



Peninsula Cancer Alliance  
SWAG Cancer Alliance

# Report on Symptomatic Faecal Immunochemical Testing in the South West:

**Directorate:**

South West Cancer Alliances

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## Report on Symptomatic Faecal Immunochemical Testing in the South West: Case for Commissioners

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## Contents

1	Executive summary.....	5
2	Acknowledgements.....	6
3	The facts about colorectal cancer .....	7
4	The case for Faecal Immunochemical Testing in Primary Care .....	8
	4.1 NICE guidance (NG12 and DG30) and FIT .....	8
	4.2 The case for change .....	9
	4.3 NHS Long Term Implementation Framework requirements .....	10
5	Transformation Programme.....	11
	5.1 Operational delivery model.....	11
6	Monitoring and Evaluation Programme .....	12
	6.1 Uptake of Tests .....	12
	6.2 GP responses to the Test.....	12
	6.3 Patient feedback .....	13
	6.4 GP management of patients following a FIT .....	13
	6.5 The impact of symptomatic FIT on endoscopy demand.....	14
	6.6 Diagnostic performance of FIT.....	15
	6.7 Implications for practice from Early Evaluation .....	16
	6.9 Cost effectiveness of FIT .....	16
7	Commissioning FIT testing laboratory service from April 2020 .....	19
	7.1 Pathology service.....	19
	7.2 Current service model and logistics of test distribution .....	19
	7.3 Current work load and expected growth in demand .....	19
	7.4 Annual cost of Service .....	20
	7.5 Savings required to breakeven .....	21
	7.6 Test Eligibility Criteria .....	22
	7.7 Potential service developments .....	22
8	Conclusions from SWAG and Peninsula Cancer Alliances .....	23
9	Contacts.....	24

## 1 Executive summary

This document contains evidence gathered from the joint SW cancer alliances transformation project to give GPs access to the Faecal Immunochemical Test (FIT) across the south west of England. This two year project was funded from the cancer alliances' budgets and we have been collecting data to support the evaluation since the roll out of FIT in July 2018. The impact of the test has been positively well received by patients and GPs. It has shown to be effective in triaging the patients into a risk group suitable for 2 week referral, and a group with a much lower risk of colorectal cancer and whom GPs are managing within primary care. The Steering Group's recommendation is for CCGs to continue commissioning the service.

The availability of FIT has now allowed over 10,000 patients across the SW who are deemed to be of "low risk, but not no risk" of colorectal cancer to be triaged by their GP and for those who receive a positive test result to be referred. The test provides a high level of assurance to those with a negative result that their risk of a colorectal malignancy is low. Commissioners have been tasked with ensuring that local systems engage with their Cancer Alliance to set out practically how they will deliver the Long Term Plan commitments for cancer over the next five years, including early diagnosis and survival, while improving operational performance through interventions to improve one year survival. Rolling out of FIT for symptomatic and non-symptomatic populations is a key part of this national policy.

Following the completion of two UK wide projects exploring the use of FIT for patients already placed on a 2WW pathway, there remains no consensus advice on the wider use of FIT triage for this group. Our evaluation supports the use of the test for the category of patients identified in NG12 and therefore we recommend that this service should be commissioned to continue the service improvement already achieved, and to demonstrate continued engagement with the aims of the long term plan for cancer.

The team are confident that the data provided will demonstrate that the test downgrades cancer, saves referrals, freeing up space for other cancer diagnostics, and it saves money. I am personally very proud of the team who have worked together to deliver this system wide change and demonstrated an ability to deal with the challenges that this has thrown at us. They have delivered a change on a big scale for the population of a whole region of the country.



Mr John Renninson, Clinical Lead, Peninsula Cancer Alliance

## 2 Acknowledgements

The Cancer Alliances would like to express their thanks to everyone who has contributed to delivering this programme. We are particularly grateful to the FIT Steering Group and our dedicated clinical experts, to Severn Pathology and Exeter Laboratories, to the Discovery Team at the University of Exeter, the CR-UK South West Facilitator Team, Sima Davarian our patient representative, and the Commissioning Support Unit.

Thanks are also due to all our Cancer Managers who have provided outcome data and to those GPs who have who have completed online surveys. The volume of data and richness of the responses received; especially during such constrained capacity is testament to your support.

### 3 The facts about colorectal cancer

Colorectal cancer is the fourth most common cancer in the UK, accounting for 12% of all new cases of cancer. There has been a 14% increase in incidence of colorectal cancer in the UK since the late 1970s and many of these cases are still diagnosed at a late stage (3 or 4).<sup>1</sup>

Nine out of ten new cases (94%) are diagnosed in people over the age of 50, and nearly six out of ten cases (59%) are diagnosed in people aged 70 or over. But colorectal cancer can affect anyone of any age. More than 2,500 new cases are diagnosed each year in people under the age of 50.<sup>2</sup>

Data relating to routes to colorectal cancer diagnosis<sup>3</sup> show that:

- 10% of all cases of colorectal cancer are detecting through screening,
- 30% through the Suspected Cancer Pathway (2WW) and a further
- 24% through an emergency presentation - 68% of which are through an A&E attendance.<sup>4</sup>
- 23% GP referral
- 7% other outpatient appointment
- 3% Inpatient elective
- 3% Death certificate or Unknown

Cancers detected through screening are more likely to be stage I or II: 68%, compared with 44% for those diagnosed through 2WW.<sup>5</sup>

In those patients who were diagnosed through an emergency presentation 68% of cancers are found to be either stage III or IV.<sup>6</sup>

There are stark differences in the survival rates of patients diagnosed with colorectal cancer at an early and late stage.

After 1 year, survival is 98% at stage I and 40% at stage IV. After 5y survival is 90% for stage I and less than 1% for stage IV<sup>7</sup>

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<sup>1</sup> <http://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/bowel-cancer> (accessed 05/06/2017)

<sup>2</sup> <https://www.bowelcanceruk.org.uk/about-bowel-cancer/bowel-cancer/>, update June 2019)

<sup>3</sup> National Cancer Intelligence Network. Routes to Diagnosis 2006-2013 workbook (a). London: NCIN; 2015

<sup>4</sup> National Cancer Intelligence Network and Cancer Research UK. Routes to diagnosis of cancer by stage, 2012-2013 workbook. London: NCIN; 2016a.

<sup>5</sup> Office for National Statistics, Cancer survival by stage at diagnosis for England 2016

<sup>6</sup>. National Cancer Intelligence Network. Routes to diagnosis 2006-2013 workbook (b). London: NCIN; 2016b

<sup>7</sup> Incisive Health and CRUK, "Saving Lives, averting costs," 2014

## 4 The case for Faecal Immunochemical Testing in Primary Care

### 4.1 NICE guidance (NG12 and DG30) and FIT

In 2015, NICE published revised suspected cancer referral guidance<sup>8</sup> advising GPs to use a lower risk threshold for symptoms suspicious of cancer. Symptoms with a 3% or more risk of cancer were agreed as the indicator for a 2 week suspected cancer pathway referral.

In addition, within the colorectal cancer guidance, a cohort of patients were identified with symptoms which have a risk of less than 3%, but which might be associated with colorectal cancer. The recommendation for these 'low risk but not no risk' patients was for them to be offered a test for occult faecal blood.

Following a clinical effectiveness evaluation by NICE, further guidance was published in July 2017 which recommended commissioning FIT for patients identified in NG12 as being at low risk of colorectal cancer.<sup>9</sup>

The advantages of FIT over the traditional FOBT / Guaiac test are:

- The FIT test consists of an antibody raised to recognise human haemoglobin which enables the test to be much more specific compared to FOBT which relies on a colour change.
- FIT does not require patients to restrict their diet prior to taking the test.
- FIT will give a quantitative result.

The guidance recommended the wider roll out of the test for suspected colorectal cancer in people without rectal bleeding who have unexplained symptoms but do not meet the referral criteria for a suspected cancer pathway referral

The South West Cancer Alliances FIT project is aimed at achieving compliance with the NG12 NICE Guidance in offering FIT to patients with "low risk but not no risk" of colorectal cancer. This distinguishes it from other projects where FIT has been used for patients in secondary care who have been referred on a 2WW pathway.

The patients included are:

- Aged 50 or over with unexplained abdominal pain or weight loss or
- Aged under 60 with changes in their bowel habit or iron-deficiency anaemia or
- Aged 60 or over and have anaemia without iron deficiency.

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<sup>8</sup> <https://www.nice.org.uk/guidance/ng12>, June 2015

<sup>9</sup> <https://www.nice.org.uk/guidance/dg30>, July 2017



The FIT test is now also being rolled out as the means of delivering the national bowel cancer screening program but with a higher threshold level of 120µg/g for referral instead of 10µg/g for symptomatic patients.

Further information on the differences between the use of FIT in symptomatic and screening patients can be found on the CRUK website:

[https://www.cancerresearchuk.org/sites/default/files/fit\\_implementation\\_england.pdf](https://www.cancerresearchuk.org/sites/default/files/fit_implementation_england.pdf)

## 4.2 The case for change

Not all GPs had access to FOBT testing locally and so, prior to symptomatic FIT being available, there was no advice for the management of this group of low risk patients.

Colorectal symptoms are common especially in older people and differentiating patients with serious bowel disease from those with benign functional disorders, such as Irritable Bowel Syndrome (IBS), and minor colorectal disease such as haemorrhoids, hyperplastic polyps and simple diverticular disease, can be very challenging. This could lead to a delay in diagnosis on top of which the symptoms can be distressing for patients and the cause of much anxiety.

As the NICE recommendations could not be followed by GPs it was suspected that many of these patients might be referred anyway helping to create an escalating demand for endoscopy services: A colonoscopy is an invasive procedure with associated risks and it requires a day of bowel cleansing prior to the test which can be stressful and unpleasant for the patient. Bowel cleansing also has associated risks. Colonoscopies tie up significant healthcare resources of staff and theatre space, and are therefore costly to the NHS. Better diagnostic accuracy is needed to ensure the correct pathway and treatment can be offered.

To explore how this group of 'low risk' patients were actually managed by primary care, a prospective audit was carried out in 9 GP practices covering a population of over 80,000 registered patients. Data was collected for 3 months in 2017-18 indicated that 217 patients over the age of 50 years old presented with lower GI symptoms without rectal bleeding. 55% (119) were referred to secondary care. The audit indicated that of these 119 patients:

- 48% (57) of patients with colorectal symptoms were being referred to secondary care (any 2ww), and
- 21% (24) were referred as routine patients
- 24% (27) radiology requested

- 5% (6) Admission (including emergency and previous secondary care investigations)
- 2% (2) Other

It was also shown from other, secondary care based audits that >90% of patients referred as colorectal 2ww received an endoscopy or CT colon.

Therefore a significant number of patients in this group were either:

- Receiving no diagnostic test for cancer or
- Receiving invasive and expensive tests which may not have been indicated if they could be appropriately triaged.

Evidence suggests that triage using FIT at a cut-off around 10 µg Hb/g faeces has the potential to correctly rule out colorectal cancer (CRC) and avoid colonoscopy in 75–80% of symptomatic patients.<sup>10</sup>

Therefore this test presents the opportunity to identify most of those who have cancer at their first presentation to the GP, achieving a definitive diagnosis in the shortest amount of time, through the most efficient care pathway, and at the earliest stage.

### 4.3 NHS Long Term Implementation Framework requirements

The NHS long term implementation framework states a requirement to roll out FIT for symptomatic patients, as follows:

2.27 Local systems should engage with their Cancer Alliances to set out practically how they will deliver the Long Term Plan commitments for cancer over the next five years including on early diagnosis and survival, while improving operational performance through interventions by:

- Improving the one-year survival rate.
- Roll-out of **FIT for symptomatic** and non-symptomatic populations in line with national policy.

The long term plan recognises that the Faecal Immunochemical Test for haemoglobin will be easier to use for patients than the old FOB Guaiac test. In trials it has been shown to improve take up rates including among groups with low participation rates such as men, people from ethnic minority backgrounds and people in more deprived areas, therefore improving health equality.

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<sup>10</sup> Westwood et al, BMC Medicine 2017 15:189

## 5 Transformation Programme

The aim of the joint SW Cancer Alliances team was to provide GPs across the region with access to the FIT test for this group of patients. With this in mind a delivery and evaluation group was convened with representation from across all areas of the healthcare services involved and patient/public support. This team has been largely consistent in membership and has designed the project, guided the delivery and monitored the evaluation processes. The two Cancer Alliances allocated project management support and provide the group chair and GP lead roles.

### 5.1 Operational delivery model

Laboratories across the region were asked to consider extending their contracts, to join the project with some guidance on the desired outcome of the implementation. It was suggested that a collaborative approach between labs in the SWAG and Peninsula areas, aiming to deliver the same specification across the region, could be most cost effective. The only laboratories, Exeter and North Bristol, to jointly apply and offer a solution which delivered the requested service within the budget were chosen as partners in the project.

Of the three test analysers available, HM-JACKarc was deployed by the laboratories. In the NICE DG30 Evidence Review HM-JACKarc reported with 100% sensitivity, 76.6% specificity, 6.1% positive predictive value and 100% negative predictive value for colorectal cancer. This allowed a system of delivering the test kit packs to GP practices with the test unit, instructions, a test order form showing the categories of symptoms where the test was indicated, and a pre-paid envelope for the patient to post the kits to the laboratory for testing. Results were returned via electronic links to the practices where they existed or via paper returns from the laboratory. All practices, who have engaged with the 2 testing laboratories when requested, have been included on electronic links.

GPs were provided with extensive written, on-line and video advice on the indications for the tests, using the service, the use of the kit packs and safety netting to ensure that the results have been received and acted upon. In addition in the early part of the project positive results which had not been followed by a secondary care referral were followed up with the practices. Practices were provided with a simple system to reorder packs when their stocks were becoming low.

## 6 Monitoring and Evaluation Programme

A full evaluation plan has been developed. Part of this is being delivered in conjunction with the CR-UK funded CanTest team at the University of Exeter under the supervision of Prof Willie Hamilton whose research portfolio includes assessment of cancer tests which are made available to GPs. The evaluation of the test will take more than 12 months follow up time to allow any missed diagnoses in FIT negative patients to be diagnosed.

In the interim funding was given to providers for data collection to identify patients with a positive result and to follow them through the system to identify those diagnosed with cancer. The number of 2ww referrals and routine referrals has been monitored to assess any rise in demand. User surveys have also been conducted to understand the GP and patient experience. The results from this monitoring are outlined below.

### 6.1 Uptake of Tests

CCGs took responsibility for sending out information about FIT through local newsletters, to the practices in their area. This was supported by the local CRUK Facilitator team who provided practice level support and training around use of FIT.

Uptake of the test has risen steadily throughout the project and has yet to peak. The Steering Group have been able to monitor the basic data using regular laboratory activity reports showing number of tests received and positive / negative rates by region, and by CCG. For the latest data please use the link below:

The uptake of FIT by individual practices has also been tracked by the laboratories. Update across the board has been good but there is some localised variation both in practice engagement and uptake. The labs continue to work with the Clinical Leads and Facilitators to ensure that all practices are aware of the test and using it.

[Please refer to FIT Dashboard](#)

### 6.2 GP responses to the Test

The feedback that has been obtained from GPs both through qualitative interviews and through a recent survey is overwhelmingly positive:

- GPs find the test easy to explain to patients and
- Are reassured that a negative result means that the patient does not have colorectal cancer.

The full results can be viewed at the link below:

<http://www.swscn.org.uk/wp/wp-content/uploads/2019/10/GP-survey-2.docx>

### 6.3 Patient feedback

Feedback on the service has been obtained from GPs and a number of the test kit packs included optional feedback forms for patients to return with their kits. Feedback has been very positive with 84% patients finding the test easy to use and reporting a positive GP experience. The full results can be viewed at the link below

[Please refer to FIT Dashboard](#)

### 6.4 GP management of patients following a FIT

Following implementation of FIT from 2018-19 a subsequent audit was commissioned across 12 practices to understand how patients, who had a FIT, were now being managed in primary care. Data were collected on 489 patients who had received a FIT test.

At the time of the audit no data were available for 39 patients – either because the patient had not completed the test, the results were pending, or the lab had rejected the sample. Of the 450 remaining patients:

- 14% (n=61) had a positive result
- 86% (n=389) had a negative result

Patients with a positive result:

- 92% (n=56) were referred on a 2WW pathway
- 8% (n=5) were not referred – due to the patients declining the referral

Patients with a negative result:

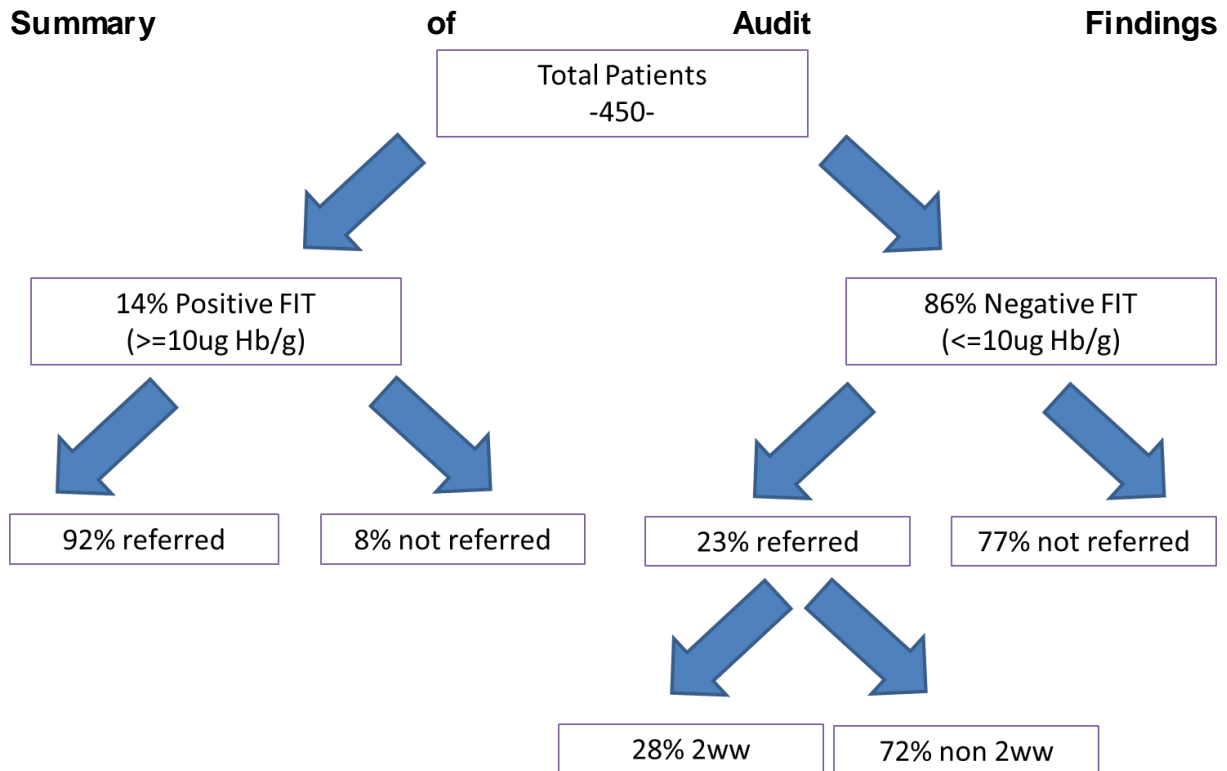
- 77% (n=301) were not referred into secondary care
- 22% (n=88) were subsequently referred into secondary care following their FIT result.

Of the 88 patients that were subsequently referred:

- 28% (n=25) of these patients were referred onto a 2WW pathway (n=13 of the 2WW referrals were onto the Lower GI pathway and n=12 of these 2WW referrals went onto other pathways including Upper GI).
- 72% (n=63) of these patients were referred onto a non-2WW pathway

In total, of the 450 patients for whom we have FIT test results (both negative and positive): 32% (n=144) were subsequently referred and, of these, 18% (n=81) were on a 2WW pathway.

These results show that GPs are using FIT as a triage to rule out colorectal cancer and thus avoid that patient from being referred onto a 2WW Lower GI pathway; and also as a tool to aid their decision making relating to which is the most appropriate 2WW pathway for that patient.



The full audit can be viewed at:

<http://www.swscn.org.uk/wp/wp-content/uploads/2019/10/Negative-FIT-audit-report-public-version.docx>

## 6.5 The impact of symptomatic FIT on endoscopy demand

The impact of the NG12 revised guidance was seen in the increased number of patients referred as suspected cancers as intended by the reduced threshold levels from 5% to 3%. This was especially prominent in colorectal cancer services and has led to increased pressure on services.

Since the introduction of FIT the audit suggests that the number of referrals to secondary care for this cohort of patients has reduced. In turn this would therefore suggest a reduction in colonoscopies requested for this 'low risk but not no risk' cohort. Of the patients seen in secondary care, data collected from trusts shows that:

- 30% (445) had a colonoscopy at the first appointment;
- 4% (56) had colon CT;
- 0.6%(9) had flexible sigmoidoscopy,

- 4% (65) had imaging of some kind, not further specified;
- 35% (519) had an outpatient appointment; these may have had imaging at a subsequent appointment.
- 24% (358) had no appointment info (& possibly pending appointment)
- 2% (30) had no referral / declined investigation /went private.

However, as FIT positive patients represent a very small subgroup of overall colorectal referrals any decreases must be considered against a backdrop of year on year growth. There has been an increase in both the number of 2WW and routine referrals recorded during the time that FIT has been in use.

The model below, developed by CADEAS, allows individual CCGs or regions to input activity data to understand demand on endoscopy, following the introduction of symptomatic FIT:

<https://future.nhs.uk/connect.ti/canc/viewdocument?docid=53243365>

A bespoke analysis using a data set from one provider (RCHT) showed that 2.6% of all investigations were carried out in patients with a positive FIT. The most common investigations in this group of patients was colonoscopy (47% - slightly above the average for Trusts overall). The most common outcome of investigations for FIT positive patients was diverticular disease and benign polyps.

## 6.6 Diagnostic performance of FIT

Following analysis of the data, the DISCOVERY team at The University of Exeter reported that the percentage of FIT positive patients subsequently diagnosed with cancer is 8.0% (95% confidence intervals 6.5–9.8). This is known as the positive predictive value (PPV) of FIT. PPV is the proportion of tested patients who have the disease in question. It tells clinicians how likely cancer is, given the positive test result. This is based on 88 cancers (C18.0-C21) diagnosed in a sample of 1106 FIT positive patients. 56 of these were staged (the remainder were pending staging); 57% were diagnosed at stage (I or II).

### Number of tests by Trust, and number of cancers diagnosed in that Trust.

Trust	Number of FITs positive (>10 ug Hb /g faeces) and (% of total +ve FITS)	Number of cancers diagnosed in the Trust
Gloucestershire Hospitals NHS Foundation Trust	238 (16.0)	25
Great Western Hospitals NHS Foundation Trust	30 (2.0)	1
North Bristol NHS Trust	149 (10.0)	7

Northern Devon Healthcare NHS Trust	55 (3.7)	4
Royal Cornwall Hospitals NHS Trust	193 (13.0)	9
Royal Devon and Exeter NHS Foundation Trust	150 (10.1)	3
Royal United Hospitals Bath	162 (10.9)	7
Salisbury NHS Foundation Trust	91 (6.1)	8
Taunton and Somerset NHS Foundation Trust	66 (4.5)	5
Torbay and South Devon NHS Foundation Trust	111 (7.5)	7
University Hospitals Bristol NHS Foundation Trust	83 (5.6)	3
University Hospitals Plymouth NHS Trust	110 (7.4)	5
Weston Area Health NHS Trust	30 (2.0)	2
Yeovil District Hospital NHS Foundation Trust	15 (1.0)	0
<b>Total</b>	<b>1,483* (100%)</b>	<b>86*</b>

\*This table shows all patients including those who had been referred but not completed through to staging.

[http://www.swscn.org.uk/wp/wp-content/uploads/2019/10/DRAFTFIT\\_evaluation\\_September2019.docx](http://www.swscn.org.uk/wp/wp-content/uploads/2019/10/DRAFTFIT_evaluation_September2019.docx)

## 6.7 Implications for practice from Early Evaluation

NICE recommend urgent investigation for suspected cancer when the risk exceeds 3%; a positive FIT represents a risk of 8%, which far exceeds that threshold. Crucially, more FIT-detected colorectal cancers were diagnosed at an early stage - 57% (the national target is to achieve 75% by 2028) compared to before the introduction of FIT (44-48% early stage). This has important implications for treatment (more effective at an early stage, with longer survival) and for costs (early stage cancers are less expensive to treat).

## 6.9 Cost effectiveness of FIT

A tool to help local commissioners understand the economic case for early diagnosis of bowel cancer, colon cancer and rectal cancer can be found at:



In patients diagnosed following a FIT, there is an increase in early stage diagnoses of 10 percentage points compared to national figures. The reduced costs of earlier stage diagnosis for CRC are well established (saving £13,000 at stage 1 or 2 compared to stage 4 – and potentially palliative care at an additional £7,000) therefore early diagnosis system savings will help offset the cost of the test (see table below).

### Potential for early stage cost savings based on evaluation findings

CCG	Trust	Number of cancers diagnosed in the Trust	Estimated no. of early stage cancers identified with fit at 57%	Estimated no. of early stage cancers identified pre fit at 46%	Total of additional early stage cancers identified	Potential cost saving at 13k
Gloucestershire CCG	GLOS	25	14	12	2	£26,000
BNSSG CCG	UHB	3	2	1	1	£13,000
	NBT	7	4	3	1	£13,000
	WAH	2	1	1	0	£0
Bath and North East Somerset CCG	RUHB	7	4	3	1	£13,000
Swindon CCG	GWH	1	1	0	1	£13,000
Wilshire CCG	SFT	8	5	4	1	£13,000
Somerset CCG	TST	5	3	2	1	£13,000
	YDH	0	0	0	0	£0
Kernow CCG	RCHT	9	5	4	1	£13,000
Devon CCG	TSD	7	4	3	1	£13,000
	RDE	3	2	1	1	£13,000
	NDH	4	2	2	0	£0
	UHP	5	3	2	1	£13,000
<b>Total</b>		<b>86</b>	<b>86</b>	<b>50</b>	<b>40</b>	<b>£156,000</b>

(N.b. Figures have been rounded up).

If, with increased uptake of the test, the proportion of patients testing positive falls from the current level of 12-15%, the numbers of patients diagnosed with earlier cancers would not be expected to rise. Adherence to clear guidance as to who should be offered testing should mitigate any change in this. The proportion of FIT-

positive patients who are diagnosed with colorectal cancer should remain constant, as this should largely be a function of the test.

A reduction in the number of outpatient appointments and rate of increase of colonoscopy should also be anticipated. The audit conducted prior to implementation demonstrated that in the absence of the test GPs would expect to refer 55% of patients into secondary care compared to 32% post FIT.

The table below shows a conservative estimate of financial savings based on audit findings, using 2018-19 activity. Please see appendix 1 for projected activity and savings by CCG.

CCG	Trust	Total number of positive FIT referrals 2018-19 to each Trust	Estimate of patients with negative FIT (if positive is 14-16%)	Estimate of patients referred pre-FIT (at 55%)	Potential number of referrals saved (if 90% of +ve and 23% of -ve)	Potential colonoscopies saved if 90%	Potential cost saving of OP at £100 per OPA	Potential cost saving of colonoscopy at £700
Gloucestershire CCG	GLOS	238	1250	818	317	285	£31,700	£199,500
BNSSG CCG	UHB	83	436	285	110	99	£11,000	£69,300
	NBT	149	782	512	198	178	£19,800	£124,600
	WAH	30	158	103	40	36	£4,000	£25,200
Bath and North East Somerset CCG	RUHB	162	851	557	215	194	£21,500	£135,800
Wilshire CCG	GWH	30	158	103	40	36	£4,000	£25,200
	SFT	91	478	313	121	109	£12,100	£76,300
Somerset CCG	TST	66	347	227	88	79	£8,800	£55,300
	YDH	15	79	52	20	18	£2,000	£12,600
Kernow CCG	RCHT	193	1186	758	312	281	£31,200	£196,700
Devon CCG	TSD	111	682	436	179	161	£17,900	£112,700
	RDE	150	921	589	242	218	£24,200	£152,600
	NDH	55	338	216	89	80	£8,900	£56,000
	UHP	5	31	20	9	7	£900	£4,900
<b>Total</b>		<b>1378</b>	<b>7693</b>	<b>4989</b>	<b>1980</b>	<b>1782</b>	<b>£198,000</b>	<b>£1,247,400</b>

At £6.50 per test, this is a moderately expensive laboratory investigation. The anticipated laboratory costs for CCGs are given in tabular form in 7.4, below. Estimates have been given that describe anticipated growth in use of the test but these may vary depending on actual uptake within individual CCGs, (section 6.1).

## 7 Commissioning FIT testing laboratory service from April 2020

### 7.1 Pathology service

Currently the laboratory FIT testing service is provided by Severn Pathology in Bristol for the SWAG Cancer Alliance and Exeter Clinical Laboratory for the Peninsula Cancer Alliance

### 7.2 Current service model and logistics of test distribution

The current service model relies on the distribution of kits from a central laboratory in Exeter or Bristol to GP localities. Kits are requested by email or telephone to the appropriate laboratory and shipped out to an individual practice. GPs hold a stock of kits that are distributed to eligible patients. The request form and collection device are then sent to the hub laboratory by the patient in a prepaid envelope and are analysed on receipt. Results are distributed to the GP electronically. (There are a small number of practices receiving reports by paper we expect this to be eliminated by 2020)

Advantages of current model	Disadvantages of current model
<ul style="list-style-type: none"> <li>Established model with acceptable processing times</li> <li>Optimal use of laboratory capital equipment</li> <li>The most cost effective service model</li> <li>Concentrated expertise in FIT testing</li> <li>Standardised reporting of FIT testing metrics</li> </ul>	<ul style="list-style-type: none"> <li>Result not in the current patient's local laboratory pathology record</li> <li>Requires hand writing of forms*</li> <li>More difficult safety netting of uncollected or lost samples*</li> </ul> <p>*could be negated by embedding a form within the GP systems which is currently being done in some practices</p>

### 7.3 Current work load and expected growth in demand

Lab	Peninsula CCG	July 19	July total extrapolated to 12 months	Work load uplift (45%)		
				C1	C2	C3
Exeter	Kernow	188	2256	3271	4734	6877
Exeter	New Devon	282	3384	4906	7114	10316
Exeter	South Devon and Torbay	79	984	1426	2068	2999

	SWAG CCG					
Bristol	BANES	55	660	957	1387	2012
Bristol	Bristol	131	1572	2279	3305	4792
Bristol	North Somerset	74	888	1287	1867	2707
Bristol	South Gloucestershire	67	804	1165	1690	2451
Bristol	BNSSG	272	3264	4732	6862	9950
Bristol	Gloucestershire	242	2904	4210	6105	8853
Bristol	Somerset	89	1068	1548	2245	3255
Bristol	Wiltshire	189	2268	3288	4768	6914

Work load projections have been calculated as follows-

- Latest monthly figure for July 2019 has been adjusted for 12 months activity at this month's level. It should be noted that projections of growth might vary within individual CCGs based on current GP uptake.
- The average workload growth for all CCGs has been calculated as 45% on the basis of the percentage increase over the previous 6 months since February 2019. Continued growth at 45% is a 'worse case' scenario.
- This figure has been applied to compound growth in demand over three cycles which would reflect the annualised workload at approximately January 2020, July 2020 and January 2021

The projected workload growth has been based on previous 6 months growth. It should be anticipated that this growth rate would at some point reduce as all practices are using the service at an equivalent level. Currently it is not possible to say when growth will reduce to a level of workload inflation typically seen in laboratory tests. CCGs should however budget for a workload greater than the 12 month projection made on July 2019 figures.

## 7.4 Annual cost of Service

Annual cost of the service is projected on the above figures using a cost per test of £6.50; this cost is derived from current laboratory consumables, overheads for undertaking analysis and distribution of kits and results.

			Work load uplift (45%)			
	Peninsula CCG	July 19	12 months	C1	C2	C3
Exeter	Kernow	188	*			
Exeter	New Devon	282				
Exeter	South Devon and Torbay	79				
	<b>SWAG CCG</b>					
Bristol	BANES	55				

Bristol	Bristol	131				
Bristol	North Somerset	74				
Bristol	South Gloucestershire	67				
Bristol	BNSSG	272				
Bristol	Gloucestershire	242				
Bristol	Somerset	89				
Bristol	Wiltshire	189				

\*Financial data removed

## 7.5 Savings required to breakeven

The table below shows that across the South West we only need to achieve 13% of the savings from a reduction in referrals to breakeven using the case C3 for anticipated demand. This assumes;

- All savings from reduced treatments costs from diagnosing earlier are realised,
- Savings for the higher demand case C3 calculated using the actual activity in 2018/19 (as in tables above) and not expanded for expanded activity.

CCG	Service Cost C3	Savings from early stage cost	Savings from reduction in referrals OP appointments	Savings from reduction in referrals Colonoscopies	Net Cost	Proportion of potential saving from reduction in referral to breakeven
Kernow		£13,000	£4,343	£27,358	£-	
New Devon		£39,000	£6,528	£41,020	£-	
BANES		£13,000	£11	£67	£-	
BNSSG		£26,000	£5,298	£33,377	£-	
Gloucestershire		£26,000	£4,321	£27,224	£-	
Somerset		£13,000	£1,118	£7,040	£-	
Wiltshire		£13,000	£4,375	£27,566	£-	
South West		£143,000	£25,994	£163,653	£-	

If we do not assume all savings from diagnosing earlier are realised, we can see we still only require less than 25% of all savings to breakeven

CCG	Service Cost C3	Total savings	Proportion of potential saving from reduction in referral to breakeven
Kernow		£240,638	
New Devon		£417,747	
BANES		£170,286	
BNSSG		£280,376	
Gloucestershire		£257,074	

Somerset		£91,643	
Wiltshire		£101,352	
South West		£1,559,116	

This also provides reassurance that the impact of any growth in the service will be cost neutral or better, as more GPs take up the FIT for suitable patients.

## 7.6 Test Eligibility Criteria

The current test eligibility criteria are based on the following criteria

- Aged 50 years and over with unexplained abdominal pain or weight loss
- Aged 50- 60 years with changes in their bowel habit or iron deficiency anaemia
- Aged 60 years and over and have anaemia – even in the absence of iron deficiency

NICE guidance NG12 “Suspected cancer: recognition and referral” makes no lower age limit in the group 60 years or younger with changes in their bowel habit or iron deficiency anaemia. If the age limit was removed it could be anticipated that work load would increase although it is not possible to project by how much. It is worth noting that lower age limit has been questioned by some GPs.

## 7.7 Potential service developments

The laboratories would work with GP practices to support the introduction of auto populated request forms within the GP LIMS. The laboratories would work with CCGs who wish to ensure that results are in the local secondary care record. Electronic data sharing between labs is possible with the right software.

## **8 Conclusions from SWAG and Peninsula Cancer Alliances**

Faecal Immunochemical Testing is a technology that is acceptable to patients and well received by GPs. It is recommended in two sets of NICE guidance: NG12 which offers recommendations for the detection and referral of cancer, and DG30 which specifically relates to the assessment of the FIT technology.

This test offers a clear pathway for the investigation of patients who are at risk of colorectal cancer but who do not cross the 3% threshold for urgent referral. It allows sub-stratification of this cohort into people who do need more urgent investigation via a two-week-wait pathway, and those who do not. This is a cost-effective and potentially cost-saving intervention which will help achieve the Long Term Plan NHS aim of diagnosing a higher proportion of colorectal cancers at an early stage

## 9 Contacts

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