South Yorkshire and Bassetlaw Integrated Care System CANCER ALLIANCE Working with Derbyshire

South Yorkshire and Bassetlaw Integrated Care System

South Yorkshire and Bassetlaw Integrated Care System Cancer Alliance FIT (Faecal Immunochemical Test) in Primary Care for high risk symptoms – part of the Optimum Lower GI Rapid Diagnostic Pathway. February 2021

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 programme and also as part of the South Yorkshire and Bassetlaw (SYB) Lower GI Integrated Pathway for people with lower risk (not NG12) LGI symptoms.

FIT can now also be used for people with symptoms consistent with NICE NG12 2ww referral criteria. 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 SYB LGI optimum pathway will consist of a number of components which support the utilisation of FIT and endeavour to minimise risk to patients; as well as providing adequate advice and guidance to primary care (and secondary care colleagues).

The following FAQs represent one of a series of educational resources for primary care to support their use of FIT in NG12 higher risk symptomatic patients:

Questions and Answers

1. Why has this change been introduced?

The change is based on emerging evidence from trials that have been running over the last few years which have demonstrated the value of FIT as a key part of LGI symptom assessment and risk stratification. The COVID-19 pandemic has accelerated its' use across high risk LGI pathways resulting in improved patient management and diagnostic resource utilisation. The latter (i.e. endoscopy) remains extremely pressurised, with capacity reduced due to infection prevention measures. 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 more appropriate or routine investigations, or are not subjected to an invasive procedure (3). It also will mean that many patients can be reassured in primary care, without the need for urgent, suspected cancer referrals and the anxiety that produces.

2. 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 (without rectal bleeding)		
FIT result	**Positive Predictive Value for CRC**	**Management**
<4	0.2%	CRC very unlikely – no 2ww referral required
4 – 9.9	0.7%	CRC low risk – no 2ww referral required **unless** anaemia **WITH** low Ferritin <25 **OR WITH** Ferritin ≥350 **OR WITH** Thrombocytosis (platelets ≥400)
>9.9 - 100	Est 1 – 10%	2ww referral for STT or out-patient consultation
>100	17.9%	2ww referral for STT
>400	22.8%	2ww referral for STT

Asymptomatic general population prevalence	<1%	Encourage participation in the National screening programme

3. Why is the Ferritin level set at <25 for the lower range?

We are aware that different labs use a different range of reporting and therefore what is regarded as abnormal (between 10 and 25). The reason we are using 25 is that the work that has been done in this area where FIT and Ferritin (and FBC) are used to identify the groups that should have investigation is 25.

4. What about isolated low or high Ferritin, or isolated thrombocytosis?

There is no evidence that these alone are a predictive risk factor of CRC unless the FIT >4 with anaemia.

5. 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 or pathways. The exceptions are people who have rectal bleeding as well as those with an abdominal, rectal or anal mass, or anal ulceration who should be referred without delay. People with IDA should still be referred if the FIT is 4-9.9mcg/g. It is important to check CA125 in women with negative FIT and unexplained symptoms. Referral to gastroenterology in patients with IDA and a FIT <4 should still be considered but on a non-cancer pathway.

For people without weight loss 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 or consider referral.
Patients with non-specific symptoms including abdominal pain and weight loss (see NG12) should be managed in accordance with the local 'Non-specific symptom' pathway

2ww - 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.

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

Yes. The result of the test will help you and subsequently, the secondary care team to direct the patient to the most appropriate onward pathway route. Primary care need to ensure they safety net FIT results and if no test result is noted within 10 days call the patient to ensure that they have completed the test? In addition with a FIT test that is negative (<4), with NG12 symptoms of change in bowel habit, no 2ww referral is necessary.

All 2WW referrals are triaged in secondary care within 0-72 hours of receipt; by including the FIT result, this helps secondary care to determine the appropriate test / or consultation and the timeliness in which this should take place.

7. 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). If FIT <4 that chance is even lower. 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. The majority (85%) of these will have anaemia OR low Ferritin (<25) OR raised platelets (≥400) or raised Ferritin (≥350). This is because the raised platelets and ferritin are acting as a marker of 'inflammation', potentially caused by a significant diagnosis. Therefore, in patients with a FIT<10 ug/g without IDA, or raised platelets or Ferritin and with normal examination (including PR) who have had no previous investigation, primary care clinicians should consider:

- Investigating other concerning symptoms via alternative diagnostic pathways 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 via your secondary care provider.

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.

8. What if the patient does not want to do a FIT test or cannot produce a sample?

GPs are strongly encouraged to arrange a FIT and review results before referring as this will greatly help stratify a patient's risk, and also prevent needless, potentially hazardous and uncomfortable luminal investigation. 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.

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

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

The use of FIT in the urgent pathway has been recommended by the National Cancer Programme Team and the 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 SYB ICS LGI Cancer Clinical Delivery Group (CDG) and in the Lead Commissioners 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 investigations or safety netting and management in primary care depending on clinical presentation. This pathway has been endorsed by the CDG and represents a component part of the overall SYB LGI Optimum Rapid Diagnostic pathway.

11. Is this in line with national recommendations?

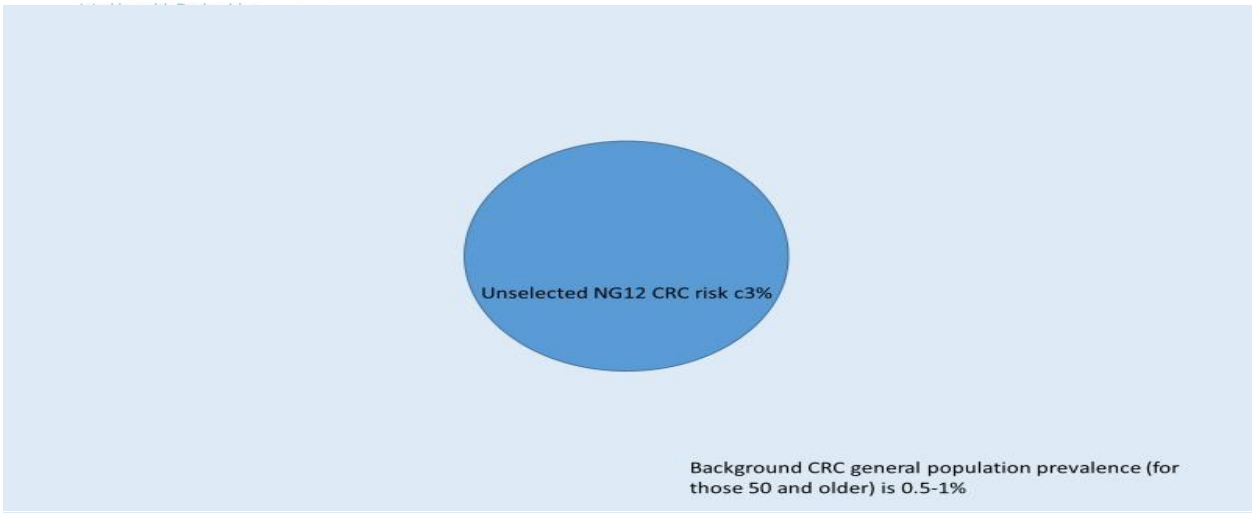
Yes. NHS England national guidance originally recommended FIT is performed on all patients referred for Lower GI 2WW since the onset of the COVID-19 pandemic to aid triage of people with lower GI symptoms. The triage may be completed in primary or secondary care (National Cancer Team update August 2020).

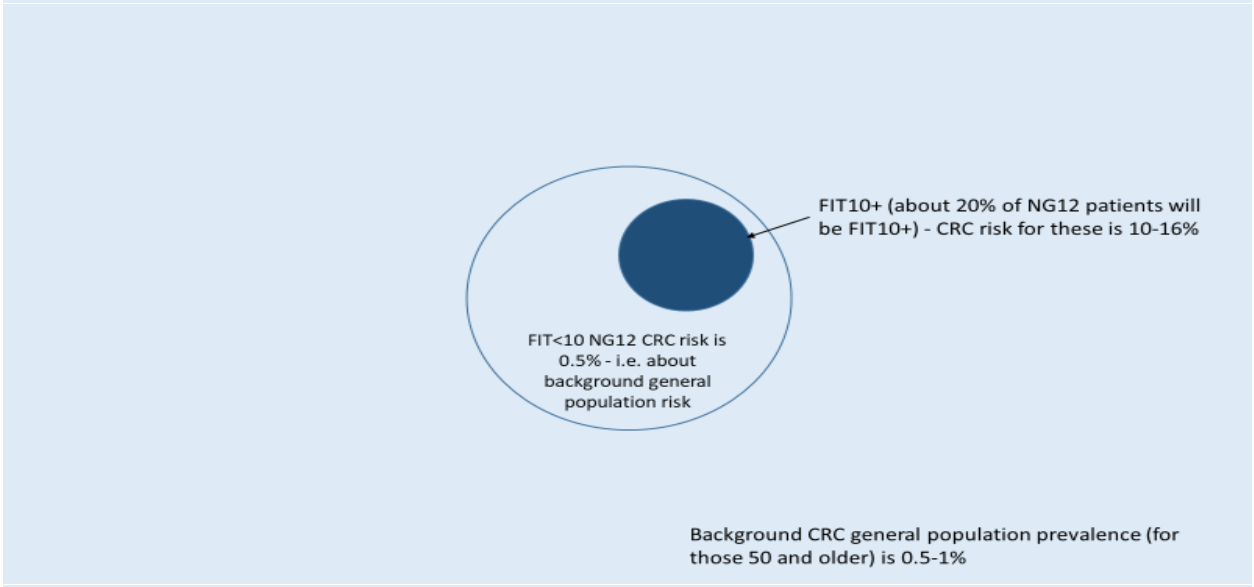
12. What is the evidence on using FIT in high risk symptomatic populations?

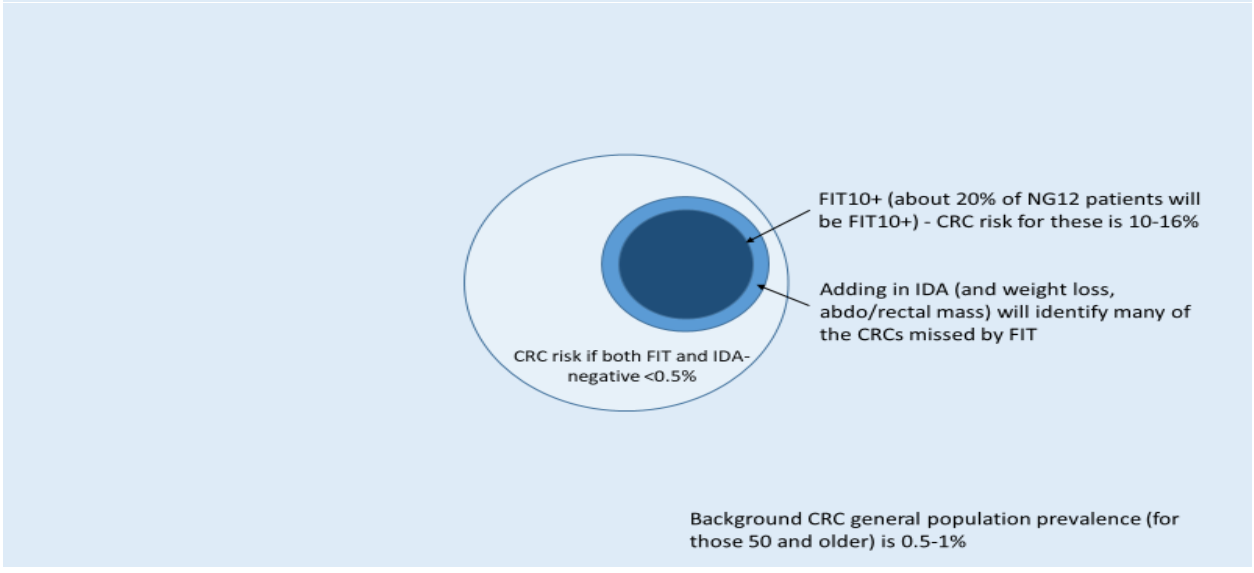
Two meta-analyses reported that a FIT≥10 µg/g identified respectively 92% (1) and 94% (2) of patients with CRC. Unpublished data from the NIHR FIT study on 9822 patients referred on a Lower GI 2WW found that 90.9% of patients with CRC had a FIT≥10 µg/g. According to the Nottingham data, the risk of CRC in patients with a FIT < 4 is 0.2%.

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).

There is some additional evidence that 85% of those very few cancers in the FIT<10 group have anaemia OR low Ferritin (<25) OR raised platelets (≥400) or raised Ferritin (≥350)







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

Yes. As the new guidelines come from the National Cancer Team and BSG and are endorsed by the regional NHSE medical director, GPs will be following expert guidance.

14. 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 refer without a FIT result (with the exceptions as described above), this may delay access to the investigation your patient needs.

15. 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 much less than 1% (0.2% risk of CRC if FIT < 4). Nevertheless, safety netting and review is very important, and it is unlikely that a 4–6 week delay in making a 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. Therefore 9/12 would be picked up by the other criteria in the recommended pathway. Data from Nottingham also supports this. For those with FIT >4 but <9.9, 85% of the cancers in this group had anaemia or a low Ferritin OR raised platelets or Ferritin.

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.

16. What will happen to patients post referral with FIT ≥10?

Once the referral is received, it will be triaged by the secondary care team against an agreed SYB LGI protocol - reflective of National guidance. This will determine the most appropriate next step. Patients eligible for STT endoscopy or radiology will be contacted by telephone to be assessed further and provided with sufficient information about the recommended diagnostic. Some patients will require F2F consultation as their first pathway step and will be sent an appointment within the 14 day window.

17. What will happen to patients referred with a FIT 4 – 9.9 but who have a palpable mass or iron deficiency anaemia OR thrombocytosis?

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 investigations i.e. for weight loss. Some people may be offered a less urgent bowel investigation. Most FIT negative people will not need any investigations because their risk of colorectal cancer is low. Our aspiration is that in the near future General Practitioners will be able to access Advice and Guidance in a timely fashion across the Alliance footprint, for all equivocal cases.

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

Currently we do not recommend the use of FIT in patients with symptoms of rectal bleeding. However, there is emerging data that this can also be useful to risk stratify these patients. We will evaluate further evidence as it becomes available, and may consider this in the future.

19. What materials are available to support delivery of the new pathway?

- A new version of the electronic 2WW referral form for LGI has been produced.
- New GP and patient resources are in production.
- The Cancer Alliance has completed the procurement process to implement a decision support tool across Primary Care to aid clinical decision making and safety netting.

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

Ideally patients meeting the described criteria should be referred on the LGI 2WW pathway, even if they are currently self-isolating or COVID-19 positive. Patients should be reassured about the safety of endoscopy; a national audit of over 6000 patients undergoing endoscopy soon after the first lockdown revealing no cases of COVID-19. 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. All providers have stringent infection control precautions in place when patients attend for investigation.

21. What if my patient is suitable for FIT but would be unfit for endoscopy investigation?

Before referral on a 'suspicious of cancer' pathway, consideration should always be given as to the patient's wishes (i.e. would they consider treatment if cancer found) and their fitness to undergo investigation and said treatment, if needed. However, some patients may not be suitable/fit enough for invasive colonic investigation (endoscopy or CTC) but are able to complete a FIT. These patients may be appropriate for plain CT scan as the choice of primary diagnostic. This would allow gross pathology to be excluded and therefore referral should be made in accordance to the guidance outlined.

All patients referred via 'suspicious of cancer' pathways should be aware of the reason for referral.

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