



ORIGINAL ARTICLE

Adoption of faecal immunochemical testing for 2-week-wait colorectal patients during the COVID-19 pandemic: an observational cohort study reporting a new service at a regional centre

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Abstract

Aim: The COVID-19 pandemic has resulted in the near-complete loss of routine endoscopy services. We describe a major reorganization of service at a regional referral centre (Royal Surrey NHS Foundation Trust) to manage the crisis. Faecal immunochemical testing (FIT) was implemented for triage to make optimum use of limited diagnostic resources. Consultations were switched from face-to-face to telephone. Our aim was to evaluate the impact FIT had on resource allocation and patient diagnoses in the first 3 months of use.

Method: All colorectal 2-week-wait patient referrals were posted a pack requesting FIT and notification of telephone consultation. A prepaid envelope was included for return of the samples. At consultation, FIT was incorporated with the presenting symptoms to guide the choice of investigation and triage urgency. FIT ≥ 10 $\mu\text{g/g}$ was interpreted as positive. Outcome data were collected prospectively and compared with retrospective audit data from pre-pandemic levels across 3 months.

Results: From 26 March 2020 to 2 July 381 patients were referred who were invited to provide FIT samples and underwent telephone consultations. Three hundred and fifty eight FIT samples were returned (94%). Onward referral for colonoscopy reduced from 62% to 34% ($P < 0.001$). There were 14 colorectal cancers (CRC) (3.7%) diagnosed, which was not statistically different from the pre-pandemic level of 3.9% ($P = 0.995$). Twelve of the 14 patients with a CRC diagnosis had provided samples; all 12 had FIT ≥ 10 $\mu\text{g/g}$ and were offered fast-track investigations.

Conclusions: The incorporation of FIT optimized the allocation of limited resources to triage those who required urgent colonic investigation for detecting CRC.

KEYWORDS

COVID-19, endoscopy, faecal immunochemical testing, two-week-wait

1 | INTRODUCTION

The COVID-19 pandemic has been an unprecedented challenge for the healthcare system, which has had to deal with a surge in hospitalizations generated by severe acute respiratory syndrome coronavirus 2. Across the NHS, elective surgery has been postponed and outpatient appointments suspended, and staff have been reassigned. In a rapid reprioritization of care surgical specialties have proceeded with only selected operations, and surgery in COVID-19-positive patients has generally been avoided [1–3]. For colorectal cancer (CRC), deferral to nonsurgical modalities for Stage II/III rectal and metastatic CRC has been a workable alternative [1]. These measures have shaped care for known disease, but difficulties remain in the diagnosis of CRC at the point of referral from primary care.

From mid-March 2020, routine access to colonoscopy became unavailable. Faecal occult blood testing requests from the NHS colorectal screening pathway were therefore paused nationally. However, the 2-week-wait (TWW) pathway for fast-track referrals from primary care continued, although there was an initial fall in referral numbers. The resultant delay in cancer diagnoses is likely to have a downstream impact on patient outcomes and mortality. The Office for National Statistics has reported that excess mortality has increased by a factor greater than can be explained solely by those who had ‘coronavirus’ listed on their death certificate [4]. Italy has already reported a drop in cancer diagnoses by 39% this year [5].

There has been a critical need to continue the triage of referrals to identify emergent cancers in the community. This has had to be conducted remotely and at scale. Faecal immunochemical testing (FIT) quantifies haemoglobin in faeces and is sensitive to the presence and severity of colorectal neoplasia [6]. At very low thresholds (<10 µg Hb/g faeces), FIT has a high sensitivity and negative predictive value for CRC [7,8]. It can therefore be a valuable tool in triage for symptomatic patients as a ‘rule out’ test in both primary and secondary care.

In 2017, the National Institute for Health and Care Excellence (NICE) published an update to the criteria (NG12) for TWW referrals from primary care with new diagnostic guidelines called DG30 [9]. This recommends the use of FIT for the detection of faecal occult blood, but can be only used for low-risk patients and a TWW referral is made if the FIT result is ≥ 10 µg/g [9]. There were no recommendations about the use of FIT for patients in a higher risk category or for its use in secondary care diagnosis. Studies with large datasets have demonstrated the advantage of using FIT for triaging both high- and low-risk patients to TWW referral from primary care [10–14]. However, there are limited data for FIT once at secondary care and the impact it has on resource allocation from the clinician.

When normal access to colonoscopy services was stopped due to the COVID-19 pandemic, the Royal Surrey NHS Foundation Trust (RSFT) redesigned the TWW colorectal pathway to incorporate FIT. We report the cancer diagnostic outcomes and their relationship to FIT results and the change in resource allocation.

What does this paper add to the literature?

This was a novel service redesign to meet the challenges of resource limitations during the COVID-19 crisis. Existing literature shows how faecal immunochemical testing (FIT) correlates with diagnostic outcomes. This paper provides information about how the application of FIT can change practice for patients with high-risk symptoms and reduce the need for diagnostic colonoscopy.

2 | METHOD

2.1 | Two-week-wait service redesign

Prior to COVID-19, patients referred on the colorectal TWW pathway were reviewed in face-to-face clinic appointments and triaged to investigations. From 26 March 2020, all TWW colorectal patient referrals from primary care to RSFT were offered a telephone consultation. They were contacted by a member of the booking team prior to the appointment to confirm contact details. At telephone consultation, a future face-to-face appointment could be requested if required.

Each patient was sent a pack 7–10 days prior to their telephone consultation. This contained the appointment details and two FIT collection devices (OC-Sensor™, Eiken Chemical Co., and QuikRead Go, Aidian Oy). The pack also contained a letter requesting the samples, an instruction leaflet and a prepaid return envelope.

2.2 | Handling of samples

Further details of specimen collection and handling, analysis, quality management and result handling can be found in Appendix S1 in the Supporting Information where these headings are described according to the FITTER checklist. Completed OC-Sensor™ (Eiken Chemical Co.) tubes were returned in the prepaid envelope and analysed at the routine blood sciences laboratory at RSFT. Analysis was carried out using a United Kingdom Accreditation Service-recognized method by a state-registered biomedical scientist. The QuikRead Go (Aidian Oy) tubes were analysed separately as part of an on-going study.

2.3 | Triage of patients

Triage decision from the telephone consultation was based on the FIT result from the OC-Sensor and clinical concerns about symptomatology. All patients were asked to perform FIT regardless of symptomatology, and therefore those with iron-deficiency anaemia or per rectal bleeding were included. A FIT result of ≥ 10 µg/g was interpreted as positive and patients with FIT ≥ 150 µg/g were prioritized. Decisions for urgent colonoscopy were discussed on a case-by-case

basis in line with the national British Gastroenterology and Joint Advisory Group guidance released in response to COVID-19 [15]. Colonoscopy was replaced by CT colonography when endoscopy access was limited or when it was felt to be more clinically appropriate.

Patients were categorized into three groups by their FIT results: (1) $<10 \mu\text{g/g}$; (2) $\geq 10 \mu\text{g/g}$ but $<150 \mu\text{g/g}$; and (3) $\geq 150 \mu\text{g/g}$. A patient tracker list (PTL) was commenced for those with FIT $<10 \mu\text{g/g}$ but with concerning symptoms or for those with FIT $\geq 10 \mu\text{g/g}$ but $<150 \mu\text{g/g}$ without concerning symptoms [16]. Concerning symptoms were classed as all those that met the criteria set out by NG12 guidance [17]. The PTL was also utilized for those shielding or those choosing to avoid hospital for investigations at the time of COVID-19. Individuals with FIT $<10 \mu\text{g/g}$ were discharged to their general practitioner (GP) if symptoms did not meet NG12 criteria or if they had resolving symptoms (Figure 1). Discharged patients were safety netted with recommendations to review with their GP if symptoms returned or persisted. In such instances, the GP was recommended to re-refer on the TWW pathway.

The FIT result for OC-Sensor interpretation was in accordance with local guidance from the Surrey and Sussex Cancer Alliance (SSCA) published in response to the COVID-19 crisis (Figure 2) in May 2020 [18]. This recommended FIT $<10 \mu\text{g/g}$ as a negative result and that those with FIT $\geq 150 \mu\text{g/g}$ required prioritization. In the first 2 months, if the FIT result was $\geq 10 \mu\text{g/g}$ and $<150 \mu\text{g/g}$ then CT colonography was commonly performed instead of colonoscopy as there was greater availability. Later (June 2020) NHS England dropped the upper threshold from 150 to $100 \mu\text{g/g}$ [16]. At the time this did not change practice as PTL was no longer required due to the return of normal availability of endoscopy in the Trust. Data collection for both SSCA and NHS England FIT criteria was maintained.

2.4 | Inclusion and exclusion criteria

All patients referred between 26 March and 2 July 2020 on the colorectal TWW pathway to RSFT were included. Patients were excluded if they cancelled or if they were hospitalized at the time of consultation.

2.5 | Data

Two-week-wait referrals are routinely entered into a secure prospective database within the Trust. Additional data regarding FIT results, choice of investigation and diagnostic outcomes were added prospectively from 26 March 2020 to ensure clinical governance of the novel service. The same data were collected from a retrospective audit of TWW patients referred between 1 October and 31 December 2019 to allow comparison between pre- and post-COVID-19 patient management. Inclusion and exclusion criteria for the retrospective audit were no different. Audit registration was approved from the Patient Safety and Quality department at RSFT.

2.6 | Statistics

Comparison of the utilization of investigations and diagnoses of CRC pre- and post-COVID-19 were made using chi-square testing. Statistical significance was determined by $P < 0.05$. The 95% confidence intervals were calculated using the Wilson procedure with a correction for continuity.

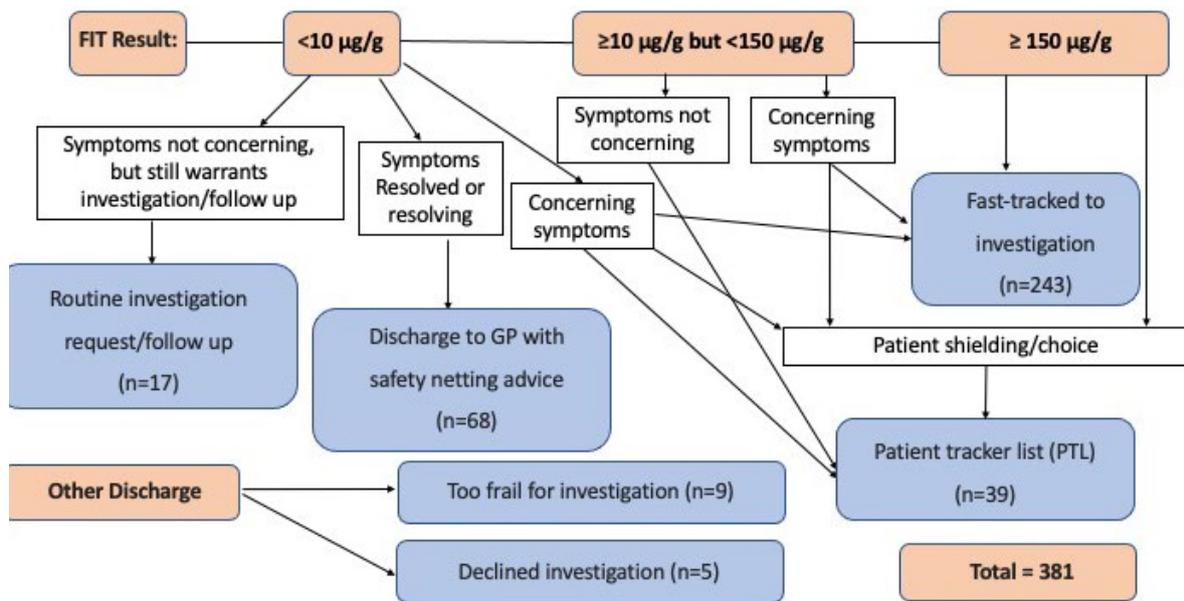


FIGURE 1 Pathway for triage of investigations used in response to COVID-19 with the Royal Surrey NHS Foundation Trust.

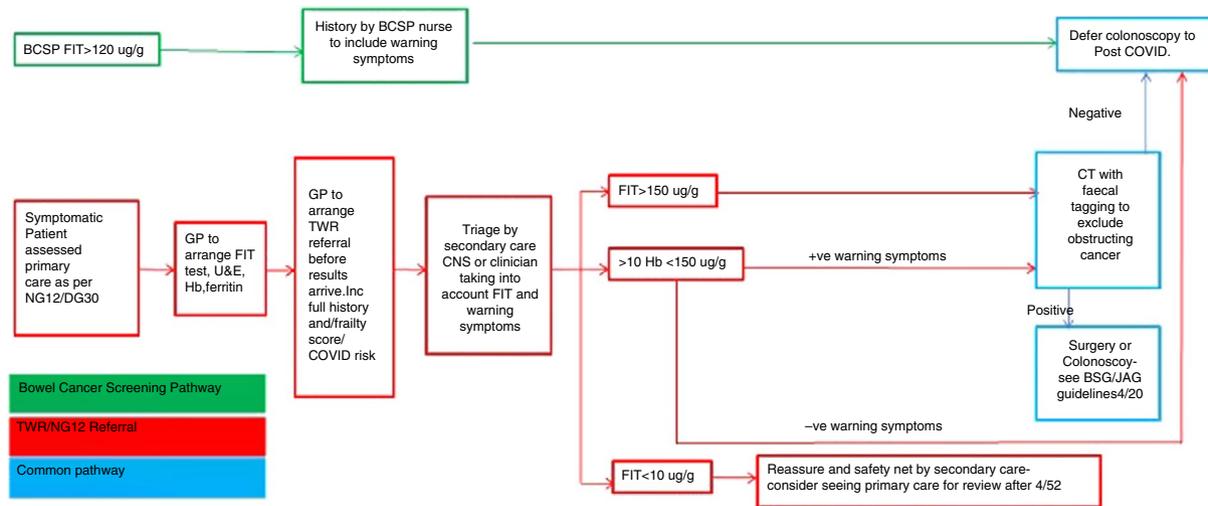


FIGURE 2 Surrey and Sussex Cancer Alliance care pathway for 2-week-wait referrals (May 2020) [18]. BCSP, Bowel Cancer Screening Programme; BSG, British Society of Gastroenterology; DG30, Diagnostic Guidelines as part of NG12 criteria; updated guidelines; FIT, faecal immunochemical testing; GP, general practitioner; Hb, haemoglobin; JAG, Joint Advisory Group; NG12, National Institute for Health and Care Excellence (NICE) updated criteria; U&E, urea and electrolytes; CNS, Clinical Nurse Specialist.

3 | RESULTS

From 26 March to 2 July 2020 there were 391 colorectal TWW referrals. Ten patients were excluded due to five hospitalizations and five cancellations, leaving 381 referrals for analysis.

3.1 | Adherence

Of 381 patients undergoing telephone consultation, 358 (94%) returned samples. Twenty-three (6%) patients did not return samples,

of whom five reported never receiving sampling kits. Overall adherence was 95%. Results were available at telephone consultation 72% of the time. Seven patients were booked for a face-to-face appointment following the telephone consultation.

3.2 | Cancer diagnoses and FIT results

Out of 381 patients reviewed in telephone clinic, the number diagnosed with CRC was 14 (3.7%, confidence interval 2.1–6.2%). There was no difference compared with the proportion diagnosed with

FIT result	Primary referral reason	Site in colon	Primary diagnostic modality
27	Weight loss	Ascending	Colonoscopy
31	Change in bowel habit	Sigmoid	Colonoscopy
41	Change in bowel habit	Sigmoid	Flexible sigmoidoscopy
44	Iron-deficiency anaemia	Hepatic flexure	Colonoscopy
45	Lower abdominal pain	Rectum	CT colonography
51	Per rectal bleeding	Rectum	Colonoscopy
117	Change in bowel habit	Caecum	Colonoscopy
190	Per rectal bleeding	Sigmoid	Colonoscopy
465	Per rectal bleeding	Rectum	Colonoscopy
524	Change in bowel habit	Rectum	Colonoscopy
1393	Per rectal bleeding	Rectum	Colonoscopy
4666	Change in bowel habit	Sigmoid	CT colonography
Did not perform	Per rectal bleeding	Transverse	Colonoscopy
Did not perform	Abdominal pain and vomiting	Caecum	CT chest, abdomen and pelvis

TABLE 1 Faecal immunochemical test (FIT) results for the 14 colorectal cancer diagnoses according to symptomology

CRC in the pre-COVID-19 cohort, which was 23 out of 590 patients (3.9%, CI 2.5–5.9%, $P = 0.995$). For those triaged to endoscopy or CT colonography, the proportion diagnosed with CRC increased compared with the pre-COVID-19 cohort but was not statistically significant. There were 13 out of 234 patients with CRC (5.6%, CI 3.1–9.5%) compared with 22 out of 501 patients in the pre-COVID group (4.4%, CI 2.8–6.7%, $P = 0.255$). There was one less CRC patient in each of these groups as they were diagnosed by plain CT abdomen and pelvis and adenocarcinoma was later confirmed by the resection histology.

Twelve of the 14 patients with CRC provided samples and all had FIT ≥ 10 $\mu\text{g/g}$. Table 1 shows the breakdown of FIT results according to symptomatology for those with CRC. Ten of the 14 patients were prioritized to colonoscopy and two to CT colonography. Two patients did not undergo these as their primary investigation for patient-specific reasons. Table 2 shows the categorization of the 358 sample results for the OC-Sensor. Using the SSCA guidance for categorization, 246 (69%) were < 10 $\mu\text{g/g}$, 79 (22%) were ≥ 10 and < 150 $\mu\text{g/g}$, and 33 (9%) were ≥ 150 $\mu\text{g/g}$.

Out of 381 patients there were also four solid organ non-CRC diagnoses; three out of four of these patients had FIT < 10 $\mu\text{g/g}$. Two further patients had concerning symptoms and returned high FIT results (≥ 150 $\mu\text{g/g}$), but both declined investigation due to frailty and have since died.

3.3 | Further clinical investigation

Table 3 shows the comparison of investigation choices compared with prepandemic levels. Those sent for colonoscopy reduced from 62% (CI 58–66%) to 34% (CI 29–39%, $P < 0.001$). Discharge to primary care without endoscopy or other imaging investigations increased from 5.3% (CI 3.7–7.5%) to 22% (CI 18–26%, $P < 0.001$).

From 381 patients, 82 (22%) patients were discharged to their GP with safety netting at the telephone consultation. Of these 82 patients, 50 (61%) were had FIT < 10 $\mu\text{g/g}$ with non-NG12 or resolving symptoms. Eighteen (22%) had resolved symptoms, nine (11%) were deemed too frail for investigation and five (6%) were through patient choice. PTL was stopped after 2 months when diagnostic services were able to resume at full capacity. Thirty nine patients were placed on the PTL and all have since been investigated. There was one diagnosis of CRC from this group in a patient with a positive FIT (44 $\mu\text{g/g}$) but who had declined urgent investigation at the hospital due to personal concerns about COVID-19.

4 | DISCUSSION

In this study, rapid implementation of FIT has successfully been incorporated into the management of symptomatic colorectal patients on the TWW pathway. Those with CRC were successfully triaged to their investigations for timely diagnosis. This pathway followed both local and national guidance [16,18]. The proportion of CRC diagnoses from all referrals did not statistically differ from pre-COVID-19 levels despite colonoscopy rates being reduced by 28%, suggesting more effective utilization of this resource. In addition, there was a high level of compliance in providing samples (95%), which demonstrates how patients are able and willing to perform FIT.

Recognition of concerning symptoms even in the presence of a FIT < 10 $\mu\text{g/g}$ is essential. If a negative FIT is obtained this can direct clinicians to more appropriate modalities such as CT colonography. In this study, incorporation of both FIT and symptomatology not only maintained rates of CRC diagnosis with limited resources but appeared to guide diagnostic modality. Colonoscopy alone would have missed the four non-CRC solid organ cancers. This supports the guidance from SSCA and NHS England that patients must not be triaged on the basis of FIT alone [16,18]. Primary care referrals

TABLE 2 Faecal immunochemical test (FIT) results by guidance of Surrey and Sussex Cancer Alliance (SSCA) and NHS England categories for 358 patients

FIT result by category	Number (%)	Number of confirmed CRC diagnosis (% within category)	Cancers of non-CRC origin (% within category)
SSCA ($\mu\text{g/g}$)			
<10	246 (69%)	0 (0%)	3 (75%)
≥ 10 and < 150	79 (22%)	7 (8.9%)	1 (25%)
≥ 150	33 (9%)	5 (15.2%)	0
NHS England ($\mu\text{g/g}$)			
<10	246 (69%)	0 (0%)	3 (75%)
≥ 10 and < 100	68 (19%)	6 (8.8%)	1 (25%)
≥ 100	44 (12%)	6 (13.6%)	0
Total of returned FIT	358	12 (3.4%)	4 (1.1%)
No FIT sample returned	23	2 (8.7%)	0
Total of telephone triaged patients	381	14 (3.7%)	4 (1.0%)

Abbreviation: CRC, colorectal cancer.

TABLE 3 Outcome decisions from telephone consultations from 26 March to 2 July 2020 compared with previous audit data for 1 October to 31 December 2019

	26 March to 2 July 2020 (percentage of total)	1 October to 31 December 2019 (percentage of total)	P-value
Colonoscopy ± OGD ± CT abdomen/pelvis	129 (34%)	365 (62%)	<0.001
Flexible sigmoidoscopy ± CT abdomen/pelvis	31 (8%)	51 (8.6%)	0.787
CT colonography	74 (19%)	85 (14%)	0.392
CT abdomen/pelvis	46 (12%)	40 (6.8%)	0.005
Other	19 (5%)	18 (3.0%)	0.124
Discharged	82 (22%)	31 (5.3%)	<0.001
Total	381	590	

Abbreviation: OGD, oesophago-gastro-duodenoscopy.

to other specialties may be more appropriate in those with negative FIT results, although there is no pathway locally for this at the time of writing. The *British Journal of General Practice* reports a successful pilot of a rapid cancer diagnosis pathway for those with vague symptoms. If run at above 80% capacity it is cost-effective and shows a reduction in mean time to diagnosis [19].

Public Health England's report on its 'Routes to Diagnosis Study', which was conducted between 2006 and 2013, stated that there was a survival benefit of earlier diagnosis in CRC [20]. Of all colorectal TWW referrals, 3–4% will end up with a diagnosis of CRC and this service ultimately identifies 30% of all cases [17,20,21]. Between 2009 and 2014 at RSFT, the yield for CRC, from an average of 709 referrals per annum, was 7.5%. Between 2017 and 2018, the number of referrals doubled to 1414 but the yield halved to 3.6% [22]. The percentage reduction in diagnostic yield has been experienced by other referral centres and the resultant increase in demand for colonoscopy has been criticized [23–26]. This study demonstrates that the use of FIT can reduce the proportion of patients referred to colonoscopy by 28% without any loss in CRC yield.

Nationally, the number of endoscopy cases per year in the UK had been set to increase from 1.7 million in 2015 to over 2.4 million in 2020 [27]. A diagnostic colonoscopy costs the NHS GBP 372–419 [7,12] so this demand is costing the NHS at least GBP 260 million extra each year. Prior to COVID-19, the availability of endoscopists and endoscopy resources within the UK was already stretched to capacity, with only 55% of services meeting their urgent cancer waiting times; further demand without increased capacity is unsustainable [25]. The impact of reducing TWW colonoscopy would help this situation and offer substantial cost-saving benefits or allow reallocation of colonoscopy resources. Such liberated colonoscopy services could be used to reduce the screening FIT threshold (currently 120 µg/g in England). This would facilitate better detection of asymptomatic cancers in the population.

An improved triage protocol is required to cope with the increasing number of TWW referrals. Early data are available from the NICE FIT study. This is a multicentre observational study involving 7194 patients undergoing colonoscopy in the high-risk

category for CRC. For those patients FIT has a sensitivity for CRC of 97.7% and 92.2% using a cut-off of <2 and <10 µg/g, respectively [13]. Pickhardt et al. determined that colonoscopy has a sensitivity for CRC of 94.7% (CI 90.4–97.2%) [28]. This suggests that FIT is at least equivalent to colonoscopy as a 'rule out' investigation for CRC.

Prior to COVID-19, other centres have reported successful initiatives using straight-to-test pathways following telephone triage [29–31]. Telephone consultations have been widely implemented by surgical teams in response to COVID-19 [32]. This has been particularly beneficial for vulnerable groups who are at significant risk from COVID-19 transmission. In our experience, patients themselves were often unwilling to attend clinic in person due to the perceived risk of hospital attendance during the pandemic. Use of the telephone consultation enabled remote access for discussion of symptoms and triage. Only seven patients required urgent face-to-face appointments to allow clinical examination following the telephone assessment.

In this study, the follow-up time is short and there may be missed diagnoses yet to be determined from those with FIT <10 µg/g. However, our proportion of patients diagnosed with CRC is not statistically different from those diagnosed prior to introduction of the new pathway. There may have been selection bias in our cohort, as the number of TWW referrals in the 3-month period was less than pre-COVID levels. During the pandemic, GPs may have selected out those about whom they had more clinical concern.

This is a single-centre experience over a short period and was carried out at a time of crisis. Patient choice towards accepting investigations and clinician choice are likely to change as we emerge from the pandemic. Therefore, the change in colonoscopy referrals may not fully reflect the impact of the pathway under normal circumstances. Longer follow-up and use of multicentre data will further elucidate these limitations.

The colorectal team at RSFT will aim to continue incorporating FIT into all TWW referrals as we have shown it to be an effective triage tool with respect to resource management. We do not plan to perform colonoscopy on those we discharged during the study period with FIT <10 µg/g unless they are re-referred by primary care. These patients were safety netted to present again should



their symptoms worsen or persist. Larger datasets from studies such as NICE FIT and Nottingham demonstrate a high sensitivity to CRC at low thresholds with a high negative predictive value [12,13]. Combining a low-threshold negative FIT result with resolving short-term symptoms poses an even lower likelihood of missing a CRC and the safety net was employed to mitigate the chances even further.

A limitation of our described pathway is the delay generated between sending the packs out and obtaining a FIT result available for the telephone consultation. This impact on the 28-day diagnostic target can be negated if primary care requests FIT at the point of referral, which is in line with the local SSCA guidance [18]. A local communication to primary care has been disseminated, requesting FIT to be arranged for all TWW colorectal referrals. In addition, as our diagnostic services have regained capacity we have been able to meet original TWW targets and no longer require the PTL.

5 | CONCLUSIONS

In response to the COVID-19 pandemic, we have rapidly adopted a new, safe and effective pathway by incorporating FIT for the triage of TWW patients. Routine use of FIT served as an invaluable adjunct allowing the identification and prioritization of those in most need of colonoscopy, and improved rationalization towards alternative investigations. This enabled access to colonoscopy for those most in need at the same time as reducing the overall proportion of those undergoing colonoscopy.

CONFLICT OF INTEREST

None declared.

AUTHOR CONTRIBUTIONS

WM, as Principle Investigator, provided conception and design of work; acquisition, analysis and interpretation of data; drafting of the article. CL and PM provided substantial contributions in acquisition, analysis and interpretation of data; drafting and critical revision of the article. MW provided substantial contributions to design of the work; data interpretation; critical revision of the article for intellectual content. SB provided substantial contributions to conception and design of the work; data interpretation; expertise in faecal immunochemical testing; critical revision of the article for intellectual content. TR and IJ provided substantial contributions to conception and design of the work; data interpretation; expertise in colorectal cancer diagnostics; critical revision of the article for intellectual content. All authors read and approved the final manuscript. All authors have agreed to be accountable for all aspects of the work.

ETHICAL CONSIDERATION

This study is a service evaluation following changes established in line with national guidance in response to COVID-19. Using the Health Research Authority Medical Research Council decision tool, ethical approval was not required.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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SUPPORTING INFORMATION

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

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