Healthy London Partnership

NHS

Transforming Cancer Services Team for London

FIT FOR SYMPTOMATIC PATIENTS IN COLORECTAL CANCER

Implementation of NICE DG30 guidance on use of Faecal Immunochemical Testing (FIT) for patients with symptoms suspicious of colorectal cancer

Pan London Business Case

July 2018

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Executive Summary

Colorectal cancer (CRC) is one of the most common cancers in England and the second commonest cause of cancer death. Diagnosis in symptomatic patients relies on identification of people with a high risk of having cancer who should be referred for specialist investigations. This approach has limitations as many people with cancer present initially with low risk symptoms so diagnosis may be delayed. Over half of all CRC is detected once the cancer has spread and a quarter after an emergency presentation to A/E, which are associated with poorer survival rates.

Faecal Immunochemical Testing (FIT) is a stool test that is highly sensitive for identifying bleeding in the gastrointestinal tract, a sign of CRC. FIT offers an improved method for identifying people with significant risk of CRC who should be referred for investigation. Recently launched, NICE guidance DG30 recommends use of FIT in groups of symptomatic patients not considered to have a $\geq$ 3% risk of cancer – the threshold that should trigger an urgent suspected cancer (USC or 2 week wait) referral. In London these patients are already included in 2ww referral recommendations due to the limitations of the previously available stool test (guaiac FOBt). With the commissioning of FIT, they could now be offered this test first.

Use of FIT in people with symptoms suspicious of CRC is likely to lead to increased speed of CRC diagnosis for many patients, with a substantially higher proportion diagnosed via an USC route. Modelling also suggests there may be improvements in the number of people diagnosed with early stage cancer and the proportion of patients satisfied with the time taken to diagnose them after they first present. It is likely that the overall numbers referred on 2ww will decrease but this will depend on the proportion of those currently referred who would meet future criteria for FIT which is currently unknown. This proportion will increase if as expected there is a national recommendation to extend use of FIT to high risk ($\geq$3% of cancer) patients.

The impact of introducing FIT for low risk symptomatic patients on endoscopy demand (colonoscopy, flexible sigmoidoscopy and CT colonography) will be influenced by many factors and there are on no published studies examining use of FIT in this way across an entire population. Nevertheless modelling using a wide range of assumptions suggests endoscopy demand will decrease with the most likely scenario predicting a reduction of 15% in all procedures (range 5-29%). This should reduce further once FIT is offered to high risk symptomatic patients.

Implementation of a new FIT for symptomatic patients' pathway will require the commissioning of FIT kit and laboratory testing activity. Modelling suggests that the costs of this activity are likely to be moderate and more than balanced by savings from reduced demand for endoscopy and specialist care for later stage disease. A number of options for commissioning FIT testing capacity are presented within the business case to support local decision making. The London FIT Steering Group has recommended that all CCGs adhere to a standard low risk symptomatic patient pathway in which FIT is provided to patients by their GP with results or non-completion followed up in primary care. This pathway is presented for CCG approval. It is recommended that CCGs consider allocating a small quantum of staff and other resources to ensure the new pathway is rapidly mobilised, safely implemented and robustly monitored.

1. Introduction

The purpose of this business case is to provide commissioners with information to enable implementation of Faecal Immunochemical Testing (FIT) in symptomatic patients in primary care whose presentation raises suspicion of colorectal cancer (CRC). Commissioners are asked to:

1. Adopt the proposed clinical pathway for offering FIT to symptomatic patients;
2. Commission sufficient quantity and quality of FIT kit and laboratory testing capacity;
3. Decide on the appropriate model for commissioning this laboratory capacity and how this will be commissioned locally (CCG or STP);
4. Allocate sufficient resource to ensure the new pathway is rapidly mobilisation and monitored.

The business case comprises:

1. **Context and strategic fit:** a summary of current data on CRC diagnosis and survival in England and London and the proposed role of FIT in diagnostic pathways;
2. **Objectives and outcomes:** The nature and estimated scale of benefits to patients and local health systems of introducing FIT;
3. **Service description:** Outline of the key features of the proposed new clinical pathway and its implications for services;
4. **Financial case:** Modelled expectations of future FIT testing and endoscopy activity, and estimated cost implications;
5. **Commissioning and Procurement:** Options for commissioning the required FIT testing capacity.

Information on risks and mitigations is also provided.

2. Context and strategic fit

2.1 Incidence and mortality CRC

Colorectal cancer (CRC) is the fourth most common malignancy in the UK, accounting for 12% of all new cancers. In London, approximately 3500 people are diagnosed with and around 1250 die from CRC each year. Over 20% of new cases in London are in people under 60 years old. The number of people in London and England diagnosed annually with CRC has increased steadily over the past decade, largely due to age-related demographic growth. Mortality has fallen progressively in the same period, reflecting improvements in diagnosis and treatment.[1]

9 in 10 people diagnosed with the earliest stage (stage 1) of CRC survive for five years or more; less than 1 in 10 people with the latest stage (stage 4) do. Over half of all cases in England and almost 60% of cases in London are diagnosed at Stages 3 and 4. Worryingly, people under 60 years are less likely to be diagnosed with early stage CRC (37%) compared to those over 60 years (44%). Around a quarter of all patients in London are diagnosed via an emergency route; only a third of these are alive after 5 years. This compares to 69% for those diagnosed via 2ww or routine referral.

Although the proportion of cases diagnosed as an emergency has fallen over the past decade, in some parts of London this decrease has been only marginal (Table 1). Similarly, there have been

relatively small improvements in the proportions of patients diagnosed with early stage CRC over the most recently recorded period (2012-16).

Table 1: Change in % CRC diagnosed via emergency route 2006-2015, London[2]

Alliance	2006	2015	% change 2006-2015
RMP	30.6%	25.4%	↓ 5.2%
UCLH CC	29.0%	28.4%	↓0.6%
SEL	26.8%	24.8%	↓2.0%

2.2 Diagnosis of CRC and the role of FIT

CRC is usually diagnosed by colonoscopy, sigmoidoscopy or CT colonography (henceforth these will be referred to collectively as "endoscopy"). National guidelines (NICE NG12) recommend referral of symptomatic patients for endoscopy determined by an assessment of whether the patient is at "high" or "low" risk of CRC.[3] This should be based on a person's age, sex, the nature and duration of their symptoms, and basic laboratory test results. High risk patients (considered to have a risk of cancer $\geq$ 3%) should be referred urgently via a 2WW pathway. Low risk patients (< 3%) should be managed according to clinicians' discretion using qualified reassurance, follow up and safety netting and - for certain groups - testing for occult blood in the stool. The strength of this distinction is that patients with the highest risk can be referred quickly for investigation. However, in real world clinical practice it is not always easy to distinguish between those with a greater or less than 3% risk, and regardless of this many people with CRC present with a "low risk" clinical picture that does not initially meet NG12 criteria for urgent referral. This means that people may be incorrectly judged to not need endoscopy and their diagnosis delayed.

An abnormal faecal blood test result suggests that there may be bleeding within the gastrointestinal tract, which requires further investigation, usually via endoscopy. At the time NG12 was published the only test widely available was a guaiac based Faecal Occult Blood Test (gFOBt). This has no specificity for human haemoglobin, leading to false positives from dietary sources of haemoglobin and antioxidants or peroxidase activity from food and drugs. As a result practitioners lost confidence in this test and it was gradually withdrawn. In response, the pan London NG12 colorectal clinical reference group decided to "upgrade" patients for which NG12 guidelines recommended a gFOBt to a suspected cancer referral (2ww); therefore London pathways encouraged referral of *greater numbers* of people via a 2ww suspected lower gastroenterology (GI) cancer route than are specified within the NG12 guidelines. **This means that implementing FIT in line with DG30 guidance will lead to many people currently being referred via 2ww being reassured they are low risk and do not need referral for endoscopy.**

FIT (Faecal Immunochemical Test) uses antibodies that specifically recognise human haemoglobin so it is a much more sensitive and specific test of gastrointestinal bleeding than gFOBt. Use of FIT has been proposed in a range of clinical situations all aimed at detecting people with CRC (Table 2). This business case is only for use of FIT in patients presenting with symptoms suggestive of possible CRC.

Table 2: Proposed uses of FIT

Clinical scenario	Patient cohort/s	This business case?
Symptomatic patients	People with symptoms suggestive of possible CRC	✓
Screening	People without symptoms invited to participate in the Bowel Cancer Screening Programme (BCSP)	✗
Surveillance	People with conditions predisposing to CRC e.g. Crohn's, ulcerative colitis, Lynch syndrome	✗

In July 2017 NICE guidance DG30 *"Quantitative faecal immunochemical tests to guide referral for colorectal cancer in primary care"* was published.[4] This recommend use of FIT in low risk symptomatic patients as follows:

- Use of FIT in primary care to guide referral for suspected CRC in low risk symptomatic patients;
- Use of the OC Sensor, HM-JACKarc or FOB Gold quantitative FIT tests for testing;
- A threshold of ≥ 10 µg Hb/g faeces as the cut off for an abnormal result.

Low risk symptomatic patient groups recommended for FIT testing are described in Table 3.

Table 3: Patient groups suitable for FIT testing according NICE DG30

Offer FIT to assess for colorectal cancer in adults without rectal bleeding who:

1. Are aged 50 years and over with unexplained:
   - Abdominal pain or
   - Weight loss or
2. Are aged under 60 with:
   - Changes in their bowel habit or
   - Iron deficiency anaemia or
3. Are aged 60 and over and have anaemia even in the absence of iron deficiency.

In summary:

- Colorectal cancer is one of the commonest cancers and causes of cancer death, and occurs in substantial numbers of people from 40 years upwards;
- Many people in London continue to be diagnosed at a late stage including via emergency presentations which are associated with poorer survival;
- Over the past decade some areas of London have seen only marginal reductions in the proportions of patients diagnosed at a late stage of cancer or via an emergency route;
- NICE guidelines recommend identification of high risk patients for immediate referral for endoscopy, and reassurance with follow up of low risk patients;
- DG30 guidance recommends use of FIT in specific low risk groups, which current London pathway recommend are referred for investigation via a 2ww;
- FIT will help to improve identification of low risk patients who need early referral for endoscopy.

3. Objectives and Outcomes

Introduction of FIT for symptomatic patients will help to achieve several objectives, listed in Table 4. For each objective, an outcome metric /s that could be used to define and measure success has been proposed.

Table 4: Objectives and proposed outcomes metrics for use of FIT in symptomatic patients

Objectives	Outcome metrics
Detect CRC at an earlier stage of disease	Percentage new CRC diagnosed at stage 1 & 2 Improved percentage <60 at stage 1 & 2 CRC
Diagnose CRC more rapidly after clinical presentation	Increased percentage CRC diagnosed via 2ww Reduced percentage CRC diagnosed as emergency
Improve patient experience of care	Improved NCPES* metrics for early diagnosis and service coordination
More efficient use of NHS care	Reduced demand for endoscopy Increased percentage of endoscopies which yield diagnosis of CRC Reduced demand for OPD gastroenterology and colorectal surgery

*National Cancer Patient Experience Survey

3.1 Earlier stage diagnosis of CRC

FIT allows rapid identification of people who need definitive testing via endoscopy, which should reduce delays following presentation to diagnosis. This may enable some people's cancers to be diagnosed at an earlier stage of disease. The impact is likely to be greatest in people presenting with a low risk clinical picture who may not otherwise be referred quickly.

The proposed metrics for evaluating success would be an increase in the percentage of new CRC diagnoses at stage 1 and 2 cancer (early stage), and a reduction in the percentage of new diagnosis detected after emergency presentation. Since controlled studies have not provided evidence of impact on these metrics, simple modelling has been undertaken to estimate what impact testing according to DG30 guidance would have on these in London.

If 50% of new cases of CRC with late stage disease were detected via a positive FIT test and 1:10 was diagnosed at an earlier stage, 93 people across London would be diagnosed with early stage CRC who would previously have been diagnosed at stage 3 or 4. This represents a 2.9% increase in the proportion diagnosed with early stage disease, in contrast to the 0.1% increase seen from 2015-2016 in London (there was no improvement across England as a whole during this period).

A fuller description of the modelling used is in section A of Appendix 1.

Table 5: Increase in % new CRC at stage 1 and 2 with FIT (using assumptions above)

STP	Percentage of recorded new CRC diagnosed at stage 1 and 2		
	2015	2016	With FIT
North Central London	43.2%	44.8%	47.7%
North East London	39.9%	40.2%	43.1%
North West London	44.2%	45.1%	48.0%
South East London	42.3%	42.5%	45.4%
South West London	43.9%	41.4%	44.3%
London	42.7%	42.8% (↑0.1%)	45.7 (↑2.9%)

Based on the reported average costs of treating different stage of colon and rectal cancers, the estimated savings associated with diagnosing 93 people at an early rather than late stage would be approximately £500k per year. This may underestimate cost savings as it does not estimate the savings from other potentially relevant metrics such as people diagnosed with Stage 3 rather than 4 disease, Stage 1 rather than Stage 2, or at Stage 3 as before but with less locally advanced disease.

3.2 Speed of diagnosis

As outlined earlier where a patient does not meet criteria for high risk referral it is recommended that GPs use clinical discretion, watchful waiting and safety netting to determine if they need further investigations. This process may take several months during which patients may be lost to follow up; when they are eventually referred this will often be routinely. FIT will allow clinicians to identify much more quickly and accurately which patients should be referred urgently.

Once again there is a limited evidence base from which to derive estimates of the expected impact of this change, and in real world practice many variables affect average times to diagnosis. To provide an idea of the expected scale of change, the impact of introducing FIT on proportions of people with CRC diagnosed via urgent, routine and emergency referral routes has been modelled using the methodology and assumptions shown in section B in Appendix 1. This uses known figures on proportions of people via different diagnostic routes in England.

Table 6 shows that the proportion diagnosed via an urgent 2ww pathway would be expected to rise substantially, while the proportion presenting as an emergency would fall from 23.2% to 16.3%.

Note this does not take into account changes in the proportion of CRC diagnosed via screening with introduction FIT in the BCSP. This is expected to rise to a certain extent with higher uptake of bowel cancer screening, which will impact to some extent on the proportions diagnosed via other routes.

Table 6: Change in proportions new CRC cases diagnosed via different routes with FIT (England)

	Current	With FIT as per DG30
% Referred via screening pathway	9.7%	9.7% (-)
% Referred urgent pathway	31.8%	59.3% (↑27.5%)
% Referred routinely	32.7%	12.1% (↓20.6%)
% Presenting as emergency	23.2%	16.3% (↓6.9%)
% Unknown referral route	2.6%	2.6% (-)

In London the reductions in proportion diagnosed after emergency presentation would be even more striking as the starting position is higher (Table 7). The modelling assumes that one third of people who would otherwise present as an emergency see their GP prior and have a FIT test which is positive, resulting in a 2ww referral. The NECL emergency admissions study suggested that 50% of patients had seen their GP prior to presentation so this assumes roughly 2/3 of these receive FIT.

Table 7: Estimated changes in % new CRC diagnosed via emergency with FIT

	Current	With FIT as per DG30	CHANGE
RMP	25.4%	17.9%	↓7.5%
UCLH CC	28.4%	20.0%	↓8.4%
SEL	24.8%	17.4%	↓7.4%
ENGLAND	23.2%	16.3%	↓6.9%

* Detailed CRC data are not available to provide modelled estimates at CCG or STP level

3.3 Patient experience

Compared to endoscopy FIT is a more convenient and accessible test with much less impact on daily activities. It may also allow patients to be more rapidly reassured about their cancer risk. There is some evidence that patients believe colonoscopy and faecal occult blood testing are equally acceptable tests to rule out CRC.[5] In actual practice for low risk patients the comparison is more often between FIT and no other testing, since guidelines recommend that patients can be followed up or even reassured without referral. Many people may wish to be investigated for a cancer risk less than <3%; offering FIT would support this expectation to a greater degree than current practice. Patient representatives at the FIT steering group also stressed the importance of offering patients the choice of having a FIT rather than endoscopy even if there was a chance that FIT may miss a cancer.

Colonoscopy is associated with a small morbidity and a very small mortality which includes major bleedings (0.8/1000 procedures, 95% CI 0.18-1.63), perforations (0.07/1000 procedures, 95% CI 0.006-0.17) and death (0.03/1000 procedures). CT colonoscopy involves delivery of quite high doses of ionising radiation that is potentially harmful, particularly for younger patients. FIT is not associated with these risks.

Improvements in patient experience could be monitored through the National Cancer Patient Experience Survey (NCPES).[6] This takes place every two years and received results from over 70,000 patients with cancer in 2016. Figures for two of the most relevant questions (England data) are shown in Table 8: it is apparent that the experience of CRC patients is lower than that for cancers patients as a whole, suggesting scope for improvement.

Table 8: Most recent performance (2016) on key questions NCPES in England: All cancers and CRC

Question	Response	Cancer patient cohort	
		All cancers	CRC
Before you were told you needed to go to hospital about cancer, how many times did you see your GP (family doctor) about the health problem caused by cancer?	Saw my GP $\geq$ 3 times	17.7%	20.9%
How do you feel about the length of time you had to wait before your first appointment with a hospital doctor?	Should have been seen a bit / a lot sooner	16.7%	18.6%

3.4 Cancer waiting times and CWT performance

Offering FIT to low risk symptomatic patients will influence numbers of lower GI urgent 2ww referrals in two mains way, outlined earlier:

- Some patients will be referred via 2WW who previously were referred non-urgently or not referred at all: This would create *additional* 2ww referrals.
- Some patients currently referred via a 2ww would receive a FIT, test negative and consequently not be referred via a 2ww: This would *remove* some "existing" 2ww referrals.

The relative impact of these factors has been modelled using the assumptions from the financial impact assessment, described in Table 10. A full description of the methodology used is in section C of Appendix 1. Results are shown in Table 9. Using the "MEDIUM" assumptions, the modelling suggests there would be a 5.9% increase in the numbers of people referred via 2ww. The "LOW" impact assumptions suggest a 13.7% increase and the "HIGH" impact assumptions a 4.6% decrease in the numbers of 2ww referrals, respectively.

Table 9: Change in numbers of people referred via 2ww with FIT (London)

	CURRENT	FUTURE SCENARIO		
		Low	Medium	High
Number referred 2ww	55,552	63,097	58,842	52,937
% ↑/↓ on current 2ww	100%	↑13.7%	↑5.9%	↓4.6%

Numbers of patients referred on an urgent suspected cancer pathway may impact on cancer waiting times (CWT) performance. The estimates above suggest that these numbers will increase with introduction of FIT for low risk patients. This reflects increases in urgent referrals in patients newly referred with a FIT positive test as well as those previously referred routinely. The latter is likely to lead to reductions in routine referrals. Note the estimates above assume widespread use of FIT by GPs in the eligible population. In reality this may not be the case initially and by the time this does occur FIT is likely to be recommended in high risk patients as well. Once high risk patients are eligible for FIT, the number of 2ww referrals is likely to reduce significantly. This is reflected in the *high impact scenario* where a higher proportion of 2ww referred patients are assumed eligible for FIT.

3.5 Demand for endoscopy

As previously stated, for the purposes of this business case "endoscopy" refers to colonoscopy, flexible sigmoidoscopy and CT colonography. The impact of introducing FIT for low risk symptomatic patients on endoscopy demand will depend on the relative numbers of patients newly *ruled in* for an endoscopy by a FIT positive result vs. the numbers previously referred who would be *ruled out* by a FIT negative result. Greater reductions in demand will be seen when more people are eligible for "rule out" FIT testing. Clearly this depends on the proposed clinical pathway.

DG30 recommends use of FIT in people who NG12 national guidelines do not recommend should be referred for endoscopy in all cases. Therefore use of FIT might "rule in" additional patients, which could lead to increased demand for endoscopy. There are also concerns that once FIT is widely available people will be tested outside of DG30 guidelines, for instance those with very low risk clinical presentations who would not otherwise have been referred.

Set against this the following factors suggest that in London providing FIT in line with DG30 guidance will reduce rather than increase demand for endoscopy:

1. London's current lower GI suspected cancer pathway recommends urgent referral of all patients DG30 recommends should in future receive a FIT: therefore these patients are already "ruled in" and FIT can now be used to "rule out" their need for endoscopy unless the result is positive.
2. It is likely that many other patients who do not meet either NG12 or DG30 criteria are currently being referred via 2WW lower GI pathways based on clinical discretion; FIT will allow GPs to better prioritise which of these patients need referral, again enabling "rule out".
3. Many low risk patients are already being referred via routine pathways and end up undergoing endoscopy to exclude significant bowel disease; here again FIT will allow better prioritisation, by both generalists and specialists, of who needs referral and investigation.

In light of the complexity of issues the expected impact on endoscopy demand is uncertain and can only be estimated through modelling assumptions for the critical influencing factors. Section D of Appendix 1 provides detail of method for modelling future demand and Table 10 shows the assumptions used and their basis. In summary, the modelling attempts to provide estimates of the major determinants of future endoscopy demand, which are the:

1. Total numbers of people eligible for FIT;
2. Proportion of those eligible who are currently receiving endoscopy;
3. Proportion of those eligible who undergo FIT testing;
4. Proportion of those tested who have a positive result;
5. Number of people who will be referred for endoscopy regardless of FIT.
6. Table X: Figures and assumptions for variables used in financial modelling

Table 10: Figures and assumptions used for modelling endoscopy demand and financial impact of introducing FIT for low risk symptomatic patients

	VARIABLE	**FIGURE or ASSUMPTION**	**BASIS FOR FIGURE or ASSUMPTION**
Endoscopy demand	***Colonoscopies and CT colonographies (CTC)***		
	Total colonoscopies per year*	79,980	Recorded numbers of colonoscopies 2017/18 from Unify data
	Total CTC per year*	7998	Assumed 10% of total colonoscopies
	% colonoscopies and CTC after 2WW referral	48-53%	% of recorded annual Lower GI 2ww referrals (55,552 from CWT database) who undergo colonoscopy - assumed 80-95%
	% colonoscopies and CTC after routine referral	47%-52%	Corollary of above
	% 2ww colonoscopies and CTC eligible for FIT	20%-40%	Clinical estimate informed by figures from national FIT pilots
	% routine colonoscopies and CTC eligible for FIT	50-70%	Clinical estimate informed by figures from national FIT pilots
	% eligible for FIT who undergo FIT	60%-90%	Clinical estimate informed by figures from national FIT pilots
	Flexible sigmoidoscopies		
	Total flexible sigmoidoscopies per year	43,968	Recorded numbers of FS 2017/18 from Unify data
	% flexible sigmoidoscopies eligible for FIT	20-40%	Assumed no difference in % eligible 2WW / routinely referred. Many referred for rectal bleeding so may not be eligible for FIT.
	Outcome of FIT testing		
	% undertaking FIT who have positive result	16-23%	Estimate from Health Technology Assessment that informed DG30 guidance recommendations
Implementation costs	**FIT testing**		
	Numbers eligible for FIT per year	14/1000, 11/1000, 7/1000 patients ≥65 years per year	Devon study asking practices to estimate numbers eligible for FIT according to DG30. This population is considerably older than the London average population.
	% eligible for FIT per year NOT currently being referred	35%-45%	Findings from Devon audit show>50% already being referred.
	Proportion of those eligible undertaking FIT	60-80%	Drawn from data in pilots and studies
	Unit costs FIT	£15-£20	Expert opinion
	Implementation costs		
	Training and education	£10k per CCG	To run programme at start
	Project management	£25k per STP	Project manager for 6-12 months
	Ongoing monitoring of activity and outcomes	10K per STP	IT manager 1 day per week

*Does not include colonoscopies and CT colonographies for surveillance or screening purposes

Three scenarios were tested:

- LOW (ALL assumptions tend to the least reduction in endoscopy demand);
- MEDIUM (a middle position);
- HIGH (ALL assumptions tend to the most reduction in endoscopy demand).

Table 11 summarises the results of the modelling calculations. The medium impact scenario, considered the most likely outcome, estimates that 15%-17% reductions in demand for colonoscopy, flexible sigmoidoscopy and CTC. This scenario assumes:

- 30% and 60% of those currently referred via 2ww and routine route would be eligible for FIT respectively (approx. 51,000 people)
- 37,000 additional people not currently being referred are FIT tested
- 70% of those eligible are tested (in total 61,000 people undergo FIT)
- 18,000 less procedures are required amongst the cohort *already receiving* endoscopy
- 6500 extra endoscopies are required in people not currently being referred who test FIT positive.

The low and high impact estimates suggests a smaller or greater decrease in demand for endoscopy respectively. None of the three scenarios estimates there will be an increase in demand.

The variation by type of endoscopy test reflects differences in the proportions offered following 2ww and routine referrals, both currently and in the future. Where an investigation is more likely to be offered after routine referral (e.g. flexible sigmoidoscopy) the reduction in demand will be greater if the proportion eligible for FIT is higher in the routine vs 2ww referred cohort. The other factor influencing change in demand is the expected numbers of "new" referrals following FIT as it is assumed that FIT positive patients will be sent for colonoscopy or CTC, not FS.

Table 11: Modelled estimates of change in demand for endoscopy with FIT for low risk patients

Investigation	**Measure**	**Current activity**	**Future impact scenario**		
			Low	**Medium**	**High**
Colonoscopy	*Number*	79980	77773	67361	54934
	Change num	-	↓2207	↓12619	↓25046
	% change	-	↓2.8%	↓15.8%	↓31.3%
CT colonography	*Number*	7998	7457	6322	5245
	Change num	-	↓154	↓1380	↓2585
	% change	-	↓1.9%	↓17.2%	↓32.2%
Flex sigmoidoscopy	*Number*	43968	38493	35302	31305
	Change num	-	↓4068	↓7479	↓11,959
	% change	-	↓9.3%	↓17.0%	↓27.2%

Expected estimates of endoscopy demand by CCG are listed in Appendix 1.

To test a more extreme scenario the following series of assumptions were used:

- Only 10% of current 2ww referred endoscopy are eligible for FIT;
- Only 30% of those current routinely referred are eligible for FIT;
- Twice the number of estimated additional people (those not being referred now) are offered FIT;
- Only 50% of people eligible for FIT undergo testing.

In this scenario, there would be an 11% increase in demand for colonoscopy and CTC respectively, and a 9.4% decrease in demand for flexible sigmoidoscopy.

In summary, the modelling suggests that London as a whole will see reductions in endoscopy demand even with the recommendation to only use FIT in low risk symptomatic patients. Clearly the estimates are subject to much uncertainty but do cover a broad range of possible assumptions. Although this possibility cannot be discounted, the extreme scenario assumes that very few people currently referred via 2ww meet DG30 criteria and that the eligible population in London is double that found in Devon, a population in which the proportion of people 65 years and over is twice that found in London.

3.6 Out-patient activity

In principle outpatient attendances at colorectal and gastroenterology should decrease with the availability of FIT, since GPs and others considering referral will be more confident to manage patients with negative results without recourse to specialist referral. In practice this will likely be modified by clinician and patient concerns if symptoms persist and, at least initially, acceptance of new the pathway and test by clinicians and patients.

In Scotland where FIT has been piloted for the longest time in the UK, data show that colorectal pathway and gastroenterology referrals have fallen by 9% and 24% respectively within 12 months of the test being introduced into mainstream practice. Note Scotland does not have specific criteria for urgent suspected cancer referrals and FIT was recommended to be offered for almost all patients with symptoms suspicious of CRC; this means the expected impact in London may be lower until FIT is offered for high as well as low risk symptomatic patients. Because of this uncertainty and the difficulties in obtaining robust up to date data on individual CCGs' colorectal pathway and gastroenterology outpatient attendance numbers, estimated reductions have not been modelled. CCGs may wish to model on the basis of a 10% reduction in gastroenterology outpatient attendances 12 months after FIT has been introduced.

4. Service description

The service proposed by the business case is to offer FIT to low risk symptomatic patients according to the London pathway described in Figure 1. This pathway was developed by the pan London FIT Steering Group through consideration of the evidence from published studies and service pilots, national policy statements and expert opinion. The group discussed the relative benefits of four main options for implementing FIT for symptomatic patients (Table 12) and recommended that:

- All parts of London should ensure implementation of DG30 guidance i.e. for low risk patients (Option 1)
- Any areas wishing to pursue a pathway offering FIT to high as well as low risk patients should do this as part of the national pilot programme (Option 2)

Of note, it is expected that within the next 6 months a national statement on the use of FIT in high risk patients will be made, informed by evidence from NIHR studies and service pilots.

The low risk pathway shown in Figure 1 includes the following key features:

- Low risk patients should be offered FIT in line with DG30 i.e. these patients come out of the currently recommended 2ww referral cohort in London
- FIT should be provided to the patient by the GP (rather than after referral to a specialist)
- High risk patients not meeting the DG30 criteria should continue to be referred via 2ww FIT should be provided to the patient by the GP (rather than after referral to a specialist)
- A positive FIT result should be actioned by immediate referral on a lower GI 2ww pathway
- A negative FIT result should trigger clinicians to consider one of the following actions:
    - Repeat FIT test
    - Ongoing watchful waiting
    - Routine referral
    - Urgent referral elsewhere
- Practices should ensure safety netting systems are in place to monitor and take action where:
    - A FIT result has been received (actions as described above)
    - Patients have not submitted a FIT sample

The implications for commissioners are:

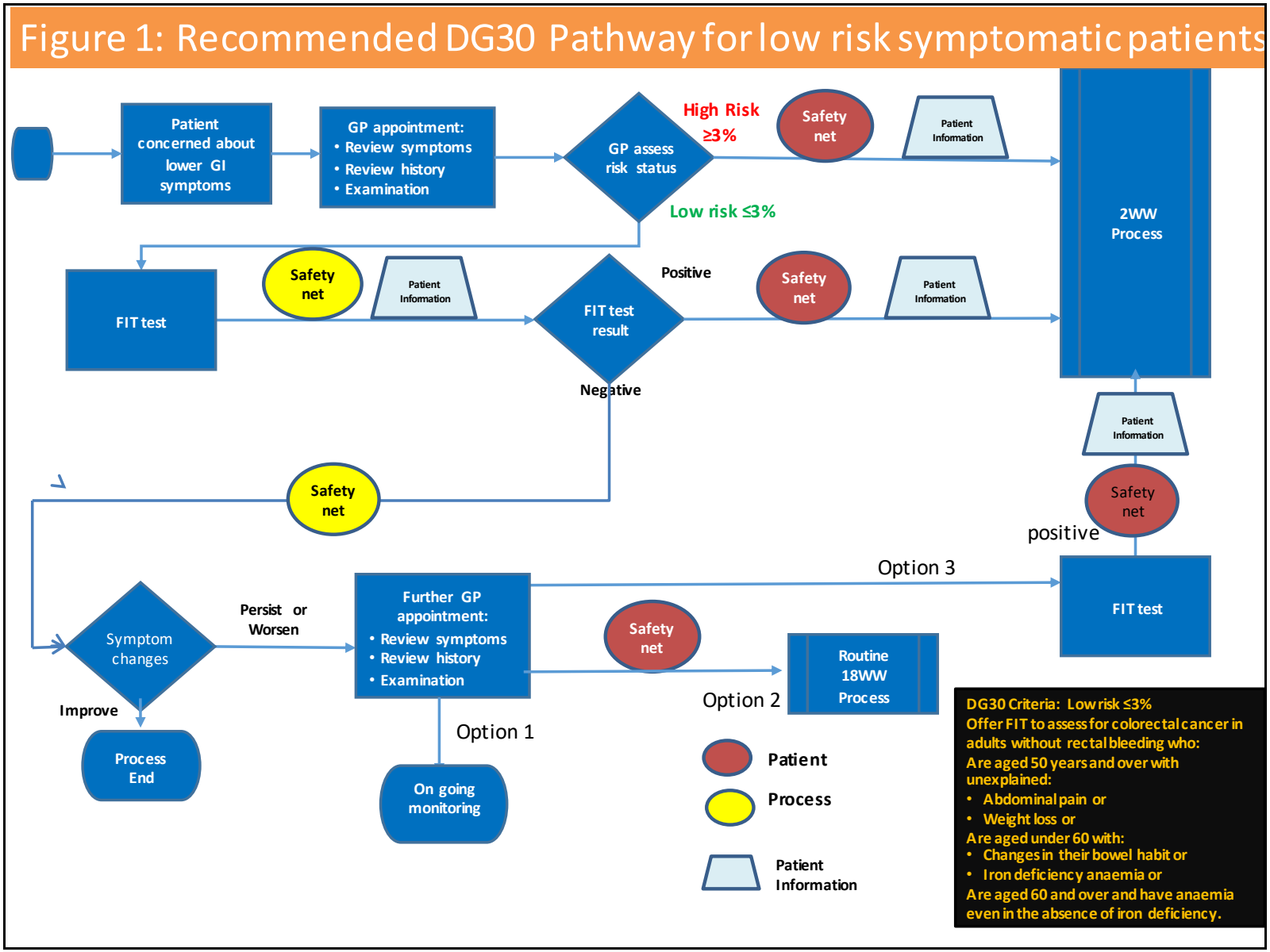
- FIT testing capacity should be commissioned in line with this pathway, including:
    - Sufficient testing and kit to meet the expected activity;
    - Robust processes for supplying and re-supplying kit to practices;
    - Arrangements for transport samples to laboratories and timely reporting of results.
- GPs and other staff in primary and secondary care should be adequately trained to deliver the pathway accurately and consistently;
- Use of safety netting systems to support the pathway should be promoted.

Commissioners are asked to endorse the London FIT for low risk symptomatic patients' pathway.

Table 12: Options for implementing FIT for symptomatic patients

OPTION	PROS	CONS
1. DG30 / low risk alone and await national guidance on high risk	• In keeping with national guidance and London position • GP learning in use of FIT for low risk in prep for use in high risk • Likely easy adaption to recommendation for use in high risk • Should reduce demand for endoscopy via element of "rule out" • In keeping with implementation in many other areas	• Requires investment for FIT testing and implementation of new pathway • Risk of increasing demand for endoscopy through "rule in" (see section 3.5) • Likely to be 2nd stage implementation once recommendations on use in high risk available
2. Delay all implementation until there is recommendation on use in high and low risk symptomatic patients	• Delays implementation until there is clarity about use in high as well as low risk patients, so potentially one step implementation • No investment required • Potential to implement "final state" pathway for low and high risk patients in one stage, so minimising complexity • No risk of increasing demand for endoscopy through creation of new "rule in" FIT pathway	• Risks lengthy delay in introducing national guidance • May be lengthy period before national recommendation on use in high risk available • Low risk patients can't receive test so no clinical benefits • No learning in use by GPs possible in this time, will all have to be learnt when "final state" recommendations available • No opportunity to curtail trend to rising demand for endoscopy via new "rule out" FIT pathway • Implementation costs will eventually be required • Will be out of synch with other areas in London that implement FIT / DG30 – inequity for patient populations
3. Low and High risk implementation at same time	• Emerging evidence from pilot studies supports this • Likely direction of travel for use of FIT in future • Likely greatest reduction in demand for endoscopy • Likely greatest financial savings	• Outside current national guidelines • Greatest investment costs • Requirement to introduce as part of NHSE pilot programme – will require broad clinical support
4. DG30 and prepare actively for inclusion of high risk patients	• Same benefits as option 1 • Able to implement in high risk early when ready to, where greatest benefits for reducing demand likely to be seen	• National recommendation in high risk may be different to that prepared for locally • May divert attention from implementation in low risk cohorts

Figure 1: Recommended DG30 Pathway for low risk symptomatic patients



5. Financial case

5.1 Outline and figures used in modelling of costs

The financial case for implementing DG30 guidance is primarily based on the expected reductions in specialist care due to less people being referred for specialist care, leading to reductions in outpatient appointments and diagnostic activity (endoscopies). This would result in an associated reductions in commissioning costs. These savings will need to be balanced against the costs of commissioning new FIT for symptomatic patient pathways, principally for testing kits and laboratory capacity. Therefore the most important factors which need to be taken account of are the:

a. Expected demand for endoscopy;
b. Expected numbers of FIT tests that will be required;
c. Unit costs of each of the above;
d. Costs of any set up resources if these require new rather than reallocation of existing resources.

The derivation of these for the purposes of modelling expected costs is outlined below.

a. Expected demand for endoscopy

This is derived from the modelling discussed in Section 3.5 above using the low, medium and high impact figures described in Table 10.

b. *Expected FIT activity*

The total number of FIT tests required will depend on:

- The total number of people eligible;
- The proportion of these who undertake the test - some may not be offered it, others will be offered but not undertake it;
- The proportion of those tested who undergo re-testing.

All of these are unknown therefore estimates of the expected future FIT activity have been made using the assumptions in Table 13.

Note the only study identified which has examined the expected overall numbers of people in a population likely to be FIT tested is a Devon study in which 14 practices (total list size of 84, 461 patients) were asked to estimate over a 3 month period the numbers of patients who would be eligible for FIT according to the DG30 guidance. This found that on average 14/1000 people per year would be eligible. Notably, the proportion of the registered population over 65 years in these practices averaged 25.8%; in London only 10.9% of the population is over 65 years. Therefore, activity was modelled at 100%, 75% and 50% of the Devon estimate.

Table 13: Assumptions used to model impact on routes to diagnosis of introducing FIT

Criteria	Assumptions	Basis for assumption
Numbers eligible for FIT per year	14/1000, 10.5/1000, 7/1000 patients ≥65 years per year	Devon study asking practices to estimate numbers eligible for FIT according to DG30 (14/1000). The % of people ≥ 65 years is double that of the London average population.
% eligible undertaking FIT	50%, 65%, 80%	Drawn from data in pilots and studies
% undergoing repeat FIT	10%, 20%, 30%	The pathway is likely to suggest (not mandate) repeat test as an option if symptoms and concerns persist; some people will lose the kit or not complete the test correctly

Table 14 details the "high", "medium" and "low" activity estimates produced by modelling the different levels of assumption above.

Table 14: Estimated annual numbers of FIT tests per year in London and population of 250,000

Estimated number who will be FIT tested	Scenario		
	High	**Medium**	**Low**
	- 14/1000 >65 eligible - 80% undertake test - 30% repeat	- 10.5/1000 >65 eligible - 70% undertake test - 20% repeat	- 7/1000 >65 eligible - 70% undertake test - 20% repeat
London	127,951	77,509	40,600
Barking & Dagenham CCG	2,292	1,504	859
Barnet CCG	4,309	2,827	1,616
Bexley CCG	2,748	1,803	1,030
Brent CCG	3,677	2,413	1,379
Bromley CCG	3,686	2,419	1,382
Camden CCG	2,735	1,795	1,026
Central London CCG	1,976	1,297	741
City & Hackney CCG	3,152	2,068	1,182
Croydon CCG	4,301	2,823	1,613
Ealing CCG	3,893	2,555	1,460
Enfield CCG	3,727	2,446	1,398
Greenwich CCG	3,118	2,046	1,169
Hammersmith & Fulham CCG	2,036	1,336	763
Haringey CCG	3,096	2,032	1,169

Harrow CCG	2,804	1,840	1,052
Havering CCG	2,826	1,855	1,060
Hillingdon CCG	3,379	2,217	1,267
Hounslow CCG	3,050	2,001	1,144
Islington CCG	2,584	1,696	969
Kingston CCG	1,969	1,292	738
Lambeth CCG	3,681	2,416	1,381
Lewisham CCG	3,374	2,214	1,265
Merton CCG	2,321	1,523	870
Newham CCG	3,777	2,478	1,416
Redbridge CCG	3,368	2,210	1,263
Richmond CCG	2,210	1,450	829
Southwark CCG	3,505	2,199	1,256
Sutton CCG	2,271	1,490	852
Tower Hamlets CCG	3,350	2,199	1,256
Waltham Forest CCG	3,077	2,019	1,154
Wandsworth CCG	3,569	2,342	1,338
West London CCG	3,406	2,235	1,277

The range of possible FIT testing activity is wide, and the estimates do not fully take account of the likely variations in acceptance and implementation of the new pathway by clinicians in different areas. What is apparent is that the scale of testing is not expected to be overly substantial; for instance for a CCG with a population of 250,000 the maximum estimated annual activity is 3676 tests which at the maximum unit cost (£20/test) would cost £73,520 per year.

Note that for the purposes of simplicity, the medium estimates of FIT test activity (and the attendant costs) have been use to obtain an overall estimate of the costs of implementing FIT in each of the three scenarios for changes in endoscopy demand Table 17).

c. Unit costs

The unit costs have been used in the financial case are shown in Table 15.

Table 15: Unit costs for endoscopies (different types) and FIT kit and testing tariff

Unit	Cost	Derivation
Colonoscopy	£450	NHSI reference cost data, available at: https://improvement.nhs.uk/resources/reference-costs/
CT colonography	£450	
Flexible sigmoidoscopy	£350	
FIT kit + testing	£15-20	Expert advice

d. Set up costs

It is recommended that commissioners allocate some resource to ensure that the new FIT pathway is implemented smoothly and that there is widespread ad rapid take up by practices and acute hospitals. The principle tasks are listed in Table 16: they include commissioning of FIT testing capacity, delivery of training and education, preparation for roll out of the new pathway and establishing systems for ongoing monitoring of service activity and outcomes. It is possible that these tasks may be fulfilled through reallocation of existing staff within organisations but for the purposes of the financial calculations the following putative costs have been assigned:

Training & Education: £5k per CCG
Project management: 30K per STP
Setting up monitoring systems: £50k across London

Table 16: Principle tasks for implementing the new FIT for symptomatic patients' pathway

	Description	**Proposed resource**
Commissioning FIT kit / lab capacity	• Contractual agreement to implement preferred pathology delivery model • Possible procurement	• Project management • Contract support • Procurement expertise
Training and education	• Training of GPs / others providing care in line with new pathway • Development of materials and events to support above	• Project management • Budget for developing materials and for running events
Preparation for launch	• Map details of pathway and ensure systems set up to deliver • Ensure awareness of new pathway all stakeholders	• Project management • Communications support
Monitoring after launch	• Agreeing and if necessary commissioning monitoring data • Setting up systems for collating and sharing data	• Project management • Data analyst support

e. Costs not included

The costs of procuring and contracting for FIT testing capacity (laboratory and kit costs) have not been included in the financial analysis. These would be influenced by the need for procurement, which in turn depends on the pathology model commissioners wish to pursue and whether CCGs undertake this individually or collectively: high value procurements may bring OEJU thresholds into play. This is considered in the Section on procurement issues.

Due to the high level of uncertainty discussed in Section 5.1, changes in outpatient demand have not been factored into the financial case. For similar reasons, estimated reductions in treatment costs associated with identifying patients at earlier more easily treatable stages of CRC have also not been included in the financial case.

5.2 Estimated costs and savings

Three financial scenarios are illustrated in Tables 17. These represent where ALL assumptions tend towards the lowest reduction in endoscopy demand (Scenario 1), the greatest reduction in endoscopy demand (Scenario 2) or a middle position. In real world practice it is of course more likely that some factors will tend towards a low estimate while others will tend towards the high or a middle assumption. The rationale for presenting estimates in this way is to provide a likely range for the potential cost changes. This range is large, which reflects the large number of factors influencing estimates and the uncertainty associated with these. Nonetheless even in the Scenario 1 costs should rise only marginally, with many non-financial benefits.

Table 17: London-wide estimates of overall costs with introduction of FIT for symptomatic patients

CURRENT			
ENDOSCOPY COSTS*	£54,106,250	£54,106,250	£54,106,250
FIT COSTS	£0	£0	£0
SET UP COSTS	£0	£0	£0
TOTAL CURRENT COSTS	£54,106,250	£54,106,250	£54,106,250
FUTURE	**SCENARIO 1**	**SCENARIO 2**	**SCENARIO 3**
ENDOSCOPY COSTS*	£51,688,150	£46,091,570	£38,631,463
FIT COSTS	£1,130,343	£1,130,343	£1,130,343
SET UP COSTS	£360,000	£360,000	£360,000
TOTAL FUTURE COSTS	£53,178,493	£47,581,913	£40,121,806
EXPECTED CHANGE OVERALL COSTS	**-£927,757**	**-£6,524,337**	**-£13,984,444**

*Planned care colonoscopy, flexible sigmoidoscopy, CT colonography

†Assumed to be £0, however FIT testing for symptomatic patients is being undertaken in some areas e.g. GSTT

Expected estimates of overall costs CCG are in Appendix 1.

Note the model used is available to commissioners and providers and contains the values of the estimates used; these can be tailored to incorporate local assumptions for the critical factors influencing estimated endoscopy and FIT activity and the associated costs.

Investment schedule – to be confirmed locally

INITIATIVE	2018/19	2019/20	2020/21
ENDOSCOPY COSTS*			
FIT COSTS			
SET UP COSTS			
TOTAL FUTURE COSTS			

6. Procurement issues

Capacity to undertake FIT is critical to delivery of the new pathway. The responsibility for commissioning this lies with CCGs as standard pathology testing lies outside NHSE prescribed specialist services. There are two main components: FIT sampling kit and the laboratory capacity to test samples. Arrangements for supplying and re-supplying practices with FIT kit to give to patients and for transporting samples to laboratories will need to be commissioned as part of these. Commissioners may choose to commission all components from the provider/s, or separately commission kit, laboratory capacity and transportation facilities.

6.1 FIT kit

DG30 guidance recommended use of one of three FIT test kits: OC Sensor, HM-JACKarc and FOB Gold. The FIT Steering Group did not recommend one of these be preferentially commissioned in the absence of obvious benefits of one test over the others since reducing diversity of provision risks service failure in the event of problems with the supply or quality of one test. The group recommended that standard criteria for the FT test's capabilities be agreed and commissioned. These would support standardised implementation of pathways across London e.g. the ability to set agreed standard test thresholds for testing positive / negative either currently or the future, since the recommended threshold may change in light of new evidence.

Commissioners are asked to approve commissioning of FIT testing kit in line with the Steering Group's recommendations for ensuring coherence of pathways and processes across London.

6.2 Laboratory capacity

Four models for commissioning laboratory capacity to support implementation of FIT in primary care are described in Table 18.

Table 18: Models for providing the pathology laboratory service for FIT

Model	Description
Distributed	Uses current pathology laboratory arrangements with primary care, where local Trusts undertake bulk of pathology provision.
Partnership	Emphasises relationships between neighbouring Trusts, where a host Trust provides the pathology laboratory service for FIT on behalf of the other Trust.
Network	The proposed networked model by NHSI: one Trust as the host on behalf of the other Trusts within the STP footprints.
Centralised	One Provider across the London region acts as the host on behalf of all other Trusts.

The FIT steering group discussed the relative merits of the different models using the criteria listed in Table 19 and concluded that:

- The Distributed and Partnership models were likely to be easiest to implement quickly and will require least education of practitioners if the arrangements dovetail with existing lab testing and reporting processes. However these may exacerbate boundary issues if there is discordance in the way FIT pathways are designed.

- The Network and Centralised models will realise economies of scale in commissioning and delivery, may help to ensure higher quality referral, testing and reporting and are in line with the national direction of travel for pathology services. However they would require pathology departments to agree to joint working arrangements and *may* necessitate a more complex procurement process, which could delay introduction of FIT into practice.

Table 19: Criteria for evaluating relative merits of different pathology models

CRITERIA	COMMENTS
Implementation – The speed and cost of mobilising a model	Models necessitating more complex procurement, with greater challenges to mitigating risks to implementation, and greater time to obtain provider/commissioner buy-in will have a longer lead in time and cost more to implement.
GP Education - The amount of GP education required and the level of associated investment (time and money). This will be a critical activity to ensure pathway concordance.	The further the proposal is from well-understood local processes ("Distributed Model") the greater the need for education.
Patient pathways/experience - The ease with which patients can access the test and return the sample. The speed with which GPs are provided with test results allowing them to discuss these with a patient and take appropriate action.	Different pathology models have different turnaround times to deliver the kit to patients and provide results to GPs.
Resilience - The level of resilience that the model offers in case of equipment breakdown or disruption to logistics.	A larger delivery unit may be more resilient but presents greater risk if service suspended as lack of alternative provision.
Running Costs - The ongoing running costs (e.g. consumables & maintenance, resources, logistics, space).	A unit responsible for a greater number of tests may save on running costs *cf* a smaller unit.
Professional and scientific expertise – The availability of sufficient expertise to manage the service well in all situations.	Larger units may be more easily able to attract a concentration of expertise.
Strategic Alignment - How well the model aligns with the national direction of travel around pathology services.	The national direction is towards Networked Model arrangements

No formal London-wide appraisal of these options has been undertaken and these recommendations are simply advisory. In the absence of a clear national strategic direction it was felt that the model and approach to commissioning would best be agreed through local discussions between commissioners and providers. This recognises that different models of pathology provision are already established within particular CCG and STP geographies alongside historical patterns of service usage; all of these are likely to influence local decision making. Local arrangements should nevertheless seek to avoid different areas establishing conflicting arrangements that interfere with coherent delivery of FIT for symptomatic patients across London as a whole.

7. Risks and mitigations

Table 20 outlines key risks and proposed mitigations for implementing FIT for symptomatic patients.

Table 20: Risks and mitigations

	Risk	Mitigation
1.	STPs and/or CCGs do not engage as they do not recognise FIT as a priority test for low risk but not no risk symptomatic colorectal cases in primary care	CCB monitor and identify STP implementation issues/TCST targeted support offered where implementation issues raised/implementation guidance in place/core business case written for CCGs that can be adapted locally and includes pathology model and criteria and recommended pathway/STPs agree named lead CCG commissioner
2.	Trusts do not engage as they are concerned FIT testing for low risk but not no risk symptomatic will increase endoscopy activity and exceed capacity	CCG modelling in place/FIT implementation working group in place in each STP/staggered roll out agreed if capacity concerns raised/CCB monitor and identify Trust concerns/TCST targeted service improvement support in place where capacity issues voiced/evidence review in place
3.	Trusts do not capture activity correctly leading to lack of robust data to evaluate the pathway	CCGs to have a named lead/champion to include data collection items included in local service specification in line with national guidance/CCG lead/champion to monitor data monthly and submit to TCST for analysis
4.	GPs do not engage as unaware of availability of pathway, unsure about how to implement in practice and/or concerned about safety netting	Core training materials, videos and communication strategy in place/safety netting pathway in place with materials available to support safety netting in practices
5.	Patient outcomes take longer to realise making it difficult to determine if investment in FIT pathway has yielded the expected benefits for low risk but not no risk patients	CCG named FIT lead/champion submits data to TCST for analysis at pan London level and TCST reports and feeds back to CCGs, STPs and CCB
6.	Patients do not engage due to cultural beliefs and/or fatalistic behaviours	Health Equalities Assessment undertaken/patient information in place and available in top 11 London languages and in easy read format/videos in place for patients/pathway adapted in line with recommendations from HEA for patients who may not wish to engage in a FIT test

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