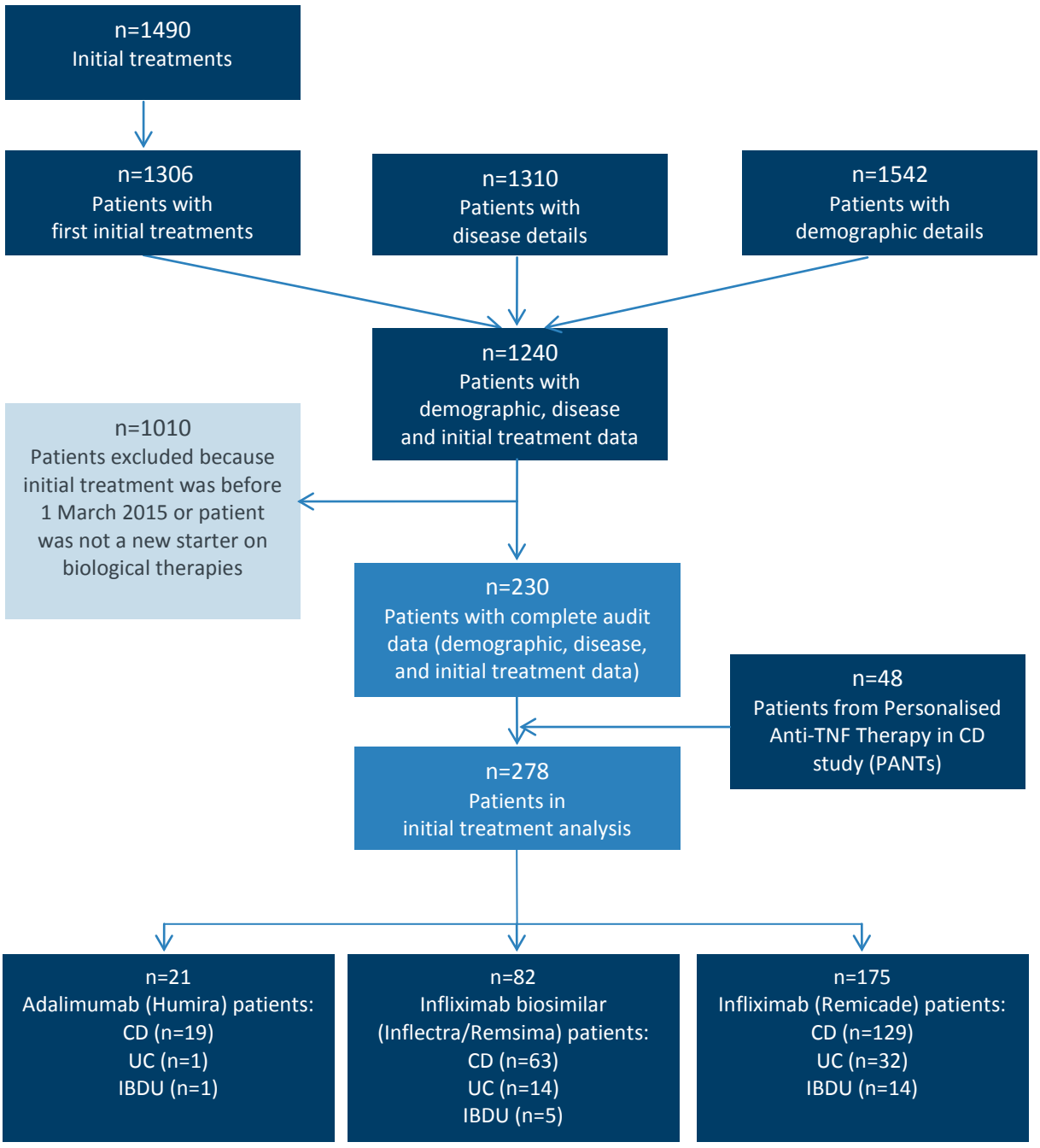
*Patients may have one or more surgeries recorded.
IBDU = inflammatory bowel disease unclassified.

3: Key results – paediatric services

Consort diagram for initial treatment – paediatric patients

Between 1 March 2015 and 29 February 2016, 278 individual paediatric patient demographic submissions had been entered on the web tool.

Fig 2 Consort diagram for initial treatment – paediatric patients



CD = Crohn's disease; IBDU = inflammatory bowel disease unclassified; UC = ulcerative colitis.

Fig 2 is integral to understanding the patient numbers and the reasons that patients were excluded from analysis when considering the results in this report. Readers are reminded that individual results are often a subset of this number and that the context and actual number of cases should be considered when interpreting findings. A consort diagram detailing patient numbers and reasons for exclusion from follow-up treatment data can be found in **Appendix 3, p 83**.

The results in this section should not be directly compared with any previous biological therapy audit report. This is due to sites being able to lock and unlock any case entered to the audit since its inception and amend data retrospectively.

Only patients with at least one initial treatment were included in the analyses. Thereafter, the numbers reduce based on whether patients were recorded as having been followed up at 3 and 12 months after initial treatment. For the follow-up time point, a 1-month window either side was used in order to best capture patients – eg for 3-month follow-up, data entered 60–120 days after initial treatment were included.

Table 22 Paediatric patient summary (2016 audit data)

This table provides a summary of the paediatric patients and their treatments included in the national analysis between 1 March 2015 and 29 February 2016.

2016 audit data	Patient group			
Treatment and biologics type	**CD**	**UC**	**IBDU**	**All IBD**
Initial treatment	**(n=211)**	**(n=47)**	**(n=20)**	**(n=278)**
Adalimumab (Humira)	9% (19)	2% (1)	5% (1)	8% (21)
Infliximab biosimilar (Inflectra/Remsima)	30% (63)	30% (14)	25% (5)	29% (82)
Infliximab (Remicade)	61% (129)	68% (32)	70% (14)	63% (175)
3-month follow-up	**(n=93)**	**(n=19)**	**(n=9)**	**(n=121)**
Adalimumab (Humira)	5% (5)	-	11% (1)	5% (6)
Infliximab biosimilar (Inflectra/Remsima)	37% (34)	21% (4)	11% (1)	32% (39)
Infliximab (Remicade)	58% (54)	79% (15)	78% (7)	63% (76)
12-month follow-up	**(n=1)**	**(n=0)**	**(n=0)**	**(n=1)**
Adalimumab (Humira)	-	-	-	-
Infliximab biosimilar (Inflectra/Remsima)	-	-	-	-
Infliximab (Remicade)	100% (1)	-	-	100% (1)

CD = Crohn's disease; IBD = inflammatory bowel disease; IBDU = inflammatory bowel disease unclassified; UC = ulcerative colitis.

Table 23 Paediatric patient summary (2011–2016 audit data)

This table provides a summary of the paediatric patients and their treatments included in the national analysis between 12 September 2011 and 29 February 2016.

2011–2016 audit data	Patient group			
Treatment and biologics type	**CD**	**UC**	**IBDU**	**All IBD**
Initial treatment	**(n=842)**	**(n=149)**	**(n=59)**	**(1050)**
Adalimumab (Humira)	6% (51)	4% (6)	3% (2)	6% (59)
Infliximab biosimilar (Inflectra/Remsima)	8% (63)	9% (14)	9% (5)	8% (82)
Infliximab (Remicade)	87% (728)	87% (129)	88% (52)	87% (909)
3-month follow-up	**(n=452)**	**(n=53)**	**(n=30)**	**(535)**
Adalimumab (Humira)	9% (40)	2% (1)	7% (2)	8% (43)
Infliximab biosimilar (Inflectra/Remsima)	8% (34)	8% (4)	3% (1)	7% (39)
Infliximab (Remicade)	84% (378)	91% (48)	90% (27)	85% (453)
12-month follow-up	**(n=228)**	**(n=13)**	**(n=4)**	**(245)**
Adalimumab (Humira)	7% (16)	-	-	7% (16)
Infliximab biosimilar (Inflectra/Remsima)	-	-	-	-
Infliximab (Remicade)	93% (212)	100% (13)	100% (4)	94% (229)

Table 24 Key demographic items data – paediatric patients

Table 24 compares demographic data and disease distribution for audited paediatric patients treated with biologics between 12 September 2011 and 29 February 2016. Denominators differ when questions were not answered.

General patient characteristics	CD	UC	IBDU	All IBD
Total number of patients	**842**	**149**	**59**	**1050**
Gender: male, % (n/N)	64% (541/841)	51% (76/149)	64% (38/59)	62% (655/1049)
Age at diagnosis in years, median (IQR)	n=837 12 (10, 14)	n=149 12 (9, 14)	n=59 12 (10, 14)	n=1045 12 (10, 14)
Age at initial treatment in years, median (IQR)	n=841 14 (12, 15)	n=149 14 (12, 15)	n=59 14 (12, 16)	n=1049 14 (12, 15)
Time from diagnosis to treatment in years, median (IQR)	n=838 1.1 (0.5, 2.4)	n=149 1.1 (0.3, 2.2)	n=59 0.9 (0.4, 2.4)	n=1046 1.1 (0.5, 2.4)
Disease distribution, % (n)				
Terminal ileum (L1)	12% (103)	-	-	10% (103)
Colonic (L2)	28% (234)	-	-	22% (234)
Ileocolonic (L3)	51% (433)	-	-	41% (433)
None of these	9% (72)	-	-	7% (72)
Any part of the gut proximal to the terminal ileum (L4)	58% (487)	-	-	46% (487)
Perianal involvement	34% (285)	-	-	27% (285)
Proctitis (E1)	-	9% (14)	0% (0)	1% (14)
Left sided (E2)	-	20% (30)	15% (9)	4% (39)
Extensive (E3)	-	71% (105)	85% (50)	15% (155)

CD = Crohn's disease; IBD = inflammatory bowel disease; IBDU = inflammatory bowel disease unclassified; UC = ulcerative colitis.

Table 25 Pre-treatment screening – paediatric patients

Table 25 shows the percentage of paediatric patients that had adequate pre-treatment screening between 1 March 2015 and 29 February 2016. PANTs data was not included in this analysis.

Patients with adequate screening prior to treatment*	CD	UC	IBDU	All IBD
Total number of patients	**163**	**47**	**20**	**230**
Screening completed, % (n)	45% (73)	60% (28)	40% (8)	47% (109)
Incomplete screening, % (n)	55% (89)	40% (19)	60% (12)	52% (120)
No screening, % (n)	0.6% (1)	0% (0)	0% (0)	0.4% (1)

*Patients that had chest X-ray, screening for hepatitis B and either Mantoux or Gamma interferon.
CD = Crohn's disease; IBD = inflammatory bowel disease; IBDU = inflammatory bowel disease unclassified; UC = ulcerative colitis.

Table 26 Pre-treatment screening by type – paediatric patients

The table below shows the percentage of paediatric patients that have had pre-treatment screening by type of screening performed between 1 March 2015 and 29 February 2016. Data collected in PANTs have not been included in this analysis.

	Screening undertaken, % (n/N)		
Screening type	**Yes**	**No**	**Not indicated**
Chest X-ray	**92% (211/230)**	**7% (16/230)**	**1% (3/230)**
CD	89% (145/163)	9% (15/163)	2% (3/163)
UC	100% (47/47)	0% (0/47)	0% (0/47)
IBDU	95% (19/20)	5% (1/20)	0% (0/20)
Gamma interferon / Mantoux screen	**81% (187/230)**	**18% (42/230)**	**0.4% (1/230)**
CD	84% (137/163)	16% (26/163)	0% (0/163)
UC	77% (36/47)	21% (10/47)	2% (1/47)
IBDU	70% (14/20)	30% (6/20)	0% (0/20)
Hepatitis B serology	**61% (140/230)**	**34% (79/230)**	**5% (11/230)**
CD	58% (94/163)	37% (60/163)	6% (9/163)
UC	75% (35/47)	21% (10/47)	4% (2/47)
IBDU	55% (11/20)	45% (9/20)	0% (0/20)
Hepatitis C serology	**47% (107/230)**	**47% (109/230)**	**6% (14/230)**
CD	44% (72/163)	50% (81/163)	6% (10/163)
UC	62% (29/47)	32% (15/47)	6% (3/47)
IBDU	30% (6/20)	65% (13/20)	5% (1/20)
HIV screen	**11% (25/230)**	**67% (153/230)**	**23% (52/230)**
CD	9% (15/163)	66% (107/163)	25% (41/163)
UC	17% (8/47)	64% (30/47)	19% (9/47)
IBDU	10% (2/20)	80% (16/20)	10% (2/20)
Varicella screen	**85% (196/230)**	**10% (23/230)**	**5% (11/230)**
CD	85% (139/163)	10% (17/163)	4% (7/163)
UC	85% (40/47)	9% (4/47)	6% (3/47)
IBDU	85% (17/20)	10% (2/20)	5% (1/20)
Stool cultures	**54% (124/230)**	**34% (78/230)**	**12% (28/230)**
CD	47% (77/163)	39% (63/163)	14% (23/163)
UC	77% (36/47)	19% (9/47)	4% (2/47)
IBDU	55% (11/20)	30% (6/20)	15% (3/20)
C. difficile test	**42% (96/230)**	**44% (102/230)**	**14% (32/230)**
CD	35% (57/163)	50% (81/163)	15% (25/163)
UC	62% (29/47)	26% (12/47)	13% (6/47)
IBDU	50% (10/20)	45% (9/20)	5% (1/20)

CD = Crohn's disease; IBDU = inflammatory bowel disease unclassified; UC = ulcerative colitis.

Table 27 Analysis of paediatric patient results over time

This table displays results over time, according to reporting timescales, for paediatric patients with IBD.

Result	Audit period				
	12 Sep 2011 – 29 Feb 2012	1 Mar 2012 – 28 Feb 2013	1 Mar 2013 – 28 Feb 2014	1 Mar 2014 – 28 Feb 2015	1 Mar 2015 – 29 Feb 2016
Participation in the biological therapy audit					
Paediatric sites with data included in analysis (n)	20	24	29	31	27
Paediatric patients audited initiating biological therapies					
Patients with CD (n)	75	159	171	226	211
Patients with UC (n)	8	32	30	32	47
Patients with IBDU (n)	2	7	11	19	20
Total (n)	85	198	212	277	278
Treatment time					
Time from diagnosis to initial treatment in years, median (IQR)	n=85 1.2 (0.5, 2.9)	n=198 1.3 (0.6, 2.4)	n=212 1.1 (0.5, 2.3)	n=277 1 (0.4, 2.2)	n=274 0.9 (0.4, 2.4)
Adverse reactions reported at initial treatment for paediatric patients					
Adverse reactions % (n/N)	2% (2/85)	1% (2/198)	0.5% (1/212)	3% (7/277)	1% (4/278)
Disease activity reported at initial treatment for paediatric patients					
PCDAI score, median (IQR)	n=52 20 (5, 33)	n=100 30 (20, 40)	n=94 30 (15, 40)	n=109 25 (15, 35)	n=71 33 (20, 43)
wPCDAI score, median (IQR)	n=1	n=2	n=3	n=9 55 (48, 60)	n=23 50 (35, 65)
PUCAI score, median (IQR)	n=22 0 (0, 35)	n=31 55 (40, 65)	n=23 65 (43, 78)	n=24 34 (20, 65)	n=35 50 (30, 65)
Paediatric patients on concomitant therapies at initial treatment					
Immunosuppressants* % (n/N)	84% (71/85)	79% (156/198)	82% (173/212)	85% (234/277)	84% (234/278)
Steroids† % (n/N)	27% (23/85)	37% (74/198)	28% (59/212)	28% (78/277)	28% (78/278)
Paediatric patients on concomitant therapies at 3-month follow-up treatment					
Immunosuppressants* % (n/N)	86% (43/50)	77% (75/97)	83% (87/105)	90% (146/162)	80% (97/121)
Steroids† % (n/N)	0% (0/50)	7% (7/97)	14% (15/105)	18% (29/162)	17% (21/121)
Surgery					
Surgery for IBD, % (n/N)	25% (21/85)	25% (49/198)	14% (29/212)	12% (34/277)	8% (23/278)
Surgery 6 months before starting biological therapies, % (n/N)	8% (7/85)	8% (15/198)	5% (10/212)	4% (11/277)	4% (11/278)
Surgery 6 months after starting biological therapies, % (n/N)	5% (4/85)	5% (10/198)	6% (12/212)	5% (13/277)	2% (5/278)

CD = Crohn's disease; HBI = Harvey–Bradshaw index; IBDU = inflammatory bowel disease unclassified; IQR = interquartile range; SCCAI = Simple Clinical Colitis Activity Index; UC = ulcerative colitis. *Immunosuppressants include azathioprine, mercaptopurine and methotrexate. †Steroids include budesonide, hydrocortisone, methylprednisolone and prednisolone.

Audit objective – safety

Table 28 Adverse reaction by biologic/biosimilar – paediatric patients

This table shows the percentage of all paediatric patients audited between 1 March 2015 and 29 February 2016 for whom an adverse reaction was recorded by type of biologic used as treatment.

Biologic/biosimilar	Adverse reactions recorded = Yes, % (n/N)	
	Initial treatment	3-month follow-up
Adalimumab (Humira)	5% (1/21)	0% (0/6)
Infliximab biosimilar (Inflectra/Remsima)	0% (0/82)	5% (2/39)
Infliximab (Remicade)	2% (3/175)	5% (4/76)

Table 29 Adverse reactions by type – paediatric patients

This table shows the percentage of all paediatric patients for whom an adverse reaction was recorded by type of reaction between 1 March 2015 and 29 February 2016.

Adverse reactions, % (n)	Initial treatment (n=278)	3-month follow-up (n=121)
Adverse reaction recorded Yes=	1% (4)	5% (6)
Abdominal pain	0% (0)	0% (0)
Alopecia	0% (0)	0% (0)
Angioedema of upper airway	0% (0)	0% (0)
Arthralgia	0% (0)	0% (0)
Blood abnormality	0% (0)	0.8% (1)
Bronchospasm (cough/wheeze/dyspnoea)	0% (0)	0% (0)
Cardiac failure	0% (0)	0% (0)
Chest pain	0% (0)	0% (0)
Chills	0% (0)	0% (0)
Confirmed demyelination	0% (0)	0% (0)
Death	0% (0)	0% (0)
Difficulty breathing	0% (0)	0.8% (1)
Dizziness	0% (0)	0% (0)
Fatigue	0% (0)	0% (0)
Fever	0% (0)	2% (2)
Flushing	0% (0)	0% (0)
Headache	0% (0)	0% (0)
Hypotension	0% (0)	0% (0)
Infection	0% (0)	0% (0)
Injection site reaction	0% (0)	0% (0)
Itching	0% (0)	0% (0)
Limb weakness	0% (0)	0% (0)
Malignancy	0% (0)	0% (0)
Nausea	0% (0)	0% (0)
Panic attacks	0% (0)	0% (0)
Rash	0% (0)	2% (2)
Serum sickness-like reaction	0% (0)	0% (0)
Urticaria	0% (0)	0% (0)
Other	0.4% (1)	2% (2)

Audit objective – efficacy

Disease activity for paediatric patients at the time of initial treatment was compared with that at the follow-up nearest to 3 and 12 months from the date of the initial treatment. Follow-up data include only those patients who had an initial treatment.

Table 30 Disease activity as defined by the Paediatric Crohn's Disease Activity Index (PCDAI)

This table shows the severity of disease as defined by PCDAI documented at baseline, 3- and 12-month review for data entered to the audit between 12 September 2011 and 29 February 2016. When severity of CD for paediatric patients is classified by PCDAI, a score <10 is considered to be clinical remission and >40 is considered to be severe disease.

PCDAI score	Initial treatment	3-month follow-up	12-month follow-up
Adalimumab (Humira), median (IQR)	n=9 20 (10, 38)	n=17 20 (8, 30)	n=1
Infliximab (Remicade), median (IQR)	n=388 28 (18, 40)	n=194 5 (0, 15)	n=115 10 (0, 23)
Infliximab biosimilar (Inflectra/Remsima combined), median (IQR)	n=29 28 (20, 40)	n=15 0 (0, 8)	n=0
Total, median (IQR)	n=426 28 (18, 40)	n=226 6 (1, 15)	n=116 10 (0, 23)

IQR = interquartile range; PCDAI = Paediatric Crohn's Disease Activity Index.

Table 31 Response to therapy and remission – paediatric patients

This table shows response to therapy and whether remission was achieved in paediatric patients with CD. Results are displayed at the 3-month time point. The PCDAI is used to quantify the disease activity for paediatric patients. Response is defined as PCDAI decrease of >15 and remission is defined as a PCDAI score of <10.

Audit period	Response* to treatment at 3-month follow-up, % (n/N)	Remission† achieved at 3-month follow-up, % (n/N)
2016 audit data (1 Mar 2015 – 29 Feb 2016)	86% (50/58)	72% (46/64)
2011 – 2016 audit data (12 Sep 2011 – 29 Feb 2016)	77% (208/272)	67% (190/284)

*Response is defined as PCDAI decrease of >15
†Remission is defined as a PCDAI score of <10

Table 32 Disease activity as defined by the weighted Paediatric Crohn's Disease Activity Index (wPCDAI)

This table shows the severity of disease defined by wPCDAI documented at baseline, 3- and 12-month review for data entered to the audit between 12 September 2011 and 29 February 2016. Severity of CD classified by wPCDAI a score of <12.5 is considered to be clinical remission and >57.5 severe disease.

wPCDAI score	Initial treatment	3-month follow-up	12-month follow-up
Adalimumab (Humira), median (IQR)	n=2	n=3	n=4 10 (0, 28)
Infliximab (Remicade), median (IQR)	n=28 51 (35, 64)	n=11 0 (0, 15)	n=4 15 (5, 28)
Infliximab biosimilar (Inflectra/Remsima combined), median (IQR)	n=8 44 (26, 60)	n=6 11 (8, 15)	n=0
Total, median (IQR)	n=38 51 (35, 65)	n=20 11 (0, 16)	n=8 15 (0, 28)

IQR = interquartile range; wPCDAI = weighted Paediatric Crohn's Disease Activity Index.

Table 33 Disease activity as defined by the Paediatric Ulcerative Colitis Activity Index (PUCAI)

This table shows the severity of disease as defined by PUCAI documented at baseline, 3- and 12-month review for data entered to the audit between 12 September 2011 and 29 February 2016. Severity of UC classified by PUCAI a score <10 is considered to be remission and ≥65 is considered to be severe disease.

PUCAI score	Initial treatment	3-month follow-up	12-month follow-up
Infliximab (Remicade), median (IQR)	n=85 55 (35, 70)	n=36 13 (5, 38)	n=8 5 (0, 15)
Infliximab biosimilar (Inflectra/Remsima combined), median (IQR)	n=7 30 (25, 35)	n=0	n=0

IQR = interquartile range; PUCAI = Paediatric Ulcerative Colitis Activity Index.

Table 34 Infliximab (Remicade) vs infliximab biosimilars (Inflectra/Remsima) – paediatric patients

This table compares data on paediatric patients treated with either infliximab (Remicade) or its biosimilar (Inflectra/Remsima) entered to the audit between 1 March 2015 and 29 February 2016.

	Infliximab (Remicade)	Infliximab biosimilar (Inflectra/Remsima)
General patient characteristics		
Gender: male, **%** (n/N)	61% (107/175)	60% (49/82)
Age at diagnosis in years, median (IQR)	n=174 12 (10, 14)	n=79 12 (10, 14)
Age at initial treatment in years, median (IQR)	n=175 14 (12, 15)	n=82 14 (12, 15)
Time from diagnosis to treatment in years, median (IQR)	n=174 0.96 (0.42, 2.35)	n=79 1.07 (0.47, 2.58)
Disease severity		
PCDAI at initial treatment, median (IQR)	n=42 36 (20, 48)	n=29 28 (20, 40)
PCDAI at 3-month follow-up, median (IQR)	n=19 5 (0, 11)	n=15 0 (0, 8)
wPCDAI at initial treatment, median (IQR)	n=13 50 (35, 65)	n=8 44 (26, 60)
wPCDAI at 3-month follow-up, median (IQR)	n=8 11 (0, 16)	n=6 11 (8, 15)
Response and remission at 3-month follow-up, % (n/N)		
Response to treatment (Response is defined as PCDAI decrease of >15)	85% (28/33)	86% (19/22)
Remission achieved (Remission is defined as a PCDAI score of <10)	68% (25/37)	79% (19/24)
Adverse reactions, % (n/N)		
At initial treatment	2% (3/175)	0% (0/82)
At 3-month follow-up	5% (4/76)	5% (2/39)
Concomitant therapy, % (n/N)		
Concomitant therapy for IBD at initial treatment	95% (167/175)	95% (78/82)
Immunosuppressants (includes azathioprine, mercaptopurine and methotrexate)	86% (150/175)	79% (65/82)
Steroids (includes budesonide, hydrocortisone, methylprednisolone and prednisolone)	29% (51/175)	31% (25/82)

IBD = inflammatory bowel disease; IQR = interquartile range; PCDAI = Paediatric Crohn's Disease Activity Index; wPCDAI = weighted Paediatric Crohn's Disease Activity Index.

Audit objective – appropriateness of prescribing anti-TNFα

Detailed information about the NICE guidance and recommendations for use of biological therapies in patients with IBD in the UK can be found in **section 5, pp 47–48** of this report. In Tables 31 and 32, NICE criterion 1.5 from technology appraisal 187[2] and criterion 1.3 from technology appraisal 329[3] have been used to assess the appropriateness of prescribing biological therapy.

Table 35 Compliance with NICE technology appraisal 187, criterion 1.5

This table shows compliance with criterion 1.5 of NICE TA187[2] in paediatric patients with CD.

NICE technology appraisal 187	2016 audit data (1 Mar 2015 – 29 Feb 2016)	2011 – 2016 audit data (12 Sep 2011 – 29 Feb 2016)
Criterion 1.5 Infliximab may be used for people aged 6–17 years with severe active CD only if (a) the disease has not responded to conventional therapy or (b) the person is intolerant of or has contraindications to conventional therapy (mercaptopurine, azathioprine, methotrexate, prednisolone, budesonide, methylprednisolone or hydrocortisone)		
CD patients with PCDAI score ≥45 before starting anti-TNFα treatment, % (n/N)	23% (16/71)	17% (74/425)
CD patients with PCDAI scores who were treated with conventional therapy at time of or prior to starting anti-TNFα treatment, % (n/N)	96% (68/71)	97% (410/425)
CD patients who were appropriately prescribed anti-TNFα treatment in compliance with criterion 1.5 of NICE technology appraisal 187, % (n/N)	20% (14/71)	16% (69/425)

CD = Crohn's disease; NICE = National Institute for Health and Care Excellence; PCDAI = Paediatric Crohn's Disease Activity Index; TNFα = tumour necrosis factor alpha.

Table 36 Compliance with NICE technology appraisal 329, criterion 1.3

This table shows compliance with NICE TA329[3] criterion 1.3 in paediatric patients with UC.

NICE technology appraisal 329	2016 audit data (1 Mar 2015 – 29 Feb 2016)	2011 – 2016 audit data (12 Sep 2011 – 29 Feb 2016)
Criterion 1.3 Infliximab is recommended for treatment for children and young people aged 6–17 years with severe active UC (a) whose disease has responded inadequately to conventional therapy or (b) who are intolerant of or have contraindications to conventional therapy (mercaptopurine, azathioprine, methotrexate, prednisolone, budesonide, methylprednisolone or hydrocortisone)		
UC patients with PUCAI score ≥65 before starting anti-TNFα treatment, % (n/N)	27% (7/26)	38% (36/95)
UC patients with PUCAI scores who were treated with conventional therapy at time of or prior to starting anti-TNFα treatment, % (n/N)	100% (26/26)	100% (95/95)
UC patients who were appropriately prescribed anti-TNFα therapy in compliance with criterion 1.3 of NICE technology appraisal 329, % (n/N)	27% (7/26)	38% (36/95)

NICE = National Institute for Health and Care Excellence; PUCAI = Paediatric Ulcerative Colitis Activity Index; TNFα = tumour necrosis factor alpha; UC = ulcerative colitis.

Table 37 Concomitant therapy for IBD – paediatric patients

This table shows the percentage of all paediatric patients on any immunosuppressant or steroid as concomitant therapy during their treatment with biological therapies between 12 September 2011 and 29 February 2016.

Type of concomitant therapy	Treatment time, % (n)	
	Initial treatment	3-month follow-up
CD patients	**842**	**452**
Concomitant therapy for IBD = Yes	93% (780)	90% (405)
Immunosuppressants*	85% (719)	85% (385)
Steroids†	22% (187)	12% (52)
UC patients	**149**	**53**
Concomitant therapy for IBD = Yes	97% (145)	89% (47)
Immunosuppressants*	70% (104)	77% (41)
Steroids†	68% (101)	23% (12)
IBDU patients	**59**	**30**
Concomitant therapy for IBD = Yes	98% (58)	93% (28)
Immunosuppressants*	76% (45)	73% (22)
Steroids†	41% (24)	27% (8)
All IBD	**1050**	**535**
Concomitant therapy for IBD = Yes	94% (983)	90% (480)
Immunosuppressants*	83% (868)	84% (448)
Steroids†	30% (312)	14% (72)

*Immunosuppressants include azathioprine, mercaptopurine and methotrexate.

†Steroids include budesonide, hydrocortisone, methylprednisolone and prednisolone.

CD = Crohn's disease; IBD = inflammatory bowel disease; IBDU = inflammatory bowel disease unclassified; UC = ulcerative colitis.

Audit objective – patient-reported outcome measures

Outcome measures have traditionally relied on disease activity indexes, but these measures fail to assess the patient's subjective view of their experience. Patient-reported outcome measures (PROMs) therefore evaluate quality from the patient's perspective. Typically, they are short, self-completed questionnaires that measure the patient's health status or health-related quality of life at a single point in time. The health status information is collected from patients by way of PROMs questionnaires completed before, during and after an intervention (in this case, initiation of biological therapy) and provides an indication of the outcomes or quality of care delivered to patients.

IMPACT-III

IMPACT-III is a health-related quality of life questionnaire for paediatric patients with IBD. The questionnaire was originally developed in Canada, but IMPACT-III (UK) has been shown to be a valid tool to measure quality of life in children with IBD in the UK.[11] It comprises 35 items that address six domains of IBD: bowel symptoms, body image, functional / social impairment, emotional impairment, tests/treatment and systemic impairment. Total scores range from 35 (poor) to 175 (best), with an increase in total score of 10.8 reported to be indicative of a clinically meaningful improvement.

In total, 84 IMPACT-III questionnaires were completed at initial treatment between 1 March 2015 and 29 February 2016 with a median (IQR) score of 125 (112, 141). At 3-month follow-up, 36 IMPACT-III questionnaires were completed, with a median (IQR) score of 143 (129, 153). Very few IMPACT-III questionnaires were completed at 12-month follow-up. The limited number of IMPACT-III questionnaires completed at initial and follow-up treatment for individual patients means that a median change in IMPACT-III score cannot be reliably reported.

Table 38 PROMs questionnaire for paediatric patients (IMPACT-III)

This table gives completion rates and results of the paediatric quality of life measure used in the biological therapies audit – the IMPACT-III questionnaire – for all paediatric patients.

IBD-PROM	2016 audit data (1 Mar 2015 – 29 Feb 2016)	2011 – 2016 audit data (12 Sep 2011 – 29 Feb 2016)
Initial treatment	**278**	**1050**
IMPACT-III score, median (IQR)	n=84 125 (112, 141)	n=302 113 (92, 130)
3-month follow-up	**121**	**535**
IMPACT-III score, median (IQR)	n=36 143 (129, 153)	n=154 137 (112, 148)
12-month follow-up	**1**	**245**
IMPACT-III score, median (IQR)	n=0	n=64 144 (130, 153)

IBD = inflammatory bowel disease; IQR, interquartile range; PROMs = patient-reported outcome measures.

IBD-related surgery in paediatric patients

Table 39 IBD-related surgery in paediatric patients with CD

This table displays the surgical procedures in paediatric patients with CD by type of procedure and whether the surgery took place within the 6 months before or after starting biological therapies.

CD-related surgery	Paediatric patients with surgery recorded (n=20)*	
	Surgery 6 months before starting biological therapies (n=10)	Surgery 6 months after starting biological therapies (n=4)
Surgical procedure by type (%, n)		
Drainage of abscess	10% (1)	-
Other surgical procedure	40% (4)	25% (1)
Perianal surgery	30% (3)	25% (1)
Right hemicolectomy / ileocaecal resection	10% (1)	25% (1)
Small bowel resection	-	25% (1)
Unknown procedure	20% (2)	-

*Patients may have one or more surgeries recorded.
CD = Crohn's disease.

Table 40 IBD-related surgery in paediatric patients with UC

This table displays the surgical procedures in paediatric patients with UC by type of procedure and whether the surgery took place within the 6 months before or after starting biological therapies.

UC-related surgery	Paediatric patients with surgery recorded (n=3) *	
	Surgery 6 months before starting biological therapies (n=1)	Surgery 6 months after starting biological therapies (n=1)
Surgical procedure by type (%, n)		
Colectomy and ileostomy	-	100% (1)
Stoma formation	100% (1)	-

*Patients may have one or more surgeries recorded.
UC = ulcerative colitis.

4: Background information

The burden of inflammatory bowel disease

The inflammatory bowel diseases UC and CD are lifelong inflammatory conditions that involve the gastrointestinal tract. The incidence of IBD has risen dramatically in recent decades and continues to do so; it is reported to be as high as 24.3 and 12.7 per 100,000 persons per year in Europe for UC and CD, respectively. The reported prevalence in Europe is as high as 505 and 322 per 100,000 persons for UC and CD, respectively.[12] IBD first presents most commonly in the second and third decades of life, but much of the recent increase has been observed in childhood, notably with CD in children increasing threefold in 30 years. Between 20% and 30% of patients with UC will require colectomy, and between 50% and 70% of patients with CD require surgery. The main symptoms of both conditions include diarrhoea, abdominal pain, anaemia and an overwhelming sense of fatigue, with, for some patients, associated features such as arthritis, anal disease, fistulae, abscesses and skin problems, which can also contribute to poor quality of life. In addition, IBD has wide-ranging effects on growth and pubertal development, psychological health, education and employment, family life, fertility and pregnancy. Effective multidisciplinary care can attenuate relapse, prolong remission, treat complications and improve quality of life.

The UK IBD audit

The UK IBD audit seeks to improve the quality and safety of care for all patients with IBD throughout the UK by auditing individual patient care and the provision and organisation of IBD service resources and by reporting on inpatient experience and PROMs. The biological therapies audit is one element of the wider UK IBD audit.

This report follows the national reports published in 2012, 2013, 2014 and 2015. It builds on the previous reports as a continuous audit with increasing rates of participation, and it provides further evidence about the safety, efficacy and appropriate use of biological therapies. Furthermore, it enables participating sites to benchmark their performance against national data. All data should be considered within the context of the actual number of treatments.

Further information on the work of the UK IBD audit project can be accessed via the IBD page of the RCP website (**www.rcplondon.ac.uk/ibd**).

The benefits of the biological therapies audit

The biological therapies audit is an electronic register of patients receiving treatment and enables IBD teams to:

- monitor the disease activity of patients over the course of their treatment with biological drugs
- monitor and encourage improved management at patient and service levels, data on adverse events, dose escalation and treatment regimens
- capture the views of patients locally on their quality of life at intervals throughout their treatment
- benchmark local results against national-level data
- generate individual patient summaries
- generate letters detailing treatment plans
- assess compliance with the **IBD standards** and **NICE quality standard 81**.[1,4]

5: What is the role of biological therapy in the treatment of IBD?

Infliximab (Remicade®)

Infliximab was first licenced in the EU in 1999 under the brand name Remicade®. It is a chimeric anti-TNFα monoclonal antibody with potent anti-inflammatory effects that are possibly dependent on apoptosis of inflammatory cells. Controlled trials have demonstrated efficacy in both active and fistulating CD and UC. Infliximab is typically administered via an intravenous infusion during a hospital appointment under the supervision of a suitably qualified health professional.

Infliximab biosimilar (Inflectra™ and Remsima™)

Inflectra and Remsima were the first biosimilar monoclonal antibodies to become available in the UK in February 2015 after the patent for Remicade® expired. They have been specifically developed to be highly similar to their reference medicine Remicade.

Adalimumab (Humira®)

Adalimumab (Humira®) was first approved in the EU in 2007. It is a recombinant human immunoglobulin (IgG1) monoclonal antibody containing only human peptide sequences. Adalimumab is typically delivered via a self-administered injection. Patients are provided with a home supply of the medication and, following tuition and close monitoring, are able to manage their own treatment with regular medical follow-up. The patent for Humira is due to expire in April 2018 when it is likely that more cost-effective biosimilar versions will become available.

Golimumab (Simponi®)

Simponi contains the active substance golimumab. Simponi is given as a once-monthly 50 mg injection under the skin on the same day every month. Golimumab is also a tumour necrosis factor alpha (TNFα) inhibitor.

Vedolizumab (Entyvio®)

Vedolizumab (Entyvio) is the first approved gut-selective prescription medicine for treatment of moderate to severe active CD and UC. Vedolizumab (Entyvio) works by blocking the integration of specific integrin receptors with a specific protein. This results in limited migration of circulating inflammatory cells across blood vessels and into areas of inflammation in the gastrointestinal tract. It is administered by intravenous infusion.

Approval in the UK

In **multiple technology appraisal 187** for patients with CD[2], NICE made the following recommendations:

- Infliximab and adalimumab may be used within their licensed indications as treatment options for adults with severe active CD, whose disease has not responded to conventional therapy (including immunosuppressive and/or corticosteroid treatments).
- Infliximab has been recommended for the treatment of active fistulating CD in patients whose disease has not responded to conventional therapy or who have medical contraindications for such therapies.
- Infliximab is recommended for the treatment of people aged 6–17 years with severe, active CD, whose disease has not responded to conventional therapy (including corticosteroids, immunomodulators and primary nutrition therapy) or who have contraindications to conventional therapy.
- Infliximab and adalimumab should be given as a planned course of treatment until treatment failure (including the need for surgery) or until 12 months after the start of treatment, whichever is shorter. Patients should then be reassessed to determine whether ongoing treatment is still clinically appropriate.

In **multiple technology appraisal 329** for patients with UC[3], NICE made the following recommendations:

- Infliximab (also known as Remicade, Inflectra or Remsima), adalimumab (Humira) and golimumab (Simponi) may be used within their licensed indications as treatment for moderate to severe active UC in adults whose disease has responded inadequately to conventional therapy or who cannot tolerate or who have medical contraindications for such therapies.
- Infliximab has been recommended for treating severely active UC in children and young people aged 6–17 years whose disease has responded inadequately to conventional therapy or who cannot tolerate or have medical contraindications for such therapies.
- Infliximab, adalimumab or golimumab should be given as a planned course of treatment until treatment failure (including the need for surgery) or until 12 months after the start of treatment, whichever occurs first. Patients should then be reassessed to determine whether ongoing treatment is still clinically appropriate.

In **technology appraisal 163**[13], NICE made the following recommendation:

- Infliximab as an option for the treatment of acute exacerbations of severely active UC only in patients for whom ciclosporin is contraindicated or clinically inappropriate.

In **technology appraisal 342**[6], NICE made the following recommendations:

- Vedolizumab (Entyvio) as an option for the treatment of adults with moderate to severe UC.
- Vedolizumab is recommended until it stops working, or surgery is required, or for 12 months after starting it, whichever is shorter. If the patient is no longer symptomatic treatment can be stopped and later restarted if and when symptoms return.
- Patients who continue to take vedolizumab should be reassessed every 12 months to decide whether treatment is still necessary.

In **technology appraisal 352**[7], NICE made the following recommendations:

- Vedolizumab (Entyvio) as an option for the treatment of adults with moderate to severe CD if a TNFα inhibitor has failed (the disease has responded inadequately or loss of response to treatment) or a TNFα inhibitor cannot be tolerated or is contraindicated.
- Vedolizumab is recommended until it stops working, or surgery is required, or for 12 months after starting it, whichever is shorter. If the patient is no longer symptomatic treatment can be stopped and later restarted if and when symptoms return.
- Patients who continue to take vedolizumab should be reassessed every 12 months to decide whether treatment is still necessary.

6: Data entry into the biological therapies audit

Data entry takes place in the form of 'submissions' to a web-based data collection tool. A submission refers to data entered in any of the following categories: patient demographics, IBD details, initial treatment, follow-up treatment and IBD-related surgery. Once all mandatory fields are completed within a category, the data are locked to form a completed submission, and they are then suitable for inclusion in national findings. Only locked data can be viewed by the UK IBD audit project team. The full audit dataset is available from the RCP website (**www.rcplondon.ac.uk/biologics**).

Patient demographics category

Patients are identified prospectively when the decision to treat using biological therapies is made by a clinician. The demographic details of the patient are entered using the web tool; this includes a number of patient identifiers that are pseudonymised at the point of data entry and are visible only to the participating site. Details of the patient's consultant and GP can also be entered, although this is not mandatory for the audit.

Disease details category

This section requires sites to provide details of the patient's IBD history, including the extent of their disease, any related comorbid conditions and details of any surgical procedures undertaken prior to the initiation of biological therapies.

Initial treatment category

This section collects details of the initial or baseline treatment. The site indicates whether the patient has CD, UC or IBDU and which biologic is being used as treatment. The system then generates appropriate questions for these options. Information is collected about pre-treatment investigations and screening up to the point of completion or abandonment of the treatment, with details of any treatment reactions that occur.

Follow-up treatment category

Each follow-up treatment that is entered must relate to a previously entered initial treatment submission. An unlimited number of follow-up treatments can be completed to allow outgoing data collection as the patient continues to be treated with biological therapies. The outcome of each follow-up treatment – that is, whether treatment will continue or be stopped – must be provided. Details of any adverse events are recorded for each follow-up treatment.

IBD-related surgery category

Details of IBD-related surgery can be added to the web tool at any time. A prompt to update this section of the web tool appears at the conclusion of all initial and follow-up treatment submissions. This allows identification of any escalation of treatment that is required while a patient is being treated with biological therapy.

PROMs category

Data on PROMs are collected at initial treatment and can then be recorded at any additional follow-up. For the purpose of the audit, the PROMs completed at 3- and 12-month follow-up treatments are of interest.

Continued development of the biological therapies audit web tool

The biological therapies audit web tool has been continually updated and developed in line with the requirements identified through feedback from participants and to reflect emerging evidence. Some examples of the adaptations made to date are summarised below.

Biosimilars

To reflect emerging evidence and changing practice, the biological therapies audit was expanded to allow auditing of patients who are newly started on biosimilar versions of the biological drugs.

Existing patients

This was one of the first adaptations of the system and allowed the inclusion of data for patients already established on biological therapy in addition to those newly started on these drugs. This allowed sites to begin to build their own local registers of patients being treated with biological therapies. This report does not contain analyses of data entered for patients already established on biological therapy; data for these patients are collected only by those sites that wish to use the data at a local level.

Reporting functions

Sites can produce patient and treatment summary reports when required; these are summarised briefly below.

Patient summary report

This is a printable summary of all treatments provided for a specific patient over the course of their management; details of any adverse events, acute reactions and relevant surgery are listed. A graphical display of the patient's disease severity scores over time allows a simple visual representation of the success/failure of treatment to encourage action when required. The patient summary can be filed in the patient's case notes or provided with an accompanying letter to the patient's GP.

Treatment summary report

This is a printable summary of any isolated initial or follow-up treatment; again, this can be filed in the case notes to avoid duplication of effort or included in correspondence with a GP to inform them of the treatment provided to their patient on any particular occasion.

Data import function

The 'Import data' function allows users to upload data held in other spreadsheets or registers directly into the biological therapy audit web tool through a simple template. This avoids duplication of both effort and data entry on sites.

Reduction of mandatory fields

Following feedback from users regarding the length of time taken to enter submissions onto the web tool, the number of mandatory fields is under constant review and is regularly reduced to make the process of entering and locking data faster and simpler.

Download function

Users are able to download their previous site reports, printable versions of the audit tools, help notes and a user guide to assist them with data entry.

Data export function

Users are able to export all data that they have submitted since the start of the audit directly from the audit web tool. Data are exported in the form of an editable Excel file.

Dashboard

The dashboard is split into various sections; each giving sites a glance at their activity on the audit to date. Fig 3 outlines the functions available on the dashboard.

Fig 3 Functions of the biological therapy audit dashboard

Patient summary
This gives an overview of how many patients have been added to the web tool by the site. It also flags up any patients for whom a follow-up treatment has not been recorded in the last 90 days.

Patients initiating biologics graph
This shows how many patients the site has started on each of the different biological therapies.

Performance summary
This gives the site an idea of how well they are performing in terms of locking their complete submissions. A happy, neutral or unhappy face is displayed depending on the percentage of locked submissions.

Submissions summary
This pie chart displays locked versus unlocked submissions. When the link is clicked, the site can see all of their unlocked submissions.

Activity over time
This gives sites an overview of submissions entered in each category over time, including the year of data entry.

System security of the biological therapies audit web tool

The document *Biological therapies audit system and hosted server security details* outlines the system security information provided to all sites invited to participate in the audit. It contains details on the following topic areas: physical data centre (location, security, admission control, climatisation, electricity and fire protection), operating system (version, user access, security, encryption, updates and patches, and backups), database software (version, user access and encryption) and application software (source control, user access and encryption). It is available to download from the RCP website (**www.rcplondon.ac.uk/biologics**).[14] The document gives an overview of the security measures in place, while providing assurance that security procedures designed by Microsoft and other industry-standard bodies have been followed. The contracted system developer also implemented the recommended procedures contained within the NHS document *Securing web infrastructure and supporting services good practice guideline*.[15]

The purpose of collecting patient-identifiable data was to make the system useful for staff at a local site level by enabling full monitoring and interpretation of the data for the purpose of immediate local service improvement and patient care. Patient-identifiable data can be viewed only by registered members of the local team, whose access to the site will have been approved via the local clinical lead (nearly always a consultant gastroenterologist). Sites using the web tool cannot view data entered at other participating sites. The UK IBD audit project team have administrative control to analyse anonymised data only and are not able to view any patient-identifiable information.

In accordance with the principles of the Data Protection Act, sites participating in the biological therapies audit are reminded that patients should be informed of the use of their data by means of the information leaflets and posters provided by the UK IBD audit project team.

7: Participation and individual site key indicator data

Participation

Since the audit's inception, levels of participation have varied. Participation falls into one of three main categories:

- Sites that have been entering data, known as participating sites (or participants), which can be broken down into two further categories:
  - those that have entered data regularly over the past year of data collection
  - those that have previously entered data into the audit but have not done so during the past year of data collection
- Sites that have never entered any data to the audit, known as non-participating sites (or non-participant).
- Sites that do not administer biological therapies to their patients with IBD, known as not eligible.

Table 40 Participation status

The table below shows the different levels of participation for all adult and paediatric registered sites.

Participation status for registered sites	Adult sites	Paediatric sites
Participants with data entry over the past year of data collection	161	27
Previous participants but no data entered during past year of data collection	37	8
Non-participant	15	9
Not eligible	2	0
Total number of sites	215	44

Key indicator data for individual adult sites

This table gives named key site data in alphabetical order of participating site in England, Northern Ireland, Scotland and Wales. These key indicators were agreed by the IBD programme steering group as reflecting the areas of particular importance to people with IBD. An asterisk next to the name of the site in the table denotes that the site has taken part in PANTs.

	Participation status	Number of patients entered to the audit between 1 March 2015 and 29 February 2016	Number of patients with adequate pre-treatment screening	Number of patients with documented follow-up at 3 months	Number of patients with documented disease activity index at 3 months	Number of patients being treated with infliximab (Remicade)	Number of patients being treated with infliximab biosimilars (Inflectra / Remsima)
National results		**2722**	**60% (1388/2308)**	**31% (855/2722)**	**56% (475/855)**	**29% (800/2722)**	**22% (596/2722)**
England (n=167)							
Aintree University Hospitals NHS Foundation Trust							
Aintree University Hospital	Participant	13	100% (13/13)	0% (0/13)	n=0	23% (3/13)	0% (0/13)
Airedale NHS Foundation Trust							
Airedale General Hospital*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Ashford and St Peter's Hospitals NHS Foundation Trust							
Ashford Hospital and St Peter's Hospital	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Barking, Havering and Redbridge Hospitals NHS Trust							
King George Hospital and Queens Hospital	Participant	9	89% (8/9)	44% (4/9)	75% (3/4)	44% (4/9)	0% (0/9)
Barnsley Hospital NHS Foundation Trust							
Barnsley District General Hospital	Participant	14	29% (4/14)	29% (4/14)	0% (0/4)	50% (7/14)	0% (0/14)
Barts Health NHS Trust							
Newham University Hospital	Participant	9	100% (9/9)	22% (2/9)	0% (0/2)	78% (7/9)	0% (0/9)
The Royal London Hospital and St Bartholomew's Hospital	Participant	98	96% (80/83)	55% (54/98)	19% (10/54)	48% (47/98)	0% (0/98)
Whipps Cross University Hospital	Participant	17	88% (15/17)	0% (0/17)	n=0	82% (14/17)	0% (0/17)

	Participation status	Number of patients entered to the audit between 1 March 2015 and 29 February 2016	Number of patients with adequate pre-treatment screening	Number of patients with documented follow-up at 3 months	Number of patients with documented disease activity index at 3 months	Number of patients being treated with infliximab (Remicade)	Number of patients being treated with infliximab biosimilars (Inflectra / Remsima)
National results		**2722**	**60% (1388/2308)**	**31% (855/2722)**	**56% (475/855)**	**29% (800/2722)**	**22% (596/2722)**
Basildon and Thurrock University Hospitals NHS Foundation Trust							
Basildon Hospital*	Participant	6	100% (5/5)	50% (3/6)	100% (3/3)	17% (1/6)	0% (0/6)
Blackpool Teaching Hospitals NHS Foundation Trust							
Blackpool Victoria Hospital*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Bedford Hospital NHS Trust							
Bedford Hospital	Participant	9	100% (9/9)	0% (0/9)	n=0	33% (3/9)	67% (6/9)
Bradford Teaching Hospitals Foundation Trust							
Bradford Royal Infirmary*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Brighton and Sussex University Hospitals NHS Trust							
Royal Sussex County Hospital* and Princess Royal Hospital	Participant	48	98% (47/48)	52% (25/48)	96% (24/25)	19% (9/48)	58% (28/48)
Buckinghamshire Healthcare NHS Trust							
Stoke Mandeville Hospital and Wycombe General Hospital	Previous participant but no data entered in past year						
Burton Hospitals NHS Foundation Trust							
Queen's Hospital, Burton	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Calderdale and Huddersfield NHS Foundation Trust							
Huddersfield Royal Infirmary and Calderdale Hospital*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Cambridge University Hospitals NHS Foundation Trust							
Addenbrooke's Hospital*	Participant	10	n=0	70% (7/10)	100% (7/7)	20% (2/10)	20% (2/10)

	Participation status	Number of patients entered to the audit between 1 March 2015 and 29 February 2016	Number of patients with adequate pre-treatment screening	Number of patients with documented follow-up at 3 months	Number of patients with documented disease activity index at 3 months	Number of patients being treated with infliximab (Remicade)	Number of patients being treated with infliximab biosimilars (Inflectra / Remsima)
National results		**2722**	**60% (1388/2308)**	**31% (855/2722)**	**56% (475/855)**	**29% (800/2722)**	**22% (596/2722)**
Central Manchester University Hospitals NHS Foundation Trust							
Manchester Royal Infirmary*	Participant	29	94% (16/17)	45% (13/29)	92% (12/13)	48% (14/29)	0% (0/29)
Trafford General Hospital	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Chelsea and Westminster Hospital NHS Foundation Trust							
Chelsea and Westminster Hospital*	Previous participant but no data entered in past year						
West Middlesex University Hospital*	Participant	20	100% (18/18)	0% (0/20)	n=0	30% (6/20)	30% (6/20)
Chesterfield Royal Hospital NHS Foundation Trust							
Chesterfield Royal Hospital*	Participant	24	56% (10/18)	42% (10/24)	100% (10/10)	4% (1/24)	92% (22/24)
City Hospitals Sunderland NHS Foundation Trust							
Sunderland Royal Hospital*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Colchester Hospital University NHS Foundation Trust							
Colchester General Hospital*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Countess of Chester Hospital NHS Foundation Trust							
Countess of Chester Hospital	Participant	n<6	n<6	n<6	n<6	n<6	n<6
County Durham and Darlington NHS Foundation Trust							
Darlington Memorial Hospital and Bishop Auckland Hospital*	Participant	19	83% (15/18)	21% (4/19)	0% (0/4)	37% (7/19)	0% (0/19)
University Hospital of North Durham	Participant	6	67% (4/6)	33% (2/6)	100% (2/2)	50% (3/6)	0% (0/6)
Croydon Health Services NHS Trust							
Croydon University Hospital	Participant	22	23% (5/22)	27% (6/22)	83% (5/6)	0% (0/22)	55% (12/22)
Dartford and Gravesham NHS Trust							
Darent Valley Hospital	Participant	24	0% (0/24)	17% (4/24)	0% (0/4)	58% (14/24)	0% (0/24)

	Participation status	Number of patients entered to the audit between 1 March 2015 and 29 February 2016	Number of patients with adequate pre-treatment screening	Number of patients with documented follow-up at 3 months	Number of patients with documented disease activity index at 3 months	Number of patients being treated with infliximab (Remicade)	Number of patients being treated with infliximab biosimilars (Inflectra / Remsima)
National results		**2722**	**60% (1388/2308)**	**31% (855/2722)**	**56% (475/855)**	**29% (800/2722)**	**22% (596/2722)**
Derby Hospitals NHS Foundation Trust							
Royal Derby Hospital*	Participant	29	0% (0/25)	10% (3/29)	33% (1/3)	17% (5/29)	28% (8/29)
Doncaster and Bassetlaw Hospitals NHS Foundation Trust							
Doncaster Royal Infirmary* and Bassetlaw District General Hospital	Previous participant but no data entered in past year						
Dorset County Hospital NHS Foundation Trust							
Dorset County Hospital*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Ealing Hospital NHS Trust							
Ealing Hospital	Non-participant						
East and North Hertfordshire NHS Trust							
Lister Hospital* and Queen Elizabeth II Hospital	Participant	20	13% (2/16)	25% (5/20)	100% (5/5)	5% (1/20)	0% (0/20)
East Cheshire NHS Trust							
Macclesfield District General Hospital	Participant	23	87% (20/23)	22% (5/23)	100% (5/5)	48% (11/23)	0% (0/23)
East Kent Hospitals University NHS Foundation Trust							
William Harvey Hospital, Kent and Canterbury Hospital and Queen Elizabeth The Queen Mother Hospital	Participant	27	0% (0/27)	48% (13/27)	0% (0/13)	0% (0/27)	11% (3/27)
East Lancashire Hospitals NHS Trust							
Royal Blackburn Hospital and Burnley District General Hospital	Participant	59	2% (1/56)	58% (34/59)	74% (25/34)	44% (26/59)	0% (0/59)
East Sussex Healthcare Trust							
Eastbourne District General Hospital and Conquest Hospital*	Previous participant but no data entered in past year						

	Participation status	Number of patients entered to the audit between 1 March 2015 and 29 February 2016	Number of patients with adequate pre-treatment screening	Number of patients with documented follow-up at 3 months	Number of patients with documented disease activity index at 3 months	Number of patients being treated with infliximab (Remicade)	Number of patients being treated with infliximab biosimilars (Inflectra / Remsima)
National results		**2722**	**60% (1388/2308)**	**31% (855/2722)**	**56% (475/855)**	**29% (800/2722)**	**22% (596/2722)**
Epsom and St Helier University Hospitals NHS Trust							
Epsom General Hospital	Participant	n<6	n<6	n<6	n<6	n<6	n<6
St Helier Hospital	Previous participant but no data entered in past year						
Frimley Health NHS Foundation Trust							
Frimley Park Hospital*	Previous participant but no data entered in past year						
Heatherwood Hospital	Non-participant						
Wexham Park Hospital	Previous participant but no data entered in past year						
Gateshead Health NHS Foundation Trust							
Queen Elizabeth Hospital, Gateshead	Participant	<6	n<6	n<6	n<6	n<6	n<6
George Eliot Hospital NHS Trust							
George Eliot Hospital	Participant	9	100% (9/9)	33% (3/9)	100% (3/3)	67% (6/9)	0% (0/9)
Gloucestershire Hospitals NHS Foundation Trust							
Gloucestershire Royal Hospital and Cheltenham General Hospital*	Participant	8	n=0	13% (1/8)	100% (1/1)	38% (3/8)	0% (0/8)
Great Western Hospitals NHS Foundation Trust							
Great Western Hospital	Participant	56	95% (53/56)	32% (18/56)	0% (0/18)	36% (20/56)	25% (14/56)
Guy's and St Thomas' NHS Foundation Trust							
Guy's Hospital and St Thomas' Hospital*	Participant	<6	n<6	n<6	n<6	n<6	n<6
Hampshire Hospitals NHS Foundation Trust							
Basingstoke and North Hampshire Hospitals*	Participant	7	n=0	57% (4/7)	100% (4/4)	14% (1/7)	71% (5/7)
Royal Hampshire County Hospital*	Participant	6	n=0	83% (5/6)	100% (5/5)	50% (3/6)	17% (1/6)

	Participation status	Number of patients entered to the audit between 1 March 2015 and 29 February 2016	Number of patients with adequate pre-treatment screening	Number of patients with documented follow-up at 3 months	Number of patients with documented disease activity index at 3 months	Number of patients being treated with infliximab (Remicade)	Number of patients being treated with infliximab biosimilars (Inflectra / Remsima)
National results		**2722**	**60% (1388/2308)**	**31% (855/2722)**	**56% (475/855)**	**29% (800/2722)**	**22% (596/2722)**
Harrogate and District NHS Foundation Trust							
Harrogate District Hospital	Participant	8	63% (5/8)	38% (3/8)	0% (0/3)	50% (4/8)	25% (2/8)
Heart of England NHS Foundation Trust							
Birmingham Heartlands Hospital and Solihull Hospital	Previous participant but no data entered in past year						
Good Hope Hospital	Participant	29	100% (29/29)	0% (0/29)	n=0	10% (3/29)	21% (6/29)
Hinchingbrooke Health Care NHS Trust							
Hinchingbrooke Hospital	Participant	24	96% (23/24)	21% (5/24)	40% (2/5)	8% (2/24)	54% (13/24)
Homerton University Hospital NHS Foundation Trust							
Homerton University Hospital	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Hull and East Yorkshire Hospitals NHS Trust							
Hull Royal Infirmary* and Castle Hill Hospital	Participant	10	57% (4/7)	10% (1/10)	100% (1/1)	10% (1/10)	0% (0/10)
Imperial College Healthcare NHS Trust							
Charing Cross Hospital, Hammersmith Hospital and St Mary's Hospital	Participant	n<6	n<6	n<6	n<6	n<6	n<6
James Paget University Hospitals NHS Foundation Trust							
James Paget Hospital*	Participant	20	26% (5/19)	20% (4/20)	0% (0/4)	40% (8/20)	45% (9/20)
Kettering General Hospital NHS Foundation Trust							
Kettering General Hospital	Previous participant but no data entered in past year						
King's College Hospital NHS Foundation Trust							
King's College Hospital	Participant	46	73% (33/45)	37% (17/46)	29% (5/17)	2% (1/46)	17% (8/46)
Princess Royal University Hospital	Participant	23	52% (12/23)	22% (5/23)	0% (0/5)	22% (5/23)	52% (12/23)

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National results		**2722**	**60% (1388/2308)**	**31% (855/2722)**	**56% (475/855)**	**29% (800/2722)**	**22% (596/2722)**
Kingston Hospital NHS Trust							
Kingston Hospital	Participant	36	97% (35/36)	39% (14/36)	50% (7/14)	14% (5/36)	31% (11/36)
Lancashire Teaching Hospitals NHS Foundation Trust							
Royal Preston Hospital and Chorley and South Ribble Hospital	Participant	21	5% (1/21)	19% (4/21)	0% (0/4)	14% (3/21)	0% (0/21)
Lewisham and Greenwich NHS Trust							
Lewisham Hospital	Participant	11	13% (1/8)	9% (1/11)	100% (1/1)	9% (1/11)	0% (0/11)
Queen Elizabeth Hospital, Woolwich	Participant	26	0% (0/26)	4% (1/26)	0% (0/1)	23% (6/26)	19% (5/26)
London North West Healthcare NHS Trust							
Central Middlesex Hospital	Non-participant						
Northwick Park and St Mark's Hospital*	Participant	112	89% (92/103)	38% (42/112)	79% (33/42)	38% (43/112)	18% (20/112)
Luton and Dunstable Hospital NHS Foundation Trust							
Luton and Dunstable Hospital*	Participant	10	50% (1/2)	50% (5/10)	40% (2/5)	100% (10/10)	0% (0/10)
Maidstone and Tunbridge Wells NHS Trust							
Maidstone Hospital*	Participant	9	25% (2/8)	0% (0/9)	n=0	67% (6/9)	22% (2/9)
Tunbridge Wells Hospital	Previous participant but no data entered in past year						
Medway NHS Foundation Trust							
Medway Maritime Hospital	Participant	13	100% (13/13)	54% (7/13)	100% (7/7)	23% (3/13)	0% (0/13)
Mid Cheshire Hospitals NHS Foundation Trust							
Leighton Hospital*	Participant	17	0% (0/15)	41% (7/17)	29% (2/7)	47% (8/17)	18% (3/17)
Mid Essex Hospitals NHS Trust							
Broomfield Hospital	Participant	37	100% (37/37)	3% (1/37)	100% (1/1)	11% (4/37)	5% (2/37)

	Participation status	Number of patients entered to the audit between 1 March 2015 and 29 February 2016	Number of patients with adequate pre-treatment screening	Number of patients with documented follow-up at 3 months	Number of patients with documented disease activity index at 3 months	Number of patients being treated with infliximab (Remicade)	Number of patients being treated with infliximab biosimilars (Inflectra / Remsima)
National results		**2722**	**60% (1388/2308)**	**31% (855/2722)**	**56% (475/855)**	**29% (800/2722)**	**22% (596/2722)**
Milton Keynes Hospital NHS Foundation Trust							
Milton Keynes Hospital*	Participant	16	94% (15/16)	25% (4/16)	100% (4/4)	13% (2/16)	50% (8/16)
NHS Isle of Wight							
St Mary's Hospital	Participant	24	0% (0/23)	25% (6/24)	0% (0/6)	42% (10/24)	8% (2/24)
Norfolk and Norwich University Hospitals NHS Foundation Trust							
Norfolk and Norwich University Hospital*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
North Bristol NHS Trust							
Southmead Hospital	Participant	60	62% (37/60)	3% (2/60)	50% (1/2)	18% (11/60)	30% (18/60)
North Cumbria University Hospitals NHS Trust							
Cumberland Infirmary*	Participant	35	3% (1/35)	17% (6/35)	0% (0/6)	40% (14/35)	0% (0/35)
West Cumberland Hospital*	Participant	9	0% (0/9)	78% (7/9)	0% (0/7)	11% (1/9)	0% (0/9)
North Middlesex University Hospital NHS Trust							
North Middlesex University Hospital	Previous participant but no data entered in past year						
North Tees and Hartlepool NHS Foundation Trust							
University Hospital of Hartlepool	Previous participant but no data entered in past year						
University Hospital of North Tees	Previous participant but no data entered in past year						
Northampton General Hospital NHS Trust							
Northampton General Hospital	Participant	43	58% (25/43)	63% (27/43)	15% (4/27)	28% (12/43)	37% (16/43)
Northern Devon Healthcare NHS Trust							
North Devon District Hospital	Participant	6	17% (1/6)	17% (1/6)	100% (1/1)	17% (1/6)	50% (3/6)

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National results		**2722**	**60% (1388/2308)**	**31% (855/2722)**	**56% (475/855)**	**29% (800/2722)**	**22% (596/2722)**
Northern Lincolnshire and Goole Hospitals NHS Foundation Trust							
Diana, Princess of Wales Hospital	Participant	20	0% (0/20)	10% (2/20)	0% (0/2)	10% (2/20)	55% (11/20)
Scunthorpe General Hospital	Participant	9	33% (3/9)	22% (2/9)	0% (0/2)	33% (3/9)	22% (2/9)
Northumbria Healthcare NHS Foundation Trust							
Wansbeck, North Tyneside and Hexham General Hospitals	Participant	37	46% (17/37)	41% (15/37)	60% (9/15)	46% (17/37)	0% (0/37)
Nottingham University Hospital NHS Trust							
Queen's Medical Centre* and Nottingham City Hospital	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Oxford University Hospitals NHS Trust							
The John Radcliffe Hospital and Horton General Hospital	Participant	51	2% (1/50)	12% (6/51)	17% (1/6)	6% (3/51)	24% (12/51)
Peterborough and Stamford Hospitals NHS Foundation Trust							
Peterborough City Hospital	Participant	24	100% (24/24)	50% (12/24)	33% (4/12)	8% (2/24)	33% (8/24)
Plymouth Hospitals NHS Trust							
Derriford Hospital*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Poole Hospital NHS Foundation Trust							
Poole General Hospital*	Participant	6	n=0	50% (3/6)	100% (3/3)	0% (0/6)	50% (3/6)
Portsmouth Hospitals NHS Trust							
Queen Alexandra Hospital*	Participant	11	n=0	46% (5/11)	100% (5/5)	18% (2/11)	73% (8/11)
Princess Alexandra Hospital NHS Trust							
Princess Alexandra Hospital, Harlow*	Participant	n<6	n<6	n<6	n<6	n<6	n<6

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National results		**2722**	**60% (1388/2308)**	**31% (855/2722)**	**56% (475/855)**	**29% (800/2722)**	**22% (596/2722)**
Royal Berkshire NHS Foundation Trust							
Royal Berkshire Hospital*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Royal Bolton Hospital NHS Foundation Trust							
Royal Bolton Hospital	Participant	23	91% (20/22)	22% (5/23)	100% (5/5)	35% (8/23)	4% (1/23)
Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust							
Royal Bournemouth Hospital*	Participant	55	4% (2/50)	26% (14/55)	36% (5/14)	33% (18/55)	57% (31/55)
Royal Cornwall Hospitals NHS Trust							
Royal Cornwall Hospital*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Royal Devon and Exeter NHS Foundation Trust							
Royal Devon and Exeter Hospital*	Participant	52	91% (20/22)	39% (20/52)	100% (20/20)	14% (7/52)	62% (32/52)
Royal Free London NHS Foundation Trust							
Barnet General Hospital	Previous participant but no data entered in past year						
Royal Free Hospital*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Royal Surrey County Hospital NHS Foundation Trust							
Royal Surrey County Hospital	Participant	16	88% (14/16)	6% (1/16)	0% (0/1)	13% (2/16)	81% (13/16)
Royal United Hospitals Bath NHS Trust							
Royal United Hospital*	Participant	8	n=0	100% (8/8)	100% (8/8)	63% (5/8)	0% (0/8)
Salford Royal NHS Foundation Trust							
Salford Royal Hospital*	Previous participant but no data entered in past year						
Salisbury NHS Foundation Trust							
Salisbury District General Hospital	Participant	8	25% (2/8)	13% (1/8)	0% (0/1)	50% (4/8)	50% (4/8)

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National results		**2722**	**60% (1388/2308)**	**31% (855/2722)**	**56% (475/855)**	**29% (800/2722)**	**22% (596/2722)**
Sandwell and West Birmingham Hospitals NHS Trust							
Birmingham City Hospital and Sandwell Hospital*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Sheffield Teaching Hospitals NHS Foundation Trust							
Royal Hallamshire Hospital and Northern General Hospital	Participant	25	100% (25/25)	4% (1/25)	0% (0/1)	60% (15/25)	0% (0/25)
Sherwood Forest Hospitals NHS Foundation Trust							
King's Mill Hospital and Newark Hospital*	Participant	16	100% (10/10)	50% (8/16)	50% (4/8)	44% (7/16)	0% (0/16)
South Tees Hospitals NHS Foundation Trust							
Friarage Hospital	Non-participant						
James Cook University Hospital*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
South Tyneside NHS Foundation Trust							
South Tyneside District Hospital*	Participant	20	92% (11/12)	70% (14/20)	100% (14/14)	100% (20/20)	0% (0/20)
South Warwickshire NHS Foundation Trust							
Warwick Hospital	Previous participant but no data entered in past year						
Southend University Hospital NHS Foundation Trust							
Southend University Hospital	Participant	9	56% (5/9)	11% (1/9)	100% (1/1)	44% (4/9)	22% (2/9)
Southport and Ormskirk Hospital NHS Trust							
Southport District General Hospital	Participant	13	77% (10/13)	0% (0/13)		15% (2/13)	23% (3/13)
St George's Healthcare NHS Trust							
St George's Hospital*	Participant	n<6	n<6	n<6	n<6	n<6	n<6

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National results		**2722**	**60% (1388/2308)**	**31% (855/2722)**	**56% (475/855)**	**29% (800/2722)**	**22% (596/2722)**
St Helens and Knowsley Hospitals NHS Trust							
Whiston Hospital	Participant	30	0% (0/30)	23% (7/30)	29% (2/7)	37% (11/30)	0% (0/30)
Stockport NHS Foundation Trust							
Stepping Hill Hospital*	Participant	20	100% (17/17)	15% (3/20)	0% (0/3)	30% (6/20)	0% (0/20)
Surrey and Sussex Healthcare NHS Trust							
East Surrey Hospital	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Tameside Hospital NHS Foundation Trust							
Tameside General Hospital*	Participant	8	0% (0/3)	50% (4/8)	100% (4/4)	38% (3/8)	0% (0/8)
Taunton and Somerset NHS Foundation Trust							
Musgrove Park Hospital*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
The Dudley Group NHS Foundation Trust							
Russells Hall Hospital*	Participant	7	60% (3/5)	29% (2/7)	50% (1/2)	57% (4/7)	0% (0/7)
The Hillingdon Hospitals NHS Foundation Trust							
Hillingdon Hospital	Participant	7	100% (7/7)	43% (3/7)	67% (2/3)	86% (6/7)	0% (0/7)
The Ipswich Hospital NHS Trust							
The Ipswich Hospital	Participant	7	14% (1/7)	0% (0/7)		0% (0/7)	29% (2/7)
The Leeds Teaching Hospitals NHS Trust							
Leeds General Infirmary*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
St James's University Hospital Leeds*	Participant	8	n=0	38% (3/8)	100% (3/3)	0% (0/8)	13% (1/8)

	Participation status	Number of patients entered to the audit between 1 March 2015 and 29 February 2016	Number of patients with adequate pre-treatment screening	Number of patients with documented follow-up at 3 months	Number of patients with documented disease activity index at 3 months	Number of patients being treated with infliximab (Remicade)	Number of patients being treated with infliximab biosimilars (Inflectra / Remsima)
National results		**2722**	**60% (1388/2308)**	**31% (855/2722)**	**56% (475/855)**	**29% (800/2722)**	**22% (596/2722)**
The Mid Yorkshire Hospitals NHS Trust							
Dewsbury and District Hospital	Non-participant						
Pinderfields General Hospital and Pontefract Hospitals*	Participant	14	n=0	71% (10/14)	90% (9/10)	36% (5/14)	7% (1/14)
The Newcastle upon Tyne Hospitals NHS Foundation Trust							
Freeman Hospital	Participant	8	75% (6/8)	50% (4/8)	0% (0/4)	75% (6/8)	0% (0/8)
Royal Victoria Infirmary, Newcastle*	Participant	12		42% (5/12)	100% (5/5)	25% (3/12)	50% (6/12)
The Pennine Acute Hospitals NHS Trust							
The Royal Oldham Hospital, Fairfield General Hospital, North Manchester General Hospital and Rochdale Infirmary*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
The Queen Elizabeth Hospital King's Lynn NHS Foundation Trust							
The Queen Elizabeth Hospital	Participant	6	n=0	67% (4/6)	100% (4/4)	0% (0/6)	50% (3/6)
The Rotherham NHS Foundation Trust							
Rotherham Hospital	Participant	15	87% (13/15)	7% (1/15)	0% (0/1)	33% (5/15)	0% (0/15)
The Royal Liverpool and Broadgreen University Hospitals NHS Trust							
Royal Liverpool University Hospital	Participant	16	6% (1/16)	31% (5/16)	80% (4/5)	63% (10/16)	0% (0/16)
The Royal Wolverhampton Hospitals NHS Trust							
Cannock Chase Hospital	Participant	n<6	n<6	n<6	n<6	n<6	n<6
New Cross Hospital*	Participant	39	62% (21/34)	28% (11/39)	91% (10/11)	39% (15/39)	5% (2/39)

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National results		**2722**	**60% (1388/2308)**	**31% (855/2722)**	**56% (475/855)**	**29% (800/2722)**	**22% (596/2722)**
The Shrewsbury and Telford Hospital NHS Trust							
Royal Shrewsbury Hospital* and Princess Royal Hospital	Participant	8	n=0	50% (4/8)	100% (4/4)	88% (7/8)	0% (0/8)
Torbay and South Devon NHS Foundation Trust							
Torbay Hospital*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
United Lincolnshire Hospitals NHS Trust							
Grantham and District Hospital*	Previous participant but no data entered in past year						
Lincoln County Hospital*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Pilgrim Hospital	Participant	16	25% (4/16)	6% (1/16)	0% (0/1)	69% (11/16)	13% (2/16)
University College London Hospitals NHS Foundation Trust							
University College Hospital*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
University Hospitals of North Midlands NHS Trust							
County Hospital	Non-Participant						
The Royal Stoke University Hospital*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
University Hospital of South Manchester NHS Foundation Trust							
Wythenshawe Hospital*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
University Hospital Southampton NHS Foundation Trust							
Southampton General Hospital*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
University Hospitals Birmingham NHS Foundation Trust							
New Queen Elizabeth Hospital Birmingham*	Participant	73	99% (71/72)	38% (28/73)	0% (0/28)	23% (17/73)	16% (12/73)
University Hospitals Coventry and Warwickshire NHS Trust							
University Hospital, Coventry*	Participant	104	26% (23/90)	34% (35/104)	29% (10/35)	8% (8/104)	28% (29/104)

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National results		**2722**	**60% (1388/2308)**	**31% (855/2722)**	**56% (475/855)**	**29% (800/2722)**	**22% (596/2722)**
University Hospitals of Bristol NHS Foundation Trust							
Bristol Royal Infirmary*	Participant	10	n=0	30% (3/10)	67% (2/3)	10% (1/10)	30% (3/10)
University Hospitals of Leicester NHS Trust							
Leicester Royal Infirmary	Previous participant but no data entered in past year						
Leicester General Hospital*	Participant	69	99% (67/68)	1% (1/69)	100% (1/1)	6% (4/69)	30% (21/69)
University Hospitals of Morecombe Bay NHS Foundation Trust							
Furness General and Royal Lancaster Infirmary and Westmorland General Hospitals	Participant	17	77% (13/17)	29% (5/17)	20% (1/5)	47% (8/17)	0% (0/17)
Walsall Healthcare NHS Trust							
Walsall Manor Hospital	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Warrington and Halton Hospitals NHS Foundation Trust							
Warrington District General Hospital*	Participant	26	100% (22/22)	19% (5/26)	100% (5/5)	23% (6/26)	31% (8/26)
West Hertfordshire Hospitals NHS Trust							
Watford General Hospital* and Hemel Hempstead General Hospital	Participant	21	74% (14/19)	29% (6/21)	100% (6/6)	14% (3/21)	57% (12/21)
West Suffolk Hospitals NHS Foundation Trust							
West Suffolk Hospital	Participant	11	100% (11/11)	27% (3/11)	0% (0/3)	46% (5/11)	0% (0/11)
Western Sussex Hospitals NHS Trust							
St Richard's Hospital	Participant	11	0% (0/11)	0% (0/11)	n=0	73% (8/11)	0% (0/11)
Worthing Hospital*	Participant	38	91% (29/32)	50% (19/38)	26% (5/19)	21% (8/38)	3% (1/38)
Weston Area Health Trust							
Weston General Hospital*	Participant	18	67% (2/3)	72% (13/18)	100% (13/13)	17% (3/18)	11% (2/18)

	Participation status	Number of patients entered to the audit between 1 March 2015 and 29 February 2016	Number of patients with adequate pre-treatment screening	Number of patients with documented follow-up at 3 months	Number of patients with documented disease activity index at 3 months	Number of patients being treated with infliximab (Remicade)	Number of patients being treated with infliximab biosimilars (Inflectra / Remsima)
National results		**2722**	**60% (1388/2308)**	**31% (855/2722)**	**56% (475/855)**	**29% (800/2722)**	**22% (596/2722)**
Whittington Health NHS Trust							
Whittington Hospital	Participant	18	33% (6/18)	22% (4/18)	0% (0/4)	28% (5/18)	72% (13/18)
Wirral University Teaching Hospital NHS Foundation Trust							
Arrowe Park Hospital	Participant	38	87% (33/38)	40% (15/38)	33% (5/15)	18% (7/38)	0% (0/38)
Worcestershire Acute Hospitals NHS Trust							
Alexandra Hospital	Not eligible						
Worcestershire Royal Hospital	Previous participant but no data entered in past year						
Wrightington, Wigan and Leigh NHS Foundation Trust							
Royal Albert Edward Infirmary*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Wye Valley NHS Trust							
County Hospital, Hereford	Participant	12	17% (2/12)	42% (5/12)	100% (5/5)	33% (4/12)	0% (0/12)
Yeovil District Hospital NHS Foundation Trust							
Yeovil District Hospital*	Participant	16	33% (4/12)	63% (10/16)	50% (5/10)	0% (0/16)	19% (3/16)
York Teaching Hospital NHS Foundation Trust							
Scarborough General Hospital	Previous participant but no data entered in past year						
York Hospital	Previous participant but no data entered in past year						
Northern Ireland (n=12)							
Belfast Health and Social Care Trust							
Belfast City Hospital	Participant	8	88% (7/8)	38% (3/8)	0% (0/3)	25% (2/8)	0% (0/8)
Mater Hospital	Previous participant but no data entered in past year						
Royal Victoria Hospital	Participant	21	5% (1/21)	29% (6/21)	33% (2/6)	43% (9/21)	0% (0/21)

	Participation status	Number of patients entered to the audit between 1 March 2015 and 29 February 2016	Number of patients with adequate pre-treatment screening	Number of patients with documented follow-up at 3 months	Number of patients with documented disease activity index at 3 months	Number of patients being treated with infliximab (Remicade)	Number of patients being treated with infliximab biosimilars (Inflectra / Remsima)
National results		**2722**	**60% (1388/2308)**	**31% (855/2722)**	**56% (475/855)**	**29% (800/2722)**	**22% (596/2722)**
Northern Health and Social Care Trust							
Antrim Area Hospital	Previous participant but no data entered in past year						
Causeway Hospital	Previous participant but no data entered in past year						
South Eastern Health and Social Care Trust							
Downe Hospital	Non-participant						
Lagan Valley Hospital	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Ulster Hospital	Participant	7	57% (4/7)	0% (0/7)	n=0	29% (2/7)	43% (3/7)
Southern Health and Social Care Trust							
Craigavon Area Hospital	Previous participant but no data entered in past year						
Daisy Hill Hospital	Previous participant but no data entered in past year						
Western Health and Social Care Trust							
Altnagelvin Area Hospital	Previous participant but no data entered in past year						
South West Acute Hospital	Previous participant but no data entered in past year						
Scotland (n=20)							
NHS Ayrshire and Arran							
University Hospital Ayr	Non-participant						
University Hospital Crosshouse	Previous participant but no data entered in past year						
NHS Borders							
Borders General Hospital	Previous participant but no data entered in past year						
NHS Dumfries and Galloway							
Dumfries and Galloway Royal Infirmary	Previous participant but no data entered in past year						

	Participation status	Number of patients entered to the audit between 1 March 2015 and 29 February 2016	Number of patients with adequate pre-treatment screening	Number of patients with documented follow-up at 3 months	Number of patients with documented disease activity index at 3 months	Number of patients being treated with infliximab (Remicade)	Number of patients being treated with infliximab biosimilars (Inflectra / Remsima)
National results		**2722**	**60% (1388/2308)**	**31% (855/2722)**	**56% (475/855)**	**29% (800/2722)**	**22% (596/2722)**
NHS Fife							
Queen Margaret Hospital	Non-participant						
Victoria Hospital*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
NHS Forth Valley							
Forth Valley Royal Hospital*	Participant	8	n=0	38% (3/8)	100% (3/3)	38% (3/8)	38% (3/8)
NHS Grampian							
Aberdeen Royal Infirmary	Non-participant						
NHS Greater Glasgow and Clyde							
Glasgow Royal Infirmary*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Inverclyde Royal Hospital	Previous participant but no data entered in past year						
Queen Elizabeth University Hospital, Glasgow, Southern General, Victoria Infirmary and Gartnavel hospital	Participant	61	95% (58/61)	2% (1/61)	0% (0/1)	26% (16/61)	41% (25/61)
Royal Alexandra Hospital	Previous participant but no data entered in past year						
Western Infirmary	Non-participant						
NHS Highland							
Raigmore Hospital	Non-participant						
NHS Lanarkshire							
Hairmyres Hospital	Previous participant but no data entered in past year						
Monklands Hospital	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Wishaw General Hospital	Participant	n<6	n<6	n<6	n<6	n<6	n<6

	Participation status	Number of patients entered to the audit between 1 March 2015 and 29 February 2016	Number of patients with adequate pre-treatment screening	Number of patients with documented follow-up at 3 months	Number of patients with documented disease activity index at 3 months	Number of patients being treated with infliximab (Remicade)	Number of patients being treated with infliximab biosimilars (Inflectra / Remsima)
National results		**2722**	**60% (1388/2308)**	**31% (855/2722)**	**56% (475/855)**	**29% (800/2722)**	**22% (596/2722)**
NHS Lothian							
St John's Hospital at Howden	Non-participant						
Western General Hospital and Royal Infirmary of Edinburgh*	Participant	8	n=0	38% (3/8)	100% (3/3)	13% (1/8)	0% (0/8)
NHS Tayside							
Ninewells Hospital*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Wales (n=16)							
Abertawe Bro Morgannwg University Health Board							
Morriston Hospital	Not eligible						
Princess of Wales Hospital	Non-participant						
Aneurin Bevan University Health Board							
Nevill Hall Hospital	Participant	21	14% (3/21)	43% (9/21)	0% (0/9)	19% (4/21)	67% (14/21)
Royal Gwent Hospital	Participant	23	83% (19/23)	9% (2/23)	100% (2/2)	17% (4/23)	61% (14/23)
Betsi Cadwaladr University Health Board							
Glan Clwyd Hospital	Participant	7	14% (1/7)	14% (1/7)	0% (0/1)	57% (4/7)	0% (0/7)
Llandudno General Hospital	Previous participant but no data entered in past year						
Wrexham Maelor Hospital	Participant	22	5% (1/22)	55% (12/22)	92% (11/12)	77% (17/22)	0% (0/22)
Ysbyty Gwynedd	Participant	7	14% (1/7)	14% (1/7)	100% (1/1)	71% (5/7)	14% (1/7)
Cardiff and Vale University Health Board							
University Hospital Llandough	Participant	n<6	n<6	n<6	n<6	n<6	n<6
University Hospital of Wales	Previous participant but no data entered in past year						

	Participation status	Number of patients entered to the audit between 1 March 2015 and 29 February 2016	Number of patients with adequate pre-treatment screening	Number of patients with documented follow-up at 3 months	Number of patients with documented disease activity index at 3 months	Number of patients being treated with infliximab (Remicade)	Number of patients being treated with infliximab biosimilars (Inflectra / Remsima)
National results		**2722**	**60% (1388/2308)**	**31% (855/2722)**	**56% (475/855)**	**29% (800/2722)**	**22% (596/2722)**
Cwm Taf University Health Board							
Prince Charles Hospital	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Royal Glamorgan Hospital	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Hywel Dda University Health Board							
Bronglais General Hospital	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Glangwili General Hospital	Previous participant but no data entered in past year						
Prince Philip Hospital	Non-participant						
Withybush General Hospital	Participant	9	100% (9/9)	44% (4/9)	100% (4/4)	11% (1/9)	67% (6/9)

Key indicator data for individual paediatric sites

This table gives named key site data in alphabetical order of participating site in England, Northern Ireland, Scotland and Wales. These key indicators were agreed by the IBD programme steering group as reflecting the areas of particular importance to people with IBD. An asterisk next to the name of the site in the table denotes that the site has taken part in PANTs.

	Participation status	Number of patients entered to the audit between 1 March 2015 and 29 February 2016	Number of patients with adequate pre-treatment screening	Number of patients with documented follow-up at 3 months	Number of patients with documented disease activity index at 3 months	Number of patients treated with infliximab (Remicade)	Number of patients treated with infliximab biosimilars (Inflectra / Remsima)
National results		**278**	**47% (109/230)**	**44% (121/278)**	**13% (16/121)**	**63% (175/278)**	**30% (82/278)**
Abertawe Bro Morgannwg University Health Board							
Morriston Hospital (paediatric gastroenterology)	Participant	6	0% (0/6)	50% (3/6)	0% (0/3)	17% (1/6)	83% (5/6)
Alder Hey Children's NHS Foundation Trust							
Alder Hey Children's Hospital	Participant	30	47% (14/30)	70% (21/30)	0% (0/21)	100% (30/30)	0% (0/30)
Ashford and St Peter's Hospitals NHS Foundation Trust							
Ashford Hospital and St Peter's Hospital (paediatric)*	Non-participant						
Barts Health NHS Trust							
Barts and The London Children's Hospital*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Belfast Health and Social Care Trust							
Royal Belfast Hospital for Sick Children (RBHSC)	Non-participant						
Birmingham Children's Hospital NHS Foundation Trust							
Birmingham Children's Hospital	Participant	19	74% (14/19)	21% (4/19)	25% (1/4)	0% (0/19)	32% (6/19)
Brighton and Sussex University Hospitals NHS Trust							
The Royal Alexandra Children's Hospital*	Participant	n<6	n<6	n<6	n<6	n<6	n<6

	Participation status	Number of patients entered to the audit between 1 March 2015 and 29 February 2016	Number of patients with adequate pre-treatment screening	Number of patients with documented follow-up at 3 months	Number of patients with documented disease activity index at 3 months	Number of patients treated with infliximab (Remicade)	Number of patients treated with infliximab biosimilars (Inflectra / Remsima)
National results		**278**	**47% (109/230)**	**44% (121/278)**	**13% (16/121)**	**63% (175/278)**	**30% (82/278)**
Burton Hospitals NHS Foundation Trust							
Queen's Hospital, Burton (paediatric)	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Cambridge University Hospitals NHS Foundation Trust							
Addenbrooke's Hospital (paediatric gastroenterology unit)*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Cardiff and Vale University Health Board							
The Noah's Ark Children's Hospital for Wales	Participant	9	0% (0/9)	67% (6/9)	0% (0/6)	22% (2/9)	78% (7/9)
Central Manchester University Hospitals NHS Foundation Trust							
Royal Manchester Children's Hospital	Participant	29	4% (1/24)	38% (11/29)	36% (4/11)	86% (25/29)	0% (0/29)
Chelsea and Westminster Hospital NHS Foundation Trust							
Chelsea and Westminster Hospital, Children's Services*	Participant	20	100% (18/18)	10% (2/20)	0% (0/2)	100% (20/20)	0% (0/20)
Doncaster and Bassetlaw Hospitals NHS Foundation Trust							
Doncaster Royal Infirmary and Bassetlaw District General Hospital (paediatric)	Non-participant						
Dorset County Hospital NHS Foundation Trust							
Dorset County Hospital, Children's Services*	Previous participant but no data entered in past year						
Epsom and St Helier University Hospitals NHS Trust							
Queen Mary's Hospital for Children	Participant	8	0% (0/8)	13% (1/8)	0% (0/1)	100% (8/8)	0% (0/8)
Great Ormond Street Hospital for Children NHS Foundation Trust							
Great Ormond Street Hospital*	Participant	n<6	n<6	n<6	n<6	n<6	n<6

	Participation status	Number of patients entered to the audit between 1 March 2015 and 29 February 2016	Number of patients with adequate pre-treatment screening	Number of patients with documented follow-up at 3 months	Number of patients with documented disease activity index at 3 months	Number of patients treated with infliximab (Remicade)	Number of patients treated with infliximab biosimilars (Inflectra / Remsima)
National results		**278**	**47% (109/230)**	**44% (121/278)**	**13% (16/121)**	**63% (175/278)**	**30% (82/278)**
Hull and East Yorkshire Hospitals NHS Trust							
Hull Royal Infirmary* and Castle Hill Hospital (paediatric)	Previous participant but no data entered in past year						
King's College Hospital NHS Foundation Trust							
King's College Hospital (paediatric gastroenterology)	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Leeds Teaching Hospitals NHS Trust							
Leeds General Infirmary (paediatric gastroenterology unit)	Participant	9	100% (9/9)	33% (3/9)	0% (0/3)	89% (8/9)	11% (1/9)
Lewisham and Greenwich NHS Trust							
The Children's Hospital, Lewisham	Non-participant						
London North West Healthcare NHS Trust							
Northwick Park and St Mark's Hospital (paediatric gastroenterology)	Participant	8	100% (8/8)	63% (5/8)	0% (0/5)	50% (4/8)	50% (4/8)
Luton and Dunstable Hospital NHS Foundation Trust							
Luton and Dunstable University Hospital (paediatric)*	Non-participant						
Maidstone and Tunbridge Wells NHS Trust							
Maidstone Hospital (paediatric)*	Non-participant						
Tunbridge Wells Hospital (paediatric)	Previous participant but no data entered in past year						

	Participation status	Number of patients entered to the audit between 1 March 2015 and 29 February 2016	Number of patients with adequate pre-treatment screening	Number of patients with documented follow-up at 3 months	Number of patients with documented disease activity index at 3 months	Number of patients treated with infliximab (Remicade)	Number of patients treated with infliximab biosimilars (Inflectra / Remsima)
National results		**278**	**47% (109/230)**	**44% (121/278)**	**13% (16/121)**	**63% (175/278)**	**30% (82/278)**
NHS Grampian							
North-East Scotland Paediatric Gastroenterology Network (Royal Aberdeen Children's Hospital, Ninewells Hospital and Raigmore Hospital)	Participant	6	83% (5/6)	0% (0/6)	n=0	50% (3/6)	33% (2/6)
NHS Greater Glasgow and Clyde							
Royal Hospital for Children, Glasgow*	Participant	20	92% (11/12)	45% (9/20)	0% (0/9)	50% (10/20)	50% (10/20)
NHS Lothian							
Royal Hospital for Sick Children, Edinburgh	Participant	9	100% (9/9)	67% (6/9)	0% (0/6)	56% (5/9)	44% (4/9)
Norfolk and Norwich University Hospitals NHS Foundation Trust							
Jenny Lind Children's Hospital*	Participant	9	0% (0/7)	78% (7/9)	29% (2/7)	22% (2/9)	78% (7/9)
North Tees and Hartlepool NHS Foundation Trust							
University Hospital of Hartlepool and University Hospital of North Tees* (paediatric)	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Nottingham University Hospitals NHS Trust							
Nottingham Children's Hospital*	Previous participant but no data entered in past year						
Oxford University Hospitals NHS Trust							
Children's Hospital, The John Radcliffe	Participant	16	100% (11/11)	44% (7/16)	29% (2/7)	6% (1/16)	94% (15/16)
Plymouth Hospitals NHS Trust							
Derriford Hospital (paediatric)	Non-participant						

	Participation status	Number of patients entered to the audit between 1 March 2015 and 29 February 2016	Number of patients with adequate pre-treatment screening	Number of patients with documented follow-up at 3 months	Number of patients with documented disease activity index at 3 months	Number of patients treated with infliximab (Remicade)	Number of patients treated with infliximab biosimilars (Inflectra / Remsima)
National results		**278**	**47% (109/230)**	**44% (121/278)**	**13% (16/121)**	**63% (175/278)**	**30% (82/278)**
Poole Hospital NHS Foundation Trust							
Poole General Hospital (paediatric)	Previous participant but no data entered in past year						
Royal Devon and Exeter NHS Foundation Trust							
Royal Devon and Exeter Hospital (paediatric)	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Royal Free London NHS Foundation Trust							
Royal Free Hospital (paediatric gastroenterology unit)	Previous participant but no data entered in past year						
Sheffield Children's NHS Foundation Trust							
Sheffield Children's Hospital	Previous participant but no data entered in past year						
St George's Healthcare NHS Trust							
St George's Hospital (paediatric gastroenterology unit)	Participant	13	8% (1/13)	69% (9/13)	11% (1/9)	23% (3/13)	77% (10/13)
The Ipswich Hospital NHS Trust							
The Ipswich Hospital (paediatric)	Non-participant						
The Newcastle upon Tyne Hospitals NHS Foundation Trust							
Great North Children's Hospital	Participant	17	0% (0/17)	35% (6/17)	0% (0/6)	94% (16/17)	6% (1/17)
University Hospital of North Midlands NHS Trust							
The Royal Stoke University Hospital (paediatric)	Participant	n<6	n<6	n<6	n<6	n<6	n<6
University Hospital Southampton NHS Foundation Trust							
Southampton Children's Hospital	Participant	14	0% (0/14)	0% (0/14)	n=0	100% (14/14)	0% (0/14)

	Participation status	Number of patients entered to the audit between 1 March 2015 and 29 February 2016	Number of patients with adequate pre-treatment screening	Number of patients with documented follow-up at 3 months	Number of patients with documented disease activity index at 3 months	Number of patients treated with infliximab (Remicade)	Number of patients treated with infliximab biosimilars (Inflectra / Remsima)
National results		**278**	**47% (109/230)**	**44% (121/278)**	**13% (16/121)**	**63% (175/278)**	**30% (82/278)**
University Hospitals of Bristol NHS Foundation Trust							
Bristol Royal Hospital for Children*	Previous participant but no data entered in past year						
University Hospitals of Leicester NHS Trust							
Leicester Royal Infirmary Children's Hospital*	Participant	6	n=0	50% (3/6)	0% (0/3)	0% (0/6)	100% (6/6)
Western Health and Social Care Trust							
Altnagelvin Area Hospital (paediatric gastroenterology)	Non-participant						

Appendices

Appendix 1: Acronyms used in this report

Anti-TNFα	Anti-tumour necrosis factor alpha
AoMRC	Academy of Medical Royal Colleges
CD	Crohn's disease
CEEU	Clinical Effectiveness and Evaluation Unit
CUCQ-12	Crohn's and ulcerative colitis questionnaire
HBI	Harvey–Bradshaw index
HQIP	Healthcare Quality Improvement Partnership
IBD	Inflammatory bowel disease
IBDU	Inflammatory bowel disease unclassified
IQR	Interquartile range
NCAPOP	National Clinical Audit and Patient Outcomes Programme
NICE	National Institute for Health and Care Excellence
PANTs	Personalised Anti-TNF Therapy in Crohn's disease study
PCDAI	Paediatric Crohn's Disease Activity Index
PROMs	Patient-reported outcome measures
RCN	Royal College of Nursing
RCP	Royal College of Physicians
SCCAI	Simple Clinical Colitis Activity Index
UC	Ulcerative colitis

Appendix 2: Biological therapy audit governance

Audit governance

The fifth round of the UK IBD audit is guided by the multidisciplinary IBD programme steering group, which is a collaborative partnership between gastroenterologists (the British Society of Gastroenterology), colorectal surgeons (the Association of Coloproctology of Great Britain and Ireland), patients (Crohn's and Colitis UK), physicians (the RCP), nurses (the Royal College of Nursing (RCN), pharmacists (the Royal Pharmaceutical Society), dietitians (the British Dietetic Association) and paediatric gastroenterologists (the British Society of Paediatric Gastroenterology, Hepatology and Nutrition).

The audit is commissioned by HQIP as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP). The audit is managed by the Clinical Effectiveness and Evaluation Unit of the RCP. Each hospital identified an overall clinical lead who was responsible for data collection and entry for their IBD service. Data were collected by hospitals using a standardised method.

Any enquiries in relation to the work of the UK IBD audit can be directed to **ibd.audit@rcplondon.ac.uk**.

IBD programme steering group members

The names of members of the biological therapy audit subgroup are shown in bold. This is the group of people tasked with leading this particular element of the UK IBD audit and who contributed considerably to the development of this element of work.

Association of Coloproctology of Great Britain and Ireland

Mr Omar Faiz, consultant colorectal surgeon, St Mark's Hospital, Harrow
Mr Graeme Wilson, consultant colorectal surgeon, Western General Hospital, Edinburgh (until March 2016)

British Dietetic Association

Ms Katie Keetarut, senior IBD dietitian, University College Hospital, London (until March 2016)

British Society of Gastroenterology

Dr Ian Arnott, IBD programme clinical director, chair of the UK IBD audit steering group; consultant gastroenterologist, Western General Hospital, Edinburgh
Dr Stuart Bloom, consultant gastroenterologist, University College Hospital, London
Dr Keith Bodger, consultant physician and gastroenterologist, University Hospital Aintree, Liverpool
Dr Fraser Cummings, consultant gastroenterologist, University Hospital Southampton
Professor Chris Probert, consultant gastroenterologist, Royal Liverpool University Hospital (until March 2016)
Dr Ian Shaw, IBD programme associate director; consultant gastroenterologist, Gloucestershire Royal Hospital
Dr Graham Turner, consultant gastroenterologist, Royal Victoria Hospital, Belfast (until March 2016)
Professor John Williams, consultant gastroenterologist, Abertawe Bro Morgannwg University Health Board; director, Health Informatics Unit, RCP (until March 2016)

British Society of Paediatric Gastroenterology, Hepatology and Nutrition

Dr Charles Charlton, consultant paediatric gastroenterologist, Queens Medical Centre, Nottingham (until March 2016)
Dr Sally Mitton, consultant paediatric gastroenterologist, St George's Hospital, London (until March 2016)
Dr Richard K Russell, consultant paediatric gastroenterologist, Royal Hospital for Children, Glasgow

Crohn's and Colitis UK (NACC)

Mr David Barker, chief executive
Ms Jackie Glatter, health service development adviser (until March 2016)
Revd Ian Johnston, patient representative (until March 2016)

Primary Care Society for Gastroenterology

Dr Jamie Dalrymple, GP partner, Drayton and St Faiths medical practice (until March 2016)

Royal College of Nursing

Ms Kay Crook, paediatric gastroenterology clinical nurse specialist, St Mark's Hospital, Harrow

Ms Diane Hall, clinical nurse specialist, Heartlands Hospital, Birmingham (until March 2016)

Dr Karen Kemp, IBD clinical nurse specialist, Manchester Royal Infirmary

Royal College of Physicians

Ms Rhona Buckingham, operations director, CEEU

Ms Kajal Mortier, project manager, UK IBD programme

Ms Susan Murray, programme manager, UK IBD programme

Ms Aimee Protheroe, programme development manager, UK IBD programme

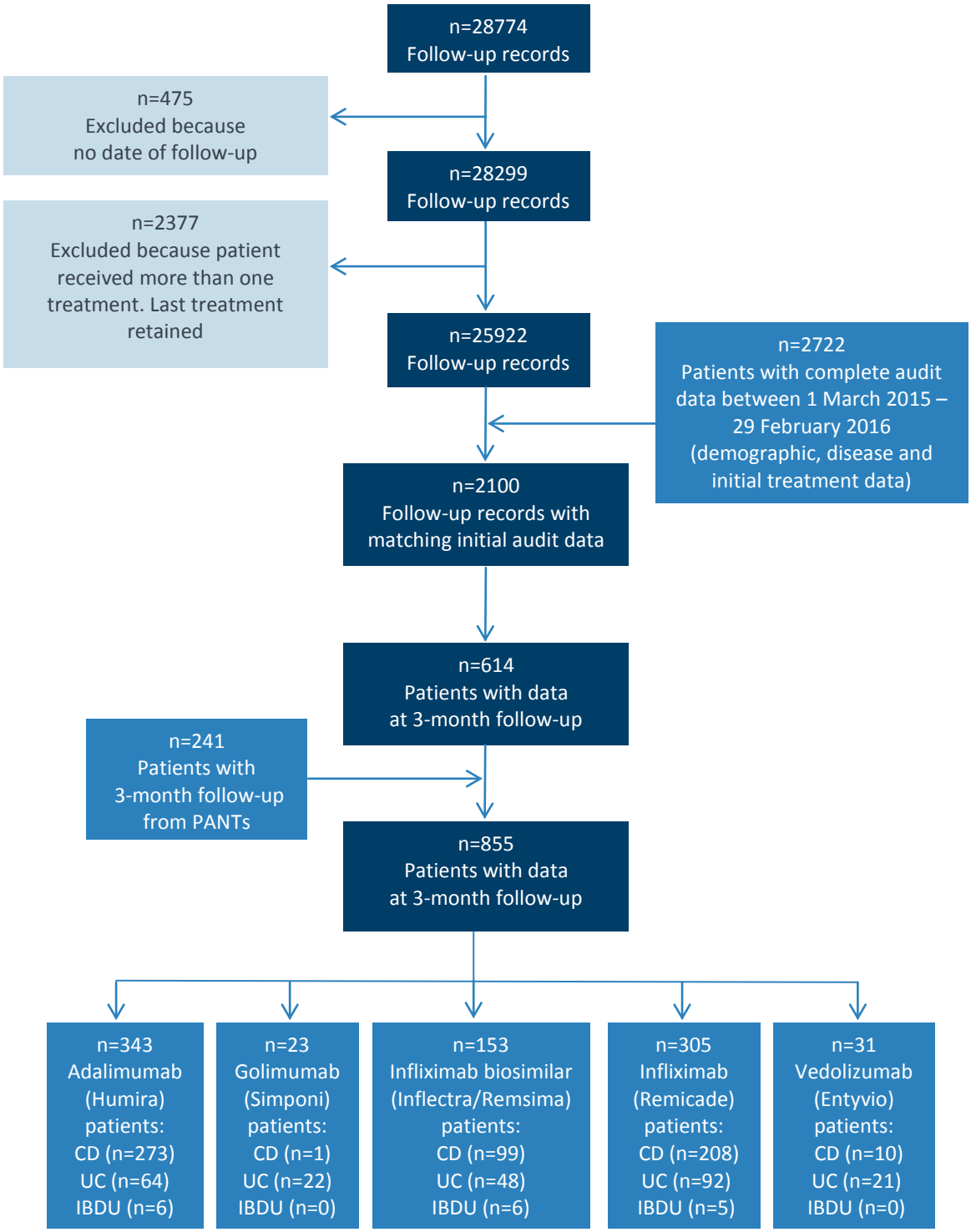
Dr Kevin Stewart, clinical director, CEEU

Royal Pharmaceutical Society of Great Britain

Ms Anja St Clair-Jones, consultant pharmacist gastroenterology, Royal Sussex County Hospital, Brighton

Appendix 3: Consort diagram of follow-up at 3 months for adult patients

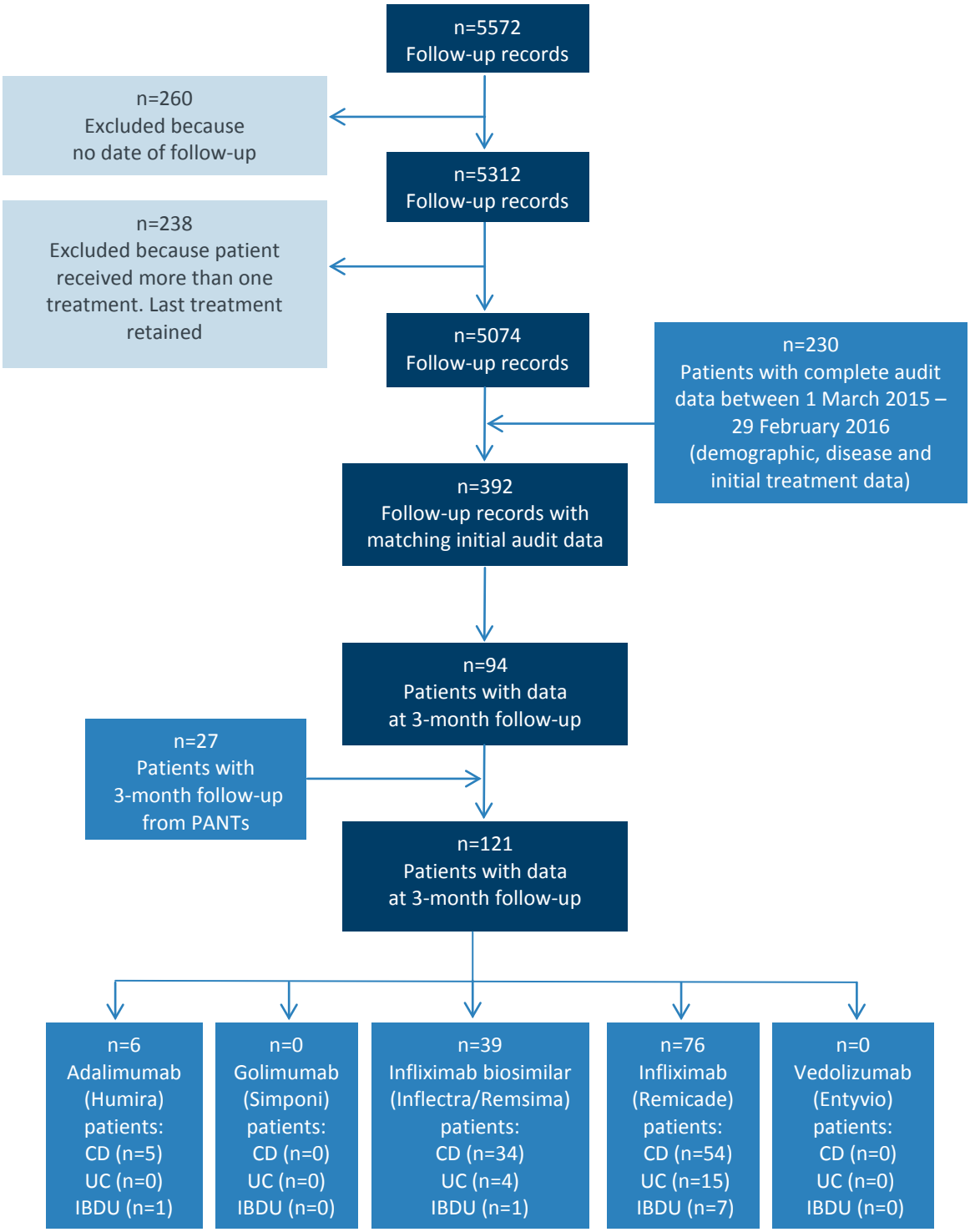
Fig 4 Consort diagram for follow-up treatment at 3 months of adult patients.



CD = Crohn's disease; IBDU = inflammatory bowel disease unclassified; PANTs = Personalised Anti-TNF Therapy in Crohn's disease study; UC = ulcerative colitis.

Appendix 4: Consort diagram of follow-up at 3 months for paediatric patients

Fig 5 Consort diagram for follow-up treatment at 3 months for paediatric patients.



CD = Crohn's disease; IBDU = inflammatory bowel disease unclassified; PANTs = Personalised Anti-TNF Therapy in Crohn's disease study; UC = ulcerative colitis.

Appendix 5: Full national audit results – adult services

Appendix 5 can be found online at: **www.rcplondon.ac.uk/biologics**.

Appendix 6: Full national audit results – paediatric services

Appendix 6 can be found online at: **www.rcplondon.ac.uk/biologics**.

References

1 IBD Standards Group, 2013. *Standards for the healthcare of people who have inflammatory bowel disease, IBD standards, 2013 update*. **www.ibdstandards.org.uk** [Accessed 21 July 2016].

2 National Institute for Health and Care Excellence, 2011. Technology appraisal 187: *Infliximab (review) and adalimumab for the treatment of Crohn's disease*. **www.nice.org.uk/guidance/TA187** [Accessed 21 July 2016].

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