DELETE THIS BLUE TEXT IN FINAL VERSION

This template includes the standard text and headings required to develop a business case for implementation of a laboratory based faecal calprotectin testing within primary care, as well as information to help you fill it in.

All notes are in square brackets: [grey] highlighting gives guidance on what you need to add and indicates where you need to add text. Please delete all notes when you have finished writing the business case. Where text is to be added blue highlighting has been used.

Business Case for the implementation of a laboratory based faecal calprotectin testing within primary care.

Author’s Name [insert name]

Author’s contact details [insert email address and/or telephone number]

Date completed [DD/MM/YYYY]

Date submitted [DD/MM/YYYY]

Version [insert version number]

**Executive Summary**

[Introduce business problem and briefly describe the actions taken to date to address the problem]

[Provide an overview of the ‘current state’ of the problem, followed by an assessment of how business needs are or are not being met]

[Include stakeholders/sponsor and costs involved, providing additional information as required]

The purpose of this business case is to consider the options for implementing a laboratory based faecal calprotectin testing service as part of a primary care pathway for adults presenting to their GP with lower gastrointestinal symptoms.

Currently when patients present to their GP with lower gastrointestinal symptoms and they are suspected to have IBS, they are likely to have a diagnosis made on the basis of their clinical history. In line with [NICE clinical guideline 61](http://www.nice.org.uk/guidance/cg61), where people present with abdominal pain, bloating or a change in bowel habit for at least 6 months, they should be asked if they have any red flag symptoms such as unexplained weight loss. They should also be clinically tested for red flag indicators, including anaemia, rectal masses, inflammatory biomarkers for IBD and late onset (older than 60 years) change in bowel habits. Where there are no red flag indicators, patients who meet the IBS diagnostic criteria should have a full blood count, erythrocyte sedimentation rate or plasma viscosity, C-reactive protein and antibody testing for coeliac disease to exclude other diagnoses.

Where IBD is suspected when a patient presents to their GP, initial laboratory investigations including full blood count, erythrocyte sedimentation rate, C-reactive protein and other tests such as kidney function tests are likely to be undertaken. Patients are likely to be referred to secondary care for further investigation which involves endoscopy (with or without biopsy), histology and imaging.

Due to the similarity of the symptoms for both irritable bowel disease (IBD) and irritable bowel syndrome (IBS), diagnosis can sometimes be difficult. This can result in many patients needing to undergo more invasive procedures such as colonoscopy before a definitive diagnosis can be made.

Faecal calprotectin testing has been recommended by [NICE (DG11)](http://www.nice.org.uk/guidance/dg11) as an option to support clinicians with the differential diagnosis of IBD and IBS in adults with recent onset lower gastrointestinal symptoms for whom specialist assessment is being considered if cancer is not suspected and where appropriate quality assurance processes and locally agreed care pathways are in place for the testing. The pathway for children will not change and it is likely that where appropriate, they may receive a faecal calprotectin test in secondary care.

[insert details]

Due to current demand for endoscopy services, which is significantly affected by referrals from primary care, name of trust is not always able to meet the following business needs.

* List business need
* List business need

The proposed recommendation outlined in this business case is for name of trust to establish a laboratory based faecal calprotectin testing service to be offered to gastroenterologists within secondary care (name(s) of acute trusts) and to GP practices within the remit of name of clinical commissioning group.

Successful implementation will be dependent on clinical support from Consultant Gastroenterologists and GPs along with CCG managers and Directorate management at name(s) of acute trusts.

The direct costs associated with establishing this service will be related to the procurement of the assay, consumables required for testing procedures and costs relating to staff training and internal and external quality assurance arrangements. It will also be necessary for annual maintenance costs to be accounted for. Consideration of these costs would be expected to come from budgetary source [eg.pathology services]

The annual savings associated with implementing the NICE guidance (DG11) are estimated to be £ [insert number] for name of trust. The majority of the savings are likely to be as a result of a [insert number] % reduction in referrals of [insert type of outpatient referral] and [insert number] % investigations such as [colonoscopies and/or sigmoidoscopies/ endoscopies]

Due to the nature of faecal calprotectin testing, evaluation of the laboratory based faecal testing service would require data from primary care and secondary care systems. Measuring the number of referrals made from primary care for patients who had a suspicion of IBD along with the number of [endoscopies/sigmoidoscopies/colonoscopies] undertaken and final diagnoses for these patients would provide appropriate information to determine the effectiveness of faecal calprotectin testing in differentiating between IBS and IBD. Analysis of this data along with faecal calprotectin test results may provide further information about appropriateness of local ‘cut off’ values, false positive and false negative results. To obtain an adequate and significantly robust level of data, it would be appropriate for data collection to take place over a minimum period of [insert number] months, with a further minimum period of [insert number] months for ‘follow up’ data to be collected. This will allow information about patients diagnosed with IBS to be reviewed to determine if these diagnoses were accurate or if these patients went on to undergo further investigations with final diagnosis that was not IBS.

To determine the impact of introducing the test has upon clinical decision making, it would be necessary to collect qualitative data via questionnaires. A similar methodology would be required to ascertain patient experience of faecal calprotectin testing.

**Purpose of the business case**

[Provide a compelling case for change in terms of current and future needs of a department, service or organisation]

[Use SMART (Specific, Measurable, Achievable, Realistic, Timebound) approach to form the objective. Include project goal, expected outcomes and how project will contribute to organisational strategy and take advantage of any available opportunities identified in SWOT analysis]

Through introducing faecal calprotectin testing into the primary care pathway, it will be possible to reduce the number of people referred to secondary care for specialist assessment and endoscopy procedures. This will aid name(s) of trusts in meeting their 18 week targets for endoscopy procedures and may enable patients to receive these investigations at an earlier time than is currently the case. The quality of patient care could be considered improved as faecal calprotectin testing provides additional information and reassurance for GPs when diagnosing IBS.

[insert details]

**Assumptions**

[Please insert any key assumptions and any internal/external factors which delivery depends on in this section]

[insert details]

**Constraints**

[In this section, please include any capability and capacity issues or contractual commitments that the organisation is obligated or contracted to fulfil]

[insert details]

Evidence on the clinical effectiveness for faecal calprotectin testing remains limited with almost all the available evidence coming from studies in secondary care, rather than in primary care.

**Option appraisal**

**Option 1 Take no action. Current state where no faecal calprotectin testing is available from laboratory remains unchanged.**

**Option 2 [name of trust] to offer laboratory-based faecal calprotectin testing upon request from gastroenterologists within secondary care. May require less funding, reduced risk but may achieve similar results.**

**Option 3 [name of trust] to offer faecal calprotectin testing to both secondary care and all GP practices with [name of Clinical Commissioning Group] Outlines course of action that would provide ‘closest fit’ to objectives in business case.**

[In this section, for each option provide the advantages which directly link to objectives stated in business case]

[Include all costs (direct, indirect, recurrent, non-recurrent, capital and marginal)]

[Include any workforce considerations including any changes to staffing resources that would need to be considered]

[Include any identified risks (threats and opportunities) for each option providing details about likelihood and impact and how these may be minimised (including any costs involved)]

**Proposing a recommendation**

[This is where the recommended option and summary of reasons can be explained in more detail. Include why the proposed recommendation is most likely to achieve any key outcomes]

[insert details]

**Impact analysis**

[Provide an overall assessment of how the change and project will affect the organisation]

[insert details]

The Outcomes Framework and CCG Indicator Set both identify the need for patients to have a positive experience of care and for people with long term conditions to feel well supported.

**Financial impact** [include estimated expenditure, ROI, additional income required]

[insert details]

**Cultural impact** [include any change to or reinforcement of the organisation’s values]

[insert details]

**Capability impact** [include an assessment of the organisation’s ability to carry out the project within the stated timescales, it can be helpful to refer to it’s previous experience of change projects]

[insert details]

[In this section, also summarise the financial forecasts which explain key assumptions that have been made. Highlight any other activities that will be affected]

[insert details]

**Risks**

[Include the key risks identified (from the change, organisation’s ability to carry out project). Refer to your organisation’s risk matrix to define appropriate scores for each of the identified risks]

[insert details]

**Implementation of project**

[Provide a high level plan of the main activities involved in the project. Include Gantt Chart and Milestone Plan. A stakeholder analysis identifying relevant stakeholders for the project should also be included]

[insert details]