

Research Article

Faecal Immunochemical Testing in Symptomatic Primary Care Patients: A Diagnostic Accuracy Study

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Aim: The faecal immunochemical test (FIT) is now widely used in English primary care to triage people who exhibit signs or symptoms of colorectal cancer (CRC). National guidelines for FIT implementation were based on data that acknowledged limitations. This study examines FIT accuracy in primary care patients with low- and high-risk symptoms of CRC.

Methods: This study describes a retrospective cohort study in South Yorkshire, UK ($n = 2029$). Consecutive symptomatic adult patients in primary care undergoing a FIT between 01/04/2021 and 30/04/2021 were assessed. A threshold $> 10 \mu\text{g Hb/g}$ was defined as a positive FIT result. Lower gastrointestinal tract (LGI) investigations were the reference standard. Follow-up over 24 months was used to identify serious colorectal diseases (CRC, high-risk polyps and inflammatory bowel disease [IBD]).

Results: Five hundred and fifteen (25.4%) patients had a positive FIT. The CRC prevalence was 1.2% (24/2029). Nineteen (79.1%) of the 24 CRC cases had NG12 symptoms, with two (8.3%) having a negative FIT. For CRC detection, FIT showed 91.7% sensitivity (95% CI: 71.5%–98.5%), 75.4% specificity (95% CI: 73.4%–77.2%), 4.3% positive predictive value (PPV) (95% CI: 2.8%–6.5%) and 99.9% negative predictive value (NPV) (95% CI: 99.5%–99.97%). Combining CRC, high-risk polyps and IBD increased PPV and specificity but decreased sensitivity and NPV.

Conclusions: In primary care, FIT safely triages patients having at-risk CRC risk symptoms. Negative FIT results indicate a low likelihood of CRC and supports safety-netting interventions.

Summary

What does this paper add to the literature?

Primary care physicians often see patients with abdominal symptoms, typically stemming from benign diseases. National guidelines recommend faecal immunochemical test (FIT) for triaging symptomatic primary-care patients; however, evidence underpinning recommendations had limitations. This study demonstrates that FIT effectively triages people with high- and low-risk symptoms, with negative FIT results providing a high level of reassurance regarding CRC risk.

1. Introduction

Colorectal cancer (CRC) is the fourth most common cancer in the UK and the second leading cause for cancer-related deaths. An expedited diagnosis and early treatment of CRC improves survival and cure rates, with 95% of patients diagnosed at stage 1 surviving 5 years or more, compared with only 10% diagnosed at stage 4 [1, 2].

In 2015, the National Institute for Health and Care Excellence (NICE NG12) recommended urgent 2 weeks wait (2WW) referral of patients in primary care with high/medium-risk symptoms of CRC [3]. This NICE NG12 guidance was updated by Diagnostics Guidance 30 (NICE

DG30) in July 2017, which endorsed FIT for use in primary care patients with low-risk CRC symptoms [4]. Quantitative FITs work by detecting blood in stool samples (faecal haemoglobin, f-Hb) using antibodies specific to human haemoglobin.

In response to the COVID-19 pandemic, NICE published a speciality guide in November 2020 for triaging patients with lower gastrointestinal symptoms [5]. This advocated increasing FIT use in primary care to triage patients meeting either NG12 or DG30 criteria, which was supported by the British Society of Gastroenterology. Expedited CRC diagnoses, improved survival, reduced emergency presentations and improved use of diagnostic resources were all potential benefits from adopting these recommendations. The evidence underpinning these recommendations, however, had recognised limitations. These included study selection bias, with patient recruitment from a mix of primary and secondary care settings, varying reference standards and uncertainty about how patient level variables, such as age and gender influenced FIT outcomes [6–9]. These problems have been discussed further in the current NICE appraisal on FIT (Diagnostics Consultation Document) [10].

Our previous study examining the diagnostic accuracy of FIT in patients with low-risk symptoms, demonstrated FIT having a high negative predictive value (NPV) (> 99.9%) [11]. FIT accuracy in combined NG12 (high/medium risk) and DG30 (low risk) primary care populations is uncertain since current studies are mainly derived from secondary care settings [12–14]. This may lead to selection bias and inaccuracies in the reporting of FIT diagnostic accuracy estimates. Studies that exist and may be representative of primary care patients fulfilling NG12 and DG30 criteria are currently limited [15–18]. Three of these identified studies are from Scotland, where FIT use extends beyond the currently adopted NICE criteria, with CRC prevalence ranging between 1.2% and 2.9%. This study examines the diagnostic accuracy of FIT in primary care patients with defined high- and low-risk symptoms of CRC.

2. Materials and Methods

2.1. Study Design. The research adhered to STARD guidelines for diagnostic accuracy reporting [19]. UK Health Research Authority (IRAS 291908) and Sheffield Teaching Hospitals (STH21340) approved the ethics and study. We examined consecutive, symptomatic patients in primary care who were managed in accordance with the NICE NG12 and DG30 criteria [4]. The primary outcome was the accuracy of FIT for CRC detection at a 10 µg/g threshold.

2.2. Patient Selection. South Yorkshire and Bassetlaw's 190 general practices, covering 1.5 million residents, formed our study primary care population. Six hospitals provide adult secondary care services to this population. We included symptomatic individuals who performed FIT from April 1st to April 30th 2021. These dates were selected as they were one year beyond changes being made to the local rapid diagnostic lower gastrointestinal cancer pathway in response

to the COVID-19 pandemic [20]. All patient referred to this rapid diagnostic pathway required a FIT assessment, except those with an abdominal or anal mass and those with rectal bleeding. Patients selected for FIT were considered to fulfil NICE NG12 or DG30 criteria by primary care physicians.

2.3. Index Test and Reference Standard. Eligible patients meeting NICE NG12 and DG30 standards received OC-Sensor™ collection kits (Eiken Chemical Company, Tokyo, Japan). Individuals collected stool samples following provided instructions, dated the FIT sampling device, and submitted it to the laboratory within a week. Sheffield's Immunology Department processed all samples within 3 working days, using OC-Sensor™ Pledia analyser (Eiken Chemical Company, Japan) to measure faecal haemoglobin levels. In accordance with test specifications, faecal samples were stored at room temperature if analysed within 7 days or refrigerated if testing occurred between 7 and 14 days. The lower limit of quantification (LOQ) for the OC-Sensor FIT was 5 µg Hb/g faeces.

A faecal haemoglobin level > 10 µg Hb/g was used to determine the need for referral to the rapid diagnostic lower gastrointestinal cancer pathway as per national standards. When a patient had several FIT outcomes, any positive finding took precedence, triggering hospital referral.

Lower GI investigations were the reference standard, with colonoscopy as the primary method. Alternatives techniques such as CT imaging (CT pneumocolon, CT colon with long oral bowel preparation and plain abdominal CT) and colon capsule endoscopy were utilised when colonoscopy was declined or previously incomplete. In routine practice, endoscopists and radiologists had access to patients' symptomatic information and FIT data while conducting these assessments.

2.4. Data Collection. In May 2023, we extracted clinical data from Sheffield Immunology's database, encompassing FIT dates, results, indications, demographics and postcodes. We then cross-checked primary and secondary healthcare records for Supporting details. Primary care analysis involved examining symptoms prompting FIT requests, their alignment with NICE guidelines, outcomes for negative FIT cases and assessment of positive FIT individuals not referred. Secondary care databases provided histological, endoscopic and radiological findings up to 24 months post-FIT.

2.5. Data Analysis. For patients with multiple LGI findings, the research team assigned a single classification based on a hierarchical system. CRC topped the ranking, followed by high-risk polyps, and then IBD. Low-risk polyps came next, above benign conditions including diverticular disease, microscopic colitis, angiodysplasia and perianal disease (haemorrhoids and anal fissures). High-risk polyp categorisation adhered to British Society for Gastroenterology (BSG) polyp surveillance guidelines [21].

In this study, anaemia was defined as a serum haemoglobin concentration less than < 110 g/L for females and < 130 g/L for males in blood tests within 3 months before FIT

performance. Based on guidance provided by the BSG, anaemia was defined using the lower limit of the normal range specific to the laboratory that was conducting the test [22]. BSG guidelines were used to classify iron deficiency with and without anaemia [23]. Deprivation was evaluated using Index of Multiple Deprivation 2019 (IMD2019) scores derived from patients' postcodes [24]. Deprivation rankings for the 32,844 neighbourhood areas in England are divided into 10 groups within IMD2019, with the first decile representing highest deprivation and the 10th indicating lowest deprivation levels.

Data were analysed using SPSS Software (version 25-0), considering a p value of < 0.05 as significant. Descriptive statistics, chi-square test or Fisher exact test were used for categorical variables. For each faecal haemoglobin cutoff, we calculated sensitivity, specificity, positive predictive value (PPV) and NPVs, including 95% confidence intervals (Cis). Receiver operating characteristics (ROCs) curves illustrate FIT performance in CRC detection.

3. Results

3.1. FIT Returns and Patient Characteristics. From the 1st to 30th April 2021, the laboratory received 2207 FIT samples from primary care. Of the 2207 received samples, a single case (0.04%) represented a repeated test on the same person. One (0.04%) of the 2207 samples analysed was a repeat test on the same individual. Medical records and 24 months of follow-up were available for 2029 (91.9%) of the eligible 2206 patients. This was influenced by national data opt-out restrictions ($n = 138$) and missing data ($n = 36$) [25]. Figure 1 presents a STARD-based study flow chart, while Table 1 outlines demographic data for the 2029 individuals.

In this group, patient ages ranged between 17 and 100 years, with a median of 69. Females constituted 55.3% of the study cohort. The mean IMD19 score was 4.6 (SD 2.9). Patient records demonstrated that 722 (35.6%) and 1177 (58.0%) patients fulfilled NICE NG12 high/medium-risk symptom criteria and DG30 criteria, respectively [3]. One hundred and thirty (6.4%) patients did not meet either NG12 or DG30 symptom criteria. Indications for testing in this group included abdominal pain, weight loss and rectal bleeding outside of NICE criteria, with iron deficiency without anaemia being the most frequent indication for testing (73/130, 56.2%)

3.2. Outcomes From FIT, Subsequent Referrals and Diagnostic Procedures. Amongst the 2029 individuals, 515 (25.4%) had positive FIT results (faecal haemoglobin cutoff values $\geq 10 \mu\text{g Hb/g}$) and 271 (52.6%) were female. Secondary care received referrals for 459 (89.1%) of the FIT positive cases. Review of primary care records for the 56 unreferral patients revealed factors including patient choice, alternative diagnoses to CRC, recent gastrointestinal examinations and severe comorbidities. A total of 436 (28.7%) of the 1514 patients (28.4%) who had a negative FIT result had lower GI investigations within 24 months of follow-up (total patients

undergoing investigation = 877 patients, Figure 1). Of these 877 patients, 719 had a colonoscopy, 49 had a CT pneumocolon, 61 had a CT colon with long oral bowel preparation, 46 had a plain abdominal CT and 2 had a colon capsule endoscopy examination.

Table 2 summarises outcomes from diagnostic procedures undertaken. A normal colon was the predominant outcome, observed in 56.8% of examined cases. CRC was identified in 24 patients (prevalence of 1.2%, 24/2029), with alternative serious colorectal diseases (high risk polyps, IBD) seen in 66 patients (3.3%, 66/2029). Noncolorectal cancers were seen in 23 patients (prevalence of 1.1%, 23/2029). These noncolorectal cancers were identified through additional diagnostic tests, which occurred following referral to secondary care. Gastrointestinal (noncolorectal, $n = 7$) and genitourinary malignancies ($n = 6$) were the most frequently seen noncolorectal cancers.

3.3. Evaluating FIT's Diagnostic Accuracy. Table 3 outlines the performance characteristics of FIT at differing thresholds. FIT sensitivity reached 91.7% (95% CI: 71.5%–98.5%) at the current $\geq 10 \mu\text{g Hb/g}$ cutoff. It dropped to 54.2% (33.2%–73.8%) at $\geq 120 \mu\text{g Hb/g}$, the threshold employed in England's Bowel Cancer Screening programme.

For this study cohort, PPV was 4.3% (2.8%–6.5%) at $\geq 10 \mu\text{g Hb/g}$, rising to 10.8% (6.1%–18.1%) at $120 \mu\text{g Hb/g}$. NPV reached 99.9% (99.5% to 99.97%) and 99.4% (98.9–1% to 99.7%) at these respective thresholds. Combining CRC with other serious colorectal diseases, lowered across all thresholds (Table 4), ranging from 91.4% (83.3%–95.9%) at $\geq 10 \mu\text{g Hb/g}$ to 37.6% (28.0%–48.3%) at $\geq 120 \mu\text{g Hb/g}$. ROC analysis (Supporting Figure 1) yielded an area under the curve (AUC) of 0.89 (0.82–0.96).

3.4. CRCs. The features of the CRCs diagnosed ($n = 24$) are summarized in Table 5. Two (8.3%) of these cancers were diagnosed following a negative FIT. Both of these FIT negative cancers were seen in the proximal colon (caecum and transverse colon), with both patients being male. The path to diagnosis differed for these two cases. In the first case, despite the negative FIT result, the patient was referred for colonoscopy due to persistent symptoms, which led to the cancer diagnosis. In the second case, the patient initially had a negative FIT and was not immediately referred but later returned to primary care with worsening symptoms, prompting a referral for investigation that ultimately led to the cancer diagnosis. Nineteen (79.1%) of the 24 CRC cases fulfilled NG12 symptom criteria, with FIT having a high NPV ($> 99.8\%$), irrespective of criteria used to stratify symptoms (Supporting Table 1).

4. Discussion

This work explored the accuracy of the OC Sensor quantitative FIT in symptomatic primary care patients within South Yorkshire and Bassetlaw, UK, aligning with NICE NG12 and DG30 criteria for suspected CRC. A CRC

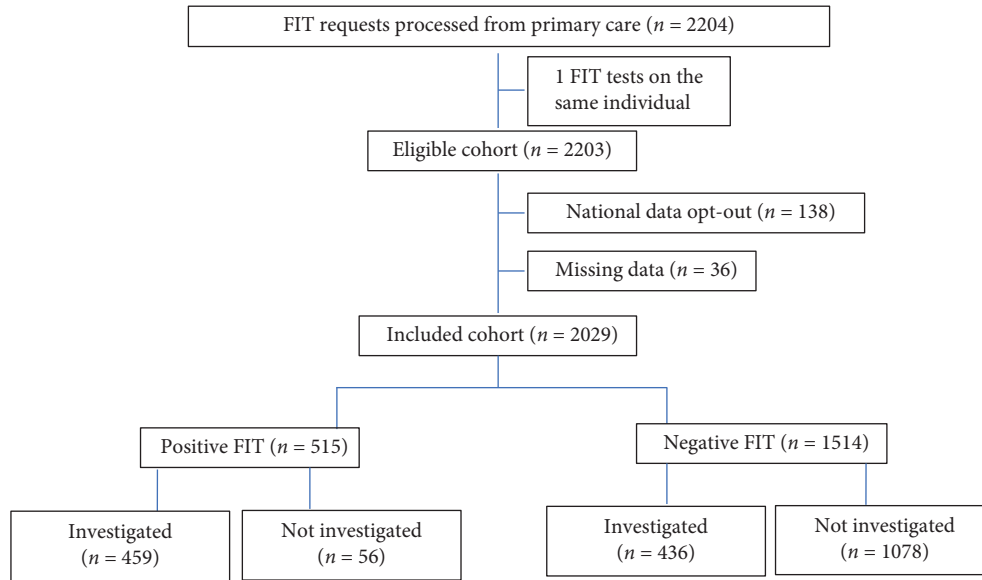


FIGURE 1: Study flow diagram.

TABLE 1: Patient demographics.

Characteristic		N	%
Total		2029	100
Sex	Women	1122	55.3
	Men	906	44.7
Age (years)	Mean	66.4	
	SD	15.4	
	Median	69	
	Minimum	17	
	Maximum	100	
Age group (years)	< 41	116	5.7
	41–50	212	10.4
	51–60	368	18.1
	61–70	406	20
	71–80	533	26.3
	81–90	348	17.2
	91–100	46	2.3
Index of deprivation	Mean	4.6	
	SD	2.9	
	Median	4	
Symptom risk category	NG12 criteria	722	35.6
	DG30 criteria	1177	58.0
	Other	130	6.4
FIT result	Positive	515	25.4
	Negative	1514	74.6

prevalence of 1.2% was identified. At the $\geq 10 \mu\text{g}$ Hb/g threshold, FIT demonstrated 91.7% sensitivity and 75.4% specificity for CRC detection. This cutoff yielded a 4.3% PPV and a 99.9% NPV. Two FIT negative CRCs were identified in the proximal colon. This is in keeping with our previous study, which identified false-negative FIT results having an association with proximal colonic cancers [11]. Elevating FIT thresholds improved PPV, but compromised sensitivity and reduced CRC detection rates.

TABLE 2: Findings from lower gastrointestinal investigations.

Diagnosis	N	%
Normal	498	56.8
Diverticulosis	150	17.1
Low-risk polyp	80	9.1
High-risk polyp	47	5.4
Perianal disease*	47	5.4
Colorectal cancer	24	2.7
Inflammatory bowel disease	19	2.2
Microscopic colitis	8	0.9
Angioectasia	4	0.5

*Perianal disease; haemorrhoids, anal fissure, anal fistula, and solitary rectal ulcer.

A key strength of this research lies in its focus within the primary care environment, which minimises selection bias. A further strength is the follow-up duration following FIT performance, which would have likely captured colorectal cancers that may have been initially missed by FIT. Our study is further bolstered by its comprehensive review of both primary and secondary healthcare records. Consistency in testing was ensured through the exclusive use of one laboratory and a single FIT method (OC Sensor) across all patients. The median age of our cohort (69 years) aligns with the peak CRC incidence age range (65–69 years), indicating that primary care clinicians were effectively targeting the most at-risk individuals [26].

Concerns have been expressed in a recent meta-analysis regarding heterogeneity in the definition of serious colorectal diseases in previous studies [27]. We have specifically addressed this by ensuring high-risk polyps fulfil BSG criteria [21], and that inflammatory bowel disease findings included only Crohn's disease and ulcerative colitis.

A significant constraint in our study stems from the fact that numerous patients with negative FIT results did not undergo colonoscopy or other examinations. This gap

TABLE 3: Diagnostic accuracy of FIT for CRC detection at differing faecal haemoglobin cutoff values.

Cutoff (ug/g)	Positivity N (%)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	TP	FN	FP	TN
10	515 (25.4)	91.7 (71.5–98.5)	75.4 (73.5–77.3)	4.3 (2.8–6.5)	99.9 (99.5–99.97)	22	2	493	1512
20	341 (16.8)	87.5 (66.5–96.7)	84.0 (82.3–85.6)	6.2(3.9–9.4)	99.8 (99.4–99.95)	21	3	320	1685
50	208 (10.2)	75.0 (52.9–89.3)	90.5 (89.1–91.8)	8.7 (5.4–13.5)	99.7 (99.2–99.86)	18	6	190	1815
80	159 (7.8)	58.3 (36.9–77.2)	92.7 (91.5–93.8)	8.8 (5.0–14.6)	99.5 (99.0–99.73)	14	10	145	1860
120	120 (5.9)	54.2 (33.2–73.8)	94.7 (93.6–95.6)	10.8 (6.1–18.1)	99.4 (98.9–99.70)	13	11	107	1898
150	106 (5.2)	45.8 (26.2–66.8)	95.3 (94.2–96.1)	10.4 (5.5–18.2)	99.3 (98.8–99.62)	11	13	95	1910

TABLE 4: Diagnostic accuracy of FIT for detection of serious colorectal disease (CRC/ high-risk polyps and IBD) at differing faecal haemoglobin cutoff values.

Cutoff (ug/g)	Positivity N (%)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	TP	FN	FP	TN
10	515 (25.4)	91.4 (83.3–95.9)	77.8 (75.9–79.6)	16.5 (13.5–20.1)	99.5 (98.9–99.8)	85	8	430	1506
20	341 (16.8)	67.7 (57.1–76.9)	85.6 (83.9–87.2)	18.5 (14.6–23.1)	98.2 (97.4–98.8)	63	30	278	1658
50	208 (10.2)	51.6 (41.0–62.0)	91.7 (90.4–92.9)	23.0 (17.7–29.5)	97.5 (96.7–98.2)	48	45	160	1776
80	159 (7.8)	44.1 (33.9–54.7)	93.9 (92.7–94.9)	25.7 (19.3–33.4)	97.2 (96.3–97.9)	41	52	118	1818
120	120 (5.9)	37.6 (28.0–48.3)	95.6 (94.6–96.4)	29.1 (21.4–38.3)	97.0 (96.1–97.7)	35	58	85	1851
150	106 (5.2)	35.5 (26.0–46.2)	96.2 (95.3–97.0)	31.1 (22.7–41.0)	96.9 (96.0–97.6)	33	60	73	1863

TABLE 5: Characteristics of the 24 CRCs diagnosed.

Variable		N	%	FIT cutoff		p value
				< 10 µg/g	≥ 10 µg/g	
Sex						
Female		13	54.2	0	11	0.48
Male		11	45.8	2	11	
Age group (years)						
< 40						0.87
41–50		1	4.2	0	1	
51–60		4	16.7	0	4	
61–70		3	12.5	0	3	
71–80		6	25.0	1	5	
81–90		7	29.2	1	6	
91–100		3	12.5	0	3	
Index of deprivation						
1		3	12.5	0	3	0.74
2		3	12.5	0	3	
3		3	12.5	1	2	
4		6	25.0	1	5	
5		3	12.5	0	3	
6		2	8.3	0	2	
7		3	12.5	0	3	
8		0	0.0	0	0	
9		1	4.2	0	1	
10		0	0.0	0	0	
Tumour site						
Proximal colon	Caecum	6	25.0	1	5	0.25
	Ascending colon	2	8.3	0	2	
	Hepatic flexure	1	4.2	0	1	
	Transverse colon	2	8.3	1	1	
	Splenic flexure	0	0.0	0	0	
Distal colon	Descending colon	0	0.0	0	0	
	Sigmoid colon	4	16.7	0	4	
	Rectosigmoid	0	0.0	0	0	
	Rectum	9	37.5	0	9	

TABLE 5: Continued.

Variable	N	%	FIT cutoff		<i>p</i> value
			< 10 µg/g	≥ 10 µg/g	
<i>Number stage of CRC</i>					
1	4	16.7	0	4	0.13
2	8	33.3	1	7	
3	10	41.7	0	10	
4	2	8.3	1	1	
<i>Anaemia</i>					
Yes	7	29.2	0	7	0.34
No	17	70.8	2	15	

introduces the possibility of verification bias, potentially inflating FIT sensitivity estimates due to an artificially lowered CRC prevalence figure. It is recognised, however, that neither colonoscopy nor CT colonography are a 100% accurate [28, 29]. Therefore, using follow-up as done in our study allows potential identification of any missed cases, with previous research suggesting a missed CRC will represent to primary or emergency care within 6 months of the initial consultation [30]. The underlying assumption here being that CRC and IBD typically present with escalating or persisting symptoms, prompting additional diagnostic procedures over time [30].

Despite the general adherence to NICE NG12 and DG30 guidelines in primary care patient management, a small subset ($n = 130$) fell outside these established criteria, presenting an additional study limitation. This may reflect challenges in utilising symptom-based criteria in primary care or reflective of evidence that FIT better predicts CRC risk than symptoms [31]. This evidence of divergent FIT practice supports ongoing national projects (e.g., COLOFIT, NICE guidance update) aimed to better risk-stratify individuals and enhance primary care implementation [32, 33]. We also recognise that the relatively small number of colorectal cancers ($n = 24$) detected in our study is a limitation when drawing conclusions, particularly regarding the characteristics of these cancers presented in Table 5. To address this limitation, we recommend future research involving larger, multicentre cohorts of symptomatic primary care patients. Such studies could provide more robust data on FIT performance across various cancer characteristics, including stage, location and histological type.

The CRC prevalence of 1.2% in our study closely aligns to the 1.5% prevalence seen in a recent and similar primary care study from Nottingham [18]. That work also excluded rectal bleeding, which is associated with an increased CRC risk. FIT use for this indication is now recommended in national guidelines [34]. Further studies to assess the diagnostic accuracy of FIT in this patient group within a “real-world” setting are now merited, with recent primary care population cohorts demonstrating varying CRC prevalence rates between 1.1% and 3.1% [16, 35, 36].

The finding that FIT has a high negative predictive value at a threshold $\geq 10 \mu\text{g Hb/g}$ in both DG30 and NG12 patients follows previous meta-analysis findings [6]. Our work would also support FIT being able to safely triage patients who may not strictly fulfil these criteria. Cumulatively, these findings

support safety-netting approaches in primary care in those having a negative FIT ($< 10 \mu\text{g Hb/g}$), which could reduce burden on currently overwhelmed 2WW diagnostic pathways [34].

The optimal pathway for patients having a negative FIT result remains to be established. This group of patients includes those with minor symptoms that may settle without intervention, patients with troublesome symptoms that need early assessment, as well as a very small number of patients who may have an underlying malignancy (both colorectal and noncolorectal). To manage this, there currently exists the concept of “safety netting” [34]. Traditionally, safety-netting referred to advice being given to patients if their symptoms were to worsen. However, this term now encompasses referral on alternative cancer pathways, referrals to differing pathways (non-2WW), repeating a FIT or gaining secondary care advice. For safety netting to be successful and acceptable to patients, these processes need to be robust, well defined and tested to ensure their safety.

5. Conclusions

FIT is demonstrated to be an appropriate triage test for investigating patients in primary care with symptoms supportive of serious colonic pathology. It safely delineates those requiring urgent investigations and supports safety netting approaches in those with negative findings. Future research should now focus on comparisons between differing FIT analysers used for measuring f-hb, appraisal of safety-netting approaches and assessment of repeated FIT. These considerations to enhance FIT accuracy need to be considered in the context of NHS resource use and costs and informed by patient/stakeholder acceptability.

Data Availability Statement

The data that support the findings from this study are available from the corresponding author upon reasonable request. This sharing of data would require agreement from the study sponsor (Sheffield Teaching Hospitals) and completion of a data sharing agreement.

Ethics Statement

The HRA and Health and Care Research Wales (HCRW, IRAS ID 291908) provided ethical clearance, while Sheffield Teaching Hospitals (STH22153) granted research approval.

Conflicts of Interest

The authors declare no conflicts of interest.

Author Contributions

AJB, IA, RS and MK designed the study. AJB, IA, MR, AM, and MK all contributed to data collection and data governance. MK and AJB carried out the data analysis. MK, AJB and IA wrote the first draft of the manuscript. All authors reviewed and revised the manuscript. MK is responsible for the overall content as the guarantor. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section.

Supporting Information. Supporting Table 1: Diagnostic Accuracy of FIT to detect CRC using symptom criteria.

Supporting Information. Supporting Figure 1: ROC curve of FIT for CRC detection.

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