FITnewsletter

The World's No. 1 Faecal Immunochemical Test

Getting FIT in Nottingham

Nottingham University Hospitals Trust (NUHT) is continuing a long and distinguished history of scientific and service enhancements in the field for colorectal cancer, by offering an accredited reference service for FIT in symptomatic patients.

Iain McElarney discusses the FIT symptomatic service using the OC SENSOR from Mast Group Ltd, with the team at the Eastern Bowel Cancer Screening Hub within NUHT.

NUHT has been involved with innovation around Bowel Cancer for many years. What was the impetus for starting a FIT service?

In 2015 the NICE guidance (NG12) on criteria warranting urgent referral for investigation for colorectal cancer (CRC) was updated to include the use of faecal occult blood testing.

The colorectal team approached us later that year to help them carry out a service evaluation study (the Getting FIT project) offering FIT testing in their patients referred as having a suspected CRC. The aim of the study was to inform the service of the potential use of FIT in their straight-to-test pathway, due to the increasing demands on the already overstretched colonoscopy services, and the fact that <10% of referred patients actually receive a cancer diagnosis.

The data, generated on over 800 samples over a 12 month period in a secondary care setting, showed that risk stratification of colorectal cancer referrals can be improved by the incorporation of simple tests such as Hb and FIT to more correctly stratify patients in need of urgent or more routine follow up of their symptoms.

These results have been presented as posters at the BSG and NCRI congresses, and the data has recently been submitted as a full publication.

During the service evaluation study a steering group was set up and this still regularly meets.

On the back of the service evaluation results (and publication of the updated NICE guidelines, DG30) the test was finally introduced into primary care in the Nottingham area late 2017.

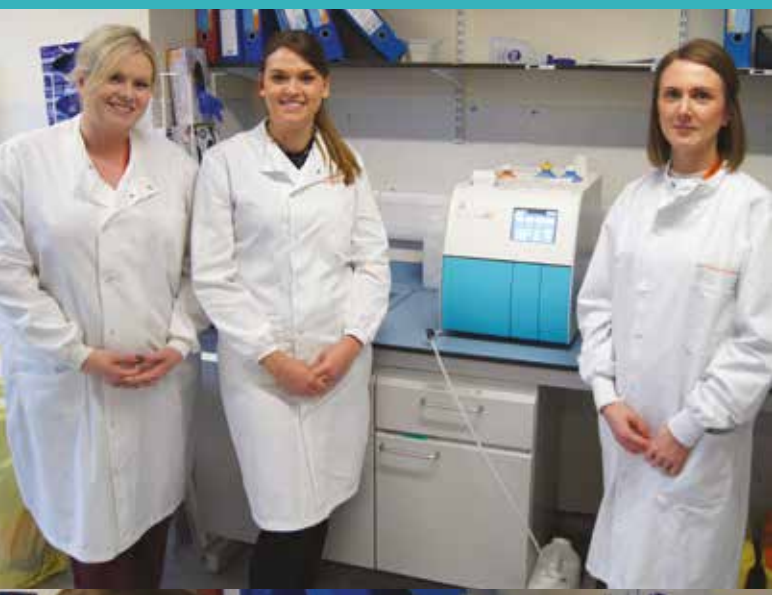
The symptomatic service went live in November 2017. Which patients are GP's requesting kits for?

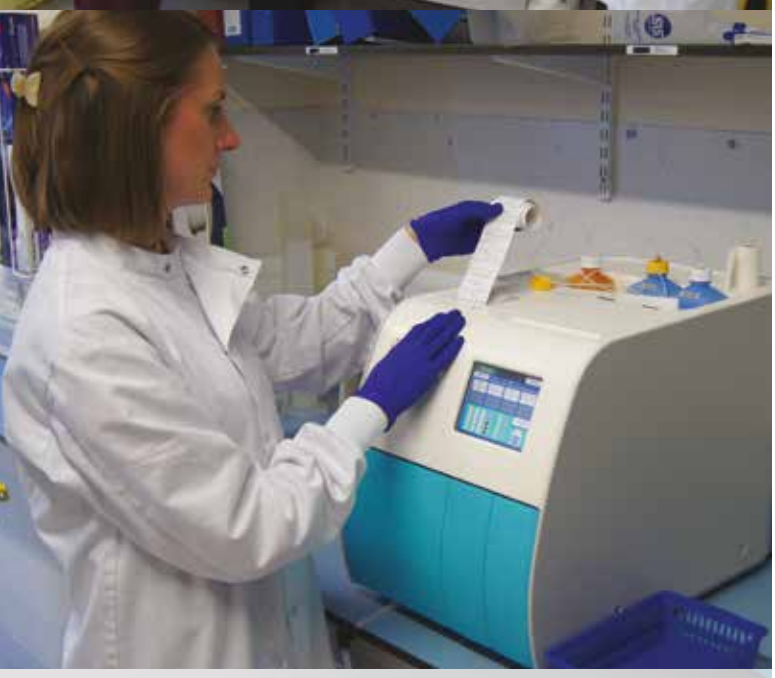
GP's can request kits for patients (without rectal bleeding) who they suspect may have symptoms of CRC (e.g. a change in bowel habit). These are requested through their usual test request system (ICE).

The GP's can still refer patients through a rapid colorectal diagnostic pathway, but a FIT and circulating Hb levels are required, and a negative result without high risk symptoms may mean the patient and their GP are reassured, redirecting to either Routine referrals, other pathways or repeat testing. Individuals with a rectal or abdominal mass, or rectal bleeding are referred without the need for a FIT result. At Nottingham there are no age restrictions in place for requesting the test.

Results of the service evaluation study showed that having a fHb level >150µg/g conferred a very high risk of also having a CRC or other significant pathology. In these case's the colorectal team call all these patients directly.

Communication between us, the CCG and clinicians was crucial. We have a really proactive steering group that has continued since the service evaluation which is really a huge help. It is also important to have a clear message to GP's so that they understand why they are referring patients, a little more about FIT and some solid instructions on how to use the new pathway.





From the left; Chloe Hughes, Deputy Laboratory Lead
Katie Dale, Laboratory Lead
Abby Duffin, Deputy Laboratory Lead

As one of the forerunners in implementing FIT for symptomatic patients you have had to develop your own model for running the service. Please can you describe the process of how a patient receives a FIT kit?

Early on, in consultation with CCG's, local cancer leads and GP's it was decided that pre-labelled sample kits, along with instructions for use and a pre-paid return envelope would be sent directly from the laboratory to patients by post. It was deemed safer than handing out packs at GP's where storage of kits may be an issue, and tracking of unreturned samples more difficult to monitor.

In Nottingham, the GP requests come to us through ICE. Although ICE automatically prints out requests we also check on the system to make sure we have them all.This is also a vital means of tracking whether FIT results are being acted upon appropriately.

NUHT clinicians can also request a FIT kit to be sent through the hospital patient management system. We do not get many through this route currently.

We also have a working system in place to offer the FIT service to other labs (and CCG's) for hospitals that have NPEx in place. This started in the Leicester area in February 2018. In these cases, where we are unable to view their ICE requests or LIMS remotely the labs send us their GP requests through NPEx, just as they may do for other send away tests. These requests come across as a shipment on a PDF with the details of the request and the originating laboratory's barcode to identify them. We then log the requests into our LIMS, linking the sample ID to the original barcode from the NPEx request, for full traceability.

The barcode labels that are printed from ICE or from WinPath (our LIMS) are then applied to the OC-Sensor sample bottle before being posted directly to the patient's home.

How quickly are the samples returned after sending them to the patients?

The vast majority of samples are returned within a week, and often within 2-3 days. Any samples not returned within 14 days are reported back to the GP as 'not-returned'. A few patients still return their kits after this time, and a revised report is then issued

That's a fantastic turn-around time. Do you know what return rate you are experiencing?

It's really very good, we are getting back over 90% of the kits that we despatch, and less than 1% of those returned cannot be analysed.

[As a failsafe in Nottingham, if the GP had already referred the patient down the rapid diagnostic pathway, and they did not return a kit, they will still get investigated.]

You seem to have done most of the work before the samples are despatched. Does that make the specimen receipt and processing very efficient?

Definitely, we would already have logged them on to WinPath through our laboratory system when making the patient packs. When we receive samples in, we would scan them to bring up the record and simply type in the receipt date and sample date, making sure it is within 14 days.

Currently we run the OC-Sensor three times a week, so if a sample is received on a day we are running tests it will be processed and run immediately, otherwise it is put in a cold room for the next day. We also check the test dates to see if they are close to the cut-off date for acceptance.

How do you manage quality control of the OC-Sensor and the results?

We have an in-house process of batch acceptance testing for new materials. When we receive a new batch of the liquid IQC's from MAST, we establish our own internal range before use. We use two controls before and two controls at the end of the batch of testing. Because the IQC's are so easy, it doesn't take any extra time.

We generally run more than 50 samples a day so we also run a control in the middle of the samples as well as at either end of the run. This means that if there is a problem, we would not have to re-run as many samples, so it acts like a checkpoint.

We also run EQA samples and are carrying out sample swaps with our labs.

Out labs have also recently had our UKAS inspection (for ISO-15189) which went well, and we hope to have UKAS accreditation for symptomatic FIT in the next few months,

So how do you report and interpret the results?

At NUHT and for our local ICE requests we report the numerical value with an interpretive comment on the result and the GP's have access to more detailed narrative in their local guidance.

<4µg/g = Negative (but refer if IDA present)
4-10µg/g = Negative with normal Hb (positive if anaemic)
>10µg/g = Positive, refer for further investigations
>150µg/g = High Risk Positive, Straight To Test (STT) team will contact the patient with the result.

Where we receive samples from other labs we report the numerical value back via NPEx with interpretive comments, as designated by their local clinical oversight groups.

How do you disseminate results back to the GP's

At the moment we enter results via a dual entry worklist which requires a primary input of results followed by a secondary 'check' input by a HCPC registered member of the team. They feed automatically through ICE so the GP can see it. We are hoping to take receipt of an automatic interface soon.

From WinPath, results are reported back to other laboratories via NPEx, where they are automatically uploaded into their own LIMS systems and on to their GP's.

What safety netting process is in place to try and ensure that patients with cancer are not missed?

As the lab, we are not directly involved in this process. There are obviously lots of discussions about safety netting as this a very topical area at the moment, especially with it being a new test.

Training and information is given to the GP's and interpretive comments are provided. If patients have a negative FIT result GP's are advised to consider alternative referral pathways, watchful waiting or up to one round of repeat FIT testing, i.e. use their own clinical judgement. In Nottingham our colorectal team contact the patients with high value results directly.

Having a clinical input is crucial, here in Nottingham we have very good relations with our colorectal team. They are very proactive and supportive. Through the steering group, the colorectal team have been giving extra communications and guidance to the GP's to support the new service. If a GP wants further support, the GP can telephone the colorectal teams directly.

Looking back, what tips or advice would you have for other laboratories looking to implement FIT?

Good communication is key!
We are lucky that we had carried out the service evaluation before introduction of the test into clinical practice this meant the Nottingham GP's were more engaged with the process.

A strong clinical lead is also crucial, as well as buy-in from clinical leads in Pathology services, IT departments, CCG's, cancer leads, and the GP's. The Steering Committee meets regularly to review the data and trouble shoot any issues.

Clear instructions and guidance for GP's is needed as well as training events.

With regard to implementation of the test in the Department, we have a Change Management System in place for updating new services like the symptomatic FIT pathway so we are all aware of what is happening.

End to end testing is of course critical, as is working out internal QC's and local acceptance criteria. We have learnt a great deal since we started and are always happy to talk to others just starting out.

MAST would like to thank the laboratory staff at NUHT for their time and sharing their experiences of the successful implementation of OC Sensor FIT in a Symptomatic pathway.

For further information about the reference service, please contact Dr Caroline Chapman
caroline.chapman@nuh.nhs.uk

Chloe Hughes and Katie Dale preparing the OC-Sensor for analysis

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OC-Sensor is routinely employed by Bowel Cancer Screening Programs worldwide to quantify very small amounts of haemoglobin in stool samples.

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