

**Outcome Report - Faecal Immunochemical Testing (FiT)
Feasibility study within primary care June 2018
Delivered within Hull and East Riding CCGs**

This report was not produced, commissioned or sanctioned by NICE

1. INTRODUCTION

In January 2016 the UK National Screening Committee (NSC) recommended a change to the test used in the Bowel Cancer Screening Programmes; the use of Faecal Immunochemical Test (FiT) as the primary test for bowel cancer should replace guaiac Faecal Occult Blood Test (gFOBt). <http://legacy.screening.nhs.uk/bowelcancer>

Key findings supporting the UK NSC recommendation that FiT

- is easier to use and can be measured more reliably using a machine rather than the human eye
- is sensitive to much smaller amount of blood than gFOBt and therefore can detect cancers more reliably and at an earlier stage the increased sensitivity enables FiT to detect more pre-cancer lesions (advanced adenomas)
- requires a single faecal sample and is more acceptable to symptomatic individuals which markedly increases participation rates

Proposed updates and amendments to the 2015 NICE guidance (NG12) '*Suspected cancer recognition and referral*' were discussed at the Hull and East Riding Pathology Productive Elective Care meeting in November 2016. The updates included guidance around the referral of patients with suspected cancers, and recommendations around the use of faecal occult blood testing in some patients with gastro intestinal (GI) symptoms.

2. BACKGROUND

Before it was updated in July 2017, NICE NG12 guideline '*Suspected Cancer: recognition and referral*', published June 2015 recommended that faecal occult blood tests should be offered to adults without rectal bleeding who:

- are aged 50 or over with unexplained:
 - abdominal pain or
 - weight loss or
- are aged under 60 with:
 - changes in their bowel habit or
 - iron-deficiency anaemia or
- are aged 60 or over and have anaemia without iron deficiency.(recommendation 1.3.4)

The guaiac FOB test was withdrawn some time ago due to the insensitivity and lack of specificity of the test to detect blood in faeces. Laboratories around the country have removed this test from their repertoire.

The consensus of opinion amongst the Royal College of Pathologists, clinical chemistry laboratories in the UK and experienced clinicians, is that the traditional guaiac-based FOB tests are considered obsolete as they are non-specific and insensitive. There has been increased interest in the Faecal Immunochemical Test (FiT) for haemoglobin (Hb) and there is growing evidence that, with a high Negative Predictive Value (NPV), it is a valuable rule-out investigation in the assessment of symptomatic patients.

The old guaiac FOB test required dietary restrictions in order to mitigate the large number of false positives and because of this; there were also more sensitivity issues (false negatives) than the FiT test which do not require dietary modification.

Analytically, FiT is still in the early stages and in areas such as the University of Dundee and as part of ‘Scotland’s Detect Cancer Early Programme’ they have been using FiT for some time and have had impressive results for diagnosing cancers.

In July 2017, NICE published guidance DG30 on [Quantitative faecal immunochemical tests to guide referral for colorectal cancer in primary care](#). This recommended faecal immunochemical tests (for faecal occult blood), for adoption in primary care to guide referral for suspected colorectal cancer in people without rectal bleeding who have unexplained symptoms but do not meet the criteria for a suspected cancer pathway referral outlined in NICE's guideline on [suspected cancer](#) (recommendations 1.3.1 to 1.3.3). [At the same time recommendation 1.3.4 in NICE’s guideline on suspected cancer was replaced by this newly published NICE diagnostics guidance DG30.](#)

When compared to guaiac FOB, FiT is easier to use, has greater sensitivity to much smaller amount of blood and can therefore detect cancers more reliably and at an earlier stage. It only requires a single faecal sample and is more cost effective. When combined with FaecalHb FIT can be used in primary care at the point of referral as a reliable and objective predictor of underlying pathology. Using FiT could maximise the efficient use of endoscopy resources by reducing the need for colonoscopy.

- Fhb, measured with quantitative FIT, can be used in primary care at the point of referral as a reliable and objective predictor of underlying pathology.
- GPs can use as an objective tool to guide who requires further investigation in secondary care.

3. INFORMATION

It was agreed at the Pathology Productive Elective Care (PEC) meeting held at the Hull and East Yorkshire Hospitals NHS Trust (HEYHT) in February 2017, that to increase detection and conversion rates and to give assurance to the CCGs, a FiT testing feasibility study should be undertaken, in both Hull and the East Riding, across both CCG’s. This would support the full implementation of the NICE guideline DG30 on a small sample size and allow the CCG to test the process before roll-out and also help to indicate patient activity around symptomatic presentation at their GPs, at what stage they present and of these, how many were tested positive.

The feasibility study commenced in June 2017, involving 11 practices across both Hull and the East Riding CCG areas. Practices were identified by location and practice population. e.g. age range. In total, 11 practices (below) agreed to participate in the feasibility study which officially commenced Monday 26 June 2017. Numbers of sample kits were calculated by practice list size and based roughly on 10% per population. In total 250 kits were distributed.

Practice	Practice list size	Kits distributed
<i>Hull CCG</i>		
Practice 1	9,646	20
Practice 2	16,862	33
Practice 3	15,040	30
Practice 4	12,101	5
Practice 5	7,580	15
<i>East Riding CCG</i>		

Practice 1	2,6805	54
Practice 2	1,2470	25
Practice 3	1,2655	25
Practice 4	11,992	24
Practice 5	9,648	19
Practice 6	4,199	8
Practice 7	2,409	5

GPs utilised the flowchart (Appendix 1) to determine patient suitability for the test and the correct course of action /and or pathway to take. The patients were then issued with the kit and the information and advice leaflet (below).



FIT instructions for patients Final Feb 201

There was no agreed or fixed end date in place for the study. Largely because it was unknown what the uptake and activity would look like and how the test would be received by the GP practices; however, it was agreed that to establish a good evidence base, and understand the population 'need' for the test, ideally, as many of the sample kits as possible should be utilised, returned and results and outcomes gathered in and evaluated.

During the study, the activity around kits being distributed and returned to the lab fluctuated month to month. Numbers varied between 2 and 13 samples being received.

Due to the low numbers being received month on month, communications were sent out to the 11 practices involved to remind and prompt the GPs that the process was still live and should be utilised at all appropriate opportunities. By the end of January 2018 both CCGs had submitted 125 samples in total. Although the overall total was lower than anticipated it was still possible to evaluate from the samples received and it was decided to call an end to the study itself.

Although the feasibility study ceased on 31 January 2018, the lab continued to receive and process samples, the results of which were monitored and logged, results saved and evaluated but not as part of this study.

Following the study completion study there was an evaluation period which was undertaken by HEYHT pathology laboratory. This was presented to the Pathology working group and Cancer Alliance group in March 2018. In total 125 samples were returned, 25 of which were positive and 3 of which underwent surgical intervention and one other patient (aged 93) was deemed not suitable for surgery.

A look back exercise highlighted areas of the study where improvement, amendments and additions needed to be made to the process to ensure the success of the roll out to all practices. These were as follows;

Issue	Solution
GP practice not keeping a record (to act as a failsafe) of patients the test kits were given to, therefore unable to audit if patients had returned samples. Some practices had hand written lists, some had spreadsheets (variation in recording methods)	READ Codes have been developed to be added to the patient record allowing audit of distributed samples and monitor their return and when appropriate, non-return

FiT testing request forms not sent onto the Labs at point of kit distribution	Request form amended to include 'Cyberlab' as first option to request FiT test. Being an electronic process is not only an instant request, is delivered directly to the lab removing the risk of loss but also acts as a safety net when matching up kits with documentation enabling missing samples to be traced
Practices not communicating that the process was 'live' and that the test was available to all practice staff and not all GPs aware - e.g. not all consulting rooms had kits to hand	Communication delivered to all GPs via CCG GP contact us, Council of Members and Protected Time for Learning (PTL) to ensure all GPs are aware of the process
Kits not being stored correctly, resulting in some being misplaced – some practices kept the kits within the admin or reception areas and they became misplaced and or forgotten about	As above – further communication delivered to reiterate the process as the numbers of samples reduced during the study process. When test kits were distributed, an information / advice sheet given to explain the process and the requirement of the practice. 'Reminder' communication sent out at regular intervals to remind GPs of the process
GP practices requesting further information – no point of contact / central area	Email address 'drop-box' for advice and guidance established – included in the referral form
Kit and supportive request form (appendix 3) not arriving 'together to act as safety net and to alert the labs that a sample for a particular patient was on the way.	Request form re – worded to promote the use of Cyberlab as the preferred option for referral and request for sample process. It is an instant referral, (quicker, easier and clearer), has audit trail, no paper avoiding potential loss

4. ROLL OUT

Key infrastructure is now in place to support effective delivery of the service. Both CCGs were fortunate to receive NHS England transformational funding as part of the Cancer Alliance to support this process going forward with regard to purchase of kits and reagents.

Roll out of the process across the whole of Hull and the East Riding CCGs took place on the week commencing the 2 April 2018. Communications were sent out to all GP practices to advise of the practices (whether part of the original study or not) via 'GP Contact Us' for Hull CCG and 'Hot Topics' for ERCCG

Both Hull and East Riding CCGs distributed 1000 kits (500 to each CCG) to all practices between the two CCGs, again in proportion to the practice list size. Each pack included an information sheet with contact details of the labs and names and numbers of key individuals to ensure practices were able to get in touch with either the labs or the CCGs in case of query or to request further kits or referral forms. The 'address' of the 'drop box' was also included so that practices could opt for general queries or advice and guidance should they need it.

Activity update reports are collated and sent on a monthly basis to both CCGs for analysis with information around the NHS number, sample number, symptoms (reason for test and referral) and general demographic profile of the patient that are being given the kits. Both CCGs review and audit this information and process on receipt, (numbers of kits returned and outcomes). This allows the uptake and activity to be further and better understood and to address any issues or concerns that have arisen with logistics, information or processing.

The overall activity and returns is as follows

Month	Samples returned	Practices range	Sample numbers
April	33	10	1 and 12
May	25	9	1 and 9

The CCG are reviewing the number of sample kits distributed and the numbers returned to mitigate risk of loss of kits and to ensure that all kits are accounted for. e.g. kits issued to symptomatic patients and not returned will need to be followed up by the practice.

5. CONCLUSION

Engagement with all stakeholders and steering group members has been paramount / fundamental ? to the success of this project and commitment from newly involved GP practices will be vital to its ongoing success and the future clinical model evolving.

Due to the fluctuation on uptake during the study, it is difficult to predict or forecast future demand for this testing option; however, early signs are that practices are fully engaged. Activity for the first two months was approximately 260 returned samples - split between both CCGs as below.

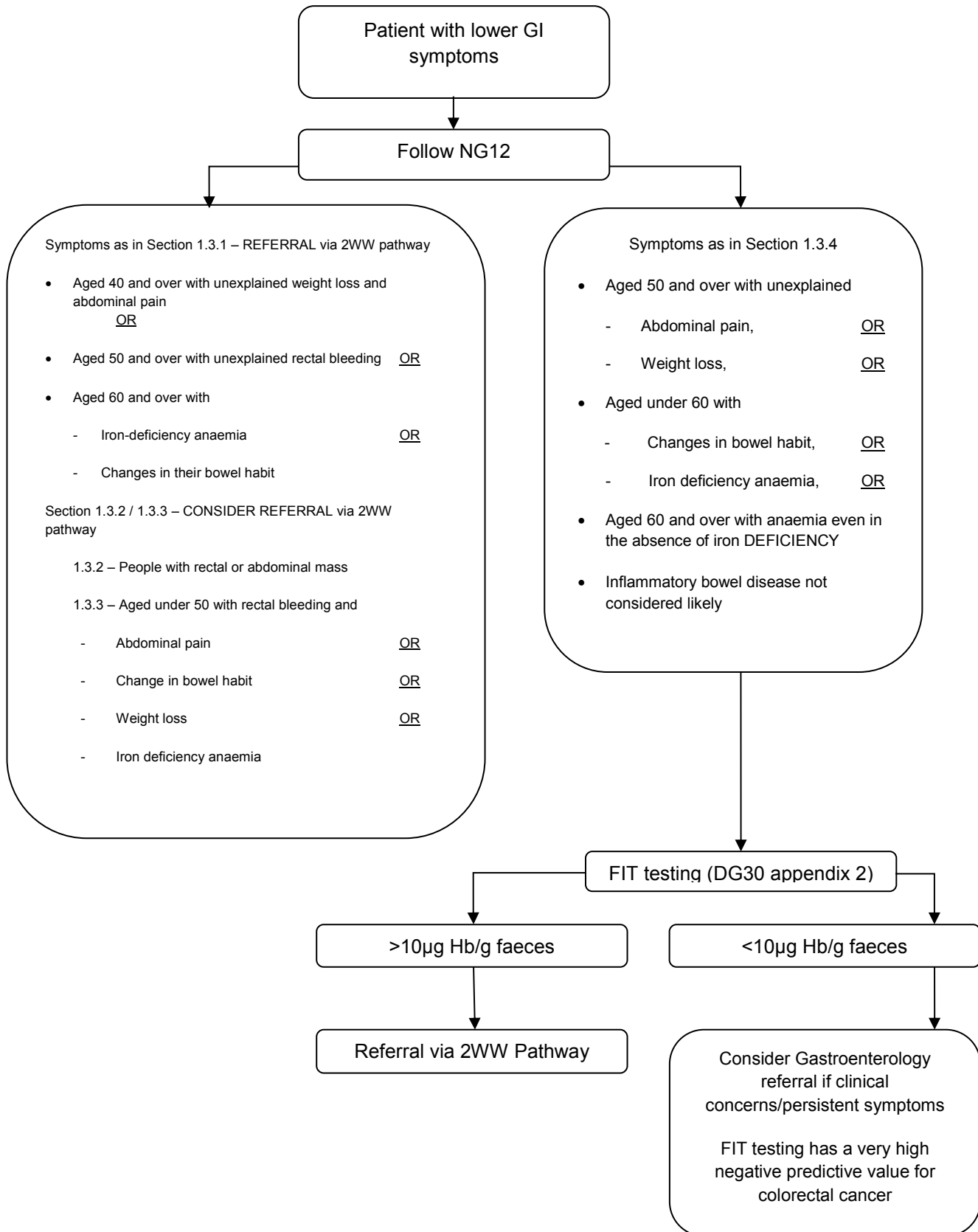
Elements to consider for the success of this process going forward include;

- Logistical costs around the distribution of the kits – more of an issue for ERCCG than Hull due to the widespread location of the practices
- Potential IT interface issues (e.g. universal access to Cyberlab)
- Ongoing communications out to GPs

NICE GUIDANCE NG12

“SUSPECTED CANCER: RECOGNITION AND REFERRAL”

Section 1.3 Lower gastrointestinal tract cancers



Faecal Immunochemical Test (FIT) – Primary Care roll out – 1 April 2018

NICE Guidance DG-30 (July 2017) states: ‘faecal immunochemical tests are recommended for adoption in primary care to guide referral for suspected colorectal cancer in people without rectal bleeding who have unexplained symptoms but do not meet the criteria for a suspected cancer pathway referral’. Following the recent feasibility study in Hull and East Riding, the Faecal Immunochemical Test (FIT) study is to be extended and rolled out across Primary Care in both Hull and East Riding, with effect from the 1 April 2018.

Advantages of the FIT test

- requires a single sample
- FIT specifically measures human haemoglobin (Hb) rather than any other blood in the diet
- FIT has a high negative predictive value – as negative result makes colorectal cancer unlikely
- will reduce the need for repeat tests

Interpretation of results

- negative result – no detectable blood (reported as ‘<10 ug Hb/g faeces’) – colorectal cancer unlikely, consider other causes of the clinical presentation
- positive result - blood detected (> or = 10 ug Hb/g faeces – a numerical result will be reported), refer patient under 2WW

The 10 ug Hb/g faeces cut-off is as recommended in NICE DG-30

Over the next few weeks, before the beginning of April 2018, packs of the FIT test kits, determined by practice population, will be delivered to your practice and will include:

- patient information sheet
- sample ‘picker’
- pathology sample bag and envelope for patient to return sample to the GP Surgery – samples are then forwarded to Hull Royal Infirmary in the routine sample transport

Please request FIT through CyberLab if available; otherwise use the paper request form

READ codes

Once a sample pack has been given to the patient – the READ code should be entered onto the patient record

Code hierarchy = *Quantitative faecal immunochemical test*

System1 = Xaf0H

EMIS = 47K

Snomed Code = 2643291000000112

Practices are asked to ensure they have a process in place to identify which patients have been given a FIT test and have not returned them.

Please see the FIT request form and the patient information leaflet below

FIT Request Form

The Faecal Immunochemical Test (FIT) measures human haemoglobin in faeces; undetectable FIT makes colorectal cancer highly unlikely.

FIT testing is for patients with suspected colorectal cancer who do not meet the 2WW as defined in NICE guidance NG-12 Section 1.3.1 to 1.3.3. These patients should be offered FIT in line with NICE DG-30 <http://www.nice.org.uk/guidance/dg30> and the result used to triage the patient.

1. Requesting through CyberLab (preferred option)

Request FIT through CyberLab Group Panels using the code FIT NICE guideline. From Extra Information select the correct code FIT1-FIT5, according to the predominant symptom (see below). Generate label, stick it on the device (lengthways) and give the device to the patient together with the instructions for collection and return of samples.

2. Requesting using this request form – only use this form if not using Cyberlab

Complete the details below and write the patient details on the collection device. Give the device and this request form to the patient, together with the instructions for collection and return of samples.

..... <i>Surgery</i>	<i>Patient Details (Please attach Label)</i>	Date of Request ---- /---- /----
..... <i>Requesting GP</i>	 <i>Signature of Clinician</i>

Give the **predominant** symptom – tick one box that pertains best to the patient's symptoms.
Any patient with rectal bleeding must be referred under 2WW.

- | | | |
|-----------|---|-------------------------------|
| <u>OR</u> | Unexplained abdominal pain | <input type="checkbox"/> FIT1 |
| <u>OR</u> | Unexplained weight loss | <input type="checkbox"/> FIT2 |
| <u>OR</u> | Changes in bowel habit | <input type="checkbox"/> FIT3 |
| <u>OR</u> | Iron deficiency anaemia | <input type="checkbox"/> FIT4 |
| <u>OR</u> | Anaemia, even in the absence of iron deficiency | <input type="checkbox"/> FIT5 |

In both cases, the patient should return the sample collection device to the GP Surgery in the envelope provided within **48 hours** of collecting the sample.

Please direct any enquires to: FIT@hey.nhs.uk

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