NHS
Royal Surrey
NHS Foundation Trust

NHS
Berkshire and Surrey Pathology Services

NHS
Cancer Screening Programmes

Are our FIT assays good enough and what is the symptomatic threshold?

Sally C Benton
Consultant Biochemist, BSPS
Director, Bowel Cancer Screening South of England Hub

Date: 17th June 2025

BSPS is a joint venture between: Ashford and St. Peter's Hospitals NHS Foundation Trust; Frimley Health NHS Foundation Trust; Royal Berkshire NHS Foundation Trust; Royal Surrey NHS Foundation Trust and Surrey and Sussex Healthcare NHS Trust

Legal entity host: Frimley Health NHS Foundation Trust

Colorectal Cancer

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- 3rd most common form of cancer worldwide (1.93 million cases in 2020)*
- 2nd most common cause of cancer death(916,000 deaths in 2020)*
- Symptoms are vague and non-specific
  - Changes in bowel habit, abdominal pain, bloating, weight loss
- Symptoms often not present until late in the disease

* World Health Organisation https://www.who.int/news-room/fact-sheets/detail/cancer

Age of diagnosis

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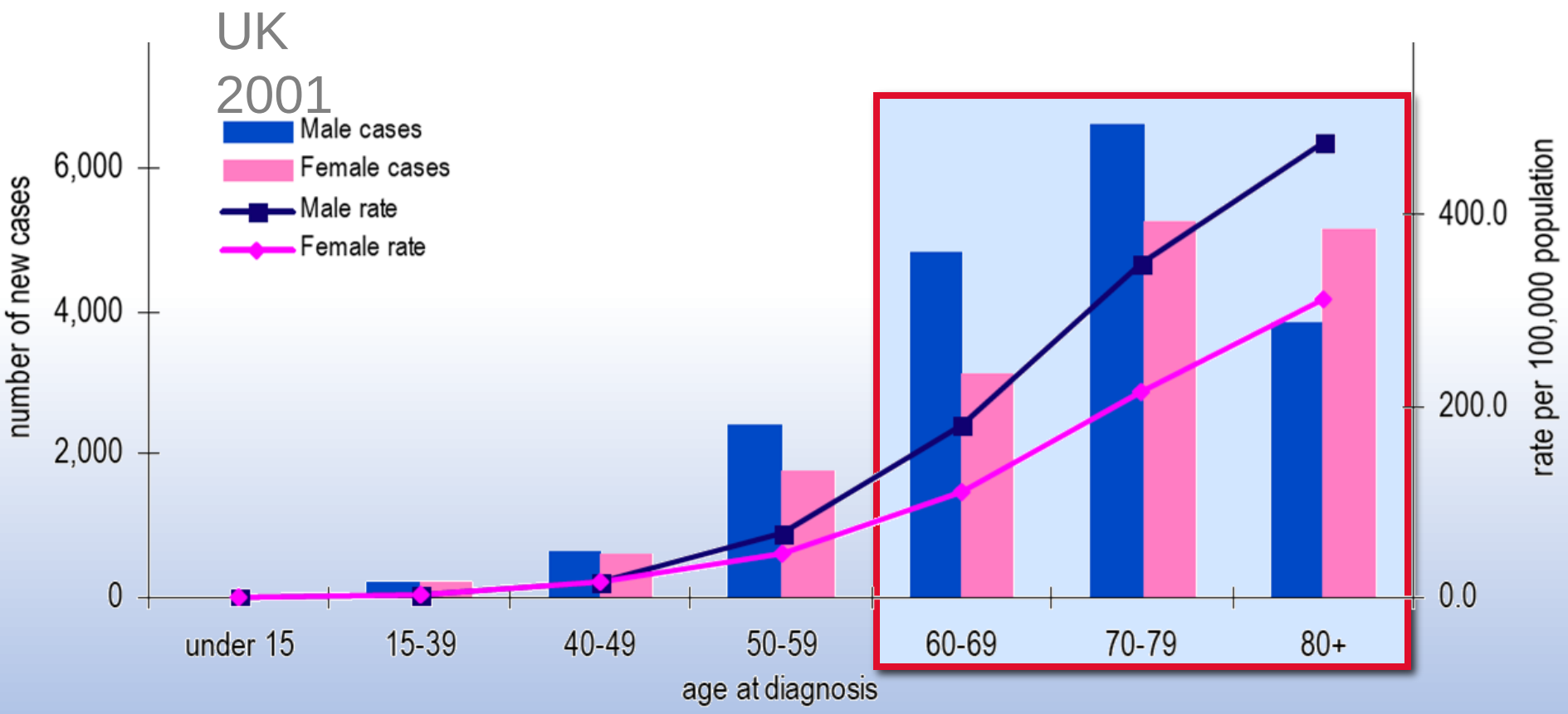

More than 80% occur in those >60 years of age

Development of Colorectal Cancer

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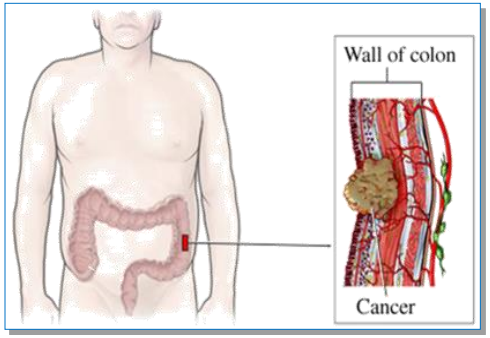
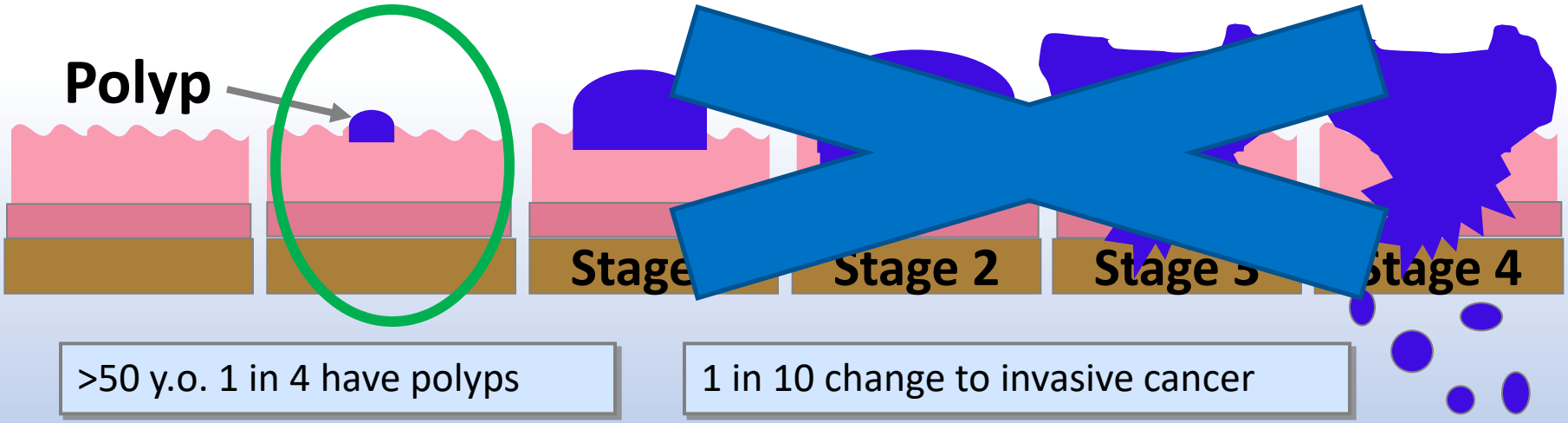




>50 y.o. 1 in 4 have polyps

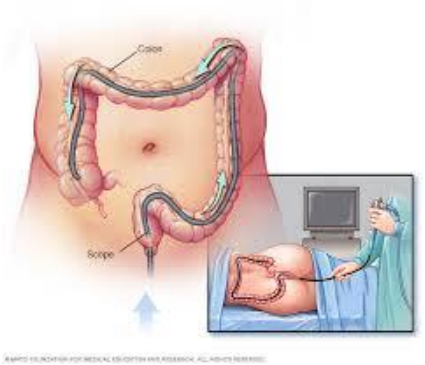
1 in 10 change to invasive cancer

Survival 5 years after treatment	95%	80%	60%	5%

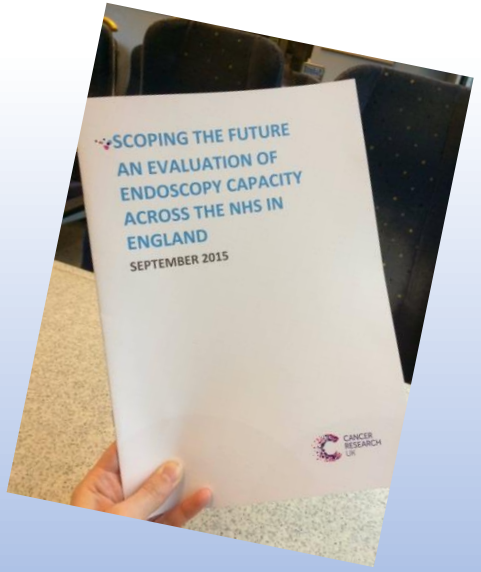
10 years

Diagnosis of Colorectal Cancer

Berkshire and Surrey Pathology Services



- **Colonoscopy**
  - Gold standard method
  - Enables visualisation of the whole bowel



- **BUT**
  - Invasive
  - Highly skilled endoscopists required
  - Risks to patient
  - Expensive
  - In many countries colonoscopy is a limited resource

Surrogate marker for colorectal cancers

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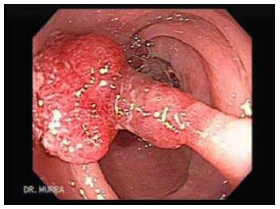

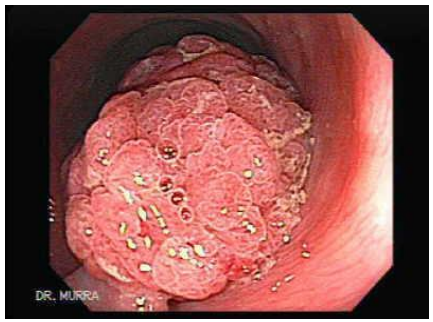

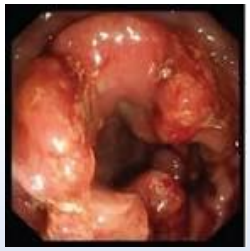

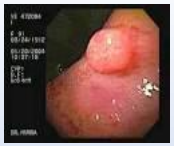

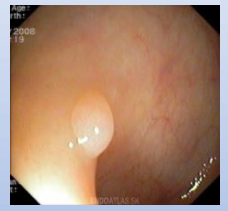

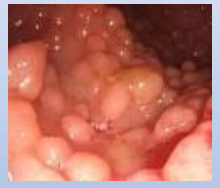

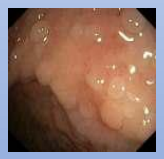

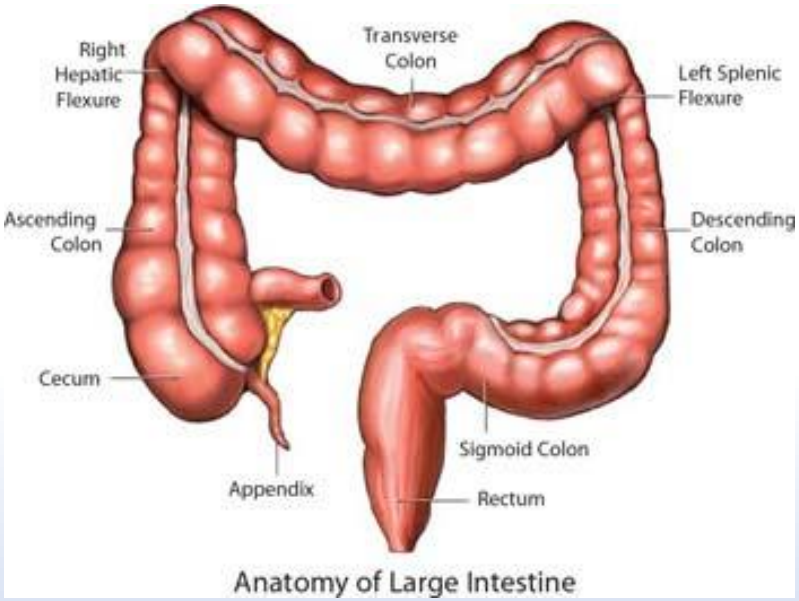

Anatomy of Large Intestine

Polyps and cancers can bleed

Blood gets excreted in the faeces

Faecal Haemoglobin (f-Hb) in Health and Disease

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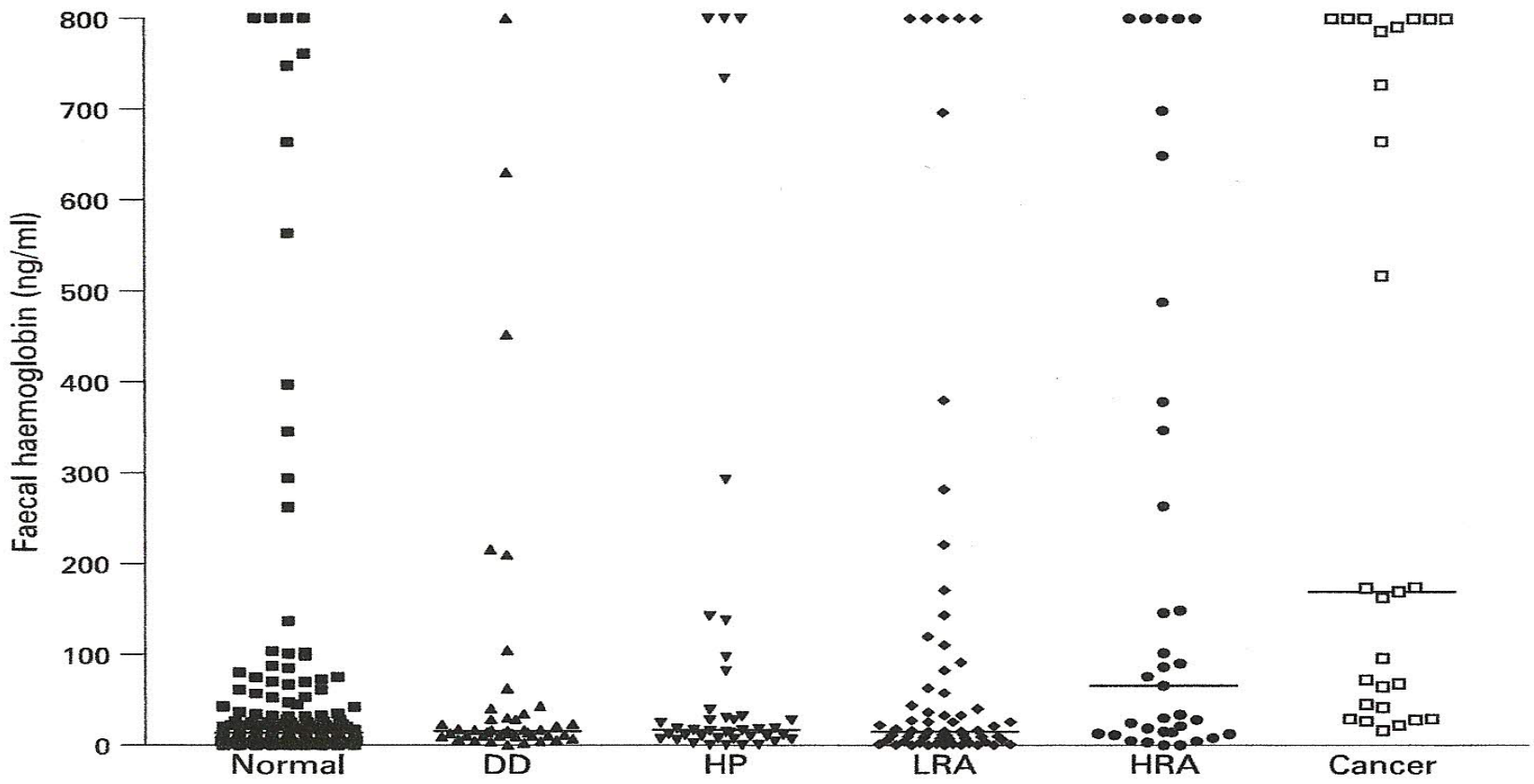
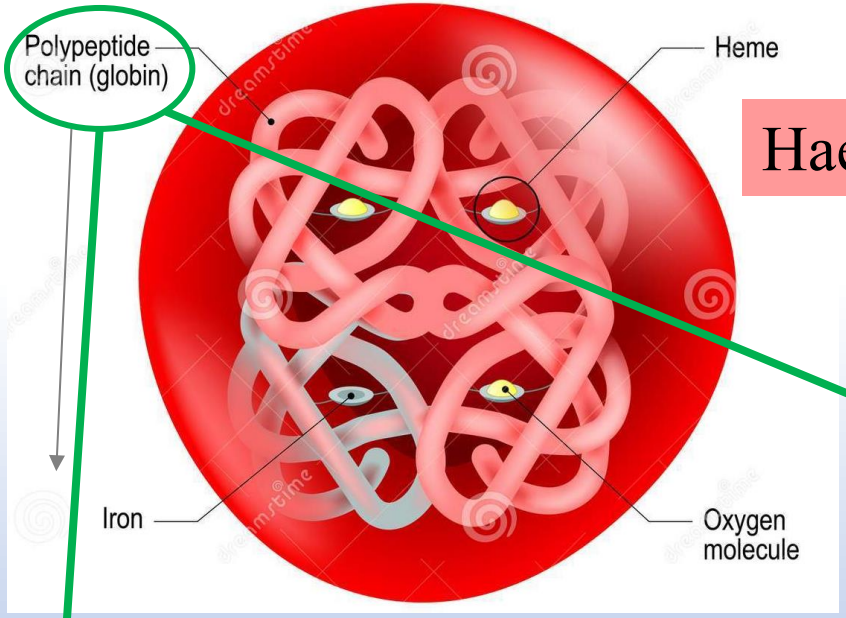


Fraser CG, et al. Gut 2008;57:1256-60

Faecal Immunochemical Test for haemoglobin (FIT)

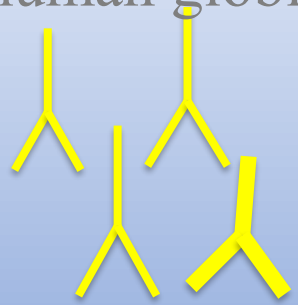
Berkshire and Surrey Path

Red blood cell



Haemoglobin

FIT has Antibodies that bind to only human globin



Different in different species

Faecal Immunochemical Test for haemoglobin (FIT)

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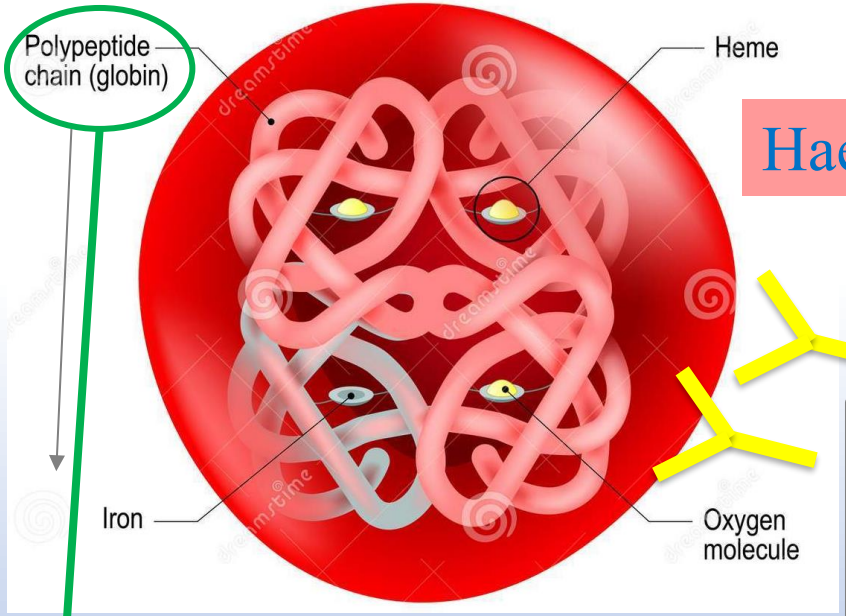
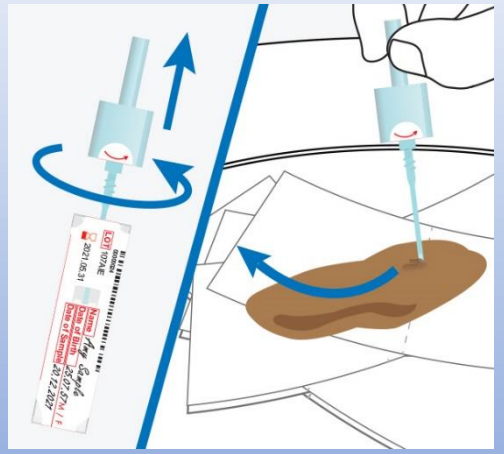
Red blood cell



Haemoglobin

Antibodies specific to human globin



Different in different species

Quantitative FIT systems

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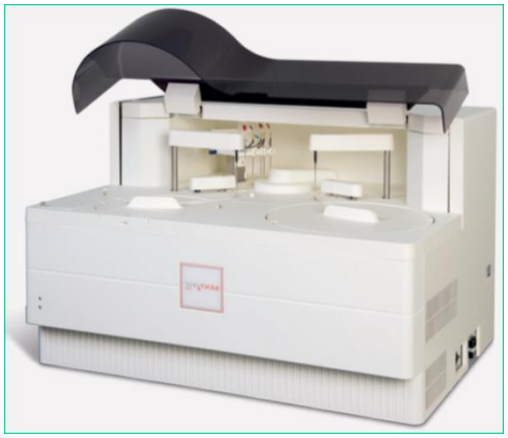
FOB gold/ SentiFIT



NS Prime

HM-JACKarc

OC Sensor PLEDIA

Piggott C, Carroll MRR, John C, O'Driscoll S, Benton SC. Analytical evaluation of four faecal immunochemistry tests for haemoglobin. Clin Chem Lab Med. 2020 Jul 21;59(1):173-178.

Quantitative FIT systems

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FOB gold

Validated CE applications on;

- Roche
- Mindray
- IL Ilab
- Beckman
- Siemens
- Jeol Biomajesty
- Ortho
- Sentinel
- Abbott

NS Prime

HM-JACKarc

OC Sensor PLEDIA

Piggott C, Carroll MRR, John C, O'Driscoll S, Benton SC. Analytical evaluation of four faecal immunochemistry tests for haemoglobin. Clin Chem Lab Med. 2020 Jul 21;59(1):173-178.

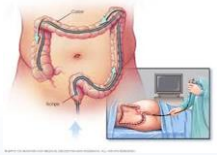
FIT in Colorectal Cancer Screening

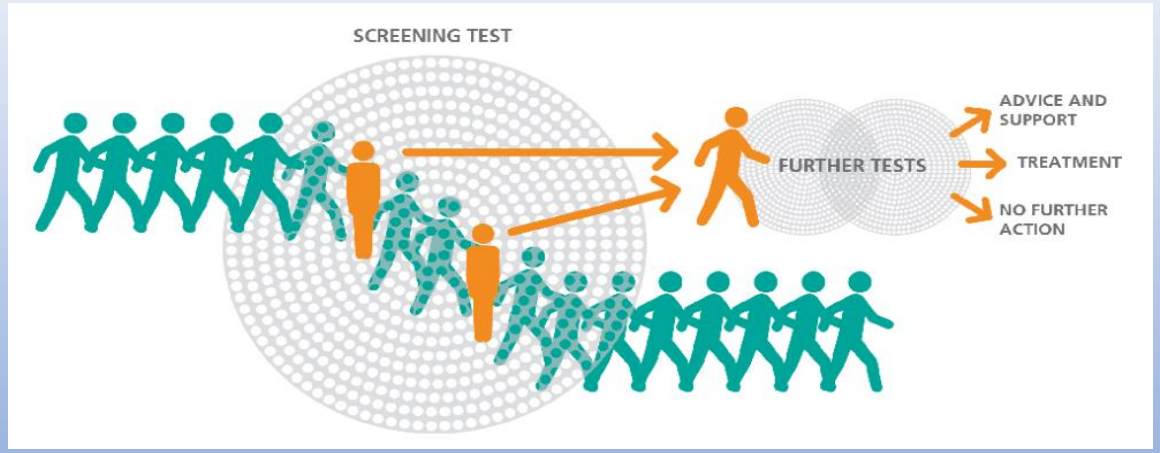
Berkshire and Surrey Pathology Services

NHS Cancer Screening Programmes

- Well established triage tool for **screening programmes** around the world

>50-60 years





FIT in Screening

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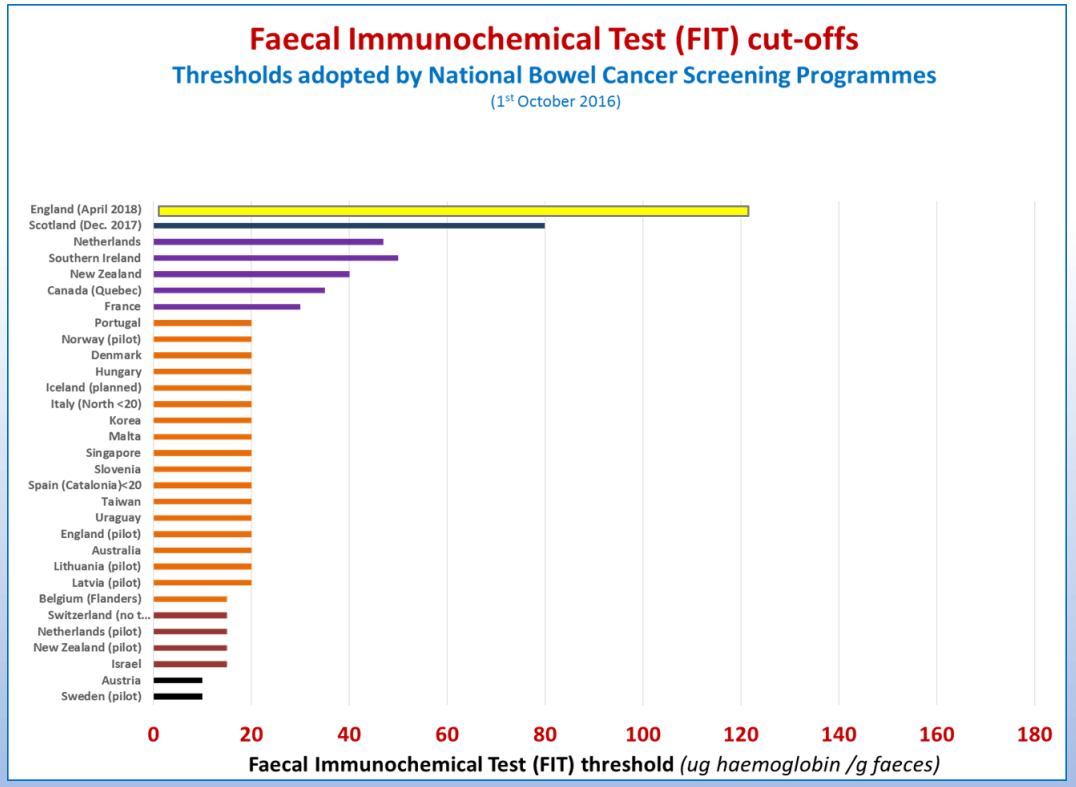
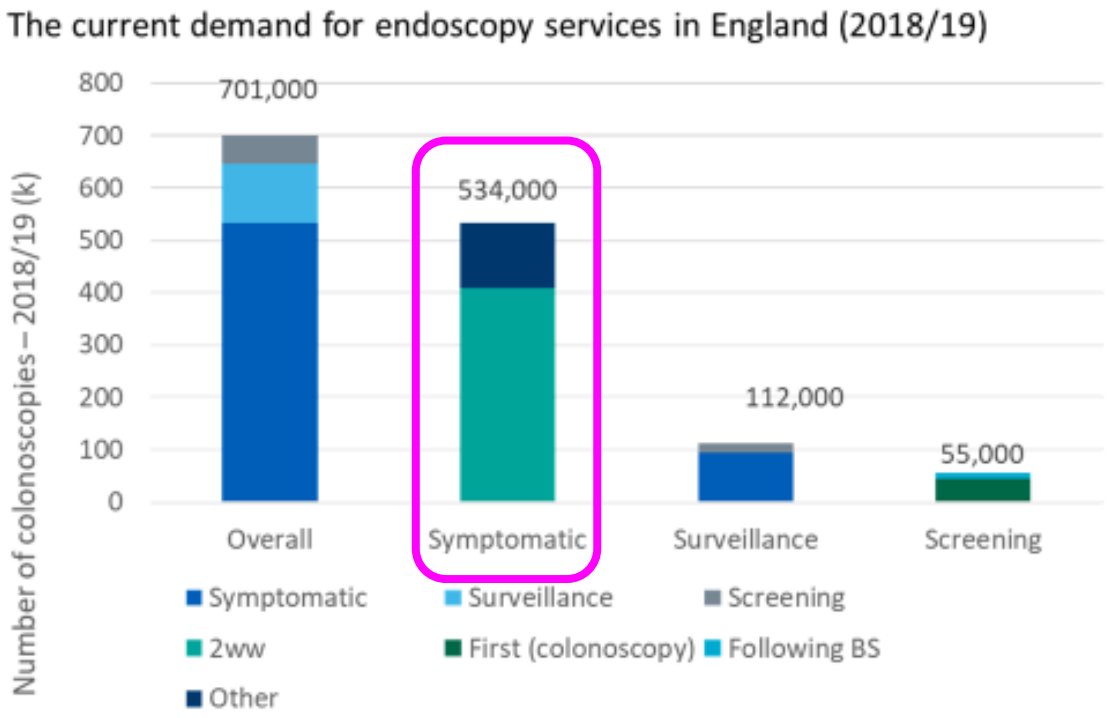
- Threshold altered depending on colonoscopy capacity



Endoscopy capacity

Berkshire and Surrey Pathology Services

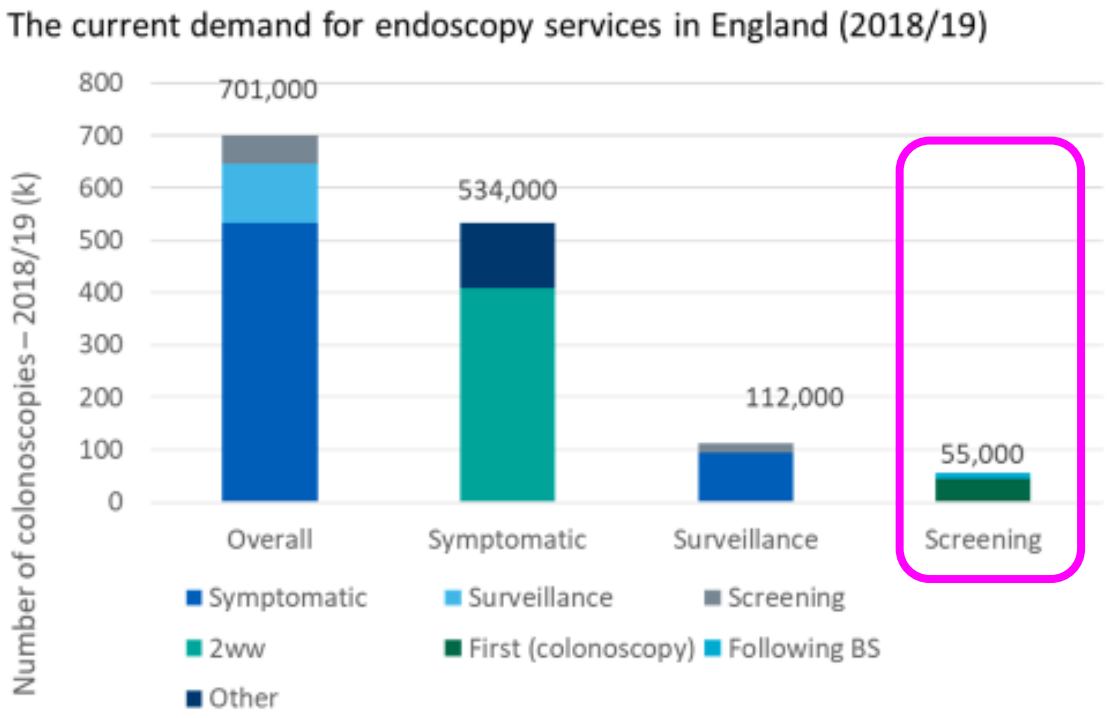


NHS England and NHS Improvement

Slide from Dr Robert Logan

Endoscopy capacity

Berkshire and Surrey Pathology Services



NHS England and NHS Improvement

Slide from Dr Robert Logan

FIT in symptomatic patients

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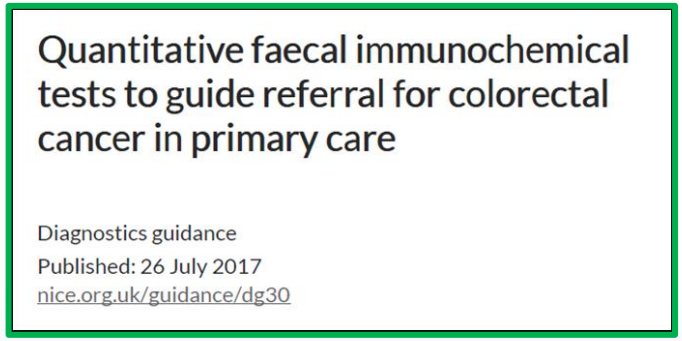
- Increasingly being used to triage **symptomatic patients** for colonoscopy
- Threshold of 10 ug Hb/g faeces - UK

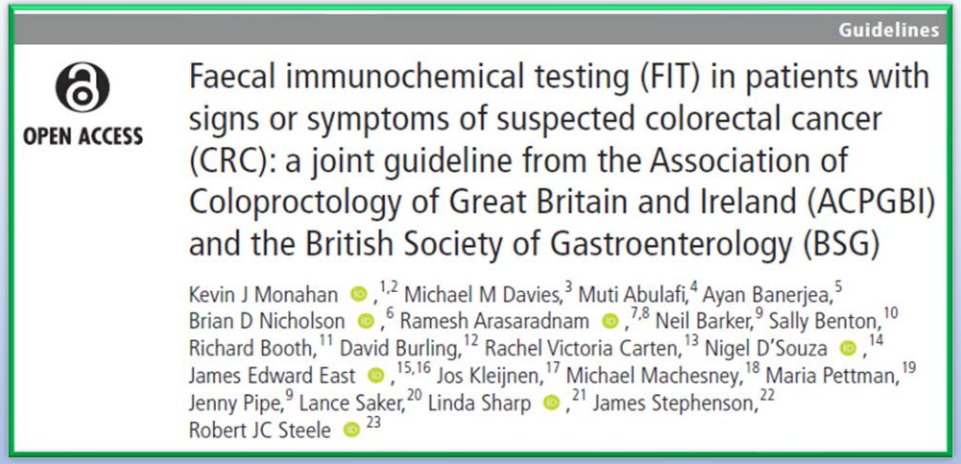


Quantitative faecal immunochemical tests to guide referral for colorectal cancer in primary care

Diagnostics guidance

Published: 26 July 2017

nice.org.uk/guidance/dg30



Guidelines

OPEN ACCESS

Faecal immunochemical testing (FIT) in patients with signs or symptoms of suspected colorectal cancer (CRC): a joint guideline from the Association of Coloproctology of Great Britain and Ireland (ACPGBI) and the British Society of Gastroenterology (BSG)

Kevin J Monahan [1,2] Michael M Davies,[3] Muti Abulafi,[4] Ayan Banerjea,[5] Brian D Nicholson [6] Ramesh Arasaradnam [7,8] Neil Barker,[9] Sally Benton,[10] Richard Booth,[11] David Burling,[12] Rachel Victoria Carten,[13] Nigel D'Souza [14] James Edward East [15,16] Jos Kleijnen,[17] Michael Machesney,[18] Maria Pettman,[19] Jenny Pipe,[9] Lance Saker,[20] Linda Sharp [21] James Stephenson,[22] Robert JC Steele [23]

NICE National Institute for Health and Care Excellence

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Quantitative faecal immunochemical testing to guide colorectal cancer pathway referral in primary care

Diagnostics guidance [DG56]

Published: 24 August 2023 Register as a stakeholder

Ref: Monahan KJ, et al Faecal immunochemical testing (FIT) in patients with signs or symptoms of suspected colorectal cancer (CRC): a joint guideline from the Association of Coloproctology of Great Britain and Ireland (ACPGBI) and the British Society of Gastroenterology (BSG). Gut. 2022 Jul 12;71(10):1939–62.

Point of Care (POC) FIT

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Quantitative POC FIT

Assessment of the analytical performance of point-of-care faecal immunochemical tests for haemoglobin

Shane O'Driscoll[1,2,3], Magdalen Carroll[1,2,3], William Maclean[3], Carolyn Piggott[1,2,3], Iain Jourdan[3] and Sally C Benton[1,2,3]

Ann Clin Biochem. 2021 May;58(3):181-189.

Qualitative POC FIT

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ARE THE FIT ASSAYS GOOD ENOUGH?

THE LABORATORY PERSPECTIVE….

Pre-analytical Variability

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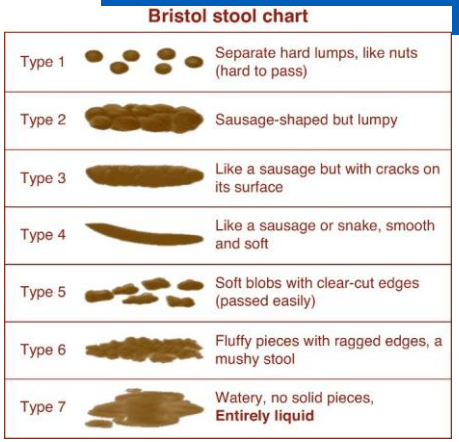
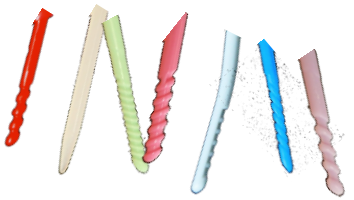
- Faeces
  - isn't homogenous
  - has variable consistency





- "Pickers" from all manufacturers are different

- Instructions from manufacturers are different
- Inconsistent sampling techniques by patients

- Haemoglobin unstable in faeces

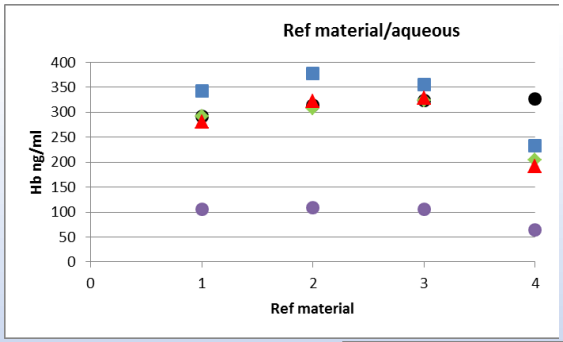
FIT laboratory challenges

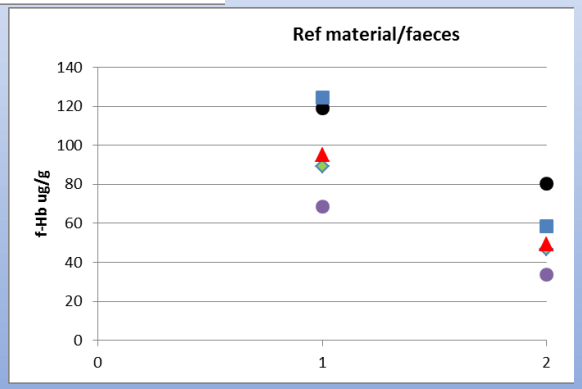
Berkshire and Surrey Pathology Services

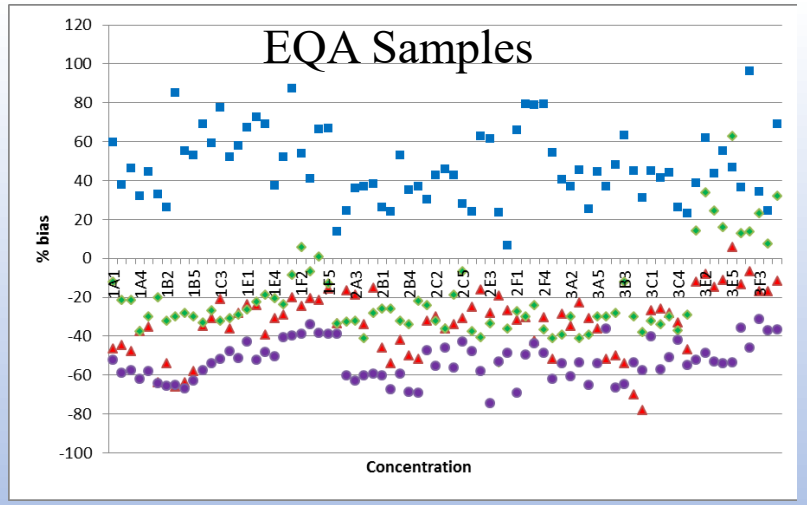
- No assay standardisation
  - Different buffers
  - Different antibodies
  - Different calibration

Different methods give different results

- No primary reference material or method







FIT laboratory challenges

Berkshire and Surrey Pathology Services

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FIT laboratory challenges

Berkshire and Surrey Pathology Services

- No assay standardisation
  - Different buffers
  - Different antibodies
  - Different calibration

Different methods give different results

- No primary reference material or method
- External Quality Assurance scheme challenges
- Third party Internal Quality Control

FIT EQA Scheme Challenges

Berkshire and Surrey Pathology Services

- Matrix – how to make a faecal like matrix?
- Hb is unstable – how to stabilise Hb in the matrix?
- Do we need to measure Hb in a faecal like matrix?

Examples of Faecal–like EQA samples

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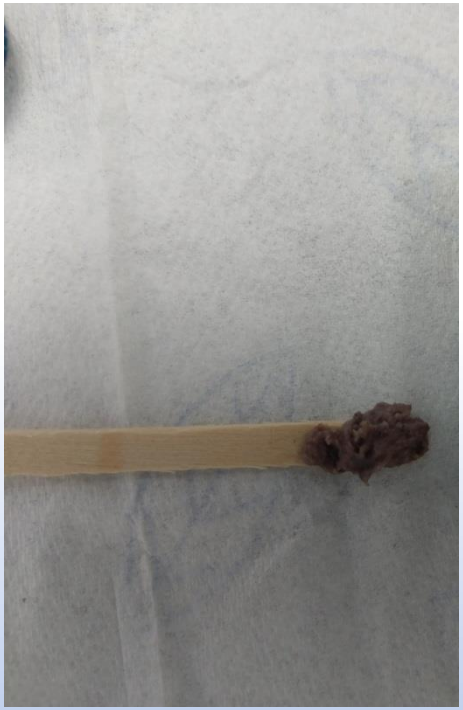

Example EQA report

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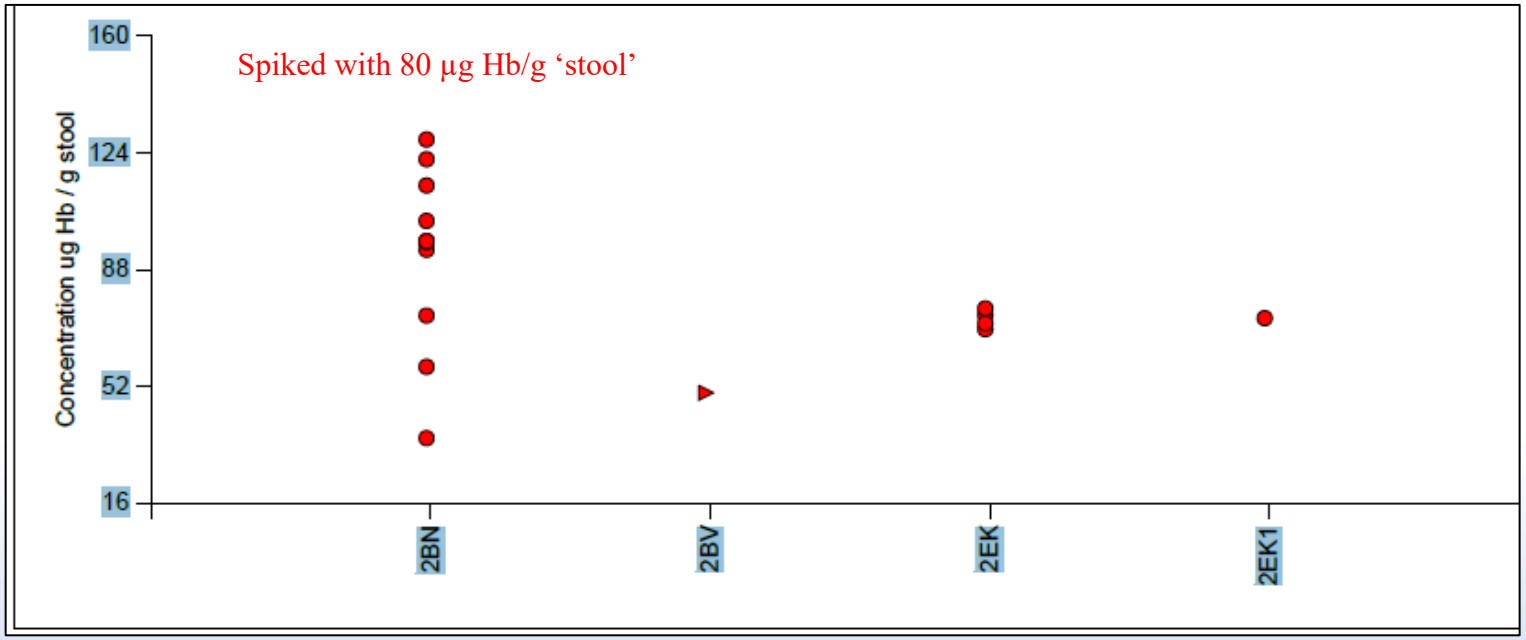

- EQA report results – high between lab variability
  - *?pre-analytical variability Or analytical variability*

- Labs need to be able to assess analytical variability

EQA for FIT

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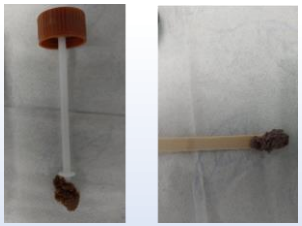
Cancer Screening Programmes

- What is the best matrix for EQA material to be provided in?
- *Labs receive FIT tubes NOT faecal samples from patients*
  - Faecal like matrix



  - Lyophilised samples
  - Pre-loaded devices


Brussels 2018

ifcc International Federation of Clinical Chemistry and Laboratory Medicine

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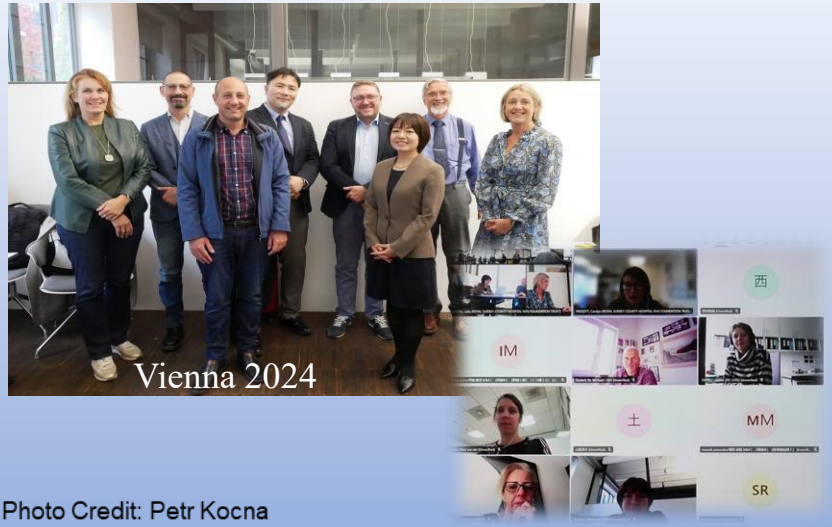
Vienna 2018


Barcelona 2019

IFCC FIT WORKING GROUP
ESTABLISHED 2017




Brussels May 2025

Photo Credit: Petr Kocna

IFCC FIT Working group

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Terms of Reference

- To harmonise and/or standardise analysis of haemoglobin in faecal samples by immunochemistry (FIT)
- To establish EQA and 3rd party IQC programmes
- To determine the feasibility of developing reference materials and/or commutable calibrators
- The IFCC FIT-WG can provide recommendations and guidance on preanalytical and analytical aspects of FIT

Current projects

- Identification of a suitable reference material and assessment of commutability for all available laboratory quantitative FIT methods
- Review of all FIT EQA programmes currently available globally

ifcc
International Federation of Clinical Chemistry and Laboratory Medicine

https://ifcc.org/ifcc-scientific-division/sd-working-groups/wg-fit/

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STANDARDISATION/ HARMONISATION SUB-GROUP

Comparison and commutability of FIT methods

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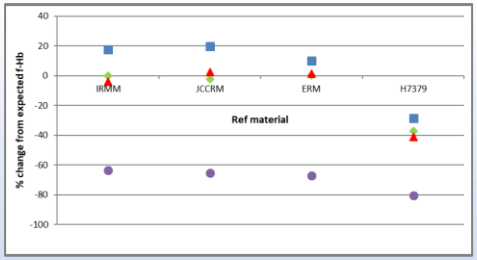
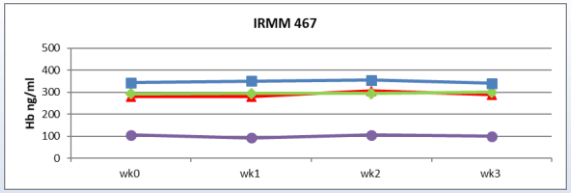
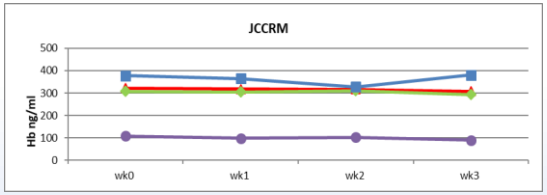
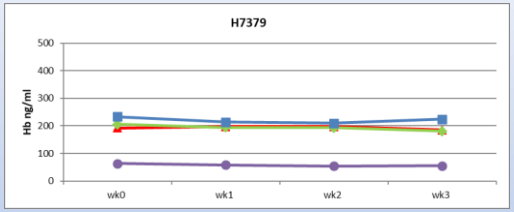
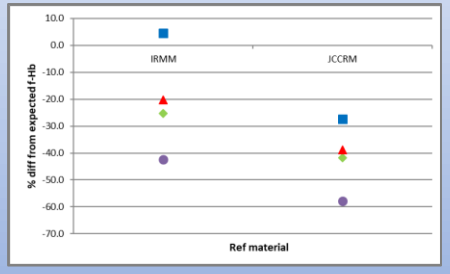
- Significant difference observed between quantitative results on different methods
- A common threshold cannot currently be applied

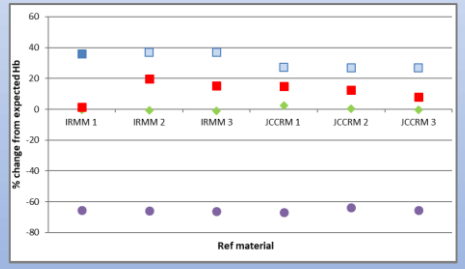


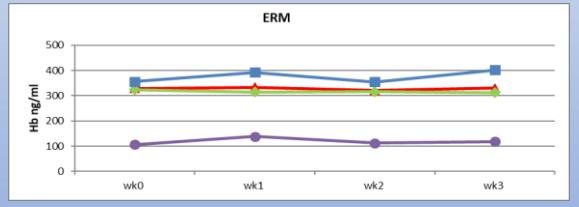












Ideal Calibration hierarchy

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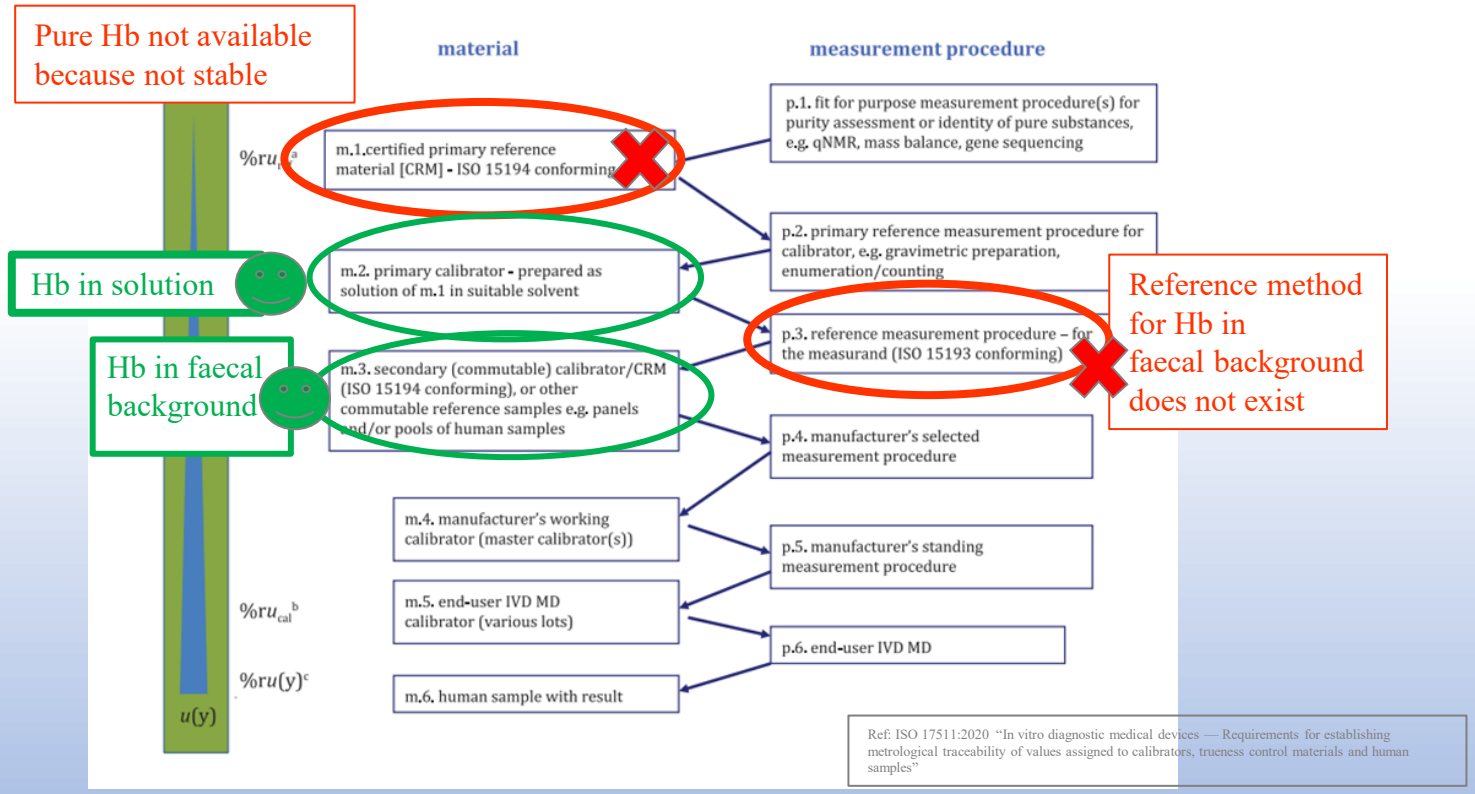

Alternative (lower) calibration hierarchy – 2 options

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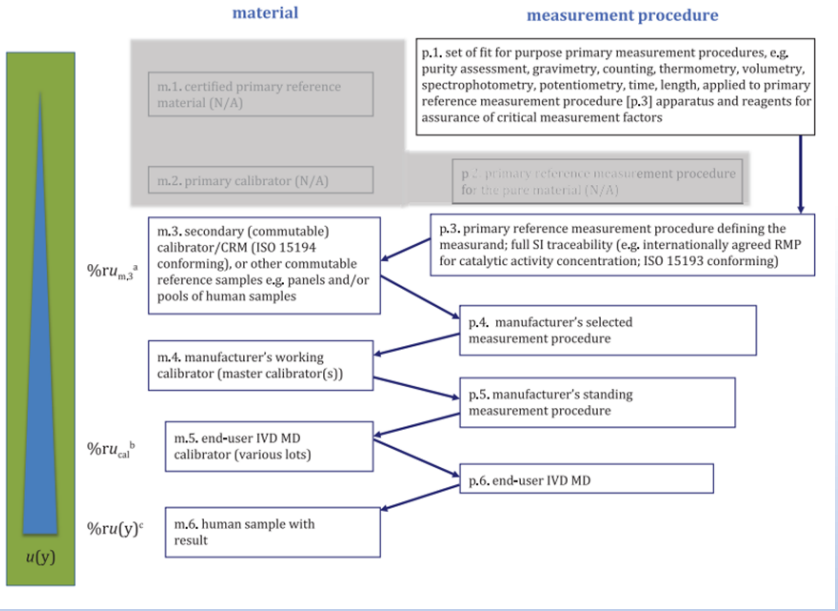

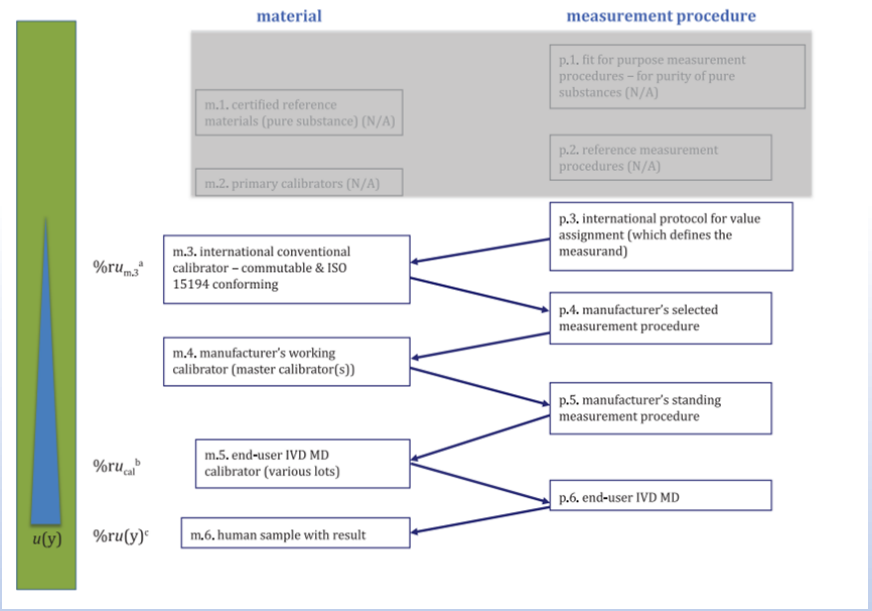

Harmonisation NOT standardisation

Alternative (lower) calibration hierarchy – 2 options

Berkshire and Surrey Pathology Services

Standardisation requires primary measurement procedure and primary reference material for the analyte.
This isn't available for the measurement of Hb in faeces

"The method harmonisation process as compared with the standardisation process may be biased and possible only in a method-dependent manner with no long-term anchor of trueness to a reference measurement system available"

Harmonisation = Results will compare well with each other because traceable to a common standard.

Harmonisation NOT standardisation

Harmonisation summary

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- A certified reference material (CRM) has been identified
- CRM needs to be in a lyophilised form for long term stability
- The CRM needs to be diluted in the FIT system specific extraction buffer
- CRM should be available within the next 2 years
- Once CRM is available, international harmonisation is dependent on FIT manufacturers re-calibrating their methods to the CRM

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EQA SUB-GROUP

IFCC EQA progress

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- Survey carried out of all EQA providers globally
- Detail on FIT EQA schemes collated
- Being written up for publication along with suggestions for a “good” FIT EQA scheme

European Country	EQA Organization with a FIT scheme
Czech Republic	SEKK
France	CTCB
Germany	INSTAND e.V.
Germany	RfB
Norway	NOKLUS
Switzerland	CSCQ
Switzerland	MQ
The Netherlands	SKML
United Kingdom	UK NEQAS
United Kingdom	Weqas
Finland	Labquality
Italy	CRRVEQ
Italy	CQLAB

ifcc
International Federation of Clinical Chemistry and Laboratory Medicine

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ARE THE FIT ASSAYS GOOD ENOUGH?

Analytical performance of laboratory FIT methods

NHS
Berkshire and Surrey Pathology Services

DE GRUYTER Clin Chem Lab Med 2020; aop

Carolyn Piggott*, Magdalen R. R. Carroll, Cerin John, Shane O'Driscoll and Sally C. Benton

Analytical evaluation of four faecal immunochemistry tests for haemoglobin

https://doi.org/10.1515/cclm-2020-0251
Received March 4, 2020; accepted June 29, 2020; published online xxx

Abstract

Background: Faecal immunochemical tests (FIT) for haemoglobin (Hb) are being used in the investigation of colorectal cancer. These tests use antibodies raised to the globin moiety of human Hb. Here, four automated quantitative FIT systems (HM-JACKarc, NS-Prime, OC-Sensor PLEDIA and SENTiFIT 270) are evaluated analytically to confirm whether the performance of the systems meet the manufacturers' claims.

Methods: Assessment of the analytical performance of the FIT systems was undertaken using Hb lysates, real patient samples and external quality assessment (EQA) samples. This analytical assessment focused on detection characteristics, imprecision, linearity, prozone effect, recovery and carryover.

Results: All four methods demonstrated good analytical performance, with acceptable within- and between-run imprecision, good recovery of f-Hb and limited carryover of samples. They also all show good linearity across the range of concentrations tested. The results of EQA samples showed different variations from the target values (−52 to 45%), due to the absence of standardisation across the different methods.

Conclusions: All four systems are fit for purpose and have an analytical performance as documented by their manufacturers.

Keywords: analytical evaluation; colorectal cancer; faecal immunochemical test; FIT.

Introduction

The quantitative faecal immunochemical test for haemoglobin (FIT) measures the concentration of human blood in faeces using polyclonal antibodies raised against the globin moiety of human haemoglobin (Hb). These tests are being used worldwide for both screening of asymptomatic individuals [1] and to aid the assessment of patients with low risk symptoms [2]. Although these tests are not currently widely used in the diagnosis and monitoring of inflammatory bowel diseases such as Crohn's disease and ulcerative colitis, there is potential for this use and studies are being carried out [3].

FIT has superseded the use of guaiac faecal occult blood testing (gFOBT). FIT offers advantages over gFOBT which include quantitative examination with the option to choose the cut-off for positive results, with low cut-offs for the triage of symptomatic patients, and higher cut-offs for asymptomatic participants in screening programmes, the antibodies are specific to human Hb, and the examination can be carried out on semi-automated instruments. One FIT collection device requiring a single faecal sample is

FOB gold/ SentiFIT

NS Prime

HM-JACKarc

OC Sensor PLEDIA

Piggott C, Carroll MRR, John C, O'Driscoll S, Benton SC. Analytical evaluation of four faecal immunochemistry tests for haemoglobin. Clin Chem Lab Med. 2020 Jul 21;59(1):173-178.

Are the FIT assays good enough…..?

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- Pre-analytical variability

  Not much we can do about this

- Do the methods perform acceptably analytically
  - Yes

- Need to address
  - Standardisation/ harmonisation
  - EQA
  - IQC

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WHAT IS THE SYMPTOMATIC THRESHOLD

Early Evidence Base for f-Hb in Symptomatic patients

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Good rule out test

Does miss cancers

Author	Year	Country	Patients in study	NPV	PPV	Sensitivity	Specificity	Number of cancers	Cancers missed
Mowat et al *	2015	Scotland	755	**99.5**	14.2	89.3	79.1	28.0	3.0
Rodriguez-Alonso et al *	2015	Spain	1003	**99.9**	12.8	96.7	79.8	30	1
Godber et al **	2015	Scotland	484	**100**		100		11	0
Droste et al *	2011	Netherlands	2145			92.4	86.4	79	6
McDonald et al *	2012	Scotland	280	**100**	7.6	100	93.9	6	0

*OC-Sensor
** HM-JACK

Quantitative faecal immunochemical tests to guide referral for colorectal cancer in primary care

Diagnostics guidance

Published: 26 July 2017

nice.org.uk/guidance/dg30

July 2017

NHS

Berkshire and Surrey Pathology Services

Recommends use of FIT in primary care referral pathway.

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

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.

1.3 Commissioning groups adopting the OC Sensor, HM-JACKarc and FOB Gold should audit their outcomes and monitor the associated resource use (see section 6.1).

Cut-off to be used; 10ug Hb/ g faeces

Quantitative faecal immunochemical tests to guide referral for colorectal cancer in primary care

Diagnostics guidance

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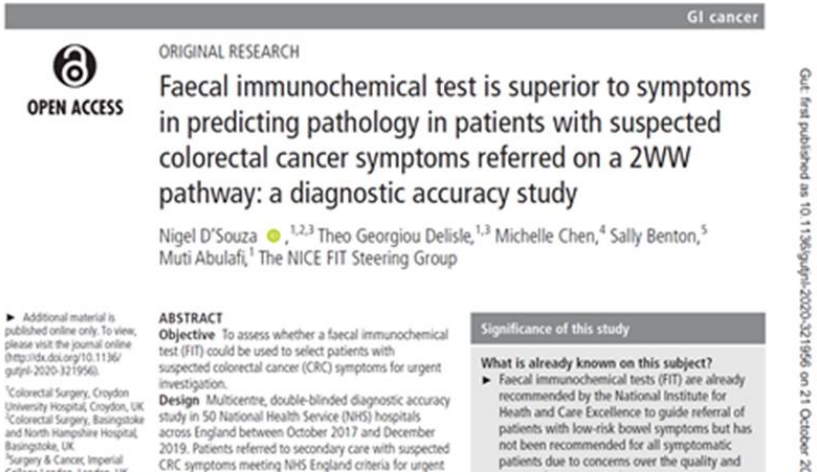
Lots and lots of emerging evidence since 2017

NICE FIT Study

Berkshire and Surrey Pathology Services



GI cancer

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ORIGINAL RESEARCH

Faecal immunochemical test is superior to symptoms in predicting pathology in patients with suspected colorectal cancer symptoms referred on a 2WW pathway: a diagnostic accuracy study

Nigel D'Souza [1,2,3] Theo Georgiou Delisle,[1,3] Michelle Chen,[4] Sally Benton,[5] Muti Abulafi,[1] The NICE FIT Steering Group

ABSTRACT

Objective To assess whether a faecal immunochemical test (FIT) could be used to select patients with suspected colorectal cancer (CRC) symptoms for urgent investigation.

Design Multicentre, double-blinded diagnostic accuracy study in 50 National Health Service (NHS) hospitals across England between October 2017 and December 2019. Patients referred to secondary care with suspected CRC symptoms meeting NHS England criteria for urgent

Significance of this study

What is already known on this subject?

- Faecal immunochemical tests (FIT) are already recommended by the National Institute for Heath and Care Excellence to guide referral of patients with low-risk bowel symptoms but has not been recommended for all symptomatic patients due to concerns over the quality and

Gut: first published as 10.1136/gutjnl-2020-321956 on 21 October 2

- Multicentre, double-blinded diagnostic accuracy study
- 50 NHS Hospitals
- October 2017 – December 2019
- >10,000 TWR referrals

Table 3 Diagnostic accuracy of FIT for CRC at different cut-offs

Cut-off (µg/g)	Positivity (%)	NNS	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	TP	FN	FP	TN
2	37.2	11.5	97.0 (94.5 to 98.5)	64.9 (63.9 to 65.8)	8.7 (7.8 to 9.7)	99.8 (99.7 to 99.9)	319	10	3336	6157
10	19.0	6.2	90.9 (87.2 to 93.8)	83.5 (82.8 to 84.3)	16.1 (14.4 to 17.8)	99.6 (99.5 to 99.7)	299	30	1563	7930
150	7.6	3.2	70.8 (65.6 to 75.7)	94.6 (94.1 to 95.0)	31.1 (27.8 to 34.6)	98.9 (98.7 to 99.1)	233	96	516	8977
<2	62.8	616.7	3 (1.5 to 5.5)	35.1 (34.2 to 36.1)	0.2 (0.1 to 0.3)	91.3 (90.3 to 92.2)	10	319	6157	3336

95% CIs within brackets.

CRC, colorectal cancer; FIT, faecal immunochemical test; FN, false negatives; FP, false positives; NNS, number needed to scope; NPV, negative predictive value; PPV, positive predictive value; TN, true negatives; TP, true positives.

July 2022

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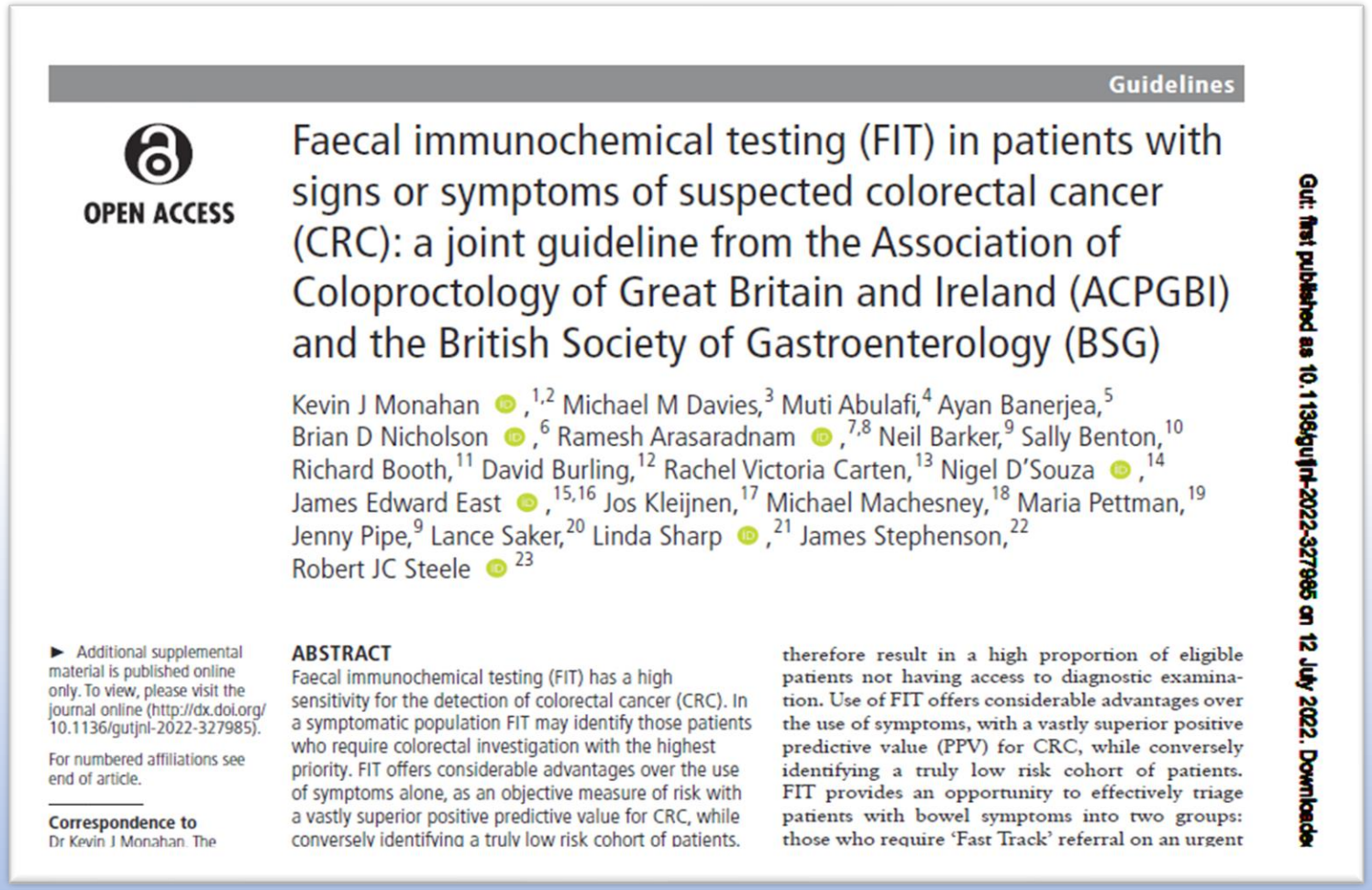

Guidelines

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Faecal immunochemical testing (FIT) in patients with signs or symptoms of suspected colorectal cancer (CRC): a joint guideline from the Association of Coloproctology of Great Britain and Ireland (ACPGBI) and the British Society of Gastroenterology (BSG)

Kevin J Monahan ,[1,2] Michael M Davies,[3] Muti Abulafi,[4] Ayan Banerjea,[5] Brian D Nicholson ,[6] Ramesh Arasaradnam ,[7,8] Neil Barker,[9] Sally Benton,[10] Richard Booth,[11] David Burling,[12] Rachel Victoria Carten,[13] Nigel D'Souza ,[14] James Edward East ,[15,16] Jos Kleijnen,[17] Michael Machesney,[18] Maria Pettman,[19] Jenny Pipe,[9] Lance Saker,[20] Linda Sharp ,[21] James Stephenson,[22] Robert JC Steele [23]

► Additional supplemental material is published online only. To view, please visit the journal online (http://dx.doi.org/10.1136/gutjnl-2022-327985).

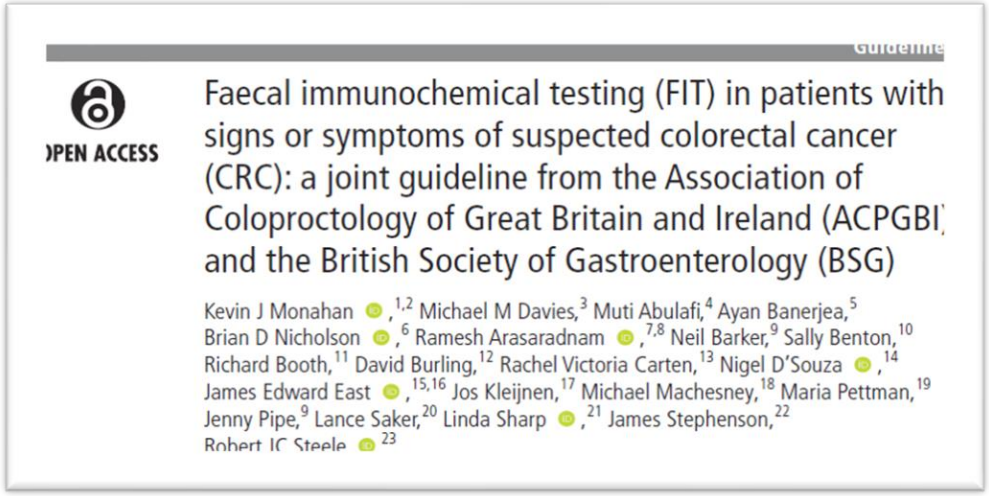
For numbered affiliations see end of article.

Correspondence to
Dr Kevin J Monahan, The

ABSTRACT

Faecal immunochemical testing (FIT) has a high sensitivity for the detection of colorectal cancer (CRC). In a symptomatic population FIT may identify those patients who require colorectal investigation with the highest priority. FIT offers considerable advantages over the use of symptoms alone, as an objective measure of risk with a vastly superior positive predictive value for CRC, while conversely identifying a truly low risk cohort of patients. FIT provides an opportunity to effectively triage patients with bowel symptoms into two groups: those who require 'Fast Track' referral on an urgent

Ref: Monahan KJ, et al Faecal immunochemical testing (FIT) in patients with signs or symptoms of suspected colorectal cancer (CRC): a joint guideline from the Association of Coloproctology of Great Britain and Ireland (ACPGBI) and the British Society of Gastroenterology (BSG). Gut. 2022 Jul 12;71(10):1939–62.



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NICE National Institute for Health and Care Excellence

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Home > NICE Guidance > Conditions and diseases > Cancer > Colorectal cancer

Quantitative faecal immunochemical testing to guide colorectal cancer pathway referral in primary care

Diagnostics guidance [DG56]
Published: 24 August 2023 Register as a stakeholder

- Can be used in all adults presenting to primary care
- Refer adults using a suspected cancer pathway referral for CRC if they have a f-Hb ≥10 µg/g
- Further research required in people aged under 40 years

Ref: Monahan KJ, et al Faecal immunochemical testing (FIT) in patients with signs or symptoms of suspected colorectal cancer (CRC): a joint guideline from the Association of Coloproctology of Great Britain and Ireland (ACPGBI) and the British Society of Gastroenterology (BSG). Gut. 2022 Jul 12;71(10):1939–62.

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Faecal immunochemical test is superior to symptoms in predicting pathology in patients with suspected colorectal cancer symptoms referred on a 2WW pathway: a diagnostic accuracy study

Nigel D'Souza ,[1,2,3] Theo Georgiou Delisle,[1,3] Michelle Chen,[4] Sally Benton,[5] Muti Abulafi,[1] The NICE FIT Steering Group

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CRC, colorectal cancer; FIT, faecal immunochemical test; FN, false negatives; FP, false positives; NNS, number needed to scope; NPV, negative predictive value; PPV, positive predictive value; TN, true negatives; TP, true positives.

There is a small risk of missed cancers

There are lots of false positives
- Resource implications if all these have colonoscopy

D'Souza N, Georgiou Delisle T, Chen M, Benton S, Abulafi M. Faecal immunochemical test is superior to symptoms in predicting pathology in patients with suspected colorectal cancer symptoms referred on a 2WW pathway: a diagnostic accuracy study. Gut. 2020.

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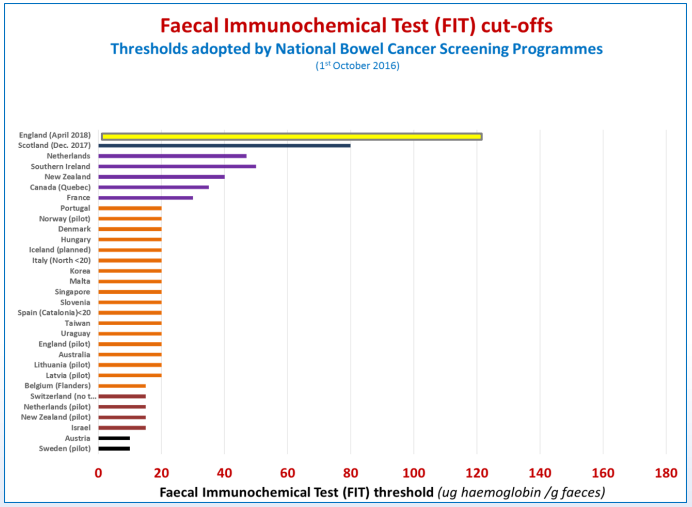
REFINING THE USE OF FIT

Refining the use of FIT

Berkshire and Surrey Pathology Services

- FIT currently used with a single f-Hb cut-off



- **Screening – defined by colonoscopy capacity**

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- **Symptomatic – defined by clinical sensitivity**

Symptomatic FIT activity (BSPS lab)……

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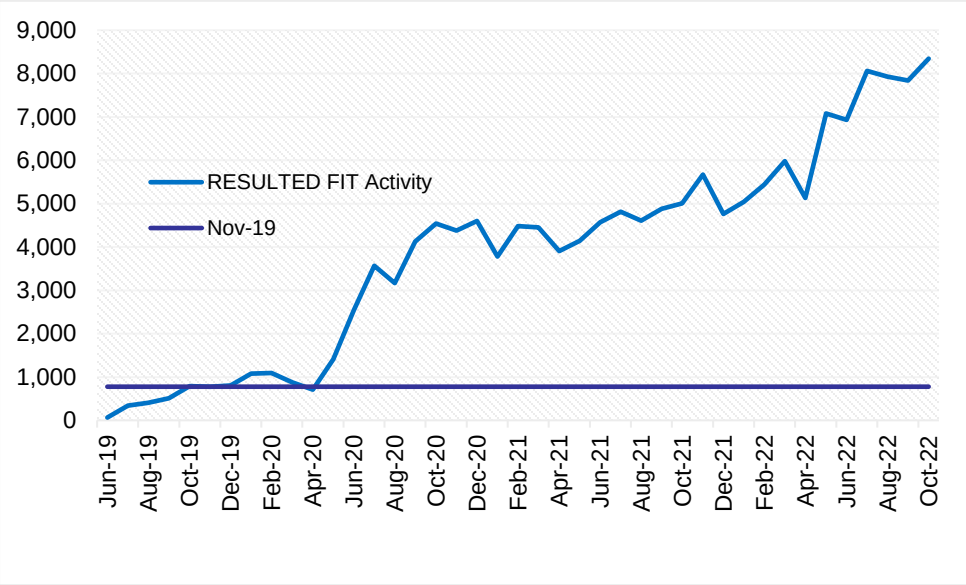
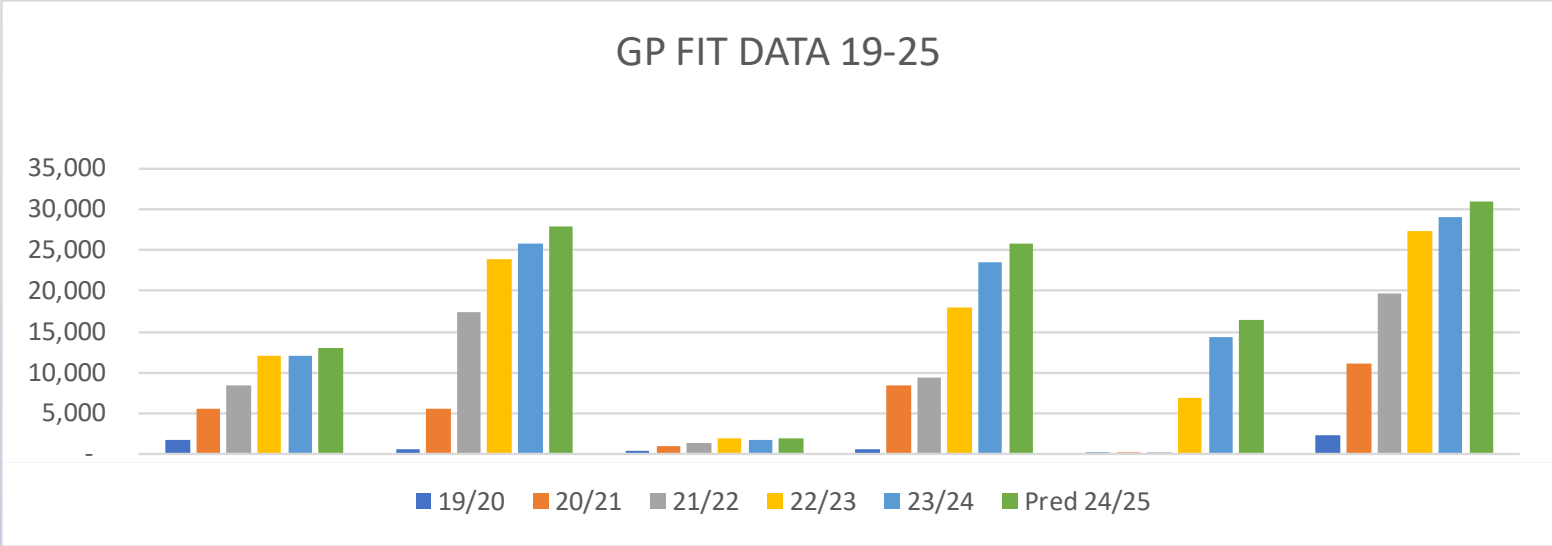
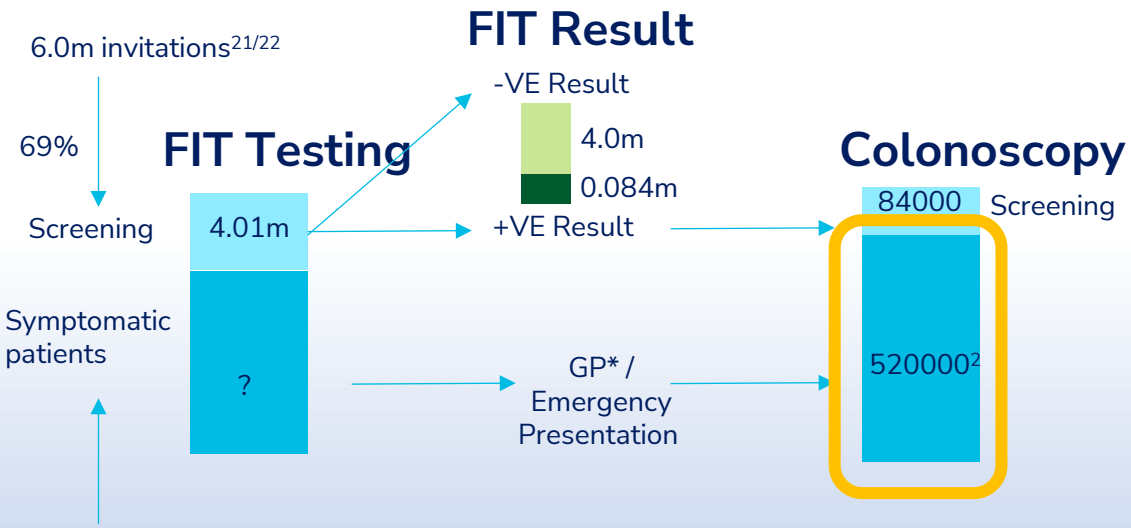


- Continuing to increase
- Anticipated to increase further





Outcome available

7.7% confirmed cancer

26% Adenoma (non-adv. + adv)

~ 4% confirmed Cancer

1. Bowel Cancer Screening Annual Report 2021 to 2022. 2. NHS Diagnostic Waiting Times and Activity Data 2024,

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ORIGINAL RESEARCH

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Refining the use of FIT

Berkshire and Surrey Pathology Services

- F-Hb ≤10 µg/g
  - Good Sensitivity (>90%)
  - NPV = 99.6% *
  - PPV = 16.1% *
- How can we maintain acceptable sensitivity but improve PPV?
  - Risk Stratification
  - Different biomarkers

* Faecal immunochemical test is superior to symptoms in predicting pathology in patients with suspected colorectal cancer symptoms diagnosed on a 2WW pathway: a diagnostic accuracy study. Nigel D'Souza et al. Gut doi:10.1136/gutjnl-2020-321956

Research

James L Turvill, Daniel Turnock, Dan Cottingham, Monica Haritakis, Laura Jeffery, Annabelle Girdwood, Tom Hearfield, Alex Mitchell and Ada Keding

NHS
Berkshire and Surrey Pathology Services

The Fast Track FIT study:

diagnostic accuracy of faecal immunochemical test for haemoglobin in patients with suspected colorectal cancer

- Statistically optimal cut off for CRC = 19 µg/g

Table 1. Primary outcome analysis and subgroup analyses

	N	Cases, *n* (%)	Optimal cut-off, µg/g	Sensitivity, % (95% CI)	Specificity, % (95% CI)	PPV, % (95% CI)	NPV, % (95% CI)	AUC (95% CI)
Primary outcome								
All participants with formal investigations	5040	151 (3.0)	19	85.4 (78.8 to 90.6)	85.2 (84.1 to 86.2)	15.1 (12.8 to 17.7)	99.5 (99.2 to 99.7)	0.89 (0.86 to 0.92)
Subgroup analyses								
Age, years								
<60	1217	30 (2.5)	37	90.0 (73.5 to 97.9)	87.4 (85.4 to 89.3)	15.3 (10.4 to 21.5)	99.7 (99.2 to 99.9)	0.92 (0.88 to 0.96)
≥60	3823	121 (3.2)	19	83.5 (75.6 to 89.6)	85.4 (84.2 to 86.5)	15.7 (13.0 to 18.8)	99.4 (99.0 to 99.6)	0.88 (0.85 to 0.92)
Sex								
Male	2242	89 (4.0)	21	85.4 (76.3 to 92.0)	83.7 (82.0 to 85.2)	17.8 (14.3 to 21.7)	99.3 (98.8 to 99.6)	0.89 (0.86 to 0.93)
Female	2798	62 (2.2)	16	87.1 (76.1 to 94.3)	85.6 (84.2 to 86.9)	12.0 (9.2 to 15.4)	99.7 (99.3 to 99.9)	0.88 (0.82 to 0.93)
Change in bowel habit								
Yes	3467	89 (2.6)	16	85.4 (76.3 to 92.0)	85.8 (84.5 to 86.9)	13.6 (10.9 to 16.8)	99.6 (99.2 to 99.8)	0.89 (0.85 to 0.93)
No	1573	62 (3.9)	21	87.1 (76.1 to 94.3)	82.3 (80.2 to 84.2)	16.8 (12.9 to 21.3)	99.4 (98.7 to 99.7)	0.89 (0.84 to 0.93)
Rectal bleeding								
Yes	1912	77 (4.0)	37	90.9 (82.2 to 96.3)	83.2 (81.4 to 84.8)	18.5 (14.7 to 22.7)	99.5 (99.1 to 99.8)	0.90 (0.87 to 0.93)
No	3128	74 (2.4)	10	79.7 (68.8 to 88.2)	84.0 (82.6 to 85.3)	10.8 (8.3 to 13.7)	99.4 (99.0 to 99.7)	0.87 (0.82 to 0.92)
Abdominal pain								
Yes	1722	47 (2.7)	10	85.1 (71.7 to 93.8)	82.5 (80.6 to 84.3)	12.0 (8.7 to 16.0)	99.5 (99.0 to 99.8)	0.88 (0.83 to 0.93)
No	3318	104 (3.1)	37	85.6 (77.3 to 91.7)	88.4 (87.2 to 89.5)	19.2 (15.7 to 23.1)	99.5 (99.1 to 99.7)	0.90 (0.86 to 0.93)
Weight loss								
Yes	1093	38 (3.5)	13	89.5 (75.2 to 97.1)	83.1 (80.7 to 85.3)	16.0 (11.4 to 21.7)	99.5 (98.8 to 99.9)	0.88 (0.82 to 0.94)
No	3947	113 (2.9)	19	85.8 (78.0 to 91.7)	85.0 (83.8 to 86.1)	14.4 (11.9 to 17.3)	99.5 (99.2 to 99.7)	0.89 (0.86 to 0.93)
ID anaemia[a]								
Yes	559	34 (6.1)	21	82.4 (65.5 to 93.2)	81.5 (77.9 to 84.8)	22.4 (15.4 to 30.7)	98.6 (97.0 to 99.5)	0.87 (0.80 to 0.93)
No	3582	101 (2.8)	19	88.1 (80.2 to 93.7)	85.3 (84.0 to 86.4)	14.8 (12.0 to 17.9)	99.6 (99.3 to 99.8)	0.90 (0.87 to 0.93)

Turvill JL, Turnock D, Cottingham D, Haritakis M, Jeffery L, Girdwood A, Hearfield T, Mitchell A, Keding A. The Fast Track FIT study: diagnostic accuracy of faecal immunochemical test for haemoglobin in patients with suspected colorectal cancer. Br J Gen Pract. 2021 Jul 29;71(709):e643-e651. doi: 10.3399/BJGP.2020.1098. PMID: 33798091; PMCID: PMC8279659.

Faecal haemoglobin

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- Higher in men than women
- F-Hb increase with age
- Higher concentrations mean a higher risk of serious disease

Should we have different thresholds and pathways depending on age and sex?

Received: 31 August 2023 | Revised: 13 October 2023 | Accepted: 7 November 2023

DOI: 10.1111/codi.16848

ORIGINAL ARTICLE

'Low' faecal immunochemical test (FIT) colorectal cancer: a 4-year comparison of the Nottingham '4F' protocol with FIT10 in symptomatic patients

J. A. Bailey[1,2] | A. J. Morton[1,2,3] | J. Jones[1] | C. J. Chapman[4] | S. Oliver[5] | J. R. Morling[5,6] | H. Patel[5] | D. J. Humes[1,3] | A. Banerjea[1]

Nottingham Colorectal Service

Received: 6 April 2023 | First decision: 24 April 2023 | Accepted: 22 June 2023

DOI: 10.1111/apt.17632

AP&T Alimentary Pharmacology & Therapeutics WILEY

Understanding colorectal cancer risk for symptomatic patients in primary care: A cohort study utilising faecal immunochemical tests and blood results in England

Colin J. Crooks[1] | Ayan Banerjea[2] | James Jones[2] | Caroline Chapman[3] | Simon Oliver[4] | Joe West[1,5] | David J. Humes[1,2]

Bailey JA, Morton AJ, Jones J, Chapman CJ, Oliver S, Morling JR, Patel H, Humes DJ, Banerjea A. 'Low' faecal immunochemical test (FIT) colorectal cancer: a 4-year comparison of the Nottingham '4F' protocol with FIT10 in symptomatic patients. Colorectal Dis. 2024 Feb;26(2):309-316. doi: 10.1111/codi.16848. Epub 2024 Jan 3. PMID: 38173125.

Crooks CJ, Banerjea A, Jones J, Chapman C, Oliver S, West J, Humes DJ. Understanding colorectal cancer risk for symptomatic patients in primary care: A cohort study utilising faecal immunochemical tests and blood results in England. Aliment Pharmacol Ther. 2023 Aug;58(4):443-452. doi: 10.1111/apt.17632. Epub 2023 Jul 8. PMID: 37421214.

Nottingham symptomatic FIT pathway

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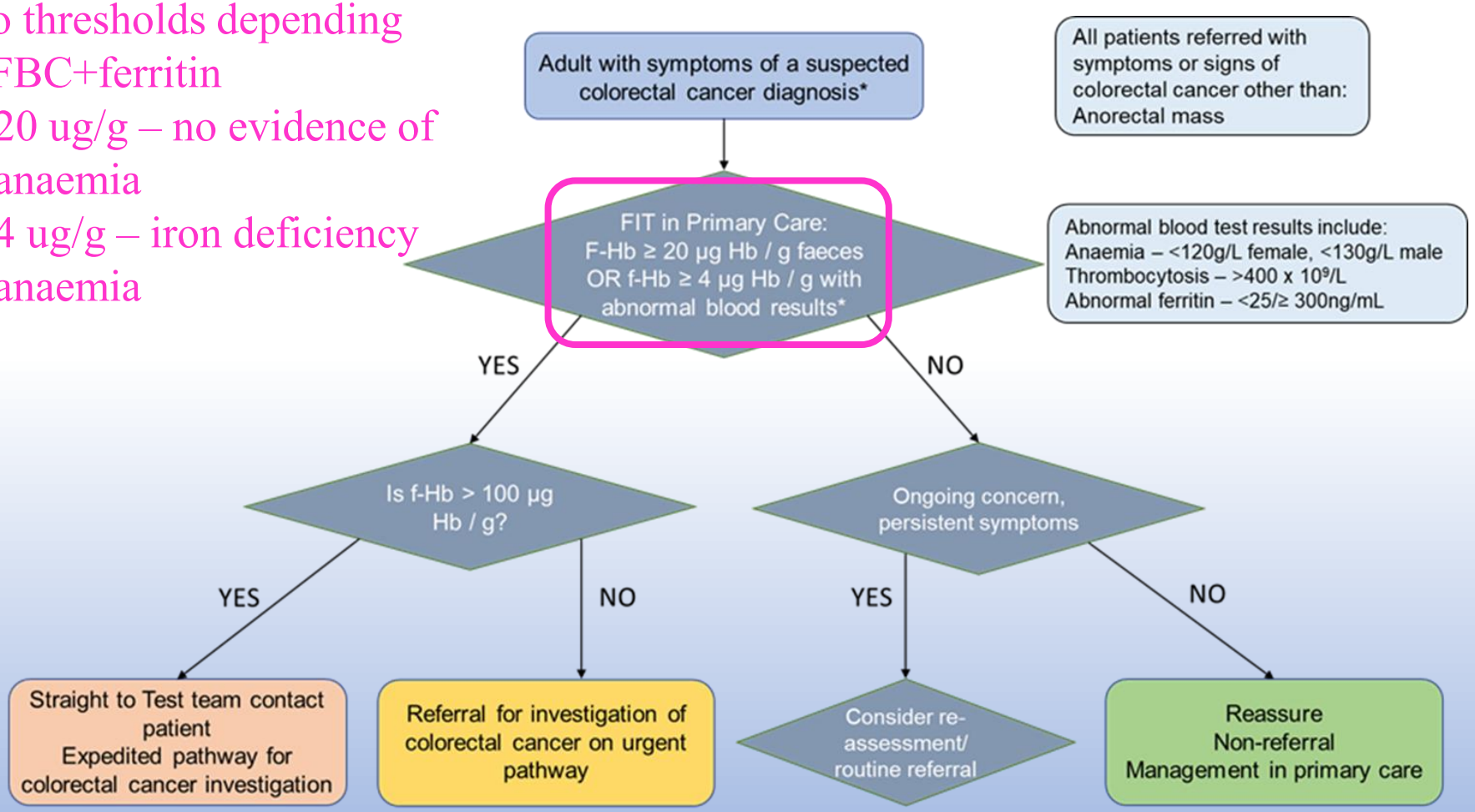
Nottingham Colorectal Service

Two thresholds depending on FBC+ferritin

- 20 ug/g – no evidence of anaemia
- 4 ug/g – iron deficiency anaemia



Slide acknowledgement: Prof David Humes

Colofit Study

- Designed to develop a prognostic risk-based algorithm that combines the FIT result with patient characteristics and laboratory tests

- The algorithm produces a probability that the person has CRC which could help optimise the use of FIT to guide referral decisions in primary care

- Data
  - All adults referred to Nottingham University Hospitals NHS Trust 2018-2022
  - symptoms of suspected CRC
- Models
  - FIT -10/40
  - FIT, age, sex, blood tests
- Validation
  - Internal – External Validation

Equation predicting 1-year CRC survival probability

$$\left(e^{-0.6592014}\right)^{\left(\begin{array}{l} +1.6685765\left(\frac{AGE}{100}\right)^{3} - 13.9435406\left(\frac{AGE}{100}\right)^{3}\cdot\ln\left(\frac{AGE}{100}\right) \\ -\frac{1.9965475}{\sqrt{\left(\frac{FIT}{100}\right)}} - \frac{0.2657153}{\sqrt{\left(\frac{FIT}{100}\right)}}\cdot\ln\left(\frac{FIT}{100}\right) \\ +0.9208493\cdot\ln\left(\frac{PLATELETS}{100}\right) \\ -\frac{3.9007829\cdot MCV}{100} \\ +0.4543275\cdot male \end{array}\right)}$$

Colofit models

- For 100,000 referrals with FIT tests, the resulting numbers of colonoscopies required and cancers detected / missed are shown below for a 0.6% and 3% colorectal cancer risk threshold

	Validation: FIT tests 1st Dec 2021 – Nov 30th 2022			
FIT/model cut-offs and thresholds of CRC risk	Colonoscopies performed for patients above predicted threshold	Detected cancer cases: (True positives)	Missed cancer cases: (False negatives)	Negative colonoscopies: (False positives)
FIT >= 10 (Survival) – 0.6%	30475	1149	88	29326
Model – 0.6%	18681	1142	95	17539
FIT >= 40 (Survival) – 3%	10654	1035	202	9619
Model – 3%	8917	1027	210	7890

COLOFIT: Development and internal-external validation of models using age, sex, faecal immunochemical and blood tests to optimise diagnosis of colorectal cancer in symptomatic patients
CJ Crooks, J West, J Jones, W Hamilton, SER Bailey, G Abel, A Banerjea, CJ Rees, A Tamm, BD Nicholson, SC Benton, COLOFIT Research Group, DJ Humes. medRxiv 2024.03.01.24303196; doi: https://doi.org/10.1101/2024.03.01.24303196

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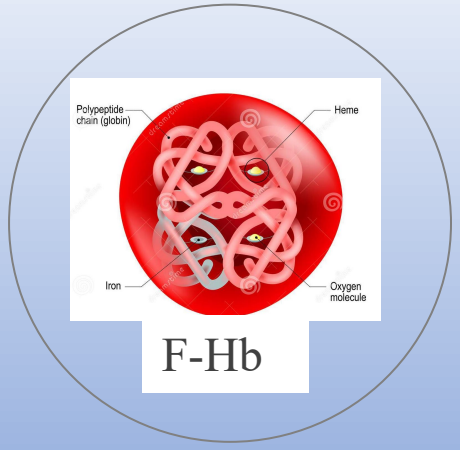
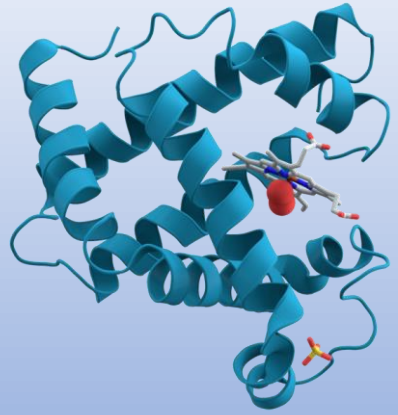
DIFFERENT BIOMARKERS?

Are there different biomarkers we can use?

- **Challenging:** at the early stage patients often asymptomatic so there is limited data on morphological features of these lesions

- Important to explore if differences neoplasia related biology





FIT and the microbiome

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CLINICAL CANCER RESEARCH

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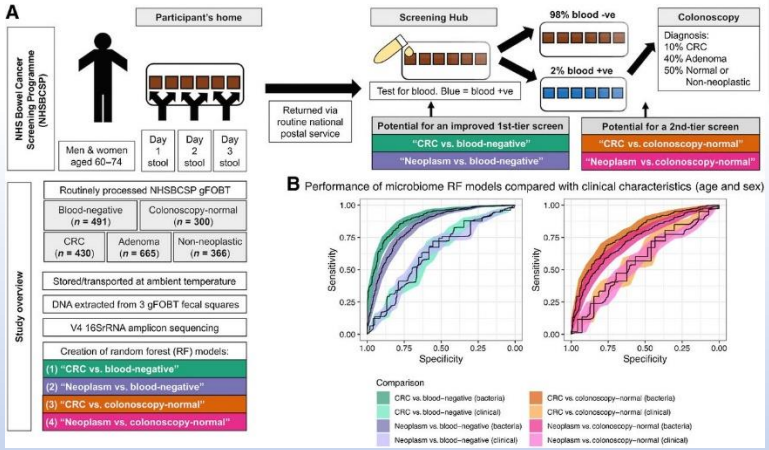
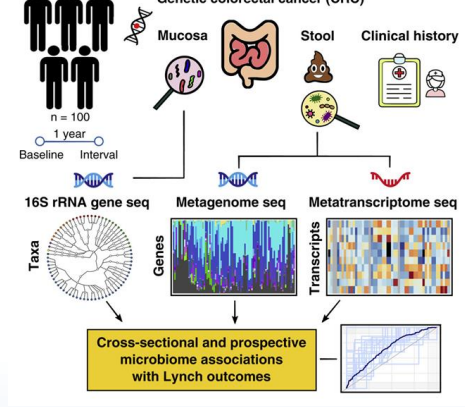
Precision Medicine and Imaging

Microbiome Analysis of More Than 2,000 NHS Bowel Cancer Screening Programme Samples Shows the Potential to Improve Screening Accuracy

Caroline Young, Henry M. Wood, Alba Fuentes Balaguer, Daniel Bottomley, Niall Gallop, Lyndsay Wilkinson, Sally C. Benton, Martin Brealey, Cerin John, Carole Burtonwood, Kelsey N. Thompson, Yan Yan, Jennifer H. Barrett, Eva J.A. Morris, Curtis Huttenhower, and Philip Quirke

DOI: 10.1158/1078-0432.CCR-20-3807 Check for updates





UNITED EUROPEAN GASTROENTEROLOGY ueg journal

Original Article

First steps towards combining faecal immunochemical testing with the gut microbiome in colorectal cancer screening

Esmée J Grobbee, Suk Yee Lam, Gwenny M Fuhler, Blerdi Blakaj, Sergey R Konstantinov, Marco J Bruno, Maikel P Peppelenbosch, Ernst J Kuipers and Manon CW Spaander

United European Gastroenterology Journal
2020, Vol. 8(3) 293–302

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DOI: 10.1177/2050640619890732
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Conclusions: These results show that the faecal microbial content can be measured in FIT samples and remains stable for six days. Total bacterial load was higher in colorectal cancer and high-grade dysplasia. These results pave the way for further research to determine the potential role of microbiota assessment in FIT screening.

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EARLY ONSET COLORECTAL CANCER

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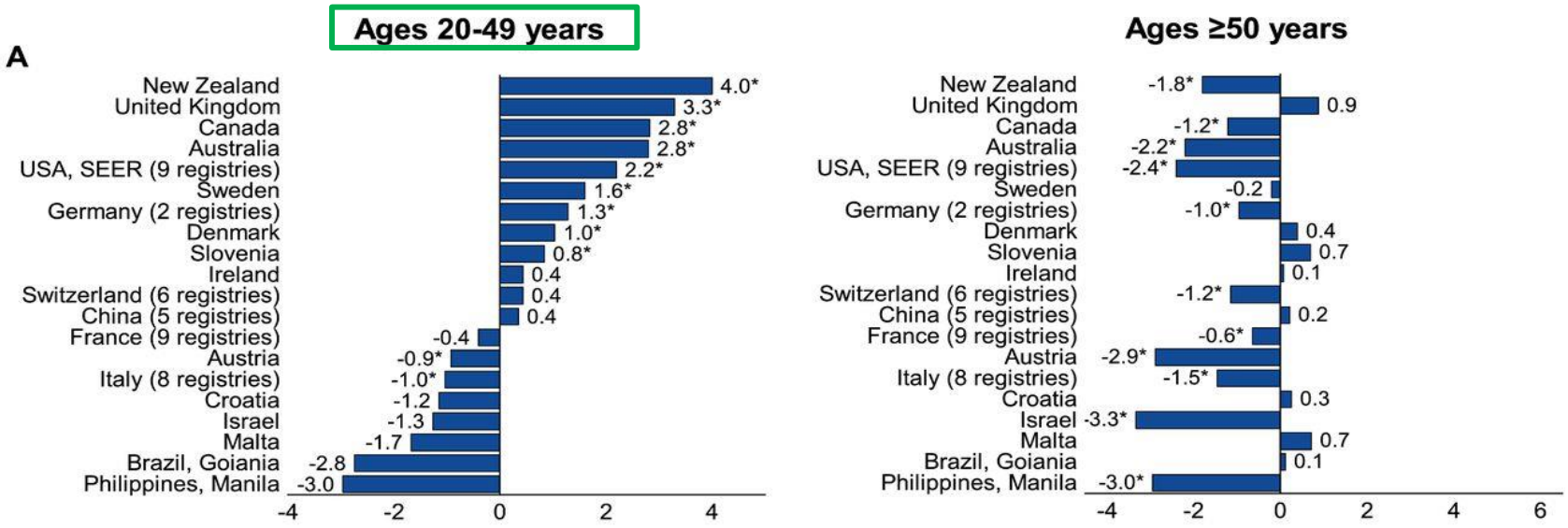
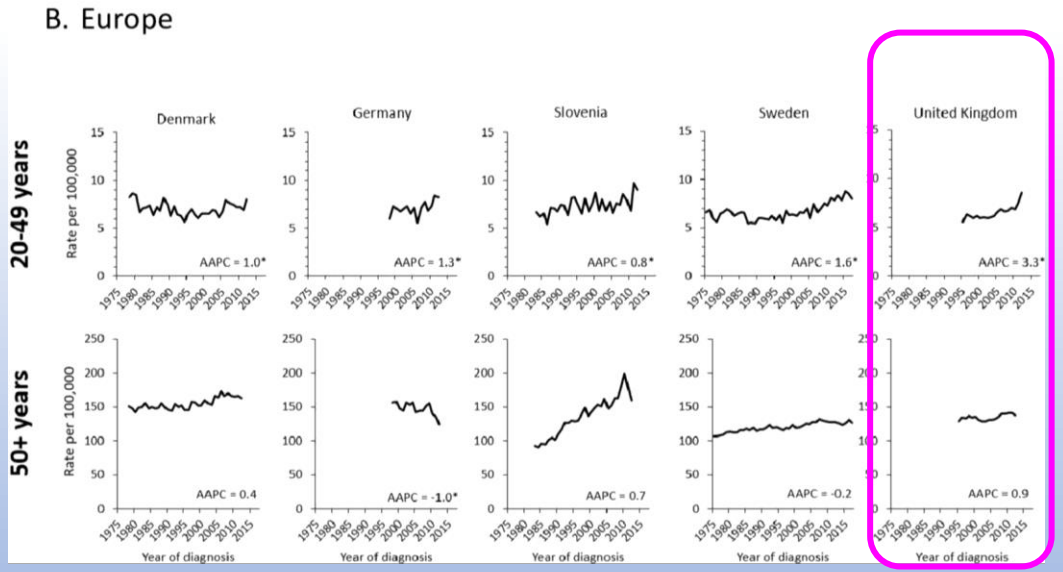


Average annual per cent change (AAPC) in colorectal cancer incidence by age during the most recent 10 years of available data (A) countries with stable or declining trend among adults age 50 and older (B) countries with increasing trend among adults age 50 and older.



Rebecca L Siegel et al. Gut 2019;68:2179-2185

GUT

Increasing incidence of EOCRC

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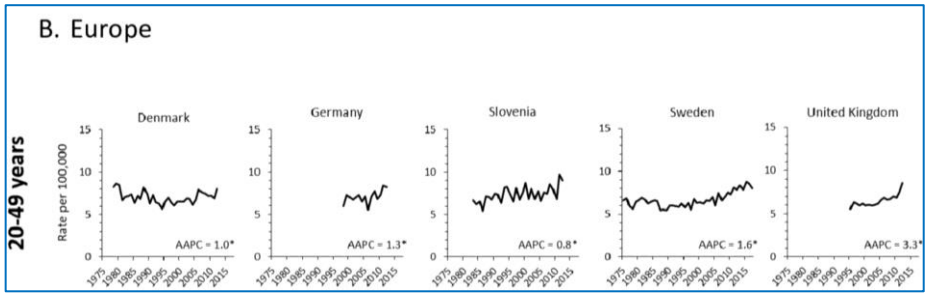
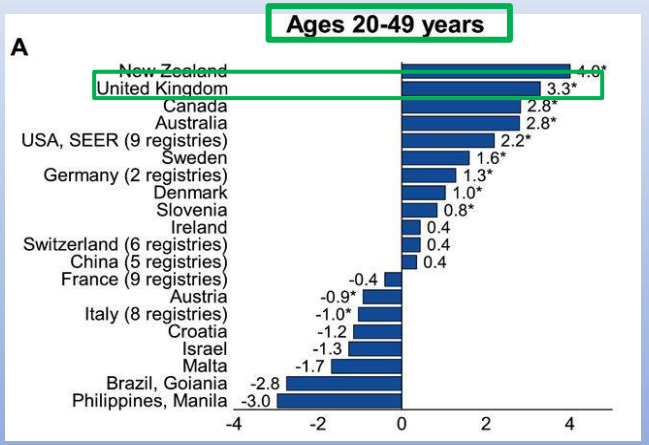
- Absolute risk remains low
- Incidence rate (England)
  - 165.9 per 100,000 aged 60-69 years
  - 7.6 per 100,000 aged 30-39 years
  - 2.8 per 100,000 aged 20-29 years





Early onset colorectal cancer

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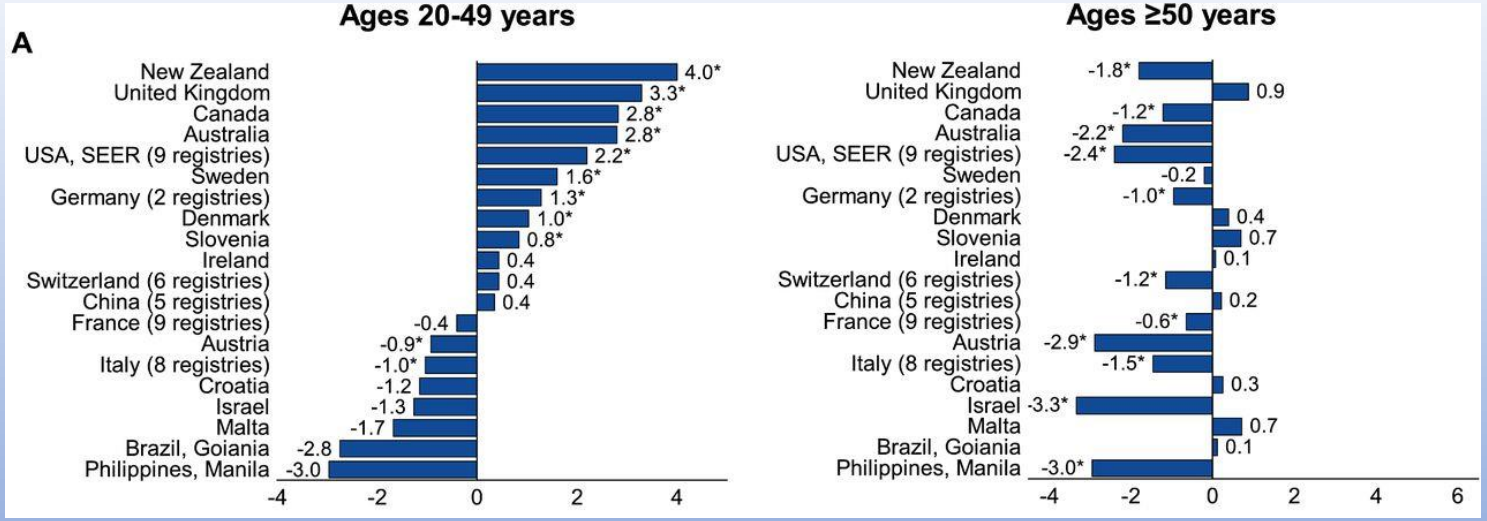
Early onset colorectal cancer (<50 years)

- Absolute risk remains low
- Incidence rate (England)
  - 165.9 per 100,000 aged 60-69 years
  - 7.6 per 100,000 aged 30-39 years
  - 2.8 per 100,000 aged 20-29 years



Rebecca L Siegel et al. Gut 2019;68:2179-2185

Why diagnosed at late stage?

- ? Delayed diagnosis
- ? Higher prevalence of biologically aggressive tumours

2.1 Diagnosis

Key findings

- Prior to being diagnosed half of people didn't know they could develop bowel cancer under the age of 50
- One in three delayed making an appointment with their GP for at least three months, and this was more common in people unaware of the symptoms of bowel cancer
- Four in ten saw their GP three or more times about their symptoms before being referred for tests

Clinical Surgery

Differences in clinicopathological characteristics of colorectal cancer between younger and elderly patients: an analysis of 322 patients from a single institution

Chia-Lin Chou, M.D.[a,b], Shih-Ching Chang, M.D., Ph.D.[a], Tzu-Chen Lin, M.D.[a], Wei-Shone Chen, M.D., Ph.D.[a], Jeng-Kae Jiang, M.D., Ph.D.[a], Huann-Sheng Wang, M.D.[a], Shung-Haur Yang, M.D., Ph.D.[a], Wen-Yih Liang, M.D.[c], Jen-Kou Lin, M.D., Ph.D.[a,*]

- 322 patients
  - 69 pts mean age 35 yrs
  - 253 pts mean age 83 yrs
- Younger patients
  - more advanced stages of disease
  - more aggressive histopathological characteristics
  - Poorer prognoses

Ref: Chou et al. American Journal of Surgery (2011) 202. 574-582

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NHS
Cancer Screening Programmes

CAN FIT AID IN DIAGNOSIS OF EOCRC?

Received: 18 April 2020 | Accepted: 21 July 2020
DOI: 10.1177/2050640620949714

ORIGINAL ARTICLE

ueg journal WILEY

Optimal diagnostic accuracy of quantitative faecal immunochemical test positivity thresholds for colorectal cancer detection in primary health care: A community-based cohort study

Noel Pin-Vieito[1,2,3] | Laura García Nimo[2,4] | Luis Bujanda[5] | Begona Román Alonso[6] | María Ángeles Gutierrez-Stampa[7] | Vanessa Aguilar-Gama[7] | Isabel Portillo[8] | Joaquín Cubiella[1,2]

ORIGINAL ARTICLE

Finding the needle in the haystack: the diagnostic accuracy of the faecal immunochemical test for colorectal cancer in younger symptomatic patients

Nigel D'Souza[1,2,3] | Kevin Monahan[3,4] | Sally C. Benton[5] | Lisa Wilde[6] | Muti Abulafi[1] | the NICE FIT Steering Group*

Annals of Clinical Biochemistry
Volume 61, Issue 1, January 2024, Pages 48-54

https://doi.org/10.1177/00045632231189386

SageJournals

Research Article

A service evaluation of the use of faecal immunochemical tests in symptomatic patients aged under 50 years presenting to primary care

Rebecca E Tibbs [1,2] and Sally C Benton [1,2]

D'Souza et al

TABLE 3 Diagnostic accuracy of FIT for CRC by age group

Age group	Cut-off (μg/g)	FIT positivity	CRC per cut-off[b]	NNS	Sensitivity	Specificity	PPV	NPV
<50 years	None[a]		16/16	68.9	–	–	–	–
	<2	69.5	02/16	333.3	12.5 (1.6–38.3)	29.6 (26.9–32.4)	0.3 (0.0–0.9)	95.8 (93.1–97.7)
	≥2	38.1	14/16	23.8	87.5 (61.7–98.4)	70.4 (67.6–73.1)	4.2 (2.3–6.9)	99.7 (99.1–100.0)
	≥10	19.2	13/16	14.7	81.3 (54.4–96.0)	83.6 (81.3–85.5)	6.8 (3.7–11.4)	99.7 (99.0–99.9)
	≥150	7.5	11/16	8.7	68.8	92.2	11.5	99.5

Cut-off Tibbs et al	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value
10 ug/g	100%	86.3%	2.7%	100%
150 ug/g	83.3%	95.2%	6.2%	99.9%

Cut-off	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value
10 ug/g	93.1%	88.5%	2.6%	99.7%

Pin-Vieto et al. United European Gastroenterol J 2020; 9:256-267

FIT in EOCRC pathway

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- Needs refining
  - Different thresholds
  - Additional biomarkers eg microbiome, blood, faecal
  - Risk stratification

Summary

Are our FIT assays good enough and what is the symptomatic threshold?

- **FIT assays** are straight forward and robust
  - Variety of pre-analytical factors to be aware of that do impact results
  - Improvements to overall analytical process required;
    - Certified reference material to align results
    - Robust EQA samples
    - 3rd party IQC materials

- Nationally recommended **Symptomatic threshold** is currently 10 ug/g
  - Needs refinement to improve specificity
    - Appropriate threshold
    - Risk stratification algorithms
    - Additional biomarkers

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Are our FIT assays good enough and what is the symptomatic threshold?

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Essentialism vs Consequentialism

Prof Patrick Bossuyt

"the theory that the value of a marker or a medical test should be judged by the 'trueness' of its results"

"the theory that the value of a marker or a medical test should be judged by the value of its consequences"

Is the test "perfect" scientifically?

Does the test support the clinical need?

Berkshire and Surrey Pathology Services

Essentialism vs Consequentialism

Prof Patrick Bossuyt

"the theory that the value of a marker or a medical test should be judged by the 'trueness' of its results"

"the theory that the value of a marker or a medical test should be judged by the value of its consequences"

FIT

Need to ensure the analytical process is;

- scientifically robust
- deficiencies understood
- Work towards improving things

- patients are appropriately categorised