

CYLCHLYTHYR IECHYD CYMRU



Dyddiad cyhoeddi: 30 Ionawr 2023

Llywodraeth Cymru
Welsh Government**STATWS: GWEITHREDU****CATEGORI: ANSAWDD A DIOGELWCH****Teitl:** Llwybr Delfrydol Cenedlaethol (FIT) newydd ar gyfer y Bibell Gastroberfeddol Isaf**Dyddiad dod i ben / Dyddiad yr adolygiad:**
Amherthnasol**I'w weithredu gan:**

Brif Weithredwyr Byrddau Iechyd a
Chyfarwyddwyr Gofal Sylfaenol
Cyfarwyddwyr Meddygol Byrddau Iechyd a
Chyfarwyddwyr Meddygol Cynorthwyol ar
gyfer Gofal Sylfaenol
Rheolwyr llawdriniaeth y colon a'r rhefr a
gastroenteroleg - y Gyfarwyddiaeth
Rheolwyr Canser y Byrddau Iechyd a
chlinigwyr cancer arweiniol
Arweinwyr ar gyfer Gwasanaethau Labordai
yn y Byrddau Iechyd

Angen gweithredu erbyn:

21 Ebrill 2023

Anfonwr:

Yr Athro Chris Jones, Cyfarwyddwr Clinigol Cenedlaethol, GIG Cymru a Dirprwy Brif Swyddog
Meddygol, Llywodraeth Cymru

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Ym mis Gorffennaf 2022, cyflwynodd [Cylchlythyr Iechyd Cymru \(2022\) 021](#) y rhestr ddiweddaraf o 21 o lwybrau clinigol cytûn cenedlaethol ar gyfer cancer. Dylai ymddiriedolaethau a byrddau iechyd lleol ei mabwysiadu fel rhan o ddarparu llwybr lle'r amheuir cancer.

Roedd y llwybr lle'r amheuir cancer y colon a'r rhefr yn adlewyrchu'r canllawiau presennol o'r Sefydliad Cenedlaethol dros Ragoriaeth mewn Iechyd a Gofal ar gyfer atgyfeirio ac ymchwilio i ganser y colon a'r rhefr; yn benodol canllawiau NG12 a DG30.

Mae'r *Association of Coloproctology of Great Britain and Ireland (ACPGBI)* a Chymdeithas Gastroenteroleg Prydain (BSG) wedyn wedi cyhoeddi canllawiau cenedlaethol ar gyfer defnyddio prawf imiwnocemegol ar ysgarthion (FIT) fel rhan o'r llwybr diagnostig i bobl sy'n dangos arwyddion neu sydd â symptomau sy'n peri amheuaeth o ganser y colon a'r rhefr.

Os yw claf yn cael canlyniad negyddol, archwiliad clinigol normal, a chyfrif gwaed llawn, mae'r risg fod ganddo ganser y colon a'r rhefr yn <0.1%. Mae hyn yn is na risg y boblogaeth yn gyffredinol, a throthwyon atgyfeirio presennol NICE.

Mae hyn yn creu cyfle sylweddol i osgoi rhoi colonosgopi i gleifion yn ddiangen, gan ryddhau capasiti yn y llwybr ar gyfer cancer y bibell gastroberfeddol isaf symptomatig, er mwyn sicrhau bod y cleifion symptomatig mwyaf brys yn cael eu gweld yn gynt.

Mae grŵp cynghori Rhwydwaith Canser Cymru ar gyfer cancer y colon a'r rhefr wedi ystyried y canllawiau diweddaraf a ddarperir gan gyrff proffesiynol, ac mae wedi argymhell i GIG Cymru a Llywodraeth Cymru y dylai'r llwybr lle'r amheuir cancer y colon a'r rhefr gael ei ddiwygio i adlewyrchu'r canllawiau newydd hyn.

Dylai ymddiriedolaethau a byrddau iechyd nawr weithredu i fabwysiadu'r Llwybr Delfrydol Cenedlaethol 'FIT' ar gyfer y Bibell Gastroberfeddol Isaf diweddaraf, sydd ar gael yn:

[Y Llwybr Canser Sengl - Cydweithrediad Iechyd GIG Cymru](#)

Bydd y llwybr newydd yn helpu i sicrhau bod cleifion ar y llwybr ar gyfer y bibell gastroberfeddol isaf yn cael diagnosis prydlon drwy ddefnyddio'r capasiti colonosgopi sydd ar gael yn y modd mwyaf effeithiol.

Mae gan holl fyrddau iechyd Cymru fynediad at brofion imiwnocemegol ar ysgarthion (FIT), ac ymhob bwrdd iechyd ond un mae'r profion hyn eisoes ar gael i'w defnyddio gan dimau gofal sylfaenol. Mae'r rhaglen endosgopi genedlaethol wedi helpu i weithredu hyn drwy ddarparu digwyddiadau addysg a hyfforddiant blaenorol ochr yn ochr â chydweithwyr yn Addysg a Gwella Iechyd Cymru.

Ar hyn o bryd, rydym yn rhagweld y bydd NICE yn adolygu ei ganllawiau tua mis Tachwedd 2023.

Cafodd y Llwybr Delfrydol Cenedlaethol 'FIT' ar gyfer y Bibell Gastroberfeddol Isaf diweddaraf ei ddatblygu gyda chymorth gan Bwyllgor Ymarferwyr Cyffredinol Cymru, Cyfarwyddwyr Meddygol Cynorthwyol ar gyfer Gofal Sylfaenol, a chlinigwyr arbenigol byrddau iechyd y cyfarfod clinigwyr arbenigol ar gyfer canser y colon a'r rhefr yn Rhwydwaith Canser Cymru.



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Lower Gastrointestinal Symptomatic Faecal Immunochemical Testing Pathway 'FIT' - National Optimal Pathway

For Welsh Health Boards
Date Published: - 30 January 2023
Review Date: - 29 January 2024

Symptomatic Faecal Immunochemical Testing (FIT)

The Faecal Immunochemical Test (FIT) can identify possible colorectal cancer by detecting small amounts of blood (globin component of haemoglobin) in stool samples. It measures the faecal haemoglobin (Hb) concentration as microgram of Hb per gram ($\mu\text{g/g}$) of faeces. In symptomatic patients, a positive FIT is a result of $\geq 10\mu\text{g Hb/g}$, processed in an UKAS ISO 15189 accredited laboratory.

FIT has a superior positive predictive value for colorectal cancer over symptoms alone¹. It has a similar diagnostic accuracy in both high and low risk symptomatic patients, including younger age groups where there is an increasing incidence of colorectal cancer¹.

At the time of publication of the first version of the National Optimal Pathway for Colorectal Cancer (NOPCC) in 2019, the recommended use of FIT was limited to people with low risk symptoms². Subsequent to the new joint national guideline by the Association of Coloproctology of Great Britain and Ireland and British Society of Gastroenterology¹, this pathway outlines the integration of symptomatic FIT into the NOPCC.

General Principals

- FIT should be available to all General Practices to support the assessment of people presenting with signs or symptoms raising the suspicion of colorectal cancer and as an adjunct to clinical history, examination (including anorectal examination) and appropriate blood tests (e.g. FBC, ferritin)
- Normal practice should be that FIT is undertaken within primary care **prior** to considering referral in people presenting with signs or symptoms suspicious of colorectal cancer
- In some cases, there may be an ongoing high suspicion of colorectal cancer based upon symptoms and clinical judgement ('gut instinct') in people with a negative FIT. Referrals should clearly outline why cancer is still suspected
- The use of FIT should be carefully considered with individualised risk and benefit discussed in people potentially unsuitable for onward diagnostic investigation
- We recommend that direct/straight to test investigation is undertaken in people who are FIT positive. Where there is uncertainty regarding suitability for investigation (e.g. frailty or significant comorbidity), referrals should clearly outline this to support decision making in the triage of referrals in secondary care
- The Bowel Screening Wales (BSW) programme is available for asymptomatic participants, with a current FIT threshold of $150\mu\text{g Hb/g}$ and plans to reduce this to $80\mu\text{g Hb/g}$ in the future. This compares with a symptomatic FIT threshold of $\geq 10\mu\text{g Hb/g}$. Therefore, we advise that FIT is undertaken in people presenting with signs or symptoms of suspected colorectal cancer at any time point, even following a negative bowel screening programme test

Criteria

- FIT should be undertaken in people presenting with signs or symptoms suspicious of colorectal cancer (see flow chart below for guidance related to use of FIT in people with Iron Deficiency Anaemia)^{1, 3} ACPGBI/BSG advise that a FIT is not required for patients with anal ulceration or anal/rectal mass prior to referral
- We recommend that patients with an abdominal mass suspicious of malignancy should have a FIT undertaken alongside investigation (e.g. CT abdomen) or suspected cancer referral
- There is no indication for FIT in people with upper GI symptoms (e.g. dyspepsia)

Point of Suspicion

A clinical suspicion of cancer may result from:

- Positive FIT result ($\geq 10\mu\text{g}$ Hb/g)
- Ongoing high clinical suspicion of colorectal cancer in patients with a negative FIT
- Clinical suspicion of cancer in patients unable to complete (e.g. due to physical disability) or declining FIT. The reason for an absent FIT test should be outlined in referrals to secondary care

First clinical suspicion of cancer	Recording the patient's entry onto the single cancer pathway – day 0	Pathway entry
Referral from primary care: <ul style="list-style-type: none">• Positive FIT stool test ($\geq 10\mu\text{g}$ Hb/g)• High clinical suspicion of colorectal cancer in FIT negative patients or those unable to complete/declining FIT	Date referral is sent from primary care to the Health Board	Referral from GP
Positive FIT stool test ($\geq 10\mu\text{g}$ Hb/g) in secondary care e.g. outpatient clinic, inpatient, emergency presentation	Date the lab validate a positive FIT test result	Referral following diagnostic - Other

Referrals and Safety Netting

Waiting times across all referral priorities including suspected cancer have been impacted by the COVID pandemic. Robust safety netting advice is therefore imperative across primary and secondary care for patients who are FIT negative or where the referral priority is downgraded on the basis of the result.

Primary care

We advise that:

- Patients with a positive FIT ($\geq 10\mu\text{g}$ Hb/g) are notified of the result and referred to secondary care as a suspected cancer priority. Safety netting advice should be provided to contact the General Practice if communication is not received from secondary care within 2 weeks

- General practices have systems in place to identify and remind patients that have not returned a FIT sample within 2 weeks of request. Where no FIT result can be obtained, clinicians should use existing guidelines to assess the risk of colorectal cancer^{2, 4}
- Patients with a negative FIT are provided with safety netting advice to seek further medical review if they have a persistent or change in symptoms or have ongoing concern (outline safety netting letter included in Appendix A)

Secondary care

- GP's are notified of all referrals downgraded from a suspected cancer priority, including the reason for priority change and recommendations for safety netting
- Patients should be advised of referral downgrades⁵ (outline letter included in Appendix B)
- ACPGBI/BSG recommend that patients should not be excluded from referral from primary care for symptoms based upon the basis of FIT testing alone. In cases where secondary care assessment or investigation is not deemed necessary following receipt of a referral, a clear plan of action should be described, including⁶:
 - i. Specific changes in symptoms to flag
 - ii. Re-referral thresholds
 - iii. Routes to assist in further management (e.g. local pathways)

Pathway Governance

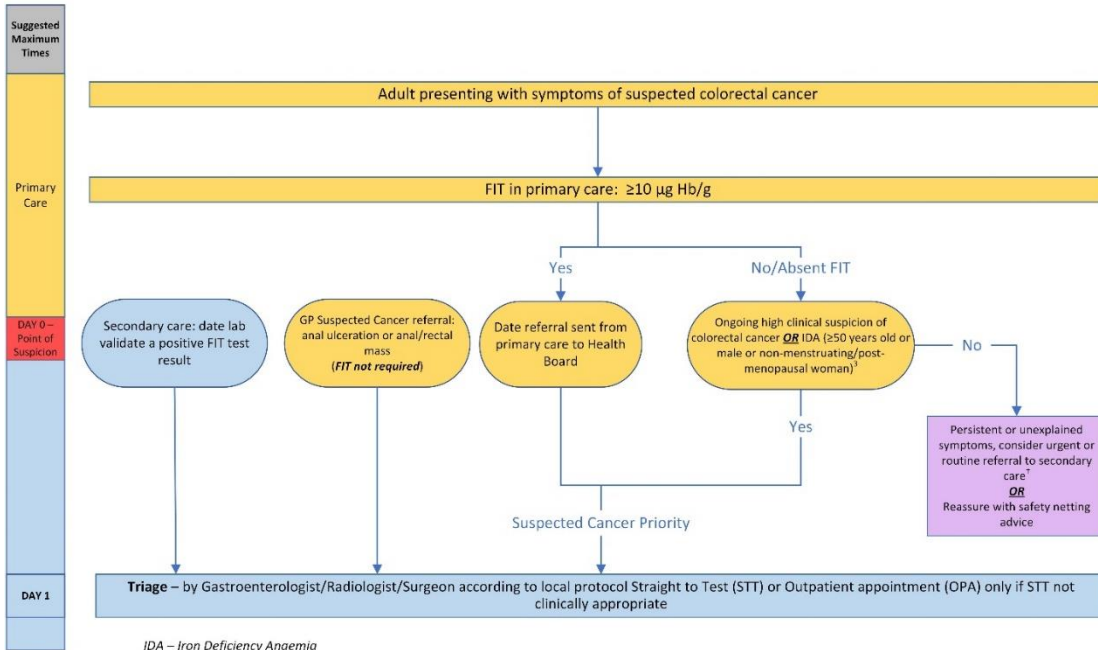
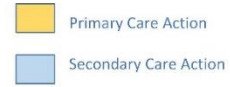
We recommend that Health Board colorectal MDT's document FIT negative cancer diagnoses and review the pathway of individual cases, including changes in referral priority, to identify any opportunities for learning or emerging themes

In the event of supply chain issues with FIT kits, we recommend that clinicians should use existing guidelines to assess the risk of colorectal cancer^{2, 4}

Educational Material

Supportive educational material is available for professionals through [GatewayC](#). Patient information is available through CRUK ([FIT Symptomatic | Cancer Research UK](#))

Symptomatic FIT Pathway



IDA – Iron Deficiency Anaemia

⁷ Advise management as per local pathways. BSG suggests referral of patients with persistent/recurrent anorectal bleeding for flexible sigmoidoscopy. Patients with an abdominal mass suspicious of malignancy should have a FIT undertaken alongside investigation (e.g CT abdomen) or referral

¹ Monahan KJ et al. Faecal immunochemical testing (FIT) in patients with signs of 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. Published Online First 12 July 2022

² NICE. Quantitative faecal immunochemical tests to guide referral for colorectal cancer in primary care. Diagnostics guidance [DG30]. 2017. Retrieved from: <http://www.nice.org.uk/guidance/DG30>

³ Snook J et al. British Society of Gastroenterology guidelines for the management of iron deficiency anaemia in adults. Gut 2021;70(11):2030-2051

⁴ NICE. Suspected cancer: recognition and referral. NICE guidance [NG12]. Updated 2021. Retrieved from: <http://www.nice.org.uk/guidance/ng12>

⁵ Welsh Health Circular 2021/001. Guidelines for managing patients on the suspected cancer pathway. 2021. Retrieved from: <https://gov.wales/sites/default/files/publications/2021-01/guidelines-for-managing-patients-on-the-suspected-cancer-pathway.pdf>

⁶ National Endoscopy Programme. National framework for the implementation of FIT in the symptomatic service. Updated 2021. Retrieved from: <https://collaborative.nhs.wales/programmes/endoscopy/workstreams1/clinical-pathways/>

Appendix A: GP safety netting letter (FIT negative)

GP contact details

@@CURRENTDATE@@

NHS Number: @@NHSNUMBER@@

**@@NAME@@ @@FORENAME1@@ @@FORENAME2@@
@@SURNAME@@**

@@v_address_pad@@

Dear **@@NAME@@ @@SURNAME@@**,

Thank you for taking the time to complete and return your Faecal Immunochemical Test (FIT) kit.

The FIT test detects very small amounts of blood in a poo sample. You have been asked to do this test, as part of investigating your symptoms which could suggest serious bowel problems such as bowel cancer.

The FIT test is very good, but as no medical test is 100% accurate, a negative FIT test cannot completely rule out bowel cancer or other types of cancer.

Your FIT result is negative

which for >99% of people rules out bowel cancer as a cause for your symptoms.

Please contact us in the GP surgery (GP telephone number/email) if your bowel symptoms (see below) change or worsen.

- B** - Bleeding from your bottom or blood in your poo
- O** - Obvious change in bowel habit
- W** - unexplained Weight loss
- E** - Extreme tiredness for no obvious reason
- L** - Lump or pain in your tummy

Yours sincerely,

GP

Appendix B: Secondary care patient downgrade letter

Secondary Care Contact Details

@@CURRENTDATE@@

NHS Number: @@NHSNUMBER@@

@@NAME@@ @@FORENAME1@@ @@FORENAME2@@
@@SURNAME@@

@@v_address_pad@@

Dear @@NAME@@ @@SURNAME@@,

Your GP has referred you for bowel symptoms, as part of that referral you did a FIT (Faecal Immunohistochemical Test). The FIT detects very small amounts of blood in a poo sample.

EITHER/

Your FIT test is negative and based on the referral information you have been listed for an urgent/routine waiting list to be seen in the Hospital with waiting time of about XXX months.

Please let your GP know if your bowel problems have got better and you no longer need the appointment, or if your symptoms worsen or change.

- B** - Bleeding from your bottom or blood in your poo
- O** - Obvious change in bowel habit
- W** - Unexplained Weight loss
- E** - Extreme tiredness for no obvious reason
- L** - Lump or pain in your tummy

OR/

Your FIT result is negative and based on the referral information you do not need to be seen at this time in Secondary care.

Please contact your GP surgery if your bowel symptoms do not get better, or if your symptoms worsen or change.

- B** - Bleeding from your bottom or blood in your poo
- O** - Obvious change in bowel habit
- W** - Unexplained Weight loss
- E** - Extreme tiredness for no obvious reason
- L** - Lump or pain in your tummy

Yours sincerely,

Secondary Care