FIT Screening and symptomatic – What do GPs need to know?

Hayley Heard
Programme Lead, National Endoscopy Programme

Steve Court
Head of Programme, Bowel Screening Wales, BSW
Plan

• Bowel Screening Wales
• gFOB and FIT
• Benefits of FIT v gFOB
• Optimisation of screening
• Endoscopy in Wales
• National Endoscopy Programme
• FIT for the Symptomatic Service
Background

Bowel Cancer

- 2nd most common cancer death in Wales
- Over 900 deaths per year
- More common in men
- More common in deprived areas
- Routes of diagnosis:
- 10% screening, 55% GP referrals, 25%A&E, 10% hosp
Bowel Screening Wales (BSW)

- BSW established in October 2008
- Screen 60-74 year olds
- Screening detects highest proportion of grade I cancers
- 90-95% grade I survive 5 years (8-10% stage IV)
- Programme aim: To reduce the mortality from bowel cancer in Wales by 15% by 2020
BSW Screening Pathway

- Eligible people invited two yearly
- Test for occult blood in stool samples
- Presence of blood → assessment → colonoscopy
- If unfit for colonoscopy → CT scan
- BSW responsible to diagnosis of cancer
First 10 years of BSW

- 808,500 people invited
- 53% uptake
- 22,500 positive results
- 19,100 attended colonoscopy
- 2,300 cancers detected
- 4,400 adenomas detected
Van Deen (1864) - guaiac can detect Hb in faeces
Hydrogen peroxide oxidises guaiac + haem = blue colouration
Three separate stool samples
Manually read by trained screeners
Limitations of gFOB Testing

- Relatively low sensitivity
- False positives – diet, bile, aspirin/NSAID
- False negatives - Vitamin C
- Haem stable in GI tract = site of bleeding difficult to determine
Limitations of gFOB Testing

- Manual test – 30/hour, relatively high staff costs
- Subjective test – inter and intra observer variability
- Qualitative, binary, test – no indication of amount of blood
- Relatively low uptake – three samples
UK NSC Recommendation (2016)
Replace gFOB with faecal immunochemical testing (FIT)

- January 2016 – UK NSC recommendation published
- Change of primary screening test from gFOB to FIT
- **Key findings:**
  - FIT easier to use (single sample)
  - FIT can be measured more reliably
  - FIT more sensitive than gFOB
  - Detects more advanced adenomas
  - FIT is cost effective
The Introduction of FIT into BSW

- 2016 – BSW planned for conversion to FIT
- 2016-2018 – procurement exercise undertaken
- 2018 – contract awarded to Alpha Laboratories (HMJack)
- January 2019 – FIT issued to 1:28 (interface)
- August 2019 – ratio increased to 1:12
- September 2019 – FIT issued to all eligible screening participants
- Positivity cut off set at 150µg haemoglobin/g faeces (Scotland/England)
BSW Primary Screening Test 2019

• Single sample
• Automated analysis of sample
• Antibodies specific for globin moiety of Hb
• Binding to globin produces latex complexes
• Size and number correlated to amount of Hb/blood
BSW Primary Screening Test 2019
The Faecal Immunochemical Test (FIT)
Quantitative result

Results reported from analyser as µg haemoglobin/g faeces

BSW positive cut off value currently 150µg haemoglobin/g faeces

Numerical value not issued to participant or GP

Result to participant –
‘Do not require further investigations at this time’
‘Require further investigations’
Benefits of FIT – Uptake for Screening

Uptake for screening

- Single sample, easier for people to complete
- Uptake for FIT in Scotland $\uparrow$ 8% (63.9%) – Wales gFoB 54%
- Increase noted in Non Responders and most deprived areas

- 26.6.% Non Responders (FIT) v 14.5% (gFOB)
- 61.5% v 50.2% first timers
- 55.1% v 46.9% - most deprived areas
Clinical benefits of FIT –
Improved sensitivity over gFOB

- Sensitivity – FIT able to detect lower levels of blood in stool samples, so able to detect more pathology
- FIT diagnostic accuracy of 95% for CRC (Lee et al)
- FIT detected 49 cancers/10,000 cf 14/10,000 (Levi et al)
- PPV (FIT) 43.4% v 39% (gFOB)
- NPV 97.5% v 95.4% (Parra-Blanco et al, 2010)
Clinical benefits of FIT – Cancer Detection Rates

Relative Increase in CDR with FIT cf gFOB

- Oort et al. (2010): 13%
- Allison et al. (2007): 17.50%
- Allison et al. (1996): 31.60%
- Parra-Blanco et al. (2010): 37.20%
- Smith et al. (2006): 37.50%
- Park et al. (2010): 53.80%
Clinical benefits of FIT – Adenoma Detection Rates

Relative Increase in ADR with FIT cf gFOB

- Allison et al (2007) 11.80%
- Smith et al (2006) 12.10%
- Oort et al (2010) 17.60%
- Park et al (2010) 20.30%
Other Benefits of FIT

- Automated test
- Cost effective
- No diet or drug interferences
- Specific for human globin (haemoglobin)
- Objective test – measurement of Hb levels
- Can adjust cut-off for age, gender and colonoscopy resources areas
Communication and Promotion

- BSW has opted for a ‘soft launch’ – uptake and positivity rate
- Plan to publicise in February / March
- Communication within professional groups only at this stage
- GP endorsement of screening – evidence to support positive effect on uptake
- Improve awareness of screening (BSW Support Officer)
Optimisation of Bowel Screening in Wales

UK NSC 2018   Recommendation
• Screening age reduced to 50 year olds
• Sensitivity of the FIT test increased (cut off value reduced)
• Aspiration is to reduce to a cut off of 20µg Hb/g

Plan for Wales
Reduce age from 60 to 50 by 2021
Reduce positivity cut off from 150 to 80µg/g by 2023
FIT for Screening

Summary

• FIT rolled out to all eligible participants from start September 2019
• FIT offers benefits over gFOB (uptake & sensitivity)
• Positive cut off set at 150
• Participants or GP not informed of the actual numerical result
• BSW – soft launch initially, active comms. early 2020
• BSW plans to optimise the programme by 2023
National Endoscopy Programme

Hayley Heard
Programme Lead
Endoscopy Services in Wales

Issues:

• Increasing demand
• Waiting times
• Environmental constraints
• JAG accreditation
• Recruitment and retention of staff
• Disparity in procedures per population
• Optimization of bowel screening
• Access to specialist services
• Variation in pathways
Endoscopy Services in Wales

Current state:

• Demand and capacity planning variable
• No national workforce plan
• Few units JAG accredited
• Limited bowel screening programme
• No national overview of physical estate
• Variation in referral pathways across Wales
• Variation in management of referrals
• Inconsistent IT systems
• HSCSC Inquiry
Endoscopy Services in Wales

Solutions

National Endoscopy Programme:
• Deliver improvement at pace
• Determine demand and capacity gap
• Improve productivity and balance demand and capacity
• Standardise referral pathways
• Review workforce and build capacity
• Achieve JAG accreditation
National Endoscopy Programme

The Vision:

• The service will have embedded balanced and responsive demand and capacity planning and will be delivering clear quality outcomes through a modern, best-in-class and optimally configured workforce in fully JAG accredited units
National Endoscopy Programme

The Aim:

• Support the achievement of improved early cancer detection
• Support developments within national diagnostics programmes
• Support optimisation of bowel screening
• Support the achievement of the single cancer pathway
• Achieve JAG accreditation
• Balance demand and capacity
National Endoscopy Programme

Measures of success:

• Waiting times controlled
• JAG accreditation
• Optimised bowel screening programme
National Endoscopy Programme

Phase 1:
• Establish programme governance and structure
• Establish programme team
• Establish programme board
• Agree terms of reference
• Establish work streams and appoint leads
• Establish work plans
National Endoscopy Programme

Phase 2:

• Deliver work plans
• Deliver against 6 CMO recommendations
• Develop robust monitoring and reporting mechanisms
• Publish action plan – HSCSC recommendation
National Endoscopy Programme

• Phase 3:
• Scope future direction of Endoscopy services and programme
National Endoscopy Programme

Where we are now:

• Programme established
• Clinical leadership established
• Baseline review completed
• Inquiry report action plan drafted
• Detailed work plans and trajectories being finalised
Health, Social Care and Sports Committee Inquiry
Recommendations

• Action Plan:
  – Screening optimisation- uptake, age & FIT
  – Capacity - diagnostic WT < 8weeks by end 2019
  – Surveillance- review and manage
  – Workforce- training- consider academy
  – JAG accreditation
  – FIT primary care
Clinical Pathways - Optimisation and Standardisation

- Map existing pathways
- Standardised evidence based pathways
- Align with NED
- Governance and quality assurance
- Patient information
- Specialist services

- **FIT for the symptomatic service**
FIT for the symptomatic service

• Symptom based referral guideline- poor predictors of underlying significant bowel disease (SBD)
• FIT shown to be effective rule out test to exclude SBD
• F Hb<10ug/g- in absence of IDA, rectal bleeding, mass or persistent diarrhoea = extremely low risk of CRC
FIT for the symptomatic service

NICE Guidance:
• NG12 2015, 2017 - high risk symptoms
• DG30 2017 - low risk symptoms
1.3 Lower gastrointestinal tract cancers

Colorectal cancer

1.3.1 Refer adults using a suspected cancer pathway referral (for an appointment within 2 weeks) for colorectal cancer if:
   - they are aged 40 and over with unexplained weight loss and abdominal pain or
   - they are aged 50 and over with unexplained rectal bleeding or
   - they are aged 60 and over with:
     - iron-deficiency anaemia or
     - changes in their bowel habit, or
   - tests show occult blood in their faeces. [new 2015]

1.3.2 Consider a suspected cancer pathway referral (for an appointment within 2 weeks) for colorectal cancer in adults with a rectal or abdominal mass. [new 2015]

1.3.3 Consider a suspected cancer pathway referral (for an appointment within 2 weeks) for colorectal cancer in adults aged under 50 with rectal bleeding and any of the following unexplained symptoms or findings:
   - abdominal pain
   - change in bowel habit
   - weight loss
   - iron-deficiency anaemia. [new 2015]
Quantitative faecal immunochemical tests to guide referral for colorectal cancer in primary care

Diagnostics guidance [DG30]  Published date: July 2017

1 Recommendations

1.1 The OC Sensor, HM-JACKarc and FOB Gold quantitative faecal immunochemical tests are recommended for adoption in primary care 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 outlined in NICE's guideline on suspected cancer (recommendations 1.3.1 to 1.3.3).

1.2 Results should be reported using a threshold of 10 micrograms of haemoglobin per gram of faeces. Companies should provide advice about the performance characteristics of the assays to laboratories, and ensure standardisation of results.
As the use of the Faecal Immunochemical Test (FIT) in ‘low risk’ colorectal symptomatic patients (as per NICE DG30, 2017) continues to gather momentum in Wales, Cancer Research UK have recently developed an infographic to outline the key differences between FIT screening and symptomatic.
Moving Forwards with FIT for Symptomatic Patients

- 8th March 2019 – BSG/ACPGBI workshop to discuss the most cost effective, evidence based and efficient way forward
- Focused on 2 WW criteria patients
- Consensus- FIT and colonoscopy – analysis
- Non 2WW- Colonoscopy if FIT positive- if negative- OPD
- Further work needed around pathways
- Ongoing pilots
England: Sally Benton is a Consultant Biochemist at the Berkshire and Surrey Pathology Services, Royal Surrey County Hospital, Guildford and also Director of the Bowel Cancer Screening Hub in the South of England.

Various studies have taken place across England over the last few years, yet there is still no definitive evidence that introducing FIT in the symptomatic patient cohort will reduce overall demand on endoscopy services. However, there is strong anecdotal evidence that its introduction in some areas, is leading to more appropriate referrals (Nottingham). Further study evaluation of evidence is needed urgently and there is pressure on study leads to publish their data.

To date there has not been an overall agreed approach in England, with health authorities largely interpreting NICE guidance in accordance to the capabilities of their local services. However, with different interpretations leading to variation in delivery, an agreed pathway has now been developed (>10 refer on urgent pathway and if <10 safety net) which will be used as guidance for adoption to standardize implementation.
Wales

- HTW- Implement DG30 or explain why not
- NEP- Clinical Pathways Sub Group:
  - ABUHB- FIT pilot
  - SBUHB-FIT pilot
  - C&V- Enhanced FIT pilot planned
  - CTMUHB-FIT pilot planned
- National evaluation strategy
- Standardised public and professional information
Wales

Next steps:

• Implement DG30
• Pilots - high risk groups
• Evaluation
• Link with UK FIT Pioneers Group
• NICE guidance review - high risk groups
Thank You

• Questions?