Humber and North Yorkshire Cancer Alliance

# HNY Guidance Note

Using FIT in patients with signs and symptoms of suspected colorectal cancer in primary care

## *Introduction*

The Faecal Immunochemical Test (FIT) has become a key test in helping to diagnose colorectal cancers (CRC) at an early stage. It has become the standard test used in the bowel cancer screening programme (replacing FOBt) and is now an essential tool in the risk assessment and management of people with worrying bowel symptoms. There is an increasing focus in national policy on the use of FIT in the colorectal pathway. The aim of this focus is to allow improved triage of high-risk patients on to further urgent investigation and the identification of patients at a lower risk of CRC who might be better directed onto less urgent or alternative pathways or managed within Primary Care.

In Humber and North Yorkshire, we are facing significant backlog and delays in diagnosing and treating CRC patients. Consistent use of FIT in these patients in Primary Care might help direct them to the most appropriate diagnostic services and onward management and treatment, including future rapid Straight to Test pathways.

The Association of Coloproctologists of Great Britain and Ireland (ACPGBI) and the British Society of Gastroenterologists (BSG) have published NICE-accredited guidelines[1] to assist services in implementing the use of FIT as a Primary Care tool in directing patients with a suspicion of CRC onto the most appropriate pathways according to their risk. There has been considerable debate on the status of these guidelines and how they relate to the established NICE NG12 referral guidelines, which are unchanged and likely to remain so until at least September 2023.

https://www.nice.org.uk/guidance/ng12/chapter/Recommendations-organised-by-site-of-cancer#lower-gastrointestinal-tract-cancers

## *The status of this advice*

The audience for this guideline is GPs and clinicians managing patients with a suspicion of CRC. The aim of this guideline is to set out the local framework for the use of FIT and to assist Primary Care clinicians in using it to best effect for their patients. The guideline should also outline the importance of a shared understanding between Primary and Secondary Care of how FIT can be used at the start of a referral pathway and the critical areas of communication needed to ensure timely and effective diagnosis and care for all patients. This guideline presents good practice and evidence identified in the published NICE-accredited ACPGBI/BSG guidance, as endorsed by NHS England.

This guidance has been developed in collaboration with representatives of YORLMC and Humberside LMC, the HNY Cancer Alliance Colorectal Clinical Delivery Group, the HNY Cancer Alliance Primary Care Strategy and Delivery Group, and Secondary Care colleagues across the Cancer Alliance area. It has the approval of the Humber and North Yorkshire Cancer Alliance Clinical Director and the Humber and North Yorkshire ICB Executive Director of Clinical and Professional.

[1] Monahan KJ, Davies MM, Abulafi M, *et al* (2022) Faecal immunochemical testing (FIT) in patients with signs or symptoms of suspected colorectal cancer (CRC): a joint guideline from the Association of Coloproctology of Great Britain and Ireland (ACPGBI) and the British Society of Gastroenterology (BSG) *Gut* 2022;**71**:1939-1962. [https://gut.bmj.com/content/71/10/1939]

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## *Our advice*

The core of this advice relates to how best we can use a FIT result in Primary Care to direct a patient to the most appropriate diagnostic service or management, in the safest way possible. This advice should sit alongside a clinician's use of the current NG12 and DG30 guidelines (see summary in FAQ). It is aimed at referring clinicians in Primary Care. The following points outline the key elements of this advice:

**Who needs a FIT result**

- Clinical assessment is a vital part of the patient evaluation when using FIT. To ensure rapid diagnostic access for the highest risk patients, all patients in whom you are suspicious of CRC should undergo abdominal and PR examination.
- Once you have assessed a patient who presents with symptoms that raise a clinical suspicion of CRC, you should order a FIT. This result should inform your assessment of the patient and so **you should obtain the FIT result before making a referral decision**.
- FIT should generally not be requested on patients without NG12/DG30 symptoms as interpreting these results can be difficult and lead to unnecessary concern for both patients and clinicians. An exception to this may include local RDC/RDS pathways.

**There are some exceptions to this approach:**

- If a patient has a palpable anorectal mass or anal ulceration, **refer the patient on the lower GI two-week wait (2WW) pathway without delay**
- If a patient has a palpable abdominal mass, **refer the patient on the lower GI two-week wait (2WW) pathway without delay and request a FIT at the same time**
- If a patient, aged 60 years or over, has previously uninvestigated Iron Deficiency Anaemia (IDA) **refer the patient on the lower GI two-week wait (2WW) pathway without delay and request a FIT at the same time.**

- Please be aware that FIT is appropriate for use in those with unexplained rectal bleeding if they are over the age of 50 years or under 50 years if suffering from abdominal pain, a change in bowel habit, or weight loss or iron deficiency anaemia.
- You may have difficulty obtaining a FIT result.
    - **If** after appropriate counselling and advice you are unable to ensure the return of the FIT by the patient in an appropriate timeframe
    - **Or** if you have serious concerns that you will be unable to ensure the return of the FIT by the patient due to their circumstances
    - **And** you have continued clinical concern
      ...**you should refer the patient on the lower GI 2WW pathway** noting your concerns and the patient issues around completing the FIT on the referral.
- Please ensure that the reasons that a FIT has not been obtained are included in the referral, this will ensure that there is no attempt in secondary care to get a FIT test when it is impracticable.
- Of note it is possible to do a FIT test as part of a PR examination, if the clinician feels this is appropriate and can be done while following all appropriate infection control measures (see FAQ).
- When ordering a FIT, appropriate information should be given to the patient about its role, purpose, and intended benefit as part of your safety netting processes.

**Using a FIT result to inform your clinical decisions**

Clinicians in Primary Care should consider the FIT result when deciding whether a patient has a high enough risk of CRC to warrant an urgent 2WW referral

- If the result is at or above 10 µg Hb/g faeces **you should refer the patient on a lower GI 2WW pathway.** This applies to both NG12 and DG30 symptoms.
- In your locality you may have access to a colorectal Straight To Test (STT) pathway for patients with a FIT at or above 10 µg Hb/g faeces – if so this will provide an accelerated diagnostic route for the patient.

***Patients with a FIT below 10 µg Hb/g faeces***

Patients with a FIT below 10 µg Hb/g faeces are often referred to as 'FIT negative'. With the exception of people over 60 years with previously uninvestigated IDA and those with an anorectal or abdominal mass, a negative FIT should be used to support an alternative approach to the patient's care, and you should not anticipate referring patients on a 2WW colorectal pathway. This is because symptomatic FIT negative patients have a risk of CRC of <0.5%, comparable to that of the asymptomatic, age matched population. For the majority of FIT negative patients, you should consider other options of care which may be more appropriate for them.

It is anticipated that most patients will have self-limiting, functional, or benign conditions that can be managed appropriately in Primary Care without the need for referral or further investigation. Local reassurance, explanation and treatment followed by 'safety netting' review and closure of the episode may be all that is required. Here the Primary Care clinician will apply his or her clinical judgement in the assessment of each patient. 'Safety netting' might ordinarily mean review of the patient's response at 4-6 weeks.

For others whose bowel symptoms persist and are unexplained or require further investigation, a colorectal or gastroenterology referral will be appropriate though not through the 2ww colorectal pathway. The Faecal Calprotectin pathway may be of help in those under 60 years.

Symptoms such as abdominal pain or weight loss may be caused by conditions, including other cancers, arising outside the bowel (that are not CRC) and here the patient may be more suitable for an alternative suspected cancer investigation, such as a site specific (eg upper GI, urology, gynaecology) or vague symptom referral such as a Rapid Diagnostic Centre (RDC) or Rapid Diagnostic Service (RDS) pathway. If for example a gynaecological cancer is suspected a CA125 might be a useful additional test to perform.

Only on occasion you may continue to have clinical concern for CRC in which case you should refer the patient into the suspected CRC 2WW colorectal pathway clearly outlining your concerns as part of the referral. Performing a second FIT to inform your assessment may be of some benefit. Careful Primary Care safety netting is essential for this assessment to be safely conducted.

**Safety netting**

As ever, it is vital to provide the patient with clear information about who to contact if they develop new symptoms or if their existing symptoms worsen. There are a range of communication routes you could use as part of this, including SMS services and email.

If at any point symptoms significantly deteriorate or there are additional clinical concerns, then you should refer on a 2WW pathway. Please highlight on the referral how the patient meets existing NG12 criteria and provide full clinical details of the reasons why you feel they need to be seen urgently as part of the referral. Consider using Advice and Guidance if you are unsure of the most appropriate referral route.

**Communication, advice, and guidance**

Open communication between primary and secondary care clinicians can play a vital part in ensuring patients are directed towards the most appropriate investigations. Including details of your concerns as part of an urgent referral helps the teams handling those referrals manage investigations efficiently, ensuring the highest risk patients are investigation urgently. As part of the triage process, you may be contacted by the Secondary Care teams for further information to ensure the best management of the patient.

Referrals meeting the 2WW criteria should not be rejected if a FIT result cannot be made available. In some areas you may be contacted by member of a colorectal team to discuss or get further information from you if the reasons for the lack of a FIT result are not clear. Without a FIT, your patient is also unlikely to benefit from a colorectal straight to test pathway. If a patient has been

unable to complete a FIT and you are unsure if referring on a lower GI 2WW pathway is the most appropriate option, consider getting Advice and Guidance from the colorectal teams.

## *FAQ*

**What is NG12**

The NICE NG12 guidelines outline how GPs should manage and refer patients they suspect may have cancer. They indicate the criteria by which to judge if a patient should be referred on an urgent 2WW pathway. The criteria to urgently refer (two week wait) a patient with suspected colorectal cancer are:

- aged 40 and over with unexplained weight loss and abdominal pain
- aged 50 and over with unexplained rectal bleeding
- aged 60 and over with either:
    - iron deficiency anaemia
    - OR alteration in bowel habit who have positively tested for occult blood in their faeces.

And to consider urgent referral (appointment within two weeks) for people:

- of any age with a rectal or abdominal mass
- aged under 50 with rectal bleeding and any of the following unexplained signs or symptoms:
    - abdominal pain
    - altered bowel habit
    - weight loss
    - iron deficiency anaemia.

NICE are currently conducting a review of the NG12 criteria for colorectal cancer, to factor in research findings on the use of FIT. A revised version is expected in Autumn 2023, following the completion of the COLOFIT study.

**What is DG30 and how is FIT used as part of it?**

DG30 is a NICE guideline which covers symptomatic patients presenting with lower risk symptoms, which could be indicative of lower gastrointestinal cancer. In accordance with NICE DG30, general practitioners should offer testing with quantitative faecal immunochemical tests (FIT) to assess for colorectal cancer in adults without rectal bleeding who:

- Are aged 50 and over with unexplained abdominal pain or weight loss, or,
- Are aged under 60 with changes in their bowel habit or iron-deficiency anaemia, or,
- Are aged 60 and over and have anaemia even in the absence of iron deficiency.

A positive FIT test result for a DG30 patient (defined as a return of 10 or above) is a relevant reason to “upgrade” them on to an urgent suspected cancer (NG12) pathway.

A negative FIT result in a DG30 indication (defined as a return of 9 or less) should be interpreted in accordance with your clinical judgement.

- If the patient subsequently develops a symptom which is categorised under NG12, consider immediate referral to secondary care.
- If clinical concern of malignancy remains, consider a referral under the non-site specific (vague symptoms) cancer pathway.
- In other cases, consider alternative management options and differential diagnoses.

**What to do if a patient might struggle to complete a FIT**

Obtaining a sample for a FIT can be difficult for patients for a number of reasons. These might include physical challenges such as limited mobility and dexterity issues, as well as social challenges such as access to suitable space and facilities for those who are socially marginalised. Getting a FIT result can greatly benefit a patient, so support should be sought when you consider it appropriate. Some of

these patients may benefit from the support of a carer or family member in completing the test. Another option is to collect a sample for the test during a digital rectal exam.

***Obtaining a FIT sample via Digital Rectal Exam (DRE-FIT***)

The ACPGBI/BSG guidance states that for those with dexterity difficulties in performing the test, digital rectal examination to obtain stool for FIT testing appears to offer similar accuracy to home performed tests. One study that supported this method outlined the following process for this [2]: Counselling and consent were obtained before sampling. As DRE is a usual part of clinical examination during colorectal assessment; a stool sample for FIT was obtained at the same time. For DRE, patients were positioned in the left lateral decubitus position with hips and knees flexed at 90° angles. Disposable, non-latex, non-sterile gloves were used. Water-based lubricant (Optilube®; Optimum Medical, Leeds, UK) was used for lubrication. After assessment of the anorectum for pathology, a small amount of faeces was collected and smeared on to the collection picker (EXTEL HEMO-AUTO MC device; Kyowa Medex, Tokyo, Japan). The sample was stored according to manufacturer guidelines and transferred immediately to the local laboratory for analysis.

**Patient information and safety netting resources**

The Cancer Alliance can provide a selection of tips, processes, and resources to use in Primary Care safety netting for patients with a suspicion of colorectal cancer. These include the use of test messaging systems, suggested content of messaging, and outline processes for ensuring patients are robustly tracked through the FIT testing process. All FIT testing in Humber and North Yorkshire is currently covered by a 'Failed FIT' protocol, through which the laboratory will directly contact a patient whose test has failed to have a conversation about the test and will send a replacement test kit direct to the patient.

[2] Khan AA, Klimovskij M, Harshen R (2020) Accuracy of faecal immunochemical testing in patients with symptomatic colorectal cancer, *BJS Open*, **4**(6), December 2020, 1180–1188 [https://doi.org/10.1002/bjs5.50346]