



Adoption support resource – insights from the NHS

Health technology adoption programme

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1 Introduction

This resource has been developed to provide practical information and advice on adopting NICE diagnostics guidance on [quantitative faecal immunochemical tests to guide referral for colorectal cancer in primary care](#) in people without rectal bleeding who have unexplained symptoms but do not meet the criteria for referral on a 2-week wait suspected cancer pathway.

The guidance includes 3 quantitative faecal immunochemical tests: OC Sensor, HM-JACKarc, and FOB Gold. NICE's adoption team worked with contributors who are evaluating or have recently implemented OC Sensor or HM-JACKarc in NHS organisations to gather their learning and experiences. The NICE adoption team has not identified any current NHS users of FOB Gold.

The NICE adoption team has also discussed the implementation of this technology with colleagues from NHS England, the British Society of Gastroenterology, Cancer Research UK and Bowel Cancer UK.

The information presented in this resource is intended for the sole purpose of supporting the NHS in adopting, evaluating the impact of adopting, or further researching this technology. It is complementary to the guidance and was not considered by the diagnostic assessment committee when developing its recommendations.

The benefits of using quantitative faecal immunochemical tests as reported by the NHS staff involved in producing this resource include:

- better triage of patients into secondary care
- avoiding unnecessary colonoscopies
- possible reduction in the number of colonoscopies done
- improved patient pathway with shorter waiting times for specialist review
- increased patient compliance with faecal occult blood testing compared with the guaiac test
- earlier identification of colorectal cancer.

2 The technology

Faecal occult blood tests is a term used to describe both traditional manual guaiac faecal occult blood tests and automated faecal immunochemical tests. Faecal immunochemical tests have been developed as an alternative to guaiac faecal occult blood tests, because they are less likely to detect globin from upper gastrointestinal bleeding. Detecting faecal occult blood in low risk symptomatic patients helps to triage patients to secondary care and guide the decision for further investigation (see [NICE recommendations](#)).

Faecal immunochemical tests consist of a sample collection device, with a reagent and buffer, which is used to collect and stabilise the sample before it is analysed in a laboratory.

Table 1 contains more information on the 3 tests that are covered in the guidance.

Table 1 NICE-appraised faecal immunochemical tests and specifications

Device (company)	Analysers	Performance capacity (number of samples)	Sample collection device and volume	Company-suggested cut-off for detecting faecal occult blood
OC Sensor (Eiken Chemical/MAST Diagnostics).	OC Sensor PLEDIA.	320 per hour, up to 200 per run.	Tubes, latex reagent and buffer; up to 10 mg of faeces.	10 micrograms of haemoglobin per 1 g of faeces (50 nanograms/ml) should be used for a symptomatic population.
	OC Sensor iO analyser.	88 per hour, up to 20 samples per run.		

HM-JACKarc (Kyowa Medex/ Alpha Laboratories).	HM-JACKarc analyser.	200 samples per hour, up to 80 samples per run.	Extel Hemo-auto MC; up to 2 mg of faeces in 2 ml of buffer and latex agglutination reagent.	10 micrograms of haemoglobin per 1 g of faeces for symptomatic populations*.
FOB Gold (Sentinel/ Sysmex).	Various including: BioMajesty JCA-6010/C, SENTiFIT270 and those supplied by Siemens, Beckman, Coulter and Abbott.	Varies depending on the analyser used.	SentiFIT pierce tube faecal collection device; up to 10 mg of faeces in 1.7 ml of buffer, and latex agglutination reagent.	Each laboratory should establish its own test cut-off according to the population the laboratory serves.
*The user needs to convert the results to micrograms of haemoglobin per 1 g of faeces. However, because the test uses 2 mg of sample and 2 ml of buffer, results reported as nanograms per ml convert directly to micrograms of haemoglobin per 1 g of faeces (that is, 10 nanograms per ml equals 10 micrograms of haemoglobin per 1 g of faeces).				

3 NICE recommendations

The NICE diagnostics guidance on quantitative faecal immunochemical tests and this resource specifically relate to using the OC Sensor, HM-JACKarc and FOB Gold systems to guide referral for colorectal cancer in primary care. The guidance recommends these 3 technologies 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).

The NICE quality standard on suspected cancer includes a statement on [testing for blood in faeces](#) and the interactive flowchart on primary care investigations in NICE's guideline on suspected cancer recognition and referral includes testing for [occult blood in faeces](#) in adults.

4 National perspective

In March 2017, NHS England, together with the British Society of Gastroenterology and the Association of Coloproctology of Great Britain and Northern Ireland, ran a workshop with clinicians on the potential use of faecal immunochemical testing (FIT). The summary of the meeting provides [further information](#). NHS England is interested to hear about other ongoing or planned

projects (research or service evaluation), or hear from groups interested in collecting data on using FIT.

Since publication of the NICE diagnostic guidance on quantitative faecal immunochemical tests in July 2017, NICE has participated in the FIT pioneering project group to consider implementing the technologies in the symptomatic population. Membership includes representatives from NHS England, Cancer Research UK, the British Society of Gastroenterology, research groups, and bowel cancer screening hubs and clinicians from across the colorectal care pathway. For further information contact [NHS England](#).

Considerations for implementation were:

- the potential for confusion because of differences in populations served and in thresholds used when the [NHS Bowel Cancer Screening Programme](#) will introduce FIT in the screening population, expected after April 2018
- the uncertain effect on endoscopy services
- the implication of a fragmented approach to implementation
- the risk of implementation without adequate local preparation
- the possible lack of understanding among commissioners about options for models of implementation, and the advantages and disadvantages of each.

The NICE diagnostic guidance recommends further research to:

- determine whether faecal haemoglobin levels are influenced by age, sex and medicines that increase the risk of gastrointestinal bleeding
- investigate the variability between technologies, encouraging the companies to ensure that results can be standardised for use in a symptomatic population.

NICE is also aware of, but has not commissioned or endorsed, ongoing studies of these technologies in the symptomatic patient population. Further information relating to these studies has been supplied by the research teams and contact details can be found in the [appendix](#).

5 Tips for adopting quantitative faecal immunochemical tests to guide referral for colorectal cancer in primary care

The NHS contributors to this resource considered the following points to be important when planning for the adoption of quantitative faecal immunochemical tests to guide referral for colorectal cancer in primary care:

- Learn from others. Contact clinical and commissioning colleagues in other organisations who have piloted or implemented the technologies and be familiar with the work of national groups considering the implementation approach, to help develop knowledge (see [national perspective](#)).
- Establish a project group. Include pathology services, clinical colleagues in secondary and primary care, and commissioning managers at all phases of the project lifecycle (see [project management](#)).
- Map the care pathway. Primary and secondary care colleagues should work together and include steps for patient selection and action for a negative faecal immunochemical test result. Decide if the test can be requested by other clinicians such as advanced nurse practitioners as well as GPs. Be aware the introduction of this test may be a new step in the care pathway for people who would not normally have had a test (see [care pathway mapping](#)).
- Consider opportunities for efficiency in service model provision. Liaise with commissioner and clinical colleagues to understand local pathology services and discuss available options for provision of service locally and regionally (see [real-world examples](#)).
- Develop documentation to support the adoption. Prepare protocols, algorithms and standard operating procedures to ensure that adequate local governance arrangements are in place. Agree safety netting for non-return of test by patient, and for the limitations of a negative result. There should be an agreed pathway for managing a negative test result (see [developing local documentation](#)).
- Communicate with stakeholders. Establish an effective communication strategy between stakeholders within the project group and wider groups who will be adopting the technology and new pathway (see [education and communication](#)).
- Collect data. Before implementation establish a process for audit and data collection to measure and monitor the effect of technology adoption and identify how the service will be measured on quality and safety, patient experience, productivity and associated resource use

and improved clinical outcomes (see [measuring success](#), [national perspective](#), [appendix](#) and NICE guidance [recommendation 6.1](#)).

- Do an evaluation. Plan a pilot period before implementation to help prepare for impact of full implementation on workload (see [real-world examples](#)).
- Agree process for test kit distribution to the patient and return to laboratory.
- Complete method verification of the company's processes and methods (see [real-world examples](#)).

6 How to implement NICE's guidance on quantitative faecal immunochemical tests to guide referral for colorectal cancer in primary care

Steps to implementation

The experiences of NHS organisations have been used to develop practical suggestions on how to implement NICE guidance on OC Sensor, HM-JACKarc and FOB Gold. Local organisations will need to assess the applicability of the learning from the examples of current practice, taking into consideration the time, resources and costs of an implementation programme. To implement this technology into routine practice, contributors to the resource suggest the following steps.

Project management

These technologies can be best adopted using a project management approach. NICE has produced the [into practice guide](#), which includes a section on what organisations need to have in place to support the implementation of NICE guidance.

Implementation team membership

The first step is to form a local project team who will work together to implement the technology and manage any changes in practice.

Individual NHS organisations will determine the membership of this team and how long the project will last. Consider the following membership of the team so that the guidance is implemented in an effective and sustainable way:

- Clinical champions in primary care and secondary care: they could be a senior clinician or manager with an interest in biochemistry or gastroenterology, and should have the relevant knowledge and understanding to be able to drive the project, answer any clinical queries and champion the project at a senior level.
- Project manager: they could be someone in a clinical or managerial role who will be responsible for the day-to-day running of the project, co-ordinating the project team and ensuring the project is running as planned.
- Management sponsor: they will help assess the financial viability of the project, ensure the business case is prepared.
- Laboratory manager and consultant clinical scientist: they will be providing the service and will need to establish a process for test distribution and collection alongside the primary care lead.
- GP practice(s) leads: they will need to establish a process for test distribution and collection alongside the pathology service lead or laboratory manager, and also plan for adoption in local practice.
- Gastroenterology team: they will need to contribute to and agree to the patient pathway, as well as contribute to data collection.
- Commissioners: they will need to look at the feasibility of commissioning this test.
- Information technology department lead: they will need to work with the laboratory manager to ensure that the process of test result transcription can be automated.
- Clinical audit facilitator: they will be able to help set up systems to collect and analyse local data needed to measure the project's performance and carry out audits.

Preparing for technology adoption

The trust may wish to assess local readiness for adoption by self-assessing using, as an example, the following questions:

- Would it be beneficial to implement the guidance with other local healthcare organisations and commissioners?
- Will a pilot period be helpful and how will it be funded?
- How will the impact of the pilot be measured?

- Which of the available technologies will be adopted?
- What method verification approach is needed?
- How will the implementation be funded?
- How will project performance measures at local level be identified and captured?
- Who will be responsible for collecting clinical data and NICE recommended audit outcomes?
- How will the education needed for adoption be provided, to patients and clinicians?
- How can effective communication be ensured?
- Are there any obvious challenges and how can these be overcome?

Business case

Producing a business case should be a priority for the implementation team. Local arrangements for developing and approving business plans will vary from area to area, and each organisation is likely to have its own process in place.

The business case for quantitative faecal immunochemical tests to guide referral for colorectal cancer in primary care should include:

- NICE and other national guidance:
 - NICE diagnostic guidance on [quantitative faecal immunochemical tests to guide referral for colorectal cancer in primary care](#)
 - the NICE guideline on [suspected cancer: recognition and referral](#)
 - the NICE guideline on [colorectal cancer: diagnosis and management](#).
- Current local performance against the national target for cancer referrals and the 6-week routine referral target for endoscopic tests.
- Evidence of any local inequalities in service provision.
- Proposed timeline for implementing the technology.
- Proposed number of requested tests and impact on workload.
- Plan for audit and data collection.

- A summary of any proposed pilot study or service evaluations or results of any already completed, including criteria reviewed and outcome.
- A resource impact assessment (see [resource impact](#)).
- A quote for the technology, including capital costs.

Consider resource impact

There are around 300,000 people each year who have [urgent GP referrals 2 week wait for lower GI cancer](#). An unknown proportion of these people would be defined as low risk. It is recommended that adopting organisations complete a resource impact assessment to identify if the technology will be cost neutral, cost saving or cost incurring. NICE has published a [resource impact report and resource impact template](#) that can be used by NHS commissioners and providers to better understand the local costs associated with adopting OC Sensor, HM-JACKarc and FOB Gold.

The guidance may lead to savings at a local level from a reduction in the number of colonoscopies done. Therefore, organisations are encouraged to evaluate their own practices against the recommendations in the NICE guidance and assess resource impact locally. The resource impact template includes illustrative figures that can be replaced with local assumptions.

Care pathway mapping

Individual organisations need to consider the point at which to implement the guidance, and the changes to the current pathway that may be needed.

Patient selection

NICE has recommended the technologies for use in people without rectal bleeding who have unexplained symptoms but do not meet the criteria for a suspected cancer pathway referral. NICE is aware that some organisations are evaluating the use of these technologies to manage referrals received in secondary care (that is, in patients who do meet urgent suspected cancer referral criteria).

Sample collection and reporting

Sample collection

There should be clarity on when GPs should request the test, and an agreed local process for giving the patient the test kit and for returning the test kit to the laboratory. These may be supplied in real

time if there is a stock of test kits at the GP, or requested via the laboratory to enable usage monitoring. Samples may be returned either by post or in person to the GP practice or laboratory depending on local service setup. Consider the impact of logistics on patient compliance. Consider a safety net to follow-up patients who don't return the test. Contributors advised that although it is possible to use faecal sample pots, the companies recommend that specialised sample collection devices should be used where possible.

Result reporting

Establish how the result will be communicated to the GP (for example, negative or positive, or if a numerical value will be provided), and if a positive result will need direct contact from a senior laboratory clinician to the GP.

- Establish the local pathway for positive test results in the context of existing pathways. Will the patient go straight to test for further diagnostic investigations, or be referred for a secondary care review before further diagnostic investigations? Will the patient be referred on the routine pathway or on a 2-week wait?
- Establish a local process for managing negative test results, including review of clinical symptoms, and ensure all stakeholders are aware of agreed local processes.

Information technology interface

Some contributors implemented the test as a worksheet-based process because of the uncertainty relating to the impact on workload. This made it difficult to interface the information technology systems. For full implementation it is unlikely this would be sustainable and the process would need to be automated, needing the analyser to interface with the electronic reporting system. This will have a financial implication.

Measuring success and collecting data

It is important to record a baseline assessment and take measurements during and after implementation to show the cost and clinical benefit of adopting these technologies.

The committee considered that clinical commissioning groups adopting the tests in primary care should audit their outcomes. Possible outcomes to audit include:

- number of people referred using a suspected cancer pathway for an appointment within 2 weeks

- number of people diagnosed with colorectal cancer
- number of colonoscopies and CT colonographies requested.

Sites involved in developing this resource suggested the following data collection, and advised the implementation team to decide at a local level who is responsible for collating and managing the data:

- number of tests issued
- number of tests returned
- number of positive test results
- number of negative test results
- number of false-negative
- number of false-positives
- number of flexible sigmoidoscopies requested
- other variables such as age, sex, diagnosis, location of tumour and the use of medicines that increase the risk of gastrointestinal bleeding, to help determine whether faecal haemoglobin levels are influenced by these factors.

Service commissioning

Like other primary care-requested pathology tests, these tests will need to be commissioned by clinical commissioning groups. NHS contributors have advised that these tests are more costly than other pathology tests on the standard pathology tariff. This will need addressing locally between commissioning groups and heads of pathology services.

Education and communication

All contributors report that training was provided by the companies for laboratory staff and where necessary they have had access to support after implementation. Pathology staff advise that the tests are not analytically difficult to use.

All contributors have advised that patient information leaflets need to be provided (see [developing local documentation](#)), and there may be an element of patient education needed. This can be provided within primary care.

Education and awareness raising for the GP clinical community was cited as essential, and should include knowledge and raising awareness about the different testing criteria and results cut-offs between symptomatic and screening populations.

The contributors described the following mechanisms as successful: including information in GP information sheets and staff bulletins, establishing a query email address or telephone line for GPs, and attending GP practice meetings.

Developing local documentation

The following are examples of tools developed by NHS services using the technologies, which can be used for developing local documentation. They have not been produced, commissioned or sanctioned by NICE:

- Hull and East Yorkshire Hospitals NHS Trust:
 - [FIT instructions: a real-world example](#)
 - [FIT request form: a real-world example](#)
 - [NICE guidance NG12 Suspected cancer: recognition and referral section 1.3 lower gastrointestinal tract cancers.](#)
- Lancashire Teaching Hospitals NHS Foundation Trust:
 - [Faecal immunochemical test: step-by-step instructions](#)
 - [Faecal occult blood testing using FIT in suspected colorectal cancer \(GP leaflet\)](#)
 - [Introduction of symptomatic patient screening for faecal occult blood \(poster\).](#)
- Oxford University Hospitals NHS Foundation Trust:
 - [Update on Faecal Occult Blood testing in Oxfordshire.](#)
- The South West Cancer Alliances:
 - [Transformation funding application: Achieving early diagnosis through the introduction of quantitative faecal immunohistochemical \(qFIT\) testing for symptomatic patients.](#)

Real-world examples of implementation

NHS contributors to this resource have worked with NICE to develop practical suggestions on how to implement NICE guidance on quantitative faecal immunochemical tests. Table 2 gives a summary of the contributing sites' demographics.

Table 2 Contributing sites: demographics

Site	Implementation lead(s)	Technology	CCG population (based on 2016 ONS estimates)	Stage of technology adoption as of December 2017
Hull and East Yorkshire Hospitals NHS Trust	Consultant clinical scientist, head of clinical biochemistry. Clinical commissioning manager.	HM-JACKarc.	City of Kingston upon Hull: 260,240 (204,153 adults). East Riding of Yorkshire: 337,696 (274,931 adults).	The project team is running an evaluation using 250 kits, which began in June 2017.
Key highlights	Out of 84 returned test results, 16 showed a positive FIT result and 2 of these people have had large polyps removed following referral through the 2-week wait programme; a third patient had a diverticular bleed. For more information, see Hull and East Riding CCG's June 2018 FIT Outcome Report .			
Lancashire Teaching Hospitals NHS Foundation Trust	Consultant clinical scientist. Principal clinical biochemist.	OC Sensor.	Preston: 141,801 (110,765 adults). Chorley: 114,351 (90,953 adults). South Ribble: 110,118 (87,492 adults).	Evaluation completed on 60 samples. Implemented into practice June 2017 process completed.

Key highlights	<p>Time from receipt of sample to report generation reduced from 2 to 3 weeks to 1 week when process was moved from external laboratory to internal laboratory.</p> <p>Concordance between both analysers was seen for 95% of patients during the pilot.</p> <p>Over 80% of low risk patients could avoid invasive colonoscopy.</p>			
Oxford University Hospital NHS Foundation Trust	Macmillan GP and clinical researcher. Consultant chemical pathologist. Head biomedical scientist.	HM-JACKarc.	Oxfordshire: 683,169 (540,272 adults).	Verification process completed January to April 2016. Fully implemented in January 2017.
Key highlights	<p>The transition of the testing method for faecal occult blood from a traditional guaiac method to the more quantitative faecal immunochemical test has resulted in improved analytical performance. Of importance for patient care and workload is the marked reduction in false positives results.</p>			
South West Cancer Network (part of the South West Clinical Network)	South west cancer programme lead.	Not yet adopted.	SWAG and Peninsula cancer alliances, comprising 10 CCGs: around 4.5 million adults.	Have been awarded national cancer transformation funding to implement FIT in symptomatic patients (August 2017). Currently planning implementation.
Key highlights	<p>The network is currently planning implementation of the technology in the SWAG and Peninsula cancer alliances.</p> <p>They conducted a prospective audit with GPs and calculated the demand for the test to be 12 to 15 per 1,000 population per year (about 32,000 per year).</p>			

Hull and East Yorkshire Hospitals NHS Trust

The [NHS Hull](#) and [NHS East Riding of Yorkshire](#) clinical commissioning groups have been working together to understand the local provision of planned or elective healthcare interventions and identify high volume specialties.

As part of this initiative, clinicians and commissioners from [Hull and East Yorkshire Hospitals NHS Trust](#) and both clinical commissioning groups review pathways and services to identify where the treatment and patient management could be appropriately transferred safely from secondary care to primary care. In 2016 faecal occult blood testing was identified as an area to consider, in line with the NICE guideline on [suspected cancer: recognition and referral](#).

A project group was established with laboratory staff, commissioners, colorectal surgeons and GPs who agreed to do a feasibility study. This study had 2 main aims: to establish the potential impact of full implementation on workload and to establish the methods and infrastructure needed for full implementation, including the interface between primary and secondary care. Because of existing knowledge of the particular technology, experience of other laboratories and a favourable GMEC (Guildford Medical Device Evaluation Centre) report, especially regarding precision at low concentrations, the project team selected HM-JACKarc for the feasibility study, and began testing 14 months after the initial call for expressions of interest.

To aid implementation, the project team:

- verified the performance of the assay
- developed standard operating procedures for the laboratory staff
- developed GP referral forms, and translated the NICE guidance into a single-page pathway on the back
- prepared patient kits comprising the collection device, with instructions for collection of faeces and subsequent collection of the sample for the laboratory (the project team acknowledge that was labour intensive and not sustainable for full implementation, and are considering other approaches).

The patient kit is provided by the GP or advanced nurse practitioner at consultation and the patient is requested to return the sample to the practice within 48 hours, which is then transferred to the laboratory via the normal pathology transport, so postage costs are not incurred. The test can be requested electronically by a web-based requesting system or by paper request form. All positive results are reviewed by a clinical scientist and communicated to the practice via telephone in addition to sending an electronic report. The laboratory reports a result of more than or equal to 10 micrograms of haemoglobin per 1 g of faeces as positive, as per [NICE diagnostic guidance](#).

The laboratory receives on average 5 samples a week, and runs the analyser twice a week in order to provide a result in 3 to 4 days. For full implementation this would increase to a daily run, which

would potentially need additional staff resources. Extra instrumentation would not be needed because of the capacity of the existing analyser.

The laboratory collects clinical data to monitor the impact of technology on patient outcomes and workload, but incomplete referral forms limit data collection. Outcomes are followed up with the lead colorectal surgeon. As of the beginning of December 2017, the project team reported that 16 of 84 returned test samples were positive. Initial data for patients referred under the 2-week wait showed that 2 patients were identified as having large polyps (which were surgically removed) and 1 patient was identified as having a diverticular bleed.

Future plans

The project team have had discussions with NHS England and [Yorkshire and the Humber Clinical Networks](#) with reference to the role that they can have in the wider implementation of this technology across the region.

Lancashire Teaching Hospitals NHS Foundation Trust

Following publication of the NICE guidance on [recognition and referral of suspected cancer](#), the pathology and oncology teams at Royal Preston Hospital, [Lancashire Teaching Hospitals NHS Foundation Trust](#) with support from the [NHS Greater Preston](#) and [NHS Chorley and South Ribble](#) clinical commissioning groups collaborated to design clinical pathways for several cancer types including lower gastrointestinal tract cancers. The first steps were to develop local processes and methods for testing for faecal occult blood, and verify the technology. For verification, they sent samples to colleagues at University Hospitals Coventry and Warwickshire, who had an established service for screening the asymptomatic population using HM-JACKarc.

The project team also liaised with colleagues in the Scottish bowel cancer screening research unit in Dundee who had experience of implementing the technology for symptomatic patients, to gain knowledge from their experiences. The project team considered all 3 technologies and decided to use OC Sensor in the verification period on the basis of the evidence available from colleagues in Scotland. They also found the sample collection device for OC Sensor provided a cleaner sample. The FOB Gold test was discounted because it was decided it was not appropriate to automate it with other samples, so it would need a standalone analyser with a large footprint.

Methods were verified using a patient comparison study. Patients provided a sample in both the HM-JACKarc and OC Sensor sample collection devices, and the results analysed by the Coventry team (using HM-JACKarc) were compared with the local sample results (using OC-sensor), for

60 samples. Any detectable level was reported as a positive test result and all positive results from either technology were followed-up. Results were not reported as a numerical value.

HM-JACKarc and OC Sensor compared very well, both analytically and clinically. Overall, 17% of patient samples were positive using HM-JACKarc compared with 18% with OC Sensor. Concordance between both methods was seen for 95% of patients. Three patients (5%) had discrepant results but all of these were close to the cut-off. Whichever method is used, over 80% of low risk patients could avoid invasive colonoscopy and resources could be redirected to reduce waiting times for higher risk patients.

Full implementation began in June 2017. A gradual introduction to primary care was planned as part of the implementation in order to allow time to finalise the patient pathway with secondary care and the management of negative test results. The project team has concluded that negative results should result in a clinical decision to repeat the test and a standard referral to secondary care services if clinical symptoms persist. They have agreed to collect data and review 6 months after implementation.

The future impact on workload remains uncertain but the team predicts the current weekly runs on the analyser may increase to 2 to 3 times per week over the next 6 months.

The GP requesting service is fully automated and local clinical oncology guidelines are available as a toolkit on all GP systems and visible at the point of request. The team is also developing GP information sheets (currently in draft form) which will be circulated to GPs once the care pathway is finalised. These will also be accessible in the integrated clinical environment (ICE) system for GPs to see in real time.

Currently the time from receiving a sample to reporting a result is at most 7 days; this has reduced from 2 to 3 weeks when the samples were referred to the external laboratory for the verification period. The team believes they can collate the data recommended by NICE to audit their outcomes and monitor the associated resource use, using current data collection processes.

Future plans

The pathology service at Royal Preston Hospital is an established hub for faecal calprotectin testing, and it has considered this model as a potential for FIT in the future. The service leads a FIT implementation group under the Lancashire and South Cumbria Cancer Alliance and plan to roll out an integrated FIT service across the cancer alliance.

Oxford University Hospital NHS Foundation Trust

Following publication of the NICE guidance on [recognition and referral of suspected cancer](#), clinicians in [Oxford University Hospitals NHS Foundation Trust](#) liaised with [NHS Oxfordshire](#) clinical commissioning group on the appropriateness to clinical care of faecal occult blood testing in low risk symptomatic patients. It was felt that continuation of the guaiac methodology, which has well known analytical limitations, would not be appropriate and the more specific FIT was evaluated.

They gave consideration to all 3 technologies and agreed to evaluate HM-JACKarc because of its reported high sensitivity. The initial method setup took less than 1 month and involved assessment of reproducibility and accuracy. After this were 3 months of parallel testing of guaiac faecal occult blood and FIT, involving over 300 samples from over 200 patients, and subsequent assessment of clinical outcomes. The most noted clinical reasons for requesting faecal occult blood determination were iron-deficient anaemia and changes in bowel habit consistent with the low risk population cited in the NICE guidance. Initial follow-up data suggested that for detecting colorectal cancer there was similar sensitivity but much better specificity, mainly because of fewer false-positives using FIT. These data informed the shared decision made by the laboratory, clinical commissioning group, GP representatives and gastroenterology that adopted FIT.

Before final implementation, the group decided to continue to monitor the health records of patients in the evaluation group to ensure that later diagnoses of colorectal cancer were not missed. No further cases were detected at 12 months so the test went into routine use in January 2017.

Following the publication of the NICE guidance there has been a noticeable increase in workload, from less than 100 tests per month for a population of 680,000 to more than 300. Since moving to using FIT, the proportion of positive results has fallen from around 27% to 13%. This is considered to be because of the lower rate of false-positives associated with the FIT test compared to the guaiac method.

The project group engaged with the GP community through newsletters, educational presentations and written guidance available on the commissioning group's website.

The evaluation identified that the 2 most important sources of assay variability were sampling and specimen stability. Faecal immunochemical testing has a specific sampling device that is designed for use by the patient. However, the group observed that even when used by laboratory staff this step has high imprecision. It was therefore decided to request that a standard stool sample be

collected, with advice to deliver to the laboratory on the same day. The sampling from the stool pot with the collection device is then done as soon as feasible after arrival in the laboratory. If samples are not stabilised within 24 hours of arrival in the laboratory, the report includes a comment that this can compromise test result. In the future this approach will be reviewed; although it was considered the best balance between sampling and stability errors for initial implementation, more data will help confirm this.

Future plans

The group plans to follow up the first 1,000 patients tested with the new method at 12 months, for evidence of malignancy and any other significant pathology.

The South West Cancer Alliances (part of the South West Clinical Network)

In August 2017, the [South West Cancer Network](#) was awarded national cancer transformation funding following a [successful bid](#) to implement quantitative FIT for symptomatic patients across the Somerset, Wiltshire, Avon and Gloucestershire (SWAG) and Peninsula Cancer Alliances. This bid was driven by an aim to improve the number of cancers diagnosed at an early stage, decreasing variation in access to screening and improving the prognosis and quality of life of people diagnosed with cancer. Both cancer alliances are challenged with a population older than the national average from both urban and large rural communities, with areas of high deprivation.

As part of the bid preparation, the network did a prospective audit. It provided a read code to capture the information and GPs included this in their notes when a patient presented with any eligible symptoms. All participating GP practices received a payment of £500, and project and clinical support. The data was returned monthly reporting the number of patients presenting and how they were managed. Results showed that demand for the test was 12 to 15 people per 1,000 population per year (equivalent to about 32,000 per year). The network also identified that over half of these people were currently referred on the 2-week wait for secondary care intervention either by the colorectal cancer or gastrointestinal teams.

Future plans

The next step for the project team is to identify the practicalities of adopting the technology at this scale. The various options being considered each have their own adoption challenges, including interoperability of IT systems, transfer of samples, capital costs of multi-site implementation and procurement.

7 Acknowledgements

NICE would like to acknowledge and thank the following people for their valuable contribution to this resource.

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Commissioning manager, NHS Hull Clinical Commissioning Group.

Mr Ian Hanning

Consultant clinical biochemist, Hull and East Yorkshire NHS Trust.

Dr Natalie Hunt

Principle clinical biochemist, Lancashire Teaching Hospitals NHS Foundation Trust.

Dr Tim James

Head biomedical scientist, Oxford University Hospital NHS Foundation Trust.

Mr Jonathan Miller

Programme lead, The South West Cancer Alliances (part of the South West Clinical Network).

Dr Martin Myers

Consultant clinical scientist and laboratory director, Lancashire Teaching Hospitals NHS Foundation Trust.

Dr Brian Nicholson

Macmillan GP and clinical researcher, Oxford University Hospital NHS Foundation Trust.

Dr Vincent Rawcliffe

Commissioning GP, NHS Hull Clinical Commissioning Group.

Dr Brian Shine

Consultant chemical pathologist, Oxford University Hospital NHS Foundation Trust.

8 Appendix

Ongoing research

NICE is aware of but has not commissioned or endorsed the following studies of these technologies in the symptomatic patient population. The following descriptions have been provided by the trial teams and NICE has not reviewed the study aims and descriptions.

Table 3 Ongoing research

Study name and contact details	Aim	Outcome or progress	Population
<p><u>qFIT PILOT (UCLH Cancer Collaborative)</u>. Chief investigator: <u>Michael Machesney</u>. Programme manager: <u>Helga Laszlo</u>.</p>	To evaluate the effectiveness of FIT as a rule-out test for colorectal cancer for patients who meet the suspected cancer referral pathway criteria.	The 12-month pilot study was launched in September 2017 and in its current phase, aims to collect at least 2,000 samples. In addition, a machine learning algorithm is evaluated in conjunction with FIT to identify people who have an increased risk of developing bowel cancer.	Eligible patients are those already referred on the normal a suspected cancer pathway for colorectal cancer (2-week wait suspected pathway) in North, Central and East London, West Essex and East Lancashire. Eligible patients are recruited via primary as well as secondary care.

<p>FIT in the symptomatic population East Midlands: 'Getting FIT' Programme hub manager: Caroline Chapman Clinical contact: Ayan Banerjea</p>	<p>Collaborative service evaluation of the value of FIT testing in suspected colorectal cancer pathways in Nottingham between September 2016 and August 2017.</p>	<p>'Getting FIT' preliminary data analysis of over 800 FIT results with respect to clinical outcomes in 2WW pathways has demonstrated:</p> <ul style="list-style-type: none"> • FIT can effectively be used by postal systems locally and patients do return FIT kits. • The results can be used to risk stratify and reduce missed diagnosis. • FIT has diagnostic value in colorectal cancer. • Performance for other pathology is weaker; a safety net of 'routine' referral may help to avoid missed diagnosis and also improve attention to the symptoms the patient actually presented with. 	<p>Patients referred for FIT testing only as per the NICE guidance, as well in patients referred on standard 2-week wait pathways for symptoms other than rectal bleeding. FIT is now being accessed by GPs directly and is part of Nottingham's Rapid Colorectal Cancer Diagnosis Pathway (as of 6 November 2017).</p>
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<p>NICE FIT – Croydon and RM partnership* Research manager: Michelle Chen.</p>	<p>NICE FIT project was launched in April 2017. The diagnostic accuracy of FIT will be investigated, while accounting for variation due to age, sex, ethnicity and deprivation, as well as clinical information such as symptoms at presentation, blood results, outcome of colonoscopy and cancer stage.</p>	<p>Analysis of results will be carried out at monthly intervals by an independent statistics team.</p>	<p>All patients undergoing colonoscopy after referral on the 2-week wait rule are eligible for recruitment.</p>
<p>*Within London, recruitment will be performed by a dedicated research team based at Croydon, in conjunction with local NIHR CRN staff at each site. As an NIHR badge approved study, each patient recruited accrues recruitment points for the local CRN. The NICE FIT study team is therefore happy to support sites outside of London opening the study, and recruiting patients through their own CRN team.</p>			

9 About this resource

This resource accompanies NICE diagnostics guidance on [quantitative faecal immunochemical tests](#). It was developed using the NICE's [process guide for adoption support resources for health technologies](#). It is an implementation tool that summarises the experiences reported by NHS sites which have adopted this technology and shares the learning that took place.

It is the responsibility of local commissioners and providers to implement the guidance at a local level, being mindful of their duty to advance equality of opportunity and foster good relations. Nothing in this document should be interpreted in a way that would be inconsistent with this.

[More information about the adoption team.](#)

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