The faecal immunochemical test (FIT) is a new way to test for occult blood in stool, and is replacing the traditional guaiac based faecal occult stool test.

**How do I know which test my patients are currently getting?** If, when you request a faecal occult blood test, you send 3 stool samples, your patients are getting the guaiac test; if you send 1 stool sample, it’s the FIT test.

NICE has updated its ‘Suspected cancer referral guidelines’ to recommend the FIT preferentially over the guaiac FOB test (NICE 2015 (updated 2017), NG12, NICE 2017, DG30). It will also be the test of choice for the national screening programme from 2019.

It is an area we lack confidence in. So, here is a guide to what you need to know.

**When will the FIT be used?**

<table>
<thead>
<tr>
<th>How the test will be used</th>
<th>Cut-off (mcg of haemoglobin/gram of faeces)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colorectal cancer screening</td>
<td>Screening test of choice for national screening programme from 2019. Probably 100–150mcg/g (higher than the diagnostic threshold to make the programme cost-effective).</td>
</tr>
</tbody>
</table>
| Patients with ‘low-but-not-no-risk’ symptoms for colorectal cancer | Used as a ‘rule-in’ test: those with ‘low-but-not-no-risk’ symptoms for colorectal cancer are offered the test.  
- Those testing positive are most likely to benefit from an urgent colonoscopy.  
- A negative FIT makes a diagnosis of colorectal cancer unlikely BUT if symptoms persist, further investigations (for colorectal or other cancers) should be considered, so safety-net well. | ≥10mcg/g. |
| To triage 2ww colonoscopy lists | As a rule-out test for patients with higher risk symptoms who meet referral criteria. Most controversial, and not part of standard practice yet: being tested in large clinical trials to see if it is safe to use in this context. | A very low threshold will be selected for this (undetectable or <10mcg/g). |

**What is the FIT and why is it better?**

Bottom line: the FIT is much better than the guaiac FOB test. It detects human haemoglobin in stools at low levels and only requires a single sample. But, like ALL tests, it isn’t perfect. Here is a useful comparison between the 2 tests (BJGP 2019;69(679):60):

<table>
<thead>
<tr>
<th></th>
<th>Guaiac FOB</th>
<th>FIT (at 10 mcg/g cut off)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity for colorectal cancer</td>
<td>50% (15–85%)</td>
<td>92.1% (86–95%)</td>
</tr>
<tr>
<td>Specificity for colorectal cancer</td>
<td>88% (85–89%)</td>
<td>85.8% (78–91%)</td>
</tr>
<tr>
<td>Type of test</td>
<td>Qualitative (a ‘yes or no’ answer)</td>
<td>Quantitative (threshold of positive result can be adjusted to affect sensitivity and specificity)</td>
</tr>
<tr>
<td>Number of samples needed</td>
<td>3 samples from 3 stools</td>
<td>1 sample from one stool</td>
</tr>
</tbody>
</table>
There is a limited evidence base for the primary care use of FIT as a diagnostic test. NICE changed its guidance based on a systematic review of 10 diagnostic cohort studies which looked at the diagnostic properties of FIT when applied to patients already referred to secondary care (BMC Medicine 2017;15:189).

NICE found that when FIT is used as a diagnostic test for colorectal cancer on patients who have no rectal bleeding and have ‘low-but-not-no-risk symptoms’:

- It has a sensitivity of 92% (CI 87–95%).
- A single study where a very low cut-off of ≥10mcg haemoglobin per gram of faeces was used showed a sensitivity of 100% (CI 71.5–100%). This is the cut-off value chosen by NICE for use in individuals with low-but-not-no-risk symptoms.
- This gives a negative predictive value of between 99.4 and 100% (so a person with a negative result will have a colorectal cancer less than 1% of the time).
- It performed less well in picking up high-risk adenomas.
- It reduced the need for colonoscopy in 75–80% of patients.

The authors report that diagnostic properties of the FIT based on a single sample and a threshold of ≥10mcg haemoglobin per gram of faeces make a negative result adequate to rule out most colorectal cancer.

To this end, there is research taking place at present to determine whether faecal immunochemical testing can be safely used to triage patients who do meet other 2ww referral criteria (so higher risk symptoms) for colorectal cancer to ‘rule-out’ malignancy, and we await the results of this with interest. However, it is not yet being used in this manner.

**Which faecal immunochemical test?**

This is just for commissioners! NICE evaluated all the available FITs and recommended any of:

- OC Sensor.
- HM–JACKarc.
- FOB Gold.

It specifically recommends against RIDASCREEN tests on the basis of insufficient evidence.

**Use in symptomatic patients**

Historically, colorectal cancer has been difficult to spot early. There are many low-but-not-no-risk symptoms. The updated NICE guidelines now recommend referral for colorectal cancer in the following circumstances.

**Colorectal cancer pathway referral NICE 2015 (updated 2017), NG12 and DG30**
So, we are being asked to use it to rule-in an additional group with low-but-not-no-risk symptoms for urgent referral.

A BJGP editorial expressed anxiety about the potential to deluge secondary care by using FIT as recommended in the NICE DG30 guidance (BJGP 2019;69(679):60).

There has been disagreement across the country about ‘What NICE means?’, so we asked NICE directly.

What does NICE really mean?

There are two possible interpretations:

- That NICE wants us to use faecal immunochemical testing in any patient without rectal bleeding with unexplained symptoms that could be suggestive of colorectal cancer who meet no other referral criteria (so discretion for primary care).

OR

- Use faecal immunochemical testing just in the group initially identified in NG12 (now superseded by DG30). Here is a reminder of what NG12 said historically:

Use occult blood testing for people without rectal bleeding but with the following unexplained symptoms AND who do not meet the other criteria for a suspected cancer pathway referral:

- ≥50y with unexplained:
  - Abdominal pain or
  - Weight loss.
- <60y with:
  - Change in bowel habit or
  - Iron-deficiency anaemia.

We have corresponded directly with NICE and it confirmed that it intended option 1, to allow primary care the freedom to decide – it did not intend faecal immunochemical testing to be restricted to only the initial NG12 population.

So, we can use our clinical judgement. Clearly, use in an 18-year-old with symptoms typical of IBS would not be appropriate, but most of us who have been in practice a short length of time have a memory of a younger patient who had a slightly odd presentation and might just have benefited from this.

However, you may have local guidance about when FIT can and cannot be used. Some areas are restricting use to the original NG12 population as detailed above. This will be based on local capacity for colonoscopy, and this capacity should be considered when deciding whether to use the test. You may, of course, not be able to access it at all yet!

Won’t this flood colonoscopy services?

We don’t know: some academics say it will, others say it shouldn’t. The diagnostic properties tell us it should reduce colonoscopies – and this is starting to be seen in real life.


- The proportion of samples considered positive by FIT was considerably lower than guaiac FOB.
- 50% fewer colonoscopies would have been needed, while maintaining the same rate of colorectal cancer detection.
One in three patients with a positive FIT had significant colorectal disease.

There are some limitations of this study. It commenced before NICE issued its thresholds, and the study set the threshold of a positive FIT at ≥7 micrograms haemoglobin/gram faeces. However, the authors reanalysed the data and state this would not have had a significant impact. The main limitation is that most patients did not have a gold standard test (colonoscopy) as this was not a controlled study. The 2y follow-up was felt adequate to allow significant pathology to be detected.

**Safety-netting**

While FIT is a good test, like most tests, it is not perfect. Looking at the confidence intervals in the systematic review, it is entirely possible to have a negative FIT and still have colorectal cancer (or another cancer), but this will be in <1% of patients. Even in the presence of a negative FIT, we need to safety-net and consider whether other tests or routine referral are appropriate if the clinical picture is not what we would expect.

**How will primary care feel about doing a FIT rather than a colonoscopy?**

This all represents a big change in practice. It is being implemented in very patchy fashion across the country, and national level policy makers recognise that attitudes vary significantly geographically, as does education.

A questionnaire study asked GPs their views about using FIT in the context of triaging patients with symptoms that would make them eligible for a 2ww referral (BJGP 2018;68(676):e757).

- Only one-third of us preferred using FIT over colonoscopy testing.
- Perception of the accuracy of FIT varied widely, but, even among GPs who felt it was highly accurate, only half would choose to use it over colonoscopy.
- We lacked confidence in discussing FIT with patients.

The authors acknowledged that much needs to be done in supporting education in primary care, and improving understanding of this test and its applications.

*We hope this article helped!*

Faecal immunochemical testing and colorectal cancer

- FIT is now preferred over guaiac testing because of lower false positive rates and ease of use.
- It will be used in screening from 2019 – watch out for the threshold.
- It should be commissioned for use in early diagnosis as per the NICE guideline.
- As a rule-out diagnostic test, the cut-off is ≥10mcg haemoglobin/g of faeces (but other thresholds apply in other situations).
- Offer a FIT to anyone with unexplained symptoms suggestive of colorectal cancer, no rectal bleeding AND who meets no other referral criteria. If positive, refer along suspected cancer pathway.

Find out if you have access to faecal immunochemical testing locally. Start to use it as recommended by NICE or local guidance, and consider auditing outcomes as a practice.
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