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Title: Model Health and Resource Consequences of Reducing the Faecal Immunochemical Test (FIT) Screening Threshold for Colonoscopy in the NHS Bowel Cancer Screening Programme (BCSP)

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Model Health and Resource Consequences of Reducing the Faecal Immunochemical Test (FIT) Screening Threshold for Colonoscopy in the NHS Bowel Cancer Screening Programme (BCSP)

Sheffield Centre for Health and Related Research (SCHARR), Population Health, University of Sheffield

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Contributions: Dr Sophie Whyte undertook data request, data analyses, health economic modelling and drafted report, Yuxaio Sun undertook data analyses and statistical analysis.
Prepared for: Department for Health & Social Care

1 INTRODUCTION

1.1 Bowel screening with FIT

In 2016 the UK National Screening Committee (NSC) recommended that faecal immunochemical testing (FIT) should replace guaiac faecal occult blood testing (gFOBt) as the primary test for bowel cancer screening. FIT replaced gFOBt in Scotland in 2017, in England and Wales in 2019, and in Northern Ireland in 2021.

1.2 FIT screening age range

Bowel screening with gFOBT was initially offered to the 60-70 age group with the upper age limit subsequently being extended up to 74. In 2018 the UK NSC review recommended that screening for bowel cancer should be offered every 2 years to men and women between the ages of 50 and 74 in the UK using the faecal-immunochemical test (FIT). (1, 2)

Current screening practice varies by country. The NHS Bowel Cancer Screening Programme (BCSP) in England currently offers screening to everyone aged 54 to 74 every 2 years but it will soon be available for everyone aged 50 to 74 years old. People older than 74 years of age can request a screening kit every 2 years.(3) The NHS BCSP in Scotland offers screening every 2 years to people aged 50-74 registered with a GP. People older than the maximum automatic screening age can request a screening kit every 2 years. The NHS BCSP in Wales offers screening every 2 years to people aged 51-74 registered with a GP. Requests for screening outside the screening age group are not currently accepted.

1.3 FIT Threshold

Currently the FIT screening threshold differs by nation being 80 µg Hb/g in Scotland and Wales, and 120 µg Hb/g in England and Northern Ireland. The UK NSC has recommended that the FIT screening threshold for referral to follow up diagnostic (colonoscopy or computed tomography colonography (CTC)) in the NHS BCSP be reduced from 120µg/g to 20µg/g and ministers agreed the recommendation that the threshold should be reduced.

1.4 Feasibility of reducing the FIT screening threshold

NHS England (NHSE) wish to determine what level of reduction in FIT threshold is achievable (in the first instance) and how this can be delivered in practice. The CMO has asked Office for Health Improvement and Disparities (OHID) and NHSE screening to quantify the potential outcomes and impact of different FIT screening thresholds. An understanding of service needs (associated costs, workforce implications etc.) of different FIT screening threshold levels is crucial for strategic planning and to understand feasibility. Colonoscopy capacity is a key quantity but as colonoscopy capacity is used for screening, symptomatic referrals, and surveillance; any changes need to be considered alongside that of FIT symptomatic usage. Key disease outcomes of interest include reduction in numbers of cancers and reductions in numbers of late-stage cancers. The predictions of health and resource consequences of reducing the FIT screening threshold for colonoscopy in the NHS BCSP will be useful to inform: threshold change decisions; communications messages with a wide range of stakeholders; and future modelling exercises.

1.5 Predicting the impact of reducing the FIT threshold

The aim of this project is to predict the impact of applying different FIT thresholds within the BCSP. The following FIT thresholds were considered: 20 µg/g, 40 µg/g, 60 µg/g, 80 µg/g, 100 µg/g and 120 µg/g and impacts for the age groups 50-59, 60-74 and 75+ were generated. Predictions relating to the population of England in 2025 were generated for a screening strategy of 2-yearly screening from age 50-74 plus the possibility to opt-in for ages 75+.

Part 1 estimates the impact on the following screening outputs: screening invitations, screening participations, persons with positive FIT (above the threshold), follow-up diagnostic tests (colonoscopy, CTC), and persons referred to surveillance or site checks. Part 2 estimates the impact on disease and long-term outputs comprising: surveillance procedures, cancer diagnoses (including early/late-stage), QALYs saved and change in treatment costs.

2 METHODS: PART 1 – Screening outputs predictions

2.1 Data used and predictions generated

Predicted screening outputs were estimated by undertaking data analysis and statistical modelling using two key data sources: (1) NHS BCSP data, and (2) ONS data.

(1) NHS BCSP data

Data was obtained from the NHS BCSP in June 2024 with the data fields and categories included being specified for this project. (4) The data set included: number of events related to individuals invited to and participating in FIT screening, the count of spoilt test kit, test kit readings, abnormal FIT results for the 2023 calendar year, and data for diagnostic tests and episode results for both the 2022 and 2023 calendar years. The data were summarised by 2-year age groups from 54 to 73, with a separate summarised group for those aged 74 and over. Data for females and males were presented separately.

The BCSP data set did not include information on previous screening episodes (screening history). Inclusion of such data would have increased the complexity of the data set considerably and likely necessitated analysis of patient level data rather than summary statistics.

(2) ONS data

Population data for England were obtained from the Office for National Statistics (ONS) subnational population projections. (5) Population estimates for the years 2023 and 2025 were extracted by single year of age, sex. The ONS data from 2023 were used to calculate invitation rates from the BCSP 2023 data. The ONS data from 2025 were used to inform predictions for 2025. Note that the age categories for the BCSP data differ slightly from the age categories for the predictions and this was accounted for within calculations. See table 2.1 for a summary of the ONS England population data used.

Table 2.1. Summary of England population counts from ONS data

Age group	England population 2023 (ONS), 1000s Female	Male
54-59	2,362	2,284
60-73	4,399	4,144
74+	3,340	2,655
all ages	10,101	9,083

Age group	England population, 2025 (ONS), 1000s Female	Male
50-59	3,790	3,683
60-74	4,842	4,550
75+	3,203	2,540
all ages	11,835	10,773

2.2 Screening outputs predictions – variation over time

Screening outputs (such as participation and positive screens) will change over time for several reasons: (1) due to population age profile changing over time, (2) due to population cancer risk factors changing over time, and (3) due to

a screening programme moving to an advanced stage of roll-out (i.e. persons having received more previous screening invitations) which will reduce disease prevalence in the population.

Screening outputs will reach a steady-state once all screening invitees receive their first invitation at age 50. For example, it will be 25 years from now until a screening invitee of age 74 will have been invited from age 50 (with up to 12 previous screens). Screening outputs will continue to change dynamically until this steady-state is reached. As time elapses and the screening programme approaches a steady state disease prevalence will reduce and so will positivity rates.

Predictions generated here assume that invitation rates, participation rates and positivity rates (by age and sex) will be the same as in the 2023 dataset i.e. the calculations assume that screening history is the same between the 2023 and 2025. As screening history will be reasonably similar between the 2025 and 2023 population this is considered a minor limitation but means that the predictions generated here will be upper bounds for expected numbers of FIT positives. We note that the predictions here should be of use for 2025 but in future years it is expected that numbers of persons with positive screens will reduce as the programme approaches steady-state.

Predictions generated here relate to screening from age 50 for the England 2025 population.

2.3 Screening invitations, participations and spoilt kits

The number of individuals invited to and participating in FIT screening and the number of spoilt kits for the 2023 calendar year were provided by BSCP data. These data were used to estimate the invitation rate (% of background population invited) and the participation rate (% of persons invited) and spoilt kit rate, see Table 2.3a. Note that for the 74+ age group invitation rate is the rate at which a test is requested as this age group is opt in rather than routinely invited. Spoilt kit rate was higher in males than females and lower for older age groups.

Table 2.3a. Invitation and participation numbers and rates from the BCSP 2023 data.

	England population 2023 (ONS), 1000s		Persons invited BCSP 2023, 1000s		Coverage (% invited and receiving test kit of background population)		Persons participating BCSP 2023, 1000s		Participation rate (of persons invited)	
Age group	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male
54-59	2,362	2,284	935	970	39.6%	42.5%	606	551	64.8%	56.8%
60-73	4,399	4,144	2,323	2,257	52.8%	54.5%	1,690	1,543	72.8%	68.4%
74+	3,340	2,655	174	152	5.2%	5.7%	128	110	73.6%	72.4%

Age group	Spoilt kit rate		
	Female	Male	Persons
54-59	2.1%	2.5%	2.3%
60-73	2.0%	2.4%	2.2%
74+	1.2%	1.3%	1.3%
all ages	2.0%	2.4%	2.2%

Based on these data, two assumptions were made regarding invitation rate. Firstly, it was assumed that the invitation rates for the 50-59 and 60-74 age groups in 2025 will be 50% (in line with the biennial screening invitations).

Secondly, the invitation rate in the 75+ age group was assumed to be 6% (74 and over age group in 2023 was 5.2% for females and 5.7% for males). Participation rates in 2025 were assumed to be the same as those calculated based on the 2023 BCSP data. The estimated invitation and participation rates were used to forecast the numbers of invitations and participations in 2025. Table 2.3b presents screening invitation rates (based on assumptions described above) and screening participation rates (based of NCSP 2023 data).

Table 2.3b. Screening invitation and participation rates assumed for England 2025

	Female			Male			Persons		
Age group	50-59	60-74	75+	50-59	60-74	75+	50-59	60-74	75+
coverage (% invited and receiving test kit of background population)	50%	50%	6%	50%	50%	6%	50%	50%	6%
% participating (of persons invited)	64.8%	72.7%	73.7%	56.9%	68.4%	72.1%	60.8%	70.6%	73.0%

2.4 Positive FIT tests by FIT threshold

Within the BCSP 2023 data the individuals participating in FIT testing were categorised by sex, age groups, and FIT score (with readings reported per 5 mcg Hb/g). For each sex and age groups the number of individuals with a FIT score below each of the six FIT thresholds was calculated (120 mcg Hb/g, 100 mcg Hb/g, 80 mcg Hb/g, 60 mcg Hb/g, 40 mcg Hb/g, and 20 mcg Hb/g). FIT positivity rates, stratified by sex, age group, and FIT threshold, were calculated as the proportion of positive individuals among those participating. See Table 2.4a.

Table 2.4a. Number of FIT positive tests, BCSP 2023

Age group	FIT result frequency							FIT positivity rate					
	All kits	FIT20	FIT40	FIT60	FIT80	FIT100	FIT120	FIT20	FIT40	FIT60	FIT80	FIT100	FIT120
Female													
54-59	600,093	28,939	17,119	12,692	10,366	8,836	7,750	4.8%	2.9%	2.1%	1.7%	1.5%	1.3%
60-73	1,756,363	106,208	60,534	43,839	34,896	29,094	24,908	6.0%	3.4%	2.5%	2.0%	1.7%	1.4%
74+	194,920	15,242	8,658	6,156	4,851	3,948	3,375	7.8%	4.4%	3.2%	2.5%	2.0%	1.7%
TOTAL	2,551,376	150,389	86,311	62,687	50,113	41,878	36,033	5.9%	3.4%	2.5%	2.0%	1.6%	1.4%
Male													
54-59	545,766	36,278	22,635	17,347	14,395	12,422	10,998	6.6%	4.1%	3.2%	2.6%	2.3%	2.0%
60-73	1,603,955	136,528	81,819	61,016	49,538	41,957	36,543	8.5%	5.1%	3.8%	3.1%	2.6%	2.3%
74+	176,328	19,093	11,305	8,239	6,647	5,609	4,794	10.8%	6.4%	4.7%	3.8%	3.2%	2.7%
TOTAL	2,326,049	191,899	115,759	86,602	70,580	59,988	52,335	8.2%	5.0%	3.7%	3.0%	2.6%	2.2%
Persons													
54-59	1,145,859	65,217	39,754	30,039	24,761	21,258	18,748	5.7%	3.5%	2.6%	2.2%	1.9%	1.6%
60-73	3,360,318	242,736	142,353	104,855	84,434	71,051	61,451	7.2%	4.2%	3.1%	2.5%	2.1%	1.8%
74+	371,248	34,335	19,963	14,395	11,498	9,557	8,169	9.2%	5.4%	3.9%	3.1%	2.6%	2.2%
TOTAL	4,877,425	342,288	202,070	149,289	120,693	101,866	88,368	7.0%	4.1%	3.1%	2.5%	2.1%	1.8%

A statistical model was fitted, this enabled predictions to be made for broader age groups for which there were limited or no data available (e.g. 50-53 ages). The statistical model was fit to estimate FIT positivity rates based on the variables age and FIT threshold. Curve fitting was conducted using R and a series of statistical methods, including linear regression, exponential regression, logarithmic regression, and polynomial regression, were applied to identify the most appropriate model. The R-squared values were compared to evaluate the goodness of fit for each model, and it was found that the exponential model provided the best fit.

Positive FIT rates were treated as the dependent variable, while age was considered a nominal independent variable, and sex and FIT thresholds were considered as categorical variables. The analysis used 2-year age bands from 54-55 to 72-73 with each 2-year age band being represented by the midpoint The age group 74+ was excluded due to the lack of breakdown by 2-year age intervals.

The exponential model was expressed as:

$$\log(Rate) = \beta_0 + \beta_1 Age + \beta_2 GenderMale + \sum_{i=1}^{5} \beta_{2+i} Threshold_i$$

where: Intercept, β_1 = -6.16 Intercept; Coefficient for sex is male β_2 = 0.42; and coefficients for thresholds (100µg/g, 80µg/g, 60µg/g, 40µg/g, 20µg/g) are (β_3 = 0.14, β_4 = 0.31, β_5 = 0.52, β_6 = 0.82, β_7 = 1.35) respectively. For example, for males aged 58, the positive rate of FIT under the 80 µg/g threshold can be calculated as: $\log(Rate\_male\_FIT80) = \beta_0 + \beta_1 \times 58 + \beta_2 + \beta_4$=2.5%

Figure 2.4a presents the fitted statistical model (lines) compared to the positivity rates from the BCSP 2023 data (points). Table 2.4b presents FIT positivity rates by threshold based on the statistical model predictions from the BCSP 2023 data.

Figure 2.4a. Plots comparing Exponential models and BCSP2023 data for FIT positivity rates

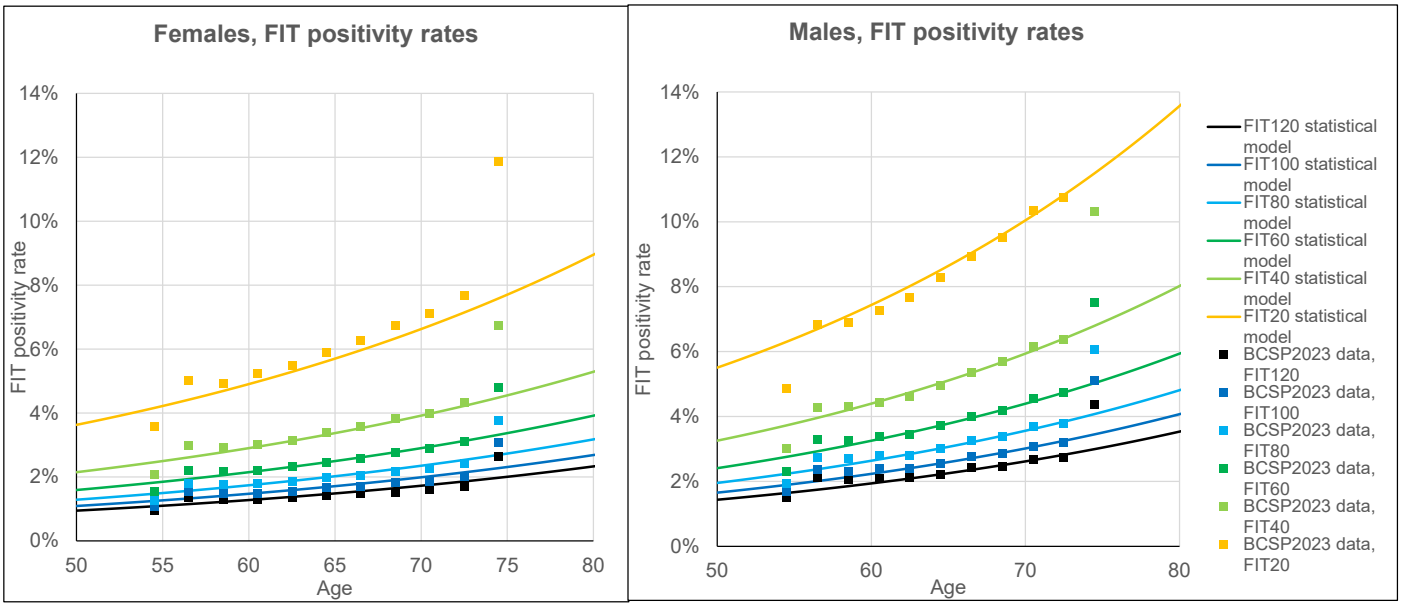

Table 2.4b. FIT positivity rates (%), statistical model predictions by FIT threshold, age and sex

	Female			Male			Persons		
Age group	50-59	60-74	75+	50-59	60-74	75+	50-59	60-74	75+
% FIT positive (of persons participating)									
FIT threshold 120 µg/g	1.1%	1.6%	2.5%	1.7%	2.4%	3.7%	1.3%	1.9%	3.0%
FIT threshold 100 µg/g	1.3%	1.8%	2.9%	1.9%	2.7%	4.2%	1.6%	2.2%	3.5%
FIT threshold 80 µg/g	1.5%	2.1%	3.4%	2.2%	3.2%	5.0%	1.8%	2.6%	4.1%
FIT threshold 60 µg/g	1.8%	2.6%	4.2%	2.8%	4.0%	6.2%	2.3%	3.3%	5.0%
FIT threshold 40 µg/g	2.5%	3.5%	5.6%	3.7%	5.4%	8.3%	3.1%	4.4%	6.8%
FIT threshold 20 µg/g	4.2%	6.0%	9.5%	6.3%	9.1%	14.1%	5.2%	7.4%	11.5%

The number of positive FIT screening results for 2025 was calculated by multiplying the positivity rates (estimated by the statistical model) by the predicted participation numbers.

2.5 Follow-up diagnostic tests

The BCSP 2023 data provides diagnostic procedure attendance data for all persons with a positive screen, see Table 2.5a.

Table 2.5a. Follow-up diagnostics attendance based on FIT 120µg/g in BCSP 2023 data

Age	Definitive FIT+ Patients	Procedure Attendance	Procedure Uptake %
54-59	19,084	15,201	80%
60-73	62,061	46,998	76%
74+	8,305	5,911	71%
Total	89,450	68,110	76%

The BCSP 2023 data provides numbers of follow-up diagnostic tests undertaken for each of colonoscopy, CTC and flexible sigmoidoscopy and these relate to the current FIT threshold of 120µg/g, see Table 2.5b. These data were split according to first and subsequent tests within an episode (as a significant proportion of persons receive more than one diagnostic test as their follow-up e.g. a CTC then a colonoscopy) but for the purposes of estimations here first and subsequent test counts were combined to give numbers for all tests in episode. The diagnostic test usage rates for both colonoscopy, CTC and flexible sigmoidoscopy (in FIT 120µg/g positives) were calculated as number of tests per positive FIT.

Table 2.5b. Follow-up diagnostics based on FIT 120µg/g in BCSP 2023 data

	2023					2022
	first test in episode	all tests in episode				all tests in episode
Age	CTC/Colon /Flexi	CTC	COL	Flexi	CTC/Colon/ Flexi	CTC/Colo n/Flexi
54-59	6,524	796	15,307	678	16,781	7,313
60-73	43,964	3,775	49,638	3,109	56,522	55,469
74+	4,921	679	5,704	435	6,818	6,337
TOTAL	55,409	5,250	70,649	4,222	80,121	69,119

	Tests per FU attendee			Tests per FIT positive person		
Age	CTC	COL	Flexi	CTC	COL	Flexi
54-59	0.12	2.35	0.10	0.10	1.87	0.08
60-73	0.09	1.13	0.07	0.07	0.86	0.05
74+	0.14	1.16	0.09	0.10	0.82	0.06
TOTAL	0.09	1.28	0.08	0.07	0.97	0.06

COL – colonoscopy; CTC - computed tomographic colonography

The predicted number of diagnostic tests (colonoscopy, CTC) for 2025 was determined by multiplying the number of FIT-positives (calculated previously) by the diagnostic test usage rate (calculated from the BCSP 2023 data). It was assumed that the usage rates for COL, CTC and Flexi remain constant, even when applying lower FIT thresholds. It was assumed that procedure rates in the 54-49 age group would also apply to the 50-53 age group.

Adverse event rates for bleeding and perforation from colonoscopy or CTC procedures were taken from the same sources used in the ScHARR 2018 Bowel Cancer Screening model. Calculations assume that 2/3 of colonoscopy procedures are therapeutic. Numbers of adverse events were calculated by multiplying predicted diagnostic test usage for 2025 by adverse event rates.

2.6 Disease detected by FIT120

The BCSP data included findings at follow-up and the number of people referred to surveillance based on FIT threshold 120 µg/g in year 2023. In 2023 findings are recorded in terms of cancer, large non-pedunculated colorectal polyp (LNPCP), and high-risk findings, in line the new 2020 British Society of Gastroenterology (BSG) surveillance guidelines.(6) BCSP 2022 included some data using the classification relating to the previous 2010 surveillance guidelines (namely ‘low risk’, ‘int risk’ and ‘high risk adenoma’) and some using the new classification relating to the 2020 guidelines (namely ‘LNPCP and high-risk finding).(7)

The BCSP data set included 5,258 cases of cancer. PPVs were calculated by dividing by the number of persons attending a follow-up procedure and having a outcome recorded and detection rates were calculated of persons completing FIT screening, see Table 2.5a.

Table 2.5a. Disease detected by FIT 120, NHS BCSP 2023

Age group	Disease detected at FIT120 screening, BCSP 2023 data							
	Persons							
	Cancer	LNPCP	High-risk Finding	Abnormal	Normal	No Result	Persons with outcome recorded	Persons screened
54-59	904	387	553	8,160	1,578	141	11,723	1,145,859
60-73	3,723	2,408	2,348	25,614	3,767	373	38,233	3,360,318
74+	631	299	271	2,962	346	21	4,530	371,248
all ages	5,258	3,094	3,172	36,736	5,691	535	54,486	4,877,425

Age group	Disease detected at FIT120 screening, BCSP 2023 data						
	PPV (of persons with outcome recorded)			Detection rates (per 1,000 persons completing FIT screening)			
	Cancer	LNPCP	High-risk Finding	Cancer	LNPCP	High-risk Finding	LNPCP/ HR findings
54-59	7.7%	3.3%	4.7%	0.79	0.34	0.48	0.82
60-73	9.7%	6.3%	6.1%	1.11	0.72	0.70	1.42
74+	13.9%	6.6%	6.0%	1.70	0.81	0.73	1.54
all ages	9.7%	5.7%	5.8%	1.08	0.63	0.65	1.28

LNPCP - large non-pedunculated colorectal polyp.

A comparison to 2022 data illustrated that cancer PPV was significantly higher in 2023 than in 2022 (in each of the age groups) and this increase appeared to relate only to males. See Table 2.5b.

Table 2.5b. Cancer detected at FIT 120 screening, NHS BCSP 2022 & 2023 comparison

Age group	PPV (of persons with outcome recorded)	
	2022	2023
	Cancer	Cancer
54-59	7.3%	7.7%
60-73	9.3%	9.7%
74+	12.6%	13.9%
all ages	9.3%	9.7%

2.7 Disease detected at lower FIT thresholds

It is not possible to estimate screen-detected disease (and thus surveillance referral rates) for lower FIT thresholds from this data (due to lack of follow-up). Data from the FIT pilot (which included follow-up of lower FIT thresholds was used to produce such predictions. The FIT pilot data was used to estimate relative FIT sensitivity for different FIT

thresholds (this assumes that underlying prevalence is constant in this study), see Table 2.7a. We note that disease detection rates largely depend on FIT sensitivity, FU compliance and underlying disease prevalence. Underlying disease prevalence will vary according to age group, screening history and cancer risk factors. If the underlying disease risk factors increase over time then disease prevalence will increase and so will detection rates.

Notes on assumptions made for this analysis are described:

- FIT pilot data from the whole pilot (all screening histories combined) was used to increase sample size and reduce uncertainty.
- Note these values will indicate the difference expected for disease detection rates by FIT threshold under the assumption that the underlying disease prevalence in the population is the same.
- As the data from age 54-59 is applied to the 50-59 age group (which will have a lower prevalence) this number may be an overestimate/upper bound.
- If prevalence changes then detection rates should also change proportionally (as detection rate=sensitivity*follow_up_compliance*prevalence (assumes constant sensitivity)). We note that the same principle does not hold for PPV.
- Here we make the assumption that FIT sensitivity is the same across different age groups which have different underlying disease prevalence.
- Relative AA sensitivity by FIT threshold has been applied to estimate predicted LNPCP/HR detection rates. This will introduce uncertainty as they are a different category of disease with different prevalence but is the best estimate we can provide with the available data.

Table 2.7a. Relative sensitivity by FIT threshold from FIT pilot

	FIT pilot, age group 59-75, (all screening histories combined)					* estimated via interpolation	
	FIT 20 µg/g	FIT 40 µg/g	FIT 60 µg/g	FIT 100 µg/g	FIT 150 µg/g	FIT 120 µg/g	FIT 80 µg/g
Cancers	73	65	44	40	36	38	42
Relative cancer sensitivity compared to FIT20	1.00	0.89	0.60	0.55	0.49	0.52	0.58
Relative cancer sensitivity compared to FIT120	1.92	1.71	1.16	1.05	0.95	1.00	1.11
AAs	471	351	183	133	116	124.5	158
Relative AA sensitivity compared to FIT20	1.00	0.75	0.39	0.28	0.25	0.26	0.34
Relative AA sensitivity compared to FIT120	3.78	2.82	1.47	1.07	0.93	1.00	1.27

2.8 Surveillance

The 2023 BCSP data includes the numbers of surveillance tests (COL and CTC) from 2023, however, due to the time gap between a patient receiving abnormal findings from FIT screening and participating in surveillance tests, the rates of surveillance tests cannot be calculated using data from the same year. Table 2.8a shows surveillance procedure numbers in 2023, however, we note that numbers of surveillance procedures is expected to increase significantly as the roll out down to age 50 is completed and approaches steady state.

Table 2.8a. Surveillance procedures NHS BCSP 2023

	Surveillance procedures (intial or subsequent)								
	CTC			COL			COL/CTC surveillance		
Age group	Female	Male	Persons	Female	Male	Persons	Female	Male	Persons
54-59	-	-	-	6	10	16	6	10	16
60-73	82	121	203	1,642	4,283	5,925	1,724	4,404	6,128
74+	8	13	21	142	338	480	150	351	501
Total	90	134	224	1,790	4,631	6,421	1,880	4,765	6,645

The 2023 BCSP data includes outcomes of surveillance tests undertaken. The data in table 2.8b includes disease detected at surveillance procedures from the FIT screening programme and does not include disease detected within the Lynch syndrome surveillance programme. The confidence interval indicate a high level of uncertainty in these values due to the small numbers of cases of disease detected.

Table 2.8b. Disease detected at surveillance procedures NHS BCSP 2023

	Findings at surveillance, BCSP 2023 data			
	Cancer	LNPCP	High-risk Finding	Any result
Count	25	101	195	5288
%	0.5%	1.9%	3.7%	100%
95%CI	(0.29%, 0.76%)	(1.54%, 3.45%)	(3.18%, 6.87%)	

3 METHODS: PART 2 – Disease and long-term outputs predictions

3.1 ScHARR 2018 Bowel Cancer Screening model

The NSC decision regarding the optimal design for the FIT screening programme (in terms of age groups and FIT thresholds) was informed by the ScHARR 2018 Bowel Cancer Screening model. Full details of this are provided in the report dated 25th June 2018: *Optimising Bowel Cancer Screening Phase 1: Optimising the cost effectiveness of repeated FIT screening and screening strategies combining bowel scope and FIT screening* (2) and in the 2022 publication "*Optimizing the Design of a Repeated Fecal Immunochemical Test Bowel Cancer Screening Programme With a Limited Endoscopy Capacity From a Health Economic Perspective"* (1)

This model was used for this project to generate predictions of disease and long-term outputs. The model was run for six screening strategies: biennial screening from ages 50-74 for FIT thresholds of 20 µg/g, 40 µg/g, 60 µg/g, 80 µg/g, 100 µg/g and 120 µg/g. Model runs took the same approach as in the 2018 report in general with alterations described here. [1] The model was originally run to produce predictions for a cohort of 785,955 50-year olds (the number in 2018). This was updated to represent a cohort of 686,667 50-year olds (the number in England in 2025). [2] The

model costs correspond to 2014/2015 so these were inflated for this project to reflect the most recent price year, 2022/2023, using NHS Cost Inflation Index adjustments. (8)

Model predictions do not include screening of the 75+ age group. Due to a lack of data on this age group their inclusion within the modelling would greatly increase the level of uncertainty in model predictions. For example, the disease risk in the group is unknown. The modelling could assume that persons aged 75+ who were screened had the same disease risk as an average person of their age. However, as persons screened in the 75+ age group are self-selecting it is possible that either (a) they are health aware and have lower than average disease risk, or (b) they are symptomatic and have higher than average disease risk. Secondly information/assumptions regarding the age distribution or average age of persons screening in the 75+ group was not available.

The surveillance pathway in the 2018 ScHARR bowel cancer screening model was developed in accordance with previous NHS BCSP guidelines. These indicate that all individuals detected with high-risk adenomas are eligible for surveillance after one year, while those with intermediate risk are eligible for surveillance after three years. Updating the surveillance pathways to align with the 2020 BSG surveillance guidelines is a not feasible due to the structure of the model.(6) However, the newer MiMiC-Bowel model will be updated to reflect new surveillance guidelines – see future work section.

When generating model predictions for outcomes such as cancer cases and cancer deaths a life-time horizon is required. However, the outcome which is most intuitive and therefore likely of most interest to decision makers is likely the change in annual numbers of cancer cases and deaths. If a single age cohort is modelled (from age 30 say) then lifetime predictions of cancer cases and cancer deaths for this cohort will roughly correspond to the annual numbers of cases/deaths for a whole population. (NB I say roughly as the age distribution for the whole population may differ slightly to the age distribution of a cohort of age 50 with all-cause mortality applied).

3.2 ScHARR 2018 Bowel Cancer Screening model validation exercise

A series of validations were undertaken to check model predictions against new data ensure that this model was fit to inform decision making. Table 3.3 below summarises the validations undertaken. Model predictions were consistent with observed data for FIT positivity rates, cancer incidence, cancer PPV and screen-detected cancers.

For HR adenomas and surveillance predictions differences in definitions for HR findings make comparison and conclusions difficult. These differences may be largely due to the differences between the new and old surveillance guidelines. Further work is required to update to the new surveillance guidelines and this is detailed in the conclusions section of this report.

Table 3.3. Validation of ScHARR 2018 Bowel Cancer Screening model

Outcome	Data	Model predictions	Notes on comparison
Cancer incidence (annual)	59,517 bowel cancer cases in UK in 2021 compared to 43,000 in 2019.	Model predicts 37,445 cases for FIT120 60-74 (steady state) for England compared to 49,936 with no screening. (lifetime predictions starting with 2025 age distribution)	Data shows incidence varies over time considerably. Will be influenced by population age distribution and cancer risk factors. Model predictions and data similar.
Screen-detected cancer incidence (annual)	3,723 cases of screen-detected cancer (in persons aged 60-73) BCSP 2023 data set	Model predicts 3,564 screen-detected cases for FIT120 60-74 (steady state for England)	Model predictions and data similar.
FIT positivity rate	The BCSP 2023 data positivity rates for FIT120 range from 1.3% for persons 50-59 to 1.9% for persons 60-74. FIT pilot (ages 59-75) males between 2.3 and 3.1%, females between 1.3 and 1.8%.	Model predicts FIT positivity rates of 2.1% for FIT120 60-74, and 1.9% for FIT120 50-74 (steady state for England)	Note that positivity rate will vary by screening history and disease prevalence will be lower in a population who have received more previous screens. Model predictions and data similar.
Cancer PPV (screen-detected cancer/ FU colonoscopy attendances)	BCSP data: Cancer PPV (age 60-73) FIT120 9.7% in 2023 data and 9.3% in 2022 data. NB the rate is 6.0% if FIT positives is used as the denominator. FIT pilot (ages 59-75) Cancer PPV between 8 and 10%	Model predicts 6.0% cancer PPV for FIT120 60-74 and 4.0% for FIT120 50-74 (steady state for England)	Model predictions lower than observed data but a lower rate would be expected in a steady-state programme.
HR adenomas (screen-detected)	BCSP 2023 data: 4,756 LNPCP/HR findings in the 60-73 age group	Model predicts 21,774 screen detected HR/IR adenomas (annually) FIT120 60-74 (steady state for England)	Differences in definitions for HR findings make comparison and conclusions difficult.

HR adenomas PPV (screen-detected HRA/ FU colonoscopy attendances)	BCSP 2023 data: LNPCP/HR findings detection rate 12.4% (in ages 60-73) FIT pilot (ages 59-75) Advanced adenomas PPV between 33% and 34%. Prevalent screen.	36.8% HRA PPV for FIT120 60-74 and 29.8% % for FIT120 50-74 (steady state for England)	Further work required (detailed in report conclusions)
Surveillance procedures (annual numbers)	Numbers of surveillance procedures: BCSP 2022 data: 6,393 BCSP 2023 data: 6,037 (of which 749 were Lynch surveillance programme)	Model predicts 31,818 for FIT120 60-74 (5 years after screening with FIT120 starts). Predictions are based on the old surveillance algorithm.	Model predictions significantly higher than data – likely a result of the change in the surveillance algorithm. Further work required (detailed in report conclusions)

4 RESULTS

4.1 Results PART 1: Screening outputs predictions

Predictions are presented for England 2025 population. Predictions assume that screening is offered to all persons from age 50. Note that if the roll out down to age 50 is not complete in all areas then these numbers will form upper estimates for screening outputs.

Table 4.1a provides estimated number of screening invitations, participations and spoilt kits. Table 4.1b provides estimated numbers of positive FITs. Table 4.1c provides diagnostic test usage for both colonoscopy and CTC. Table 4.1d provides predicted numbers of adverse events associated with follow-up diagnostic procedures. Table 4.1e shows expected disease detected at screening (which will result in surveillance referrals) for the England 2025 population.

Table 4.1a Screening invitations, participations, and spoilt kits: predictions for England 2025

Age group	Persons 50-59	60-74	75+	Total
England population (in 1,000s)	7,473	9,391	5,743	22,607
Number of Invited individuals (in 1,000s)	3,736	4,696	345	8,777
Number of participating individuals (in 1,000s)	2,271	3,315	251	5,837
Number of spoilt test kits	51,894	71,465	3186.182	26,302

Table 4.1b Screening positive FITs: predictions for England 2025

FIT Threshold	Number of positive FIT tests				% change	Attending FU procedure				% change
	Persons					Persons				
	50-59	60-74	75+	Total		50-59	60-74	75+	Total	
120 µg/g	30,707	64,293	7,551	102,551	0%	24,459	48,688	5,374	78,522	0%
100 µg/g	35,361	74,036	8,696	118,093	15%	28,166	56,067	6,189	90,422	12%
80 µg/g	41,791	87,498	10,277	139,566	36%	33,288	66,261	7,315	106,863	28%
60 µg/g	51,577	107,989	12,683	172,250	68%	41,083	81,779	9,027	131,888	52%
40 µg/g	69,664	145,857	17,131	232,652	127%	55,490	110,456	12,193	178,138	97%
20 µg/g	117,877	246,803	28,987	393,667	284%	93,893	186,901	20,631	301,425	217%

Table 4.1c. Diagnostic tests usage for following up FIT positives, predictions for England 2025

	Number of follow up diagnostic procedures									TOTAL	% change
	CTC			COL			Flexi				
FIT Threshold	50-59	60-74	75+	50-59	60-74	75+	50-59	60-74	75+		
120 µg/g	2,984	4,181	742	57,387	54,972	6,229	2,542	3,443	475	132,955	0%
100 µg/g	3,437	4,814	854	66,085	63,302	7,174	2,927	3,965	547	153,106	15%
80 µg/g	4,061	5,690	1,009	78,102	74,813	8,478	3,459	4,686	647	180,945	36%
60 µg/g	5,013	7,022	1,246	96,391	92,333	10,463	4,269	5,783	798	223,318	68%
40 µg/g	6,770	9,484	1,682	130,193	124,711	14,133	5,767	7,811	1,078	301,629	127%
20 µg/g	11,456	16,048	2,847	220,297	211,022	23,914	9,758	13,217	1,824	510,382	284%

Table 4.1d. Adverse event rates, predictions for England 2025

	Number of adverse events from follow up diagnostic procedures							
	Adverse Event: Bleeding				Adverse Event: Perforation			
FIT Threshold	50-59	60-74	75+	Total	50-59	60-74	75+	Total
120 µg/g	23	22	2	47	41	40	5	86
100 µg/g	26	25	3	55	48	46	5	99
80 µg/g	31	30	3	65	56	54	6	117
60 µg/g	39	37	4	80	69	67	8	144
40 µg/g	52	50	6	108	94	90	10	195
20 µg/g	88	84	10	182	159	153	18	329

Table 4.1e. Disease detected at FIT screening, predictions for England 2025

Predicted disease detection (rates per 1,000 persons completing FIT)

	Predicted cancer detection rates (per 1000 persons completing FIT)						Predicted LNPCP/HR detection rates (per 1000 persons completing FIT)					
Age group	120	100	80	60	40	20	120	100	80	60	40	20
54-59	0.79	0.83	0.87	0.91	1.35	1.52	0.82	0.88	1.04	1.21	2.31	3.10
60-73	1.11	1.17	1.22	1.28	1.90	2.13	1.42	1.51	1.80	2.08	3.99	5.35
74+	1.70	1.79	1.88	1.97	2.91	3.27	1.54	1.64	1.95	2.26	4.33	5.81
all ages	1.08	1.13	1.19	1.25	1.84	2.07	1.28	1.37	1.63	1.89	3.62	4.86

Predicted disease detection (annual counts)

	Persons completing FIT	Predicted numbers of cancers detected						Predicted numbers of LNPCP/HR findings detected					
Age group	(in 1000s)	120	100	80	60	40	20	120	100	80	60	40	20
50-59	2,271	1,792	1,886	1,980	2,075	3,065	3,442	1,863	1,990	2,364	2,738	5,252	7,048
60-74	3,315	3,673	3,866	4,059	4,253	6,282	7,056	4,692	5,012	5,954	6,896	13,228	17,750
75+	251	427	449	472	494	730	820	385	412	489	566	1,086	1,458
Total	5,837	6,292	6,624	6,955	7,286	10,763	12,088	7,499	8,011	9,516	11,022	21,141	28,369

4.2 Results PART 2: Disease and long-term outputs predictions

Predictions of cancers, early-stage cancers, HR adenomas, QALYs, CRC treatment costs and surveillance colonoscopy procedures are presented in Tables 4.2a, 4.2b and 4.2c.

Model predictions presented here are for a fully rolled out (steady state) screening programme of 2-yearly FIT screening for ages 50-74 and do not include screening of the 75+ age group. Model predictions were generated for the 2025 population of England with 686,667 50-year-olds. Model predictions relate to the previous surveillance algorithm as in the 2010 guidelines.

The cost savings relate to a fully rolled out steady state screening programme of FIT. They relate to lifetime-savings for a cohort of x thousand 50-year-olds. However, lifetime-savings for a cohort of 50-year-olds will roughly* correspond to annual savings for the whole population. (*they would correspond precisely if the age distribution of the whole population matched the age distribution of an ageing cohort).

Table 4.2a: Long-term outputs for 2-yearly FIT screening ages 50-74: cancer incidence and mortality

2018 ScHARR model: Predictions for full roll out (steady-state), England 2025 population 785,955 50 year olds

	Absolute					Incremental compared to FIT120					% reduction compared to FIT120				
	Cancer cases	Early stage cancer cases	Late stage cancer cases	High risk polyps*	Cancer deaths	Cancer cases	Early stage cancer cases	Late stage cancer cases	High risk polyps*	Cancer deaths	Cancer cases	Early stage cancer cases	Late stage cancer cases	High risk polyps*	Cancer deaths
2-yearly, age 50-74, FIT120	39,004	16,040	22,964	30,114	15,663	0	0	0	0	0	0%	0%	0%	0%	0%
2-yearly, age 50-74, FIT100	38,186	15,794	22,392	31,907	15,275	-818	-245	-572	1,793	-388	-2%	-2%	-2%	6%	-2%
2-yearly, age 50-74, FIT80	37,162	15,477	21,684	34,138	14,796	-1,842	-562	-1,280	4,024	-867	-5%	-4%	-6%	13%	-6%
2-yearly, age 50-74, FIT60	35,816	15,044	20,771	37,048	14,177	-3,188	-995	-2,193	6,934	-1,486	-8%	-6%	-10%	23%	-9%
2-yearly, age 50-74, FIT40	33,899	14,394	19,506	41,147	13,320	-5,104	-1,646	-3,458	11,033	-2,343	-13%	-10%	-15%	37%	-15%
2-yearly, age 50-74, FIT20	30,698	13,206	17,492	47,886	11,956	-8,306	-2,834	-5,472	17,772	-3,706	-21%	-18%	-24%	59%	-24%

* High risk polyps detected via screening or surveillance and classified intermediate/high risk according to 2010 surveillance guidelines

Table 4.2b: Long-term outputs for 2-yearly FIT screening: screen-detected cancers and cancer PPV

Screening strategy	Screen-detected cancers	Cancer PPV (screen-detected cancers rate in persons with FU COL/CTC undertaken)
2-yearly, age 60-74, FIT120	3,564	6.0%
2-yearly, age 50-74, FIT120	3,686	4.0%
2-yearly, age 50-74, FIT100	3,757	3.7%
2-yearly, age 50-74, FIT80	3,825	3.3%
2-yearly, age 50-74, FIT60	3,881	2.8%
2-yearly, age 50-74, FIT40	3,891	2.1%
2-yearly, age 50-74, FIT20	3,709	1.2%

Table 4.2c: Long-term outputs for 2-yearly FIT screening ages 50-74: cancer treatment costs, QALYs and surveillance

2018 ScHARR model: Predictions for full roll out (steady-state), England 2025 population 785,955 50 year olds

	Absolute			Incremental compared to FIT120		
Screening strategy	Cancer management (inc. pathology) (discounted)	QALYs (discounted)	Surveillance colonoscopy procedures*	Cancer management (inc. pathology) (discounted)	QALYs (discounted)	Surveillance colonoscopy procedures*
2-yearly, age 50-74, FIT120	£684.59m	10.70m	39,002	£0.00m	-	-
2-yearly, age 50-74, FIT100	£670.54m	10.70m	41,774	-£14.05m	1,394	2,773
2-yearly, age 50-74, FIT80	£652.82m	10.70m	45,509	-£31.76m	3,135	6,507
2-yearly, age 50-74, FIT60	£629.30m	10.70m	50,933	-£55.28m	5,416	11,931
2-yearly, age 50-74, FIT40	£595.36m	10.70m	59,896	-£89.23m	8,642	20,895
2-yearly, age 50-74, FIT20	£537.39m	10.71m	79,471	-£147.19m	13,948	40,470

*surveillance modelled used the 2010 surveillance guidelines

5 CONCLUSIONS AND RECOMMENDATIONS FOR FUTURE RESEARCH

5.1 Conclusions

The results generated here provide predictions of screening outcomes (invitations, participations, positive tests, follow-up procedures, adverse events) and long-term and disease outcomes (surveillance procedures, cancer diagnoses, QALYs and treatment costs).

The predictions of screening outcomes are associated with a high level of certainty. Predictions are generated for 2025, however, we note that follow-up colonoscopy usage in years subsequent to 2025 is likely to slowly decrease as the screening programme approaches steady-state and underlying disease prevalence in the population decreases.

The predictions of long-term and disease outcomes are associated with a high level of uncertainty. We note that predictions are based on a steady-state screening programme, hence, they provide an upper bound on expected benefits for 2025. In years subsequent to 2025, as the screening programme approaches steady-state, the benefits of screening seen (costs saved and reduction in cancer cases) will gradually increase towards the steady-state predictions. The modelling of surveillance does not reflect current guidelines and the implications of this are that predictions presented here could be considered an upper bound for expected surveillance colonoscopy usage.

Unpredictable changes in a population's age profile and cancer risk factors over time result in uncertainty in model predictions. In addition to this in this study uncertainty in model predictions is also a result of the following two key limitations: (1) the high level of uncertainty in FIT sensitivity and specificity estimates, and (2) the surveillance pathways modelled do not reflect the currently used guidelines. Further work to address these limitations and reduce uncertainty is described in the future work section.

5.2 Prioritizing colonoscopy capacity between symptomatic, screening and surveillance

We note that even with an intensive screening strategy (such as 50-74 at FIT 20) the majority of cancer cases will still not be screen-detected. Hence colonoscopy capacity decisions need to prioritize between symptomatic, screening and surveillance for bowel cancer.

FIT is now being used in primary care to guide referral for people with signs or symptoms of suspected colorectal cancer (CRC). NICE recommend that adults who have a FIT result of at least 10μg/g should be referred for diagnostic investigations on a suspected cancer pathway. Whilst there is some variation in the referral criterion for suspected CRC in different places in England, broadly the adoption of FIT in primary care practice is changing clinician behaviour and influencing colonoscopy capacity. FIT symptomatic data on FIT results, colonoscopy usage and bowel cancer diagnoses will allow estimation of FIT score distribution, colonoscopy uptake and detection rates/PPV for symptomatic FIT referrals.

The UK NSC uses 'quality adjusted life years' (QALYs) and Net Monetary Benefit (NMB) to inform recommendations. Ministers or the public may prefer a simpler metric such as number of cancer cases detected but it is key that the limitations of such metrics are emphasised and understood. For example, numbers of cancer cases detected by screening does not detail (1) whether cancers are detected at an earlier stage (2) whether cancer detected are overdiagnosis (3) the age cohort in which cancers are detected e.g. young versus old persons. The advantage of the

QALY measure is that reductions in cancer incidence, stage shift, reductions in cancer mortality and screening adverse events are all included within one measure.

To inform decisions about optimising use of additional colonoscopy capacity (e.g. lowering screening FIT threshold, use in symptomatic setting, use within surveillance) it is recommended that the following two metrics are considered. Firstly, comparison of cancer PPV between symptomatic, surveillance and screening settings. Secondly, the metric 'Met Monetary Benefit (NMB) per additional colonoscopy resource required' could be useful.

5.3 Future planned work

In 2020 a new ScHARR bowel cancer model was developed, Microsimulation Model in Cancer of the Bowel (MiMiC-Bowel), which is an individual-level simulation model developed in the R programming language. It simulates the life course of patients, and each have a unique set of individual characteristics that determine their cancer risk, as well as their responses to screening and surveillance. The MiMiC-Bowel model includes a disease natural history component which simulates the development and progression of cancer. Model predictions of screening use this natural history model in combination with estimates of FIT test characteristics (sensitivity, specificity, uptake, inadequate rate etc). A detailed explanation and a comprehensive description of the model's calibration and validity testing are available online. (9, 10) The MiMiC-Bowel model could be used to generate predictions of long-term and disease outcomes.

There are two planned updates to MiMiC-Bowel which will result in improved accuracy of the model predictions.

Firstly, the surveillance algorithm will be updated. The surveillance pathway in MiMiC-Bowel was developed in accordance with previous NHS BCSP guidelines. These indicate that all individuals detected with high-risk adenomas are eligible for surveillance after one year, while those with intermediate risk are eligible for surveillance after three years. Updating the surveillance pathways within MiMiC-Bowel to align with the 2022 BSG surveillance guidelines is a significant piece of work. This work is planned to start in April 2025 as part of both James Kangs PhD project (exploring using risk stratification within surveillance algorithms https://fundingawards.nihr.ac.uk/award/NIHR303274) and it will also feed into the CONSCOP2 project https://fundingawards.nihr.ac.uk/award/NIHR127914). Outcomes are expected late 2025/2026.

The second planned update aims to improve accuracy of FIT sensitivity modelling within MiMiC-Bowel as part of the Bowel-Star project (start date June 2024; end date May 2029) https://usher.ed.ac.uk/research/population-health-sciences/bowel-star-uk. (11) Within the MiMiC-Bowel model estimates of both FIT sensitivity and FIT false positive rate by FIT threshold rely on data from the FIT pilot undertaken in 2014. It is important to note that the number of cases of cancer (N=73) within the FIT pilot results was small so model predictions based on this data were associated with considerable levels of uncertainty. Ideally an English study in which persons with a lower FIT threshold are followed up (as proposed by Professor Amanda Cross) would be undertaken to generate robust data to inform this key component of the model. The 2023 BCSP data could not be used to update the FIT sensitivity and specificity estimates within MiMiC-Bowel because only persons with a FIT result of over 120 are followed up so no information at thresholds below 120 was available. The planned analyses will primarily use English data (newer BCSP data) and Scottish data (FIT 80). Other data sources which may be utilised as appropriate e.g. Italian/Dutch data. Analysis will be dependent upon what data is obtained, successful data linkages and statistical analyses undertaken in the other work packages of this project.(11)

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