Responding to the Covid-19 pandemic – The TVCA FIT in primary care pathway

Wednesday 9th June 2021
Welcome

- Welcome & introduction – Mrs Jennifer Graystone, Clinical Director, TVCA
- Introducing the pathway – Dr Anant Sachdev
- Reviewing the evidence – Dr Brian Nicholson
- Pathway impact - The Frimley experience – Mr Ian Laidlaw
- Summary successes and key learnings – Mrs Jennifer Graystone
- Q & A
Setting the scene

- 62 day performance for lower GI cancers already challenged pre-pandemic
- March 2020 saw a 75% drop in the number of two-week wait referrals for all suspected cancers
- BSG advice on endoscopy at that point stated that only urgent cases should be investigated to ensure patient and staff safety during the pandemic
- Increasing evidence base around the use of FIT testing and the importance of different values in terms of risk of colorectal cancer

The Solution

FIT testing in primary care for suspected lower gastrointestinal cancers can support planning and recovery from the impact of COVID-19.
Using FIT in primary care & Lower GI Pathway Changes during COVID-19

Dr Anant Sachdev
GP
TVCA Clinical Lead for Prevention & Early Diagnosis
CRUK Strategic GP
NEW: Lower GI Pathway
An example of partnership working whilst responding to the pandemic

CAG & Academic Leads

The colorectal CAG leads and Oxfordshire Primary Care -FIT lab provided clinical expertise and academic rigor to ensure the pathway is evidence-based.

Commissioning & Trust Leads

CCG and Trust leads were pivotal in shaping the pathway.
Acting as a critical friend, CCG GP cancer leads and Trust leads provided important feedback to ensure the roles and responsibilities between primary and secondary care clinicians are clearly defined and patients are managed safely.

BBO Local Medical Committees

Provided additional feedback & engagement to support acceptance of the pathway changes within the wider GP community.

Primary Care Engagement

Continue to provide guidance and tools to implement the pathway.

We would also like to thank our charitable partners, CRUK and Macmillan Cancer Support for their advice and guidance.
Thames Valley Cancer Alliance Lower GI
Urgent Suspected Cancer Pathway during Covid-19

**GPs should continue to refer patients with abdominal/rectal mass even if FIT Negative

**Abd lump, anal/rectal lump/ unexplained rectal bleeding. GP to arrange U&E, Hb, ferritin.

Other symptoms as per NG12, incl. abdo pain, change in bowel habit, weight loss and iron-deficiency anaemia. GP to arrange FIT test*, U&E, Hb, ferritin & coeliac blood test.

Patient presents with bowel symptoms

FIT>10ug/g (=10% patients) 90% of cancers are in this group

If clinically concerned, or with progressing or alarm symptoms, then refer on TWR form with clear information

FIT<10 ug/g

This is likely to exclude a cancer risk (1:300)***

Safety-net and review in 2-4 weeks, If still concerned, seek A&G specialist advice, exclude other pathology

Triage by secondary care CNS or clinician taking into account tests including FIT level with red flag symptoms

Accepted by secondary care and taken forward for appropriate investigations e.g CT MRI faecal tagging

Consider deferring colonoscopy To Post COVID.

* Where available – if FIT not available, then Trust to manage the TWR referral as appropriate on receiving the referral

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BCSP FIT >120ug/g

Temporarily suspended due to COVID-19

History by BCSP nurse to include warning symptoms

Primary Care

Secondary Care

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**Nicholson et al., Diagnostic accuracy of FIT for patients with symptoms of colorectal cancer: a retrospective cohort study of 14,487 consecutive test request from English primary care.***
Safety Netting

Safety netting decisions should always be focused on balancing risk and made between the patient and clinician.

➢ Put systems in place to document safety netting actions during and following COVID
➢ Check locally for existing safety-netting templates tailored to your IT system
➢ Record the safety-netting advice provided to patients incl. method of consultation. Record that the patient has been safety netted and if they have been referred during COVID-19
➢ Ensure patient is clear about the next steps following the consultation
➢ Ensure patient contact details are up-to-date

Visit cruk.org/safetynettingtools for further resources
Further remote support may be available in your area. Contact facilitators@cancer.org.uk to find out how they can support you with safety netting in your practice.
Safety Netting

1. Ensure that other non-Gastrointestinal pathology is excluded e.g. renal, gynaecological etc.

2. When FIT is <10ug/g, this suggests an extremely low probability of LGI cancer

3. Lower GI cancer needs to be excluded when there is:
   a) the presence of a palpable mass
   b) iron deficiency anaemia

4. Safety-netting includes reviewing the patient at an interval of no more than 4 weeks
Safety Netting

5. If patient continues to display concerning signs/symptoms, refer regardless of the FIT result.

6. There is currently no data to support repeating a FIT test, if patient has persistent or worsening symptoms, refer regardless of FIT result.

7. **Never ignore gut feeling!** If there is still concern or uncertainty about fulfilling the pathway criteria, seek advice and guidance, refer to local RDC or refer on via LGI urgent suspected referral pathway (even if FIT < 10ug/g).
Using FIT to improve outcomes in colorectal cancer patients

The context:
The COVID-19 pandemic has caused disruption across cancer pathways for diagnosis and treatment. In England, 32% of colorectal cancer (CRC) is diagnosed via urgent symptomatic referral from primary care, the “2-week-wait” (2WW) pathway.

Access to routine endoscopy is likely to be a critical bottleneck causing delays in CRC management due to chronic limitation in capacity, acute competition for physician time, and safety concerns.

How can FIT help?
To avoid significant numbers of avoidable deaths from CRC, normal diagnostic and surgical throughput must be maintained. An accrued backlog of cases will present to primary care following release of lockdown, supranormal endoscopy capacity will be required to manage this without undue delays.

FIT-triage of symptomatic cases provides a rational approach by which to avoid patient delay and mitigate pressure on capacity in endoscopy. This would also reduce exposure to nosocomial COVID-19 infection, relevant in particular to older patient groups.

90% of the life years lost to delayed cancer diagnostics can be “recouped” by use of FIT triage.

1Quantifying and mitigating the impact of the COVID-19 pandemic on outcomes in colorectal cancer
What are the benefits of this approach?

<table>
<thead>
<tr>
<th>For Patients...</th>
<th>For GPs...</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Improved patient experience and quality of referral.</td>
<td>• Better patient prioritisation and triage during COVID-19.</td>
</tr>
<tr>
<td>• FIT provides a high level of reassurance to patients with negligible results and improved access to services for patients who are at high risk of colorectal cancer.</td>
<td>• National guidance (incl. BSG) cite FIT as an effective and key diagnostic test by which patients can be prioritised according to their results and symptomology.</td>
</tr>
<tr>
<td>• Alternative pathology is not missed.</td>
<td>• There are a number of patients who have had their 2ww referral suspended due to COVID-19, FIT will enable those at high risk to be brought in to the trust for urgent investigations where required.</td>
</tr>
<tr>
<td></td>
<td>• Alternative pathology is not missed.</td>
</tr>
</tbody>
</table>
Patient Feedback FIT

• 'My experience of the kit was swift and effective in getting referred to the Endoscopy unit for colonoscopy. After the positive result of the stool sample I was anxious and worried to find out what was wrong, but the quick referral was received. The whole process was quick, effective and transparent'

• 'The FIT test was easy and self explanatory to use. I didn't mind doing it as I knew it would help with my speedy referral/ diagnosis.'
Faecal Immunochemical Testing (FIT) for patients with colorectal cancer symptoms

Dr Brian D Nicholson MRCGP DPhil
NIHR Academic Clinical Lecturer
Nuffield Department of Primary Care Health Sciences
University of Oxford
Colonoscopy and sigmoidoscopy procedures

Impact of COVID-19

UK’s National Endoscopy Database (NED)

The average weekly number of procedures, cancers, proportion of missing cancers and cancer detection rates were calculated.

NICE 2015 – Faecal Occult Blood Testing (FOBT)

>50 yrs

<60 yrs

≥60 yrs

or

or

WHAT! No Spinach?
### 2015 - English GPs with access to FOBT

<table>
<thead>
<tr>
<th>ENGLAND</th>
<th>English Region %</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=511</td>
<td></td>
</tr>
<tr>
<td><strong>% (95% CI)</strong></td>
<td>1</td>
</tr>
<tr>
<td>FOBT</td>
<td><strong>54 (49-59)</strong></td>
</tr>
</tbody>
</table>

Nicholson (2016)
Halving of positive tests
Lower false positive rate
11% vs 34% (p<0.01)

DG30: Quantitative faecal immunochemical tests to guide referral for colorectal cancer in primary care (2017)

• 10 studies identified
• None reported data that on people with symptoms who are judged to be at low risk of colorectal cancer.
• Only one study was done in primary care (almost).

Recommendation
• FIT recommended 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
• ≥10 micrograms hb/g faeces
Analysis of FIT use in primary care

- 14,487 consecutive cohort of FITs
- 12,509 patients from primary care prior to referral
- Oxfordshire CCG / OUH laboratories
- Within the context of NG12/DG30
- HM-JACKarc laboratory method
- Symptom capture from FIT requests
- Follow-up in the linked hospital record

- Focus here on the 9,896 people with ≥6 months follow-up
### Age-group (years)

<table>
<thead>
<tr>
<th>Age-group (years)</th>
<th>N (% FIT ≥7 µg/g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-39</td>
<td>793 (8.8)</td>
</tr>
<tr>
<td>40-49</td>
<td>1400 (7.1)</td>
</tr>
<tr>
<td>50-59</td>
<td>2749 (7.9)</td>
</tr>
<tr>
<td>60-69</td>
<td>1651 (9.1)</td>
</tr>
<tr>
<td>70-79</td>
<td>1868 (14.2)</td>
</tr>
<tr>
<td>≥80</td>
<td>1435 (20.6)</td>
</tr>
</tbody>
</table>

### Clinical Features

<table>
<thead>
<tr>
<th>Clinical Feature</th>
<th>N (% FIT ≥7 µg/g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal pain</td>
<td>2,501 (7.9)</td>
</tr>
<tr>
<td>Anaemia</td>
<td>2,791 (14.5)</td>
</tr>
<tr>
<td>Blood in stools</td>
<td>1,477 (19.7)</td>
</tr>
<tr>
<td>Change in bowel habit</td>
<td>5,011 (7.6)</td>
</tr>
<tr>
<td>Inflammation</td>
<td>173 (18.5)</td>
</tr>
<tr>
<td>Iron deficiency</td>
<td>1,208 (11.7)</td>
</tr>
<tr>
<td>Thrombocytosis</td>
<td>134 (8.2)</td>
</tr>
<tr>
<td>Tired all the time</td>
<td>66 (7.6)</td>
</tr>
<tr>
<td>Weight loss</td>
<td>951 (10.8)</td>
</tr>
</tbody>
</table>

### Outcome

<table>
<thead>
<tr>
<th>Outcome</th>
<th>N (% FIT ≥7 µg/g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colorectal cancer</td>
<td>105 (91.4)</td>
</tr>
<tr>
<td>Benign disease (Polyp &lt;10mm/Diverticulosis)</td>
<td>80 (22.5)</td>
</tr>
<tr>
<td>Bowel inflammation</td>
<td>204 (36.3)</td>
</tr>
<tr>
<td>High risk adenoma (Polyp &gt;10mm or high-grade dysplasia)</td>
<td>373 (41.6)</td>
</tr>
<tr>
<td>No significant pathology</td>
<td>418 (16.3)</td>
</tr>
<tr>
<td>No further investigation</td>
<td>8,716 (7.9)</td>
</tr>
</tbody>
</table>
## Diagnostic accuracy of FIT in primary care

<table>
<thead>
<tr>
<th>FIT Threshold (µg/ε)</th>
<th>Sensitivity (95% CI)</th>
<th>Specificity (95% CI)</th>
<th>PPV (95% CI)</th>
<th>NPV (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥7</td>
<td>91.4 (86.1-96.8)</td>
<td>89.8 (89.2-90.4)</td>
<td>8.74 (7.07-10.4)</td>
<td>99.9 (99.8-100.0)</td>
</tr>
<tr>
<td>≥10</td>
<td>90.5 (84.9-96.1)</td>
<td>91.3 (90.8-91.9)</td>
<td>10.1 (8.15-12.0)</td>
<td>99.9 (99.8-100.0)</td>
</tr>
<tr>
<td>≥20</td>
<td>84.8 (77.9-91.6)</td>
<td>93.7 (93.2-94.2)</td>
<td>12.6 (10.2-15.1)</td>
<td>99.8 (99.7-99.9)</td>
</tr>
<tr>
<td>≥50</td>
<td>74.3 (65.9-82.6)</td>
<td>96.4 (96.0-96.7)</td>
<td>17.9 (14.3-21.5)</td>
<td>99.7 (99.6-99.8)</td>
</tr>
<tr>
<td>≥100</td>
<td>61.0 (51.6-70.3)</td>
<td>97.6 (97.3-97.9)</td>
<td>21.3 (16.7-26.0)</td>
<td>99.6 (99.4-99.7)</td>
</tr>
<tr>
<td>≥120</td>
<td>57.1 (47.7-66.6)</td>
<td>97.8 (97.6-98.1)</td>
<td>22.1 (17.2-27.1)</td>
<td>99.5 (99.4-99.7)</td>
</tr>
<tr>
<td>≥150</td>
<td>54.3 (44.8-63.8)</td>
<td>98.1 (97.8-98.4)</td>
<td>23.4 (18.1-28.7)</td>
<td>99.5 (99.4-99.6)</td>
</tr>
</tbody>
</table>
## FIT performance per 1,000 patients tested

<table>
<thead>
<tr>
<th>FIT Threshold (µg/g)</th>
<th>Positive FITs n (%)</th>
<th>Cancers detected n (%)</th>
<th>Positive FITs to detect one cancer</th>
<th>Negative FITs n (%)</th>
<th>Patients with cancer and a negative FIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥7</td>
<td>111 (11)</td>
<td>10 (91)</td>
<td>11</td>
<td>889 (89)</td>
<td>1</td>
</tr>
<tr>
<td>≥10</td>
<td>96 (10)</td>
<td>10 (91)</td>
<td>10</td>
<td>904 (90)</td>
<td>1</td>
</tr>
<tr>
<td>≥20</td>
<td>71 (7)</td>
<td>9 (85)</td>
<td>8</td>
<td>929 (93)</td>
<td>2</td>
</tr>
<tr>
<td>≥50</td>
<td>44 (4)</td>
<td>8 (74)</td>
<td>6</td>
<td>956 (96)</td>
<td>3</td>
</tr>
<tr>
<td>≥100</td>
<td>30 (3)</td>
<td>7 (61)</td>
<td>5</td>
<td>970 (97)</td>
<td>4</td>
</tr>
<tr>
<td>≥120</td>
<td>28 (3)</td>
<td>6 (57)</td>
<td>5</td>
<td>972 (97)</td>
<td>5</td>
</tr>
<tr>
<td>≥150</td>
<td>25 (2)</td>
<td>6 (54)</td>
<td>4</td>
<td>975 (98)</td>
<td>5</td>
</tr>
</tbody>
</table>
FIT performance per 1,000 patients tested

**CA125**  
(≥35 U/ml)  
23% ovarian cancers missed

**PSA**  
25% prostate cancers missed

**CXR**  
20% lung cancers missed

**FIT**  
(≥10 ug/g)  
10% colorectal cancers missed

SAFETY NET - PATIENTS WITH NEGATIVE TESTS AND PERSISTENT SYMPTOMS
Risks of colorectal cancer

Risk of colorectal cancer in a 60 year old with abdominal pain and change in bowel habit is

1.0% to 2.6%

Risk of colorectal cancer in a 60 year old without symptoms is

0.1% to 0.2%

Risk of colorectal cancer in a person with a positive FIT is

≥10.0%

Risk of colorectal cancer in a person with a negative FIT is

0.1% to 0.2%
Pathway Impact – the Frimley experience

Ian Laidlaw
Chief of Service Surgery, Urology & Cancer Services
Frimley Health NHS Foundation Trust

Committed to excellence  Working together  Facing the future

thamesvalleycanceralliance.nhs.uk  @ThamesV_Cancer
Patients

- 2917 patients referred 19/6/20 to 30/4/21
- 257 patients excluded as still on investigation pathway
- 2660 patients included
- 110 (4.1%) patients diagnosed with colorectal or anal cancer
FIT Test Referral Pattern

- 2096 (79%) Patients referred with FIT
  - 617 negative FIT (<10)
    - Colorectal/anal cancer incidence 0.2% (1 patient)
  - 1479 positive FIT
    - Colorectal/anal cancer incidence 5.4% (80 patients)
  - 447 patients with FIT >120
    - Colorectal/anal cancer incidence 12.1% (54 patients)

- 564 (21%) Patients didn’t have FIT
  - Colorectal/anal cancer incidence 5.1% (29 patients)
<table>
<thead>
<tr>
<th>Group</th>
<th>Positive FIT</th>
<th>Negative FIT</th>
<th>No FIT</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colonoscopy</td>
<td>901 (61%)</td>
<td>190 (31%)</td>
<td>198 (35%)</td>
<td>1289 (48%)</td>
</tr>
<tr>
<td>Flexible Sigmoidoscopy</td>
<td>194 (13%)</td>
<td>109 (18%)</td>
<td>122 (22%)</td>
<td>425 (16%)</td>
</tr>
<tr>
<td>OGD</td>
<td>167 (11%)</td>
<td>127 (21%)</td>
<td>63 (11%)</td>
<td>357 (13%)</td>
</tr>
<tr>
<td>CT colonoscopy</td>
<td>243 (16%)</td>
<td>44 (7%)</td>
<td>59 (10%)</td>
<td>346 (13%)</td>
</tr>
<tr>
<td>CT scan</td>
<td>408 (28%)</td>
<td>250 (41%)</td>
<td>166 (29%)</td>
<td>824 (31%)</td>
</tr>
<tr>
<td>MRI</td>
<td>62 (4%)</td>
<td>10 (2%)</td>
<td>22 (4%)</td>
<td>94 (4%)</td>
</tr>
<tr>
<td>Ultrasound</td>
<td>12 (&lt;1%)</td>
<td>7 (1%)</td>
<td>1 (&lt;1%)</td>
<td>19 (&lt;1%)</td>
</tr>
<tr>
<td>No investigation (or investigated off 2WW pathway)</td>
<td>189 (13%)</td>
<td>123 (20%)</td>
<td>125 (22%)</td>
<td>437 (16%)</td>
</tr>
</tbody>
</table>
CR Cancer in FIT negative Patients

• Single Patient
  – 1/617 FIT negative 0.16%
  – 1/2917 total referrals 0.034%

• 76 year old male
  – Presented with change in bowel habit
  – Not anaemic (Hb 157)
  – Palpable Polypoidal lesion overlying hemorrhoid
  – Biopsy confirmed T2 adenocarcinoma of rectum

• Examine the Patient!
Benefits

• Quality and Timeliness
  – Appropriate prompt reassurance of Community based –FIT patients
  – Quality of patient experience

• Timeliness
  – Expedites FIT + patient
  – Reassures FIT - patient

• Quantity
  – Increased Colonoscopy capacity
  – Half of FIT negative avoided colonoscopy
  – Approx 300 colonoscopies – 50 lists in 10 months
  – Brings forward 300 into these slots
  – NB Virtual financial saving as no closed lists

• Safety
  – Secure data on value of test
  – No complications possible in pts who don’t proceed to colonoscopy
  – In Covid times has prevented risk to patient and staff of exposure,

• Appropriately diverts patients to investigation on non cancer pathway
Implementation

• **Preparation**
  - Agree the Direction and team approach
  - Evidence base
  - Documentation, Referral forms Guidance in DXS
  - Q and A
  - Flow diagrams

• **Education**
  - Joint venture
  - Champions from primary and secondary care
  - Webinar and Place based Education – repetition

• **Feedback to practices / practitioners**
  - Weekly contact cancer office to practice managers with support from primary care lead clinicians

• **Reassurance**
Area for further work

- Include Polyp detection
- Identify community-based patients FIT-ve and their outcomes needs long run in
  – as yet unaware of Primary care FIT negative patient subsequently identified with delayed diagnosis
Potential Impact on CRC FIT Screening

• Symptomatic positive 10 +
• Screening positive 120+
• ? As community testing become more prevalent should we review recruitment to screening within a defined period after negative FIT
• If So, How? Automated through Lab?
Summary Observations

• Key elements that supported adoption of the pathway:
  - Published data and evidence to support the pathway
  - Leaders across the system engaged
  - Everyone committed to the same goal
  - Education, education and more education
  - Share the successes

• Key Learnings:
  - Data monitoring – to drive further adoption
  - Map your geography – look at who hasn’t attended education sessions not who has
  - Recognize local variation and tailor approaches accordingly
  - Formal capture of patient experience needs to be a more central focus in all we do

• Applying the learning
Q & A