

Primary Care FAQ - Lower GI 2WW pathway during the COVID-19 Pandemic

1. How has the referral pathway for Lower GI 2WW referrals changed?

All patients with symptoms and signs suggestive of possible bowel cancer should have a FIT test <u>before</u> referral unless they have a rectal or anal mass, or anal ulceration. Patients with a FIT>10 ug/g, rectal or anal mass or anal ulceration should be referred on the Lower GI (LGI) 2WW pathway for suspected colorectal cancer (CRC).

2. 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). 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<10. Therefore in patients with a FIT<10 ug/g GPs should consider:

- Safety netting, medical management if appropriate and review at 4-6 weeks to consider need for referral, either LGI 2WW if patient meets NG12 criteria or routinely if 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;
- If concerned about a cancer in the GI tract but not in the large bowel please refer on the Upper GI pathway which is more amenable to arranging further investigations.
- 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 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.

3. 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. NHSE/I recommends that FIT tests are made available as an additional tool to help providers prioritise referrals. If it is impossible to obtain FIT and serious concerns remain, as above GPs may refer explaining why they feel the patient needs to be investigated.

4. Why has this change been recommended?

Diagnostic capacity for investigating patients with suspected lower GI cancer is limited during the Covid pandemic due to redeployment of staff and concerns that colonoscopy may be a high risk aerosol generating procedure. The limited CT colonography (CTC) capacity available 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. Even during the recovery phase, turnaround time for endoscopy will be lengthened due to infection control procedures.

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

The change was proposed by a group of specialists representing all cancer alliances in London and modified in light of discussions with regional, STP and alliance GP cancer leads. It was approved by the NHSE London Clinical Advisory Group on 24th March 2020. This group has formal authority to recommend changes to pathways during the Covid pandemic.

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

Since the new guidelines have been formally approved by NHSE London, GPs will be following expert guidance in the context of the COVID-19 pandemic.

7. 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. Please ensure the practice bypass number and referring GP contact details are correct when sending the referral. Practices may be contacted by the hospital if they have referred without a FIT test to ask for this to be done.

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

Referrals should not be 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.

9. 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.

10. What about cases of CRC who have FIT<10 ug/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 a referral will influence the outcome of treatment if CRC is present.

It should be recognised that NICE "high risk" criteria are likely to have lower sensitivity than FIT for detecting CRC e.g. only around 40% of CRCs are detected after 2ww referral.

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

Once the referral is received, the colorectal team will risk stratify the patient in line with the agreed Pan London protocol for managing patients with suspected CRC during COVID 19:

- Patients with FIT 10 149 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 deal with in the recovery phase of the pandemic.
- Patients with FIT ≥ 150 will be invited for investigation either with CTC or colonoscopy depending on availability since this value predicts a 1 in 3 chance of having a cancer.

The hospital will inform practices about the triage decision, in particular if there is a decision to investigate the patient with CT colonoscopy or other test, or to hold them on a waiting list to be investigated later in the recovery phase.

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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. Health Technol Assess 2017;21:1-234.

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

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

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.

13. 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 lower GI surgery.

14. 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.

15. 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.

16. 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 available on GP systems (Lower GI Suspected Cancer June update COVID MSWORD)
- A new Patient Information Leaflet for patients referred on 2ww during COVID-19
- A new suspected bowel cancer patient information during COVID-19
- Practices should ensure they have sufficient supplies of FIT testing kits
- Patient instructions on how to collect their poo sample

All materials are available via the dedicated London COVID-19 resources page: https://www.healthylondon.org/resource/covid-19-cancer-referral-resources/

17. 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 status of the patient.

18. 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.

19. Who do I contact if I do not receive the results within 5 working days?

Please contact the pathology department or CCG to follow up delayed results.

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