Implementing of Population-based FOBT Screening
gFOBT to FIT
Experience from England
Haem

\[ 2\text{H}_2\text{O}_2 = 2\text{H}_2\text{O} + \text{O}_2 \]

Oxidised guaiaconic acid is blue
Biennial Bowel Cancer Screening in the UK

1990 Trial evidence

2000 Pilot programmes

2006 Commence screening

- **England** — Two yearly FOBT screen
  - **Phase 1** 60 - 69 year olds
  - **Phase 2** 70 – 74
  - **Phase 3** 55 Flexi Sig
England 2006

**Biennial Screening for Bowel Cancer**

England

5 Hubs

**Screening Hub Activities**

- Organisation
- Call & recalls (25,000 /week)
- Laboratory analysis
- Helpline (>3,000 /week)
- Make appointments

**Web-based Screening Data System**
Bowel Cancer Screening

Southern Hub (Guildford)

Screening Centres (17)

Colonoscopy Site

Clinic Sites

Clinic Sites

Clinic Sites

Screening Centre Activities
• Explain procedures
• Assess suitability
• Provide colonoscopy, CTC, etc

Quality Assurance
1. Accreditation: Centres & labs, lab staff, endoscopists
2. Facilities: Scope cleaning, patient facilities & privacy
3. Key Performance indicators: Centres monitor quality
4. Continuous audit: Intermediate outcomes
5. Continuous evaluation: Programme evaluation group
6. Peer Review: Labs, endoscopy, pathology, etc

14.6 million
Bowel Cancer Screening

External review to assess Wexford General Hospital cancer programme

- 615 patients recalled
- 13 missed cancers?
- Consultant suspended

BowelScreen
An Clár Náisiúnta Scagtháistála Putóige
The National Bowel Screening Programme

14.6 million
Screening Timeline

Start
2 yearly Screening Cycle

Day 1
Pre-Invitation
At Screening Due Date

Day 8
Invitation
Kit & Spatula
Return Envelope

Kit Read
(1 day)

Day 14
+ve Result
Specialist Screening Practitioner
Clinic Appointment

Day 29
-ve Result
Patient letter & GP Letter

Month 3
Reminder Letter

2 Years
Next
Pre-Invitation

Surveillance Colonoscopy

Web-based Screening Data System

Dedicated Freephone Helpline Service
NHS BCSP News

Headline Statistics!
(July 2006 – August 31st 2017)

- 36 million invitations
- 22 million gFOBt analysed
- 411,000 colonoscopies
  - 29,600 cancers
  - 95,800 advanced adenomas
Cancer Registry
Age Standardised CRC Incidence
2001 - 2015

Directly age standardised incidence rate per 100,000 population

Colorectal Cancer Screening?
Have done well?
Why change to FIT?
Time for an overhaul!
...now have the tools, to do job... even better!
Gender % Uptake

Area deprivation

FIT Pilot (England)

Quality Control

Training

IT

Finance

Info.

Mailing

Harrogate, Leeds...
NHS Harrogate...
NHS Leeds North...
NHS Leeds South...
NHS Leeds West...
NHS Vale Of York...

70%
65%
60%
55%
50%

% Uptake

0 10 20 30 40 50 60 70 80

FIT NEGATIVE
POSITIVE

Elderly people
- Target pop’n - 50% of England
- 40,000 FIT invitations
- Complete in 6 months

1 FIT in every 28 gFOBT

Selected a low FIT threshold (20ug/g)
- High positivity
- High colonoscopy rate
- High detection rate
Make FIT Packaging

- Attractive
- Simple to use
- Safe for mailing
- Informative
- Reliable

**Midlands & North West Hub**

**More Deprivation**

- Population 13.1 m
- gFOBT Kits = 537,770
- FIT Kits = 19,289

**Southern Hub**

**Less Deprivation**

- Population 14.7 m
- gFOBT Kits = 588,317
- FIT Kits = 21,641

**Both Hubs**

- Population 27.8 m
- gFOBT Kits = 1,126,087
- FIT Kits = 40,930
FIT Pilot QA data
5 batches of 30 samples in both Hubs
April – October 2014

Line of best fit
y = 0.997x + 0.1122
R² = 0.9975
Uptake & Deprivation
2014 South, Midlands & NW Pilot
(IMD – Index of Multiple Deprivation)
Uptake & Deprivation
2014 South, Midlands & NW Pilot
(IMD – Index of Multiple Deprivation)
Deprivation Index in the Two Pilot Hubs

(IMD – Index of Multiple Deprivation)
Uptake at First Invitation
2014/5 South, Midlands, NW & London Pilots

1st invitation (mostly 60 year old subjects)

Both

10.9% Increase

Southern

9.7%

London 52.4%

14.4% Increase

Mid & NW

12.2%

FIT

gFOBt

40% 45% 50% 55% 60% 65%
Uptake in Prevalent Episodes
2014/5 South, Midlands, NW & London Pilots

1 – 5 invitations but no previous response

11.6% Increase

Uptake doubles!

FIT
gFOBt
Uptake in Incident Episodes
2014/5 South, Midlands, NW & London Pilots

1 – 5 previous participation episodes

- **Both**: 4.2% Increase
- **Southern**: 4.1%
- **Mid & NW**: 4.3%

<table>
<thead>
<tr>
<th>Region</th>
<th>FIT</th>
<th>gFOBt</th>
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<tbody>
<tr>
<td>82%</td>
<td>84%</td>
<td>86%</td>
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<td>88%</td>
<td>90%</td>
<td>92%</td>
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</table>
Uptake by Age and Sex
2014 South, Midlands, NW Pilot

All invitation by age and sex

<table>
<thead>
<tr>
<th>Age Group</th>
<th>FIT (%)</th>
<th>gFOBt (%)</th>
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<tbody>
<tr>
<td>70-74</td>
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<td>65-69</td>
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<td>60-64</td>
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<tr>
<td>All Age</td>
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</tbody>
</table>

10.6%
Uptake & All Episodes
2014 South, Midlands, NW Pilot

0 – 5 previous screening invitations

Both

Southern

Mid & NW

FIT

gFOBt

7.1% Increase

7.0%

7.3%

290,000
Additional screens each year!
% Positivity & Deprivation

FIT Cut-off - 20 ug Hb/g Faeces
‘My age? You mean now... or when we first sat down?’
Faecal Immunochemical Test (FIT) & Positivity
Thresholds adopted by National Bowel Cancer Screening Programmes
(1st October 2016)

Predicted FIT positivity - % of participants referred for colonoscopy

<table>
<thead>
<tr>
<th>Country</th>
<th>Threshold</th>
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</thead>
<tbody>
<tr>
<td>England (April 2018)</td>
<td>12%</td>
</tr>
<tr>
<td>Scotland (Dec. 2017)</td>
<td>7.8%</td>
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<tr>
<td>Netherlands</td>
<td>5.2%</td>
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<tr>
<td>Southern Ireland</td>
<td>2.9%</td>
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<tr>
<td>New Zealand</td>
<td>2.1%</td>
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<tr>
<td>Canada (Quebec)</td>
<td>1.7%</td>
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<tr>
<td>France</td>
<td>1.5%</td>
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<td>Hungary</td>
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<tr>
<td>Iceland (planned)</td>
<td>1.5%</td>
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<tr>
<td>Italy (North &lt;20)</td>
<td>1.5%</td>
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<tr>
<td>Korea</td>
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<td>Malta</td>
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<tr>
<td>Sweden (pilot)</td>
<td>1.5%</td>
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<tr>
<td>Threshold used in the FIT pilot in England</td>
<td>?</td>
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</table>

Faecal Immunocutaneous Test (FIT) threshold (ug haemoglobin /g faeces)
### Faecal Immunochemical Test (FIT) & Positivity

**Thresholds adopted by National Bowel Cancer Screening Programmes**

(1st October 2016)

<table>
<thead>
<tr>
<th>Country</th>
<th>No. of cancers missed relative to those detected using a 20ug/g threshold</th>
</tr>
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<tbody>
<tr>
<td>England (April 2018)</td>
<td>0</td>
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<tr>
<td>Scotland (Dec. 2017)</td>
<td>780</td>
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<tr>
<td>Netherlands</td>
<td>1,900</td>
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<tr>
<td>Southern Ireland</td>
<td>2,900</td>
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<tr>
<td>New Zealand</td>
<td>3,500</td>
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<td>Canada (Quebec)</td>
<td>3,600</td>
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<td>France</td>
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</table>

**Colonoscopy Capacity Problems**

- **Data from 2014/5**
- **FIT Screening Pilot in England**
  - Based on Pilot uptake and extrapolated to 2.6 million completed FIT p.a.
## FIT & Missed Advanced Adenomas

Thresholds adopted by National Bowel Cancer Screening Programmes  
(1st October 2016)

<table>
<thead>
<tr>
<th>Country</th>
<th>No. of missed advanced adenomas</th>
<th>12,000</th>
<th>25,000</th>
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</table>

Data from 2014/5  
FIT Screening Pilot in England  
Based on Pilot uptake and extrapolated to 2.6 million completed FIT p.a.

**Challenge...**

Faecal Immunochemical Test (FIT) threshold (ug haemoglobin /g faeces)
Colonoscopy

- gFOBT
- FIT 180
- FIT 150
- FIT 100
- FIT 40
- FIT 20

Levels:
- Normal
- Cancer
- High-risk Adenoma
- Intermediate-risk Adenoma
- Low-risk Adenoma
- Abnormal

4.0%
FIT 180

Cancer

High-risk Adenoma

Intermediate-risk Adenoma

Low-risk Adenoma

Abnormal

12.1%

10.6%

18.3%

18.6%

Polypectomy rate increase to >64%

...more polyps in each category

Challenge...

Impact on Colonoscopy & Pathology activity

Colonoscopy
Proportion of colorectal cancers that occur in Women

(C18-C20 2011-2013)

Source: cruk.org/cancerstats

Age Range (years)

Proportion of CR cancers diagnosed in women

60:40 split
Men:Women

Source: cruk.org/cancerstats
All Registered Colorectal Cancers - % by gender

July 2006 – December 2014

Screen -ve - 2y interval cancer
Screen +ve cancer

Screen +ve

Male

Screen +ve

Female

0,0% 10,0% 20,0% 30,0% 40,0% 50,0% 60,0% 70,0%
All Registered Colorectal Cancers - % by gender

July 2006 – December 2014

Screen -ve - 2y interval cancer
Screen +ve cancer

Male
Female

Screen +ve

33.7%

66.3%

0.0%
10.0%
20.0%
30.0%
40.0%
50.0%
60.0%
70.0%
Gender inequality in gFOBt Screen for cancer

All Registered Colorectal Cancers - % by gender
July 2006 – December 2014

Screen -ve - 2y interval cancer
Screen +ve cancer

Male
Female

Screen -ve
Screen +ve

Male
Female

Gender inequality in gFOBt Screen for cancer

Challenge...
Cancers Detection in 10,000 FIT Screened Participants
(50:50 male & female)

2014 Pilot Data

Gender inequality with FIT screening?

Expected Male
Cancers detected in men

Expected Female
Cancers detected in women

Expect 60% of cancers to be in men

Expect 40% of cancers to be in women

Cancers detected /5,000 male & 5,000 female participants (completed FIT)

FIT Concentration ug/g

0  20  40  60  80  100  120  140  150  180  200 gFOBt
Cancers Detection in 10,000 FIT Screened Participants (50:50 male & female)

2014 Pilot Data

- Expected Male
- Cancers detected in men
- Expected Female
- Cancers detected in women

Inequality increases with FIT screening?

Cancers detected /5,000 male & 5,000 female participants (completed FIT)

Expect 60% of cancers to be in men

Expect 40% of cancers to be in women

Challenge...
Cancers Detection in 10,000 FIT Screened Participants

(50:50 male & female)

2014 Pilot Data

Cancers detected in men

Cancers detected in women

Cancers detected /5,000 male & 5,000 female participants

FIT Concentration ug/g

Cancers detected in men

Cancers detected in women

FIT Concentration ug/g

2014 Pilot Data
Cancers Detection in 10,000 FIT Screened Participants

*(50:50 male & female)*

2014 Pilot Data

- **Cancers detected in men**
- **Cancers detected in women**

Cancers detected /5,000 male & 5,000 female participants

- Men: 60% (60%) 10 cancers/5,000 participants

**FIT Concentration ug/g**

### Cancers Detection
- **Men**
- **Women**

**FIT Concentration ug/g**

- 20μg
- 40μg
- 60μg
- 80μg
- 100μg
- 120μg
- 140μg
- 150μg
- 180μg
- 200μg

**Value at 180μg**

- Men: 60% (60%) 10 cancers/5,000 participants
Cancers Detection in 10,000 FIT Screened Participants

(50:50 male & female)

2014 Pilot Data

Cancers detected in men

Cancers detected in women

- Men (60%) 10 cancers/5,000 participants
- Women (40%) 6.7 cancers/5,000 participants
Cancers Detection in 10,000 FIT Screened Participants
(50:50 male & female)

2014 Pilot Data

FIT can remove gender inequality but...
detects less cancers within available endoscopy resource

Challenge...

Women
FIT Threshold 60μg/g
Positivity = 2.8%
PPV = 5.1%

Men
FIT Threshold 180μg/g
Positivity = 2.0%
PPV = 12.6%
Screen Episode & FIT threshold – Cancer Detection Rate

Opportunity for better screening
Screen Episode & FIT threshold – Cancer Detection Rate

% Cancer Detection Rate

- First Invitation (60 year olds)
- No response to previous invitations
- Participated previously

Benefits of low FIT threshold is greatest in previous non-responders

Opportunity...
Age & FIT Threshold – Cancer Detection Rate

Should age, incidence... or QALY (Quality-adjusted Life Years Gained) influence threshold?

Opportunity...
The Future of Quantitative FIT Multivariate Risk Scores

- Quantitative FIT concentration
- Age & Sex
- Screening history
- Indices of Deprivation – Postcode
- Medical History – IBD, Crohns, DM, etc
- Family History – 1st and 2nd deg. relatives
- Life style – Smoking, exercise, diet, obesity

Better Screening! PPV Cost Effectiveness Colonoscopy Referrals
Developed a Multivariable Risk Prediction Model

- Logistic linear regression
- Artificial neural networks
- Machine learning

So far neural networks in the lead....

Marked increase in detection of advanced adenomas

Better Screening!
- PPV
- Cost Effectiveness
- Colonoscopy Referrals

Collaborators...
Jennifer Cooper, Nick Parsons, Sian Taylor-Phillips
FIT – An opportunity to **personalise** population-based screening?

Better Screening by -
...focusing on **individuals**...
...as well as on **populations**?

‘**Personalising population-based screening**’

1. Intelligent use of FIT data
2. Incorporate personal risk
3. Personalised invitation
4. Personalised interpretation of the FIT Screen
What threshold in England?

Depends on capacity of high quality colonoscopy & pathology?

Commence FIT screening... 2018

1. Initial FIT **threshold** to be **confirmed**
2. Monthly **review of threshold** to maximise clinical benefit
3. Revise current **surveillance** criteria
4. Exploit low threshold **FIT in primary care**
5. Develop risk-based **personalised screening**
FUTURE OF PERSONALIZED MEDICINE

Better evidence for diagnostics and therapies
Translate research
Empower patients!
Take care of your own health!

Make MY screen the best for ME

Test before you treat
Giant leaps in medicine are just around the corner!

Get to the right drug the first time!

All of the data from the internet can be stored in DNA in a small test tube.

www.DiscoveryDoodles.com
Screening needs to join the ‘Personalised Medicine’ band wagon.

Make MY screen the best for ME.
Plan for ‘sophisticated’, multi-variate, FIT-based risk score

Start with a ‘simple’, single FIT threshold

1. Understand **impact of FIT** on **Volume & Complexity** of colonoscopy/pathology

2. **Review current colonoscopy resource**
   - Current volume current colonoscopy volume
   - Current performance - 2 week breaches, bowel scope rollout etc
   - Variation between areas - Hubs and Screening Centres

3. **Estimates for 2018/9**
   - ?Eligible population, ?FIT uptake
   - What would have been the... gFOBt uptake, positivity and referral rates
   - FIT positivity and referral rates at different thresholds

4. **Agree** a single FIT threshold - based on OC-Sensor

5. **Advise Commissioners, Centres and CEOs** of likely impact of FIT in 2018/8

6. **Check performance** of procured FIT test against that used in the pilot.
Tuesday, September 26, 2017 9:30 – 11:30

Chairs: O. Májek, S. Halloran

- 9:30 – 9:50 Faecal testing in colorectal cancer screening: state of art
  S. Halloran
- 9:50 – 10:00 Czech National Coordination Centre for Prevention of Serious Diseases: platform for systematic introduction of innovations to early disease detection
  O. Májek
- 10:00 – 10:20 Implementation of population-based faecal occult blood testing and transition to immunochemical tests: experience from England
  S. Halloran
- 10:20 – 10:35 Role of general practitioners in population-based colorectal cancer screening: current situation and future prospects
  B. Seifert
- 10:35 – 10:50 Quantitative immunochemical tests: evidence on accuracy and implementation considerations in the Czech Republic
  P. Kocna
- 10:50 – 11:05 Quality-assured immunochemical testing – proposal for a pilot project in the Czech Republic
  O. Májek, Š. Suchánek
- 11:05 – 11:30 Structured discussion & wrap-up
- 26th Tuesday 12:00 - press conference - Thierry Ponchon could give insight into goals of UEG.
- SPH programme in England and how important is to have a good governance, quality assurance and political support
- **Session title:** Why do we have different levels of participation in Europe? Influence of the population type. How to tackle inequalities.
- **Date:** Wednesday, September 27
- **Time:** 14:20 – 15:50
British Society of Gastroenterologists - Guidelines

High Risk: >=5 adenomas / > 2 cm adenoma
Intermediate Risk: 3/4 small adenomas / >= 1 cm adenoma
Low Risk: 1-2 <1 cm adenomas

England Screening Outcomes Episode 1 2011/12

Polyp/Adenoma

1st Episode (Prevalent)
FIT Threshold and Positivity
2014 South, Midlands & NW Pilot

Uncertainty & Pilot

7.9%

1.7%

1.56%

FIT Threshold and Positivity

Positivity

FIT 20
FIT 40
FIT 100
FIT 150
FIT 180

ug Haemoglobin / g Faeces

gFOBt