# Clinical prioritisation guidance for patients with symptoms of a suspected LGI cancer

## Version 0.23 4th May 2023

**In 2022, the British Society of Gastroenterology (BSG) and the Association of Coloproctology of Great Britain and Ireland (ACPGBI) published further guidance on the use of FIT for patients with symptoms of a suspected colorectal cancer.**

**This updated guidance builds on guidance for prioritisation produced during the COVID19 pandemic. This guidance aligns with the new BSG/ACPGBI joint guidance and the Cheshire & Merseyside FIT pathway guidance and principles.**

**Clinical teams should ensure that colorectal triage processes and diagnostic planning incorporate this updated guidance.**

## Revision History

| Version(s) | Revision Date | Previous Revision Date | Summary of Changes | Changes Marked |
|---|---|---|---|---|
| 0.1 to 0.17 | Version produced during 2020. | | Guidance produced in support of National guidance during the Covid19 pandemic. | Previous versions available via CMCA |
| 0.18 | 23/09/2022 | 2020 | Guidance aligned to BSG/ACPGBI joint guidance and National Guidance. Covid19 Pandemic restrictions removed. | No |
| 0.19 | 06/10/2022 | 23/09/2022 | Amendments to further align with guidance. | No |
| 0.20 | 07/10/2022 | 06/10/2022 | Sections reviewed further and amended as required. | No |
| 0.21 | 11/10/2022 | 07/10/2022 | Section 1: Purpose of this guidance; final paragraph. | No |
| 0.22 | 18/11/2022 | 11/10/2022 | Section 3: Clarification of priority levels and inclusion of sub-section 3.1.1 concerning coding for endoscopic investigation.<br>Section 7: Additional information added for evaluation and data monitoring. | No |
| 0.23 | 04/05/2023 | 18/11/2023 | Section 3.11; 4; 5 and 6: Secondary FIT Negative Pathway Protocol altered following receipt of national guidance and agreement with FIT Steering Group and Pathway Working Groups to: ***FIT <10* µg WITH no *IDA AND/OR no palpable mass AND/OR no obstructive symptoms, have a normal FBC and normal examination* (EXCLUDES patients with FIT <10µg AND with persistent/recurrent anorectal bleeding who should receive a flexi-sig).** | |

## Approvals

| Name | Date of Issue | Versions | Signature confirming approval |
|---|---|---|---|
| FIT Pathway Working Group (FIT PWG) | 07/10/2022 | 0.20 | |
| Endoscopy Network | 07/10/2022 | 0.20 | |
| Colorectal Clinical Quality Group (CQG) | 07/10/2022 | 0.20 | |

## Distribution

| Name of individual/group | Date of issue | Version |
|---|---|---|
| Endoscopy Management Team | | |
| Imaging Network | | |
| Pathology Network | | |
| Cancer Managers Action Group | | |
| Trust Cancer Leads | | |

**Date of next review: November 2023**

# Contents


1 Purpose of this guidance ....4
2 Guidance scope ....4
3 Clinical guidance ....5
3.1 Priority levels ....5
3.1.1 Subset guidance: Coding priority levels for endoscopy ....7
4 Supporting referral, reporting and patient management ....8
5 Safety netting in Secondary Care ....8
6 Cancer Waiting Times Guidance (CWT) ....9
7 Evaluation and data monitoring ....10
8 References ....10
Appendix 1: New Symptomatic FIT Pathway v0.14 ....13
Appendix 2: Secondary Care Negative FIT Pathway v0.15 ....14
Appendix 3: National Colorectal Best Practice Timed Pathway ....16
Appendix 4: Background ....17
1. What is FIT? ....17
2. Strategic context ....17
3. The challenge facing LGI: key data ....19
4. Evaluation of FIT in Cheshire & Merseyside ....19

# 1 Purpose of this guidance

The purpose of this guidance is to provide an update of and supersede the previous Cheshire & Merseyside FIT Prioritisation Guidance v0.17 dated 11th November 2020. The aim of the guidance is to provide information pertaining to clinical triage of patients who are referred into Secondary Care with suspected Lower GI cancer. This guidance should be used in conjunction with the Cheshire & Merseyside Symptomatic Primary Care FIT Pathway (Appendix 1). Additionally, this guidance contains the Secondary Care Negative FIT Pathway Protocol (Appendix 2) which has been agreed by stakeholders to ensure targeted use of limited diagnostic capacity. Both pathways support compliance against the National Colorectal Best Practice Timed Pathway, which all Trusts should work towards in terms of key pathway steps and timings (Appendix 3).

The information contained within this document aligns to new Cheshire & Merseyside FIT Pathway Guidance and that of joint guidance from the BSG/ACPGBI (2022), taking into account the following:

- Patient reported symptoms together with
- Iron Deficiency Anaemia (IDA)[1]; and
- FIT (faecal immunochemical test) result.

This guidance aims to support:

- Targeted use of limited diagnostic capacity and availability.
- Avoidance of emergency presentations.
- Increase cancer detection rates.
- Patient communication at the right time and by the right people
- A standardised approach to triage and clinical prioritisation across Cheshire and Merseyside for suspected LGI cancer.

Further background information on FIT testing and the strategic context can be found in appendix 4.

This guidance should also be used by independent provider organisations where appropriate and relevant for patient care.

**Key changes from v0.17 of the C&M Prioritisation Guidance are as follows:**

- Removal of guidance appropriate for use during the Covid19 pandemic.
- Alignment of priority levels with:
    a. BSG/ACPGBI Joint guidance.
    b. National Guidance.
    c. C&M FIT Pathway Guidance.

**This guidance should be reviewed annually whilst FIT guidance continues to develop.**

# 2 Guidance scope

This guidance relates to all Trusts who deliver diagnostic services for patients via an Urgent suspected LGI Cancer Referral (currently Two Week Wait (TWW). It should be used in conjunction with Cheshire & Merseyside and National Pathway guidance (refer to appendices).

[1] Please note: Iron studies are important to establish IDA status and therefore guide triage in identifying the appropriate investigation

# 3 Clinical guidance

## 3.1 Priority levels

Clinical teams will need to ensure that their colorectal triage process incorporates this guidance and adheres to the most recent Cancer Waiting Times Guidance. This includes ensuring continued adherence to Cancer Waiting Times Guidance (section 2.5), which states that if a TWW referral is deemed inappropriate then it should be discussed with the referrer. Only the referrer can downgrade or withdraw a referral. **A referral must not be rejected with the reason being the absence of a FIT result**.

Patients should be contacted via telephone/face-to-face (whichever is clinically appropriate) by an appropriately trained clinician to discuss the referral and planned diagnostics.

Key points to consider for all patients are:

- The risk versus benefit of further diagnostics and treatment at this time.
- The practicalities of providing stool samples as there may be mobility issues which need to be considered or other reasons why someone cannot give the stool sample
- Ensuring that patient iron studies are also viewed during the triage process to ascertain IDA status if this has not been indicated on the referral form. This will inform the urgency of investigation as per guidance given below.

**The following priority levels and protocols should be used.**

**I. Priority level 1a: For urgent colonoscopy or CT (CTC or plain CT)**

Patients will have

i. Early signs of bowel obstruction e.g. lower abdominal pain and distension; AND/OR
ii. FIT test result of ≥100µg (refer to BSG/ACPGBI Guidance for CRC risk); AND/OR
iii. Symptoms deemed by specialist GI surgeons/ gastroenterologists at the point of triage, to merit urgent intervention:

   a. Anal ulceration; AND/OR
   b. A rectal/anal mass; AND/OR
   c. Abdominal mass; AND/OR
   d. Patients with FIT <10µg AND with persistent/recurrent anorectal bleeding (Flexi-sigmoidoscopy to be carried out as per BSG/ACPGBI Guidance).
   e. Iron deficiency anaemia: investigation should also include Gastroscopy (OGD)

**II. Priority level 1b: For prioritised colonoscopy or urgent CT Abdomen/Pelvis**.

Patients will have:

- FIT 10-99.99µg (refer to BSGACPGBI Guidance for CRC risk)

**III. Secondary Negative FIT Pathway protocol to be followed (protocol in appendix 2)**

Patients will have:

- **FIT result of <10µg *WITH no IDA AND/OR no palpable mass AND/OR no obstructive symptoms, have a normal FBC and normal examination.***
- **EXCLUDED PATIENTS:** FIT <10µg AND with persistent/recurrent anorectal bleeding who should have a flexi-sigmoidoscopy at priority level 1a.

**Please note: Depending on the review of these patients and their signs/symptoms status, they may be:**

- Referred to an alternative cancer pathway if symptoms indicate this is an appropriate course of action; OR
- Discharged back to Primary Care for management; OR
- Investigated on a routine pathway either via endoscopy or imaging; OR
- Remain on a LGI Cancer Pathway if there is ongoing clinical concern.

**Notes for Secondary Care Negative FIT Pathway**

Where patients are discharged back to Primary Care, the following information should be communicated/discussed with them by an appropriately trained clinician via a telephone/face-to-face consultation (whichever is clinically appropriate) e.g. Consultant, Clinical Nurse Specialist or Endoscopy Nurse:

a. Reassurance to the patient that cancer has been excluded as possible diagnosis (this includes other cancers as well as colorectal).

b. Ensure appropriate safety netting is in place including advising the patient to be vigilant of similar signs and symptoms and others that are not normal for them. These include the following:

   - A change in bowel habits, such as diarrhea, constipation, or narrowing of the stool, that lasts for more than a few days
   - A feeling that you need to have a poo that is not relieved by having one
   - Bleeding from your bottom
   - Dark poo, or blood in the poo
   - Cramping or abdominal (tummy) pain
   - Weakness and tiredness for no obvious reason
   - Unexplained weight loss

c. Inform the patient that they are being referred to their GP for management with explanation why, informing them that a letter will be sent to their GP and them summarising this outcome with further advice.

There should be shared decision making with the patient around risks of colorectal cancer vs doing colonoscopy or imaging vs doing nothing. Utilise the available patient leaflet for negative FIT in Secondary Care to advise of risks. Complete the Secondary Care Negative FIT Pathway form and save it in the patients' notes for further reference and assurance.

**Subset guidance for coding can be viewed on the next page. This is vital to ensuring that patients are coded according to their priority and investigated in relation to their risk of colorectal cancer.**

### 3.1.1 Subset guidance: Coding priority levels for endoscopy

**All colonoscopy referrals are received and coded as Diagnostic Code D2 based on the referral criteria. The table below provides information on the appropriate coding following referral review of FIT scores and ineligible patients. This includes the Secondary Care Negative FIT Pathway cohort.**

| **When the FIT score is received the following priority levels and protocols should be used.** | | | |
|---|---|---|---|
| **Priority Level** | **FIT Score** | **Patients will have** | **Move to Diagnostic Code** |
| **Priority level 1a: For urgent colonoscopy or CT (CTC or plain CT)** | FIT test result of ≥100µg<br><br>OR ineligible for FIT but with priority signs/symptoms<br><br>(refer to BSGACPGBI Guidance for CRC risk) | Early signs of bowel obstruction e.g. lower abdominal pain and distension; AND/OR<br><br>FIT test result of ≥100µg (refer to BSG/ACPGBI Guidance for CRC risk); AND/OR<br><br>Symptoms deemed by specialist GI surgeons/ gastroenterologists at the point of triage, to merit urgent intervention:<br><br>a. Anal ulceration; AND/OR<br>b. A rectal/anal mass; AND/OR<br>c. Abdominal mass; AND/OR<br>d. Patients with FIT <10µg AND with persistent/recurrent anorectal bleeding (Flexi-sigmoidoscopy to be carried out as per BSG/ACPGBI Guidance).<br>e. Iron deficiency anaemia: investigation should also include Gastroscopy (OGD) | **Diagnostic Code D1** |
| **Priority level 1b: For prioritised colonoscopy or urgent CT Abdomen/Pelvis**. | FIT 10-99.99µg<br><br>(refer to BSGACPGBI Guidance for CRC risk) | Any sign or symptom EXCLUDING those given in priority 1a | **Remain at Diagnostic Code D2** |
| **Secondary Negative FIT Pathway protocol to be followed (protocol in appendix 3)**<br><br>**CODE DEPENDENT ON PATHWAY OUTCOME – POTENTIALLY 1C IF ROUTINE INVESTIGATION** | FIT result of <10µg | ***IDA AND/OR no palpable mass AND/OR no obstructive symptoms, have a normal FBC and normal examination (*EXCLUDES patients with FIT <10µg AND with persistent/recurrent anorectal bleeding who should receive a flexi-sig)*.** | **Diagnostic Code D3** |
| **EXCLUDED PATIENTS:** | FIT <10µg | **AND WITH** persistent/recurrent anorectal bleeding who should have a flexi-sigmoidoscopy | **Move to D1 – Flexi Sig Pathway** |

## 4 Supporting referral, reporting and patient management

To ensure appropriate primary care referrals and support patients, it is advised that the following are considered by Trusts:

- **ALL Trusts should ensure that there are escalation processes and protocols in place** where GPs and/or secondary care clinicians have clinical concerns for specific patients, such as deteriorating and/or worsening symptoms that require prompt review and/or investigation. Such protocols should include contact details for raising such concerns to the relevant clinical teams and include a process for re-evaluation of the patient if required.
- **Telephone access** must be provided by hospital specialists to support primary care referrers before and after referral, this could be through existing Advice and Guidance services
- **Patients should be contacted via telephone/face-to-face consultation** (whichever is clinically appropriate) by an appropriately trained clinician to discuss the referral and planned diagnostics in line with C&M pathways and guidance.
- **A Trust contact should be provided to the patient** if they have been referred should they have any clinical concerns or other queries; this may be a Support Worker or Clinical Nurse Specialist. This supports positive patient experience.
- **Trusts should consider CMS/Email appointment reminders** to support patient attendance and help to minimise Do Not Attends (DNAs).
- **Trusts and their stakeholders should ensure that ALL referrals are made using NHS eRS.**
- **Trusts and their stakeholders should ensure that guidance to GPs and feedback loops is in place to support effective and accurate referrals.**
- **All patients** on a pathway within Secondary Care should have access to telephone-based specialist cancer nursing services after triage and prioritisation if they are to remain on a cancer pathway.
- **All patients** should have access to details of support services available in the local area.
- **All patients** should be recorded on the Patient Tracking List (PTL) and tracked in line with Cancer Waiting Times Guidance if they remain on a cancer pathway. The Secondary Care Negative FIT Pathway should be followed for patients with a FIT result of <10µg WITH NO sign of IDA AND/OR no palpable abdominal mass AND/OR or obstructive symptoms AND/OR no ongoing clinical concerns (e.g. unexplained weight loss). EXCLUDED PATIENTS: FIT <10µg AND with persistent/recurrent anorectal bleeding who should have a flexi-sigmoidoscopy at priority level 1a.
- **All patients** should be seen as soon as possible according to their priority level and service availability.
- **Appropriate safety netting** should be put in place for these patients to ensure patients understand what new or changing symptoms to alert the team to and allow for a further clinical assessment should this be required. This includes Tracking Dashboards for monitoring FIT results and provision of Early Diagnosis Support Workers (EDSWs) or Patient Navigators.
- **All samples (regardless of history of symptoms)** should be processed as per relevant Public Health England Guidance[2].

## 5 Safety netting in Secondary Care

Both clinical and administrative safety netting measures should be in place and considered throughout the patient journey in Secondary Care. For patients who have been eligible for a FIT, for example, Trusts should have the following elements in place:

- 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.

[2] https://www.gov.uk/government/publications/wuhan-novel-coronavirus-guidance-for-clinical-diagnostic-laboratories/wuhan-novel-coronavirus-handling-and-processing-of-laboratory-specimens

- A Tracking Dashboard to facilitate accelerated referral or investigation of FIT positive patients in line with agreed pathways and guidance.
- An Early Diagnosis Support Worker, Navigator or similar role to act as a single point of contact for patients during the diagnostic phase of their journey, including the need to support the acceleration of referrals from Primary Care where FIT results are positive.

The agreed Secondary Care Negative FIT Pathway should be used to inform further action for patients with a FIT result of <10µg WITH NO sign of IDA, no palpable abdominal mass AND/OR no obstructive symptoms**,** have a normal FBC and normal examination. EXCLUDED PATIENTS: FIT <10µg AND with persistent/recurrent anorectal bleeding who should have a flexi-sigmoidoscopy at priority level 1a.

## 6 Cancer Waiting Times Guidance (CWT)

Current Cancer Waiting Times Guidance should be followed as business as usual. Key summary points relevant to prioritisation of patients with LGI symptoms are provided below. Please see CWT guidance for further detail:

- The CWT clock begins when the Urgent suspected LGI Cancer Referral (currently TWW) referral is received by the Trust.

- The CWT clock cannot be paused if a FIT has yet to be returned if ordered at the same time as the Urgent suspected LGI Cancer Referral (currently TWW) referral is made by Primary Care. If a FIT has not been returned within five days, it is recommended that the patient is contacted twice to encourage completion. If the kit is still not returned, then the patient should progress along the pathway without this result and triaged based on existing referral information.

- Where the Urgent suspected LGI Cancer Referral (currently TWW) referrals are received without a FIT test, the patient will remain on the 28 day Faster Diagnosis Standard (FDS) pathway until a FIT is completed or cancer is diagnosed or excluded. The Trust will make every effort to contact the patient directly to ensure a kit is returned. Please refer to Cancer Waiting Times Guidance Section 2.5 for information concerning the national requirements for management of TWW referrals:

    - If a clinician thinks the Urgent Suspected LGI Cancer Referral (currently TWW) referral is inappropriate this should be discussed with the referrer. Only the referrer can downgrade or withdraw a referral. This includes where it is considered that insufficient information has been provided. The Secondary Care Negative FIT Pathway should be implemented and used operationally and clinically.
    - The date of receipt of initial referral or the conversion of the UBRN into a booking should always count as the start of the pathway and recorded as CANCER REFFERAL TO TREATMENT PERIOD START DATE. This includes scenarios where additional information is requested from the referrer and where a patient is unavailable for a period of time.
    - A patient should not be discharged because they are unavailable within a specified time-frame, and processes should be in place to ensure patients have the choice to book outside of the two week wait time-frame.

- The date on which a consultation takes place with an appropriately trained clinician is recorded as the Date First Seen. This consultation can be via telephone.

- Patients should not be discharged from the pathway on the basis of a FIT test alone. In Cheshire & Merseyside, the Secondary Care Negative FIT Pathway protocol should be followed by all Trusts. This includes the requirement that a face-to-face OR telephone consultation (whichever is most clinically appropriate), by an appropriate trained clinician e.g. Consultant, Clinical Nurse

Specialist or Endoscopy Nurse, takes place to explain the outcome of the triage and next steps e.g. diagnostics or discharge.

- Where a patient is followed up, even routinely the FDS standard continues unless the patient has been informed that cancer has been excluded and the Faster Diagnosis Date has been completed within Somerset Cancer Register as part of Cancer Waiting Times data collection and completeness. The Secondary Care Negative FIT Pathway protocol should be followed by all Trusts.

- Those patients excluded from FIT AND/OR with a positive result AND/OR those with iron deficiency anaemia remain on the 62 day cancer pathway and managed as such.

- All patients referred into the LGI FDS pathway will be the clinical responsibility of secondary care. Where a patient is referred and FIT result of <10µg WITH NO sign of IDA, no palpable abdominal mass AND/OR no obstructive symptoms**,** have a normal FBC and normal examination, the Secondary Care Negative FIT Pathway will be followed by all Trusts. PLEASE NOTE: This EXCLUDES patients with FIT <10µg AND with persistent/recurrent anorectal bleeding who should receive a flexi-sig as a priority 1a.

## 7 Evaluation and data monitoring

Cheshire & Merseyside and National KPIs are outlined within the FIT KPIs document which is available on request. Trusts are required to report these monthly to Cheshire & Merseyside Cancer Alliance (CMCA). These KPIs support implementation, further improvements and effective commissioning of FIT. Additional activities may be required to support effective pathway implementation, improvements and further evidence gathering.

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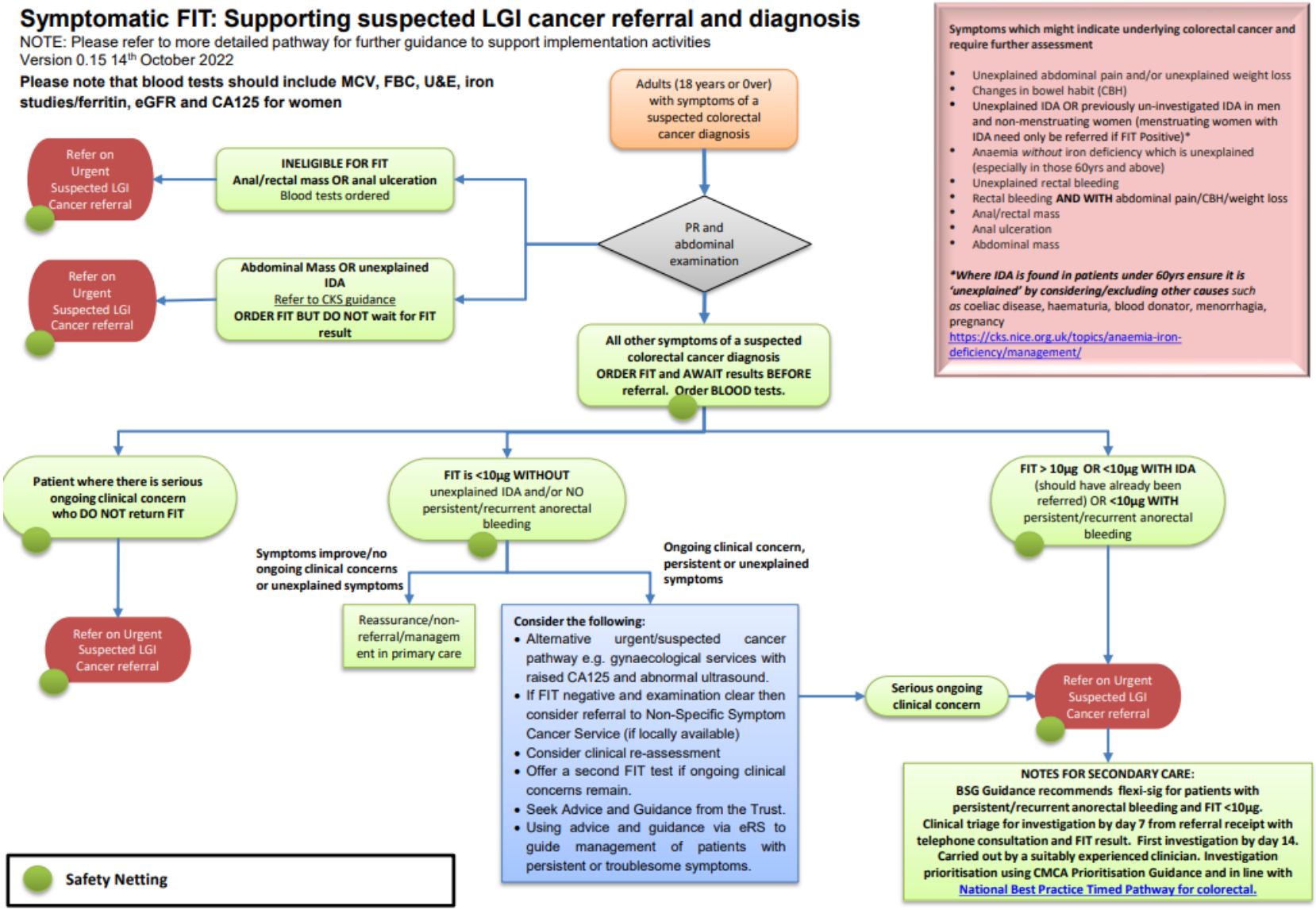
# Appendix 1: New Symptomatic FIT Pathway v0.15 14th October 2022



# Appendix 2: Secondary Care Negative FIT Pathway v0.16

## FIT NEGATIVE PATHWAY v0.16 – FOR PATIENTS IN SECONDARY CARE

***This pathway should be used by Secondary Care ONLY. It is explicitly concerned with patients who are FIT <10µg WITH no IDA AND/OR no palpable mass AND/OR no obstructive symptoms, have a normal FBC and normal examination (EXCLUDES patients with FIT <10µg AND with persistent/recurrent anorectal bleeding who should receive a flexi-sig). These may have been referred on a suspected LGI cancer referral (currently TWW) a FIT has been requested at the same time rather than results informing Primary Care Triage.***
***This form should be completed following review and discussion with the patient and saved within the patient notes.***

***Where patients are discharged back to Primary Care, the following information should be communicated/discussed with them by an appropriately trained clinician:**

a. Reassurance to the patient that colorectal cancer has been excluded as possible diagnosis.
b. Advise the patient to be vigilant of similar signs and symptoms and others that are not normal for them. Safety netting advice should go alongside that e.g. losing weight, night sweats etc.…
c. Inform the patient that they are being referred to their GP for management with explanation why, informing them that a letter will be sent to their GP and them summarising this outcome with further advice.

There should be shared decision making with the patient around risks of colorectal cancer vs doing colonoscopy or imaging vs doing nothing.

**CLINICIAN NAME:** _____ **NHS Number**_____

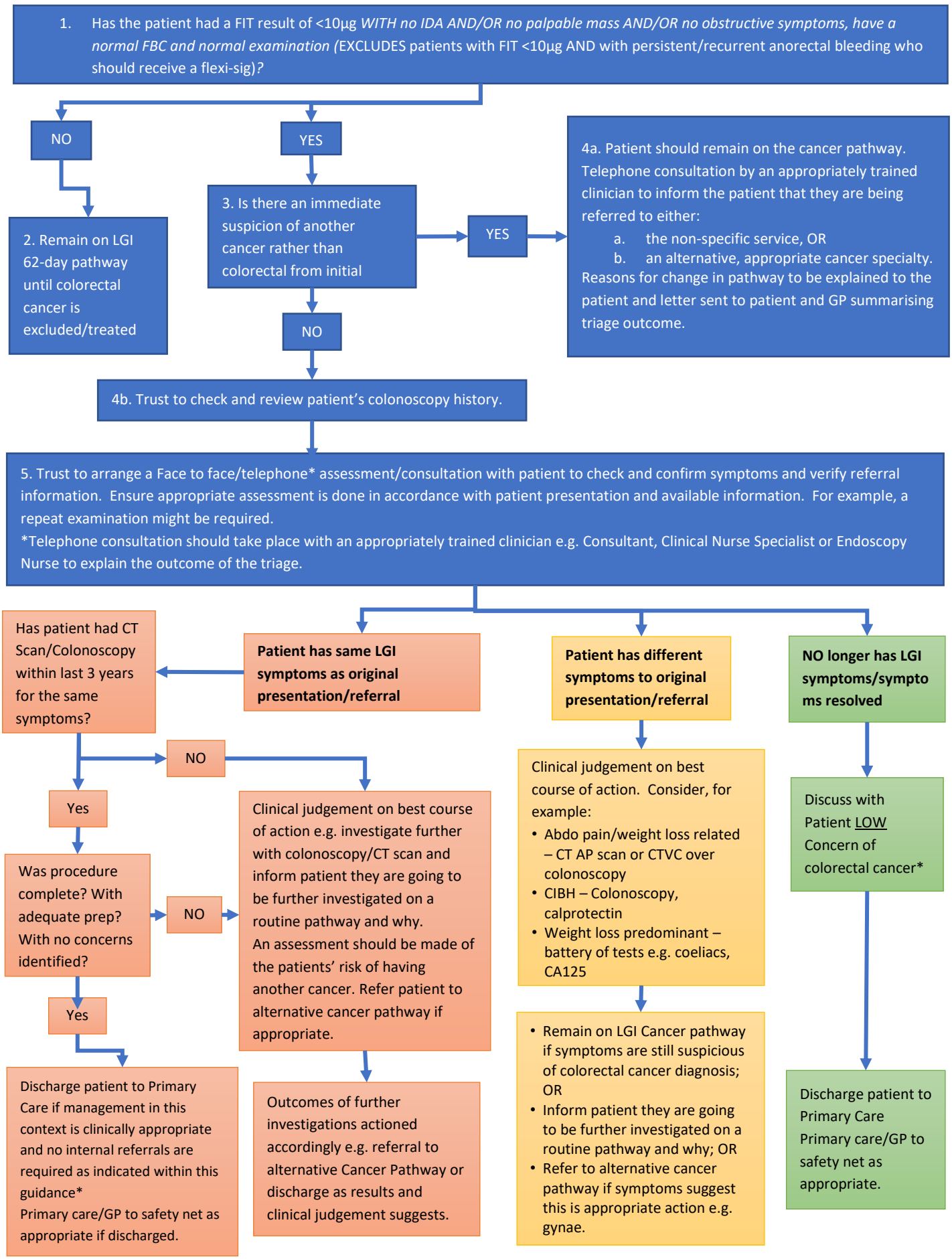
**PATIENT NAME**_____ **Date FIT Test reported**_____

**Date of Referral**_____ **Rockwood Frailty score from TWW referral:**

**FIT Result**_____**µg/L (-VE= 0-9ug/L)** **Hb**_____**g/L (Female =115-165g/L / Male = 130-180g/L)**

**Ferritin**_____**ug/L (15-200)** **MCV**_____**fL (80.0 – 100.0)**

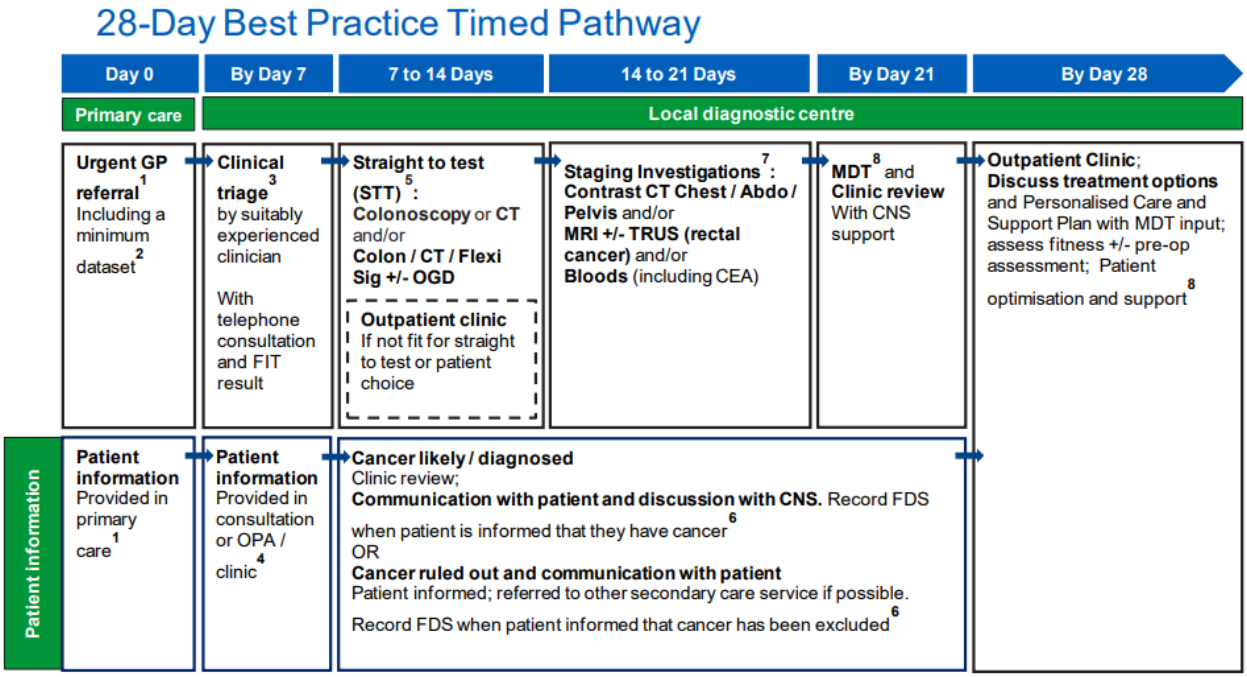
| Protocol | Comments | Clinician signature | Date |
|---|---|---|---|
| Has the patient had a FIT result of <10µg *WITH no IDA AND/OR no palpable mass AND/OR no obstructive symptoms, have a normal FBC and normal examination (*EXCLUDES patients with FIT <10µg AND with persistent/recurrent anorectal bleeding who should receive a flexi-sig). | | | |
| Is there an immediate suspicion of another cancer rather than colorectal from initial referral information? | | | |
| Patient's colonoscopy history has been reviewed | | | |
| Patient referral information has been reviewed | | | |
| Face-to-face/telephone consultation has taken place | | | |
| Next steps discussed and confirmed with the patient | | | |
| Summary of next steps: | | | |


1. Has the patient had a FIT result of <10µg *WITH no IDA AND/OR no palpable mass AND/OR no obstructive symptoms, have a normal FBC and normal examination* (EXCLUDES patients with FIT <10µg AND with persistent/recurrent anorectal bleeding who should receive a flexi-sig)*?*
NO
YES
2. Remain on LGI 62-day pathway until colorectal cancer is excluded/treated
3. Is there an immediate suspicion of another cancer rather than colorectal from initial
YES
4a. Patient should remain on the cancer pathway. Telephone consultation by an appropriately trained clinician to inform the patient that they are being referred to either:
a. the non-specific service, OR
b. an alternative, appropriate cancer specialty.
Reasons for change in pathway to be explained to the patient and letter sent to patient and GP summarising triage outcome.
NO
4b. Trust to check and review patient's colonoscopy history.
5. Trust to arrange a Face to face/telephone* assessment/consultation with patient to check and confirm symptoms and verify referral information. Ensure appropriate assessment is done in accordance with patient presentation and available information. For example, a repeat examination might be required.
*Telephone consultation should take place with an appropriately trained clinician e.g. Consultant, Clinical Nurse Specialist or Endoscopy Nurse to explain the outcome of the triage.
Has patient had CT Scan/Colonoscopy within last 3 years for the same symptoms?
Patient has same LGI symptoms as original presentation/referral
Patient has different symptoms to original presentation/referral
NO longer has LGI symptoms/symptoms resolved
NO
Yes
Was procedure complete? With adequate prep? With no concerns identified?
NO
Yes
Clinical judgement on best course of action e.g. investigate further with colonoscopy/CT scan and inform patient they are going to be further investigated on a routine pathway and why.
An assessment should be made of the patients' risk of having another cancer. Refer patient to alternative cancer pathway if appropriate.
Clinical judgement on best course of action. Consider, for example:
• Abdo pain/weight loss related – CT AP scan or CTVC over colonoscopy
• CIBH – Colonoscopy, calprotectin
• Weight loss predominant – battery of tests e.g. coeliacs, CA125
Discuss with Patient LOW Concern of colorectal cancer*
Discharge patient to Primary Care if management in this context is clinically appropriate and no internal referrals are required as indicated within this guidance*
Primary care/GP to safety net as appropriate if discharged.
Outcomes of further investigations actioned accordingly e.g. referral to alternative Cancer Pathway or discharge as results and clinical judgement suggests.
• Remain on LGI Cancer pathway if symptoms are still suspicious of colorectal cancer diagnosis; OR
• Inform patient they are going to be further investigated on a routine pathway and why; OR
• Refer to alternative cancer pathway if symptoms suggest this is appropriate action e.g. gynae.
Discharge patient to Primary Care Primary care/GP to safety net as appropriate.

## Appendix 3: National Colorectal Best Practice Timed Pathway

The Symptomatic FIT pathway supports implementation of the National Optimal Lower GI Pathway. The NHS Planning Guidance 2022/23 cites that organisations should ensure that least 65% of urgent cancer referrals for suspected colorectal. For 2022/23, there is a particular emphasis on the diagnostic milestones, which are supported by the FIT Symptomatic Pathway:

- Clinical triage for investigation by day 7 from referral receipt with telephone consultation and FIT result.
- First investigation by day 14



# Appendix 4: Background

## 1. What is FIT?

Many of our challenges lie at the diagnostic end of the pathway and therefore it is becoming increasingly important to utilise tests that have lower associated risks and can rule out cancer at the same time as improving early detection, patient experience and outcomes. Furthermore, such tests enable targeted use of limited diagnostic and cancer clinical team capacity, ensuring that patients at highest risk are prioritised for investigation and those who have minimal risk avoid unnecessary investigation.

FIT is a stool test that is designed to identify possible signs of bowel disease by detecting faecal occult blood (hidden blood). In combination with clinical review FIT testing provides a safe, minimally invasive, rapid and accurate way to determine a patient's risk of having a LGI cancer. The test has a high negative predictive value of at least 97% which means that FIT is an effective diagnostic test and superior to symptoms in predicting pathology in patients with suspected cancer symptoms.[3][4][5][6][7]

## 2. Strategic context

The NHS Long Term Plan (LTP)[8] sets the ambition that, from 2028, an extra 55,000 people each year will survive for five years or more following their cancer diagnosis, and three in four cancers (75%) will be diagnosed at an early stage. By getting patients from referral to diagnosis more quickly, we can increase the chance of an early-stage diagnosis, offering faster and more efficient cancer pathways to support this LTP ambition. The 28 day Faster Diagnosis Standard (FDS) was announced as part of this, which sets a maximum 28-day wait for communication of a cancer diagnosis or ruling out of cancer for patients referred urgently for investigation of cancer (including those with breast symptoms) and from NHS cancer screening. Formal monitoring of this standard began in quarter 3 2021 with a target for 75% of patients meeting this standard.

The NHS Planning Guidance 2022/23, whilst prioritising elective recovery activities, firmly steers the focus back on to the LTP ambitions to ensure that:

- Cancers are diagnosed earlier and faster.
- Every patient has access to optimal, personalised treatment and care as well as effective follow-up.

[3] Mole, G.; Withington, J. and Logan, R. (2019) *Clinical Medicine, Conference Report, 19(3):196-9*

[4] Souza, N.D.; Delisle, T.G.; Benton, S.; Chen, M.; Abulafi, M.; NICE FIT Study Investigators (2020) FIT can rule out colorectal cancer in patients with high risk symptoms? Diagnostic Accuracy Results of the Faecal Immunochemical Test in 9822 patients in the NICE FIT study. Colorectal Disease; BJS Prize Session; https://doi.org/10.1111/codi.15167

[5] D'Souza, N.; Delisle, T.G.; Chen, M.; Benton, S and Abulafi, M. (2021) *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 Published Online First: 21 October 2020. doi: 10.1136/gutjnl-2020-321956

[6] Westwood, M.; Lang, S.; Armstrong, N.; van Turenhout, S.; Cubiella, J.; Stirk, L.; Corro Ramos, I.; Luyendijk, M.; Zaim, R.; Kleijnen, J. and Fraser, C. (2017) Faecal immunochemical tests (FIT) can help to rule out colorectal cancer in patients presenting in primary care with lower abdominal symptoms: a systematic review conducted to inform new NICE DG30 diagnostic guidance. *BMC Medicine, 15:189, DOI 10.1186/s12916-017-0944-z*

[7] Bailey, S.E.R., Abel, G.A.; Byford, R.; Davies, S-J; Mays, J.; McDonald, T.J.; Neck, C.; Renninson, J.; Thomas, P; Walter, F.M.; Warren, S. & Hamilton, W. (2021) Diagnostic performance of a faecal immunochemical test for patients with low-risk symptoms of colorectal cancer in primary care: an evaluation in the South West of England. *British Journal of Cancer* **volume 124**, pages1231–1236

[8] NHS Long Term Plan - 2019

- Research, and innovation are enabled so that new, smarter and kinder diagnosis and treatment methods are developed and quickly adopted.

Importantly, we need to ensure that all that we do:

- Improves quality of life outcomes.
- Improves patient experience outcomes.
- Reduces variation.
- Reduces inequalities.

To support this, the guidance cites that priority actions should ensure that there is sufficient diagnostic and treatment capacity to meet recovering levels of demand. The focus here is on the three cancers which make up two-thirds of the national backlog i.e. Lower GI (LGI), Prostate and Skin. For LGI, this includes ensuring there is provision of sufficient commissioned capacity so that every urgent suspected Two Week Wait (TWW) LGI cancer referral is accompanied by a faecal immunochemical test (FIT) result.

Publication of the Elective recovery planning supporting guidance in April of this year reflects this priority with Integrated Care Boards (ICBs) and Trust being asked to work with Cancer Alliances to develop plans to support key ambitions for the next three years, including ensuring 95% of patients requiring a diagnostic test receive one within six weeks. This also includes ensuring that Trust plans incorporate the use of FIT as a key intervention for LGI pathways. The national target for this has been set at 80%.

The GP contract 2022/23 reflects the priority of FIT at a national level, with GP practices being incentivised to ensure that a percentage of lower gastrointestinal two week wait (fast track) cancer referrals are accompanied by a FIT result. The incentive specifically asks that the result is recorded either in the seven days leading up to the referral, or in the fourteen days after the referral. The thresholds set for these are as follows:

- 2022/23: Lower threshold 40%; upper threshold 80%
- 2023/24: Lower threshold 65%; upper threshold 80%

## 3. The challenge facing LGI: key data

All diagnostic services are under pressure. In Cheshire & Merseyside, there are 9373 patients currently on the endoscopy waiting list with 3712 of these waiting for either a colonoscopy or a flexi-sigmoidoscopy. Of these, 1369 have been waiting longer than 13 weeks. This has certainly reduced from the 14581 that were waiting in late March however, the pressures on the service are clear. This is set to continue as the trend for TWW referrals is upwards, with a 28% increase in the last year alone and a 41% increase since 2017/18. From April 2021 to March 2022, Cheshire & Merseyside Trusts received 29,837 urgent suspected LGI Two Week Wait (TWW) referrals, with figures steadily rising though out the year (refer to Chart 1). At Trust level, Liverpool University Hospitals NHS Foundation Trust (LUFT) received 26% of these referrals, with St Helens & Knowsley Teaching Hospitals NHS Trust and Wirral University Teaching Hospitals NHS Foundation Trust receiving 16% and 14% respectively.

The demand on diagnostic services and LGI clinical teams is also evident through consideration of 28 day FDS performance, with this not meeting the operational standard and consistently being under 60% at an Alliance-level (refer to Chart 2). Individual Trust performance for this varies from 32.3% to 68.6%.

**Chart 1; The number of urgent suspected TWW LGI referrals received by financial year**

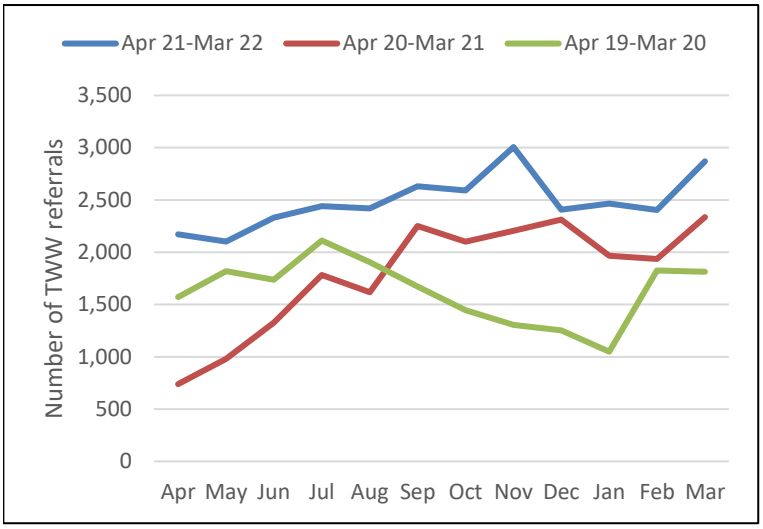
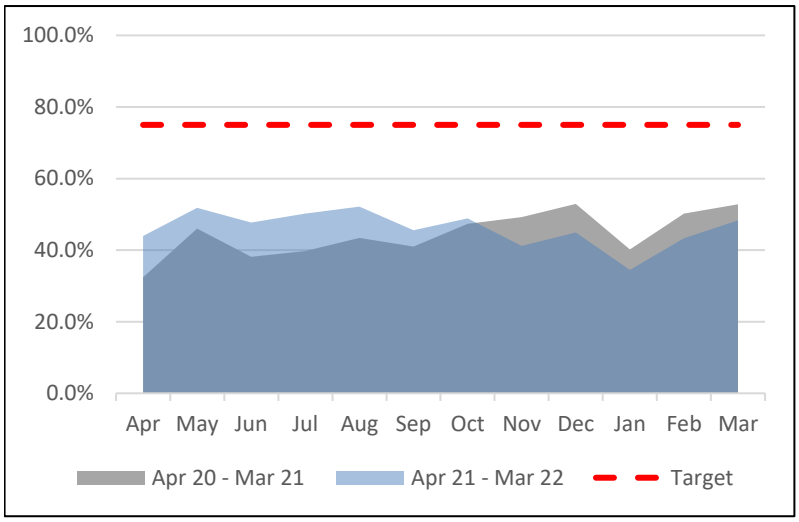



**Chart 2; Percentage of patients receiving a diagnosis or ruling out of cancer within 28 days of referral in Cheshire and Merseyside (Urgent TWW LGI referrals)**




## 4. Evaluation of FIT in Cheshire & Merseyside

Key points from the comprehensive evaluations of the initial FIT pilot sites at St Helens & Knowsley Teaching Hospitals NHS Trust (StH&K) and Warrington & Halton NHS Foundation Trust (WHH) are articulated below. The full evaluations of each have previously been shared and are available from CMCA on request.

StH&K:

- This evaluation included 1125 high risk patients and 1786 low risk patients.
- Of high risk patients eligible to be downgraded from urgent to routine pathways (FIT less than 10µg and no IDA found), 55% did not receive an endoscopy or CT within the following six months and 28% did not have an outpatient appointment. This reduced

pressure on appointments and diagnostic procedures and could be equivalent to over £103,000 of potential costs avoided.

- Of low risk patients eligible to remain under primary care (FIT less than 10µg and no IDA found), 71% did not have a gastroenterology or general surgery outpatient appointment within the following six months. This reduced pressure on appointments and could be equivalent to over £97,000 of potential costs avoided.
- Note that it cannot be assured, in the absence of FIT, these low risk patients would been referred into secondary care. Also, FIT may have encouraged referrals instead of patients remaining in primary care. However, there is evidence that implementing FIT has led to procedures and outpatient appointments being released, with a conservative potential cost avoided estimate in one financial year of over £200,000.
- For high risk patients, there was no evidence that FIT had a negative impact on suspected colorectal cancer pathway timing (28 day faster diagnosis and 62 day GP referral to first treatment standards).
- Following the CM FIT pathway timings, almost 90% of FIT kits were sent to patients with 24 hours of being requested (88%, rising to 98% within 72 hours – weekends may have led to slightly longer periods). Almost two-thirds of FIT kits were returned by patients within 5 days and all FIT kits were analysed and reporting by the pathology laboratory within 48 hours. Pathology also concentrated significant effort to quickly achieve UKAS accreditation for the assay to ISO 15189:2012
- Positive feedback on the pathway was received from patients, consultants, and primary care colleagues. GPs comments included that FIT was “easy to navigate with simple written guidance … fast turnaround”.
- Further opportunities were identified to improve FIT for patients as part of a study carried out by University College London. The study found that while FIT is highly acceptable, the symptomatic FIT pathway could be improved by; 1) ensuring the purpose of the test is explained (during the GP consultation), 2) providing clearer kit instructions/wider sample tubes and, 3) always providing the patient with the test result. In terms of future work, this study found that satisfaction with the GP consultation and the way the results are delivered are lower in the more socioeconomically deprived parts of Cheshire and Merseyside.
- Positive feedback on the pathway was received from patients, consultants, and primary care colleagues. Consultants commented that FIT was “vital for triaging patients … not continuing FIT is not a feasible option”.

WHH:

- This evaluation included 786 high risk patients and 1554 low risk patients.
- Of eligible high risk patients (FIT less than 10µg and no IDA found), 40% were downgraded from urgent to routine pathways. No colorectal cancers were found in downgraded patients.
- In an audit of low risk patients eligible to remain in primary care (FIT less than 10µg and no IDA found), 64% were not referred into gastroenterology within the following six months. This freed up outpatient appointments within pressured colorectal service.
- In low risk patients, the potential costs avoided by patients who were not referred into secondary care was estimated to be greater than the cost of running the FIT service for both high and low risk patients.
- For high risk patients and low risk patients who were upgraded from routine to urgent pathways, there was no evidence that FIT had a negative impact on suspected colorectal cancer pathway timing (28 day faster diagnosis and 62 day GP referral to first treatment standards). However FIT pilot pathways had alternative Cancer Waiting Times guidance approved by NHS England as part of the National FIT Pioneers Group (the clock stop was the date the FIT result was reported, rather than the date the patient was first seen).

Following implementation of FIT across additional Trusts in Cheshire & Merseyside, an evaluation was carried out on 6,610 high risk patients from July 2020 to June 2021. The full evaluation has previously been shared and is available on request. Key findings from this are as follows:

- **High risk FIT requests only covered 42% of urgent suspected lower gastrointestinal cancer referrals in the same period** (range by trust 24% to 59%)**.** According to available evidence, which suggests 79% of patients would be eligible for a FIT test, numbers of high risk FIT requests could double.
- **40% of the 6,799 high risk patients were found to have FIT less than 10µg with no iron deficiency anaemia (IDA) i.e. FIT negative.** Such patients were eligible to be downgraded from an urgent to a routine pathway (i.e. no need for urgent endoscopy).
- **Almost one-third (30%) of patients had FIT greater than 10µg,** meaning they had a colorectal cancer risk of 4.8% or more. **Another 8% of patients had FIT less than 10µg with IDA** and these patients were also prioritised for investigations in line with guidance.
- **Another 22% of patients had FIT less than 10µg but with no blood results, which meant their IDA status was not known.** This represents a sizeable, missed opportunity for patient to potentially be downgraded and avoid invasive procedures.
- **154 colorectal cancers were diagnosed in patients who had FIT results (2.3%), with 145 colorectal cancers found in patients with FIT greater than 10µg.** The colorectal cancer risk in patients with FIT greater than 10µg was 7.1% (higher than 4.8% in the literature) and in patients with FIT greater than 100µg was 18.1% (potentially lower than the literature, where colorectal cancer risk was >22% for FIT between 100µg and150µg and >35% for FIT greater than or equal to 150 µg). The success of FIT in ruling out colorectal cancer (at the time of FIT) in patients with FIT less than 10 µg and no IDA found was more than 99.96%.
- **Almost 30% of colorectal cancers were found at an early stage, compared with 42% for CMCA overall.** This could reflect the greater risk in high risk patients than in low risk and bowel screening patients, which are likely to find earlier stage cancers.
- **Where symptoms were recorded, almost 60% of patients were referred aged 60 or over with change in bowel habit or IDA.** 12% of patients who received FIT were referred with rectal bleeding or rectal or abdominal mass, which are exclusion criteria for the CM FIT pathways.