Improving Bowel Cancer Detection by Getting FIT

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Consultant Colorectal Surgeon
Addenbrookes
Routes to Diagnosis of Bowel Cancer

% OF PATIENTS DIAGNOSED IN ENGLAND

- Via national screening programmes: 10%
  - Earliest: 37%
  - Latest: 8%

- By urgent GP two week wait referral for suspected cancer symptoms: 31%
  - Earliest: 15%
  - Latest: 24%

- By routine GP referral: 23%
  - Earliest: 22%
  - Latest: 23%

- In an emergency, via emergency GP transfer to hospital, as a hospital patient, or via A&E: 23%
  - Earliest: 7%
  - Latest: 41%

- Hospital in- or outpatient: 10%
  - Earliest: 21%
  - Latest: 25%

- Unknown route: 3%

For this infographic, EARLIEST = Stage 1, LATEST = Stage 4.
LET'S BEAT CANCER SOONER
cruk.org

Cancer Research UK is a registered charity in England and Wales (1099434), Scotland (SC041864), the Isle of Man (10944) and Jersey (203).
2ww Referrals to Addenbrooke’s

Annual Referrals

<table>
<thead>
<tr>
<th>Year</th>
<th>Referrals</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009/10</td>
<td>800</td>
</tr>
<tr>
<td>2010-11</td>
<td>900</td>
</tr>
<tr>
<td>2011/12</td>
<td>1100</td>
</tr>
<tr>
<td>2012/13</td>
<td>1200</td>
</tr>
<tr>
<td>2013/14</td>
<td>1300</td>
</tr>
<tr>
<td>2014/15</td>
<td>1700</td>
</tr>
<tr>
<td>2016/17</td>
<td>2200</td>
</tr>
<tr>
<td>2017</td>
<td>3000</td>
</tr>
<tr>
<td>2018</td>
<td>3300</td>
</tr>
</tbody>
</table>
How do you diagnose colorectal cancer?

- Symptoms
- Signs
- Blood tests
- Investigations – colonoscopy/CT etc
How do you diagnose colorectal cancer?

- Symptoms – NICE guidelines – 3% pickup
- Signs – PR important; mass
- Blood tests – anaemia important
- Investigations – colonoscopy/CT etc – expensive and most are negative
NG12 Criteria for 2ww 2015

- >40 wt loss/abdo pain
- >50 Rectal bleeding
- >60 IDA or CIBH
- Rectal/abdo mass
- <50 with bleeding and pain/CIBH/wt loss/IDA
NG12

- Designed to have a pickup rate of cancer of 3%
- Cambridge: 3.8% CRC; 6.1% overall cancer
- Compare with 8% CRC detection in BCSP in ‘asymptomatic’ patients
FOBt for patients without RB
- >50 with abdo pain/wt loss
- <60 with CIBH or IDA
- >60 with any anaemia

Positive FOBt -> 2ww referral

Until now we have recommended avoidance of FOBt
FIT testing
## FIT vs Haemoccult

<table>
<thead>
<tr>
<th></th>
<th>Haemoccult</th>
<th>FIT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Method</strong></td>
<td>Guaiac</td>
<td>Immunochemical</td>
</tr>
<tr>
<td><strong>Tests for</strong></td>
<td>Haem</td>
<td>Human globin</td>
</tr>
<tr>
<td><strong>Specific for lower GI</strong></td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Number tests</strong></td>
<td>3 consecutive days</td>
<td>Single</td>
</tr>
<tr>
<td><strong>Dietary effects</strong></td>
<td>Important</td>
<td>No effect</td>
</tr>
<tr>
<td><strong>Result</strong></td>
<td>Qualitative</td>
<td>Quantitative</td>
</tr>
<tr>
<td><strong>Useful outside screening</strong></td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>
FIT is quantitative

- measured in µg/g stool
  - undetectable – low likelihood of significant disease
  - high – likely cancer
FIT should be used to guide referral for suspected cancer (*ie 2ww*) in **people without rectal bleeding** who do not meet NG12

- Threshold should be **10ug/g** faeces
- Commissioning groups should audit outcome and monitor resource use
FIT – Some evidence

- No studies reported on low risk DG30 patients

- Evidence is based on the higher risk patients
FIT in Symptomatic Patients

- Scottish study of GP referrals with colorectal symptoms – NB no 2ww pathway
- 755 had colonoscopy + FIT

<table>
<thead>
<tr>
<th>Any detectable Faecal Hb</th>
<th>Number</th>
<th>PPV</th>
<th>NPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer</td>
<td>28 (3.7%)</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>High risk Adenoma</td>
<td>41 (5.4%)</td>
<td>97.8%</td>
<td></td>
</tr>
<tr>
<td>Low risk adenoma</td>
<td>65 (8.6%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IBD</td>
<td>34 (4.5%)</td>
<td></td>
<td>98.4%</td>
</tr>
<tr>
<td>All</td>
<td></td>
<td>58.3%</td>
<td></td>
</tr>
<tr>
<td>Any significant disease</td>
<td></td>
<td>20.6%</td>
<td></td>
</tr>
</tbody>
</table>

Mowat *Gut* 2016; 65: 1463
FIT in 2ww Patients

- Coventry study
- 430 fast track referrals

<table>
<thead>
<tr>
<th>Faecal Hb &gt;7ug/g</th>
<th>Number</th>
<th>PPV</th>
<th>NPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer + 1 adenoma with HGD</td>
<td>25</td>
<td>44%</td>
<td>99%</td>
</tr>
<tr>
<td>Adenoma</td>
<td>42</td>
<td>15%</td>
<td>94%</td>
</tr>
<tr>
<td>IBD</td>
<td>7</td>
<td>6%</td>
<td>100%</td>
</tr>
</tbody>
</table>

- 3 cancers missed by FIT (one hepatic flexure and 2 descending colon; none had IDA)

Widlak *Aliment Pharmacol Ther* 2017; *45*: 354
Nottingham ‘Getting FIT’

- slides from Mr Ayan Banerjea / Dr Caroline Chapman
- Two week wait pathway
  - 1891 referrals vetted
  - 1106 HM-JAC kits sent
  - 891 returned (80.6%)
  - Median return time 7 days (2-79)
  - 93.8% returned within 14 days
- 810 had clinical outcomes
Nottingham Study

% of 891 FIT returns
81 DNA/declined

n=538 (60.4%)
1 Colorectal cancer
0.2%

n=83 (9.3%)
4 Colorectal cancers
3 IDA and 1 rectal mass
4.8%

n=198 (22.2%)
11 Colorectal cancers
5.5%

n=72 (8.1%)
26 Colorectal cancers
CRC detection rate
36.1%

n=538 (60.4%)
1 Colorectal cancer
(IDA)
0.2%
## Nottingham FIT and symptoms

<table>
<thead>
<tr>
<th>Referral symptom</th>
<th>% of referrals**</th>
<th>Overall risk of CRC (%)</th>
<th>CRC detection rate stratified by FIT cut offs (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>&lt;4</td>
</tr>
<tr>
<td>Combined symptoms*</td>
<td>9.4</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>IDA</td>
<td>23.2</td>
<td>7.2</td>
<td>1.1</td>
</tr>
<tr>
<td>CIBH alone</td>
<td>57.5</td>
<td>2.9</td>
<td>0</td>
</tr>
<tr>
<td>Abdo mass</td>
<td>3.3</td>
<td>10.7</td>
<td>0</td>
</tr>
<tr>
<td>Rectal mass</td>
<td>4.1</td>
<td>5.9</td>
<td>0</td>
</tr>
<tr>
<td>Other”</td>
<td>2.4</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

*Includes IDA and CIBH combined with other sx
**As a proportion of all referrals without rectal bleeding
“Abdo pain/weight loss/abnormal imaging
Table 4. Number of patients with colorectal diseases missed using faecal haemoglobin concentration at $\geqslant 10 \mu g \text{Hb/g faeces}$ cut-off and number missed using NICE NG12 guidelines.

<table>
<thead>
<tr>
<th>Disease</th>
<th>No missed using faecal haemoglobin concentration at $10 \mu g \text{Hb/g faeces}$ cut-off</th>
<th>No missed using NICE NG12 guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRC</td>
<td>3</td>
<td>10</td>
</tr>
<tr>
<td>HRA</td>
<td>47</td>
<td>43</td>
</tr>
<tr>
<td>All neoplasia (CRC + HRA)</td>
<td>50</td>
<td>53</td>
</tr>
<tr>
<td>IBD</td>
<td>35</td>
<td>43</td>
</tr>
<tr>
<td>Significant colorectal disease (CRC + HRA + IBD)</td>
<td>85</td>
<td>96</td>
</tr>
</tbody>
</table>

CRC: colorectal cancer; HRA: higher risk adenoma; IBD: inflammatory bowel disease.

Approximate costs (NICE)

- Haemoccult (guaiac) £1
- FIT £5
- Colonoscopy £375
- CT colonography £135
- CT scan £115
How FIT can change diagnosis

- FIT as a ‘rule out’
  - Negative fit avoids colonoscopy
  - Low risk symptomatic pts (DG30)
  - ? Extend to 2ww patients (NG12)

- FIT as a ‘rule in’
  - Bowel cancer screening programme
  - ? Extend to polyp surveillance
Cambridgeshire and Peterborough Sustainability and Transformation Partnership (STP) Faecal Immunochemical Testing (FIT) in Primary Care Clinical Pathway

**Cambridge Colorectal Unit**

**Fit for the Future**
Working together to keep people well

**Patient concerned about lower GI symptoms**

**GP appointment:**
- Review symptoms
- Review history
- Examination

**GP Makes Decision**

- **High Risk ≥3% (NG12)**
  - 2WW Process

- **Low Risk ≤3% DG30**
  - Rectal bleeding
    - Yes
      - Not suitable for FIT – GP discretion to refer or arrange colonoscopy
    - No bleeding or single episode
      - FIT test and FBC

**FIT test result**

- Positive
  - FIT Positive > 10μg/g
    - 2WW Process
  - FIT Negative < 10μg/g with anaemia
    - Refer (non 2ww)

- Negative
  - FIT Negative < 10μg/g NO anaemia
    - Symptom changes
      - Improve
        - End
      - Persist or worsen
        - Re-evaluate and refer if appropriate

**DG30 Criteria**

Offer FIT for people without rectal bleeding (also consider low risk patient with single episode of blood) but with unexplained symptoms that do not meet the criteria for a suspected cancer pathway referral in line with recommendations 1.3.1 to 1.3.3 (NG12 Guidance updated July 2017)

**Algorithm:**
Altered bowel habit, vague abdominal symptoms and anaemia without iron deficiency
Caveats for FIT

- FIT is not perfect
- Safety netting
  - Patient does not return test
  - Persistent symptoms
  - Clinical judgement
Initial Experience

- **Go live was 7 weeks ago**

<table>
<thead>
<tr>
<th></th>
<th>Peterborough</th>
<th>Cambridgeshire</th>
</tr>
</thead>
<tbody>
<tr>
<td>Successful tests</td>
<td>177</td>
<td>210</td>
</tr>
<tr>
<td>Positive</td>
<td>20 (11.3%)</td>
<td>25 (11.9%)</td>
</tr>
<tr>
<td>No result</td>
<td>96</td>
<td>55</td>
</tr>
</tbody>
</table>
Initial Experience

- Issues
  - Some patients are being given old Blue top faeces tube
  - Buffer is being emptied out
  - Sample over-filled with stool
FIT in Bowel Cancer Screening

- Introduced this month
- Cut off level for ‘positivity’ is 120µ/g
- Uptake expected to increase by 7% points

<table>
<thead>
<tr>
<th></th>
<th>Low cut off eg 20µg/g</th>
<th>High cut off eg 120µg/g</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specificity</td>
<td>High</td>
<td>Low</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>Low</td>
<td>High</td>
</tr>
<tr>
<td>Colonoscopies</td>
<td>Many more</td>
<td>Same as now</td>
</tr>
<tr>
<td>Cancer detection</td>
<td>Greatly increased</td>
<td>Increased</td>
</tr>
<tr>
<td>Advanced adenoma</td>
<td>Massive increase</td>
<td>Big increase</td>
</tr>
</tbody>
</table>
FIT in Bowel Cancer Screening

- Consequences of FIT testing:
  - more positive tests
  - more people do the test
  - a positive test has a higher predictive value for pathology
  - a struggling system will find it hard to cope

- What will happen to Bowel Scope screening?
Future of FIT

- FIT to reduce 2ww referrals
  - NICE-FIT study
  - Risk adjusted referrals
- Surveillance
Table 1: Illustrative potential resource savings if 1%, 5% or 10% of people who are referred from primary care to secondary care as a suspected colorectal cancer 2 week wait have a faecal immunochemical test initially.

<table>
<thead>
<tr>
<th></th>
<th>Number</th>
<th>Cost £’000</th>
<th>Number</th>
<th>Cost £’000</th>
<th>Number</th>
<th>Cost £’000</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Current practice</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>People who meet the criteria for</td>
<td>302,643</td>
<td>121,965</td>
<td>302,643</td>
<td>121,965</td>
<td>302,643</td>
<td>121,965</td>
</tr>
<tr>
<td>colonoscopy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Future practice</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proportion of people who may have</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>faecal immunochemical test</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>People who go directly from primary</td>
<td>299,617</td>
<td>120,745</td>
<td>287,511</td>
<td>115,867</td>
<td>272,379</td>
<td>109,767</td>
</tr>
<tr>
<td>care to colonoscopy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>People who have a faecal</td>
<td>3,026</td>
<td>15</td>
<td>15,132</td>
<td>73</td>
<td>30,264</td>
<td>146</td>
</tr>
<tr>
<td>immunochemical test</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>People who have colonoscopy</td>
<td>757</td>
<td>305</td>
<td>3,783</td>
<td>1,525</td>
<td>7,566</td>
<td>3,049</td>
</tr>
<tr>
<td>following a positive faecal</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>immunochemical test</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>121,065</td>
<td>117,465</td>
<td>112,962</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Potential annual saving</strong></td>
<td>900</td>
<td>4,500</td>
<td></td>
<td></td>
<td></td>
<td>9,003</td>
</tr>
</tbody>
</table>
FIT to Reduce Colonoscopies

- NICE-FIT trial
  - Multicentre – Croydon
  - FIT sent to 2ww patients triaged to colonoscopy
  - Evaluate levels and strategy for use of FIT in 2ww referrals
  - Recruitment completed
  - Results ? late 2019
FIT to Reduce Colonoscopies

- Surveillance
  - polyp
  - BCSP
  - FIT test may allow avoidance of routine surveillance
Take home messages:

- Bowel cancer is difficult to diagnose; symptoms are unreliable
- FIT is a big advance over guaiac FOBt
- Do not use FIT if overt rectal bleeding
- FIT now available for use in low risk patients in Primary Care
- Combine FIT with FBC to check for anaemia
- True benefit of FIT may come in next few years when we can reduce numbers of colonoscopies in 2ww patients
Cancer Alliance/STP

Fit for the Future
Working together to keep people well