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## **Sociodemographic Variations in the Uptake of Faecal Immunochemical Tests in Primary Care**

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Ethical approval gained locally (NUH Registration Number: 20-135C), all work using routinely collected data.

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## **Abstract**

### **Background**

Faecal Immunochemical Testing (FIT) usage for symptomatic patients is increasing, but variations in use by sociodemographics are unknown. We introduced FIT for symptomatic patients in November 2017.

### **Aim**

Identify whether demographics, ethnicity or social deprivation affect FIT return in symptomatic patients.

### **Design and Setting**

FIT was introduced as a triage tool in Primary Care and was mandated for all colorectal referrals (except rectal bleeding/mass) to secondary care. FIT was used, alongside full blood count and ferritin, to stratify colorectal cancer risk.

### **Method**

All referrals November 2017-December 2021 were retrospectively reviewed. Sociodemographic factors affecting FIT return were analysed by multivariate logistic regression.

### **Results**

35,289 patients returned their index FIT (90.7%), 3631 (9.3%) did not. On multivariate analysis, males were less likely to return FIT (OR 1.11, 95%CI 1.03-1.19). Patients over 65 were more likely to return FIT (OR 0.78 for non-return, 95%CI 0.72-0.83). Unreturned FIT was more than doubled in the most compared to the least deprived (OR 2.20, 95%CI 1.99-2.43). Patients from Asian (OR 1.82, 95%CI 1.58-2.10), Black (OR 1.21, 95%CI 0.98-1.49) and Mixed/Other ethnic groups (OR 1.29, 95%CI 1.05-1.59) were more likely to not return FIT compared to White ethnicity. 599 colorectal cancers were detected (1.5%), 561 in those who returned a first FIT request, 38 in those who did not.

### **Conclusion**

FIT return in those suspected of having colorectal cancer varies by gender, age, ethnicity, and socioeconomic deprivation. Strategies to mitigate effects on FIT return and colorectal cancer detection should be considered as FIT usage expands.

### **How This Fits In**

FIT is increasingly used to triage patients with symptoms suggestive of colorectal cancer but variations in use by demographics, ethnicity and socioeconomic status are unknown. We show, in a large regional dataset, that male patients, patients under 65 years, the most deprived patients and ethnic minority groups are less likely to return a FIT sample. It is important that strategies are developed to ensure patients with these protected characteristics are not disadvantaged with the increasing usage of FIT to prioritise urgency of investigations.

**Key words: Colorectal Cancer, Faecal Immunochemical Testing, Inequality, Social Deprivation.**

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## Introduction

Colorectal cancer (CRC) is common with 42,000 new cases and 16,000 deaths in the UK annually<sup>1</sup>. Survival is related to stage<sup>2</sup> - 90% of early-stage diagnoses survive >5 years, compared to <10% diagnosed at advanced stage<sup>1</sup>. Population-based screening of asymptomatic patients and expedited diagnostic pathways for patients with symptoms aim to improve outcomes. Screening is cost-effective, reducing CRC mortality<sup>3 4</sup> by diagnosing earlier-stage disease, but most diagnoses follow symptomatic referrals, where similar improvements have not been achieved<sup>5 6</sup>.

The Faecal Immunochemical Test (FIT) is used in the Bowel Cancer Screening Programme (BCSP), detecting occult faecal blood that indicates increased risk of CRC. More recently, FIT has been evaluated in patients with lower gastrointestinal symptoms following NICE guidance<sup>7</sup>, identifying patients with the highest CRC-risk for expedited investigation<sup>8-16</sup>. In our pathway, introduction of FIT in 2017 increased the proportion diagnosed on CRC two-week-wait (2WW) pathways<sup>17</sup>. Early outcomes reported at that time suggested a higher proportion of patients diagnosed at an earlier stage; however, low numbers of patients included in that study and the confounding effects of the COVID-19 pandemic merit further study into any stage shift achieved by FIT, which is ongoing. New guidelines recommend urgent referral for those with a FIT result >10 µgHb/g faeces<sup>18</sup>, clinicians are advised for those below this level to consider alternate cancer diagnoses, routine referral or safety-netting in primary care. Higher FIT return-rates have been reported in symptomatic populations<sup>14 15 19</sup>, however sociodemographic variations in symptomatic FIT uptake are a research priority<sup>18</sup>.

There is considerable gender-based, ethnic and socio-economic variability in CRC diagnosis and treatment<sup>20 21</sup>. Differential screening participation-rates are related to demographics and social deprivation<sup>21-24</sup>. Screening participation varies by ethnicity, suggesting complex interactions between socioeconomic, cultural and physician factors<sup>25 26</sup>. Participation is lower for males, deprived and certain ethnic groups<sup>25 27-29</sup>, whereas CRC is more common in males and deprived groups. CRC incidence is lower in Asian and Black populations<sup>30</sup> but outcomes are worse<sup>25</sup>.

These differences in screening-participation have not been demonstrated in symptomatic populations. Patient concern may explain higher returns in symptomatic pathways (~90%<sup>19</sup>) than screening (~65%<sup>20 31</sup>). Understanding sociodemographic factors in uptake is important when ethnic minority and deprived patients have poorer outcomes<sup>4 25</sup>, especially as FIT usage in symptomatic pathways increases<sup>7 18</sup>. We aim to evaluate whether sociodemographic factors affect FIT return in symptomatic pathways.

## Methods

### Study Population

We introduced FIT as a triage tool for all adult symptomatic patients in 2017 (excluding rectal bleeding/mass)<sup>19,32</sup>. The pathway was commissioned to provide direct access to FIT for General Practitioners (GPs), requesting and acting upon results independently or submitting a secondary care referral (including mandatory FIT and blood results). All FIT requests for patients with symptoms were recorded prospectively from pathway inception 03/11/2017 to 31/12/2021. FIT return was reviewed retrospectively. FIT return was defined as returning a sample after first request. Non-return was defined as no return by 14 days after request. GPs were informed electronically if samples were not returned, recommending a further FIT request. Subsequent FIT requests made for first-test non-returners were analysed as a sub-group.

FIT requests were submitted via an electronic request system (ICE) with guidance provided on interpretation. FIT kits were sent/returned via post and analysed in a BCSP-accredited laboratory. The OC-Sensor FIT System (Eiken Chemical, Tokyo, Japan) was used to analyse all samples (Appendix I).

### Exposures, Covariates and Outcomes

A 65 year threshold was used to assess return between age-groups, owing to the categorisation used in Primary Care datasets locally. Gender was classified as female, male or unknown. Patient ethnicity was recorded as declared by the patient on the Patient Administration System (Appendix II). Ethnicities were categorised into five broad groups (defined by the UK Government for Census research purposes) as follows: (1)White; (2)Asian or Asian British; (3)Black, African, Caribbean or Black British; (4)Mixed/multiple or other ethnic groups; (5)Unknown. Socioeconomic data were obtained from 6-digit postcodes using the Index of Deprivation tool (IoD19) to derive Index of Multiple Deprivation (IMD) quintiles, from least (5<sup>th</sup> Quintile) to most deprived (1<sup>st</sup> Quintile). Base population data were obtained from NHS Nottingham and Nottinghamshire Clinical Commissioning Group (CCG). Patients with missing data were categorised as "Unknown". The primary outcome was FIT return/non-return. Cancer Outcomes and Services Datasets (COSD) were used to evaluate the diagnosis of colorectal cancer: ICD codes C18-C20 (excluding C18.1).

## Thresholds

Our threshold for urgent investigation in patients with anaemia, abnormal ferritin or thrombocytosis was 4 µgHb/g faeces. In March 2020, the threshold for urgent investigation for patients with normal haemoglobin, ferritin and platelet count increased from 10 to 20 µgHb/g faeces. The clinical pathway is shown in Figure 1.

## Statistical Analysis

Demographics were presented as proportions, stratified by FIT-return. Histograms were constructed to assess distribution for continuous data. Means were calculated for parametric and medians for non-parametric data. Differences in proportions between groups were evaluated using  $\chi^2$ . Study population characteristics were compared with Nottinghamshire population data using  $\chi^2$ .

Factors predicting FIT non-return were evaluated using  $\chi^2$ . Univariate then multivariate logistic regression analyses were undertaken to evaluate FIT return/non-return by gender, age, ethnicity and socioeconomic deprivation, adjusted for other significant variables. Age was treated as a categorical variable (18-64 and  $\geq 65$ ). CRC outcomes were examined first by  $\chi^2$  comparison, subsequently analysed within a univariate and multivariate model to report the CRC probability in FIT non-returners compared to the overall referred population and those returning a “negative” FIT.

Stata 17 (Stata Corp, USA) was used for analysis with significance if  $p < 0.05$ .

Service evaluation audit Registration Number:20-135C.

## Results

### Cohort demographics

49,166 FITs were requested for 40,817 individual patients in the study period (Figure 2). 1,897 ineligible requests were excluded (Table 1). The first FIT requests for 38,920 individual patients were included in the main analysis. 35,289 patients returned a FIT sample after the first request (90.7%). Of the 3631 non-returners, 1637 (45.1%) had a subsequent request within 6 months. After a second request, 1022 of these patients (62.4%) returned a FIT sample. 20 CRCs were detected in 1826 patients (1.1%) who had no further FIT requests made, despite an alert being made to GPs of non-return. Median follow-up was 17.9 months (IQR 8.8-30.4), 14.2 months for non-returners (IQR 6.2-26.6) and 19.0 months for those with a fHb <4 µgHb/g faeces (IQR 9.6-31.9). The median age was 66yrs (IQR 54-77). The largest ethnic group was White (27,278, 70.1%). The largest socioeconomic group of the investigated population was the least deprived quintile (11,036, 28.4%).

### Comparison with the Nottinghamshire population

There were significantly more females in the study compared to Nottinghamshire population (56% vs 49.9%,  $p < 0.001$ ). The study population was older, 53.7%  $\geq 65$ yrs compared to 21.9% of the base population ( $p < 0.001$ ). There were differences between the ethnicities of the study and Nottinghamshire populations ( $p < 0.001$ ), the largest of which was in the Unknown group (21.5% of the study population, 11.4% of Nottinghamshire). Social deprivation differed significantly ( $p < 0.001$ ). The least deprived (5<sup>th</sup> Quintile) were overrepresented in the study population, accounting for 28.4% of all FIT requests whilst constituting just 19.7% of the Nottinghamshire population. The most deprived quintile accounted for 22.9% of all FIT requests and represented 19.6% of the Nottinghamshire population (Table 2).

### FIT Return

FIT return varied by gender, age, ethnicity, and social deprivation (Table 3). Males had lower return, 90.2% compared to 91% in females ( $p = 0.01$ ). Non-returners were younger (median 62 years, IQR 49-77) than FIT-returners (median 67 years, IQR 55-77). FIT return in patients under 65yrs was lower than over 65yrs (89.2% vs 91.9%,  $p < 0.001$ ). FIT return was significantly higher for White ethnicities (91.2%) compared to ethnic minority groups (83.8% for Asian patients, 86.6% for Black patients, and



87.2% for patients from mixed/other races,  $p < 0.001$ ). FIT return was lower in the most deprived quintile (86.3%) compared to the least (93.6%,  $p < 0.001$ ).

### **Predictors of FIT return**

Male patients were less likely than female to return FIT, after adjustment for other factors (OR 1.11 for non-return, 95%CI 1.03-1.19). Patients  $\geq 65$  yrs were more likely to return a FIT compared to those 18-64 years (OR 0.78, 95%CI 0.72-0.83 for non-return). People from Asian and Black ethnicities had a 1.8 and 1.2 fold increased non-return compared to White ethnicities, respectively (OR 1.82, 95%CI 1.58-2.10/OR 1.21, 95%CI 0.98-1.49 respectively). Non-return was higher in the Mixed/Other ethnic group (OR 1.29 95% CI 1.05-1.59) but not the Unknown group (OR 0.99 95% CI 0.90-1.08) compared to White ethnicity. Non-return increased across each increasing deprivation quintile. After adjustment for confounders, the most deprived quintile were over twice as likely to not return FIT than the least (OR 2.20, 95%CI 1.99-2.43).

### **CRC Diagnosis**

599 CRC were detected in the overall study population (1.5%), 561 in FIT-returners (1.6%) and 38 (1.0%) in 3631 first FIT non-returners. In non-returners, 20 CRCs were detected from 1826 patients via routine or emergency pathways after no further FIT requests were made. 18 were detected in 1805 patients who had a further FIT requested (16 of these from 1637 patients having re-request within 6 months of initial request).

Non-returners after first FIT request were significantly more likely to be diagnosed with CRC than patients returning a FIT $<4$  (1% vs 0.1%,  $p < 0.001$ ) or FIT $<20$  (1% vs 0.3%,  $p < 0.001$ ).

Patients who returned their first FIT request were significantly more likely to be diagnosed with CRC than patients returning a FIT after a further request was made (1.6% vs 1.0%,  $p = 0.05$ ). Patients who did not return their first request were significantly more likely to have a delay in diagnosis than patients returning their first request ( $p = 0.024$ , Appendix IV).

## **Discussion**

### **Summary**

This is the first study describing sociodemographic variations in FIT return in symptomatic patients from Primary care. Our study identified clear demographic, ethnic and socioeconomic variations in FIT return and clinicians need to be aware of these when requesting FIT, counselling patients and “safety-netting” in practice. Fewer male patients had a FIT requested and they were less likely to return FIT than females. Return was lower in younger patients (<65 years) and ethnic minority groups. The least-deprived patients were over-represented in the referred population. FIT return decreased with increasing deprivation.

### **Strengths and limitations**

The large cohort and high FIT return are strengths of this study. The data presented is from primary care, representing an unselected real-life experience of FIT usage in patients consulting with symptoms. One limitation includes the large proportion of Unknown ethnicity in the referred population, limiting further comparisons of outcomes with the base population. FIT was not used locally for rectal bleeding or rectal mass in this period and cancer diagnoses in distant trusts would not be captured but we expect this number to be small. We considered the first FIT request for each patient to yield accurate cohort risks: subgroup analysis of additional requests did not identify divergence in return-rate or test performance. Over-representation of the least deprived patients in the referred population is in line with screening studies, with lowest engagement in the most deprived<sup>22 23</sup>. This may be due to deprived patients presenting less to primary care or less-likely to be referred by GPs. Symptomatic patients may be more motivated to complete FIT than asymptomatic patients due to a perceived threat to their health. This may overcome negative emotions associated with lower engagement such as embarrassment, disgust and fear<sup>33 34</sup>. This reinforces the need to counsel patients when requesting FIT, promoting a more positive view of cancer outcomes to minimise fear-related avoidance.

### **Comparison with existing literature**

The lower referrals and FIT-return for males represents a well-described trend of lower male engagement with healthcare services. Numerous explanations exist for this trend, including

masculinity ideologies<sup>35</sup>, fearful health beliefs and lower health awareness<sup>36</sup>. Practical systems-based solutions such as pro-active follow-up of patients after non-return may yield higher engagement than strategies targeting the patient to change behaviour<sup>37 38</sup>. Solving this imbalance may meaningfully reduce CRC mortality, given higher incidence and more pronounced screening disparities for males<sup>31</sup>.

Patients <65 years were less likely to return a FIT. This reinforces the need to engage younger patients in whom CRC incidence is rising<sup>39 40</sup>. Thorough counselling of risk at the time of FIT request is imperative when used in younger individuals, especially those who may rightly assume their absolute risk of CRC is lower until a high FIT result modifies that risk. This group face delayed diagnosis if FIT return is not actively encouraged<sup>41 42</sup>. FIT represents an opportunity to identify high-risk younger patients, reducing missed curable pathology for those whom early-stage diagnosis has the largest survival benefit.

FIT return was highest in patients from White ethnicities and lowest in ethnic minorities. Ethnic minority groups and non-English speakers appear less likely to return FIT, as demonstrated in screening<sup>21 23</sup>. CRC is less common in patients of Asian and Black ethnicity in the UK<sup>30</sup>, but often presents at later stage<sup>25</sup>. This disparity demands novel strategies to minimise ethnic inequalities, with appropriate safety-netting and counselling<sup>43</sup>. Recently, we have introduced visual instructions in multiple languages to address this barrier to healthcare participation in linguistically diverse populations. Further work on other communication challenges such as difficulties with hearing or vision is required<sup>44 45</sup>. Focused media campaigns, including social media, may have a role, but surveyed preference for FIT is lower in younger and non-white ethnicity patients<sup>46</sup>.

### **Implications for practice**

There is understandable interest in the CRC-risk for “FIT-negative” patients in Primary care. The rate of CRC for non-returners, 1.0%, is lower than the 3% threshold defined by NICE for urgent referral, but higher than those with fHb below 10 (0.2%) or 20 µgHb/g faeces (0.3%). Patients who returned a FIT after a further request was made had a similarly lower rate of CRC (1.0%) compared to those returning their first request (1.6%). Awareness in Primary Care of groups less likely to respond may reduce missed diagnoses more effectively than current concerns around “negative-FIT” CRC. Frank conversations around willingness to sample faeces in at-risk groups and additional safety-netting

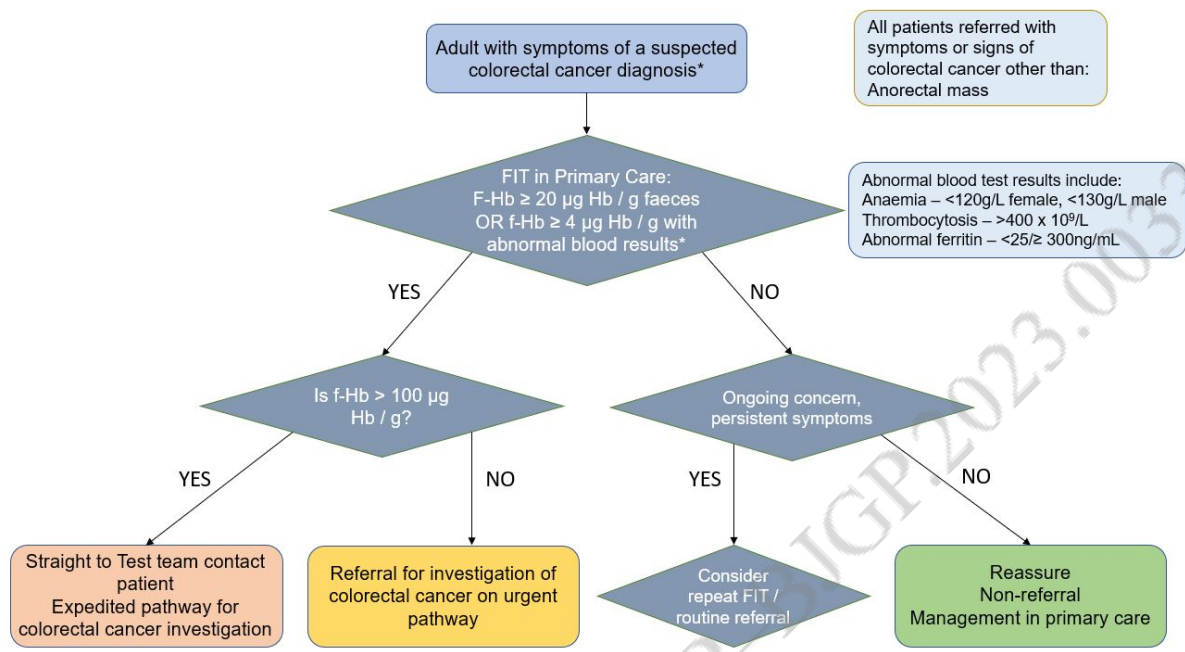
strategies are advisable. Access to secondary care investigation for non-returners should underpin FIT implementation in Primary Care. Reported CRC rates in this subgroup suggest routine referral may be an appropriate safety net for FIT non-return, provided there is a robust system in place to alert GPs to FIT non-return and mitigate any risk to patients where the index of suspicion for CRC is high.

### **Conclusions**

FIT usage in Primary Care appears to be broadly acceptable to patients with >90% return. Non-return is related to gender, age, ethnicity and socioeconomic deprivation, with similar patterns to screening programmes. Disparities should be considered as FIT for symptomatic patients continues to expand, ensuring patients with these protected characteristics are not disadvantaged.

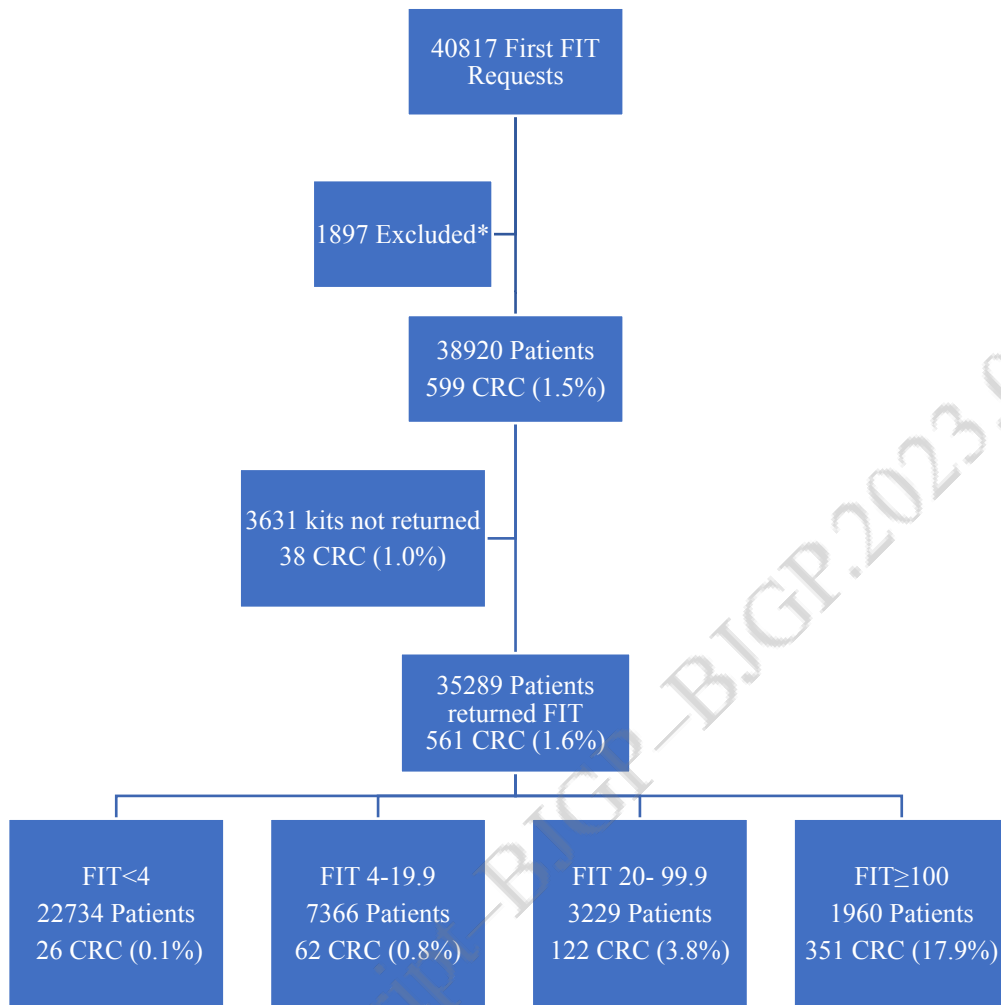
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Figure 1: Clinical Pathway in Nottingham 2020-2022



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**Figure 2: Flow chart showing first FIT requests made per patient, returns and CRC diagnoses by FIT strata.**



**Table 1: Excluded FIT Requests**

Reason for Exclusion	Number Excluded
Rectal Bleeding	1218
Duplicate Request	315
Request from Out of Area	197
Sampling Error	101
Incomplete Request	39
Not indicated under 18 yrs	16
Incomplete Records	11
<b>Total Excluded</b>	<b>1897</b>

**Table 2: Baseline characteristics of patients who had a FIT request from November 2017 to December 2021 compared with baseline Nottinghamshire population**

		Base population	Investigated population	
Variable	Categories	Totals (%)	Totals (%)	CRC detected (%)
Gender	Female	496525 (49.9)	21800 (56)	252 (1.2)
	Male	498755 (50.1)	17112 (44)	347 (2)
	Unknown	35 (0.0)	8 (0.0)	0 (0.0)
Age	<65 yrs	777085 (78.1)	18029 (46.3)	130 (0.7)
	≥65 yrs	218195 (21.9)	20891 (53.7)	469 (2.2)
	Unknown	35 (0.0)	0 (0.0)	0 (0.0)
Ethnicity	White	753845 (75.7)	27277 (70.1)	439 (1.6)
	Asian	66220 (6.7)	1584 (4.1)	6 (0.4)
	Black	29565 (3.0)	801 (2.1)	7 (0.9)
	Mixed/Other	31750 (3.2)	876 (2.3)	8 (0.9)
	Unknown	113935 (11.4)	8382 (21.5)	139 (1.7)
Social Deprivation*	5 <sup>th</sup> Quintile	195680 (19.7)	11036 (28.4)	183 (1.7)
	4 <sup>th</sup> Quintile	204595 (20.6)	6278 (16.1)	124 (2)
	3 <sup>rd</sup> Quintile	205315 (20.6)	6454 (16.6)	95 (1.5)
	2 <sup>nd</sup> Quintile	194310 (19.5)	6177 (15.9)	95 (1.5)
	1 <sup>st</sup> Quintile	195325 (19.6)	8927 (22.9)	102 (1.1)
	Unknown	90 (0.0)	48 (0.1)	0
* 5 <sup>th</sup> Quintile refers to least deprived group, 1 <sup>st</sup> Quintile refers to most deprived group				

**Table 3: Univariate and Multivariate Logistic Regression Analysis of FIT Return by Gender, Age, Ethnicity and Social Deprivation**

	Categories	Return (%)	Non-Return (%)	Univariate	Multivariate
				OR (95% CI)	OR (95% CI)
Gender*	Female	19841 (91)	1959 (9)	Reference	
	Male	15442 (90.2)	1670 (9.8)	1.10 (1.02-1.17)	1.11 (1.03-1.19)
Age	<65 yrs	16080 (89.2)	1949 (10.8)	Reference	
	≥65 yrs	19209 (91.9)	1682 (8.1)	0.72 (0.67-0.77)	0.78 (0.72-0.83)
Ethnicity	White	24864 (91.2)	2413 (8.8)	Reference	
	Asian	1328 (83.8)	256 (16.2)	1.99 (1.73-2.29)	1.82 (1.58-2.10)
	Black	694 (86.6)	107 (13.4)	1.59 (1.29-1.96)	1.21 (0.98-1.49)
	Mixed/Other	764 (87.2)	112 (12.8)	1.51 (1.23-1.85)	1.29 (1.05-1.59)
	Unknown	7639 (91.1)	743 (8.9)	1.00 (0.92-1.09)	0.99 (0.90-1.08)
Deprivation	5 <sup>th</sup> Quintile	10328 (93.6)	708 (6.4)	Reference	
	4 <sup>th</sup> Quintile	5808 (92.5)	470 (7.5)	1.18 (1.05-1.33)	1.18 (1.04-1.33)
	3 <sup>rd</sup> Quintile	5885 (91.2)	569 (8.8)	1.41 (1.26-1.58)	1.39 (1.24-1.56)
	2 <sup>nd</sup> Quintile	5521 (89.4)	656 (10.6)	1.73 (1.55-1.94)	1.68 (1.50-1.87)
	1 <sup>st</sup> Quintile	7703 (86.3)	1224 (13.7)	2.32 (2.10-2.55)	2.20 (1.99-2.43)
	Unknown	44 (91.8)	4 (8.2)	1.30 (0.47-3.62)	1.28 (0.46-3.57)

\*8 requests for patients of Unknown gender with 6 samples returned not displayed in table.



### **Additional information**

**Funding:** No external funding was received for this study.

**Ethical approval:** Ethical approval for the work was gained locally (NUH Registration Number: 20-135C) with all work using routinely collected data.

**Competing interests:** We have no conflicts of interest to disclose. All co-authors have seen and agree with the contents of the manuscript and there is no financial interest to report. We certify that the submission is original work and is not under review at any other publication.

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