

LOCAL PRIMARY CARE GUIDELINES

USE OF FAECAL CALPROTECTIN IN THE
ASSESSMENT OF PATIENTS WITH LOWER
GASTROINTESTINAL SYMPTOMS

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Directive

NICE have recently recommended 'faecal calprotectin testing as...an option in adults with lower gastrointestinal symptoms for whom specialist investigations are being considered, if:

- cancer is not suspected, and
- it is used to support a diagnosis of IBD or irritable bowel syndrome (IBS).....'
(<http://www.NICE.org.uk/dg11>).

Based upon this information, local guidelines are proposed:

Introduction

Calprotectin is released from neutrophils when they degranulate. In inflammatory conditions of the gastrointestinal tract where mucosal neutrophil migration occurs, calprotectin is released into the lumen. It is a stable protein, so can be detected in the stool by an Enzyme-Linked Immuno-Sorbent Assay (ELISA). Faecal calprotectin levels are increased in the context of ischaemia, infection, cancer and Nonsteroidal Anti-inflammatory Drug (NSAID) usage but in particular in inflammatory bowel disease (IBD): Crohn's disease and ulcerative colitis. By contrast, the faecal calprotectin is highly likely to be normal in the irritable bowel syndrome (IBS). Other functional gastrointestinal diseases such as lactose intolerance, bile salt malabsorption and pancreatic exocrine failure are unlikely to affect faecal calprotectin levels. In other conditions such as coeliac disease, bacterial overgrowth and microscopic colitis the role of faecal calprotectin is unknown. There is no role for faecal calprotectin testing in patients presenting where cancer is suspected (18 week commissioning pathway - change in bowel habit. 2008. Available from: <http://www.18weeks.nhs.uk>).

The strength of faecal calprotectin lies in its high sensitivity. The evidence suggests that a normal faecal calprotectin has a sensitivity for excluding organic (non-functional) disease in patients with lower gastrointestinal symptoms of 96%. A normal faecal calprotectin can therefore provide the clinician with a high degree of confidence in supporting a positive clinical diagnosis of IBS when a patient presents with lower gastrointestinal symptoms not suggestive of colorectal cancer. It is hoped that this would reassure the patient, permit confident local management, reduce the need for further investigations and referral to secondary care (<http://pathways.nice.org.uk/pathways/irritable-bowel-syndrome-in-adults>).

The difficulty in using faecal calprotectin lies in the relatively high chance of a false positive result. Local evidence suggests a false positive rate of 30%. This falls to 20% if the test is repeated. However, taken in isolation, a falsely raised faecal calprotectin has the potential to skew clinical decision making and unnecessarily escalate the investigative and referral pathway, so negating any of the benefits of its sensitivity.

Nonetheless it is believed that faecal calprotectin can be used as a risk assessment tool to facilitate in the initial clinical assessment of patients presenting to Primary Care with lower gastrointestinal symptoms. It should be used only as a screening tool, supporting the clinical assessment of the patient. In order to address the strengths and weaknesses of faecal calprotectin it is proposed:

- 1) Setting the normal range at <100mcg/g rather than the standard 50mcg/g. This will reduce the negative predictive power to 90% but increase the positive predictive power to 90%.
- 2) Introduce a two tier referral pathway for patients with an elevated faecal calprotectin:
 - i) Faecal calprotectin 100-250: routine gastroenterology outpatients
 - ii) Faecal calprotectin >250: straight to urgent colonoscopy.

Pathway (see appendix 1)

1. Inclusion criteria:
 - Adult 18-60 years
 - Change of bowel habit where IBS (<http://guidance.nice.org.uk/CG61>) or IBD likely
 - Normal or negative initial workup:
 - FBC
 - U & E, Cr
 - CRP
 - TFT
 - Calcium
 - Coeliac screen
 - Stool culture / *C. difficile* screen as appropriate

2. Exclusion criteria:

1. Cancer suspected (<http://www.18weeks.nhs.uk>)

- in patients aged 40 years and older, reporting rectal bleeding with a change of bowel habit towards looser stools and/or increased stool frequency persisting for 6 weeks or more
- in patients aged 60 years and older, with rectal bleeding persisting for 6 weeks or more without a change in bowel habit and without anal symptoms
- in patients aged 60 years and older, with a change in bowel habit to looser stools and/or more frequent stools persisting for 6 weeks or more without rectal bleeding
- in patients presenting with a right lower abdominal mass consistent with involvement of the large bowel
- in patients presenting with a palpable rectal mass (intraluminal and not pelvic), irrespective of age
- in men of any age with unexplained iron deficiency anaemia and a haemoglobin of 11 g/100 ml or below
- in non-menstruating women with unexplained iron deficiency
 - anaemia and a haemoglobin of 10 g/100 ml or below

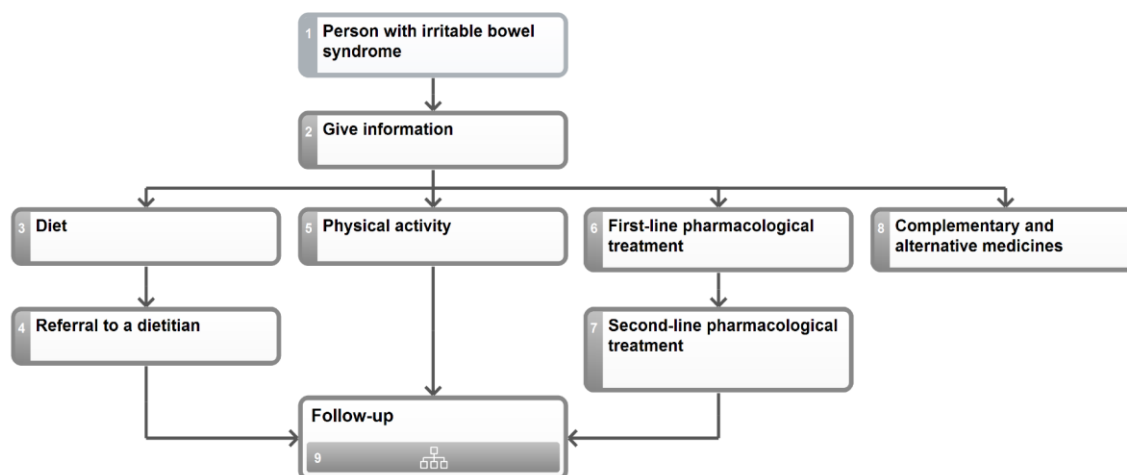
2. Cancer suspected despite not fulfilling fast track criteria.

3. Primary care physician to request faecal calprotectin (laboratory turn around one week):

- <100 mcg/g
- 100-250 mcg/g
- >250 mcg/g

4. Faecal calprotectin <100: IBS likely:

1. This finding supports a positive clinical diagnosis of IBS
2. Treat IBS locally (<http://pathways.nice.org.uk/pathways/irritable-bowel-syndrome-in-adults/managing-irritable-bowel-syndrome>)



3. Review at 8 weeks:

1. Symptoms resolved: continue with local management
2. Symptoms persist: refer to gastroenterology

5. Faecal calprotectin 100-250: role of faecal calprotectin uncertain:

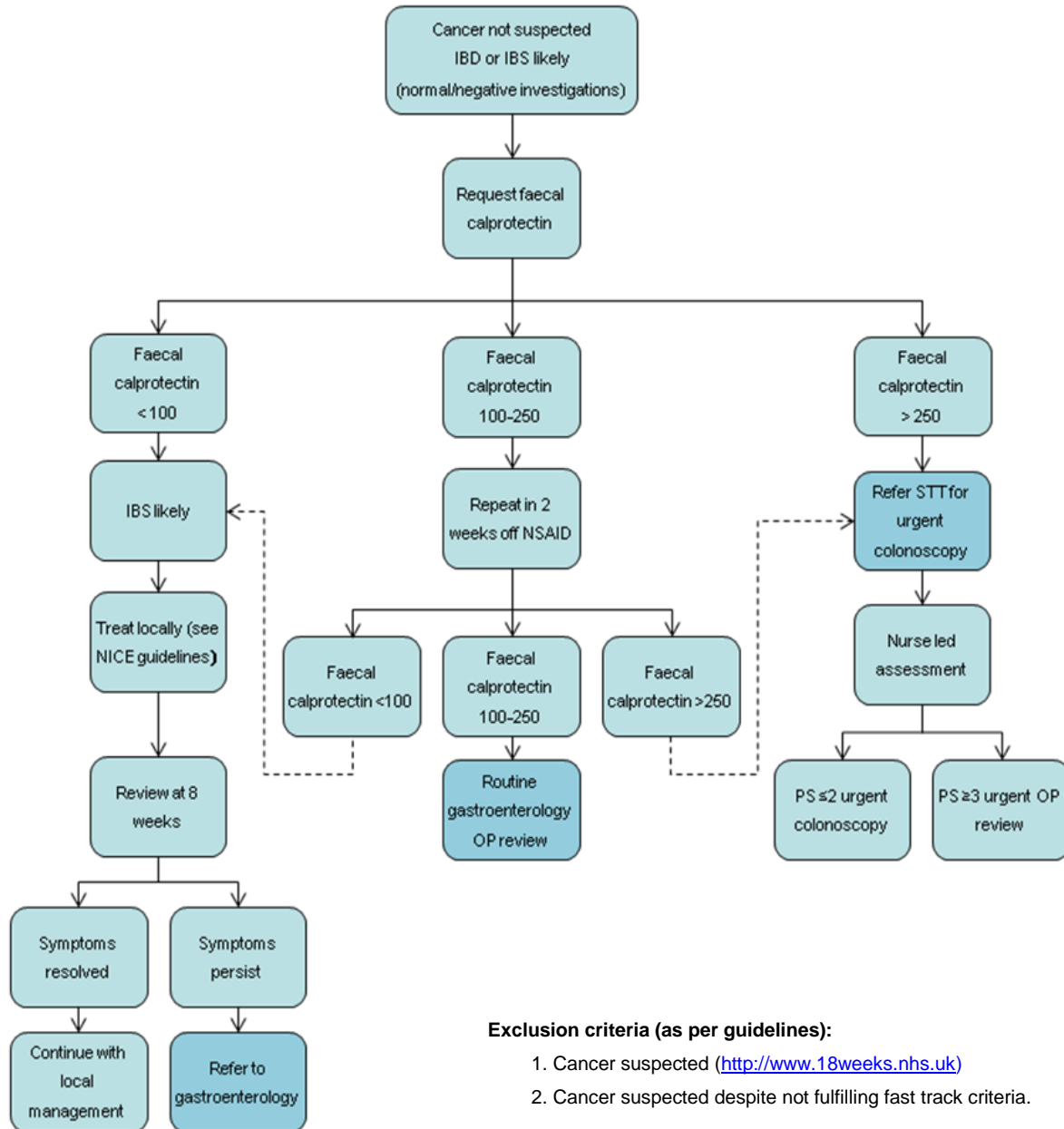
1. Exclude causes for a false positive result
 - 1.1. Avoid NSAID
 - 1.2. Avoid aspirin usage where permissible
2. Repeat faecal calprotectin in 2 weeks:
 - 2.1. <100: treat as IBS likely
 - 2.2. 100-250: refer routinely to gastroenterology outpatients
 - 2.3. >250: refer to straight to test pathway

6. Faecal calprotectin >250: IBD likely:

1. Urgent straight to test consultant colonoscopy
2. Nurse led assessment:
 - performance status
 - antiplatelet therapy: see local guidelines
 - anticoagulation: see local guidelines
 - diabetes: see local guidelines
 - chronic kidney disease: see local guidelines
 - pacemaker: see local guidelines

- co-morbidity: discuss with consultant lead
 - other: discuss with consultant lead
3. Patient performance status ≤ 2 : colonoscopy
 4. Patient performance status ≥ 3 : urgent outpatient review

Flowchart: Patient presents to primary care with lower gastrointestinal symptoms



Exclusion criteria (as per guidelines):

1. Cancer suspected (<http://www.18weeks.nhs.uk>)
2. Cancer suspected despite not fulfilling fast track criteria.

Inclusion criteria:

- Adult 18-60 years
- Change of bowel habit where IBS (<http://guidance.nice.org.uk/CG61>) or IBD likely
- Normal or negative initial workup (FBC, U & E, Cr, CRP, TFT, Calcium, Coeliac screen, Stool culture / *C. difficile* screen as appropriate).