

About the qFIT PILOT

Information pack for
PARTICIPATING ORGANISATIONS

The UCLH Cancer Collaborative is a part of the national Cancer Vanguard, working with Greater Manchester Cancer Vanguard Innovation and RM Partners

INTRODUCTION TO THE qFIT PILOT

What is the qFIT Pilot?

This is an important pilot that will begin in early 2017 and will involve a minimum of 2,000 patients who are given an urgent (2 week wait) referral for suspected colorectal cancer.

The study builds upon recent evidence from two Scottish trials that found that a normal qFIT showing no evidence of haemoglobin in stool, may rule out the presence of colorectal cancer

with over 95% accuracy. UCLH Cancer Collaborative is leading on a large, multi-centre pilot that aims to demonstrate similar results within the London population by testing the process and accuracy of the qFIT test.

Why does this pilot matter?

Colorectal cancer is the fourth most common cancer registered in England and the UK's second biggest cancer killer, but if diagnosed early enough there's more than a 90% chance of successful treatment. Last year,



over 240,000 patients with lower abdominal symptoms were seen by a specialist following an urgent GP referral for suspected cancer. The majority of these patients were referred for a colonoscopy but only about 4% of them will have cancer.

If the test is introduced in primary care, it may be able to reduce the number of colonoscopies by approximately 40%, freeing up endoscopy capacity for other programmes such as bowel scope.

qFIT test

qFIT is short for Quantitative Faecal Immunochemical Test. It uses specific antibodies against human haemoglobin and detects hidden blood in a stool as a potential indicator of colorectal cancer. If blood is detected, the patient will require follow-up tests to determine the reason for the presence of blood in the stool.

The qFIT test (that quantifies the amount of blood in stool) is much more sensitive than other similar tests such as FOBT (Faecal Occult Blood Test) that is only qualitative, thus giving only positive or negative results.

In addition, other international studies have demonstrated that there is a greater uptake of the

qFIT test due to ease of use and no dietary restrictions.

We are asking you to help us by taking part and trialling the qFIT test. We want to validate the accuracy and process of the test with patients in London, before introducing the qFIT test to patients across the UK.





This observational study will involve six NHS trusts and 33 GP practices.

Patients with lower GI symptoms will be invited to take the qFIT test as part of their 2ww referral pathway. The test kit, containing a sample collection tube, patient information sheet (PIS) with sample collection instruction, patient data sheet and pre-labelled return envelope will be given out by:

a) Participating GPs

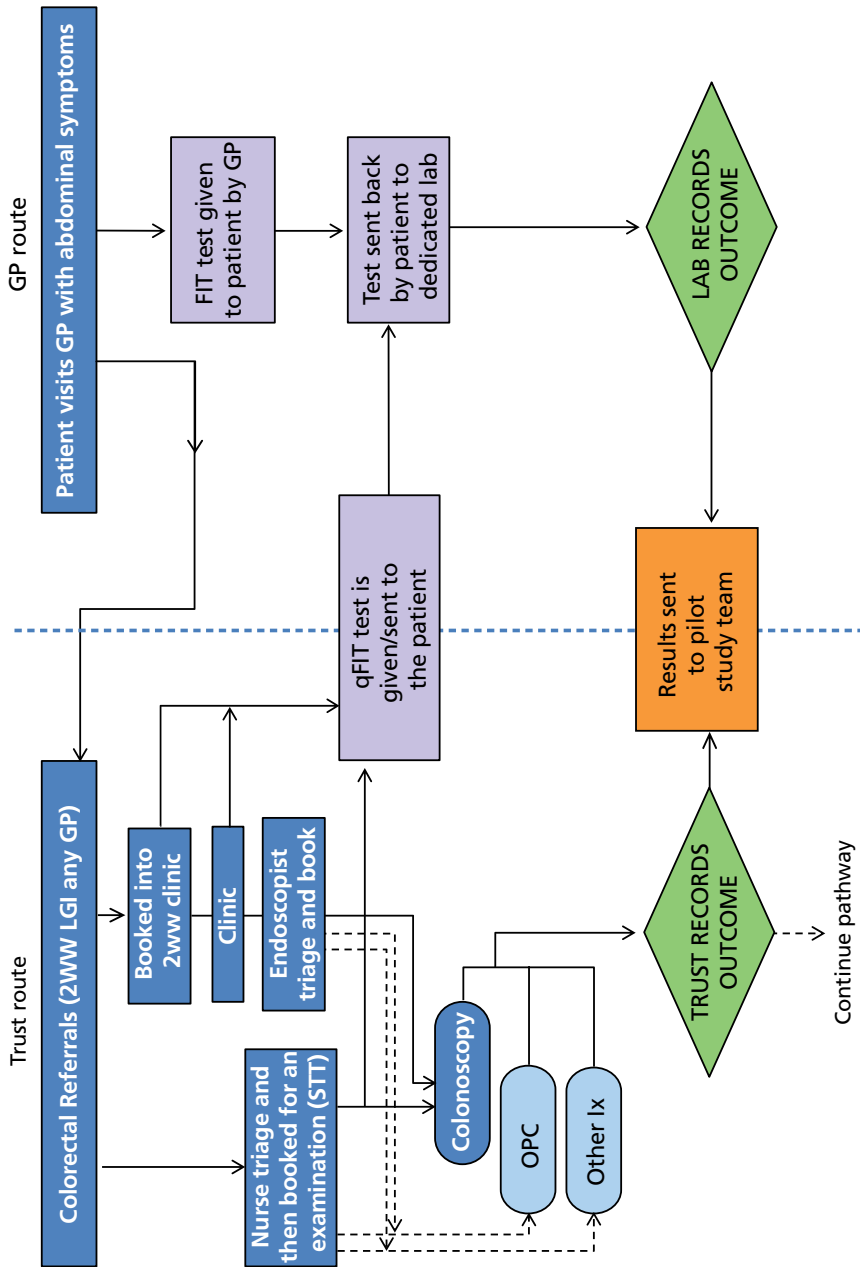
The GP makes a 2ww referral for a patient with lower GI symptoms and at the same time gives the qFIT test kit to the patient.

b) Participating trusts

If a 2ww patient is referred to endoscopy, the endoscopy unit staff (or CNS if 'straight to test' is available) checks if the patient was given the qFIT test by their GP. If not, the qFIT test kit is handed out/sent out together with the bowel prep.

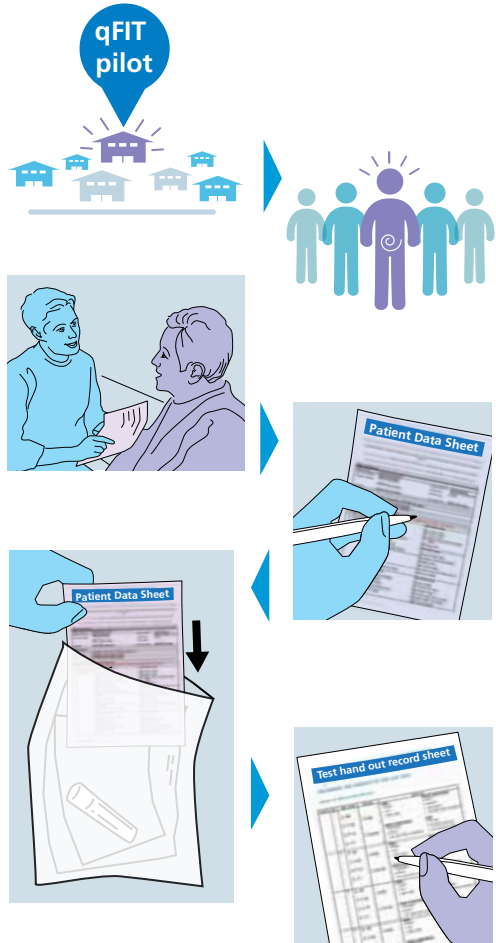
Completing the qFIT test does not change the patient's pathway. No intervention will be made to the treatment plan based on the outcome of the qFIT test.

The patient will be asked to take a single sample at their next bowel movement and send this to a dedicated lab via the post. Faecal haemoglobin concentration is measured in the sample and compared with the outcome of their colonoscopy.



WHAT TO DO IF YOU ARE A GP?

1. Check if your GP practice is one of the participating practices in the qFIT pilot.
2. Check if your patient is eligible to take part in the qFIT Pilot. A patient is eligible if he/ she is being referred for a 2ww appointment for suspected colorectal cancer.
3. Offer your patient the opportunity to take part in this study.
4. Complete and print the patient data sheet. This is available in your electronic patient record system as a pre-populated template. Make sure you select the trust you refer your patient to.
5. Place the completed patient data sheet in the qFIT sample pack and hand over to your patient to take home.
6. Ask all patients who you offered the qFIT test to complete the 'test hand out record sheet'. This additional sheet will help us to understand the test uptake.



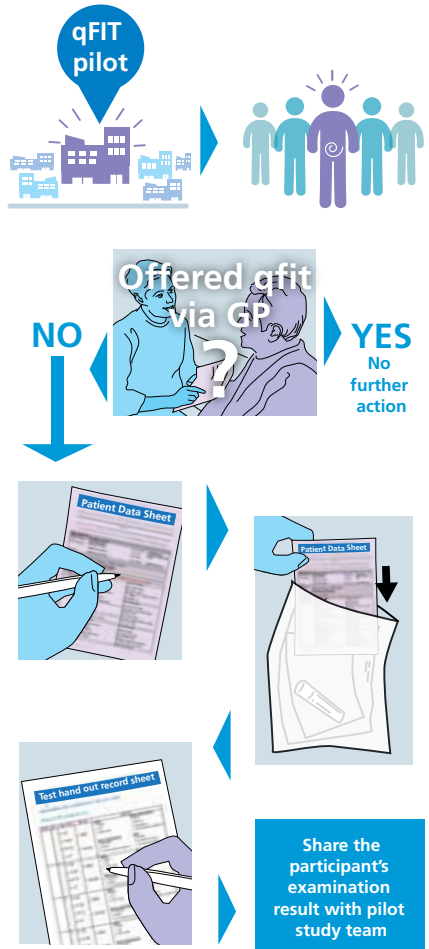
Neither you nor your patient will receive any results back from this pilot study because the qFIT test in this study will not change your patient's pathway.

This pilot study will help to guide the NHS and you will be helping us to get it right.

Have a question? • Michael Machesney - Chief Investigator
• 020 3447 2789
• qfit.pilot@uclh.nhs.uk
• www.uclh.nhs.uk/cancercollaborative

WHAT TO DO IF YOU ARE WORKING AT AN NHS TRUST?

1. Check if your NHS trust is one of the participating organisations in the qFIT pilot.
2. Check if your patient is eligible to take part in the qFIT Pilot. A patient is eligible if he/she was referred for a 2ww appointment for suspected colorectal cancer.
3. Check if the patient was offered the qFIT test by his/her GP.
4. If yes, you do not need to do anything else. If not, offer your patient the opportunity to take part in this study.
5. Complete and print the patient data sheet. This is available either in your electronic patient record system as a pre-populated template or as a paper form.
6. Place the completed patient data sheet in the qFIT sample pack and hand over to your patient. Make sure you indicate on the form whether the patient was given the pack or if the pack was posted.
7. Ask all patients who you offered the qFIT test to complete the 'test hand out record sheet'. This additional sheet will help us understanding test uptake.
8. Share the participant's colonoscopy examination result with pilot study data administrator on a monthly basis.



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Other information

Who is organising and funding the study?

The qFIT study is funded by the UCLH Cancer Collaborative, which is part of the national Cancer Vanguard working with RM Partners and Greater Manchester Cancer Vanguard Innovation. The study is sponsored by University College London.

Who has reviewed the pilot study?

The plans for the qFIT pilot were reviewed by an independent group of scientists before it was given funding. The study has been approved by the NHS Research Ethics Committee and the Health Research Authority (IRAS/213710).



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