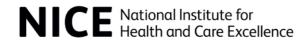
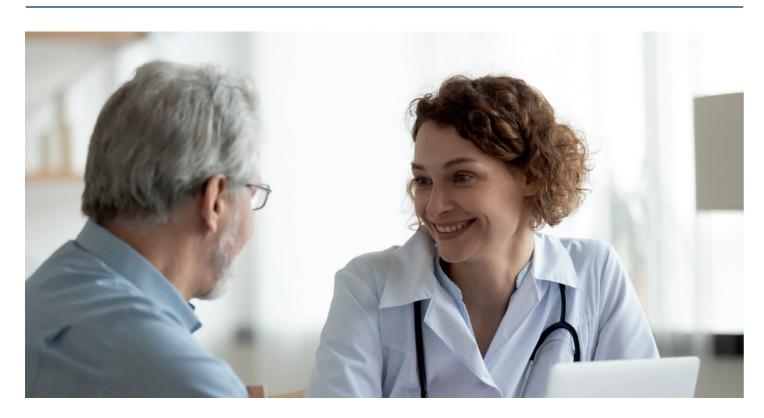
NICE DG56 vs. NICE DG30

Updates to FIT Guidance

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In August 2023 NICE published updated guidance on 'Quantitative faecal immunochemical testing (FIT)' to guide colorectal cancer pathway referral in primary care. This update expands and clarifies the previous recommendations, based on the extensive clinical evidence

that has accumulated since DG30 was originally published, back in July 2017.

What are the main changes?

DG30 set the foundation for improving the primary care pathway for colorectal cancer, by utilising FIT in place of the guaiac faecal occult blood tests (gFOBt) for initial testing, following presentation with related symptoms. DG30 provided an overview of the diagnosis and care pathways at the time. This included referrals based on gFOBt outcomes, and identified the main problem to be addressed.

DG56 has been able to utilise the huge base of clinical efficacy data and evidence, amassed since July 2017, to confirm the diagnostic accuracy of FIT, which has successfully resulted in the reduction of unnecessary colonoscopies. Additionally, with COVID-19 permanently changing the way patients engage with healthcare, FIT too has been adapted to this changed environment, to better serve the diagnostic pathway.

Original DG30 Recommendations

DG30 recommended that FIT was adopted in primary care to guide referrals for suspected colorectal cancer in people without rectal bleeding who have unexplained symptoms, but who did not meet the criteria for a suspected cancer pathway (NICE NG12). Historically, the guaiac test has had low compliance and return rates and was susceptible to user errors both at initial sampling and when reading results in the lab. Utilisation of FIT meant that low-risk symptomatic patients could be triaged more effectively, addressing both clinical and cost concerns.

DG56 Expanded Recommendations

DG56 has expanded its recommendations to include a wider cohort of patients and symptoms. Thus, high-risk patients that wouldn't have been offered FIT under DG30 will now be offered a FIT in conjunction with their colonoscopy referral. DG56 also states that FIT should be offered even if a patient has previously had a negative FIT result through the NHS Bowel Cancer Screening Programme, due to the differences between the threshold criteria. It also emphasises that safety netting should be put in place if a patient has a negative FIT result. This aims to prevent patients from being lost on the primary care pathway, by ensuring suitable follow-up reviews are conducted and alternative diagnostic tests are performed as necessary.

The threshold for referral to a suspected cancer pathway remains unchanged at 10 micrograms of haemoglobin (Hb) per gram of faeces. DG56 reiterates that economic models still suggest a

threshold of 10 micrograms Hb / gram of faeces is more cost effective than lower thresholds, and also addresses concerns that higher thresholds could reduce physician confidence in the test

Following the publication of DG56, NICE released a news article stating:

Our recommendations can help around 100,000 people avoid having a colonoscopy [...].

What does this mean for FIT?

With a wider scope of patients being recommended for FIT there will be measurable benefits to gastroenterology clinics and Trusts due to:

- Earlier detection and treatment of serious bowel disease, including low-risk and high-risk adenomas, diverticulitis, as well as colorectal cancer.
- Improved triaging of symptomatic patients, allowing efficient allocation of resource, and a reduction of people on extended waiting lists for colonoscopies.
- Reduced likelihood of complications during colonoscopies as FIT provides quantitative results that indicate potential seriousness of the problem.

Alongside these benefits also comes a greater requirement for the easy and efficient distribution of FIT kits to GP sites and patients across the UK, as well as improved workflows. In the same way that patients need safety netting, the operational aspects of providing the FIT service may require review to ensure that testing can be provided to all patients, as needed, without delay.

DG56 recognises that "certain groups may need tailored resources or additional clinical or carer support to enable them to use FIT". Therefore, it may be appropriate to perform an assessment of local sociodemographic needs to maximise inclusivity and ensure patients can complete the sample collection process to minimise pre-analytical variation.

Customisable elements of FIT-KITs include language, font or instructions on IFU's, sample return methods, or the inclusion of Fe-Col® faeces collection papers.

A recent initiative, The Alpha Portal (TAP), direct ordering and stock control platform, is also now available to help reduce logistical burden, and support the traceable distribution of FIT-KITs to any UK location by enabling users to order additional kits via an online portal, and view:

- Pictures and descriptions of kit contents, including custom pack items.
- Real-time stock availability.
- Current LOT numbers and expiry dates.
- Usage reports enabling quick and easy oversight of ordering frequency and demand.



Additionally, Alpha Laboratories recognises the importance of on-going advice and support, training, and logistical co-operation. As part of the support services available, our dedicated specialists are on-hand to assist with technical and operational queries, help with workflow analysis, and facilitate discussions with key opinion leaders to ensure the best quality of care can continuously be provided to patients.

Contact us to discuss how we can further support your FIT service: digestivedx@alphalabs.co.uk

Scan the QR code to see how the FIT-KIT works. To sign up, or for more information please contact: fit-kit@alphalabs.co.uk

How does Alpha Laboratories support NICE DG56?

Alpha Laboratories offers a number of bespoke solutions to accommodate the DG56 requirements and ensure that high levels of service can be provided, and patient usability and compliance can be improved.

As DG56 alludes above, one size does not FIT all when taking a patient-centred approach to healthcare. Therefore Alpha Laboratories offers customisable "FIT-KIT" patient packs, that can be tailored based on the requirements of different sites across the UK.

