the two groups. Patients with active fistulas had significantly more work impairment (median 0.20 vs. 0.10, p = 0.010). Furthermore, patients with active fistulas held more negative views concerning the effects of their illness on daily functioning (adjusted β = 0.78; CI(95%) = 0.28 to 1.27 (95% CI), p = 0.003). No differences were found in coping strategies between the two groups.

Conclusions: Patients with active perianal fistulas have a lower physical health, experience more work impairment and perceived more illness consequences compared with CD patients without perianal fistulas, which is important for the gastroenterologist to consider when treating these patients.

Reference

**P446**

**Patient and public involvement in a clinical trial for perianal Crohn’s fistula**

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Background: The James Lind Alliance agreed a research agenda in inflammatory bowel disease (IBD), involving 400 patients, carers and charitable representatives. “What is an optimal treatment strategy for perianal Crohn’s disease and what individual factors determine this?” was prioritised fifth on the IBD research agenda. This question is now the subject of the Evaluating Goal Directed MANagement (ENiGMA) trial for patients’ with fistulising perianal Crohn’s Disease (pCD).

Methods: Four patient co-applicants have been integral to all meetings and teleconferences of the ENiGMA study group. These patients have influenced trial design and help prioritise outcomes, Figure 1.

Results: (a) Initiation of the trial: A formal patient and public involvement exercise was carried out to present the trial proposal to 23 patients with perianal Crohn’s fistula and to assess their views on all aspects of the study. Patients agreed that a prospective cohort study design would be easy to recruit to, indicating that they may even wish to transfer care between institutions to allow participation. Quality of life and patient-reported outcomes were felt to be important and patients attending felt MYMOP, a method to allow patients to set their own treatment goals, should be introduced into routine clinical practice as a means of exploring patients’ wishes in a structured way. The burden of the suggested questionnaires was deemed reasonable and patients completed the questionnaires within 15 min. In addition, an anonymised perineal photograph, as means of classifying the type/stage of fistulising pCD, was deemed both acceptable and useful. (b) Development of the trial: Two separate workstreams were developed from the initial PPI involvement day. The first was a core outcome set for fistulising pCD, which has recently been submitted for publication and involved 83 patients within one of the three stakeholder groups. The second was the development of a specific Crohn’s anal fistula quality of life (CaF-QoL) score. CaF-QoL is in the second phase (of five) of development and is due to be completed in April 2018. (c) Future directions: The ENiGMA study includes the final consensus of front-running options in trial development; patients will form one of the three stakeholder groups in final trial design. One of our patient representatives (SB) edits the ENiGMA Collaboration’s newsletter.

Conclusions: Patients and representatives of patient groups have been partners in ENiGMA from conception through study development and design, and remain integral to delivery of this study proposal.

Reference

**P447**

**Infliximab trough levels are decreasing overtime in patients with inflammatory bowel disease on maintenance treatment with infliximab**

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Background: The measurement of infliximab trough levels (IFX-TLs) and antibodies to infliximab (ATIs) has been suggested as an important parameter for the optimisation of treatment in patients with inflammatory bowel disease (IBD). We aimed to estimate the patterns overtime of IFX-TLs and ATIs in IBD patients on maintenance treatment with IFX.

Methods: Consecutive patients on maintenance treatment with IFX were included. Two different measurements of IFX-TLs x ATI ATIs were made (ELISA, Eagle BioSciences) with a 10-month interval using serum samples drained before IFX infusion. From the same samples certain biomarkers (haemoglobin, ESR, CRP, platelets, albumin) were measured and at the same time quality of life (SIBDQ) and clinical disease activity [Harvey-Bradshaw index (HBI) for Crohn’s disease (CD), simple colitis activity index (SCAI) for ulcerative colitis (UC)] were assessed.

Overview of the PPI workstream.