

SATURDAY, November 5, 2022

Canada Future Directions in IBD



SESSION I

MEETING OF THE MINDS JUNIOR INVESTIGATOR AWARD PRESENTATION

**CORE-IBD: A Multidisciplinary International Consensus Initiative to Develop a Core Outcome Set for IBD RCTs**

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**Background & Aims:** Endpoints to determine the efficacy and safety of medical therapies for Crohn's disease (CD) and ulcerative colitis (UC) are evolving. Given the heterogeneity in current outcome measures, harmonizing endpoints in a core outcome set (COS) for randomized controlled trials (RCTs) is a priority for drug development in inflammatory bowel disease (IBD).

**Methods:** Candidate outcome domains and outcome measures were generated from systematic literature reviews and patient engagement surveys and interviews. Patients ranked outcome domains of importance, and patients previously participating in an IBD trial completed semi-structured qualitative interviews that focused on understanding the patient journey through an RCT. Subsequently, an iterative Delphi process was conducted to establish consensus: expert panelists anonymously voted on items using a 9-point Likert scale, and feedback was incorporated between rounds to refine statements. Two consensus meetings were held to ratify the core outcome measures. Stakeholders were recruited internationally, and included gastroenterologists, colorectal surgeons, methodologists, and clinical trialists.

**Results:** A total of 235 patients and 53 experts participated. A total of 475 statements were considered. Patient-reported outcomes (PROs), quality of life, endoscopy, biomarkers, and safety were considered core domains; histopathology was an additional domain for UC. In CD, there was consensus to use the PRO2 (abdominal pain, stool frequency), Crohn's Disease Activity Index, Simple Endoscopic Score for CD, C-reactive protein, fecal calprotectin, and a co-primary endpoint of symptomatic remission and endoscopic response. In UC, there was consensus to use the 9-point Mayo Clinic Score, fecal urgency, Robarts Histopathology Index or Geboes Score, fecal calprotectin, and a composite primary endpoint including both symptomatic and endoscopic remission. Safety outcomes should be reported using the Medical Dictionary for Regulatory Activities.

**Discussion:** This multidisciplinary international collaboration involving patients and clinical experts has produced the first COS that can be applied to RCTs of CD and UC. Adoption of this COS will reduce heterogeneity in outcome reporting. The COS defines novel innovations for IBD trial designs, including tapering of corticosteroids during induction and measurement of novel PROs such as fecal urgency, in addition to highlighting areas of research priority for index validation.

Key reference

Ma C, Hanzel J, Panaccione R, et al. CORE-IBD: A Multidisciplinary International Consensus Initiative to Develop a Core Outcome Set for Randomized Controlled Trials in Inflammatory Bowel Disease. *Gastroenterology*. 2022;163(4):950–64.