

The Introduction and Evaluation of FIT

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October 2019

Faecal Immunochemical Test for haemoglobin

- **FIT**
 - BCSP
 - Asymptomatic screening
 - 60-74years
 - Cut-off 120µg Hb/g faeces
 - 2ww patients for suspected colorectal cancer
 - Research
 - Patients at low risk for colorectal cancer
 - NICE DG30

Faecal Immunochemical Test for haemoglobin

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 - Research
 - **Patients at low risk for colorectal cancer**
 - **NICE DG30**

Indications for use of FIT in DG30

People:

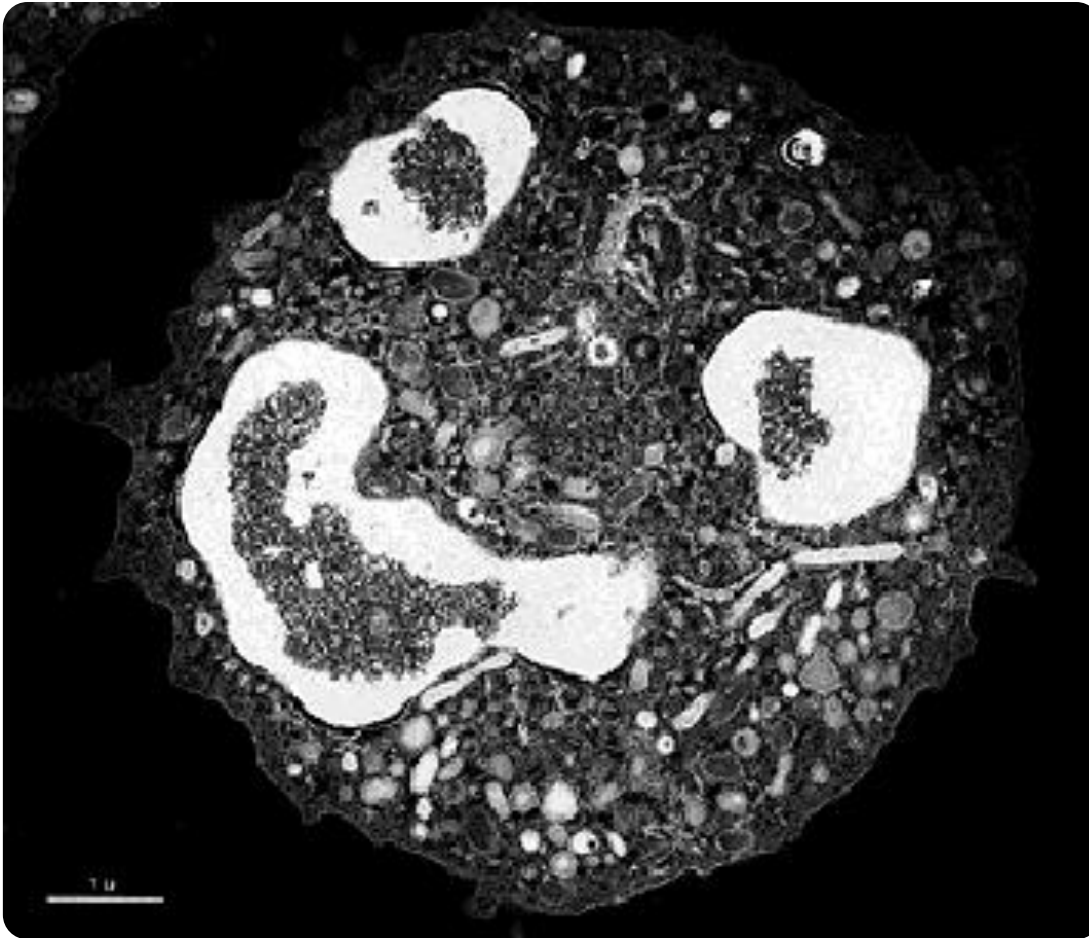
- without rectal bleeding
- who have unexplained symptoms that do not meet the criteria for a suspected cancer pathway

REPLACES

People:

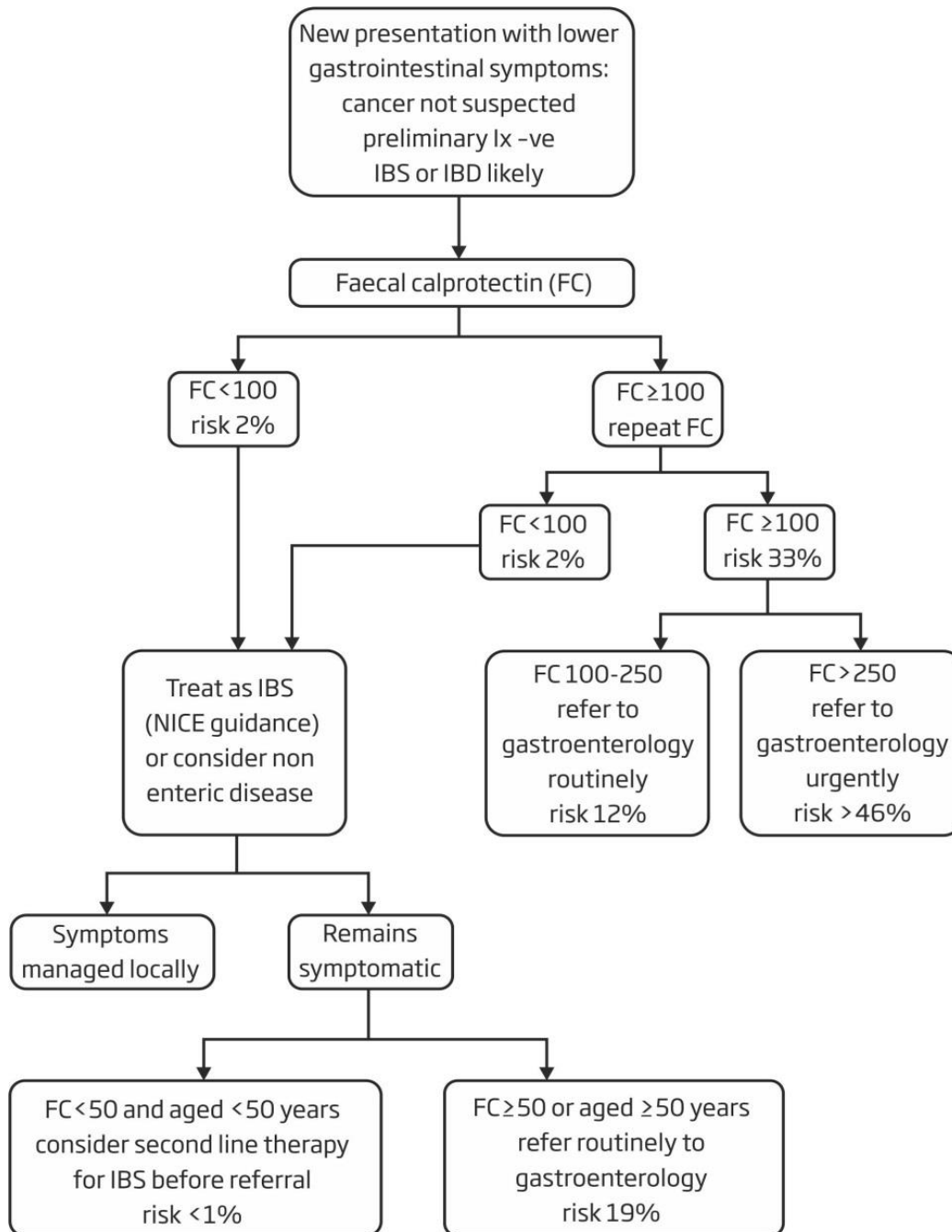
- >50yrs with unexplained
 - abdominal pain
 - weight loss
- <60yrs with
 - changes in their bowel habit
 - iron-deficiency anaemia
- >60yrs with anaemia even in the absence of iron deficiency

Faecal Calprotectin



IBS v IBD

- use in adults
- new lower gastrointestinal symptoms
- cancer is not suspected
- NICE DG11



Exclusion criteria:

- Cancer suspected (NICE guideline NG12. <https://www.nice.org.uk/guidance/ng12>)

Inclusion criteria:

- Adult 18-60 years
- New lower gastrointestinal symptoms
- Normal or negative initial workup (FBC, U&E, Cr, TFT, CRP, Ca, coeliac screen)
- Stool culture / C. difficile screen as appropriate

YFCCP

economic evaluation

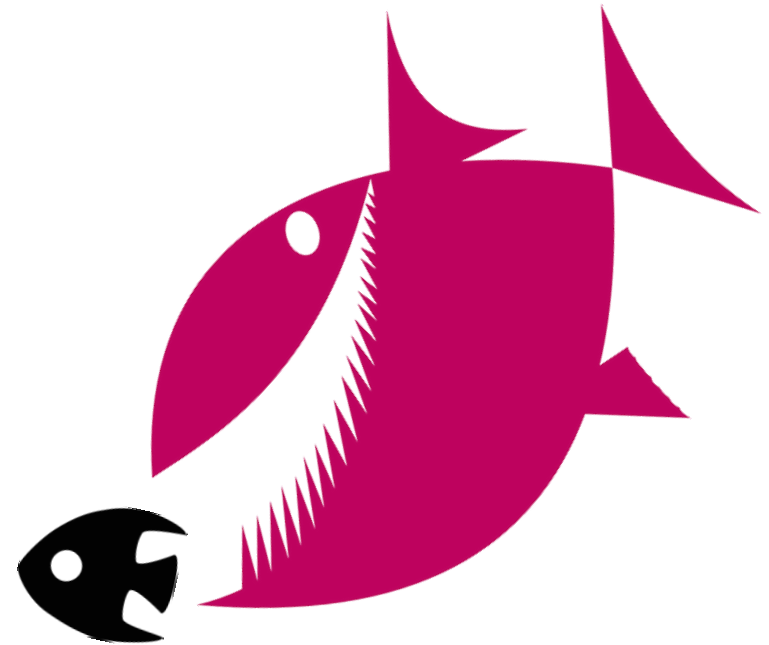
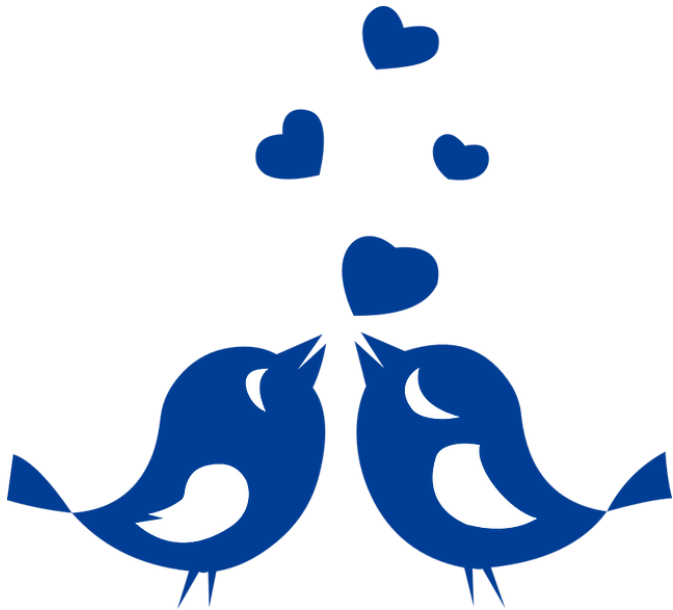
- Health economic evaluation with YHEC
- Outcome data compared against historic standard care, predicted outcomes from FC usage and outcomes from this implementation using standard cut off (per 1000 pts)

	Intervention	No FC (ESR + CRP)	Incremental
Total costs	£308,954	£416,839	-£107,885
Correctly diagnosed IBS cases	849	677	172
Correctly diagnosed IBD cases	66	25	41
Unnecessary colonoscopies (i.e. false +ves)	79	251	-172

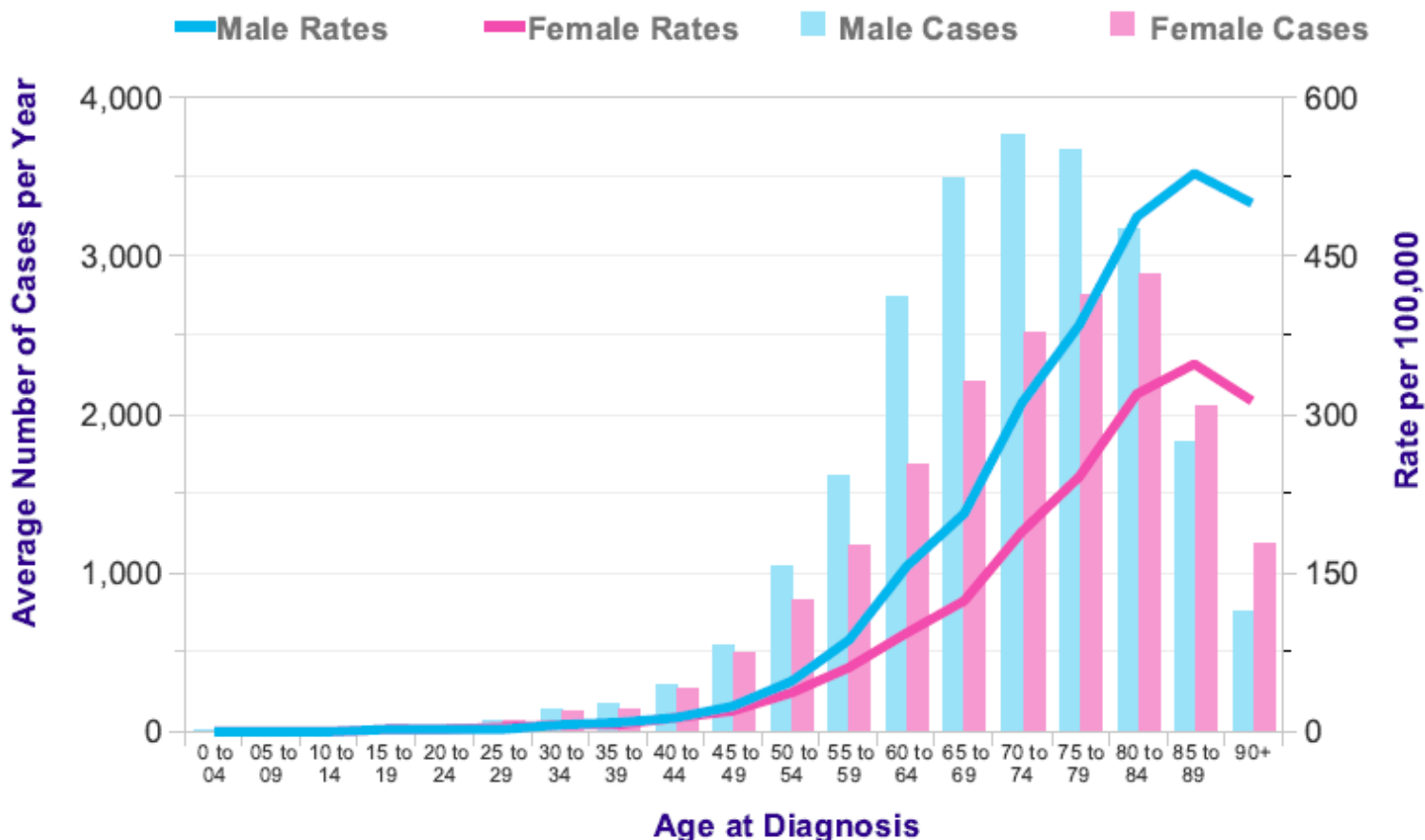
	Intervention	Standard cut-off	Incremental
Total costs	£308,954	£467,820	-£158,866
Correctly diagnosed IBS cases	849	562	287
Correctly diagnosed IBD cases	66	68	-1
Unnecessary colonoscopies (i.e. false +ves)	79	366	-287

FIT NICE DG30: FIT for low risk patients

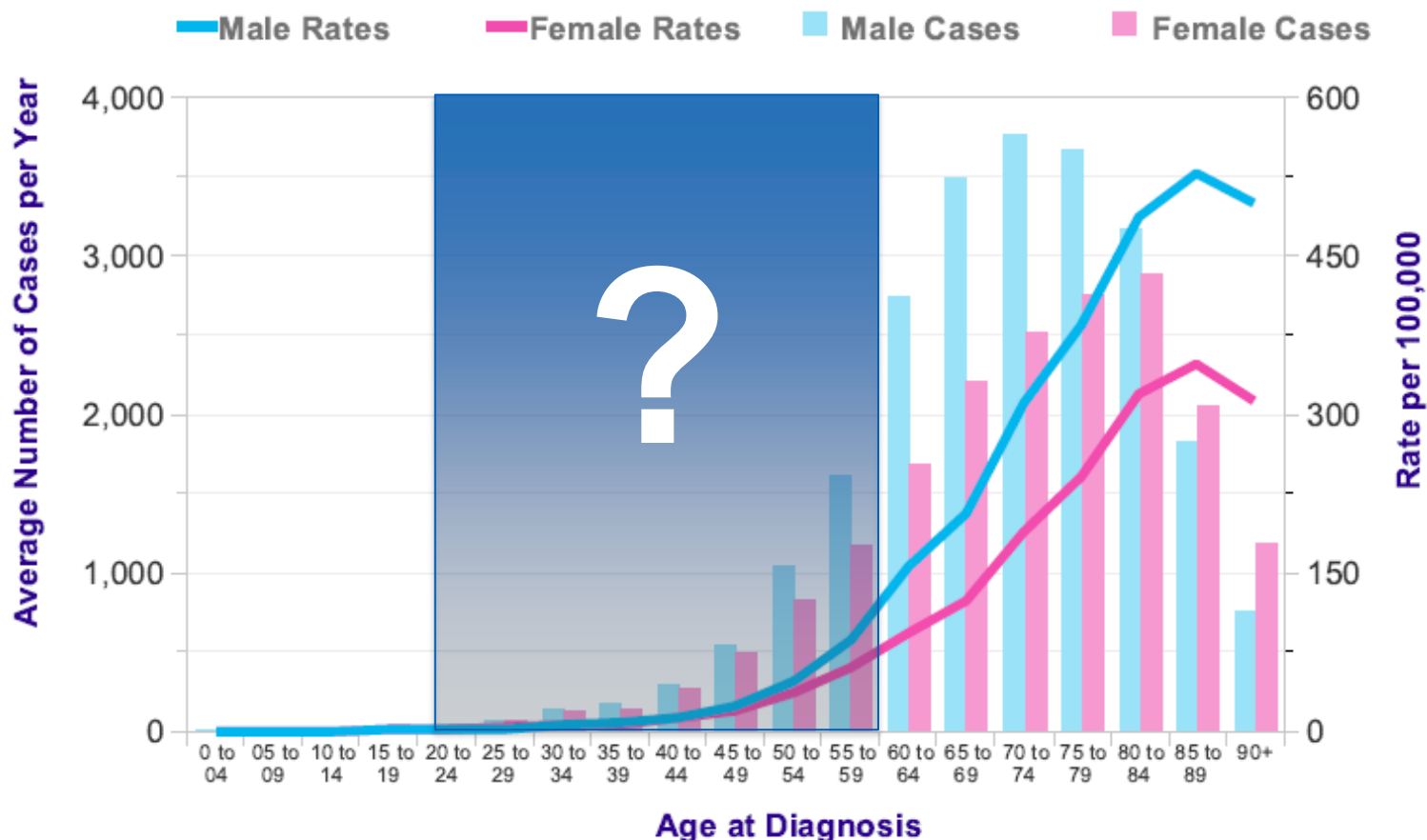
How does it fit with FC?



FIT NICE DG30: FIT for low risk patients



FIT NICE DG30: FIT for low risk patients



FIT or FC?

CRC, polyps & IBD	Disease prevalence (%)	Sensitivity (CI)	P value	Specificity (CI)	P value	NPV (CI)	PPV (CI)
FIT ≥10µgHb/g faeces comparator: Mowat et al*							
	13.6	68.6 (58.7-77.5)		83.6 (80.6-86.4)		94.4 (92.2-96.0)	39.8 (32.6-47.4)
FC ≥100µg/g faeces							
50-59years	5.8	65.0 (41.0-84.0)	1.0	85.0 (80.6-88.6)	0.11	97.5 (94.8-98.9)	21.0 (12.1-33.5)
40-49years	5.5	88.9 (63.9-98.1)	0.81	89.4 (85.3-92.5)	0.001	99.3 (97.2-99.9)	32.7 (20.4-47.7)
30-39years	3.6	100 (62.9-100)	0.051	91.7 (87.2-94.7)	<0.001	100 (97.9-100)	31.0 (16.0-51.0)
18-29years	8.7	100 (83.4-100)	<0.001	89.3 (84.7-92.6)	0.002	100 (98.0-100)	47.2 (33.5-61.2)

Roll out of FIT: the challenges

- Introduce FIT
- Evaluate FIT
- Compare the effectiveness of FC and FIT

18-59 years

FC v FIT

YFCCP + FIT

not high risk for CRC (2ww)

baseline investigations normal

diagnostic uncertainty

not isolated rectal bleeding

FC and FIT

≥60 years

not high risk for CRC (2ww)

abdominal pain

weight loss

anaemia in the absence of
iron deficiency

FIT

Diagnostic accuracy study: 1

- Patient presents with possible lower gastrointestinal disease
- Baseline assessment and investigations as appropriate
 - FBC, CRP, ferritin, TFT, coeliac screen
 - Stool culture, *C.difficile* toxin
- Not 2ww for cancer
- Diagnostic uncertainty
- Not isolated rectal bleeding: surgical referral

Patient 18-59yrs

Faecal Calprotectin →

Faecal Immunochemical Test (FIT)

Only Calprotectin available to request

Question to prompt GP to request FC for:

- 1) Diagnostic care pathway: IBS v IBD
- 2) IBD monitoring

Rules -- Webpage Dialog

Faecal Calprotectin

Please select the reason for Calprotectin request

Diagnostic Care Pathway: IBS vs IBD
IBD Monitoring

OK

Faecal Immunochemical Test (FIT)

If you tick 'IBS v IBD' FIT auto requested

This "Help" prompt appears to help:

- universal pot
- and FIT pack

If 'IBD monitoring': you just get the FC

Rules -- Webpage Dialog

Faecal Immunochemical Test (FIT)

Please use standard collection pot for calprotectin and provide the dedicated collection pack for FIT
Please ask patient to complete consent form and questionnaire

OK

requests and referrals

2016	Endoscopy unit or pathway		
Age	York medical %	Scarborough (pooled) %	York surgical %
18-29	24	25	7
30-39	17	19	7
40-49	14	15	4
50-59	5	13	1

2018	Endoscopy unit or pathway		
Age	York medical %	Scarborough (pooled) %	York surgical %
18-29	51	34	17
30-39	41	24	15
40-49	30	17	13
50-59	24	5	9

YFCCP

prevalence of disease

Age	Prevalence (%)											
	York medical				Scarborough (pooled)				York surgical			
	OCD	IBD	Polyps	CRC	OCD	IBD	Polyps	CRC	OCD	IBD	Polyps	CRC
18-29	34.6	34.0	0.4	0.2	17.6	16.8	0.8	0	8.1	6.8	0.9	0.4
30-39	39	36.8	1.5	0.7	16.5	13.1	3	0.2	11.1	6.7	3.5	0.9
40-49	24.3	21.0	2.6	0.7	9.8	7.6	1.3	0.9	10.1	4.5	3.1	2.5
50-59	14.8	11.3	1.3	2.2	12.0	5.4	5.0	1.6	14.6	2.4	8.7	3.5

Prevalence of organic colonic disease: IBD, significant polyps and colorectal cancer by age and referral/endoscopic pathway.

Suspecting cancer.....

how to interpret 1.3.3

- **consider** a suspected cancer pathway referral for colorectal cancer in adults
 - < 50y with rectal bleeding & unexplained:
 - abdominal pain
 - change in bowel habit
 - weight loss
 - iron-deficiency anaemia

Patient ≥60yrs

Faecal Calprotectin →

Faecal Immunochemical Test (FIT) →

Both tests available to request if needed
Choose an option in order to proceed.

Rules -- Webpage Dialog

Faecal Immunochemical Test (FIT)

Please select the indication for FIT testing

Abdominal pain
Anaemia without Iron Deficiency
unexplained weight loss

OK

FIT test selected - this pop-up box appears

Rules -- Webpage Dialog

Faecal Immunochemical Test (FIT)

FIT requests only accepted following NICE DG30. Patients with rectal bleeding, IDA or change in bowel habit should be referred under 2WW as per NG12

Please use dedicated collection pack for this test. Blue Stool pot CANNOT be accepted

OK

One of the top three options selected:
This pop-up box then appears

Faecal Calprotectin →

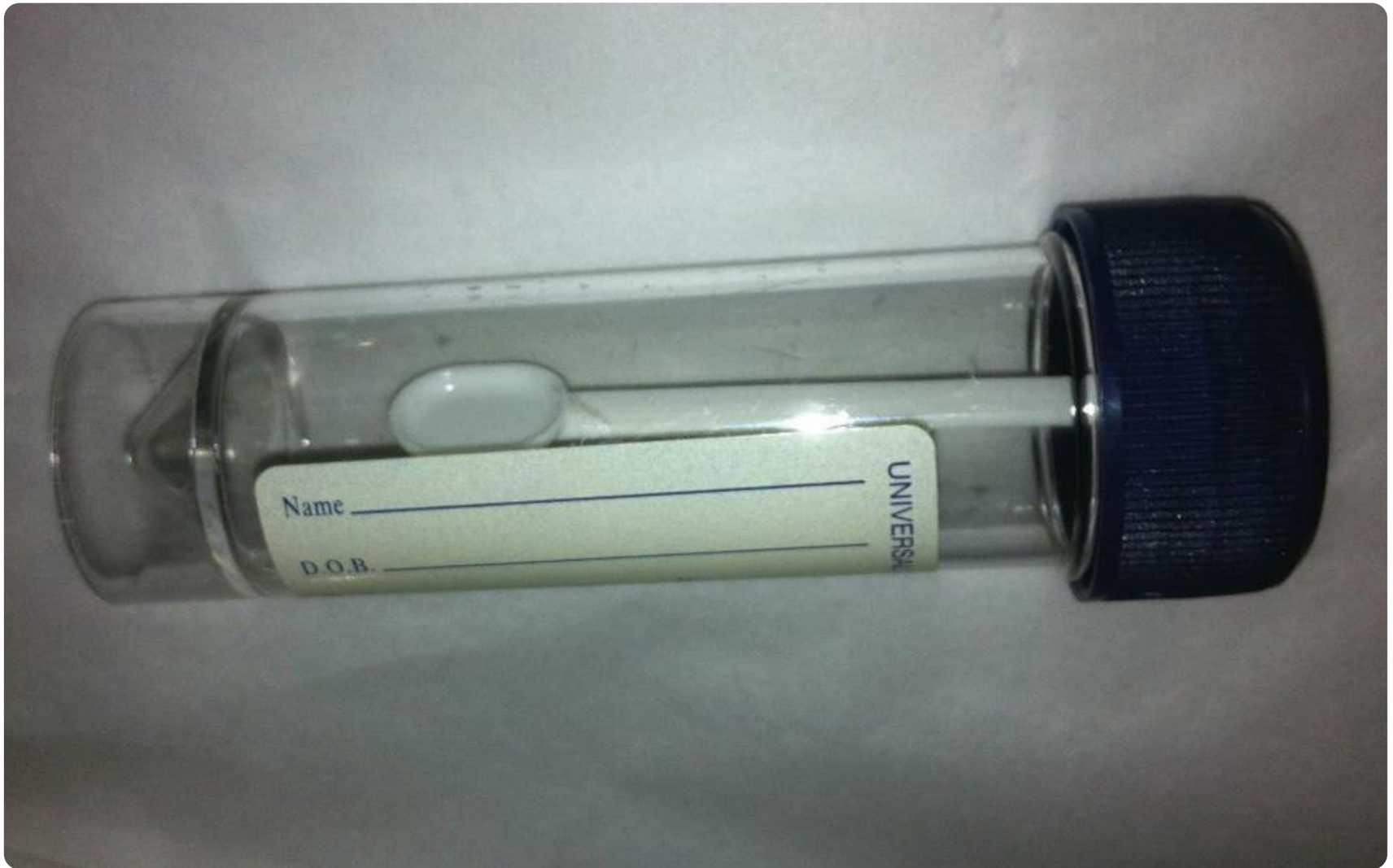
Faecal Immunochemical Test (FIT)

Calprotectin cannot be co-requested with FIT

Diagnostic accuracy study: 2

- **18-59 years:** option to request FC
 - ICE will ask then you to request FIT
- **≥60 years:** option to request FIT
 - Specific indications for referral
- **Patient pack**
 - Information sheet
 - Patient questionnaire
 - Consent form
 - FIT picker
 - Instructions for use
 - SAE
- Universal container (blue top)
- Conventional (safety netted) follow up with results

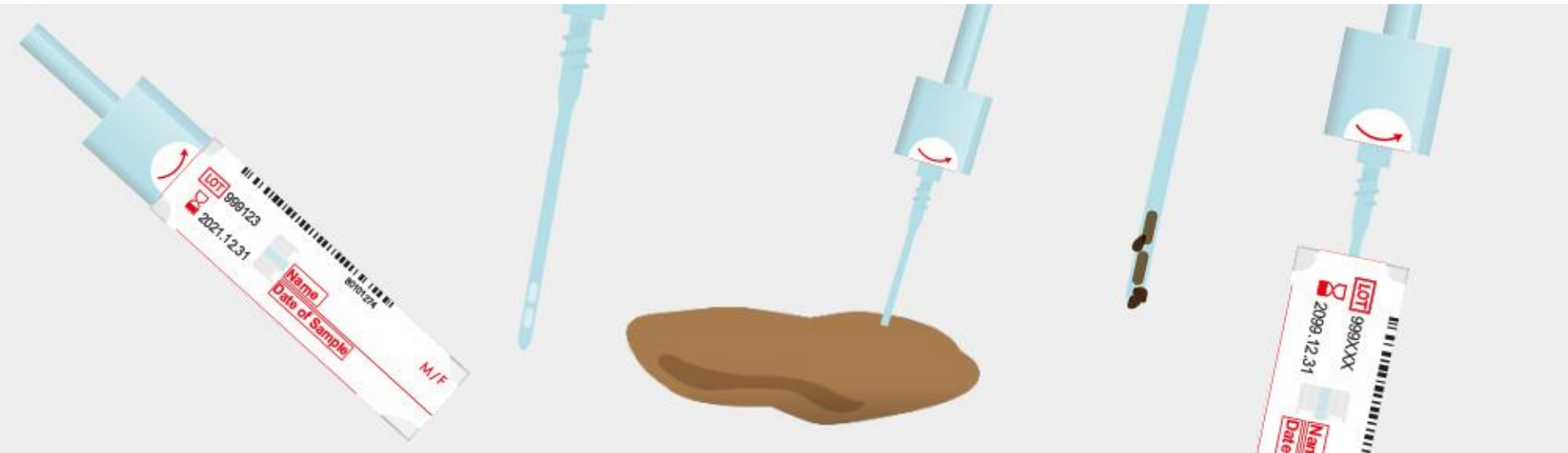
FC needs a universal pot



FIT needs a picker



FIT needs a picker



What the patient needs to do:

- Name
- Date of birth
- Date of sampling

Diagnostic accuracy study: 3

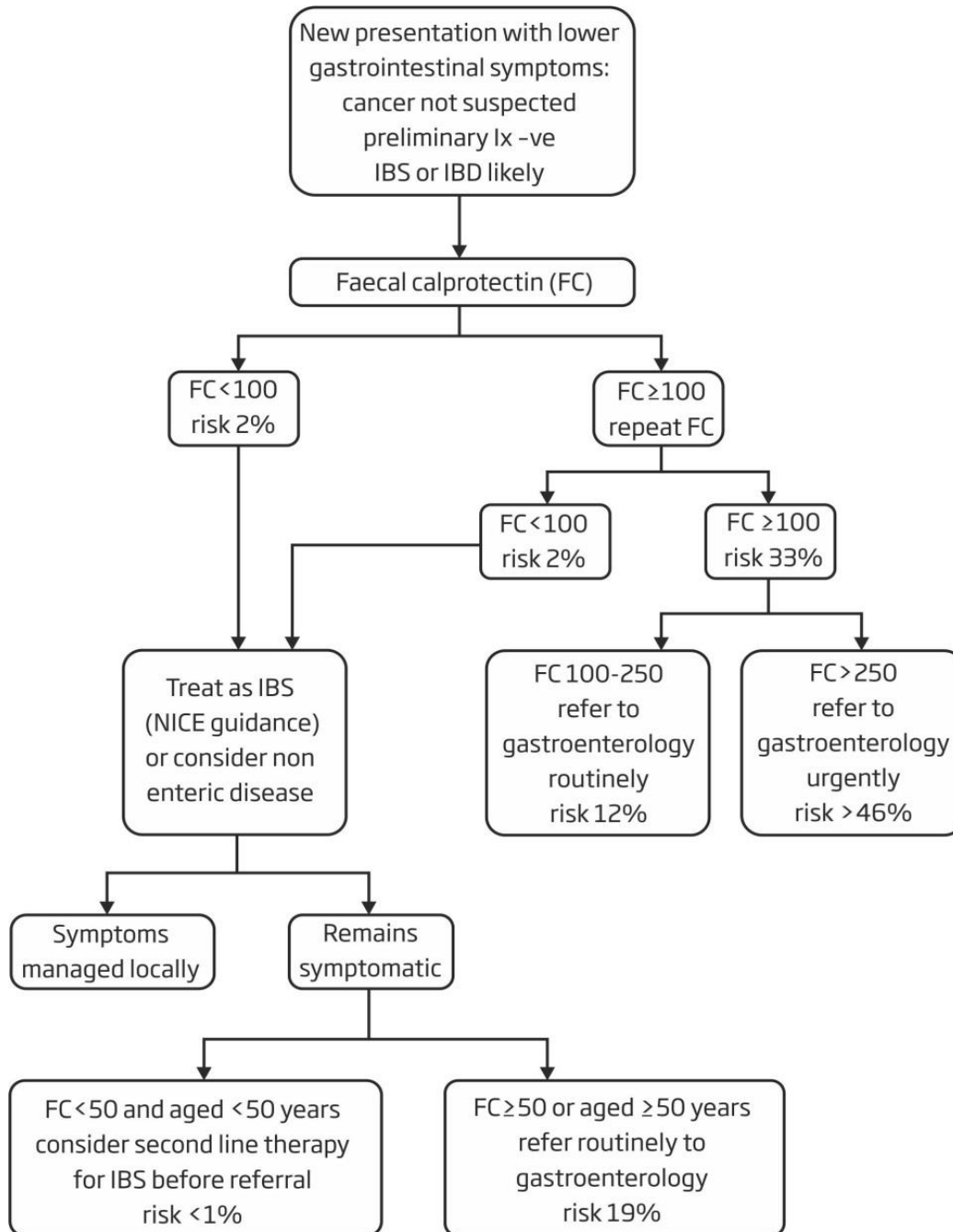
≥60 years:

- FIT positive: 2ww colorectal referral
- FIT negative: reassure colorectal cancer very unlikely
 - treat symptomatically and review
 - routine referral or consider uro-gynaecological disease

18-59 years:

- follow the YFCCP
- FC <100: IBS likely
- FC ≥100: repeat
 - repeat FC <100: IBS likely
 - repeat FC 100-250: routine gastroenterology referral
 - repeat FC >250: STT colonoscopy/urgent gastroenterology referral

**IF FC <250 ON COMPLETION OF YFCCP
BUT ANY FIT IS POSITIVE:
2WW COLORECTAL REFERRAL**

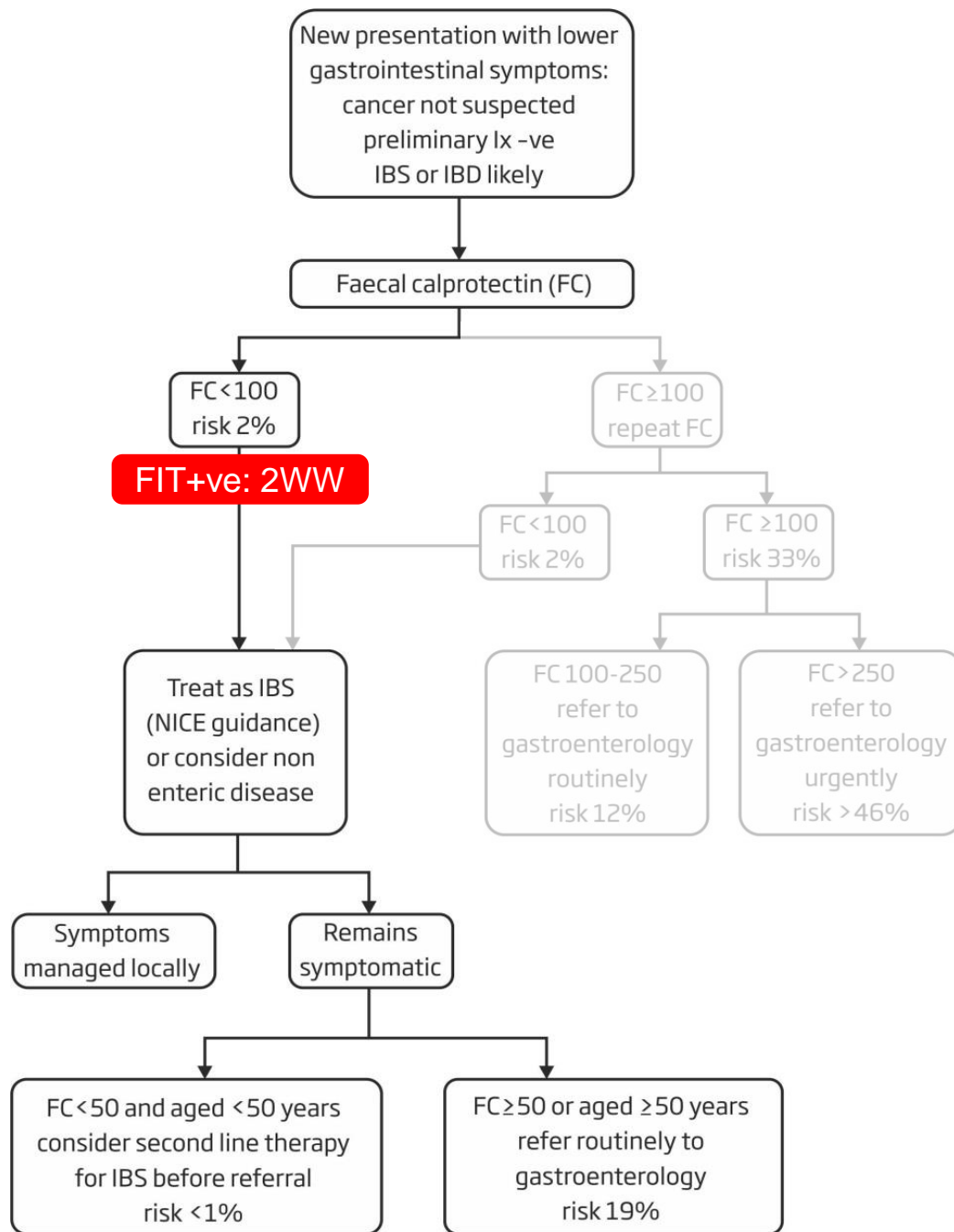


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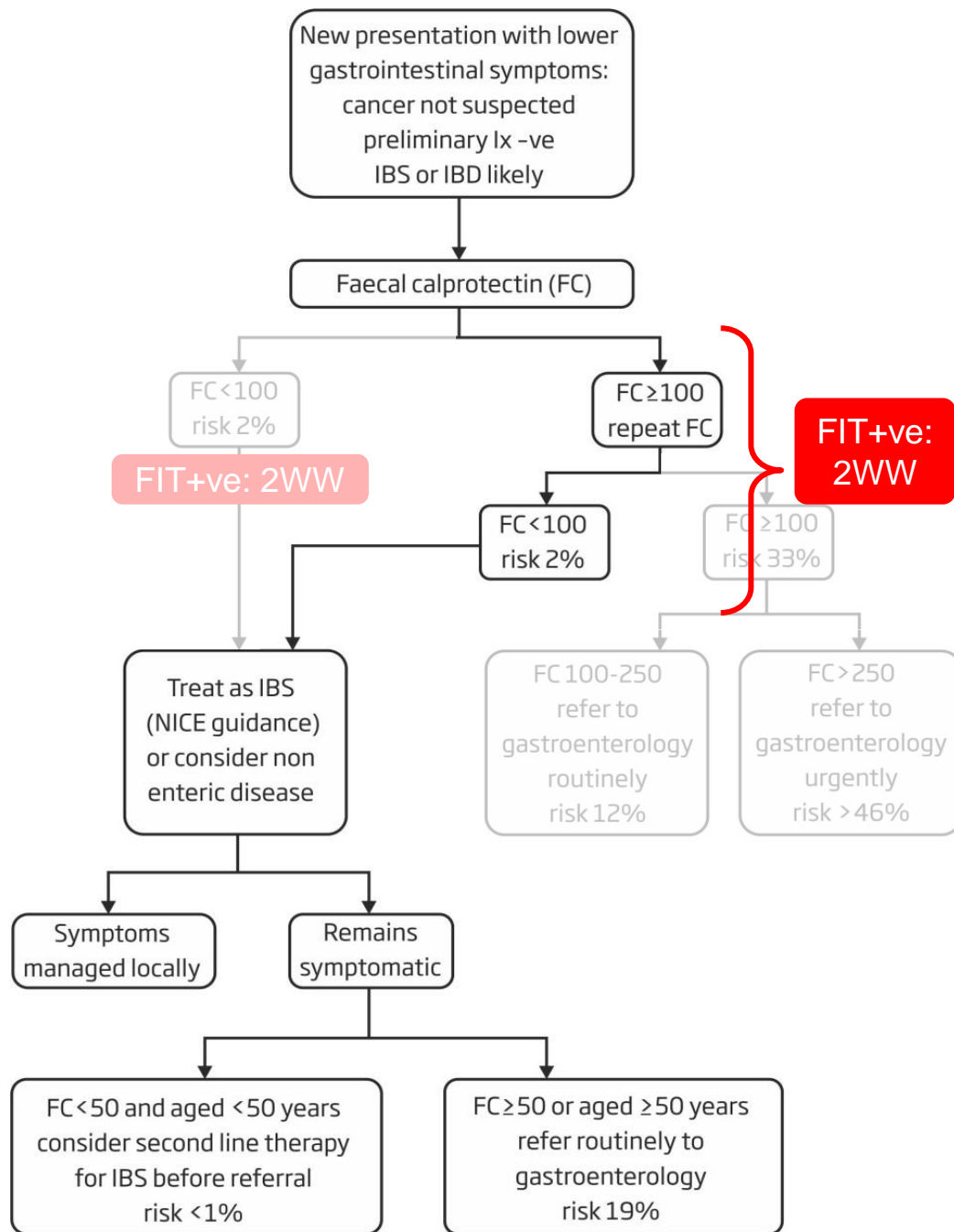


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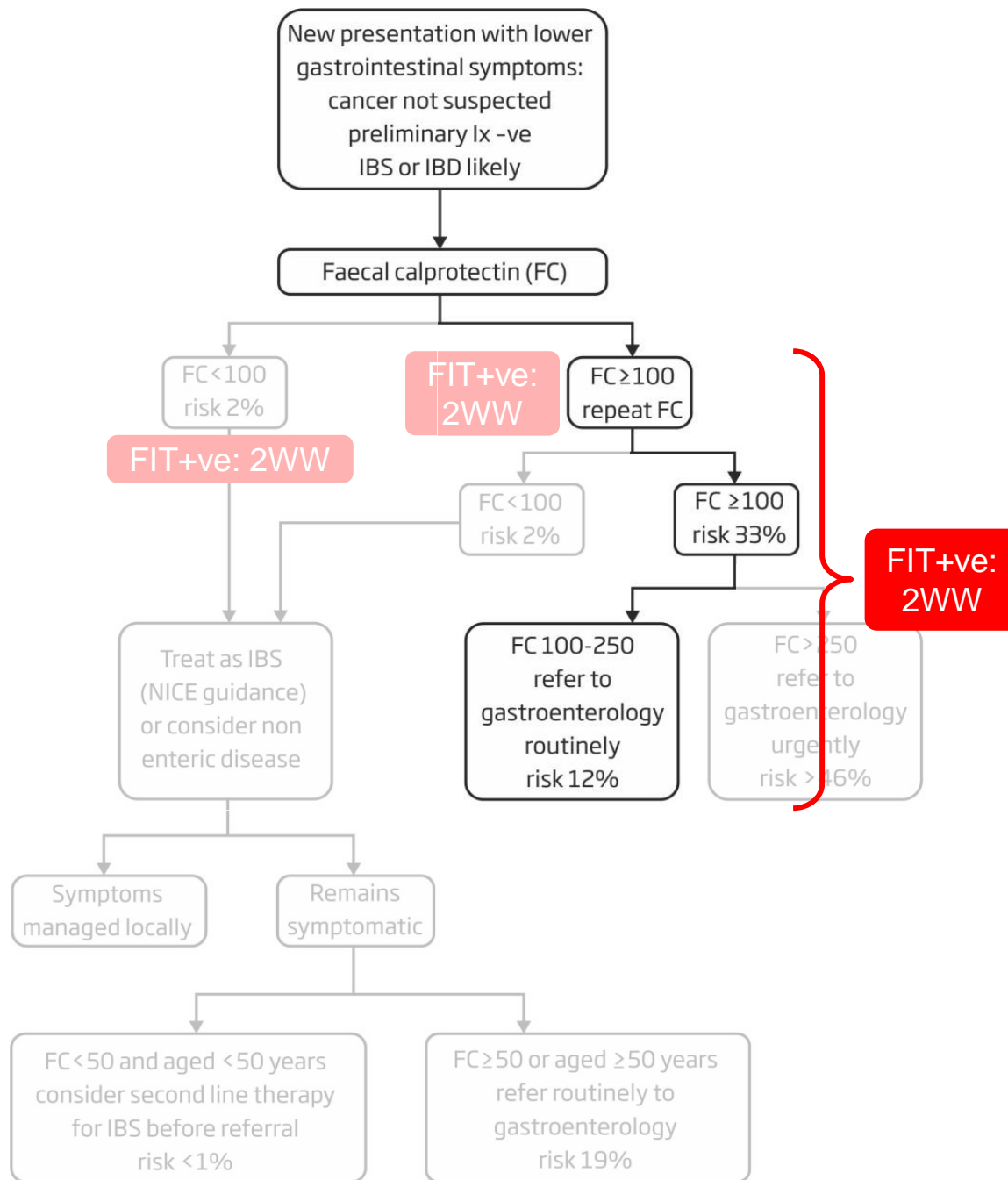


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Diagnostic accuracy study: 4

- GP management/referral guidance will be provided by the laboratory to accompany the FC/FIT result
- GP information sheet
- Training video
- 'FIT positive indication for referral' will be added to the 2ww for suspected colorectal proforma
- Safety netting
- Data collection

Expected outcomes

≥60 years:

- numbers?
- FIT positive: 10%
- significant disease: 50%

18-59 years:

- numbers?
 - current YFCCP requests: 4000/year
 - FC requests as a proportion of referrals: 15%
- FC positive: 15%
 - FC>250 significant disease: 50%
- FIT positive and FC negative: 5%
 - significant disease: 60%
- numbers needed to diagnose significant disease
 - YFCCP: 3.8
 - No YFCCP: 6.8
- FC/FIT negative: follow the YFCCP
 - reassure, treat and review

Thank you

Any queries, contact me:

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NHS Foundation Trust