

Faecal Calprotectin

Faecal Calprotectin testing in Primary Care

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EXECUTIVE SUMMARY

This report relates to an implementation project for faecal calprotectin (FCP) undertaken in two North East Clinical Commissioning Groups (CCGs) within Northumberland and Durham Dales during 2011/12. The aims of the project were primarily focussed on using either point of care (POC) or laboratory based FCP testing to assist GPs to better differentiate between irritable bowel syndrome (IBS) and suspected irritable bowel disease (IBD). The objectives of the project were:

- To effect an improvement in the quality and productivity of the NICE patient pathway for the diagnosis and management of IBS in primary care
- To enable improved management of endoscopy services through reduced referrals to secondary care
- Improve patient experience through quicker diagnosis and treatment decisions
- To realise potential cost savings in commissioning endoscopy services for suspect IBS/IBD
- To avoid referral of patients with IBS to secondary care and thus avoid unnecessary invasive tests
- To identify and fast-track patients with significant organic gastrointestinal (GI) pathology to secondary care.

The NHS Technology Adoption Centre (NTAC) had been commissioned by the Department of Health to support the implementation of FCP testing in these two CCGs. The project commenced prior to NTAC becoming involved and unfortunately no pre implementation baseline data was available to accurately measure the impact of the project. Some of the data collected during the work has however allowed calculation of cost savings to be made in the order of £730 per patient (this was calculated on 2012/13 tariff (outpatient + day case endoscopy) minus the cost of the disposables). It should be remembered that 79,000 patients are diagnosed with IBS every year in the UK.

Making a diagnosis of IBS or IBD can be difficult and frustrating both for patients and clinicians due to the similarities in clinical symptoms. Correct diagnosis is important however as management and treatment for IBS and IBD are different. Where IBS is diagnosed, patients will receive lifestyle and dietary advice with appropriate medication to treat symptoms, whilst those patients with a suspicion of IBD will be referred to gastroenterology for specialist assessment, along with further tests and interventions including endoscopy.

FCP is a simple diagnostic test which can aid clinicians to more accurately identify those patients who have IBS and those who have a high probability of IBD who will require urgent referral for specialist assessment. Through the emergence of rapid point-of-care tests, in addition to the traditional enzyme linked immunosorbent assay (ELISA) testing technologies, access and usability of FCP testing is becoming more widely available and easier to integrate into clinical practice within primary care. Clearly, a simple, reliable, reproducible, and non-invasive test, with the ability to differentiate IBD from other gastrointestinal conditions, such as IBS, would be of substantial benefit.¹

IBS is reported to have a prevalence in the general population of more than four million people, with most of these affected being between 20 and 30 years of age. However, more recently, IBS appears to be increasing with a significant prevalence in older people.

IBD covers a number of chronic and relapsing conditions, with two of the most common forms of IBD being ulcerative colitis and Crohn's Disease. Both of these conditions have a profound impact on the lives of about 240,000 patients, approximately 400 patients per 100,000 population in the UK.

¹ Sutherland, AD; Geary, RB; Frizelle, FA. (2008) Review of fecal biomarkers in inflammatory bowel disease. Dis. Colon Rectum. Vol 51. Pp 1283 – 1291.

The cost of IBD to the NHS has been estimated at about £720 million annually, based on the prevalence and average cost of £3,000 per year per patient^{2 3}.

The financial costs, as well as the impact that both IBS and IBD have on patients, is significant. By implementing FCP testing within clinical pathways in Northumberland and Durham Dales CCGs, it was anticipated that many patients who received a diagnosis of IBS would be spared from undergoing more invasive procedures such as endoscopy. If this could be shown to be true it would also potentially contribute towards reducing waiting lists for these procedures, which would in turn positively impact on those patients whose symptoms or diagnosis warrant referral for specialist assessment.

In Durham Dales, nine patients who had a low FCP result and 34 with a high FCP result were referred for endoscopy (43). Of these 43 patients, 33 (77%) actually had an endoscopy, five (15%) had no abnormality, five (15%) were diagnosed with IBS, 12 (36%) had IBD, one (3%) had cancer and the remainder (30%) had a range of other diagnoses.

In Northumberland, three patients who had a “green” FCP result, i.e. low risk, four patients who had an “amber” FCP result, i.e. medium risk and 15 patients with a “red” FCP result, i.e. high risk, were referred for endoscopy (22). Of these 22 patients, only three (14%) had IBD, the remainder (19) receiving other diagnoses including IBS.

As a number of patients with low FCP results were referred for specialist care it is difficult to conclusively demonstrate that the introduction of FCP in Durham Dales and Northumberland has diverted all patients with IBS from an unnecessary endoscopy as was originally envisaged.

In Northumberland, three patients (7%) who had “green” results were still referred. Records indicate that one of these patients was over the age of 60 years but no reason for referral can be found for the remaining two patients. In Durham Dales, nine patients (11%) with a low result were still referred. It should be remembered however that FCP is an aid to diagnosis and the referrals would have been made on the basis of a clinical assessment too, which for some patients may have caused GPs to be considering other diseases e.g. malignancy or the presence of other ‘red flag’ symptoms which under NICE guidance would warrant a referral.

Following a survey of all GP practices, GPs felt the benefits of FCP testing to be:

- Provides additional reassurance for patients who may have anxiety or uncertainty about IBS or IBD
- Reduced number of referrals from those tests which have been clearly negative. During this project, a total of 129 patients were spared from referral to secondary care
- Identified cases for referral that may not previously have been clinically indicated
- Greater confidence in diagnosing IBS within primary care without the need for endoscopy.

Patients from this project reported positively about FCP testing as part of their overall clinical assessment. Following their consultation, 94% of patients reported that they had an improved understanding of their condition and 92% of patients felt able to keep themselves healthy following the consultation. Positively, all of the patients who responded reported that the person they had seen really listened to them, showed an holistic interest in them, showed care and compassion and fully understood their concerns. Whilst not a formal research trial, NTAC feels that this work is highly suggestive that FCP is a useful tool in the diagnosis of IBS within primary care.

² Luces, C; Bodger, K (2006) Economic burden of inflammatory bowel disease: a UK perspective. Expert Review of Pharmacoeconomics and Outcomes Research. Vol 6. No 4. Pp471-482.

³ Cummings, JFR; Keshav, S; Travis, SPL (2008) The management of Crohn’s Disease. British Medical Journal. Vol 336. Pp1062-6.

INTRODUCTION

FCP is a simple, non-invasive diagnostic test which is undertaken using patients' stool samples to measure the levels of calprotectin present. Calprotectin levels have been shown to be a marker of bowel inflammation and can therefore be used as a tool, along with clinical assessment, to determine if patients have IBS or require referral to secondary care for further investigations to determine if they have IBD. Due to its ability to remain stable against bacterial degradation, it is possible for samples to be kept up to five days without any effect on the testing process or results. Calprotectin offers a diagnostic accuracy that other tests such as serological tests (ESR, CRP) are not able to provide. This is due to their inability to measure bowel inflammation specifically and these tests can be influenced by a number of other non-intestinal diseases.

It is estimated that more than four million people suffer from IBS in the UK, with approximately 79,000 new cases being diagnosed each year. It has also been estimated that 57% of the prevalent population have consulted a healthcare professional about their symptoms in the past six months, although it is acknowledged that realistically this figure may be much higher if looked at over a 12 month period. Patients will often suffer from symptoms for a long period of time before consulting health professionals as many may find discussions embarrassing.

There is no one definitive blood or stool test that is able to conclusively diagnose IBS. Diagnosis occurs as a result of an assessment to identify what symptoms the patient is experiencing. The National Institute for Health and Clinical Excellence (NICE) guidance⁴ suggests that initial assessment should include:

- Abdominal pain or discomfort
- Bloating
- Change in bowel habit

NICE⁴ also recommend that a diagnosis of IBS should only be considered if the person has abdominal pain or discomfort that is either relieved by defecation or associated with altered bowel frequency or stool form. This should be accompanied by at least two of the following symptoms:

- Altered stool passage
- Abdominal bloating
- Symptoms made worse by eating
- Passage of mucus

Furthermore, all people presenting with possible IBS symptoms should be assessed and clinically examined for 'red flag' indicators which are:

- Unintentional/unexplained weight loss
- Rectal bleeding
- Family history of bowel or ovarian cancer
- Change in bowel habit to looser and/or more frequent stools persisting for more than six weeks in a person aged over 60 years

It has been reported that implementing the NICE guidance will lead to savings of £6.7 million through reducing unnecessary tests⁵.

⁴ National Institute for health and Clinical Evidence. (2008) Irritable bowel syndrome in adults. CG61. www.nice.org.uk/CG061

⁵ National Institute for Health and Clinical Excellence (2008) Irritable bowel syndrome: Costing Report; Implementing NICE guidance. CG61. www.nice.org.uk/CG061

FCP testing offers an additional tool to aid clinicians, along with their clinical assessment, to identify those patients who are likely to have IBS and can therefore leave the assessment for IBD pathway at an earlier time. This should result in many patients being spared from invasive investigations (e.g. endoscopy) where it is likely that a negative result will be found.

Those patients found to have a high probability of IBD through FCP testing can be referred without delay for further investigations. The FCP test can be used by clinicians in conjunction with existing tests i.e. ESR (erythrocyte sedimentation rate) to help them in their clinical decision making.

SCOPE

This document focuses on the experience gained from two CCGs in the North East of England, covering multiple GP practices that used either point of care or laboratory based FCP testing technologies to assess patients for IBS with FCP. The author recognises that the effect on the patient care pathways will be dependent on whether the technology is introduced within a primary care environment or, alternatively, within secondary care pathology laboratories.

This report is intended to provide guidance for those NHS organisations planning to implement FCP testing. It does not identify any specific products or recommend any preference between point of care testing and laboratory based testing arrangements. Appendix 5 summarises the different FCP testing technologies available on the market detailing manufacturers and UK distributors, the technology employed, costs and training requirements. This report is limited to those products identified through market research; it is possible that other manufacturers and equipment are available but are not known to NTAC. It is the responsibility of individual trusts, in discussion with their own clinical experts, to select the most appropriate equipment based upon the evidence available, clinical opinion, cost and system considerations.

This report gives a clear and concise account of the project undertaken and, by outlining and drawing from the experiences gained from the GP practices involved in this project; it provides recommendations on how others could learn from this experience.

Specifically excluded from the scope of this document is the use of FCP testing for use in the disease monitoring of IBD patients. It is acknowledged, however, that there is a significant research interest and a developing evidence base in this area. Appraisal of the available evidence is not in the scope of this report.

BACKGROUND TO THE PROJECT

In 2009, the Department of Health set up the Innovative Technologies Adoption and Procurement Programme (iTAPP) which was established to encourage NHS-wide adoption of high impact innovative medical technologies that could increase the quality of care provided to patients, whilst reducing the overall cost of care.

The Department of Health invited medical technology companies to submit details of specific medical technologies which could contribute to iTAPP. In total over 100 submissions were received from over 50 manufacturers.

NTAC was commissioned by the Department of Health to support Strategic Health Authorities (SHAs) in NHS England with the delivery of iTAPP. The North East SHA planned to implement an FCP test from the iTAPP list of technologies and requested assistance from NTAC with programme support; including the identification of metrics.

NTAC joined the project after the implementation of FCP testing had started in two Clinical Commissioning Groups (CCGs) in the North East of England. Both West Northumberland and Durham Dales CCGs were using the FCP testing within routine clinical practice. Since the start of the project, West Northumberland has expanded its testing, which now covers the whole of Northumberland.

Durham Dales CCG used a semi-quantitative point of care FCP test designed for use in this setting with the analysis being carried out in each of their GP practices.

West Northumberland CCG used a fully quantitative test with samples being analysed in the laboratory. Whilst it is technically possible to use laboratory equipment to conduct point of care test in primary care, it is unlikely that this would be economical in practice due to cost and the size of the equipment.

Irrespective of testing arrangements, patients from both sites followed identical arrangements for returning their stool samples to their GP practice.

WHAT IS FAECAL CALPROTECTIN TESTING?

CURRENT PRACTICES AND PATHWAYS

The information in this section has been largely based on NICE Clinical Guideline 61: Irritable Bowel Syndrome in Adults, Diagnosis and management of irritable bowel syndrome in primary care. At the start of the project, both areas produced and implemented revised diagnosis and management pathways, including FCP testing, which was to be used by GPs when patients presented with symptoms of IBS/IBD.

West Northumberland Primary Care IBS Pathway

The FCP testing was available for all patients who were registered at West Northumberland GP practices. The full revised pathway used in West Northumberland can be found in Appendix 1. When patients returned their stool samples to the GP practices, they were sent on to the secondary care laboratory for FCP testing to be carried out. The FCP results were sent to individual GP practices in the same way as other test results.

The FCP test results were categorised into three groups with the following cut off values as follows:

- FCP Green <30ug/g
- FCP Amber >30ug/g to < 70ug/g
- FCP Red >70ug/g

The cut off values were agreed between all of the stakeholders involved.

Patients presenting in primary care with IBS and IBD have very similar symptoms, which can make diagnosis difficult. The patient is initially assessed for the following symptoms which indicate that IBS is likely:

- Abdominal pain or discomfort which is
 - Relieved by defecation or associated with altered bowel frequency or stool form
- And at least two of the following
 - Altered stool passage (straining, urgency, incomplete evacuation)
 - Abdominal bloating, distension, tension or hardness
 - Symptoms made worse by eating
 - Lethargy, nausea, backache and bladder symptoms may support diagnosis

If the above symptoms are identified, then FCP testing is recommended. Patients are given a sample container along with a Patient Information Leaflet (Appendix 3) and are asked to return their faecal sample to the GP Practice where it will be sent to the Pathology Laboratory at Wansbeck Hospital for FCP testing. Other tests (Full Blood Test, ESR, CRP (C-reactive protein), tTG (tissue transglutaminase)) may be performed at this time or following the return of the FCP test. Patients are requested to cease taking NSAIDs (nonsteroidal anti-inflammatory drugs) four weeks prior to FCP testing.

Where symptoms such as unintentional weight loss, rectal bleeding, anaemia, abdominal or rectal mass or a family history of bowel or ovarian cancer exist or if the patient is over 60 years of age then the pathway instructs GPs to consider a referral to a consultant, with the stipulation of the two week referral rule, if cancer is suspected.

Where FCP is “green” then this indicates that patients probably have IBS and there is a low probability of IBD. Following a negative FCP test result, GPs will give patients a lifestyle and dietary advice sheet and will encourage patients to take physical activity. GPs may decide to refer patients to a dietician for advice and may prescribe antispasmodic medication to help control patients’ symptoms. Where the FCP result is indeterminate then the pathway indicates that a further FCP test needs to be repeated in four weeks. Where the FCP test is then negative, the patient is managed as above, otherwise, if the repeat FCP test is indeterminate or positive and symptoms persist, the pathway recommends referral to a consultant.

Where the FCP test is “amber”, this indicates that there is a moderate probability of IBD and referral to consultant is recommended. For those patients whose FCP test is “red” this indicates a high probability of IBD and these patients are referred on a fast-track to be seen by a consultant which should occur within two weeks.

NICE guidance states that where symptoms have persisted for more than six months then a consultant referral should be considered. NTAC’s experience suggests that the six month minimum timeframe is more relaxed in clinical practice dependent on the severity of the patient’s symptoms. There is a suggestion that GPs may be referring patients on the basis of symptoms rather than timescale.

Durham Dales

The FCP testing was available for all patients who were registered at Durham Dales GP practices. The care pathway for Durham Dales, where the POC FCP testing was implemented, is almost identical to the one used in Northumberland. The main difference is that, for the POC testing, patients are required to return their sample to the GP practice; the faecal sample is tested on the premises rather than sending it to the laboratory. Patients taking NSAIDs were instructed to cease their medication for a period of two weeks prior to taking the FCP test.

The FCP test results were also categorised into three groups but the cut off values differed from those used in Northumberland. Durham Dales used the following cut off values:

- FCP negative <15ug/g
- FCP indeterminate 15-60ug/g
- FCP positive >60ug/g

The cut off values were determined by all of the stakeholders through discussion with other areas that were already using FCP testing and had tried and tested various values.

The same indicators for referral to a consultant as those in Northumberland were used and the two week referral rule applied where cancer was suspected.

PROJECT FEEDBACK

FCP testing is a tool which aims to aid clinicians in their clinical decision making. As previously discussed, symptoms can be very similar for both IBS and IBD. FCP testing is a non-invasive test which in Northumberland demonstrated high compliance (100%) and, in Durham Dales (99%), from patients in returning their stool samples to GP practices. Qualitative surveys were sent to patients who had received GP consultations, including FCP testing for suspicion of IBS. From the 73 surveys sent out, 38 (52%) were completed and returned. Data analysis of the returned surveys indicated that as a result of the consultation:

- 94% of patients reported that they had an improved understanding of their condition
- 92% of patients felt able to keep themselves healthy following the consultation
- 100% of patients felt that they were listened to and were happy with the action planning
- 85% of patients received advice about diet, 61% received lifestyle advice from the consultation

Qualitative data was also collected from 19 GPs in Northumberland and results suggest a degree of confidence from primary care clinicians in FCP testing who participated in this project. They felt that FCP testing is a useful tool to aid clinicians in their clinical decision making and results from the survey support this. Data analysis of the returned surveys reported that:

- 58% of the GPs surveyed had requested FCP tests for one or more patients in the six months prior
- 100% of these GPs reported that the FCP test result helped with the management of their patients' care
- 37% of these reported that the FCP test result avoided referral to secondary care

Despite GPs reported confidence in using FCP to aid their diagnosis of IBS they remain uncertain about how to manage patients with borderline FCP results. This has highlighted an area for development of a national agreement or guidance for these cases. Without such guidance, this issue may become an implementation hurdle.

Another challenge associated with introducing FCP testing within primary care which may be encountered was ensuring that GPs followed the revised care pathway. It was difficult during this project to conclude if the referral rates and final diagnosis were a direct result of correct interpretation of FCP test results. Almost 30% of patients also had CRP and/or ESR tests which may have been interpreted by GPs along with the FCP test results. A small proportion of those patients with a low probability of IBD were referred to secondary care from both sites (7% and 11%) with no explanation for the deviation from the FCP referral pathway.

Throughout this project and resulting from contact that NTAC has made with secondary care clinicians, there continues to be a lack of confidence about the use of FCP testing to definitively identify patients who have IBD and therefore these clinicians would still wish to undertake endoscopy to rule out other pathology.

The most significant challenge to this project was the difficulty in establishing and collecting baseline metrics at the commencement of the implementation of FCP testing. This was partly due to the fact that the data that needed to be collected is not routinely available, partly because both primary and secondary care data is needed and also because the referral data did not show details of why patients have been referred for endoscopy e.g. suspicion of IBD. The baseline data which is most appropriate to collect prior to implementing FCP testing is detailed in the Measuring Success - Setting Metrics section.

Through implementing FCP testing in Durham Dales and Northumberland, the following benefits have been identified:

- To effect an improvement in the quality and productivity of the NICE pathway for the diagnosis and management of IBS in primary care

In Durham Dales, 82 (99%) patients with a low FCP test were diagnosed with IBS and were managed within primary care. In Northumberland, 39 patients (91%) who had a negative test were spared referral to secondary care.

GPs from both project sites reported that FCP testing had supported their clinical decision making whilst also increasing their confidence in diagnosing IBS in primary care.

- To enable improved management of endoscopy services in secondary care
This project experience suggests that there is a potential to improve waiting times for endoscopies as a result of reduced numbers of patients being referred.
- To improve the experience of the patient through quicker diagnosis and treatment decisions Both project sites were able to demonstrate significant numbers of patients who were able to leave the pathway at an earlier point, providing care closer to home and avoidance of hospital attendance for many. This, along with the positive patient feedback, indicates that improved patient care was achieved at both project sites.
- To realise potential cost savings in commissioning endoscopy services for suspect IBS/IBD There were potential cost savings and efficiencies identified for those patients leaving the pathway at both Durham Dales and Northumberland. If all of the patients who received negative FCP tests and were managed in primary care had been referred for an outpatient appointment and a subsequent colonoscopy procedure, then in Durham Dales, the 82 patients would have incurred £22,000 outpatient referral costs along with £39,000 costs for colonoscopy. A further £10,000 outpatient referral costs and £19,000 colonoscopy costs would have been incurred by Northumberland for the 39 patients who were managed within primary care had they been sent to secondary care.
- To avoid referral of patients with IBS to secondary care and thus avoid unnecessary invasive tests
From both sites, a significant number of patients who may have previously, were not referred to secondary care. Reassuringly, almost 100% of these patients at both sites were found to have IBS and management within primary care was wholly appropriate.

In Durham Dales, 77 patients (64%) were not referred and in Northumberland, 52 patients (68%) were not referred following an FCP test.

- To identify and fast-track patients with significant organic GI pathology to secondary care
In Durham Dales, 34 patients (97%) with a high FCP result were referred, only one patient was not referred and this was because an alternative diagnosis had been established. There were also nine patients (11%) who had a low FCP result but due to GPs clinical assessment and the identification of 'red flag' symptoms in three patients, they were referred for specialist assessment. It is important to note that one of these patients was diagnosed with rectal cancer following referral.
In Northumberland, a total of 19 patients (61%) with a high result were referred, the 13 patients who were not referred did not go on to receive a diagnosis of IBD. There were three patients (7%) with a low FCP result were referred, at least one patient had a 'red flag' symptom although none went onto receive a diagnosis of IBD.

Datasets from both Northumberland and Durham Dales suggest that FCP successfully aided clinicians at ruling out IBD as 99% (Durham Dales) and 100% (Northumberland) of patients with low FCP levels (indicating low probability of IBD) were found not to have IBD. A detailed analysis of the data collected from both sites during this project is included in the report by the York Health Economics Consortium (YHEC) (Appendix 4).

Evidence^{6,7} suggests that FCP levels have consistently been shown to be elevated in both adults and children with IBD relative to healthy controls despite FCP levels being subject to day-to-day variances and affected by age, suggesting that FCP is influenced by factors other than disease.⁸ A meta-analysis including 13 diagnostic accuracy studies demonstrated that FCP is useful as a screening tool for identifying those patients with suspected IBD who are most likely to need endoscopy.⁹

Interestingly, this project has suggested that patients with “low” FCP levels were found to have IBS rather than those with “high” FCP levels being found to have IBD.

NTAC conducted a qualitative survey of GP practices who had participated in the project and returns were received from 100% (24). Details of the short questionnaire are available in Appendix 6. Findings indicated:

- 96% viewed FCP testing as a triage tool to complement clinical judgement
- 83% would feel confident to refer patients based on the FCP test along with clinical assessment
- 78% reported their intention to continue to use FCP tests in the future

GPs reported that they felt the benefits of FCP testing included:

- Provides additional reassurance for patients who may have anxiety or uncertainty about IBS or IBD
- Reduced number of referrals from those tests which have been clearly negative. During this project, a total of 129 patients were spared from referral to secondary care.
- Has identified cases for referral that may not previously have been clinically indicated
- Greater confidence in diagnosing IBS within primary care without the need for endoscopy

It was reported that there had been one case where Crohn’s disease had been diagnosed in a patient that would not normally have been referred. Clinicians reported concerns where borderline FCP test results were gained. They suggested that it would be beneficial to have some guidelines to inform clinical practice for these cases. A detailed analysis of the data collected from both sites is included within the YHEC report (Appendix 4).

In addition to GP feedback, patient feedback was important in understanding how they felt about using the FCP testing as part of their overall clinical assessment. From the 73 surveys that were sent out, 38 were returned (52%) by patients.

⁶ Judd, T; Day, A; Lemberg, DA; Turner, D; Leach, ST (2011) Update of fecal markers of inflammation in inflammatory bowel disease. *Journal of Gastroenterology and Hepatology*. Vol 26. Iss 10. Pp 1493 – 1499.

⁷ Konikoff, MR; Denson, LA (2006) Role of fecal calprotectin as a biomarker of intestinal inflammation in inflammatory bowel disease. *Inflamm. Bowel Dis*. Vol 12. Pp 524-534.

⁸ Husebye, E; Ton, H; Johne, B. (2001) Biological variability of fecal calprotectin in patients referred for colonoscopy without colonic inflammation or neoplasm. *American Journal of Gastroenterology*. Vol 96. Pp2683-2687.

⁹ Van Rheenen, PF; van de Vijver, E; Fidler, V (2010) Faecal calprotectin for screening patients with suspected inflammatory bowel disease: diagnostic meta-analysis. *BMJ*. Vol 341. C3369.

Following their consultation, 94% of patients felt that they were able to understand their condition and 92% felt able to keep themselves healthy. All of the responding patients reported that during their consultation, things had been explained clearly to them; with 94% reporting that the doctors' explanation of why tests were needed was done in a way that they could understand. Most of the patients (97%) found the instructions explaining how to collect the stool sample easy to follow and were aware of what actions to take following collection of the sample. Positively, all of the patients who responded reported that the person they had seen had really listened to them and showed an holistic interest in them, showed care and compassion and fully understood their concerns.

QUALITY ASSURANCE

In diagnostics, quality assurance exists to ensure that the correct results are being provided for the correct sample. External Quality Assessment (EQA) is an essential part of this process in ensuring that results are comparable and accurate between laboratories and manufacturers. Manufacturers publish their own data in relation to quality assurance measures.

Birmingham Quality (University Hospitals Birmingham NHS Foundation Trust) operates the UK EQA scheme for Faecal Calprotectin. The scheme is available to all laboratories, clinics and other organisations in the UK and Northern Europe undertaking analysis of Faecal Calprotectin samples.

The scheme collects donor samples from patients both with and without IBD. Each month, three patient samples are distributed amongst scheme participants, who are asked to analyse them as they normally would and return the results. Participants are also asked for a 'positive' or 'negative' interpretation of the results. Birmingham Quality analyse the returns and provide a report back to each participant comparing their performance with the rest of the scheme.

Further information on the United Kingdom National External Quality Assessment Service can be found at: <http://www.ukneqas.org.uk/>

Further information on the Birmingham Quality UKNEQAS Centre can be found at: <http://www.birminghamquality.org.uk/>

FACTORS TO CONSIDER IN IMPLEMENTING FAECAL CALPROTECTIN TESTING

PROJECTING COSTS AND SAVINGS

York Health Economics Consortium (YHEC) has developed an economic model structure which is intended to assist NHS organisations to assess the potential benefits of using FCP. This tool can be found in Appendix 4. This will allow the potential cost savings of implementing Faecal Calprotectin into primary care to be compared to current practice. The decision tree structure is well suited to allow the total cost of each of the pre and post implementation pathways to be calculated.

HOW TO MEASURE SUCCESS – SETTING METRICS

It is essential in the introduction of any medical technology to record measurements pre and post implementation. Unfortunately, the projects at Durham Dales and Northumberland began prior to NTAC involvement and baseline data was not collected. In the light of the experience of this work it is suggested that the following metrics should be collected:

- Number of patients presenting with suspicion of IBS
- Number of patients presenting with suspicion of IBD
- How many of these patients had ESR and/or CRP tests
- How many patients referred for specialist assessment, including endoscopy
- How many patients had a confirmed diagnosis of IBS/IBD

- Endoscopy waiting list figures/ times

Evaluation data collected during and following implementation may also include:

- Number of FCP tests undertaken
- Number of positive/negative/indeterminate FCP test results
- Number of repeat tests undertaken (due to indeterminate result or continuation of symptoms)
- Number of referrals to secondary care for specialist assessment
- Number of endoscopies undertaken from those patients referred
- Patient experience data

Collection of healthcare data can present many challenges, especially when working across primary and secondary care boundaries; it is therefore essential to engage with the trusts' informatics departments at the earliest opportunity.

Collection of these metrics will allow comprehensive data analysis to take place and appropriate conclusions to be drawn about the reliability, suitability and cost effectiveness of FCP testing.

PROCUREMENT

Historically there have been concerns about maintenance of equipment and quality assurance in primary care settings. Within laboratories, calibration and regulation exists to meet all required standards. When introducing the laboratory based FCP testing, there is virtually no additional input required by GP practices. Patients simply return their stool samples to the practice which will have collection arrangements for all patient specimens in place. FCP test results will be sent back to the GP as per local arrangements. No training is required by GP practice staff for laboratory based FCP testing and laboratory staff will only require minimal training as these tests tend to work with the existing equipment.

Dependent on the locally agreed charges made by laboratories for FCP testing, it may prove to be more cost effective for GP practices to use laboratory based services rather than invest in the POC FCP tests and the staff training that would be required to offer this service within primary care. This decision should be subject to local dialogue and negotiation.

It is not NTAC's role to recommend specific suppliers, and CCGs and trusts will need to conduct their own appraisal of the available assays and purchase the most suitable equipment for their particular laboratory or primary care setting. It should however be noted that the evaluation currently being undertaken by NICE may provide recommendations about the use of certain products. It is understood that the British Society of Gastroenterology (BSG) is investigating whether they may recommend the standardisation across the NHS on a particular assay.

A full list of assays made known to NTAC can be found in Appendix 5; including supply chain details where relevant.

WORKFORCE CONSIDERATIONS

Staffing

It is important to ensure that the skill mix of the full multi-disciplinary team is considered during implementation of FCP testing, including the opportunity for some staff groups to enhance their roles.

Training

It is advisable and recommended that all healthcare professionals using both the POC and laboratory based FCP testing devices should receive training and their competency proven. The manufacturers of each of the technologies should provide all necessary product training and support.

Further details of the product specific training can be seen in Appendix 5, which were obtained from the manufacturers or distributors of the specific products.

MANAGEMENT OF RISK

As with all projects there is an element of risk associated with implementing FCP testing. The following are identified risk areas with suggested control measures available to mitigate those risks:

Risk Area	Control Measures
Leadership	Nominate clinical, executive and management champions
Engagement	Identify and include all key stakeholders in planning and implementation Ensure that MDT are kept fully informed of progress and problems – primary and secondary care
Finance	Prepare a robust business case Work together with commissioners
Capability & Education	Ensure clear understanding of why FCP testing is being implemented Thorough planning Train and educate all stakeholders – use supplier
Information	Plan for good data quality Ensure clear outcome measures are identified and accessible Establish baseline Benchmark and audit Consider information governance issues
Process	Integrate FCP testing into IBS/IBD care pathways Plan timescales

COMMUNICATIONS

In order to achieve successful widespread adoption it is essential that communication takes place with all relevant stakeholders. Lack of communication is often a barrier to adoption because unless each stakeholder has the opportunity to understand the reasons for technology implementation, they cannot be expected to support it.

Where POC FCP testing is to be introduced, GP practice staff need to be involved in the implementation process and communication is essential. Where laboratory based FCP testing is to be introduced, clear

channels of communication need to be established between GP practices/primary care and secondary care/laboratory services.

Information is an important part of the patient journey. It is central to the overall quality of each patient's experience of the NHS. When introducing FCP testing, patients need information to:

- Remind them what their doctor or nurse has told them if, due to stress or language difficulties, they are unable to remember
- Enable them to make informed decisions, giving them time to go away, read the information that is relevant to them, and think about the issues involved
- Involve them in their condition and their treatment (research has shown that good information can improve medical outcomes¹⁰ and reduce patient anxiety¹¹, and that patients want access to it¹²)
- Give them confidence, improving their overall experience of the NHS

It is important for patients to understand what is required from them for FCP testing. By providing information, you can ensure that patients follow procedures and that important details are not omitted, causing delays or inconvenience to them. An example of the patient information leaflet provided during this project can be viewed in Appendix 3.

CONCLUSION

Overall, the implementation of FCP testing, despite equivocal results in relation to the diagnosis of IBD, was felt by GPs and patients to have been successful. Both sites have continued to use this technology, with Northumberland extending its use of FCP testing since the start of the project.

From the patient experience data collected during this project, NTAC concludes that patients viewed the FCP test as a positive element of their overall clinical assessment:

- 94% of patients reported that they had an improved understanding of their condition
- 92% of patients felt able to keep themselves healthy following the consultation.

The data collected from GPs during the project showed FCP testing to:

- Provide additional reassurance for patients who may have anxiety or uncertainty about IBS or IBD
- Reduce the number of referrals from those tests which have been clearly negative. During this project, a total of 129 patients were spared from referral to secondary care.
- Have identified cases for referral that may not previously have been clinically indicated.
- Provided greater confidence in diagnosing IBS within primary care without the need for endoscopy.

Questionnaires completed by GPs indicate they support FCP testing as a definitive tool but in conjunction with their clinical diagnosis and sometimes other tests, e.g. ESR to aid diagnosis of IBS in patients at this point in time (April 2013).

Currently, on a national scale, clinical confidence in FCP testing appears to be varied with many clinicians preferring to refer some patients for specialist assessment despite FCP testing results indicating this is not

¹⁰ Audit Commission. What seems to be the matter: Communication between Hospital and Patients. London. HMSO, 1993

¹¹ George CF, Waters WE, Nicholas JA. Prescription information leaflets: a pilot study in general practice. Br Med J 1983; 28:1193 – 1196

¹² Bunker TD. An information leaflet for surgical patients. Annuals of the Royal College of Surgeons of England 1983; 65: 242 – 243

necessary, e.g. low risk. It is acknowledged that, with the increased awareness of conditions such as bowel cancer, clinicians may prefer to refer some patients to rule out any uncertainty about their diagnosis.

During this project, all of the patients with a low probability/green FCP test result were subsequently found to have IBS. This included those patients whose GPs had decided, possibly due to other clinical indicators, to refer for a specialist opinion. Whilst not a formal research trial, NTAC feels that this is highly suggestive that FCP is a useful tool in the diagnosis of IBS within primary care.

RECOMMENDATIONS

On the basis of the projects in Durham Dales and Northumberland and following discussions with clinicians from both primary and secondary care in England, the following recommendations are made:

- Before implementing FCP it is critical that a local pathway is defined and baseline data collected to be able to:
 - Audit care against the new pathway
 - Measure the quality of and the cost implications of the new service
- GPs reported a lack of confidence in how to manage patients with equivocal test results and there continues to be variation between centres about what constitutes a low, medium or high probability of having IBD. It is recommended, therefore, that guidance around these issues should be developed on a national basis.
- The apparent ability of FCP to identify patients in primary care who have IBS is significant. It is recommended, on the basis of the findings of this project, that FCP should be considered for incorporation into all new IBS pathways.

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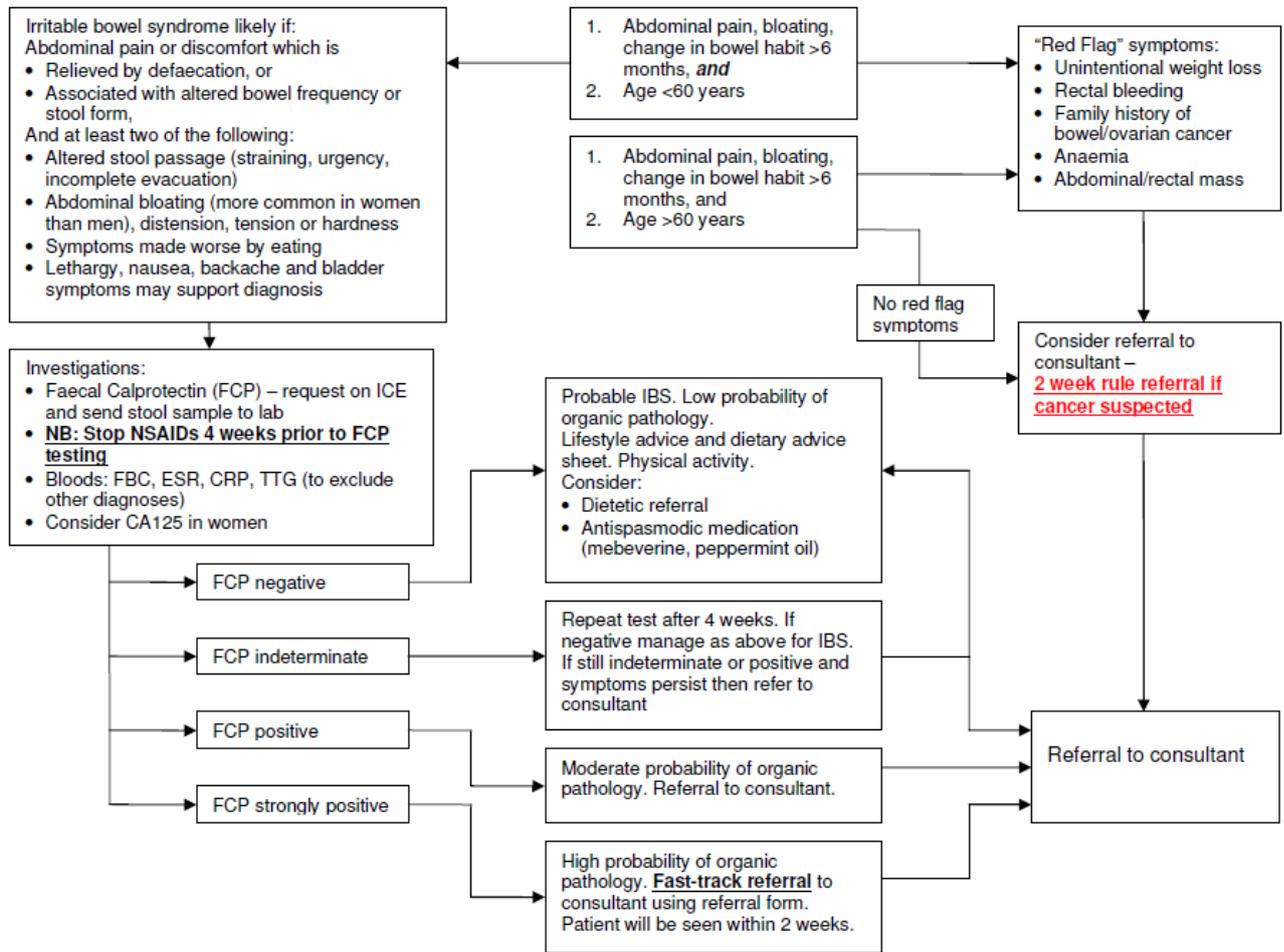
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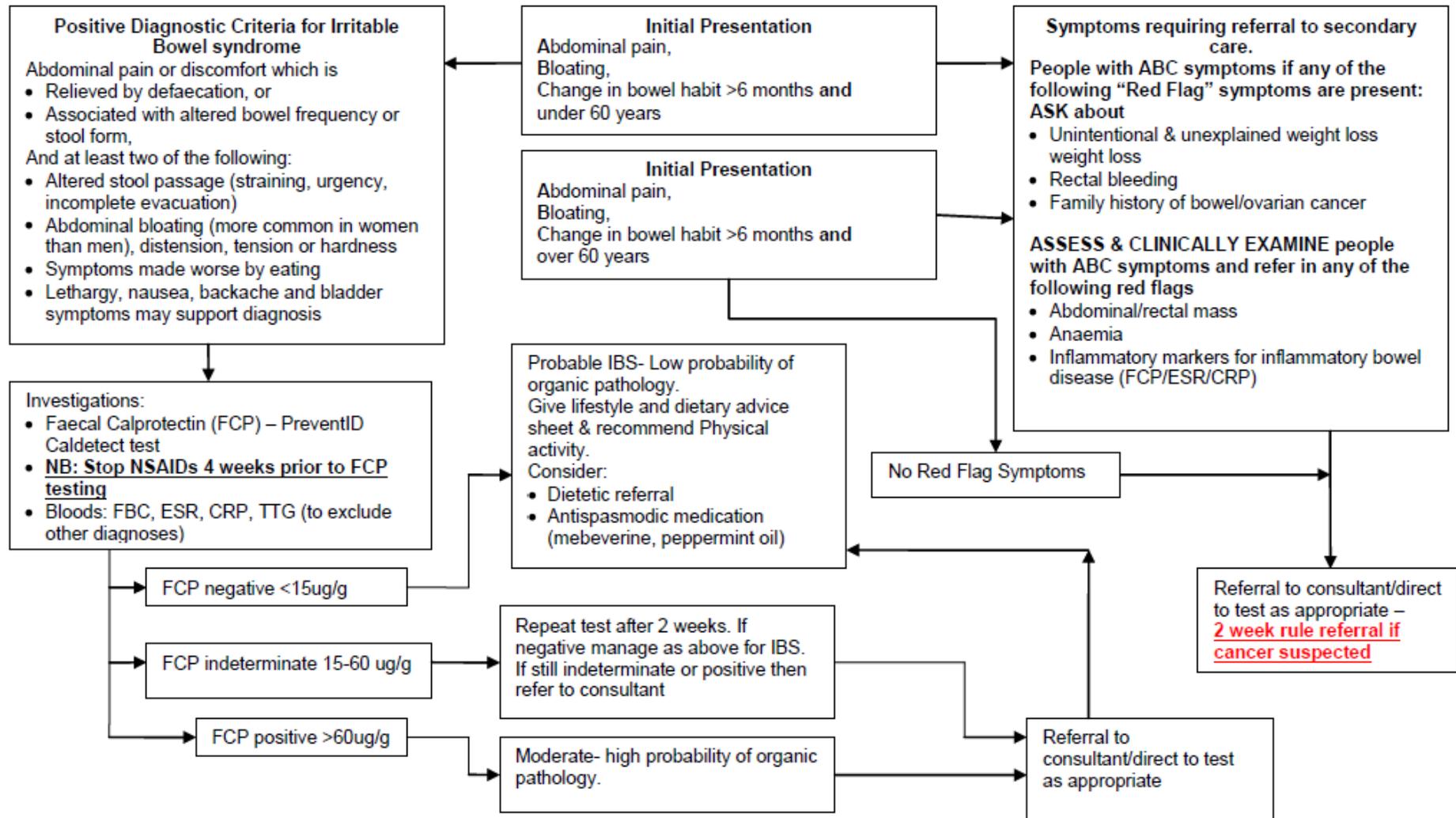
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Northumberland Primary Care IBS Pathway (Based on NICE CG61 Pathway)



APPENDIX 2 DURHAM DALES PRIMARY CARE IBS DIAGNOSIS & MANAGEMENT PATHWAY WITH POC TEST FOR FCP



Faecal Calprotectin Test Stool Sample Collection Instructions

Your GP has asked you to provide sample of your stool (bowel motion) to be tested for faecal Calprotectin (FCP). This will help your GP to know whether your bowels are inflamed or not.

Some tablets and medicines can affect the result (especially anti-inflammatory tablets like Ibuprofen, Naproxen or Diclofenac), giving a false reading. **If you are taking any of these medications you need to stop taking them for 4 weeks before you do the test.**

Collecting the stool sample

You have been given a plastic collection pot with a small spoon attached to the lid, and a green envelope.

It is important that the bowel motion you take the sample from has not been in the toilet bowl, as this could affect the test result. It is also important that the sample does not come into contact with any toilet cleaner or freshener products.

Suggested ways to catch your sample are:

- Folded pieces of toilet paper
- Your hand covered in a small plastic bag
- A clean disposable container

Using the blue-topped sample pot, unscrew the lid and use the attached spoon to collect a sample of the motion. A sample about 2cm diameter is required (about the size of a small walnut). It is important that sufficient sample is provided; otherwise the test may not be able to be completed.

Carefully transfer the sample into the container and screw the lid on tightly.

Write the date you collected your sample on the pot label. This is most important because if the sample is too old (over 7 days) when it gets to the lab it cannot be tested.

Place the container inside the green envelope and seal the envelope.

The envelope should then be taken to your GP surgery as soon as possible and within 3 days of collecting it, from where it will be transported to the pathology lab.

Ensure that your hands are washed thoroughly, and that any dirty equipment is disposed of safely.

To access the YHEC Report, please [click here](#)

APPENDIX 5 SUMMARY OF AVAILABLE FCP TESTING TECHNOLOGIES

Name of manufacturer and Distributer	Manufacturer: PreventisGmbH Distributer: Alpha Laboratories	Manufacturer: Buhlmann Distributer: Alpha Laboratories	Manufacturer: Buhlmann Distributer: Alpha Laboratories
Address	40 Parham Drive, Eastleigh, Hants SO50 4NU	40 Parham Drive, Eastleigh, Hants SO50 4NU	40 Parham Drive, Eastleigh, Hants, SO50 4NU
Website	www.alphalabs.co.uk	www.alphalabs.co.uk	www.alphalabs.co.uk
Telephone Number	02380 483000	02380 483000	
Testing Product name	KST1105 PreventID Caldetect Calprotectin Rapid Test	Quantum Blue	Quantum Blue Reader
Basis	(Point of care) single use. Semi-quantitative assay. Test takes less than 10 minutes. Stand alone test that does not require laboratory infrastructure, additional devices or instruments.	(Point of care) Single use quantitative.	(point of care or laboratory) Quantum Blue Cassette Reader
Cost of equipment	£150 per pack of 10 tests i.e. £15 per test	List £507 Web £456.30	List £2,665 Web £2398.50
Cost of consumables	Not applicable	20 units £25.35 list £22.82 web	Not applicable
Training	All necessary training is provided by Alpha Laboratories	All necessary training is provided by Alpha Laboratories	All necessary training is provided by Alpha Laboratories
Cost of training	Included as part of sales package	Included as part of sales package	Included as part of sales package

Name of manufacturer and Distributer	Manufacturer: Buhlmann Distributer: Alpha Laboratories	Manufacturer: Immundiagnostik AG Distributer: Biohit Healthcare Limited
Address	40 Parham Drive, Eastleigh, Hants SO50 4NU	Pioneer House, Pioneer Business Park, North Road, Ellesmere Port, Cheshire, CH65 1AD
Website	www.alphalabs.co.uk	www.biohithealthcare.co.uk
Telephone Number	02380 483000	0151 550 4 550
Testing Product name	Calprotectin EK-CAL	Immundiagnostik Faecal Calprotectin ELISA (K6927)
Basis	(point of care or laboratory) 96 well plate. Differential diagnosis, Therapy monitoring, relapse Prediction	(point of care or laboratory) Monoclonal antibody ELISA kit for the quantitative determination of calprotectin in stools.
Cost of equipment	List £574 Web £516	£550
Cost of consumables	1 unit £14 list £12.92	1 unit £14
Training Requirements	All necessary training is provided by Alpha Laboratories	ELISA process training. Stool extraction training.
Cost of training	Included as part of sales package	Free

Technology Adoption Centre

Faecal Calprotectin Survey

1. Which Faecal Calprotectin test is currently being used at your practice?

- Which Faecal Calprotectin test is currently being used at your practice? Lab Based Test Point of Care Test

Please provide any additional information that you feel may be beneficial

2. How have you used the Faecal Calprotectin Test within your practice? (please select the most appropriate option below or provide details in the space provided)

- How have you used the Faecal Calprotectin Test within your practice? (please select the most appropriate option below or provide details in the space provided) As a triage tool to compliment clinical judgement

- As a stand alone method of determining which patients to refer

Please provide any further information about how your practice has deployed the test

3. How confident are you to make a decision whether to refer patients for a specialist assessment based on the result of the Calprotectin Test along with your clinical assessment?

Would not refer based just on test result and assessment

Fairly Confident

Very Confident

Extremely confident of referring based on test result and assessment

*How confident are you to make a decision whether to refer patients for a specialist assessment based on the result of the Calprotectin Test along with your clinical assessment? Would not refer based just on test result and assessment

Fairly Confident

Very Confident

Extremely confident of referring based on test result and assessment

Please provide any additional information that you think may be beneficial

4. How useful has the Faecal Calprotectin Test been to your practice?

No use

Limited Use

Quite Useful

Extremely Useful

*How useful has the Faecal Calprotectin Test been to your practice?

Limited Use

Quite Useful

Extremely Useful

No use

Please provide any additional information that you think may be beneficial

5. What benefits has the Faecal Calprotectin Test offered to your practice? (please list the benefits of the test to your practice in the space below)

What benefits has the Faecal Calprotectin Test offered to your practice? (please list the benefits of the test to your practice in the space below)

6. Do you intend to continue to use the Faecal Calprotectin Test following the completion of the evaluation?

Do you intend to continue to use the Faecal Calprotectin Test following the completion of the evaluation? Yes

No

Don't Know

If you have answered "No", please provide the reasons for not wishing to continue using the test

Done