Centre for Sustainable Delivery

NHS SCOTLAND

Quantitative Faecal Immunohistochemical Testing (qFIT)

for patients with new lower gastrointestinal symptoms

2024

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Purpose

As an adjunct to clinical acumen, the 2022 Quantitative Faecal Immunochemical Test (qFIT) for Patients with Colorectal Symptoms: primary[1] and secondary[2] care guidance was published by Scottish Government to improve the prioritisation of patients with new lower gastrointestinal symptoms to lower endoscopy. Adherence with the existing guidance has been variable but the length of waits for investigation and the associated negative impact on patient outcome[3] prompted the timing of this clinical consensus review.

On 1 March 2024, 153 delegates from across Scotland convened for the 4th National qFIT meeting to review the current evidence and available Scottish data.

The purpose of this document is to update the previous guidance into a single document, with best practice recommendations based on the evidence available, and expert consensus from primary and secondary care.

Local implementation and pathways

The pathways for qFIT testing need to be agreed at a local Health Board level including for timing of referral (i.e. with result, pending result or secondary care arranging qFIT), initial and repeat qFIT testing or managing symptomatic patients where no qFIT is received. Local procedures and implementation of the recommendations are not within the scope of this document.

Performance data

In 2023 the number of urgent suspicion of cancer (USC) referrals in Scotland had increased by 22.3% compared to 2019. The number of qFITs performed increased by 19.4% to over 219,000 tests. The number of colorectal cancer patients with an active or surveillance treatment plan increased by 6.5%.

For patients that are referred, colonoscopy or flexible sigmoidoscopy is often the first line of investigation. Despite an appropriate application of the Covid recovery guidance, in December 2023 only 44.1% of colonoscopy and 25.2% of flexible sigmoidoscopy were performed within 6 weeks of referral.[4] 9.6% of patients waiting for a diagnostic colonoscopy and 19.2% of patients waiting for a diagnostic flexible sigmoidoscopy waited over 52 weeks, 2,325 patients in total.[4]

In addition, in March 2024, there were 8,377 patients more than 52 weeks overdue for a surveillance lower endoscopic procedure. Many of these individuals may be at higher risk for colorectal cancer than the new referrals [unpublished data from national endoscopy surveillance database April 2024].

Predominantly due to the endoscopic delays, colorectal cancer performance figures were lower than 2019 with 35.4% of care delivery not meeting the 62-day colorectal cancer standard.[5]

Background

By 2021, qFIT had been implemented in all Scottish Health Boards. Significant progress has been made in appropriately prioritising endoscopy access. Applying the current Scottish qFIT[1,2] and Scottish Referral Guidelines for Suspected Cancer[6] up to 78% of colonoscopies could be avoided. However, even in those Boards where adherence to guidance is high, meeting the current demand is challenging.

The current referral pathway, indications for qFIT, and thresholds for investigation for patients with new colorectal symptoms have been reviewed. The key focus areas were:

1. Indications for qFIT testing
2. qFIT threshold for lower gastrointestinal USC referral
3. qFIT threshold for lower gastrointestinal investigation in the presence of Iron Deficiency Anaemia (IDA)
4. qFIT threshold for non-USC lower gastrointestinal investigation

This clinical consensus document replaces Scotland's qFIT guidance for primary and secondary care.[1,2]

This consensus document applies to patients presenting to primary or secondary care with lower gastrointestinal symptoms in Scotland.

Key changes

The indications for qFIT are more clearly defined. The indications include new:

- Repeated anorectal bleeding without an obvious anal cause.
- Blood mixed through the stool.
- ≥ 4 weeks change in bowel habit, particularly looser or more frequent stool.
- Iron deficiency anaemia (haemoglobin below reference range and ferritin < 30mg/l or confirmed on iron studies).
- Persistent Abdominal Pain (>4 weeks) and Weight loss (>5%).

qFIT is not indicated for the investigation of:

- A rectal or abdominal mass or unexplained anal ulceration. **These should be referred as USC.**
- Weight loss (>5%) without one of the qFIT indications above.
- Abdominal pain without other concerning symptoms.
- Thrombocytosis in the absence of persistent (>4 weeks) lower GI symptoms.
- Haemorrhoids, anal fissures or warts in absence of other concerning symptoms .
- Family history of colorectal cancer, polyps or a genetic condition that predisposes to colorectal cancer.
- Acute symptoms such as a clinical episode of gastroenteritis or diverticulitis.
- Long-standing symptoms such as constipation, bloating or abdominal pain.
- Or as a screening test out-with the bowel screening programme.

Testing and referral guidance

The threshold for USC priority has increased from 10 to 20μgHb/g faeces (see pages 7 and 8 for the impact of these changes).

All patients with unexplained new iron deficiency anaemia should undergo a second qFIT within 6 weeks, if the first is <20μgHb/g faeces. If the second qFIT is ≥20μgHb/g faeces, the patient should be referred as USC for lower gastrointestinal investigations. If the second qFIT is <20μgHb/g faeces the patient can be referred as non-USC (see figure 2).

For all other patients, where the first qFIT was <20μgHb/g faeces, a second qFIT should be performed if the patient has persistent lower gastrointestinal symptoms causing clinical concern or support is required for symptom management. If the second qFIT is ≥20μgHb/g faeces the patient should be referred as USC for lower gastrointestinal investigations.

If a patient has two qFIT's <20μgHb/g faeces, secondary care referral can still be made on a non-USC pathway if there are ongoing concerning symptoms.

Secondary care consensus:

Patients with new unexplained iron deficiency anaemia should be prioritised for lower gastrointestinal investigation using the qFIT results. Patients with one or more qFIT≥20mgHb/g faeces should be triaged as USC. Patients with one or more qFITs 10-19mgHb/g faeces can be triaged as Urgent.

Patients with both qFIT results <10mgHb/g faeces can be considered for routine lower gastrointestinal investigation if there is ongoing clinical concern.

Unchanged:

A rectal and abdominal examination should be performed prior to requesting a qFIT. Haemoglobin, ferritin or iron studies, and renal function are also advised.

The qFIT result should guide the priority of secondary care referral and investigation.

Patients who are unable to complete a qFIT where indicated should still be referred as USC. The reason for the qFIT not being completed should be provided in the referral.

Figure 1: qFIT for patients with new lower gastrointestinal symptoms. Primary Care Guidance

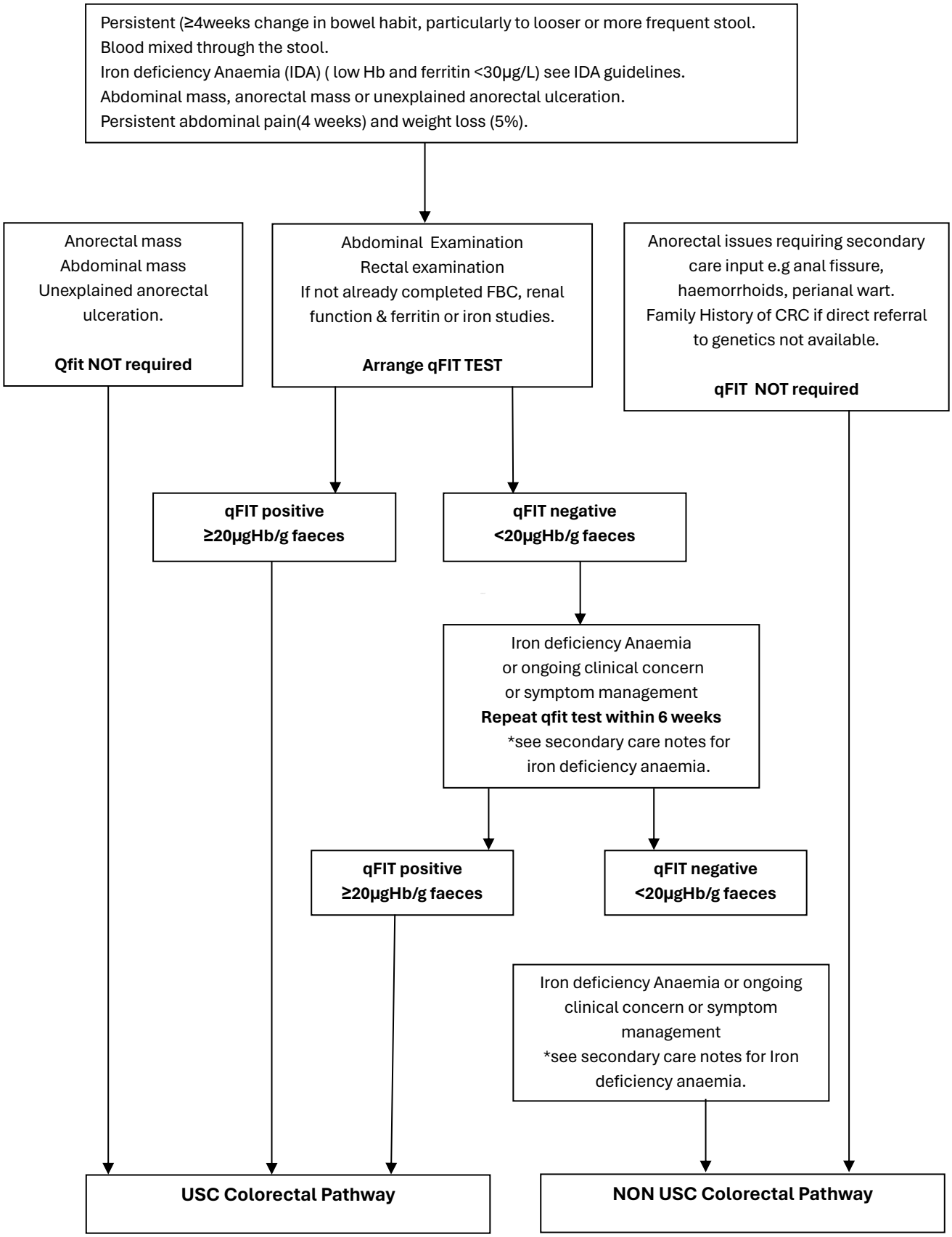
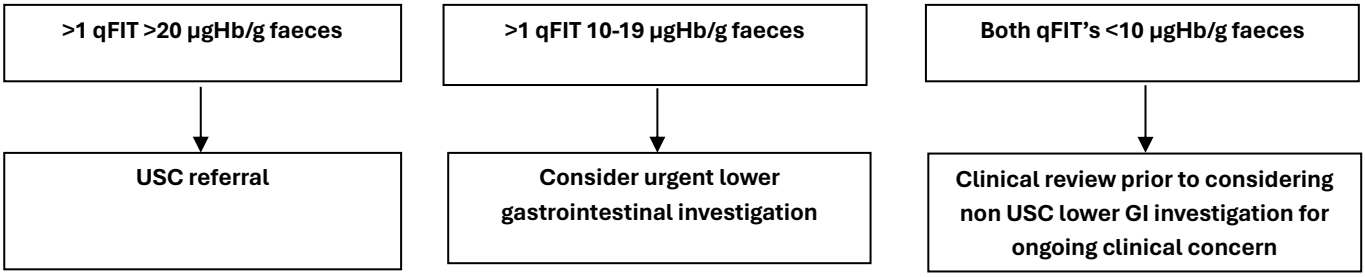
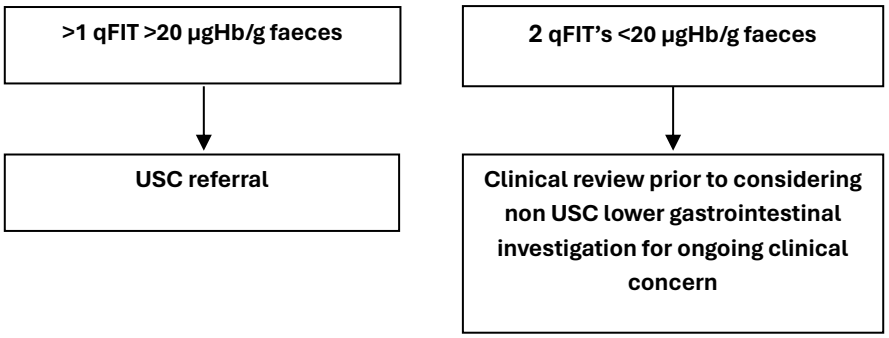


Figure 2: Lower gastrointestinal investigation priority based on qFIT for patients with new unexplained iron deficiency anaemia (Secondary Care Investigatory Guidance)



Lower gastrointestinal investigation priority based on qfit result for new persistent lower gastrointestinal red flag symptoms (except iron deficiency anaemia)



For Patient referred to secondary care without new USC colorectal symptoms or new unexplained iron deficiency anaemia and a qfit ≥20µgHb/g faeces, a secondary care review may be requested. Where secondary care confirms no new /persistent colorectal symptoms or a new unexplained Iron deficiency the following is recommended:

- qFIT <80 µgHb/g faeces – return to referrer without investigation.
- qFIT >80 µg/gHb/g faeces – luminal investigation may be considered where the Board has capacity and the patient has not had luminal investigation in the preceding 2 years.

Supporting Information

Local implementations and pathways:

The implementation and pathways for qFIT testing needs to be agreed at a local Health Board level including for timing of referral (i.e. with result, pending result or secondary care arranging qFIT), initial and repeat qFIT testing or managing symptomatic patients where no qFIT is received. Local procedures and implementation of the recommendations are not within the scope of this document.

Suggested areas to discuss are as follows:

- A qFIT may happen for another reason out with the remit of this guidance. In these cases, local arrangements should be made between primary and secondary care. Positive qFITs in these cases must be referred in as outlined above.
- Circumstances where a referral may be regraded.
- Timing of second qFIT test.
- Responsibility for review and secondary testing if initial qFIT is under 20μgHb/g.
- Management of non-returned/inadequate qFIT tests in qFIT pending referrals.
- Strategy to adopt primary or secondary care testing as applicable.
- There should be recognition of local endoscopy provision and capacity.

In patients with persistent abdominal pain (4 weeks) and weight loss (5%) cross sectional imaging should be considered as a first line investigation because of the likelihood of other abdominal and pelvic cancers. qFIT will guide the requirement for further luminal investigation, although, it is accepted there is limited data available to define this further.

Timing of the second qFIT:

The current guidance recommends a repeat qFIT within 6 weeks of the first. There are no randomised control trials advising the timing of the second qFIT. NHS Lothian data reports a second FIT completed in 77% of patients where it was requested at a median of 13 days (17-45) following the first qFIT.[7] NHS Greater Glasgow & Clyde data reports that a second qFIT still adds clinical value if performed within 12 months of the first, although the local advice recommends 6 weeks.[8]

The clinical consensus was a repeat in 6-8 weeks.

qFIT threshold for USC Referral; impact of increasing USC qFIT threshold to 20μgHb/g faeces:

If cancer diagnosis delays are to be reduced, a further optimisation of the triage process requires consideration. It is understood that improving the pathway for many patients may delay the diagnosis of some within the current resource constraints.

Symptoms alone are unreliable predictors of those who may have a diagnosis of colorectal cancer.[9] qFIT is therefore imperative in the triage process. In 2020, Scotland recommended qFIT as a support to clinical expertise to prioritise Lower GI. Subsequent publications report that qFIT at a threshold of ≥10μgHb/g faeces yields a sensitivity and Positive Predictive Value (PPV) of 84% and 5.5% respectively, for a colorectal cancer diagnosis.[10] The addition of secondary care triage increases the sensitivity and PPV to 94.7% and 9.4% respectively.[11]

Similar data has been published for secondary care administered qFIT. A single qFIT at a threshold of ≥10 μgHb/g faeces yielding a sensitivity and PPV for colorectal cancer of 84% and 10.5%.

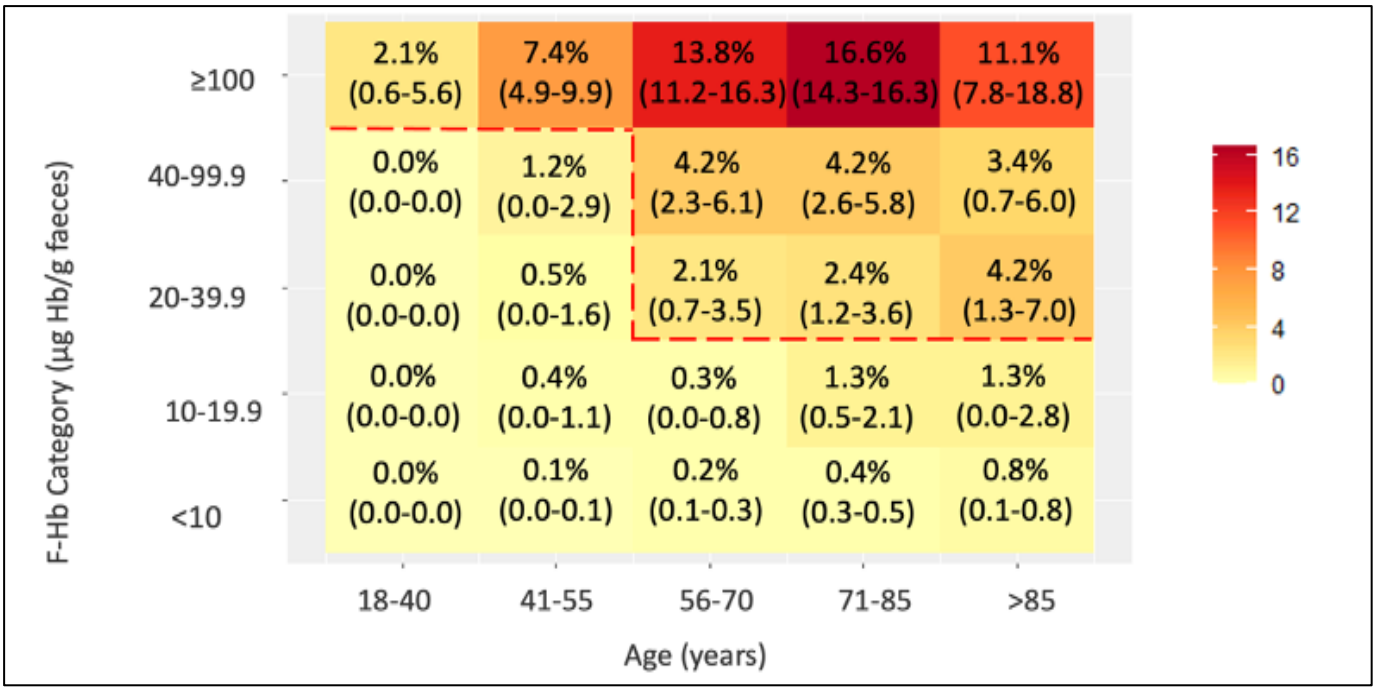
The addition of a second qFIT (highest result used) increases the sensitivity and PPV to be 96.6% and 10.4%.[7]

At a threshold of ≥10mgHb/g faeces and single testing, 11 patients will undergo a colonoscopy to diagnose one colorectal cancer. Increasing the threshold to 20mgHb/g faeces reduces the number needed to scope to diagnose one colorectal cancer to 9. The biggest impact, however, is the reduction in USC colonoscopy demand by 20% with a reduction in waiting times for the majority of higher risk patients. The impact of raising the threshold of a single qFIT is a fall in sensitivity falls from 94.7% to 91.0%. This can be offset by double testing patients who remain symptomatic with a qFIT test below 20mgHb/g faeces.

As Scotland doesn't currently include age in the colorectal cancer algorithm, it is anticipated that the impact of increasing the qFIT threshold may be less than anticipated.

Preliminary data from NHS Tayside presented at the qFIT event reporting the colorectal cancer PPV by qFIT level for 34,353 patients, evidenced that except for those patients over 85 years, the PPV of colorectal cancer was below 3% at a single qFIT. This data has now been published in full [21].

Figure 3: Heat map of 1-year cumulative colorectal cancer risk by FIT category. Tayside data



As further data is published double, qFIT may have an impact on reducing the potential missed colorectal cancers with a FIT threshold of 20μgHb/g faeces. One paper has reported a 2.3% reduction in missed colorectal cancer cases using a double qFIT protocol at a threshold of 20μgHb/g.[7] However, the workforce and financial requirements to achieve this are substantial.

FIT threshold and Iron Deficiency Anaemia:

A number of publications evidence an increase in colorectal cancer in the presence of iron deficiency anaemia (IDA).[12-14] However, in keeping with earlier publications, NHS Fife presentation reported low colorectal cancers numbers at a threshold of 20μgHb/g faeces. The PPV of colorectal cancer with a FIT10-19μgHb/g faeces and IDA was 1.1%.[20]

Table 1: Colorectal cancers and qFIT thresholds of anaemia. Fife data (3 year follow up).

All IDA (asymptomatic and symptomatic)			
qFIT μg/gHb	Total number of patients	colorectal cancer numbers	PPV for colorectal cancer %
<10	1226	**7**	0.6
10-19	177	2	1.1
20-49	148	7	4.7
50-100	92	9	9.8
100-399	93	16	17.2
>400	129	45	34.9

Although conflicting qFIT results are more likely in the presence of anaemia, data from NHS Lothian presented at the event, reported that the risk of a missing colorectal cancer was low if 2 qFIT results were ≤10μg/gHb. Data on the value of double FIT at a threshold of 20μgHb/g faeces was not presented.

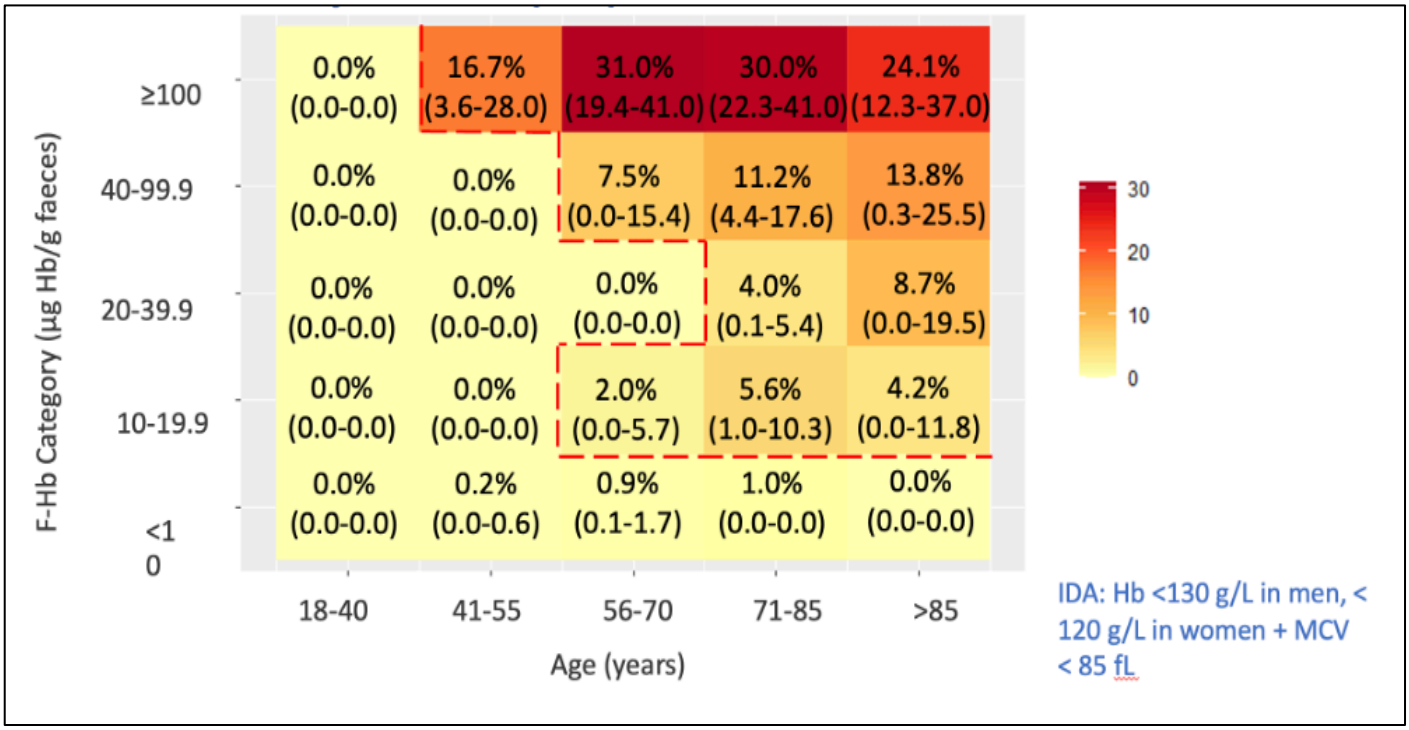
Table 2: Double qFIT and anaemia. Lothian data

FIT result	All	Not anaemic				Anaemic			
		N	CRC	CRC Prev	NNI	N	CRC	CRC Prev	NNI
<10, <10	3327	2683	4	0.1%	671	447	1	0.2%	447
<10, >10	343	242	2	0.8%	121	75	1	1.3%	75
>10, <10	369	274	1	0.4%	274	80	2	2.5%	40
>10, >10	568	373	45	12.2%	8	165	30	18.2%	6
	4607	3572	52	1.5%	69	767	34	4.4%	23

Looking beyond Scotland, Nottingham NHS Trust, reported that as long as the abdominal and rectal examinations were normal, a qFIT ≥100μg/gHb in the presence of iron deficiency anaemia was required to yield a PPV of 3% (NG12[19]) for colorectal cancer in those under 70 years.[15]

A PPV of 3% (NG12[19]) for colorectal cancer in those under 70 years.[15] The data also supports no lower gastrointestinal investigations for patients with IDA and a FIT<10mgHb/g faeces as the risk of colorectal cancer as ≤1% across all ages.[15] This data was reproduced in Tayside and presented at the Scottish 2024 qFIT event. The results are provided in Figure 4.

Figure 4: Heat map of 1-year cumulative colorectal cancer risk by FIT category for patients with iron deficiency anaemia. Tayside



In the absence of age stratification it was agreed that all patients with iron deficiency anaemia and a qFIT ≥10mg/gHb should be triaged separately from patients with other lower gastrointestinal symptoms.

The NICE qFIT guidance[16] and NICE iron deficiency anaemia guidance[17], published after the BSG guidance[18], removed the recommendation for gastrointestinal investigation if the qFIT is <10mgHb/g faeces.

Our Scottish consensus recommends a second qFIT. A threshold was agreed of ≥20mgHb/g faeces for USC priority referral. Secondary care should provide the additional triage required for those with qFIT < 20mgHb/g faeces.

qFIT event programme

Quantitative Faecal Immunohistochemical Testing (qFIT) for patients with new lower gastrointestinal symptoms

1 March 2024

GJNH and Teams

Time		Lead
10.00am	Welcome and housekeeping	
10.00am-10.20am	Today's objectives	M Thornton
10.20am-10.30am	USoC Referrals and Colorectal Cancer Sata 2023	N Barnstaple
The qFIT pathways and thresholds		
10.35am-10.45am	UK qFIT guidelines variation and activity	M Thornton
10.50am-11.00am	Primary Care Experience	D Rigg
11.10am-11.20am	The Lothian qFIT pathway	F Din
11.30am-11.40am	qFIT thresholds and diagnostic yield	C Mowat
11.50am-12.00pm	qFIT testing and referral patterns	N Cruickshank
12.00pm-12.45pm	Discussion and decision	All
12.45pm-1.30pm	**Time to refuel**	**All**
qFIT and Iron Deficiency Anaemia		
1.30pm-1.40pm	Current position and guideline variation	M Thornton
1.40pm-1.50pm	Fife data	N Cruickshank
1.50pm-2.20pm	Discussion and decision	All
Asymptomatic patients with a qFIT		
2.20pm-2.30pm	Current position	M Thornton
2.30pm-3.00pm	Discussion and decision	All
3.00pm-4.00pm	Achieving the balance and best for our patients	MT/ All
4.00pm	Close	

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