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Introduction of symptomatic patient screening for faecal occult blood

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Background

NICE updated guidance NG12 on Suspected cancer: recognition and referral (June 2015), recommends faecal occult blood (FOB) testing in patients suspected of having colorectal cancer. Although NICE do not specify which method of analysis to use, we chose faecal immunochemical testing (FIT) as it is a more sensitive and specific method of detecting human haemoglobin than guaiac acid methods.

Lancashire Teaching Hospitals released local guidance in June 2016 to mirror NICE guidance on using FOB to triage low risk patients for colorectal cancer without red flag symptoms. We send our FOB requests for FIT analysis to a referral laboratory and we have carried out a FIT method evaluation with the aim of measuring it locally.

There is debate about which cut-off to use in symptomatic patients and we use a cut off of 10µg/g which we anticipate to be recommended by NICE².

Methods

Two faecal collection devices were sent to each patient with an FOB request between Sept-Dec 2016 (n=60). One device was sent to the referral laboratory for analysis using HM-JACK arc and the other was processed in-house using the iO OC sensor. Analyse It was used for statistical analysis.

Results

Overall, 17% patient samples were positive using HM-JACK arc compared with 18% with OC sensor. Concordance between both methods was seen for 95% of patients. Three patients (5%) had discrepant results but all of these were close to the cut off, this will need to be explored but may be due to sampling from different parts of the faeces with separate devices.

	FIT result (µg/g) Coventry HM-Jack arc	FIT result (µg/g) Preston iO OC Sensor
A	12.9	2.8
B	4.8	18.6
C	9.4	48.4

Table 1: Comparison of quantitative results obtained using each of the FIT assays during patient comparison. Results in blue are below the cut off of 10µg/g and those in red are above the cut off.

Patient A was a 78 year old female with iron deficiency anaemia. She had a colonoscopy where nothing abnormal was detected.

Patient B was a 90 year old female with mild iron deficiency anaemia, nothing abnormal detected on examination it was decided clinically not to perform a colonoscopy.

Patient C was a 45 year old female with loose stools, weight loss and borderline faecal calprotectin (55 µg/g). A colonoscopy was performed with biopsies, nothing abnormal was detected.

Precision profile for FOB by FIT OC sensor

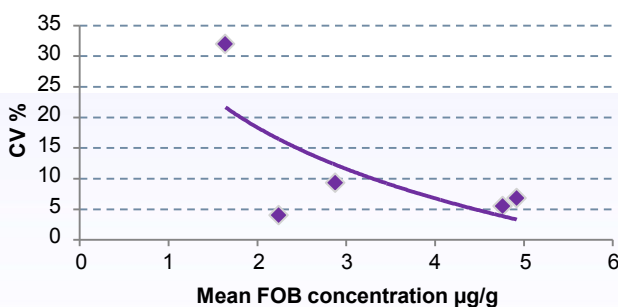


Figure 1: Shows the precision profile for FOB analysis by OC sensor FIT assay. Patient samples with low FOB results were analysed repeatedly to obtain between batch precision (n=5). The mean result for each sample is plotted against percentage CV obtained.

Results

We are confident of the OC sensor method precision to levels lower than the recommended cut-off of 10µg/g making the assay fit for the purpose of symptomatic patient screening.

We will begin performing FIT analysis for FOB in line with NICE guidelines in the context of the following proposed patient pathway.

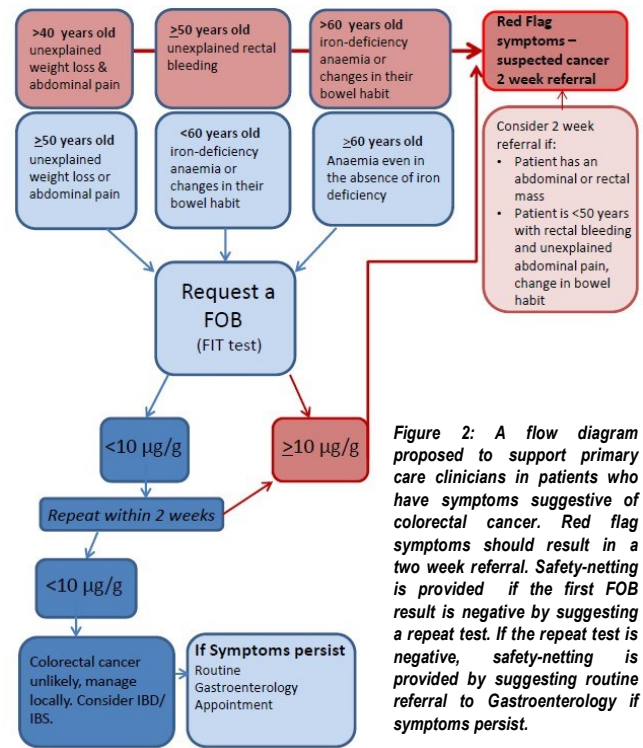


Figure 2: A flow diagram proposed to support primary care clinicians in patients who have symptoms suggestive of colorectal cancer. Red flag symptoms should result in a two week referral. Safety-netting is provided if the first FOB result is negative by suggesting a repeat test. If the repeat test is negative, safety-netting is provided by suggesting routine referral to Gastroenterology if symptoms persist.

We will provide a GP information leaflet containing the above algorithm and advise around the analysis of FOB. Importantly, if frank rectal bleeding is present, the FIT result will be positive and will only delay investigation.

Adequate safety netting of patients with a negative FIT result is essential to try to ensure cancer diagnoses are not missed. If a patient has two negative FIT results, the negative predictive value is close to 100%, but as with any screening tests, if clinical suspicion remains high or symptoms persist, referral for further investigation is recommended. This would be a routine Gastroenterology referral, rather than a 2 week suspected cancer referral.

Conclusions

HM-JACK arc and OC sensor methods compared very well, both analytically and clinically, in this patient comparison study. We are happy that the lower limit of quantitation of the OC Sensor method will be lower than the 10 µg/g cut-off being considered by NICE. Whichever method is used, over 80% of low risk patients could avoid invasive colonoscopy by introducing FIT testing. The more capacity released by the colonoscopy service the more capacity will be available to lower the cut-off used in asymptomatic patient screening to detect more colorectal cancers at an earlier stage. The need for repeating negative results will be determined by clinical audit once enough data is available.

References

1. Suspected cancer: recognition and referral NICE NG12 (<https://www.nice.org.uk/guidance/ng12>)
2. Diagnostics Assessment Report commissioned by the NIHR HTA Programme on behalf of the National Institute for Health and Care Excellence - Protocol (<https://www.nice.org.uk/guidance/GID-DG10005/documents/final-protocol>)
3. Mowat C, et al (2015): Faecal haemoglobin and faecal calprotectin as indicators of bowel disease in patients presenting to primary care with bowel symptoms. Gut ; 0 :1-7.