North Central London
Clinical Commissioning Group

Primary Care FAQ - Lower GI pathway change in NCL – April 2021

1. How does the Lower GI referral pathway changes in NCL?

All patients with symptoms and signs suggestive of possible colorectal cancer (CRC) should have a FIT test before referral unless they have iron deficiency anaemia, rectal or anal mass, or anal ulceration. These patients should be referred straight to LGI 2ww pathway. Patients with other lower gastrointestinal (LGI) symptoms should complete a FIT test prior to referral. Depending on patient symptoms, blood and faecal tests, GPs should consider the following pathways:

- Patients with NG12 symptoms of suspected bowel cancer:
  - If the patient has iron deficiency anaemia, rectal or anal mass, or anal ulceration, refer patient on Lower GI (LGI) 2ww for suspected CRC.
  - Any other NG12 symptoms – Complete FIT prior to referral.
    - FIT>10+NG12 LGI symptom – refer patient on LGI 2ww
    - FIT<10+NG12 LGI symptoms – refer patient on FIT<10 NG12 follow-up pathway
- Patients with DG30 symptoms (See below in section 2) – complete FIT prior to referral
  - FIT>10+DG30 symptoms – refer patient on LGI 2ww
  - FIT<10+DG30 symptoms – safety net patient in primary care
- Patients with unexplained weight loss, no definite GI symptoms, but high clinical suspicion of cancer – consider other cancer sites and diagnostics (Also see section 20 on RDC). If those do not lead to diagnosis, complete FIT.
  - FIT>10 – refer patient on LGI 2ww
  - FIT<10– refer patient on FIT<10 NG12 follow up pathway

2. What are the NG12 LGI urgent referral and DG30 referral criteria?

NICE NG12 urgent referral criteria:

- ≥ 40 years with unexplained abdominal pain AND weight loss
- ≥50 with unexplained rectal bleeding
- ≥ 60 with iron deficiency anaemia OR change in bowel habit
- ≤ 50 with rectal bleeding AND any one of following abdominal pain, change in bowel habit, weight loss or iron deficiency anaemia

DG 30 criteria in adults without rectal bleeding

- ≥ 50 years with unexplained abdominal pain or weight loss
- <60 years with changes in bowel habit
- <60 years with iron-deficiency anaemia
- ≥ 60 years with anaemia, but without iron deficiency

Iron deficiency anaemia is described as follows:

- Men aged >15 years — Hb <130 g/L.
- Non-pregnant women aged >15 years — Hb <120 g/L.
- Children aged 12–14 years — Hb below 120 g/L.
- In pregnant women — Hb below 110 g/L throughout pregnancy. An Hb level of 110 g/L or more appears adequate in the first trimester, and a level of 105 g/L appears adequate in the second and third trimesters.
- Postpartum — below 100 g/L.

3. 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. The most recent UK studies led by two London Cancer Alliances involved over 14,000 high risk patients. Data from the research study led by North Central London Cancer Alliance found that positive predictive value of FIT for CRC ≥10µg/g is almost fourfold that of the NG12 urgent referral pathway (9.7% vs 2.5%).[3] The data on 3596 patients referred for bowel symptoms on a lower GI 2ww also showed that 83.3% of patients with CRC had a FIT >10µg/g. Data from the research study led by the West London Cancer Alliance[4] on 9822 patients referred urgently for a colonoscopy found that 90.9% of patients with CRC had a FIT≥10 µg/g.

4. What will happen to patients urgently referred with FIT ≥10µg/g?

Once the 2ww 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; the two most recent UK studies predict a 1 in 3 or a 1 in 4 chance of having a cancer, respectively. This variation is due to studies involved slightly different patient groups.

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.

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

FIT will detect most but not all CRC; the latest evidence from the research study led by North Central London Cancer Alliance showed that if FIT is used in conjunction with the clinical features of anaemia and consideration of abdominal pain, the missed cancer rate is 5.5% at FIT 10µg/g cut off. These figures should be compared with the reported three-year post-colonoscopy CRC rate in England which was 7.4%.[5] The research study led by the West London Cancer Alliance found that if FIT is used alone for triaging patients, up to 10% of CRC will be missed. Therefore, safety netting and review is very important. It is unlikely that an 8 week delay in making referral will influence the outcome of treatment if cancer is present.

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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

[3] HE Laszlo, E Seward, R Ayling, et al. (2020) Quantitative faecal immunochemical test for patients with high risk bowel symptoms: a prospective cohort study. Submitted. Preprint available from https://www.medrxiv.org/content/10.1101/2020.05.10.20096941v1

[4] D'Souza N, Delisle TG, Chen M, et al. Faecal immunochemical test is superior to symptoms in predicting pathology in patients with suspected colorectal cancer symptoms referred on a 2WW pathway: a diagnostic accuracy study. Gut ublished Online First: 21 October 2020. doi: 10.1136/gutjnl-2020-321956

[5] Burr NE, Derbyshire E, Taylor J, Whalley S, Subramanian V, Finan PJ *et al.* Variation in post-colonoscopy colorectal cancer across colonoscopy providers in English National Health Service: population based cohort study. *BMJ* 2019;367:l6090.

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

GPs are required to arrange FIT before referring as this will enable stratify a patient's risk. 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. However, these patients are likely to be assessed as low risk and have to wait several months before being investigated.
If the patient does not/cannot complete the repeat blood and/or FIT on the FIT<10 NG12 follow-up pathway, the hospital may contact you to discuss further management of the patient.

7. 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. 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.

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

Yes. Data from the most recent UK studies 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 CR surgery.

9. Can the LGI 2ww 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.
If the GP has not done the FIT prior to referral, the Trust will contact the practice to request this is done immediately so as the patient's progress through the pathway is not delayed.
Referrals CANNOT be rejected out of hand for any reason.

10. What should the practice do if a 2ww referral is rejected?

Referrals should not be rejected. Please inform the relevant lead commissioning manager (lucy.mclaughlin@nhs.net, but please do not share any PID) or NCL Cancer Commissioning, Clinical SRO, Clare Stephens, who will follow this up with the hospital provider.

11. What about patients meeting NICE NG12 high risk criteria but has FIT<10?

A patient with abdominal symptoms and FIT<10 has a 99.5% chance of NOT having CRC (negative predictive value).[6] 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 µg/g GPs should consider:

- Referring your patient onto the FIT<10 NG12 follow-up pathway. The patient will complete a repeat FIT and blood test 8-10 weeks after the referral ordered by the hospital and will be seen at a follow up clinic.
- If you have a strong clinical suspicion, there is still the potential for pathology being present. Therefore, in these instances you may still decide to refer the patient on the 2WW.
- 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 such as a falling haemoglobin or new anaemia, then the GP should refer via a 2ww pathway. Please highlight how the patient meets existing NICE 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 referral form.

12. What to say to patients who are eligible to be referred onto the FIT<10 NG12 follow-up pathway.

Your patient who initially presents with NG12 symptoms but has a FIT<10 has over 99% chance of NOT having CRC. However as no diagnostic test are 100% accurate, your patient who is referred onto the FIT<10 NG12 pathway will be offered a repeat FIT and blood test by the hospital and will be booked in for an appointment for a consultation 8-10 weeks' time. It is to check any changes in their symptom and/or tests to make sure they do not have any underlying significant pathology. Once the hospital receives the referral, they will contact your patient to confirm that their referral is processed, what the next steps are and share their contact details should the patient need to contact them about any worsening in symptoms or to change appointment date. It is important that your patient completes the repeat tests before seeing a clinician at the hospital.

13. What happens with my patients once referred onto a FIT<10 NG12 follow-up pathway?

The patient will be notified about being booked into the pathway and that a repeat blood and FIT will be requested 8-10 weeks after referral received. The hospital will arrange the repeat blood and repeat FIT tests and the patient is booked into a follow-up clinic where a senior decision maker will assess the test results and symptoms. We may contact you to discuss further management if the patients declines more than one appointment or does not return the second FIT test or blood test. After the FIT<10 NG12 follow-up clinic we will write to you to either:

- discharge the patient back to your care
- perform further diagnostics under a cancer upgrade pathway

[6] HE Laszlo, E Seward, R Ayling, et al. (2020) Quantitative faecal immunochemical test for patients with high risk bowel symptoms: a prospective cohort study. Submitted. Preprint available from https://www.medrxiv.org/content/10.1101/2020.05.10.20096941v1

14. Why has this change been recommended?

The majority of patients with high risk bowel symptoms do not have CRC. Diagnostic capacity for investigating patients with suspected lower GI cancer is limited during the COVID-19 pandemic and recovery. 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. FIT can be used to risk stratify patient with the added secondary care safety netting for those presenting with specific NG12 symptoms but their FIT is less than 10 µg/g.

15. When does this change take place?

The new LGI pathway is implemented from April 2021. The FIT<10 NG12 follow-up pathway will initially be established as a one year service evaluation in secondary care that enables data collection and audit of patients with very low CRC risk. You will be able to book patients with NG12 symptoms but FIT<10 onto this new pathway using a dedicated referral form on eRS. Initially you can refer patients onto the FIT<10 NG12 follow-up pathway at the following hospitals: Royal Free Barnet and Chase Farm site, UCLH, North Middlesex Hospital and Whittington Hospital. Royal Free Hampstead site will enable referrals onto this new pathway from late spring 2021.

16. 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 North Central London Clinical Advisory Group on 27th November 2020. This group has formal authority to recommend changes to pathways across NCL.

17. Is this in line with national recommendations?

NHS England national guidance recommends FIT is performed on all patients referred for Lower GI 2WW during COVID-19 to aid triage. In addition, due to the earlier and to date greater impact of COVID-19 on London's population and services, there has been a need to make evidence-based pathway changes ahead of other regions.

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

YES. Since the new COVID-19 guidelines on using FIT to support the risk stratification of patients have been formally approved by NHSE London, GPs acting in accordance with this will be following expert guidance in the context of the COVID-19 pandemic.

19. What about referrals to the Rapid Diagnostic Centre (RDC)?

RDC offers a diagnostic pathway for patients with non-specific symptoms that could indicate cancer. If your patient presents with symptoms that do not meet the NICE NG12 or DG30 referral criteria for suspected CRC (for example a 36 year old presents with unexplained abdominal pain) but you have a clinical suspicion that the patient might have some type of cancer, you should use the RDC referral route.

20. 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.

21. 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.

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

- The latest version of the electronic 2WW Pan London COVID-19 Suspected Lower GI 2WW referral form has been made available on GP systems
- A new electronic FIT<10 NG12 follow-up referral form has been made available on GP systems from April 20
- Patient Information Leaflet for patients referred on 2WW during COVID-19
- Patient Information Leaflet for Suspected Bowel Cancer during COVID-19
- Patient Information leaflet for patients referred on FIT<10 NG12 follow-up pathway
- Practices should ensure they have sufficient supplies of FIT testing kits
- NCL developed patient instructions on how to collect complete FIT

All materials are available via the dedicated resources page:
https://gps.northcentrallondonccg.nhs.uk/service/faecal-immunochemical-test-fit

23. 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.

24. 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.