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Evaluating the impact of faecal immunochemical testing (FIT) on suspected colorectal cancer referrals and outcomes in the South West

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ABSTRACT

Objective Patients with colorectal cancer (CRC) often face diagnostic delays. Faecal immunochemical testing (FIT) was introduced across the South West (SW) of England in October 2022 to support referral triage. This study evaluates the impact of FIT on referral patterns, investigations, outcomes and service adaptation across the region.

Design/methods We performed a retrospective service evaluation using secondary care data from nine National Health Service (NHS) Trusts in the SW. Data were collected for July 2019, 2022 and 2023, representing prepandemic, pre-FIT and post-FIT periods. Outcomes included referral characteristics, investigation pathways, waiting times and cancer detection rates (CDRs), stratified by the National Institute for Health and Care Excellence guideline (NG12 (2023)) compliance.

Results 10 140 records were analysed. In 2023, 87.0% of referrals included FIT. Compared to 2019, a greater proportion of patients were referred with an asymptomatic FIT ≥10 µg Hb/g ($p<0.001$) and fewer with traditional symptoms ($p<0.001$). Colonoscopy and clinic attendance fell ($p=0.023$ and $p<0.001$), with increased use of direct-to-test pathways ($p<0.001$). Total investigation volume was unchanged. The CDR rose from 4.1% (2019) to 4.7% (2023) but not significantly ($p=0.266$). Waiting times returned to prepandemic levels. Among non-NG12 compliant referrals, 48.6% still underwent colonoscopy, with modest CDRs (2.3%)—the clinical appropriateness of this was unclear. Asymptomatic FIT-positive patients aged >50 with FIT >100 µg Hb/g had a CDR of 7.1%.

Conclusion FIT has been widely adopted in primary care, facilitating more efficient secondary care triage and helping restore diagnostic capacity. While NG12 (2023) non-compliant referrals yield fewer cancers, some high-risk groups (particularly asymptomatic FIT-positive patients) should not be excluded from investigation.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Patients with suspected colorectal cancer (CRC) experience long diagnostic delays, often due to limited colonoscopy capacity.
⇒ Faecal immunochemical testing (FIT) has been introduced to support CRC referral triage, with high negative predictive value in symptomatic patients.

WHAT THIS STUDY ADDS

⇒ This is one of the first regional evaluations of the secondary care CRC pathway following FIT implementation.
⇒ FIT use has transformed referral profiles and enabled increased direct-to-test triage, reducing reliance on clinic review and colonoscopy.
⇒ A significant proportion of referrals now arise from asymptomatic patients with FIT ≥10 µg Hb/g, some of whom have cancer despite lacking traditional symptoms.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ FIT-driven triage has streamlined secondary care, yet overall investigation rates remain unchanged.
⇒ Although non-NG12 (2023) compliant referrals yield fewer cancers overall, some subgroups such as older, asymptomatic patients with FIT >100 µg Hb/g with CDRs comparable to the screening population still require investigation.
⇒ Future pathway refinements and policy changes may need to incorporate age-FIT stratification to maintain efficiency while capturing high-risk cases.

INTRODUCTION

Colorectal cancer (CRC) is responsible for the second-highest number of cancer-related deaths per year.[1] The National Institute for Health and Care Excellence (NICE) defines 'NG12' symptoms which should prompt suspicion. Patients presenting to primary care are typically entered onto 'fast-track' referral pathways.[2] Over 35% experience a diagnostic delay (the sixth worst of all tumours), largely due to increasing waiting times for colonoscopy.[3 4] The UK Faster Diagnosis Standard requires diagnosis or rule-out of CRC within 28 days of referral.[5]

Faecal immunochemical testing (FIT) detects blood from the colon. In those with NG12 symptoms, a FIT of <10 μg Hb/g has a negative predictive value (NPV) of ~99.5%, negating the need for urgent referral for colonoscopy.[6] This 'rule-out' is not as strong in those with iron deficiency anaemia (IDA) or a rectal mass. NHS England endorsed the implementation of FIT in urgent suspected CRC pathways in October 2022.[6 7] Prior to this, the South West (SW) cancer alliances and endoscopy network reached a similar consensus, petitioning the regional medical director to outline that NG12 patients with FIT<10μgHb/g, without IDA or a rectal mass, do not require colonoscopy to rule out CRC. In autumn of 2022, the regional referral pathway was updated to reflect this. Referrals accepted by secondary care are either triaged 'Direct to Test (DTT)' where a colonoscopy or cross-sectional imaging is requested, or to an outpatient clinic. NICE updated NG12 in August 2023 to include the same criteria, hereon termed NG12 (2023), and does not recommend performing FIT in asymptomatic populations.[2 8]

This purpose of this study was to evaluate the impact of FIT on the SW CRC pathways. We appraise the impact of FIT on referrals, investigations and outcomes of those with suspected CRC, how primary and secondary care have adapted to use this new resource, and the cancer detection performance of NG12 (2023) compliant and non-compliant referrals.

METHODS

A retrospective service evaluation was performed across the SW. Three month-long periods reflect the pathway before and after the COVID-19 pandemic and the introduction of FIT in 2022.

- July 2019—prepandemic, prereferral pathway update.
- July 2022—postpandemic, prereferral pathway update.
- July 2023—postpandemic, postreferral pathway update.

Data on referrals, FIT results and outcomes were collected from SW NHS trusts receiving urgent suspected CRC referrals in these periods. Sites were approached through a trainee research network and colorectal pathway leads. Primary care activity outside of referrals received by secondary care was not capturable. Duplicate episodes, surveillance and Bowel Cancer Screening Programme (BCSP) episodes were excluded. Figure 1 outlines the primary and secondary care components of the pathway, highlighting the areas from which data were available and collected. NG12 (2023) compliant referrals were defined as symptomatic patients with FIT ≥10 μg Hb/g, or IDA or rectal mass.

Statistical analysis

Categorical differences between two time periods were analysed using the χ^2 test and continuous data using the Mann-Whitney test. Trends across the three time periods were analysed using χ^2 for trend. Correlations were assessed using Spearman. Analysis was performed in R V.4.4.2 (R Foundation for Statistical Computing, Vienna, Austria).

Ethics

As this work constituted a service evaluation, ethical approval was not required.

RESULTS

Data quality

A total of 10 140 anonymous records were examined from nine Trusts. Data quality was variable between sites and required manual imputing, standardising and transforming to ensure fields were uniform. Some sites kept in-depth databases, whereas others required a trawl through electronic systems. One site held no data for 2019. Online supplemental table 1 details the population demographics and data quality.

Impact of FIT: primary care referrals

Table 1 shows the referral patterns across the periods. Between 2019 and 2023, the number of referrals for symptoms that require a FIT ≥10 μg Hb/g to be labelled as NG12 (2023) compliant trended down significantly (p=<0.001). 2023 saw a significant increase in the number of asymptomatic patients referred due to an incidental FIT ≥10 μg Hb/g (17.5% of referrals in 2023 vs 6.7% in 2022, p=<0.001). The median FIT value in this group across the three periods was 33 (IQR 17–84). Figure 2 shows the breakdown of referral indications by year. 87.0% of referrals in 2023 were accompanied by a FIT result, significantly more than the previous year (67.4%, p=<0.001). 62.1% of referrals in 2023 were NG12 (2023) compliant compared with 47.2% in 2022 (p=<0.001).

Impact of FIT: secondary care patient journey

Triage

Figure 1 shows the numbers of patients at each stage of the pathway in July 2023. Table 2 details the impact of FIT on investigations, outcomes and waiting times.

The proportion of referrals across the cohort undergoing colonoscopy (either DTT or after clinic) has trended down significantly since 2019 (p=0.023), and a significantly smaller proportion of referrals are undergoing colonoscopy compared with prepandemic

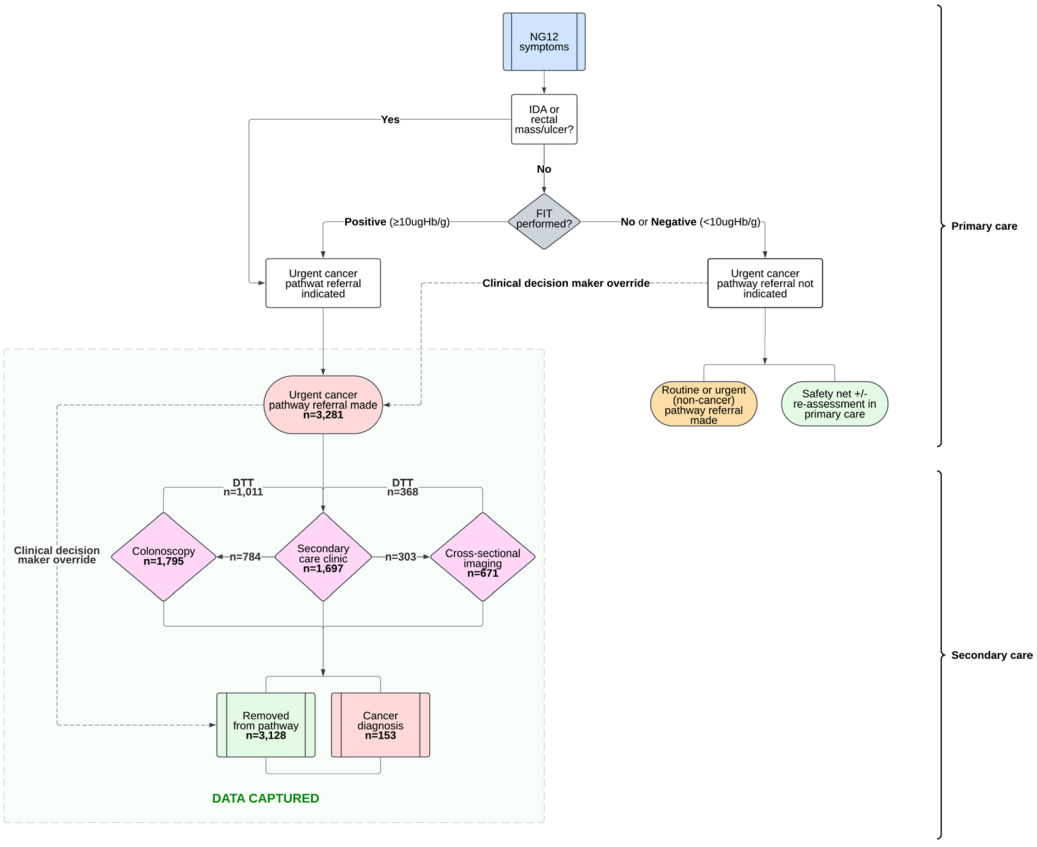

Figure 1 The South West suspected colorectal cancer referral pathway, showing primary and secondary care components and the data captured in secondary care. NG12: NICE guidelines on the recognition and referral of suspected cancer. DTT, direct to test; FIT, faecal immunochemical test; IDA, iron deficiency anaemia.

(57.7% in 2019 vs 54.7% in 2023, p=0.016). The use of CT colonoscopy (CTC) has fallen significantly since 2019 (14.9% in 2019 vs 8.3% in 2023, p=<0.001). Significantly more patients are undergoing plain CT scans in 2023 versus 2019 (4.9% vs 12.2% p=<0.001). The overall proportion of patients undergoing any investigation has not significantly changed (77.5% in 2019 to 75.2% in 2023, p=0.054).

The proportion of patients sent to the outpatient clinic has trended down since 2019 (60.5% to 51.7%, p=<0.001). Since 2019, colonoscopy, CTC and plain CT have seen a significant uptrend in the proportion of tests occurring DTT, with a consequent downtrend in the proportion arising from clinic (DTT colonoscopy: 43.0% in 2019 to 56.3% in 2023; DTT CTC: 36.7% to 50.2%; DTT plain CT: 25.7% to 58.0%,

Table 1 Primary care referral patterns

	July 2019*	July 2022	July 2023
Number of referrals	3048	3811	3281
► Female (%)	55.6%	55.9%	53.8%
► % accompanied by FIT (any result)	6.1%	67.4%	87.0%
► % for asymptomatic FIT-positive	1.9%	6.7%	17.5% (p≤0.001)
► % NG12 (2023) compliant	17.4%	47.2%	62.1% (p≤0.001)
Number of referrals not for IDA or rectal mass (% total)	2304 (75.6%)	2976 (78.1%)	2074 (63.2%) (p≤0.001)
► % FIT ≥10 µg Hb/g	7.1%	39.9%	67.7%
► % FIT<10 µg Hb/g or absent	92.9%	60.1%	32.3%
Median FIT value in FIT-positive asymptomatic referrals (IQR)	19 (13.5–68.5)	40 (20.5–106)	32.5 (17–77.5)

NG12 (2023): NICE guidelines on the recognition and referral of suspected cancer—updated to include FIT criteria.
P values represent the trend across the 3 years.
*One site unable to provide data from 2019.
FIT, faecal immunochemical test; IDA, iron deficiency anaemia.

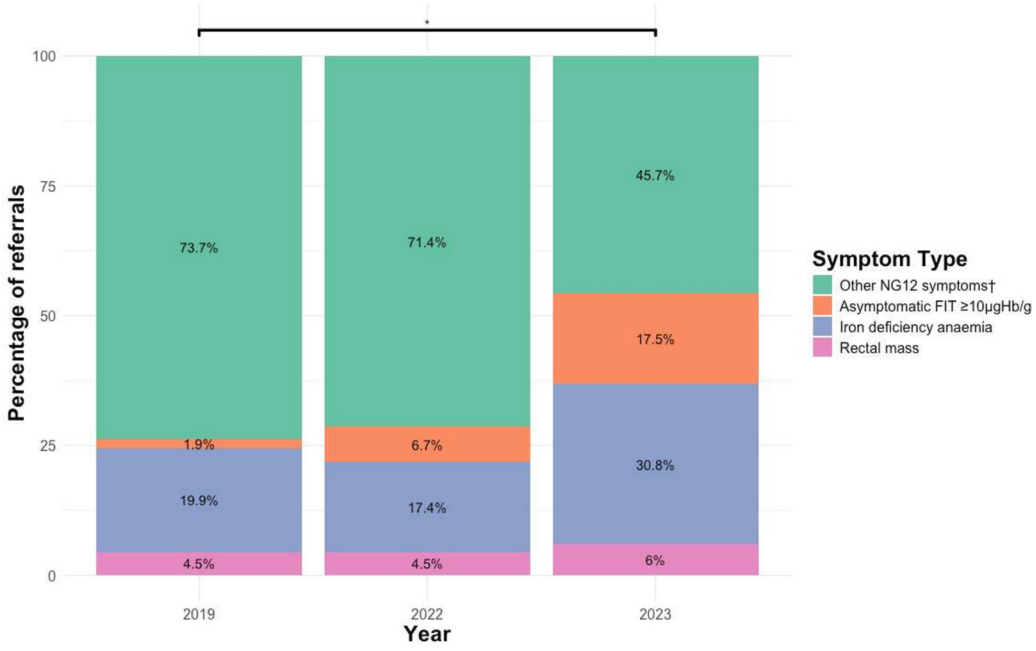

Figure 2 Symptom referral patterns across the three time periods. *p<0.001. †Other NG12 symptoms: weight loss, abdominal pain, change in bowel habit and rectal bleeding. FIT, faecal immunochemical test.

p=<0.001). Of the patients who attend clinic, fewer are referred for colonoscopy and CTC and more are referred for plain CT (54.3%, 15.6% and 6.0% of clinic patients referred for colonoscopy, CTC and plain CT in 2019, respectively, vs 46.2%, 8.0% and 9.9% in 2023, p=<0.001). The number being discharged from the pathway without colonic investigation has increased (11.7% to 17.1%, p=<0.001).

The median age of those undergoing colonoscopy was 66 (IQR 55–75), significantly lower than that of CTC and CT scans (p≤0.001) (78 (72–80) and 80 (71.5–85), respectively), which were not significantly different from each other (p=0.92). The median age of those attending the clinic was 73 (61–80). This did not change significantly pre- and post-FIT (p=0.1618).

Outcomes

Colorectal cancer detection rate (CDR) and colonoscopic CDR (CCDR) have both increased insignificantly since 2019 (CDR 4.1% to 4.7%, CCDR 4.5% to 5.2%, p=0.266 and 0.388, respectively). The number of patients needing to undergo colonoscopy to find one cancer ('number needed to scope'—NNS) in 2023 was 19.2. Rates of cancer from referrals with FIT <10 μg Hb/g without IDA or rectal mass were low (0.6% of these referrals in 2023). FIT remained a poor predictor of cancer in IDA: 16% of IDA cancers in 2023 were FIT <10 μg Hb/g. At a trust level, there was no correlation between the proportion of colonoscopies performed for NG12 (2023) non-compliant referrals and CDR or CCDR (p=0.121 and p=0.948, respectively).

Table 3 details the referrals and outcomes from 2023, split by NG12 (2023) compliance. In 2023, there were 2037 NG12 (2023)-compliant referrals. 1011 were for IDA, 196 for rectal mass and 830 for the remaining NG12 symptoms with FIT ≥10 μg Hb/g. 58.5% of this group underwent colonoscopy. The CDR and CCDR of this cohort were 6.1% and 6.8%, respectively (NNS 14.7). By symptom, rectal mass had the highest CDR/CCDR (11.2%/12.0%), with an NNS of 8.3. 12.5% of patients in this group exceeded the faster diagnosis standard.

There were 1244 non-compliant referrals yielding 29 cancers (CDR 2.3%). These were: 14 asymptomatic FIT ≥10 μg Hb/g, 13 FIT absent and two FIT <10 μg Hb/g. As multiple symptoms were frequently recorded for each case, analysis by symptom was not possible. 48.6% of this group underwent colonoscopy on a 2-week-wait basis, rather than urgent non-cancer or routine if still indicated (eg, in chronic diarrhoea), with a CCDR of 2.6% (NNS 38.5). The CDR and CCDR of this group are both significantly lower than the NG12 (2023)-compliant population (p≤0.001). 8.8% of patients in this group exceeded the faster diagnosis standard, significantly fewer than the NG12 (2023)-compliant group (p≤0.001).

The FIT absent/<10 μg Hb/g group with symptoms other than IDA/rectal mass (n=670) consisted of 337 FIT absent (CDR 3.9%) and 333 FIT <10 μg Hb/g (CDR 0.6%). 38.7% of this group of patients underwent 2-week-wait colonoscopy.

Online supplemental table 2 provides a breakdown of the asymptomatic FIT ≥10 μg Hb/g group. 14 cancers were identified in this group, yielding a CDR of 2.4% and a CCDR of 2.7%. In this group, 57.1% of cancers were in those with FIT >100 μg Hb/g aged

Table 2 The impact of FIT on secondary care investigations, outcomes and waiting times

	July 2019*	July 2022	July 2023
Investigations/clinic appointments (% total referrals)			
Colonoscopy	1759 (57.7%)	1941 (50.9%)	1795 (54.7%) (p=0.023)
► DTT (% of colonoscopy)	757 (43.0%)	970 (50.0%)	1011 (56.3%) (p≤0.001)
► Following clinic (%)	1002 (57.0%)	971 (50.0%)	784 (43.7%) (p≤0.001)
CTC	455 (14.9%)	303 (8.0%)	271 (8.3%) (p≤0.001)
► DTT (%)	167 (36.7%)	125 (41.3%)	136 (50.2%) (p≤0.001)
► Following clinic (%)	288 (63.3%)	178 (58.7%)	135 (49.8%) (p≤0.001)
Plain CT	148 (4.9%)	389 (10.2%)	400 (12.2%) (p≤0.001)
► DTT (%)	38 (25.7%)	206 (53.0%)	232 (58.0%) (p≤0.001)
► Following clinic (%)	110 (74.3%)	183 (47.0%)	168 (42.0%) (p≤0.001)
Total investigations	2362 (77.5%)	2633 (69.1%)	2466 (75.2%) (p=0.054)
► DTT (%)	962 (40.7%)	1301 (49.4%)	1379 (55.9%) (p≤0.001)
► Following clinic (%)	1400 (59.3%)	1332 (50.6%)	1087 (44.1%) (p≤0.001)
Clinic	1844 (60.5%)	2093 (54.9%)	1697 (51.7%) (p≤0.001)
Discharged without investigation	358 (11.7%)	651 (17.1%)	562 (17.1%) (p≤0.001)
Outcomes			
Cancers	125	159	153
Median age at diagnosis	73 (60.25–79.75)	74.5 (64–81)	76 (65–81)
% female	54.0%	49.3%	48.3%
CDR	4.1%	4.2%	4.7% (p=0.266)
CCDR	4.5%	5.2%	5.2% (p=0.388)
NNS	22.2	19.2	19.2
Waiting times			
Median time to diagnosis (IQR)	16 (13–22)	23 (14–39)	16 (12–24) (p=0.533)*
Patients not meeting FDS (% total)	276 (10.5%)	976 (28.0%)	363 (12.1%) (p=0.059)*
Median time to DTT colonoscopy (IQR)	14 (11–19)	19.5 (14–31)	14 (11–19) (p=0.271)*
Median time to DTT CTC (IQR)	14 (13–14)	17 (14–28.75)	14 (12–23) (p=0.203)*
Median time to DTT CT (IQR)	14 (11.75–15)	16 (12–22)	13 (10–19) (p=0.539)*
Median time to clinic (IQR)	8 (6–11)	12 (7–19)	7 (4–13) (p=0.012)*

Plain CT: CT scan of the abdomen with or without intravenous contrast.
P values represent the trend across the 3 years, unless accompanied by *, which represents significance compared with 2019.
*One site unable to contribute data for 2019.
CCDR, colonoscopic colorectal cancer detection rate (number of colorectal cancers detected at colonoscopy/total number of colonoscopies); CDR, colorectal cancer detection rate; CTC, CT virtual colonoscopy; DTT, direct to test; FDS, faster diagnosis standard; FIT, faecal immunochemical testing; NNS, number needed to scope.

>50 (CDR 7.1%). 92.9% of cancers were aged >50, with the CDR of this group being 2.9% compared with 1.1% in those aged <50.

Waiting times

Median time to diagnosis rose from 16 days in 2019 to 23 days following the pandemic, but has since returned to 16 days (p=0.533). The proportion of patients not meeting the 28-day faster diagnosis standard rose in 2022 from 10.5% to 28%, but has since fallen to 12.1% in 2023, which is not significantly different from 2019 (p=0.059). The majority of cases not meeting the faster diagnosis standard were triaged to clinic (64.2% in 2023). DTT colonoscopy was the next largest group (24.0%). There was no significant difference between median waiting times for DTT investigations between 2019 and 2023 (14 days for colonoscopy and CTC (IQR 11–19 and 12–23, respectively) p=0.271/p=0.203). Median clinic waiting times fell significantly from 8 (IQR 6–11) to 7 (4–13) days (p=0.012). A full breakdown of waiting times can be found in online supplemental table 3.

DISCUSSION

Primary care

There has been a shift in referral patterns, with fewer referrals for symptoms outside of IDA or a rectal mass, reflecting primary care safety-netting FIT <10 μg Hb/g patients who historically would have been referred. Unintendedly, there has been an increase in asymptomatic referrals. This underlines existing data that strong collaborative working has led to widespread

Table 3 2023 referrals, investigations and outcomes

	NG12 compliant				NG12 non-compliant		
	IDA	Rectal mass	Other	Total	Asymptomatic FIT ≥10 µg Hb/g	FIT-negative or absent	Total
Number of referrals	1011	196	830	2037	574	670	1244
Colonoscopies (%)	546 (54.0%)	92 (46.9%)	553 (66.6%)	1191 (58.5%)	345 (60.1%)	259 (38.7%)	604 (48.6%)
CTCs (%)	122 (12.1%)	11 (5.6%)	66 (8.0%)	199 (9.8%)	54 (9.4%)	18 (2.7%)	72 (5.8%)
Plain CTs (%)	162 (16.0%)	38 (19.4%)	73 (8.8%)	273 (13.4%)	42 (7.3%)	85 (12.7%)	127 (10.2%)
Cancers	52	22	50	124	14	15 (n=2 FIT <10 µg Hb/g)	29
CDR	5.1%	11.2%	6.0%	6.1%	2.4%	2.2%	2.3%
CCDR	5.7%	12.0%	7.1%	6.8%	2.6%	2.7%	2.6%
NNS	17.5	8.3	14.1	14.7	38.5	37.0	38.5
Number not meeting FDS (%)	70 (6.9%)	44 (22.4%)	140 (16.9%)	254 (12.5%)	59 (10.3%)	50 (7.5%)	109 (8.8%)

Plain CT: CT scan of the abdomen with or without intravenous contrast.
CCDR, colonoscopic colorectal cancer detection rate (number of colorectal cancers detected at colonoscopy/total number of colonoscopies); CDR, colorectal cancer detection rate; CTC, CT virtual colonoscopy; FDS, faster diagnosis standard; IDA, iron deficiency anaemia; NG12, NICE guidelines on the recognition and referral of suspected cancer—updated to include FIT criteria.; NNS, number needed to scope.

uptake of FIT in primary care: The SW consistently reports the lowest number of FIT-absent referrals nationwide and CDRs exceeding national figures.[9 10]

Only a small portion of the total pathway is auditable from secondary care. In particular, we cannot evaluate primary care FIT requesting activity beyond that primary care referrals for an asymptomatic FIT ≥10 µg Hb/g have risen. The SW has the oldest population in the UK, and an asymptomatic raised FIT should not be dismissed out of hand, especially if >100 µg Hb/g in those aged over 50, where our CDR was 7.1%. This is in keeping with the CDR of the Bowel Cancer Screening Programme (BCS) where the FIT cut-off is currently ≥120 µg Hb/g (CDR 7.1%–7.5%).[11–13]

Secondary care

Our results illustrate how uptake of FIT has the ability to streamline the patient journey in secondary care. We have seen a reduction in the proportion of patients undergoing colonoscopy and an increase in the proportion of investigations performed as DTT, bypassing the clinic, which is responsible for the majority of the 28-day diagnostic standard breaches. The clinic is able to be used more discerningly, with fewer appointments and shorter waits. The increased discharge without investigation rates coupled with the reduction seen in colonoscopy requested from the clinic (and the increase in plain CT) suggests that more appropriate patients such as the frail or comorbid, where more complex decision-making is required, are getting to clinic. All of these factors will have contributed to the recovery in waiting times seen in our data and across the nation.[14]

The reasons for the overall increase in plain CT are likely multifactorial and include an ageing population in whom colonoscopy may be inappropriate and FIT excluding CRC in a population with often vague symptoms including weight loss, in which CT is a useful first-line investigation. Our anecdotal experience is also that CT with 48 hours of oral contrast may have partially replaced CTC in those felt unsuitable for colonoscopy; however, the NPV of this is unclear. The advent of the colon capsule may also explain this; however, in our cohort, very few patients underwent this (n=7 and 4 in 2022 and 2023).

In 2020, the Northern Cancer Alliance mandated FIT for suspected CRC referrals.[15] This change increased CCDR and reduced the total number of procedures.[9] Our pathway differs in that FIT is advised but not mandated to the same extent. Despite the demonstrated efficiency gains, our total proportion of patients undergoing any investigation did not change, nor did CDR. Although 48.6% of non-compliant referrals still underwent colonoscopy, our data shows that there is some yield in these referrals. The majority of this comes from those either without an FIT result or with an asymptomatic FIT ≥10 µg Hb/g (with the most cancer coming from those aged >50 with FIT >100 µg Hb/g—ie, similar to the BCS population). It is for this reason that secondary care may struggle to drastically improve on this number.

Colonoscopy pressures are set to increase with BCS introducing a reduced FIT threshold of ≥80 µg Hb/g alongside the phased age extension.[13 16] For services struggling to meet these demands, it might be tempting not to investigate non-compliant referrals; however, such an approach will miss some cancer cases. We would therefore encourage them to examine their own data around the subset that has a documented FIT <10 µg Hb/g without IDA or a rectal mass, where CDRs are low (0.6% in our population) and plan case by case

for this group. Our data suggests that it is reasonable to not subject these patients to urgent colonoscopy. We would also encourage services to agree on a local approach to asymptomatic FIT ≥10 μg Hb/g and FIT-absent referrals to maximise efficiency. Those referrals without FIT values should be held where possible until FIT is available and then investigated if they meet pathway criteria.

Regional approaches differ, with some areas implementing even stricter FIT criteria, such as a FIT threshold of ≥100 μg Hb/g in those aged under 40.[17] Since completing our study, the COLOFIT study has shown that symptomatic FIT can be safely combined with age, sex and blood results in a risk-prediction model and potentially reduce colonoscopy burden by ~20%.[18] Such an approach is likely to prove a better way to choose who and how to investigate.

Limitations

Our study had several limitations. Data quality was variable due to manual inputting, requiring manual cleansing, which could have led to errors. We feel that despite this, our data is validated by our CDRs and FIT-negative cancer rates, which are similar to national figures. Our data does not capture primary care activity and FIT requesting practices, and we also only capture one strand of colonoscopy activity (ie, we do not capture non-cancer pathways or BCS activity). Our plain CT data consist of several protocols, including intravenous or oral contrast, which limits our understanding of why plain CT numbers have increased. Finally, despite obtaining a large volume of data, this only reflects 1 month in each time period.

CONCLUSIONS

Primary care has seen excellent uptake of FIT, resulting in changed referral patterns. Secondary care has used FIT to streamline services, reduce colonoscopy use and recover waiting times from the COVID-19 pandemic. Referrals outside of strict NG12 (2023) criteria should be approached with caution, as a small proportion still harbour cancer.

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Contributors KP, PS, MF, CT, AS and PD designed the study. KP drafted and revised the manuscript with input from LN, RA, CT, AR, AF, AS, MF, PS and PD. SPRinG collaborators (SUPPLEMENTARY) collected data. KP analysed the data and acts as guarantor for the work and conduct of the study. All authors approved the manuscript for submission.

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