

# TRANSLATING EVIDENCE INTO PRACTICE THROUGH EVIDENCE-BASED RESOURCES FOR THE MANAGEMENT OF INFLAMMATORY BOWEL DISEASE

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## Background

- ▶ The Value in Prescribing bDMARDs program is a national program for clinicians and consumers to support optimal use of biologics for better health outcomes.
- ▶ A key focus area of the program for inflammatory bowel disease (IBD) is the monitoring of treatment response to guide decision making around subsequent therapy and dose modification.

## Objective

- ▶ To identify the evidence and knowledge gaps around biologic therapy for IBD
- ▶ To develop evidence-based resources to support change in practice.

## Action

- ▶ The consortium-based approach provided a collaborative model for developing a multifaceted program addressing multiple perspectives optimising the use of biologics in IBD.
- ▶ A review of the literature, an online survey and qualitative telephone interviews with IBD specialists and general gastroenterologists were conducted.
- ▶ Knowledge, confidence and practice were reviewed to identify and characterise the barriers and enablers that were likely to influence practice change.
- ▶ Knowledge and evidence gaps identified were:
  - The role of faecal calprotectin in monitoring disease activity.
  - The role of Therapeutic Drug Monitoring (TDM) in the management of IBD and recommendations for the timing of TDM and how TDM guides subsequent treatment choices.

## Evaluation

- ▶ Evidence summaries addressing these gaps were developed by the University of South Australia, with an expert review group.
  - ▶ Two resources were then co-designed with input from expert gastroenterologists and consumers with IBD to:
    - Assist decision-making for health professionals
    - Provide guidance for pharmacists
    - Assist in the delivery of good governance for health service organisations and medicines governance committees.
  - ▶ These resources have been promoted via:
    - Educational visiting with gastroenterologists
    - Professional organisations such as GESA, SHPA
    - CATAG and the jurisdictions
    - Websites
- <https://www.nps.org.au/bdmards/gastroenterology#hp>
- [www.catag.org.au](http://www.catag.org.au)

## Resources

- ▶ Faecal calprotectin and disease activity algorithm for IBD

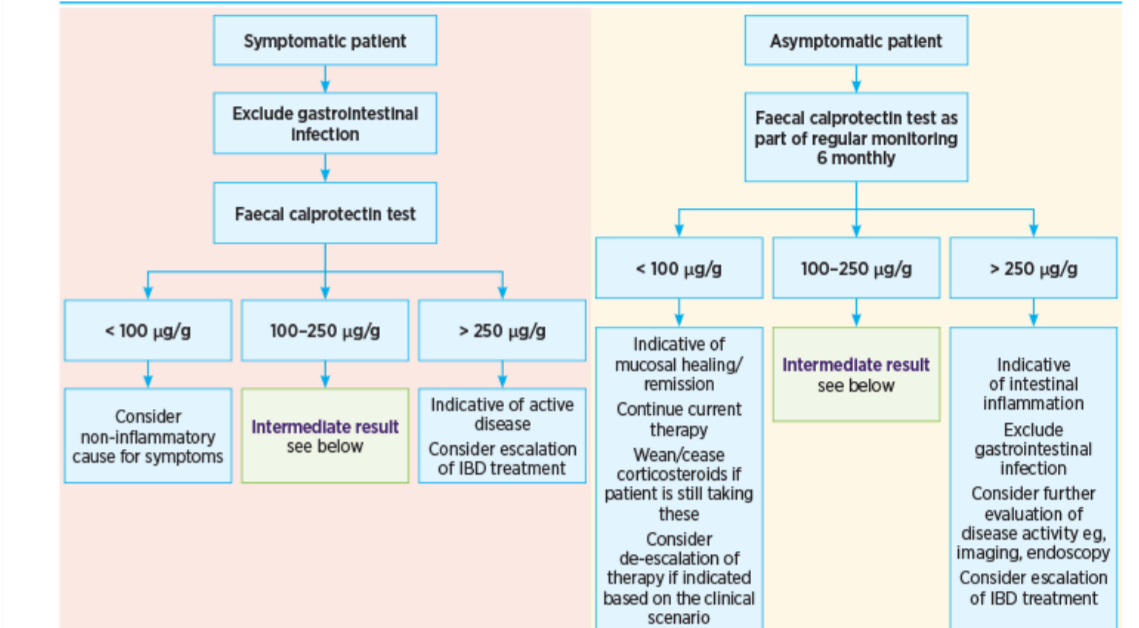
Faecal calprotectin is a surrogate marker of intestinal inflammation which assists in the differentiation of noninflammatory conditions (eg, irritable bowel syndrome) from inflammatory diseases (eg, IBD).

Faecal calprotectin guides the selection of patients requiring further investigations and can be used to assist with clinical decision making in IBD management.

### FAECAL CALPROTECTIN IN INFLAMMATORY BOWEL DISEASE (IBD)

- ▶ Faecal calprotectin (FC) is a surrogate marker of intestinal inflammation which can assist in the differentiation of non-inflammatory conditions (eg, irritable bowel syndrome) from inflammatory diseases (eg, IBD) thereby guiding the selection of patients requiring further investigations.
- ▶ FC can be used to assist with clinical decision making in IBD management.
- ▶ FC levels >100 micrograms correspond to mucosal healing/histological remission in ulcerative colitis (UC) and luminal Crohn Disease (CD).
- ▶ FC prior to therapeutic de-escalation is inversely related to risk of relapse. FC levels >100 micrograms are associated with higher risk of relapse within 1 year.
- ▶ Elevated FC correlates with endoscopic inflammation in UC and CD, with FC levels >250 micrograms differentiating active disease from remission (sensitivity 80%, specificity 62%).
- ▶ In CD affecting the small bowel without affecting the colon, accuracy of FC may be lower; patients with isolated small bowel CD may have normal FC despite active disease.
- ▶ FC levels may begin to rise 3 months before symptoms of relapse become apparent.

### Use of FC in clinical decision making for patients with diagnosed IBD



- ▶ Needs to be interpreted in the clinical context.
- ▶ Check adherence to therapy.
- ▶ Consider the change from baseline and past levels and trends of FC in the individual patient.
- ▶ Consider other factors which can increase FC results (eg, infection, gastrointestinal medications (non-steroidal anti-inflammatory drugs, proton pump inhibitors), excessive alcohol intake).
- ▶ A FC cut-off of 250 micrograms, in conjunction with other indicators of disease activity, has been used to guide dose escalation and de-escalation in a head to head approach.
- ▶ Consider repeating FC test in 2-3 weeks to assess trend (NB: Only one FC/year Medicare-reimbursable item descriptor).
- ▶ Consider FC with more specific investigations eg, imaging, endoscopy.

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- ▶ TDM in IBD factsheet

TDM includes drug trough concentrations and anti-drug antibodies and is indicated in patients with IBD after primary and secondary loss of response and assists with decision making such as dose intensification, change within class or change out-of-class.

Proactive TDM (routine TDM in patients who are clinically well) may be indicated in patients with IBD when considering step down therapy and drug holidays.

The thumbnail for the TDM factsheet features a blue header with the title 'Therapeutic drug monitoring in inflammatory bowel disease' and 'Version 1 - September 2021'. Below the title, it states 'Facilitating the translation of evidence into best practice: Therapeutic drug monitoring in inflammatory bowel disease'. The main content area is divided into 'Key points' and 'Background'. The 'Key points' section lists: 'Therapeutic drug monitoring (TDM) including drug trough concentrations and anti-drug antibodies is indicated in inflammatory bowel disease (IBD) after primary and secondary loss of response', 'After primary non-response, TDM in this circumstance can help to decide if primary non-response is a result of pharmacokinetic issues, from disease refractory to the specific monoclonal antibody', and 'After secondary loss of response, TDM in this setting may guide appropriate intervention that might include dose intensification, change within class or change out-of-class'. The 'Background' section lists: 'TDM of biologic therapy in IBD is being increasingly utilised as a helpful tool to optimise remission rates and prevent relapse', 'Biologic TDM involves the measurement of serum drug concentrations and anti-drug antibody titres', 'TDM is intended to measure drug trough concentrations and therefore is usually performed immediately prior to the next scheduled biologic treatment dose, although for medicines used subcutaneously this may be less important', 'TDM comprises just one aspect of patient monitoring and should be interpreted alongside other relevant clinical, endoscopic, imaging and biomarker findings to aid clinical decision making based on TDM results alone has not been established', and 'Dosing regimen modifications should be tailored to the individual'. At the bottom, it provides contact information for CATAG (Council of Australian Therapeutic Advisory Groups) with phone, fax, email, and website details.

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## Discussion

- ▶ A multidisciplinary evidence-based approach was used to develop resources on the use of faecal calprotectin tests and TDM.
- ▶ These resources will assist hospital pharmacists and other clinicians to provide the most appropriate clinical advice by facilitating optimal monitoring of patients' response to treatment and guide subsequent treatment decisions by clinicians and good governance of biologics for health service organisations and medicines governance committees.
- ▶ Collaboration should promote greater engagement, uptake and impact of these resources.

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### + TARGETED THERAPIES ALLIANCE

Helping consumers and health professionals make safe and wise therapeutic decisions about biological disease-modifying antirheumatic drugs (bDMARDs) and other specialised medicines. Funded by the Australian Government Department of Health through the Value in Prescribing bDMARDs Program Grant.

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CATAG Council of Australian Therapeutic Advisory Groups

In collaboration with:

GESA Gastroenterological Society of Australia

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