

Triaging colorectal urgent referrals in the COVID-19 era using faecal immunochemical testing: a prospective UK real-world multicentre cohort study

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ABSTRACT

Objective During the early COVID-19 pandemic, UK guidelines advocated faecal immunochemical tests (FIT) with a threshold of 10 µg/g to help secondary care clinicians triage urgent suspected colorectal cancer (CRC) referrals. We aimed to evaluate the real-world performance and impact of FIT in a high-risk cohort referred against National Institute for Health and Clinical Excellence NG12 (2015) criteria.

Methods Multicentre prospective observational cohort study of FIT at all four secondary care hospitals in Devon (UK) between 1 April 2020 and 31 December 2020. FIT use was at the discretion of primary and secondary care clinicians. Incident CRC cases were identified ≥12 months after general practitioner (GP) referral using regional National Bowel Cancer Audit data linkage. We assessed diagnostic accuracy and healthcare utilisation in patients with and without FIT.

Results Overall, 6698 patients were included: 55% female, median age 72 years (IQR 65–82). Just over half (53%, 3552) of patients underwent FIT with a positivity rate of 34% (n=1237). CRC prevalence in patients with no FIT, positive FIT and negative FIT was 6% (189), 11% (137) and 0.5% (11), respectively. The prevalence of all cancers, including non-CRCs, was similar among FIT and no-FIT cohorts (p=0.74). Sensitivity and specificity of FIT for CRC were 0.93 (95% CI 0.87 to 0.96) and 0.68 (95% CI 0.66 to 0.69), respectively. Patients with negative FIT underwent fewer lower gastrointestinal endoscopies (no FIT 62% (1964) vs positive FIT 69% (857) vs negative FIT 36% (835)), p=0.0005).

Conclusions FIT is a useful triage tool for patients with suspected CRC which safely reduces endoscopy demand and prioritises those at greatest cancer risk. Standardised regional referral pathways, greater use of 'straight-to-test' investigations and GP support are needed to maximise its impact.

INTRODUCTION

Colorectal cancer (CRC) is the second leading cause of cancer-related death in the

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Before the COVID-19 pandemic, faecal immunochemical testing (FIT) was gaining recognition as a valuable tool for detecting colorectal cancer in symptomatic patients. However, concerns remained about missed cancer cases, especially in patients with high-risk symptoms.

WHAT THIS STUDY ADDS

⇒ In one of the largest real-world multicentre studies to date, we demonstrate that FIT can safely reduce the demand for endoscopic and outpatient services by efficiently triaging patients with high-risk symptoms indicative of colorectal cancer, despite considerable heterogeneity in secondary care investigative pathways.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The 2023 National Institute for Health and Clinical Excellence NG12 guidelines have incorporated the use of FIT in the primary care evaluation of symptomatic patients. However, further real-world research is necessary to evaluate its impact on primary care workload, the diagnostic yield of endoscopic procedures, the feasibility of expanding asymptomatic screening programmes, and whether these revised care pathways enhance earlier-stage colorectal cancer detection and improve patient outcomes.

UK, with over 41 000 new cases diagnosed annually.^{1 2} Bowel cancer screening detects fewer than 10% of CRC cases, leaving the majority diagnosed after symptoms develop.³ Early-stage diagnosis is crucial, as it enables better treatment options and improves survival rates.^{2 4}

Before the COVID-19 pandemic, clinicians and researchers sought to balance the need for earlier CRC detection in symptomatic patients with the capacity constraints of diagnostic services. Quantitative faecal immunochemical testing (FIT) emerged as a potential solution. Studies demonstrated that FIT, at a threshold of 10 µg/g, offered clinically useful positive and negative predictive values (PPV: 9%–23%; NPV ≥ 99%) for CRC detection.^{5–9} However, concerns remained about missed cancer rates, which ranged from 3% to 15%, particularly in patients with high-risk symptoms meeting NG12 (National Institute for Health and Clinical Excellence, NICE) criteria (including change in bowel habit, rectal bleeding, abdominal pain, iron deficiency anaemia and unexplained weight loss).^{5–9}

The COVID-19 pandemic placed an unprecedented strain on healthcare systems, significantly disrupting CRC diagnostic pathways.¹⁰ Early in the pandemic, endoscopic services were largely paused, except for emergencies.¹¹ During the gradual resumption in 2020, services faced a substantial diagnostic backlog with limited capacity. This necessitated a paradigm shift to prioritise investigations for patients at the highest cancer risk, maximising diagnostic efficiency and minimising delays.¹² In response, joint guidance from UK gastroenterology and surgical societies (The Association of Coloproctology of Great Britain and Ireland [ACPGBI], The British Society of Gastroenterology [BSG] and The British Society of Gastrointestinal and Abdominal Radiology [BSGAR]) recommended FIT as a triage tool for urgent CRC referrals.¹³ It was further advised that patients with a negative FIT result (<10 µg/g) might not require immediate diagnostic testing, provided adequate safety measures were in place.^{12–14} We aimed to evaluate the real-world, clinician-led use of FIT by comparing patient outcomes and healthcare utilisation between individuals meeting high-risk CRC referral criteria who underwent FIT testing and those who did not, across primary and secondary care settings.

METHODS

Study design

We conducted a multicentre, pragmatic, prospective observational cohort study to evaluate the use of FIT in patients meeting the NICE NG12 (2015) high-risk symptom criteria for urgent suspected CRC pathway. These patients were referred to secondary care by their general practitioners (GPs). At the time of study inception, national guidelines recommended but did not mandate FIT use with a threshold of ≥10 µg/g before referral.¹⁴ Consequently, we included patients referred via the same pathway who did not complete FIT in either primary or secondary care as a comparator group.

The study aimed to:

1. Compare outpatient, endoscopy and radiology utilisation, as well as cancer prevalence, between patients referred with and without FIT.
2. Assess the diagnostic validity of FIT (sensitivity, specificity and predictive values) for identifying CRC.

This service evaluation was developed by the Southwest FIT Audit Group (see online supplemental appendix A). Using a pragmatic design, not all patients underwent gold-standard diagnostic testing. Outcome data were obtained from the National Bowel Cancer Audit (NBOCA) databases via record linkage,¹⁵ with a minimum follow-up of 12 months from the initial referral. All cancer service providers in England and Wales are required to submit monthly Cancer Outcomes and Services Data, ensuring comprehensive CRC case capture. These methods attempted to identify missed cancers in patients initially discharged without investigation who subsequently represented with persistent symptoms. We report this study according to the Standards for Reporting of Diagnostic Accuracy Studies guidelines (online supplemental material, research checklist).¹⁶

Clinical setting

All four Devon secondary care NHS hospitals were invited to participate in this service evaluation: Royal Devon & Exeter (RDE) NHS Foundation Trust, Torbay and South Devon (TSD) NHS Foundation Trust, University Hospitals Plymouth (UHP) NHS Trust and North Devon Healthcare (NDH) NHS Trust. Commissioned by Devon Clinical Commissioning Group (Devon CCG), these hospitals serve a population of 1.2 million across Devon.¹⁷ During the study period, none had implemented a formal FIT referral pathway.

Participants

We included all adult patients (aged ≥18 years) referred by their GP on the urgent CRC pathway for gastrointestinal (GI) symptom investigation between 1 April 2020 and 31 December 2020. While all referrals were expected to meet NICE NG12 (2015) criteria, specific qualifying symptoms were not recorded. Recognising the discretionary use of FIT, we included patients both with and without FIT results. Patients who died after GP referral but before secondary care contact were excluded. Additionally, referrals to surgical or gastroenterology services on routine low-risk (non-cancer suspected) pathways were excluded.

Variables and data acquisition

Each hospital generated a list of eligible patients by querying their NBOCA database to identify those referred on urgent 2-week wait CRC pathways during the study period. Outcome data were collected after 31 January 2022, ensuring a minimum 12-month follow-up from the last GP referral, though follow-up duration varied between patients. We collected data on demographics, service utilisation (outpatient clinic attendance, cross-sectional imaging and lower GI endoscopy), cancer diagnoses and compliance with NHS (National Health

Service) England's 14-day and 28-day Faster Diagnosis Standard targets in patients with and without FIT (online supplemental appendix B).^{18 19}

Reference standard

For diagnostic accuracy calculations, the reference standard for determining the final outcome (CRC diagnosed or excluded) was based on a composite approach. This included results from lower GI endoscopy (flexible sigmoidoscopy and/or colonoscopy) and/or abdominal imaging (CT or MRI), where available, along with a minimum 12-month follow-up for patients discharged without a diagnostic test. This indirect approach, as outlined by Brenner *et al*,²⁰ makes the following assumptions:

1. All CRC cases detected within 1 year derive from pre-clinical CRCs that are already present at the time of FIT testing.
2. All preclinical CRCs present at the time of FIT testing become clinically manifest or otherwise detected within the follow-up period (typically 1 year).

FITs (index test)

Primary care practices across Devon have used FIT for low-risk patients meeting NICE DG30 criteria since June 2018, enabling its rapid adoption for high-risk patients meeting NICE NG12 criteria during the COVID-19 pandemic.²¹ All FITs in the region are processed centrally at the RDE Hospital. Our study included FIT results from both primary and secondary care. Additional details on FIT processing are provided in online supplemental appendix C.

Statistical tests

All analyses were two-tailed, with $p < 0.05$ considered statistically significant. No corrections were applied for multiple comparisons. Summary statistics are presented as medians with IQRs. Patients with missing clinical data were included in analyses where data were available, with denominators specified for each variable. Univariable analyses were conducted using Fisher's exact test for categorical variables and the Mann-Whitney U test for continuous variables. FIT results from both primary and secondary care were combined to assess the diagnostic accuracy of FIT for detecting CRC, excluding patients with non-CRCs. Receiver operating characteristic (ROC) curves and area under the curve (AUC) analyses were used to evaluate faecal haemoglobin as a continuous variable. Youden's formula was applied to determine the optimal FIT threshold that maximised sensitivity and specificity. Sensitivity, specificity, PPV and NPV were calculated at the prespecified cut-off and at additional thresholds (2, 10 and 100 µg/g). Missed CRC cases per 1000 tests and the number needed to scope (NNS) were also estimated for various thresholds. Statistical analyses were performed using R V.4.2.0 (R Foundation for Statistical Computing, Vienna, Austria), with the *epi.tests* and *pROC* packages. Data visualisation was completed using

Microsoft Excel 2019 (Microsoft, Redmond, Washington, USA) and R Studio V.2022.02.1-461 (RStudio, Boston, Massachusetts, USA).

Sample size

As this was a service evaluation, no power calculations were undertaken.

Patient and public involvement

None.

RESULTS

Demographics and prevalence of cancer

Overall cohort

We present data in the order shown in figure 1. Between 1 April 2020 and 31 December 2020, a total of 6698 patients were referred on the urgent colorectal pathway across four Devon NHS hospitals: RDE Hospital (2122 patients), NDH (783 patients), TSD NHS Foundation Trust (1685 patients) and UHP (2108 patients) (see online supplemental table 1). The median follow-up period from GP referral to data collection was 74 weeks (IQR 65–84 weeks). Of these patients, 54.9% (3680/6698) were female, with a median age of 71.8 years (IQR 61.0–80.1 years) (see table 1). Patient ethnicity data showed that 92.7% (6207/6698) were white, 0.3% (22/6698) were mixed race, 0.3% (20/6698) were Asian, 0.1% (7/6698) were black and ethnicity was not recorded or unknown for 6.6% (442/6698) of patients.

The overall prevalence of cancer among referred patients was 5.9% (394/6698). This included:

- CRC: 5.0% (337/6698).
- Other GI (non-colorectal) cancers: 0.7% (47/6698).
- Cancer of unknown primary: 0.1% (10/6698).

Thus, cancer was excluded in 94.1% (6304/6698) of referrals. Among patients diagnosed with CRC, 5.0% (15/298) were under 50 years old; however, age data were missing for 39 patients.

Uptake and use of FIT in the 2WW referral pathway

Patients referred with and without primary care FIT

Approximately one-third (30.9% (2069/6698)) of patients completed a primary care FIT (see online supplemental table 2). The uptake of primary care FIT varied significantly across hospitals, ranging from 18.1% to 42.7% of referrals ($p = 0.0005$; see online supplemental table 1). The prevalence of all cancers (including non-CRCs) did not differ between patients referred with FIT and without a FIT ($p = 0.74$; see online supplemental table 2). A comparison between patients referred with and without primary care FIT revealed the following: those with FITs were more likely to be female ($p = 0.038$), had a higher median income decile ($p < 0.0001$) and were less likely to have left-sided CRCs ($p = 0.0005$). However, there was no difference in the stage of CRC at diagnosis ($p = 0.51$) (see online supplemental table 2). Of the 4629 patients referred without primary care FIT, 32.0% (1483/4629) underwent a secondary care FIT.

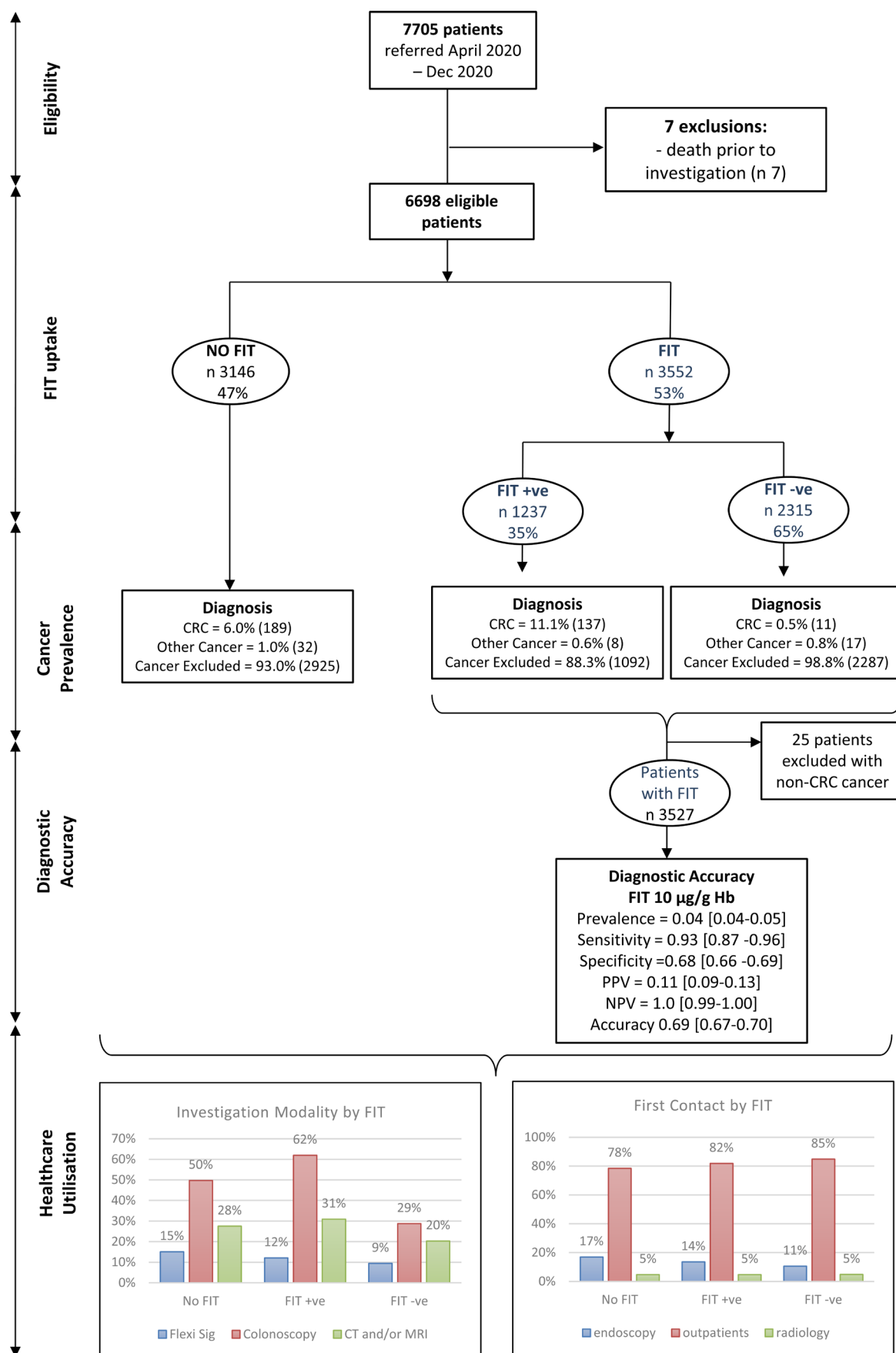


Figure 1 Flow diagram showing derivation of the cohort, FIT uptake, CRC prevalence, diagnostic accuracy and healthcare utilisation. CRC, colorectal cancer; FIT, faecal immunochemical test; NPV, negative predictive value; PPV, positive predictive value.

Table 1 Cohort demographics and cancer diagnoses among patients referred on colorectal cancer pathway with and without FIT colorectal cancer

Variable	N	No FIT n=3146	FIT performed*†		P value‡
			Negative FIT (<10 µg/g) n=2315	Positive FIT (≥10 µg/g) n=1237	
Age at referral (median (IQR))	5873	69.4 (57.5–79.2)	72.9 (63.5–79.9)	74.9 (62.3–82.3)	<0.0001
Sex					
Female	6698	52.8% (1661/3146)	59.2% (1371/2315)	52.4% (648/1237)	0.0005
Ethnicity					
White	6698	92.5% (2909/3146)	92.5% (2141/2315)	93.5% (1157/1237)	0.15
Asian		0.4% (13/3146)	0.2% (5/2315)	0.2% (2/1237)	
Black		0.2% (5/3146)	0.0% (0/2315)	0.2% (2/1237)	
Mixed		0.5% (15/3146)	0.2% (5/2315)	0.2% (2/1237)	
Unrecorded		6.5% (204/3146)	7.1% (164/2315)	6.0% (74/1237)	
Income decile§					
Median (IQR)	6274	6.0 (4.0–7.0)	6.0 (4.0–7.0)	6.0 (4.0–7.0)	0.85
Diagnosis					
Cancer excluded	6698	93.0% (2925/3146)	98.8% (2287/2315)	88.3% (1092/1237)	0.0005
Colorectal cancer		6.0% (189/3146)	0.5% (11/2315)	11.1% (137/1237)	
Other GI cancer (non-colorectal)		0.5% (16/3146)	0.3% (6/2315)	0.2% (3/1237)	
Cancer unknown primary		0.2% (5/3146)	0.2% (4/2315)	0.1% (1/1237)	
Non-GI cancer		0.3% (11/3146)	0.3% (7/2315)	0.3% (4/1237)	
Colorectal cancer location					
Left sided¶	312	75.1% (142/189)	36.4% (4/11)	61.3% (84/137)	0.0065
Right sided		23.8% (45/189)	63.6% (7/11)	37.2% (51/137)	
Unrecorded site		1.1% (2/189)	0.0% (0/11)	1.5% (2/137)	
Colorectal cancer stage early versus late					
Stage I and II	277	42.0% (63/150)	33.3% (3/9)	40.7% (48/118)	0.91
Stage III and IV		58.0% (87/150)	66.7% (6/9)	59.3% (70/118)	

*Includes both primary and secondary care requested FIT.

†FIT threshold ≥10 µg/g.

‡P value represents Fisher's exact test (bold indicates significance values $p < 0.05$).

§Income decile from postcode and lower-layer super output area where 10=highest income decile; 1=lowest income decile.

¶Left-sided cancer=cancer at or distal to splenic flexure.

FIT, quantitative immunochemical tests; GI, gastrointestinal.

Patients with positive and negative FIT

The combined (primary and secondary care) positivity rate of FIT at 10 µg/g threshold was 34.8% (1237/3552) (see online supplemental table 3). The prevalence of CRC in patients with a positive FIT was 11.1% (137/1237) as compared with 0.5% (11/2315) in patients with a negative FIT. Patients with a positive rather than a negative FIT were more likely to be male ($p=0.0005$) and older ($p=0.004$). No significant difference in the proportion of patients with right-sided CRCs ($p=0.24$) or early (stages I and II) versus late (stages III and IV) CRC ($p=0.75$) was observed.

Case note review of patients with CRC and negative FIT

Of the 11 patients with CRC and an FIT result <10 µg/g, 10 had symptoms or signs that warranted further

investigation despite the negative test. The most common symptoms included iron-deficiency anaemia, weight loss and/or a rectal mass (see online supplemental table 5).

Service evaluation

70.1% (4702/6698) of patients referred through the lower GI CRC pathway underwent diagnostic testing, including lower GI endoscopy and/or imaging (CT/MRI) (see table 2). Patients with either no FIT or a positive FIT were more likely to be directed straight to a test (ie, the first point of contact was either endoscopy or radiology after the primary care referral) compared with patients with a negative FIT ($p=0.0005$) (see table 2 and figure 2a). Those with a negative FIT had fewer lower GI investigations than those with a positive FIT or no FIT ($p=0.0005$) (see figure 2b). Nearly half (48.8% (1130/2315)) of patients with a negative FIT were

Table 2 Healthcare utilisation and cancer target times in subcohorts of referred patients with no FIT, positive FIT and negative FIT

Variable	N	No FIT performed n=3146	FIT performed*		P value†
			Negative FIT (<10 ug/g) n=2315	Positive FIT (≥ 10 ug/g) n=1237	
Patient first contact					
Endoscopy	6497	16.9% (515/3050)	7.7% (172/2233)	15.6% (189/1214)	0.0005
Outpatients		78.4% (2391/3050)	87.9% (1962/2233)	79.1% (960/1214)	
Radiology		4.7% (144/3050)	4.4% (99/2233)	5.4% (65/1214)	
Patient directed straight-to-test‡	6498	21.6% (659/3050)	12.1% (271/2233)	20.9% (254/1214)	0.0005
Endoscopy§					
Flexible sigmoidoscopy	6698	15.1% (476/3146)	8.2% (190/2315)	11.6% (143/1237)	0.0005
Colonoscopy	6698	49.7% (1564/3146)	28.7% (665/2315)	61.9% (766/1237)	0.0005
Lower GI endoscopy (colonoscopy or flexible sigmoidoscopy)	6698	62.4% (1964/3146)	36.1% (835/2315)	69.3% (857/1237)	0.0005
Imaging¶					
CT and/or MRI	6698	27.5% (864/3146)	20.3% (469/2315)	30.9% (382/1237)	0.0005
Imaging and/or lower GI endoscopy					
Scan and/or lower GI endoscopy (flexible sigmoidoscopy and/or colonoscopy)	6698	79.1% (2489/3146)	51.2% (1185/2315)	83.1% (1028/1237)	0.0005
Cancer target times					
Time from GP referral to being first seen (median (IQR)) days	6638	10.0 (7.0–15.0)	8.0 (6.0–14.0)	9.0 (6.0–15.0)	<0.0001
14-day target breached**	6638	32.9% (1026/3118)	27.5% (629/2287)	32.3% (398/1233)	0.0005
28-day target breached**	5449	40.0% (1095/2738)	58.0% (926/1597)	53.4% (595/1114)	0.0005

*Includes both primary and secondary care requested FIT.

†P value represents Fisher's exact test (bold indicates significance values $p < 0.05$).

‡Endoscopy or imaging as first point of contact after patient referred.

§First endoscopic test rather than total tests.

¶Excludes staging scans for patients with cancer diagnosis

**14-day target=NHS England cancer target to see patients within 14 days of being referred urgently by GP for suspected cancer and 28-day target=faster diagnosis standard national target to either diagnose or have cancer excluded within 28 days of urgent GP referral.

FIT, quantitative immunochemical tests; GI, gastrointestinal; GP, general practitioner.

discharged without undergoing either an endoscopic or radiological investigation, compared with 20.9% (657/3146) of patients with no FIT and 16.9% (209/1237) of patients with a positive FIT. Overall, about one in three patients referred on the urgent colorectal pathway were not seen within the 14-day target set by NHSE (30.9% (2053/6638)), and nearly half (48.0% (2616/5449)) did not have cancer excluded within the 28-day target (NHSE 28-day cancer diagnosis target). Achievement of the 14-day and 28-day targets varied by FIT status: patients with a negative FIT were most likely to be seen within 14 days ($p=0.0005$) but were least likely to meet the 28-day target ($p=0.0005$) (see [table 2](#)); suggesting prompt review and then deferred investigation following negative FIT. Similarly, there was substantial variation among the four hospitals in the proportion of patients meeting 28-day targets, which ranged from 30% to 68% (see online supplemental table 4).

Diagnostic accuracy of FIT in distinguishing CRC from no CRC

Sensitivity and specificity analyses

Approximately one-third (29.8%, 1996/6698) of patients did not undergo initial investigation with lower GI endoscopy or imaging. These patients were classified as having cancer excluded after at least 12 months of follow-up. For the diagnostic accuracy analysis, we included 3527 patients (see [figure 1](#)). At the FIT threshold of $10 \mu\text{g/g}$, we found a sensitivity of 0.93 (95% CI 0.87 to 0.96) and a specificity of 0.68 (95% CI 0.66 to 0.69) (see online supplemental figure 1).

Receiver operator characteristic analyses

Using FIT as a continuous variable in ROC analysis, we found an AUC of 0.89 for distinguishing CRC from non-cancer cases (see online supplemental figure 2). The

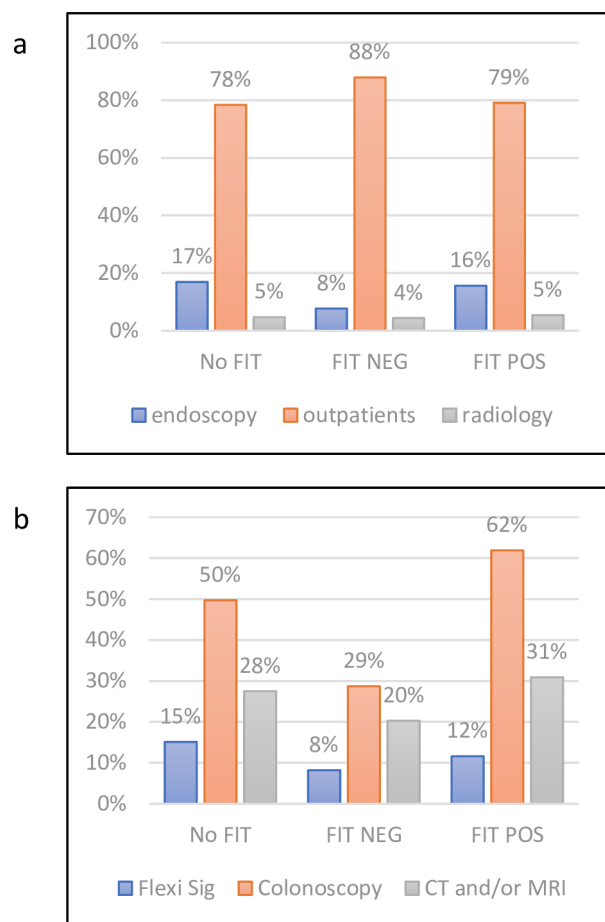


Figure 2 Bar charts of (a) first hospital contact (b) investigations among patients with and without FIT. FIT, faecal immunochemical test; Flexi Sig, Flexible Sigmoidoscopy.

optimal FIT threshold was estimated to be 30 µg/g, based on Youden's formula.

Sensitivity analysis: exploring FIT threshold

We compared the performance of FIT at 2 (limit of detection), 10 (as per national guidance)¹⁴ and 100 µg/g thresholds (see table 3). At the 10 µg/g threshold, we estimated that five CRCs would be missed per 1000 tests, with a 'NNS'—the number of lower GI endoscopies required to diagnose one CRC—of 9 (see table 3).

DISCUSSION

Major findings

We present a large, real-world, multicentre prospective cohort study conducted during the early COVID-19 pandemic and prior to the latest NICE NG12 (2023) guidelines. FIT was used at the discretion of primary and secondary care clinicians to help triage patients referred through the urgent colorectal suspected cancer pathway. Just under one-third of patients underwent FIT in primary care before referral. The combined FIT positivity rate (across both primary and secondary care) at a threshold of ≥10 µg/g was 35%. The prevalence of CRC in patients with no FIT, a positive FIT and a negative FIT

Table 3 Effect of FIT threshold on diagnostic accuracy for the diagnosis of CRC that would have presented over the next 12 months and estimates for number of missed cancers and number needed to scope (NNS)

Threshold of FIT (µg/g)	Sensitivity (95% CI)	Specificity (95% CI)	Positive predictive value (PPV) (95% CI)	Negative predictive value (NPV) (95% CI)	Positive likelihood ratio (95% CI)	Negative likelihood ratio (95% CI)	False negative tests	FIT % positivity (n/N)	Number missed cancers per 1000 tests (prevalence CRC=4%)*	NNS to diagnose one colorectal cancer†
2	0.95 (0.90 to 0.98)	0.56 (0.55 to 0.58)	0.09 (0.07 to 0.10)	1.00 (0.99 to 1.00)	2.18 (2.07 to 2.29)	0.08 (0.04 to 0.17)	7	46% (1620/3527)	3	11
10	0.93 (0.87 to 0.96)	0.68 (0.66 to 0.69)	0.11 (0.09 to 0.13)	1.00 (0.99 to 1.00)	2.86 (2.68 to 3.06)	0.11 (0.06 to 0.19)	11	35% (1229/3527)	5	9
100	0.72 (0.64 to 0.79)	0.89 (0.88 to 0.90)	0.23 (0.19 to 0.27)	0.99 (0.98 to 0.99)	6.64 (5.78 to 7.63)	0.31 (0.24 to 0.40)	41	13% (475/3527)	13	4

Given the 12-month follow-up time period, the performance values for FIT (sens, spec, PPV, etc) reflect the appearance of CRC over this time frame, for example, the NPV is not the 'NPV for colorectal cancer' but rather the 'NPV for colorectal cancer that would have otherwise presented in the next 12 months'.

*Number missed cancers per 1000 tests=post-test probability cancer with negative FIT (%)×1000 where post-test probability=post test odds/(post-test odds+1) where post-test odds=(pretest odds×NLR) and pretest odds=(pretest probability/(1−pretest probability)).

†NNS=(1/PPV).

FIT, quantitative faecal immunochemical tests; ;

was 6%, 11% and 0.5%, respectively. This suggests an estimated miss rate of 5 CRCs per 1000 tests with an FIT result $<10\mu\text{g/g}$. The sensitivity and specificity of FIT for CRC at the $10\mu\text{g/g}$ threshold were 93% and 68%, respectively. We observed significant variability in secondary care triage, use of straight-to-test pathways as well as cross-sectional imaging. A negative FIT result was associated with lower use of endoscopic and/or radiological investigations compared with patients with either no FIT or a positive FIT.

Interpretation

In pre-pandemic large UK studies, the prevalence of CRC among patients referred under NICE NG12 (2015) criteria was 3%–4%.^{22–24} The marginally higher 5% CRC prevalence in our study likely reflects both GP gatekeeping amid a time of constrained secondary care services and patient reluctance to seek care during the early COVID-19 pandemic. Our observed sensitivity (93%) and specificity (68%) align with findings from two meta-analyses using a $10\mu\text{g/g}$ threshold in symptomatic patients. Pin Vieito *et al*²⁵ reported sensitivity of 92% and specificity of 70% and Saw *et al*²⁶ found sensitivity of 89% (95% CI 85% to 91%) and specificity of 81% (95% CI 75% to 85%). The miss rate of 5 CRCs per 1000 tests in our study is consistent with other UK studies, providing further reassurance for using FIT in high-risk patient cohorts.^{6 23 24 27} This risk is well below the current NICE threshold for urgent cancer investigation ($\geq 3\%$ cancer risk) and aligns with the background risk of CRC in asymptomatic 45–49 years in the UK.^{28 29}

In reviewing FIT-negative CRC cases, we found that 10 of 11 patients had symptoms (eg, anaemia, weight loss, rectal mass) that warranted further investigation, despite a negative FIT result. This highlights the importance of thorough physical examination, including a digital rectal exam and blood tests during GP face-to-face consultation, which may help identify non-CRCs or FIT-negative CRCs. Among the six FIT-negative CRC cases with anaemia, three had FIT $<2\mu\text{g/g}$, suggesting that lowering the FIT threshold may not capture all missed cancers. Anaemia, particularly when new, warrants urgent investigation in FIT-negative patients. Rodríguez-Alonso *et al* found iron deficiency anaemia increased the odds of CRC by threefold, independent of FIT result, age, or gender.⁵ However, D'Souza *et al* found no significant variation in FIT's ability to detect CRC in the presence of anaemia.²²

We also observed a trend towards a higher proportion of left-sided and early-stage CRC in patients with a positive FIT, likely reflecting differences in symptoms, tumour biology or haemoglobin degradation in right-sided lesions.^{30–32}

Secondary care triage revealed significant variability in FIT use and performance across four hospitals in the same CCG. One hospital directed 55% of referrals straight to test, while others used this pathway less than 3% of the time. Furthermore, nearly 80% of FIT-positive patients were first seen in outpatient clinics before

undergoing tests, despite evidence that straight-to-test pathways reduce time to cancer diagnosis.³³ FIT use did reduce the need for lower GI endoscopy: 50% of patients without FIT underwent colonoscopy, compared with 29% with negative FIT and 62% with positive FIT. However, as GPs increasingly use FIT for both high-risk and low-risk symptoms, the number of 2-week urgent colorectal referrals may be expected to rise. Bailey *et al* reported a 33% increase in urgent referrals over 13 months following the introduction of their Rapid Colorectal Cancer Diagnosis Pathway, in which GPs were encouraged to use FIT for all lower GI symptoms except rectal bleeding and mass.³⁴

Strengths and weaknesses

Our study has several strengths. First, to our knowledge, despite the pandemic setting, this is the largest prospective multicentre UK study to explore the real-world diagnostic accuracy of FIT in a high-risk cohort referred on a suspected cancer urgent 2-week wait pathway. Previous studies in high-risk cohorts have largely consisted of diagnostic accuracy studies which reference FIT against gold-standard investigations in all referred patients.^{22–24} While other UK large-scale pragmatic record-linkage studies have also been undertaken, these have either been conducted in patients with low-risk symptoms^{35 36} or in patients with all GI symptoms regardless of risk.^{37 38} Second, we compared healthcare utilisation in patients with and without FIT, offering valuable insights for improving regional FIT pathways to maximise impact and reduce time to cancer diagnosis/exclusion. Third, although this is a UK-based study, we hope that the detailed data presented and the sensitivity analyses will provide valuable insights for clinicians and policy makers in other countries. Lastly, our study included a minimum 12-month follow-up, facilitating the detection of missed cancers. However, Brenner *et al* suggest that a longer follow-up may improve accuracy—this would identify slow-growing cancers in patients who were falsely reassured and did not undergo diagnostic testing.²⁰ There is also a counterargument that any cancer diagnosed more than a year after entry into a symptomatic cancer pathway is unrelated to the initial presenting symptoms; that is, it is a serendipitous detection.³⁹ Our 12-month follow-up period, therefore, attempts to balance these two competing issues. It is also worth clarifying that our performance values for FIT reflect the appearance of CRC over a 12-month time frame, for example, the NPV is not the NPV for CRC, but rather the NPV for CRC that would have otherwise presented in the next 12 months.

However, there are several limitations. First, the lack of symptom and blood test data prevents definitive conclusions about healthcare savings and use of FIT in combination with specific symptoms. Second, we did not capture data on general gastroenterology referrals in FIT-negative patients, although previous data shows up to 10% of patients may still be referred routinely on non-suspected cancer pathways to surgical or gastroenterology services within 3 months of a negative FIT.⁴⁰ Third, our study was conducted during the

early COVID-19 pandemic, which will limit its applicability outside of this period. Patients may have delayed or avoided presenting to their GP with GI symptoms due to pandemic-related concerns. Fourth, our cohort was predominantly white British, and FIT's acceptability may differ in non-white ethnic groups.²⁷ Fifth, we did not capture FIT return rates, although studies show return rates of 60%–94%.^{27 41–43} Sixth, the NBOCA database does not capture delayed non-GI cancer diagnoses, so non-GI cancers may be under-reported. Seventh, we did not assess FIT's performance in detecting other significant pathologies, such as inflammatory bowel disease or high-risk adenomas, where its accuracy is lower.^{23 44} This highlights the importance of primary care safety-netting and timely gastroenterology referrals.⁴⁵ Eighth, in keeping with our real-world study design, not every patient referred with suspected cancer has undergone a lower GI endoscopy and/or cross-sectional imaging, even after a positive FIT test. Notably, 17% of individuals referred on the pathway with a positive FIT and 21% of those with no FIT result did not undergo any endoscopic or radiological investigations. Prior colonoscopy and cross-sectional imaging results may have been considered when determining the need for further investigations; however, these data were not captured in our study. Secondary care clinicians often balance the risk of overinvestigation and underinvestigation after detailed patient discussions, sometimes in very elderly and comorbid patients. In such instances, some patients may accept the risk of an undiagnosed cancer and decline further tests. This is also a drawback of straight-to-test pathways which bypass this patient-centred approach in favour of improving time to cancer diagnosis/exclusion at a population level. Ninth, FIT testing was left to clinician discretion rather than being mandated by a predefined pathway, although it was encouraged by COVID-19 emergency society guidelines. As a result, our data offer a unique perspective on the real-world use of this biomarker. However, our findings should be interpreted with caution within this context. Lastly, we examined single-use FIT, not repeat testing—a large UK study suggests repeat FIT testing may reduce false negatives and positives.⁴⁶

Implications for future practice

Based on this service evaluation and ACPGBI/BSG guidance, a new Peninsula Urgent Lower GI Referral Pathway was implemented regionally (see online supplemental figure 3). Regional cancer funds are supporting the appointment of additional nurse specialists to manage the suspected CRC pathway and free up consultant time. An expansion of 'non-site specific' referral services is also underway, allowing FIT-negative patients with concerning symptoms to receive timely investigation, while colorectal teams continue to investigate where needed.

In the post-COVID-19, post-FIT era, it will be important to assess whether diagnostic yield improves, and if this translates to faster diagnosis, earlier cancer stages and better prognosis. If wider FIT use increases diagnostic capacity, this could be directed towards a more inclusive asymptomatic bowel cancer screening programme, which arguably would have a greater impact on reducing CRC and improving early-stage

diagnosis. Additionally, the impact of FIT on primary and secondary care utilisation should be evaluated, particularly if referrals are shifted from urgent to routine pathways. National guidance and support are crucial, as GPs may be concerned about managing risk in unreferred FIT-negative patients and handling the increased workload from safety-netting, unreturned FITs, and result follow-ups. Computer systems may help streamline these tasks, and this is an area of ongoing study.⁴⁷ Future service evaluations of the FIT test should take into consideration the following key factors: patient symptoms and time of onset, test return rate, use of repeat testing, secondary care referral pathways (both urgent and routine), primary and secondary workload, endoscopic diagnostic yield, missed cancers, stage of cancer at diagnosis, endoscopy unit capacity and cost-effectiveness.

CONCLUSIONS

In keeping with other recent large studies, our evaluation demonstrates that FIT is an effective triage tool for high-risk patients, reducing endoscopy demand and prioritising those at greatest risk of cancer. This study highlights the variability in FIT uptake and its impact on triage and diagnostic pathways for suspected CRC. Our results need to be interpreted with caution due to the constraints placed on investigations during the pandemic. Since our study was completed, the joint ACPGBI/BSG guidelines (2022) and NICE NG12 (2023) have been updated to recommend the targeted use of FIT (threshold $\geq 10 \mu\text{g/g}$) for guiding referrals for suspected CRC in adults, with appropriate safety netting and specific exemptions.^{48 49} Further real-world studies will be needed to evaluate the impact of these new recommendations.

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