GIG CYMRU NHS WALES
Rhaglen Endosgopi Cenedlaethol
National Endoscopy Programme

National Framework for the Implementation of FIT in the Symptomatic Service

For Welsh Health Boards

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Version 2

National Framework for the Implementation of FIT in the Symptomatic Service

Contents

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Glossary of Terms:

The below terms have been used

Suspected cancer: Previously or elsewhere defined as Urgent Suspected Cancer (USC) and/or 2 Week Wait (2WW).

High risk: Usually in relation to NG12/suspected cancers.

Low risk: Usually in relation to DG30.

STT: Straight to test: Following clear referral criteria into secondary care (usually NICE guidance) the secondary care clinician (defined as per local protocol) will arrange a diagnostic procedure as the first episode of care in place of an outpatient episode. The clinician will retain clinical responsibility for the result including acting on the result. (Source: NHS England).

Version Control:

Version	Date	Reason for Update
1	17.03.2021	Issued
2	19.05.2021	• U&Es added to “Standard Blood Tests” across all documents (where relevant) • Sentence changed to “OR if inappropriate for STT” in secondary care DG30 pathway across all documents (where relevant)

EXECUTIVE SUMMARY

In 2017 NICE published "Quantitative faecal immunochemical tests to guide referral for colorectal cancer in primary care" (DG30). This guidance recommended the use of FIT to guide referral for people without rectal bleeding who have unexplained symptoms but do not meet the criteria for a suspected cancer pathway referral outlined in NICE's guideline NG12 "Suspected cancer: recognition and referral" . In February 2019 Health Technology Wales (HTW) reviewed the evidence and published a report (Health Technology Wales (HTW) Guidance 007) which supported the adoption of DG30 in Welsh Health Boards, stating that "NHS Wales should adopt this guidance or justify why it has not been followed".

In order to ensure standardised implementation of DG30 and to evaluate emerging data to inform future policy on the use of FIT in other cohorts such as the NG12 suspected cancer group, a NEP FIT subgroup was established in 2020 to develop the agreed national framework (list of members can be found in Appendix 5).

The framework has been divided into 3 parts:

1. **Part 1** provides practical guidance for the implementation of FIT within the symptomatic service with supporting appendices and includes:
    - National FIT pathways for both primary and secondary care
    - Information for the public and professionals
    - An education programme for clinicians
    - A national evaluation strategy.
2. **Part 2** provides the evidence base for the approach and practical implications and includes:
    - The guiding principles for symptomatic FIT implementation
    - Emerging evidence
    - Local variation considerations
    - Threshold considerations.
3. **Part 3** is two "quick guides" which contain the pathways for both primary and secondary care and some of the key points.

1. INTRODUCTION

1.1. Faecal Immunochemical Test

The Faecal Immunochemical Test (FIT) is a test that can identify possible signs of bowel disease by detecting small amounts of blood in faeces. FIT detects the globin component of haemoglobin (Hb) by immunoassay and measures the faecal Hb concentration (*f*-Hb) as microgram of Hb per gram (μg/g) of faeces.

1.2. COVID-19

Health Boards (HBs) have been encouraged to implement DG30, but the COVID-19 pandemic has inevitably delayed progress in implementation of FIT as a triage tool for referrals in this category with some exceptions. COVID-19 has brought additional challenges with increasing backlogs of patients waiting for procedures and has resulted in some HBs beginning to use FIT as a triage tool in suspected cancer referrals. Evidence to support this approach is emerging, with recent publications focusing on diagnostic accuracy of FIT in this group, providing more data on which to base clinical decision-making. HBs have been asked to collect data to feed into the growing body of information that may be useful to inform future guidance and policy decisions. All further reference to the use of FIT in the suspected cancer cohort in this document should therefore be considered as interim guidance for use currently during the COVID-19 pandemic. It is likely, however, that much of it may continue being applicable and relevant in the post-pandemic period depending on further evidence and recovery capacity within endoscopy services in NHS Wales.

1.3. NATIONAL ENDOSCOPY PROGRAMME

The National Endoscopy Programme (NEP) has been established since April 2019 and the implementation of FIT for the symptomatic service was identified as one of the aims of the Clinical Pathways workstream. The NEP's action plan supports development of a national framework with recommendations and options for implementation of FIT in both high (NG12) and low (DG30) risk referral streams for lower gastro-intestinal (LGI) symptoms. It also supports an enhanced FIT pilot within Cardiff and Vale University HB which will build on the evidence base for the use of FIT in the symptomatic service with additional parameters in order to inform future guidance for patients with suspected cancer symptoms.

PART 1: PRACTICAL GUIDANCE FOR IMPLEMENTATION OF FIT

1. PRINCIPLES OF IMPLEMENTING FIT

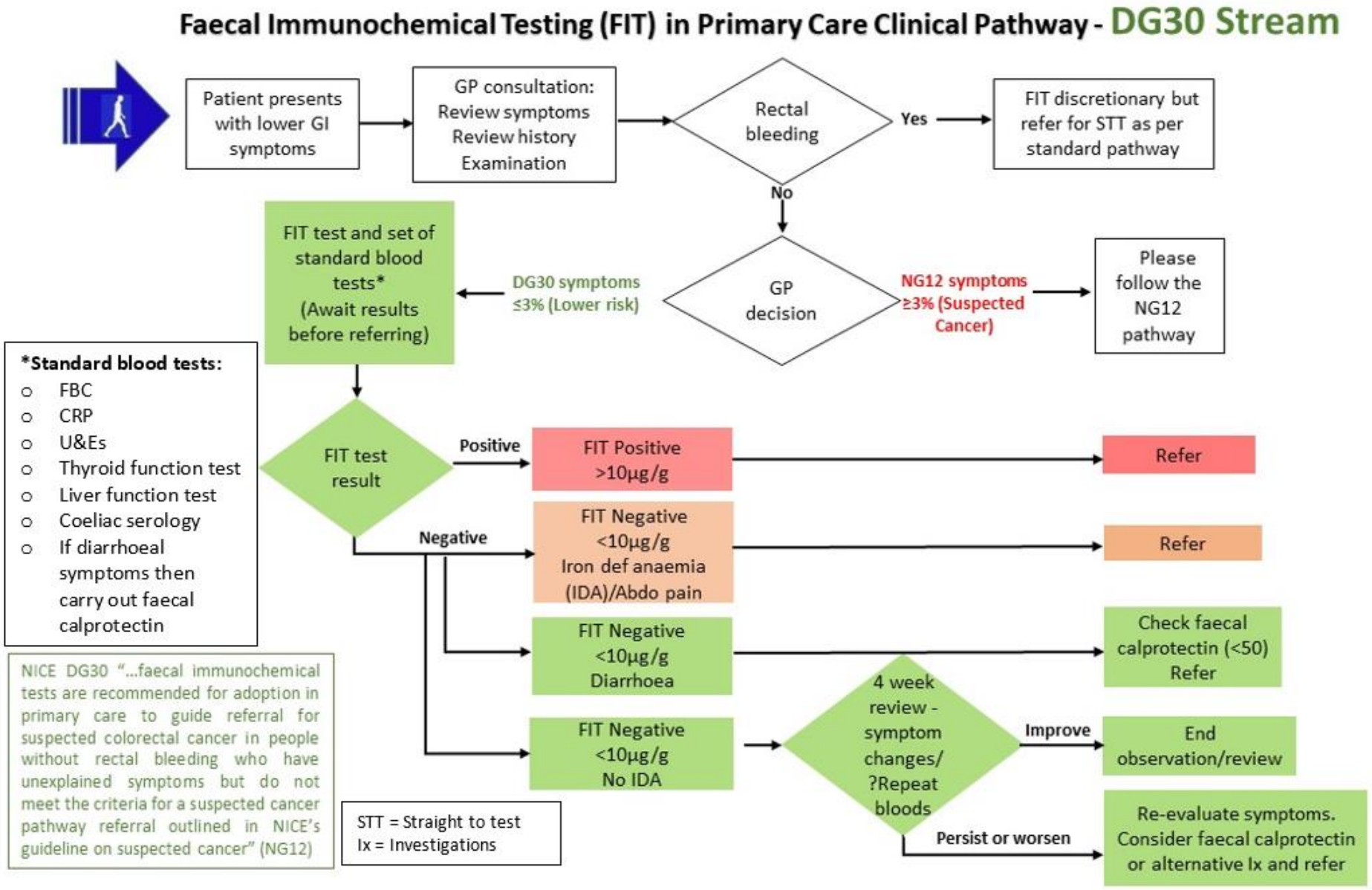
- FIT should only be performed in UKAS ISO 15189 accredited laboratory.
- FIT should only be used as a risk stratification triage tool, as part of a comprehensive patient assessment, for the investigation of patients with symptoms of suspected lower gastrointestinal (LGI) cancer.
- Communication with patients and clinical teams regarding management of FIT based triage in both primary and secondary care is vital.
- The interpretation of FIT is appropriate only if local pathways and robust safety netting mechanisms are in place.
- Alarm symptoms should not be set aside due to a FIT value being <10 μg/g. Cancers may be missed if used in isolation as a diagnostic test rather than as a component of FIT integrated comprehensive clinical assessment. Alternative pathways need to be in place to ensure these patients are investigated appropriately.
- Patients meeting NG12 criteria should still be referred for assessment on the suspected cancer pathway. A FIT may, however, be requested at the point of referral, so the result is available as part of the overall assessment and help with secondary care clinical triage. This interim guidance may change if and when NICE change or update these guidelines.

2. NATIONAL FIT PATHWAY

The primary and secondary care pathways for patients that present with low risk (DG30) symptoms, suspected cancer (NG12) symptoms and vague symptoms can be found on pages 7-14.

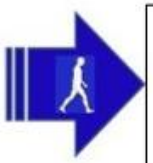
A list of safety netting systems to follow have also been provided. We suggest that all primary and secondary care safety net measures should be agreed across primary and secondary care in each HB and that any variation in these should be documented and closely audited through local Clinical Governance mechanisms. Local pathways and variation should be reported to the NEP.

2.1. NATIONAL PRIMARY CARE FIT PATHWAYS



Faecal Immunochemical Testing (FIT) in Primary Care Clinical Pathway – NG12 Stream

FIT is currently being used with patients that present with NG12 (suspected cancer) symptoms in many HBs as part of their COVID mitigation strategy. This pathway is to assist with the prioritisation process. The NEP framework should be considered as interim guidance on use of FIT in this setting at present but awaiting further high quality evidence and NICE guidelines.



Patient presents with lower GI symptoms

GP consultation:
Review symptoms
Review history
Examination

Rectal bleeding

Yes → Undertake FIT but refer for STT as per National Optimal Pathway for Suspected and Confirmed Colorectal Cancer

No → GP decision

NG12 symptoms ≥3% (Suspected Cancer) → Refer as suspected cancer and do set of standard bloods* following NG12 guidelines

Carry out FIT at the same time as the referral but do not wait for the result prior to referral

Consider Imaging if abdominal or rectal mass palpable

NICE NG12:
- Age > 40 with unexplained weight loss **and** abdominal pain
- Age > 50 with **unexplained** rectal bleeding
- Age > 60 **plus** iron-deficiency anaemia
- Age > 60 **plus** changes in their bowel habit
- Positive faecal occult blood
- A rectal mass
- An abdominal mass that may be colorectal
- Tests show occult blood in their faeces.

Age < 50 with rectal bleeding **and** any of the following (unexplained):
- Iron-deficiency anaemia
- Change in bowel habit
- Weight loss
- Abdominal pain

***Standard blood tests:**
- FBC
- CRP
- U&Es
- Thyroid function test
- Liver function test
- Coeliac serology
- If diarrhoeal symptoms then carry out faecal calprotectin

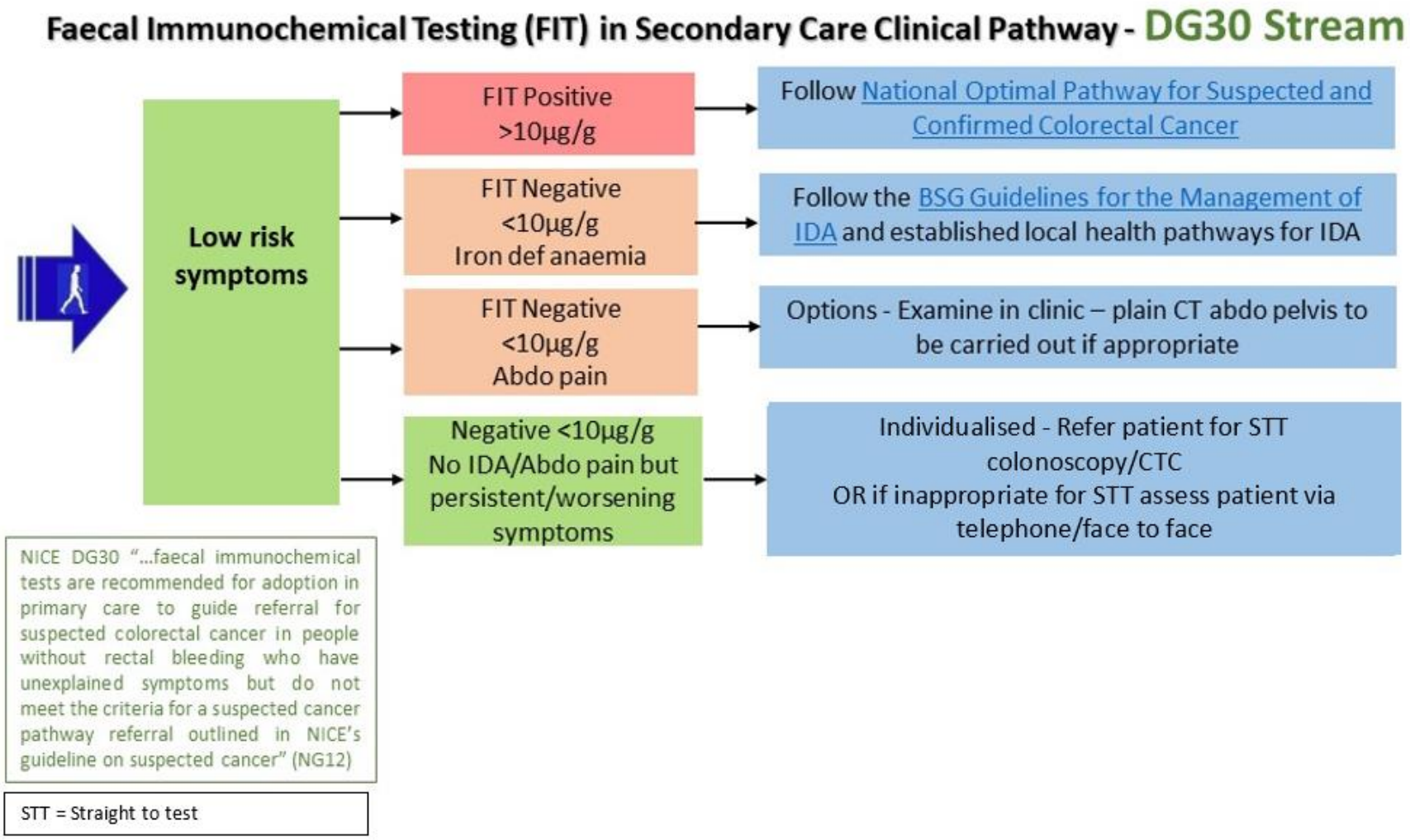
STT = Straight to test

Safety Net Systems in a Primary Care Setting –

We suggest that the following steps are embedded into referral pathways as part of using FIT as a component triage tool. Additional local measures may also need to be put in place.

- Patients with IDA as defined within BSG guidelines for the management of iron deficiency anaemia (Goddard et al, 2011) , or an abdominal or rectal mass should not wait for a FIT result to be referred as suspected cancer unless otherwise precluded due to other patient factors.
- A rectal examination in patient with LGI symptoms is part of standard care.
- Patients with obstructive type abdominal pain should be managed as suspected cancer and referred STT (as per National Optimal Pathway for Colorectal Cancer) even if the FIT level is below threshold due to evidence suggesting that obstructive colorectal pathology may be responsible for a proportion of false negative FIT results.
- Patients with FIT <10µg Hb/g faeces who have not been referred to secondary care require ongoing review – we suggest no more than 4 weeks for review of symptoms including consideration of alternative diagnoses and alternative pathways if appropriate.
- Options to consider at review are repeat FBC and FIT, and referral to secondary care if their symptoms change or persist with a change in laboratory results. There may be need for further review and/or alternative investigative pathways if deemed appropriate.

2.2. NATIONAL SECONDARY CARE FIT PATHWAYS



Faecal Immunochemical Testing (FIT) in Secondary Care Clinical Pathway – NG12 Stream

FIT is currently being used to prioritise patients that present with NG12 (suspected cancer) symptoms in many HBs as part of their COVID mitigation strategy. This pathway is only a suggestion to assist with this process.

NG12 (suspected cancer) symptoms Referral from Primary Care

FIT Positive >10µg/g → Follow National Optimal Pathway for Suspected and Confirmed Colorectal Cancer → FIT result aids with prioritisation in secondary care to STT – Colonoscopy/CTC

FIT Negative < 10µg/g → Consider suspected cancer clinic (Face to Face or Virtual)
OR
Suspected cancer CT – Abdo/Pelvis
OR
Other suspected cancer investigations as individualised/appropriate
OR
Detailed specific plan of management to GP with clear options for review and re-refer within 4 weeks if necessary

NICE NG12:

- Age > 40 with unexplained weight loss **and** abdominal pain
- Age > 50 with **unexplained** rectal bleeding
- Age > 60 **plus** iron-deficiency anaemia
- Age > 60 **plus** changes in their bowel habit
- Positive faecal occult blood
- A rectal mass
- An abdominal mass that may be colorectal
- Tests show occult blood in their faeces.

Age < **50** with rectal bleeding **and** any of the following (unexplained):

- Iron-deficiency anaemia
- Change in bowel habit
- Weight loss
- Abdominal pain

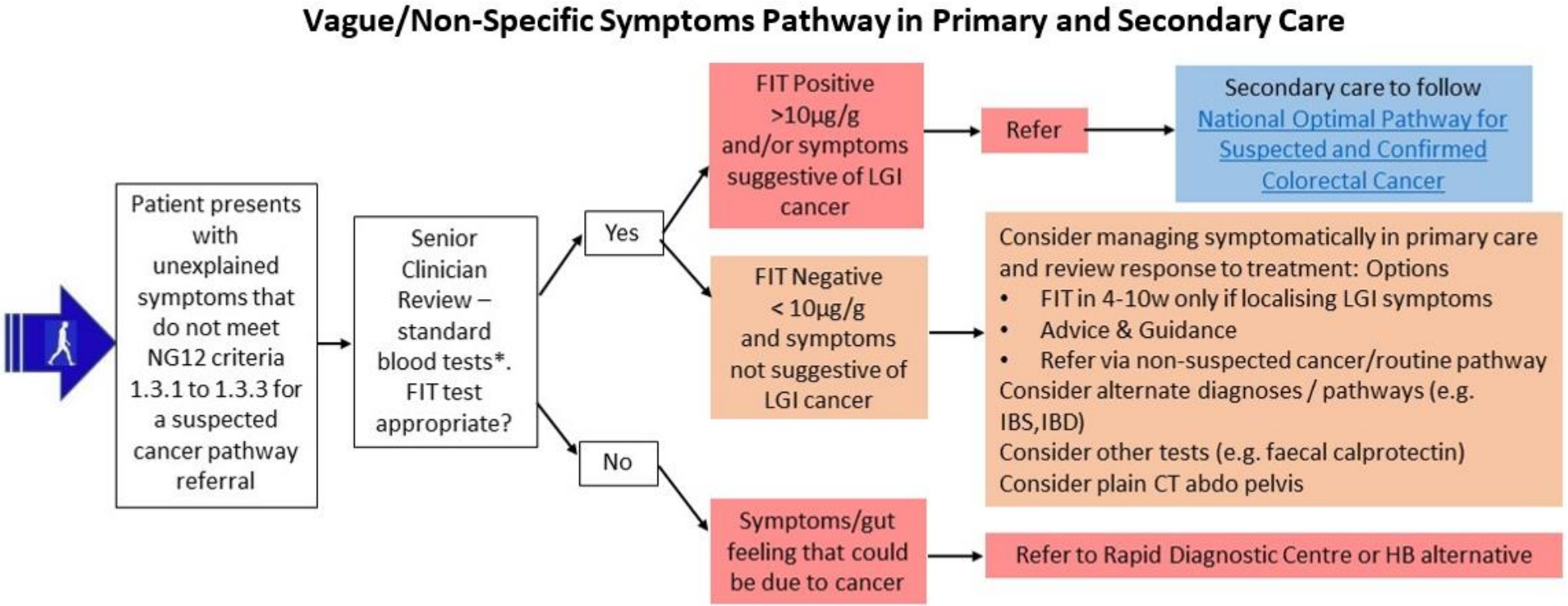
STT = Straight to test

Safety Net systems in a Secondary care setting –

- As per BSG (April 2020 Guidance & August 2020 Guidance) and ACPGBI (ACPGBI COVID-19 Updates) guidelines during the pandemic all referrals should be triaged by senior secondary care clinicians who apply the same triage criteria and assess all relevant factors and not just the FIT value.
- Patients who are not for colonoscopy should be considered for alternative routes of consultation.
    - This may be in the form of secondary care virtual consultations or via alternative streams such as rapid diagnostic centre (RDC) if the referral is felt to be more consistent with a "Vague or non-specific/undefined symptom pathway".
- Patients with **rectal bleeding** should be considered for a suspected cancer flexible sigmoidoscopy or colonoscopy if considered appropriate by a senior clinician even if their FIT value is less than 10 μg/g.
- Patients who are not appropriate for further investigation should be discharged to primary care with a clear plan of action, describing:
    - review time points
    - specific changes to flag
    - re-referral thresholds
    - routes to assist in further management.

  The patient should be included in the communication that outlines the interpretation of a "negative" test.
- If local HB policy results in a higher threshold for investigation than recommended (i.e. higher than using 10 μg/g of faeces as the threshold) or sub-stratification, then appropriate interpretation of this with its caveats should be communicated to the patient and primary care teams.
- Evidence suggests that the primary care clinician "gut instinct" (Smith et al, 2020) has value as a discriminator for Colorectal Cancer (CRC) and all secondary care teams should give serious consideration to a comprehensive assessment in this context rather than relying on a FIT value in isolation to inform further investigation.

2.3. THE VAGUE OR UNDEFINED/NON-SPECIFIC SYMPTOM GROUP AND USE OF FIT



Safety Netting Vague/Non-Specific Symptoms

- In general we would caution against indiscriminate use of FIT in a cohort with vague/non-specific symptoms where there is inadequate localisation of symptoms to the LGI tract.
- Patients with vague/non-specific symptoms are likely to achieve an earlier diagnosis of malignancy or diagnosis of other pathology via alternative routes such as via an Rapid Diagnostic Centre (RDC), or via direct communication/advice/access to radiologic imaging and other blood tests alongside clinical review as per the HBs provision for this pathway.
- Supply constraints on test kits have recently been an issue therefore they should be used where there is a clear or high level of evidence present which may not be the case in this group of patients.

3. PUBLIC AND PROFESSIONAL INFORMATION

Detailed information has been produced to be used to inform the public, and health care professional across primary and secondary care found in appendices 1-3.

Cancer Research UK (CRUK) has developed information on FIT that can be used if HBs would like to. They have developed a CRUK symptomatic vs screening infographic and a leaflet to assist patients collect their samples. It is understood that the laboratories provide information for patients, but HB teams can decide whether the CRUK leaflets would be useful additions. The leaflets can be accessed on the CRUK website via this link.

Recommendations for use:

3.1. Primary care information (appendix 1) -

- Disseminate via email to all GPs within the HB.
- Confirm receipt with practice managers
- Request the appropriate primary care safety netting systems to be in place as outlined in the framework and part of regular audit
- Nominate a primary care link person within your HB
- Ensure the LMC are briefed.

3.2. Secondary care information (appendix 2) -

- Disseminate the document to all LGI health care professionals.
- Nominate appropriate administrative staff (who are fully aware of the primary and secondary care roles and responsibilities) to ensure there is a robust system to track the waiting list and appoint patients based on referral times and to sample receipt times in the laboratory. This group of staff should send reminders to patients where necessary and liaise closely with the laboratory and clinicians regarding appropriate pathway management for these patients.
- Plan to discuss FIT at monthly audit sessions to review progress and data quality.

- Ensure the appropriate secondary care safety netting systems are in place and included in regular audit

3.3. Patient information (appendix 3) -

This information is intended to be included with the test kit envelope sent to patients by the laboratory. If your HB would like to use these, please contact the laboratory that processes your FIT and ask them to include in the pack. The patient information document will also be available on the NEP's website.

4. PROFESSIONAL EDUCATION

An online education resource for primary and secondary care clinicians is in development in conjunction with Health Education and Improvement Wales (HEIW). It will include educational modules and provide the opportunity for virtual discussion.

HEIW will send details of this resource via email to all Welsh primary and secondary care clinicians and it will be available on the NEP's website which is accessible via this link.

5. EVALUATION STRATEGY (Appendix 4)

Evaluating FIT in the symptomatic service is paramount to developing improved understanding. The Cardiff and Vale UHB enhanced pilot will generate data relating to the impact of FIT combined with the FAST predictive score, but routine data collection for the use of FIT in the symptomatic service in addition to this is essential in determining the future use of FIT in different cohorts.

The NEP recommends development of local HB mechanisms based on this National Framework to enable collection of the data items found in Appendix 4 to facilitate future national audit and NEP central evaluation.

6. LOCAL VARIATION CONSIDERATIONS

Different areas in Wales and different HBs may have significant variation in their COVID-19 prevalence as well as variations in colonoscopy capacity. There is therefore a need for consideration of local flexibility as a result of these constraints.

I. **Variation in threshold** - We suggest that if a HB adopts a higher threshold than the recommended 10 μg/g of faeces for use of FIT in the suspected cancer (NG12) cohort (see Section 8 in Part 2 for evidence base for threshold) then this should be approved by the Local HB Clinical Governance as well as service delivery teams to ensure that the additional safety net and tracking mechanisms required in that situation are in place prior to implementation of a higher sub-threshold or sub-stratification of the recommended pathway.

   We also suggest that if a HB decides to adopt a lower threshold e.g. at the limit of detection (e.g. 2 μg/g of faeces) that they ensure that there is operational endoscopy capacity to meet the additional demand and that this is documented and approved by local HB service delivery teams. Any and all variations to thresholds should be documented in the evaluation metrics as outlined in Appendix 4.

II. **Variation in use of FIT with additional parameters** – We are aware of the Cardiff and Vale pilot plans to use FAST scores as part of their triage with FIT. We suggest that any HB planning to implement these or other parameters and or scoring systems should document this in their evaluation metrics and have measures in place for the additional input required for collation of these scores including resource for any additional parameters (investigations) that may not otherwise be part of the standard triage recommendations.

III. **Variation in process for issue and transport of FIT kits and samples from referrer to laboratory** – We have set out the process that the majority of Health Boards in Wales are likely to follow; mainly based of central issue of kits through the post and similarly transported from the patient to the lab via the post. However if an individual Health Board prefers to issue kits through primary care they will need to track and monitor the dispatch and receipt of samples and impact on pathway diagnostic time similarly as set out in this guidance.

PART 2: EVIDENCE BASE FOR APPROACH AND PRACTICAL IMPLICATIONS

7. THRESHOLDS AND RECOMMENDATION FOR WALES:

NICE guidelines (NICE, 2017) and Health Technology Wales (HTW, 2019) have already presented all available evidence relating to the use of FIT in the **low risk symptoms group (DG30)** and we support the recommendation of **using 10 micrograms per gram of faeces (10 μg/g) as the threshold at or above** which investigation should be triggered in this group.

There are several studies that have examined the use of FIT as part of an integrated triage in the **suspected cancer group (conforming to the NICE NG12 guidelines)** (NICE, 2016). **We recommend using a FIT threshold of 10 μg/g of faeces or above for this cohort as part of a comprehensive triage step** to allocate those at or above this threshold to a STT investigative pathway.

It is important to be aware of the trade-offs and consequences for patients and healthcare providers in implementation of a higher or lower threshold if that is decided as part of local variation in policy.

The following table summarises key evidence on FIT thresholds.

Reference/Title	Results/Findings
D'Souza N, *et al*. *Gut* 2020 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	The prevalence of CRC at colonoscopy was 3.3%. The FIT positivity decreased from 37.2% to 19.0% and 7.6%, respectively, at cut-offs of 2, 10 and 150 μg haemoglobin/g faeces (μg/g). The positive predictive values (PPV) of FIT for CRC at these cut-offs were 8.7% (95% CI, 7.8% to 9.7%), 16.1% (95% CI 14.4% to 17.8%) and 31.1% (95% CI 27.8% to 34.6%), respectively and the negative predictive values (NPV) were 99.8% (95% CI 99.7% to 99.9%), 99.6% (95% CI 99.5% to 99.7%) and 98.9% (95% CI 98.7% to 99.1%), respectively.
McSorley S T et al. Colorectal Disease 2020 Yield of colorectal cancer at colonoscopy according to faecal haemoglobin concentration in symptomatic patients referred from primary care	Primary care referrals with lower GI symptoms in 4841 symptomatic patients who underwent colonoscopy. Of the 2166 patients (44.7%) with f-Hb <10 μg Hb/g faeces (μg/g), 14 (0.6%) were diagnosed with CRC, with a number needed to scope (NNS) of 155. Of the 2675 patients (55.3%) with f-Hb ≥10 μg/g, 252 were diagnosed with CRC (9.4%) with a NNS of 11. Of the 705 patients with f-Hb ≥400 μg/g, 158 (22.4%) were diagnosed with CRC with a NNS of 5. Over half of those diagnosed with CRC with f-Hb <10 μg/g had coexisting anaemia.

Key Points for Consideration

- In D'Souza's study using a threshold of 2 μg/g instead of 10 μg/g resulted in an increase in the NPV from 99.6% (CI – 99.5 – 99.7) at 10 μg/g to a NPV of 99.8% (CI – 99.7 – 99.9). This however came at a trade-off of significantly more colonoscopies (1773 more false positive colonoscopies at the lower threshold against 20 more false negative colonoscopies at the higher threshold).

- Significantly more colonoscopy will need to be undertaken to find false negatives at a threshold of 10μg/g if there is a local decision to use a threshold of 2μg/g which is the limit of detection in the above study.
- It is key to communicate to both clinical teams and patients that even the lowest threshold at the limit of detection of 2μg/g will still have some false negative cases and that the risk is not zero even below this threshold. Therefore, FIT should only be used as part of comprehensive assessment with clinical input from both primary and secondary care. FIT has much lower sensitivity for other significant bowel pathology such as suspected cancer adenomas and inflammatory bowel disease and even at the lowest threshold it is highly likely to miss such pathology which may be clinically relevant.
- Another way to look at this from the study data is that if we currently do not change anything then the number of colonoscopies we need to undertake to find one cancer in this suspected cancer group is around 30, whereas if we use a FIT threshold of 150 μg/g of faeces (current threshold in the Bowel Screening Program in Wales for asymptomatic people) we detect a cancer for every around 3 colonoscopies (3.2); with a threshold of 10 μg/g of faeces we need to undertake around 6 colonoscopies to detect one cancer (6.2) and with a threshold of 2 μg/g we need to do 11.5 colonoscopies to detect a cancer. Thus, using a lower threshold of 2 μg/g results in almost doubling the numbers of colonoscopy numbers required to detect a single cancer as compared to 10 μg/g.
- Both studies are fairly consistent in the numbers needed to scope at a threshold of 10μg/g of faeces of 11 or 11.5 for a cancer to be detected. The Scottish study also highlights the fact that merely having a lower than threshold FIT value may not be sufficient to exclude CRC if there is co-existing anaemia and this is also the rationale for the recommended national FIT pathway.

8. SERVICE IMPACT DUE TO THE PANDEMIC AND IMPLICATION OF FIT THRESHOLD:

The studies below suggest that **using a higher FIT threshold** for investigation as a suspected cancer may be a more pragmatic option particularly in a pandemic situation where colonoscopy capacity has been significantly constrained.

The following table summarises key evidence on the service impact due to different thresholds.

Reference/Title	Results/Findings
Loveday C, et al. Gut 2020 Prioritisation by FIT to mitigate the impact of delays in the 2-week wait colorectal cancer referral pathway during the COVID-19 pandemic: a UK modelling study	A modelling study using several different thresholds evaluated the impact of FIT prioritisation to mitigate the impact of delays in the colorectal cancer (CRC) urgent diagnostic (2-week-wait (2WW)) pathway consequent from the COVID-19 pandemic. Risk– benefit from urgent investigatory referral is particularly sensitive to nosocomial COVID-19 rates for patients aged >60. Prioritisation out of delay for the 18% of symptomatic referrals with FIT >10 μg Hb/g would avoid 89% of these deaths attributable to presentational/diagnostic delay while reducing immediate requirement for colonoscopy by >80%. Although FIT triage of symptomatic patients in primary care could streamline access to colonoscopy, reduce delays for true-positive CRC cases and reduce nosocomial COVID-19 mortality

	in older true-negative suspected cancer referrals, this strategy offers benefit only in short-term rationalisation of limited endoscopy services: the false-negative rate of FIT in symptomatic patients means most colonoscopies will still be required.
Mowat et al., Annals of clinical Biochemistry, 2020 Faecal haemoglobin concentration thresholds for reassurance and urgent investigation for colorectal cancer based on a faecal immunochemical test (FIT) in symptomatic patients in primary care	Recently published data from Scotland suggesting that low f-Hb thresholds of <2, <7, <10 and <20 μg/g gave respective CRC risks of 0.1, 0.3, 0.3 and 0.4%, Numbers Needed to Scope (NNS) for one CRC of 871, 335, 300 and 249, and "false negative" rates of 2.9, 11.4, 13.3 and 17.1%. With thresholds of <2, <7, <10, and <20 μg/g, 48.6, 74.6, 78.1 and 83.2% respectively of symptomatic patients could be managed without further investigation. With reassurance thresholds of <2 μg/g, <7 μg/g and <10 μg/g, the thresholds for referral for urgent investigation would be >400 μg/g, >200 μg/g and >100 μg/g. However, patients with an f-Hb concentration of <10 or <20 μg/g with iron deficiency anaemia, or with severe or persistent symptoms, should not be denied further investigation.
Bailey JA et al., Surgeon, 2020 GP access to FIT increases the proportion of colorectal cancers detected on urgent pathways in symptomatic patients in Nottingham	Between November 2017 and December 2018, 6747 GP FIT test requests yielded 5733 FIT results, of which 4082 (71.2%) were <4.0 μg Hb/g faeces, 579 (10.1%) were 4.0–9.9 μg Hb/g faeces, 836 (14.6%) were 10.0–149.9 μg Hb/g faeces, and 236 (4.1%) were ≥150.0 μg Hb/g faeces. The proportion of "rule out" results <4.0 μg Hb/g faeces was significantly higher than in the Getting FIT cohort (71.2% vs 60.4%, Chi squared 42.8, $p < 0.0001$) and the proportion of "rule in" results ≥150.0 μg Hb/g faeces was significantly lower (4.1% vs 8.1%, Chi squared 27.3, $P < 0.0001$). There was a 33% rise in urgent referrals across Nottingham overall during the evaluation period. 2 CRC diagnoses were made in 4082 patients who had FIT<4.0 μg Hb/g faeces. 58.4% of new CRC diagnoses associated with a positive FIT were early stage cancers (Stage I and II). The proportion of all CRC diagnoses that follow an urgent referral s rose after introduction of FIT.

Key Points for Consideration

- Based on this data, in Scotland the guidance for example applies a higher cut off of ≥400 μg Hb/g faeces for being considered as requiring prioritisation. This however exists with clear local treatment, review and referral guidance and Scotland is not subject to the constraints of NICE NG12.
- The trade-off to be aware of with using higher thresholds (whether 20 μg/g, 100 μg/g, or 400 μg/g) is between cancers likely to be missed and colonoscopy capacity, with a clear need for alternative mechanisms and pathways to be in place alongside clear communication with patients and clinical teams about what the "negative" at that threshold means in terms of the patient's investigative journey to avoid false reassurance due to misinterpretation.
- The precise impact of using FIT in a suspected cancer cohort including what constitutes an optimal FIT pathway remains an area where evidence is emerging rather than at a high level currently. When FIT was used in primary care in Scotland, referrals to secondary care were reduced by 15.1% (Mowat et al, 2020). However when FIT accompanied referral in Nottingham (Bailey JA et al Surgeon 2020), suspected cancer referrals and suspected cancer CTC usage increased while there was no long-term reduction in suspected cancer

colonoscopy usage; possibly due to referral of a larger lower risk group of patients. The direction of travel does however seem to be likely to be based on at least partly quantitative triage based on FIT alongside senior clinical decision making and assessment. Overall the consensus seems to be that use of a FIT triage threshold of 10 μg/g should result in reduction in the numbers of colonoscopies as compared to the current NG12 pathway using symptoms alone.

9. SPECIFIC SITUATIONS: RECTAL BLEEDING AND SUSPECTED IBD

a) **Rectal bleeding** – Our recommendation and approach to referrals with rectal bleeding is based on evidence from Digby et al (2020) and Hicks et al (2021) where it seems clear that whilst FIT is helpful in triage assessment of cases with CRC presenting with rectal bleeding there are still instances of significant pathology including cancer not being detected. Results from Digby et al (2020) using a threshold of 10 μg/g of stool suggest a pragmatic approach where flexible sigmoidoscopy may be able to detect most false negative cases as they are predominantly in the left colon. Hicks et al (2021) also concludes f-Hb is undetectable (<2μg/g) in 56% of patients with rectal bleeding, and also suggest that in patients with rectal bleeding and undetectable f-Hb, use of flexible sigmoidoscopy would reduce the probability of undetected CRC to 0.03%.

b) **Suspected IBD** – The are several studies evaluating the combined use of Faecal Calprotectin along with F-Hb in different settings (suspected IBD, relapse of known IBD and detection of cancer) and it is beyond the scope of this document to detail these here. Our approach reflects the fact that results are dependent on the setting in which they are used and that there does not seem much added value to undertaking a Faecal Calprotectin along with FIT at the outset (Turvill et al (2018) being one of these). We were also mindful that despite most clinical assessment of patients with diarrhoea and rectal bleeding also relies on age to an extent (with younger patients more likely to be investigated as suspected IBD and older ones as suspected cancer) (Pavlidis et al, 2013), there is a rising incidence of colorectal cancer in younger patients (Howren et al, 2021) and IBD onset is not uncommonly late in presentation. Our proposed pathway therefore relies on these faecal biomarkers only being used as part of a comprehensive clinical assessment rather than in isolation.

Appendices

Appendix 1: Primary Care Information

GIG CYMRU NHS WALES | Rhaglen Endosgopi Cenedlaethol / National Endoscopy Programme

Faecal Immunochemical Test (FIT): Information for Primary Care

This document contains guidance for the implementation of the Faecal Immunochemical Test (FIT) in primary care.

What is FIT?

FIT is a type of faecal immunochemical blood test used to detect traces of blood in stool samples. The test uses antibodies that specifically recognise human haemoglobin and therefore it is a more sensitive and specific test than the guaiac based FOB test. It also measures the faecal Hb concentration (f-Hb) as microgram of Hb per gram (μg/g) of faeces.

NICE Guidance DG30 (July 2017) states: "Faecal Immunochemical Tests (FIT) are recommended for adoption in primary care to guide referral for suspected colorectal cancer in people without rectal bleeding who have unexplained symptoms but do not meet the criteria for a suspected cancer pathway referral."

FIT is currently being used with patients that present with NG12 (suspected cancer) symptoms in many Health Boards as part of their COVID mitigation strategy. This guidance therefore recommends that if used for prioritisation in this group within secondary care for patients that present with NG12 (suspected cancer) symptoms, a FIT is requested at the same time as referring the patient to secondary care.

Who should be offered a FIT test?

NICE DG30 (lower risk symptoms): Offer a FIT prior to considering referral for any patient with abdominal symptoms but without rectal bleeding who doesn't fit the NG12 guidance on suspected cancer.

NICE NG12 (higher risk symptoms/suspected cancer): Offer a FIT to any patient that presents with suspected cancer symptoms at the same time as referring the patient to secondary care.

Benefits of FIT

- Possible reduction in unnecessary invasive procedures.
- FIT specifically measures human haemoglobin (Hb) rather than any other blood in the diet.
- FIT is a quality assured test as the analysers that carry out the testing are fully automated.
- A numerical figure result is provided which can help to inform future management of patients.

Clinical Pathway

Please see Figure 1 for the national FIT pathway for both primary and secondary care.

Testing Kits

- When can GPs start using the test?

- FITs will be available to request from …. *Please insert date dependent on availability within HB*

- How will we access the FIT test kits?
  - You will make an online request which will be processed by the laboratory. The FIT kits will be sent to the patient from the laboratory in a pack that contains patient information and instructions and the patient will return their sample directly back to the laboratory.

Pathology Process

Different laboratories follow different processes. Please see Figures 2 and 3 for the process from the Bowel Screening Wales/Cwm Taf Morgannwg laboratory pathway – please use the one appropriate to your Health Board.

Safety Netting

Whilst FIT is a very sensitive test, even at a level of < 10 mcg/g there will be false negative results and cases of colorectal cancer (CRC) (sometimes in the presence of iron deficiency anaemia (IDA) or abdominal pain), therefore safety netting is essential and FIT should always be used as part of comprehensive assessment.

A negative FIT result either in the absence of suspected cancer features such as IDA, a palpable abdominal or rectal mass or strong clinical suspicion, can exclude CRC (though not necessarily pre-cancerous polyps to the same extent) in the vast majority of cases and the patient is unlikely to require an onward referral. Studies have predominately been secondary care based, however two recent and relevant studies to our framework include a primary care study from Oxford[1] and one that is a large primary and secondary care based study from London[2] both published very recently. This clearly demonstrates our approach as being evidence based and practically feasible with adequate safety netting within the national FIT pathways proposed.

As previously mentioned it is essential to note that not all patients with CRC will have a positive FIT result, and some patients' symptoms might also be an indication of another type of cancer that will require onward referral and/or investigation. Equally if a patient has a positive FIT but a negative endoscopy, they may require further investigation to rule out another type of cancer.

Knowing the potential for missed cancers reinforces the need for safety netting. The following steps are an essential part of the safety netting process:

- Discussing the reason for the test with the patient.
- Reinforce to patients that the test is not 100% accurate and that they should return if symptoms continue or worsen.
- Checking that the patient's contact details are up to date.
- Check the patient's FBC/ferritin in their blood work-up.
- Perform an abdominal/rectal examination on all consenting patients.
- It would be good practice to use the read code 4791 as this will allow you to easily review which patients you have requested a FIT for.

[1] Nicholson B et al *Aliment Pharmacol Ther.* 2020;52:1031–1041.

[2] Loveday C, et al. *Gut* 2020;0:1–8. doi:10.1136/gutjnl-2020-321650

- The longer the test is complete but not processed, the more likely you are to get a false negative. It is therefore important to ask that the patient complete the test as soon as they are able to and send it to the lab as quickly as possible.

Tracking of tests issued to patients but not completed

Please refer to the process appropriate to your Health Board:

Cwm Taf Morgannwg laboratory: If the patient does not return the test to the laboratory within 1 week, the laboratory will flag this up with the referring clinician who should then contact the patient to discuss if the sample has been sent.

Bowel Screening Wales laboratory: The laboratory will alert local coordinators based in Health Boards if the sample has not been received within 14 days.

Results

- How soon can I expect the results?
  The results should be available within 1 week of the patient sending in the sample.

- Where can the results be accessed?
  The FIT result is reported via Welsh Clinical Portal and GP Link.

- What do I need to do with the results?
  Please refer to the national FIT pathway (Figure 1) to assist with your decision making.

What if a patient has a query about the test?

If a patient has questions about the test they should be signposted back to the doctor that referred them. If the patient requires the information in a different language and/or interpreting services then these should be requested as usual.

What if a patient has recently completed their Bowel Cancer Screening?

Irrespectively of how recently your patient was screened by the national Bowel Cancer Screening programme, their new FIT result should NOT be ignored in considering a patient presenting with new symptoms of concern which should be considered on their own merit.

In symptomatic patients FIT is used as a 'rule out' tests and the test is made as sensitive as possible (>10 µg Hb/g faeces) in order that the chance of missing cancer is minimised. In screening the test is used as a 'rule in' test and the test is much less sensitive (>150 µg Hb/gram faeces currently) in order to not overwhelm colonoscopy capacity. A negative screening FIT is therefore very different from a negative symptomatic FIT. If your patient has symptoms, don't be falsely reassured by a negative screening FIT result as pathology could still be present.

Where can I access further information and support?

Insert contact details of Health Board team

FIGURE 1 – NATIONAL FIT PATHWAY

Insert copy of pathway– not included here to reduce file size

Please note – each appendix (including pathways) can be found as a separate document for ease of use on the NEP's website.

FIGURE 2 – CWM TAF MORGANNWG LABORATORY PATHOLOGY PATHWAY

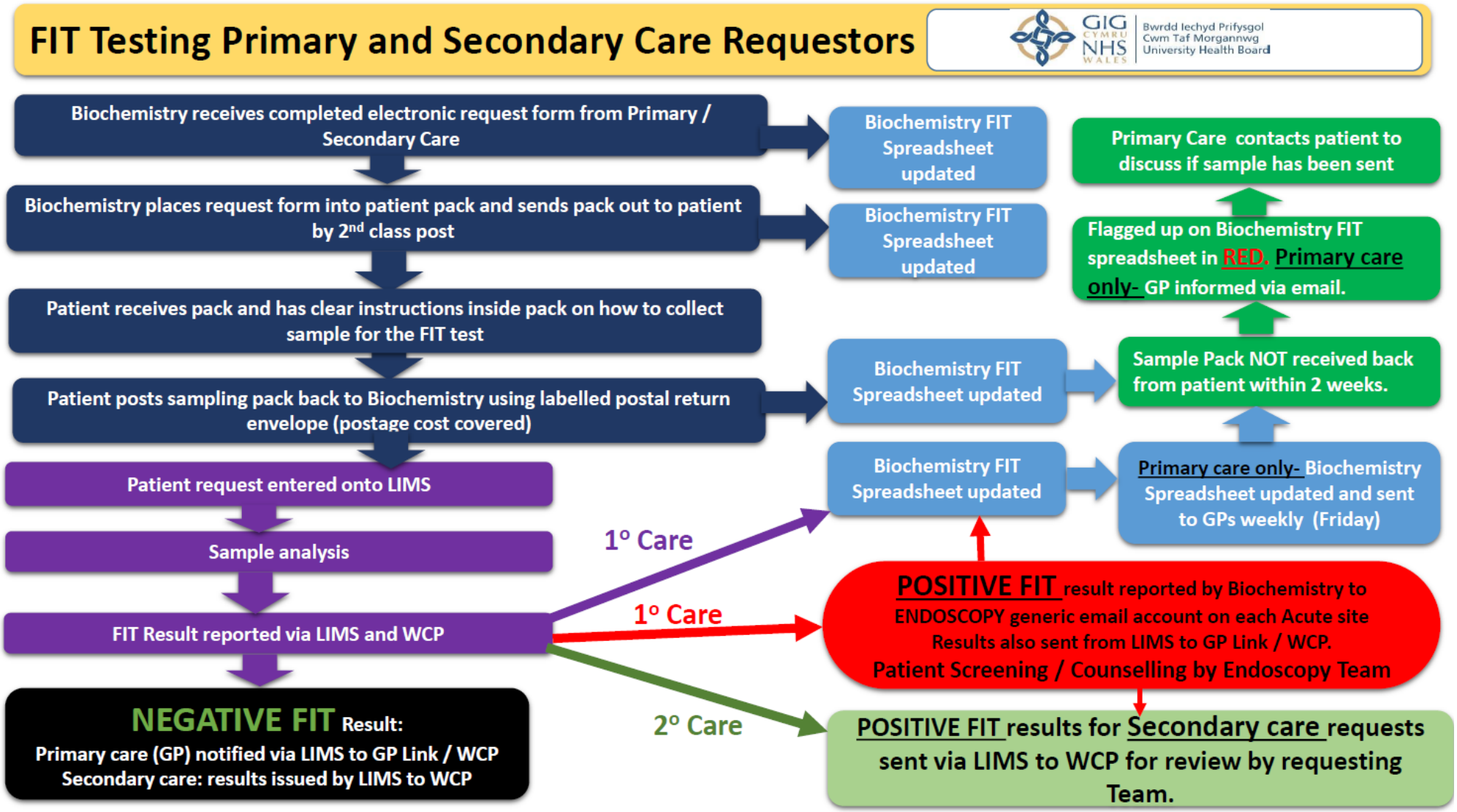
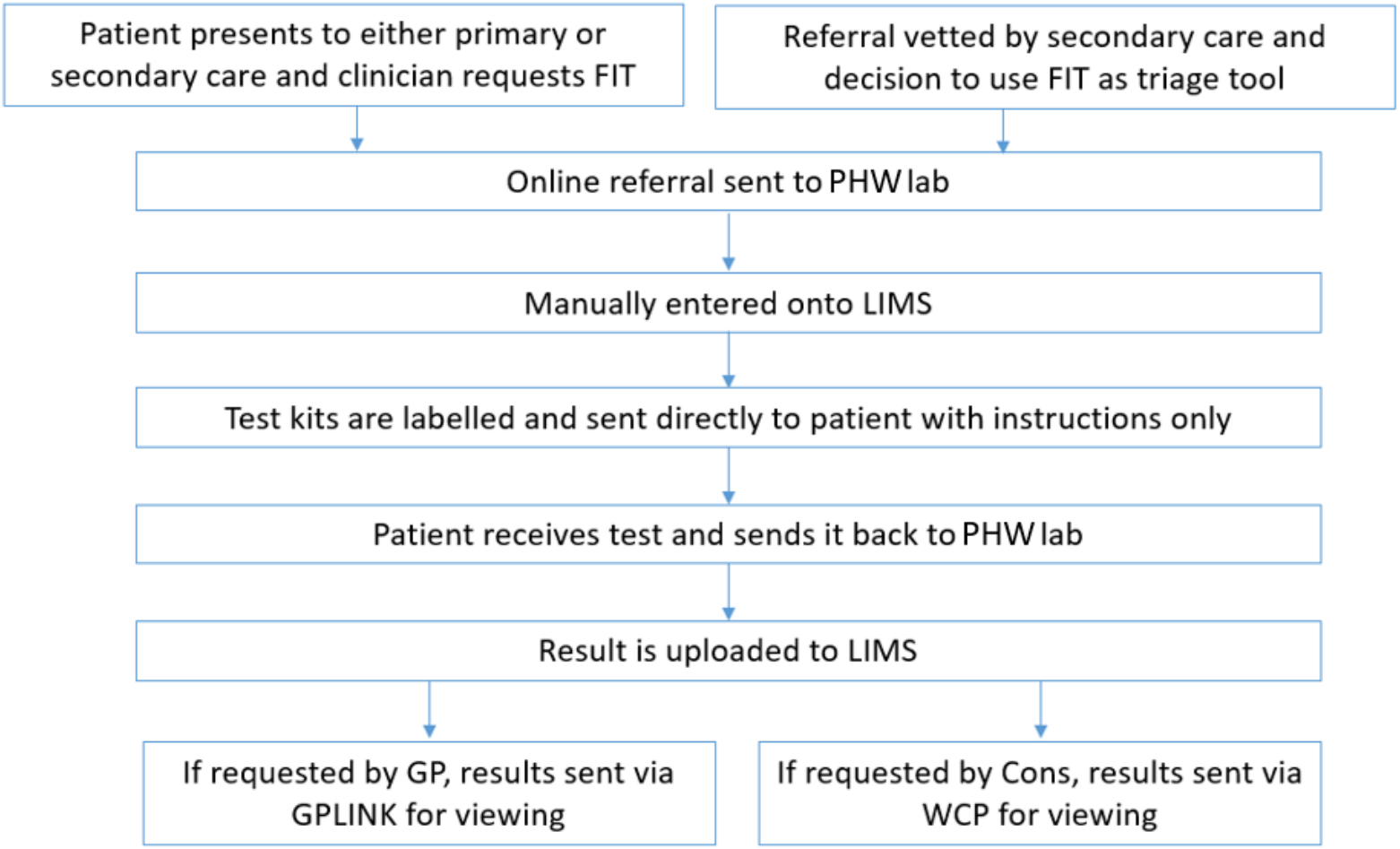


FIGURE 3 – BOWEL SCREENING WALES LABORATORY PATHOLOGY PATHWAY


Patient presents to either primary or secondary care and clinician requests FIT
Referral vetted by secondary care and decision to use FIT as triage tool
Online referral sent to PHW lab
Manually entered onto LIMS
Test kits are labelled and sent directly to patient with instructions only
Patient receives test and sends it back to PHW lab
Result is uploaded to LIMS
If requested by GP, results sent via GPLINK for viewing
If requested by Cons, results sent via WCP for viewing

GIG CYMRU NHS WALES
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National Endoscopy Programme

Faecal Immunochemical Test (FIT): Information for Secondary Care Clinicians

This document contains guidance for the implementation of the Faecal Immunochemical Test (FIT) in secondary care.

As a secondary care clinician you will be vetting referrals from primary care where a patient has undertaken a FIT or you might be using FIT in your Health Board as a COVID mitigation strategy to assist with prioritisation of patients with NG12/suspected cancer symptoms. This guidance is intended to assist you in both situations.

What is FIT?

FIT is a type of faecal immunochemical blood test used to detect traces of blood in stool samples. The test uses antibodies that specifically recognise human haemoglobin and therefore it is a more sensitive and specific test than the guaiac based FOB test. It also measures the faecal Hb concentration (f-Hb) as microgram of Hb per gram (μg/g) of faeces.

NICE Guidance DG30 (July 2017) states: "Faecal Immunochemical Tests (FIT) are recommended for adoption in primary care to guide referral for suspected colorectal cancer in people without rectal bleeding who have unexplained symptoms but do not meet the criteria for a suspected cancer pathway referral."

FIT is currently being used with patients that present with NG12 (suspected cancer) symptoms in many Health Boards as part of their COVID mitigation strategy. This guidance therefore recommends that if used for prioritisation in this group within secondary care for patients that present with NG12 (suspected cancer) symptoms, a FIT is requested at the same time as referring the patient to secondary care.

Who will be offered a FIT test in primary care?

NICE DG30 (lower risk symptoms): A FIT will be offered prior to considering referral for any patient with abdominal symptoms but without rectal bleeding who doesn't fit the NG12 guidance on suspected cancer.

NICE NG12 (suspected cancer symptoms): A FIT may be offered to any patient that presents with suspected cancer symptoms at the same time as referring the patient to secondary care.

Using FIT in secondary care

If a FIT has not been requested in primary care, it can be requested from secondary care as a COVID mitigation strategy to assist with prioritisation of patients referred in via the NG12/suspected cancer symptom route. This use of FIT should be recorded and patient outcomes captured in order to facilitate future audit and evaluation.

Benefits of FIT

- Possible reduction in unnecessary invasive procedures.
- FIT specifically measures human haemoglobin (Hb) rather than any other blood in the diet.
- FIT is a quality assured test as the analysers that carry out the testing are fully automated.

- A numerical figure result is provided which can help to inform future management of patients.

Clinical Pathway

Please see Figure 1 for the national FIT pathway for both primary and secondary care.

Ordering a testing kit

- When can we start using the test?
  - FITs will be available to request from …. *Please insert date dependent on availability within HB*
- How do we order a FIT?
  - You will make an online request which will be processed by the laboratory. The FIT kits will be sent to the patient from the laboratory in a pack that contains patient information and instructions and the patient will return their sample directly back to the laboratory.

Pathology Process

Different laboratories follow different processes. Please see Figures 2 and 3 for the process from the Bowel Screening Wales/Cwm Taf Morgannwg laboratory pathway. *Please refer to the process appropriate to your Health Board.*

Safety Netting

Whilst FIT is a very sensitive test, even at a level of < 10 mcg/g there will be false negative results and cases of colorectal cancer (CRC) (sometimes in the presence of iron deficiency anaemia (IDA) or abdominal pain), therefore safety netting is essential and FIT should always be used as part of comprehensive assessment.

A negative FIT result either in the absence of suspected cancer features such as IDA, a palpable abdominal or rectal mass or strong clinical suspicion, can exclude CRC (though not necessarily pre-cancerous polyps to the same extent) in the vast majority of cases and the patient is unlikely to require an onward referral. Studies have predominately been secondary care based, however two recent and relevant studies to our framework include a primary care study from Oxford[3] and one that is a large primary and secondary care based study from London[4] both published very recently. This clearly demonstrates our approach as being evidence based and practically feasible with adequate safety netting within the national FIT pathways proposed.

As previously mentioned it is essential to note that not all patients with CRC will have a positive FIT result, and some patients' symptoms might also be an indication of another type of cancer that will require onward referral and/or investigation. Equally if a patient has a positive FIT but a negative endoscopy, they may require further investigation to rule out another type of cancer.

Tracking of tests issued to patients but not completed

Please refer to the process appropriate to your Health Board:

- *Cwm Taf Morgannwg laboratory*: If the patient does not return the test to the laboratory within 1 week, the laboratory will flag this up with the referring clinician who should then contact the patient to discuss if the sample has been sent.

[3] Nicholson B et al *Aliment Pharmacol Ther.* 2020;52:1031–1041.

[4] Loveday C, et al. *Gut* 2020;0:1–8. doi:10.1136/gutjnl-2020-321650

- *Bowel Screening Wales laboratory*: The laboratory will alert local coordinators based in Health Boards if the sample has not been received within 14 days.

Results

- How soon can results be expected?
  The results should be available within 1 week of the patient sending in the sample.

- Where can the results be accessed?
  The results can be accessed on Welsh Clinical Portal.

- What do I need to do with the results?
  Please refer to the national FIT clinical pathway (Figure 1) to assist with your decision making

What if a patient has recently completed their Bowel Cancer Screening?

Irrespectively of how recently your patient was screened by the national Bowel Cancer Screening programme, their new FIT result should NOT be ignored in considering a patient presenting with new symptoms of concern which should be considered on their own merit.

In symptomatic patients FIT is used as a 'rule out' tests and the test is made as sensitive as possible (>10 µg Hb/gram faeces) in order that the chance of missing cancer is minimised. In screening the test is used as a 'rule in' test and the test is much less sensitive (>150 µg Hb/gram faeces currently) in order to not overwhelm colonoscopy capacity. A negative screening FIT is therefore very different from a negative symptomatic FIT. If your patient has symptoms, don't be falsely reassured by a negative screening FIT result as pathology could still be present.

Where can I access further information and support?

Insert contact details of Health Board team

FIGURE 1 – NATIONAL FIT PATHWAY

Insert copy of pathway or send as slides – not included here to reduce file size

Please note – each appendix (including pathways) can be found as a separate document for ease of use on the NEP's website.

FIGURE 2 – CWM TAF MORGANNWG LABORATORY PATHOLOGY PATHWAY

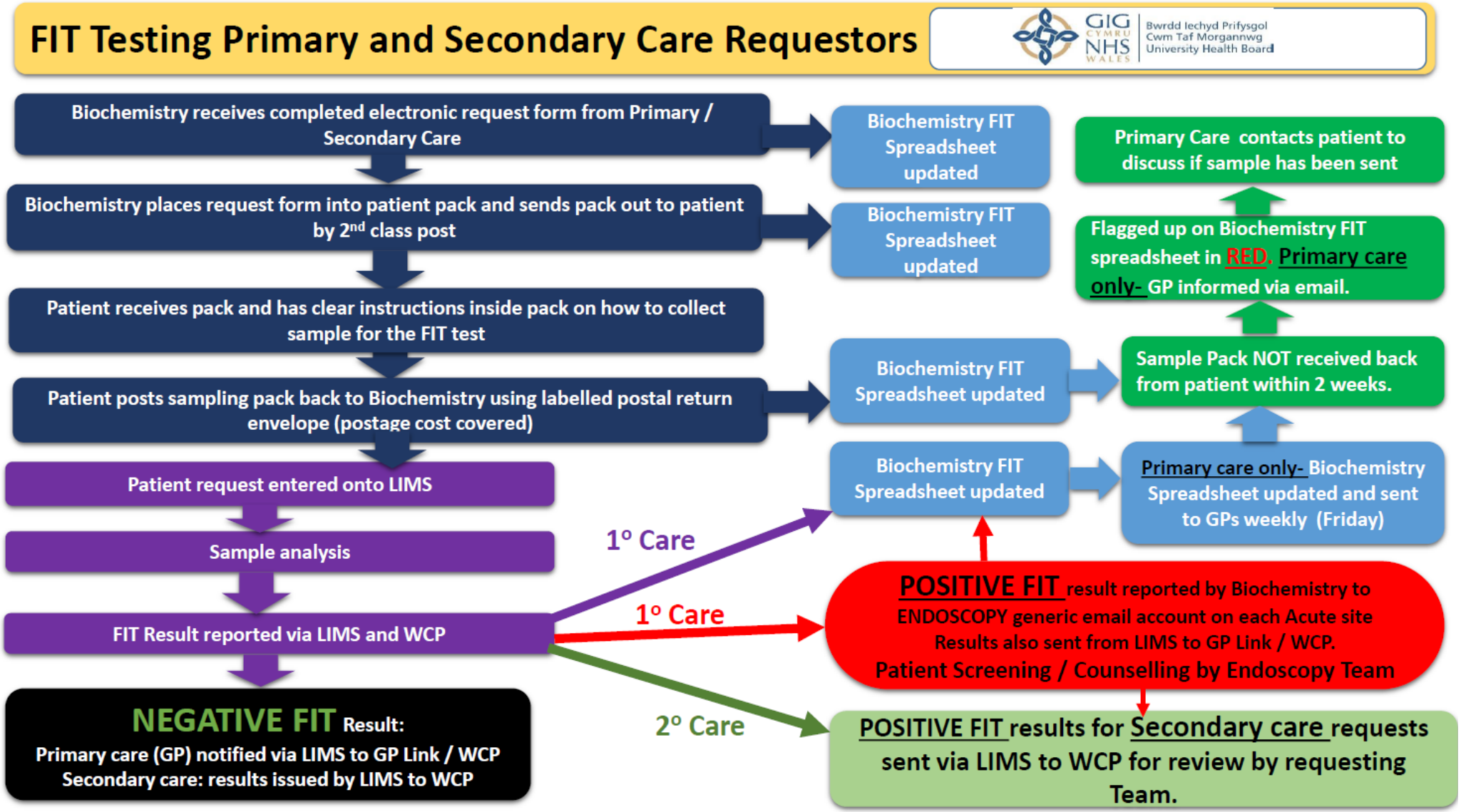
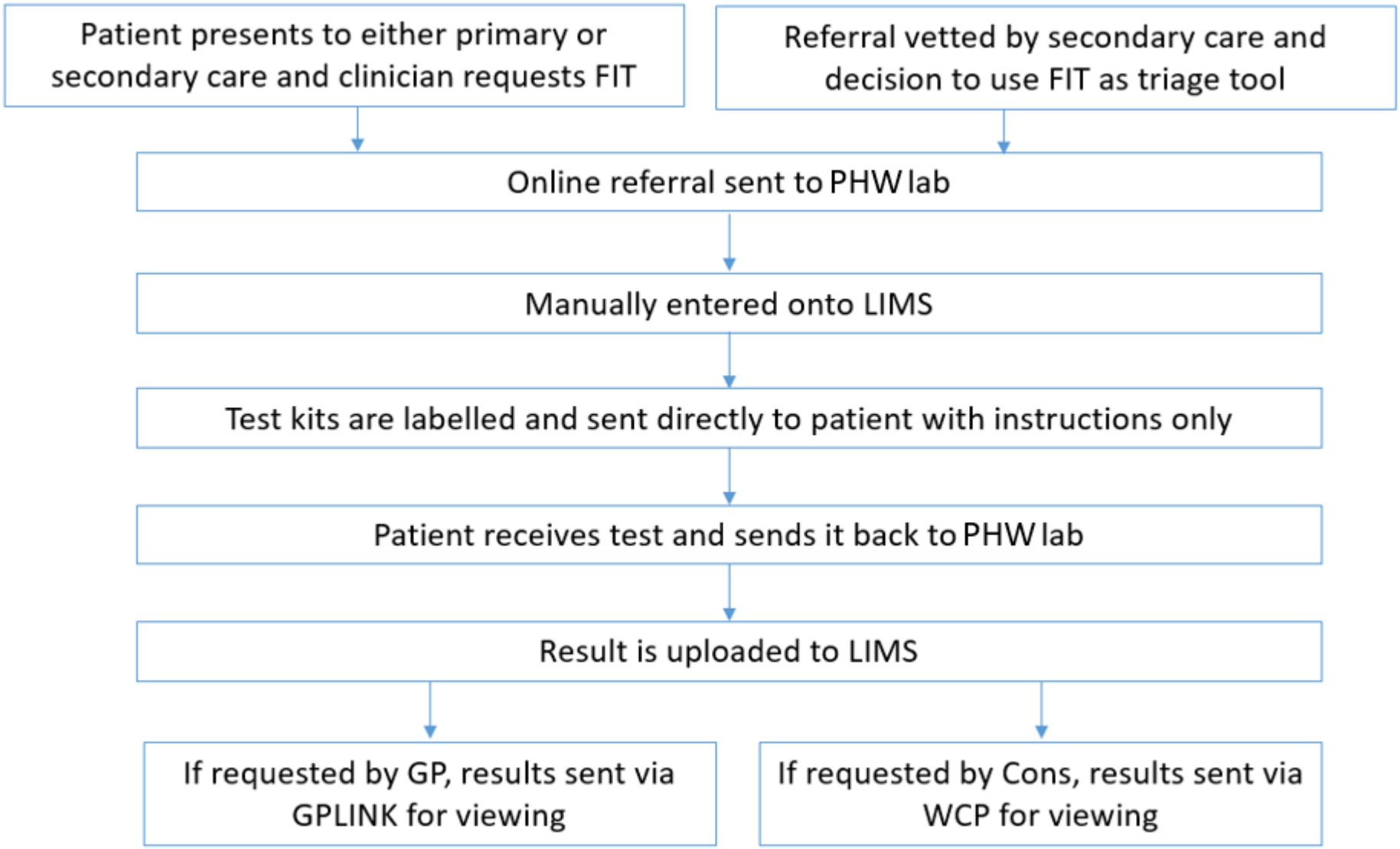


FIGURE 3 – BOWEL SCREENING WALES LABORATORY PATHOLOGY PATHWAY



Appendix 3: Patient Information

Faecal Immunochemical Test (FIT): Information for Patients

You are reading this because your doctor has asked you to take a Faecal Immunochemical Test (FIT).

Why is a FIT done?

A FIT is a test that looks for the presence of blood in your poo. Sometimes, bleeding within your stomach or bowels is so small that it isn't visible in your poo. This test can detect this smaller amount of blood.

Your doctor has ordered this test for you as part of the investigation of your current symptoms. A FIT will help them decide the next steps.

The Bowel Screening programme also uses FIT, but this is a different test than the one that your doctor is asking you to complete. Even if you have had a screening test very recently, or you have had a negative screening result at any time, it is important that you still do this separate FIT.

What will happen now?

You will be sent a pack in the post directly to your home. Once you have collected your poo sample, you will send it directly to the laboratory.

Once you receive your pack please check that it contains:

- FIT test kit - It is really important that you write the **date that you collect your poo sample** on the label on the pot that you put it in. If the date is not included the laboratory might not be able to use your sample.
- Request form (this should have been completed by the doctor that asked you to do this test. If this has not been done, please contact: *insert details of either GP practice or secondary care service*)
- Instruction sheet
- Addressed and pre-paid return envelope

If any of the above is missing, please contact: *insert details of lab or GP surgery*

Once you receive your pack, please read the instruction sheet, collect your poo sample and post it back as soon as possible. **Do not do the test when you are menstruating** (having your period). Wait until it has finished and then do the test.

How soon can I expect the results?

Your doctor should receive the results of the test within 1 week from the date that your sample is received by the laboratory. If you have not heard from your doctor within 1 week please contact them.

What do the results mean?

- If the result is **positive**

There are lots of possible causes for a positive test result and further investigations may need to be done to find out what is causing this bleeding. A positive result doesn't necessarily mean that you have cancer but if it is cancer, finding it at an earlier stage means that it is easier to treat successfully. Your doctor will refer you for further investigations.

- If the result is **negative**

A negative test result means that it is unlikely that you have bowel cancer, but your doctor will need to consider your result as well as the symptoms that you are experiencing to decide on the next steps. If you are not referred for further investigations but your symptoms persist it is really important that you go back to your doctor who might refer you for further investigations or for specialist advice.

I have a question, who do I ask?

Insert details of either Health Board team/GP practice.

Appendix 4: Evaluation Metrics

Data Metrics for evaluation of FIT in the symptomatic service

DG30

Health Boards are to offer a FIT test for patients with low risk symptoms according to NICE guidelines DG30 and Health Technology Wales (HTW) Guidance 007 February 2019. As this is a relatively new intervention for some Health Boards evaluation is important to inform development of future guidelines. The National Endoscopy Programme (NEP) recommends development of mechanisms to enable collection of the following data items in primary care to facilitate future national audit.

DG30 Pathway	
Data Item	**Data Source**
Number of patients presenting in primary care with GI symptoms broken down by symptom type	Request form from GP to the laboratory (where symptoms are broken down)
Number and rate of patients presenting with suspected cancer symptoms	Request form from GP to the laboratory (where symptoms are broken down)
Number of patients referred to secondary care as suspected cancer	Referral data in secondary care
Number of patients referred direct/straight to test and the type of test	Referral data in secondary care
Number of patients referred to outpatient clinic	Secondary care triage data
Number of FIT kits requested by each Primary Care practice	Laboratory data
Number and rate of FIT returned by patient (per practice)	Laboratory data
Number of FIT not returned by patient (per practice)	Laboratory data
Interval time from time of request to time when kit issued to patient	Laboratory data
Interval time from time of kit issued to patient to time returned to lab	Laboratory data
Interval time from return of kit to lab to time when result released	Laboratory data
Interval time from result released to date of action/prioritisation in primary or secondary care	Laboratory data and primary/secondary care data
Overall interval time from date of test request to date of action/prioritisation in primary or secondary care	Laboratory data and primary/secondary care data

NG12

NICE guideline NG12 relates to patients with suspected cancer symptoms. Although there is a growing body of evidence to suggest that FIT may be useful in this cohort, further data is needed to recommend routine use of FIT alone for patients with symptoms that are highly suggestive of bowel cancer.

The NEP recommend that patients with suspected cancer symptoms should be referred to secondary care for diagnostic tests in line with NICE guidance and usual referral processes. If Health Boards choose to use FIT in patients with high-risk symptoms in addition to referral, data collection must evaluate outcomes and contribute to the evidence base in order to inform future service model change. The following data items should be collected from secondary care.

NG12 Pathway	
Data Item	**Data Source**

Number of patients referred with suspected cancer symptoms	Referral data in secondary care
Number and rate of patients with suspected cancer symptoms issued FIT in primary care	GP practice data
Number and rate of patients with suspected cancer symptoms issued FIT in secondary care	Secondary care data
Outcomes for patients with positive FIT	
: Procedure outcomes	Secondary care data
: Final outcomes (Cancer/SBD/Non SBD/Normal)	Secondary care data
: Review in primary care	Primary care data
: Review in secondary care	Secondary care data
Outcomes for patients with negative FIT	
: Procedure outcomes	Secondary care data
: Final outcomes (Cancer/SBD/Non SBD/Normal)	Secondary care data
: Review in primary care	Primary care data
: Review in secondary care	Secondary care data
FIT threshold used in Health Board	Health Board information
Interval time from time of request to time when kit issued to patient	Laboratory data
Interval time from time of kit issued to patient to time returned to lab	Laboratory data
Interval time from return of kit to lab to time when result released	Laboratory data
Interval time from result released to date of action/prioritisation in primary or secondary care	Laboratory data and primary/secondary care data
Overall interval time from date of test request to date of action/prioritisation in primary or secondary care	Laboratory data and primary/secondary care data

Routine collection of these data items will enable national audit to establish negative and positive predictive values.

Appendix 5 – NEP FIT Subgroup Membership

NEP FIT Subgroup Membership:

Health Board/Organisation	Name	Role
Aneurin Bevan HB	Catherine Bailey	Consultant Clinical Scientist
	Gareth Blandford	Directorate Manager
	Mary Craig	GP
Betsi Cadwaladr HB	Monica Harris	Endoscopy Network Manager
	Michael Thornton	Consultant Colorectal Surgeon
Cardiff and Vale HB	Rwth Ellis Owen	Consultant Radiologist
	John Green	Consultant Gastroenterologist
	Rachel Lee	Macmillan GP Cancer Lead
	Raji Ramaraj	Consultant Gastroenterologist
	Steven Short	GP
	Jared Torkington	Consultant Colorectal Surgeon
	Jeff Turner	Consultant Gastroenterologist
Cwm Taf HB	Jane Armstrong	GP
	John Geen	Consultant Clinical Biochemist
	Ruth Morrissey	Deputy Clinical Service Group Manager
	Faiz Ali	Consultant Gastroenterologist

Hywel Dda HB	Carly Buckingham	Service Delivery Manager
	Victoria Coppack	Service Manager
Powys HB	Nicola Kelly	Senior Manager – Planned Care
Swansea Bay HB	Dean Harris	Consultant Colorectal Surgeon
	Fiona Hughes	Service Group Manager
	Imran Rao	Senior Service Manager
	Rhodri Stacey	Consultant Gastroenterologist
Public Health Wales	Steve Court	Head of Bowel Screening Wales
	Gareth Powell	Laboratory Services Manager
	Ardiana Gjini	Consultant in Public Health Medicine
Cancer Research UK	Shona Auty	Senior Early Diagnosis Manager
	Deborah Haworth	Regional Manager
Bowel Cancer UK	Lowri Griffiths	Head of Wales
	Jessica Lewington	Policy Manager
	Lisa Wilde	Director of Research and External Affairs
Bowel Cancer Initiative	Bethan Jones	Project Manager
National Endoscopy Programme	Hattie Cox	Senior Project Manager
	Sunil Dolwani	Clinical Lead
	Hayley Heard	Programme Director
	Dana Knoyle	Clinical Pathways Manager and Lead Nurse

Contributors to framework:

Public Health Wales	Benji Williams	Service Improvement Lead (Bowel Screening Wales)
Betsi Cadwaladr HB	Jenny Liddell	GP

References

1. Bailey, J., Khawaja, A., Andrews, H., Weller, J., Chapman, C., Morling, J., …Banerjea, A. (2020). GP access to FIT increases the proportion of colorectal cancers detected on urgent pathways in symptomatic patients in Nottingham. Surgeon, https://doi.org/10.1016/j.surge.2020.03.002
2. British Society of Gastroenterology. 2020. *BSG multi-society guidance on further recovery of endoscopy services during the post-pandemic phase of COVID-19.* https://www.bsg.org.uk/covid-19-advice/bsg-multi-society-guidance-on-further-recovery-of-endoscopy-services-during-the-post-pandemic-phase-of-covid-19/
3. British Society of Gastroenterology. 2020. *Service Recovery Documents: The What, When and How.* https://www.bsg.org.uk/covid-19-advice/service-recovery-documents-the-what-when-and-how/
4. Digby J, Strachan JA, McCann R, Steele RJ, Fraser CG, Mowat C. 2020. Measurement of faecal haemoglobin with a faecal immunochemical test can assist in defining which patients attending primary care with rectal bleeding require urgent referral. *Ann Clin Biochem.* 2020 Jul;57(4):325-327
5. D'Souza N, Georgiou Delisle T, Chen M, et al. 2020. 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* Epub doi:10.1136/ gutjnl-2020-321956
6. Goddard, A., James, M., McIntyre, A. & Scott, B.. 2011. *Guidelines for the management of iron deficiency anaemia.*https://www.bsg.org.uk/wp-content/uploads/2019/12/Guidelines-for-the-management-of-iron.pdf
7. Health Technology Wales. 2019. *Faecal immunochemical testing (FIT)-based prediction tools as triage for referral for colorectal cancer investigations.* [Health Technology Wales (HTW) Guidance 007]. http://www.healthtechnology.wales/wp-content/uploads/2019/02/GUI007-FIT-based-prediction-tools.pdf
8. Hicks G, D'Souza N, Georgiou Delisle T, Chen M, Benton SC, Abulafi M. 2021. Using the faecal immunochemical test in patients with rectal bleeding: Evidence from the NICE FIT Study. NICE FIT Steering Group. *Colorectal Disease*. 2021 Feb 19. doi: 10.1111/codi.15593
9. Howren A, Sayre EC, Loree JM, Gill S, Brown CJ, Raval MJ, Farooq A, De Vera MA. 2021. Trends in the incidence of young-onset colorectal cancer with a focus on years approaching screening age: A population-based longitudinal study. *J Natl Cancer Inst*. 2021 Jan 25:djaa220. doi: 10.1093/jnci/djaa220
10. Loveday C, Sud A, Jones ME, et al. 2020. Prioritisation by FIT to mitigate the impact of delays in the 2-week wait colorectal cancer referral pathway during the COVID-19 pandemic: a UK modelling study. *Gut*. Epub doi:10.1136/ gutjnl-2020-321650.
11. McSorley, S. T., Digby, J., Clyde, D., Cruickshank, N., Burton, P., Barker, L., Strachan, J. A., Fraser, C. G., Smith, K., Mowat, C., Winter, J., & Steele, R. J. C. 2020. Yield of colorectal cancer at colonoscopy according to faecal haemoglobin concentration in symptomatic patients referred from primary care. *Colorectal Disease.* https://doi.org/10.1111/codi.15405
12. Mowat, C. et al. 'Faecal haemoglobin concentration thresholds for reassurance and urgent investigation for colorectal cancer based on a faecal immunochemical test (FIT) in symptomatic patients in primary care', *Annals of Clinical Biochemistry* (2020). DOI: 10.1177/0004563220985547.
13. National Institute for Health and Care Excellence. 2017. *Quantitative faecal immunochemical tests to guide referral for colorectal cancer in primary care.* [NICE Diagnostics Guidance DG30]. https://www.nice.org.uk/guidance/dg30/resources/quantitative-faecal-immunochemical-tests-to-guide-referral-for-colorectal-cancer-in-primary-care-pdf-1053744003781
14. National Institute for Health and Care Excellence. 2015. *Suspected cancer: recognition and referral.* [NICE guideline NG12]. https://www.nice.org.uk/guidance/ng12/resources/suspected-cancer-recognition-and-referral-pdf-1837268071621
15. NHS England. *Delivering Cancer Waiting Times: A Good Practice Guide.* Accessible at: https://www.england.nhs.uk/wp-content/uploads/2015/03/delivering-cancer-wait-times.pdf
16. Pavlidis P, Chedgy FJ, Tibble JA. 2013. Diagnostic accuracy and clinical application of faecal calprotectin in adult patients presenting with gastrointestinal symptoms in primary care. *Scand J Gastroenterol*. 2013 Sep;48(9):1048-54

17. Smith, C., Drew, S., Ziebland, S., & Nicholson, B., 2020. Understanding the role of GPs' gut feelings in diagnosing cancer in primary care: a systematic review and meta-analysis of existing evidence. *Br J Gen Pract*. 2020 Sep; 70(698): e612–e621. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7449376/
18. Turvill J, Mellen S, Jeffery L, Bevan S, Keding A, Turnock D. 2018. Diagnostic accuracy of one or two faecal haemoglobin and calprotectin measurements in patients with suspected colorectal cancer. *Scand J Gastroenterol*. 2018 Dec;53(12):1526-1534