INTRODUCTION

The faecal immunochemical test (FIT) is proving to be a satisfactory replacement for the faecal occult blood test in the National Bowel Cancer Screening Programme [1]. The FIT has proved to be more acceptable to the population and better at detecting colorectal cancer (CRC) and high risk adenomas [2]. Even before the COVID-19 pandemic, FIT had proved useful in triaging patients referred on the urgent CRC pathway (National Institute for Health and Care Excellence [NICE] clinical guidelines NG12 for suspected cancer) to endoscopy [3].

The use of the faecal immunochemical test during the COVID-19 pandemic to triage urgent colorectal cancer referrals

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Abstract
Aim: During the first wave of the COVID-19 pandemic in 2020, elective gastrointestinal endoscopy services were abbreviated for fear of viral transmission. However, urgent suspected colorectal cancer (CRC) referrals continued. Serendipitously, a national study suggested that a new faecal immunochemical test (FIT) might be helpful in triaging patients with colorectal alarm symptoms.

Methods: This was a single centre observational study of patients referred using NG12 criteria between March and August 2020. Patients were triaged to the urgent cancer pathway for FIT ≥ 10 μg/g and investigated using the latest National Health Service England guidance. Demographic data, method of investigations, cancer and polyp detection rates were compared to patients referred in the 6 months prior to the use of FIT as a triage tool.

Results: In all, 1192 patients (median age 70) were referred using NG12 guidelines during the pandemic period, compared with 1592 patients (median age 72) in the previous 6 months. CRC detection was similar in both groups (n = 45, 2.8% vs. n = 38, 3.5%; P = 0.248). Two patients with a negative FIT (0.36%) had CRC. Using FIT as a triage tool resulted in a significant reduction in the use of endoscopy (n = 477, 43.6% vs. n = 1186, 74.5%; P < 0.001) with a significant increase in CT scanning (n = 696, 63.6% vs. n = 750, 47.1%; P < 0.001).

Conclusion: The use of FIT in NG12 patients triaged during the first wave of the COVID-19 pandemic reduced endoscopy but not CT scanning and did not compromise CRC detection rates. It is a safe method that aids in reducing the burden on services greatly. A negative FIT test does not absolutely exclude CRC.

Keywords
colorectal cancer, FIT screening, urgent suspected cancer triage
During the first wave of the COVID-19 pandemic in March 2020, the British Society of Gastroenterologists and the Association of Coloproctology of Great Britain and Ireland (ACPGBI) issued guidance that only urgent colonoscopy should be performed. This reflected colonoscopy being potentially aerosol generating and the subsequent COVID-19 risk posed to staff and patients [4]. The guidelines recommended that clinicians should identify high-risk patients, determined by the nature of clinical signs and symptoms, and proceed to plain contrast CT imaging or, if available, CT colonography to identify any cancers. This was at a time of reduced staffing due to illness, self-isolation and redeployment.

In order to address the growing concerns and disturbance on healthcare services caused by the COVID-19 pandemic, we adopted the local alliance guidelines which stated that secondary care should use FIT to triage patients to an urgent and non-urgent pathway and that this should be issued but not interpreted by primary care [5].

The primary outcome of this study was to establish whether using FIT to triage patients referred under the urgent suspected cancer (USC) pathway was safe, in terms of any cases of CRC being missed in FIT-negative patients. Its sensitivity and specificity for CRC and significant polyps was also assessed. The secondary aim was to assess the impact on CT imaging and endoscopy utilization.

**METHODOLOGY**

Local ethical approval was granted by the trust’s audit department where this study was registered as an audit (Local registration number TASCC Colo 2020–06).

This was a single centre retrospective study based in a district general hospital in Surrey, UK, that serves a population of around 400,000 people. The study focused on all patients referred under the USC pathway as per NICE NG12 guidelines for suspected lower gastrointestinal cancer. Two cohorts of referrals were analysed: first, patients referred between 1 September 2019 and 28 February 2020 prior to the implementation of the FIT based triage (pre-FIT triage cohort); second, patients referred between 1 March 2020 and 31 August 2020 after the implementation of FIT triage (FIT triage cohort). Patients from the FIT triage cohort were followed up until the end of August 2021 in order to identify any FIT-negative pathology. Data between September 2019 and February 2020 were recorded retrospectively.

Patient eligibility included any patient above the age of 18 years who was referred under the USC pathway as per the NICE NG12 criteria pathway for CRC [6] (Table 1). Any patients who declined investigation or were lost to follow-up were excluded from this study. Lost to follow-up was defined as patients who did not attend consultations or booked investigations. Eligible patients were identified by the local cancer services department that keep a record of all patients referred under the USC pathway. Individual patient data were collected from the electronic patient records system available in the trust. All patient data were pseudonymized to maintain patient confidentiality.

| Recommended action                              | Criteria                                                                 |
|-------------------------------------------------|--------------------------------------------------------------------------|
| Refer using suspected cancer pathway            | Age >40  
• Unexplained weight loss  
• Abdominal pain  
• Age >50  
• Unexplained rectal bleeding  
• Age >60  
• Iron deficiency anaemia  
• Changes in bowel habit  
• Any age  
• Confirmed occult blood in faeces  
• Any age  
• Rectal or abdominal mass  
| Offer FIT to assess for colorectal cancer in adults without rectal bleeding | Age >50  
• Unexplained abdominal pain  
• Weight loss  
• Age <60  
• Change in bowel habit  
• Iron deficiency anaemia  
• Age >60  
• Anaemia even in the absence of iron deficiency |

**TABLE 1** The NICE NG12 guidelines for the referral of patients under the urgent suspected cancer pathway in the UK [6]

The primary end-point measured was whether the use of FIT triage to assess the need for further investigations in patients referred under the USC pathway for suspected lower gastrointestinal cancer was safe. Safety was defined by any cases of CRC that were diagnosed in patients with a negative FIT (faecal haemoglobin [f-Hb] <10 μg/g). Alongside CRC, other diagnoses that were focused on included significant polyps as per the current ACPGBI guidelines [7], diverticular disease, haemorrhoids and colitis.

Secondary end-points were the utilization of CT imaging and endoscopy in both pre-FIT and FIT triage based on the proportion of patients referred in each cohort undergoing these investigations compared to the total number of patients referred.

**Investigation pathway**

Each referral was triaged by a colorectal specialist nurse or consultant colorectal surgeon, where a combination of the f-Hb level from an FIT sample was assessed if it was available alongside patient symptoms. If the clinician triaging the patient felt that the patient suffered from any red flag symptoms that warranted urgent
investigation, then this was performed regardless of the FIT level. The choice of investigation, either CT imaging or endoscopy, was determined by the assessing clinician, being dependent on patient symptoms, comorbidity and frailty. A summary of the referral pathway for patients when FIT triage was implemented is displayed in Figure 1. When FIT was used to triage patients for investigations, patients who were not given an FIT sample collection kit in primary care were sent the OC-Sensor™ kit (Eiken Chemical Company Ltd) by our colorectal specialist nurse. All samples were analysed in the laboratory using the OC-Sensor™ PLEDIA (Eiken Chemical Co. Ltd) as per the manufacturer protocols, with the results uploaded electronically to the patient records system.

During the study period, patients were triaged into three FIT groups: group 1, f-Hb < 10 μg/g (FIT-negative); group 2, f-Hb = 10–100 μg/g; and group 3, f-Hb ≥ 100 μg/g. Patients in group 1 (FIT-negative) were given a telephone appointment with a consultant colorectal surgeon at 4 weeks and, if symptoms were thought to be significant, were triaged to further investigation. FIT-positive patients were triaged as follows: group 2 with red flag symptoms and all of those in group 3 underwent either CT scan or luminal endoscopy depending on symptoms. Change in bowel habit would warrant luminal investigation whereas investigation of abdominal pain and/or weight loss would be favoured by imaging.

**Statistical analysis**

Statistical analysis was performed using IBM SPSS® version 25. Non-parametric data were expressed as median (interquartile range, IQR). Categorical data were compared using the chi-squared test. Numerical data were compared using the Mann–Whitney U test. Sensitivity and specificity of colonoscopy based on the various FIT cut-off levels were estimated by plotting a receiver operating characteristic curve. This was expressed along with their 95% confidence interval (CI). Statistical significance was defined as $P < 0.05$.

**RESULTS**

Between September 2020 and February 2021 (pre-FIT triage), a total of 1634 patients were referred under the USC colorectal pathway, of whom 32 either declined investigation or were lost to follow-up. Ten patients had missing data. Of the remaining 1592 patients, the median age was 70 years (IQR 58–79 years) with a 53.9% male predominance. Between March and August 2021 (post-FIT triage), 1112 patients were referred under the USC colorectal pathway, of whom 13 either declined investigation or were lost to follow-up. Five patients had missing data leaving 1094 patients with a median age of 72 years (IQR 59.5–81 years) and a

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**FIGURE 1** A summary of the patient pathway for referrals of patients under the urgent suspected cancer pathway under the NICE NG12 clinical guidelines that were adopted during the COVID-19 pandemic at a local district general hospital (DGH) in Surrey, UK. For these patients, f-Hb levels as assessed using the faecal immunochemical test (FIT) were used to triage patients for urgent investigations.
49.2% male representation. Table 2 demonstrates that there was no significant difference in baseline demographics. The most common reason for referral within both cohorts was change in bowel habit, accounting for over 40% of referrals (Figure 2). Patients who were lost to follow-up were those who did not attend initial consultation or investigation.

There was no difference in the overall CRC detection rates between the pre-FIT triage cohort and the FIT triaged cohort (45/1592, 2.8% vs. 38/1094, 3.5%; P = 0.248). Within the FIT triage cohort, 944/1094 (86.3%) patients returned their test, of whom 383/944 (40.6%) were positive (f-Hb ≥ 10 μg/g). These were divided into three groups: group 1 (f-Hb < 10 μg/g), n = 561; group 2 (f-Hb = 10–100 μg/g), n = 236, 61.6%; group 3 (f-Hb > 100 μg/g), n = 147, 38.4%. A total of 13.7% (150/1094) of patients did not return an FIT sample.

### TABLE 2 Baseline demographics of referred patients in the different cohorts

| Age | Pre-FIT triage | FIT triage total | Positive FIT >10 μg/g | Negative FIT <10 μg/g |
|-----|----------------|------------------|------------------------|----------------------|
|     | 70 IQR 58–79   | 72 IQR 59.5–81   | 75 IQR 62–82           | 69 IQR 59–78         |
|     | 53.9%          | 49.2%            | 55.3%                  | 53.8%                |

Abbreviations: FIT, faecal immunochemical test; IQR, interquartile range.

### FIGURE 2 The reasons for referral for patients under the urgent suspected cancer pathway for lower gastrointestinal cancer. (A) Patients in the pre-faecal immunochemical test (FIT) triage cohort. (B) Patients in the FIT triage cohort

### FIGURE 3 The proportion of patients undergoing endoscopic luminal investigation across all cohorts. Faecal immunochemical test (FIT) triage cohort includes all patients referred at the time when FIT was used to triage patients for investigations. FIT triage tested cohort includes all patients who returned an FIT sample within the FIT triage cohort. Negative FIT cohort includes those patients with a negative FIT (f-Hb < 10 μg/g). Positive FIT cohort includes patients with an f-Hb ≥ 10 μg/g. The FIT 10–100 cohort includes patients with f-Hb = 10–100μg/g. The FIT > 100 cohort includes patients with f-Hb > 100μg/g.

### Endoscopic luminal investigation

The introduction of FIT triage was associated with a significant reduction in the use of endoscopy (n = 477, 43.6% vs. n = 1186, 74.5%; P > 0.001). After the introduction of FIT as the triage tool, more FIT-positive patients underwent endoscopy than those with a negative FIT (n = 265, 69.1% vs. n = 161, 28.6%; P < 0.001). A summary of the proportion of patients undergoing endoscopic luminal investigation across all the cohorts can be seen in Figure 3. More pathology was demonstrated at endoscopy after a positive FIT than before its introduction. A higher detection rate of CRC, diverticular disease and high risk polyps was observed when a comparison was made between the cohort of patients who were triaged with FIT to pre-FIT triage: CRC, n = 39, 8.2% vs. n = 45,
3.8% (P < 0.001); diverticular disease, n = 133, 27.9% vs. n = 57, 4.8% (P < 0.001); and high risk polyps, n = 33, 6.9% vs. n = 31, 2.6% (P < 0.001). Endoscopic investigation in the pre-FIT triage cohort was more likely to show an absence of pathology (n = 546, 46% vs. n = 96, 20.1%; P = 0.008). The most common findings at endoscopy were a combination of diverticular disease, haemorrhoids or absence of pathology and these accounted for more than 60% of diagnoses in both pre-FIT and FIT triage cohorts, with the overall endoscopic findings shown in Table 3.

**Computed tomography imaging investigation**

More patients underwent CT imaging after the introduction of FIT triage (n = 696, 63.6% vs. n = 750, 47.1%; P < 0.001). A summary of the proportion of patients undergoing CT investigation in each patient cohort is summarized in Figure 4. The overall detection rate for CRC was the same for both cohorts (n = 45, 6% vs. 38, 5.6%; P = 0.761). More patients were given a diagnosis of diverticular disease in the FIT triage group (n = 142, 20.4% vs. n = 57, 7.6%; P = 0.004). There was no significant difference in the rates of absence of pathology or colitis between the two cohorts (Table 4).

**Faecal immunochemical test triage subgroup analysis**

Subgroup analysis of the proportion of patients undergoing endoscopic investigation within the FIT triage cohort based on the FIT result is seen in Table 5. The subgroup with the highest endoscopy rate was group 3 (f-Hb > 100 μg/g), which is significantly greater compared to all patients within the FIT triage cohort (n = 124, 81.8% vs. n = 467, 43.6%; P < 0.001). As expected, CRC detection was greater in FIT-positive patients (f-Hb > 10 μg/g) compared to FIT-negative patients (f-Hb < 10 μg/g; n = 32, 12.1% vs. n = 2, 1.24%; P < 0.001) and greatest in group 3 (f-Hb > 100 μg/g) compared to the entire cohort (n = 24, 19.4% vs. n = 38, 8.0%; P = 0.002). There was no difference in overall polyp detection rates across all subgroups within the FIT triage cohort, but the high risk adenoma rate was higher in the FIT-positive patients (f-Hb > 10 μg/g) compared to FIT-negative patients (f-Hb < 10 μg/g; n = 27, 10.2% vs. n = 7, 4.3%; P < 0.001). There was no difference in low risk polyp detection rates (Table 6).

Overall CRC detection rates were highest in group 3 (f-Hb > 100 μg/g) at 16.3% (n = 24/147) and lowest in patients with a negative FIT (f-Hb < 10 μg/g), with two patients (n = 2/561, 0.36%) in this cohort who did have CRC. Both patients had alarm symptoms: one presented with anaemia and the other with rectal bleeding. The overall CRC detection rates across the different cohorts are summarized in Figure 5. The specificity of a negative FIT in this study was 91.5% (95% CI 88.7–94.3), with a sensitivity in group 2 of 80.0% (95% CI 55.2–99.9) and 92.3% (95% CI 88.9–95.6) in group 3 (Table 7 and Figure 6).
DISCUSSION

COVID-19 has changed surgical practice in both the primary and secondary care setting. This study reflects a change in practice which was necessary when endoscopy services were limited due to the real fear of COVID-19 cross-infection to patients and staff. This coincided with a temporary reduction in urgent CRC referrals reported nationally [8]. The use of FIT to triage patients to CT scanning and endoscopy was supported by the guidelines which evolved during the pandemic, and which our hospital trust rapidly adopted [9,10].

Since there was no statistical difference in the age and gender of pre-FIT and FIT triage patients, we felt we were justified in comparing the two cohorts. The CRC detection rate of 3.2% in the FIT triage and 2.8% in the pre-FIT group were similar suggesting that at the very least FIT was a safe triage method with rates similar to the 3.1% in the year 2019–2020 [11]. Pre-COVID-19, studies have demonstrated the potential value of FIT in CRC detection and

TABLE 4 Comparison of CT findings between the pre-FIT and FIT triage cohorts

| Patients undergoing CT imaging | CRC | Diverticular disease | Absence of pathology | Colitis | Other | DA |
|-------------------------------|-----|----------------------|-----------------------|---------|-------|----|
| Pre-FIT triage n = 1592       | 750 (47.1%) | 45 (6%) | 57 (7.6%) | 546 (72.8%) | 6 (0.8%) | 96 (12.8%) | 603 (80.4%) |
| FIT triage n = 1094           | 696 (63.6%) | 38 (5.5%) | 142 (20.4%) | 417 (60.0%) | 8 (1.1%) | 91 (13.1%) | 559 (80.3%) |
| P value                       | <0.001 | 0.791 | 0.003 | 0.037 | 0.649 | 0.926 | 0.247 |

Abbreviations: CRC, colorectal cancer; DA, combination of diverticular disease and absence of pathology as a combined diagnosis; FIT, faecal immunochemical test.

TABLE 5 Subgroup analysis comparing the proportion of patients undergoing endoscopic investigation within the FIT triage cohort based on FIT cut-off levels compared to the total number of patients within the FIT triage cohort

| Patients undergoing endoscopic investigation | FIT triage total (n = 1094) | Negative FIT (n = 561) | Positive FIT > 10 μg/g (n = 383) | FIT = 10–100 μg/g (n = 236) | FIT > 100 μg/g (n = 147) | No FIT (n = 150) |
|---------------------------------------------|----------------------------|----------------------|---------------------------------|--------------------------|----------------------|-----------------|
| 477 (43.6%)                                 | 161 (28.6%)                | 265 (69.1%)          | 141 (63.7%)                     | 124 (81.8%)              | 51 (34%)             |
| P value                                     | <0.001                     | 0.043                | 0.015                           | <0.001                   | 0.116                |

Abbreviation: FIT, faecal immunochemical test.
There was a specificity of 91.5% (95% CI 88.7–95.6) in group 3 patients (f- Hb 100 μg/g). While these findings are in line with those of D’Souza et al. [12] who reported a specificity of 95.8% in asymptomatic symptomatic patients under the age of 50, and higher than the 50.9% from the recent multicentre trial looking into Faecal immunochemical test (FIT) sensitivity reported by D’Souza et al. [12], the levels were lower in group 2 (f- Hb 10–100 μg/g) and higher for a negative FIT (f- Hb 10 μg/g) and those in group 3 (f- Hb >100 μg/g), which may reflect the disparity in sample sizes [12]. Two patients (0.36%) had CRC despite a negative FIT (f- Hb <10 μg/g), which is similar to the 0.31% reported by the D’Souza et al. [12] multicentre study. The two FIT-negative CRC patients suffered from anaemia and per rectum bleeding. Both symptoms led to them being investigated along the urgent pathway. Despite this, 0.36% is much lower than the 4%–6% of cancers which may be missed when colonoscopy is used as a screening tool [15–17]. A recent subgroup analysis of a multicentre trial looking into the use of FIT as a predictive tool for CRC has shown that a positive f-Hb using FIT on symptomatic patients under the age of 50 may indicate the need for referral for investigation of CRC or serious bowel
disease [18]. The age group is significantly younger than the median age of the cohort in our study (72 years). However, the conclusion is still similar to what we have found in our study given the significantly higher detection rates of CRC and high risk polyps in the FIT-positive (f-Hb > 10 μg/g) cohort.

Colorectal cancer is the most important pathology that must be ruled out when investigating patients referred under a USC pathway. Following this, the detection and subsequent removal of polyps is also of utmost importance, given the adenoma pathway that is involved in the pathogenesis of CRC [19]. Therefore, it is imperative that these lesions are detected at an early stage and excised to prevent the subsequent development of a malignant lesion. A recent meta-analysis showed a 33% (95% CI 0.26–0.41) rate of missed high risk adenomas in symptomatic patients undergoing colonoscopy [20]. A recent single centre study comparing adenoma detection rates in patients who underwent FIT testing to screening colonoscopies showed significantly higher adenoma detection rates in those patients who underwent FIT testing but did not differentiate between high and low risk lesions [21]. A greater detection of adenomas can lead to a subsequent reduction in progression to CRC.

The proportion of patients returning an FIT sample in our study was 86.4%. This is higher than many other studies and may reflect the fact that, as part of our CRC triage, patients are telephoned on referral by a health professional in secondary care rather than primary care where uptake rates can be as low as 63.9%, as seen in the Scottish Bowel Screening Programme [22]. This may be relevant to primary care where FIT is being proposed as a triage tool for urgent CRC referral as per the NICE guidelines [3].
Endoscopy

The faecal immunochemical test triage system led to a reduction in luminal endoscopy after USC referral at a time when there was uncertainty as to the safety of this investigation during COVID-19. This reduction in the need for endoscopy has been reported previously due to the increase in demand for services [23]. The national tariff for a colonoscopy is £460, rising to £528 if biopsies are taken. Diagnostic flexible sigmoidoscopy is £310 rising to £395 with biopsies. CT colonography would fall into the complex CT scan category, with a tariff of £290. CT scan of three body areas (chest/abdomen/pelvis) is £99 including reporting [24]. Not only does reducing the proportion of patients undergoing endoscopic investigation save the National Health Service a significant amount of money, but imagining is also much less labour intensive in comparison. Colonoscopy is also very invasive, with associated risk including colonic perforation. Many patients find it uncomfortable despite sedation. It may therefore be beneficial to patients and healthcare trusts to arrange focused colonoscopy for patients with positive FIT test or CT findings.

Computed tomography imaging

The use of CT imaging increased after the implementation of FIT triage. This was no surprise as CT was carried out during COVID-19 in both FIT-positive as well as FIT-negative patients who had symptoms suggestive of CRC. This triage system inevitably increased the radiology workload which has been acknowledged elsewhere [25]. In our study, CRC detection rates were similar between the two cohorts despite the change in practice and suggests that CT scanning remains a good tool for CRC detection as reported elsewhere [26,27]. Although less expensive than colonoscopy, CT scan interpretation requires radiologist expertise and the Royal College of Radiologists reports a 93% shortage in workforce which is predicted to rise up to 44% by 2025 [28]. Ironically, there is a similar issue in endoscopy [29]. Artificial intelligence and development of training schemes for non-medical practitioners may help in the future for both disciplines [30,31].

Limitations

All of the data for pre-FIT triage patients were collected retrospectively, and even with the authors best attempts these results are still open to selection bias. Despite the large cohort of patients in the FIT triage group, overall there were fewer patients who underwent endoscopic investigations compared to some other studies, which can account for the difference in sensitivities and specificities observed.

CONCLUSION

Our trust is one of the first in the UK to have implemented the use of FIT for triage to investigation for urgent suspected CRC referrals secondary to the COVID-19 pandemic. This system helped our hospital cope in the management of patients referred on the USC pathway. There was a decreased use of endoscopy and an increased use of radiology during this period. This change in practice did not lead to a decrease in detection of CRC.

In the future, we will continue to use this system for triaging patients for urgent investigation, as it is both safe and aids in reducing the overall burden on endoscopic services which was already an issue prior to the pandemic.

AUTHOR CONTRIBUTIONS

All authors listed contributed to either data collection or manuscript editing or both.

ETHICAL APPROVAL

Ethical approval was gained locally from the trust research and development department and registered as an audit (TASCC Colorectal 2020-06).

CONFLICT OF INTEREST

None.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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