Introduction of FIT120 into the national screening programme
Background

• Colorectal cancer (CRC) in the UK in 2014 [1]
  • is the fourth most common cancer with 41,300 new cases (12% of all cancers)
  • second most common cause of cancer death with 15,903 deaths (10% of all cancer deaths)

• The Bowel Cancer Screening Programme (BCSP) uses the guaiac faecal occult blood test (gFOBt) in England

• The faecal immunochemical test f (FIT) compared to gFOBt has higher uptake and improved clinical outcomes [2]

• National screening programmes in the Netherlands and Ireland already use FIT for CRC screening

1] Cancer Research UK. Bowel cancer statistics.201
Structure of haemoglobin

haem + globin

Red blood cell (erythrocyte)

Iron

β-chain

Heme group

α-chain

β-chain

Haemoglobin (Hb)

Each erythrocyte (RBC) contains ~270 million haemoglobin molecules
Haemoglobin Concentration is Related to Disease Severity

Normal → Low risk adenoma → High risk adenoma → Cancer

Faecal Haemoglobin

gFOBT Kit
We're getting FIT for bowel cancer screening

TJ Day, 25 July 2016 - NHS Bowel Cancer Screening Programme

10 years on from the launch of the NHS Bowel Cancer Screening Programme (BCSP) we're gearing up to change the primary screening test we use to detect and prevent cancers.

What is bowel cancer screening?

Bowel cancer screening aims to detect bowel cancer early, when treatment is more likely to be successful.

Screening, using a home test kit, is offered every two years to men and women in England aged 60-74.

Find out more at www.nhs.uk/bowel

On 7 June 2016, Public Health Minister Jane Ellison announced that the faecal immunochemical test (FIT) will replace the current guaiac faecal occult blood test (gFOBT).

PHE screening

Organisations: Public Health England

New home test kit for bowel cancer screening: what GPs need to know

Dr Jim McMorran, 4 August 2017 - NHS Bowel Cancer Screening Programme

The NHS Bowel Cancer Screening Programme reduces the risk of dying from bowel cancer by detecting disease before symptoms appear when it is easier to treat and there is a better chance of survival.

The programme will introduce a new improved home test kit for screening from April 2018. It is called a faecal immunochemical test (FIT) and it will replace the guaiac faecal occult blood test (gFOBT).

It's important that GPs and others working in primary care understand this change to the screening programme and its implications for their patients, so here is a brief summary.
The FIT kit

- The overall supplier for FIT is Chrystal
- Only 1 sample is needed
- Measures human blood
- Higher detection of cancers and adenomas
- Anticipated increase in uptake
The FIT kit - packaging
The FIT kit - packaging
Collecting samples

1. Write the sample date on the tube
2. Collect the stool sample
3. Open the sample tube
4. Run the stick along the poo
5. Return the stick to the tube
6. Click the lid shut
7. Post it in the pre-paid envelope
The FIT kit - analysers

The barcode is scanned to identify the tube
How it works

1. The FIT kit tube contains a buffer and a probe.
2. The participant uses the probe to collect a sample. Any excess is wiped off when the probe is placed into the tube.
3. The sample will mix with a buffer that is contained within the FIT kit.
4. The reagent contains an antibody which is specific to human haemoglobin. When blood is present in the stool, the antibody will bind to the haemoglobin making a turbid solution.
5. The analyser will pass a beam of light through the reaction cells which is measured on the other side. The more haemoglobin present, the more turbid the solution, therefore less light is transmitted.
6. The analyser will provide a numerical value of how much haemoglobin is present based on how much light is transmitted.
Antibody and human globin molecules complex demonstrated by immunofluorescence
The FIT kit results

- Subjects will receive a ‘normal’ or an ‘abnormal’ result
- Individuals can request numerical results but these will only be provided following a formal request. Screening centres will **not** be able to view numerical results. Only HCPC registered hub staff will have access to analytical values on the BCSS system
- A letter has been developed for issuing analytical results
- There is functionality built into BCSS to enable the threshold to be changed to increase the sensitivity or for particular groups, should this be agreed in the future
- Kits will be spoiled and a re-test kit issued if:
  - the kit is received into the hub more than 14 days from the sample date
  - the sample is undated and the kit was issued more than 14 days from the date of receipt
  - the sample has been collected incorrectly
FIT increases uptake vs gFOBt

- Overall uptake increased by 7.6%
  - Single sample
  - Pot vs card

- Increased uptake
  - Men
  - Previous non compliant (doubled)
  - Older Age groups
  - Socially deprived

The FIT results

For 100 people getting their FIT kit results:

98 will have a normal result

2 will have an abnormal result
Estimated increased colonoscopy activity of FIT vs gFOBt

FIT is associated with more colonoscopies

@FIT 180 µg Hb/g faeces
  32 additional colonoscopies per 1000 people invited
@FIT 20 µg Hb/g faeces)
  421 additional colonoscopies per 1000 people invited

Jacqueline Murphy et al. BMJ Open 2017;7:e017186
Likely findings from 100 screening colonoscopies

For every 100 people having colonoscopy after an abnormal FIT kit result:

- 13 will have a normal result
- 53 will have adenomas that need to be removed
- 25 will have minor findings needing no additional treatment
- 9 will have cancer
A revised storyboard has been developed with factual information for SSPs to develop their own local storyboards. This includes updated risk figures for diagnostic procedures taken from programme information.

**The FIT test**

**Faecal Immunochemical Test**
- The FIT test is used for bowel cancer screening
- The test will pick blood in your poo sample
- 2 in every 100 people using FIT kit have an abnormal result
- This does not mean that you have a cancer
- Other things that may cause bleeding are haemorrhoids, medications or bowel polyps

**Complications from colonoscopy**
- The risk of a perforation (hole in the bowel wall)
  1 in 1,700 (around half of which may require surgery)
- Heavy bleeding needing a transfusion
  1 in 2,400
- The chance of missing cancer or a polyp
  3 in 100
Invite rates

- Hubs can set invite rates to allow smoothing so there is no bulge for gFOBt and FIT kits
- This is for individual hubs and screening centres to discuss and agree
- Changes to invite rates which exceed +/- 6 weeks of the screening due date would need to be discussed with regional QA and local commissioners
Pathway changes

• Once an episode has started in gFOBt it will continue on that pathway if the kit is returned

• If a subject self refers more than 6 months after their initial invitation they will receive a FIT kit

• Subjects should be encouraged to complete the kit that they are sent, and not to delay screening in order to receive a FIT kit
Personal Characteristics Influence Screening Outcomes

More positive tests in...
- Male
- Elderly
- Deprived
- Screening non-compliant

FIT cut-off at a high threshold disproportionately disadvantages...
- Female
- Elderly
- Screening non-compliant

Pathology detection  FIT vs gFOBt

- 40 ug/g FIT = gFOBt for CRC
- 180 ug/g FIT > gFOBt for adenomas
Summary

- FIT will increase
  - CRC screening uptake by 10%
  - Detection of adenomas and colorectal cancer

- For the BCSP there is an increase in FIT positivity (compared with gFOBt) in
  - Socially deprived
  - Males
  - Elderly
  - Screening non compliers

- FIT is cost effective @ all detection thresholds for bowel cancer screening

- FIT will lead to an increase in colonoscopy and pathology demand but demand can be adjusted by FIT detection thresholds
Cost effectiveness of FIT vs gFOBt

FIT is cost-effective compared with gFOBt due to savings in cancer care costs vs implementation of FIT.

Markov state transition model of CRC disease progression and screening. Screening uptake, detection, adverse event, mortality and cost data were taken from BCSP data/FIT pilot.

Jacqueline Murphy et al. BMJ Open 2017;7:e017186
The Future of Assessing Patients Presenting in Primary Care?

- No test is perfect - but FIT can be used to **rule in** cancer in symptomatic patients and, perhaps more importantly, **rule out** significant colorectal disease.
- No. of referrals for urgent colonoscopy could be cut by up to half.
- Some – smaller adenomas and cases of IBD - would be missed.
Leaflets and letters

Leaflets

• A new facts booklet has been produced
• An easy read guide is in development
• Kit instructions are included on the kit packaging

Letters

• All letters on BCSS have been amended to reflect the changes for FIT
• A new easy read invitation letter in in development

National FAQs & briefings

• NHS England have developed a set of FAQs to be used by professionals and for the public
• FIT briefings have been produced for GPs and detained estates

30 day questionnaire

• The 30 day questionnaire is still appropriate for FIT and will be reviewed nationally
Thank You

Any Questions