



Bowel Disease
Research Foundation



The Association of Coloproctology
of Great Britain and Ireland

ENiGMA Trial Collaborative

Chief Investigator (Surgery) – Nicola Fearnhead

Chief Investigator (Medicine) – Ailsa Hart

Help needed to develop a Core Outcomes Set for perianal Crohn's fistula.

An exciting new collaboration of UK gastroenterologists and colorectal surgeons is seeking to better understand perianal fistulas in Crohn's disease. This collaborative research initiative is being led by Miss Nicola Fearnhead on behalf of the Association of Coloproctology of Great Britain and Ireland and Dr Ailsa Hart on behalf of the British Society of Gastroenterology, and will involve multiple IBD (Inflammatory Bowel Disease) units across the UK. The initial work has been funded by the Bowel Disease Research Foundation and the British Society of Gastroenterologists.

Background

The goal of our research is to work out whether one type of treatment is better than any other. We assess the success of treatments using **outcome measures**. These include things like: 'how much pain patients have after a procedure'; 'whether the medicine given leads to healing of the fistula'; 'improvement seen using MRI scans'; 'side effects of treatment' and so on. Not all studies use the same outcome measures making it hard to compare results of treatments across different studies.

Which outcomes are important should not be determined solely by study doctors or researchers, but rather in concert with patients, IBD nurses and all the other health professionals involved in the care of people with perianal fistula in Crohn's disease. Our aim is to create a group of doctors, IBD nurses and patients who will work out which outcomes should be used in all future studies – **a Core Outcome Set**.

What it involves

Developing a core outcome set involves a Delphi consensus exercise (a 'round-table' approach in which surveys are used to gather opinions from all relevant participants). In this case there will be three groups: Group 1 (patients and their relatives/carers), Group 2 (gastroenterologists and IBD nurses), Group 3 (surgeons and radiologists). Each group will rank each of the outcome measures on a scale of 1-9, with 1 being 'not important' and 9 being 'really important.'

What we will ask you to do

There are three rounds of a short electronic survey. All medical terms will be explained and there is an 'I don't know' option for those that are unsure. In the survey, you will be asked to rank the importance of each outcome measure, based on your own opinion - there are no right or wrong answers. The three rounds will result in an ordered list, indicating what all three groups believe are the most-to-least important outcome measures.

The most meaningful data is from people who complete all 3 rounds, so we really would value your help in seeing the process to the end! Of those that complete all three rounds, a proportion of the



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panels will be invited to an optional face-to-face consensus meeting later this year. Participants who complete all 3 online Delphi rounds will be acknowledged on any publications.

For any further information, please email:

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We would be grateful for your support and hope that together we may work towards improving the lives of patients with perianal Crohn's disease.