Somerset, Wiltshire, Avon and Gloucestershire Cancer Alliance

Peninsula Cancer Alliance

Information Pack for GP's

The implementation of the Faecal Immunochemical Test (FIT) across the South West

The South West Cancer Alliances have been awarded transformation funding to provide access to FIT for General Practice. The FIT can be requested in patients who meet the criteria described in the group of patients in the 2015 NICE guidelines on the recognition and referral of patients with suspected cancer (NG12): Those without rectal bleeding who are classed as "low risk, but not no risk" of having colorectal cancer.

This is one of a number of programmes of work aimed at increasing the proportion of cancers diagnosed at an early stage, and at reducing the numbers of people presenting with cancers in emergency settings.

What is FIT?

The Quantitative Faecal Immunochemical Test is a test to detect hidden or 'occult' blood in stool samples. Unlike older FOB tests, FIT uses antibodies that specifically recognise human haemoglobin and so there is no need for patients to undergo dietary restriction prior to using the test. As it is antibody based, FIT is a more sensitive and specific test than the guaiac test, which most GPs would know as the old FOB test, and which is still being used by the English Bowel Cancer Screening Programme. This reduces the chances of false positives.

Which patients are eligible for FIT?

The NICE Guideline for Suspected Cancer 2015 (NG12) recommended that faecal occult blood tests should be offered to adults without rectal bleeding who were classed as "low risk, but not no risk" of having colorectal cancer.

These are patients who:

- **Over 50 with unexplained abdominal pain or weight loss**
- **50 to 60 with changes in bowel habit or iron-deficiency anaemia**
- **60 or over with anaemia without iron deficiency**

Following an HTA Assessment, NICE published further guidance in July 2017 – DG30 which confirms that FIT is the faecal occult blood test of choice for this group of patients.

DG30 guidance encourages use of the test for any patient with abdominal symptoms who doesn't fit the NG12 2WW criteria. However, at the moment we are only offering the test to the cohort previously referred to in NG12 and tests for patients that do not meet the above criteria will not be analysed.

NICE Guideline CG61 explicitly states that testing for occult blood in faeces is not necessary for the diagnosis of IBS. We would encourage GPs to continue to feel confident in diagnosing IBS in younger adults where the symptoms are typical of this without recourse to qFIT testing.

N.B: It is possible for patients who don't fit the criteria for testing to have significant bowel pathology, so if you have concerns about a patient with persistent abdominal symptoms please continue to use your existing local referral systems.

How will this process work?

FIT packs will be delivered to each GP practice in June. The pack contains the sample collection device, patient instructions, a referral form and return envelopes.

To request a test for eligible patients the referral form (provided inside the pack) will need to be completed and placed back into the pack before handing it to the patient for completion at home. Electronic test requests are not currently available.

GP's will need to advise patients to return the sample directly to the lab in the pre-paid envelope as quickly as possible. Patients should be advised to follow the collection instructions carefully, including taking care not to let the stool sample touch the water in the toilet bowl.

Because the patient sends off the test themselves, practices may wish to make a note on the patient's record that a test has been issued and ensure a process is in place to follow up, the result in addition to giving the patient their usual safety netting advice.

Using a READ code will allow you to search for patients who have been advised to send qFIT tests but for whom you have not received a result.

READ Code 4791 (Faecal Occult Blood Requested) is recommended.
SNOMED ID 167666002

Differentiation with the Screening programme

The screening programme currently uses the old Guaiac FOB test and will be moving to using qFIT in the near future. No date has been set yet for the launch and the threshold has not yet been confirmed;.

GPs will receive a numerical result for their patients; and a "positive/negative" category in the same way that they currently do for the Guaiac based test.

The quantitative threshold for the Bowel Cancer Screening Programme qFIT is much higher than that used in our 'Symptomatic qFIT' testing, so a recent 'normal' or 'negative' from the screening programme should not be relied on by GPs for reassurance.

Irrespective of how recently a patient has been screened by the national screening programme, their test result should not influence the decision to investigate if they present with new symptoms of concern.

How soon can I expect the results?

GP's will receive the results of the analysis within 7 working days from the date the test is sent to the laboratory by the patient. If you have not heard the results within 10 days of issuing the test then please contact the patient to ensure the test was sent.

The way results will be communicated will vary according to local arrangements. Practices will be notified individually by the laboratories when the initial supplies of patient packs are distributed.

What do I need to do with the results?

If the Faecal occult blood test is positive: Consider using a referral for suspected cancer under the local 2WW arrangements. Occult blood in the stool can be caused by a wide variety of benign conditions as well as colorectal cancer, and further assessment may be appropriate to rule out these out before referring.

READ Code 4794 FOB+ve is recommended

Referral forms to secondary care have been updated to allow GP's to record the FIT test result.

If the Faecal occult blood test is negative: qFIT negative patients have an extremely low risk both of colorectal cancer, and of high risk adenoma. Your patient therefore *does not need referral for suspected colorectal cancer*, but as always you should consider seeking specialist advice if worrying symptoms persist. In patients with symptoms of significant concern, you should consider non-luminal cancers and may still wish to send a suspected upper GI cancer referral. Advice and guidance services may also be used in line with local arrangements.

The Widlak study (see below) also showed a sensitivity of 86% and Negative Predictive Value of 100% for inflammatory bowel disease.

READ Code 4792 FOB –ve is recommended

What is the level of confidence in the test?

The patient population for whom we are recommending qFIT are at less than 3% risk as they do not meet the NG12 suspected cancer referral criteria. At the test threshold we are using, and in this specific population, research demonstrates a **negative predictive value of over 99%** and specificity variously reported at 84 or 100%.

The two main studies from the UK using HM JackArc state:

Godber et al Clin Chem Lab Med 2016; 54(4): 595–602

Scottish study using FIT at a 10µg/g threshold

Sensitivity for colorectal cancer -> 100% and specificity -> 80.2%

PPV -> 26.3% and NPV -> 100%

Widlak et al Aliment Pharmacol Ther 2017; 45: 354–363

English study

Sensitivity -> 84% and specificity -> 93%

NPV -> 99%

It is important to note that in patients with more significant symptoms or other test abnormalities (for example Iron Deficiency Anaemia), the test is less sensitive and may miss some cancers, so it is important to use the test criteria carefully and still refer to NG12 for patients with symptoms of greater concern.

When can GP's start using the test?

Implementation is scheduled for June. Your clinical commissioning group will inform you of the exact start date and a supply of packs will be sent to your practice soon.

Will the test be suitable for all patients?

The test may not be suitable for patients who have a disability that would make it difficult for them to complete at home for example those with arthritic hands.

The test instructions are also given in other languages.

Patients, carers and GP's may feedback their experience of issuing and using the test online. The details of the website will be provided inside the test pack and in supporting documentation provided to GP's.

If any practices would be interested in supporting a more detailed evaluation of FIT then please contact sarah-jane.davies@nhs.net for further information.

Where can I access further information and support?

- Contact the programme team for information about the project: sarah-jane.davies@nhs.net

- For more information about the test kit visit: www.exeterlaboratory.com/ and www.nbt.nhs.uk/severn-pathology or email: Paul Thomas, Consultant Clinical Scientist Paul.Thomas@nbt.nhs.uk Or Tim McDonald, Consultant Clinical Scientist: timothy.mcdonald@nhs.net

- Your local Cancer Research Facilitator will be in touch shortly to discuss any support that you may need. If you would like to arrange a visit or call to discuss FIT please contact: Rachel.byford@cancer.org.uk

- For more information about FIT the following website might be of interest: www.faecal-immunochemical-test.co.uk/

- Information video for GP's link: https://youtu.be/zb1o8ykvS6U