Royal College of Physicians | Inflammatory Bowel Disease Programme

Biological therapy

National clinical audit of biological therapies

UK inflammatory bowel disease (IBD) audit

Paediatric executive summary report
September 2015

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

Paediatric

The Royal College of Physicians

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

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Executive summary

Background

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

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

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

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

Key messages

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

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

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

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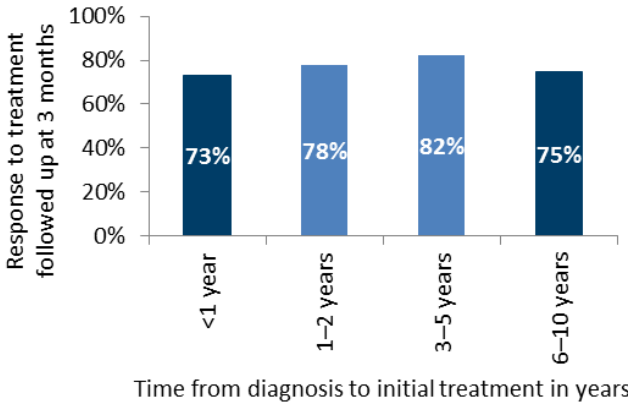
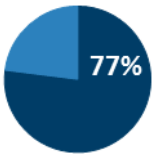
Key findings

Clinical findings

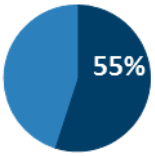
79% of audited paediatric patients were being treated with biological therapies within 2 years of being diagnosed with Crohn's disease (CD). (**Section 5, p 35**)

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





Response to treatment



Remission achieved

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

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

30 **PCDAI** **25**

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

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

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

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

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

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

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Participation findings

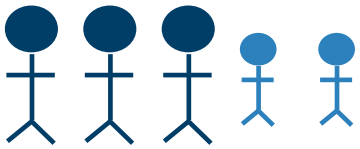
The number of sites engaging with the biological therapy audit since its inception has been gradually increasing:

from 

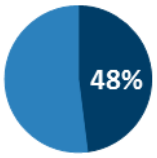
to 

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

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



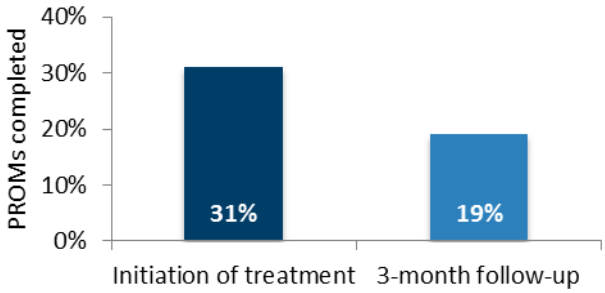
Submission of follow-up data has improved but remains incomplete. (**Section 2, p 19**)



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

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

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



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Recommendations

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

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

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

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

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

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

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

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Implementing change: action plan

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

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

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

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

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References

1 IBD Standards Group, 2013. *Standards for the healthcare of people who have inflammatory bowel disease, IBD standards, 2013 update*. **www.ibdstandards.org.uk** [Accessed 17 July 2015].

2 National Institute for Health and Care Excellence, 2011. Technology appraisal 187: *Infliximab (review) and adalimumab for the treatment of Crohn's disease*. **www.nice.org.uk/guidance/TA187** [Accessed 17 July 2015].

3 National Institute for Health and Care Excellence, 2011. 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 17 July 2015].

4 National Institute for Health and Care Excellence, 2015. Quality standard 81: *Inflammatory bowel disease.* **www.nice.org.uk/guidance/QS81** [Accessed 17 July 2015].

5 Personalised Anti-TNF Therapy in Crohn's disease study (PANTs). **www.pantsdb.co.uk** [Accessed 17 July 2015].

6 Royal College of Physicians, 2014. *National clinical audit of biological therapies. UK IBD audit. Paediatric report*. **www.rcplondon.ac.uk/sites/default/files/national_clinical_audit_report_of_biological_therapies_-_paediatric_report_sep_2014_web.pdf [Accessed 1 September 2015].**

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