# Faecal immunochemical test (FIT) based prioritisation of new patient symptomatic cases referred for colorectal investigation

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## ABSTRACT

**AIM:** Quantitative faecal haemoglobin (fHb) measurement by faecal immunochemical test (FIT) is a powerful biomarker for colorectal cancer (CRC) and is incorporated in referral, prioritisation and triage protocols for symptomatic cases in other countries. We report our use of FIT to prioritise new patient symptomatic cases referred for colorectal investigation.

**METHOD:** Cases referred for investigation of new colorectal symptoms who were aged ≥50 years (≥40 years Māori/Pacific peoples), who would otherwise be triaged to non-urgent colonoscopy, were asked to provide a stool sample for FIT. Following FIT testing, cases were re-triaged to either urgent colonoscopy, non-urgent colonoscopy or computed tomography colonography (CTC) depending on fHb concentration (measured in micrograms haemoglobin per gram of stool [mcg/g]) and incorporating clinical judgement. At pathway initiation, cases already waiting for colonoscopy on the non-urgent new patient waiting list were approached first, and then new patient (NP) referrals for colonoscopy could be triaged to the pathway at the discretion of the triaging consultant.

**RESULTS:** Out of 739 cases, 715 (97%) returned FIT samples, and 691 cases completed colorectal investigations. Overall FIT positivity ≥10mcg/g was 17.1%. Fifteen colorectal cancers (CRC) were detected (2.2%). The sensitivity and specificity of FIT ≥10mcg/g for CRC were 80.0% (54.0–93.7%) and 84.3 (81.4–86.9%) respectively. A total of 432 cases (62.5%) completed the pathway without recourse to colonoscopy, and the median time to CRC diagnosis for NP from referral was 25 days.

**CONCLUSION:** FIT based prioritisation of cases referred with symptoms concerning for CRC is feasible and reduces time to CRC diagnosis.


The incidence of colorectal cancer (CRC) in Aotearoa New Zealand is among the highest in the world,[1] and the diagnosis is usually established by diagnostic colonoscopy, which allows biopsy of suspicious lesions as well as removal of precancerous polyps. However, colonoscopy capacity in New Zealand is finite, and waiting times often exceed Health New Zealand – Te Whatu Ora targets. Many patients are referred for colonoscopy due to concern that symptoms may indicate an underlying CRC. In current practice, referrals are made, received and triaged according to symptom, age and haemoglobin criteria as defined in the New Zealand Ministry of Health Direct Access Outpatient Colonoscopy or Computed Tomography Colonography (CT colonography, or CTC) guidelines (hereafter the direct access criteria).[2] However, these criteria have a low specificity for CRC,[3] and this results in many New Zealanders undergoing colonoscopy with no significant finding, thus depleting the limited colonoscopy capacity.

In contrast to these criteria, quantitative faecal haemoglobin (fHb) measurement by the faecal immunochemical test (FIT) is a powerful biomarker for colorectal disease, with high sensitivity and specificity for CRC.[4,5] In the United Kingdom, FIT is incorporated into the primary care assessment and referral pathway for patients presenting with colorectal symptoms concerning for CRC, and has been proven to improve case detection, reduce time to colorectal investigation and also to identify patients with low risk of colorectal cancer who do not need to proceed directly to colonoscopy.[6] In Waitaha Canterbury, our group have contributed to this field by reporting the diagnostic outcomes of the current direct access criteria,[3] and by demonstrating how FIT could be incorporated into the assessment, referral and prioritisation of such cases in order to improve access to definitive investigation for patients at greatest risk of disease.[5] Here we report on an interim clinical pathway (pending a national solution to the use of FIT in symptomatic

individuals) that incorporates FIT in the triage of non-urgent cases who were referred for investigation of colorectal symptoms. The pathway was developed with the goals of reducing time to definitive investigation for those at greatest risk of malignancy, and to redirect patients with low risk of CRC from investigation with colonoscopy to investigation with CTC, a less invasive procedure with similar sensitivity for colorectal cancer,[7] and in so doing, reduce overall waiting times for colonoscopy in our region.

## Methods

The FIT pathway was developed in consultation with Māori and Pacific health practitioners, primary care, general and colorectal surgeons, radiology and laboratory staff. Patients referred for investigation of new colorectal symptoms, aged ≥50 years, who would otherwise be triaged to non-urgent colonoscopy were asked to provide a stool sample for FIT. Once the FIT result was available, cases were re-triaged by a FIT team clinician (Gastroenterology Department liaison GP, Gastroenterology fellow, or Gastroenterology consultant), incorporating the FIT result into the triaging process. The suggested usual outcomes followed this algorithm: fHb ≥150 micrograms haemoglobin per gram of stool (mcg/g)—urgent colonoscopy <2 weeks; 10–149mcg/g—colonoscopy <6 weeks; <10mcg/g—computed tomography colonography (CTC). For reference, the National Bowel Screening Programme FIT threshold is fHb 200ng/ml buffer, approximately equivalent to fHb 40mcg/g stool.[8] CTCs were performed in house through funding for additional out of hours lists and had no impact on usual CT capacity or waiting lists.

At pathway initiation, patients already waiting for colonoscopy on the non-urgent new patient waiting list were contacted first, and thereafter new referrals for colonoscopy could be triaged to the pathway by the triaging consultant gastroenterologist at their discretion. Waiting list review followed strict age parameters, however thereafter, age thresholds for entry to the pathway were not strictly enforced, allowing clinicians to exercise clinical judgement. All public referrals for direct access colonoscopy and CTC within our region are triaged by consultant gastroenterologists. The threshold for accepting new referrals for investigation were adjusted 10 years younger for Māori and Pacific peoples to reflect lower age at CRC presentation.[9,10] Patients were excluded from the FIT pathway if they had a definite indication for colonoscopy including screening, surveillance or on clinical grounds (e.g., history or concern for inflammatory bowel disease or microscopic colitis), or if urgent investigation was required. Patients were contacted by phone or text message by administrative staff (up to three times by differing modes and time of day including evening) and invited to participate in the pathway. Phone contact was followed by posting a FIT kit, which included a letter of invitation, instructions, a standard stool collection pottle and laboratory form. Stool samples were returned fresh, Monday to Friday, via delivery to central laboratory, community laboratories or General Practitioner (GP) surgeries. Samples were tested on the same day or frozen for later analysis. Patients not returning a sample within 21 days were followed up by phone. Thereafter, patients who did not return a sample were returned to the non-urgent colonoscopy waiting list.

FIT analysis was performed at Canterbury Health Laboratories using a Beckman Coulter DXC 700 AU, with limit of quantification 3mcg/g. Results below 3mcg/g were recorded as undetectable. FIT results were reported quantitatively and reviewed by a FIT team clinician daily and re-triaged as above. Clinical staff were encouraged to use clinical judgement over suggested "per protocol" outcomes where appropriate. CTC results were reviewed by the same medical team and actioned accordingly (e.g., referral for colonoscopy or flexible sigmoidoscopy for colonic findings, or follow on imaging, or referral to other specialties for incidental findings). Primary care was notified by letter at each stage in the pathway. A Microsoft Teams Excel spreadsheet was used to track patients and results, and for prospective audit. In analysis, advanced polyp includes adenomas with villous architecture, or high-grade dysplasia (HGD), a sessile serrated polyp (SSP) with dysplasia, or an adenoma or SSL ≥10mm. All other polyps were considered simple polyps. Endoscopically or histological demonstrated inflammation that is not attributable to inflammatory bowel disease is termed inflammation not otherwise specified (NOS). Analysis is largely descriptive; however, where appropriate, 95% confidence intervals have been calculated using the modified Wald method. Mean fHb in pathological groups are described by the mean and standard deviation. The audit was authorised by the Health New Zealand – Te Whatu Ora Waitaha Canterbury Research Office.

## Results

From 6 July 2022 to 16 April 2023, 776 cases were referred to the pathway, 116 from the pre-existing waiting list and 660 via new patient triage. On review or first contact, 37 were found to be not appropriate for further investigation via the pathway. A flow diagram of case inclusion and loss is shown in Figure 1. Thereafter 715/739 (97%) of cases returned a stool sample, of whom 691 completed the investigation pathway. Of the 739 cases, the median age was 62 years (range 22–85) and 39.7% were male. Ethnicity data and rate of sample return are shown in Table 1. There was no significant difference in sample return rate between population groups. Of 691 cases completing investigation, primary symptom at presentation was anaemia in 61 (8.8%), rectal bleeding in 188 (27.2%), change in bowel habit 417 (60.3%) and other symptoms in 25 (3.6%).

Among 691 cases, 15 were found to have CRC (2.2%) and 57 had advanced polyps (8.2%). The investigational route for cases included in the pathway is shown in Figure 2. The overall fHb positivity rate (threshold of ≥10mcg/g) was 17.1% and is shown according to age in Figure 3. Colorectal findings by fHb threshold are shown in Table 2. The rate of CRC diagnosis was 22% for those with fHb ≥150mcg/g, 6.6% when fHb between 10 and 149mcg/g, and 0.5% when fHb <10mcg/g. Among 547 CTCs, there were 47 non-colonic radiological findings that required further investigation or referral: 12 gynaecological, 12 pulmonary, nine renal, eight hepatobiliary, two adrenal, two hernias, one aneurysm and one mesenteric mass. The median time to CRC diagnosis (from date of referral to colonoscopy) for new referrals triaged to the pathway was 25 days (n=11, range 22 to 79 days), shown in Figure 4. The sensitivity and specificity of FIT ≥10mcg/g for CRC were 80.0% (54.0–93.7%) and 84.3 (81.4–86.9%) respectively. Three CRC had FIT <10mcg/g. One was a CRC in the transverse colon in a patient who presented with rectal bleeding and anaemia (fHb 0mcg/g), and two were polyp cancers, the first a 3mm focus of cancer in a 11mm rectosigmoid tubular adenoma with high grade dysplasia, who presented with PR bleeding (FIT 3mcg/g), and the second a 2mm focus of cancer in a rectal tubulovillous adenoma in a patient who also presented with rectal bleeding (FIT 0mcg/g).

## Discussion

Incorporating FIT into the assessment, referral and triage pathway for New Zealanders with colorectal symptoms promises to streamline access to definitive colorectal investigation and make better use of our constrained colonoscopy resource.[5] In the hiatus before a national directive on the use of FIT in patients presenting with colorectal symptoms, this local initiative has provided an interim solution for a proportion of the patients referred to our service. Compared with a usual colonoscopy waiting time of between 4 and 6 months (at pathway initiation for patients triaged to non-urgent care), the median time to cancer diagnosis for new patients in our pathway was 25 days. Only 2 of 10 new case referrals waited for more than 30 days for colonoscopy. In addition, while we do not propose that a national solution should triage all cases with a FIT≤10mcg/g to CTC, by doing so here, we have reduced colonoscopy demand in this population by 63%, freeing capacity for other patients and improving access across the board. Two CRC cases were detected via the CTC route, justifying the use of a robust safety net for this early adoption of FIT in symptomatic cases in New Zealand.

Within the international literature a fHb threshold of ≥10mcg/g has become the *de facto* rule-out threshold for FIT in symptomatic cases. The sensitivity and specificity for CRC at this threshold are estimated to be 89.0% and 80.1% respectively.[5] Below this threshold, there is a disproportionate loss of specificity for every point gain of sensitivity, and a very low cancer detection rate for cases with symptoms but fHb detectable below 10mcg/g, making investigation of these cases uneconomic.[11] We used the *de facto* threshold because it reflects international practice,[6] and also because patients with FIT below threshold were offered CTC, providing a diagnostic safety net for the 10% of CRCs that are missed at this threshold.[5] If the pathway had not used CTC for patients with a "negative" FIT, then a lower threshold might have been more appropriate. The FIT thresholds in the symptomatic and screening populations differ. In the bowel screening programme, a relatively higher threshold (40mcg/g) is applied to an asymptomatic population with a low prior probability of cancer (~0.2% in the New Zealand bowel screening target population),[12] with the intention of detecting as many cancers as possible while limiting the number of false positive results. The bowel screening threshold is a "rule in" threshold. In the symptomatic population, the prior probability of colorectal cancer is much higher (4% in all direct access referrals to

Canterbury in 2018),[3] and a much lower threshold test is needed to effectively and safely "rule out" colorectal cancer, detecting as many cancers as possible while minimising false negative results. The sensitivity for colorectal cancer in our dataset is lower than previous reports, albeit not significantly so.[11,13] This difference likely relates to low CRC case numbers, which was to be expected given our method of case identification, which favoured inclusion of low risk (for organic disease) patients based on specialist triage. Furthermore, two of the "missed" CRC were microscopic foci within adenomatous polyps, highlighting the lower sensitivity of FIT for advanced polyps, as previously reported, and emphasising the need for rigorous safety net practice, including primary care follow-up and repeat FIT testing where necessary.[11] While it is perhaps inevitable that polyp cancers should predominate in cases of malignancy with low or negative FIT results, it should be recognised that only three of 573 cases with fHb <10mcg/g had CRC, a prevalence of 0.52%, four times lower than the rate of cancer found among referrals to our service who fell outside of the national direct access criteria (2.1%).[3] It follows that some patients who have a low or undetectable fHb should not undergo further investigation due to very low likelihood of significant pathology, real risk of harm from the investigation and economic considerations.[5,6]

Inevitably there were a number of non-colorectal findings on CT imaging that required additional imaging or referral to another specialty, some of which were highly significant. While we have not investigated causality between symptom presentation and radiological finding, our data does raise a question regarding how general practitioners should further investigate the clinical suspicion of organic disease in the face of negative FITs. In this group, CTC may be preferred due to both the low probability of luminal organic disease, the facility to detect non-luminal pathology and acceptability to patients, both as a less invasive test and because with evolution in scanning technology, modern CTC requires relatively low levels of radiation exposure.[14,15]

The successful implementation of a FIT in symptomatic pathway is dependent on a high level of patient participation. Our pathway had a high rate of sample return. We attribute this to the appropriate resourcing, efforts and personal qualities of our administration team, to the quality of our written resources and to the emphasis placed on the importance of the test result to determine the next step of investigation during contact with patients. Of particular note, our administration team were sympathetic to individual patient needs, and volunteered to make and respond to calls outside of office hours. In addition, they had sufficient local knowledge to help patients troubleshoot sample return. The equivalent of one full-time administrator was required to manage the initial waiting list cohort, and thereafter, the pathway was managed with approximately 0.2 full-time equivalent's administration work. We found no significant difference in rate of sample return between population groups in our cohort; however, a larger cohort would be needed to confirm that this approach delivers equity. Previous work by our group found a strong preference for FIT testing in primary care, as it was believed this would encourage sample return, improve patient centredness and streamline care.[5] Such an approach has not, however, been investigated in New Zealand.

In planning our pathway we estimated that the prevalence of CRC in cases with positive FIT would be high, and that their investigations should be prioritised.[5] Indeed, despite the low overall prevalence of CRC in our dataset (2.2%), the risk of CRC among those with FIT ≥10mcg/g was 10%, greater even than that for patients presenting for colonoscopy within the New Zealand National Bowel Cancer Screening Programme and justifying our decision to award priority to these patients.[16]

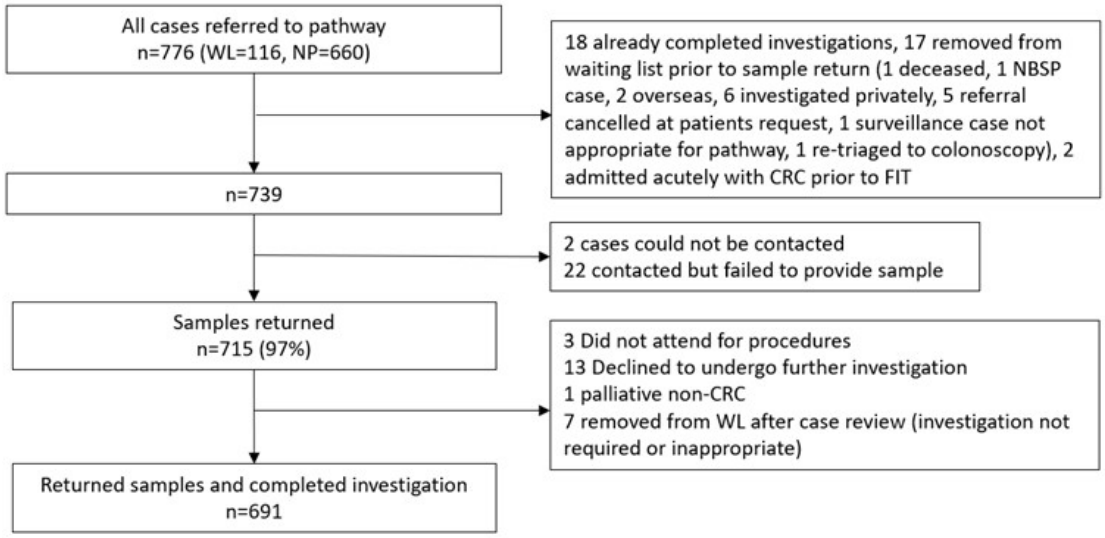
This prospective audit gathered data regarding those who were referred to the pathway and completed investigation following FIT. A more complete picture of departmental activity would have been achieved if we had collected referral and outcome data on all new patients referred for investigation of colorectal symptoms, irrespective of whether they were accepted for investigation or completed investigation. In addition, it would be of interest to understand how those who were triaged to the pathway differed from those who were not; however, this data was not collected. A recent audit from our department does provide some historical context to the current work.[3]

Since the end of this reporting period, April 2023, the pathway has undergone iterative change to embed it in business-as-usual pending national advice on the use of FIT in patients presenting with colorectal symptoms. First of all, the standard stool pottle has been substituted for a buffered FIT collection device, which reduces the risk of Hb degradation prior to analysis and potentially

increases the sensitivity of the test. In addition, this change relaxes the need for same day delivery of the sample to the laboratory, which we believe should further facilitate patient engagement. Thereafter, the pathway was incorporated in usual eTriage process, obviating the need for parallel (to usual hospital process) spreadsheet-based tracking, and involving all triaging consultants in FIT interpretation and re-triage.

Informal feedback regarding the pathway has been universally positive, albeit with some criticism that general practitioners cannot yet request the test directly. Nevertheless, we anticipate with enthusiasm a national directive on the use of FIT in patients presenting with colorectal symptoms, a work in progress under the supervision of the national bowel cancer working group, which we hope will revolutionise the assessment, referral and triage of these cases, and help obtain the greatest benefit from our colonoscopy resource.

**Figure 1:** Case inclusion and loss.

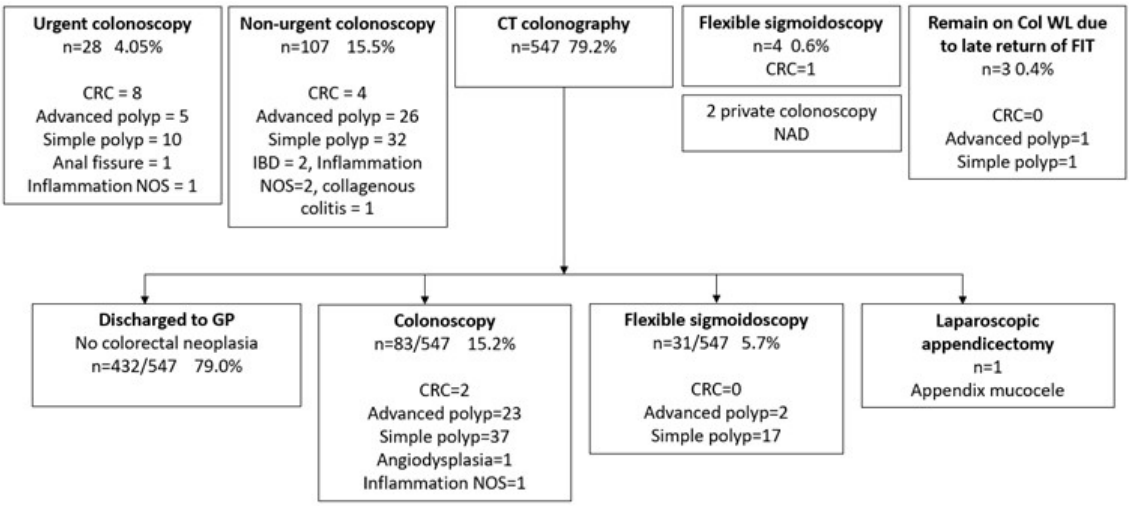



Waiting list = WL; New patient referral = NP; colorectal cancer = CRC; Faecal immunochemical test = FIT.

**Table 1:** Cohort ethnicity and sample return rate (confidence interval [CI]).

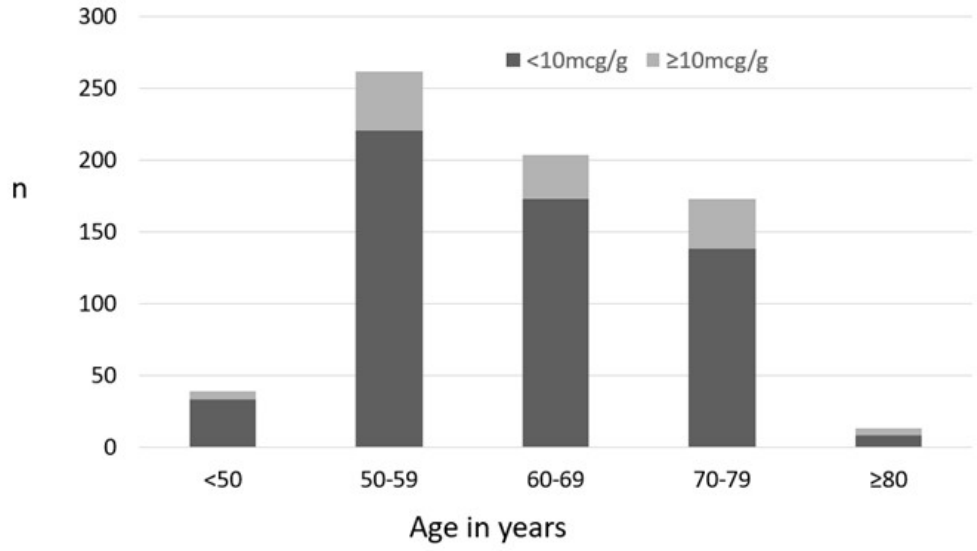
| Ethnicity | Percent of cohort | Returned/invited | Return % (95% CI) |
|---|---|---|---|
| Māori | 6.5 | 44/48 | 92 (80–97) |
| Pacific peoples | 0.9 | 6/7 | 86 (47–99) |
| NZ Other | 92.6 | 665/684 | 97 (96–98) |
| Total | 100 | 715/739 | 97 (95–98) |

**Figure 2:** Investigational route and findings for cases completing investigation.




Waiting list = WL; computed tomography = CT; colorectal cancer = CRC; not-otherwise specified = NOS; no abnormality detected = NAD.

**Figure 3:** Faecal immunochemical test positivity (≥10mcg/g) by age.

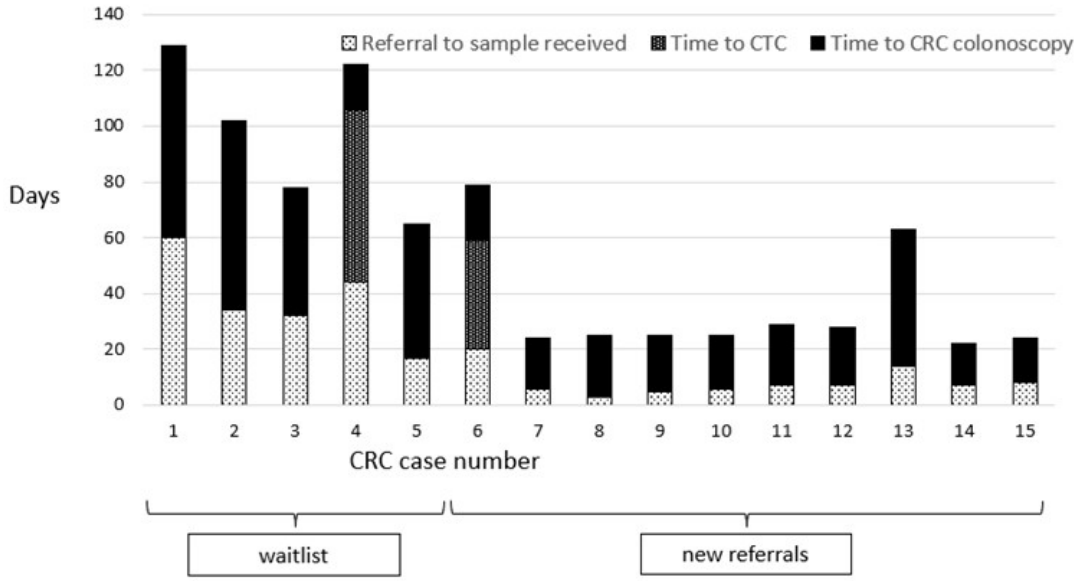



| | <50 | 50-59 | 60-69 | 70-79 | ≥80 |
|---|---|---|---|---|---|
| n | 39 | 262 | 204 | 173 | 13 |
| % ≥10mcg/g | 15.4 | 15.6 | 15.2 | 20.2 | 38.4 |

**Table 2:** Colorectal pathology by faecal haemoglobin threshold.

| | Faecal haemoglobin mcg/g | | | |
|---|---|---|---|---|
| | **≥150mcg/g n=27 (3.9%)** | **10–149mcg/g n=91 (13.2%)** | **Detectable <10mcg/g n=22 (3.2%)** | **Undetectable n=551 (79.7%)** |
| Colorectal cancer | 6 (22%) | 6 (6.6%) | 1 (4.5%) | 2 (0.36%) |
| Advanced polyp | 6 (22%) | 22 (24.2%) | 2 (9.1%) | 27 (4.9%) |
| Simple polyp | 10 (37%) | 29 (31.9%) | 6 (27.3%) | 51 (9.3%) |
| Other | 1 anal fissure, 1 non-specific inflammation | 1 non-specific inflammation, 2 inflammatory bowel disease | 1 non-specific inflammation | 1 each; collagenous colitis, angiodysplasia, appendiceal mucocele, non-specific inflammation |
| No neoplasia or inflammation | 3 (11%) | 31 (34%) | 12 (54.5%) | 467 (84.8%) |

**Figure 4:** Time to colorectal cancer diagnosis from initial referral.



**COMPETING INTERESTS**
The authors have no competing interests.

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