Thames Valley Cancer Alliance

# Primary Care FAQ

## Lower GI two-week wait pathway during COVID-19

June 2020

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| **Document Name: FAQ: Lower GI two-week wait pathway guidance during COVID-19** | | | |
| **Programme:** | Primary Care (Restoration & Recovery) | | |
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This FAQ on the Lower GI Pathway changes for primary care has been developed collaboratively between Thames Valley Cancer Alliance (TVCA) and Oxfordshire PC-FIT - Primary Care Faecal Immunochemical Testing Lab and Colorectal Specialists.

This document should be read in conjunction with the **Lower GI two-week wait pathway guidance during COVID-19.**

### What is the NICE NG12 Criteria for referring suspected colorectal patients?

NICE guidance states to refer adults using a suspected cancer pathway referral (for an appointment within 2 weeks) for colorectal cancer if:

- they are aged 40 and over with unexplained weight loss and abdominal pain or
- they are aged 50 and over with unexplained rectal bleeding or
- they are aged 60 and over with:
- iron-deficiency anaemia or
- changes in their bowel habit, or
- tests show occult blood in their faeces

The full referral guideline can be found here (click link).

### How has the referral pathway for Lower GI 2ww referrals changed?

All patients with signs and symptoms suggestive of possible bowel cancer should have a FIT test **before** referral unless they have a rectal or anal mass or anal ulceration. Patients with a FIT ≥10µg/g, should be referred on the Lower GI (LGI) two-week wait (2ww) pathway for suspected colorectal cancer (CRC). Patients with unexplained rectal bleeding or anal mass or anal ulceration should continue to be referred even if FIT result is negative.

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

A patient with abdominal symptoms and FIT<10µg/g has a 99.6% chance of **not** having CRC (negative predictive value). Symptoms such as abdominal pain, weight loss and abdominal mass may be caused by conditions arising outside the bowel and the patient may be more suitable for investigation via a different pathway. Nevertheless a small proportion of patients with CRC will have a FIT<10µg/g. Therefore in patients with a FIT<10 µg/g, GPs should consider:

- Safety-netting and medical management if appropriate, and review at 4-6 weeks to consider the need for referral, either LGI 2ww if patient meets NG12 criteria or routinely if they do not;
- Ensuring symptoms are not related to an alternative diagnostic pathway e.g. upper GI, urology, gynaecology, or appropriate for a Rapid Diagnostic Centre (RDC) if available;
- Seeking advice from a specialist via Advice & Guidance or a similar service.

If at any point symptoms significantly deteriorate or there are additional clinical concerns, the GP may refer via a 2ww pathway. Please highlight how the patient meets existing NG12 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.

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

GPs are **strongly** encouraged to arrange FIT before referring, as this will greatly help stratify a patient's risk. However, if it is impossible to obtain a FIT or there remains serious concerns, as above, GPs may refer explaining the reasons why they feel the patient needs to be investigated.

## Why have these changes been recommended?

Diagnostic capacity for investigating patients with suspected lower GI cancer is limited during the coronavirus pandemic, due to redeployment of staff and concerns that colonoscopy may be a high-risk aerosol generating procedure. The limited CT colonography (CTC) capacity is being prioritised to those at highest risk of having CRC, who could be harmed by delayed treatment, particularly those with cancer developing bowel obstruction. Additionally, bowel and abdominal symptoms could be a sign of other-than-bowel pathology, which will need consideration, with further investigations and onward referral on another pathway. Occasionally, there have been "failed" tests, usually due to incorrect patient identifiers on the test sample, and this could present a delay – primary care is best placed to ensure mitigation of this delay.

Similar pathway changes have been adopted in other areas, including London[1], to support the NHS response to the pandemic.

## Who has recommended and approved this change in practice?

The proposed changes were recommended by the CCG Primary Care Cancer leads across Thames Valley, and local Lower GI Trust leads. It has also been approved by the Thames Valley Cancer Alliance (TVCA) Clinical Advisory Group in May 2020. This group has formal authority to recommend changes to pathways during the COVID-19 pandemic.

## Is this in line with national recommendations?

NHS England guidance recommends FIT is performed on all patients referred for Lower GI 2ww referrals during COVID-19 to aid triage in secondary care. In the TVCA area, it was felt GPs are better placed to offer FIT as majority have access to testing kits and are already using it for low-risk symptomatic patients, and the pathway for referral starts after all the baseline tests have been completed (FBC, U&E, Ferritin, Coeliac).

As outlined in the BSG COVID-19 recovery guidance, NHS England recommends that if FIT is <10, do not proceed to LGI endoscopy but develop local safety net and criteria for further assessment and management based upon symptoms. FIT levels of <10 can be used to inform decisions on patient investigation by specialists in secondary care and not solely in primary care. More detailed advice on FIT cut off levels is expected to be published soon.

## What is the difference between FIT for symptomatic patients and FIT for Bowel Cancer Screening?

FIT testing in symptomatic patients differs from the use of FIT in the National Bowel Cancer Screening Programme (BCSP). FIT thresholds used as part of the BCSP are different to FIT thresholds in symptomatic patients. Patients with a negative FIT screening result may still have colorectal cancer and should be offered a symptomatic FIT test if appropriate. The Doctors Laboratory has produced some guidance on the differences between the use of FIT for screening and symptomatic patients (click here).

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

**No**. Under the latest National Cancer Waiting Times v10 guidance, a 2ww referral can only be downgraded with the consent of the referring GP.

If a consultant thinks the two-week wait referral is inappropriate this should be discussed with the referring GP.

[1] COVID-19 Impact on primary care cancer services in London

### What should the practice do if a referral is rejected?
Referrals should not be rejected. Please inform the relevant lead commissioning manager or clinical cancer lead at your CCG who should ensure this is followed up with the hospital provider.

### What is the evidence on using FIT in high-risk symptomatic populations?
Recent findings found that FIT triage of >10µg/g during the COVID-19 pandemic would salvage 1,292/1,419 of the attributable deaths and reduce colonoscopy requirements by more than 80%[2].

Two meta-analyses reported that a FIT ≥10µg/g identified respectively 92%[3] and 94%[4] of patients with CRC. Data from FIT testing on 9,896 adults in Oxfordshire has also found a sensitivity of 91% and a positive predictive value (PPV) of 10%.

### What about cases of CRC who have FIT<10 µg/g?
FIT will detect most but not all CRC; up to 10% of CRC will be missed. Therefore safety netting and review is very important. It is unlikely that a 4–6 week delay in making referral will influence the outcome of treatment if cancer is present.

It should be recognised that NICE "high-risk" criteria are likely to have much lower sensitivity than FIT for detecting CRC e.g. 60% of CRCs are missed after a 2ww referral.

### What will happen to patients referred with FIT ≥10µg/g?
Once the referral is received, the colorectal team will risk stratify the patient in line with the agreed protocol for managing patients with suspected CRC during COVID-19:

- Patients with positive FIT >10µg/g will have a telephone consultation within 2 weeks and a decision whether to investigate with CT scan, if they display obstructive symptoms or go on a deferred urgent list to be followed-up in the recovery phase of the pandemic.

The hospital will inform practices of the triage decision, specifically whether the patient will have early investigation with CT colonoscopy or held on a waiting list to be investigated later.

### What will happen to patients referred with a FIT <10µg/g, but with alarm symptoms?
The colorectal team will undertake a telephone consultation with these patients within two weeks to decide if and how to investigate the patient. They may decide to keep the patient on a deferred urgent list to be investigated as soon as service capacity improves.

### Is FIT a useful test in patients with rectal bleeding?
**Yes**. Data from the NIHR FIT study showed that FIT was as sensitive for detecting colorectal cancer in patients with a history of rectal bleeding, as those without. Patients should ideally take a sample from a stool that does not contain frank blood. However, if you suspect that the bleeding is likely due to haemorrhoids or other benign pathology, please do not order FIT; either treat the patient with topical preparations or refer routinely to colorectal surgery.

### What are the symptoms of developing bowel obstruction?
Most common symptoms include; 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.

[2] Quantifying and mitigating the impact of the COVID-19 pandemic on outcomes of colorectal cancer
[3] 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.
[4] High-risk symptoms and quantitative faecal immunochemical test accuracy: Systematic review and meta-analysis

### Will there be delays in pathology analysing FIT samples sent by general practice?
Delays are not expected. Pathology labs are aware of the changes and a potential increase in testing. Laboratory specimens kept at optimum temperature will still be viable for 4 weeks. Majority of the reporting should be within 5-7 working days of sample being sent in.

### What if my patient declines their Lower GI referral due to COVID-19?
Ideally patients meeting the described criteria should be referred on the Lower GI 2ww 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 should indicate the COVID-19 status of the patient.

### How do I order more FIT kits?
Primary care should continue to order kits through their usual requesting routes and ensure they have enough supply of kits during COVID-19, to provide all suspected bowel cancer patients a kit (including high-risk patients).

### Who do I contact if I do not receive the results within 7 working days?
Please contact the pathology department to follow up delayed results.

### Will the FIT kits be sent directly to patients and the result to the GP to action?
Check local arrangements with your clinical commissioning group (CCG). Where FIT is available in primary care, kits can be ordered through the usual routes and results sent to the GP to inform the patient.

### What process is in place for primary care to recall patients with a +ve FIT and refer them to secondary care or for those that may need other interventions i.e the Vague Symptoms pathway?
Practices/GPs have to safety-net all patients in the usual way and use tools to help with this. It is always good practice to follow-up patients when being investigated, and review in a timely way if symptoms have not improved.

### If patient has a negative FIT, should I consider repeating the test?
There is little data to support repeating, but if being repeated, then there probably ought to be a 4-week interval. However, if the patient presenting with persistent symptoms, even with a negative FIT, then it may be prudent to see advice and guidance from specialists.

### Which areas will be using FIT testing in this way?
This pathway will be adopted by all CCGs under the Cancer Alliance footprint where FIT is available in primary care. TVCA is supporting the roll out of FIT in Primary Care in both Buckinghamshire & Berkshire West CCGs. Please contact your local cancer commissioning lead to identify when FIT testing will 'go-live' in your area.

### Recently, there is an increase in lower GI cancer in those under 40, and FIT is not accepted <50yrs. What shall we do?
FIT can be carried out in those >40. But if in any doubt, unsure or concerned, then please seek advice and guidance from specialists.

### Is there a role for calprotectin, especially in younger age groups?
An elevated calprotectin level in a person's stool indicates that inflammation is likely present in the intestines but, this does not indicate either its location or cause. Increases in faecal

calprotectin concentrations are seen with IBD, but also with bacterial infections, some parasitic infections, and with colorectal cancer, but cannot be relied on for lower GI cancers.

### If FIT result is between 7-10 and patient asymptomatic, is the advice to monitor at regular intervals?

No. There is no data to support monitoring and best to go with wider the clinical picture, seek advice and guidance where necessary.

### Do patients on iron treatment need to stop before carrying out a FIT test?

No, patients can still complete the tests.

### Any useful resources?

Cancer Research UK (CRUK) has produced some useful resources on FIT.

### Who do I contact if I have any more questions about the Lower GI pathway changes?

Please contact Daniella Dzikunoo, Quality Improvement Manager at Thames Valley Cancer Alliance on Daniella.dzikunoo@nhs.net.



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