Royal College of Physicians | Inflammatory Bowel Disease Programme

Biological therapy

National clinical audit of biological therapies

UK inflammatory bowel disease (IBD) audit

Adult report
September 2014

Prepared by the Clinical Effectiveness and Evaluation Unit at the Royal College of Physicians on behalf of the IBD programme steering group

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Publication date	25 September 2014
Audience	Healthcare professionals, NHS managers, service commissioners and policymakers
Description	This is the third biological therapy report published from the UK IBD audit. This report is addressed to 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, 12 September 2011 – 28 February 2014.
Supersedes	UK IBD audit – National clinical audit of biological therapies – adult report, August 2013
Related publications	*National clinical audit of inflammatory bowel disease (IBD) service provision (adult)* (Royal College of Physicians, 2014) *National clinical audit of inpatient care for adults with ulcerative colitis* (Royal College of Physicians, 2014) *Experience of inpatients with ulcerative colitis throughout the UK* (Royal College of Physicians, 2014) *Standards for the healthcare of people who have inflammatory bowel disease* (IBD Standards), 2013 update. **www.ibdstandards.org.uk** NICE TA187: *Infliximab (review) and adalimumab for the treatment of Crohn's disease.* **http://www.nice.org.uk/guidance/TA187** NICE TA163: *Infliximab for acute exacerbations of ulcerative colitis.* **http://www.nice.org.uk/guidance/TA163**
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Foreword

The first round of UK IBD audit took place in 2006–8 and demonstrated considerable variation in service provision. Much has changed since this time. IBD services have seen substantial, real and sustainable improvement and the UK IBD audit itself has undergone much development. While this has delivered higher quality, it undoubtedly places additional pressures on the clinical teams who continue to collect and submit the data. The future therefore brings challenges to deliver an effective, cost efficient, relevant and acceptable audit.

The first round of UK IBD audit examined inpatient care of 40 adults with inflammatory bowel disease (IBD) at each site, along with the organisation and structure of IBD services. Paediatric services were included in round 2 (2008–10) and biological therapies and inpatient experience were added in round 3 (2010–12). Round 4 (2012–14) has seen substantial changes to methodology, with the prospective collection of data for up to 50 patients with ulcerative colitis per site and the adoption of the IBD quality improvement project (IBDQIP) tool for the assessment of organisation of services and to drive quality improvement. The audit has assessed patient outcomes more thoroughly in terms of disease activity, quality of life, patient-reported outcome measures and patient experience.

The progress of the UK IBD audit has been supported by the development of the service standards for patients with IBD. This was led by the patient organisation Crohn's and Colitis UK, and the standards serve to complement, underpin and inform the recent quality standard for IBD published by NICE.

However, there continue to be aspects of care that need improvement. It is clear, particularly from this round, that this is true of some aspects of therapeutics. It is also important that we tackle areas that are harder to change, for example the provision of dietetic and psychological support, as well as addressing aspects of care that have not previously been assessed, such as outpatient care and colon cancer surveillance.

Further rounds of the UK IBD audit will continue to drive improvement. The challenge for the IBD community is to engage the support necessary to allow this to continue. We must think of smarter, more efficient ways of working and it is vital to allow clinicians to help patients as efficiently as possible. Increased engagement with patients is essential and adoption of new technologies, such as those being driven forward by the IBD Registry, will support this process. It is also vital to put a greater emphasis on quality improvement and the IBDQIP is an important step to help clinical teams implement change in what is already a time-poor environment.

The single and most heartfelt thanks must go to the clinical teams, who continue to give their time selflessly to enter data to the UK IBD audit.

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Contents

Report preparation

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Acknowledgements

The IBD programme steering group would like to thank all hospitals who continue to contribute to this national audit. We would also like to thank all who have participated in the piloting and development of the UK IBD audit since it began in 2005. Thank you also to participating NHS hospitals that have provided invaluable suggestions on ways to improve the audit. The web-based data collection tool was developed by Westcliff Solutions Ltd: **www.westcliffsolutions.co.uk**

Executive summary

Background

The purpose of this audit is to measure the efficacy, safety and appropriate use of biological therapies, also known as anti-tumour necrosis factor α (TNFα) therapy (infliximab and adalimumab), in patients with inflammatory bowel disease (IBD) in the UK and to capture the views of patients on their quality of life at intervals during their treatment.

This is the third report of the biological therapy element of the UK IBD audit and all analyses within this report include only those patients who were newly started on biological therapies between 12 September 2011 (start of data collection) and 28 February 2014. The data contained within this report have been taken from **only** completed submissions within the biological therapy audit web tool (**www.ibdbiologicsaudit.org**).

Participation in the biological therapies audit provides IBD teams in hospitals with the means to meet Standard A6 of the **IBD Standards**;[1] specifically, the regular review of patient outcomes and auditing of biological therapy. Participation in the audit also provides the opportunity to review treatment against National Institute for Health and Care Excellence (NICE) recommendation **TA187**.[2]

Key message

The data presented in this report suggest that biological therapies are safe and effective treatments for IBD and that they are used to good effect throughout the participating adult sites in the UK. There are still issues that, when addressed, will improve the delivery of these medicines and the quality of patient care.

There are 163 adult trusts/health boards eligible to participate in round 4 of the UK IBD audit; of these, 150 (92%) are participating in the biological therapies element or in the Personalised Anti-TNF Therapy in Crohn's disease study (PANTS).[3] A total of 3272 adult patients have been included in this national analysis. Engagement in the biologics audit has continued to improve, but clinicians should be encouraged to enter data on all appropriate patients. Objective assessment of response to therapy continues to be an important part of using these expensive medicines, and the collection of disease activity scores and quality of life data continues to be central to this.

Clinicians should continue to review concomitant therapies: 17% of Crohn's disease patients are prescribed 5-aminosalicylic acid (5-ASA) drugs at initial treatment, and it is unlikely that these are effective in this patient group. The biologics data demonstrate a good steroid-sparing effect, and prescribing the correct loading dose of the drug will ensure that patients receive the most benefit from the prescribed medicine. Continued audit of biological therapy remains vitally important to be able to assess trends over time as clinical practice changes, eg changing use of co-immunosuppression, use of therapeutic drug monitoring and the introduction of biosimilars. Only by continuing the audit to take account of these issues can we ensure that the quality of care for patients with IBD continues to improve.

Key findings

1 The rate of participation in the biological therapies audit at a trust/health board level is encouraging (92%), but in some cases it is likely that a minority of cases are being entered into the audit. (**Section 1, p 12**)

2 83% of patients treated with a biological therapy have Crohn's disease. Refractory luminal Crohn's disease is the commonest indication for treatment (77% and 87% of patients on infliximab and adalimumab, respectively), with severe perianal Crohn's disease second (19% and 9% of patients on infliximab and adalimumab, respectively). (**Section 5, p 25**)

3 Acute severe ulcerative colitis (UC) is the commonest indication for treatment with infliximab (62%) in patients with UC. Refractory UC and indeterminate colitis are less common indications for treatment. (**Section 5, p 32**)

4 23% of patients with Crohn's disease are given a lower-dose (80/40 mg) and 77% a higher dose (160/80 mg) induction regime for adalimumab. This is associated with a greater frequency of dose escalation in the long term. (**Section 5, p 26**)

5 2% of patients with Crohn's disease are on higher-dose infliximab (10 mg/kg) and 4% of patients are on higher-dose adalimumab (80 mg) at follow-up. (**Section 5, p 28**)

6 53% of patients with Crohn's disease are clearly recorded as having been appropriately prescribed anti-TNFα treatment when compared with NICE TA187 criterion 1.1. **(Section 2, table 7)**

7 22% of patients with Crohn's disease are on steroids at initial treatment. There is evidence of a steroid-sparing effect in 8% of these patients who are on steroids at follow-up. (**Section 1, table 3**)

8 8% of patients with Crohn's disease had discontinued treatment by follow-up during the audit. In only 11% of these patients was the treatment effective and discontinued. (**Section 5, p 28**)

9 Severity of Crohn's disease at initial treatment was reported as moderate in 49% of patients, severe in 43% and mild in 8%. (**Section 5, p 27**)

10 Recorded adverse events for patients with IBD are uncommon. Acute treatment reactions and infections are the commonest events recorded. Malignancy was reported in 4/2028 patients (0.2%). (**Section 2, table 4**)

11 For patients with Crohn's disease, treatment with a biologic resulted in a response rate of 87% and remission in 70% of patients. (**Section 2, table 2**)

Recommendations

1 Sites should continue to participate in the national biological therapy audit and aim to submit data on **all** appropriate patients. Data can also be entered by taking part in the Personalised Anti-TNF Therapy in Crohn's disease study (PANTS).[3] Data entered in the study will be analysed and included in the next national report, to be published next year.

2 160/80 mg of adalimumab should be used for induction therapy.

3 Clinicians should consider stopping 5-aminosalicylic acid (5-ASA) drugs in patients on biologics with Crohn's disease. Steroids should be weaned and stopped where possible.

4 Sites should routinely assess disease activity at baseline and again at 3- and 12-month follow-up; this measure forms an important part of objective assessment of response to treatment and the quality of care provided by the IBD service.

5 Local teams should encourage patients to complete patient-reported outcome measures (EQ-5D[4] and CCQ12) at baseline and again at 3- and 12-month follow-up; this measure also forms an important part of objective assessment of response to treatment and the quality of care provided by the IBD service.

6 Sites participating in the audit should export their own local data and use them for local analyses, benchmarking and quality improvement activities.

7 The findings and recommendations of this report should be shared at relevant multidisciplinary and clinical governance / audit meetings, and local action plans for implementing change should be devised.

Implementing change: action plan

This action plan has been produced to enable you to take forward the recommendations of this national audit and allows adaptation through the addition of further actions as you feel appropriate for your own service. You can download a copy of this action plan from **www.rcplondon.ac.uk/ibd**.

National recommendation	Action required	Staff responsible	Progress at your site (Include date of review, name of individual responsible for action)
1 Sites should continue to participate in the national biological therapy audit and aim to submit data on **all** appropriate patients. Data can also be entered by taking part in the Personalised Anti-TNF Therapy in Crohn's disease study (PANTS). Data entered in the study will be analysed and included in the next national report, to be published next year.	Eligible sites should participate in either the biological therapy audit or the PANTS research study and submit data on all newly started patients on biologics. Where possible, collaborate with other sites that have a well-established methodology for capturing data on new patients starting on biological therapies	Consultant gastroenterologists IBD nurses Infusion clinic staff	
2 160/80 mg of adalimumab should be used for induction therapy.	Ensure that the appropriate starting dose is in local protocols	Consultant gastroenterologists IBD nurses	
3 Clinicians should consider stopping 5-aminosalicylic acid (5-ASA) drugs in patients on biologics with Crohn's disease. Steroids should be weaned and stopped where possible.	Review concomitant medication of patients on biologics. Consider stopping 5-ASA	Consultant gastroenterologists IBD nurses	
4 Sites should routinely assess disease activity at baseline and again at 3- and 12-month follow-up; this measure forms an important part of objective assessment of response to treatment and the quality of care provided by the IBD service.	Ensure that a mechanism is in place to allow the collection of disease activity scores at baseline and follow-up	Consultant gastroenterologists IBD nurses Infusion clinic staff	

5	Local teams should encourage patients to complete patient-reported outcome measures (EQ-5D and CCQ12) at baseline and again at 3- and 12-month follow-up; this measure also forms an important part of objective assessment of response to treatment and the quality of care provided by the IBD service.	Ensure that a mechanism is in place to allow the collection of quality of life scores at baseline and follow-up. Copies of the scores can be downloaded from the web tool (**www.ibdbiologicsaudit.org/**)	Consultant gastroenterologists IBD nurses Infusion clinic staff	
6	Sites participating in the audit should export their own local data and use them for local analyses, benchmarking and quality improvement activities.	Identify an appropriate time to discuss results and decide priority areas for improvement	NHS managers Consultant gastroenterologists IBD nurses	
7	The findings and recommendations of this report should be shared at relevant multidisciplinary and clinical governance / audit meetings, and local action plans for implementing change should be devised.	Identify an individual to present the findings at an appropriate meeting. Ensure that this activity has been planned and, when planned, that there is capacity in the meeting to review where changes are required and that action plans for implementing changes are devised	NHS managers All members of the IBD team	
8	ENTER THE LOCAL ACTIONS YOU HAVE IDENTIFIED HERE			
9	ENTER THE LOCAL ACTIONS YOU HAVE IDENTIFIED HERE			

1: Introduction and methodology

Introduction

Biological therapies are now an established part of inflammatory bowel disease (IBD) care. Use of these has been increasing rapidly in the UK over the last few years. Clinical trials have demonstrated that the anti-tumour necrosis factor α (TNFα) agents infliximab (IFX) and adalimumab (ADA) are effective treatments for IBD. These drugs can have life-changing effects for patients when other therapies, including surgery, have failed to control the disease adequately. Data that are currently available suggest that adverse events are relatively uncommon, but unselected national data, as collected in this audit, will help to address this issue. Biological therapies are expensive, with a year of treatment for one patient costing roughly £10,000, although it is likely that costs will reduce with the imminent introduction of biosimilar drugs in the UK.

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 IBD patients' views on their quality of life at defined intervals throughout their use of biological therapies.

Methodology

This is a prospective audit, with data collection taking place in 'real time' during the clinical appointment with the patient. Participating sites were 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 on **p 21** of this report.

Definition of a 'site'

Lead clinicians were asked to collect data on the basis of a unified IBD service that would be registered as a named 'site'. This was typically a single hospital within a trust / health board, but where a trust / health board had more than one hospital offering independent IBD services, they entered data for separate 'sites'. Some organisations running a coordinated IBD service across several hospitals with the same staff participated 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. There are 163 adult trusts / health boards eligible to participate in round 4 of the UK IBD audit; of these, 150 (92%) are participating in the biological therapies element and/or in the Personalised Anti-TNF Therapy in Crohn's disease (PANTS) research study. These 150 trusts / health boards provided the 181 sites that submitted data. A list of participating and non-participating sites can be found in **section 6** of this report.

PANTS

Personalised Anti-TNF Therapy in Crohn's disease is a 3-year prospective uncontrolled cohort study investigating primary non-response, loss of response and adverse drug reactions to IFX and ADA in patients with severe active luminal Crohn's disease. The collected clinical data are aligned with the data collected by the biological therapy audit. Relevant anonymised data from the PANTS study will be shared with the project team at the Royal College of Physicians (RCP) for inclusion in the next report of biological therapy use in IBD, scheduled for publication in 2015. The sites submitting data to the PANTS

research study are indicated by an asterisk in the list of participating and non-participating sites in **section 6** of this report.

Inclusion and exclusion criteria

Only those patients with diagnosed IBD, ie ulcerative colitis (UC), Crohn's disease (CD) and IBD type 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 inclusion and exclusion of data in national analyses is detailed in the consort diagram on **p 15** of this report.

Denominators

Denominators throughout the report vary depending upon the number of submissions to which the data analysed relate. 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. To illustrate, 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 and readers should review all table notes and explanatory text provided within the report.

Data collection tool

Security and confidentiality are maintained through the use of site codes. Sites access the dataset by using unique usernames and passwords; only the lead clinician at each site can authorise local access. Data can be saved during, as well as 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 the collection of high-quality data. For an explanation of the different submission types in the biological therapies audit, please see **p 21** of this report.

Site-level data

Owing to low numbers of patients with UC or IBDU, site-level data are restricted to CD only. The IBD programme steering group, having taken statistical advice, has identified a sample size of fewer than six patients as potentially compromising patient anonymity in the age and gender fields in Table 2. Therefore, results in site reports that meet this criterion have been replaced with 'N<6'. In the case of the national report, no data will appear in the 'Your site' columns, but these have been left *in situ* to show the format of the individualised site reports.

Evidence

Guidance referred to within this document is taken from the following.

- National Institute for Health and Care Excellence, 2011. TA187: *Infliximab (review) and adalimumab for the treatment of Crohn's disease*. **www.nice.org.uk/guidance/TA187** [Accessed 17 July 2014].
- 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.
- IBD Standards Group. *Standards for the healthcare of people who have inflammatory bowel disease* (IBD Standards), 2013 update. **www.ibdstandards.org.uk** [Accessed 17 July 2014].

Availability of audit results in the public domain

Full and executive summary copies of this report are available in the public domain via the RCP website (**www.rcplondon.ac.uk/biologics**). The national report of results will be made available to the Department of Health, Healthcare Improvement Scotland, NHS Wales Health and Social Care department and the Department of Health, Social Services and Public Safety in Northern Ireland. A number of key indicators for each of the 181 participating sites are published in the public domain in

section 6 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 a percentage for categorical data, and as median and interquartile range (IQR) for numerical data. This report summarises adult site data provided from those sites that registered to the audit indicating that they provide their IBD service to mainly adult patients. A separate report has been prepared for paediatric IBD services and can be viewed on the RCP website (**www.rcplondon.ac.uk/biologics**). Where measures are comparable, both adult and paediatric data are provided for review.

Section 2: Summary of key results, divided into groups that address the main objectives of the biological therapies audit: safety, efficacy and appropriateness.
Fig 1: Consort diagram
Table 1: Summary of adult patients included in the national analysis
Table 2: Summary table highlighting key items for CD adult and paediatric data comparison
Table 3: Percentage of all patients with CD on any immunosuppressant or any steroid as a concomitant therapy during treatment
Table 4: Percentage of all adult patients who had an adverse reaction recorded at follow-up treatment, by type of reaction
Table 5: Disease activity at initial treatment compared with that at any follow-up treatment within 10–14 weeks for combined patients with CD, UC and IBDU
Table 6: Surgical activity recorded in the 6 months pre-treatment and the 6 months post-treatment with biological therapies for combined patients with CD, UC and IBDU
Table 7: CD adult compliance with a selected TA187 NICE criterion
Table 8: Completion and results of the PROMs questionnaires calculated using EQ-5D[4] and CCQ12

Section 3: Background information to the UK IBD audit and the benefits of participation in the biological therapies audit.

Section 4: Explanation of the role of the biological therapy audit in the treatment of IBD, with information about the licensing of biological therapies and their approval for use. The categories of data entered are explained, as are the improvements made to both the methodology of the audit and the web tool following feedback from participating sites.

Section 5: Full national results for all mandatory data items collected as part of the biological therapy audit. Participating sites that provided sufficient data to be included in national analyses will receive a spreadsheet enabling comparison of their own local data with each national data item in the CD dataset. This section of the report also provides further detail about the IBD-related surgical data and patient-reported outcome measures (PROMs) data and methodology.
Table 9: Surgical procedures that were carried out pre- and post-initiation of biological therapy (ADA and IFX combined) for adult patients with CD
Table 10: Surgical procedures that were carried out pre- and post-initiation of biological therapy (ADA and IFX combined) for adult patients with UC
Table 11: Surgical procedures that were carried out pre- and post-initiation of biological therapy (ADA and IFX combined) for adult patients with IBDU

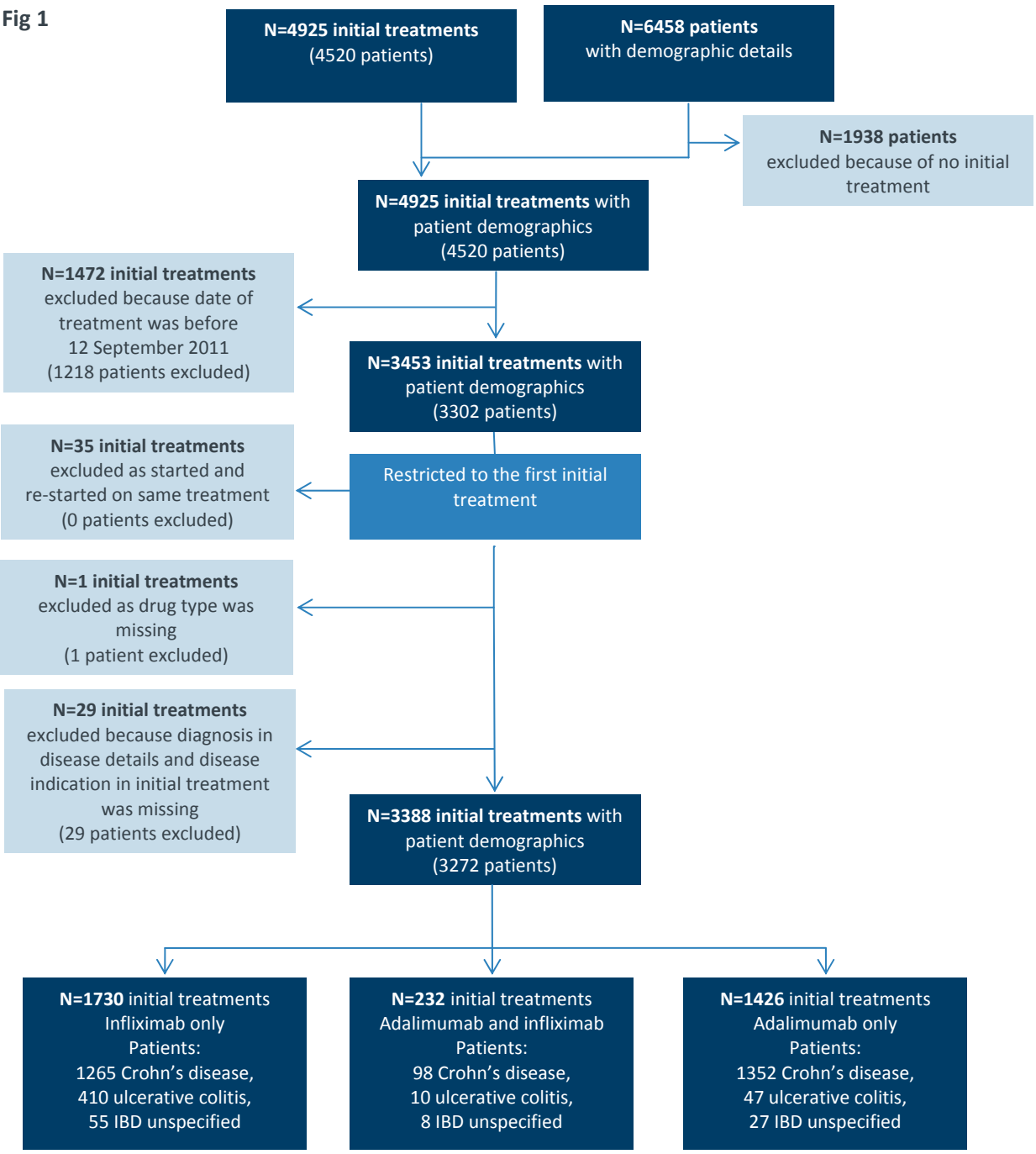
Section 6: Publicly available data from each of the participating sites. This also acts as a list of participating sites.

2: Summary of key results

Consort diagram

On 28 February 2014, there were 6458 individual adult patient demographic submissions entered on the web tool. Readers are reminded to consider 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.
Fig 1 (below) is therefore integral when considering the results in this report. It is also important to note that there are more treatments than patients, as some patients were treated with more than one biological therapy.

Fig 1



All analyses within this report include all patients who were newly started on anti-TNFα treatment from 12 September 2011 (the onset of the audit). See Fig 1 (above) to review the number and reasons for exclusion from analysis.

Key data tables

The tables below use key data items to address the objectives of the biological therapies audit and provide an overall view of the main characteristics of the patient group included.

Table 1 Summary of adult patients included in the national analysis

	CD	YOUR SITE	UC	IBDU	TOTAL
Patients[a]	2715		467	90	3272
Initial treatments	**2813**		**477**	**98**	**3388**
IFX	1363		420	63	1846
ADA	1450		57	35	1542
Follow-up treatments	**5147**		**828**	**216**	**6191**
IFX	3302		760	150	4212
ADA	1845		68	66	1979
All treatments total	**7960**		**1305**	**314**	**9579**

[a]98 patients with CD / 10 with UC / 8 with IBDU were treated with both IFX and ADA.

Table 2 Summary table highlighting key items for CD adult and paediatric data comparison

The table below demonstrates demographic data, disease details and response to therapy in patients with CD treated with either IFX or ADA.

	CD – Adult % (n/N)	CD – Paediatric % (n/N)	YOUR SITE
Percentage of all patients who were classified as having CD (of all patients with CD, UC or IBDU included)	83% (2715/3272)	82% (429/524)	
General patient characteristics			
Gender: male	47% (1282/2715)	62% (267/429)	
Age at diagnosis, years, median (IQR)[a]	(N=2549) 26 (19, 37)	(N=412) 12 (9, 14)	
Age at initial treatment, years, median (IQR)[a]	(N=2549) 35 (25, 48)	(N=412) 14 (12, 16)	
Time from diagnosis to treatment, years, median (IQR)[b]	(N=2553) 5.23 (1.55, 12.21)	(N=414) 1.42 (0.63, 2.97)	
Disease distribution (162 adult patients and 15 paediatric patients had no IBD disease details recorded)			
Terminal ileum (L1)	25% (644/2553)	10% (40/410)	
Colonic (L2)	35% (884/2553)	40% (164/410)	
Ileocolonic (L3)	32% (806/2553)	40% (166/410)	
None of these	9% (219/2553)	10% (40/410)	
Any part of the gut proximal to the terminal ileum (L4)			
Yes	50% (1165/2308)	79% (288/364)	
Perianal involvement			
Yes	33% (643/1955)	54% (146/270)	
Pre-treatment surgery recorded[a]			
Yes	30% (822/2715)	16% (67/429)	
Response to treatment and remission (at any follow-up between 10 and 14 weeks)[a]			
Response to treatment (adult patients – HBI drop of >3; paediatric patients – PCDAI drop of ≥15)	87% (195/224)	77% (53/69)	
Remission achieved (adult patients – HBI score of ≤4; paediatric patients – PCDAI score of ≤10)	70% (170/244)	65% (46/71)	

(Continued overleaf)

Table 2 continued Summary table highlighting key items for CD adult and paediatric data comparison

	CD – Adult % (n/N)	CD – Paediatric % (n/N)	YOUR SITE
Adverse events (at any follow-up treatment)			
Number of adverse events reported	4% (224/5092)	3% (43/1480)	
Number of patients who experienced at least one adverse event	11% (180/1667)	10% (32/316)	

[a]Denominators change to exclude cases where date / disease severity score was not provided.
[b]Where a patient switched treatment, the first treatment that the patient received was used.
HBI = Harvey–Bradshaw index; PCDAI = Paediatric Crohn's Disease Activity Index.

Table 3 Percentage of all patients with CD on any immunosuppressant or any steroid as a concomitant therapy during treatment

	IFX		ADA	
	Initial	Follow-up	Initial	Follow-up
Immunosuppressants[a]	55% (755/1363)	54% (1760/3276)	54% (787/1450)	43% (779/1816)
Steroids[b]	25% (334/1363)	7% (238/3276)	20% (294/1450)	10% (176/1816)

[a]Immunosuppressant group includes azathioprine, mercaptopurine and methotrexate.
[b]Steroid group includes budesonide, hydrocortisone, methylprednisolone and prednisolone.

Audit objective: safety

Table 4 Percentage of all adult patients who had an adverse reaction recorded at follow-up treatment, by type of reaction

Adverse reaction type	% (n/N)
Acute treatment reaction[a]	10% (202/2028)
Infection[b]	5% (95/2028)
Rash[b]	0.9% (19/2028)
Blood abnormality[b]	1% (21/2028)
Drug-induced lupus[b]	0.3% (6/2028)
Serum sickness-like reaction[b]	0.5% (11/2028)
Malignancy[b]	0.2% (4/2028)
Suspected demyelination[b]	0.3% (6/2028)
Headaches[b]	0.1% (3/2028)
Arthritis[b]	0.4% (9/2028)
Psoriasis[b]	0.2% (4/2028)
Cardiac failure[b]	0.1% (2/2028)
Chest pain[b]	0.1% (3/2028)
Alopecia[b]	0.1% (2/2028)
Death[b]	0.1% (3/2028)
Other[b]	2% (33/2028)

[a]All patients who had initial treatment data recorded.
[b]All patients who had initial and follow-up treatment data recorded.

Audit objective: efficacy

Table 5: Disease activity at initial treatment compared with that at any follow-up treatment within 10–14 weeks of treatment for combined patients with CD, UC and IBDU

	Initial treatment	Any follow-up treatment within 10–14 weeks of treatment
Disease activity scores: median (IQR)		
Harvey–Bradshaw index (HBI)	N=1857 6 (3, 10)	N=267 3 (1,6)
Simple Clinical Colitis Activity Index (SCCAI)	N=394 6 (3, 9)	N=44 2 (0,5)

Follow-up treatment category includes any follow-up treatment data entered, and is restricted to those who provided initial treatment data.

Table 6 Surgical activity recorded in the 6 months pre-treatment and the 6 months post-treatment with biological therapies for combined patients with CD, UC and IBDU

Surgical activity	Adult % (n/N)	Paediatric % (n/N)
Number of patients with surgery recorded in the 6 months before starting on biological therapy	5% (177/3272)	7% (36/524)
Number of patients with surgery recorded in the 6 months after starting on biological therapy	4% (128/3272)	5% (27/524)

Further information about the surgical data collected in the biological therapies audit can be found on **p 44** of this report.

Audit objective: appropriateness of prescribing anti-TNFα

Detailed information about the National Institute for Health and Care Excellence (NICE) guidance and recommendations for use of biological therapies in IBD in the UK can be found in **section 4** of this report. Here, one of the NICE criteria from TA187 (1.1) has been used to assess the appropriateness of prescribing anti-TNFα therapy.

Table 7 CD adult compliance with a selected TA187 NICE criterion

NICE (TA187)	National CD data % (n/N)	YOUR SITE
Criterion 1.1 Adults prescribed anti-TNFα should be categorised as having severe active CD and a) have CD that has not responded to conventional therapy, or b) be intolerant of or have contraindications to conventional therapy (mercaptopurine, azathioprine, methotrexate, prednisolone, budesonide, methylprednisolone or hydrocortisone)		
Percentage of patients on biological therapy who had an HBI score of ≥8 prior to commencing anti-TNFα	58% (592/1028)	
Percentage of patients who were treated with conventional therapy at time of or prior to commencing biological therapy	82% (2237/2715)	
Percentage of patients on biological therapy who were appropriately prescribed anti-TNFα in compliance with NICE criterion 1.1 (TA187)	54% (552/1028)	

Audit objective: patient-reported outcome measures

Table 8: Completion and results of the PROMs questionnaires calculated using EQ-5D[4] and CCQ12

IBDPROM	Initial treatment	Follow-up treatment[a]
Number of treatments	3388	6191
Number with EQ-5D PROM data completed	14% (485/3388)	9% (544/6191)
EQ-5D PROM score: median (IQR)	0.725 (0.587, 0.796)	0.796 (0.725, 1)
Number with CCQ12 PROM data completed	13% (424/3388)	8% (490/6191)
CCQ12 PROM score: median (IQR)	75 (44, 103)	37 (16, 64)

[a]Follow-up treatment category includes any follow-up treatment PROMs data entered, and is restricted to those who provided initial treatment PROMs data.

Further information about the adult quality of life measures used in the biological therapies audit (EQ-5D and CCQ12) can be found on **pp 46–7** of this report.

3: 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 rise; 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. Reported prevalence is as high as 505 and 322 per 100,000 persons for UC and CD respectively in Europe.[5] IBD most commonly first presents 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. 20–30% of patients with UC will require colectomy, and approximately 50–70% of patients with CD require surgery over their lifetime. The main symptoms 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 a poor quality of life. In addition, there are 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.

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 through reporting on inpatient experience and patient-reported outcome measures. The biological therapies audit is one element of the wider UK IBD audit.

This report follows the national report published last year. This report builds on the previous report, as it is a continuous audit with increasing rates of participation and provides further evidence about the safety, efficacy and appropriate use of biological therapies. Furthermore, this report 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 anti-TNFα treatment
- monitor and encourage improved management at both patient and service levels, data on adverse events, dose escalation and treatment regimes
- capture the views of local patients 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.

4: The biological therapies audit

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

Infliximab

IFX (Remicade®) 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. Typically, IFX is administered via an intravenous infusion during a hospital appointment, supervised by a suitably qualified health professional.

Adalimumab

ADA (Humira™) is a recombinant human immunoglobulin (IgG1) monoclonal antibody containing only human peptide sequences. Typically, ADA is 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.

Licence in the UK

IFX and ADA are licensed for treatment of moderately to severely active CD in adult patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant, or who are intolerant to or have medical contraindications for such therapies. IFX is also licensed for the treatment of active fistulating CD. In children and adolescents aged 6–17 years, IFX is licensed for the treatment of severe, active CD and for the treatment of severely active UC. ADA is also licensed for the treatment of severe, active CD in paediatric patients (aged 6–17 years).

Approval in the UK

NICE, in a multitechnology appraisal (TA187),[2] recommends that IFX and ADA are 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). They recommend that IFX and ADA 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 have their disease reassessed to determine whether ongoing treatment is still clinically appropriate.

NICE, in a technology appraisal (TA163),[6] has also recommended IFX as an option for the treatment of acute exacerbations of severely active UC only in patients for whom ciclosporin is contraindicated or clinically inappropriate. They have not recommended its use for the maintenance of remission of UC. The Scottish Medicines Consortium (SMC) has not, however, recommended use of IFX for moderate to actively severe UC.

NICE and the SMC recommend that IFX is used within its licensed indication for the treatment of patients aged 6–17 years with severely active CD whose disease has not responded to conventional therapy (including immunosuppressive and/or corticosteroid treatments). They recommend that the need to continue treatment is reviewed at least annually. The SMC recommends treatment with IFX for children with severely active UC.

Data entry to 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 disease details, initial anti-TNFα treatment, follow-up anti-TNFα treatment and IBD-related surgery. Once all mandatory fields are completed within a category, the data are locked and 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 this 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 to the participating site only. Details of the patient's consultant and GP can also be entered.

IBD disease details category

This section requires sites to provide details of the IBD history of a patient, 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 anti-TNFα treatment category

Here, the details of the initial or baseline anti-TNFα treatment are provided. The site indicates whether the patient is being treated with either ADA or IFX and the system generates the appropriate questions for either option. Information is collected with regard to pre-treatment investigations and screening up to the point of completion or abandonment of the treatment, with details of any treatment reactions that may occur.

Follow-up anti-TNFα treatment category

Each follow-up treatment that is entered must relate to a previously entered initial anti-TNFα treatment submission. An unlimited number of follow-up treatments can be completed to allow continuous data collection as the patient continues to be treated with biological therapies. The outcome of each follow-up treatment must be provided to state whether treatment will continue or be stopped. 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 anti-TNFα treatment submissions. This allows identification of any escalation of treatment that is required while a patient is being treated with biological therapy.

PROMs (patient-reported outcome measures) category

PROM data are collected at initial anti-TNFα treatment and then again at 3- and 12-month follow-up treatments. For further information, about PROM data, see **p 46**.

Continued development of the biological therapies audit web tool

The biological therapies audit web tool has been updated and developed in line with the requirements identified through feedback from sites. The changes below summarise some examples of the adaptations made to date. There are plans to make further changes following this report.

Existing patients

One of the first adaptations of the system was to allow the submission of data for patients who are already established on biological therapy, in addition to those who are newly started on these medications. 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 who are already established on anti-TNFα therapy; data are collected for these patients at only those sites that wish to use the data at a local level.

Reporting functions

Sites can produce both patient and treatment summary reports when required.

Patient summary report – provides a printable summary of all treatment provided for a specific patient over time; details of any adverse events, acute reactions and relevant surgery are listed. A graphical display of the patient's disease severity scoring 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 – provides 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 and also included in correspondence with a GP to inform them of the treatment provided to their patient.

Data import function

The import function allows users to upload data held in other spreadsheets or registers directly into the web tool via the use of a simple template in order to register patients for the audit.

Reduction of mandatory fields

Following feedback from users regarding the length of time taken to enter submissions onto the web tool, the numbers of mandatory fields have been reduced by approximately 50%, making the process of entering and locking data far faster and simpler.

System security of the biological therapies audit web tool

The 'UK IBD audit biological therapies audit system and hosted server security details' document is available on the RCP website (**www.rcplondon.ac.uk/biologics**) and outlines the system security information provided to all sites upon invitation to participate in the audit. 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 'Securing web infrastructure and supporting services good practice guideline'.

Further details can be found on the following: 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).

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 seen only by the 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 uses of their data by means of information leaflets and posters provided by the UK IBD audit project team.

5: Full adult national audit results tables

Crohn's disease: IBD details

Crohn's disease IBD details	Frequency (%)	
	Infliximab	Adalimumab
	National (N=1279)	National (N=1370)
Diagnosis		
Maximal disease distribution at the time of decision to initiate biological therapy, as defined by the Montreal classification		
Terminal ileum (L1)	24% (302/1279)	27% (364/1370)
Colonic (L2)	39% (494/1279)	31% (424/1370)
Ileocolonic (L3)	29% (372/1279)	34% (463/1370)
None of these	9% (111/1279)	9% (119/1370)
Any part of the gut proximal to the terminal ileum (L4)		
Yes	46% (523/1145)	56% (701/1248)
Perianal involvement?		
Yes	36% (360/1003)	30% (301/1013)
Date of diagnosis		
<1 year ago	26% (338/1279)	15% (204/1370)
1–5 years ago	35% (447/1279)	34% (472/1370)
6–10 years ago	13% (172/1279)	16% (214/1370)
>10 years ago	25% (322/1279)	35% (480/1370)

Crohn's disease: initial anti-TNFα treatment

Crohn's disease Initial anti-TNFα treatment	Frequency (%)	
	Infliximab	Adalimumab
	National (N=1363)	National (N=1450)
Consent		
Was informed consent to receive anti-TNFα treatment taken from this patient?		
Yes	97% (1328/1363)	99% (1439/1450)
No	3% (35/1363)	0.8% (11/1450)
If yes, was this written or verbal?		
Verbal	84% (1109/1328)	83% (1191/1439)
Written	16% (219/1328)	17% (248/1439)
Treatment details		
Time between date of decision to start and date of initial treatment (first loading dose)		
Median (IQR), days	15 (6, 34)	18 (8, 38)
What was the clinical indication for this treatment?		
Severe perianal Crohn's disease	19% (257/1362)	9% (132/1447)
Active luminal Crohn's disease	77% (1051/1362)	87% (1259/1447)
Fistulating Crohn's disease	2% (21/1362)	0.5% (7/1447)
Other clinical indication	0.5% (7/1362)	0.6% (9/1447)
Not known	2% (26/1362)	3% (40/1447)
Dose given at this infusion (mg/kg)		
5	100% (1115/1120)	NA
10	0.4% (4/1120)	NA
Other	0.1% (1/1120)	NA
Duration of infusion (mins)		
30	0.4% (4/1076)	NA
60	1% (13/1076)	NA
120	96% (1035/1076)	NA
180	2% (23/1076)	NA
240	0.1% (1/1076)	NA
Infusion completion outcome		
Completed successfully at prescribed rate	98% (1332/1363)	NA
Completed successfully at lower rate	0.9% (12/1363)	NA
Repeat infusion at lower rate and discontinued	0.1% (1/1363)	NA
Infusion discontinued and not restarted	1% (17/1363)	NA
Other	0.1% (1/1363)	NA

NA = not applicable.

Crohn's disease Initial anti-TNFα treatment	Frequency (%)	
	Infliximab	Adalimumab
	National (N=1363)	National (N=1450)
Treatment details continued		
Induction dose (mg)		
160/80	NA	77% (1112/1449)
80/40	NA	23% (333/1449)
Other	NA	0.3% (4/1449)
Planned maintenance dose		
40 mg every other week	NA	95% (1370/1449)
40 mg every week	NA	5% (69/1449)
Other	NA	0.7% (10/1449)
Were any acute reactions recorded for this treatment?		
Yes	2% (30/1363)	2% (27/1450)
Which acute reactions? (more than one may have been selected)		
Angioedema of upper airway	0.1% (2/1363)	0.1% (2/1450)
Bronchospasm (cough/wheeze/dyspnoea)	0.6% (8/1363)	0.1% (1/1450)
Chills	0% (0/1363)	0.1% (1/1450)
Dizziness	0.3% (4/1363)	0.1% (2/1450)
Fatigue	0.1% (1/1363)	0% (0/1450)
Fever	0.4% (6/1363)	0.2% (3/1450)
Flushing	0.9% (12/1363)	0.1% (1/1450)
Headache	0.5% (7/1363)	0.1% (1/1450)
Hypotension	0.2% (3/1363)	0% (0/1450)
Itching	0.7% (9/1363)	0.2% (3/1450)
Nausea	0.4% (5/1363)	0.3% (5/1450)
Panic attacks	0.1% (1/1363)	0% (0/1450)
Rash	0.4% (6/1363)	0.6% (8/1450)
Urticaria	0.1% (1/1363)	0.1% (1/1450)
Other	0.4% (5/1363)	0.3% (5/1450)

NA = not applicable.

Crohn's disease Initial anti-TNFα treatment	Frequency (%)	
	Infliximab	Adalimumab
	National (N=1363)	National (N=1450)
Treatment details continued		
Is the patient receiving any concomitant therapies for the management of IBD at the time of this treatment?		
Yes	74% (1008/1363)	69% (998/1450)
If yes, indicate which concomitant therapies (more than one may have been selected)		
Azathioprine / mercaptopurine	50% (686/1363)	48% (691/1450)
Methotrexate	5% (70/1363)	7% (100/1450)
Steroids	25% (334/1363)	20% (295/1450)
5-ASA	18% (246/1363)	16% (235/1450)
Antibiotics	2% (30/1363)	1% (16/1450)
Dietary therapy	4% (48/1363)	2% (34/1450)
Ciclosporin	0.2% (3/1363)	0% (0/1450)
Mycophenolate	0.3% (4/1363)	0.1% (1/1450)
Other	0.7% (9/1363)	1% (16/1450)
On any immunosuppressant (azathioprine, mercaptopurine or methotrexate)	55% (755/1363)	54% (787/1450)
Has the patient failed to respond or are they intolerant to immunosuppressive drugs / corticosteroids?		
Yes	55% (550/993)	67% (674/1004)
If yes, indicate which previous therapies (more than one may have been selected)		
Azathioprine / mercaptopurine	72% (398/550)	70% (471/676)
Methotrexate	10% (55/550)	16% (106/676)
Steroids	37% (203/550)	28% (192/676)
Anti-TNFα	13% (72/550)	33% (223/676)
5-ASA	26% (145/550)	20% (134/676)
Dietary therapy	4% (23/550)	4% (28/676)
Antibiotics	0.9% (5/550)	1% (7/676)
Ciclosporin	0.5% (3/550)	0.1% (1/676)
Tacrolimus	0% (0/550)	0.1% (1/676)
Topical	0.2% (1/550)	0.1% (1/676)
Mycophenolate	0.4% (2/550)	0.1% (1/676)
Other	0.9% (5/550)	0.3% (2/676)
On any immunosuppressant (azathioprine, mercaptopurine or methotrexate)	74% (407/550)	74% (501/676)
Disease severity score		
Severity of disease		
Mild	7% (40/564)	9% (48/563)
Moderate	47% (267/564)	50% (283/563)
Severe	46% (257/564)	41% (232/563)

5-ASA = 5-aminosalicylic acid.

Crohn's disease: follow-up anti-TNFα treatment

Crohn's disease Follow-up anti-TNFα treatment (Includes all follow-up treatment entered at any time after initial treatment)	Frequency (%)	
	Infliximab	Adalimumab
	National (N=3302)	National (N=1845)
Follow-up treatment details		
Was the patient:		
Seen for follow-up?	99% (3284/3302)	99% (1821/1844)
Lost to follow-up?	0.1% (2/3302)	0.3% (6/1844)
Transitioned to adult care?	0.1% (2/3302)	0% (0/1844)
Transferred to another service?	0.3% (9/3302)	0.7% (13/1844)
Deceased?	0.2% (5/3302)	0.2% (4/1844)
Time between date of initial treatment and date of follow-up		
Median (IQR), days	150 (42, 320)	156 (66, 332)
Current infliximab dose number		
0–5	61% (2003/3274)	NA
6–10	27% (876/3274)	NA
>10	12% (395/3274)	NA
Infliximab dose given at this treatment (mg/kg)		
5	98% (3207/3276)	NA
10	2% (62/3276)	NA
Other	0.2% (7/3276)	NA
Continue infliximab treatment plan		
Continue treatment with infliximab	94% (3074/3276)	NA
Stop treatment with infliximab	6% (202/3276)	NA
Review of adalimumab treatment plan		
Continue treatment with adalimumab	NA	90% (1626/1816)
Stop treatment with adalimumab	NA	10% (190/1816)
If treatment was stopped, what were the reasons for stopping?		
Treatment effective and discontinued	12% (24/202)	11% (21/190)
Loss of response	12% (25/202)	19% (36/190)
Poor response	23% (47/202)	25% (48/190)
Side effects / adverse events	40% (80/202)	34% (64/190)
Patient became pregnant since initiating anti-TNFα treatment	3% (7/202)	3% (6/190)
Patient choice	4% (8/202)	5% (9/190)
Other	5% (11/202)	3% (6/190)

NA = not applicable.

Crohn's disease Follow-up anti-TNFα treatment (Includes all follow-up treatment entered at any time after initial treatment)	Frequency (%)	
	Infliximab	Adalimumab
	National (N=3302)	National (N=1845)
Follow-up treatment details continued		
If continuing adalimumab treatment, what is the planned continued treatment frequency?		
Every week	NA	11% (178/1626)
Every other week	NA	89% (1448/1626)
If continuing adalimumab treatment, what is the planned continued treatment dose? (mg)		
20/25	NA	0.1% (1/1626)
40	NA	95% (1552/1626)
80	NA	4% (73/1626)
Did the patient report complete compliance with the maintenance regime since the last adalimumab review?		
Yes	NA	95% (1690/1784)
No	NA	5% (94/1784)
If incomplete compliance, state reason (more than one may have been selected)		
Number of missed doses	NA	21% (20/94)
Increased interval between doses	NA	11% (10/94)
Patient missed out some treatment weeks	NA	28% (26/94)
Patient stopped treatment	NA	27% (25/94)
Other compliance difference	NA	20% (19/94)
Did the patient report any acute reactions?		
Yes	2% (73/3276)	4% (66/1816)
Which acute reactions? (more than one may have been selected)		
Angioedema of upper airway	0.2% (6/3276)	0% (0/1816)
Arthralgia	0% (1/3276)	0% (0/1816)
Chest pain	0.1% (4/3276)	0% (0/1816)
Chills	0.2% (8/3276)	0.1% (2/1816)
Dizziness	0.5% (15/3276)	0.3% (5/1816)
Fatigue	0.2% (7/3276)	0.3% (6/1816)
Fever	0.1% (2/3276)	0.2% (3/1816)
Flushing	1% (33/3276)	0.2% (3/1816)
Headache	0.5% (16/3276)	0.2% (4/1816)
Hypotension	0.3% (9/3276)	0.1% (1/1816)
Injection site reaction	0% (0/3276)	0.4% (8/1816)
Itching	0.4% (13/3276)	0.9% (17/1816)
Nausea	0.4% (14/3276)	0.4% (7/1816)
Panic attacks	0.2% (5/3276)	0% (0/1816)
Rash	0.4% (12/3276)	2% (29/1816)
Urticaria	0% (1/3276)	0.4% (7/1816)
Other	0.3% (10/3276)	0.2% (3/1816)

Crohn's disease Follow-up anti-TNFα treatment (Includes all follow-up treatment entered at any time after initial treatment)	Frequency (%) Infliximab National (N=3302)	 Adalimumab National (N=1845)
Follow-up treatment details continued		
Is the patient currently receiving any other therapies for the management of IBD?		
Yes	65% (2126/3276)	56% (1020/1816)
If yes, indicate which other therapies (more than one may have been selected)		
Azathioprine / mercaptopurine	50% (1640/3276)	38% (698/1816)
Methotrexate	4% (120/3276)	5% (82/1816)
Steroids	7% (238/3276)	10% (176/1816)
5-ASA	15% (507/3276)	12% (224/1816)
Antibiotics	0.5% (16/3276)	1% (20/1816)
Dietary therapy	0.9% (31/3276)	2% (31/1816)
Mycophenolate	0.1% (3/3276)	0% (0/1816)
Topical	0% (0/3276)	0.2% (3/1816)
Other	0.4% (12/3276)	2% (38/1816)
On any immunosuppressant (azathioprine, mercaptopurine or methotrexate)	54% (1760/3276)	43% (779/1816)
Were there any adverse events since the last review?		
Yes	3% (111/3276)	6% (113/1816)
What adverse events? (more than one may have been selected)		
Alopecia	0% (1/3276)	0.1% (1/1816)
Arthralgia	0.2% (6/3276)	0.2% (3/1816)
Blood abnormality	0.2% (8/3276)	0.6% (11/1816)
Cardiac failure	0.1% (2/3276)	0% (0/1816)
Chest pain	0.1% (2/3276)	0.1% (1/1816)
Death	0.1% (3/3276)	0% (0/1816)
Drug-induced lupus	0% (1/3276)	0.3% (5/1816)
Headache	0.1% (3/3276)	0% (0/1816)
Infection	1% (49/3276)	3% (53/1816)
Malignancy	0.1% (3/3276)	0.1% (2/1816)
Psoriaform rash	0% (1/3276)	0.1% (2/1816)
Rash	0.3% (9/3276)	0.6% (10/1816)
Serum sickness-like reaction	0.4% (13/3276)	0% (0/1816)
Suspected demyelination	0% (1/3276)	0.2% (3/1816)
Other adverse event	0.3% (9/3276)	1% (22/1816)
Disease severity score		
Severity of disease		
Mild	57% (1038/1834)	52% (535/1038)
Moderate	28% (517/1834)	34% (353/1038)
Severe	15% (279/1834)	14% (149/1038)

Ulcerative colitis: IBD disease details

Ulcerative colitis IBD details	Frequency (%)	
	Infliximab	Adalimumab
	National (N=396)	National (N=55)
Diagnosis		
Maximal disease distribution at the time of decision to initiate biological therapy, as defined by the Montreal classification		
Proctitis (E1)	6% (23/395)	9% (5/55)
Left sided (E2)	46% (184/395)	45% (25/55)
Extensive (E3)	47% (188/395)	45% (25/55)
Date of diagnosis		
<1 year ago	35% (140/396)	20% (11/55)
1–5 years ago	35% (138/396)	53% (29/55)
6–10 years ago	14% (55/396)	11% (6/55)
>10 years ago	16% (63/396)	16% (9/55)

Ulcerative colitis: initial anti-TNFα treatment

Ulcerative colitis Initial anti-TNFα treatment	Frequency (%)	
	Infliximab	Adalimumab
	National (N=420)	National (N=57)
Consent		
Was informed consent to receive anti-TNFα treatment taken from this patient?		
Yes	99% (415/420)	100% (57/57)
No	1% (5/420)	0% (0/57)
If yes, was this written or verbal?		
Verbal	77% (320/415)	77% (44/57)
Written	23% (95/415)	23% (13/57)
Treatment details		
Time between date of decision to start and date of initial treatment (first loading dose)		
Median (IQR), days	5 (1, 15)	20 (7, 32)
What was the clinical indication for this treatment?		
Acute severe ulcerative colitis	62% (260/419)	32% (18/57)
Chronic refractory ulcerative colitis	35% (147/419)	53% (30/57)
Other clinical indication	2% (9/419)	11% (6/57)
Not known	0.7% (3/419)	5% (3/57)
Dose given at this infusion (mg/kg)		
5	99% (351/353)	NA
10	0.6% (2/353)	NA
Duration of infusion (mins)		
60	0.6% (2/346)	NA
120	96% (333/346)	NA
180	3% (11/346)	NA
Infusion completion outcome		
Completed successfully at prescribed rate	97% (408/420)	NA
Completed successfully at lower rate	1% (5/420)	NA
Infusion discontinued and not restarted	2% (7/420)	NA
Induction dose (mg)		
160/80	NA	86% (49/57)
80/40	NA	14% (8/57)
Planned maintenance dose		
40 mg every other week	NA	95% (54/57)
40 mg every week	NA	5% (3/57)

NA = not applicable.

Ulcerative colitis Initial anti-TNFα treatment	Frequency (%)	
	Infliximab	Adalimumab
	National (N=420)	National (N=57)
Treatment details continued		
Were any acute reactions recorded for this treatment?		
Yes	1% (6/420)	0% (0/57)
Which acute reactions? (more than one may have been selected)		
Bronchospasm (cough/wheeze/dyspnoea)	0.2% (1/420)	0% (0/57)
Dizziness	0.5% (2/420)	0% (0/57)
Fatigue	0.2% (1/420)	0% (0/57)
Fever	0.2% (1/420)	0% (0/57)
Flushing	0.7% (3/420)	0% (0/57)
Headache	0.5% (2/420)	0% (0/57)
Hypotension	0.2% (1/420)	0% (0/57)
Nausea	0.5% (2/420)	0% (0/57)
Other	0.2% (1/420)	0% (0/57)
Is the patient receiving any concomitant therapies for the management of IBD at the time of this treatment?		
Yes	86% (361/420)	81% (46/57)
If yes, indicate which concomitant therapies (more than one may have been selected)		
Azathioprine / mercaptopurine	50% (212/420)	33% (19/57)
Methotrexate	3% (13/420)	11% (6/57)
Steroids	49% (206/420)	33% (19/57)
5-ASA	49% (204/420)	39% (22/57)
Antibiotics	2% (7/420)	2% (1/57)
Dietary therapy	0.2% (1/420)	0% (0/57)
Tacrolimus	0.2% (1/420)	0% (0/57)
Topical	0% (0/420)	2% (1/57)
Mycophenolate	0.7% (3/420)	0% (0/57)
Other	1% (4/420)	2% (1/57)
On any immunosuppressant (azathioprine, mercaptopurine or methotrexate)	54% (225/420)	44% (25/57)

5-ASA = 5-aminosalicylic acid.

Ulcerative colitis Initial anti-TNFα treatment	Frequency (%)	
	Infliximab	Adalimumab
	National (N=420)	National (N=57)
Treatment details continued		
Has the patient failed to respond or are they intolerant to immunosuppressive drugs / corticosteroids?		
Yes	57% (196/341)	76% (38/50)
If yes, indicate which previous therapies (more than one therapy may have been selected)		
Azathioprine / mercaptopurine	70% (137/195)	71% (27/38)
Methotrexate	7% (14/195)	16% (6/38)
Steroids	51% (100/195)	34% (13/38)
Anti-TNFα	4% (7/195)	53% (20/38)
5-ASA	42% (83/195)	34% (13/38)
Antibiotics	0.5% (1/195)	0% (0/38)
Ciclosporin	3% (5/195)	3% (1/38)
Other	0.5% (1/195)	3% (1/38)
On any immunosuppressant (azathioprine, mercaptopurine or methotrexate)	72% (141/195)	74% (28/38)
Disease severity score		
Severity of disease		
Mild	4% (9/217)	13% (4/32)
Moderate	25% (55/217)	44% (14/32)
Severe	71% (153/217)	44% (14/32)

5-ASA = 5-aminosalicylic acid.

Ulcerative colitis: follow-up anti-TNFα treatment

Ulcerative colitis Follow-up anti-TNFα treatment (Includes all follow-up treatment entered at any time after initial treatment)	Frequency (%)	
	Infliximab	Adalimumab
	National (N=760)	National (N=68)
Follow-up treatment details		
Was the patient:		
Seen for follow-up?	99% (756/760)	99% (67/68)
Lost to follow-up?	0.1% (1/760)	0% (0/68)
Transferred to another service?	0.4% (3/760)	1% (1/68)
Time between date of initial treatment and date of follow-up		
Median (IQR), days	98 (30, 238)	88 (38, 204)
Current infliximab dose number		
0–5	70% (531/755)	NA
6–10	20% (149/755)	NA
>10	10% (75/755)	NA
Infliximab dose given at this treatment (mg/kg)		
5	99% (744/754)	NA
10	1% (9/754)	NA
Other	0.1% (1/754)	NA
Continue infliximab treatment plan		
Continue treatment with infliximab	85% (641/754)	NA
Stop treatment with infliximab	15% (113/754)	NA
Review of adalimumab treatment plan		
Continue treatment with adalimumab	NA	85% (57/67)
Stop treatment with adalimumab	NA	15% (10/67)
If treatment was stopped, what were the reasons for stopping?		
Treatment effective and discontinued	29% (33/113)	10% (1/10)
Loss of response	6% (7/113)	10% (1/10)
Poor response	18% (20/113)	50% (5/10)
Side effects / adverse events	15% (17/113)	20% (2/10)
Patient became pregnant since initiating anti-TNFα treatment	0% (0/113)	10% (1/10)
Patient choice	0.9% (1/113)	0% (0/10)
Funding	14% (16/113)	0% (0/10)
NICE	11% (12/113)	0% (0/10)
Other	6% (7/113)	0% (0/10)

NA = not applicable.

Ulcerative colitis **Follow-up anti-TNFα treatment** (Includes all follow-up treatment entered at any time after initial treatment)	**Frequency (%)**	
	Infliximab	**Adalimumab**
	National (N=760)	**National (N=68)**
Follow-up treatment details continued		
If continuing adalimumab treatment, what is the planned continued treatment frequency?		
Every week	NA	4% (2/57)
Every other week	NA	96% (55/57)
If continuing adalimumab treatment, what is the planned continued treatment dose? (mg)		
80	NA	5% (3/57)
40	NA	95% (54/57)
Did the patient report complete compliance with the maintenance regime since the last adalimumab review?		
Yes	NA	95% (61/64)
No	NA	5% (3/64)
If incomplete compliance, state reason		
Patient missed out some treatment weeks	NA	33% (1/3)
Patient stopped treatment	NA	33% (1/3)
Other compliance difference	NA	33% (1/3)
Did the patient report any acute reactions?		
Yes	3% (23/754)	3% (2/67)
Which acute reactions? (more than one may have been selected)		
Angioedema of upper airway	0.3% (2/754)	0% (0/67)
Arthralgia	0.4% (3/754)	0% (0/67)
Chills	0.1% (1/754)	0% (0/67)
Dizziness	0.1% (1/754)	1% (1/67)
Flushing	0.9% (7/754)	0% (0/67)
Headache	0.3% (2/754)	1% (1/67)
Hypotension	0.5% (4/754)	0% (0/67)
Injection site reaction	0% (0/754)	1% (1/67)
Itching	0.3% (2/754)	0% (0/67)
Nausea	0.1% (1/754)	0% (0/67)
Panic attacks	0.1% (1/754)	0% (0/67)
Rash	0.7% (5/754)	0% (0/67)
Urticaria	0.1% (1/754)	0% (0/67)
Other	0.5% (4/754)	0% (0/67)

NA = not applicable.

Ulcerative colitis **Follow-up anti-TNFα treatment** (Includes all follow-up treatment entered at any time after initial treatment)	**Frequency (%)**	
	Infliximab	**Adalimumab**
	National (N=760)	**National (N=68)**
Follow-up treatment details continued		
Is the patient currently receiving any other therapies for the management of IBD?		
Yes	77% (584/754)	76% (51/67)
If yes, indicate which other therapies (more than one may have been selected)		
Azathioprine / mercaptopurine	54% (410/754)	42% (28/67)
Methotrexate	4% (29/754)	3% (2/67)
Steroids	16% (117/754)	13% (9/67)
5-ASA	41% (312/754)	42% (28/67)
Antibiotics	0.5% (4/754)	0% (0/67)
Dietary therapy	0.1% (1/754)	0% (0/67)
Mycophenolate	0.4% (3/754)	0% (0/67)
Topical	0.4% (3/754)	2% (1/67)
Other	0.5% (4/754)	0% (0/67)
On any immunosuppressant (azathioprine, mercaptopurine or methotrexate)	58% (439/754)	45% (30/67)
Were there any adverse events since the last review?		
Yes	2% (16/754)	3% (2/67)
What adverse events?		
Blood abnormality	0.1% (1/754)	0% (0/67)
Infection	1% (10/754)	2% (1/67)
Psoriaform rash	0.1% (1/754)	0% (0/67)
Rash	0.1% (1/754)	0% (0/67)
Other adverse event	0.4% (3/754)	2% (1/67)
Disease severity score		
Severity of disease		
Mild	60% (309/519)	51% (19/37)
Moderate	27% (139/519)	16% (6/37)
Severe	14% (71/519)	32% (12/37)

5-ASA = 5-aminosalicylic acid.

IBD type unclassified: IBD details

IBD type unclassified IBD details	Frequency (%)	
	Infliximab	Adalimumab
	National (N=60)	National (N=35)
Diagnosis		
Maximal disease distribution at the time of decision to initiate biological therapy, as defined by the Montreal classification		
Proctitis (E1)	2% (1/60)	6% (2/35)
Left sided (E2)	40% (24/60)	57% (20/35)
Extensive (E3)	58% (35/60)	37% (13/35)
Date of diagnosis		
<1 year ago	27% (16/60)	14% (5/35)
1–5 years ago	58% (35/60)	37% (13/35)
6–10 years ago	5% (3/60)	20% (7/35)
>10 years ago	10% (6/60)	29% (10/35)

IBD type unclassified: initial anti-TNFα treatment

IBD type unclassified Initial anti-TNFα treatment	Frequency (%)	
	Infliximab	Adalimumab
	National (N=63)	National (N=35
Consent		
Was informed consent to receive anti-TNFα treatment taken from this patient?		
Yes	100% (63/63)	100% (35/35)
If yes, was this written or verbal?		
Verbal	70% (44/63)	91% (32/35)
Written	30% (19/63)	9% (3/35)
Treatment details		
Time between date of decision to start and date of initial treatment (first loading dose)		
Median (IQR), days	13 (5, 21)	13 (3, 22)
What was the clinical indication for this treatment?		
Acute severe IBD type unclassified	63% (39/62)	43% (15/35)
Chronic refractory IBD type unclassified	37% (23/62)	51% (18/35)
Other clinical indication	0% (0/62)	6% (2/35)
Dose given at this infusion (mg/kg)		
5	98% (53/54)	NA
10	2% (1/54)	NA
Duration of infusion (mins)		
120	98% (51/52)	NA
180	2% (1/52)	NA
Infusion completion outcome		
Completed successfully at prescribed rate	97% (61/63)	NA
Infusion discontinued and not restarted	3% (2/63)	NA
Induction dose (mg)		
160/80	NA	63% (22/35)
80/40	NA	34% (12/35)
Other	NA	3% (1/35)
Planned maintenance dose		
40 mg every other week	NA	94% (33/35)
40 mg every week	NA	6% (2/35)
Were any acute reactions recorded for this treatment?		
Yes	0% (0/62)	0% (0/35)

NA = not applicable.

IBD type unclassified Initial anti-TNFα treatment	Frequency (%)	
	Infliximab	Adalimumab
	National (N=63)	National (N=35)
Treatment details continued		
Is the patient receiving any concomitant therapies for the management of IBD at the time of this treatment?		
Yes	90% (56/62)	83% (29/35)
If yes, indicate which concomitant therapies (more than one may have been selected)		
Azathioprine / mercaptopurine	48% (30/62)	54% (19/35)
Methotrexate	3% (2/62)	6% (2/35)
Steroids	50% (31/62)	34% (12/35)
5-ASA	53% (33/62)	37% (13/35)
Antibiotics	2% (1/62)	3% (1/35)
Other	0% (0/62)	3% (1/35)
On any immunosuppressant (azathioprine, mercaptopurine or methotrexate)	52% (32/62)	60% (21/35)
Has the patient failed to respond or are they intolerant to immunosuppressive drugs / corticosteroids?		
Yes	61% (30/49)	70% (19/27)
If yes, indicate which previous therapies (more than one may have been selected)		
Azathioprine / mercaptopurine	67% (20/30)	58% (11/19)
Methotrexate	13% (4/30)	11% (2/19)
Steroids	27% (8/30)	37% (7/19)
Anti-TNFα	3% (1/30)	53% (10/19)
5-ASA	33% (10/30)	42% (8/19)
Ciclosporin	7% (2/30)	0% (0/19)
On any immunosuppressant (azathioprine, mercaptopurine or methotrexate)	70% (21/30)	58% (11/19)
Disease severity score		
Severity of disease		
Mild	5% (1/20)	9% (1/11)
Moderate	50% (10/20)	64% (7/11)
Severe	45% (9/20)	27% (3/11)

5-ASA = 5-aminosalicylic acid.

IBD type unclassified: follow-up anti-TNFα treatment

IBD type unclassified Follow-up anti-TNFα treatment (Includes all follow-up treatment entered at any time after initial treatment)	Frequency (%)	
	Infliximab	Adalimumab
	National (N=150)	National (N=66)
Follow-up treatment details		
Was the patient:		
Seen for follow-up?	100% (150/150)	100% (66/66)
Time between date of initial treatment and date of follow-up		
Median (IQR), days	163 (48,336)	172 (77,298)
Current infliximab dose number		
0–5	54% (81/150)	NA
6–10	26% (39/150)	NA
>10	20% (30/150)	NA
Infliximab dose given at this treatment (mg/kg)		
5	98% (147/150)	NA
10	2% (3/150)	NA
Continue infliximab treatment plan		
Continue treatment with infliximab	92% (138/150)	NA
Stop treatment with infliximab	8% (12/150)	NA
Review of adalimumab treatment plan		
Continue treatment with adalimumab	NA	88% (58/66)
Stop treatment with adalimumab	NA	12% (8/66)
If treatment was stopped, what were the reasons for stopping?		
Treatment effective and discontinued	8% (1/12)	0% (0/8)
Loss of response	25% (3/12)	25% (2/8)
Poor response	33% (4/12)	25% (2/8)
Side effects / adverse events	17% (2/12)	38% (3/8)
Patient choice	0% (0/12)	13% (1/8)
Funding	8% (1/12)	0% (0/8)
Other	8% (1/12)	0% (0/8)
If continuing adalimumab treatment, what is the planned continued treatment frequency?		
Every week	NA	3% (2/58)
Every other week	NA	97% (56/58)
If continuing adalimumab treatment, what is the planned continued treatment dose? (mg)		
80	NA	2% (1/58)
40	NA	98% (57/58)

NA = not applicable.

IBD type unclassified Follow-up anti-TNFα treatment (Includes all follow-up treatment entered at any time after initial treatment)	Frequency (%)	
	Infliximab	Adalimumab
	National (N=150)	National (N=66)
Follow-up treatment details continued		
Did the patient report complete compliance with the maintenance regime since the last adalimumab review?		
Yes	NA	95% (62/65)
No	NA	5% (3/65)
If incomplete compliance, state reason		
Number of missed doses	NA	67% (2/3)
Patient missed out some treatment weeks	NA	67% (2/3)
Did the patient report any acute reactions?		
Yes	0.7% (1/150)	9% (6/66)
Which acute reactions? (more than one may have been selected)		
Dizziness	0.7% (1/150)	0% (0/66)
Fatigue	0% (0/150)	2% (1/66)
Fever	0% (0/150)	2% (1/66)
Flushing	0% (0/150)	2% (1/66)
Injection site reaction	NA	2% (1/66)
Itching	0% (0/150)	6% (4/66)
Panic attacks	0.7% (1/150)	0% (0/66)
Rash	0% (0/150)	6% (4/66)
Urticaria	0% (0/150)	2% (1/66)
Is the patient currently receiving any other therapies for the management of IBD?		
Yes	65% (97/150)	68% (45/66)
If yes, indicate which other therapies (more than one may have been selected)		
Azathioprine / mercaptopurine	41% (61/150)	59% (39/66)
Methotrexate	0.7% (1/150)	2% (1/66)
Steroids	10% (15/150)	5% (3/66)
5-ASA	37% (56/150)	32% (21/66)
Other	0% (0/150)	5% (3/66)
On any immunosuppressant (azathioprine, mercaptopurine or methotrexate)	41% (62/150)	61% (40/66)
Were there any adverse events since the last review?		
Yes	2% (3/150)	6% (4/66)
What adverse events?		
Arthralgia	0.7% (1/150)	3% (2/66)
Blood abnormality	0.7% (1/150)	3% (2/66)
Infection	0.7% (1/150)	2% (1/66)

5-ASA = 5-aminosalicylic acid; NA = not applicable.

IBD type unclassified Follow-up anti-TNFα treatment (Includes all follow-up treatment entered at any time after initial treatment)	Frequency (%)	
	Infliximab	Adalimumab
	National (N=150)	National (N=66)
Disease severity score		
Severity of disease		
Mild	74% (61/82)	56% (10/18)
Moderate	20% (16/82)	39% (7/18)
Severe	6% (5/82)	6% (1/18)

IBD-related surgery

In total, 998 adult patients had surgery. There were details of 1887 adult IBD-related surgical procedures entered using the biological therapies web tool. For the purpose of this analysis, only those procedures relating to patients who had a date of initial treatment recorded within their initial treatment submission were included.

Table 9 Surgical procedures that were carried out pre- and post-initiation of biological therapy (ADA and IFX combined) for adult patients with CD

Crohn's disease IBD-related surgery	Procedures 95% (1784/1887)	
Surgical procedure by type	**Pre-biologic initiation 86% (1530/1784)**	**Post-biologic initiation 14% (254/1784)**
Right hemicolectomy	23% (353/1530)	18% (46/254)
Total proctocolectomy ileoanal pouch	0.9% (14/1530)	0% (0/254)
Total proctocolectomy permanent ileostomy	2% (30/1530)	4% (10/254)
Colectomy ileostomy with retained rectal stump	3% (47/1530)	6% (14/254)
Colectomy colostomy with retained rectal stump	0.7% (10/1530)	1% (3/254)
Total colectomy with ileorectal anastomosis	0.3% (4/1530)	0% (0/254)
Partial colectomy	3% (48/1530)	3% (8/254)
Segmental colectomy	0.1% (1/1530)	0% (0/254)
Small bowel resection	19% (285/1530)	17% (42/254)
Insertion of seton	9% (131/1530)	11% (27/254)
Drainage of perianal sepsis	10% (158/1530)	12% (31/254)
Radiological drainage of abscess	0.5% (7/1530)	2% (4/254)
Gastric surgery	0.1% (2/1530)	0.4% (1/254)
Stricturoplasty	3% (48/1530)	4% (9/254)
Appendectomy	0.5% (8/1530)	0% (0/254)
Cholecystectomy	0.5% (7/1530)	0.4% (1/254)
EUA fistula procedure	15% (227/1530)	14% (36/254)
Proctocolectomy	0.8% (12/1530)	0.8% (2/254)
Proctocolectomy ileoanal pouch	3% (44/1530)	4% (10/254)
Proctectomy	0.9% (14/1530)	0% (0/254)
Restorative proctectomy	0.2% (3/1530)	0% (0/254)
Partial colectomy	0.9% (14/1530)	0.4% (1/254)
Ileocaecal resection	3% (48/1530)	3% (8/254)
Stoma formation	0.1% (1/1530)	0% (0/254)
Other surgical procedure	0.9% (14/1530)	0.4% (1/254)

Table 10 Surgical procedures that were carried out pre- and post-initiation of biological therapy (ADA and IFX combined) for adult patients with UC

Ulcerative colitis IBD-related surgery	Procedures 4% (76/1887)	
Surgical procedure by type	**Pre-biologic initiation 37% (28/76)**	**Post-biologic initiation 63% (48/76)**
Total proctocolectomy ileoanal pouch	11% (3/28)	4% (2/48)
Total proctocolectomy permanent ileostomy	0% (0/28)	2% (1/48)
Colectomy ileostomy with retained rectal stump	46% (13/28)	60% (29/48)
Colectomy colostomy with retained rectal stump	0% (0/28)	10% (5/48)
Partial colectomy	0% (0/28)	0% (0/48)
Small bowel resection	4% (1/28)	0% (0/48)
Insertion of seton	0% (0/28)	6% (3/48)
Drainage of perianal sepsis	4% (1/28)	2% (1/48)
EUA fistula procedure	14% (4/28)	2% (1/48)
Proctocolectomy	0% (0/28)	2% (1/48)
Proctocolectomy ileoanal pouch	11% (3/28)	6% (3/48)
Proctectomy	11% (3/28)	4% (2/48)
Ileocaecal resection	0% (0/28)	0% (0/48)

Table 11 Surgical procedures that were carried out pre- and post-initiation of biological therapy (ADA and IFX combined) for adult patients with IBDU

IBD type unclassified IBD-related surgery	Procedures 1% (27/1887)	
Surgical procedure by type	**Pre-biologic initiation 59% (16/27)**	**Post-biologic initiation 41% (11/27)**
Total proctocolectomy ileoanal pouch	19% (3/16)	9% (1/11)
Total proctocolectomy permanent ileostomy	0% (0/16)	9% (1/11)
Colectomy ileostomy with retained rectal stump	0% (0/16)	46% (5/11)
Colectomy colostomy with retained rectal stump	6% (1/16)	0% (0/11)
Partial colectomy	0% (0/16)	0% (0/11)
Insertion of seton	13% (2/16)	0% (0/11)
Drainage of perianal sepsis	25% (4/16)	9% (1/11)
EUA fistula procedure	0% (0/16)	0% (0/11)
Proctocolectomy ileoanal pouch	19% (3/16)	18% (2/11)
Proctectomy	19% (3/16)	9% (1/11)
Ileocaecal resection	0% (0/16)	0% (0/11)

Patient-reported outcome measures (PROMs)

PROMs measure quality from the patient perspective. They are typically 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 before, during and after an intervention (in this case, the initiation of biological therapy) and provides an indication of the outcomes or quality of care delivered to patients.

EQ-5D

The EQ-5D 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. The responses record three levels 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), with an increase in score denoting improved health. Scores from each domain are weighted and converted into a single summary index. Scores are presented as a weighted index and, in the case of data within this report, in the form of a median (IQR). The EQ-5D has been shown to be valid, reliable and responsive in patients with IBD.[7]

There were 485 EQ-5D questionnaires completed at an initial treatment across both anti-TNFα types and all disease types. The median (IQR) score was 0.725 (0.587, 0.796). There were 544 EQ-5D questionnaires completed at follow-up treatment across both anti-TNFα types and all disease types. The median (IQR) score was 0.796 (0.725, 1).

We were not able to calculate the difference between the EQ-5D scores at initial and follow-up treatment, owing to the limited number of patients with EQ-5D scores at both time periods. However, we were able to calculate the median scores at these two stages for all patients who had a score, and compare these medians. There was an increase in the median EQ-5D score of 0.071 between initial and follow-up treatment. This may suggest a clinical improvement in quality of life after starting anti-TNFα treatment. A limitation to this analysis is that patients with EQ-5D scores at follow-up infusion are not always the same patients as those at initial infusion. All patients with a score were included. Restricting the analysis to those patients who had an EQ-5D score at initial treatment was not possible, owing to limited numbers in this analysis.

CCQ12

The CCQ12 is a relatively new and shortened version of the CCQ32, a quality of life measurement tool developed specifically for patients with IBD for use in both the acute and chronic settings. The items in the CCQ12 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. Early results have shown that the CCQ12 performs well in the IBD population and reveal positive correlations compared with the EQ-5D and SF12.

Total CCQ12 scores range from 0 (best) to 168 (poor), with each question scored between 0 (best) and 14 (poor); these numbers correspond to the number of days affected by a parameter in a fortnight. CCQ12 scores of <45 and <50 suggest remission in UC and CD, respectively. The minimal significant change of CCQ12 is 13 for both UC and CD.

There were 424 CCQ12 questionnaires completed at initial treatment across both anti-TNFα types and all disease types. The median (IQR) score of 75 (44, 103) would suggest active IBD at this time. There were 490 questionnaires completed at follow-up treatment across both anti-TNFα types and all disease types. The median (IQR) score was 37 (16,64).

We were not able to calculate the difference between the CCQ12 scores at initial and follow-up treatment, owing to the limited number of patients with CCQ12 scores at both time periods. However, we were able to calculate the median scores at these two stages for all patients who had a score, and compare these medians. There was a reduction in the median CCQ12 score of 38 between initial and follow-up treatment. This may suggest a clinically significant improvement in quality of life after starting anti-TNFα treatment. A limitation to this analysis is that patients with CCQ12 scores at follow-up infusion are not always the same patients as those at initial infusion. All patients with a score at the relevant time periods were included. Restricting the analysis to those patients who had a CCQ12 score at initial treatment was not possible, owing to limited numbers in this analysis. We expect that there will be sufficient data available to facilitate a more robust analysis of CCQ12 scores in the next national report of this audit (scheduled for publication in August 2015). The CCQ12 findings of the biological therapy audit will be used to inform learning and the ongoing validity assessment of this PROM tool.

Table 8 from **section 2** of this report is provided again for reference.

Table 8 Completion and results of the PROMs questionnaires calculated using EQ-5D and CCQ12

IBDPROM	Initial treatment	Follow-up treatment[a]
Number of treatments	3388	6191
Number with EQ-5D PROM data completed	14% (485/3388)	9% (544/6191)
EQ-5D PROM score: median (IQR)	0.725 (0.587, 0.796)	0.796 (0.725, 1)
Number with CCQ12 PROM data completed	13% (424/3388)	8% (490/6191)
CCQ12 PROM score: median (IQR)	75 (44, 103)	37 (16, 64)

[a]Follow-up treatment category includes any follow-up treatment PROMs data entered, and is restricted to those who provided initial treatment PROMs data.

6: Individual site key indicator data

The table in this section gives named 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. The combined results for all 214 sites (181 participating) are shown for comparison in the table below and this also forms a list of participating sites. Sites that have taken part in the PANTS research study are also counted as having participated in this audit. An asterisk in the table below denotes sites that have taken part in the PANTS research study; data entered to this study will be included in the 2015 national report.

Key indicators	Number of patients with CD entered at your site	Patients with CD given 160/80 mg of ADA at induction	Response to treatment	Remission achieved	Patients with at least one adverse event	Patients with CD on concomitant therapy, 5-ASA at induction	Patients with CD, treatment effective and discontinued at follow-up
Results	2715	77% (1112/1449)	87% (195/224)	70% (170/244)	11% (180/1667)	17% (481/2813)	11% (45/392)
England							
Aintree University Hospitals NHS Foundation Trust							
Aintree University Hospital	N<6	N<6	N=0	N=0	N<6	N<6	N<6
Airedale NHS Foundation Trust							
Airedale General Hospital*	21	23% (3/13)	83% (5/6)	67% (4/6)	11% (2/18)	5% (1/22)	0%(0/6)
Ashford and St Peter's Hospitals NHS Foundation Trust							
Ashford Hospital and St Peter's Hospital combined	Not participated in biological therapy audit						
Barking, Havering and Redbridge Hospitals NHS Trust							
King George Hospital and Queens Hospital combined	35	58% (7/12)	N<6	N<6	3% (1/31)	17% (6/35)	N<6
Barnet and Chase Farm Hospitals NHS Trust							
Barnet General Hospital	48	97% (29/30)	N=0	N=0	N=0	21% (10/48)	N=0
Barnsley Hospital NHS Foundation Trust							
Barnsley District General Hospital	N<6	N=0	N=0	N=0	N=0	N<6	N=0

Key indicators	Number of patients with CD entered at your site	Patients with CD given 160/80 mg of ADA at induction	Response to treatment	Remission achieved	Patients with at least one adverse event	Patients with CD on concomitant therapy, 5-ASA at induction	Patients with CD, treatment effective and discontinued at follow-up
Results	2715	77% (1112/1449)	87% (195/224)	70% (170/244)	11% (180/1667)	17% (481/2813)	11% (45/392)
Barts Health NHS Trust							
Newham University Hospital	16	N<6	N=0	N=0	6% (1/16)	19% (3/16)	N<6
The Royal London Hospital* and St Bartholomew's Hospital combined	8	N<6	N<6	N<6	0% (0/6)	11% (1/9)	N<6
Whipps Cross University Hospital	N=0	N=0	N=0	N=0	N=0	N=0	N=0
Basildon and Thurrock University Hospitals NHS Foundation Trust							
Basildon Hospital*	17	100% (11/11)	N=0	N=0	0% (0/11)	24% (4/17)	N<6
Bedford Hospital NHS Trust							
Bedford Hospital	N=0	N=0	N=0	N=0	N=0	N=0	N=0
Blackpool Teaching Hospitals NHS Foundation Trust							
Blackpool Victoria Hospital	7	N<6	N<6	N<6	N<6	0% (0/8)	N<6
Bradford Teaching Hospitals Foundation Trust							
Bradford Royal Infirmary*	24	100% (17/17)	N=0	N=0	13% (2/15)	8% (2/24)	13%(1/8)
Brighton and Sussex University Hospitals NHS Trust							
Royal Sussex County Hospital* and Princess Royal Hospital combined	84	100% (49/49)	N=0	N=0	0% (0/76)	0% (0/85)	0%(0/6)
Buckinghamshire Healthcare NHS Trust							
Stoke Mandeville Hospital and Wycombe General Hospital combined	N=0	N=0	N=0	N=0	N=0	N=0	N=0
Burton Hospitals NHS Foundation Trust							
Queen's Hospital, Burton	10	N<6	N=0	N=0	0% (0/9)	0% (0/10)	N<6

Key indicators	Number of patients with CD entered at your site	Patients with CD given 160/80 mg of ADA at induction	Response to treatment	Remission achieved	Patients with at least one adverse event	Patients with CD on concomitant therapy, 5-ASA at induction	Patients with CD, treatment effective and discontinued at follow-up
Results	2715	77% (1112/1449)	87% (195/224)	70% (170/244)	11% (180/1667)	17% (481/2813)	11% (45/392)
Calderdale and Huddersfield NHS Foundation Trust							
Huddersfield Royal Infirmary and Calderdale Hospital* combined	44	4% (1/26)	N=0	N=0	N<6	36% (16/44)	N<6
Cambridge University Hospitals NHS Foundation Trust							
Addenbrooke's Hospital*	N=0	N=0	N=0	N=0	N=0	N=0	N=0
Central Manchester University Hospitals NHS Foundation Trust							
Manchester Royal Infirmary*	8	N<6	N=0	N=0	N<6	25% (2/8)	N=0
Trafford General Hospital	10	N<6	N=0	N=0	N=0	80% (8/10)	N=0
Chelsea and Westminster Hospital NHS Foundation Trust							
Chelsea and Westminster Hospital*	N=0	N=0	N=0	N=0	N=0	N=0	N=0
Chesterfield Royal Hospital NHS Foundation Trust							
Chesterfield Royal Hospital*	38	67% (10/15)	85% (11/13)	85% (11/13)	3% (1/33)	21% (8/39)	0%(0/8)
City Hospitals Sunderland NHS Foundation Trust							
Sunderland Royal Hospital*	N=0	N=0	N=0	N=0	N=0	N=0	N=0
Colchester Hospital University NHS Foundation Trust							
Colchester General Hospital*	N=0	N=0	N=0	N=0	N=0	N=0	N=0
Countess of Chester Hospital NHS Foundation Trust							
Countess of Chester Hospital	19	N<6	91% (10/11)	91% (10/11)	16% (3/19)	45% (9/20)	N<6
County Durham and Darlington NHS Foundation Trust							
Darlington Memorial Hospital and Bishop Auckland Hospital combined*	22	100% (10/10)	N<6	N<6	0% (0/20)	9% (2/23)	50%(4/8)
University Hospital of North Durham	11	100% (11/11)	N=0	N=0	N<6	18% (2/11)	N<6

Key indicators	Number of patients with CD entered at your site	Patients with CD given 160/80 mg of ADA at induction	Response to treatment	Remission achieved	Patients with at least one adverse event	Patients with CD on concomitant therapy, 5-ASA at induction	Patients with CD, treatment effective and discontinued at follow-up
Results	2715	77% (1112/1449)	87% (195/224)	70% (170/244)	11% (180/1667)	17% (481/2813)	11% (45/392)
Croydon Health Services NHS Trust							
Croydon University Hospital	18	N<6	N<6	67% (4/6)	6% (1/16)	14% (3/21)	0%(0/11)
Dartford and Gravesham NHS Trust							
Darent Valley Hospital	N=0	N=0	N=0	N=0	N=0	N=0	N=0
Derby Hospitals NHS Foundation Trust							
Royal Derby Hospital*	13	43% (3/7)	N=0	N=0	N<6	0% (0/13)	N<6
Doncaster and Bassetlaw Hospitals NHS Foundation Trust							
Doncaster Royal Infirmary* and Bassetlaw District General Hospital combined	N=0	N=0	N=0	N=0	N=0	N=0	N=0
Dorset County Hospital NHS Foundation Trust							
Dorset County Hospital*	Not participated in biological therapy audit (participated in PANTS)						
Ealing Hospital NHS Trust							
Ealing Hospital	Not participated in biological therapy audit						
East and North Hertfordshire NHS Trust							
Lister Hospital* and Queen Elizabeth II Hospital combined	22	68% (13/19)	N<6	N<6	5% (1/19)	18% (4/22)	N<6
East Cheshire NHS Trust							
Macclesfield District General Hospital	N=0	N=0	N=0	N=0	N=0	N=0	N=0
East Kent Hospitals University NHS Foundation Trust							
William Harvey Hospital, Kent and Canterbury Hospital and QEQM Hospital combined	6	N<6	N=0	N=0	N<6	0% (0/7)	N<6

Key indicators	Number of patients with CD entered at your site	Patients with CD given 160/80 mg of ADA at induction	Response to treatment	Remission achieved	Patients with at least one adverse event	Patients with CD on concomitant therapy, 5-ASA at induction	Patients with CD, treatment effective and discontinued at follow-up
Results	2715	77% (1112/1449)	87% (195/224)	70% (170/244)	11% (180/1667)	17% (481/2813)	11% (45/392)
East Lancashire Hospitals NHS Trust							
Royal Blackburn Hospital and Burnley District General Hospital combined	48	6% (2/33)	67% (4/6)	43% (3/7)	6% (3/47)	12% (6/52)	0%(0/7)
East Sussex Healthcare Trust							
Eastbourne District General Hospital and Conquest Hospital combined*	N<6	N<6	N=0	N=0	N=0	N<6	N=0
Epsom and St Helier University Hospitals NHS Trust							
Epsom General Hospital	7	N<6	N<6	N<6	N<6	43% (3/7)	N<6
St Helier Hospital	6	N<6	N=0	N=0	0% (0/6)	33% (2/6)	N=0
Frimley Park Hospital NHS Foundation Trust							
Frimley Park Hospital*	44	100% (31/31)	100% (6/6)	83% (5/6)	19% (7/37)	7% (3/45)	N<6
Gateshead Health NHS Foundation Trust							
Queen Elizabeth Hospital, Gateshead	N=0	N=0	N=0	N=0	N=0	N=0	N=0
George Eliot Hospital NHS Trust							
George Eliot Hospital	Not participated in biological therapy audit						
Gloucestershire Hospitals NHS Foundation Trust							
Gloucestershire Royal Hospital and Cheltenham General Hospital combined*	N=0	N=0	N=0	N=0	N=0	N=0	N=0
Great Western Hospitals NHS Foundation Trust							
Great Western Hospital	34	100% (12/12)	N=0	N=0	N=0	15% (5/34)	N=0
Guy's and St Thomas' NHS Foundation Trust							
Guy's Hospital and St Thomas' Hospital combined*	N=0	N=0	N=0	N=0	N=0	N=0	N=0

Key indicators	Number of patients with CD entered at your site	Patients with CD given 160/80 mg of ADA at induction	Response to treatment	Remission achieved	Patients with at least one adverse event	Patients with CD on concomitant therapy, 5-ASA at induction	Patients with CD, treatment effective and discontinued at follow-up
Results	2715	77% (1112/1449)	87% (195/224)	70% (170/244)	11% (180/1667)	17% (481/2813)	11% (45/392)
Hampshire Hospitals NHS Foundation Trust							
Basingstoke and North Hampshire Hospitals*	Not participated in biological therapy audit (participated in PANTS)						
Royal Hampshire County Hospital*	Not participated in biological therapy audit (participated in PANTS)						
Harrogate and District NHS Foundation Trust							
Harrogate District Hospital	8	N<6	N=0	N=0	N=0	38% (3/8)	N=0
Heart of England NHS Foundation Trust							
Birmingham Heartlands Hospital and Solihull Hospital combined	12	100% (6/6)	N=0	N=0	N=0	0% (0/12)	N=0
Good Hope Hospital	N<6	N<6	N=0	N=0	N=0	N<6	N=0
Heatherwood and Wexham Park Hospitals NHS Foundation Trust							
Heatherwood Hospital	Not participated in biological therapy audit						
Wexham Park Hospital	Not participated in biological therapy audit						
Hinchingbrooke Health Care NHS Trust							
Hinchingbrooke Hospital	N=0	N=0	N=0	N=0	N=0	N=0	N=0
Homerton University Hospital NHS Foundation Trust							
Homerton University Hospital	25	N<6	N<6	N<6	4% (1/23)	20% (5/25)	N<6
Hull and East Yorkshire Hospitals NHS Trust							
Hull Royal Infirmary* and Castle Hill Hospital combined	57	92% (12/13)	N<6	N<6	10% (4/39)	9% (5/58)	N<6
Imperial College Healthcare NHS Trust							
Charing Cross Hospital, Hammersmith Hospital and St Mary's Hospital combined	N=0	N=0	N=0	N=0	N=0	N=0	N=0

Key indicators	Number of patients with CD entered at your site	Patients with CD given 160/80 mg of ADA at induction	Response to treatment	Remission achieved	Patients with at least one adverse event	Patients with CD on concomitant therapy, 5-ASA at induction	Patients with CD, treatment effective and discontinued at follow-up
Results	2715	77% (1112/1449)	87% (195/224)	70% (170/244)	11% (180/1667)	17% (481/2813)	11% (45/392)
James Paget University Hospitals NHS Foundation Trust							
James Paget Hospital	N<6	N=0	N=0	N=0	N=0	N<6	N=0
Kettering General Hospital NHS Foundation Trust							
Kettering General Hospital	N<6	N=0	N=0	N=0	N=0	N<6	N=0
King's College Hospital NHS Foundation Trust							
King's College Hospital	N=0	N=0	N=0	N=0	N=0	N=0	N=0
Princess Royal University Hospital	Not participated in biological therapy audit						
Kingston Hospital NHS Trust							
Kingston Hospital	13	88% (7/8)	N=0	N=0	N=0	31% (4/13)	N=0
Lancashire Teaching Hospitals NHS Foundation Trust							
Royal Preston Hospital and Chorley and South Ribble Hospital combined	Not participated in biological therapy audit						
Leeds Teaching Hospitals NHS Trust							
Leeds General Infirmary	N<6	N<6	N=0	N=0	N=0	N<6	N=0
St James's University Hospital Leeds*	Not participated in biological therapy audit (participated in PANTS)						
Lewisham and Greenwich NHS Trust							
Lewisham Hospital	9	N<6	N=0	N=0	0% (0/8)	11% (1/9)	N<6
Queen Elizabeth Hospital, Woolwich	Not participated in biological therapy audit						
Luton and Dunstable Hospital NHS Foundation Trust							
Luton and Dunstable Hospital	N=0	N=0	N=0	N=0	N=0	N=0	N=0

Key indicators	Number of patients with CD entered at your site	Patients with CD given 160/80 mg of ADA at induction	Response to treatment	Remission achieved	Patients with at least one adverse event	Patients with CD on concomitant therapy, 5-ASA at induction	Patients with CD, treatment effective and discontinued at follow-up
Results	2715	77% (1112/1449)	87% (195/224)	70% (170/244)	11% (180/1667)	17% (481/2813)	11% (45/392)
Maidstone and Tunbridge Wells NHS Trust							
Maidstone Hospital*	N<6	N=0	N=0	N=0	N=0	N<6	N=0
Tunbridge Wells Hospital	8	71% (5/7)	N=0	N=0	N=0	0% (0/8)	N=0
Medway NHS Foundation Trust							
Medway Maritime Hospital	6	N=0	N=0	N=0	N<6	0% (0/6)	N=0
Mid Cheshire Hospitals NHS Foundation Trust							
Leighton Hospital*	N<6	N<6	N=0	N=0	N=0	N<6	N=0
Mid Essex Hospitals NHS Trust							
Broomfield Hospital	Not participated in biological therapy audit						
Mid Staffordshire NHS Foundation Trust							
Staffordshire General Hospital and Cannock Chase Hospital combined	9	N=0	N<6	N<6	0% (0/9)	33% (3/9)	N=0
Milton Keynes Hospital NHS Foundation Trust							
Milton Keynes Hospital*	Not participated in biological therapy audit (participated in PANTS)						
NHS Isle of Wight							
St Mary's Hospital	25	86% (6/7)	90% (9/10)	90% (9/10)	17% (4/24)	8% (2/26)	N<6
Norfolk and Norwich University Hospitals NHS Foundation Trust							
Norfolk and Norwich University Hospital*	N=0	N=0	N=0	N=0	N=0	N=0	N=0
North Bristol NHS Trust							
Frenchay Hospital	22	89% (16/18)	N=0	N=0	6% (1/17)	26% (6/23)	N<6

Key indicators	Number of patients with CD entered at your site	Patients with CD given 160/80 mg of ADA at induction	Response to treatment	Remission achieved	Patients with at least one adverse event	Patients with CD on concomitant therapy, 5-ASA at induction	Patients with CD, treatment effective and discontinued at follow-up
Results	2715	77% (1112/1449)	87% (195/224)	70% (170/244)	11% (180/1667)	17% (481/2813)	11% (45/392)
North Cumbria University Hospitals NHS Trust							
Cumberland Infirmary*	Not participated in biological therapy audit (participated in PANTS)						
West Cumberland Hospital	Not participated in biological therapy audit						
North Middlesex University Hospital NHS Trust							
North Middlesex University Hospital	N=0	N=0	N=0	N=0	N=0	N=0	N=0
North Tees and Hartlepool NHS Foundation Trust							
University Hospital of Hartlepool	N<6	N<6	N=0	N=0	N=0	N<6	N=0
University Hospital of North Tees	35	100% (14/14)	N=0	N=0	3% (1/38)	2% (1/41)	9%(1/11)
North West London Hospitals NHS Trust							
Central Middlesex Hospital	6	N<6	N<6	N<6	N<6	83% (5/6)	N=0
Northwick Park Hospital and St Mark's Hospital* combined	N=0	N=0	N=0	N=0	N=0	N=0	N=0
Northampton General Hospital NHS Trust							
Northampton General Hospital	8	N<6	N=0	N=0	N=0	50% (4/8)	N=0
Northern Devon Healthcare NHS Trust							
North Devon District Hospital	9	0% (0/9)	N=0	N=0	N=0	11% (1/9)	N=0
Northern Lincolnshire and Goole Hospitals NHS Foundation Trust							
Diana, Princess of Wales Hospital	6	N<6	N=0	N=0	N<6	33% (2/6)	N=0
Scunthorpe General Hospital	9	N<6	N=0	N=0	0% (0/6)	33% (3/9)	N<6

Key indicators	Number of patients with CD entered at your site	Patients with CD given 160/80 mg of ADA at induction	Response to treatment	Remission achieved	Patients with at least one adverse event	Patients with CD on concomitant therapy, 5-ASA at induction	Patients with CD, treatment effective and discontinued at follow-up
Results	2715	77% (1112/1449)	87% (195/224)	70% (170/244)	11% (180/1667)	17% (481/2813)	11% (45/392)
Northumbria Healthcare NHS Foundation Trust							
Northumbria Healthcare NHSFT (Wansbeck, North Tyneside and Hexham General Hospitals combined)	29	95% (20/21)	N<6	N<6	7% (2/27)	0% (0/29)	0%(0/6)
Nottingham University Hospital NHS Trust							
Queen's Medical Centre* and Nottingham City Hospital combined	N=0	N=0	N=0	N=0	N=0	N=0	N=0
Oxford University Hospitals NHS Trust							
John Radcliffe Hospital and Horton General Hospital combined	N<6	N<6	N<6	N<6	N<6	N<6	N<6
Peterborough and Stamford Hospitals NHS Foundation Trust							
Peterborough City Hospital	N=0	N=0	N=0	N=0	N=0	N=0	N=0
Plymouth Hospitals NHS Trust							
Derriford Hospital*	N<6	N=0	N=0	N=0	N=0	N<6	N=0
Poole Hospital NHS Foundation Trust							
Poole General Hospital*	Not participated in biological therapy audit (participated in PANTS)						
Portsmouth Hospitals NHS Trust							
Queen Alexandra Hospital*	23	N<6	N=0	N=0	N=0	48% (11/23)	N=0
Princess Alexandra Hospital NHS Trust							
Princess Alexandra Hospital, Harlow*	Not participated in biological therapy audit (participated in PANTS)						
Royal Berkshire NHS Foundation Trust							
Royal Berkshire Hospital*	N=0	N=0	N=0	N=0	N=0	N=0	N=0

Key indicators	Number of patients with CD entered at your site	Patients with CD given 160/80 mg of ADA at induction	Response to treatment	Remission achieved	Patients with at least one adverse event	Patients with CD on concomitant therapy, 5-ASA at induction	Patients with CD, treatment effective and discontinued at follow-up
Results	2715	77% (1112/1449)	87% (195/224)	70% (170/244)	11% (180/1667)	17% (481/2813)	11% (45/392)
Royal Bolton Hospital NHS Foundation Trust							
Royal Bolton Hospital	66	65% (31/48)	N<6	N<6	10% (4/42)	21% (15/71)	33%(4/12)
Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust							
Royal Bournemouth Hospital*	89	100% (42/42)	92% (23/25)	88% (22/25)	7% (6/89)	9% (9/95)	18%(5/28)
Royal Cornwall Hospitals NHS Trust							
Royal Cornwall Hospital*	33	56% (10/18)	N<6	N<6	7% (2/27)	21% (7/34)	15%(2/13)
Royal Devon and Exeter NHS Foundation Trust							
Royal Devon and Exeter Hospital*	N=0	N=0	N=0	N=0	N=0	N=0	N=0
Royal Free London NHS Foundation Trust							
Royal Free Hospital*	7	N=0	N=0	N=0	N<6	29% (2/7)	N=0
Royal Liverpool and Broadgreen University Hospitals NHS Trust							
Royal Liverpool University Hospital	18	N=0	N<6	N<6	0% (0/15)	6% (1/18)	N<6
Royal Surrey County Hospital NHS Foundation Trust							
Royal Surrey County Hospital	12	N<6	N=0	N=0	N=0	50% (6/12)	N=0
Royal United Hospital Bath NHS Trust							
Royal United Hospital	Not participated in biological therapy audit						
Salford Royal NHS Foundation Trust							
Salford Royal Hospital*	85	100% (62/62)	74% (17/23)	46% (12/26)	24% (21/86)	4% (4/91)	0%(0/31)
Salisbury NHS Foundation Trust							
Salisbury District General Hospital	N<6	N<6	N=0	N=0	N=0	N<6	N=0

Key indicators	Number of patients with CD entered at your site	Patients with CD given 160/80 mg of ADA at induction	Response to treatment	Remission achieved	Patients with at least one adverse event	Patients with CD on concomitant therapy, 5-ASA at induction	Patients with CD, treatment effective and discontinued at follow-up
Results	2715	77% (1112/1449)	87% (195/224)	70% (170/244)	11% (180/1667)	17% (481/2813)	11% (45/392)
Sandwell and West Birmingham Hospitals NHS Trust							
Birmingham City Hospital and Sandwell Hospital combined*	N=0	N=0	N=0	N=0	N=0	N=0	N=0
Sheffield Teaching Hospitals NHS Foundation Trust							
Royal Hallamshire Hospital and Northern General Hospital combined	108	98% (42/43)	100% (13/13)	73% (11/15)	4% (3/73)	4% (4/111)	11%(2/18)
Sherwood Forest Hospitals NHS Foundation Trust							
King's Mill Hospital and Newark Hospital combined*	13	78% (7/9)	N=0	N=0	67% (4/6)	8% (1/13)	N<6
South Devon Healthcare NHS Foundation Trust							
Torbay Hospital*	Not participated in biological therapy audit (participated in PANTS)						
South Tees Hospitals NHS Foundation Trust							
Friarage Hospital	Not participated in biological therapy audit						
James Cook University Hospital*	8	N<6	N=0	N=0	N<6	13% (1/8)	N<6
South Tyneside NHS Foundation Trust							
South Tyneside District Hospital*	19	100% (11/11)	100% (8/8)	100% (8/8)	20% (4/20)	40% (8/20)	0%(0/9)
South Warwickshire NHS Foundation Trust							
Warwick Hospital	30	8% (2/25)	N=0	N=0	N=0	10% (3/30)	N=0
Southend University Hospital NHS Foundation Trust							
Southend University Hospital	N<6	N<6	N=0	N=0	N<6	N<6	N=0
Southport and Ormskirk Hospital NHS Trust							
Southport District General Hospital	N=0	N=0	N=0	N=0	N=0	N=0	N=0

Key indicators	Number of patients with CD entered at your site	Patients with CD given 160/80 mg of ADA at induction	Response to treatment	Remission achieved	Patients with at least one adverse event	Patients with CD on concomitant therapy, 5-ASA at induction	Patients with CD, treatment effective and discontinued at follow-up
Results	2715	77% (1112/1449)	87% (195/224)	70% (170/244)	11% (180/1667)	17% (481/2813)	11% (45/392)
St George's Healthcare NHS Trust							
St George's Hospital*	23	N<6	N<6	N<6	33% (6/18)	0% (0/24)	N<6
St Helens and Knowsley Hospitals NHS Trust							
Whiston Hospital	N=0	N=0	N=0	N=0	N=0	N=0	N=0
Stockport NHS Foundation Trust							
Stepping Hill Hospital*	N=0	N=0	N=0	N=0	N=0	N=0	N=0
Surrey and Sussex Healthcare NHS Trust							
East Surrey Hospital	N=0	N=0	N=0	N=0	N=0	N=0	N=0
Tameside Hospital NHS Foundation Trust							
Tameside General Hospital	N<6	N<6	N=0	N=0	N<6	N<6	N=0
Taunton and Somerset NHS Foundation Trust							
Musgrove Park Hospital*	11	75% (6/8)	N=0	N=0	N=0	9% (1/11)	N=0
The Dudley Group NHS Foundation Trust							
Russells Hall Hospital*	58	98% (47/48)	N<6	N<6	8% (3/38)	29% (17/59)	N=0
The Hillingdon Hospitals NHS Foundation Trust							
Hillingdon Hospital	Not participated in biological therapy audit						
The Ipswich Hospital NHS Trust							
The Ipswich Hospital	N=0	N=0	N=0	N=0	N=0	N=0	N=0

Key indicators	Number of patients with CD entered at your site	Patients with CD given 160/80 mg of ADA at induction	Response to treatment	Remission achieved	Patients with at least one adverse event	Patients with CD on concomitant therapy, 5-ASA at induction	Patients with CD, treatment effective and discontinued at follow-up
Results	2715	77% (1112/1449)	87% (195/224)	70% (170/244)	11% (180/1667)	17% (481/2813)	11% (45/392)
The Mid Yorkshire Hospitals NHS Trust							
Dewsbury and District Hospital	Not participated in biological therapy audit						
Pinderfields General Hospital and Pontefract Hospitals combined*	N=0	N=0	N=0	N=0	N=0	N=0	N=0
The Newcastle upon Tyne Hospitals NHS Foundation Trust							
Freeman Hospital	31	90% (19/21)	N<6	N<6	13% (4/30)	10% (3/31)	0%(0/10)
Royal Victoria Infirmary, Newcastle*	N<6	N=0	N=0	N=0	N=0	N<6	N=0
The Pennine Acute Hospitals NHS Trust							
The Royal Oldham Hospital, Fairfield General Hospital, North Manchester General Hospital and Rochdale Infirmary combined*	82	100% (35/35)	N=0	N=0	N<6	48% (40/83)	N=0
The Queen Elizabeth Hospital King's Lynn NHS Foundation Trust							
The Queen Elizabeth Hospital	N=0	N=0	N=0	N=0	N=0	N=0	N=0
The Rotherham NHS Foundation Trust							
Rotherham Hospital	N=0	N=0	N=0	N=0	N=0	N=0	N=0
The Royal Wolverhampton Hospitals NHS Trust							
New Cross Hospital*	70	97% (33/34)	80% (12/15)	63% (10/16)	6% (3/47)	30% (21/71)	29%(2/7)
The Shrewsbury and Telford Hospital NHS Trust							
Royal Shrewsbury Hospital* and Princess Royal Hospital combined	6	N<6	N=0	N=0	N<6	0% (0/6)	N=0

Key indicators	Number of patients with CD entered at your site	Patients with CD given 160/80 mg of ADA at induction	Response to treatment	Remission achieved	Patients with at least one adverse event	Patients with CD on concomitant therapy, 5-ASA at induction	Patients with CD, treatment effective and discontinued at follow-up
Results	2715	77% (1112/1449)	87% (195/224)	70% (170/244)	11% (180/1667)	17% (481/2813)	11% (45/392)
United Lincolnshire Hospitals NHS Trust							
Grantham and District Hospital	Not participated in biological therapy audit						
Lincoln County Hospital*	8	N<6	N=0	N=0	0% (0/7)	13% (1/8)	N=0
Pilgrim Hospital	N=0	N=0	N=0	N=0	N=0	N=0	N=0
University College London Hospitals NHS Foundation Trust							
University College Hospital*	84	98% (42/43)	81% (13/16)	81% (13/16)	10% (8/78)	22% (20/90)	0%(0/9)
University Hospital of North Staffordshire NHS Trust							
City General Hospital, Stoke-on-Trent	N<6	N<6	N=0	N=0	N=0	N<6	N=0
University Hospital of South Manchester NHS Foundation Trust							
Wythenshawe Hospital*	26	94% (17/18)	N<6	N<6	19% (3/16)	0% (0/27)	13%(1/8)
University Hospital Southampton NHS Foundation Trust							
Southampton General Hospital*	44	89% (34/38)	N=0	N=0	7% (3/43)	0% (0/46)	N<6
University Hospitals Birmingham NHS Foundation Trust							
Queen Elizabeth Hospital, Birmingham*	133	99% (83/84)	N=0	N=0	32% (42/130)	1% (2/141)	17%(9/54)
University Hospitals Coventry and Warwickshire NHS Trust							
University Hospital, Coventry*	N=0	N=0	N=0	N=0	N=0	N=0	N=0
University Hospitals of Bristol NHS Foundation Trust							
Bristol Royal Infirmary	10	N<6	N<6	N<6	0% (0/6)	0% (0/10)	N<6
University Hospitals of Leicester NHS Trust							
Leicester Royal Infirmary	110	11% (8/70)	N=0	N=0	N<6	8% (9/110)	N<6

Key indicators	Number of patients with CD entered at your site	Patients with CD given 160/80 mg of ADA at induction	Response to treatment	Remission achieved	Patients with at least one adverse event	Patients with CD on concomitant therapy, 5-ASA at induction	Patients with CD, treatment effective and discontinued at follow-up
Results	2715	77% (1112/1449)	87% (195/224)	70% (170/244)	11% (180/1667)	17% (481/2813)	11% (45/392)
University Hospitals of Morecombe Bay NHS Foundation Trust							
Furness General Hospital	16	43% (6/14)	N=0	N=0	0% (0/15)	50% (8/16)	N=0
Royal Lancaster Infirmary and Westmorland General Hospitals combined	Not participated in biological therapy audit						
Walsall Healthcare NHS Trust							
Walsall Manor Hospital	25	75% (6/8)	N=0	N=0	36% (4/11)	33% (9/27)	0%(0/9)
Warrington and Halton Hospitals NHS Foundation Trust							
Warrington District General Hospital*	N<6	N=0	N=0	N=0	N=0	N<6	N=0
West Hertfordshire Hospitals NHS Trust							
Watford General Hospital* and Hemel Hempstead General Hospital combined	29	100% (15/15)	100% (7/7)	86% (6/7)	26% (8/31)	13% (4/31)	45%(5/11)
West Middlesex University Hospital NHS Trust							
West Middlesex University Hospital*	41	100% (23/23)	N=0	N=0	N=0	2% (1/43)	N=0
West Suffolk Hospitals NHS Foundation Trust							
West Suffolk Hospital	16	100% (7/7)	100% (6/6)	33% (2/6)	0% (0/17)	0% (0/17)	0%(0/6)
Western Sussex Hospitals NHS Trust							
St Richard's Hospital	10	13% (1/8)	N=0	N=0	N=0	40% (4/10)	N=0
Worthing Hospital	N<6	N<6	N=0	N=0	N<6	N<6	N=0
Weston Area Health Trust							
Weston General Hospital*	7	N<6	N=0	N=0	0% (0/7)	13% (1/8)	N<6
Whittington Health NHS Trust							
Whittington Hospital	N=0	N=0	N=0	N=0	N=0	N=0	N=0

Key indicators	Number of patients with CD entered at your site	Patients with CD given 160/80 mg of ADA at induction	Response to treatment	Remission achieved	Patients with at least one adverse event	Patients with CD on concomitant therapy, 5-ASA at induction	Patients with CD, treatment effective and discontinued at follow-up
Results	2715	77% (1112/1449)	87% (195/224)	70% (170/244)	11% (180/1667)	17% (481/2813)	11% (45/392)
Wirral University Teaching Hospital NHS Foundation Trust							
Arrowe Park Hospital	34	100% (20/20)	N<6	N<6	0% (0/31)	47% (16/34)	N<6
Worcestershire Acute Hospitals NHS Trust							
Alexandra Hospital	Not eligible to participate in biological therapy audit						
Worcestershire Royal Hospital	15	N<6	N=0	N=0	N<6	27% (4/15)	N<6
Wrightington, Wigan and Leigh NHS Foundation Trust							
Royal Albert Edward Infirmary*	N=0	N=0	N=0	N=0	N=0	N=0	N=0
Wye Valley NHS Trust							
County Hospital, Hereford*	7	N<6	N<6	N<6	N<6	29% (2/7)	N=0
Yeovil District Hospital NHS Foundation Trust							
Yeovil District Hospital*	19	60% (9/15)	N<6	N<6	8% (1/13)	5% (1/20)	N=0
York Teaching Hospital NHS Foundation Trust							
Scarborough General Hospital	N=0	N=0	N=0	N=0	N=0	N=0	N=0
York Hospital	N=0	N=0	N=0	N=0	N=0	N=0	N=0
Northern Ireland							
Belfast Health and Social Care Trust							
Belfast City Hospital	28	94% (15/16)	N=0	N=0	7% (2/27)	62% (18/29)	20%(2/10)
Mater Hospital	N=0	N=0	N=0	N=0	N=0	N=0	N=0
Royal Victoria Hospital	15	N<6	N=0	N=0	N=0	27% (4/15)	N=0

Key indicators	Number of patients with CD entered at your site	Patients with CD given 160/80 mg of ADA at induction	Response to treatment	Remission achieved	Patients with at least one adverse event	Patients with CD on concomitant therapy, 5-ASA at induction	Patients with CD, treatment effective and discontinued at follow-up
Results	2715	77% (1112/1449)	87% (195/224)	70% (170/244)	11% (180/1667)	17% (481/2813)	11% (45/392)
Northern Health and Social Care Trust							
Antrim Area Hospital	8	N<6	N=0	N=0	N=0	25% (2/8)	N=0
Causeway Hospital	10	N<6	N=0	N=0	N<6	10% (1/10)	N=0
South Eastern Health and Social Care Trust							
Downe Hospital	Not participated in biological therapy audit						
Lagan Valley Hospital	6	N<6	N=0	N=0	N<6	67% (4/6)	N=0
Ulster Hospital	N=0	N=0	N=0	N=0	N=0	N=0	N=0
Southern Health and Social Care Trust							
Craigavon Area Hospital	8	N<6	N=0	N=0	0% (0/8)	50% (4/8)	N<6
Daisy Hill Hospital	7	N=0	N=0	N=0	14% (1/7)	29% (2/7)	N<6
Western Health and Social Care Trust							
Altnagelvin Area Hospital	10	100% (10/10)	N=0	N=0	N=0	30% (3/10)	N=0
South West Acute Hospital	N=0	N=0	N=0	N=0	N=0	N=0	N=0
Scotland							
NHS Ayrshire and Arran							
University Hospital Ayr	Not participated in biological therapy audit						
University Hospital Crosshouse	N<6	N=0	N=0	N=0	N=0	N<6	N=0
NHS Borders							
Borders General Hospital	N=0	N=0	N=0	N=0	N=0	N=0	N=0
NHS Dumfries and Galloway							
Dumfries and Galloway Royal Infirmary	Not participated in biological therapy audit						

Key indicators	Number of patients with CD entered at your site	Patients with CD given 160/80 mg of ADA at induction	Response to treatment	Remission achieved	Patients with at least one adverse event	Patients with CD on concomitant therapy, 5-ASA at induction	Patients with CD, treatment effective and discontinued at follow-up
Results	2715	77% (1112/1449)	87% (195/224)	70% (170/244)	11% (180/1667)	17% (481/2813)	11% (45/392)
NHS Fife							
Queen Margaret Hospital	Not participated in biological therapy audit						
NHS Forth Valley							
Forth Valley Royal Hospital*	34	53% (8/15)	N=0	N=0	11% (3/27)	44% (18/41)	0%(0/6)
NHS Grampian							
Aberdeen Royal Infirmary	Not participated in biological therapy audit						
NHS Greater Glasgow and Clyde							
Glasgow Royal Infirmary*	N=0	N=0	N=0	N=0	N=0	N=0	N=0
Inverclyde Royal Hospital	N<6	N=0	N=0	N=0	N<6	N<6	N=0
Royal Alexandra Hospital	6	N<6	N=0	N=0	N<6	33% (2/6)	N=0
Southern General Hospital	Not participated in biological therapy audit						
Victoria Infirmary	Not participated in biological therapy audit						
Western Infirmary	Not participated in biological therapy audit						
NHS Highland							
Raigmore Hospital	Not participated in biological therapy audit						
NHS Lanarkshire							
Hairmyres Hospital	9	86% (6/7)	N<6	N<6	13% (1/8)	11% (1/9)	N<6
Monklands Hospital	N=0	N=0	N=0	N=0	N=0	N=0	N=0
Wishaw General Hospital	15	13% (2/15)	N=0	N=0	15% (2/13)	33% (5/15)	N<6

Key indicators	Number of patients with CD entered at your site	Patients with CD given 160/80 mg of ADA at induction	Response to treatment	Remission achieved	Patients with at least one adverse event	Patients with CD on concomitant therapy, 5-ASA at induction	Patients with CD, treatment effective and discontinued at follow-up
Results	2715	77% (1112/1449)	87% (195/224)	70% (170/244)	11% (180/1667)	17% (481/2813)	11% (45/392)
NHS Lothian							
St John's Hospital at Howden	Not participated in biological therapy audit						
Western General Hospital and Royal Infirmary of Edinburgh combined	6	N=0	N=0	N=0	N<6	0% (0/6)	N=0
NHS Tayside							
Ninewells Hospital	21	100% (12/12)	N=0	N=0	0% (0/11)	9% (2/22)	N=0
Wales							
Abertawe Bro Morgannwg University Health Board							
Morriston Hospital	Not eligible to participate in biological therapy audit						
Princess of Wales Hospital	Not participated in biological therapy audit						
Aneurin Bevan University Health Board							
Nevill Hall Hospital	38	100% (24/24)	N<6	N<6	0% (0/16)	18% (7/40)	N<6
Royal Gwent Hospital	19	67% (12/18)	N=0	N=0	N<6	10% (2/20)	N=0
Betsi Cadwaladr University Health Board							
Glan Clwyd Hospital	Not participated in biological therapy audit						
Llandudno General Hospital	N=0	N=0	N=0	N=0	N=0	N=0	N=0
Wrexham Maelor Hospital	30	6% (1/16)	N=0	N=0	6% (2/35)	41% (15/37)	20%(2/10)
Ysbyty Gwynedd	Not participated in biological therapy audit						
Cardiff and Vale University Health Board							
University Hospital Llandough	16	38% (6/16)	N=0	N=0	11% (1/9)	0% (0/16)	N<6
University Hospital of Wales	28	100% (8/8)	100% (6/6)	100% (6/6)	0% (0/27)	3% (1/30)	N<6

Key indicators	Number of patients with CD entered at your site	Patients with CD given 160/80 mg of ADA at induction	Response to treatment	Remission achieved	Patients with at least one adverse event	Patients with CD on concomitant therapy, 5-ASA at induction	Patients with CD, treatment effective and discontinued at follow-up
Results	2715	77% (1112/1449)	87% (195/224)	70% (170/244)	11% (180/1667)	17% (481/2813)	11% (45/392)
Cwm Taf University Health Board							
Prince Charles Hospital	Not participated in biological therapy audit						
Royal Glamorgan Hospital	Not participated in biological therapy audit						
Hywel Dda University Health Board							
Bronglais General Hospital	N<6	N<6	N<6	N<6	N<6	N<6	N<6
Glangwili General Hospital	N=0	N=0	N=0	N=0	N=0	N=0	N=0
Prince Philip Hospital	Not participated in biological therapy audit						
Withybush General Hospital	N=0	N=0	N=0	N=0	N=0	N=0	N=0

Appendices

Appendix 1: Acronyms used in this report

ADA	Adalimumab
Anti-TNFα	Anti-tumour necrosis factor α
AoMRC	Academy of Medical Royal Colleges
CD	Crohn's disease
CEEU	Clinical Effectiveness and Evaluation Unit
HBI	Harvey–Bradshaw index
HQIP	Healthcare Quality Improvement Partnership
IBD	Inflammatory bowel disease
IBDU	Inflammatory bowel disease type unclassified
IFX	Infliximab
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
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
5-ASA	5-Aminosalicylic acid

Appendix 2: Biological therapy audit governance

Audit governance

The UK IBD audit fourth round 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 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 CEEU 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 that was tasked with leading this particular element of the UK IBD audit and 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 (from Dec 2012)
Mr Graeme Wilson, consultant colorectal surgeon, Western General Hospital, Edinburgh

British Dietetic Association

Ms Katie Keetarut, senior IBD dietitian, University College Hospital, London (from Mar 2012)

British Society of Gastroenterology

Dr Ian Arnott, clinical director of the IBD programme, chair of the UK IBD audit steering group and 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 Simon Campbell, consultant gastroenterologist, Manchester Royal Infirmary (from Jan 2014)
Dr Fraser Cummings, consultant gastroenterologist, University Hospital Southampton
Professor Chris Probert, consultant gastroenterologist, Royal Liverpool University Hospital
Dr Barney Hawthorne, consultant gastroenterologist, University Hospital of Wales
Mrs Chris Romaya, executive secretary, British Society of Gastroenterology, London
Dr Ian Shaw, IBD programme associate director and consultant gastroenterologist, Gloucestershire Royal Hospital
Dr Graham Turner, consultant gastroenterologist, Royal Victoria Hospital, Belfast (from Dec 2012)
Dr Abraham Varghese, consultant gastroenterologist, Causeway Hospital, Coleraine
Professor John Williams, consultant gastroenterologist, Abertawe Bro Morgannwg University Health Board, director of the Health Informatics Unit at the RCP

British Society of Paediatric Gastroenterology, Hepatology and Nutrition

Dr Charles Charlton, consultant paediatric gastroenterologist, Queens Medical Centre, Nottingham (from Dec 2012)
Dr Sally Mitton, consultant paediatric gastroenterologist, St George's Hospital, London
Dr Richard Russell, consultant paediatric gastroenterologist, Royal Hospital for Sick Children (Yorkhill), Glasgow

Crohn's and Colitis UK (NACC)

Mr David Barker, chief executive (from Feb 2013)
Mr Peter Canham, patient involvement adviser
Ms Jackie Glatter, health service development adviser (from Jan 2014)

Revd Ian Johnston, patient representative, (from Dec 2012)

Primary Care Society for Gastroenterology

Dr Jamie Dalrymple, GP partner, Drayton and St Faiths medical practice (from Jan 2014)
Dr John O'Malley, medical director, Mastercall Healthcare, Stockport (until Dec 2013)

Royal College of Nursing Crohn's and Colitis Special Interest Group

Ms Kay Crook, paediatric gastroenterology clinical nurse specialist, St Mark's Hospital, Harrow
Ms Diane Hall, clinical nurse specialist, Heartlands Hospital, Birmingham (from Dec 2012)
Ms Veronica Hall, nurse consultant in gastroenterology, Royal Bolton Hospital (from Dec 2012)
Dr Karen Kemp, IBD clinical nurse specialist, Manchester Royal Infirmary

Royal College of Physicians

Ms Rhona Buckingham, operations manager, Clinical Effectiveness and Evaluation Unit
Ms Hannah Evans, medical statistician, Clinical Effectiveness and Evaluation Unit (from Jan 2013)
Dr Emma Fernandez, project manager, IBDQIP (until Mar 2013)
Mr Derek Lowe, medical statistician, Clinical Effectiveness and Evaluation Unit
Ms Kajal Mortier, project coordinator, UK IBD programme
Ms Susan Murray, programme manager, UK IBD programme (from Oct 2012)
Ms Aimee Protheroe, project manager, UK IBD programme
Dr Kevin Stewart, clinical director, Clinical Effectiveness and Evaluation Unit (from Aug 2011)

Royal Pharmaceutical Society of Great Britain

Ms Anja St Clair-Jones, lead pharmacist – surgery and digestive diseases, Royal Sussex County Hospital, Brighton

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