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 2015

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

Paediatric

The Royal College of Physicians

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

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Author	On behalf of the IBD programme steering group
Publication date	24 September 2015
Audience	Healthcare professionals, NHS managers, service commissioners and policymakers
Description	This is the fourth 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 on 12 September 2011 until 28 February 2015.
Supersedes	National clinical audit of biological therapies. UK inflammatory bowel disease (IBD) audit. Paediatric report. September 2014.
Related publications	IBD Standards Group, 2013. *Standards for the healthcare of people who have inflammatory bowel disease (IBD): IBD standards, 2013 update*. **www.ibdstandards.org.uk** Mowat C, Cole A, Windsor A *et al*, on behalf of the IBD Section of the British Society of Gastroenterology. Guidelines for the management of inflammatory bowel disease in adults. *Gut* 2011;60:571–607. National Institute for Health and Care Excellence, 2008. Technology appraisal 163: *Infliximab for acute exacerbations of ulcerative colitis.* **www.nice.org.uk/guidance/TA163** National Institute for Health and Care Excellence, 2011. Technology appraisal 187: *Infliximab (review) and adalimumab for the treatment of Crohn's disease.* **www.nice.org.uk/guidance/TA187** National Institute for Health and Care Excellence, 2015. Technology appraisal 329: *Infliximab, adalimumab and golimumab for treating moderately to severely active ulcerative colitis after the failure of conventional therapy (including a review of TA140 and TA262)*. **www.nice.org.uk/guidance/TA329** National Institute for Health and Care Excellence, 2015. Quality standard 81: *Inflammatory bowel disease.* **www.nice.org.uk/guidance/QS81** Royal College of Physicians, 2014. *Experience of inpatients with ulcerative colitis throughout the UK.* Royal College of Physicians, 2014. *National audit of inflammatory bowel disease (IBD) service provision. Paediatric report.* Royal College of Physicians, 2014. *National clinical audit of inpatient care for young people with ulcerative colitis*.
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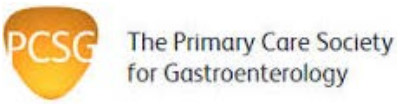
Commissioned by:

In partnership with:



Contents

Report preparation

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Acknowledgements

The IBD programme steering group would like to thank all hospitals that continue to contribute to this national audit. We would also like to thank all who have participated in piloting and development of the UK IBD audit since it began in 2005. Thanks 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

Biological therapies are the newest group of drugs to be used in inflammatory bowel disease (IBD). Most of these drugs work by targeting a protein in the body called tumour necrosis factor alpha (TNFα). Overproduction of this protein is thought to be partly responsible for the chronic inflammation in patients with IBD.

The purpose of this audit is to measure the efficacy, safety and appropriate use of the biological therapies infliximab and adalimumab, also known as anti-TNFα drugs, in patients with IBD in the UK. The audit also aims to capture patients' views on their quality of life at intervals during their treatment.

This is the fourth report of the biological therapy element of the UK IBD audit; all analyses within this report include only those patients who were newly started on biological therapies between 12 September 2011 (the start of data collection) and 28 February 2015. The data contained within this report have **only** been taken from completed submissions within the biological therapy audit web tool (**www.ibdbiologicsaudit.org**).

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

Key messages

Participation in the biological therapies audit has improved substantially over time. Of 25 IBD specialist paediatric sites in the UK, 23 (92%) are participating in either the audit or the Personalised Anti-TNF Therapy in Crohn's disease study (PANTs).[5] A total of 696 paediatric patients have now been included in this national analysis. This is a clear demonstration of the effectiveness of collaboration between national audit and research, which results in a reduced burden of data entry for clinicians and greater engagement.

The organisational audit in 2013 collected data on the number of paediatric patients newly started on infliximab, with 16% of sites estimating this figure. When current data are compared with this, it is encouraging that 62% of eligible new starters have been audited.

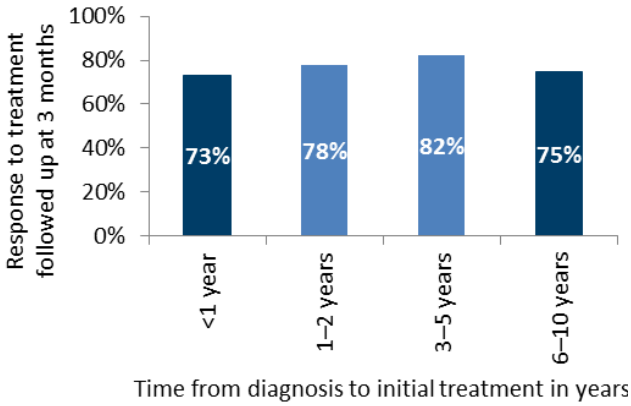
The data presented in this report demonstrate that biological therapies for IBD are effective and relatively safe treatments. Patterns of use are changing, with earlier use in patients with less severe disease. It is likely that this reflects more appropriate prescribing as physicians become more familiar with these drugs. It is also clear that only a minority of patients have their treatment stopped when effective, as recommended in the NICE guidance. Further audit will clarify this issue, identifying those patients in whom treatment can be stopped. These data are vital for local quality improvement.

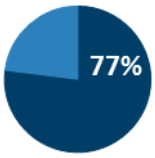
Key findings

Clinical findings

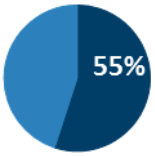
79% of audited paediatric patients were being treated with biological therapies within 2 years of being diagnosed with Crohn's disease (CD). (**Section 5, p 35**)

Response to treatment is not related to duration of disease: the response rate was 73% in patients treated within 1 year of diagnosis and 75% in those treated 6–10 years from diagnosis. (**Section 2, p 21**)





Response to treatment



Remission achieved

Response and remission rates remain stable, with no change over the audit cycles. Treatment of CD with a biological therapy is effective: 77% of audited paediatric patients experienced a response, with remission in 55%. (**Section 2, p 21**)

Over the last three rounds of audit, pre-treatment Paediatric Crohn's Disease Activity Index (PCDAI) scores have fallen from 30 to 25 (**Section 2, p 22**)

30 **PCDAI** **25**

55 **PUCAI** **35** and pre-treatment Paediatric Ulcerative Colitis Activity Index (PUCAI) scores have fallen from 55 to 35. (**Section 2, p 22**)

Use of concomitant immunosuppression therapy has fallen from 80% to 60%. (**Section 2, p 22**)

80% **Immunosuppression** **60%**

30% **Steroids** **13%** Use of concomitant steroid therapy has also fallen – from 30% to 13%. (**Section 2, p 22**)

These results suggest earlier use of biological therapies in patients with milder disease.

6% of patients reported an adverse event when assessed at 3-month follow-up. Infection was seen in only 2% of patients, and no deaths or malignancies were reported. (**Section 2, p 25**)

Participation findings

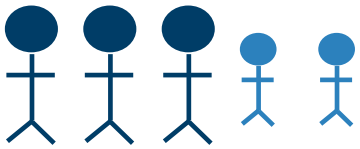
The number of sites engaging with the biological therapy audit since its inception has been gradually increasing:

from 

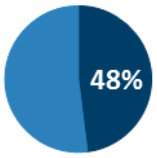
to 

of specialist paediatric sites participating in the UK. (**Section 6, p 55**)

Encouragingly, participation in the audit has improved over time, with about 3 in 5 eligible patients on infliximab audited in 2013. (**Section 2, pp 23–24**)



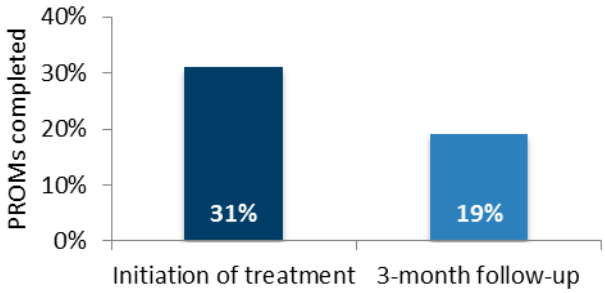
Submission of follow-up data has improved but remains incomplete. (**Section 2, p 19**)



Only 48% of audited paediatric patients had complete follow-up data at 3 months.

The proportion was even lower for 12-month follow-up, with only 20% of patients recorded as having been followed up at this timepoint.

More patient-reported outcome measures (PROMs) were completed at the start of treatment (31%) than for the previous report[6] (18%), although fewer PROMs were completed at the 3-month timepoint (19%). **(Section 2, p 28)**



Recommendations

1 Sites that prescribe and administer biological therapies to their patients with inflammatory bowel disease (IBD) should continue to participate in the national biological therapy audit. They should aim to submit complete data on all new starters. This includes data at baseline and at least 3- and 12-month follow-up. Sites that enter data to the Personalised Anti-TNF Therapy in Crohn's disease study (PANTs) are counted as participating; these sites are reminded that data on patients not applicable for inclusion in the research study should be entered into the biological therapy audit web tool so that all new starters on biological therapies are captured.

2 Disease activity should be routinely assessed and monitored, especially at baseline and again at 3- and 12-month follow-up.

3 Sites should continue to encourage patients to complete patient-reported outcome measures (PROMs) at baseline, as they provide an indication of patient outcomes and the quality of care delivered to patients. It is important to ensure that PROMs are completed at follow-up.

4 The audit has been extended to include patients started on biosimilar versions of infliximab and other biological treatments. Patients newly started on these treatments should now be audited.

5 Sites should use the 'Export data' function of the web tool to check the completeness of the data entered. Exported data can also be used for any local analyses, which can support quality improvement activities.

6 Sites should continue to monitor safety and efficacy over the long term and should stop biological therapies in patients who have failed to respond to treatment.

7 The findings and recommendations of this report should be shared at relevant multidisciplinary team, clinical governance and audit meetings, and a local action plan 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. It can be adapted through the addition of further actions that you feel are appropriate for your own service. You can download a copy of this action plan from **www.rcplondon.ac.uk/ibd**.

National recommendation	Action required	Staff responsible	Progress at your site (Include date of review, name of individual responsible for action)
1 Sites that prescribe and administer biological therapies to their patients with inflammatory bowel disease (IBD) should continue to participate in the national biological therapy audit. They should aim to submit complete data on all new starters. This includes data at baseline and at least 3- and 12-month follow-up. Sites that enter data to the Personalised Anti-TNF Therapy in Crohn's disease study (PANTs) are counted as participating; these sites are reminded that data on patients not applicable for inclusion in the research study should be entered into the biological therapy audit web tool so that all new starters on biological therapies are captured.	Eligible sites should ensure that all newly started patients are entered into the biological therapies audit. Have a system in place to ensure that data are collected at 3- and 12-month follow-up.	Consultant gastroenterologists IBD nurses Infusion clinic staff	
2 Disease activity should be routinely assessed and monitored, especially at baseline and again at 3- and 12-month follow-up.	Ensure that the relevant disease activity index is available in clinical areas. Ensure that IBD clinical teams are made aware of its availability and importance. Disease activity scoring forms for patients can be downloaded directly from the biological therapy audit web tool (**www.ibdbiologicsaudit.org**)	Consultant gastroenterologists IBD nurses Infusion clinic staff	

3	Sites should continue to encourage patients to complete patient-reported outcome measures (PROMs) at baseline, as they provide an indication of patient outcomes and the quality of care delivered to patients. It is important to ensure that PROMs are completed at follow-up.	Ensure that the PROM forms are available in clinical areas. Ensure that IBD clinical teams are made aware of their availability and importance. PROM forms for patients can be downloaded directly from the biological therapy audit web tool (**www.ibdbiologicsaudit.org**).	Consultant gastroenterologists IBD nurses Infusion clinic staff	
4	The audit has been extended to include patients started on biosimilar versions of infliximab and other biological treatments. Patients newly started on these treatments should now be audited.	Ensure that data on all patients newly started on biosimilar versions of drugs are entered into the biological therapies audit. Have a system in place to ensure that data are collected at 3- and 12-month follow-up.	Consultant gastroenterologists IBD nurses Infusion clinic staff	
5	Sites should use the 'Export data' function of the web tool to check the completeness of the data entered. Exported data can also be used for any local analyses, which can support quality improvement activities.	Ensure that staff are aware that the export function can be used at any time. Site-level data can be analysed at any time, independent of the annual report. Data can be exported directly from the biological therapy audit web tool by clicking the 'Export data' function (**www.ibdbiologicsaudit.org**).	NHS managers Consultant gastroenterologists	
6	Sites should continue to monitor safety and efficacy over the long term and should stop biological therapies in patients who have failed to respond to treatment.	In keeping with guidance from the National Institute for Health and Care Excellence (NICE), processes should be put in place to ensure that patients are assessed at 12 months.	Consultant gastroenterologists Infusion clinic staff	

7	The findings and recommendations of this report should be shared at relevant multidisciplinary team, clinical governance and audit meetings, and a local action plan for implementing change should be devised.	Identify an appropriate time to discuss the results of the audit and decide key priority areas for improvement. Present the findings and recommendations at an appropriate meeting and ensure that action plans for implementing change are devised.	NHS managers Consultant gastroenterologists IBD nurses 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 methods

Introduction

Biological therapies are the newest group of drugs to be used in inflammatory bowel disease (IBD). Most of these drugs work by targeting a protein in the body called tumour necrosis factor alpha (TNFα). Overproduction of this protein is thought to be partly responsible for the chronic inflammation in patients with IBD. Biological therapies have revolutionised the treatment of IBD, with usage increasing rapidly in the UK over the past few years. Available data suggest that they are effective treatments, with a relatively low frequency of adverse events. They remain a significant cost burden for hospitals in the UK – approximately £10,000 per patient per year – and so audit of their effectiveness, safety and appropriateness remains a clinical priority. Further information about biological therapies and their licensing can be found in **section 4, p 30**.

Aims of the biological therapies audit

To assess nationally:

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

Methods

This is a prospective audit, with data collection taking place in 'real time' during the clinical appointment with the patient. Participating sites are asked to identify and enter data on patients newly started on biological therapies. Data entry takes place in the form of 'submissions' to a web-based data collection tool (**www.ibdbiologicsaudit.org**). A submission refers to data entered in any of the following categories: patient demographics, IBD disease details, initial anti-TNFα treatment, follow-up anti-TNFα treatment and IBD-related surgery. Further detail about each of the categories can be found on **p 31** of this report.

Definition of a 'site'

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

Eligibility and participation

Sites are eligible to participate in the biological therapies audit if they prescribe and administer biological therapy to their patients with IBD. Of the 25 specialist paediatric IBD sites in the UK, 23 (92%) are participating in the biological therapies audit and/or in the Personalised Anti-TNF Therapy in Crohn's disease (CD) study (PANTs). There are 14 paediatric sites participating in the biological therapies audit and/or PANTs in addition to the specialist paediatric IBD sites (37 in total). Paediatric patients may also be receiving biological therapies under adult gastroenterology services. A list of participating and non-participating sites can be found in **section 6, p 56** of this report.

PANTs

This is a 3-year, prospective, uncontrolled, cohort study investigating primary non-response, loss of response and adverse drug reactions to infliximab and adalimumab in patients with severe active luminal CD. The collected clinical data are aligned with data collected by the biological therapy audit. Relevant anonymised data from PANTs have been included and analysed in this report. Sites

participating in PANTs are reminded that patients not eligible for inclusion in this research study should still be entered into the biological therapy audit web tool so that all new starters are captured. Sites submitting data to PANTs are indicated by an asterisk in the list of participating and non-participating sites in **section 6, p 56** of this report.

Inclusion and exclusion criteria

Only patients with diagnosed IBD – that is, CD, ulcerative colitis (UC) 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. The process of including and excluding data in national analyses is detailed in the consort diagram on **p 18** of this report.

Denominators

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

Data-collection tool

Security and confidentiality are maintained during data collection by using unique usernames and passwords; only the lead clinician at each site can authorise local access. Data can be saved during and at the end of an input session, and online help – including definitions and clarifications of data items, internal logical data checks and instant feedback mechanisms – ensure that high-quality data are collected. For an explanation of the different submission types in the biological therapies audit, please see **p 31** of this report.

Site-level data

The small numbers of patients with UC and IBDU mean that site-level data are restricted to patients with CD. 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. Results in site reports that meet this criterion have therefore 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 sources:

- IBD Standards Group, 2013. *Standards for the healthcare of people who have inflammatory bowel disease: IBD standards, 2013 update*. **www.ibdstandards.org.uk** [Accessed 16 July 2015].
- Mowat C, Cole A, Windsor A *et al.* on behalf of the IBD Section of the British Society of Gastroenterology. Guidelines for the management of inflammatory bowel disease in adults. *Gut* 2011;60:571–607.
- National Institute for Health and Care Excellence, 2008. Technology appraisal 163: *Infliximab for acute exacerbations of ulcerative colitis*. **www.nice.org.uk/guidance/TA163**. [Accessed 16 July 2015].
- National Institute for Health and Care Excellence, 2011. Technology appraisal 187: *Infliximab (review) and adalimumab for the treatment of Crohn’s disease*. **www.nice.org.uk/guidance/TA187** [Accessed 16 July 2015].
- National Institute for Health and Care Excellence, 2015. Technology appraisal 329: *Infliximab, adalimumab and golimumab for treating moderately to sever active ulcerative colitis after the*

failure of conventional therapy (including a review of TA140 and TA262). **www.nice.org.uk/guidance/TA329** [Accessed 16 July 2015].

- National Institute for Health and Care Excellence, 2015. Quality standard 81: Inflammatory bowel disease. **www.nice.org.uk/guidance/QS81** [Accessed 16 July 2015].
- Royal College of Physicians, 2014. *Experience of inpatients with ulcerative colitis throughout the UK.*
- Royal College of Physicians, 2014. *National audit of inflammatory bowel disease (IBD) service provision. Paediatric report.*
- Royal College of Physicians, 2014. *National clinical audit of inpatient care for young people with ulcerative colitis*.

Availability of audit results in the public domain

Full and executive summary copies of this report are available in the public domain via the Royal College of Physicians (RCP) website (**www.rcplondon.ac.uk/biologics**). The national report of results will be made available to NHS England; the Department of Health, Social Services and Public Safety in Northern Ireland; Healthcare Improvement Scotland; and the Department for Health and Social Services in Wales. A number of key indicators for each of the 37 participating sites are published in the public domain in **section 6, pp 56–62** of this report; these findings are also available via **www.data.gov.uk**, in line with the government's transparency agenda.

Presentation of results

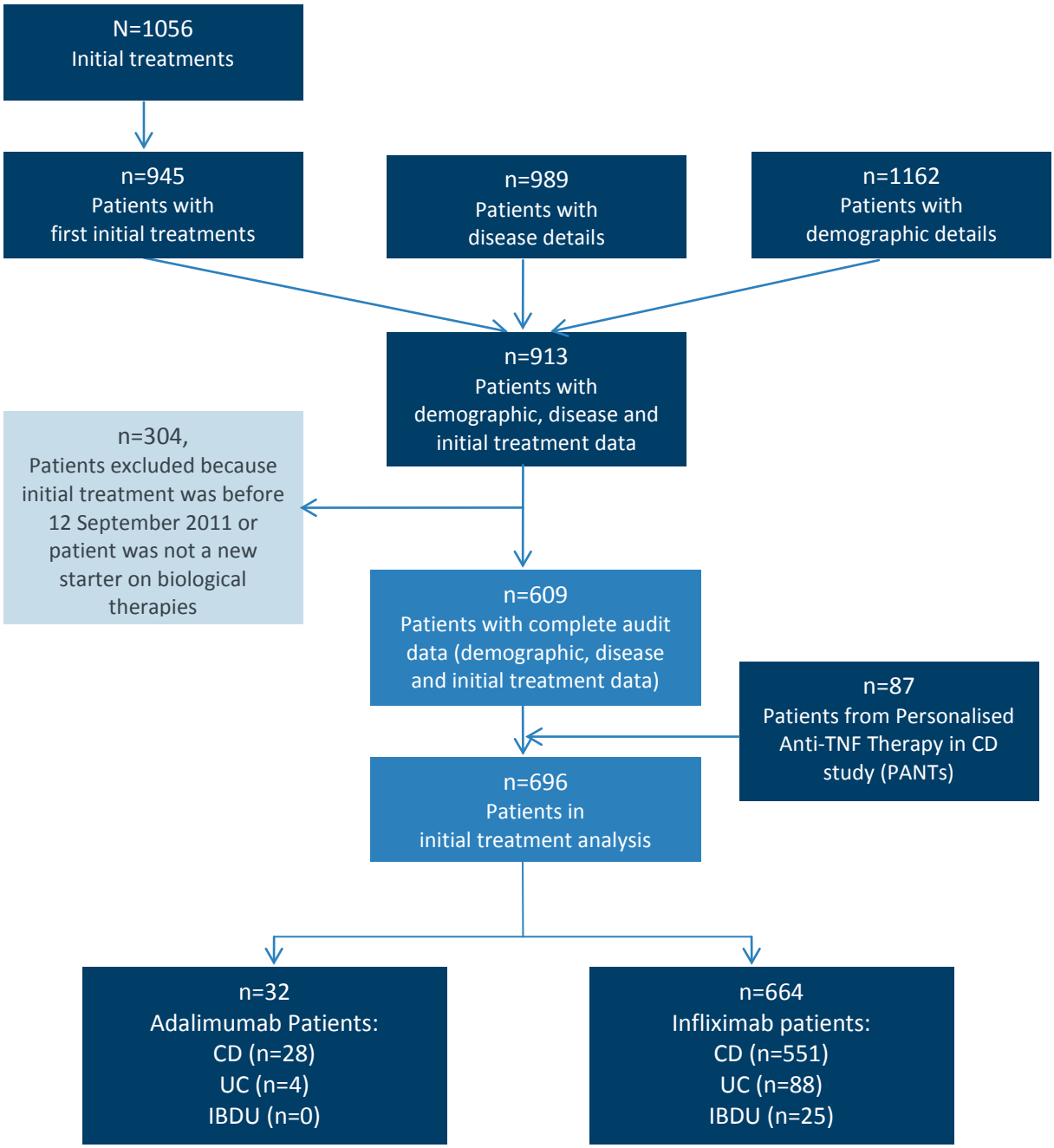
National results are presented as percentages for categorical data and as medians and interquartile ranges (IQRs) for numerical data. This report summarises data on paediatric patients provided by sites that registered to participate in the audit and indicated that they provide their IBD service to paediatric patients. A separate report prepared for adult IBD services can be viewed on the RCP website (**www.rcplondon.ac.uk/biologics**). When measures are comparable, both adult and paediatric data are provided for review.

2: Summary of key results

Consort diagram – initial treatment

On 28 February 2015, 1162 individual paediatric patient demographic submissions had been entered on the web tool. Readers are reminded that individual results are often a subset of this number and that the context and actual number of cases should be considered when interpreting findings. Fig 1 is therefore integral to understanding the patient numbers and the reasons that patients were excluded from analysis when considering the results in this report.

Fig 1 Consort diagram for initial treatment. CD = Crohn's disease; IBDU = inflammatory bowel disease type unclassified; UC = ulcerative colitis.



All analyses within this report include all patients who were newly started on biological therapies since 12 September 2011 (the start of the audit). A consort diagram detailing patient numbers and reasons for exclusion from follow-up treatment data can be found in **Appendix 3, p 66**.

Key data tables

Understanding these results

The tables in this section use key data items to address the objectives of the biological therapies audit and provide an overall view of the main characteristics of the included patients. It is important to note that this report is patient focused rather than treatment based; therefore, although some of the tables may seem to be similar to those in the reports from 2013 and 2014, these analyses have been conducted differently, so it is not advisable to compare directly with those in the previous reports.

Table 1 Patient summary

This table provides a summary of the patients and treatments included in the national analysis. The consort diagram in Fig 1 (**p 18**) shows that only those patients with at least one initial treatment were included in the analyses. Thereafter, the numbers reduce based on whether patients were recorded as having been followed up at 3 and 12 months after initial treatment. For the follow-up timepoint, a 1-month window either side was used in order to best capture patients – eg for 3-month follow-up, data entered 60–120 days after initial treatment were included.

Patient group	Initial treatment (n)	3-month follow-up (n)	12-month follow-up (n)
CD	**579**	**286**	**128**
Adalimumab	28	12	3
Infliximab	551	274	125
UC	**92**	**33**	**10**
Adalimumab	4	0	0
Infliximab	88	33	10
IBDU	**25**	**13**	**3**
Adalimumab	0	0	0
Infliximab	25	13	3
Total	**696**	**332**	**141**
YOUR SITE, patients with CD			

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

Table 2 Key items to compare data from paediatric and adult patients with CD

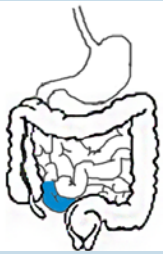
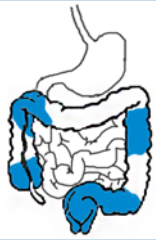
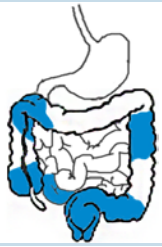
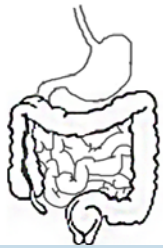
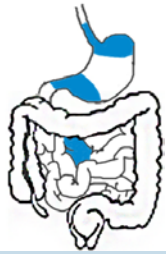
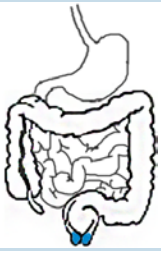
This table compares demographic data for paediatric and adult patients with CD treated with adalimumab or infliximab. The denominators differ when questions were not answered.

General patient characteristics	CD		YOUR SITE
	Paediatric	Adult	
Total number of patients	**n=579**	**n=3900**	
Gender: male (%, n/N)	63% (365/579)	47% (1837/3884)	
Age at diagnosis, years, median (IQR)	n=566 13 (10, 14)	n=3739 27 (20, 39)	
Age at initial treatment, years, median (IQR)	n=578 14 (12, 16)	n=3894 36 (26, 49)	
Time from diagnosis to treatment, years, median (IQR)	n=567 1 (1, 2)	n=3739 4 (1, 12)	

CD = Crohn's disease; IQR = interquartile range.

Table 3 Disease distribution

Crohn's disease can be classified in terms of severity – mild, moderate or severe – or by the Montreal classification, which proposes the maximum extent of involvement as the acute factor.[7] This table describes the distribution of CD across audited paediatric and adult patients treated with adalimumab or infliximab.

Disease distribution	CD		YOUR SITE
	Paediatric (%, n/N)	Adult (%, n/N)	
	n=579	n=3900	
 Terminal ileum (L1)	12% (68/573)	27% (1035/3849)	
 Colonic (L2)	31% (176/573)	31% (1188/3849)	
 Ileocolonic (L3)	49% (283/573)	36% (1380/3849)	
 None of these	8% (46/573)	6% (239/3849)	
 Any part of the gut proximal to the terminal ileum (L4)	Yes= 71% (352/495)	Yes= 45% (1312/2925)	
 Perianal involvement	Yes= 47% (187/397)	Yes= 31% (838/2688)	

CD = Crohn's disease.

Table 4 Response to therapy

This table shows response to therapy in patients with CD who were treated with infliximab or adalimumab. Results are displayed at the 3-month follow-up timepoint. The Paediatric Crohn's Disease Activity Index (PCDAI) is used to quantify disease activity for paediatric patients with CD. The Harvey–Bradshaw index (HBI) is used to measure disease activity for adult patients with CD. The denominators change when dates of diagnosis for patients are missing.

CD patient group	Response to treatment* at 3-month follow-up (%, n/N)					
Time from diagnosis to initial treatment (years)	<1	1–2	3–5	6–10	>10	Total
Paediatric	73% (35/48)	78% (52/67)	82% (18/22)	75% (9/12)	0% (0/0)	77% (114/149)
Adult	79% (121/154)	79% (115/145)	80% (89/112)	81% (86/106)	77% (159/207)	80% (570/715)
YOUR SITE						

*Decrease of >15 in Paediatric Crohn's Disease Activity Index for paediatric patients and >3 in Harvey–Bradshaw index for adult patients. CD = Crohn's disease.

Table 5 Remission achieved

This table shows whether remission was achieved in patients with CD who were treated with infliximab or adalimumab. Results are displayed at the 3-month follow-up timepoint. As before, the PCDAI is used to quantify disease activity for paediatric patients with CD and the HBI for adult patients with CD, and the denominators change when dates of diagnosis for patients are missing.

CD patient group	Remission* achieved at 3-month follow up (%, n/N)					
Time from diagnosis to initial treatment (years)	<1	1–2	3–5	6–10	>10	Total
Paediatric	59% (30/51)	66% (45/68)	68% (15/22)	75% (9/12)	0% (0/0)	55% (54/99)
Adult	68% (105/155)	67% (101/150)	72% (83/116)	71% (78/110)	64% (135/210)	68% (502/741)
YOUR SITE						

*Harvey–Bradshaw index (HBI) score <4 for adult patients and Paediatric Crohn's Disease Activity Index (PCDAI) score <10 for paediatric patients. CD = Crohn's disease.

Table 6 Concomitant therapy

This table shows the percentage of all paediatric patients with CD on any immunosuppressant or any steroid as concomitant therapy during their treatment with biological therapies. Data collected in PANTs have not been included in this analysis owing to time constraints but are expected to be included in the next report.

Type of concomitant therapy	Treatment time (%, n/N)		
	Initial treatment	3-month follow-up	12-month follow-up
Immunosuppressants*	83% (407/492)	83% (190/229)	69% (74/108)
YOUR SITE			
Steroids†	21% (104/492)	3% (7/229)	2% (2/104)
YOUR SITE			

*Immunosuppressants include azathioprine, mercaptopurine and methotrexate.

†Steroid group includes budesonide, hydrocortisone, methylprednisolone and prednisolone.

Table 7 Analysis of results over time

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

Result	Audit period			
	June 2012 (12.09.11–29.02.12	August 2013 (01.03.12–28.02.13)	September 2014 (01.03.13–28.02.14)	September 2015 (01.03.14–28.02.15)
Participation in the biological therapy audit				
Paediatric sites participating (n)	16	23	28	29
Paediatric patients audited initiating biological therapies				
Patients with CD (n)	67	155	160	197
Patients with UC (n)	2	5	7	11
Patients with IBDU (n)	8	31	26	27
Total (n)	77	191	193	235
Treatment time				
Time from diagnosis to initial treatment, median (IQR)	n=76 1 (1, 3)	n=190 1 (1, 3)	n=191 1 (1, 3)	n=227 1 (0, 2)
Adverse events				
Adverse events reported at initial treatment (%, n)	3% (2/77)	1% (2/191)	0.5% (1/193)	2% (4/235)
Disease activity for paediatric patients reported at initial treatment				
PCDAI score, median (IQR)	(n=51) 20 (5, 35)	(n=100) 30 (20, 38)	(n=93) 30 (15, 40)	(n=102) 25 (15, 35)
PUCAI score, median (IQR)	(n=8) 45 (24, 69)	(n=29) 55 (40, 65)	(n=21) 65 (43, 78)	(n=19) 35 (20, 65)
Number of paediatric patients with CD on concomitant therapy at initial treatment				
Immunosuppressants (%, n/N)	84% (56/67)	80% (124/155)	68% (108/160)	60% (119/197)*
Steroids (%, n/N)	24% (16/67)	30% (47/155)	10% (16/160)	13% (25/197)

*p<0.001.

CD = Crohn's disease; IBDU = inflammatory bowel disease type unclassified; IQR = interquartile range; PCDAI = Paediatric Crohn's Disease Activity Index; PUCAI = Paediatric Ulcerative Colitis Activity Index; UC = ulcerative colitis.

Table 8 National comparison of key results for paediatric patients with CD

This table below depicts national variation in results of the biological therapy audit between England, Northern Ireland, Scotland and Wales. It only includes sites that submitted enough data to be included in the national analysis. A full list of participating and non-participating sites can be found in **section 6, p 56** of this report.

Result	Country			
	England	Northern Ireland	Scotland	Wales
Sites participating in the audit (%)	29	0	3	2
Patients audited (n)	466	0	86	27
Time from diagnosis to initial treatment in (years median (IQR))	(n=456) 1 (1, 2)	(n=0)	(n=85) 2 (1, 4)	(n=26) 1 (0, 2)
Patients with an adverse reaction recorded during initial treatment (%, n/N)	1% (5/466)	0% (0)	0	0
Disease severity (PCDAI) at initial treatment, median (IQR)	(n=255) 30 (18, 40)	(n=0)	(n=76) 22 (15, 35)	(n=15) 35 (28, 42)
Patients with follow-up recorded at 3 months (%, n/N)	47% (219/466)	0% (0)	52% (45/86)	81% (22/27)
Patients on biological therapy who were appropriately prescribed anti-TNFα in compliance with NICE technology appraisal 187[2] criterion 1.5 (%, n/N)	77% (197/255)	0% (0)	84% (64/76)	93% (14/15)

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

Tables 9 and 10 Biological therapies audit case ascertainment

These two tables compare results as reported in the ***National audit of paediatric inflammatory bowel disease (IBD) service provision (September 2014)***.[8] Sites participating in this audit were asked to report on the number of paediatric patients with IBD who had newly started infliximab or adalimumab between 1 January 2013 and 31 December 2013. Sites were able to indicate whether the figure was an estimate or was taken from an existing database of patients. The number of patients reported as newly started on biological therapy in the organisational audit was then compared with the actual number of patient audited in the biological therapy audit for the same time period and used to produce a case ascertainment figure.

Patients newly started on adalimumab	National	YOUR SITE
Patients with IBD who were newly started on adalimumab between 1 January 2013 and 31 December 2013, as reported in organisational audit (September 2014)[8] (n)	73 (reported by 31 sites)	
Newly started patients – estimated (n)	7 (reported by 5 sites)	
Newly started patients – taken from a database (n)	66 (reported by 26 sites)	
Patients with IBD entered into biological therapies audit who were newly started on adalimumab between 1 January 2013 and 31 December 2013 (n)	5	
Case ascertainment rate (%)	7%	

IBD = inflammatory bowel disease.

Patients newly started on infliximab	National	YOUR SITE
Patients with IBD who were newly started on infliximab between 1 January 2013 and 31 December 2013, as reported in organisational audit (September 2014)[8] (n)	314 (reported by 31 sites)	
Newly started patients – estimated (n)	33 (reported by 5 sites)	
Newly started patients – taken from a database (n)	281 (reported by 26 sites)	
Patients with IBD who were newly started on infliximab between 1 January 2013 and 31 December 2013, as entered into biological therapies audit (n)	195	
Case ascertainment rate (%)	62%	

IBD = inflammatory bowel disease.

Audit objectives

Safety

Table 11 Adverse events

This table shows the percentage of all paediatric patients for whom an adverse reaction was recorded during their treatment, by type of reaction.

Adverse event (%, n)	Initial treatment (n=696)	3-month follow-up (n=332)	12-month follow-up (n=141)
Adverse event recorded Yes=	1% (9)	6% (20)	3% (4)
Abdominal pain	0.3% (2)	0% (0)	0% (0)
Angioedema of upper airway	0% (0)	0.3% (1)	0% (0)
Blood abnormality	0% (0)	0.9% (3)	0% (0)
Chest pain	0% (0)	0.3% (1)	0% (0)
Death	0% (0)	0% (0)	0% (0)
Difficulty breathing	0% (0)	0% (0)	0.7% (1)
Dizziness	0.1% (1)	0.3% (1)	0% (0)
Fatigue	0% (0)	0.3% (1)	0% (0)
Fever	0% (0)	0.3% (1)	0% (0)
Flushing	0.1% (1)	0.6% (2)	0% (0)
Hypotension	0.3% (2)	0.3% (1)	0% (0)
Infection	0% (0)	2% (8)	0.7% (1)
Itching	0.1% (1)	0.6% (2)	0.7% (1)
Malignancy	0% (0)	0% (0)	0% (0)
Nausea	0.3% (2)	0% (0)	0% (0)
Panic attacks	0% (0)	0.3% (1)	0% (0)
Rash	0.3% (2)	0.3% (1)	0.7% (1)
Other	0.3% (2)	1% (4)	0% (0)

Efficacy

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

Table 12 Disease activity – CD

When severity of CD is classified with by PCDAI, a score <10 is considered to be clinical remission and >40 is considered to be severe disease.

PCDAI score	Initial treatment	3-month follow-up	12-month follow-up
Adalimumab, median (IQR)	(n=9) 20 (10, 39)	(n=5) 8 (4, 45)	(n=1)
Infliximab, median (IQR)	(n=338) 28 (18, 38)	(n=151) 8 (2, 18)	(n=62) 5 (0, 13)
Total	(n=347) 28 (18, 38)	(n=156) 8 (2, 18)	(n=63) 5 (0, 15)
YOUR SITE			

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

Table 13 Disease activity – UC

When severity of UC is classified by Paediatric Ulcerative Colitis Activity Index (PUCAI), a score <10 is considered to be remission and ≥65 is considered to be severe disease.

PUCAI score	Initial treatment	3-month follow-up	12-month follow-up
Adalimumab, median (IQR)	(n=3)	(n=0)	(n=0)
Infliximab, median (IQR)	(n=90) 48 (19, 65)	(n=33) 15 (0, 40)	(n=7) 15 (0, 20)
Total	(n=93) 45 (18, 65)	(n=33) 15 (0, 40)	(n=7) 15 (0, 20)

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

Table 14 Surgery

This table shows combined surgical activity for patients with CD, UC and IBDU recorded in the 6 months before and after treatment with biological therapies. Further information about the surgical data collected in the biological therapies audit can be found on **p 53** of this report.

Surgical activity	Paediatric (%, n/N)	Adult (%, n/N)
Pre-treatment surgery recorded		
Yes	9% (65/696)	23% (1066/4718)
Patients with surgery recorded 6 months before starting biological therapies	6% (39/696)	5% (244/4718)
Patients with surgery recorded in 6 months after starting biological therapies	5%(31/696)	3% (157/4718)

Appropriateness of prescribing anti-TNFα

Detailed information about the NICE guidance and recommendations for use of biological therapies in patients with IBD in the UK can be found in **section 4, p 30** of this report. In tables 15 and 16, NICE criterion 1.5 from technology appraisal 187[2] and criterion 1.3 from technology appraisal 329[3] have been used to assess the appropriateness of prescribing biological therapy.

Table 15 Compliance with NICE technology appraisal 187

This table shows compliance with criterion 1.5 of NICE technology appraisal 187[2] in paediatric patients with CD. Patients with no recorded PCDAI were excluded from this analysis.

NICE technology appraisal 187	National CD data (%, n/N)	YOUR SITE
Criterion 1.5 Infliximab may be used for people aged 6–17 years with severe active CD only if (a) the disease has not responded to conventional therapy or (b) the person is intolerant of or has contraindications to conventional therapy (mercaptopurine, azathioprine, methotrexate, prednisolone, budesonide, methylprednisolone or hydrocortisone)		
Patients with CD treated with infliximab who had PCDAI score ≥45 before starting anti-TNFα treatment	17% (57/337)	
Patients with CD treated with infliximab who were being treated with conventional therapy at time of or prior to starting biological therapy	89% (301/337)	
Patients with CD treated with infliximab who were appropriately prescribed anti-TNFα treatment in compliance with criterion 1.5 of NICE technology appraisal 187	14% (47/337)	

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

Table 16 Compliance with NICE technology appraisal 329

This table shows compliance with criterion 1.3 of NICE technology appraisal 329.[3] Patients with no recorded PUCAI were excluded from this analysis.

NICE technology appraisal 329	National UC data (%, n/N)
Criterion 1.3 Infliximab is recommended for treatment for children and young people aged 6–17 years with severe active UC (a) whose disease has responded inadequately to conventional therapy or (b) are intolerant of or have contraindications to conventional therapy (mercaptopurine, azathioprine, methotrexate, prednisolone, budesonide, methylprednisolone or hydrocortisone)	
Patients with UC on biological therapy who had PUCAI score ≥65 before starting anti-TNFα treatment	40% (26/65)
Patients with UC who were treated with conventional therapy at time of or before starting biological therapy	99% (64/65)
Patients with UC on biological therapy who were appropriately prescribed anti-TNFα treatment in compliance with criterion 1.3 of NICE technology appraisal 329	40% (26/65)

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

Although compliance with NICE guidance seems to be low, many patients are likely to have had the prerequisite disease activity before starting biological therapy. Many patients will have been treated with corticosteroids, resulting in the observed values.

Patient-reported outcome measures

Table 17 PROMs (IMPACT-III)

This table gives completion rates and results of the paediatric quality-of-life measure used in the biological therapies audit – the IMPACT-III questionnaire – for all paediatric patients. This 35-item questionnaire addresses six domains of IBD: bowel symptoms, body image, functional / social impairment, emotional impairment, tests/treatment and systemic impairment.[9] Each question scores between 1 and 5. Total IMPACT-III scores range from 35 (poor) to 175 (best), and an increase in total score of 10.8 is reported to be indicative of a clinically meaningful improvement. Further information about IMPACT-III can be found on **p 54** of this report.

IMPACT-III	Initial treatment	3-month follow-up
Patients with completed IMPACT-III questionnaire (%, n/N)	31% (216/696)	19% (64/332)
YOUR SITE number of patients with IMPACT-III questionnaire completed		
IMPACT-III score, median (IQR)	116 (102, 137)	132 (93, 146)

IQR, interquartile range; PROMs = patient-reported outcome measures.

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 do so; it is reported to be as high as 24.3 and 12.7 per 100,000 persons per year in Europe for UC and CD, respectively. The reported prevalence in Europe is as high as 505 and 322 per 100,000 persons for UC and CD, respectively.[10] Inflammatory bowel disease first presents most commonly in the second and third decades of life, but much of the recent increase has been observed in childhood, notably with CD in children increasing threefold in 30 years. Between 20% and 30% of patients with UC will require colectomy, and about 50–70% of patients with CD require surgery. The main symptoms of both conditions include diarrhoea, abdominal pain, anaemia and an overwhelming sense of fatigue, with, for some patients, associated features such as arthritis, anal disease, fistulae, abscesses and skin problems, which can also contribute to poor quality of life. In addition, IBD has wide-ranging effects on growth and pubertal development, psychological health, education and employment, family life, fertility and pregnancy. Effective multidisciplinary care can attenuate relapse, prolong remission, treat complications and improve quality of life.

The UK IBD audit

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

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

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

The benefits of the biological therapies audit

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

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

4: The biological therapies audit

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

Infliximab

Infliximab (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. Infliximab is typically administered via an intravenous infusion during a hospital appointment under the supervision of a suitably qualified health professional.

Adalimumab

Adalimumab (Humira™) is a recombinant human immunoglobulin (IgG1) monoclonal antibody containing only human peptide sequences. Adalimumab is typically delivered via a self-administered injection. Patients are provided with a home supply of the medication and, following tuition and close monitoring, are able to manage their own treatment with regular medical follow-up.

Approval in the UK

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

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

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

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

In **technology appraisal 163**,[11] NICE made the following recommendation:

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

Data entry into the biological therapies audit

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

Patient demographics category

Patients are identified prospectively when the decision to treat using biological therapies is made by a clinician. The demographic details of 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 only to the participating site. Details of the patient's consultant and GP can also be entered, although this is not mandatory for the audit.

Disease details category

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

Initial treatment category

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

Follow-up treatment category

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

IBD-related surgery category

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

PROMs category

Data on PROMs are collected at initial treatment and can then be recorded at any additional follow-up. For the purpose of the audit, the PROMs completed at 3- and 12-month follow-up treatments are of interest. For further information about PROMs data, see **p 54**.

Continued development of the biological therapies audit web tool

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

Biosimilars

From March 2015, to reflect emerging evidence and changing practice, the biological therapies audit was expanded to allow auditing of patients newly started on biosimilar versions of the biological drugs.

Existing patients

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

Reporting functions

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

Patient summary report

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

Treatment summary report

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

Data import function

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

Reduction of mandatory fields

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

Download function

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

Data export function

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

Dashboard

The dashboard is the latest development for the web tool. It is split into various sections, each giving sites a glance at their activity on the audit to date. Fig 2 outlines the functions available on the dashboard.

Fig 2 Functions of the biological therapy audit dashboard

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

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

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

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

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

System security of the biological therapies audit web tool

The document *Biological therapies audit system and hosted server security details* outlines the system security information provided to all sites invited to participate in the audit and is available on the RCP's website (**www.rcplondon.ac.uk/biologics**).[12] The document gives an overview of the security measures in place, while providing assurance that security procedures designed by Microsoft and other industry standard bodies have been followed. The contracted system developer also implemented the recommended procedures contained within the NHS document *Securing web infrastructure and supporting services good practice guideline*.[13]

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 viewed only by registered members of the local team, whose access to the site will have been approved via the local clinical lead (nearly always a consultant gastroenterologist). Sites using the web tool cannot view data entered at other participating sites. The UK IBD audit project team have administrative control to analyse anonymised data only and are not able to view any patient-identifiable information.

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

5: Full national audit results tables

Crohn's disease details

CD: disease details	Frequency (%, n)			
	Infliximab		Adalimumab	
	National (n=551)	YOUR SITE	National (n=28)	YOUR SITE
Diagnosis				
Maximal disease distribution at the time of decision to initiate biological therapy, as defined by the Montreal classification	**(n=545)**			
Terminal ileum (L1)	12% (64)		14% (4)	
Colonic (L2)	31% (171)		18% (5)	
Ileocolonic (L3)	49% (265)		64% (18)	
None of these	8% (45)		4% (1)	
Any part of the gut proximal to the terminal ileum (L4)	**(n=469)**		**(n=26)**	
Yes	72% (339)		50% (13)	
Perianal involvement?	**(n=372)**		**(n=25)**	
Yes	49% (183)		16% (4)	
Time between date of diagnosis and date of initial treatment	**(n=539)**		**(n=27)**	
<1 year	40% (215)		48% (13)	
1–2 years	40% (215)		22% (6)	
3–5 years	13% (72)		11% (3)	
6–10 years	7% (35)		19% (5)	
>10 years	0.4% (2)		0% (0)	

CD = Crohn's disease.

Crohn's disease Initial treatment

CD: initial treatment	Frequency (%, n)			
	Infliximab		Adalimumab	
	National (n=551)	YOUR SITE	National (n=28)	YOUR SITE
Consent				
Was informed consent to receive anti-TNFα treatment taken from this patient?				
Yes	99% (547)		100% (28)	
No	0.7% (4)		0% (0)	
If yes, was this verbal or written?	**(n=547)**			
Verbal	39% (213)		68% (19)	
Written	61% (334)		32% (9)	
Treatment details				
Time between date of decision to start and date of initial treatment (first loading dose)				
Median (IQR) time (days)	10 (5, 23)		17 (8, 31)	
What was the clinical indication for this treatment?	**(n=542)**			
Severe perianal CD	16% (87)		0% (0)	
Active luminal CD	81 (438)		89 (25)	
Fistulating CD	2% (8)		0% (0)	
Other clinical indication	0.6% (3)		7% (2)	
Not known	1% (6)		4% (1)	
Dose given at this infusion (mg/kg)	**(n=497)**			
5	100% (495)		NA	
Other	0.4% (2)		NA	
Duration of infusion (mins)	**(n=398)**			
60	1% (4)		NA	
85	0.3% (1)		NA	
120	96% (382)		NA	
180	1% (5)		NA	
240	1% (5)		NA	
Other	0.3% (1)		NA	
Infusion completion outcome	**(n=465)**			
Completed successfully at prescribed rate	99% (458)		NA	
Completed successfully at lower rate	1% (5)		NA	
Restart infusion reaction at lower rate and discontinued	0.2% (1)		NA	
Infusion discontinued and not restarted	0.2% (1)		NA	

CD = Crohn's disease; IQR = interquartile range; NA = not applicable; TNFα = tumour necrosis factor alpha.

CD: initial treatment	Frequency (%, n)			
	Infliximab		Adalimumab	
	National (n=551)	YOUR SITE	National (n=28)	YOUR SITE
Treatment details continued				
Induction dose (mg)				
160/80	NA		50% (15)	
80/40	NA		46% (13)	
Planned maintenance dose			**(n=27)**	
40 mg every other week	NA		100% (27)	
Were any adverse events recorded for this treatment?				
Yes	0.9% (5)		0% (0)	
Which adverse events? (more than one may have been selected)				
Abdominal pain	0.4% (2)		0% (0)	
Hypotension	0.2% (1)		0% (0)	
Nausea	0.2% (1)		0% (0)	
Rash	0.2% (1)		0% (0)	
Is the patient receiving any concomitant therapies for the management of IBD at the time of this treatment?	**(n=465)**		**(n=27)**	
Yes	91% (425)		89% (24)	
If yes, indicate which concomitant therapies (more than one may have been selected)				
Azathioprine/mercaptopurine	76% (351)		74% (20)	
5-aminosalicylic acid	26% (122)		22% (6)	
Antibiotics	9% (40)		0% (0)	
Dietary therapy	11% (50)		4% (1)	
Methotrexate	7% (33)		11% (3)	
Mycophenolate	0.2% (1)		0% (0)	
Steroids	22% (100)		15% (4)	
Tacrolimus	0.6% (3)		0% (0)	
Topical	0.6% (3)		0% (0)	
Other	4% (19)		11% (3)	

CD = Crohn's disease; IBD = inflammatory bowel disease; NA = not applicable

CD: initial treatment	Frequency (%, n)			
	Infliximab		Adalimumab	
	National (n=551)	YOUR SITE	National (n=28)	YOUR SITE
Treatment details continued				
Has the patient failed to respond or are they intolerant to immunosuppressive drugs / corticosteroids?	**(n=551)**		**(n=28)**	
Yes	60% (330)		75% (21)	
If yes, indicate which previous therapies (more than one therapy may have been selected)				
Azathioprine/mercaptopurine	3% (19)		64% (18)	
5-aminosalicylic acid	11% (59)		14% (4)	
Antibiotics	5% (27)		0% (0)	
Anti-TNFα	1% (7)		18% (5)	
Ciclosporin	0.2% (1)		0% (0)	
Dietary therapy	29% (157)		18% (5)	
Methotrexate	6% (32)		4% (1)	
Steroids	34% (188)		21% (6)	
Topical	0.5% (3)		0% (0)	
Other	2% (9)		0% (0)	
Disease severity score				
Severity of disease	**(n=299)**		**(n=23)**	
Mild	9% (28)		9% (2)	
Moderate	53% (159)		70% (16)	
Severe	38% (112)		22% (5)	

CD = Crohn's disease; TNFα = tumour necrosis factor alpha.

Crohn's disease follow-up treatment at 3 months

CD: follow-up treatment at 3 months	Frequency (%, n)			
	Infliximab		Adalimumab	
	National (n=274)	YOUR SITE	National (n=12)	YOUR SITE
Follow-up treatment details				
Infliximab dose given (mg/kg)	**(n=271)**			
5	96% (260)		NA	
10	4% (10)		NA	
Other	0.4% (1)		NA	
Review of treatment plan				
Continue treatment	96% (262)		12 (100%)	
Stop treatment	4% (12)		0% (0)	
If treatment was stopped, what were the reasons for stopping?	**(n=12)**			
Treatment effective and discontinued	8% (1)		NA	
Loss of response	8% (1)		NA	
Poor response	50% (6)		NA	
Side effects/adverse events	17% (2)		NA	
Other	17% (2)		NA	
If continuing adalimumab treatment, planned continued treatment frequency				
Every week	NA		8% (1)	
Every other week	NA		92% (11)	
If continuing adalimumab treatment, planned continued treatment dose? (mg)				
40	NA		92% (11)	
80	NA		8% (1)	
Did the patient report complete compliance with the maintenance regime since the last adalimumab review?				
Yes	NA		100% (12)	

CD, Crohn's disease; NA = not applicable.

CD: follow-up treatment at 3 months	Frequency (%, n)			
	Infliximab		Adalimumab	
	National (n=274)	YOUR SITE	National (n=12)	YOUR SITE
Follow-up treatment details continued				
Were there any adverse events since the last review?				
Yes	6% (16)		8% (1)	
Which adverse events? (more than one may have been selected)				
Angioedema of upper airway	0.4% (1)		0% (0)	
Blood abnormality	1% (3)		0% (0)	
Chest pain	0.4% (1)		0% (0)	
Dizziness	0.4% (1)		0% (0)	
Fatigue	0.4% (1)		0% (0)	
Fever	0.4% (1)		0% (0)	
Flushing	0.4% (1)		0% (0)	
Hypotension	0.4% (1)		0% (0)	
infection	2% (6)		8% (1)	
Panic attacks	0.4% (1)		0% (0)	
Other	1% (3)		0% (0)	
Is the patient currently receiving any other therapies for the management of IBD?	**(n=217)**			
Yes	88 (191)		92 (11)	
If yes, indicate which other therapies (more than one may have been selected)				
Azathioprine/mercaptopurine	74% (160)		75% (9)	
5-aminosalicylic acid	17% (36)		17% (2)	
Antibiotics	2% (5)		8% (1)	
Dietary therapy	5% (11)		0% (0)	
Methotrexate	9% (19)		17% (2)	
Steroids	3% (6)		8% (1)	
Tacrolimus	0.5% (1)		0% (0)	
Other	4% (8)		0% (0)	
Disease severity score				
Severity of disease	**(n=122)**		**(n=10)**	
Mild	62% (75)		90% (9)	
Moderate	31% (38)		0% (0)	
Severe	7% (9)		10% (1)	

CD = Crohn's disease; IBD = inflammatory bowel disease.

Crohn's disease follow-up treatment at 12 months

CD: follow-up treatment at 12 months	Frequency (%, n)			
	Infliximab		Adalimumab	
	National (n=125)	YOUR SITE	National (n=3)	YOUR SITE
Follow-up treatment details				
Infliximab dose given (mg/kg)	**(n=124)**			
5	90% (112)		NA	
10	9% (11)		NA	
Other	0.8% (1)		NA	
Review of treatment plan				
Continue treatment	99% (124)		100% (3)	
Stop treatment	0.8% (1)		0% (0)	
If treatment was stopped, what were the reasons for stopping?	**(n=1)**			
Loss of response	100% (1)		0% (0)	
If continuing adalimumab treatment, planned continued treatment frequency				
Every week	NA		33% (1)	
Every other week	NA		67% (2)	
If continuing adalimumab treatment, planned continued treatment dose? (mg)				
40	NA		100% (3)	
Did the patient report complete compliance with the maintenance regime since the last adalimumab review?			**(n=2)**	
Yes	NA		100% (2)	
Were there any adverse events since the last review?				
Yes	3% (4)		0% (0)	
Which adverse events? (more than one may have been selected)				
Difficulty breathing	0.8% (1)		0% (0)	
Infection	0.8% (1)		0% (0)	
Itching	0.8% (1)		0% (0)	
Rash	0.8% (1)		0% (0)	
Is the patient currently receiving any other therapies for the management of IBD?	**(n=106)**		**(n=2)**	
Yes	78% (83)		100% (2)	
If yes, indicate which other therapies (more than one may have been selected)				
Azathioprine/mercaptopurine	66% (70)		50% (1)	
5-aminosalicylic acid	22% (23)		50% (1)	
Antibiotics	0% (0)		50% (1)	
Dietary therapy	2% (2)		0% (0)	
Methotrexate	3% (3)		0% (0)	
Steroids	2% (2)		0% (0)	
Other	5% (5)		0% (0)	

CD = Crohn's disease; NA = not applicable.

CD: follow-up treatment at 12 months	Frequency (%, n)			
	Infliximab		Adalimumab	
	National (n=125)	YOUR SITE	National (n=3)	YOUR SITE
Disease severity score				
Severity of disease	**(n=76)**		**(n=2)**	
Mild	70% (53)		50% (1)	
Moderate	28% (21)		0% (0)	
Severe	3% (2)		50% (1)	

CD = Crohn's disease; IBD = inflammatory bowel disease.

Ulcerative colitis disease details

UC: disease details	Frequency (%, n)	
	Infliximab	Adalimumab
	National (n=88)	National (n=4)
Diagnosis		
Maximal disease distribution at the time of decision to initiate biological therapy, as defined by the Montreal classification		
Proctitis (E1)	7% (6)	50% (2)
Left sided (E2)	24% (21)	0% (0)
Extensive (E3)	69% (61)	50% (2)
Time between date of diagnosis and date of initial treatment		
<1 year ago	44% (39)	25% (1)
1–2 years ago	42% (37)	25% (1)
3–5 years ago	11% (10)	0% (0)
6–10 years ago	2% (2)	50% (2)

UC = ulcerative colitis.

Ulcerative colitis initial treatment

UC: initial treatment	Frequency (%, n)	
	Infliximab	Adalimumab
	National (n=88)	National (n=4)
Consent		
Was informed consent to receive anti-TNFα treatment taken from this patient?		
Yes	100% (88)	100% (4)
If yes, was this verbal or written?		
Verbal	31% (27)	75% (3)
Written	69% (61)	25% (1)
Treatment details		
Time between date of decision to start and date of initial treatment (first loading dose)		
Median (IQR) time (days)	7 (2, 17)	17 (5, 64)
What was the clinical indication for this treatment?		
Acute severe UC	51% (45)	0% (0)
Chronic refractory UC	47% (41)	75% (3)
Other clinical indication	2% (2)	25% (1)
Dose given at this infusion (mg/kg)	**(n=79)**	
5	100% (79)	NA
Duration of infusion (mins)	**(n=78)**	
120	99% (77)	NA
180	1% (1)	NA
Infusion completion outcome		
Completed successfully at prescribed rate	98% (86)	NA
Completed successfully at lower rate	1% (1)	NA
Infusion discontinued and not restarted	1% (1)	NA
Induction dose (mg)		
160/80	NA	25% (1)
80/40	NA	50% (2)
Other	NA	25% (1)
Planned maintenance dose		
40 mg every other week	NA	75% (3)
Other	NA	25% (1)

IQR = interquartile range; NA = not applicable; TNFα = tumour necrosis factor alpha; UC = ulcerative colitis.

UC: initial treatment	Frequency (%, n)	
	Infliximab	Adalimumab
	National (n=88)	National (n=4)
Treatment details continued		
Were any adverse events recorded for this treatment?		
Yes	3% (3)	0% (0)
Which adverse events? (more than one may have been selected)		
Dizziness	1% (1)	0% (0)
Hypotension	1% (1)	0% (0)
Nausea	1% (1)	0% (0)
Panic attacks	1% (1)	0% (0)
Rash	1% (1)	0% (0)
Is the patient receiving any concomitant therapies for the management of IBD at the time of this treatment?		
Yes	98% (86)	100% (4)
If yes, indicate which concomitant therapies (more than one may have been selected)		
Azathioprine/mercaptopurine	68% (60)	50% (2)
Methotrexate	2% (2)	0% (0)
Steroids	67% (59)	25% (1)
5-aminosalicylic acid	44% (39)	100% (4)
Antibiotics	7% (6)	0% (0)
Dietary therapy	2% (2)	0% (0)
Tacrolimus	1% (1)	0% (0)
Ciclosporin	2% (2)	0% (0)
Topical	2% (2)	0% (0)
Mycophenolate	1% (1)	0% (0)
Other	7% (6)	25% (1)
Has the patient failed to respond or are they intolerant to immunosuppressive drugs / corticosteroids?		
Yes	53% (47)	25% (1)
If yes, indicate which previous therapies (more than one may have been selected)		
Azathioprine/mercaptopurine	26% (23)	25% (1)
Methotrexate	2% (2)	0% (0)
Steroids	46% (40)	25% (1)
Anti-TNFα	1% (1)	0% (0)
5-aminosalicylic acid	21% (18)	25% (1)
Ciclosporin	2% (2)	0% (0)
Disease severity score		
Severity of disease	**(n=60)**	
Mild	12% (7)	25% (1)
Moderate	38% (23)	50% (2)
Severe	50% (30)	25% (1)

IBD, inflammatory bowel disease; TNFα = tumour necrosis factor alpha; UC = ulcerative colitis.

Ulcerative colitis follow-up treatment at 3 months

UC: follow-up treatment at 3 months	Frequency (%, n)	
	Infliximab	Adalimumab
	National (n=33)	National (n=0)
Follow-up treatment details		
Infliximab dose given at this treatment (mg/kg)		
5	97% (32)	NA
10	3% (1)	NA
Review of treatment plan		
Continue treatment	91% (30)	NA
Stop treatment	9% (3)	NA
If treatment was stopped, what were the reasons for stopping?	**(n=3)**	
Loss of response	33% (1)	NA
Poor response	67% (2)	NA
Were there any adverse events since the last review?		
Yes	6% (2)	NA
Which adverse events? (more than one may have been selected)		
Infection	3% (1)	NA
Itching	3% (1)	NA
Is the patient currently receiving any other therapies for the management of IBD?		
Yes	85% (28)	NA
If yes, indicate which other therapies (more than one may have been selected)		
Azathioprine/mercaptopurine	79% (26)	NA
5-aminosalicylic acid	42% (14)	NA
Antibiotics	3% (1)	NA
Steroids	15% (5)	NA
Other	12% (4)	NA
Disease severity score		
Severity of disease	**(n=24)**	
Mild	50% (12)	NA
Moderate	38% (9)	NA
Severe	13% (3)	NA

IBD = inflammatory bowel disease; NA = not applicable; UC = ulcerative colitis.

Ulcerative colitis follow-up treatment at 12 months

UC: follow-up treatment at 12 months	Frequency (%, n)	
	Infliximab	Adalimumab
	National (n=10)	National (n=0)
Follow-up treatment details		
Infliximab dose given at this treatment (mg/kg)		
5	100% (10)	NA
Review of treatment plan		
Continue treatment	90% (9)	NA
Stop treatment	10% (1)	NA
If treatment stopped, what were the reasons for stopping?	**(n=1)**	
Loss of response	100% (1)	NA
Were there any adverse events since the last review?		
Yes	0% (0)	NA
Is the patient currently receiving any other therapies for the management of IBD?		
Yes	90% (9)	NA
If yes, indicate which other therapies (more than one may have been selected)		
Azathioprine/mercaptopurine	60% (6)	NA
5-aminosalicylic acid	60% (6)	NA
Mycophenolate	10% (1)	NA
Tacrolimus	10% (1)	NA
Disease severity score		
Severity of disease	**(n=5)**	
Mild	20% (1)	NA
Moderate	80% (4)	NA

IBD = inflammatory bowel disease; NA = not applicable; UC = ulcerative colitis.

IBD type unclassified disease details

IBDU: disease details	Frequency (%, n)	
	Infliximab	Adalimumab
	National (n=25)	National (n=0)
Diagnosis		
Maximal disease distribution at the time of decision to initiate biological therapy, as defined by the Montreal classification		
Left sided (E2)	4% (1)	NA
Extensive (E3)	96% (24)	NA
Time between date of diagnosis and date of initial treatment		
<1 year	60% (15)	NA
1–2 years	20% (5)	NA
3–5 years	16% (4)	NA
6–10 years	4% (1)	NA

IBD = inflammatory bowel disease; IBDU = inflammatory bowel disease type unclassified; NA = not applicable.

IBD type unclassified initial treatment

IBDU: initial treatment	Frequency (%, n)	
	Infliximab	Adalimumab
	National (n=25)	National (n=0)
Consent		
Was informed consent to receive anti-TNFα treatment taken from this patient?		
Yes	100% (25)	NA
If yes, was this verbal or written?		
Verbal	36% (9)	NA
Written	64% (16)	NA
Treatment details		
Time between date of decision to start and date of initial treatment (first loading dose)		
Median (IQR) time (days)	6 (2, 12)	NA
What was the clinical indication for this treatment?		
Acute severe IBDU	68% (17)	NA
Chronic refractory IBDU	32% (8)	NA
Dose given at this infusion (mg/kg)	**(n=21)**	
5	95% (20)	NA
Other	5% (1)	NA
Duration of infusion (mins)	**(n=20)**	
60	10% (2)	NA
120	85% (17)	NA
240	5% (1)	NA
Infusion completion outcome		
Completed successfully at prescribed rate	96% (24)	NA
Repeat infusion reaction at lower rate and discontinued	4% (1)	NA
Were any adverse events recorded for this treatment?		
Yes	4% (1)	NA
Which adverse events?		
Itching	4% (1)	NA

IBDU = inflammatory bowel disease type unclassified; IQR = interquartile range; NA = not applicable; TNFα = tumour necrosis factor alpha.

IBDU: initial treatment	Frequency (%, n)	
	Infliximab	Adalimumab
	National (n=25)	National (n=0)
Treatment details continued		
Is the patient receiving any concomitant therapies for the management of IBD at the time of this treatment?		
Yes	96% (24)	NA
If yes, indicate which concomitant therapies (more than one may have been selected)		
Azathioprine/mercaptopurine	68% (17)	NA
5-aminosalicylic acid	44% (11)	NA
Antibiotics	16% (4)	NA
Dietary therapy	8% (2)	NA
Methotrexate	4% (1)	NA
Steroids	56% (14)	NA
Other	16% (4)	NA
Has the patient failed to respond or are they intolerant to immunosuppressive drugs / corticosteroids?		
Yes	72% (18)	NA
If yes, indicate which previous therapies (more than one therapy may have been selected)		
Azathioprine/mercaptopurine	32% (8)	NA
5-aminosalicylic acid	12% (3)	NA
Antibiotics	4% (1)	NA
Dietary therapy	4% (1)	NA
Methotrexate	8% (2)	NA
Steroids	68% (17)	NA
Disease severity score		
Severity of disease	**(n=21)**	
Mild	0% (0)	NA
Moderate	24% (5)	NA
Severe	76% (16)	NA

IBD = inflammatory bowel disease; IBDU = inflammatory bowel disease type unclassified; NA = not applicable.

IBD type unclassified follow-up treatment at 3 months

IBDU: follow-up treatment at 3 months	Frequency (%, n)	
	Infliximab	Adalimumab
	National (n=13)	National (n=0)
Follow-up treatment details		
Infliximab dose given at this treatment (mg/kg)		
5	92% (12)	NA
Other	8% (1)	NA
Review of treatment plan		
Continue treatment	92% (12)	NA
Stop treatment	8% (1)	NA
If treatment stopped, what were the reasons for stopping?	**(n=1)**	
Side effects / adverse events	100% (1)	NA
Were there any adverse events since the last review?		
Yes	8% (1)	NA
Which adverse events? (more than one may have been selected)		
Flushing	8% (1)	NA
Itching	8% (1)	NA
Rash	8% (1)	NA
Other	8% (1)	NA
Is the patient currently receiving any other therapies for the management of IBD?		
Yes	92% (12)	NA
If yes, indicate which other therapies (more than one may have been selected)		
Azathioprine/mercaptopurine	62% (8)	NA
5-aminosalicylic acid	54% (7)	NA
Methotrexate	8% (1)	NA
Steroids	8% (1)	NA
Topical	8% (1)	NA
Other	31% (4)	NA
Disease severity score		
Severity of disease	**(n=9)**	
Mild	22% (2)	NA
Moderate	67% (6)	NA
Severe	11% (1)	NA

IBD = inflammatory bowel disease; IBDU = inflammatory bowel disease type unclassified; NA = not applicable.

IBD type unclassified follow-up treatment at 12 months

IBDU: follow-up treatment at 12 months	Frequency (%, n)	
	Infliximab	Adalimumab
	National (n=3)	National (n=0)
Follow-up treatment details		
Infliximab dose given at this treatment (mg/kg)		
5	100% (3)	NA
Review of treatment plan		
Continue treatment	100% (3)	NA
Were there any adverse events since the last review?		
Yes	0% (0)	NA
Is the patient currently receiving any other therapies for the management of IBD?		
Yes	100% (3)	NA
If yes, indicate which other therapies (more than one may have been selected)		
Azathioprine/mercaptopurine	33% (1)	NA
5-aminosalicylic acid	67% (2)	NA
Methotrexate	33% (1)	NA
Steroids	67% (2)	NA
Disease severity score		
Severity of disease	**(n=2)**	
Mild	50% (1)	NA
Severe	50% (1)	NA

IBD = inflammatory bowel disease; IBDU = inflammatory bowel disease type unclassified; NA = not applicable.

IBD-related surgery

Of the analysed paediatric patients, 114 had one or more surgical procedures related to their IBD. The surgery performed on these patients is categorised according to whether it was carried out before or after biological therapies were started. Only surgeries for patients included in the national analysis are presented in the following tables. One table is given for each disease type.

Table 18 Surgical procedures in paediatric patients with CD

CD-related surgery	Paediatric patients with surgery recorded (n=90)	
	Before starting biological therapy (n=64)*	After starting biological therapy (n=36)*
Surgical procedure by type (%, n)		
Appendicectomy	2% (1)	0% (0)
Colectomy and ileostomy	8% (5)	14% (5)
Drainage of abscess	6% (4)	3% (1)
Excision of fistula	2% (1)	0% (0)
Other surgical procedure	36% (23)	33% (12)
Partial colectomy	6% (4)	0% (0)
Perianal surgery	42% (27)	14% (5)
Right hemicolectomy / ileocaecal resection	11% (7)	33% (12)
Small bowel resection	5% (3)	11% (4)
Stricturoplasty	3% (2)	3% (1)
Total proctocolectomy ileoanal pouch	2% (1)	0% (0)
Total proctocolectomy permanent ileostomy	0% (0)	3% (1)

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

Table 19 Surgical procedures in paediatric patients with UC

UC-related surgery	Paediatric patients with surgery recorded (n=21)	
	Before starting biological therapy (n=1)	After starting biological therapy (n=20)
Surgical procedure by type (%, n)		
Colectomy and ileostomy	100% (1)	85% (17)
Partial colectomy	0% (0)	10% (2)
Right hemicolectomy / ileocaecal resection	0% (0)	5% (1)

UC = ulcerative colitis.

Table 20 Surgical procedures in paediatric patients with IBDU

IBDU-related surgery	Paediatric patients with surgery recorded (n=3)	
	Before starting biological therapy (n=0)	After starting biological therapy (n=3)
Surgical procedure by type (%, n)		
Colectomy and ileostomy	0% (0)	100% (3)

IBDU = inflammatory bowel disease type unclassified; NA = not applicable.

Patient-reported outcome measures (PROMs)

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

IMPACT-III

IMPACT-III is a health-related quality of life questionnaire for paediatric patients with IBD. The questionnaire was originally developed in Canada, but IMPACT-III (UK) has been shown to be a valid tool to measure quality of life in children with IBD in the UK.[9] It comprises 35 items that address six domains of IBD: bowel symptoms, body image, functional / social impairment, emotional impairment, tests/treatment and systemic impairment. Total scores range from 35 (poor) to 175 (best), with an increase in total score of 10.8 reported to be indicative of a clinically meaningful improvement.

In total, 216 IMPACT-III questionnaires were completed at initial treatments for patients taking infliximab and adalimumab and for all disease types, with a median (IQR) score of 116 (102, 137). At 3-month follow-up, 64 IMPACT-III questionnaires were completed for patients taking infliximab and adalimumab and for all disease types, with a median (IQR) score of 132 (93, 146). Very few IMPACT-III questionnaires were completed at 12-month follow-up, so this figure has not been reported. The limited number of IMPACT-III questionnaires completed at initial and follow-up treatment for individual patients means that a median change in IMPACT-III score cannot be reliably reported.

Table 17 from **section 2** of this report is provided again for reference.

Table 17 PROMs (IMPACT-III)

IMPACT-III	Initial treatment	Follow-up treatment at 3 months
Patients with completed IMPACT-III questionnaire (%, n/N)	31% (216/696)	19% (64/332)
IMPACT-III score, median (IQR)	116 (102, 137)	132 (93, 146)

IQR = interquartile range; PROMs = patient-reported outcome measures.

6: Participation and individual site key indicator data

Participation

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

- Sites that have been entering data, which are known as participating sites (or participants), which can be broken down into three further categories:
  - Those that have entered data regularly over the past year of data collection.
  - Those that have previously entered data into the audit but have not done so during the past year of data collection.
  - Those that have entered data but the data do not meet the audit criteria (for example, already established patients or unlocked submissions).
- Sites that have never entered any data to the audit, which are known as non-participating sites (or non-participants).
- Sites that do not administer biological therapies to their patients with IBD, which are known as not eligible.

Table 21 shows the different levels of paediatric site participation.

Table 21 Participation status for paediatric sites

Participation status paediatric sites	Sites (n)
Participated with regular data entry	33
Participated but data submitted do not meet audit criteria	3
Previously participated but no data entered in past year of data collection	1
Not participated	7
Not eligible to participate	0
Total number of paediatric sites	44

Table 22 Paediatric site participation status over time

Table 22 shows participation of paediatric sites, trusts / health boards by country over time. Some services have reconfigured, so participating denominators vary.

Participating site	Audit reporting dates (%, n/N)			
	June 2012	August 2013	September 2014	September 2015
England				
Sites	58% (11/19)	75% (15/20)	86% (31/36)	84% (31/37)
Trusts	58% (11/19)	75% (15/20)	86% (30/35)	83% (30/36)
Northern Ireland				
Sites	0% (0/2)	50% (1/2)	50% (1/2)	50% (1/2)
Trusts	0% (0/2)	50% (1/2)	50% (1/2)	50% (1/2)
Scotland				
Sites	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Health boards	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Wales				
Sites	50% (1/2)	100% (2/2)	100% (2/2)	100% (2/2)
Health boards	50% (1/2)	100% (2/2)	100% (2/2)	100% (2/2)
Total				
All sites	58% (15/26)	78% (21/27)	86% (37/43)	84% (37/44)
Specialist sites	56% (14/25)	76% (19/25)	92% (23/25)	92% (23/25)
Trusts / health boards	58% (15/26)	78% (21/27)	86% (36/42)	84% (36/43)

Individual site key indicator data

The table below gives named key site data in alphabetical order of 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 IDB. An asterisk next to the name of the site in the table denotes that the site has taken part in PANTs.

	Participation status	Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR)	Initial treatment PCDAI score, Median (IQR)	Crohn's disease patients – remission achieved	Crohn's disease patients – on concomitant immunosuppression at start of treatment	Crohn's disease patients with adverse event recorded at 3 month follow-up	Crohn's disease patients – PROMs completed at start of treatment
Results		n=567 1 (1, 2)	n=347 28 (18, 38)	55% (54/99)	83% (407/492)	6% (17/286)	31% (216/696)
England (n=36)							
Alder Hey Children's NHS Foundation Trust							
Alder Hey Children's Hospital	Participant	n=61 1 (1, 3)	n=52 25 (12, 32)	72% (23/32)	97% (59/61)	3% (1/34)	71% (43/61)
Ashford and St Peter's Hospitals NHS Foundation Trust							
Ashford Hospital and St Peter's Hospital combined (paediatric)*	Non-participant						
Barts Health NHS Trust							
Barts and The London Children's Hospital*	Participant	n=32 2 (1, 3)	n=0	n=0	86% (18/21)	n<6	31% (10/32)
Birmingham Children's Hospital NHS Foundation Trust							
Birmingham Children's Hospital	Participant	n=64 1 (0, 2)	n=17 15 (5, 32)	n<6	79% (51/65)	8% (4/49)	0% (0/65)
Brighton and Sussex University Hospitals NHS Trust							
The Royal Alexandra Children's Hospital*	Participant	n=6 4 (2, 7)	n=6 26 (11, 35)	n<6	n=0	n<6	83% (5/6)
Burton Hospitals NHS Foundation Trust							
Queen's Hospital, Burton (paediatric)	Participant	n<6	n<6	n<6	n<6	n<6	n<6

	Participation status	Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR)	Initial treatment PCDAI score, Median (IQR)	Crohn's disease patients – remission achieved	Crohn's disease patients – on concomitant immunosuppression at start of treatment	Crohn's disease patients with adverse event recorded at 3 month follow-up	Crohn's disease patients – PROMs completed at start of treatment
Results		n=567 1 (1, 2)	n=347 28 (18, 38)	55% (54/99)	83% (407/492)	6% (17/286)	31% (216/696)
Cambridge University Hospitals NHS Foundation Trust							
Addenbrooke's Hospital (paediatric gastroenterology unit)*	Participant	n=19 1 (1, 2)	n=17 25 (22, 45)	50% (6/12)	100% (16/16)	18% (3/17)	15% (3/20)
Central Manchester University Hospitals NHS Foundation Trust							
Royal Manchester Children's Hospital	Participant	n=22 1 (0, 3)	n=0	n=0	86% (19/22)	14% (1/7)	0% (0/22)
Chelsea and Westminster Hospital NHS Foundation Trust							
Chelsea and Westminster Hospital, Children's Services*	Participant	n=28 1 (1, 2)	n=9 30 (19, 44)	n<6	83% (20/24)	7% (1/14)	11% (3/28)
Doncaster and Bassetlaw Hospitals NHS Foundation Trust							
Doncaster Royal Infirmary and Bassetlaw District General Hospital combined (paediatric)	Non-participant						
Dorset County Hospital NHS Foundation Trust							
Dorset County Hospital, Children's Services*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Epsom and St Helier University Hospitals NHS Trust							
Queen Mary's Hospital for Children	Participant but data submitted do not meet audit criteria						
Great Ormond Street Hospital for Children NHS Foundation Trust							
Great Ormond Street Hospital*	Participant	n=13 1 (0, 2)	n=8 19 (15, 34)	38% (3/8)	n<6	11% (1/9)	40% (6/15)

	Participation status	Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR)	Initial treatment PCDAI score, Median (IQR)	Crohn's disease patients – remission achieved	Crohn's disease patients – on concomitant immunosuppression at start of treatment	Crohn's disease patients with adverse event recorded at 3 month follow-up	Crohn's disease patients – PROMs completed at start of treatment
Results		n=567 1 (1, 2)	n=347 28 (18, 38)	55% (54/99)	83% (407/492)	6% (17/286)	31% (216/696)
Hull and East Yorkshire Hospitals NHS Trust							
Hull Royal Infirmary* and Castle Hill Hospital combined (paediatric)	Participant	n<6	n<6	n<6	n<6	n<6	n<6
King's College Hospital NHS Foundation Trust							
King's College Hospital (paediatric gastroenterology)	Participant	n=19 1 (1, 2)	n=10 33 (24, 49)	17% (1/6)	68% (13/19)	0% (0/8)	0% (0/19)
Leeds Teaching Hospitals NHS Trust							
Leeds General Infirmary (paediatric gastroenterology unit)	Participant	n=13 2 (1, 3)	n=8 31 (25, 38)	n<6	85% (11/13)	n<6	31% (4/13)
Lewisham and Greenwich NHS Trust							
The Children's Hospital, Lewisham	Non-participant						
London North West Healthcare NHS Trust							
Northwick Park and St Mark's Hospital combined (paediatric gastroenterology)	Participant	n=7 1 (0, 2)	n=6 26 (8, 45)	n<6	100% (7/7)	n<6	57% (4/7)
Luton and Dunstable Hospital NHS Foundation Trust							
Luton and Dunstable University Hospital (paediatric)*	Participant but data submitted do not meet audit criteria						
Maidstone and Tunbridge Wells NHS Trust							
Maidstone Hospital (paediatric)*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Tunbridge Wells Hospital (paediatric)	Participant	n<6	n<6	n<6	n<6	n<6	n<6

	Participation status	Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR)	Initial treatment PCDAI score, Median (IQR)	Crohn's disease patients – remission achieved	Crohn's disease patients – on concomitant immunosuppression at start of treatment	Crohn's disease patients with adverse event recorded at 3 month follow-up	Crohn's disease patients – PROMs completed at start of treatment
Results		n=567 1 (1, 2)	n=347 28 (18, 38)	55% (54/99)	83% (407/492)	6% (17/286)	31% (216/696)
Norfolk and Norwich University Hospitals NHS Foundation Trust							
Jenny Lind Children's Hospital*	Participant	n=22 1 (1, 2)	n=19 28 (12, 45)	79% (11/14)	71% (15/21)	0% (0/18)	65% (15/23)
North Tees and Hartlepool NHS Foundation Trust							
University Hospital of Hartlepool and University Hospital of North Tees* combined (paediatric)	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Nottingham University Hospitals NHS Trust							
Nottingham Children's Hospital*	Participant	n=26 1 (1, 2)	n=13 22 (18, 56)	n<6	83% (15/18)	0% (0/12)	37% (11/30)
Oxford University Hospitals NHS Trust							
Children's Hospital, The John Radcliffe	Participant	n=13 1 (1, 3)	n=12 23 (19, 30)	n<6	92% (12/13)	n<6	0% (0/13)
Plymouth Hospitals NHS Trust							
Derriford Hospital (paediatric)	Non-participant						
Poole Hospital NHS Foundation Trust							
Poole General Hospital (paediatric)	Participant	n<6	n<6	n<6	n<6	n<6	n<6
Royal Devon and Exeter NHS Foundation Trust							
Royal Devon and Exeter Hospital (paediatric)	Non-participant						

	Participation status	Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR)	Initial treatment PCDAI score, Median (IQR)	Crohn's disease patients – remission achieved	Crohn's disease patients – on concomitant immunosuppression at start of treatment	Crohn's disease patients with adverse event recorded at 3 month follow-up	Crohn's disease patients – PROMs completed at start of treatment
Results		n=567 1 (1, 2)	n=347 28 (18, 38)	55% (54/99)	83% (407/492)	6% (17/286)	31% (216/696)
Royal Free London NHS Foundation Trust							
Royal Free Hospital (paediatric gastroenterology unit)	Previous participant but no data entered in past year	n=12 1 (1, 3)	n=12 29 (21, 34)	n=0	75% (9/12)	n=0	0% (0/12)
Sheffield Children's NHS Foundation Trust							
Sheffield Children's Hospital	Participant	n<6	n<6	n<6	n<6	n<6	n<6
St George's Healthcare NHS Trust							
St George's Hospital (paediatric gastroenterology unit)	Participant	n=17 2 (1, 4)	n=10 31 (27, 51)	17% (1/6)	94% (16/17)	0% (0/8)	59% (10/17)
The Ipswich Hospital NHS Trust							
The Ipswich Hospital (paediatric)	Non-participant						
The Newcastle upon Tyne Hospitals NHS Foundation Trust							
Royal Victoria Infirmary Children's Services	Participant	n=9 1 (0, 2)	n=9 25 (13, 30)	n<6	78% (7/9)	0% (0/6)	0% (0/9)
University Hospital of North Midlands NHS Trust							
The Royal Stoke University Hospital (paediatric)	Participant	n=7 1 (0, 6)	n<6	n=0	n<6	n<6	0% (0/7)
University Hospital Southampton NHS Foundation Trust							
Southampton Children's Hospital	Participant	n=30 1 (1, 3)	n=23 35 (30, 42)	n=0	70% (21/30)	n=0	0% (0/30)

	Participation status	Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR)	Initial treatment PCDAI score, Median (IQR)	Crohn's disease patients – remission achieved	Crohn's disease patients – on concomitant immunosuppression at start of treatment	Crohn's disease patients with adverse event recorded at 3 month follow-up	Crohn's disease patients – PROMs completed at start of treatment
Results		n=567 1 (1, 2)	n=347 28 (18, 38)	55% (54/99)	83% (407/492)	6% (17/286)	31% (216/696)
University Hospitals of Bristol NHS Foundation Trust							
Bristol Royal Hospital for Sick Children*	Participant	n<6	n<6	n<6	n<6	n<6	n<6
University Hospitals of Leicester NHS Trust							
Leicester Royal Infirmary Children's Hospital*	Participant	n=19 1 (0, 2)	n=11 35 (32, 45)	43% (3/7)	100% (11/11)	8% (1/12)	32% (6/19)
Northern Ireland (n=2)							
Belfast Health and Social Care Trust							
Royal Belfast Hospital for Sick Children (RBHSC)	Non-participant						
Western Health and Social Care Trust							
Altnagelvin Area Hospital (paediatric gastroenterology)	Participant but data submitted do not meet audit criteria						
Scotland (n=3)							
NHS Grampian							
North-East Scotland Paediatric Gastroenterology Network (Royal Aberdeen Children's Hospital, Ninewells Hospital and Raigmore Hospital combined)	Participant	n=28 1 (1, 3)	n=21 30 (25, 38)	n<6	89% (25/28)	11% (1/9)	21% (6/28)
NHS Greater Glasgow and Clyde							
Royal Hospital for Sick Children (Yorkhill)*	Participant	n=41 2 (1, 4)	n=41 20 (10, 29)	57% (12/21)	86% (25/29)	8% (2/25)	83% (35/42)

	Participation status	Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR)	Initial treatment PCDAI score, Median (IQR)	Crohn's disease patients – remission achieved	Crohn's disease patients – on concomitant immunosuppression at start of treatment	Crohn's disease patients with adverse event recorded at 3 month follow-up	Crohn's disease patients – PROMs completed at start of treatment
Results		n=567 1 (1, 2)	n=347 28 (18, 38)	55% (54/99)	83% (407/492)	6% (17/286)	31% (216/696)
NHS Lothian							
Royal Hospital for Sick Children, Edinburgh	Participant	n=16 5 (3, 8)	n=14 20 (14, 39)	n<6	38% (6/16)	0% (0/11)	13% (2/16)
Wales (n=2)							
Abertawe Bro Morgannwg University Health Board							
Morriston Hospital (paediatric gastroenterology)	Participant	n=12 1 (0, 2)	n=12 34 (29, 42)	29% (2/7)	92% (11/12)	11% (1/9)	100% (12/12)
Cardiff and Vale University Health Board							
The Noah's Ark Children's Hospital for Wales (previously Department of Child Health, University Hospital of Wales)	Participant	n=14 0 (0, 2)	n<6	n=0	60% (9/15)	8% (1/13)	20% (3/15)

CD = Crohn's disease; IQR = interquartile range; PCDAI = Paediatric Crohn's Disease Activity Index; PROMs = patient-reported outcome measures.

Appendices

Appendix 1: Acronyms used in this report

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

Appendix 2: Biological therapy audit governance

Audit governance

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

The audit is commissioned by Healthcare Quality Improvement Partnership (HQIP) as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP). The audit is managed by the Clinical Effectiveness and Evaluation Unit (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 of people tasked with leading this particular element of the UK IBD audit and who contributed considerably to the development of this element of work.

Association of Coloproctology of Great Britain and Ireland

Mr Omar Faiz, consultant colorectal surgeon, St Mark's Hospital, Harrow
Mr Graeme Wilson, consultant colorectal surgeon, Western General Hospital, Edinburgh

British Dietetic Association

Ms Katie Keetarut, senior IBD dietitian, University College Hospital, London

British Society of Gastroenterology

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

British Society of Paediatric Gastroenterology, Hepatology and Nutrition

Dr Charles Charlton, consultant paediatric gastroenterologist, Queens Medical Centre, Nottingham
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
Mr Peter Canham, patient involvement adviser
Ms Jackie Glatter, health service development adviser
Revd Ian Johnston, patient representative

Primary Care Society for Gastroenterology

Dr Jamie Dalrymple, GP partner, Drayton and St Faiths medical practice

Royal College of Nursing

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

Ms Diane Hall, clinical nurse specialist, Heartlands Hospital, Birmingham

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

Royal College of Physicians

Ms Rhona Buckingham, operations director, CEEU

Ms Kajal Mortier, project manager, UK IBD programme

Ms Susan Murray, programme manager, UK IBD programme

Ms Aimee Protheroe, programme development manager, UK IBD programme

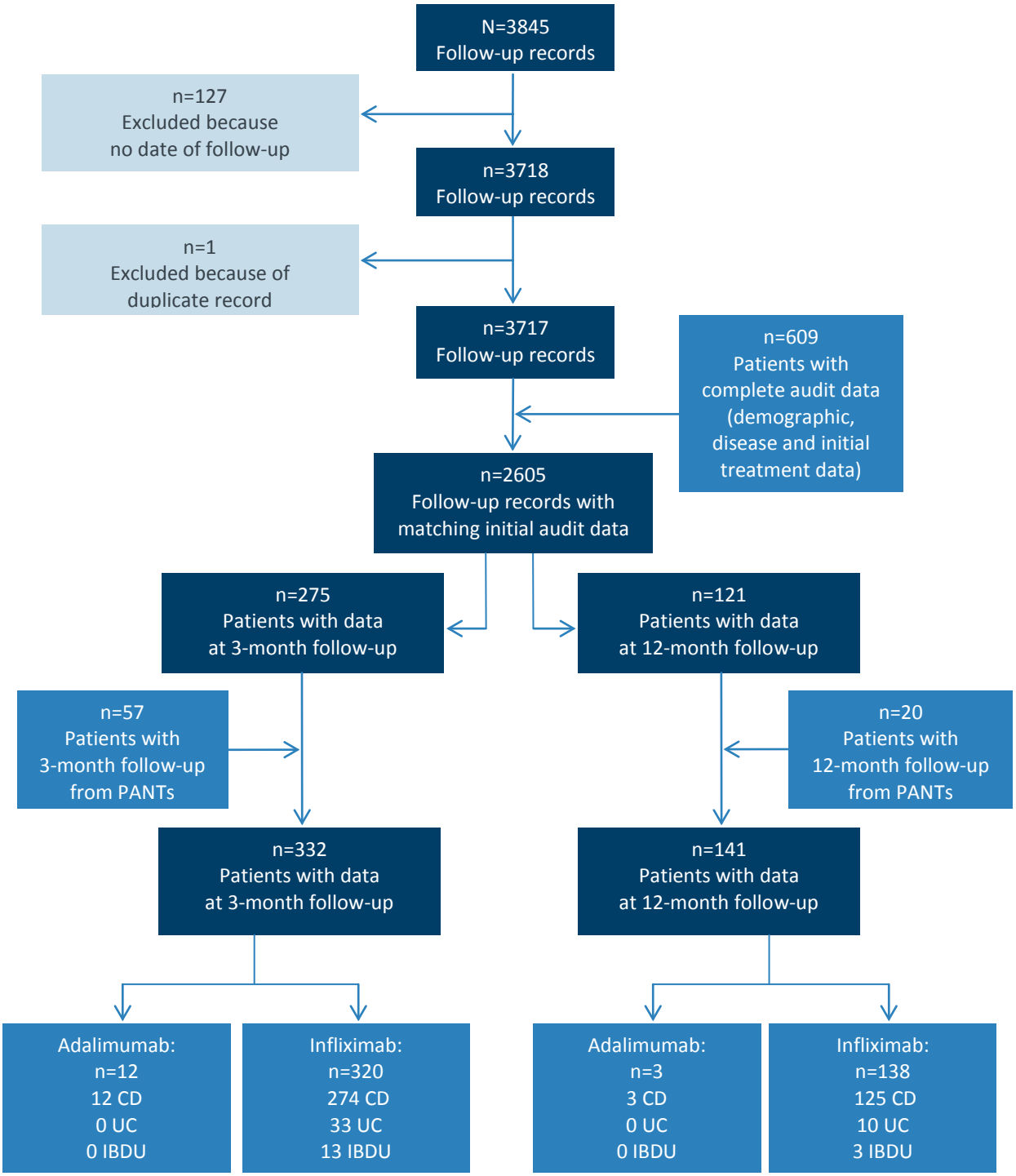
Dr Kevin Stewart, clinical director, CEEU

Royal Pharmaceutical Society of Great Britain

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

Appendix 3: Consort diagram – follow-up treatment

Fig 3 Consort diagram for follow-up treatment of paediatric patients. CD = Crohn's disease; IBDU = inflammatory bowel disease type unclassified; PANTs = Personalised Anti-TNF Therapy in Crohn's disease study; UC = ulcerative colitis.



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