Royal College of Physicians | Inflammatory Bowel Disease Programme

Biological therapy

National clinical audit of biological therapies

UK inflammatory bowel disease (IBD) audit

Paediatric 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

Paediatric

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Author	On behalf of the IBD programme steering group
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 – paediatric report, August 2013
Related publications	*National clinical audit of inflammatory bowel disease (IBD) service provision (paediatric)* (Royal College of Physicians, 2014) *National clinical audit of inpatient care for young people 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

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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 generally safe and effective treatments for IBD and that they are used to good effect throughout the participating paediatric sites in the UK. Of the 25 specialist paediatric IBD sites in the UK, 23 are participating in the biological therapies audit or in the Personalised Anti-TNF Therapy in Crohn's disease study (PANTS).[3] A total of 524 paediatric patients have been included in this national analysis.

Engagement in the biologics audit has continued, but clinicians should be encouraged to enter data on all appropriate patients to ensure a more comprehensive assessment of all patients receiving biologics. Objective assessment of response to therapy continues to be an important part of using these expensive medicines. The collection of disease activity scores and quality of life data continues to be central to this, especially after induction and on a regular basis for patients who then progress to maintenance therapy.

The data available on the use of biological therapies in paediatric patients remain limited, but results presented in this report seem encouraging in terms of reducing disease activity at follow-up. However, 5% of treatments were stopped with a biologic by follow-up; 25% of these patients attributed this to loss of response and 13% to experiencing side effects or an adverse event. It is therefore apparent that although adverse events are uncommon, loss of response in the longer term is still an important clinical issue. 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 in addition to the increased use in ulcerative noted in the current audit. Only by continuing the audit to take account of these issues can we ensure that the quality of care for paediatric patients with IBD continues to improve.

Key findings

1 The rate of participation in the biological therapies audit by specialist paediatric sites is encouraging (92%), but in some cases it is likely that only a minority of cases are being entered into the audit. (**Section 1, p 12**)

2 The majority of paediatric patients received infliximab as their biological therapy. Of the 524 paediatric patients audited, there were 488 initial treatments with infliximab and 74 with adalimumab. Important to note that there are more treatments than patients as some patients were treated with more than one biologic. **(Section 2, table 1)**

3 For patients with Crohn's disease, treatment with a biologic resulted in a response rate of 77% and remission in 65% of patients **(Section 2, table 2)**
4 Informed consent to receive treatment is taken for the majority of patients (99%) and usually takes the form of written consent (54%). **(Section 5, pp 24, 31, 37)**
5 80% of patients with Crohn's disease are receiving concomitant immunosuppression at initial treatment. Of these, 71% are receiving thiopurines and 9% are receiving methotrexate. **(Section 5, p 26)**
6 Recorded adverse events for patients with IBD are uncommon. Acute treatment reactions and infections are the commonest events, recorded among 10% and 7% of all patients, respectively. No deaths or cases of malignancy were reported at follow-up. **(Section 2, table 4)**
7 Routine collection of patient-reported outcome measures (IMPACT III) is low in clinical practice, with 18% of all IBD patients recording this at baseline and 5% at either 3- or 12-month follow-up. **(Section 2, table 8)**
8 Only 12% of patients with Crohn's disease were clearly recorded as having been appropriately prescribed anti-TNFα treatment, compared with NICE TA187 criterion 1.5. **(Section 2, table 7)**
9 Severity of Crohn's disease at initial treatment, assessed using Physician's Global Assessment (PGA), was reported as moderate in 54% of patients, severe in 37% and mild in 8%. **(Section 5, p 25)** However, the majority of patients being started on anti-TNFα treatment for Crohn's disease had a median Paediatric Crohn's Disease Activity Index (PCDAI) score of 23 (interquartile range 10–33), indicating a disparity between the two assessments. **(Section 2, table 5)**
10 Children with Crohn's disease receive treatment with a biologic significantly earlier in the disease course than adults (1.42 vs 5.23 years, respectively). However, the response and remission rates in the two groups are similar. **(Section 2, table 2)**
11 The use of biologics in paediatric patients with ulcerative colitis is increasing. The commonest indication for use is chronic refractory ulcerative colitis (59%), with acute severe ulcerative colitis a less common indication (39%). **(Section 5, p 31)**

Recommendations

1 Sites should continue to participate in the national biological therapy audit and aim to submit data on **all** appropriate patients wherever possible. 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 Sites should routinely assess disease activity at baseline and again at 3- and 12-month follow-up. This measure is a vital part of objective assessment of the appropriateness of initial treatment, response and whether ongoing treatment is still clinically appropriate.
3 The PCDAI may not fully capture the appropriateness of biologics treatment for all patients based on current clinical use. Using different disease activity assessments, such as the Weighted Paediatric Crohn's Disease Activity Index (wPCDAI)[4] or PGA, or combining assessment with other parameters may help to address this issue.
4 Local teams should encourage patients to complete IMPACT III, patient-reported outcome measure 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.
5 Sites participating in the audit should export their own local data and use them for local analyses, benchmarking and local quality improvement activities.
6 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 wherever possible. 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.	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 Sites should routinely assess disease activity at baseline and again at 3- and 12-month follow up. This measure is a vital part of objective assessment of the appropriateness of initial treatment, response and whether ongoing treatment is still clinically appropriate.	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	
3 The PCDAI may not fully capture the appropriateness of biologics treatment for all patients based on current clinical use. Using different disease activity assessments, such as the wPCDAI or PGA, or combining assessment with other parameters may help to address this issue.	Ensure that a mechanism is in place to fully capture the appropriateness of biologics treatment for all patients based on current clinical use.	Consultant gastroenterologists IBD nurses Infusion clinic staff	

4	Local teams should encourage patients to complete IMPACT III, patient-reported outcome measure 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 patient-reported outcome measures at baseline and follow-up. A copy of the IMPACT III questionnaire can be downloaded from the web tool (**www.ibdbiologicsaudit.org/**)	Consultant gastroenterologists IBD nurses Infusion clinic staff	
5	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	
6	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	
7	ENTER THE LOCAL ACTIONS YOU HAVE IDENTIFIED HERE			
8	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 20** 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 25 specialist paediatric IBD sites in the UK; of these, 23 (92%) are participating in the biological therapies audit and/or in the PANTS research study. There are 14 paediatric sites participating in the biological therapies audit and/or Personalised Anti-TNF Therapy in Crohn's disease (PANTS) research study in addition to the specialist paediatric IBD sites (37 in total). There may also be paediatric patients receiving biological therapies under adult gastroenterology services. 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. Children 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 37 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 paediatric site data provided from those sites that registered to the audit indicating that they provide their IBD service to paediatric patients. A separate report has been prepared for adult 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 paediatric patients included in the national analysis
Table 2: Summary table highlighting key items for CD paediatric and adult 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 paediatric 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 of treatment for combined CD, UC and IBDU patients
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 paediatric 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 paediatric patients with CD
Table 10: Surgical procedures that were carried out pre- and post-initiation of biological therapy (ADA and IFX combined) for paediatric patients with UC
Table 11: Surgical procedures that were carried out pre- and post-initiation of biological therapy (ADA and IFX combined) for paediatric patients with IBDU

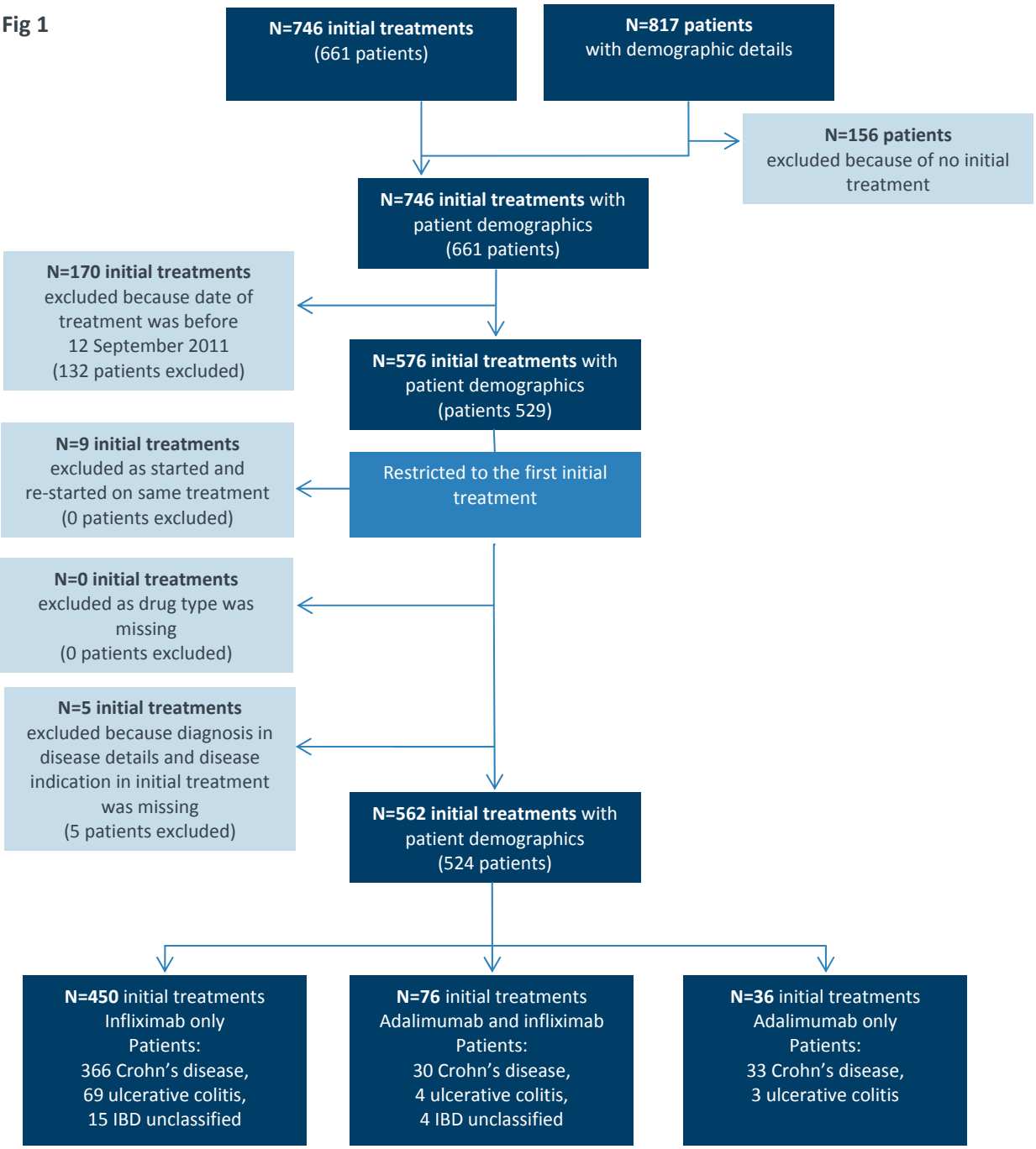
Section 6: Publicly available data from each of the participating sites. This also acts as a list of participating sites.

2: Summary of key results

Consort diagram

On 28 February 2014, there were 817 individual paediatric 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 biologic al 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 paediatric patients included in the national analysis

	CD	YOUR SITE	UC	IBDU	TOTAL
Patients[a]	429		76	19	524
Initial treatments	**459**		**80**	**23**	**562**
IFX	396		73	19	488
ADA	63		7	4	74
Follow-up treatments	**1511**		**180**	**34**	**1725**
IFX	1414		174	32	1620
ADA	97		6	2	105
All treatments total	**1970**		**260**	**57**	**2287**

[a]30 patients with CD / 4 with UC / 4 with IBDU were treated with both IFX and ADA.

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

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

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

(Continued overleaf)

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

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

[a]Denominators change to exclude cases where date / disease severity score was not provided.
[b]Where a patient switched treatment, the first treatment 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]	81% (320/396)	75% (1041/1389)	76% (48/63)	58% (53/91)
Steroids[b]	20% (79/396)	4% (58/1389)	16% (10/63)	16% (15/91)

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

Audit objective: safety

Table 4 Percentage of all paediatric 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% (40/385)
Infection[b]	7% (26/385)
Rash[b]	0.8% (3/385)
Blood abnormality[b]	0.8% (3/385)
Headaches[b]	0.3% (1/385)
Chest pain[b]	0.3% (1/385)
Alopecia[b]	0.3% (1/385)
Other[b]	2% (6/385)

[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

	Disease activity scores: median (IQR)	
	Initial treatment	Any follow-up treatment between 10-14 weeks
Paediatric Crohn's Disease Activity Index (PCDAI)	(N=368) 23 (10, 33)	(N=74) 8 (0,18)
Paediatric Ulcerative Colitis Activity Index (PUCAI)	(N=111) 40 (20, 60)	(N=14) 10 (5, 28)

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

Further information about the surgical data collected in the biological therapies audit can be found on **p 41** 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 (1.5) has been used to assess the appropriateness of prescribing anti-TNFα therapy.

Table 7 CD paediatric compliance with a selected TA187 NICE criterion

NICE (TA187)	National CD data % (n/N)	YOUR SITE
Criterion 1.5 IFX should be used for people aged 6–17 years with severe active CD only if a) the disease has not responded to conventional therapy, or b) the person is intolerant of or has contraindications to conventional therapy (mercaptopurine, azathioprine, methotrexate, prednisolone, budesonide, methylprednisolone or hydrocortisone)		
Percentage of patients with CD treated with IFX who had a PCDAI score of ≥45 prior to commencing anti-TNFα	14% (28/201)	
Percentage of patients with CD treated with IFX who were treated with conventional therapy at or prior to commencing biological therapy	93% (354/382)	
Percentage of patients with CD treated with IFX who were appropriately prescribed treatment in compliance with NICE criterion 1.5 (TA187)	12% (25/201)	

Audit objective: patient-reported outcome measures (PROMs)

Table 8 Completion and results of the PROMs questionnaires (IMPACT III)

IMPACT III	Initial treatment	Follow-up treatment[a]
Number of treatments	562	1725
Number with IMPACT III PROM data completed	18% (101/562)	5% (78/1725)
IMPACT III PROM score: median (IQR)	95 (75, 112)	70 (54.5, 95.5)

[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 paediatric quality of life measure used in the biological therapies audit (IMPACT III) can be found on **p 43** 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 national 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 severely active UC in adults, but has recommended its use for induction treatment in children.

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 43**.

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 paediatric national audit results tables

Crohn's disease: IBD details

Crohn's disease IBD details	Frequency (%)	
	Infliximab	Adalimumab
	National (N=383)	National (N=60)
Diagnosis		
Maximal disease distribution at the time of decision to initiate biological therapy, as defined by the Montreal classification		
Terminal ileum (L1)	10% (37/379)	7% (4/60)
Colonic (L2)	40% (152/379)	48% (29/60)
Ileocolonic (L3)	40% (151/379)	37% (22/60)
None of these	10% (39/379)	8% (5/60)
Any part of the gut proximal to the terminal ileum (L4)		
Yes	80% (268/337)	82% (42/51)
Perianal involvement?		
Yes	55% (135/247)	46% (18/39)
Date of diagnosis		
<1 year ago	37% (140/383)	25% (15/60)
1–5 years ago	54% (205/383)	63% (38/60)
6–10 years ago	9% (36/383)	12% (7/60)
>10 years ago	0.5% (2/383)	0% (0/60)

Crohn's disease: initial anti-TNFα treatment

Crohn's disease Initial anti-TNFα treatment	Frequency (%)	
	Infliximab	Adalimumab
	National (N=396)	National (N=63)
Consent		
Was informed consent to receive anti-TNFα treatment taken from this patient?		
Yes	99% (393/396)	100% (63/63)
No	0.8% (3/396)	0% (0/63)
If yes, was this written or verbal?		
Verbal	44% (174/393)	65% (41/63)
Written	56% (219/393)	35% (22/63)
Treatment details		
Time between date of decision to start and date of initial treatment (first loading dose)		
Median (IQR), days	10 (5, 22)	13 (8, 23)
What was the clinical indication for this treatment?		
Severe perianal Crohn's disease	19% (74/395)	5% (3/63)
Active luminal Crohn's disease	77% (304/395)	81% (51/63)
Fistulating Crohn's disease	1% (4/395)	0% (0/63)
Other clinical indication	2% (6/395)	2% (1/63)
Not known	2% (7/395)	13% (8/63)
Dose given at this infusion (mg/kg)		
5	99% (347/349)	NA
10	0.3% (1/349)	NA
Other	0.3% (1/349)	NA
Duration of infusion (mins)		
85	0.3% (1/345)	NA
120	98% (337/345)	NA
180	0.9% (3/345)	NA
240	1% (4/345)	NA
Infusion completion outcome		
Completed successfully at prescribed rate	98% (387/396)	NA
Completed successfully at lower rate	1% (4/396)	NA
Repeat infusion reaction at lower rate and discontinued	0.3% (1/396)	NA
Infusion discontinued and not restarted	1% (4/396)	NA

NA = not applicable.

Crohn's disease Initial anti-TNFα treatment	Frequency (%)	
	Infliximab	Adalimumab
	National (N=396)	National (N=63)
Treatment details continued		
Induction dose (mg)		
160/80	NA	25% (16/63)
80/40	NA	71% (45/63)
Other	NA	3% (2/63)
Planned maintenance dose		
40 mg every other week	NA	90% (57/63)
40 mg every week	NA	6% (4/63)
Other	NA	3% (2/63)
Were any acute reactions recorded for this treatment?		
Yes	1% (5/396)	0% (0/63)
Which acute reactions? (more than one may have been selected)		
Angioedema of upper airway	0.5% (2/396)	0% (0/63)
Bronchospasm (cough/wheeze/dyspnoea)	0.3% (1/396)	0% (0/63)
Flushing	0.5% (2/396)	0% (0/63)
Hypotension	0.3% (1/396)	0% (0/63)
Nausea	0.3% (1/396)	0% (0/63)
Rash	0.3% (1/396)	0% (0/63)
Other	0.3% (1/396)	0% (0/63)
Is the patient receiving any concomitant therapies for the management of IBD at the time of this treatment?		
Yes	89% (354/396)	89% (56/63)
If yes, indicate which concomitant therapies (more than one may have been selected)		
Azathioprine / mercaptopurine	73% (290/396)	59% (37/63)
Methotrexate	8% (30/396)	19% (12/63)
Steroids	20% (79/396)	16% (10/63)
5-ASA	29% (114/396)	35% (22/63)
Dietary therapy	11% (45/396)	8% (5/63)
Antibiotics	10% (41/396)	0% (0/63)
Heparin	0.3% (1/396)	0% (0/63)
Tacrolimus	1% (4/396)	0% (0/63)
Topical	0.5% (2/396)	0% (0/63)
Mycophenolate	0.3% (1/396)	0% (0/63)
Other	4% (16/396)	10% (6/63)
On any immunosuppressant (azathioprine, mercaptopurine or methotrexate)	81% (320/396)	76% (48/63)

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

Crohn's disease Initial anti-TNFα treatment	Frequency (%)	
	Infliximab	Adalimumab
	National (N=396)	National (N=63)
Treatment details continued		
Has the patient failed to respond or are they intolerant to immunosuppressive drugs / corticosteroids?		
Yes	51% (168/332)	73% (16/22)
If yes, indicate which previous therapies (more than one therapy may have been selected)		
Azathioprine / mercaptopurine	67% (113/168)	63% (10/16)
Methotrexate	14% (24/168)	13% (2/16)
Steroids	54% (90/168)	50% (8/16)
Anti-TNFα	5% (9/168)	81% (13/16)
5-ASA	24% (41/168)	13% (2/16)
Dietary therapy	42% (70/168)	44% (7/16)
Antibiotics	0.6% (1/168)	0% (0/16)
Ciclosporin	0.6% (1/168)	0% (0/16)
Topical	0.6% (1/168)	0% (0/16)
Other	0.6% (1/168)	0% (0/16)
On any immunosuppressant (azathioprine, mercaptopurine or methotrexate)	71% (120/168)	63% (10/16)
Disease severity score		
Severity of disease		
Mild	8% (13/163)	13% (2/16)
Moderate	55% (90/163)	44% (7/16)
Severe	37% (60/163)	44% (7/16)

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=1414)	National (N=97)
Follow-up treatment details		
Was the patient:		
Seen for follow-up?	98% (1389/1414)	91% (88/97)
Transitioned to adult care?	2% (23/1414)	8% (8/97)
Transferred to another service?	0.1% (2/1414)	1% (1/97)
Time between date of initial treatment and date of follow-up		
Median (IQR), days	167 (46, 350)	81 (35, 232)
Current infliximab dose number		
0–5	51% (707/1389)	NA
6–10	30% (420/1389)	NA
>10	19% (262/1389)	NA
Infliximab dose given at this treatment (mg/kg)		
5	92% (1282/1389)	NA
10	7% (99/1389)	NA
Other	0.6% (8/1389)	NA
Continue infliximab treatment plan		
Continue treatment with infliximab	97% (1346/1388)	NA
Stop treatment with infliximab	3% (42/1388)	NA
Review of adalimumab treatment plan		
Continue treatment with adalimumab	NA	91% (84/92)
Stop treatment with adalimumab	NA	9% (8/92)
If treatment was stopped, what were the reasons for stopping?		
Treatment effective and discontinued	21% (9/42)	0% (0/8)
Loss of response	17% (7/42)	38% (3/8)
Poor response	29% (12/42)	50% (4/8)
Side effects/adverse events	14% (6/42)	0% (0/8)
Other	19% (8/42)	13% (1/8)
If continuing treatment, what is the planned continued treatment frequency?		
Every week	NA	24% (20/83)
Every other week	NA	76% (63/83)

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=1414)	National (N=97)
Follow-up treatment details continued		
If continuing treatment, what is the planned continued treatment dose? (mg)		
20/25	NA	1% (1/83)
40	NA	82% (68/83)
80	NA	14% (12/83)
160	NA	2% (2/83)
Did the patient report complete compliance with the maintenance regime since the last adalimumab review?		
Yes	NA	99% (89/90)
Did the patient report any acute reactions?		
Yes	1% (16/1389)	0% (0/92)
Which acute reactions? (more than one may have been selected)		
Angioedema of upper airway	0.1% (1/1389)	0% (0/92)
Chest pain	0.2% (3/1389)	0% (0/92)
Dizziness	0.1% (1/1389)	0% (0/92)
Fatigue	0.1% (1/1389)	0% (0/92)
Flushing	0.1% (1/1389)	0% (0/92)
Headache	0.1% (1/1389)	0% (0/92)
Hypotension	0.1% (1/1389)	0% (0/92)
Itching	0.1% (2/1389)	0% (0/92)
Nausea	0.2% (3/1389)	0% (0/92)
Panic attacks	0.1% (1/1389)	0% (0/92)
Rash	0.3% (4/1389)	0% (0/92)
Urticaria	0.1% (2/1389)	0% (0/92)
Other	0.1% (2/1389)	0% (0/92)

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=1414)	National (N=97)
Follow-up treatment details continued		
Is the patient currently receiving any other therapies for the management of IBD?		
Yes	82% (1139/1389)	80% (73/91)
If yes, indicate which other therapies (more than one may have been selected)		
Azathioprine / mercaptopurine	70% (979/1389)	45% (41/91)
Methotrexate	4% (62/1389)	13% (12/91)
Steroids	4% (58/1389)	16% (15/91)
5-ASA	16% (226/1389)	34% (31/91)
Antibiotics	2% (28/1389)	5% (5/91)
Dietary therapy	3% (37/1389)	9% (8/91)
Ciclosporin	0.1% (1/1389)	0% (0/91)
Tacrolimus	0.3% (4/1389)	1% (1/91)
Mycophenolate	0.1% (1/1389)	0% (0/91)
Topical	0.1% (1/1389)	0% (0/91)
Other	3% (45/1389)	10% (9/91)
On any immunosuppressant (azathioprine, mercaptopurine or methotrexate)	75% (1041/1389)	58% (53/91)
Were there any adverse events since the last review?		
Yes	3% (41/1389)	2% (2/91)
What adverse events?		
Blood abnormality	0.1% (2/1389)	0% (0/91)
Chest pain	0.1% (2/1389)	0% (0/91)
Headache	0.1% (1/1389)	0% (0/91)
Infection	2% (30/1389)	2% (2/91)
Rash	0.1% (2/1389)	0% (0/91)
Other adverse event	0.3% (4/1389)	0% (0/91)
Disease severity score		
Severity of disease		
Mild	69% (500/726)	26% (17/65)
Moderate	26% (186/726)	51% (33/65)
Severe	6% (40/726)	23% (15/65)

5-ASA = 5-aminosalicylic acid.

Ulcerative colitis: IBD disease details

Ulcerative colitis IBD details	Frequency (%)	
	Infliximab	Adalimumab
	National (N=71)	National (N=7)
Diagnosis		
Maximal disease distribution at the time of decision to initiate biological therapy, as defined by the Montreal classification		
Proctitis (E1)	3% (2/70)	0% (0/7)
Left sided (E2)	24% (17/70)	14% (1/7)
Extensive (E3)	73% (51/70)	86% (6/7)
Date of diagnosis		
<1 year ago	55% (39/71)	14% (1/7)
1–5 years ago	44% (31/71)	71% (5/7)
6–10 years ago	1% (1/71)	14% (1/7)

Ulcerative colitis: initial anti-TNFα treatment

Ulcerative colitis Initial anti-TNFα treatment	Frequency (%)	
	Infliximab	Adalimumab
	National (N=73)	National (N=7)
Consent		
Was informed consent to receive anti-TNFα treatment taken from this patient?		
Yes	100% (73/73)	100% (7/7)
If yes, was this written or verbal?		
Verbal	34% (25/73)	86% (6/7)
Written	66% (48/73)	14% (1/7)
Treatment details		
Time between date of decision to start and date of initial treatment (first loading dose)		
Median (IQR), days	7 (2, 17)	24 (0, 77)
What was the clinical indication for this treatment?		
Acute severe ulcerative colitis	43% (31/72)	0% (0/7)
Chronic refractory ulcerative colitis	56% (40/72)	100% (7/7)
Not known	1% (1/72)	0% (0/7)
Dose given at this infusion (mg/kg)		
5	100% (66/66)	NA
Duration of infusion (mins)		
120	98% (64/65)	NA
180	2% (1/65)	NA
Infusion completion outcome		
Completed successfully at prescribed rate	99% (72/73)	NA
Infusion discontinued and not restarted	1% (1/73)	NA
Induction dose (mg)		
160/80	NA	14% (1/7)
80/40	NA	86% (6/7)
Planned maintenance dose		
40 mg every other week	NA	86% (6/7)
Other	NA	14% (1/7)

NA = not applicable.

Ulcerative colitis Initial anti-TNFα treatment	Frequency (%)	
	Infliximab	Adalimumab
	National (N=73)	National (N=7)
Treatment details continued		
Were any acute reactions recorded for this treatment?		
Yes	4% (3/73)	0% (0/7)
Which acute reactions? (more than one may have been selected)		
Dizziness	1% (1/73)	0% (0/7)
Flushing	1% (1/73)	0% (0/7)
Hypotension	1% (1/73)	0% (0/7)
Nausea	1% (1/73)	0% (0/7)
Panic attacks	1% (1/73)	0% (0/7)
Rash	1% (1/73)	0% (0/7)
Is the patient receiving any concomitant therapies for the management of IBD at the time of this treatment?		
Yes	99% (72/73)	100% (7/7)
If yes, indicate which concomitant therapies (more than one may have been selected)		
Azathioprine / mercaptopurine	67% (49/73)	86% (6/7)
Methotrexate	5% (4/73)	0% (0/7)
Steroids	60% (44/73)	0% (0/7)
5-ASA	45% (33/73)	100% (7/7)
Antibiotics	7% (5/73)	0% (0/7)
Dietary therapy	3% (2/73)	0% (0/7)
Tacrolimus	1% (1/73)	0% (0/7)
Ciclosporin	1% (1/73)	0% (0/7)
Topical	5% (4/73)	0% (0/7)
Mycophenolate	1% (1/73)	0% (0/7)
Other	4% (3/73)	14% (1/7)
On any immunosuppressant (azathioprine, mercaptopurine or methotrexate)	73% (53/73)	86% (6/7)

5-ASA = 5-aminosalicylic acid.

Ulcerative colitis Initial anti-TNFα treatment	Frequency (%)	
	Infliximab	Adalimumab
	National (N=73)	National (N=7)
Treatment details continued		
Has the patient failed to respond or are they intolerant to immunosuppressive drugs / corticosteroids?		
Yes	44% (28/64)	33% (1/3)
If yes, indicate which previous therapies (more than one may have been selected)		
Azathioprine / mercaptopurine	46% (13/28)	0% (0/1)
Methotrexate	7% (2/28)	0% (0/1)
Steroids	89% (25/28)	0% (0/1)
Anti-TNFα	4% (1/28)	100% (1/1)
5-ASA	50% (14/28)	0% (0/1)
Ciclosporin	4% (1/28)	0% (0/1)
On any immunosuppressant (azathioprine, mercaptopurine or methotrexate)	50% (14/28)	0% (0/1)
Disease severity score		
Severity of disease		
Mild	8% (3/37)	0% (0/2)
Moderate	43% (16/37)	50% (1/2)
Severe	49% (18/37)	50% (1/2)

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=174)	National (N=6)
Follow-up treatment details		
Was the patient:		
Seen for follow-up?	97% (168/174)	83% (5/6)
Lost to follow-up?	0% (0/0)	17% (1/6)
Transitioned to adult care?	2% (3/174)	0% (0/6)
Transferred to another service?	2% (3/174)	0% (0/6)
Time between date of initial treatment and date of follow-up		
Median (IQR), days	94 (21, 215)	130 (114, 304)
Current Infliximab dose number		
0–5	71% (119/168)	NA
6–10	20% (34/168)	NA
>10	9% (15/168)	NA
Infliximab dose given at this treatment (mg/kg)		
5	98% (164/168)	NA
10	2% (4/168)	NA
Continue infliximab treatment plan		
Continue treatment with infliximab	88% (147/168)	NA
Stop treatment with infliximab	13% (21/168)	NA
Review of adalimumab treatment plan		
Continue treatment with adalimumab	NA	100% (5/5)
Stop treatment with adalimumab	NA	0% (0/5)
If treatment stopped, what were the reasons for stopping?		
Treatment effective and discontinued	10% (2/21)	NA
Loss of response	38% (8/21)	NA
Poor response	38% (8/21)	NA
Side effects / adverse events	10% (2/21)	NA
Patient choice	5% (1/21)	NA

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=174)	National (N=6)
Follow-up treatment details continued		
Did the patient report any acute reactions?		
Yes	2% (4/168)	0% (0/5)
Which acute reactions? (more than one may have been selected)		
Dizziness	0.6% (1/168)	0% (0/5)
Flushing	0.6% (1/168)	0% (0/5)
Itching	1% (2/168)	0% (0/5)
Rash	0.6% (1/168)	0% (0/5)
Urticaria	0.6% (1/168)	0% (0/5)
Is the patient currently receiving any other therapies for the management of IBD?		
Yes	95% (160/168)	100% (5/5)
If yes, indicate which other therapies (more than one may have been selected)		
Azathioprine / mercaptopurine	78% (131/168)	80% (4/5)
Methotrexate	1% (2/168)	0% (0/5)
Steroids	26% (43/168)	0% (0/5)
5-ASA	52% (87/168)	100% (5/5)
Antibiotics	4% (6/168)	0% (0/5)
Ciclosporin	0.6% (1/168)	0% (0/5)
Tacrolimus	2% (4/168)	0% (0/5)
Mycophenolate	3% (5/168)	0% (0/5)
Other	5% (8/168)	0% (0/5)
On any immunosuppressant (azathioprine, mercaptopurine or methotrexate)	79% (133/168)	80% (4/5)
Were there any adverse events since last review?		
Yes	4% (7/168)	0% (0/5)
What adverse events?		
Alopecia	0.6% (1/168)	0% (0/5)
Blood abnormality	0.6% (1/168)	0% (0/5)
Infection	2% (3/168)	0% (0/5)
Other adverse event	1% (2/168)	0% (0/5)
Disease severity score		
Severity of disease		
Mild	54% (51/95)	40% (2/5)
Moderate	34% (32/95)	60% (3/5)
Severe	13% (12/95)	0% (0/5)

5-ASA = 5-aminosalicylic acid.

IBD type unclassified: IBD details

IBD type unclassified IBD details	Frequency (%)	
	Infliximab	Adalimumab
	National (N=17)	National (N=4)
Diagnosis		
Maximal disease distribution at the time of decision to initiate biological therapy, as defined by the Montreal classification		
Left sided (E2)	6% (1/17)	0% (0/4)
Extensive (E3)	94% (16/17)	100% (4/4)
Date of diagnosis		
<1 year ago	59% (10/17)	50% (2/4)
1–5 years ago	29% (5/17)	50% (2/4)
6–10 years ago	12% (2/17)	0% (0/4)

IBD type unclassified: initial anti-TNFα treatment

IBD type unclassified Initial anti-TNFα treatment	Frequency (%)	
	Infliximab	Adalimumab
	National (N=19)	National (N=4)
Consent		
Was informed consent to receive anti-TNFα treatment taken from this patient?		
Yes	100% (19/19)	100% (4/4)
If yes, was this written or verbal?		
Verbal	37% (7/19)	100% (4/4)
Written	63% (12/19)	0% (0/4)
Treatment details		
Time between date of decision to start and date of initial treatment (first loading dose)		
Median (IQR), days	7 (0, 13)	5 (5, 5)
What was the clinical indication for this treatment?		
Acute severe IBD type unclassified	47% (9/19)	50% (2/4)
Chronic refractory IBD type unclassified	53% (10/19)	25% (1/4)
Not known	0% (0/0)	25% (1/4)
Dose given at this infusion (mg/kg)		
5	93% (14/15)	NA
Other	7% (1/15)	NA
Duration of infusion (mins)		
120	86% (12/14)	NA
180	7% (1/14)	NA
240	7% (1/14)	NA
Infusion completion outcome		
Completed successfully at prescribed rate	95% (18/19)	NA
Completed successfully at lower rate	5% (1/19)	NA
Induction dose (mg)		
160/80	NA	25% (1/4)
80/40	NA	75% (3/4)
Planned maintenance dose		
40 mg every other week	NA	75% (3/4)
Other	NA	25% (1/4)
Were any acute reactions recorded for this treatment?		
Yes	11% (2/19)	0% (0/4)
Which acute reactions?		
Itching	5% (1/19)	0% (0/4)
Other	5% (1/19)	0% (0/4)

NA = not applicable.

IBD type unclassifed Initial anti-TNFα treatment	Frequency (%)	
	Infliximab	Adalimumab
	National (N=19)	National (N=4)
Treatment details continued		
Is the patient receiving any concomitant therapies for the management of IBD at the time of this treatment?		
Yes	95% (18/19)	100% (4/4)
If yes, indicate which concomitant therapies (more than one may have been selected)		
Azathioprine / mercaptopurine	63% (12/19)	100% (4/4)
Methotrexate	5% (1/19)	0% (0/4)
Steroids	58% (11/19)	0% (0/4)
5-ASA	47% (9/19)	75% (3/4)
Antibiotics	11% (2/19)	25% (1/4)
Dietary therapy	5% (1/19)	0% (0/4)
Other	11% (2/19)	0% (0/4)
On any immunosuppressant (azathioprine, mercaptopurine or methotrexate)	68% (13/19)	100% (4/4)
Has the patient failed to respond or are they intolerant to immunosuppressive drugs / corticosteroids?		
Yes	60% (9/15)	100% (1/1)
If yes, indicate which previous therapies (more than one therapy may have been selected)		
Azathioprine / mercaptopurine	67% (6/9)	0% (0/1)
Methotrexate	22% (2/9)	0% (0/1)
Steroids	89% (8/9)	100% (1/1)
Anti-TNFα	0% (0/9)	100% (1/1)
5-ASA	11% (1/9)	0% (0/1)
Antibiotics	11% (1/9)	0% (0/1)
On any immunosuppressant (azathioprine, mercaptopurine or methotrexate)	67% (6/9)	0% (0/1)
Disease severity score		
Severity of disease		
Mild	0% (0/9)	0% (0/4)
Moderate	22% (2/9)	0% (0/4)
Severe	78% (7/9)	0% (0/4)

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=32)	**National (N=2)**
Follow-up treatment details		
Was the patient:		
Seen for follow-up?	97% (31/32)	100% (2/2)
Transferred to another service?	3% (1/32)	0% (0/2)
Time between date of initial treatment and date of follow-up		
Median (IQR), days	44 (14, 98)	220 (75, 364)
Current infliximab dose number		
0–5	87% (26/30)	NA
6–10	10% (3/30)	NA
>10	3% (1/30)	NA
Infliximab dose given at this treatment (mg/kg)		
5	90% (27/30)	NA
Other	10% (3/30)	NA
Continue infliximab treatment plan		
Continue treatment with infliximab	83% (25/30)	NA
Stop treatment with infliximab	17% (5/30)	NA
Review of adalimumab treatment plan		
Continue treatment with adalimumab	NA	100% (2/2)
Stop treatment with adalimumab	NA	0% (0/2)
If treatment stopped, what were the reasons for stopping?		
Loss of response	20% (1/5)	NA
Poor response	40% (2/5)	NA
Side effects / adverse events	40% (2/5)	NA
Did the patient report any acute reactions?		
Yes	10% (3/30)	0% (0/2)
Which acute reactions? (more than one may have been selected)		
Fever	3% (1/30)	NA
Flushing	7% (2/30)	NA
Itching	3% (1/30)	NA
Nausea	3% (1/30)	NA
Rash	7% (2/30)	NA
Other	3% (1/30)	NA

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=32)	National (N=2)
Follow-up treatment details continued		
Is the patient currently receiving any other therapies for the management of IBD?		
Yes	97% (29/30)	100% (2/2)
If yes, indicate which other therapies (more than one may have been selected)		
Azathioprine / mercaptopurine	63% (19/30)	100% (2/2)
Methotrexate	10% (3/30)	0% (0/2)
Steroids	27% (8/30)	0% (0/2)
5-ASA	27% (8/30)	0% (0/2)
Antibiotics	3% (1/30)	0% (0/2)
Topical	3% (1/30)	0% (0/2)
Other	20% (6/30)	0% (0/2)
On any immunosuppressant (azathioprine, mercaptopurine or methotrexate)	73% (22/30)	100% (2/2)
Were there any adverse events since the last review?		
Yes	3% (1/30)	0% (0/2)
What adverse events?		
Rash	3% (1/30)	NA
Disease severity score		
Severity of disease		
Mild	11% (2/19)	0% (0/2)
Moderate	74% (14/19)	100% (2/2)
Severe	16% (3/19)	0% (0/2)

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

IBD-related surgery

In total, 105 paediatric patients had surgery. There were details of 166 paediatric IBD-related surgical procedures entered using the biological therapies web tool. For the purpose of this analysis, only those procedures that related to patients who had a date of initial treatment recorded within their treatment submission were included.

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

Crohn's disease IBD-related surgery	Procedures 87% (144/166)	
Surgical procedure by type	**Pre-biologic initiation 71% (102/144)**	**Post-biologic initiation 29% (42/144)**
Right hemicolectomy	6% (6/102)	17% (7/42)
Total proctocolectomy ileoanal pouch	1% (1/102)	0% (0/42)
Total proctocolectomy permanent ileostomy	0% (0/102)	2% (1/42)
Colectomy ileostomy with retained rectal stump	6% (6/102)	7% (3/42)
Colectomy colostomy with retained rectal stump	0% (0/102)	2% (1/42)
Partial colectomy	4% (4/102)	2% (1/42)
Small bowel resection	7% (7/102)	7% (3/42)
Insertion of seton	9% (9/102)	5% (2/42)
Drainage of perianal sepsis	26% (27/102)	7% (3/42)
Radiological drainage of abscess	2% (2/102)	10% (4/42)
Stricturoplasty	2% (2/102)	2% (1/42)
Appendectomy	2% (2/102)	0% (0/42)
EUA fistula procedure	26% (27/102)	29% (12/42)
Proctocolectomy	1% (1/102)	0% (0/42)
Proctocolectomy ileoanal pouch	1% (1/102)	2% (1/42)
Proctectomy	1% (1/102)	0% (0/42)
Partial colectomy	0% (0/102)	5% (2/42)
Ileocaecal resection	4% (4/102)	2% (1/42)
Other surgical procedure	2% (2/102)	0% (0/42)

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

Ulcerative colitis IBD-related surgery	Procedures 8% (14/166)	
Surgical procedure by type	Pre-biologic initiation 0% (0/14)	Post-biologic initiation 100% (14/14)
Colectomy ileostomy with retained rectal stump	0% (0/0)	79% (11/14)
Colectomy colostomy with retained rectal stump	0% (0/0)	7% (1/14)
Partial colectomy	0% (0/0)	7% (1/14)
Ileocaecal resection	0% (0/0)	7% (1/14)

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

IBD type unclassified IBD-related surgery	Procedures 5% (8/166)	
Surgical procedure by type	Pre-biologic initiation 50% (4/8)	Post-biologic initiation 50% (4/8)
Total proctocolectomy ileoanal pouch	0% (0/4)	0% (0/4)
Total proctocolectomy permanent ileostomy	0% (0/4)	0% (0/4)
Colectomy ileostomy with retained rectal stump	0% (0/4)	100% (4/4)
Colectomy colostomy with retained rectal stump	25% (1/4)	0% (0/4)
Partial colectomy	25% (1/4)	0% (0/4)
Insertion of seton	0% (0/4)	0% (0/4)
Drainage of perianal sepsis	0% (0/4)	0% (0/4)
EUA fistula procedure	25% (1/4)	0% (0/4)
Proctocolectomy ileoanal pouch	0% (0/4)	0% (0/4)
Proctectomy	0% (0/4)	0% (0/4)
Ileocaecal resection	25% (1/4)	0% (0/4)

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.

IMPACT III

IMPACT III is a health-related quality of life questionnaire for paediatric patients with IBD. Originally developed in Canada, IMPACT III (UK) has been shown to be a valid tool to measure quality of life in British children with IBD.[7] Outcome measures have traditionally relied on disease activity indexes, but these measures fail to assess the patient's subjective view of their experience.

The IMPACT III questionnaire is a 35-item questionnaire that addresses six domains of IBD: bowel symptoms, body image, functional / social impairment, emotional impairment, tests / treatment and systemic impairment. Total scores range from 35 (best) to 175 (poor) and a decrease in total score of 10.8 is reported to be indicative of a clinically meaningful improvement.

There were 101 IMPACT III questionnaires completed at initial treatments across both anti-TNFα types and all disease types, reporting a median (IQR) score of 95 (75, 112).

There were 78 IMPACT III questionnaires completed at follow-up treatments across both anti-TNFα types and all disease types, reporting a median (IQR) score of 70 (54.5, 95.5).

Owing to the limited number of IMPACT III questionnaires completed at both initial and follow-up treatment for individual patients, a median change in IMPACT III score cannot be reliably reported. We expect that there will be sufficient data available to facilitate a more robust analysis of IMPACT III scores in the next national report of this audit (August 2015).

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

Table 8 Completion and results of the PROMs questionnaires (IMPACT III)

IMPACT III	Initial treatment	Follow-up treatment[a]
Number of treatments	562	1725
Number with IMPACT III PROM data completed	18% (101/562)	5% (78/1725)
IMPACT III PROM score: median (IQR)	95 (75, 112)	70 (54.5, 95.5)

[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 43 sites (37 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	Number of CD follow-up treatments after initial infusion	Response to treatment	Remission achieved	Patients with CD treated with infliximab appropriately prescribed in compliance with NICE criterion 1.5 (TA187)	Number of CD patients with PROM data completed at initial treatment	Number of CD patients with PROM data completed at follow-up treatment
Results	524	1511	77% (53/69)	65% (46/71)	12% (25/201)	19% (88/459)	5% (71/1511)
Abertawe Bro Morgannwg University Health Board							
Morriston Hospital (paediatric gastroenterology)	8	46	N<6	N<6	13% (1/8)	56% (5/9)	2% (1/46)
Alder Hey Children's NHS Foundation Trust							
Alder Hey Children's Hospital	46	173	93% (14/15)	80% (12/15)	3% (1/31)	58% (28/48)	6% (11/173)
Ashford and St Peter's Hospitals NHS Foundation Trust							
Ashford Hospital and St Peter's Hospital combined (paediatric)*	Not participating in biological therapy audit (participating in PANTS)						
Barts Health NHS Trust							
Barts and The London Children's Hospital*	16	N=0	N=0	N=0	N=0	0% (0/16)	N=0

Key indicators	Number of patients with CD entered at your site	Number of CD follow-up treatments after initial infusion	Response to treatment	Remission achieved	Patients with CD treated with infliximab appropriately prescribed in compliance with NICE criterion 1.5 (TA187)	Number of CD patients with PROM data completed at initial treatment	Number of CD patients with PROM data completed at follow-up treatment
Results	524	1511	77% (53/69)	65% (46/71)	12% (25/201)	19% (88/459)	5% (71/1511)
Belfast Health and Social Care Trust							
Royal Belfast Hospital for Sick Children (RBHSC)	Not participating in biological therapy audit						
Birmingham Children's Hospital NHS Foundation Trust							
Birmingham Children's Hospital	59	448	N<6	N<6	10% (1/10)	0% (0/59)	0% (0/448)
Brighton and Sussex University Hospitals NHS Trust							
The Royal Alexandra Children's Hospital*	Not participating in biological therapy audit (participating in PANTS)						
Burton Hospitals NHS Foundation Trust							
Queen's Hospital, Burton (paediatric)	N=0	N=0	N=0	N=0	N=0	N=0	N=0
Cambridge University Hospitals NHS Foundation Trust							
Addenbrooke's Hospital (paediatric gastro unit)*	19	141	75% (6/8)	50% (5/10)	15% (2/13)	0% (0/19)	0% (0/141)
Cardiff and Vale University Health Board							
The Noah's Ark Children's Hospital for Wales (previously Department of Child Health, University Hospital of Wales)	13	94	N=0	N=0	N<6	20% (3/15)	0% (0/94)
Central Manchester University Hospitals NHS Foundation Trust							
Royal Manchester Children's Hospital	6	17	N=0	N=0	N=0	0% (0/8)	0% (0/17)

Key indicators	Number of patients with CD entered at your site	Number of CD follow-up treatments after initial infusion	Response to treatment	Remission achieved	Patients with CD treated with infliximab appropriately prescribed in compliance with NICE criterion 1.5 (TA187)	Number of CD patients with PROM data completed at initial treatment	Number of CD patients with PROM data completed at follow-up treatment
Results	524	1511	77% (53/69)	65% (46/71)	12% (25/201)	19% (88/459)	5% (71/1511)
Chelsea and Westminster Hospital NHS Foundation Trust							
Chelsea and Westminster Hospital, Children's Services*	23	92	N<6	N<6	0% (0/6)	0% (0/23)	0% (0/92)
Doncaster and Bassetlaw Hospitals NHS Foundation Trust							
Doncaster Royal Infirmary and Bassetlaw District General Hospital combined (paediatric)	Not participating in biological therapy audit						
Dorset County Hospital NHS Foundation Trust							
Dorset County Hospital, Children's services*	Not participating in biological therapy audit (participating in PANTS)						
Epsom and St Helier University Hospitals NHS Trust							
Queen Mary's Hospital for Children	8	6	N=0	N=0	N=0	0% (0/8)	0% (0/6)
Great Ormond Street Hospital for Children NHS Foundation Trust							
Great Ormond Street Hospital*	31	22	N=0	N=0	N=0	0% (0/39)	0% (0/22)
Hull and East Yorkshire Hospitals NHS Trust							
Hull Royal Infirmary* and Castle Hill Hospital combined (paediatric)	Not participating in biological therapy audit (participating in PANTS)						
King's College Hospital NHS Foundation Trust							
King's College Hospital (paediatric gastro)	14	27	N<6	N<6	38% (3/8)	0% (0/15)	0% (0/27)

Key indicators	Number of patients with CD entered at your site	Number of CD follow-up treatments after initial infusion	Response to treatment	Remission achieved	Patients with CD treated with infliximab appropriately prescribed in compliance with NICE criterion 1.5 (TA187)	Number of CD patients with PROM data completed at initial treatment	Number of CD patients with PROM data completed at follow-up treatment
Results	524	1511	77% (53/69)	65% (46/71)	12% (25/201)	19% (88/459)	5% (71/1511)
Leeds Teaching Hospitals NHS Trust							
Leeds General Infirmary (paediatric gastro unit)	10	29	N=0	N=0	17% (1/6)	45% (5/11)	31% (9/29)
Lewisham and Greenwich NHS Trust							
The Children's Hospital, Lewisham	Not participating in biological therapy audit						
Luton and Dunstable Hospital NHS Foundation Trust							
Luton and Dunstable University Hospital (paediatric)*	Not participating in biological therapy audit (participating in PANTS)						
Maidstone and Tunbridge Wells NHS Trust							
Maidstone Hospital (paediatric)*	Not participating in biological therapy audit (participating in PANTS)						
Tunbridge Wells Hospital (paediatric)	N=0	N=0	N=0	N=0	N=0	N=0	N=0
NHS Grampian							
North-East Scotland Paediatric Gastroenterology Network (Royal Aberdeen Children's Hospital, Ninewells Hospital and Raigmore Hospital combined)	20	68	N<6	N<6	17% (2/12)	23% (6/26)	25% (17/68)
NHS Greater Glasgow and Clyde							
Royal Hospital for Sick Children (Yorkhill)*	26	44	55% (6/11)	55% (6/11)	9% (2/23)	68% (19/28)	36% (16/44)

Key indicators	Number of patients with CD entered at your site	Number of CD follow-up treatments after initial infusion	Response to treatment	Remission achieved	Patients with CD treated with infliximab appropriately prescribed in compliance with NICE criterion 1.5 (TA187)	Number of CD patients with PROM data completed at initial treatment	Number of CD patients with PROM data completed at follow-up treatment
Results	524	1511	77% (53/69)	65% (46/71)	12% (25/201)	19% (88/459)	5% (71/1511)
NHS Lothian							
Royal Hospital for Sick Children, Edinburgh	19	90	N<6	N<6	10% (1/10)	11% (2/19)	0% (0/90)
Norfolk and Norwich University Hospitals NHS Foundation Trust							
Jenny Lind Children's Hospital*	18	141	83% (10/12)	83% (10/12)	14% (2/14)	45% (10/22)	6% (9/141)
North Tees and Hartlepool NHS Foundation Trust							
University Hospital of Hartlepool and University Hospital of North Tees* combined (paediatric)	N<6	N<6	N=0	N=0	N=0	N=0	N=0
North West London Hospitals NHS Trust							
Northwick Park and St Mark's Hospital combined (paediatric gastroenterology)	N<6	N=0	N=0	N=0	N=0	N=0	N=0
Nottingham University Hospitals NHS Trust							
Nottingham Children's Hospital*	18	20	N=0	N=0	N<6	17% (3/18)	25% (5/20)
Oxford University Hospitals NHS Trust							
Children's Hospital, the John Radcliffe	16	10	N<6	N<6	8% (1/12)	0% (0/16)	0% (0/10)
Plymouth Hospitals NHS Trust							
Derriford Hospital (paediatric)	Not participating in biological therapy audit						

Key indicators	Number of patients with CD entered at your site	Number of CD follow-up treatments after initial infusion	Response to treatment	Remission achieved	Patients with CD treated with infliximab appropriately prescribed in compliance with NICE criterion 1.5 (TA187)	Number of CD patients with PROM data completed at initial treatment	Number of CD patients with PROM data completed at follow-up treatment
Results	524	1511	77% (53/69)	65% (46/71)	12% (25/201)	19% (88/459)	5% (71/1511)
Royal Devon and Exeter NHS Foundation Trust							
Royal Devon and Exeter Hospital (paediatric)	Not participating in biological therapy audit						
Royal Free London NHS Foundation Trust							
Royal Free Hospital (paediatric gastroenterology unit)	15	N<6	N=0	N=0	7% (1/15)	0% (0/15)	N=0
Sheffield Children's NHS Foundation Trust							
Sheffield Children's Hospital	N<6	N<6	N=0	N=0	N<6	N<6	N<6
St George's Healthcare NHS Trust							
St George's Hospital (paediatric gastro unit)	9	25	N<6	N<6	N<6	67% (6/9)	8% (2/25)
The Ipswich Hospital NHS Trust							
The Ipswich Hospital (paediatric)	Not participating in biological therapy audit						
The Newcastle upon Tyne Hospitals NHS Foundation Trust							
Royal Victoria Infirmary Children's Services	N<6	N=0	N=0	N=0	N<6	N=0	N=0
University Hospital of North Staffordshire NHS Trust							
City General Hospital, Stoke-on-Trent (paediatric)	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	Number of CD follow-up treatments after initial infusion	Response to treatment	Remission achieved	Patients with CD treated with infliximab appropriately prescribed in compliance with NICE criterion 1.5 (TA187)	Number of CD patients with PROM data completed at initial treatment	Number of CD patients with PROM data completed at follow-up treatment
Results	524	1511	77% (53/69)	65% (46/71)	12% (25/201)	19% (88/459)	5% (71/1511)
University Hospital Southampton NHS Foundation Trust							
Southampton Children's Hospital	22	N<6	N=0	N=0	21% (4/19)	0% (0/23)	N=0
University Hospitals of Bristol NHS Foundation Trust							
Bristol Royal Hospital for Sick Children*	Not participating in biological therapy audit (participating in PANTS)						
University Hospitals of Leicester NHS Trust							
Leicester Royal Infirmary Children's Hospital*	N<6	6	N<6	N<6	N<6	N=0	0% (0/6)
Western Health and Social Care Trust							
Altnagelvin Area Hospital (paediatric gastroenterology)	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
PGA	Physician's Global Assessment
PUCAI	Paediatric Ulcerative Colitis Activity Index
RCN	Royal College of Nursing
RCP	Royal College of Physicians
UC	Ulcerative colitis
wPCDAI	Weighted Paediatric Crohn's Disease Activity Index
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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