Northern Cancer Alliance
FIT (faecal immunochemical test) in Primary Care for - Lower GI 2WW pathway FAQs September 2020

Introduction

FIT (faecal immunochemical test) is changing how we assess colorectal symptoms and identify risk of colorectal cancer. It has been used for the last couple of years in the bowel cancer screening program and for people with low and medium risk colorectal symptoms.

FIT can now also be used for people with symptoms consistent with NICE NG12 2ww referral critera. The use of FIT in this group has been validated in national studies. (1,2,).
Since the onset of the Covid pandemic, the quantitative result of the FIT has been used to stratify the urgency of colorectal investigations in all groups: 2ww, routine, and screening. This may mitigate some of the risks associated with the significant backlog of investigations (3). There is now national and regional support to use the FIT result to stratify risk in primary care and direct the patient depending on the result (National briefing document)
The following FAQs are to support primary care to use FIT in this group of patients.

1. What does the FIT result tell us about risk of colorectal cancer?

The result is used to determine bowel cancer risk and to direct people to the most appropriate investigation (4). The result will also influence the urgency of the test:

Symptomatic but without rectal bleeding	**Positive predictive value for CRC**	**Actions required**	**Numbr of colonoscopies to identify one CRC**
FIT > 400mcg/g	22.8%	High priority colonoscopy/ CTC	4
FIT >100mcg/g	17.9%		
FIT 10-99mcg/g	est 1-10%	Less urgent colon investigation	
FIT <10mcg/g	<0.7%	Consider other non-colon urgent investigation or low priority colon investigation or no investigation	148

Asymptomatic general population prevelance	<1%	Encourage participation in the National screeing program

2. How is FIT being used in the new pathway for Lower GI 2WW referrals?

FIT is now integral to the assessment of patients with symptoms and signs suggestive of possible bowel cancer. All should have a FIT test as part of their assessment as the result will inform the clinical decision to refer or to direct the patient to other investigations. The exceptions are people who have an abdominal, rectal or anal mass, or anal ulceration who should be referred without delay. People with high risk IDA, unexplained weight loss or persistent rectal bleeding will need some investigation whatever the outcome of the FIT test but may not need colonoscopy. It is important to check CA125 in women with negative FIT and unexplained symptoms.
For people without weight loss, persistent rectal bleeding or IDA and with normal examination (including PR), a negative FIT test can be used to support GPs to do safety netting in primary care. The risk of colorectal cancer in this group is < 1% which is about the same as the general population. In this case,

the recommendation is to review the patient in primary care at 4-6 weeks and if there are persistent or troublesome symptoms, seek advice and guidance from the colorectal team.

The FIT result MUST be included in the referral as this will directly affect the management (both the secondary care pathway and the prioritisation) of your patient.

3. Do I need to wait for the result before I send the referral?

Yes. The result of the test will help you and the secondary care team direct the patient to the most appropriate test. The new postal service for FIT will reduce the turnaround time to get results and has a built in safety-net to let primary care know if a sample has not be received by the lab after 10 days and then 21 days.

The 2WW referrals are triaged within 24 hours of receipt; including the result helps secondary care to offer the appropriate test / consultation within 2 weeks. Secondary care do not always have direct access to FIT results in ICE (FIT tests are processed centrally) or the rapid test requests and result safety-netting.

4. What about patients meeting NICE NG12 high risk criteria but with FIT<10?

A patient with abdominal symptoms and FIT<10 has a 99.6% chance of NOT having CRC (negative predictive value; this is approximately the risk in the general population). Thus, benign conditions are a far more likely explanation for the patient's gastrointestinal symptoms. Symptoms such as abdominal pain or weight loss may be caused by conditions arising outside the bowel and the patient may be more suitable for an alternative investigation.
Nevertheless a small proportion of patients with CRC will have a FIT<10. Therefore, in patients with a FIT<10 ug/g without IDA or weight loss and with normal examination (including PR) who have had no previous investigation, clinical teams should consider:

- Investigating other concerning symptoms via alternative diagnostic pathway e.g. upper GI, urology, gynaecology, or direct access tests. Remember to check CA125 in women;
- Safety netting, medical management if appropriate and review at 4-6 weeks to consider need for investigation, either LGI 2WW if there are significant concerns or advice and guidance from the colorectal team.

If at any point symptoms significantly deteriorate or there are additional clinical concerns then the GP may refer via a 2ww pathway. Please highlight how the patient meets existing NG 12 criteria and provide full clinical details of the reasons why you feel they need to be investigated in the "additional clinical information" box on the 2ww form.

5. What if the patient refuses to do a FIT test or cannot produce a sample?

GPs are <u>strongly</u> encouraged to arrange FIT before referring as this will greatly help stratify a patient's risk. Consider the reasonable adjustments that may be needed to support the patient. However if it is impossible to obtain a FIT and there remain serious concerns, as above GPs may refer explaining the reasons why the test could not be done and why they feel the patient needs to be investigated.

6. Who do I contact if I do not receive the results within 10 working days?

Please contact the patient to check they have been able to complete the test. If specific support for people with a learning disability is needed please consider the community learning disability team. If

your paitent is unlikely to be able to complete the test, please send the referral including the reason they cannot do the FIT test.

7. Why has this change been introduced?

The change is based on emerging evidence from trials that have been running over the last few years. Introduction has been accelerated due to the pandemic. Diagnostic capacity for investigating patients with suspected lower GI cancer is limited during the Covid pandemic due to initial suspension of services, redeployment of staff and concerns about infection prevention and control. FIT is helping to make sure that people with the greatest risk of colorectal cancer are investigated most urgently, and people who are less likely to benefit from colonoscopy are either directed to a more appropriate investigation or are not subjected to an invasive procedure (3).

8. Who has recommended and approved this change in practice?

The use of FIT in the urgent pathway has been recommended by the National Cancer Team and British Society of Gastroenterology and is based on a number of national studies on the use of FIT in 2ww patients (see references below). All CCGs and trusts across the country have been encouraged to use FIT in this way since the onset of the Covid pandemic. The guidance has been discussed and agreed by the NCA colorectal and endoscopy clinical groups, and the NCA commissioning and cancer in the community group. There is national support from Peter Johnson (National Clinical Director for Cancer) and Robert Logan (National Clinical Advisor for Endoscopy) for the FIT to be requested by primary care and the result used in primary care to direct FIT positive patients to 2WW colorectal referral and FIT negative people to other urgent investigations or safetynetting and management in primary care depending on clinical presentation. This has been endosrsed by the medical directors for The North East and Yorkshire Region and Cumbria and North East, Dr David Black and Dr Jonathan Slade.

9. Is this in line with national recommendations?

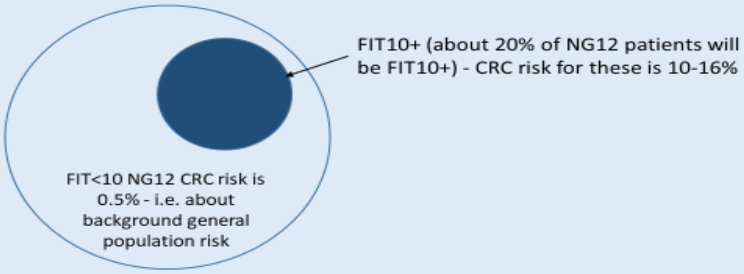
Yes. NHS England national guidance recommends FIT is performed on all patients referred for Lower GI 2WW since the onset of the COVID-19 pandemic to aid triage of people with lower GI symptoms. The triage may be completed in primary or secondary care (National Cancer Team update August 2020).

10. What is the evidence on using FIT in high risk symptomatic populations?

Two meta-analyses reported that a FIT$\geq$10 µg/g identified respectively 92% (1) and 94% (2) of patients with CRC. Unpublished data from the NIHR FIT study on 9822 patients referred on a Lower GI 2WW found that 90.9% of patients with CRC had a FIT$\geq$10 µg/g.

Perhaps most importantly from a patient perspective, a FIT<10 result means a patient has less than a 1% chance of having CRC: similar to the risk in the general population (50 years and older).

Background CRC general population prevalence (for those 50 and older) is 0.5-1%



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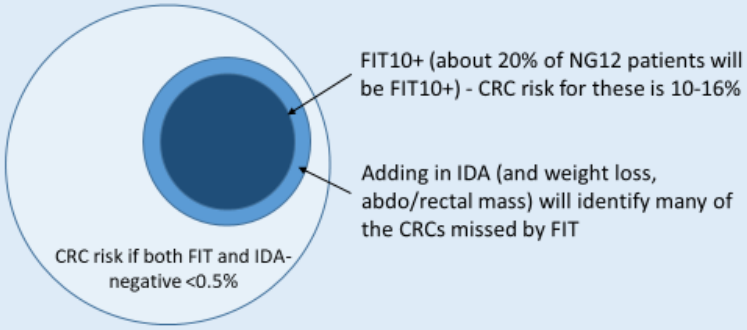

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11. Am I protected medico-legally if I follow the changes in the new LGI pathway?

YES. Since the new guidelines have been come from the National Cancer Team and BSG and endorsed by the regional NHSE medical director, GPs will be following expert guidance in the context of the COVID-19 pandemic.

12. Can the referral be rejected if a FIT test is not ordered?

The FIT result is now required information which must be included with the 2ww referral. Referrals with incomplete information will generate a query to the practice. Under the latest National Cancer Waiting Times v11 guidance a 2ww referral can only be downgraded with the consent of the referring GP (CWT V11 SEE SECTION 2.5.1)It also states that the duty of care is with the referring practice to provide the required information for the referral. If you do not order a FIT and await the result, this may delay access to the investigation your patient needs or result in inappropriate investigation.

13. What should the practice do if a referral is rejected?

Referrals should not be rejected but you may be asked to downgrade the referral if there is not enough information (CWT V11 SEE SECTION 2.5.1). If referrals are rejected, please inform the relevant lead commissioning manager or clinical lead at your CCG who should ensure this is followed up with the hospital provider.

14. What about cases of CRC who have FIT<10 ug/g?

FIT will detect most but not all CRC: up to 10% of CRC are FIT negative – however the absolute risk that a patient with FIT<10 has CRC is less than 1%. Nevertheless, safety netting and review is very important, and it is unlikely that a 4–6 week delay in making referral will influence the outcome of treatment if colorectal cancer is present. In a large Scottish study of 5327 people, 12 people had CRC with negative FIT. Of these 8 had anaemia and 1 had a palpable mass and one had weight loss. 8 / 12 would be picked up bby the other criteria in the recommended pathway.

FIT testing is an improvement on using NICE “high risk” criteria, which have much lower sensitivity than FIT for detecting CRC (4).
Remember, even colonoscopy and CTC is not 100% sensitive for colorectal cancer.

15. What will happen to patients referred with FIT ≥10?

Once the referral is received, the secondary care team will assess the patient in line with the National guidance to decide on the most appropriate next step.

16. What will happen to patients referred with a FIT<10?

The secondary care team will assess the patient using the information in the referral to decide if and how to investigate the patient. Some people will be offered alternative urgent investigations ie. for weight loss. Some people will be offered a less urgent investigation of the colon. Most FIT negative people will not need any investigations because their risk of colorectal cancer is low.

17. Is FIT a useful test in patients with rectal bleeding?

Yes. Data from the NIHR FIT study (reference) showed that FIT was as sensitive for detecting colorectal cancer in patients with a history of rectal bleeding as those without. Rectal examination is essential as rectal / anal mass or ulceration consistent with CRC require immediate referral.

Patients over 40Y should ideally take a FIT sample from a stool that does not contain frank blood.
FIT positive >10 - 2WW referral
FIT negative <10 and abnormal findings or other concern of CRC refer 2ww
FIT negative <10 advice and safety-net and conservative management. Advice and guidance if ongoing troublesome symptoms
People under 40 should be managed conservatively in primary care using advice and guidance or routine referral for persistent troublesome symptoms.

18. What are the symptoms of developing bowel obstruction?

Most commonly abdominal cramps and pain, bloating, nausea and vomiting, lack of appetite and new severe constipation. A referral for possible colorectal cancer should include details of whether these symptoms are present or absent.

19. Will there be delays in pathology analysing FIT samples sent by general practice?

Delays are not expected. The new postal pathway in Northumberland, North Tyneside, Newcastle and Gateshead (Starting August September 2020) and Durham Darlington and Tees Valley (starting November 2020) will reduce the turn around time to 5 days in most cases. This should be similar to the exisiting process in Cumbria and Sunderland and South Tyneside. Gateshead and Cumbria lab are able to process all the samples they are sent. Waiting for this result means that GPs can then make an more informed decision on whether to refer under the 2WW.

20. What materials should be obtained to support delivery of the new pathway?

- A new version of the electronic 2WW referral form for colorectal cancer has been made LINK TO NCA 2WW FORMS
- A new Patient Information Leaflet for patients referred on 2ww during COVID-19LINK to NCA leaflets
- New accessible patient instructions on how to collect poo sample have been developed to include in the postal packs sent from the lab.

21. What if my patient declines their LGI referral due to Covid-19?

Ideally patients meeting the described criteria should be referred on the LGI WW pathway, even if they are currently self-isolating or COVID-19 positive. If patients choose to defer the referral (having discussed the risk versus benefit of this approach) then these patients should be safety netted by primary care with a review date set with the patient.
The referral form provides a box to indicate the COVID-19 risk status of the patient.

22. How do I order more FIT kits?

Primary care should continue to order kits through their usual requesting routes until you switch to the new postal service. When the new postal service is in place you will not need to have kits in the practice.

References

1. Westwood M, Corro Ramos I, Lang S, Luyendijk M, Zaim R, Stirk L, et al. Faecal immunochemical tests to triage patients with lower abdominal symptoms for suspected colorectal cancer referrals in primary care: a systematic review and cost-effectiveness analysis

2. Pin Vieito N, Zarraquiños S, Cubiella J. High-risk symptoms and quantitative faecal immunochemical test accuracy: Systematic review and meta-analysis. World J Gastroenterol 2019;25:2383-401

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4. Quyn AJ, Steele RJ, Digby J, Strachan JA, Mowat C, McDonald PJ, et al. Application of NICE guideline NG12 to the initial assessment of patients with lower gastrointestinal symptoms: not FIT for purpose? Ann Clin Biochem 2018;55:69-76.

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6. Mowat C, Digby J, Strachan JA, et al. Impact of introducing a faecal immunochemical test (FIT) for haemoglobin into primary care on the outcome of patients with new bowel symptoms: a prospective cohort study. BMJ Open Gastro 2019;6:e000293. doi:10.1136/bm