NHS England

COLOFIT: a consensus statement to support implementation

Endorsed by:

Association for Laboratory Medicine

BRITISH SOCIETY OF GASTROENTEROLOGY

The Association of Coloproctology of Great Britain & Ireland

IBMS Institute of Biomedical Science

RCGP Royal College of General Practitioners

The Royal College of Pathologists
Pathology: the science behind the cure

PCSG The Primary Care Society for Gastroenterology

1. Scope of this guidance

This guidance is for all patients with NICE NG12 symptoms of possible colorectal cancer excluding those with an anal or rectal mass/ulceration who should be referred on a lower gastrointestinal (LGI) Urgent Suspected Cancer (USC) pathway immediately.

This guidance should be used in place of existing NICE DG56/NICE NG12 guidance for the use of the faecal immunochemical test for haemoglobin (FIT) in the lower GI urgent suspected cancer pathway. This guidance suggests a faecal haemoglobin (f-Hb) of≥10µg haemoglobin /gram faeces (µg/g) measured with a faecal immunochemical test (FIT) should be replaced with a COLOFIT ≥1% for referral to the Lower GI Urgent Suspected Cancer pathway. This threshold will be reviewed over time and may increase in future.

2. Introduction

Current practice dictates that when a patient presents to general practice with symptoms of colorectal cancer, as per the NICE NG12 guidance, they will be offered a FIT. Anyone with a result over or equal to 10µg/g should be referred on a lower gastrointestinal (GI) urgent suspected cancer (USC) pathway.This approach however fails to adequately exploit the quantitative nature of the FIT result and the risks associated with higher FIT values, in combination with other well-recognised risk factors for colorectal cancer (age and sex).

COLOFIT is a clinical calculator, which enhances the current specificity without significantly compromising the sensitivity of the test. This determines each individual patient's personal risk of colorectal cancer by combining a f-Hb (measured through FIT), mean corpuscular volume (MCV), platelet count age and sex. This can be used to support decision making for clinical management of the patient's symptoms and/or the need for colonoscopy or alternative methods of colonic imaging.

Health economic analysis has demonstrated COLOFIT to be cost effective[2]. Health professionals and patients were broadly accepting of FIT[1].

NHS England has asked each Cancer Alliance to implement advanced risk-based calculators, such as COLOFIT, in the Lower GI USC referral pathway, and to produce an initial plan and assessment of site readiness to transition to COLOFIT, including identifying at least one system as an early adopter.

Local systems should work to implement COLOFIT, in collaboration with Endoscopy Leads, Cancer Alliances, and Pathology Networks.

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3. Validation

Validation is the application of the COLOFIT formula to patient datasets independent from the original trial dataset to determine its accuracy and reliability in those populations compared to the results of the trial population.

Several local population validations have been completed[6,13] including in Nottingham, the North West of England, London[9,12] and Oxford[11]. A large scale national validation across England and Wales will be published shortly.

COLOFIT was developed from a population with the FIT positivity rate of at least 17% (defined as ≥10µg/g), the cancer rate of 1.3%-1.6%, using HM-Jackarc or OC-Sensor FIT assays[1]. If the local FIT positivity rate, cancer rate and FIT assays do not align with these parameters then validation must be completed before implementation can be considered.

If the local FIT positivity rate, cancer detection rate and FIT assay align with these parameters then local validation is not mandatory. But should be considered if additional reassurance is required to persuade local stakeholders to adopt COLOFIT. Validation guidance has been published.

4. Implementation into Local Systems

The ColoFIT equation (Annex A) should be embedded in local systems.

Referring Clinicians (usually in primary care) will undertake a digital rectal examination, request a FIT and a full blood count for all patients with NICE NG12 symptoms of possible colorectal cancer. Patients with an anal or rectal mass should be referred on a LGI USC pathway immediately.

When results are available, the COLOFIT colorectal cancer risk score will be calculated. This will replace the FIT result (f-Hb) as the threshold for referral. The referring clinician, after discussion with the patient, will decide if, how and when to refer the patient for further investigation. This discussion should consider the patient's broader context and comorbidities. This discussion should be recorded within the patient record and should include discussion on the various options available to the patient.

A SNOMED code has been accepted to record a ColoFIT score.

- Code: 3000321000000102
- SNOMED CT Term: COLOFIT colorectal cancer risk score (observable entity)

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FIT kits for patients with NICE NG12 symptoms of colorectal cancer are fully funded by Integrated Care Boards.

5. Target Populations and Safety Netting

NICE NG12 Guidance defines possible colorectal cancer symptoms. Patients with symptoms and an anal or rectal mass should be referred on an LGI USC pathway immediately. All other patients with symptoms should be given a FIT and a full blood count should be requested to allow the COLOFIT colorectal cancer risk score to be calculated.

Patient materials are expected to be in place to support patients in:

- Explaining the importance and function of a FIT
- How to complete and return a FIT
- Understanding why they have been referred on an Urgent Suspected Cancer referral pathway and what next steps are expected
- Understanding why they have not been referred on an Urgent Suspected Cancer referral pathway and what next steps are expected

NHS England is exploring the development of national patient materials specifically for COLOFIT.

A clinical discussion with the patient should also include the approximate time to the next appointment, and expectations of this appointment.

Electronic safety netting should be in place to make sure patients return their FIT kit in an appropriate time frame.

Where COLOFIT is implemented into laboratory information management systems, laboratories should seek an extension of scope for ISO 15189:2022 for the use of COLOFIT through UKAS and include COLOFIT assessment within their quality management system processes.

6. Referral to a Lower GI Urgent Suspected Cancer Pathway

Referral to a LGI USC pathway should be made in line with the following guidance:

- Patients with a rectal or anal mass should not be tested and should be referred immediately

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- Patients over the age of 18 with a COLOFIT score of ≥ 1% risk of colorectal cancer should be referred for consideration of colonoscopy or other colonic imaging

The Faster Diagnosis Standard clock does not start until an USC referral is made; however the patient should be encouraged to complete both their FIT and blood test as soon as possible to avoid delays in referral for those at high risk.

7. Ongoing Service Evaluation

Local systems are encouraged to develop service evaluations to review COLOFIT. It will be expected that service evaluations should include the assessment of the below metrics;

- Number of cancers diagnosed
- Number of endoscopy procedures delivered
- Type of colonic imaging provided
- Cancer detection rate
- Cancer conversion rate
- Faster Diagnosis Standard
- DM01 standard
- Review of any cancers not initially detected by COLOFIT

In particular, evaluations should focus on patients with FIT≥10µg/g and COLOFIT<1% who go on to develop cancer.

Evaluation of data will also be used to consider further changes to thresholds. Changes will only be appropriate upon review of the above metrics, ensuring that no deterioration in metrics are found.

To support the role out of COLOFIT and to ensure its safety and efficacy, the National Cancer Team will develop a dashboard to monitor ongoing implementation of COLOFIT.

NICE is assessing the growing evidence base for COLOFIT ahead of potential recommendations and updated guidance. This includes consideration of the threshold. NICE's current position across all cancers is that a risk of cancer of ≥3% should be referred on an urgent suspected cancer pathway.

Further research on the 1% threshold of referral on the LGI USC pathway using COLOFIT is underway, and it is expected that the threshold for referral may ***increase*** in the future. This will be informed by ongoing data and evidence, including real world use of COLOFIT through service evaluations.

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Annex A

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

Units

- Age is measured in years
- FIT is measured in micrograms of haemoglobin per gram of faeces (ug Hb/g)
- PLATELETS or platelet count is measured in thousands per microlitre (K/uL)
- MCV is measured in femtolitres (fL)
- Where the term ‘male’ is used, this should be replaced by a 1 if the person being assessed is male, and a 0 if they are female.

Annex B. Clinical Evidence for ColoFIT

Below includes pertinent studies which provide further evidence of the use of COLOFIT:

1. Rees, Colin, and Willie Hamilton. *Overview of the COLOFIT study.* Frontline Gastroenterology (2025).
2. Thomas, C., et al., *Cost-effectiveness of FIT and a FIT-based model to optimise symptomatic diagnosis of colorectal cancer: health economic modelling for the COLOFIT project.* BMJ Public Health, 2025. 3(1): p. e002089.
3. Dobson, C., et al., *Practitioner perspectives on symptomatic faecal immunochemical testing in the UK: a qualitative interview study.* British Journal of General Practice, 2025: p. BJGP.2024.0358.
4. Crooks, C.J., et al., *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.* Alimentary Pharmacology & Therapeutics, 2025. 61(5): p. 852-864.

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5. Adam Biran, et al., *Patient experiences and expectations of faecal immunochemical testing for investigation of colorectal cancer symptoms: a cross-sectional qualitative interview study with patients and practitioners in the UK.* BMJ Open, 2025. 15(5):e093215.

6. Anderson, Rebecca, et al. *FP17 The COLOFIT model for colorectal cancer (CRC) prediction: a real-world evaluation.* (2025).

7. Morton A.J. et al., *Variations in the Use of Faecal Immunochemical Testing (FIT) in Primary Care in England: A Population-Based Cohort of 531,735 FITs from 495,121 Patients Between 2019 and 2023.* Clin Epidemiol. 2025 Jun 8;17:523-535. doi: 10.2147/CLEP.S518048

8. Crooks C.J. et al., *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.

9. Morrison et al., O3 *The COLOFIT model for triage of urgent colorectal cancer referrals: a multi-centre study*. Gut 2026;75:A3.

10. Malcolm et al., O86 *The use of the faecal immunochemical test in patients with symptoms of colorectal cancer in Wales: a population-based cohort study*. Gut 2026;75:A359-A360.

11. Tamm et al., *External validation of the COLOFIT colorectal cancer risk prediction model in the Oxford-FIT dataset: the importance of population characteristics and clinically relevant evaluation metrics.* BMC Med. 2025 Aug 27;23(1):503. doi: 10.1186/s12916-025-04339-w.

12. Gerard et al., Evaluating COLOFIT for triage of urgent colorectal cancer referrals: a multi-centre validation study. Endoscopy. 58. 2026 S132-S132. 10.1055/s-0046-1820857.

13. Alastair Morton, *External validation of COLOFIT, a risk-prediction model for optimising the use of Faecal Immunochemical Testing (FIT) using sex, age and blood tests in symptomatic patients: a national cohort of 137,544 FITs in England.* 2026 Short paper presented to ACPGBI Conference

Acknowledgement

This document is endorsed by:

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