

Primary Care Guidance:

Lower GI two-week wait pathway during COVID-19

July 2020

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Programme:	Primary Care (Restoration & Recovery)			
SRO: Project Manager:	Dr Anant Sachdev, Clinical Lead for Prevention & Early Diagnosis Daniella Dzikunoo, Quality Improvement Manager			
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Introduction

This pathway has been agreed by trust lead colorectal clinicians, commissioners and CCG GP Cancer leads in Thames Valley. This includes stakeholders from the following organisations:

- Berkshire West CCG & Royal Berkshire NHS Foundation Trust
- Buckinghamshire CCG & Buckinghamshire Healthcare NHS Trust
- East Berkshire CCG & Frimley Health NHS Foundation Trust
- Oxfordshire CCG & Oxford University Hospitals NHS Foundation Trust
- Swindon CCG & Great Western Hospitals NHS Foundation Trust
- Milton Keynes CCG & Milton Keynes University Hospital NHS Foundation Trust
- Cancer Research UK (Thames Valley Facilitators)

The guidance and measures outlined in this document have been introduced to the colorectal cancer pathway to support capacity during the COVID-19 pandemic.

Thames Valley Cancer Alliance (TVCA) regularly discusses two-week wait (2WW) referrals with suspected colorectal cancer symptoms and management of existing patients with a confirmed cancer diagnosis. As a result of these discussions, this paper focusses on 2WW referrals and outlines the recommendations made by our stakeholders to the colorectal cancer pathway.

Recommendation

The group recommends that this pathway is adopted across the Thames Valley Cancer Alliance footprint. It mandates FIT testing in primary care for all patients with suspected colorectal cancer symptoms including high risk patients as per NICE NG12 guidance. TVCA are working with Buckinghamshire CCG to accelerate adoption of FIT in primary care by July 2020.

Rationale

The problem: NHS England sent a letter to healthcare professionals on 17 March 2020 outlining the NHS response to the COVID-19 pandemic¹. This letter advised that secondary care prepare to free-up the maximum possible inpatient and critical care capacity and prepare for, and respond to, large numbers of inpatients requiring respiratory support. Trusts in Thames Valley have postponed routine outpatient appointments and routine elective surgery to cope with the expected demand on services. TVCA has led the development of a pan Alliance prioritisation plan to ensure, where possible, surgical capacity for cancer remains in place whilst we respond to the pandemic.

The current advice from the British Society of Gastroenterology (BSG) for endoscopy services is to investigate only the urgent cases, an advice that is likely to change soon due to the expected shortage of staff and endoscopists who are being diverted to manage COVID-19 patients or are in self-isolation. Patients are already practicing social distancing as per national guidance and are reluctant to venture out of their homes to attend hospital or endoscopy units which are perceived as crowded locations.

Nationally a 75% drop in the number of two-week wait referrals for suspected cancers was observed during the peak of the pandemic. Patients practicing social distancing as per government guidance were not engaging with health services for fear of burdening the NHS or were worried about contracting the virus.

¹ Next Steps on NHS response to COVID-19 Letter from Simon Stevens & Amanda Prichard

Currently, (May 2020) Covid-19 presentations have continued to reduce across TVCA. Alongside this there have been widespread media campaigns both confirming the NHS is 'open for business' as well as cancer specific messaging around contacting your GP if you have worrying signs and symptoms. The result of this is that numbers of 2WW referrals are increasing and with this, significant increases in demand for secondary care services which need to be managed alongside the large numbers of patients who safely had their diagnosis and treatment deferred during the peak of the covid-19.

The Solution: FIT for low-risk symptomatic patients in primary care has been implemented in four out of five CCGs in Thames Valley². A task and finish group has been established to support implementation of FIT in Buckinghamshire CCG. This provides primary care with an opportunity to support safe and effective management of patients with a suspected colorectal cancer during COVID-19.

FIT testing in primary care has been used in line with NICE DG30, therefore scaling up this provision to include NG12 symptoms will be straightforward. Primary care knows how to instruct patients on the use of the kits and patient information is already available. In addition, procurement processes are in place within primary care regarding access to FIT kits. Primary care has agreements in place to replace kits directly from pathology labs and have transport channels set up for the FIT kits to go from each GP practice to specific pathology labs. TVCA has reviewed these processes with commissioning leads to ensure pathology labs have the capacity to process the tests.

Clinical pathway

It is proposed that all patients with bowel symptoms meeting NG12 2WW criteria and DG30 should be tested in primary care before referrals are made (see figure 1).

- A threshold of 10 μg Hb/g faeces will be used for a positive test. This threshold is already being used by labs for positive result as part of DG30. It is expected that 19% of those tested will be positive (>10 μg Hb/g).
- Patients with FIT values <10µg Hb/g (FIT negative) should be retained in Primary Care with GPs and followed up as appropriate with relevant safety-netting processes in place. For those patients whereby alternative pathology has been excluded, and with unexplained symptoms, GPs should seek advice and guidance from secondary care clinicians or refer in via the 2WW route if clinically concerned, with progressive or alarm symptoms
- Generally, aside from that above, only results of >10µg Hb/g (FIT positive) will be referred and triaged by secondary care.
- Patients with FIT values >10µg Hb/g should be remotely triaged (telephone or video) and assessed by secondary care with clinical judgement of risk and therefore onward diagnostics planned.

Additional guidance in the form of frequently asked questions has been developed to support GPs embed this approach (see appendix 1).

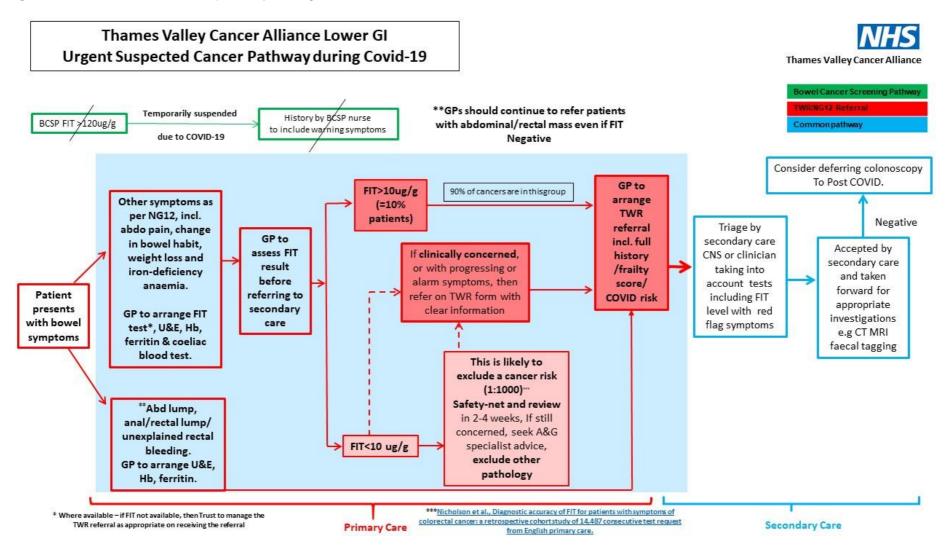
Ongoing Assessment

The Thames Valley Cancer Alliance along with the colorectal clinical advisory group will keep the pathway changes under rigorous review; to monitor implementation, at 3 months and again at 6 months. This is to monitor the impact on patients with a negative FIT to ensure appropriate safety-netting and follow-up processes are audited. TVCA will hold a

² TVCA are working with Buckinghamshire CCG to implement qFIT in primary care.

Primary Care webinar to ensure GPs are updated about the use of FIT testing and pathway changes. The Cancer Alliance will continue to work with CCG's to develop gold standard proforma to support the referrals process.

Figure 1. The colorectal cancer pathway during COVID-19



Guidance to support appropriate safety netting of patients

All patients with signs and symptoms suggestive of possible bowel cancer should have a quantitative FIT test **before** referral unless they have an abdominal, rectal or anal mass or anal ulceration. Patients with a FIT >10 μ g/g, should be referred on the Lower GI (LGI) two-week wait (2ww) pathway for suspected colorectal cancer (CRC) according to local clinical pathways. For patients with a FIT test result of <10 μ g/g refer to the safety netting guidance below and consider local guidance and pathways.

Lower Gastro-intestinal (LGI) Cancer Safety Netting Guidance <10ug/g FIT Result

- 1. Ensure that other non-Gastrointestinal pathology is excluded e.g. Renal, gynaecological, intra-abdominal; further investigations available are carried out e.g. US, and patient directed to appropriate pathways.
- Specifically, when FIT is <10ug/g, this suggests an extremely low probability of LGI cancer. However, it should be remembered that LGI cancers with FIT <10ug/g, do occur². It is important to remember, patients with bowel cancer and a FIT <10μg/g often have other signs of cancer, including anaemia, weight loss etc.
- 3. Hence, LGI cancer needs to be excluded when there is:
 - a. the presence of a palpable mass, or
 - b. iron deficiency anaemia
 - c. weight loss
- 4. Safety-netting includes reviewing the patient at an interval of no more than 4 weeks after the FIT test result to assess for "red flags" or alarm, persistent, new, or worsening symptoms for LGI cancers, e.g. rectal bleeding, abdominal pain, appetite loss, weight loss, and ongoing change in bowel habit ⁵
- 5. With any combination of the above symptoms, signs, and tests, then the you should consider referring the patient, regardless of the FIT result
- 6. At the time of writing this guidance, there is currently no data to support repeating the FIT Test again, but various areas nationally are considering this, when the patient's symptoms still do not fulfil the NICE NG12 LGI Cancer criteria. However, to avoid delay, if FIT is <10 ug/g and you are concerned due to new, persistent, or worsening symptoms, or are so concerned that considering repeating the FIT investigation, it is appropriate to seek advice or refer the patient rather than repeating the FIT
- 7. If there is still concern or uncertainty without fulfilling the pathway criteria, but still a "gut-feeling" by the GP, then timely advice should be sought by employing Advice & Guidance, referral to local Rapid Diagnostic Centre (if available), or onward referral on the LGI Urgent Suspected referral pathway (e.g. even if FIT test is <10ug/g)

Safety-netting in Suspected Cancer

Safety netting¹, thereby empowering patients and protecting healthcare professionals, is an essential process to help manage uncertainty in the diagnosis and management of patients by providing information for patients and organising follow-up after contact with a health professional. It may be performed at the time of the contact between health professional and

patient or may happen after the contact through active monitoring and administrative systems to manage results and referrals. A patient information leaflet can be <u>found here</u> to support clinicians discuss the suspected colorectal cancer referral with patients.

Suspected Cancer: Recognition and Referral (NG12)

National Institute of Health and Care Excellence (NICE) in 2015 (updated in 2017) with the release of NG12 (Suspected cancer: recognition and referral), includes an explicit section on safety netting:

- 1.15.1 Ensure that the results of investigations are reviewed and acted upon appropriately, with the healthcare professional who ordered the investigation taking or explicitly passing on responsibility for this. Be aware of the possibility of false-negative results for chest X-rays and tests for occult blood in faeces.
- 1.15.2 Consider a review for people with any symptom that is associated with an increased risk of cancer, but who do not meet the criteria for referral or other investigative action. The review may be:
 - planned within a time frame agreed with the person or
 - patient-initiated if new symptoms develop, the person continues to be concerned, or their symptoms recur, persist, or worsen.

The literature suggests that it should include a discussion with the patient on the problem of uncertainty, advice on potential red-flag symptoms, the likely time course of the illness, advice on accessing further medical care, follow-up, and the management of investigations. Safety netting also includes other factors such as providing written information and documenting advice in the medical notes.

Specifically, in the management of a patient with potential cancer symptoms, there should be a step-by-step process for all scenarios ²:

- Put a system in place to document safety netting actions, to ensure appropriate followup action is taken
- Check locally for existing safety netting templates tailored to your IT system that clinicians can use during consultations and administrative staff can use to track/follow up with patients
- Record the safety netting advice provided to patients in medical notes (as understood by the patient) including the method and type of consultation, and next steps
- Ensure that tests are carried out in a timely way with the lowest of risk in terms of rejection by the pathology department (e.g. appropriate patient identifiers, correct kit)
- The referral is of a high quality in that there is a full detail of the history, assessments, and tests, with patient performance status, wishes and COVID-19 status, thus facilitating secondary care to be able to triage and prioritise appropriately. It may be helpful to also advise if patient has been isolating (or advised to) and thereby facilitating imaging or intervention as early as possible
- Ensure patient contact details are up to date
- Ensure patient available over next 2 weeks

Once a decision has been made and patient placed on a 2 week wait referral pathway for suspected cancer, safety netting actions include:

Document that the patient is sent on an 2ww referral pathway

- Record how their referral is progressed in secondary care e.g. ensuring that the patient informs the practice/GP of receipt or otherwise of the appointment within a certain time (around 7-10 days)
- Maintain and regularly review patient to monitor progress of the cancer referral. This
 would be good practice to support the patient and family after a serious diagnosis and
 facilitate a Cancer Care Review
- Make the patient aware they are receiving an urgent referral for suspected cancer, supported by written information (Urgent Suspected Leaflet)
- The patient should be advised when they are likely to hear from the hospital, and what
 to do if they have not heard anything within an explicit period
- Inform the patient that initial consultations might be on the telephone and tests might be delayed during the COVID-19 phase
- Inform the patient that treatment may be delayed during this time. The evidence suggests if patients with colorectal cancer need to wait for investigation or treatment, they are very unlikely to come to harm from disease advancement.

If the decision is taken not to refer a patient due to ongoing primary care investigations, the level of risk and/or patient concern (Best interests' decision for the patient made) or choice, safety-netting action needed includes:

- Document that the patient is not being referred and reasons why (ongoing assessment and investigations, if presentation indicates low level of cancer risk or patient does not want to be referred during COVID-19)
- Use GP IT systems to set reminders to proactively review patients, to review results, and to see if their symptoms have resolved, continue to persist, or worsen. Clinical decision (CDS) tools may help facilitate this (e.g. Gateway C, Macmillan CDS, C-The Signs, Ardens, EMIS template, Mind Maps, etc)
- Regularly review patients who are being monitored during the COVID-19 recovery phase to ensure they are introduced into the diagnostic/cancer referral system when it is safe to do so
- Document eventual referrals on the GP IT system

Patient communication principles include:

- Check the patient understands why their cancer risk vs. COVID-19 risk needs to be assessed and the
- Importance of making a joint decision about the next course of action
- Ensure that the patient understands the need for suggested investigation and its completion, and the process facilitating the timely review of results
- Ensure the patient understands the referral process, what is expected of them and what to expect from the hospital
- Check the patient fully understands the safety netting advice provided especially if the appointment is by remote consultation (telephone, video)
- Remind the patient that if their symptoms worsen, or persist beyond an explicit time period, they should contact their GP
- If the patient has chosen not to be referred at that time, inform the patient to contact their GP if they change their mind

References:

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Appendix 1: Primary Care FAQ Lower GI two-week wait pathway during COVID-19

June 2020

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 <u>Lower GI two-week wait pathway</u> <u>quidance during COVID-19</u>.

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<10 μ g/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<10 μ g/g. Therefore in patients with a FIT<10 μ g/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 London³, 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.

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³ COVID-19 Impact on primary care cancer services in London

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

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 >10 µg/g during the COVID-19 pandemic would salvage 1,292/1,419 of the attributable deaths and reduce colonoscopy requirements by more than 80%⁴.

Two meta-analyses reported that a FIT $\geq 10 \mu g/g$ identified respectively 92%⁵ and 94%⁶ 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.

⁴ Quantifying and mitigating the impact of the COVID-19 pandemic on outcomes of colorectal cancer

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.

⁵ <u>High-risk symptoms and quantitative faecal immunochemical test accuracy: Systematic review and meta-analysis</u>

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.

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.