Royal College of Physicians | Inflammatory Bowel Disease Programme

Biological therapy

# National clinical audit of biological therapies

## UK inflammatory bowel disease (IBD) audit

**Adult report**
**September 2015**

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

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| Publication date | 24 September 2015 |
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| Supersedes | National clinical audit of biological therapies. UK inflammatory bowel disease (IBD) audit. Adult report. September 2014. |
| Related publications | IBD Standards Group, 2013. *Standards for the healthcare of people who have inflammatory bowel disease, IBD standards, 2013 update*. **www.ibdstandards.org.uk**<br><br>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.<br><br>National Institute for Health and Care Excellence, 2008. Technology appraisal 163: *Infliximab for acute exacerbations of ulcerative colitis.* **www.nice.org.uk/guidance/TA163**<br><br>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**<br><br>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**<br><br>National Institute for Health and Care Excellence, 2015. Quality standard 81: *Inflammatory bowel disease.* **www.nice.org.uk/guidance/QS81**<br><br>Royal College of Physicians, 2014. *Experience of inpatients with ulcerative colitis throughout the UK*.<br><br>Royal College of Physicians, 2014. *National audit of inflammatory bowel disease (IBD) service provision. Adult report.*<br><br>Royal College of Physicians, 2014. *National clinical audit of inpatient care for adults with ulcerative colitis*. |
| Contact | **ibd.audit@rcplondon.ac.uk** |

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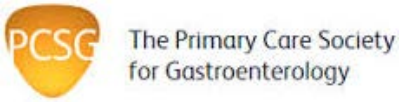



# Contents

# 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 159 adult trusts / health boards eligible to participate in this audit, 152 (96%) are participating in either the audit or the Personalised Anti-TNF Therapy in Crohn's disease study (PANTs).[5] A total of 4718 adult 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.

At some sites, data from only a minority of cases are being entered. The organisational audit in 2013 collected data on the number of patients newly started on biological therapies. Although 40% of sites estimated this figure, when current data are compared with this, it appears possible that only 22% 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

**41%** of audited adult patients were being treated with biological therapies within 2 years of being diagnosed with Crohn's disease (CD). (**Section 5, p 35**)

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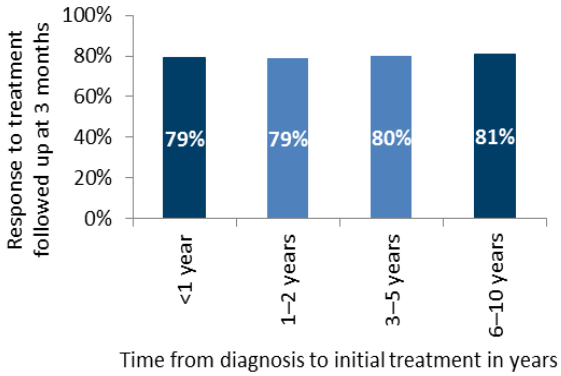
Response to treatment is not related to duration of disease: the response rate was 79% in patients treated within 1 year of diagnosis and 81% in those treated 6–10 years from diagnosis. (**Section 2, p 21**)

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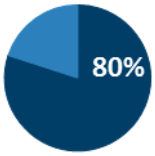
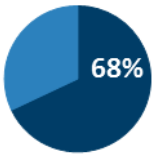



**Response to treatment**




**Remission achieved**

Treatment of CD with a biological therapy is effective: 80% of adult patients audited experienced a response, with remission in 68%. (**Section 2, p 21**)

Quality of life also improved after treatment, with a 61% reduction in median Crohn's and ulcerative colitis questionnaire (CUCQ)-12 scores. (**Section 2, p 28**)

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Over the last three rounds of audit, pre-treatment Harvey–Bradshaw index (HBI) has fallen from 9 to 7. (**Section 2, p 22**)

**9** **HBI** **7**

**58%** **Immunosuppression** **34%**

Use of concomitant immunosuppression therapy has also fallen from 58% to 34%, which suggests earlier use of biological therapies in patients with milder disease. (**Section 2, p 22**)

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**8%** of patients reported an adverse event when assessed at 3-month follow-up. Infection was seen in 2% of patients and mortality in 0.1%; no malignancies were reported. (**Section 2, p 25**)

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Treatment was stopped in **9%** of patients with CD who were followed up at 12 months.

The audit data suggest that the treatment was discontinued because it was effective in 34% of these patients, while another 23% stopped treatment after experiencing side effects / an adverse event. (**Section 5, p 43**)

## Participation findings

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

from 

to 

of adult trusts participating in the UK. (**Section 6, p 64**)

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Although participation in the audit has improved over time, only about 1 in 5 eligible patients were audited in 2013. (**Section 2, p 24**)

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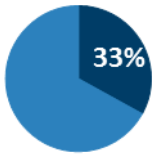
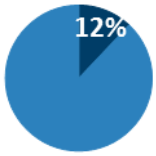
Submission of follow-up data has improved but remains incomplete. (**Section 2, p 19**)




Only 33% of adult patients audited had complete follow-up data at 3 months.




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

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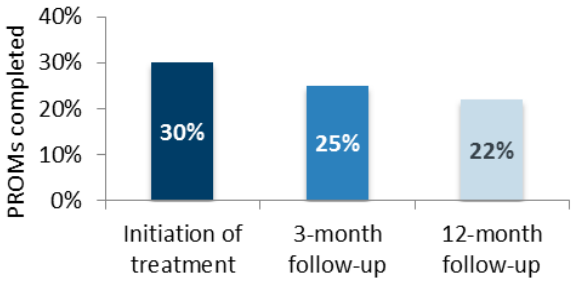
More patient-reported outcome measures (PROMs) were completed at the start of treatment (30%) than for the previous report (14%), although fewer PROMs were completed at the 3- and 12-month review points (25% and 22%, respectively).[6] (Section 2, p 28)



## 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 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<br>IBD nurses<br>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.<br>Ensure that IBD clinical teams are made aware of its availability and importance.<br>Disease activity scoring forms for patients can be downloaded directly from the biological therapy audit web tool (**www.ibdbiologicsaudit.org**). | Consultant gastroenterologists<br>IBD nurses<br>Infusion clinic staff | |

| National recommendation | Action required | Staff responsible | Progress at your site (Include date of review, name of individual responsible for action) |
|---|---|---|---|
| 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.<br>Ensure that IBD clinical teams are made aware of their availability and importance.<br>PROM forms for patients can be downloaded directly from the biological therapy audit web tool (**www.ibdbiologicsaudit.org**). | Consultant gastroenterologists<br>IBD nurses<br>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.<br>Have a system in place to ensure that data are collected at 3- and 12-month follow-up. | Consultant gastroenterologists<br>IBD nurses<br>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.<br>Site-level data can be analysed at any time, independent of the annual report.<br>Data can be exported directly from the biological therapy audit web tool by clicking the 'Export data' function (**www.ibdbiologicsaudit.org**). | NHS managers<br>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<br>Infusion clinic staff | |

| National recommendation | Action required | Staff responsible | Progress at your site (Include date of review, name of individual responsible for action) |
|---|---|---|---|
| 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<br>Consultant gastroenterologists<br>IBD nurses<br>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 thus 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 where more than one hospital under a trust / health board offers independent IBD services, data are entered for separate 'sites'. Some organisations that run a coordinated IBD service across several hospitals with the same staff participate in the audit as one trust / health board-wide site.

### Eligibility and participation

Sites are eligible to participate in the biological therapies audit if they prescribe and administer biological therapy to their patients with IBD. Of the 159 adult trusts / health boards eligible to participate in the IBD audit in the UK, 152 are participating in the biological therapies element and/or in the Personalised Anti-TNF Therapy in Crohn's disease (CD) study (PANTs); see below for further information). These 152 trusts / health boards provided the 194 sites that submitted data. Further information on participation and a list of participating and non-participating sites can be found in **section 6, p 64** 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 on to 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 64** 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 from participation. 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 severely active ulcerative colitis after the failure of conventional therapy (including a review of TA140 and TA262).* **www.nice.org.uk/guidance/TA329** [Accessed 16 July 2015].

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


## Availability of audit results in the public domain

Full and executive summary copies of this report are available in the public domain via the Royal College of Physicians (RCP) website (**www.rcplondon.ac.uk/biologics**). The national report of results will be made available to NHS England; the Department of Health, Social Services and Public Safety in Northern Ireland; Healthcare Improvement Scotland; and the Department for Health and Social Services in Wales. A number of key indicators for each of the 194 participating sites are published in the public domain in **section 6, pp 64–85** of this report; these findings are also available via **www.data.gov.uk**, in line with the government's transparency agenda.

## Presentation of results

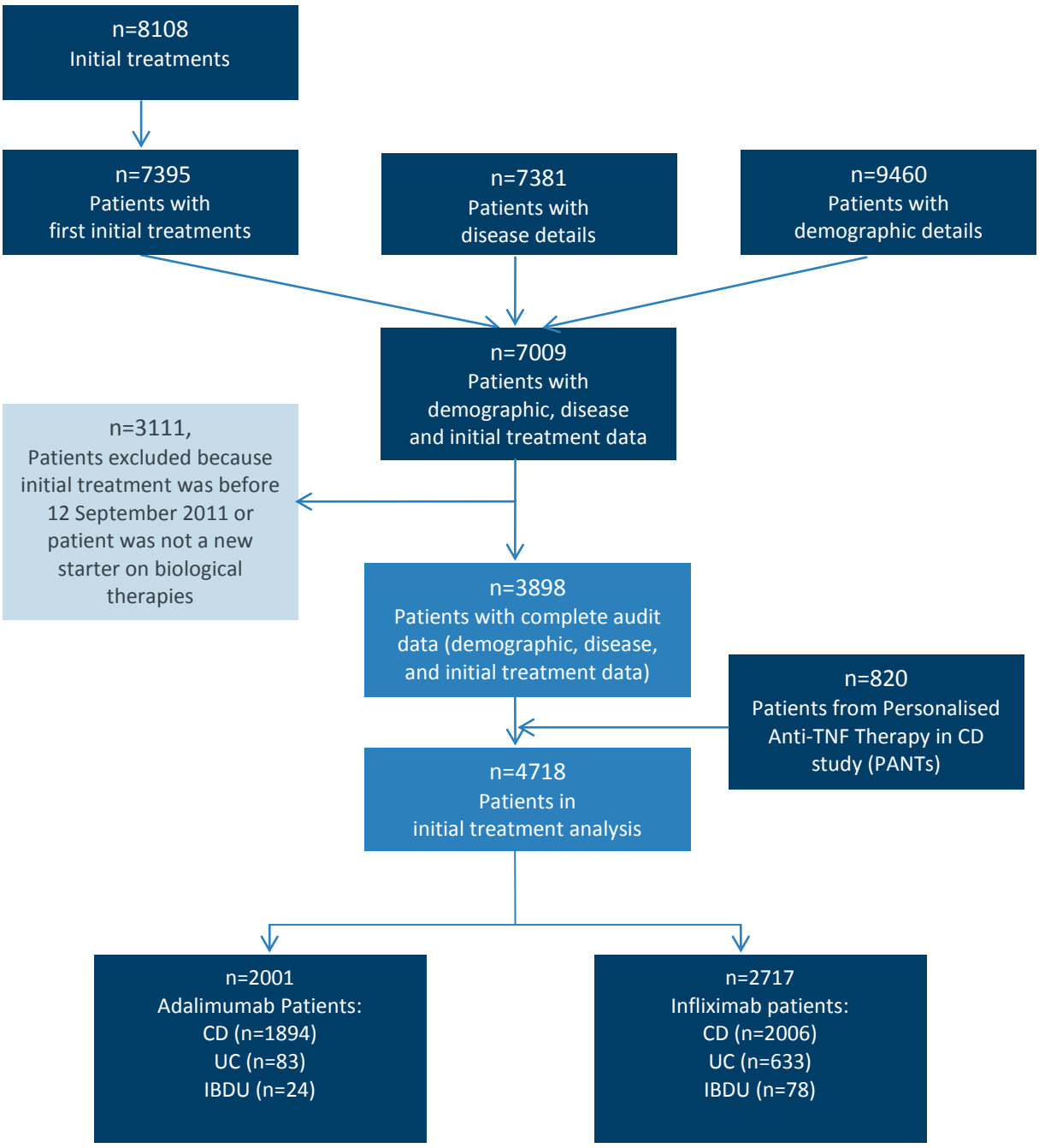
National results are presented as percentages for categorical data and as medians and interquartile ranges (IQRs) for numerical data. This report summarises data on adults provided by sites that registered to participate in the audit and indicated that they provide their IBD service to mainly adult patients. A separate report for paediatric 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, 9460 individual adult 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 96**.

## 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 appear similar to those in the reports produced in 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 patients** | **3900** | **1343** | **520** |
| Adalimumab | 1894 | 525 | 181 |
| Infliximab | 2006 | 818 | 339 |
| **UC patients** | **716** | **176** | **52** |
| Adalimumab | 83 | 19 | 3 |
| Infliximab | 633 | 157 | 49 |
| **IBDU Patients** | **102** | **42** | **14** |
| Adalimumab | 24 | 12 | 2 |
| Infliximab | 78 | 30 | 12 |
| **Total patients** | **4718** | **1561** | **586** |
| **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 adult and paediatric patients with CD

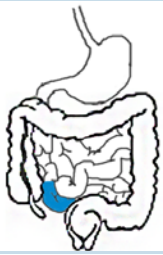
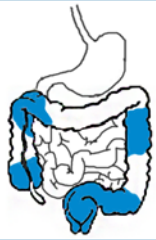
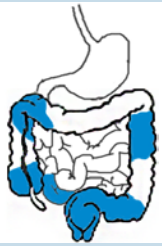
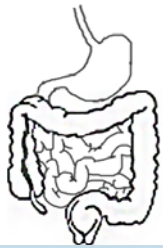
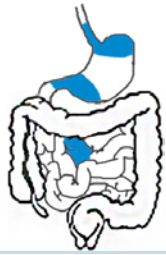
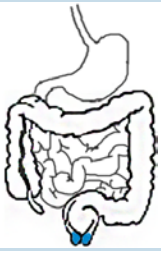
This table compares demographic data for adult and paediatric patients with CD treated with infliximab or adalimumab. The denominators differ when questions were not answered.

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

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 adult and paediatric patients treated with adalimumab or infliximab.

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

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 Harvey–Bradshaw index (HBI) is used to quantify disease activity for adult patients with CD. The Paediatric Crohn's Disease Activity Index (PCDAI) is used to measure disease activity for paediatric 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 in years | <1 | 1–2 | 3–5 | 6–10 | >10 | Total |
| Adult | 79% (121/154) | 79% (115/145) | 80% (89/112) | 81% (86/106) | 77% (159/207) | 80% (570/715) |
| Paediatric | 73% (35/48) | 78% (52/67) | 82% (18/22) | 75% (9/12) | 0% (0/0) | 77% (114/149) |
| YOUR SITE | | | | | | |

*Decrease of >3 in Harvey–Bradshaw index for adult patients and >15 in Paediatric Crohn's Disease Activity Index for paediatric 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 HBI was used to quantify disease activity in adults with CD and the PCDAI to measure disease activity for paediatric patients with CD, and the denominators change when dates of diagnosis for patients are missing.

| CD patient group | Remission* achieved when followed up at 3 months (%, n/N) | | | | | |
|---|---|---|---|---|---|---|
| Time from diagnosis to initial treatment in years | <1 | 1–2 | 3–5 | 6–10 | >10 | Total |
| Adult | 68% (105/155) | 67% (101/150) | 72% (83/116) | 71% (78/110) | 64% (135/210) | 68% (502/741) |
| Paediatric | 59% (30/51) | 66% (45/68) | 68% (15/22) | 75% (9/12) | 0% (0/0) | 55% (54/99) |
| 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 adult patients with CD on any immunosuppressant or 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* | 53% (1644/3080) | 48% (479/1000) | 48% (192/404) |
| YOUR SITE | | | |
| Steroids† | 27% (819/3080) | 6% (64/1000) | 5% (21/404) |
| YOUR SITE | | | |

*Immunosuppressants include azathioprine, mercaptopurine and methotrexate.
†Steroids include budesonide, hydrocortisone, methylprednisolone and prednisolone.

### Table 7 Analysis of results over time

This table compares some key results over time for adults with IBD included in the audit according to reporting timescales. A reduction in site participation between 2014 and 2015 was due to the reconfiguration of services across sites during the year.

| 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** | | | | |
| Adult sites with data included in analysis (n) | 78 | 94 | 143 | 134 |
| **Adult patients audited initiating biological therapies** | | | | |
| Patients with CD (n) | 347 | 837 | 1252 | 1464 |
| Patients with UC (n) | 49 | 146 | 236 | 285 |
| Patients with IBDU (n) | 20 | 29 | 22 | 31 |
| Total (n) | 416 | 1012 | 1510 | 1780 |
| **Treatment time** | | | | |
| Time from diagnosis to initial treatment (years, median IQR) | n=413<br>4 (1, 11) | n=1007<br>4 (1, 11) | n=1475<br>4 (1, 12) | n=1657<br>4 (1, 10) |
| **Adverse events** | | | | |
| Adverse events reported at initial treatment (%, n/N) | 2% (9/416) | 3% (26/1012) | 3% (40/1510) | 2% (42/1780) |
| **Disease activity reported at initial treatment for adult patients** | | | | |
| HBI score, median (IQR) | n=226<br>6 (0, 10) | n=421<br>9 (6, 12) | n=710<br>8 (4, 11) | n=925<br>7 (4, 10)* |
| SCCAI score, median (IQR) | n=44<br>6 (0, 9) | n=90<br>9 (6, 11) | n=99<br>8 (6, 11) | n=129<br>9 (6, 12) |
| **Adult patients with CD on concomitant therapies at initial treatment** | | | | |
| Immunosuppressants (%, n/N) | 54% (189/347) | 58% (482/837) | 38% (473/1252) | 34% (500/1464)* |
| Steroids (%, n/N) | 27% (93/347) | 27% (222/837) | 22% (274/1252) | 16% (230/1464) |

*p<0.001.

CD = Crohn's disease; HBI = Harvey–Bradshaw index; IBDU = inflammatory bowel disease type unclassified; IQR = interquartile range; SCCAI = Simple Clinical Colitis Activity Index; UC = ulcerative colitis.

### Table 8 National comparison of key results for adults with CD

This table depicts national variation in the results of the biological therapy audit between England, Northern Ireland, Scotland and Wales. It only includes sites that submitted enough data to be included in the national analysis. A full list of participating and non-participating sites can be found in **section 6, p 64** of this report.

| Result | Country | | | |
|---|---|---|---|---|
| | England | Northern Ireland | Scotland | Wales |
| Sites participating in the audit (%, n/n) | 84% (141/167) | 75% (9/12) | 52% (11/21) | 44% (7/16) |
| Patients audited (n) | 3531 | 90 | 126 | 153 |
| Time from diagnosis to initial treatment (years, median (IQR)) | n=3379 4 (1, 12) | n=90 4 (1, 10) | n=119 5 (1, 12) | n=151 4 (1, 12) |
| Patients with an adverse reaction recorded during initial treatment (%, n/n) | 3% (97/3531) | 2% (2/90) | 2% (3/126) | 3% (4/153) |
| Disease severity (HBI) at initial treatment, median (IQR) | n=2082 8 (4, 11) | n=27 9 (5, 11) | n=66 6 (3, 9) | n=109 7 (4, 10) |
| Patients with follow-up recorded at 3 months (%, n/N) | 35% (1238/3531) | 11% (10/90) | 31% (39/126) | 37% (56/153) |
| Patients on biological therapy who were appropriately prescribed anti-TNFα in compliance with NICE technology appraisal 187[2] criterion 1.1 (%, n/N) | 46% (949/2082) | 56% (15/27) | 33% (22/66) | 46% (50/109) |

HBI = Harvey–Bradshaw index; IQR = interquartile range; 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 inflammatory bowel disease (IBD) service provision*** **(September 2014)**.[8] Sites participating in this audit were asked to report on the number of patients with IBD who had newly started on 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 patients 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) | 2692 (reported by 171 sites) | |
| Newly started patients – estimated (n) | 949 (reported by 69 sites) | |
| Newly started patients – taken from a database (n) | 1728 (reported by 101 sites) | |
| Newly started patients – taken from unknown source (n) | 15 (reported by 1 site) | |
| Patients with IBD entered into biological therapies audit who were newly started on adalimumab between 1 January 2013 and 31 December 2013 (n) | 566 | |
| Case ascertainment rate (%) | 21% | |

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) | 3400 (reported by 170 sites) | |
| Newly started patients – estimated (n) | 1330 (reported by 68 sites) | |
| Newly started patients – taken from a database (n) | 2048 (reported by 101 sites) | |
| Newly started patients – taken from unknown source (n) | 22 (reported by 1 site) | |
| Number of patients with IBD who were newly started on infliximab between 1 January 2013 and 31 December 2013, as entered into biological therapies audit (n) | 793 | |
| Case ascertainment rate (%) | 23% | |

IBD = inflammatory bowel disease.

## Audit objectives

### Safety

**Table 11 Adverse events**

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

| Adverse event (%, n) | Initial treatment (n=4718) | 3-month follow-up (n=1516) | 12-month follow-up (n=586) |
|---|---|---|---|
| Adverse event recorded Yes= | 3% (117) | 8% (126) | 6% (33) |
| Abdominal pain | 0.04% (2) | 0.3% (5) | 0.2% (1) |
| Alopecia | 0% (0) | 0.1% (1) | 0.2% (1) |
| Angioedema of upper airway | 0.06% (3) | 0.1% (2) | 0.2% (1) |
| Arthralgia | 0.3% (13) | 0.6% (10) | 0% (0) |
| Blood abnormality | 0.02% (1) | 0.4% (7) | 0% (0) |
| Bronchospasm (cough/wheeze/dyspnoea) | 0.3% (13) | 0.5% (8) | 0.5% (3) |
| Cardiac failure | 0% (0) | 0% (0) | 0% (0) |
| Chest pain | 0.1% (5) | 0.1% (1) | 0% (0) |
| Chills | 0.04% (2) | 0.1% (1) | 0.9% (5) |
| Confirmed demyelination | 0.04% (2) | 0% (0) | 0% (0) |
| Death | 0% (0) | 0.1% (1) | 0% (0) |
| Difficulty breathing | 0% (0) | 0.2% (3) | 0% (0) |
| Dizziness | 0.3% (12) | 0.4% (6) | 0% (0) |
| Fatigue | 0.1% (5) | 0.3% (5) | 0.2% (1) |
| Fever | 0.2% (9) | 0.2% (3) | 0% (0) |
| Flushing | 0.3% (16) | 0.7% (11) | 0.2% (1) |
| Headache | 0.4% (21) | 0.4% (6) | 0.5% (3) |
| Hypotension | 0.1% (5) | 0.3% (4) | 0% (0) |
| Infection | 0.1% (4) | 2% (36) | 2% (11) |
| Injection site reaction | 0.1% (4) | 0.2% (3) | 0% (0) |
| Itching | 0.3% (12) | 0.3% (5) | 0.2% (1) |
| Limb weakness | 0.04% (2) | 0.1% (1) | 0% (0) |
| Malignancy | 0% (0) | 0% (0) | 0% (0) |
| Nausea | 0.4% (17) | 0.7% (11) | 0.2% (1) |
| Panic attacks | 0.1% (5) | 0.1% (1) | 0% (0) |
| Rash | 0.4% (18) | 1% (21) | 0.3% (2) |
| Serum sickness-like reaction | 0% (0) | 0% (0) | 0% (0) |
| Urticaria | 0.04% (2) | 0.3% (4) | 0% (0) |
| Other | 0.7% (32) | 2% (24) | 2% (10) |

## Efficacy

Disease activity for adult 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 by HBI, a score <5 is considered to be clinical remission and >16 is considered to be severe disease.

| HBI score | Initial treatment | 3-month follow-up | 12-month follow-up |
|---|---|---|---|
| Adalimumab, median (IQR) | n=1081<br>8 (4, 11) | n=264<br>3 (1, 6) | n=95<br>3 (1, 5) |
| Infliximab, median (IQR) | n=1201<br>7 (4, 10) | n=524<br>2 (1, 5) | n=215<br>2 (0, 4) |
| Total | n=2282<br>8 (4, 10) | n=788<br>3 (1, 6) | n=310<br>2 (0, 5) |
| YOUR SITE | | | |

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

### Table 13 Disease activity – UC

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

| SCCAI score | Initial treatment | 3-month follow-up | 12-month follow-up |
|---|---|---|---|
| Adalimumab, median (IQR) | n=41<br>7 (6, 8) | n=9<br>3 (1, 6) | n=2 |
| Infliximab, median (IQR) | n=321<br>9 (6, 11) | n=77<br>2 (0, 6) | n=18<br>3 (1, 4) |
| Total | n=362<br>9 (6, 11) | n=86<br>2 (0, 5) | n=20<br>3 (1, 4) |

IQR = interquartile range; SCCAI = Simple Clinical 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 60** of this report.

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

## 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 1.1 from technology appraisal 187[2] and criterion 1.1 from technology appraisal 329[3] have been used to assess the appropriateness of prescribing biological therapy.

### Table 15 Compliance with NICE technology appraisal 187

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

| NICE technology appraisal 187 | National CD data, % (n/N) | YOUR SITE |
|---|---|---|
| **Criterion 1.1** Infliximab and adalimumab are recommended as treatment options for adults with severe active CD if (a) the disease has not responded to conventional therapy or (b) the person is intolerant of or have contraindications to conventional therapy (mercaptopurine, azathioprine, methotrexate, prednisolone, budesonide, methylprednisolone or hydrocortisone) | | |
| Patients with CD on biological therapy with HBI score ≥8 before starting anti-TNFα treatment | 51% (1159/2282) | |
| Patients with CD who were treated with conventional therapy at time of or prior to starting biological therapy | 86% (1951/2282) | |
| Patients with CD on biological therapy who were appropriately prescribed anti-TNFα treatment in compliance with criterion 1.1 of NICE technology appraisal 187 | 45% (1035/2282) | |

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

Although compliance with NICE guidance seems to be low for patients with CD, 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.

### Table 16 Compliance with NICE technology appraisal 329

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

| NICE technology appraisal 329 | National UC data (%, n/N) |
|---|---|
| **Criterion 1.1** Infliximab, Adalimumab and golimumab are recommended as treatment options for adults with moderate to severe active UC (a) whose disease has responded inadequately to conventional therapy or (b) are intolerant of or have contraindications to conventional therapy (mercaptopurine, azathioprine, methotrexate, prednisolone, budesonide, methylprednisolone or hydrocortisone) | |
| Patients on biological therapy with SCCAI score ≥5 before starting anti-TNFα treatment | 87% (276/318) |
| Patients who were treated with conventional therapy at time of or prior to starting biological therapy | 95% (301/318) |
| Patients on biological therapy who were appropriately prescribed anti-TNFα therapy in compliance with criterion 1.1 of NICE technology appraisal 329 | 82% (262/318) |

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

## Patient-reported outcome measures

### Table 17 PROMs questionnaire for IBD (IBD-PROM)

This table gives completion rates and results of the IBD-PROM questionnaires used in the biological therapies audit – the EQ-5D[9] and Crohn's and ulcerative colitis questionnaire (CUCQ)-12[10] – for all adult patients calculated. Total EQ-5D scores range from 0 (worst health / death) to 1 (best health), with an increase in score denoting improved health. Total CUCQ-12 scores range from 0 (best health) to 168 (poor health), with each question scored between 0 (best) and 14 (poor). Further information about the EQ-5D and CUCQ-12 can be found on **pp 62–63** of this report.

| IBD-PROM | Initial treatment | 3-month follow-up | 12-month follow-up |
|---|---|---|---|
| Patients with completed IBD-PROM (%, n/N) | 30% (1416/4718) | 25% (384/1561) | 22% (129/586) |
| **YOUR SITE number of patients with IBD-PROM completed** | | | |
| Patients with EQ-5D data completed, (%, n/N) | 97% (1367/1416) | 94% (361/384) | 44% (57/129) |
| EQ-5D score, median (IQR) | 0.76 (0.66, 0.85) | 0.80 (0.73, 1) | 0.80 (0.69, 1) |
| Patients with CUCQ-12 data completed (%, n/N) | 89% (1256/1416) | 87% (332/384) | 87% (112/129) |
| CUCQ-12 score, median (IQR) | 68 (39, 100) | 34 (14, 60) | 27 (10, 49) |

CUCQ = Crohn's and ulcerative colitis questionnaire; IBD = inflammatory bowel disease; 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.[11] 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 regimens
- capture the views of patients locally on their quality of life at intervals throughout their treatment
- benchmark local results against national-level data
- generate individual patient summaries
- generate letters detailing treatment plans
- assess compliance with the **IBD standards** and **NICE quality standard 81**.[1,4]

# 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 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 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 or 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 occurs first. Patients' disease should then be reassessed to determine whether ongoing treatment is still clinically appropriate.

In **technology appraisal 163**,[12] NICE made the following recommendation:

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

## 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 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 **pp 62–63**.

## 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 who are newly started on biosimilar versions of the biological drugs.

### Existing patients

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

### Reporting functions

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

#### Patient summary report

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

#### Treatment summary report

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

### Data import function

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

### Reduction of mandatory fields

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

### Download function

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

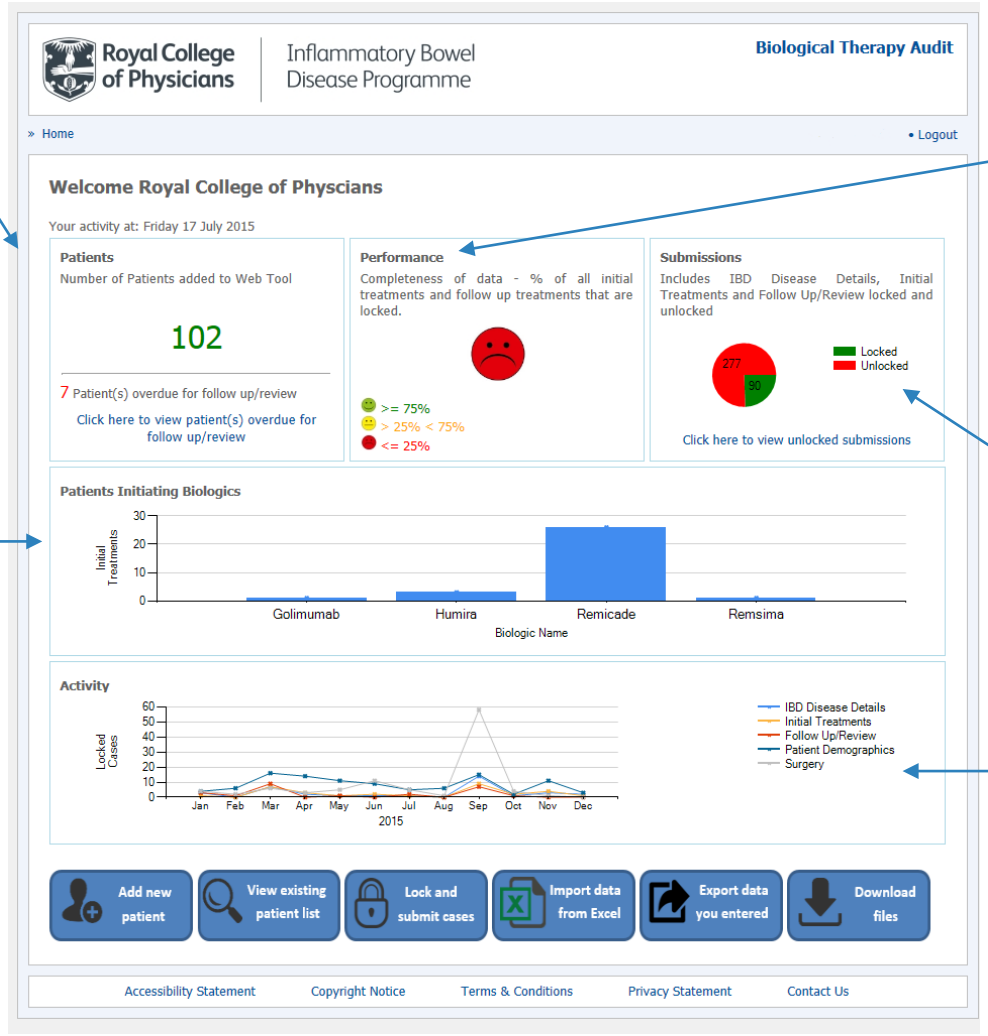
### Data export function

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

## Dashboard

The dashboard is 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 last 90 days.

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

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

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

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

## System security of the biological therapies audit web tool

The document *Biological therapies audit system and hosted server security details* outlines the system security information provided to all sites invited to participate in the audit and is available on the RCP website (**www.rcplondon.ac.uk/biologics**).[13] 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*.[14]

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=2006) | YOUR SITE | National (n=1894) | YOUR SITE |
| **Diagnosis** | | | | |
| **Maximal disease distribution at the time of decision to initiate biological therapy, as defined by the Montreal classification** | **(n=1973)** | | **(n=1876)** | |
| Terminal ileum (L1) | 25% (501) | | 29% (534) | |
| Colonic (L2) | 34% (671) | | 28% (517) | |
| Ileocolonic (L3) | 34% (678) | | 37% (702) | |
| None of these | 6% (123) | | 7% (123) | |
| **Any part of the gut proximal to the terminal ileum (L4)** | **(n=1438)** | | **(n=1487)** | |
| Yes | 42% (604) | | 48% (708) | |
| **Perianal involvement?** | **(n=1357)** | | **(n=1331)** | |
| Yes | 36% (484) | | 27% (354) | |
| **Time between date of diagnosis and date of initial treatment** | **(n=1912)** | | **(n=1823)** | |
| <1 year | 26% (497) | | 18% (330) | |
| 1–2 years | 18% (351) | | 20% (367) | |
| 3–5 years | 15% (287) | | 16% (294) | |
| 6–10 years | 15% (287) | | 17% (314) | |
| >10 years | 26% (490) | | 28% (518) | |

CD = Crohn's disease.

## Crohn's disease initial treatment

| CD: initial treatment | Frequency (%, n) | | | |
|---|---|---|---|---|
| | Infliximab | | Adalimumab | |
| | National (n=2006) | YOUR SITE | National (n=1894) | YOUR SITE |
| **Consent** | | | | |
| **Was informed consent to receive anti-TNFα treatment taken from this patient?** | | | | |
| Yes | 98% (1973) | | 99% (1872) | |
| No | 2% (33) | | 1% (22) | |
| **If yes, was this verbal or written?** | **(n=1973)** | | **(n=1872)** | |
| Verbal | 63% (1247) | | 63% (1175) | |
| Written | 37% (726) | | 37% (697) | |
| **Treatment details** | | | | |
| **Time between date of decision to start and date of initial treatment** (first loading dose) | | | | |
| Median (IQR) time (days) | 16 (6, 36) | | 21 (10, 42) | |
| **What was the clinical indication for this treatment?** | **(n=1926)** | | **(n=1851)** | |
| Severe perianal CD | 15% (297) | | 9% (157) | |
| Active luminal CD | 81% (1560) | | 88% (1625) | |
| Fistulating CD | 1% (22) | | 0.5% (10) | |
| Other clinical indication | 2% (29) | | 1% (21) | |
| Not known | 1% (19) | | 2% (38) | |
| **Dose given at this infusion** (mg/kg) | **(n=1594)** | | | |
| 5 | 100% (1590) | | NA | NA |
| 10 | 0.3% (4) | | NA | NA |
| **Duration of infusion** (mins) | **(n=1105)** | | | |
| 30 | 0.3% (3) | | NA | NA |
| 60 | 0.7% (8) | | NA | NA |
| 120 | 95% (1054) | | NA | NA |
| 180 | 3% (37) | | NA | NA |
| 240 | 0.2% (2) | | NA | NA |
| Other | 0.1% (1) | | NA | NA |
| **Infusion completion outcome** | **(n=1528)** | | | |
| Completed successfully at prescribed rate | 98% (1492) | | NA | NA |
| Completed successfully at lower rate | 0.9% (13) | | NA | NA |
| Restart infusion at lower rate and discontinued | 0.2% (3) | | NA | NA |
| Infusion discontinued and not restarted | 1% (19) | | NA | NA |
| Other | 0.1% (1) | | NA | 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=2006) | YOUR SITE | National (n=1894) | YOUR SITE |
| **Treatment details continued** | | | | |
| **Induction dose** (mg) | | | **(n=1870)** | |
| 160/80 | NA | NA | 80% (1492) | |
| 80/40 | NA | NA | 18% (342) | |
| Other | NA | NA | 2% (36) | |
| **Planned maintenance dose (mg)** | | | **(n=1662)** | |
| 40 mg every other week | NA | NA | 95% (1573) | |
| 40 mg every week | NA | NA | 5% (74) | |
| Other | NA | NA | 0.9% (15) | |
| **Were any adverse events recorded for this treatment?** | | | | |
| Yes | 3% (58) | | 3% (48) | |
| **Which adverse events?** (more than one may have been selected) | | | | |
| Abdominal pain | 0.1% (1) | | 0.1% (1) | |
| Angioedema of upper airway | 0.1% (2) | | 0.1% (1) | |
| Arthralgia | 0.5% (9) | | 0.2% (3) | |
| Blood abnormality | 0% (0) | | 0.1% (1) | |
| Bronchospasm (cough/wheeze/dyspnoea) | 0.5% (10) | | 0.1% (1) | |
| Chest pain | 0.1% (3) | | 0.1% (1) | |
| Chills | 0% (0) | | 0.1% (2) | |
| Confirmed demyelination | 0% (0) | | 0.1% (2) | |
| Dizziness | 0.2% (4) | | 0.3% (5) | |
| Fatigue | 0.1% (2) | | 0.1% (2) | |
| Fever | 0.3% (6) | | 0.1% (2) | |
| Flushing | 0.6% (12) | | 0% (0) | |
| Headache | 0.6% (13) | | 0.3% (6) | |
| Hypotension | 0.1% (2) | | 0.1% (1) | |
| Infection | 0.1% (1) | | 0.2% (3) | |
| Injection site reaction | 0% (0) | | 0.2% (4) | |
| Itching | 0.4% (8) | | 0.2% (3) | |
| Nausea | 0.3% (6) | | 0.5% (9) | |
| Panic attacks | 0.1% (1) | | 0% (0) | |
| Rash | 0.5% (9) | | 0.5% (9) | |
| Serum sickness-like reaction | 0% (0) | | 0% (0) | |
| Urticaria | 0.1% (2) | | 0% (0) | |
| Other | 0.4% (8) | | 0.2% (4) | |

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

| CD: initial treatment | Frequency (%, n) | | | |
|---|---|---|---|---|
| | Infliximab | | Adalimumab | |
| | National (n=2006) | YOUR SITE | National (n=1894) | YOUR SITE |
| **Treatment details continued** | | | | |
| **Is the patient receiving any concomitant therapies for the management of IBD at the time of this treatment?** | **(n=1528)** | | **(n=1552)** | |
| Yes | 75% (1140) | | 72% (1120) | |
| **If yes, indicate which concomitant therapies** (more than one may have been selected) | | | | |
| Allopurinol | 0.3% (4) | | 0.1% (1) | |
| Azathioprine/mercaptopurine | 51% (772) | | 45% (701) | |
| 5-aminosalicylic acid | 20% (300) | | 17% (267) | |
| Antibiotics | 2% (28) | | 1% (16) | |
| Ciclosporin | 0.1% (2) | | 0% (0) | |
| Dietary therapy | 3% (42) | | 2% (36) | |
| Methotrexate | 4% (62) | | 7% (113) | |
| Mycophenolate | 0.1% (2) | | 0% (0) | |
| Steroids | 27% (412) | | 26% (407) | |
| Other | 1% (16) | | 2% (25) | |
| **Has the patient failed to respond or are they intolerant to immunosuppressive drugs / corticosteroids?** | **(n=2006)** | | **(n=1894)** | |
| Yes | 62% (1250) | | 69% (1313) | |
| **If yes, indicate which previous therapies** (more than one may have been selected) | | | | |
| Allopurinol | 0.1% (2) | | 0% (0) | |
| Azathioprine/mercaptopurine | 42% (835) | | 49% (933) | |
| 5-aminosalicylic acid | 16% (324) | | 17% (326) | |
| Antibiotics | 7% (145) | | 6% (104) | |
| Anti-TNFα | 4% (82) | | 10% (183) | |
| Ciclosporin | 0.2% (4) | | 0.1% (2) | |
| Dietary therapy | 5% (100) | | 4% (84) | |
| Methotrexate | 6% (115) | | 9% (162) | |
| Mycophenolate | 0.1% (3) | | 0.1% (2) | |
| Steroids | 30% (606) | | 29% (547) | |
| Tacrolimus | 0.1% (1) | | 0.1% (1) | |
| Topical | 0% (0) | | 0.1% (1) | |
| Ustekinumab | 0% (0) | | 0.1% (1) | |
| Other | 0.7% (14) | | 0.8% (16) | |

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

| CD: initial treatment | Frequency (%, n) | | | |
|---|---|---|---|---|
| | Infliximab | | Adalimumab | |
| | National (n=2006) | YOUR SITE | National (n=1894) | YOUR SITE |
| **Disease severity score** | | | | |
| **Severity of disease** | **(n=1107)** | | **(n=1160)** | |
| Mild | 7% (75) | | 6% (67) | |
| Moderate | 43% (480) | | 45% (526) | |
| Severe | 50% (552) | | 49% (567) | |

CD = Crohn's disease.

## Crohn's disease follow-up treatment at 3 months

| CD: follow-up treatment at 3 months | Frequency (%, n) | | | |
|---|---|---|---|---|
| | Infliximab | | Adalimumab | |
| | National (n=818) | YOUR SITE | National (n=525) | YOUR SITE |
| **Follow-up treatment details** | | | | |
| **Infliximab dose given** (mg/kg) | **(n=803)** | | | |
| 5 | 99% (795) | | NA | NA |
| 10 | 0.4% (3) | | NA | NA |
| Other | 0.6% (5) | | NA | NA |
| **Review of treatment plan** | | | | |
| Continue treatment | 94% (772) | | 89% (467) | |
| Stop treatment | 6% (46) | | 11% (58) | |
| **If treatment was stopped, what were the reasons for stopping?** | **(n=46)** | | **(n=58)** | |
| Treatment effective and discontinued | 2% (1) | | 0% (0) | |
| Loss of response | 11% (5) | | 17% (10) | |
| Poor response | 37% (17) | | 31% (18) | |
| Side effects / adverse events | 33% (15) | | 41% (24) | |
| Patient became pregnant since initiating anti-TNFα treatment | 0% (0) | | 2% (1) | |
| Patient choice | 11% (5) | | 5% (3) | |
| Other | 7% (3) | | 3% (2) | |
| **If continuing adalimumab treatment, planned continued treatment frequency?** | | | **(n=453)** | |
| Every week | NA | NA | 5% (21) | |
| Every other week | NA | NA | 95% (432) | |
| **If continuing adalimumab treatment, planned continued treatment dose** (mg) | | | **(n=467)** | |
| 40 | NA | NA | 99% (461) | |
| 80 | NA | NA | 1% (6) | |
| **Did the patient report complete compliance with the maintenance regime since the last adalimumab review?** | | | **(n=440)** | |
| Yes | NA | NA | 95% (419) | |
| No | NA | NA | 5% (21) | |
| **If incomplete compliance, state reason** (more than one may have been selected) | | | **(n=21)** | |
| Number of missed doses | NA | NA | 14% (3) | |
| Increased interval between doses | NA | NA | 14% (3) | |
| Patient missed out some treatment weeks | NA | NA | 38% (8) | |
| Patient stopped treatment | NA | NA | 19% (4) | |
| Compliance affected due to interventions in treatment | NA | NA | 10% (2) | |
| Other compliance difference | NA | NA | 10% (2) | |

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

| CD: follow-up treatment at 3 months | Frequency (%, n) | | | |
|---|---|---|---|---|
| | Infliximab | | Adalimumab | |
| | National (n=818) | YOUR SITE | National (n=525) | YOUR SITE |
| **Follow-up treatment details continued** | | | | |
| **Were there any adverse events since the last review?** | | | | |
| Yes | 6% (51) | | 11% (57) | |
| **What adverse events?** (more than one may have been selected) | | | | |
| Abdominal pain | 0.1% (1) | | 0.4% (2) | |
| Alopecia | 0% (0) | | 0.2% (1) | |
| Angioedema of upper airway | 0.1% (1) | | 0% (0) | |
| Arthralgia | 0.6% (5) | | 1% (5) | |
| Blood abnormality | 0.2% (2) | | 0.8% (4) | |
| Bronchospasm (cough/wheeze/dyspnoea) | 0.4% (3) | | 0.2% (1) | |
| Cardiac failure | 0.1% (1) | | 0% (0) | |
| Chest pain | 0.1% (1) | | 0% (0) | |
| Chills | 0.1% (1) | | 0% (0) | |
| Death | 0.1% (1) | | 0% (0) | |
| Difficulty breathing | 0.2% (2) | | 0.2% (1) | |
| Dizziness | 0.4% (3) | | 0.2% (1) | |
| Fatigue | 0.1% (1) | | 0.6% (3) | |
| Fever | 0.1% (1) | | 0.4% (2) | |
| Flushing | 0.6% (5) | | 0.2% (1) | |
| Headache | 0.5% (4) | | 0% (0) | |
| Hypotension | 0.1% (1) | | 0.2% (1) | |
| Infection | 2% (13) | | 0.2% (1) | |
| Injection site reaction | 0% (0) | | 0.6% (3) | |
| Itching | 0.1% (1) | | 0.6% (3) | |
| Nausea | 0.6% (5) | | 1% (5) | |
| Rash | 0.9% (7) | | 3% (13) | |
| Urticaria | 0% (0) | | 0.6% (3) | |
| Other | 2% (12) | | 2% (10) | |

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

| CD: follow-up treatment at 3 months | Frequency (%, n) | | | |
|---|---|---|---|---|
| | Infliximab | | Adalimumab | |
| | National (n=818) | YOUR SITE | National (n=525) | YOUR SITE |
| **Follow-up treatment details continued** | | | | |
| **Is the patient currently receiving any other therapies for the management of IBD?** | **(n=554)** | | **(n=446)** | |
| Yes | 63% (351) | | 55% (246) | |
| **If yes, indicate which other therapies** (more than one may have been selected) | | | | |
| Allopurinol | 0.2% (1) | | 0% (0) | |
| Azathioprine/mercaptopurine | 50% (277) | | 35% (156) | |
| Methotrexate | 4% (20) | | 6% (27) | |
| Steroids | 4% (23) | | 9% (41) | |
| 5-aminosalicylic acid | 17% (92) | | 10% (46) | |
| Antibiotics | 0% (0) | | 0.4% (2) | |
| Dietary therapy | 1% (6) | | 2% (9) | |
| Topical | 0% (0) | | 0.2% (1) | |
| Other | 0.7% (4) | | 3% (13) | |
| **Disease severity score** | | | | |
| **Severity of disease** | **(n=363)** | | **(n=321)** | |
| Mild | 54% (195) | | 48% (153) | |
| Moderate | 29% (104) | | 37% (120) | |
| Severe | 18% (64) | | 15% (48) | |

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

## Crohn's disease follow-up treatment at 12 months

| CD: follow-up treatment at 12 months | Frequency (%, n) | | | |
|---|---|---|---|---|
| | Infliximab | | Adalimumab | |
| | National (n=339) | YOUR SITE | National (n=181) | YOUR SITE |
| **Follow-up treatment details** | | | | |
| **Infliximab dose given at this treatment** (mg/kg) | **(n=334)** | | | |
| 5 | 97% (323) | | NA | NA |
| 10 | 3% (9) | | NA | NA |
| Other | 0.6% (2) | | NA | NA |
| **Review of treatment plan** | | | | |
| Continue treatment | 93% (314) | | 88% (159) | |
| Stop treatment | 7% (25) | | 12% (22) | |
| **If treatment was stopped, what were the reasons for stopping?** | **(n=25)** | | **(n=22)** | |
| Loss of response | 16% (4) | | 9% (2) | |
| Treatment effective and discontinued | 40% (10) | | 27% (6) | |
| Side effects / adverse events | 20% (5) | | 27% (6) | |
| Funding | 4% (1) | | 5% (1) | |
| Poor response | 4% (1) | | 9% (2) | |
| Patient choice | 4% (1) | | 9% (2) | |
| Patient became pregnant since initiating anti-TNFα treatment | 4% (1) | | 9% (2) | |
| Other | 4% (1) | | 5% (1) | |
| **If continuing adalimumab treatment, planned continued treatment frequency** | | | **(n=154)** | |
| Every week | NA | NA | 12% (19) | |
| Every other week | NA | NA | 86% (133) | |
| Other | NA | NA | 1% (2) | |
| **If continuing adalimumab treatment, planned continued treatment dose** (mg) | | | **(n=158)** | |
| 20/25 | NA | NA | 0.6% (1) | |
| 30 | NA | NA | 0.6% (1) | |
| 40 | NA | NA | 96% (152) | |
| 80 | NA | NA | 3% (4) | |
| **Did the patient report complete compliance with the maintenance regime since the last adalimumab review?** | | | **(n=157)** | |
| Yes | NA | NA | 93% (146) | |
| No | NA | NA | 7% (11) | |

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

| CD: follow-up treatment at 12 months | Frequency (%, n) | | | |
|---|---|---|---|---|
| | Infliximab | | Adalimumab | |
| | National (n=339) | YOUR SITE | National (n=181) | YOUR SITE |
| **Follow-up treatment details continued** | | | | |
| **If incomplete compliance, state reason** (more than one may have been selected) | | | **(n=11)** | |
| Number of missed doses | NA | NA | 36% (4) | |
| Patient missed out some treatment weeks | NA | NA | 36% (4) | |
| Patient stopped treatment | NA | NA | 27% (3) | |
| **Were there any adverse events since the last review?** | | | | |
| Yes | 6% (20) | | 6% (11) | |
| **What adverse events?** (more than one may have been selected) | | | | |
| Abdominal pain | 0% (0) | | 0.6% (1) | |
| Alopecia | 0.3% (1) | | 0% (0) | |
| Angioedema of upper airway | 0% (0) | | 0.6% (1) | |
| Bronchospasm (cough/wheeze/dyspnoea) | 0.6% (2) | | 0.6% (1) | |
| Chills | 1% (4) | | 0.6% (1) | |
| Fatigue | 0% (0) | | 0.6% (1) | |
| Flushing | 0.3% (1) | | 0% (0) | |
| Headache | 0.3% (1) | | 0.6% (1) | |
| Infection | 3% (9) | | 1% (2) | |
| Itching | 0.3% (1) | | 0% (0) | |
| Malignancy | 0.3% (1) | | 0% (0) | |
| Rash | 0.3% (1) | | 0.6% (1) | |
| Serum sickness-like reaction | 0.3% (1) | | 0% (0) | |
| Other | 2% (5) | | 2% (4) | |
| **Is the patient currently receiving any other therapies for the management of IBD?** | **(n=247)** | | **(n=157)** | |
| Yes | 58% (143) | | 59% (93) | |
| **If yes, indicate which other therapies** (more than one may have been selected) | | | | |
| Allopurinol | 0.4% (1) | | 0% (0) | |
| Azathioprine/mercaptopurine | 45% (112) | | 40% (62) | |
| 5-aminosalicylic acid | 14% (34) | | 12% (18) | |
| Antibiotics | 0% (0) | | 0.6% (1) | |
| Dietary therapy | 0.4% (1) | | 0% (0) | |
| Methotrexate | 3% (7) | | 7% (11) | |
| Mycophenolate | 0% (0) | | 0% (0) | |
| Steroids | 2% (6) | | 10% (15) | |
| Other | 1% (3) | | 3% (5) | |

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

| CD: follow-up treatment at 12 months | Frequency (%, n) | | | |
|---|---|---|---|---|
| | Infliximab | | Adalimumab | |
| | National (n=339) | YOUR SITE | National (n=181) | YOUR SITE |
| **Disease severity score** | | | | |
| **Severity of disease** | **(n=193)** | | **(n=140)** | |
| Remission | 0% (0) | | 0.7% (1) | |
| Mild | 60% (116) | | 58% (81) | |
| Moderate | 25% (49) | | 30% (42) | |
| Severe | 15% (28) | | 11% (16) | |

CD = Crohn's disease.

## Ulcerative colitis disease details

| UC: disease details | Frequency (%, n) | |
|---|---|---|
| | Infliximab | Adalimumab |
| | National (n=633) | National (n=83) |
| **Diagnosis** | | |
| **Maximal disease distribution at the time of decision to initiate biological therapy, as defined by the Montreal classification** | **(n=632)** | |
| Proctitis (E1) | 10% (61) | 6% (5) |
| Left sided (E2) | 45% (284) | 37% (31) |
| Extensive (E3) | 45% (287) | 57% (47) |
| **Time between date of diagnosis and date of initial treatment** | **(n=630)** | **(n=81)** |
| <1 year ago | 31% (195) | 16% (13) |
| 1–2 years ago | 22% (139) | 30% (24) |
| 3–5 years ago | 16% (101) | 26% (21) |
| 6–10 years ago | 15% (97) | 14% (11) |
| >10 years ago | 16% (98) | 15% (12) |

UC = ulcerative colitis.

## Ulcerative colitis initial treatment

| UC: initial treatment | Frequency (%, n) | |
|---|---|---|
| | Infliximab | Adalimumab |
| | National (n=633) | National (n=83) |
| **Consent** | | |
| **Was informed consent to receive anti-TNFα treatment taken from this patient?** | | |
| Yes | 99% (624) | 100% (83) |
| No | 1% (9) | 0% (0) |
| **If yes, was this verbal or written?** | **(n=624)** | |
| Verbal | 79% (495) | 80% (66) |
| Written | 21% (129) | 21% (17) |
| **Treatment details** | | |
| **Time between date of decision to start and date of initial treatment** (first loading dose) | | |
| Median (IQR) time (days) | 5 (1,17) | 23 (10, 45) |
| **What was the clinical indication for this treatment?** | **(n=632)** | |
| Acute severe UC | 69% (436) | 40% (33) |
| Chronic refractory UC | 28% (179) | 53% (44) |
| Other clinical indication | 1% (7) | 4% (3) |
| Not known | 2% (10) | 4% (3) |
| **Dose given at this infusion** (mg/kg) | **(n=485)** | |
| 5 | 100% (484) | NA |
| 10 | 0.2% (1) | NA |
| **Duration of infusion** (mins) | **(n=476)** | |
| 60 | 2% (7) | NA |
| 120 | 96% (457) | NA |
| 180 | 3% (12) | NA |
| **Infusion completion outcome** | | |
| Completed successfully at prescribed rate | 98% (622) | NA |
| Completed successfully at lower rate | 0.8% (5) | NA |
| Infusion discontinued and not restarted | 0.8% (5) | NA |
| Other | 0.2% (1) | NA |
| **Induction dose** (mg) | | |
| 160/80 | NA | 89% (74) |
| 80/40 | NA | 10% (8) |
| Other | NA | 1% (1) |
| **Planned maintenance dose** | | |
| 40 mg every other week | NA | 94% (78) |
| 40 mg every week | NA | 6% (5) |

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

| UC: initial treatment | Frequency (%, n) | |
|---|---|---|
| | Infliximab | Adalimumab |
| | National (n=633) | National (n=83) |
| **Treatment details continued** | | |
| **Were any adverse events recorded for this treatment?** | | |
| Yes | 2% (10) | 1% (1) |
| **Which acute reactions?** (more than one may have been selected) | | |
| Arthralgia | 0.2% (1) | 0% (0) |
| Bronchospasm (cough/wheeze/dyspnoea) | 0.3% (2) | 0% (0) |
| Chest pain | 0.2% (1) | 0% (0) |
| Dizziness | 0.5% (3) | 0% (0) |
| Fatigue | 0.2% (1) | 0% (0) |
| Hypotension | 0.3% (2) | 0% (0) |
| Itching | 0.2% (1) | 0% (0) |
| Nausea | 0.3% (2) | 0% (0) |
| Other | 0.5% (3) | 1% (1) |
| **Is the patient receiving any concomitant therapies for the management of IBD at the time of this treatment?** | | |
| Yes | 89% (561) | 87% (72) |
| **If yes, indicate which concomitant therapies** (more than one may have been selected) | | |
| Allopurinol | 0.2% (1) | 0% (0) |
| Azathioprine/mercaptopurine | 46% (288) | 42% (35) |
| 5-aminosalicylic acid | 46% (293) | 48% (40) |
| Antibiotics | 2% (12) | 2% (2) |
| Dietary therapy | 0.6% (4) | 0% (0) |
| Methotrexate | 4% (22) | 5% (4) |
| Mycophenolate | 0.8% (5) | 0% (0) |
| Steroids | 54% (344) | 42% (35) |
| Tacrolimus | 0.3% (2) | 0% (0) |
| Topical | 0% (0) | 1% (1) |
| Other | 2% (11) | 1% (1) |

IBD = inflammatory bowel disease; UC = ulcerative colitis.

| UC: initial treatment | Frequency (%, n) | |
|---|---|---|
| | Infliximab | Adalimumab |
| | National (n=633) | National (n=83) |
| **Treatment details continued** | | |
| **Has the patient failed to respond or are they intolerant to immunosuppressive drugs / corticosteroids?** | | |
| Yes | 64% (403) | 78% (65) |
| **If yes, indicate which previous therapies** (more than one therapy may have been selected) | | |
| Azathioprine/mercaptopurine | 41% (260) | 63% (52) |
| 5-aminosalicylic acid | 25% (155) | 28% (23) |
| Antibiotics | 0.6% (4) | 0% (0) |
| Anti-TNFα | 1% (7) | 21% (17) |
| Ciclosporin | 1% (7) | 1% (1) |
| Methotrexate | 5% (29) | 12% (10) |
| Steroids | 34% (218) | 22% (18) |
| Tacrolimus | 0.3% (2) | 1% (1) |
| Other | 0.3% (2) | 1% (1) |
| **Disease severity score** | | |
| **Severity of disease** | **(n=513)** | **(n=71)** |
| Mild | 4% (19) | 3% (2) |
| Moderate | 24% (125) | 42% (30) |
| Severe | 72% (369) | 55% (39) |

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=157) | National (n=19) |
| **Follow-up treatment details** | | |
| **Infliximab dose given at this treatment** (mg/kg) | | |
| 5 | 99% (155) | NA |
| 10 | 0.6% (1) | NA |
| Other | 0.6% (1) | NA |
| **Review of treatment plan** | | |
| Continue treatment | 82% (128) | 74% (14) |
| Stop treatment | 19% (29) | 26% (5) |
| **If treatment was stopped, what were the reasons for stopping?** | **(n=29)** | **(n=5)** |
| Treatment effective and discontinued | 41% (12) | 0% (0) |
| Loss of response | 3% (1) | 20% (1) |
| Poor response | 17% (5) | 60% (3) |
| Side effects / adverse events | 28% (8) | 20% (1) |
| Funding | 7% (2) | 0% (0) |
| Other | 3% (1) | 0% (0) |
| **If continuing adalimumab treatment, planned continued treatment frequency** | | **(n=14)** |
| Every week | NA | 7% (1) |
| Every other week | NA | 93% (13) |
| **If continuing adalimumab treatment, planned continued treatment dose** (mg) | | **(n=14)** |
| 80 | NA | 7% (1) |
| 40 | NA | 93% (13) |
| **Did the patient report complete compliance with the maintenance regime since the last adalimumab review?** | | |
| Yes | NA | 90% (17) |
| No | NA | 11% (2) |
| **If incomplete compliance, state reason** | | **(n=2)** |
| Patient missed out some treatment weeks | NA | 50% (1) |
| Other compliance difference | NA | 50% (1) |

NA = not applicable; UC = ulcerative colitis.

| UC: follow-up treatment at 3 months | Frequency (%, n) | |
|---|---|---|
| | Infliximab | Adalimumab |
| | National (n=157) | National (n=19) |
| **Follow-up treatment details continued** | | |
| **Were there any adverse events since the last review?** | | |
| Yes | 9% (14) | 16% (3) |
| **What adverse events?** (more than one may have been selected) | | |
| Abdominal pain | 1% (2) | 0% (0) |
| Angioedema of upper airway | 0.6% (1) | 0% (0) |
| Blood abnormality | 0.6% (1) | 0% (0) |
| Bronchospasm (cough/wheeze/dyspnoea) | 2% (3) | 0% (0) |
| Dizziness | 0% (0) | 5% (1) |
| Fatigue | 0% (0) | 5% (1) |
| Flushing | 3% (4) | 5% (1) |
| Headache | 1% (2) | 0% (0) |
| Hypotension | 1% (2) | 0% (0) |
| Infection | 3% (5) | 11% (2) |
| Itching | 0.6% (1) | 0% (0) |
| Nausea | 0.6% (1) | 0% (0) |
| Rash | 0.6% (1) | 0% (0) |
| Suspected demyelination | 0.6% (1) | 0% (0) |
| Urticaria | 0.6% (1) | 0% (0) |
| Other | 0.6% (1) | 5% (1) |
| **Is the patient currently receiving any other therapies for the management of IBD?** | | |
| Yes | 74% (116) | 79% (15) |
| **If yes, indicate which other therapies** (more than one may have been selected) | | |
| Allopurinol | 0.6% (1) | 0% (0) |
| Azathioprine/mercaptopurine | 55% (87) | 16% (3) |
| Methotrexate | 1% (2) | 5% (1) |
| Steroids | 7% (11) | 16% (3) |
| 5-aminosalicylic acid | 32% (50) | 53% (10) |
| Other | 0.6% (1) | 0% (0) |
| **Disease severity score** | | |
| **Severity of disease** | **(n=128)** | **(n=15)** |
| Mild | 56% (71) | 47% (7) |
| Moderate | 28% (36) | 13% (2) |
| Severe | 16% (21) | 40% (6) |

IBD = inflammatory bowel disease; UC = ulcerative colitis.

## Ulcerative colitis follow-up treatment at 12 months

| UC: follow-up treatment at 12 months | Frequency (%, n) | |
|---|---|---|
| | Infliximab | Adalimumab |
| | National (n=49) | National (n=3) |
| **Follow-up treatment details** | | |
| **Infliximab dose given at this treatment** (mg/kg) | | |
| 5 | 96% (47) | NA |
| 10 | 2% (1) | NA |
| Other | 2% (1) | NA |
| **Review of treatment plan** | | |
| Continue treatment | 94% (46) | 67% (2) |
| Stop treatment | 6% (3) | 33% (1) |
| **If treatment was stopped, what were the reasons for stopping?** | **(n=3)** | **(n=1)** |
| Treatment effective and discontinued | 33% (1) | 100% (1) |
| Side effects / adverse events | 33% (1) | 0% (0) |
| Funding | 33% (1) | 0% (0) |
| **If continuing adalimumab treatment, planned continued treatment frequency** | | **(n=2)** |
| Every other week | NA | 100% (2) |
| **If continuing adalimumab treatment, planned continued treatment dose** (mg) | | **(n=2)** |
| 40 | NA | 100% (2) |
| **Did the patient report complete compliance with the maintenance regime since the last adalimumab review?** | | |
| Yes | NA | 100% (3) |
| **Were there any adverse events since the last review?** | | |
| Yes | 2% (1) | 33% (1) |
| **What adverse events?** (more than one may have been selected) | | |
| Nausea | 2% (1) | 0% (0) |
| Other | 0% (0) | 33% (1) |
| **Is the patient currently receiving any other therapies for the management of IBD?** | | |
| Yes | 86% (42) | 100% (3) |
| **If yes, indicate which other therapies** (more than one may have been selected) | | |
| Azathioprine/mercaptopurine | 59% (29) | 67% (2) |
| 5-aminosalicylic acid | 51% (25) | 33% (1) |
| Methotrexate | 6% (3) | 33% (1) |
| Steroids | 2% (1) | 33% (1) |
| Other | 2% (1) | 0% (0) |

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

| UC: follow-up treatment at 12 months | Frequency (%, n) | |
|---|---|---|
| | Infliximab | Adalimumab |
| | National (n=49) | National (n=3) |
| **Disease severity score** | | |
| **Severity of disease** | **(n=43)** | **(n=2)** |
| Mild | 51% (22) | 100% (2) |
| Moderate | 33% (14) | 0% (0) |
| Severe | 16% (7) | 0% (0) |

UC = ulcerative colitis.

## Inflammatory bowel disease type unclassified disease details

| IBDU: disease details | Frequency (%, n) | |
|---|---|---|
| | Infliximab | Adalimumab |
| | National (n=78) | National (n=24) |
| **Diagnosis** | | |
| **Maximal disease distribution at the time of decision to initiate biological therapy, as defined by the Montreal classification** | | |
| Proctitis (E1) | 1% (1) | 4% (1) |
| Left sided (E2) | 44% (34) | 54% (13) |
| Extensive (E3) | 55% (43) | 42% (10) |
| **Time between date of diagnosis and date of initial treatment** | | |
| <1 year | 39% (30) | 13% (3) |
| 1–2 years | 28% (22) | 25% (6) |
| 3–5 years | 21% (16) | 25% (6) |
| 6–10 years | 5% (4) | 8% (2) |
| >10 years | 8% (6) | 29% (7) |

IBDU = inflammatory bowel disease type unclassified.

## Inflammatory bowel disease type unclassified initial treatment

| IBDU: initial treatment | Frequency (%, n) | |
|---|---|---|
| | Infliximab | Adalimumab |
| | National (n=78) | National (n=24) |
| **Consent** | | |
| **Was informed consent to receive anti-TNFα treatment taken from this patient?** | | |
| Yes | 99% (77) | 100% (24) |
| No | 1% (1) | 0% (0) |
| **If yes, was this verbal or written?** | **(n=77)** | |
| Verbal | 71% (55) | 92% (22) |
| Written | 29% (22) | 8% (2) |
| **Treatment details** | | |
| **Time between date of decision to start and date of initial treatment** (first loading dose) | | |
| Median (IQR), days | 9 (2, 21) | 15 (4, 30) |
| **What was the clinical indication for this treatment?** | **(n=77)** | |
| Acute severe IBDU | 66% (51) | 46% (11) |
| Chronic refractory IBDU | 34% (26) | 50 (12) |
| Other clinical indication | 3% (2) | 4% (1) |
| **Dose given at this infusion** (mg/kg) | **(n=64)** | |
| 5 | 98% (63) | NA |
| 10 | 2% (1) | NA |
| **Duration of infusion** (mins) | **(n=63)** | |
| 120 | 97% (61) | NA |
| 180 | 3% (2) | NA |
| **Infusion completion outcome** | | |
| Completed successfully at prescribed rate | 97% (76) | NA |
| Infusion discontinued and not restarted | 1% (1) | NA |
| Other | 1% (1) | NA |
| **Induction dose** (mg) | | |
| 160/80 | NA | 63% (15) |
| 80/40 | NA | 38% (9) |
| **Planned maintenance dose** | | |
| 40 mg every other week | NA | 92% (22) |
| 40 mg every week | NA | 8% (2) |
| **Were any adverse events recorded for this treatment?** | | |
| Yes | 0% (0) | 0% (0) |

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=78) | National (n=24) |
| **Treatment details continued** | | |
| **Is the patient receiving any concomitant therapies for the management of IBD at the time of this treatment?** | | |
| Yes | 92% (72) | 88% (21) |
| **If yes, indicate which concomitant therapies** (more than one may have been selected) | | |
| Allopurinol | 0% (0) | 4% (1) |
| Azathioprine/mercaptopurine | 41% (32) | 63% (15) |
| Methotrexate | 3% (2) | 8% (2) |
| Steroids | 59% (46) | 42% (10) |
| 5-aminosalicylic acid | 55% (43) | 46% (11) |
| Antibiotics | 1% (1) | 0% (0) |
| **Has the patient failed to respond or are they intolerant to immunosuppressive drugs / corticosteroids?** | | |
| Yes | 65% (51) | 67% (16) |
| **If yes, indicate which previous therapies** (more than one may have been selected) | | |
| Azathioprine/mercaptopurine | 41% (32) | 46% (11) |
| Methotrexate | 8% (6) | 8% (2) |
| Steroids | 27% (21) | 29% (7) |
| Anti-TNFα | 1% (1) | 25% (6) |
| 5-aminosalicylic acid | 22% (17) | 25% (6) |
| Ciclosporin | 4% (3) | 0% (0) |
| **Disease severity score** | | |
| **Severity of disease** | **(n=50)** | **(n=12)** |
| Mild | 8% (4) | 0% (0) |
| Moderate | 36% (18) | 75% (9) |
| Severe | 56% (28) | 25% (3) |

IBD = inflammatory bowel disease; IBDU = inflammatory bowel disease type unclassified; TNFα = tumour necrosis factor alpha.

## Inflammatory bowel disease type unclassified follow-up treatment at 3 months

| IBDU: follow-up treatment at 3 months | Frequency (%, n) | |
|---|---|---|
| | Infliximab | Adalimumab |
| | National (n=30) | National (n=12) |
| **Follow-up treatment details** | | |
| **Infliximab dose given at this treatment** (mg/kg) | | |
| 5 | 100% (30) | NA |
| **Review of treatment plan** | | |
| Continue treatment | 93% (28) | 92% (11) |
| Stop treatment | 7% (2) | 8% (1) |
| **If treatment was stopped, what were the reasons for stopping?** | **(n=2)** | **(n=1)** |
| Poor response | 0% (0) | 100% (1) |
| Side effects / adverse events | 50% (1) | 0% (0) |
| Other | 50% (1) | 0% (0) |
| **If continuing adalimumab treatment, planned continued treatment frequency** | | **(n=11)** |
| Every other week | NA | 100% (11) |
| **If continuing adalimumab treatment, planned continued treatment dose** (mg) | | **(n=11)** |
| 40 | NA | 100% (11) |
| **Did the patient report complete compliance with the maintenance regime since the last adalimumab review?** | | |
| Yes | NA | 100% (12) |
| **Did the patient report any adverse events?** | | |
| Yes | 3% (1) | 0% (0) |
| **Which adverse events?** (more than one may have been selected) | | |
| Bronchospasm (cough/wheeze/dyspnoea) | 3% (1) | 0% (0) |
| Dizziness | 3% (1) | 0% (0) |
| Panic attacks | 3% (1) | 0% (0) |
| **Is the patient currently receiving any other therapies for the management of IBD?** | | |
| Yes | 77% (23) | 75% (9) |
| **If yes, indicate which other therapies** (more than one may have been selected) | | |
| Azathioprine/mercaptopurine | 57% (17) | 67% (8) |
| Steroids | 17% (5) | 17% (2) |
| 5-aminosalicylic acid | 50% (15) | 25% (3) |

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

| IBDU: follow-up treatment at 3 months | Frequency (%, n) | |
|---|---|---|
| | Infliximab | Adalimumab |
| | National (n=30) | National (n=12) |
| **Disease severity score** | | |
| **Severity of disease** | **(n=18)** | **(n=5)** |
| Mild | 56% (10) | 40% (2) |
| Moderate | 33% (6) | 40% (2) |
| Severe | 11% (2) | 20% (1) |

IBDU = inflammatory bowel disease type unclassified.

## Inflammatory bowel disease type unclassified follow-up treatment at 12 months

| IBDU: follow-up treatment at 12 months | Frequency (%, n) | |
|---|---|---|
| | Infliximab | Adalimumab |
| | National (n=12) | National (n=2) |
| **Follow-up treatment details** | | |
| **Infliximab dose given at this treatment** (mg/kg) | | |
| 5 | 100% (12) | NA |
| **Review of treatment plan** | | |
| Continue treatment | 83% (10) | 50% (1) |
| Stop treatment | 17% (2) | 50% (1) |
| **If treatment was stopped, what were the reasons for stopping?** | **(n=2)** | **(n=1)** |
| Loss of response | 50% (1) | 0% (0) |
| Treatment effective and discontinued | 50% (1) | 100% (1) |
| **If continuing adalimumab treatment, planned continued treatment frequency** | | **(n=1)** |
| Every week | NA | 100% (1) |
| **If continuing adalimumab treatment, planned continued treatment dose** (mg) | | **(n=1)** |
| 40 | NA | 100% (1) |
| **Did the patient report complete compliance with the maintenance regime since the last adalimumab review?** | | |
| Yes | NA | 100% (2) |
| **Did the patient report any adverse events?** | | |
| Yes | 0% (0) | 0% (0) |
| **Is the patient currently receiving any other therapies for the management of IBD?** | | |
| Yes | 58% (7) | 100% (2) |
| **If yes, indicate which other therapies** (more than one may have been selected) | | |
| Azathioprine/mercaptopurine | 42% (5) | 100% (2) |
| 5-aminosalicylic acid | 33% (4) | 0% (0) |
| Steroids | 8% (1) | 50% (1) |
| **Disease severity score** | | |
| **Severity of disease** | **(n=10)** | **(n=1)** |
| Mild | 80% (8) | 100% (1) |
| Moderate | 20% (2) | 0% (0) |

IBD = inflammatory bowel disease; IBDU = inflammatory bowel disease type unclassified.

## IBD-related surgery

Of the analysed adult patients, 1241 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 tables 18–20. One table is given for each disease type.

**Table 18 Surgical procedures in adult patients with CD**

| CD-related surgery | Adult patients with surgery recorded (n=1151) | |
|---|---|---|
| | Before starting biological therapy (n=1034)* | After starting biological therapy (n=200)* |
| **Surgical procedure by type (%, n)** | | |
| Anterior resection | 0.3% (3) | 0% (0) |
| Appendicectomy | 2% (15) | 0% (0) |
| Cholecystectomy | 1% (11) | 0% (0) |
| Colectomy and ileostomy | 6% (62) | 8% (15) |
| Drainage of abscess | 3% (30) | 3% (5) |
| Excision of fistula | 2% (15) | 0% (0) |
| Gastric surgery | 0.1% (1) | 0.5% (1) |
| Other surgical procedure | 22% (226) | 25% (50) |
| Partial colectomy | 5% (48) | 2% (4) |
| Perianal surgery | 23% (238) | 24% (47) |
| Proctectomy | 0.3% (3) | 0% (0) |
| Right hemicolectomy / ileocaecal resection | 42% (431) | 16% (31) |
| Small bowel resection | 22% (225) | 22% (44) |
| Stoma formation | 2% (21) | 0.5% (1) |
| Stricturoplasty | 4% (43) | 4% (8) |
| Total colectomy with ileorectal anastomosis | 0.4% (4) | 0% (0) |
| Total proctocolectomy ileoanal pouch | 1% (14) | 0% (0) |
| Total proctocolectomy permanent ileostomy | 3 (31) | 4 (8) |

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

**Table 19 Surgical procedures in adult patients with UC**

| UC-related surgery | Adult patients with surgery recorded (n=78) | |
|---|---|---|
| | Before starting biological therapy (n=26)* | After starting biological therapy (n=54)* |
| **Surgical procedure by type (%, n)** | | |
| Appendicectomy | 4% (1) | 0% (0) |
| Colectomy and ileostomy | 46% (12) | 74% (40) |
| Other surgical procedure | 35% (9) | 6% (3) |
| Partial colectomy | 4% (1) | 4% (2) |
| Perianal surgery | 15% (4) | 6% (3) |
| Right hemicolectomy / ileocaecal resection | 4% (1) | 0% (0) |
| Small bowel resection | 4% (1) | 0% (0) |
| Total proctocolectomy ileoanal pouch | 15% (4) | 4% (2) |
| Total proctocolectomy permanent ileostomy | 0% (0) | 9% (5) |

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

**Table 20 Surgical procedures in adult patients with IBDU**

| IBDU-related surgery | Adult patients with surgery recorded (n=12) | |
|---|---|---|
| | Before starting biological therapy (n=6)* | Before starting biological therapy (n=7)* |
| **Surgical procedure by type (%, n)** | | |
| Colectomy and ileostomy | 17% (1) | 71% (5) |
| Perianal surgery | 67% (4) | 14% (1) |
| Total proctocolectomy ileoanal pouch | 17% (1) | 14% (1) |

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

## 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.

### EQ-5D

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

The EQ-5D is a descriptive system of health-related quality of life states consisting of five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression), each of which can take one of three responses depending on level of severity – no problems / some or moderate problems / extreme problems – within a particular EQ-5D dimension. Total EQ-5D scores range from 0 (worst health / death) to 1 (best health), with an increase in score denoting improved health. Scores from each domain are weighted and converted into a single weighted summary index. The data within this report are presented in the form of a median (IQR). The EQ-5D has been shown to be valid, reliable and responsive in patients with IBD.[15]

In total, 1416 EQ-5D questionnaires were completed at an initial treatment for patients taking infliximab and adalimumab and for all disease types, with a median (IQR) score of 0.76 (0.66, 0.85). At 3-month follow-up, 361 EQ-5D questionnaires were completed for patients taking infliximab and adalimumab and for all disease types, with a median (IQR) score of 0.80 (0.73, 1.0). At 12-month follow-up, 57 EQ-5D questionnaires were completed for patients taking infliximab and adalimumab and for all disease types, with a median (IQR) score of 0.80 (0.69, 1.0).

The limited number of patients with EQ-5D scores at initial and follow-up treatment means that the difference between the EQ-5D scores at these timepoints could not be calculated. However, the median scores at these two stages was calculated for all patients who had a score; comparison of these medians showed an increase in the median EQ-5D score of 0.04 between initial and 3-month follow-up treatment. This may suggest a clinical improvement in quality of life after patients started biological therapies.

### CUCQ-12

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

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

In total, 1256 CUCQ-12 questionnaires were completed at initial treatment for patients taking infliximab and adalimumab and for all disease types. The median (IQR) score of 68 (39, 100) suggests active IBD at this timepoint. At follow-up treatment, 332 questionnaires were completed for patients taking infliximab and adalimumab and for all disease types. The median (IQR) score was 34 (14, 60).

The limited number of patients with CUCQ-12 scores at initial and follow-up treatment means that the difference between the CUCQ-12 scores at these timepoints could not be calculated. However, the median scores at these two stages could be calculated for all patients who had a score; comparison of these medians showed a reduction in the median CUCQ-12 score of 34 between initial and follow-up treatment. This may suggest a clinically significant improvement in quality of life after starting biological therapies. The CUCQ-12 findings of the biological therapy audit will be used to inform learning and the ongoing validity assessment of this PROM tool.

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

**Table 17 PROMs questionnaire for IBD (IBD-PROM)**

| IBD-PROM | Initial treatment | 3-month follow-up | 12-month follow-up |
|---|---|---|---|
| Patients with IBD-PROM completed (%, n/N) | 30% (1416/4718) | 25% (384/1561) | 22% (129/586) |
| Patients with EQ-5D data completed (%, n/N) | 97% (1367/1416) | 94% (361/384) | 44% (57/129) |
| EQ-5D score, median (IQR) | 0.76 (0.66, 0.85) | 0.80 (0.73, 1) | 0.80 (0.69, 1) |
| Patients with CUCQ-12 data completed (%, n/N) | 89% (1256/1416) | 87% (332/384) | 87% (112/129) |
| CUCQ-12 score, median (IQR) | 68 (39, 100) | 34 (14, 60) | 27 (10, 49) |

CUCQ-12 = Crohn's and ulcerative colitis questionnaire; IBD = inflammatory bowel disease; 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-participant).
- 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 adult site participation.

**Table 21 Participation status for adult sites**

| Participation status for adult sites | Sites (n) |
|---|---|
| Participated with regular data entry | 151 |
| Participated but data submitted do not meet audit criteria | 11 |
| Previously participated but no data entered during past year of data collection | 32 |
| Not participated | 20 |
| Not eligible to participate | 2 |
| Total number of adult sites | 216 |

**Table 22 Adult site participation status over time**

Table 22 shows participation of adult 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 | 43% (76/177) | 68% (115/169) | 90% (149/165) | 96% (160/166) |
| Trusts | 52% (75/143) | 79% (106/135) | 94% (133/141) | 98% (134/137) |
| **Northern Ireland** | | | | |
| Sites | 17% (2/12) | 67% (8/12) | 92% (11/12) | 92% (11/12) |
| Trusts | 40% (2/5) | 100% (5/5) | 100% (5/5) | 100% (5/5) |
| **Scotland** | | | | |
| Sites | 44% (8/18) | 67% (12/18) | 55% (11/20) | 62% (13/21) |
| Health boards | 80% (8/10) | 82% (9/11) | 64% (7/11) | 91% (10/11) |
| **Wales** | | | | |
| Sites | 41% (7/17) | 39% (7/18) | 60% (9/15) | 67% (10/15) |
| Health boards | 67% (4/6) | 67% (4/6) | 67% (4/6) | 67% (4/6) |
| **Total** | | | | |
| Sites | 42% (93/224) | 65% (142/217) | 84% (180/214) | 90% (194/216) |
| Trusts / health boards | 54% (89/164) | 79% (124/157) | 91% (149/163) | 96% (153/159) |

## Key indicator data for individual sites

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

| | Participation status | Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR) | Initial treatment Harvey Bradshaw Index, 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 | All patients – PROMs completed at start of treatment |
|---|---|---|---|---|---|---|---|
| Results | | (n=3739)<br>4 (1, 12) | n=2282<br>8 (4, 10) | 68% (502/741) | 53% (1644/3080) | n=1343<br>8% (108) | 30%<br>(1416/4718) |
| **England (n=167)** | | | | | | | |
| **Aintree University Hospitals NHS Foundation Trust** | | | | | | | |
| Aintree University Hospital | Participant | n=22<br>3 (1, 8) | n<6 | n<6 | 64% (14/22) | 13% (1/8) | 6% (2/32) |
| **Airedale NHS Foundation Trust** | | | | | | | |
| Airedale General Hospital* | Participant | n=28<br>2 (1, 9) | n=26<br>10 (7, 12) | 60% (6/10) | 20% (5/25) | 18% (2/11) | 45% (17/38) |
| **Ashford and St Peter's Hospitals NHS Foundation Trust** | | | | | | | |
| Ashford Hospital and St Peter's Hospital | Participant but data submitted do not meet audit criteria | | | | | | |
| **Barking, Havering and Redbridge Hospitals NHS Trust** | | | | | | | |
| King George Hospital and Queens Hospital combined | Participant | n=46<br>5 (1, 10) | n=22<br>11 (7, 13) | 71% (5/7) | 59% (27/46) | 4% (1/26) | 0% (0/63) |
| **Barnsley Hospital NHS Foundation Trust** | | | | | | | |
| Barnsley District General Hospital | Participant | n=50<br>3 (1, 12) | n<6 | n=0 | 43% (22/51) | 4% (1/24) | 0% (0/68) |

| | Participation status | Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR) | Initial treatment Harvey Bradshaw Index, 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 | All patients – PROMs completed at start of treatment |
|---|---|---|---|---|---|---|---|
| Results | | (n=3739)<br>4 (1, 12) | n=2282<br>8 (4, 10) | 68% (502/741) | 53% (1644/3080) | n=1343<br>8% (108) | 30%<br>(1416/4718) |
| **Barts Health NHS Trust** | | | | | | | |
| Newham University Hospital | Participant | n=12<br>2 (1, 16) | n<6 | n=0 | 50% (6/12) | 0% (0/7) | 0% (0/14) |
| The Royal London Hospital and St Bartholomew's Hospital combined | Participant | n=28<br>4 (2, 10) | n=24<br>5 (1, 8) | 90% (9/10) | 73% (8/11) | 0% (0/11) | 56% (18/32) |
| Whipps Cross University Hospital | Participant but data submitted do not meet audit criteria | | | | | | |
| **Basildon and Thurrock University Hospitals NHS Foundation Trust** | | | | | | | |
| Basildon Hospital* | Participant | n=24<br>4 (1, 15) | n=26<br>10 (6, 11) | 67% (4/6) | 57% (8/14) | 0% (0/6) | 52% (14/27) |
| **Blackpool Teaching Hospitals NHS Foundation Trust** | | | | | | | |
| Blackpool Victoria Hospital* | Participant | n=7<br>0 (0, 2) | n=8<br>11 (5, 13) | n<6 | n<6 | 50% (1/2) | 88% (7/8) |
| **Bradford Teaching Hospitals Foundation Trust** | | | | | | | |
| Bradford Royal Infirmary* | Participant | n=34<br>3 (1, 13) | n=19<br>5 (3, 8) | 57% (4/7) | 52% (12/23) | 15% (2/13) | 44% (18/41) |
| **Brighton and Sussex University Hospitals NHS Trust** | | | | | | | |
| Royal Sussex County Hospital* and Princess Royal Hospital combined | Participant | n=39<br>8 (1, 21) | n=16<br>6 (2, 10) | 56% (5/9) | 58% (22/38) | 0% (0/17) | 7% (4/56) |
| **Buckinghamshire Healthcare NHS Trust** | | | | | | | |
| Stoke Mandeville Hospital and Wycombe General Hospital combined | Previous participant but no data entered in past year | | | | | | |

| | Participation status | Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR) | Initial treatment Harvey Bradshaw Index, 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 | All patients – PROMs completed at start of treatment |
|---|---|---|---|---|---|---|---|
| Results | | (n=3739)<br>4 (1, 12) | n=2282<br>8 (4, 10) | 68% (502/741) | 53% (1644/3080) | n=1343<br>8% (108) | 30%<br>(1416/4718) |
| **Burton Hospitals NHS Foundation Trust** | | | | | | | |
| Queen's Hospital, Burton | Participant | n=14<br>3 (1, 16) | n<6 | n=0 | 21% (3/14) | n<6 | 0% (0/20) |
| **Calderdale and Huddersfield NHS Foundation Trust** | | | | | | | |
| Huddersfield Royal Infirmary and Calderdale Hospital* combined | Participant | n=37<br>7 (1, 13) | n=7<br>6 (0, 12) | n<6 | 73% (24/33) | n<6 | 13% (7/54) |
| **Cambridge University Hospitals NHS Foundation Trust** | | | | | | | |
| Addenbrooke's Hospital* | Participant | n=26<br>11 (5, 16) | n=7<br>7 (5, 14) | n<6 | 46% (11/24) | n<6 | 21% (8/39) |
| **Central Manchester University Hospitals NHS Foundation Trust** | | | | | | | |
| Manchester Royal Infirmary* | Participant | n=14<br>2 (1, 5) | n=13<br>3 (2, 7) | n=0 | 33% (2/6) | n<6 | 52% (11/21) |
| Trafford General Hospital | Participant | n=10<br>2 (1, 8) | n<6 | n=0 | 40% (4/10) | n=0 | 0% (0/10) |
| **Chelsea and Westminster Hospital NHS Foundation Trust** | | | | | | | |
| Chelsea and Westminster Hospital* | Participant | n<6 | n<6 | n<6 | n<6 | n<6 | n<6 |
| **Chesterfield Royal Hospital NHS Foundation Trust** | | | | | | | |
| Chesterfield Royal Hospital* | Participant | n=55<br>4 (1, 10) | n=47<br>8 (4, 10) | 70% (14/20) | 46% (24/52) | 14% (3/21) | 10% (7/67) |
| **City Hospitals Sunderland NHS Foundation Trust** | | | | | | | |
| Sunderland Royal Hospital* | Participant | n=11<br>4 (1, 10) | n=7<br>9 (7, 11) | n<6 | n=0 | n<6 | 100% (13/13) |

| | Participation status | Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR) | Initial treatment Harvey Bradshaw Index, 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 | All patients – PROMs completed at start of treatment |
|---|---|---|---|---|---|---|---|
| Results | | (n=3739)<br>4 (1, 12) | n=2282<br>8 (4, 10) | 68% (502/741) | 53% (1644/3080) | n=1343<br>8% (108) | 30%<br>(1416/4718) |
| **Colchester Hospital University NHS Foundation Trust** | | | | | | | |
| Colchester General Hospital* | Participant | n=32<br>10 (3, 17) | n=16<br>14 (10, 16) | 50% (3/6) | 61% (17/28) | 9% (2/22) | 11% (4/37) |
| **Countess of Chester Hospital NHS Foundation Trust** | | | | | | | |
| Countess of Chester Hospital | Participant | n=25<br>6 (2, 14) | n=23<br>5 (1, 9) | 75% (15/20) | 48% (12/25) | 9% (2/22) | 0% (0/51) |
| **County Durham and Darlington NHS Foundation Trust** | | | | | | | |
| Darlington Memorial Hospital and Bishop Auckland Hospital combined* | Participant | n=27<br>3 (1, 13) | n=28<br>9 (6, 12) | n<6 | 68% (17/25) | 0% (0/6) | 16% (7/43) |
| University Hospital of North Durham | Participant | n=9<br>5 (2, 9) | n=9<br>7 (6, 10) | n<6 | 44% (4/9) | n<6 | 9% (1/11) |
| **Croydon Health Services NHS Trust** | | | | | | | |
| Croydon University Hospital | Participant | n=20<br>8 (1, 16) | n=16<br>7 (6, 10) | 57% (4/7) | 90% (18/20) | 0% (0/7) | 0% (0/23) |
| **Dartford and Gravesham NHS Trust** | | | | | | | |
| Darent Valley Hospital | Previous participant but no data entered in past year | | | | | | |
| **Derby Hospitals NHS Foundation Trust** | | | | | | | |
| Royal Derby Hospital* | Participant | n=11<br>7 (1, 15) | n=9<br>9 (6, 11) | n=0 | 25% (2/8) | n<6 | 47% (8/17) |
| **Doncaster and Bassetlaw Hospitals NHS Foundation Trust** | | | | | | | |
| Doncaster Royal Infirmary* and Bassetlaw District General Hospital combined | 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 Harvey Bradshaw Index, 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 | All patients – PROMs completed at start of treatment |
|---|---|---|---|---|---|---|---|
| Results | | (n=3739)<br>4 (1, 12) | n=2282<br>8 (4, 10) | 68% (502/741) | 53% (1644/3080) | n=1343<br>8% (108) | 30%<br>(1416/4718) |
| **Dorset County Hospital NHS Foundation Trust** | | | | | | | |
| Dorset County Hospital* | Participant | n=6<br>4 (1, 10) | n=6<br>5 (4, 11) | n<6 | n=0 | n<6 | 100% (6/6) |
| **Ealing Hospital NHS Trust** | | | | | | | |
| Ealing Hospital | Non-participant | | | | | | |
| **East and North Hertfordshire NHS Trust** | | | | | | | |
| Lister Hospital* and Queen Elizabeth II Hospital combined | Participant | n=59<br>5 (1, 12) | n=59<br>9 (7, 13) | 70% (14/20) | 59% (30/51) | 0% (0/23) | 73% (52/71) |
| **East Cheshire NHS Trust** | | | | | | | |
| Macclesfield District General Hospital | Participant | n=25<br>5 (2, 9) | n=24<br>11 (9, 12) | n=0 | 68% (17/25) | n=0 | 0% (0/27) |
| **East Kent Hospitals University NHS Foundation Trust** | | | | | | | |
| William Harvey Hospital, Kent and Canterbury Hospital and Queen Elizabeth The Queen Mother Hospital combined | Participant | n=7<br>10 (1, 20) | n<6 | n=0 | 43% (3/7) | n=0 | 0% (0/7) |
| **East Lancashire Hospitals NHS Trust** | | | | | | | |
| Royal Blackburn Hospital and Burnley District General Hospital combined | Participant | n=73<br>4 (1, 11) | n=48<br>7 (3, 11) | 42% (10/24) | 23% (17/75) | 3% (1/40) | 50% (46/93) |
| **East Sussex Healthcare Trust** | | | | | | | |
| Eastbourne District General Hospital and Conquest Hospital combined* | Participant | n=8<br>1 (0, 13) | n<6 | n<6 | n<6 | n<6 | 40% (4/10) |

| | Participation status | Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR) | Initial treatment Harvey Bradshaw Index, 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 | All patients – PROMs completed at start of treatment |
|---|---|---|---|---|---|---|---|
| Results | | (n=3739)<br>4 (1, 12) | n=2282<br>8 (4, 10) | 68% (502/741) | 53% (1644/3080) | n=1343<br>8% (108) | 30%<br>(1416/4718) |
| **Epsom and St Helier University Hospitals NHS Trust** | | | | | | | |
| Epsom General Hospital | Participant | n=7<br>3 (2, 23) | n=7<br>10 (9, 12) | n<6 | 71% (5/7) | n<6 | 0% (0/10) |
| St Helier Hospital | Participant | n=6<br>4 (1, 11) | n<6 | n=0 | 83% (5/6) | n=0 | 17% (1/6) |
| **Frimley Health NHS Foundation Trust** | | | | | | | |
| Frimley Park Hospital* | Participant | n=32<br>7 (2, 16) | n=27<br>11 (7, 14) | 70% (7/10) | 78% (21/27) | 13% (2/16) | 14% (5/35) |
| Heatherwood Hospital | Non-participant | | | | | | |
| Wexham Park Hospital | Participant | n<6 | n<6 | n<6 | n<6 | n<6 | n<6 |
| **Gateshead Health NHS Foundation Trust** | | | | | | | |
| Queen Elizabeth Hospital, Gateshead | Participant but data submitted do not meet audit criteria | | | | | | |
| **George Eliot Hospital NHS Trust** | | | | | | | |
| George Eliot Hospital | Participant | n=37<br>1 (0, 2) | n<6 | n=0 | 43% (16/37) | 0% (0/12) | 50% (21/42) |
| **Gloucestershire Hospitals NHS Foundation Trust** | | | | | | | |
| Gloucestershire Royal Hospital and Cheltenham General Hospital combined* | Participant | n=13<br>1 (0, 9) | n=17<br>4 (2, 8) | 67% (4/6) | n=0 | 14% (1/7) | 88% (15/17) |
| **Great Western Hospitals NHS Foundation Trust** | | | | | | | |
| Great Western Hospital | Participant | n=53<br>4 (1, 11) | n<6 | n=0 | 40% (21/53) | 100% (1/1) | 0% (0/69) |

| | Participation status | Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR) | Initial treatment Harvey Bradshaw Index, 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 | All patients – PROMs completed at start of treatment |
|---|---|---|---|---|---|---|---|
| Results | | (n=3739)<br>4 (1, 12) | n=2282<br>8 (4, 10) | 68% (502/741) | 53% (1644/3080) | n=1343<br>8% (108) | 30%<br>(1416/4718) |
| **Guy's and St Thomas' NHS Foundation Trust** | | | | | | | |
| Guy's Hospital and St Thomas' Hospital combined* | Participant | n=14<br>1 (1, 6) | n=17<br>5 (4, 9) | n<6 | n=0 | n<6 | 94% (16/17) |
| **Hampshire Hospitals NHS Foundation Trust** | | | | | | | |
| Basingstoke and North Hampshire Hospitals* | Participant | n=10<br>3 (1, 14) | n=10<br>9 (5, 12) | n<6 | n=0 | n<6 | 100% (10/10) |
| Royal Hampshire County Hospital* | Participant | n=12<br>2 (0, 19) | n=15<br>7 (4, 15) | n<6 | n=0 | n<6 | 93% (14/15) |
| **Harrogate and District NHS Foundation Trust** | | | | | | | |
| Harrogate District Hospital | Previous participant but no data entered in past year | n=8<br>4 (1, 7) | n<6 | n=0 | 50% (4/8) | n=0 | 0% (0/10) |
| **Heart of England NHS Foundation Trust** | | | | | | | |
| Birmingham Heartlands Hospital and Solihull Hospital combined | Participant | n<6 | n<6 | n<6 | n<6 | n<6 | n<6 |
| Good Hope Hospital | Participant | n=6<br>5 (2, 10) | n<6 | n=0 | 67% (4/6) | n<6 | 0% (0/7) |
| **Hinchingbrooke Health Care NHS Trust** | | | | | | | |
| Hinchingbrooke Hospital | Participant but data submitted do not meet audit criteria | | | | | | |
| **Homerton University Hospital NHS Foundation Trust** | | | | | | | |
| Homerton University Hospital | Participant | n=49<br>4 (1, 12) | n=44<br>9 (7, 10) | 32% (6/19) | 84% (41/49) | 5% (1/21) | 6% (4/63) |

| | Participation status | Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR) | Initial treatment Harvey Bradshaw Index, 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 | All patients – PROMs completed at start of treatment |
|---|---|---|---|---|---|---|---|
| Results | | (n=3739)<br>4 (1, 12) | n=2282<br>8 (4, 10) | 68% (502/741) | 53% (1644/3080) | n=1343<br>8% (108) | 30%<br>(1416/4718) |
| **Hull and East Yorkshire Hospitals NHS Trust** | | | | | | | |
| Hull Royal Infirmary* and Castle Hill Hospital combined | Participant | n=62<br>2 (0, 8) | n=49<br>5 (2, 7) | 79% (19/24) | 63% (17/27) | 5% (2/40) | 79% (53/67) |
| **Imperial College Healthcare NHS Trust** | | | | | | | |
| Charing Cross Hospital, Hammersmith Hospital and St Mary's Hospital combined | Previous participant but no data entered in past year | | | | | | |
| **James Paget University Hospitals NHS Foundation Trust** | | | | | | | |
| James Paget Hospital* | Participant | n=6<br>0 (0, 3) | n=6<br>7 (1, 10) | n<6 | n<6 | n<6 | 83% (5/6) |
| **Kettering General Hospital NHS Foundation Trust** | | | | | | | |
| Kettering General Hospital | Previous participant but no data entered in past year | | | | | | |
| **King's College Hospital NHS Foundation Trust** | | | | | | | |
| King's College Hospital | Participant | n<6 | n<6 | n<6 | n<6 | n<6 | n<6 |
| Princess Royal University Hospital | Participant | n=8<br>4 (1, 12) | n<6 | n=0 | 63% (5/8) | n=0 | 0% (0/16) |
| **Kingston Hospital NHS Trust** | | | | | | | |
| Kingston Hospital | Participant | n=15<br>1 (1, 6) | n<6 | n=0 | 73% (11/15) | n=0 | 0% (0/19) |
| **Lancashire Teaching Hospitals NHS Foundation Trust** | | | | | | | |
| Royal Preston Hospital and Chorley and South Ribble Hospital combined | Participant but data submitted do not meet audit criteria | | | | | | |

| | Participation status | Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR) | Initial treatment Harvey Bradshaw Index, 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 | All patients – PROMs completed at start of treatment |
|---|---|---|---|---|---|---|---|
| Results | | (n=3739)<br>4 (1, 12) | n=2282<br>8 (4, 10) | 68% (502/741) | 53% (1644/3080) | n=1343<br>8% (108) | 30%<br>(1416/4718) |
| **Lewisham and Greenwich NHS Trust** | | | | | | | |
| Lewisham Hospital | Participant | n<6 | n<6 | n=0 | n<6 | n<6 | 0% (0/7) |
| Queen Elizabeth Hospital, Woolwich | Participant but data submitted do not meet audit criteria | | | | | | |
| **London North West Healthcare NHS Trust** | | | | | | | |
| Central Middlesex Hospital | Participant but data submitted do not meet audit criteria | | | | | | |
| Northwick Park and St Mark's Hospitals Combined* | Participant | n=14<br>20 (8, 29) | n=16<br>5 (2, 10) | 67% (8/12) | n=0 | 0% (0/12) | 100% (16/16) |
| **Luton and Dunstable Hospital NHS Foundation Trust** | | | | | | | |
| Luton and Dunstable Hospital* | Participant | n<6 | n<6 | n=0 | n=0 | n<6 | 0% (0/6) |
| **Maidstone and Tunbridge Wells NHS Trust** | | | | | | | |
| Maidstone Hospital* | Participant | n<6 | n<6 | n<6 | n<6 | n<6 | n<6 |
| Tunbridge Wells Hospital | Participant | n=19<br>8 (3, 16) | n=11<br>9 (0, 9) | n=0 | 53% (10/19) | n<6 | 10% (2/20) |
| **Medway NHS Foundation Trust** | | | | | | | |
| Medway Maritime Hospital | Participant | n=18<br>4 (2, 13) | n<6 | n=0 | 72% (13/18) | n<6 | 0% (0/20) |
| **Mid Cheshire Hospitals NHS Foundation Trust** | | | | | | | |
| Leighton Hospital* | 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 Harvey Bradshaw Index, 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 | All patients – PROMs completed at start of treatment |
|---|---|---|---|---|---|---|---|
| Results | | (n=3739)<br>4 (1, 12) | n=2282<br>8 (4, 10) | 68% (502/741) | 53% (1644/3080) | n=1343<br>8% (108) | 30% (1416/4718) |
| **Mid Essex Hospitals NHS Trust** | | | | | | | |
| Broomfield Hospital | Participant | n=25<br>6 (2, 12) | n=23<br>10 (9, 12) | n=0 | 52% (13/25) | n=0 | 0% (0/25) |
| **Milton Keynes Hospital NHS Foundation Trust** | | | | | | | |
| Milton Keynes Hospital* | Participant | n<6 | n=8<br>7 (4, 11) | n<6 | n=0 | n<6 | 100% (8/8) |
| **NHS Isle of Wight** | | | | | | | |
| St Mary's Hospital | Previous participant but no data entered in past year | | | | | | |
| **Norfolk and Norwich University Hospitals NHS Foundation Trust** | | | | | | | |
| Norfolk and Norwich University Hospital* | Participant | n=12<br>4 (2, 9) | n=12<br>3 (1, 6) | n<6 | n=0 | n<6 | 100% (12/12) |
| **North Bristol NHS Trust** | | | | | | | |
| Southmead hospital | Participant | n=13<br>3 (1, 10) | n<6 | n=0 | 62% (8/13) | n<6 | 7% (1/14) |
| **North Cumbria University Hospitals NHS Trust** | | | | | | | |
| Cumberland Infirmary* | Participant | n=13<br>4 (2, 9) | n<6 | n=0 | 46% (5/11) | n<6 | 14% (2/14) |
| West Cumberland Hospital* | Participant | n=9<br>2 (1, 8) | n<6 | n=0 | 100% (7/7) | n<6 | 13% (2/15) |
| **North Middlesex University Hospital NHS Trust** | | | | | | | |
| North Middlesex University Hospital | Previous participant but no data entered in past year | | | | | | |

| | Participation status | Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR) | Initial treatment Harvey Bradshaw Index, 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 | All patients – PROMs completed at start of treatment |
|---|---|---|---|---|---|---|---|
| Results | | (n=3739)<br>4 (1, 12) | n=2282<br>8 (4, 10) | 68% (502/741) | 53% (1644/3080) | n=1343<br>8% (108) | 30%<br>(1416/4718) |
| **North Tees and Hartlepool NHS Foundation Trust** | | | | | | | |
| University Hospital of Hartlepool | Participant | n<6 | n<6 | n<6 | n<6 | n<6 | n<6 |
| University Hospital of North Tees | Participant | n=31<br>4 (1, 13) | n<6 | n=0 | 55% (17/31) | 11% (2/19) | 13% (5/40) |
| **Northampton General Hospital NHS Trust** | | | | | | | |
| Northampton General Hospital | Participant | n=36<br>6 (1, 13) | n<6 | n<6 | 44% (16/36) | 0% (0/9) | 0% (0/53) |
| **Northern Devon Healthcare NHS Trust** | | | | | | | |
| North Devon District Hospital | Previous participant but no data entered in past year | n<6 | n<6 | n<6 | n<6 | n<6 | n<6 |
| **Northern Lincolnshire and Goole Hospitals NHS Foundation Trust** | | | | | | | |
| Diana, Princess of Wales Hospital | Participant | n=26<br>4 (1, 9) | n<6 | n=0 | 62% (16/26) | n<6 | 0% (0/45) |
| Scunthorpe General Hospital | Previous participant but no data entered in past year | n=9<br>4 (2, 10) | n<6 | n=0 | 67% (6/9) | n<6 | 0% (0/10) |
| **Northumbria Healthcare NHS Foundation Trust** | | | | | | | |
| Northumbria Healthcare NHS Foundation Trust (Wansbeck, North Tyneside and Hexham General Hospitals combined) | Participant | n=28<br>5 (1, 12) | n=27<br>11 (8, 14) | 43% (3/7) | 61% (17/28) | 0% (0/8) | 38% (12/32) |

| | Participation status | Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR) | Initial treatment Harvey Bradshaw Index, 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 | All patients – PROMs completed at start of treatment |
|---|---|---|---|---|---|---|---|
| Results | | (n=3739)<br>4 (1, 12) | n=2282<br>8 (4, 10) | 68% (502/741) | 53% (1644/3080) | n=1343<br>8% (108) | 30%<br>(1416/4718) |
| **Nottingham University Hospital NHS Trust** | | | | | | | |
| Queen's Medical Centre* and Nottingham City Hospital combined | Participant | n=7<br>3 (1, 17) | n=10<br>7 (3, 9) | n<6 | n=0 | 33% (2/6) | 100% (10/10) |
| **Oxford University Hospitals NHS Trust** | | | | | | | |
| The John Radcliffe Hospital and Horton General Hospital combined | Participant | n=36<br>3 (1, 8) | n<6 | n=0 | 67% (24/36) | 13% (1/8) | 0% (0/41) |
| **Peterborough and Stamford Hospitals NHS Foundation Trust** | | | | | | | |
| Peterborough City Hospital | Participant | n=26<br>8 (2, 22) | n<6 | n<6 | 65% (17/26) | 0% (0/8) | 0% (0/31) |
| **Plymouth Hospitals NHS Trust** | | | | | | | |
| Derriford Hospital* | Participant | n=9<br>0 (0, 7) | n=10<br>4 (2, 8) | n=0 | n=0 | 0% (0/6) | 93% (13/14) |
| **Poole Hospital NHS Foundation Trust** | | | | | | | |
| Poole General Hospital* | Participant | n=8<br>5 (0, 10) | n=8<br>6 (3, 8) | n=0 | n=0 | n<6 | 94% (15/16) |
| **Portsmouth Hospitals NHS Trust** | | | | | | | |
| Queen Alexandra Hospital* | Participant | n=51<br>6 (1, 14) | n=10<br>4 (4, 7) | 57% (4/7) | 64% (27/42) | 0% (0/7) | 12% (8/65) |
| **Princess Alexandra Hospital NHS Trust** | | | | | | | |
| Princess Alexandra Hospital, Harlow* | Participant | n=14<br>4 (0, 13) | n=17<br>11 (6, 15) | n<6 | n=0 | 0% (0/6) | 100% (17/17) |
| **Royal Berkshire NHS Foundation Trust** | | | | | | | |
| Royal Berkshire Hospital* | Participant | n=9<br>1 (1, 13) | n=10<br>5 (3, 14) | n<6 | n=0 | n<6 | 100% (10/10) |

| | Participation status | Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR) | Initial treatment Harvey Bradshaw Index, 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 | All patients – PROMs completed at start of treatment |
|---|---|---|---|---|---|---|---|
| Results | | (n=3739)<br>4 (1, 12) | n=2282<br>8 (4, 10) | 68% (502/741) | 53% (1644/3080) | n=1343<br>8% (108) | 30% (1416/4718) |
| **Royal Bolton Hospital NHS Foundation Trust** | | | | | | | |
| Royal Bolton Hospital | Participant | n=65<br>6 (2, 12) | n=45<br>5 (3, 9) | 38% (3/8) | 81% (54/67) | 6% (1/16) | 10% (9/91) |
| **Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust** | | | | | | | |
| Royal Bournemouth Hospital* | Participant | n=97<br>5 (1, 15) | n=95<br>7 (5, 11) | 64% (28/44) | 60% (55/91) | 6% (3/48) | 8% (10/121) |
| **Royal Cornwall Hospitals NHS Trust** | | | | | | | |
| Royal Cornwall Hospital* | Participant | n=27<br>7 (2, 16) | n=10<br>6 (2, 6) | n<6 | 57% (13/23) | 0% (0/11) | 30% (11/37) |
| **Royal Devon and Exeter NHS Foundation Trust** | | | | | | | |
| Royal Devon and Exeter Hospital* | Participant | n=47<br>1 (0, 4) | n=48<br>6 (3, 10) | 81% (21/26) | n=0 | 4% (1/27) | 86% (42/49) |
| **Royal Free London NHS Foundation Trust** | | | | | | | |
| Barnet General Hospital | Previous participant but no data entered in past year | n=6<br>4 (1, 15) | n=6<br>22 (14, 25) | n=0 | 83% (5/6) | n=0 | 0% (0/8) |
| Royal Free Hospital* | Participant | n=8<br>6 (2, 14) | n<6 | n=0 | 50% (3/6) | n<6 | 42% (5/12) |
| **Royal Liverpool and Broadgreen University Hospitals NHS Trust** | | | | | | | |
| Royal Liverpool University Hospital | Participant | n=28<br>2 (1, 7) | n=27<br>7 (0, 10) | n<6 | 64% (18/28) | 0% (0/6) | 0% (0/33) |
| **Royal Surrey County Hospital NHS Foundation Trust** | | | | | | | |
| Royal Surrey County Hospital | Participant | n=7<br>10 (2, 27) | n=6<br>14 (12, 14) | n=0 | 71% (5/7) | n=0 | 0% (0/9) |

| | Participation status | Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR) | Initial treatment Harvey Bradshaw Index, 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 | All patients – PROMs completed at start of treatment |
|---|---|---|---|---|---|---|---|
| Results | | (n=3739)<br>4 (1, 12) | n=2282<br>8 (4, 10) | 68% (502/741) | 53% (1644/3080) | n=1343<br>8% (108) | 30%<br>(1416/4718) |
| **Royal United Hospital Bath NHS Trust** | | | | | | | |
| Royal United Hospital | Non-participant | | | | | | |
| **Salford Royal NHS Foundation Trust** | | | | | | | |
| Salford Royal Hospital* | Participant | n=108<br>7 (2, 15) | n=85<br>9 (8, 11) | 12% (6/49) | 36% (38/106) | 13% (7/56) | 2% (2/114) |
| **Salisbury NHS Foundation Trust** | | | | | | | |
| Salisbury District General Hospital | Participant | n=19<br>2 (1, 6) | n<6 | n=0 | 37% (7/19) | n<6 | 0% (0/32) |
| **Sandwell and West Birmingham Hospitals NHS Trust** | | | | | | | |
| Birmingham City Hospital and Sandwell Hospital combined* | Participant | n=20<br>6 (1, 12) | n=11<br>8 (5, 9) | n<6 | 75% (6/8) | n<6 | 44% (10/23) |
| **Sheffield Teaching Hospitals NHS Foundation Trust** | | | | | | | |
| Royal Hallamshire Hospital and Northern General Hospital combined | Participant | n=145<br>6 (2, 13) | n=99<br>7 (4, 10) | 64% (16/25) | 44% (64/146) | 0% (0/42) | 65% (125/192) |
| **Sherwood Forest Hospitals NHS Foundation Trust** | | | | | | | |
| King's Mill Hospital and Newark Hospital combined* | Participant | n=30<br>2 (1, 9) | n=20<br>4 (2, 7) | 67% (4/6) | 33% (5/15) | 10% (1/10) | 55% (18/33) |
| **South Devon Healthcare NHS Foundation Trust** | | | | | | | |
| Torbay Hospital* | Participant | n=24<br>5 (1, 18) | n=24<br>8 (4, 12) | 64% (7/11) | n=0 | 23% (3/13) | 100% (24/24) |

| | Participation status | Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR) | Initial treatment Harvey Bradshaw Index, 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 | All patients – PROMs completed at start of treatment |
|---|---|---|---|---|---|---|---|
| Results | | (n=3739)<br>4 (1, 12) | n=2282<br>8 (4, 10) | 68% (502/741) | 53% (1644/3080) | n=1343<br>8% (108) | 30%<br>(1416/4718) |
| **South Tees Hospitals NHS Foundation Trust** | | | | | | | |
| Friarage Hospital | Non-participant | | | | | | |
| James Cook University Hospital* | Participant | n=15<br>2 (0, 15) | n=12<br>4 (2, 11) | 88% (7/8) | n<6 | 0% (0/8) | 56% (10/18) |
| **South Tyneside NHS Foundation Trust** | | | | | | | |
| South Tyneside District Hospital* | Participant | n=23<br>5 (2, 14) | n=24<br>5 (3, 7) | 86% (12/14) | 58% (11/19) | 11% (2/18) | 30% (10/33) |
| **South Warwickshire NHS Foundation Trust** | | | | | | | |
| Warwick Hospital | Participant | n=75<br>3 (1, 10) | n<6 | n=0 | 32% (24/75) | n=0 | 0% (0/89) |
| **Southend University Hospital NHS Foundation Trust** | | | | | | | |
| Southend University Hospital | Previous participant but no data entered in past year | n<6 | n<6 | n=0 | n<6 | n<6 | 0% (0/11) |
| **Southport and Ormskirk Hospital NHS Trust** | | | | | | | |
| Southport District General Hospital | Previous participant but no data entered in past year | | | | | | |
| **St George's Healthcare NHS Trust** | | | | | | | |
| St George's Hospital* | Participant | n=39<br>8 (2, 11) | n=42<br>10 (9, 12) | 67% (10/15) | 74% (26/35) | 16% (3/19) | 31% (15/48) |

| | Participation status | Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR) | Initial treatment Harvey Bradshaw Index, 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 | All patients – PROMs completed at start of treatment |
|---|---|---|---|---|---|---|---|
| Results | | (n=3739)<br>4 (1, 12) | n=2282<br>8 (4, 10) | 68% (502/741) | 53% (1644/3080) | n=1343<br>8% (108) | 30%<br>(1416/4718) |
| **St Helens and Knowsley Hospitals NHS Trust** | | | | | | | |
| Whiston Hospital | Participant but data submitted do not meet audit criteria | | | | | | |
| **Stockport NHS Foundation Trust** | | | | | | | |
| Stepping Hill Hospital* | Participant | n<6 | n<6 | n<6 | n<6 | n<6 | n<6 |
| **Surrey and Sussex Healthcare NHS Trust** | | | | | | | |
| East Surrey Hospital | Previous participant but no data entered in past year | | | | | | |
| **Tameside Hospital NHS Foundation Trust** | | | | | | | |
| Tameside General Hospital* | Participant | n<6 | n<6 | n<6 | n<6 | n<6 | 43% (3/7) |
| **Taunton and Somerset NHS Foundation Trust** | | | | | | | |
| Musgrove Park Hospital* | Participant | n=14<br>4 (1, 17) | n=11<br>0 (0, 5) | n<6 | 55% (6/11) | n<6 | 95% (19/20) |
| **The Dudley Group NHS Foundation Trust** | | | | | | | |
| Russells Hall Hospital* | Participant | n=43<br>4 (1, 12) | n=39<br>8 (5, 10) | n<6 | 62% (26/42) | 10% (1/10) | 49% (32/65) |
| **The Hillingdon Hospitals NHS Foundation Trust** | | | | | | | |
| Hillingdon Hospital | Non-participant | | | | | | |
| **The Ipswich Hospital NHS Trust** | | | | | | | |
| The Ipswich Hospital | Previous participant but no data entered in past year | | | | | | |

| | Participation status | Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR) | Initial treatment Harvey Bradshaw Index, 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 | All patients – PROMs completed at start of treatment |
|---|---|---|---|---|---|---|---|
| Results | | (n=3739)<br>4 (1, 12) | n=2282<br>8 (4, 10) | 68% (502/741) | 53% (1644/3080) | n=1343<br>8% (108) | 30%<br>(1416/4718) |
| **The Leeds Teaching Hospitals NHS Trust** | | | | | | | |
| Leeds General Infirmary* | Participant | n<6 | n<6 | n=0 | n<6 | n<6 | n<6 |
| St James's University Hospital Leeds* | Participant | n=14<br>5 (1, 10) | n=15<br>5 (2, 7) | 67% (4/6) | n=0 | 13% (1/8) | 94% (16/17) |
| **The Mid Yorkshire Hospitals NHS Trust** | | | | | | | |
| Dewsbury and District Hospital | Non-participant | | | | | | |
| Pinderfields General Hospital and Pontefract Hospitals combined* | Participant | n=12<br>2 (0, 5) | n=16<br>2 (0, 9) | n<6 | n=0 | 0% (0/6) | 82% (14/17) |
| **The Newcastle upon Tyne Hospitals NHS Foundation Trust** | | | | | | | |
| Freeman Hospital | Participant | n=40<br>9 (2, 20) | n=10<br>11 (6, 17) | n<6 | 43% (17/40) | 5% (1/22) | 0% (0/43) |
| Royal Victoria Infirmary, Newcastle* | Participant | n=23<br>3 (1, 10) | n=24<br>6 (3, 10) | 83% (15/18) | n=0 | 5% (1/19) | 100% (24/24) |
| **The Pennine Acute Hospitals NHS Trust** | | | | | | | |
| The Royal Oldham Hospital, Fairfield General Hospital, North Manchester General Hospital and Rochdale Infirmary combined* | Participant | n=88<br>5 (1, 11) | n=11<br>5 (4, 10) | n<6 | 55% (43/78) | n<6 | 9% (10/107) |
| **The Queen Elizabeth Hospital King's Lynn NHS Foundation Trust** | | | | | | | |
| The Queen Elizabeth Hospital | Previous participant but no data entered in past year | | | | | | |

| | Participation status | Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR) | Initial treatment Harvey Bradshaw Index, 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 | All patients – PROMs completed at start of treatment |
|---|---|---|---|---|---|---|---|
| Results | | (n=3739)<br>4 (1, 12) | n=2282<br>8 (4, 10) | 68% (502/741) | 53% (1644/3080) | n=1343<br>8% (108) | 30%<br>(1416/4718) |
| **The Rotherham NHS Foundation Trust** | | | | | | | |
| Rotherham Hospital | Participant | n=13<br>5 (2, 12) | n=6<br>11 (5, 18) | n<6 | 54% (7/13) | n<6 | 0% (0/17) |
| **The Royal Wolverhampton Hospitals NHS Trust** | | | | | | | |
| Cannock Chase Hospital | Participant | n<6 | n<6 | n=0 | n<6 | n<6 | n<6 |
| New Cross Hospital* | Participant | n=60<br>5 (2, 12) | n=46<br>8 (5, 9) | 47% (9/19) | 46% (25/54) | 0% (0/21) | 26% (22/84) |
| **The Shrewsbury and Telford Hospital NHS Trust** | | | | | | | |
| Royal Shrewsbury Hospital* and Princess Royal Hospital combined | Participant | n=13<br>6 (1, 11) | n=15<br>5 (4, 10) | 71% (5/7) | n<6 | 0% (0/8) | 88% (14/16) |
| **United Lincolnshire Hospitals NHS Trust** | | | | | | | |
| Grantham and District Hospital* | Participant | n=6<br>1 (1, 6) | n=6<br>8 (1, 8) | n<6 | n<6 | n<6 | 14% (1/7) |
| Lincoln County Hospital* | Participant | n=18<br>2 (1, 5) | n=6<br>6 (5, 10) | n<6 | 53% (8/15) | n<6 | 13% (3/23) |
| Pilgrim Hospital | Participant | n=17<br>5 (1, 17) | n<6 | n=0 | 53% (9/17) | 17% (1/6) | 0% (0/19) |
| **University College London Hospitals NHS Foundation Trust** | | | | | | | |
| University College Hospital* | Participant | n=70<br>4 (1, 8) | n=57<br>7 (3, 9) | 73% (16/22) | 75% (51/68) | 10% (3/30) | 4% (3/80) |

| | Participation status | Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR) | Initial treatment Harvey Bradshaw Index, 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 | All patients – PROMs completed at start of treatment |
|---|---|---|---|---|---|---|---|
| Results | | (n=3739)<br>4 (1, 12) | n=2282<br>8 (4, 10) | 68% (502/741) | 53% (1644/3080) | n=1343<br>8% (108) | 30%<br>(1416/4718) |
| **University Hospitals of North Midlands NHS Trust** | | | | | | | |
| County Hospital | Participant but data submitted do not meet audit criteria | | | | | | |
| The Royal Stoke University Hospital* | Participant | n<6 | n<6 | n<6 | n<6 | n<6 | n<6 |
| **University Hospital of South Manchester NHS Foundation Trust** | | | | | | | |
| Wythenshawe Hospital* | Participant | n=30<br>4 (1, 10) | n=29<br>10 (6, 14) | 83% (5/6) | 59% (10/17) | 0% (0/6) | 34% (13/38) |
| **University Hospital Southampton NHS Foundation Trust** | | | | | | | |
| Southampton General Hospital* | Participant | n=48<br>3 (1, 10) | n=47<br>7 (4, 13) | 52% (11/21) | 46% (5/11) | 10% (3/30) | 77% (46/60) |
| **University Hospitals Birmingham NHS Foundation Trust** | | | | | | | |
| Queen Elizabeth Hospital, Birmingham | Participant | n=134<br>8 (3, 15) | n=14<br>8 (3, 11) | n=0 | 44% (60/135) | 11% (11/102) | 5% (9/170) |
| New Queen Elizabeth Hospital Birmingham* | Participant | n=7<br>3 (0, 15) | n=9<br>4 (0, 10) | n<6 | n=0 | n<6 | 100% (10/10) |
| **University Hospitals Coventry and Warwickshire NHS Trust** | | | | | | | |
| University Hospital, Coventry* | Participant | n=18<br>4 (1, 19) | n=18<br>5 (3, 9) | n<6 | n=0 | n<6 | 100% (18/18) |
| **University Hospitals of Bristol NHS Foundation Trust** | | | | | | | |
| Bristol Royal Infirmary* | Participant | n=10<br>3 (1, 5) | n=6<br>6 (2, 9) | n<6 | 44% (4/9) | n<6 | 15% (2/13) |

| | Participation status | Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR) | Initial treatment Harvey Bradshaw Index, 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 | All patients – PROMs completed at start of treatment |
|---|---|---|---|---|---|---|---|
| Results | | (n=3739)<br>4 (1, 12) | n=2282<br>8 (4, 10) | 68% (502/741) | 53% (1644/3080) | n=1343<br>8% (108) | 30%<br>(1416/4718) |
| **University Hospitals of Leicester NHS Trust** | | | | | | | |
| Leicester Royal Infirmary | Previous participant but no data entered in past year | n=8<br>2 (1, 3) | n<6 | n=0 | 38% (3/8) | n=0 | 0% (0/8) |
| Leicester General Hospital* | Participant | n<6 | n<6 | n<6 | n<6 | n<6 | n<6 |
| **University Hospitals of Morecombe Bay NHS Foundation Trust** | | | | | | | |
| Furness General and Royal Lancaster Infirmary and Westmorland General Hospitals combined | Participant | n=22<br>9 (2, 20) | n<6 | n=0 | 59% (13/22) | n<6 | 0% (0/27) |
| **Walsall Healthcare NHS Trust** | | | | | | | |
| Walsall Manor Hospital | Previous participant but no data entered in past year | n=21<br>2 (1, 8) | n=19<br>13 (10, 16) | n<6 | 52% (11/21) | n<6 | 65% (20/31) |
| **Warrington and Halton Hospitals NHS Foundation Trust** | | | | | | | |
| Warrington District General Hospital* | Participant | n=18<br>5 (2, 11) | n=17<br>7 (5, 13) | n<6 | n<6 | n<6 | 57% (13/23) |
| **West Hertfordshire Hospitals NHS Trust** | | | | | | | |
| Watford General Hospital* and Hemel Hempstead General Hospital combined | Participant | n=66<br>3 (1, 10) | n=48<br>10 (8, 13) | 65% (11/17) | 51% (32/63) | 5% (2/40) | 4% (3/70) |
| **West Middlesex University Hospital NHS Trust** | | | | | | | |
| West Middlesex University Hospital* | Participant | n=17<br>5 (2, 13) | n=17<br>10 (8, 12) | n=0 | 56% (9/16) | n<6 | 5% (1/22) |

| | Participation status | Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR) | Initial treatment Harvey Bradshaw Index, 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 | All patients – PROMs completed at start of treatment |
|---|---|---|---|---|---|---|---|
| Results | | (n=3739)<br>4 (1, 12) | n=2282<br>8 (4, 10) | 68% (502/741) | 53% (1644/3080) | n=1343<br>8% (108) | 30%<br>(1416/4718) |
| **West Suffolk Hospitals NHS Foundation Trust** | | | | | | | |
| West Suffolk Hospital | Participant | n=15<br>4 (1, 12) | n=14<br>14 (11, 21) | 29% (2/7) | 27% (4/15) | 10% (1/10) | 0% (0/17) |
| **Western Sussex Hospitals NHS Trust** | | | | | | | |
| St Richard's Hospital | Participant | n=19<br>6 (1, 15) | n=11<br>8 (2, 9) | n=0 | 68% (13/19) | n=0 | 0% (0/25) |
| Worthing Hospital* | Participant | n=7<br>0 (0, 8) | n<6 | n<6 | n<6 | n<6 | 57% (4/7) |
| **Weston Area Health Trust** | | | | | | | |
| Weston General Hospital* | Participant | n=19<br>11 (1, 20) | n=20<br>9 (5, 12) | n<6 | 21% (3/14) | 11% (1/9) | 69% (18/26) |
| **Whittington Health NHS Trust** | | | | | | | |
| Whittington Hospital | Participant but data submitted do not meet audit criteria | | | | | | |
| **Wirral University Teaching Hospital NHS Foundation Trust** | | | | | | | |
| Arrowe Park Hospital | Participant | n=31<br>5 (2, 19) | n=16<br>7 (6, 9) | n<6 | 36% (11/31) | 0% (0/7) | 0% (0/31) |
| **Worcestershire Acute Hospitals NHS Trust** | | | | | | | |
| Alexandra Hospital | Not eligible | | | | | | |
| Worcestershire Royal Hospital | Previous participant but no data entered in past year | n=12<br>10 (2, 16) | n<6 | n=0 | 67% (8/12) | n=0 | 0% (0/17) |

| | Participation status | Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR) | Initial treatment Harvey Bradshaw Index, 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 | All patients – PROMs completed at start of treatment |
|---|---|---|---|---|---|---|---|
| Results | | (n=3739)<br>4 (1, 12) | n=2282<br>8 (4, 10) | 68% (502/741) | 53% (1644/3080) | n=1343<br>8% (108) | 30%<br>(1416/4718) |
| **Wrightington, Wigan and Leigh NHS Foundation Trust** | | | | | | | |
| Royal Albert Edward Infirmary* | Participant | n=7<br>6 (2, 33) | n=7<br>7 (1, 11) | n<6 | n=0 | n<6 | 100% (7/7) |
| **Wye Valley NHS Trust** | | | | | | | |
| County Hospital, Hereford | Participant | n=19<br>2 (1, 9) | n=18<br>9 (7, 14) | 38% (3/8) | 42% (8/19) | 0% (0/8) | 0% (0/20) |
| **Yeovil District Hospital NHS Foundation Trust** | | | | | | | |
| Yeovil District Hospital* | Participant | n=37<br>6 (1, 16) | n=23<br>6 (4, 7) | 60% (6/10) | 36% (11/31) | 33% (7/21) | 92% (54/59) |
| **York Teaching Hospital NHS Foundation Trust** | | | | | | | |
| Scarborough General Hospital | Previous participant but no data entered in past year | | | | | | |
| York Hospital | Participant | n=15<br>4 (1, 12) | n<6 | n=0 | 60% (9/15) | n=0 | 0% (0/18) |
| **Northern Ireland (n=12)** | | | | | | | |
| **Belfast Health and Social Care Trust** | | | | | | | |
| Belfast City Hospital | Participant | n=30<br>3 (1, 10) | n=7<br>6 (5, 8) | n=0 | 67% (20/30) | n<6 | 23% (8/35) |
| Mater Hospital | Previous participant but no data entered in past year | | | | | | |
| Royal Victoria Hospital | Participant | n=15<br>5 (0, 14) | n<6 | n=0 | 80% (12/15) | n=0 | 0% (0/16) |

| | Participation status | Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR) | Initial treatment Harvey Bradshaw Index, 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 | All patients – PROMs completed at start of treatment |
|---|---|---|---|---|---|---|---|
| Results | | (n=3739)<br>4 (1, 12) | n=2282<br>8 (4, 10) | 68% (502/741) | 53% (1644/3080) | n=1343<br>8% (108) | 30%<br>(1416/4718) |
| **Northern Health and Social Care Trust** | | | | | | | |
| Antrim Area Hospital | Previous participant but no data entered in past year | | | | | | |
| Causeway Hospital | Participant | n=8<br>5 (1, 8) | n<6 | n=0 | 25% (2/8) | n=0 | 0% (0/13) |
| **South Eastern Health and Social Care Trust** | | | | | | | |
| Downe Hospital | Non-participant | | | | | | |
| Lagan Valley Hospital | Participant | n=6<br>3 (1, 5) | n=6<br>11 (7, 16) | n=0 | 50% (3/6) | n<6 | 0% (0/6) |
| Ulster Hospital | Participant | n<6 | n<6 | n<6 | n<6 | n<6 | n<6 |
| **Southern Health and Social Care Trust** | | | | | | | |
| Craigavon Area Hospital | Previous participant but no data entered in past year | n=8<br>7 (1, 14) | n<6 | n=0 | 88% (7/8) | n=0 | 9% (1/11) |
| Daisy Hill Hospital | Participant | n=7<br>3 (0, 10) | n<6 | n=0 | 43% (3/7) | n<6 | 44% (4/9) |
| **Western Health and Social Care Trust** | | | | | | | |
| Altnagelvin Area Hospital | Previous participant but no data entered in past year | n=8<br>13 (3, 22) | n=8<br>10 (4, 13) | n=0 | 50% (4/8) | n=0 | 0% (0/9) |
| South West Acute Hospital | Previous participant but no data entered in past year | | | | | | |

| | Participation status | Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR) | Initial treatment Harvey Bradshaw Index, 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 | All patients – PROMs completed at start of treatment |
|---|---|---|---|---|---|---|---|
| Results | | (n=3739)<br>4 (1, 12) | n=2282<br>8 (4, 10) | 68% (502/741) | 53% (1644/3080) | n=1343<br>8% (108) | 30%<br>(1416/4718) |
| **Scotland (n=21)** | | | | | | | |
| **NHS Ayrshire and Arran** | | | | | | | |
| University Hospital Ayr | Non-participant | | | | | | |
| University Hospital Crosshouse | Previous participant but no data entered in past year | | | | | | |
| **NHS Borders** | | | | | | | |
| Borders General Hospital | Previous participant but no data entered in past year | | | | | | |
| **NHS Dumfries and Galloway** | | | | | | | |
| Dumfries and Galloway Royal Infirmary | Participant | n<6 | n<6 | n<6 | n<6 | n<6 | n<6 |
| **NHS Fife** | | | | | | | |
| Queen Margaret Hospital | Non-participant | | | | | | |
| Victoria Hospital* | Participant | n<6 | n<6 | n<6 | n<6 | n<6 | n<6 |
| **NHS Forth Valley** | | | | | | | |
| Forth Valley Royal Hospital* | Participant | n=46<br>4 (1, 9) | n=18<br>4 (0, 8) | 86% (6/7) | 65% (22/34) | 5% (1/22) | 96% (65/68) |
| **NHS Grampian** | | | | | | | |
| Aberdeen Royal Infirmary | Non-participant | | | | | | |

| | Participation status | Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR) | Initial treatment Harvey Bradshaw Index, 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 | All patients – PROMs completed at start of treatment |
|---|---|---|---|---|---|---|---|
| Results | | (n=3739)<br>4 (1, 12) | n=2282<br>8 (4, 10) | 68% (502/741) | 53% (1644/3080) | n=1343<br>8% (108) | 30%<br>(1416/4718) |
| **NHS Greater Glasgow and Clyde** | | | | | | | |
| Glasgow Royal Infirmary* | Participant | n=11<br>5 (1, 7) | n=11<br>5 (3, 9) | n<6 | n=0 | n<6 | 91% (10/11) |
| Inverclyde Royal Hospital | Previous participant but no data entered in past year | | | | | | |
| Royal Alexandra Hospital | Previous participant but no data entered in past year | | | | | | |
| Southern General Hospital | Non-participant | | | | | | |
| Victoria Infirmary | Non-participant | | | | | | |
| Western Infirmary | Non-participant | | | | | | |
| **NHS Highland** | | | | | | | |
| Raigmore Hospital | Non-participant | | | | | | |
| **NHS Lanarkshire** | | | | | | | |
| Hairmyres Hospital | Participant | n=9<br>8 (2, 14) | n=8<br>8 (4, 9) | n<6 | 44% (4/9) | n<6 | 0% (0/9) |
| Monklands Hospital | Participant | n=14<br>8 (1, 17) | n=7<br>9 (5, 10) | n<6 | 57% (8/14) | n<6 | 43% (6/14) |
| Wishaw General Hospital | Previous participant but no data entered past year | | | | | | |

| | Participation status | Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR) | Initial treatment Harvey Bradshaw Index, 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 | All patients – PROMs completed at start of treatment |
|---|---|---|---|---|---|---|---|
| Results | | (n=3739)<br>4 (1, 12) | n=2282<br>8 (4, 10) | 68% (502/741) | 53% (1644/3080) | n=1343<br>8% (108) | 30%<br>(1416/4718) |
| **NHS Lothian** | | | | | | | |
| St John's Hospital at Howden | Non-participant | | | | | | |
| Western General Hospital and Royal Infirmary of Edinburgh combined* | Participant | n=17<br>4 (1, 9) | n=14<br>7 (4, 10) | n<6 | n<6 | 0% (0/6) | 62% (13/21) |
| **NHS Tayside** | | | | | | | |
| Ninewells Hospital* | Participant | n=15<br>5 (2, 18) | n=7<br>6 (0, 8) | n=0 | 47% (7/15) | n<6 | 23% (6/26) |
| **Wales (n=16)** | | | | | | | |
| **Abertawe Bro Morgannwg University Health Board** | | | | | | | |
| Morriston Hospital | Not eligible | | | | | | |
| Princess of Wales Hospital | Non-participant | | | | | | |
| **Aneurin Bevan University Health Board** | | | | | | | |
| Nevill Hall Hospital | Participant | n=41<br>4 (1, 8) | n=24<br>6 (2, 10) | n<6 | 49% (20/41) | 0% (0/9) | 46% (23/50) |
| Royal Gwent Hospital | Participant | n=18<br>4 (1, 11) | n=16<br>8 (4, 10) | n<6 | 44% (8/18) | n<6 | 75% (18/24) |

| | Participation status | Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR) | Initial treatment Harvey Bradshaw Index, 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 | All patients – PROMs completed at start of treatment |
|---|---|---|---|---|---|---|---|
| Results | | (n=3739)<br>4 (1, 12) | n=2282<br>8 (4, 10) | 68% (502/741) | 53% (1644/3080) | n=1343<br>8% (108) | 30%<br>(1416/4718) |
| **Betsi Cadwaladr University Health Board** | | | | | | | |
| Glan Clwyd Hospital | Non-participant | | | | | | |
| Llandudno General Hospital | Previous participant but no data entered in past year | | | | | | |
| Wrexham Maelor Hospital | Participant | n=38<br>3 (1, 13) | n=19<br>10 (8, 12) | n<6 | 45% (17/38) | 7% (2/29) | 19% (8/42) |
| Ysbyty Gwynedd | Participant but data submitted do not meet audit criteria | | | | | | |
| **Cardiff and Vale University Health Board** | | | | | | | |
| University Hospital Llandough | Participant | n=10<br>8 (3, 16) | n=10<br>6 (3, 8) | n=0 | 64% (7/11) | n=0 | 39% (5/13) |
| University Hospital of Wales | Previous participant but no data entered in past year | n=25<br>3 (1, 12) | n=22<br>5 (3, 9) | 89% (8/9) | 76% (19/25) | 0% (0/9) | 78% (21/27) |
| **Cwm Taf University Health Board** | | | | | | | |
| Prince Charles Hospital | Non-participant | | | | | | |
| Royal Glamorgan Hospital | Non-participant | | | | | | |

| | Participation status | Crohn's disease patients – time from diagnosis to initial treatment, years, Median (IQR) | Initial treatment Harvey Bradshaw Index, 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 | All patients – PROMs completed at start of treatment |
|---|---|---|---|---|---|---|---|
| Results | | (n=3739)<br>4 (1, 12) | n=2282<br>8 (4, 10) | 68% (502/741) | 53% (1644/3080) | n=1343<br>8% (108) | 30%<br>(1416/4718) |
| **Hywel Dda University Health Board** | | | | | | | |
| Bronglais General Hospital | Participant | n<6 | n<6 | n<6 | n<6 | n<6 | n<6 |
| Glangwili General Hospital | Previous participant but no data entered in past year | | | | | | |
| Prince Philip Hospital | Non-participant | | | | | | |
| Withybush General Hospital | Participant | n=17<br>5 (1, 13) | n=16<br>8 (6, 10) | n<6 | 77% (13/17) | n<6 | 30% (6/20) |

CD = Crohn's disease; IQR = interquartile range; 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 |
| CUCQ-12 | Crohn's and ulcerative colitis questionnaire |
| HBI | Harvey–Bradshaw index |
| HQIP | Healthcare Quality Improvement Partnership |
| IBD | Inflammatory bowel disease |
| IBDU | Inflammatory bowel disease 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 |
| PROMs | Patient-reported outcome measures |
| RCN | Royal College of Nursing |
| RCP | Royal College of Physicians |
| SCCAI | Simple Clinical Colitis Activity Index |
| UC | Ulcerative colitis |

# Appendix 2: Biological therapy audit governance

## Audit governance

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

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

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

## IBD programme steering group members

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

**Association of Coloproctology of Great Britain and Ireland**

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

**British Dietetic Association**

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

**British Society of Gastroenterology**

**Dr Ian Arnott**, clinical director of the IBD programme, chair of the UK IBD audit steering group; consultant gastroenterologist, Western General Hospital, Edinburgh
**Dr Stuart Bloom**, consultant gastroenterologist, University College Hospital, London
Dr Keith Bodger, consultant physician and gastroenterologist, University Hospital Aintree, Liverpool
**Dr Fraser Cummings**, consultant gastroenterologist, University Hospital Southampton
Professor Chris Probert, consultant gastroenterologist, Royal Liverpool University Hospital
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**

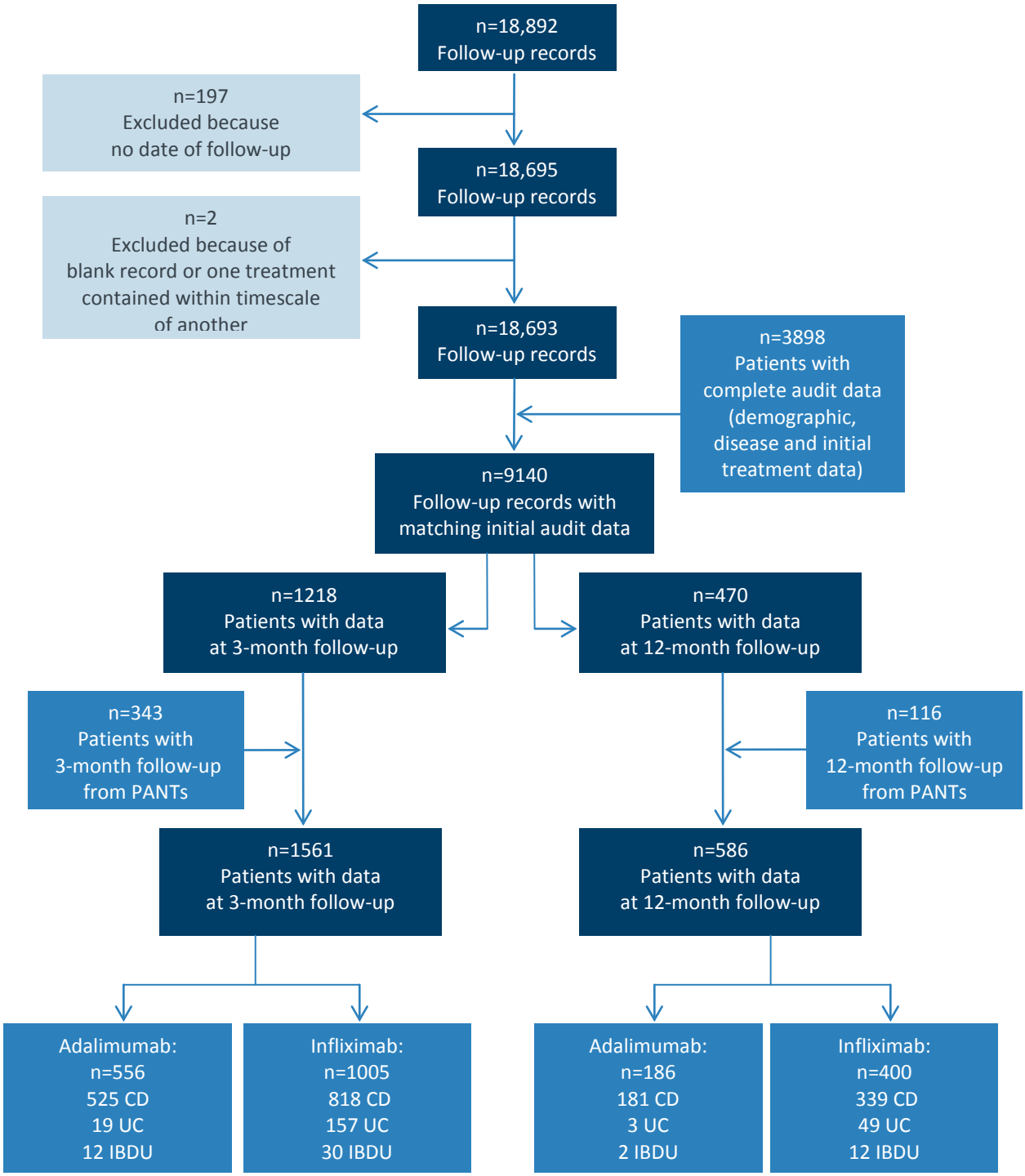
Ms Rhona Buckingham, operations director, CEEU
**Ms Kajal Mortier**, project manager, UK IBD programme
Ms Susan Murray, programme manager, UK IBD programme
Ms Aimee Protheroe, programme development manager, UK IBD disease programme
Dr Kevin Stewart, clinical director, CEEU

**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 adult 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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