

## **UK IBD audit highlights potential huge cost savings of using new biosimilar medicines**

A new report into the use of biological therapies to treat inflammatory bowel disease (IBD) has found that new biosimilar\* medicines, which work in the same way as the more expensive existing treatments, are safe and effective for patients and if adopted can halve the cost of treatment.

Biological therapies are drugs that are produced by a biological rather than chemical process and block the excessive inflammation that occurs in diseases such as IBD, a serious life-long condition causing inflammation to the bowel. This year's national clinical audit of biological therapies for IBD, published by the Royal College of Physicians on behalf of the IBD audit programme today (September 22), is the latest report to assess the use of these therapies in treating the condition.

The audit is the first to include data on new Infliximab 'biosimilar' drugs Inflectra and Remsima, now being used on patients as alternatives to the original Remicade in the treatment of IBD. These drugs have been available in the UK from February 2015 and are designed to have active properties similar to the biological treatment already licensed.

The report finds that biological therapies, which have revolutionised the treatment of IBD, are safe and are increasingly used on patients in the UK. It recommends the adoption of Infliximab biosimilars, as the data indicates they work as well as the original therapies and are far more cost effective to provide. Their use can reduce the cost of treatment from approximately £10,000 per patient per year to less than £5,000.

The audit, which was focused only on patients starting treatment with biologics, found that a fifth of patients are currently receiving Infliximab biosimilars and if the therapy was extended to all patients in the audit it would equate to an annual saving to the NHS of £3 million. The potential overall saving to the NHS could be much higher if patients already established on these therapies also switched to biosimilar substitutes. Remicade is used in the UK to treat a number of serious health conditions including IBD and in 2014 providing the therapy to patients cost the NHS £142 million\*\*.

The majority of hospitals in the UK treating patients with IBD took part in the RCP audit. It included 3,000 patients (adults, children and young people) who began biological therapy treatment in the 12 months to February 2016, the largest number entered in a single year since the audit started in 2011.

The report, commissioned by the Healthcare Quality Improvement Partnership as part of the National Clinical Audit Programme (NCA), highlights that patients continue to benefit from being on biological therapies. These are being adopted earlier in the treatment of patients with IBD and frequency of surgery prior to treatment has reduced (from 36% of adults in 2011 to 15% in 2016). Patients are also reporting improvement in their health and quality of life after starting treatment.

However it also notes with concern that not all patients are pre-screened for infections before undergoing biological therapy treatment. It recommends that full pre-screening in

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line with NICE guidelines\*\*\* takes place with all patients before treatment starts to reduce the chances of an adverse reaction. It also cautions against the over use of steroids in the treatment of IBD and stresses the importance of systematic patient monitoring afterwards to check and record outcomes.

Several areas for improvement and note are contained in the report:

- A need for comprehensive pre-treatment infection screening – Only 60% of adult and 47% of paediatric patients audited had complete pre-treatment screening for opportunistic infections
- Better post-treatment monitoring - Only 31% of adult and 44% of paediatric patients audited in 2016 were recorded as having been followed up at 3 months
- Biological treatments are being used earlier in the disease course. The median time from diagnosis to treatment for adult patients has fallen from 4.5 years in 2012 to 3.8 years in 2016.

Key recommendations include:

- Clinicians should completely screen all patients for infections prior to treatment with biological therapies
- Clinicians should document follow-up in all patients within 3 months and at 1 year following initial treatment with biologics. A record of disease activity should also be captured at these time points using a disease activity index
- Steroid use in all patients should be kept to a minimum. Infliximab has a steroid sparing effect and steroids should be stopped at the first opportunity
- Clinicians must continue to audit all patients on biological therapies to ensure safe and appropriate use.

The 2016 national clinical audit of biological therapies for UK inflammatory bowel disease (IBD), hosted by the Royal College of Physicians (RCP), is the last IBD audit to be undertaken by the inflammatory bowel disease programme. In order to continue to monitor the effectiveness of biological therapies and the impact of treatments on outcomes, quality and patient care, reporting into the IBD registry, where possible, should remain a priority for IBD services.

Dr Ian Arnott, IBD programme clinical director and Consultant Gastroenterologist at Western General Hospital, Edinburgh said: “This report is the first from the UK IBD audit to include data on the safety and effectiveness of biosimilar Infliximab to treat inflammatory bowel disease. The analysis shows that biosimilars are as effective as originals during initial treatment, which is invaluable knowledge for doctors balancing budget restraints with providing the best care for their patients.”

“This will be the final report produced by the UK IBD audit at the Royal College of Physicians. We are currently in the process of transitioning the data collection to the UK IBD Registry. It is hoped this will further drive safe and effective use of these medicines.”

Dr Richard K Russell, Consultant Paediatric Gastroenterologist at the Royal Hospital for Children, Glasgow said: “This report highlights the significant benefits of using biosimilar medicines in adults with IBD are equally applicable to children and young people. It is important that having established this we continue to audit the safety and effects of these

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medicines in the longer term. The significant cost savings that this represents will hopefully now be reinvested into local IBD services to continue to further improve patient care.”

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