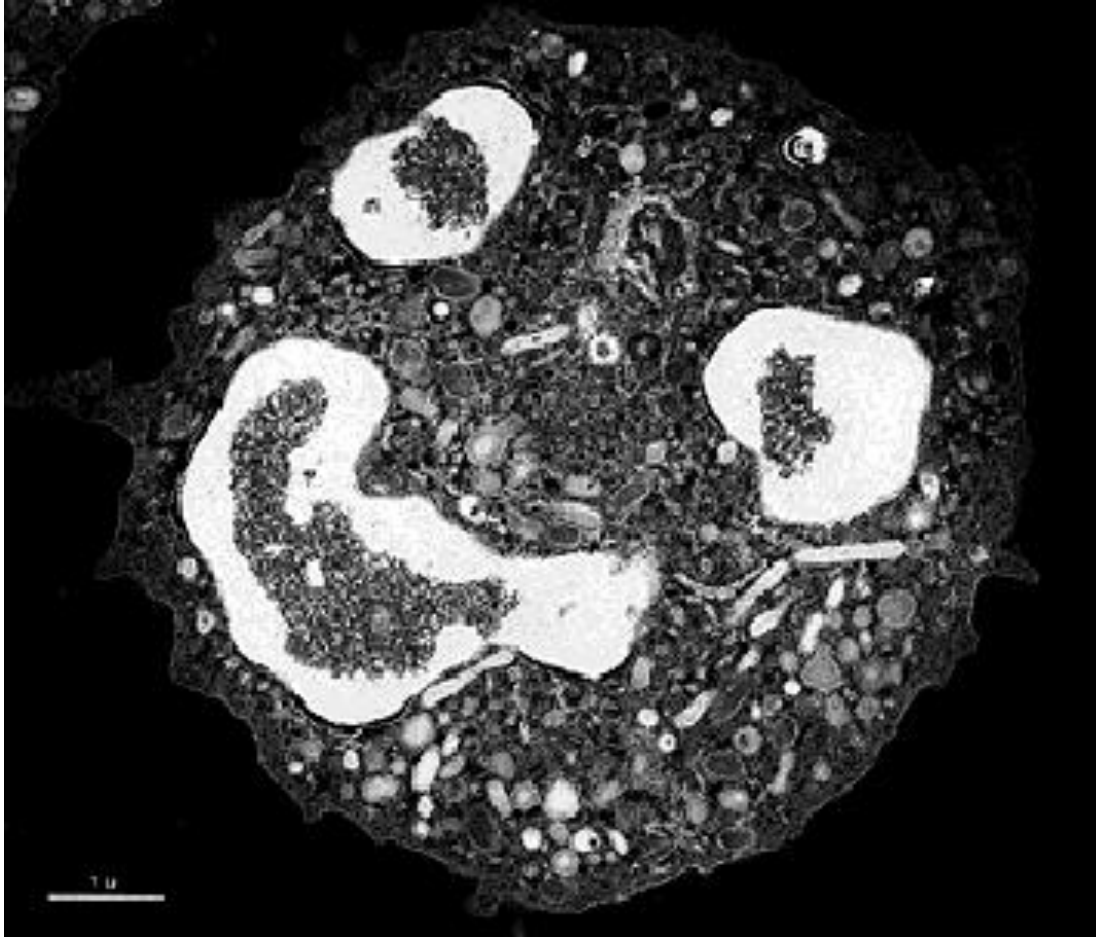




The York Faecal Calprotectin Care Pathway

James Turvill



- ## Faecal Calprotectin
- IBS v IBD (NICE DG11)
 - Crohn's disease monitoring

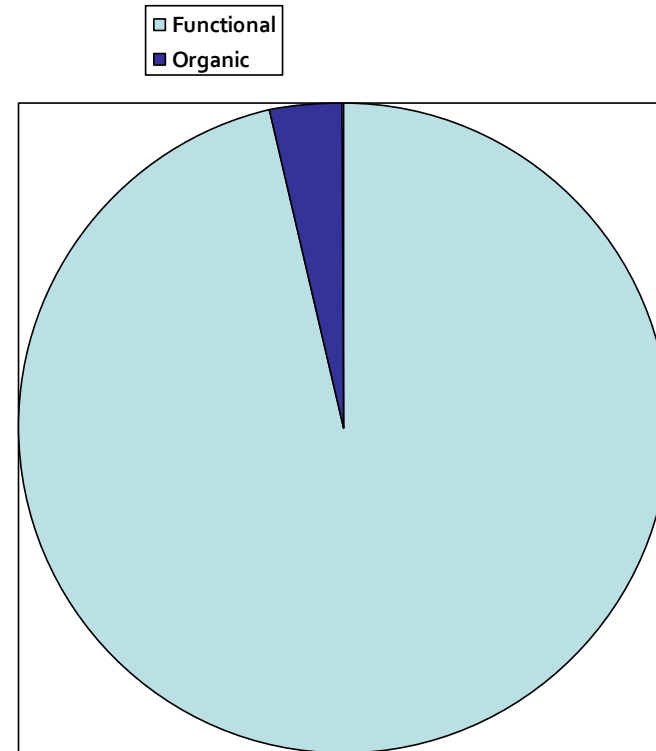
NICE guidance: dg11

Faecal calprotectin (FC) testing as...an option in adults with recent onset of lower gastrointestinal symptoms for whom specialist investigations are being considered if cancer is not suspected and it is used to support a diagnosis of IBD or IBS.

(<http://www.NICE.org.uk/dg11>).

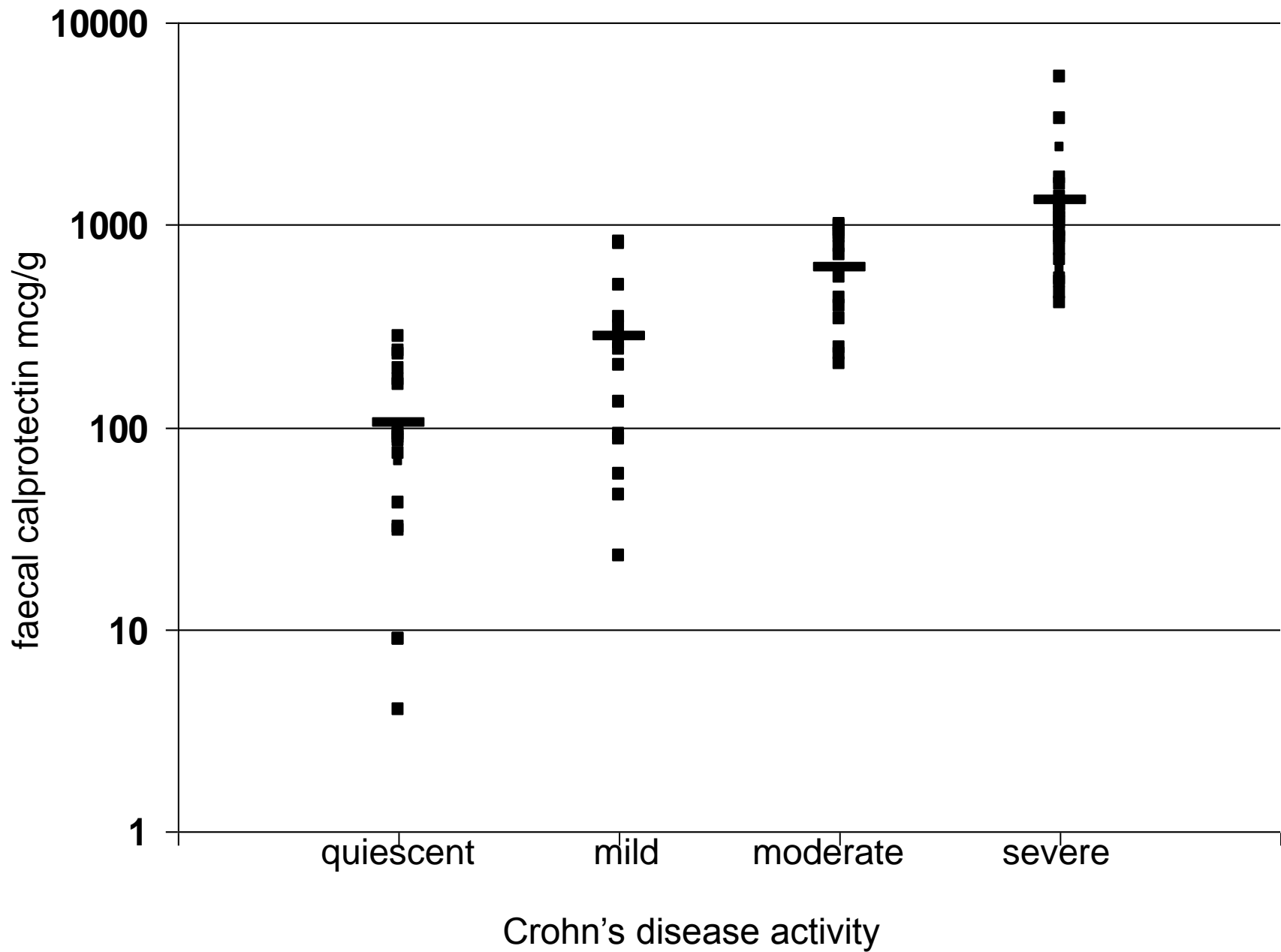
High negative predictive value of a normal faecal calprotectin

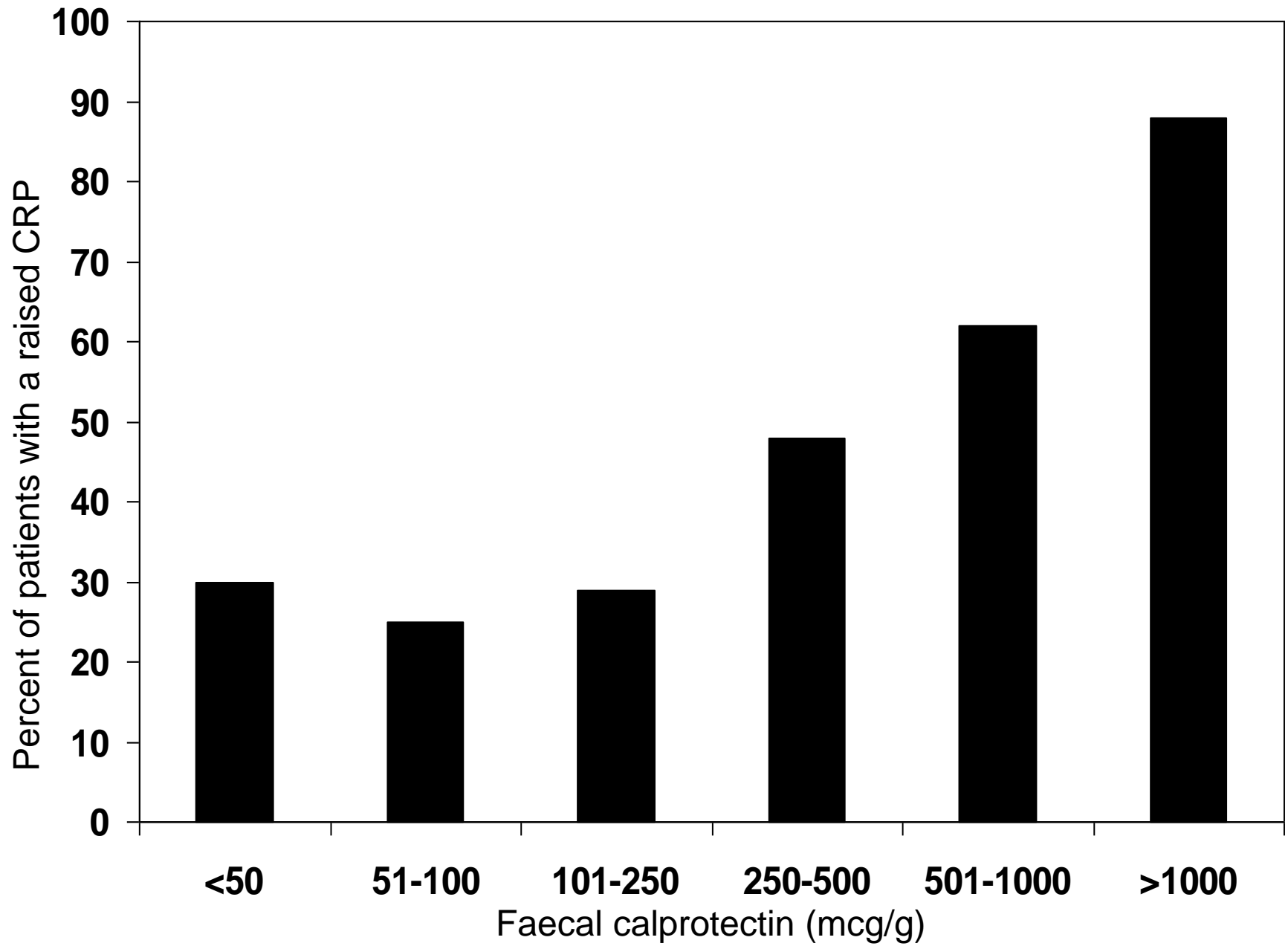
Bile salt malabsorption
Giardiasis
Microscopic colitis
Diverticulitis
Crohn's disease
Coeliac disease
Chronic pancreatitis
Thyrotoxicosis
Small bowel bacterial overgrowth
Lactose intolerance
Sorbitol induced diarrhoea



NPV 96.4%

n=500 secondary care referrals



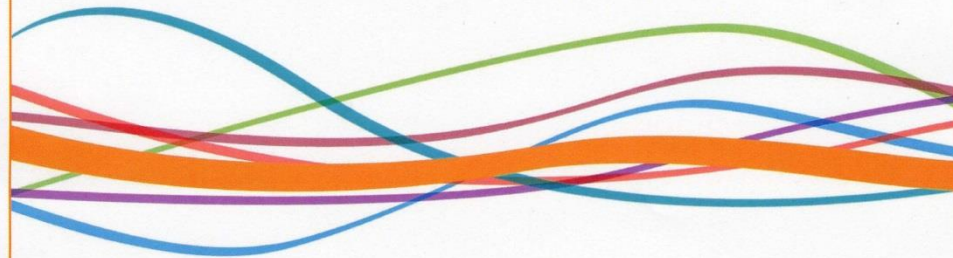


Economic report

Value of calprotectin in screening out irritable bowel syndrome

CEP09041

February 2010



Economic report

Value of calprotectin in screening out irritable bowel syndrome

CEP09041

February 2010

£13,463 per
1000 patients

DG11: Manufacturers recommendations

Cut-off value of $<50\text{mcg/g}$:

- sensitivity: 100% (CI 72-100)
- specificity 59% (CI 52-65)

- NPV 100% (CI 96-100)
- PPV 13% (CI 7-21)

DG11: Manufacturers recommendations

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Economic report

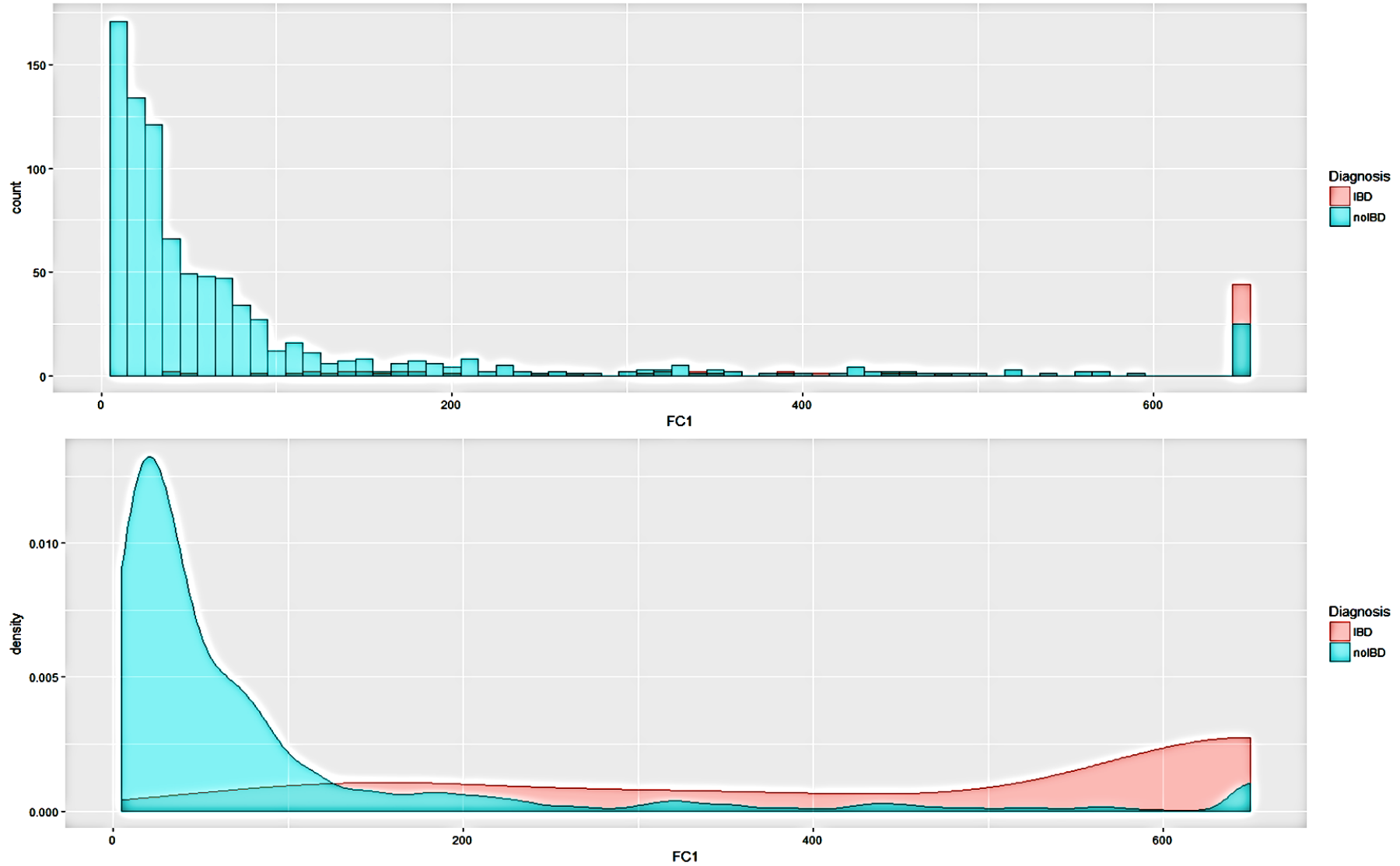
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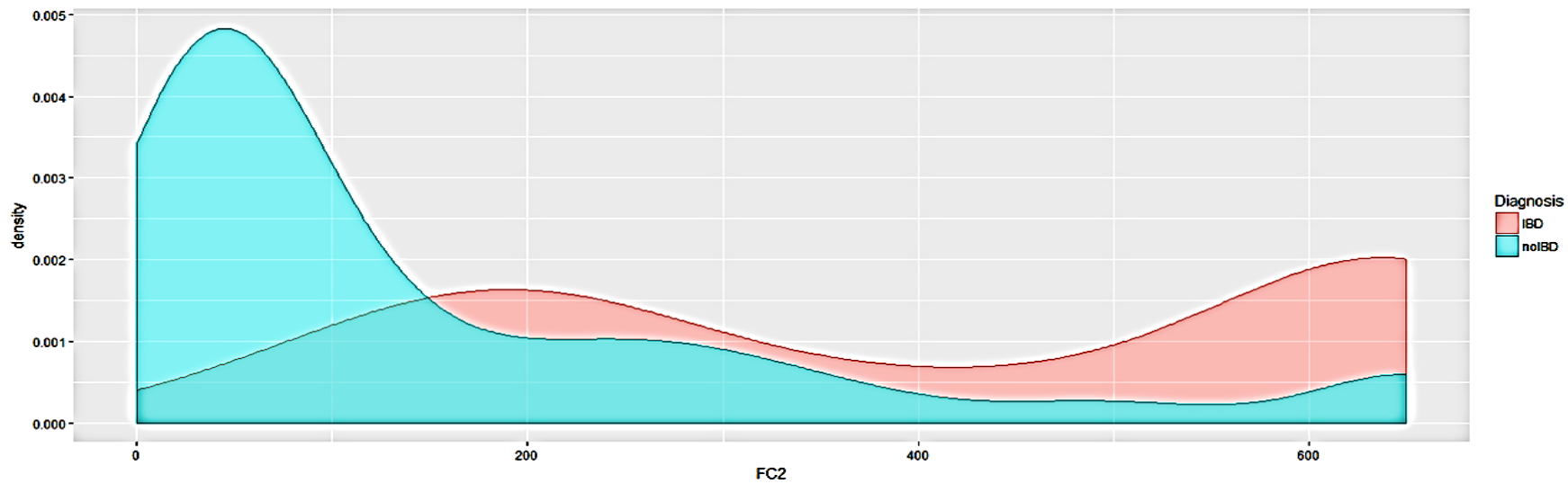
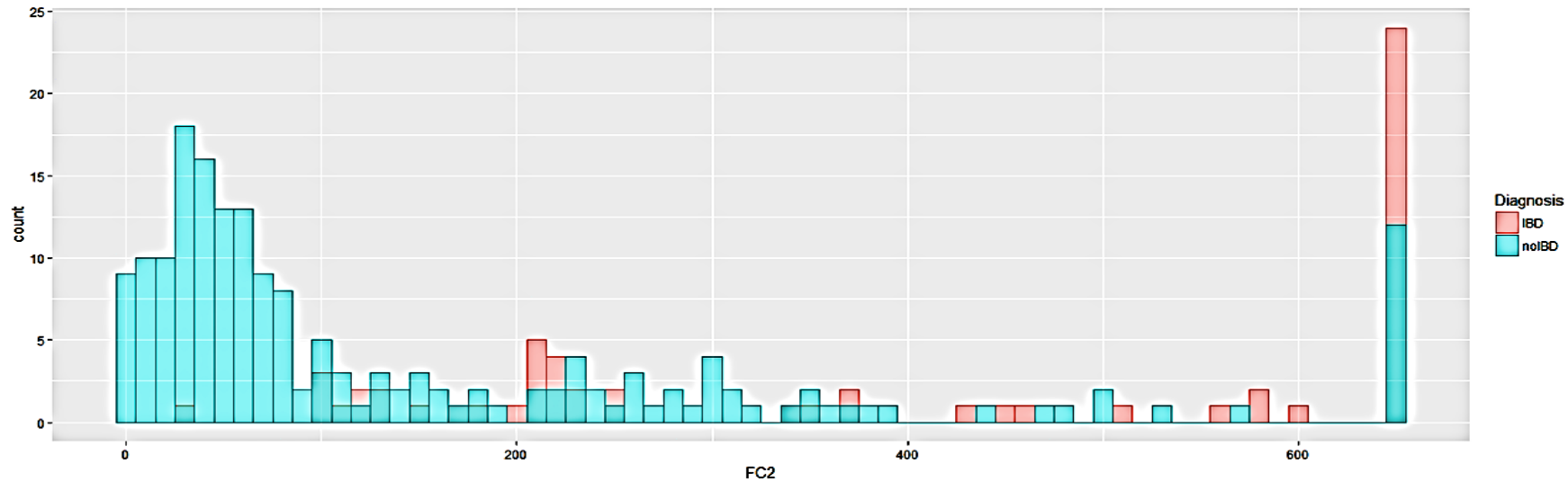
February 2010

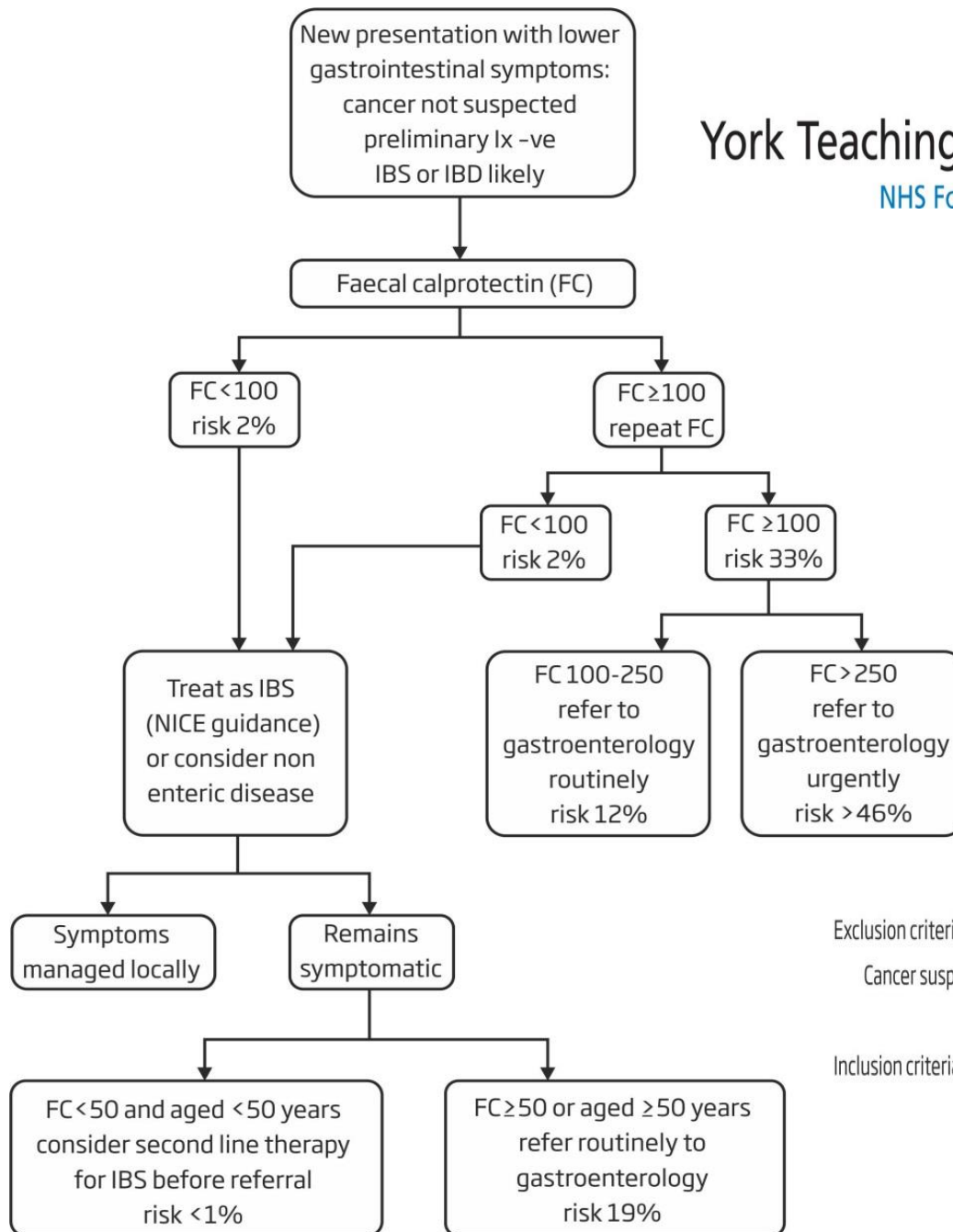
£180,000 per
1000 patients

Primary care: FC and clinical outcomes



Primary care: FC and clinical outcomes





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.

Primary Care Pilot

FC <50	FC 50-100	FC >100
58% of patients	30% of patients	12% of patients
3% risk of disease	3% risk of disease	33% risk of disease

	NPV %	PPV %
FC care pathway	97	40
FC <50mcg/g	98	20

Primary Care Pilot

FC <50	FC 50-100	FC >100
58% of patients	30% of patients	12% of patients
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	NPV %	PPV %
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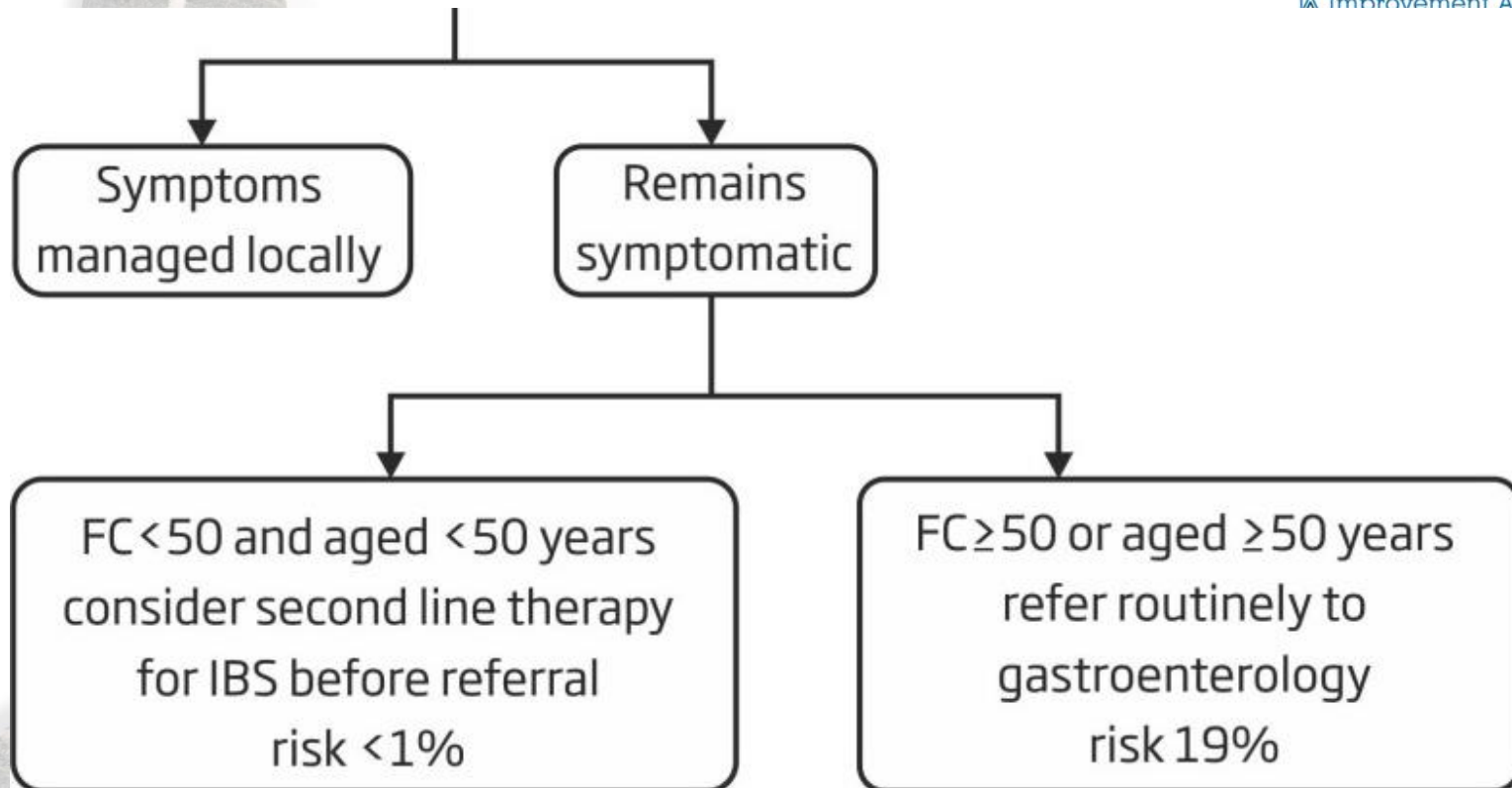
	NPV %	PPV %
FC care pathway	97	40
FC <50mcg/g	98	20

Ring fenced pathway



YORKSHIRE & HUMBER
ACADEMIC HEALTH SCIENCE NETWORK

IA Improvement Academy



YFCCP evaluation



YORKSHIRE & HUMBER
ACADEMIC HEALTH SCIENCE NETWORK

Improvement Academy

York Teaching Hospital 
NHS Foundation Trust

- **6 month outcomes on 1000 patients**
- median age: 38 [27-48]
- 63% female
- 7% prevalence of IBD (organic enteric disease)
- 53% FC > 100 normalise on repeat
- compliance 85%
- NPV: 99% (98-100); PPV: 50% (42-59)
- Sens: 94% [85-98]; spec: 92% [90-94]
- non-pathway (FC<50): NPV 99% PPV 16%
- comparator:
 - retrospective evaluation of the NPV and PPV of FC usage (cut off 50mcg/g)
 - 280 patients Scarborough and Ryedale CCG in the six months before the pathway went live
 - NPV of 100% but a PPV of 13%

YFCCP evaluation



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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

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YFCCP

Sensitivity analysis

- Prevalence of IBD
 - varied the range from 0% to 20% (YFCCP CI 6.5% - 10%)
 - YFCCP is cost saving with health benefits across all outcomes except at a prevalence of 0%
- GP Adherence
 - varied GP adherence with the intervention arm between 0-100%
 - as soon as we reach 1% the YFCCP is cost saving with better health benefits.
- Effectiveness
 - varied sensitivity and specificity between 50% and 100%
 - YFCCP is dominant at all levels of specificity above 75%
 - YFCCP is more effective at diagnosing IBD at a sensitivity & specificity > 70%

YFCCP

activity and outcomes: 2016-2018



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- Audit
 - All primary care FC requests
 - All first colonoscopies/flexible sigmoidoscopies
 - Clinical outcomes
- Number of FC requests
 - 2016: 1037 patient tests
 - 2017: 3126 patient tests
 - 2018: 4279 patient tests
- Referrals
 - 2016: 23.8% patients referred
 - 2017: 12.2% patients referred
 - 2018: 12.9% patients referred

YFCCP

requests & 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

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YFCCP

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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.

YFCCP

Prevalence of disease



Age	Prevalence (%)											
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	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

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YFCCP

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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.

YFCCP

Diagnostic accuracy



Referral pathway	Diagnostic yield expressed as a percentage [absolute numbers]					NNT
	18-29y	30-39y	40-49y	50-59y	Total	
YFCCP	32.9% [78/237]	33.0% [82/248]	22.9% [61/266]	18.5% [53/287]	26.4% [274/1038]	3.8
Non-YFCCP	20.1% [143/709]	19.2% [193/1003]	12.7% [237/1864]	12.3% [225/1828]	14.8% [798/5404]	6.8

- Colonoscopic savings per thousand patients:
 - £39,410.22
- Median time to diagnosis:
 - 29 days (interquartile range: 15-47)
 - versus 41 days (19-72).

YFCCP conclusion

York Teaching Hospital 
NHS Foundation Trust



- **Think of requesting FC**

Acknowledgements

York Teaching Hospital 
NHS Foundation Trust



YFCCP

Outstanding challenges



- When to repeat a raised FC?
 - 2-6weeks?
- What about a very high FC?
 - maybe VERY high
- Assay variability
- FIT

FIT NICE DG30:

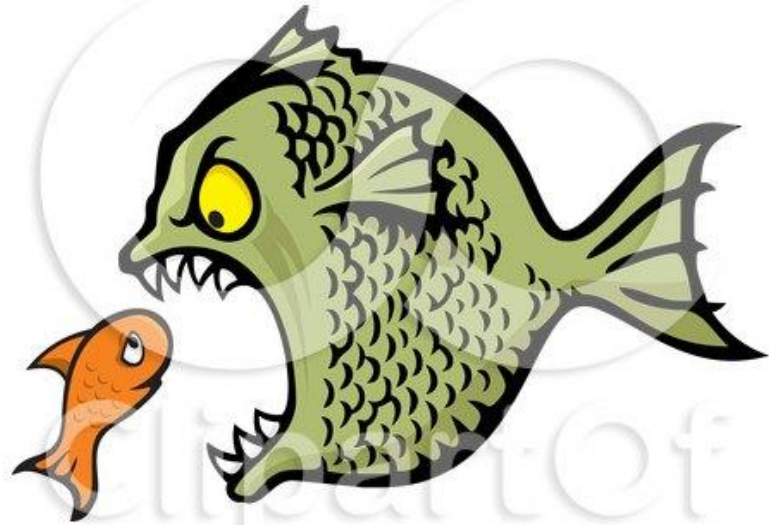
FIT for low risk patients

- NICE guidance DG30 states the OC Sensor, HM-JACKarc and FOB Gold quantitative faecal immunochemical tests (FIT) 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).

FIT NICE DG30:

FIT for low risk patients

- How does it fit with FC?

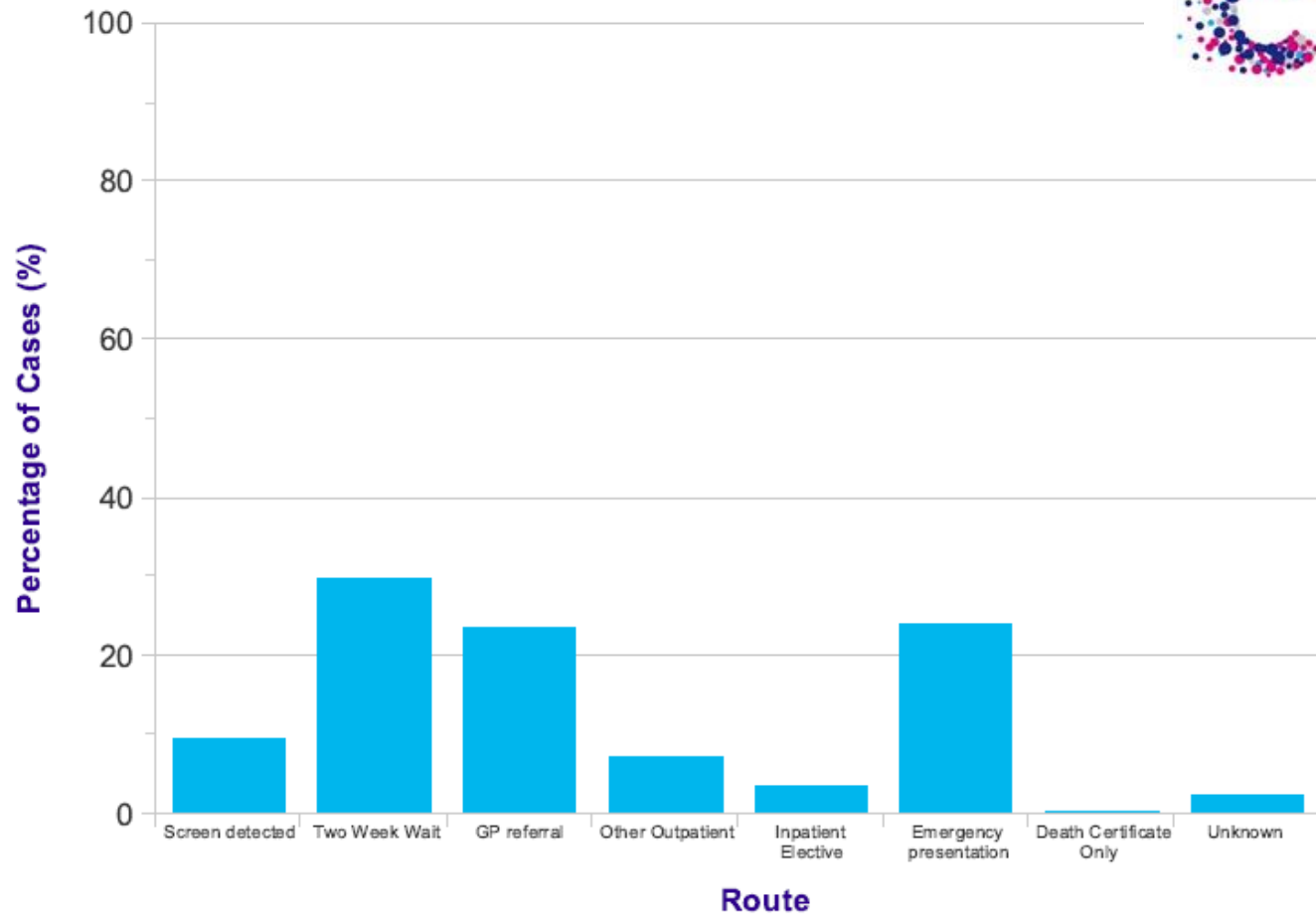


FC in suspected colorectal cancer

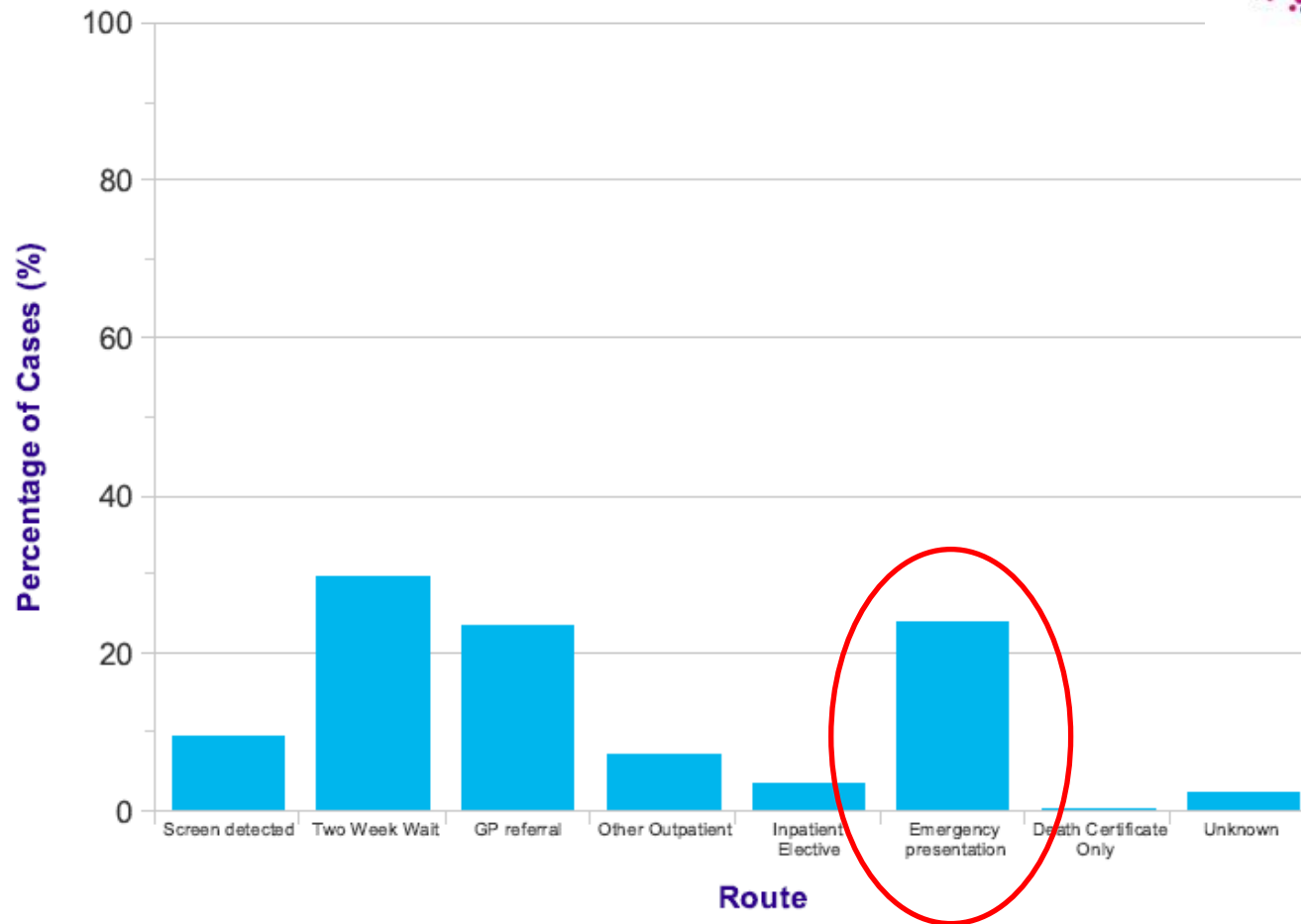
Diagnostic accuracy of faecal calprotectin for neoplasia and organic enteric disease

	Median	NPV	PPV	Sensitivity	Specificity
Neoplasia					
• cancer	227 (94.5-496)	98.6 (95.7-99.6)	8.7 (6.3-11.9)	92.7 (79-98)	35.2 (31.5-39.2)
• cancer and polyps	189.5 (88-494)	97.2 (93.8-98.9)	15.6 (12.4-19.4)	91.9 (82.6-96.7)	36.4 (32.5-40.5)
Organic enteric disease					
	232 (79-580)	89.4 (84.3-93)	32.7 (28.4-37.4)	86.1 (79.7-90.8)	39.8 (35.4-44.3)

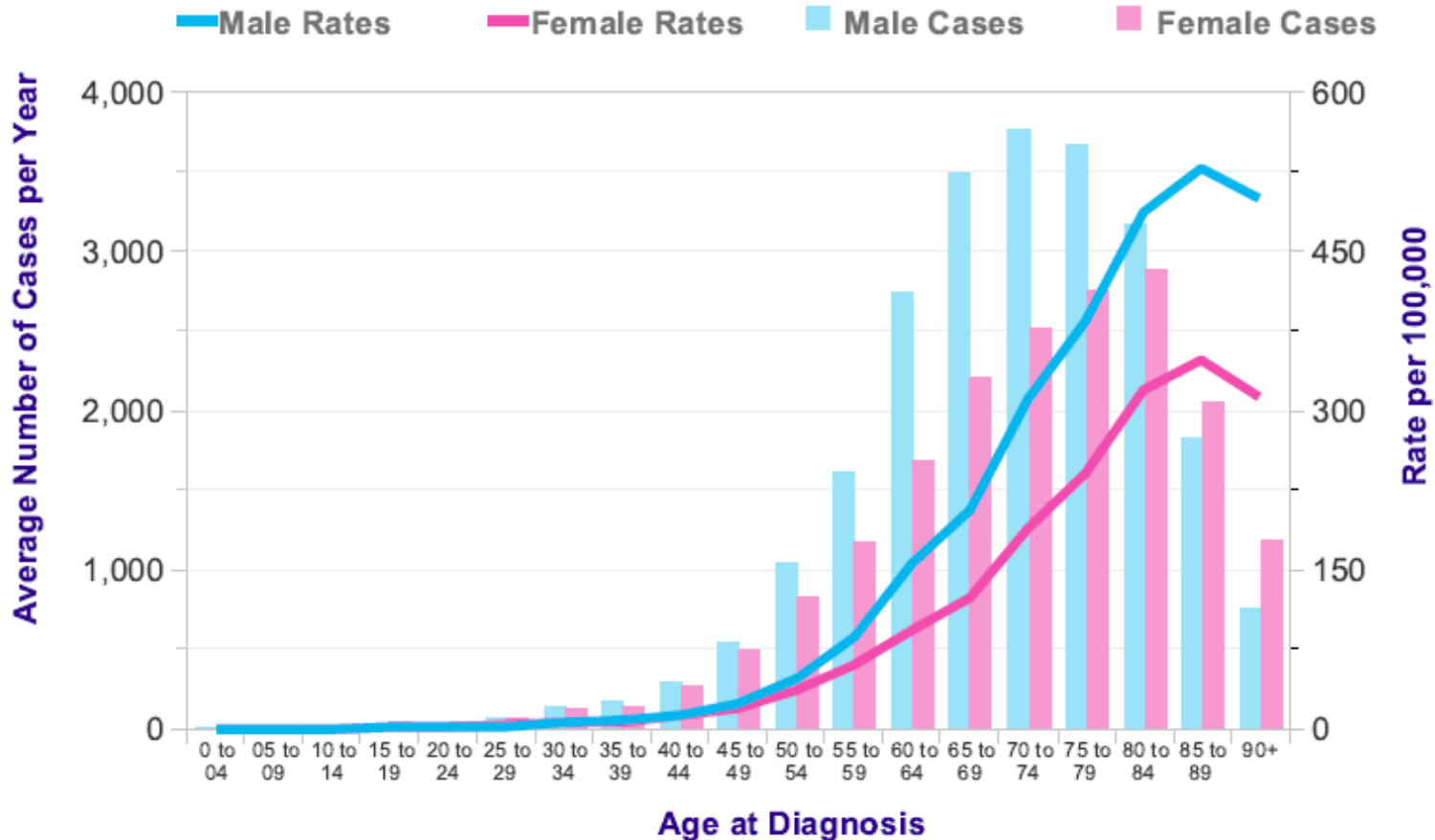
FIT NICE DG30: FIT for low risk patients



FIT NICE DG30: FIT for low risk patients



FIT NICE DG30: FIT for low risk patients



FIT v FC:

1229 patients <60y fulfilling DG30 criteria applied to YFCCP

	Age range (yrs)	Sensitivity (CI)	Specificity (CI)	NPV (CI)	PPV (CI)
CRC					
FIT\geq10mcg/g*		89.3	79.1	99.5	14.2
FC \leq100mcg/g	50-59	50	83	99	5
	40-49	N/A	N/A	N/A	N/A
	30-39	100	89	100	3
	18-29	N/A	N/A	N/A	N/A
CRC, polyps & IBD					
FIT\geq10mcg/g*		68.6	83.6	94.4	39.8
FC \leq100mcg/g	50-59	65	85	98	21
	40-49	89	90	99	33
	30-39	100	92	100	31
	18-29	100	89	100	47

* Mowat C, et al. Gut 2015;0:1–7. doi:10.1136/gutjnl-2015-309579

Integrated FIT-ID management pathway

