



Adoption support resource – insights from the NHS

Implementation support
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Contents

1 Introduction	3
2 Current practice	5
Diagnosis and management of irritable bowel syndrome	5
Diagnosis and management of inflammatory bowel disease	6
3 Summary of NICE guidance	7
4 Tips from the NHS for adopting faecal calprotectin testing	8
5 NHS adopter sites	9
Adoption site recruitment process	9
6 Insights from the NHS.....	10
York Teaching Hospital NHS Foundation Trust and NHS Vale of York Clinical Commissioning Group.....	10
St George's University Hospitals NHS Foundation Trust and NHS Wandsworth CCG.....	19
7 How to implement NICE's guidance on faecal calprotectin tests for inflammatory diseases of the bowel	23
Project management.....	23
Overcoming implementation hurdles	27
Developing a business case.....	28
Developing local documentation	29
8 The technologies.....	30
9 Acknowledgements	33
10 About this resource	35

1 Introduction

This resource has been developed to provide practical information and advice relating to NICE diagnostics guidance on faecal calprotectin diagnostic tests for inflammatory diseases of the bowel.

It is intended for use by both clinical and non-clinical staff planning to implement this NICE guidance and start using this technology.

Members of NICE's Health Technologies Adoption Programme worked with NHS organisations that participated in a NICE adoption project to share their learning and experiences of implementing faecal calprotectin testing into their care pathways in primary care. The information presented in this resource is intended for the sole purpose of supporting the NHS to adopt or further research faecal calprotectin testing.

The information presented here has not been evaluated by the independent External Assessment Group and was not considered by the Diagnostic Assessment Committee, when making its decision on the use of faecal calprotectin diagnostic tests for inflammatory diseases of the bowel in the NHS.

Faecal calprotectin is a substance that is released in excessive amounts when there is inflammation in the intestines. Its presence can mean that a person has an inflammatory bowel disease, such as Crohn's disease or ulcerative colitis. These conditions can cause very similar symptoms to irritable bowel syndrome. Testing for the presence of faecal calprotectin in the stools can help distinguish between inflammatory bowel diseases and non-inflammatory bowel diseases (for example, irritable bowel syndrome).

Staff and patients from the NHS organisations involved in the adoption project reported that the benefits of using faecal calprotectin include:

- Improved clinical management of people who present with lower gastrointestinal symptoms.
- Greater reassurance and clinical confidence in reaching an accurate diagnosis.
- Reduced anxiety for patients.

The learning gained from the organisations that implemented faecal calprotectin testing in

their primary care pathways is presented as a series of examples of current practice, which do not necessarily fully accord with the guidance. They are not presented as best practice, but as real-life examples of how NHS centres have adopted and used this technology. The examples included in this document that differ from the positive guidance recommendations, such as the manufacturers' recommended cut-off value (see section 4.4 in the guidance on [faecal calprotectin diagnostic tests for inflammatory diseases of the bowel](#)) are presented to help organisations and clinicians to develop appropriate care pathways for local implementation.

The names of the tests used by sites were correct at the time of publication. However, since DG11 published, several of the faecal calprotectin tests mentioned in the guidance document have been renamed. Details of the changes can be found in table 1, appendix 1 of the [guidance review decision](#).

2 Current practice

Chronic abdominal pain or discomfort with bloating, diarrhoea or constipation is common. The symptoms can be caused by several different conditions, including irritable bowel syndrome (IBS) and inflammatory bowel disease (IBD). Getting an accurate diagnosis is essential to managing the condition appropriately.

Diagnosis and management of irritable bowel syndrome

IBS is a common condition of the digestive system and the NICE guideline on [irritable bowel syndrome in adults](#) suggests that it affects 10–20% of people, mostly those aged between 20 and 30 years. It is twice as common in women as in men.

People with IBS report a range of abdominal symptoms that vary in severity and frequency and can be triggered by stress or eating certain types of food. It is an unpredictable, chronic condition that can 'flare up' for several months at a time.

In most cases, the diagnosis of IBS can be made on the basis of clinical history alone. The NICE guideline on [irritable bowel syndrome in adults](#) recommends that people presenting with abdominal pain, bloating or a change in bowel habit for at least 6 months should be asked if they have any 'red flag' indicators such as unexplained weight loss and rectal bleeding. They should also be examined and tested for anaemia, abdominal and rectal masses and inflammatory markers for IBD. People who do not have 'red flag' indicators but whose condition meets the IBS diagnostic criteria should have the following laboratory tests to exclude other diagnoses: a full blood count, an erythrocyte sedimentation rate or plasma viscosity, C-reactive protein and antibody testing for coeliac disease. The next level of investigation involves endoscopy and imaging.

Treatment for IBS involves dietary and lifestyle advice and management of symptoms through medication.

Diagnosis and management of inflammatory bowel disease

IBD is a term used to describe a group of conditions that involve inflammation of the gastrointestinal tract (gut) such as ulcerative colitis and Crohn's disease. It is estimated that IBD affects about 1 in every 250 people in the UK. There are about 120,000 people with ulcerative colitis and 90,000 with Crohn's disease in the UK.

Symptoms for ulcerative colitis and Crohn's disease are similar and can include abdominal pain, recurring or bloody diarrhoea, weight loss, anaemia, extreme tiredness and nausea. IBD can be unpredictable and cause significant disruption to the person's quality of life and social functioning.

These conditions can sometimes have serious complications, including a high risk of surgery and an increased risk of colorectal cancer. In both ulcerative colitis and Crohn's disease some people have active disease but no symptoms.

The NICE quality standard for [inflammatory bowel disease](#) states that people with suspected inflammatory bowel disease should have a specialist assessment within 4 weeks of referral and that there should be local referral pathways to ensure this happens.

There is no cure for IBD and treatment aims to manage and relieve symptoms. An estimated 20% of people with ulcerative colitis have severe symptoms that often do not respond to treatment, and may need to have the inflamed section of their bowel removed.

3 Summary of NICE guidance

NICE diagnostics guidance on faecal calprotectin diagnostic tests for inflammatory diseases of the bowel recommends these tests as an option to support clinicians with the differential diagnosis of inflammatory bowel disease (IBD) or irritable bowel syndrome (IBS) in adults with recent onset lower gastrointestinal symptoms for whom specialist assessment is being considered, if:

- cancer is not suspected, having considered the risk factors (for example, age) described in the NICE referral guideline for suspected cancer **and**
- appropriate quality assurance processes and locally agreed care pathways are in place for the testing.

Faecal calprotectin testing is recommended as an option to support clinicians with the differential diagnosis of IBD or non-IBD (including IBS) in children with suspected IBD who have been referred for specialist assessment, if:

- appropriate quality assurance processes and locally agreed care pathways are in place for the testing.

4 Tips from the NHS for adopting faecal calprotectin testing

- Before implementation, collect baseline data and agree metrics to be collected during and after implementation (see [measuring success](#) for more details).
- Consult all stakeholders to ensure clinical confidence in using faecal calprotectin testing in both primary and secondary care (see [project management](#) for more details).
- Consider implementing faecal calprotectin testing on a pilot basis in a limited number of practices (see [insights from the NHS](#) for more details).
- Agree cut-off values and subsequent local referral pathways to maximise the benefit of the test (see [insights from the NHS](#) for more details).
- Clearly define the patient selection criteria and how many patients will be expected to benefit from the introduction of the test. This will be key to how cost effective the technology will be and will contribute to NHS organisations' case for change and development of a business case (see [insights from the NHS](#) for more details).

5 NHS adopter sites

During the development of this resource, NICE worked with 2 NHS trusts and their clinical commissioning groups in an adoption project for introducing faecal calprotectin testing in primary care. The organisations agreed to provide feedback on their experiences of adopting and using the technology and to collect qualitative and quantitative data.

Adoption site recruitment process

The Health Technologies Adoption Programme (HTAP) worked with Academic Health Science Networks (AHSNs) to identify NHS organisations interested in participating in a NICE adoption project to evaluate the impact of introducing faecal calprotectin testing for inflammatory diseases of the bowel into primary care.

Interested organisations were asked to complete a questionnaire giving information about: their planned implementation, including the proposed scale of implementation; funding arrangements; clinical, organisational and commissioning support; metrics; and progress to date. Organisations were shortlisted for interview on the following criteria:

- identification of a named clinical lead
- preparation or submission of a business case
- allocation of funding within the financial year
- discussions already held with commissioners
- availability of baseline data
- projected number of patients for testing.

Two sites were selected to participate in the project. They each proposed different approaches to their intended adoption of faecal calprotectin testing. NICE did not stipulate the technology to be used or the method of testing.

6 Insights from the NHS

York Teaching Hospital NHS Foundation Trust and NHS Vale of York Clinical Commissioning Group

York Teaching Hospital NHS Foundation Trust provides acute hospital and specialist healthcare services for approximately 800,000 people living in and around York, North Yorkshire, North East Yorkshire and Ryedale – an area covering 3,400 square miles. The gastroenterology service provides diagnosis and management of all gastroenterological conditions including hepatology, inflammatory bowel disease (IBD) and functional gastrointestinal disorders. Vale of York Clinical Commissioning Group (CCG) serves the city of York and the towns of Selby, Tadcaster, Easingwold, Pickering and Pocklington. The area includes 30 GP practices and a population of nearly 350,000 people. It is the main commissioner of gastroenterological services for the York Hospital.

A faecal calprotectin testing service has been available to gastroenterologists in York for secondary care referral since 2004. Between January 2004 and May 2007, the gastroenterology department at York carried out a retrospective feasibility study to determine whether a normal faecal calprotectin in new patients with symptoms could safely predict for functional intestinal disease. They concluded that it did and that it may be a powerful screening tool for excluding organic intestinal disease in primary care. However, there had been some anxieties in the gastroenterology service about extending the use of faecal calprotectin testing to primary care as a result of limited research in this area and uncertainty about the potential benefits and cost effectiveness of the test in this setting.

Vale of York CCG wanted to find out whether introducing calprotectin testing in primary care could be effective for identifying appropriate referrals for secondary care assessment and specialist investigations. The CCG worked with the hospital trust to form a project team for the NICE adoption project that included a consultant gastroenterologist (project lead), the CCG GP lead for planned care, a CCG innovation and improvement manager, the laboratory lead and the deputy directorate manager for acute and general medicine. The team agreed and produced guidelines and a treatment algorithm for faecal calprotectin testing in primary care for GPs in 5 of the 30 practices in the CCG. A 6-month pilot project was planned, followed by an evaluation of the guidelines.

The team decided that faecal calprotectin testing should be offered to people aged 18–60 years presenting to their GP with lower gastrointestinal symptoms, in whom irritable bowel syndrome (IBS) or IBD was likely and whose routine investigations were normal or negative and cancer was not suspected.

The locally produced guideline explains that the strength of faecal calprotectin testing lies in its high sensitivity with a positive faecal calprotectin test result supporting a clinical diagnosis of IBD. The project team proposed that this would reassure patients, allow confident local management and reduce the need for further investigations and referral to secondary care. The guideline acknowledges that the difficulty in using faecal calprotectin testing lies in the relatively high chance of a false-positive result. Local evidence suggests that about 30% of the test results could be false positives. Taken in isolation, a falsely raised level of faecal calprotectin has the potential to skew a GP's clinical decision resulting in patients being unnecessarily referred for further investigations, thereby negating the benefits of its sensitivity. In order to address the strengths and weaknesses of faecal calprotectin testing, the local guideline proposed:

1. Setting the normal range at <100 micrograms/g rather than the manufacturer recommended standard of 50 micrograms/g. This reduces the negative predictive power to 90% but increases the positive predictive power to 90%.
2. Repeating the faecal calprotectin test 2 weeks later (avoiding non-steroidal anti-inflammatory drugs and aspirin if possible) if in the intermediate range 100–250 micrograms/g.
3. Introducing a 2-tier referral pathway for patients with elevated faecal calprotectin:
 1. faecal calprotectin 100–250 micrograms/g: routine gastroenterology in the outpatients department
 2. faecal calprotectin greater than 250 micrograms/g: straight to urgent colonoscopy.

The consultant gastroenterologist provided clinical leadership for the project and visited each of the participating GP practices to advise how faecal calprotectin testing would fit into the treatment pathway for patients and the guidelines to be followed. These visits gave GPs a chance to ask questions about the project or to discuss their concerns. GPs were also told that they could contact the consultant gastroenterologist for advice or support during the project.

All the practices were asked to record on an [audit spreadsheet](#):

- symptoms and provisional diagnosis
- faecal calprotectin results and action
- drug usage that might affect the faecal calprotectin level
- management
- primary care outcomes.

Reminder letters were sent to the practices every 6 weeks asking them to submit their data and updating them on the progress of the pilot.

As part of implementation of faecal calprotectin testing into primary care, sample collection procedures were incorporated into the care pathway. After being given the appropriate request form and sample pot, patients could either take their stool sample directly to the hospital laboratory or leave it with their GP practice from where it would be collected at the same time as their other routine samples. Scheduled collections continued according to the arrangements that were already in place at individual practices (usually once or twice daily collections).

The York laboratory developed a [flowchart](#) for processing stool samples for testing during the pilot. It used the [Buhlmann EK-CAL calprotectin enzyme-linked immunosorbent \(ELISA\)^{\[1\]}](#) quantitative test.

The results of the faecal calprotectin tests were reported in a standardised way throughout the project, using following text:

- For calprotectin results less than 100 micrograms/g – IBS likely. Treat locally and review at 6 weeks.
- Borderline calprotectin 100–250 micrograms/g – stop NSAIDs and repeat in 2 weeks.
- Calprotectin greater than 250 micrograms/g – refer for urgent colonoscopy.

Before the implementation of the faecal calprotectin testing service, patients would have been referred to secondary care unless GPs were certain of an IBS diagnosis that could be managed locally.

An audit was conducted for the 6-month pilot period (March–August 2014). The 5 participating practices were asked to keep a record of all patients who had a faecal calprotectin test, the test results and the outcomes. Data were submitted for 288 patients. The data from 19 people were excluded from the analyses because they did not meet the eligibility criterion of being between 18–60 years to be offered faecal calprotectin testing in primary care (3 were under 18; 16 were over 60). Data were analysed for the remaining 269 people (mean age 37 years). Symptoms on presentation to the GP are shown in table 1, with pain and diarrhoea being the most common. Most people presented with 1 (123, 45.7%) or 2 (111, 41.3%) symptoms.

Table 1 Instances of symptoms in 269 people on presentation to GP

Presenting symptom	Number	%
Pain	142	52.8%
Diarrhoea	134	49.8%
Bloating	77	28.6%
Altered bowel habit	32	11.9%
Bleeding	19	7.1%
Constipation	17	6.3%
Weight loss	3	1.1%
Food hypersensitivity	3	1.1%
Anaemia	2	0.7%
Nausea	1	0.4%
Non-recorded	8	3.0%

Initial normal result (<100 micrograms/g)

Three quarters of people (75.8%, 204/269) had an initial normal faecal calprotectin test result. Of these:

- 64.7% (132/204) continued to be successfully managed in primary care.

- 30.4% (62/204) continued to have symptoms that were not improving and were referred for a specialist assessment or investigations.
- Data were not available for the remaining 10 people.

Regardless of the final diagnostic pathway being in primary or secondary care:

- 85.3% (174/204) had a final diagnosis of IBS.
- None were diagnosed with IBD.
- 10.3% (21/204) received a non-gastrointestinal 'other' diagnosis.
- Data were not available for the remaining 9 people.

Initial borderline result (100–250 micrograms/g)

There was an initial borderline calprotectin result for 13.0% of people (35/269). All of these should have had a second calprotectin test 2 weeks later (in accordance with the local guideline). Thirty-one people were managed according to the protocol with the following results and outcomes:

- 17 people had a normal second test result (less than 100 micrograms/g) and of these:
 - 13 were managed in primary care.
 - 4 continued to have symptoms and were referred for specialist investigations (endoscopy, MRI or CT scan).
 - 16 had a final diagnosis of IBS.
 - 1 was diagnosed with IBD (this person did not have a repeat faecal calprotectin test because their symptoms were such that the GP referred for urgent colonoscopy).
- 13 people had a borderline second test result (100–250 micrograms/g) and of these:
 - 11 continued to have a raised faecal calprotectin on repeat testing and were referred for specialist investigations. Nine of these had a final IBS diagnosis and 2 a non-GI final diagnosis.
 - 2 were managed in primary care with a final diagnosis of IBS.

- 1 person had a high second-test result (more than 250 micrograms/g) and was referred for specialist investigations resulting in an IBS diagnosis.
- 4 people did not have a second faecal calprotectin test. Of these:
 - 1 was referred for endoscopy resulting in an IBD diagnosis.
 - 2 were managed in primary care with an IBS diagnosis.
 - 1 person was lost to follow-up.

Initial high result (more than 250 micrograms/g)

Of those tested, 11.2% of people (30/269) had an initial high faecal calprotectin result and all but 1 were referred urgently for specialist investigations according to the local guidelines. Of these 29 people:

- 8 had a final diagnosis of IBD.
- 14 were diagnosed with IBS.
- 7 were given other diagnoses.

The 1 person who wasn't referred, despite a high result, had campylobacter gastroenteritis that resolved spontaneously, so was not sent for colonoscopy.

Table 2 shows the final diagnosis for all people who had a faecal calprotectin test that fulfilled the local guideline criteria. The faecal calprotectin results used are the final test results for each person.

Table 2 Final diagnosis for all people receiving a faecal calprotectin test

Faecal calprotectin in mcg/g*	IBS	IBD	Other	Unknown	Total
<100 (normal)	190	0	22	9	221
100–250 (intermediate)	13	1	2	1	17
>250 (high)	15	8	8	0	31
TOTAL	218	9	32	10	269

* Final test results (31 people originally borderline received a second test).
Abbreviation: mcg, micrograms.

Table 2 shows that no one with a normal faecal calprotectin result had IBD. An intermediate result was also a low indicator of IBD (1/17, 5.9%). However, one quarter (25.8%, 8/31) of people with a high faecal calprotectin test result had a final diagnosis of IBD.

The initial management pathway leading to the final diagnosis for all people who had a faecal calprotectin test is shown in table 3.

This table shows that the condition in:

- 65.6% of people (145/221) with a normal test result was diagnosed and managed in primary care.
- 85.4% of people (41/48) with an intermediate or high test result was diagnosed following specialist secondary care investigations.

Table 3 Management pathway for all patients receiving a faecal calprotectin test

Faecal calprotectin in mcg/g*	GP	Gastro-enterology outpatient	Investigation [#]	Unknown	Total
<100 (normal)	145	20	46	10	221
100–250 (intermediate)	4	0	11	2	17
>250 (high)	1	0	30	0	31
TOTAL	150	20	87	12	269

* Final test results (31 people originally borderline received a second test).

[#] Endoscopy, MRI or CT scan.

Abbreviation: mcg, micrograms.

The audit was not able to determine how the patients who were referred for a faecal calprotectin test would have been managed and diagnosed if the test had not been available.

Comparator data from the Leeds Teaching Hospital NHS Trust, where faecal calprotectin testing is not used in either primary or secondary care, was available for a cohort of 103 patients. They were referred to secondary care with lower GI symptoms where IBS or IBD were likely and cancer was not suspected. Fifty-five people (53%) had an endoscopy and 2 people were diagnosed with IBD. This gives a diagnostic yield from endoscopic investigations of 3.6% (2/55) for IBD. This is the only 'comparator' data available to assess the diagnostic yield of the locally developed guidelines.

In the York pilot project using locally agreed guidelines for faecal calprotectin testing in 5 primary care practices, 87 people (32.3%) had a specialist investigation (endoscopy, MRI or CT scan) to determine the cause of their symptoms. Of these:

- 10 people (11.5%) had IBD
- 54 people (62.1%) had IBS.

Seventy-three of these people had an endoscopic investigation (65 colonoscopy and 8 flexible sigmoidoscopy). Of these:

- 9 people (12.3%) had IBD
- 49 people (67.1%) had IBS.

This gives a diagnostic yield from endoscopic investigations of 12.3% (9/73) for IBD for people managed in this care pathway.

Feedback was collected about how valuable GPs found faecal calprotectin testing throughout the project. Informal, face-to-face feedback was given by all of the pilot practices. There was positive feedback about the consultant gastroenterologist's visit to each of the practices at the start of the project. The visits provided an opportunity for clinicians to become acquainted with the new care and treatment pathway and with patient selection criteria. It also gave them a chance to discuss any concerns that they had.

A survey of all the GPs in the 5 pilot practices was carried out by the CCG to assess the use of the guidelines for faecal calprotectin testing. Twenty-one GPs completed this and the [results](#) showed a high level of trust in the test results with most (19/21) agreeing that the testing had been useful in making their clinical decision. Eighteen respondents stated that they would continue to use the test in the diagnostic pathway.

A number of common compliance issues were identified during the audit:

- People aged over 60 being included.
- Referring people with high-risk faecal calprotectin directly to a colorectal surgeon, rather than for urgent colonoscopy assessment.
- Not identifying patients' results as being included within the audit on referral.
- Not repeating the calprotectin test in patients with an intermediate risk.
- Not performing other clinically indicated blood and stool tests.

Feedback from the GP survey suggested that education is needed to ensure that the test is used appropriately and the results understood, if the test is to be rolled out on a CCG-wide basis.

Following this pilot, the CCG now needs to reach agreement with the local gastroenterologists and laboratory colleagues on the criteria for faecal calprotectin testing in primary care. The guideline generated 300 referrals for faecal calprotectin testing (269 initial and 31 repeat) across 5 practices in a 26-week period (10 per month per practice). [National general practice profiles](#), from 2013, published by Public Health England, indicate that the 5 practices involved in the pilot project had 28.4% of the CCG's population of people aged 20–60 years. Therefore, if testing were to be rolled out across the CCG, it is likely that there would be more than 2000 requests for faecal calprotectin tests each year from primary care.

The pilot indicates that, with guidance, the test is useful for identifying people with a low risk of IBD, but who have functional disorders that can be managed appropriately in primary care. The project team consider that GPs need greater awareness of the limitations of the test, how to manage the results, when to refer a patient to secondary care and with what urgency to make the referral.

Further learning from York Teaching Hospital NHS Foundation Trust and NHS Vale of York CCG can be found in this NICE [shared learning case study](#) published in 2018.

St George's University Hospitals NHS Foundation Trust and NHS Wandsworth CCG

St George's University Hospitals NHS Foundation Trust serves a population of 1.3 million across southwest London. A large number of services, such as cardiothoracic medicine and surgery, neurosciences and renal transplantation, also cover significant populations from Surrey and Sussex, totalling around 3.5 million people. The gastroenterology and hepatology department specialises in the diagnosis and treatment of conditions of the gastrointestinal tract, liver, pancreas and gall bladder. Wandsworth CCG consists of 43 GP practices with over 368,000 registered patients. It is one of the largest commissioners of services from the trust.

St George's Hospital has historically referred approximately 40–50 faecal calprotectin tests per month to an external laboratory. In 2013, 9 months before the start of the NICE project, this service was moved to the in-house laboratory to reduce both costs and the long turnaround times for results, which had been up to 3 weeks. The in-house service offered the test with a maximum turnaround time of 1 week, which enabled more rapid referral for endoscopy if the test results indicated a diagnosis of inflammatory bowel disease (IBD). The Phadia AB EliA Calprotectin quantitative fluorescence enzyme immunoassay (FEIA)^[1] test was used.

A retrospective review of secondary care gastroenterology clinics at St George's Hospital over a 13-month period (January 2013–January 2014) was carried out. This included all patients aged 16–40 with lower gastro-intestinal symptoms without red flag symptoms who had a faecal calprotectin test. Testing had been requested for 538 patients, and final results were available for 519. Of these results, 183 (35.3%) were abnormal (> 50 micrograms/g, in line with the manufacturer's cut-off value). The results are shown in table 4.

Table 4 Faecal calprotectin testing in secondary care January 2013 to January 2014

Faecal calprotectin (FCP)	Colonoscopy	Flexible sigmoidoscopy	No endoscopy	Total
FCP: normal (<50 mcg/g)	80	55	201	336

FCP: abnormal (>50 mcg/g)	82	52	49	183
Total	162	107	250	519
Abbreviation: mcg, micrograms.				

It should be noted that, as can be seen from table 4, 49 people with abnormal faecal calprotectin results did not have a procedure. The reasons for this are likely to include resolution of symptoms, endoscopy carried out elsewhere, and in some cases an alternative diagnosis being made before endoscopy.

The gastroenterology team considered that before the availability of faecal calprotectin testing, these patients would probably have had an invasive endoscopy procedure.

Local data indicated that the referral and endoscopy numbers were in line with national data, but that these were increasing year-on-year. This prompted the gastroenterology team to propose the introduction of faecal calprotectin testing in primary care as a way of enabling appropriate and fast-tracked referral of patients with a suspicion of IBD to secondary care. It also prevented unnecessary IBS referrals and instead allowed primary care centres to manage the treatment of people in this group. The team was hoping to see a reduction in endoscopies in line with the results from the introduction of the test into secondary care.

The gastroenterology research group had used the AXON database for data specific to Wandsworth CCG to carry out a retrospective analysis of Hospital Episode Statistics data, and assessed referrals to outpatient lower-gastrointestinal specialities (for example, gastroenterology and colorectal surgery) for people aged 16–40. In Wandsworth CCG, for this age group, there has been a consistent annual referral pattern of about 3000 patients to these outpatient specialities.

Through the CCG prioritisation process, the trust's business case to implement faecal calprotectin testing into all 43 GP practices in the CCG with support from 2 laboratories had already been approved. A joint project team was formed, which included a consultant gastroenterologist (project lead), the CCG GP lead, the laboratory leads, and a pathology project manager.

It was decided that calprotectin testing should be offered to people aged 16–40 presenting to their GP with lower gastrointestinal symptoms following a clinical

assessment using Rome III criteria for IBS where a diagnosis is uncertain. A pathway [algorithm](#) was developed and agreed. People aged 16–18 were included because local experience suggested these young people would generally be referred directly to adult services or soon after their initial appointment with paediatric services. People aged over 40 were excluded because the team decided that this group, presenting to their GP with new changes in their bowel habit or other symptoms, would always warrant a referral to gastroenterology for specialist assessment. This algorithm was disseminated across the CCG to all practices with a supporting [letter](#) and additional [information](#) on the test.

GPs were advised that if the faecal calprotectin result was:

- 50 micrograms/g or below (normal), a diagnosis of IBS should be considered along with alternative diagnoses and the patient's condition managed in primary care.
- greater than 50 micrograms/g (abnormal), patients should be referred for investigation of possible inflammatory bowel disease.

The project team reported that GP engagement was a major challenge to the adoption project, particularly in relation to data collection with GPs expressing concerns about data sharing and information governance. Data was collected from the central pathology database in secondary care. Data on follow-up and outcomes of patients who had negative faecal calprotectin results (and therefore not referred to secondary care) were collected from the patient database at each GP practice.

During a 5-month pilot project (March–July 2014) all requests from primary care for faecal calprotectin testing were identified from the local pathology database. Of the 43 practices, 29 made requests for 269 patients to have a faecal calprotectin test during this time. Of these patients, 61 (22.7%) had an abnormal result, compared with 35.3% of the patients tested in secondary care between January 2013 and January 2014. The project team have been unable to assess whether the results of the tests in primary care had an effect on GP decision-making about endoscopy referral.

The St George's and Wandsworth team reported that if other CCGs and secondary care sites wish to introduce faecal calprotectin testing into primary care it is important to work together to engage with practices before implementation. This is particularly important for data collection, because it is helpful to define and agree the data that is to be collected.

At the end of the project the team analysed the St George's endoscopy database for the 8-month period before and the 8-month period after Wandsworth CCG GP practices were

invited to ask for faecal calprotectin testing for people in the target age range (table 5).

Table 5 Lower gastro-intestinal endoscopies before and after introduction of faecal calprotectin testing in primary care for people aged 16–40

	Before (1 April–30 November 2013)	After (1 April–30 November 2014)
Colonoscopies	236	330
Flexible sigmoidoscopies	305	426
Total*	541	756
* It has not been possible to identify the percentage of referrals from Wandsworth CCG practices.		

The project team has been unable to show whether faecal calprotectin testing can reduce the CCG's lower gastrointestinal endoscopy workload for a number of reasons:

- It was not possible to identify which patients were referred from practices in Wandsworth CCG.
- Not all practices in Wandsworth CCG participated in the project.
- Year-on-year growth in lower gastroenterology referrals may be greater than the reduction in referrals following faecal calprotectin testing.
- Faecal calprotectin testing may not influence a GP's decision to refer a patient for specialist assessment.

The project team now plan to continue to educate primary care practitioners about faecal calprotectin and to collect long-term follow-up data on the use of faecal calprotectin testing and its effect on referral patterns.

^[1] Since DG11 published, this test has been renamed. Details can be found in table 1, appendix 1 of the [guidance review decision](#).

7 How to implement NICE's guidance on faecal calprotectin tests for inflammatory diseases of the bowel

The experiences of the 2 NHS trusts who took part in NICE's adoption project have been used to develop practical suggestions for how to implement NICE guidance on [faecal calprotectin diagnostic tests for inflammatory diseases of the bowel](#).

Project management

It is the experience of the Health Technologies Adoption Programme that in order to gain maximum benefit, this technology should be adopted using a project management approach.

NICE has produced the [Into practice guide](#), which includes a section on what organisations need to have in place to support the implementation of NICE guidance.

Project team

The first step in this approach is to form a local project team who will work together to implement the technology and manage any changes in practice.

Individual NHS organisations will determine the membership of this team and how long the project will last. In order to implement this guidance in an effective and sustainable way, consider the following membership of the team:

- Clinical champion(s): could be a consultant gastroenterologist, directorate manager or GP with an interest in gastroenterology. They should have the knowledge and understanding to be able to drive the project, answer any clinical queries and champion the project at a senior level.
- Project manager: could be someone in a clinical or managerial role and will have responsibility for the day-to-day running of the project, coordinating the project team and ensuring the project is running as planned.

- Management sponsor: will be able to help assess the financial viability of the project, drive the formulation of a business case and help to demonstrate the cost savings achieved.
- Other stakeholders or staff: these may include laboratory staff or staff working in the local clinical commissioning group who will be valuable members of the project team because they will be involved in providing the service.

Some of the early questions that the implementation teams involved in this project considered were:

- Which technology will be selected and why; laboratory-based or near patient faecal calprotectin test?
- Where will the funding come from?
- How will local metrics be identified and measured?
- Who will be responsible for collecting the clinical data?
- How will issues surrounding information governance be addressed?
- How will the necessary education or training be provided?
- Are there any obvious challenges and how can these be overcome?
- How can effective communication with all involved be ensured?
- How long should the follow-up period be for those patients who have a negative faecal calprotectin test?
- At what point and how should GP feedback be evaluated?
- How should patient experience data be collected?
- How can awareness of faecal calprotectin testing be raised in primary care?

Communication and collaborative working

Experience shared by NHS sites has indicated that when implementing faecal calprotectin testing in primary care, it is important that there is clear and wide communication between all stakeholders. This will include the gastroenterology department, laboratory staff,

managers and primary care providers. The communication strategy for the project should be considered alongside planned educational activities.

The specific communications may include information on the following:

- Local rationale for using faecal calprotectin testing.
- An explanation of the reporting results and actions to be taken.
- The needs and arrangements for clinical audit.
- Who to contact for further information and how to report problems.

Measuring success

In order to demonstrate the benefits of adopting faecal calprotectin testing it is important to collect data before, during and after implementation. Some of these measures will not routinely be collected, and consideration will need to be given to the data-collection methodology appropriate to the service. Suggested measures from the sites involved in developing this resource are:

- number of patients presenting to GP with lower-abdominal symptoms
- number of patients with negative or low faecal calprotectin test results
- number of patients with indeterminate faecal calprotectin test results
- number of patients with positive or high faecal calprotectin test results
- number of patients diagnosed with irritable bowel syndrome (IBS)
- number of patients diagnosed with IBS referred on for gastroenterology specialist assessment
- number of patients with suspicion of inflammatory bowel disease (IBD)
- number of patients with suspicion of IBD referred for gastroenterology specialist assessment
- number of colonoscopy/sigmoidoscopy/endoscopy procedures undertaken.

Clinical coding

Read codes are the standard clinical technology system used in general practice in the UK. The Read codes are designed to support a fully computerised clinical record of each patient encounter. Codes for abdominal pain, diarrhoea and constipation are often used by GPs for IBS and the IBS diagnostic Read code is rarely used in practice. This has led to a large underestimate of the prevalence of IBS in the community. Sites wishing to implement faecal calprotectin testing into primary care will need to establish the local clinical coding practice.

Table 6 shows the most recent Read codes (released October 2014) relevant for faecal calprotectin testing and IBS diagnosis.

Table 6 Read codes for faecal calprotectin testing and IBS diagnosis

J5211	Irritable bowel syndrome characterised by constipation
J5212	Irritable bowel syndrome characterised by alternating bowel habit
47J0	Faecal calprotectin test indeterminate
47J1	Faecal calprotectin test invalid
47J2	Faecal calprotectin test positive
47J3	Faecal calprotectin test negative

It may be desirable to code patient encounters to 1 of the national statistical classifications such as ICD-10, because this may help with data collection and analysis when looking at both primary and secondary care data. Although there are no ICD-10 codes that could be cross-mapped for faecal calprotectin testing, it is possible to cross-map diagnoses of IBS and IBD using the Read codes shown in table 7.

Table 7 Read codes available for IBS and IBD

XE0as	Irritable bowel syndrome
XabiQ	Irritable bowel syndrome characterised by alternating bowel habit
XabiP	Irritable bowel syndrome characterised by constipation
X305z	Irritable bowel syndrome variant of childhood

X3060	Irritable bowel syndrome variant of childhood with diarrhoea
X3061	Irritable bowel syndrome variant of childhood with constipation
J5210	Irritable bowel syndrome with diarrhoea
XE0ae	Inflammatory bowel disease
X7021	Juvenile arthritis of inflammatory bowel disease
X702C	Seronegative arthritis secondary to inflammatory bowel disease
XSE1V	Idiopathic chronic inflammatory bowel disease

Further information about Read Codes and cross mapping is available from the [Health & Social Care Information Centre](#).

Overcoming implementation hurdles

The implementation challenges reported by the 2 NHS sites using faecal calprotectin testing in primary care are set out in table 8.

Table 8 Reported implementation challenges when using faecal calprotectin testing in primary care

Implementation challenge	Solution
Capturing and measuring appropriate data from both primary and secondary care to demonstrate the impact of faecal calprotectin testing.	Use of appropriate Read codes and ICD-10 codes. Ensure accuracy of coding data at trust level. Obtain good-quality GP and patient feedback.
Clinical confidence	Select appropriate metrics to demonstrate cost and clinical benefits, safety and demand. Provide adequate training, information and evidence base for testing.

<p>Risk management</p>	<p>Securing engagement from primary and secondary care can be challenging and can pose a significant risk to successfully completing the project.</p> <p>Ensure that there is an effective <u>communication plan</u> in place to help stakeholders become and remain engaged with the project through to fruition.</p>
<p>Financial resources</p>	<p>Securing the necessary <u>funding</u> may need a collaborative approach from both primary and secondary care.</p> <p>Balance consideration of the loss of income from reduced referrals for gastroenterology specialist assessment against the potential to reduce endoscopy waiting lists for secondary care.</p>

Developing a business case

Resource impact

Laboratories at each of the project sites secured additional funding to enable them to order the consumables needed for faecal calprotectin testing for primary care referrals during the pilot.

Both were already offering faecal calprotectin testing following secondary care referral, so the service infrastructure was already in place. Following evaluation of the project data, it may be necessary for both laboratories to prepare business cases to secure long-term funding for their pathology budget if they plan to extend faecal calprotectin testing to the whole of their primary care catchment areas.

Each of the laboratories involved in the project negotiated the costs of the tests with their respective suppliers. It is expected that if their use of faecal calprotectin tests increases significantly, these costs will be reconsidered.

Business case

The implementation team should treat the development of a robust business case as an early priority in the life of the implementation project.

Local arrangements for developing and approving business plans will vary from trust to trust and each organisation is likely to have its own template and process in place. The organisations involved in the development of this resource advised NICE on the development of a [template business case](#) for faecal calprotectin.

Developing local documentation

The following are examples developed by NHS organisations using faecal calprotectin testing in primary care that can inform the development of local documentation.

Guidelines and algorithms:

- St George's University Hospitals NHS Foundation Trust: [Algorithm for the use of faecal calprotectin in general practice in patients presenting with lower gastrointestinal symptoms](#)
- York Teaching Hospital NHS Foundation Trust: [Local primary care guidelines for the use of faecal calprotectin in the assessment of patients with lower gastrointestinal symptoms](#)
- Wandsworth CCG: [Invite to GPs to take part in faecal calprotectin pilot](#)
- St George's University Hospitals NHS Foundation Trust: [Introduction to faecal calprotectin for GPs](#)
- York Teaching Hospital NHS Foundation Trust: [Laboratory faecal calprotectin testing process](#)
- NHS England [consensus guidance document](#): The use of faecal calprotectin in primary care as a decision diagnostic for inflammatory bowel disease and irritable bowel syndrome.

Audit templates:

- York Teaching Hospital NHS Foundation Trust: [Faecal calprotectin audit template](#).

8 The technologies

Several faecal calprotectin tests are available to the NHS in England, including fully quantitative laboratory-based technologies (many of which use an enzyme-linked immunosorbent assay [ELISA] platform), fully quantitative rapid tests and semi-quantitative point-of-care tests (POCTs). Table 9 details the 12 tests that are included in the guidance. The reference standard was histology after endoscopy.

Table 9 Faecal calprotectin technologies included in the assessment for guidance^[2]

Manufacturer	Test	Platform
Buhlmann	EK-CAL calprotectin ELISA test	ELISA – quantitative Range (depending on dilution): 10–600 mcg/g 30–1800 mcg/g.
Buhlmann	LF-CAL25 Quantum Blue calprotectin test	Rapid test – immunoassay designed for the quantitative determination of faecal calprotectin in combination with the Buhlmann Quantum Blue reader. Range: 30–300 mcg/g.
Buhlmann	LF-CHR 25 Quantum Blue calprotectin test	Rapid test – immunoassay designed for the quantitative determination of faecal calprotectin in combination with the Buhlmann Quantum Blue reader. Range: 100–1800 mcg/g.
Calpro	CALPRO CALPROTECTIN ELISA TEST (ALP) – formerly known as the Phical test CAL0100	ELISA – quantitative Range: up to 1250 mg/kg.

Calpro	CALPROLAB CALPROTECTIN ELISA (ALP) – formerly known as the Phical test CALP0170	ELISA – quantitative Range: up to 2500 mg/kg.
Eurospital	Calprest	ELISA – quantitative.
Eurospital	CalFast	Rapid test – quantitative determination of faecal calprotectin in combination with a dedicated reader.
Immundiagnostik	ELISA (K 6927)	ELISA – quantitative.
Phadia AB, part of Thermo Fisher Scientific	EliA Calprotectin	EliA – quantitative Quantitative fluorescence enzyme immunoassay (FEIA) test. Range: 15–3000 mg/kg.
Preventis (sister company to Immundiagnostik)	KST11005 PreventID CalDetect Calprotectin Rapid test (version 1 – Caldetect)	POCT – immunochromatographic rapid test. A semi-quantitative test with 3 lines corresponding to: Calprotectin 'negative' Calprotectin ≤ 15 mcg/g Calprotectin 16–60 mcg/g Calprotectin > 60 mcg/g stool.
Preventis (sister company to Immundiagnostik)	KST11004 PreventID CalScreen Calprotectin Rapid test (version 3 – CalScreen)	POCT – immunochromatographic rapid test. A yes/no test with only 1 test-line corresponding to the cut-off value of 50 mcg/g stool (no inflammation = < 50 mcg/g and inflammation present = ≥ 50 mcg/g).
Abbreviations: ELISA, enzyme-linked immunosorbent assay; mcg, micrograms; POCT, point-of-care test.		

While assaying calprotectin, laboratories should be aware of the lack of international standardisation (as demonstrated by the between-assay variability), of the high biological variation and of the criticality of the extraction.

For further details and up-to-date costs please contact the relevant company.

Contact details

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^[2] The names of the tests used by sites were correct at the time of publication. However, since DG11 published, several of the faecal calprotectin tests mentioned in the guidance document have been renamed. Details of the changes can be found in table 1, appendix 1 of the [guidance review decision](#).

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10 About this resource

The NICE Health Technologies Adoption Programme produces practical advice on adopting health technologies in the NHS in England.

NICE's Health Technologies Adoption Programme recruited, selected and worked with 2 NHS organisations to share their experience of using faecal calprotectin testing with organisations that may wish to use it in the future. The information gained from these NHS organisations and included in this resource is intended for the sole purpose of supporting the NHS in adopting or researching faecal calprotectin testing.

The information was not assessed by the Independent External Assessment Group or considered by the Diagnostics Advisory Committee when making its decision on the use of faecal calprotectin testing as an option to support clinicians with the differential diagnosis of inflammatory bowel disease (IBD) or irritable bowel syndrome (IBS) in adults with recent onset lower gastrointestinal symptoms for whom specialist assessment is being considered.

This resource accompanies the NICE diagnostics guidance on [faecal calprotectin diagnostics tests for inflammatory diseases of the bowel](#). It was developed using the NICE Health Technologies Adoption Programme process. It is an implementation tool that discusses and summarises the experiences reported by staff at NHS sites who have previously adopted this technology, and it shares the learning that took place.

Implementation of the guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this document should be interpreted in a way that would be inconsistent with compliance with those duties.

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