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ORIGINAL ARTICLE

Faecal immunochemical testing reduces demand and improves yield of Leicester's 2-week pathway for change in bowel habit

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Abstract

Aim: We look at the effect of introducing the faecal immunochemical test (FIT) in the straight-to-test 2-week pathway for change in bowel habit (CIBH).

Method: The FIT in primary care triages 2-week wait (2WW) colorectal referrals for patients aged 60 years and above for straight-to-test CT colonography (CTC). We compare the impact of the FIT on numbers of 2WW CTCs, in the year before and after FIT, in both colorectal cancer (CRC) detection and cost-effectiveness at both 4 μg Hb/g faeces and 10 μg Hb/g faeces.

Results: At a threshold of 4 μg Hb/g faeces, the positive predictive value of the FIT for diagnosis of CRC is 5.0% with a negative predictive value of 99.8% and a polyp detection rate of 25.5%. The introduction of the FIT resulted in a reduction in the number of CTCs performed through the CIBH pathway from a mean of 143.9 per month prior to the FIT to 66.8 CTCs per month once the FIT was well established. Given a FIT threshold of 10 μg Hb/g the number of CTCs would be predicted to fall by 70.4% to 42.6 CTCs per month resulting in higher CRC and polyp detection rate, and an estimated annual cost saving of £238 258 in our institution.

Conclusion: The FIT use in primary care improves the yield of 2WW referrals for CIBH alone and reduces the burden and cost of investigations to exclude CRC. Improvements may be possible by increasing the cut-off employed, without adversely affecting the risk of missing a cancer.

KEYWORDS
CRC detection, faecal immunichemical testing, FIT, 2WW

INTRODUCTION

In the UK, bowel cancer is the fourth most common with around 42 300 new cases every year. Disappointingly, more than half of bowel cancer cases in England are still being diagnosed at a late stage [1].

Most cancer patients will present to their primary care physicians with symptoms although some present as an emergency to the Accident and Emergency Department [2]. Many of the symptoms of early cancer are non-specific and referrals based on vague symptoms alone, for example a change in bowel habit (CIBH), yield a very low cancer detection rate (often <3%) with a high associated cost to the National Health Service (NHS) and a potentially unnecessary risk of investigation to the patient. Regrettably, whilst the number of people referred via the 2-week wait (2WW) pathway in England

has increased, there has not been a corresponding improvement in survival [3]. Furthermore, increased resources spent on the 2WW pathway can adversely cause delays in cancer diagnosis to patients who are low risk or have atypical symptoms [4].

The faecal immunochemical test (FIT) is for detection of occult blood in faeces. Using antibodies specific for human haemoglobin, the FIT, unlike previous tests, offers a quantitative result [5]. The FIT is currently recommended to guide referral for suspected colorectal cancer (CRC) for 'low risk' patients as per National Institute for Health and Care Excellence (NICE) guidance (DG30) [6]. It is also used in the bowel cancer screening programme in England following extensive randomized controlled trials [7]. During the COVID pandemic NHS England guidance advised a cut-off of 10 μg Hb/g faeces for symptomatic patients because of limited endoscopy capacity.

The use of the FIT as a triaging tool in primary care is increasing. Chapman et al. [8] demonstrated that cancer detection pathways that include FIT are clinically better than pathways that focus on symptoms alone.

NICE FIT is a multicentre study conducted across 50 centres in England with 9822 patients included in the final analysis. By using the lowest limit of detectability for the FIT (2 μg Hb/g faeces using the HM-JACKarc system), FIT sensitivity proved to be 97.0% for CRC. This also demonstrated that a negative FIT has potential as a rule-out test for CRC [9]. A recent 2-year evaluation of the FIT in a clinical setting also confirmed the clinical utility of using the FIT to identify as well as 'rule out' urgent referral from primary care and reported that only a small number of cancers were missed [10].

To date, whilst FIT has been shown to be better than symptoms alone [3, 4, 6, 8, 9] in the detection of CRC and significant bowel pathology, there have been few studies which have looked at the impact of the FIT on service provision and the associated cost benefit. The concern has been that widespread introduction of the FIT in primary care could increase referrals and put further strain on the 2WW pathway.

In this study we looked at the impact of the FIT on service provision in the Leicester two-week pathway for CIBH, in terms of both CRC detection and whether it offered an opportunity to be cost effective at both 4 μg Hb/g faeces, that is, the limit of quantification using the OC-Sensor (Eiken Chemical Co.), as well as the recent NICE recommended cut-off of 10 μg Hb/g faeces.

The University Hospitals of Leicester NHS Trust (UHL) shifted towards CT colonography (CTC) due to increased pressures on endoscopy services. A retrospective analysis of the UHL 2WW lower gastrointestinal pathway by Stephenson et al. (2018) determined CTCs as an appropriate first-line test for CRC exclusion; CTC detection rates were comparable to colonoscopy for both CRCs (4.5% for colonoscopies and 4.9% for CTCs) and polyps larger than 5 mm (9.6% for colonoscopies and 13.5% for CTCs) while colonoscopies had higher detection rates of polyps of any size at 25% [15]. These findings were similar to the outcomes of the multicentre randomized trial SIGGAR for detection rates of large polyps and CRCs between CTC and colonoscopy [16].

What does this paper add to the literature?

Our paper is unique in looking at the effect of FIT introduction in real time on straight-to-test pathways while simultaneously relaying the distinctive effect of resources and finances of the pathway.

In assessing additional pertinent factors, the Leicester study reported higher completion rates 100% (vs. 86% for colonoscopies) and fewer cancellations (colonoscopy cancellation rate significantly higher at 6.5% vs. only 2% for CTCs) [15]. These findings are similar to the results of the second round of UK CRC screening pilot that showed the colonoscopy uptake rate at 82.8% [17]. Moreover, colonoscopies are more likely to be non-diagnostic at 10.7% whereas the CTC non-diagnostic level was found to be as low as 1.6% [15]. CTCs allow earlier and quicker testing resulting in 'health economic benefits' that deliver better patient experience [12, 18]. It is worth noting that as high as 24.2% of patients at CRC risk were unwilling to undergo colonoscopy [19]. CTC is favoured as it is deemed a less invasive investigation [12] and patients are more likely to undergo investigations if offered CTC [20].

When the straight-to-test 2WW CTC was introduced in UHL in 2015, the number of CTCs requested in our hospitals was twice as high as the year prior [12]. This higher uptake of CTCs mandated a triaging tool for referral on the straight-to-test pathway. The FIT prior to referral became required in February 2018 for all patients over the age of 60 with CIBH. Patients with an obvious abdominal or rectal mass, rectal bleeding, weight loss or iron deficiency anaemia were excluded. Since introduction a steady number of around 350 FIT requests are done each month. The number of CTCs requested on the pathway post FIT introduction dropped significantly but the number of CRCs and polyps detected on the pathway improved.

METHODS

Leicester pathway

In November 2015, following an agreement with healthcare commissioners all patients in Leicester referred on the lower gastrointestinal 2WW pathway with iron deficiency anaemia and/or CIBH would undergo straight-to-test faecal tagging CTC as the first-line investigation for bowel cancer exclusion. A year review undertaken by Stephenson et al. [12] concluded that CTCs are an appropriate first-line test for the exclusion of CRC as the results of the CTCs were comparable to colonoscopy.

In February 2018, the pathway was amended with the introduction of the FIT in primary care to help triage referrals. The FIT became a prerequisite for all patients over the age of 60 with a CIBH referred on the straight-to-test 2WW pathway. Exclusion criteria

were an abdominal or rectal mass, rectal bleeding, weight loss and iron deficiency anaemia.

Faecal immunochemical test requests in primary care were made using the electronic Integrated Clinical Environment (ICE) system, with the FIT kit being sent to the patient's home address. FIT dispatch and return were entirely postal, and kits were analysed according to the manufacturer's protocols in a UK Accreditation Service bowel cancer screening programme laboratory, as described elsewhere [8, 13, 14]. The results were made available on ICE with guidance on which patients to refer on the 2WW pathway.

A cut-off of >4 μg Hb/g faeces using the OC-Sensor was used as a positive test to triage referrals for a CTC. Patients with a negative FIT result, that is, below the level of quantification <4 μg Hb/g faeces, were referred back to their general practitioner (GP). Guidance was provided to the GPs whereby if there were ongoing concerns these patients could still be referred on an urgent or routine pathway as appropriate.

All positive results were referred on the 2-week pathway via the electronic referral system (PRISM). Patients with fitness of World Health Organization (WHO) 0, 1, 2 underwent a straight-to-test CTC. Patients who were WHO 3, 4 were seen in clinic to assess fitness for further investigation.

To help facilitate this new pathway, educational videos on FIT and the new referral pathway were made available for GPs. To cater to the diversity of the Leicestershire population, videos and brochures for patients explaining how to provide a sample using FIT were created in multiple languages and pictorial instructions were also sent with each kit.

Data collection and analysis

This retrospective study utilized routinely collected data and was approved as a service evaluation via local departmental processes.

From February 2018 FIT was incorporated as a triage tool into the local lower gastrointestinal cancer exclusion pathway for adults aged ≥60 years with CIBH: all people in this cohort with positive FIT (≥4 μg Hb/g faeces) were referred for a straight-to-test CTC. Prior to February 2018 the same pathway operated without use of FIT as a triage tool. We therefore aimed to compare the impact on service provision, in terms of numbers of CTCs performed through this pathway, in the 12 months prior to introduction of the FIT (February 2017–January 2018) with the 12 months immediately after introduction of the FIT (February 2018–January 2019).

Data were extracted from three main sources: (1) a locally maintained database detailing all FIT referrals and results, (2) radiology data from the local Radiology Information Systems and (3) CRC data from the local cancer registry (populated by local multidisciplinary team diagnosed cancers and the national cancer registry). All FIT referrals made between February 2018 and January 2019 inclusive were included. All positive FIT results (>4 μg Hb/g faeces) were cross-matched with radiology data by patient identification number (NHS number) to identify relevant subsequent imaging (normally CTC) performed within 90 days of the FIT result. Where patients had more than one positive FIT result, imaging was only considered if performed within 90 days of the first positive result. CTC reports were individually examined to obtain CRC and polyp detection rates. Where no relevant imaging was initially identified from the radiology database, individual patient electronic records were scrutinized for other relevant investigations (e.g., endoscopy). All FIT results (positive and negative) were cross-matched with the CRC database, using a follow-up period of at least 12 months to allow assessment of the diagnostic accuracy of FIT for the detection of CRC. Diagnostic accuracy was summarized using negative and positive predictive values and receiver operator characteristic curves. A crude economic impact analysis was calculated by multiplying the number of CTCs saved by the cost of an individual CTC on this pathway (£196) [11].

Statistics

Data analysis was performed using MATLAB (MathWorks, MATLAB 2020b). 95% confidence intervals were calculated using the MATLAB function *binofit* which uses the Clopper–Pearson method of interval estimation. Group comparisons were conducted with two-tailed one-sample *t* tests using the MATLAB function *t test*, with significance assigned at 5%.

RESULTS

Introduction of the FIT to the CIBH 2WW pathway for investigation of CRC

From 1 February 2018 to 31 January 2019 there were a total of 3307 FIT requests for people over the age of 60 (eligible for investigation for CRC via the CIBH 2WW pathway). The median age of this cohort was 74 (range 60–98, interquartile range 13), and 55.7% were women. Of these requests 3050 (92.2%) returned a valid result, and 924 (30.3%) were positive (≥4 μg Hb/g faeces), resulting in 911 patients with a positive FIT. In all, 584 of these patients underwent CTC within 90 days of the FIT result being generated (median 16 days, range 1–76, interquartile range 9). The mean time from referral being received by radiology to CTC was 11 days with 91% of cases scanned within 14 days and 97% scanned within 18 days. Seventy-nine patients went straight to endoscopy while 84 patients underwent another form of CT imaging (e.g., routine CT abdomen without bowel preparation). In a small number of patients CTC was not tolerated, imaging was unavailable or imaging was delayed. A total of 146 patients had no further investigation (Figure 1). For comparison, in 2016 in our institution there were a total of 1811 GP referrals under the 2WW CIBH pathway which resulted in 1450 CTCs while 361 patients with performance status 3 or 4 were referred to clinic prior to any test. In the 12 months prior to introduction of the FIT (February 2017 to January 2018) there were a total of 1727

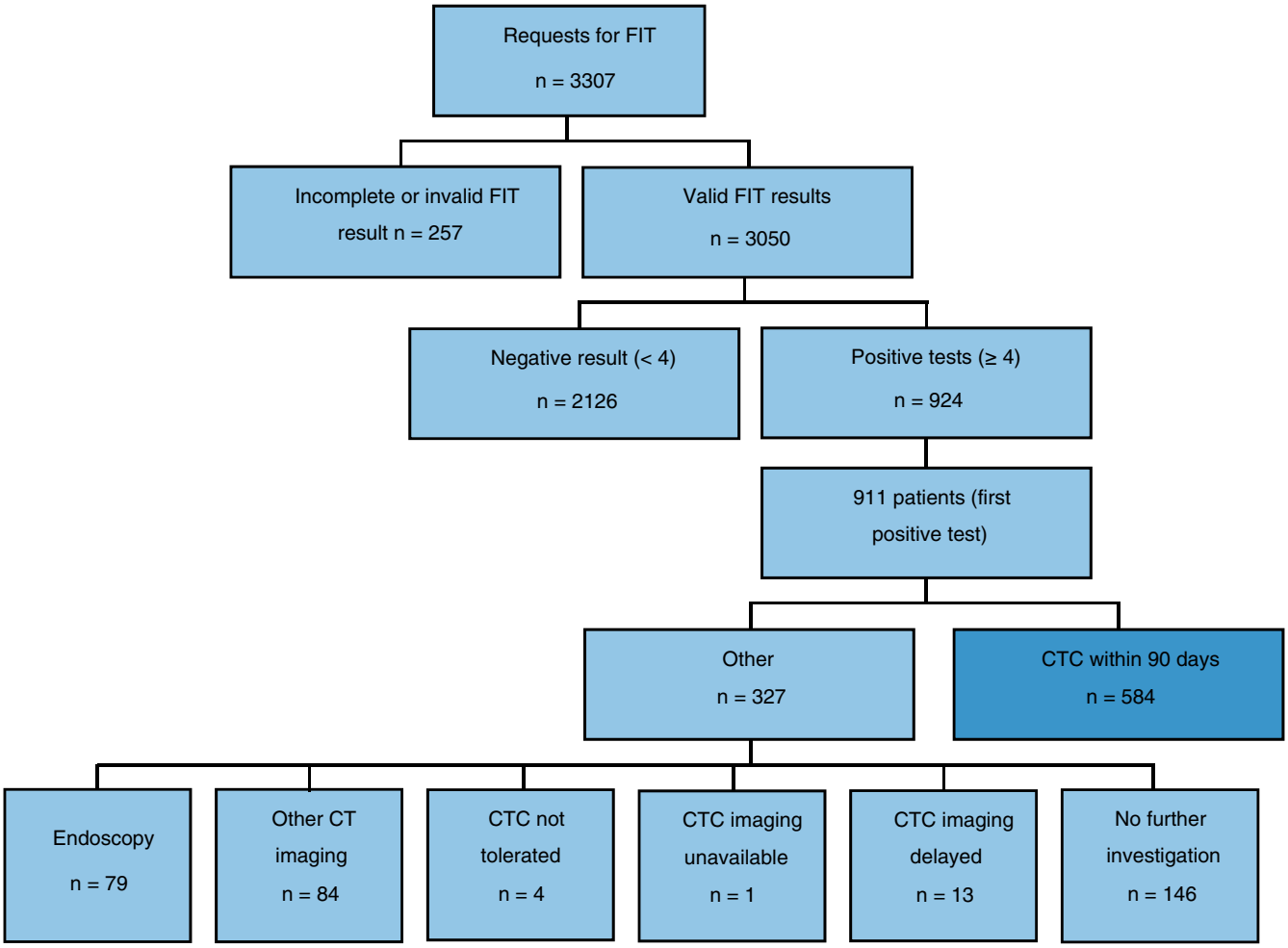

FIGURE 1 Summary of FIT requests from February 2018 to January 2019

CIBH CTCs (total number of CIBH 2WW referrals not available for this period).

Diagnostic accuracy

The overall accuracy for the diagnosis of CRC in this cohort after 12 months' follow-up is quantified in Figure 2A: in our cohort we found an area under the receiver operating curve of 0.9 (95% CI 0.83–0.94). The diagnostic accuracy by FIT thresholds is described in Figure 2B–D. The positive predictive value increased from 5.0% (3.6%–6.5%) at a threshold of 4 μg Hb/g faeces to 29.8% (18.4%–43.4%) at a threshold of 500 μg Hb/g. The corresponding negative predictive values decreased slightly from 99.8% (99.5%–100.0%) to 98.9% (98.5%–99.2%). The polyp detection rate increased from 25.5% (22.0%–29.3%) at a threshold of 4 μg Hb/g faeces to 43.9% (28.5%–60.3%) at a threshold of 500 μg Hb/g. When considering a shorter follow-up period of 3 months (allowing less time for undetected CRC to accrue), the sensitivity was slightly higher, 95.2% (84.0%–99.4%) at a threshold of 4 μg Hb/g and 93.0% (80.5%–98.5%) at a threshold of 10 μg Hb/g while specificity was unchanged.

The diagnostic accuracy of the pathway depended on tumour location. Right-sided lesions on CTC were doubly read by radiologists and if the consensus was a radiological tumour no biopsy was undertaken. Left-sided lesions were all confirmed by endoscopy.

Impact on CTC service

Referrals for FIT increased rapidly in the 3 months after introduction and showed a more gradual increase thereafter. There were approximately 350 FIT requests per month towards the end of the study period (November 2018 to January 2019). The introduction of the FIT resulted in a substantial reduction in the number of CTCs performed through the CIBH pathway (Table 1) from a mean of 143.9 per month prior to the introduction of the FIT to 66.8 CTCs per month once the FIT was well established (the first 3 months after introduction of the FIT pathway were excluded from this comparison when uptake was still significantly increasing). Corresponding CRCs, polyp detection rates and estimated cost savings from CTC volume reduction are shown in Table 1. Given a FIT threshold of 10 μg Hb/g the number of CTCs would be predicted to fall by 70.4% to 42.6 CTCs per month resulting in higher CTC and polyp detection rates and an estimated

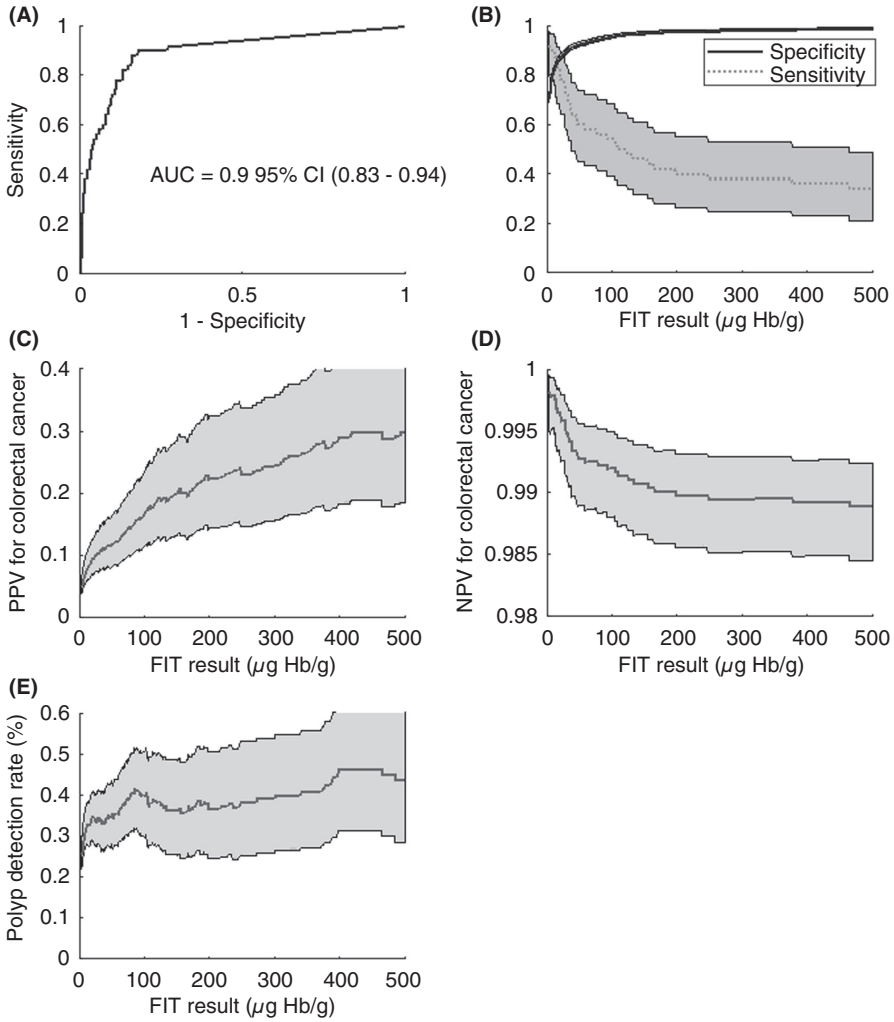

FIGURE 2 (A) Receiver operating curve for diagnosis of CRC using FIT threshold of 4 μg Hb/g. (B) Sensitivity and specificity by FIT threshold (±95% CI). (C) Positive predictive value by FIT threshold (±95% CI). (D) Negative predictive value by FIT threshold (±95% CI). (E) Polyp detection rate by FIT threshold (±95% CI)

TABLE 1 Comparison of monthly CIBH CTCs, CRC detection rate and polyp detection rate before and after introduction of the FIT

	Pre-FIT	FIT ≥ 4	FIT ≥ 10
CTCs per month (mean)	143.9 (February 2017 to January 2018)	66.8 (May 2018 to January 2019)	42.6 (May 2018 to January 2019)
CRC detection rate (%, 95% CI)	3.7 (2.9–4.8)	6.7 (4.8–9)	10.0 (7.2–13.5)
Polyp detection rate (%, 95% CI)	11.9 (10.4–13.5)	25.6 (22.0–29.3)	32.0 (27.3–37.0)
Estimated cost savings (£)	–	181 300	238 258

Abbreviations: CIBH, change in bowel habit; CRC, colorectal cancer; CTC, computed tomography colonography; FIT, faecal immunochemical test.

TABLE 2 Comparison of diagnostic accuracy of the faecal immunochemical test (FIT) at a cut-off of 4 μg Hb/g faeces and 10 μg Hb/g faeces

	Total cancers	True positive	False negative
FIT < 4	50	46	4
FIT < 10	50	45	5

annual cost saving of £238 258 in our institution. Higher FIT thresholds would lead to a progressively greater reduction in the number of CTCs at the expense of detection rates of CRC (Table 2).

DISCUSSION

In the current climate of reducing NHS spending this has significant impact on safe cost-effective interventions. However, in this publication we follow the patients for only a year while a post-colonoscopy CRC is usually defined as diagnosed after 6 months up to 3 years after endoscopy. We are continuing to follow up these results in real time and will report further cancers as diagnosed.

Our evaluation confirms that the FIT is relatively safe as a triaging test for high risk patients to rule out CRC with high negative predictive value. Most importantly, the FIT increased the

pathway's polyp detection rate by 115.1% and the CRC detection rate by 82.0%. We acknowledge that more work is needed to assess risk of CRC at different FIT results and assure an acceptable negative predictive value for FIT negative patients. The exclusion criteria were included to avoid the risk of missing FIT negative cancers.

Our findings are comparable to other studies in the UK. NICE FIT reported 97.7% sensitivity for CRC at a cut-off value of 2 μg/g, the lowest detectable rate on the HM-JACKarc analytical system [15]. Similar outcomes were reported by Chapman et al. [8] with a sensitivity of 97.2% using a cut-off of 4.0 μg Hb/g faeces. The NICE FIT steering group concluded that the FIT at the lowest cut-off of 2 μg/g (using HM-JACKarc) was more sensitive than symptoms suggestive of CRC and could effectively be used as a rule-out test for CRC; a negative FIT result at this cut-off can effectively rule out CRC and a positive FIT result is better than symptoms to select patients for urgent investigations [9,21].

In a separate publication, Hicks et al. [22] also concluded that FIT can be used to help triage patients with rectal bleeding; as in this study FIT was not always positive in patients with rectal bleeding and FIT can be safely used with high sensitivity to help rule out CRC even in patients with bleeding per rectum. The 'Fast Track FIT' study used a cut-off point of 19 μg Hb/g faeces on the HM-JACKarc yielding a sensitivity of 85.4% and specificity of 85.2% for CRC [23]. These results raise the question of a need for consensus for a relatively safe cut-off point at which patients will benefit from the straight-to-test pathway and which can be referred on an urgent or routine basis.

It is important, however, to consider the analyser platform when assigning the cut-off, or assessing the Hb levels, as they are not directly comparable [8, 24] due to different analyser chemistries.

Our data report a significant reduction on referral services even when using a modest cut-off point of ≥4 μg Hb/g faeces for a positive FIT for CIBH. Introduction of the FIT in primary care has demonstrated a 58.9% reduction in the number of CTCs from 144 in 2018 to 67 in 2019. The resulting estimated annual cost savings was £181 300. This diverges from findings in Nottingham by Bailey et al. (2020) where FIT was more widely introduced in primary care and resulted in a 33% increment in urgent referrals, with only two CRCs detected in the <4 μg Hb/g faeces group. It is worth noting, however, that they only excluded rectal bleeding and rectal mass in this study [25]. A more recent study by Bailey et al. [10] broke down the cancer detection rate using a variety of cut-offs and suggested that improvements in referrals could be made by increasing the cut-off used, with little loss in sensitivity in their referral system.

We noted, however, that the number of FIT tests undertaken due to 'suspected CRC due to CIBH' during this period of analysis was nearly 82% more than the number of CTCs previously requested and undertaken for the 2WW CIBH pathway. In other words, the introduction of the FIT probably led to it being more widely used by GPs than just for CRC suspected CIBH alone. The selective use of the FIT may offer a larger impact on numbers being referred through the 2WW pathway as well as using a higher FIT cut-off for investigation. The latter is supported by our data using a cut-off of 10 μg Hb/g.

In this study we can confirm that FIT introduction has a significant impact on our service provision by reducing 2WW referrals and number (and ensuing cost) of CTCs. The utilization of FIT as a classification test for referral has improved the yield of the 2WW by increasing the number of both CRCs and polyps detected. We corroborate the high negative predictive values of FIT reported by D'Souza et al. [9] as our figures demonstrate a negative predictive value of 99.8% for 4 μg Hb/g, 99.2% for 100 μg Hb/g and 98.9% for 500 μg Hb/g.

The steady number of tests requested by GPs monthly demonstrates the confidence and reliability of FIT in patients with a CIBH just as with symptoms within the criteria of NICE guidance (DG30). We validate recent publications that FIT improves the yield of 2WW but also show that FIT can decrease the overall cost of investigations [8, 9]. An international review found that, although CTCs were potentially more cost effective compared to colonoscopies mainly because of patients' adherence to the test, there must be a consensus on the threshold for polyp reporting [26].

Some CRCs detected on CTC, especially right sided, can be referred straight for surgery; however, some findings require urgent colonoscopies and some polyps depending on the size can be suitable for surveillance rather than prompt excision. It may be reasonable to implement a pathway where positive FIT results in the range 10–100 could be investigated with CTC or newer imaging modalities such as colon capsule and FIT >100 could be considered for urgent colonoscopy. This would allow the symptomatic colonoscopy service to mirror the pathway for bowel cancer screening having dedicated lists with a higher number of therapeutic procedures being undertaken at the index colonoscopy. These findings if adopted into NICE guidance will considerably reduce the burden on urgent referral pathways and offer more relevant results.

It is worthy of note that our data show that FIT has missed four CRCs at a cut-off of <4 μg Hb/g faeces. This number increases to five at a cut-off of <10 μg Hb/g faeces.

Finally, using the FIT as an arbitrary number might not be enough to avoid missing CRCs and like any investigation needs to be considered in the general presentation of the patient including age, blood haemoglobin level and iron deficiency anaemia, anticoagulant use, presenting symptoms and physical examination findings such as an abdominal or rectal mass.

CONCLUSION

Faecal immunochemical test use in primary care improves the yield of 2WW referrals for CIBH alone and reduces the burden and cost of investigations to exclude CRC. Additional improvements may also be possible by increasing the cut-off employed, without adversely affecting the risk of missing a cancer.

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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