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Norfolk & Norwich University Hospital Trust : FIT Pilot Study

Norfolk & Norwich University Hospital (NNUH) Biochemistry Department is a hub laboratory closely aligned with our spoke laboratories at James Paget University Hospital and Queen Elizabeth Hospital, Kings Lynn.

When NICE published the guidance that everyone should be using Faecal Immunochemical Test (FIT) in symptomatic individuals in triaging for colonoscopy we were interested. The CCG's with the STP cancer alliance for Norfolk were keen to introduce this test. Our gastroenterology team at NNUH had out-performed the national standard for waiting times for colonoscopy and as a result, had been granted advanced funding for the introduction of FIT. The STP approached us to say we have this funding we want to introduce this service; how shall we go about it?

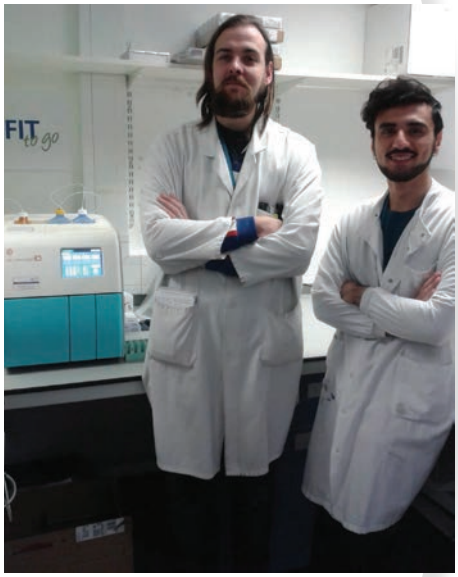
Stage 1: Stakeholder engagement

Right from the beginning we engaged all the stakeholders who would be involved when the service went live. We had a consultant gastroenterologist, consultant colorectal surgeon, a representative from the STP cancer alliance and the CCG lead within the cancer alliance. From the laboratory were myself, Professor Garry John Head of Department and our service manager who was looking at how we would provide the service contractually and how we would obtain the equipment. We also had a gastroenterology or colorectal surgeon representative from James Paget Hospital (Great Yarmouth) and Queen Elizabeth Hospital (Kings Lynn) as this would be a county-wide service.

Was there any resistance to the introduction of FIT?

No. The STP agreed to fund FIT for early detection of cancer, to test the right patient at the right time and to improve survival rates. They were keen to see the economical and clinical benefits evidenced with good data as they fund the colonoscopy services also. Would there be a reduction in referrals, and would this lead to the CCG's saving money, as well as improving patient care? There is limited evidence at the moment that investing in FIT in primary care will save money on colonoscopy referrals, as few studies have been published yet where this has been assessed, but there was no resistance to the introduction of the service, it was just a concern.

Another concern was a possible increase in referrals for colonoscopy and whether each Trust had the capacity to absorb that. Obviously our goal is not to increase the overall number of referrals, but to weed out the patients with a negative FIT, who are less likely to need a colonoscopy, and refer the positive FIT patients. In the early stages we were conscious that there may be a cohort of patients in the community with non-specific symptoms, that weren't severe enough to warrant referral on their own, but who may now have a positive FIT result, and be referred on that basis.



FIT to go - from left to right; Liam Pudwell and Kambiz Ashar

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We assumed that we would see an initial 'hump' and then it will settle down to referring the right patients instead of having inappropriate testing.

At NNUH, it was recognised that if this initial "hump" did occur, that this workload would be absorbed. We are lucky in Norwich that we had literally just opened the Quadram Institute, which is a state of the art facility for colonoscopy and endoscopy so capacity at NNUH has massively increased overnight. James Paget Hospital and Queen Elizabeth Hospital didn't have a triage system so they were bringing everyone up to clinic regardless, to decide if they needed further investigation. The assumption was that we would just have to live through the 'hump' and then hope it would settle down fairly quickly.

Stage 2:
The Pilot study

About 18 months' ago in our initial meetings we decided to have a pilot study where we could directly co-run FIT against colonoscopy outcome. We started those discussions in the first meeting where we had all of our stakeholders for the service around the table and it was quite easy to get agreement from everyone that we would find a method of consenting patients to take part in that study and sending out kits to them. Everyone was in agreement that that was perfectly acceptable. We found that it was much easier to get buy-in from the patients at James Paget Hospital and Queen Elizabeth Hospital because of the way they brought everyone up to clinic. Patients were told about the study in clinic, consented in clinic and handed the pack to take the sample. NNUH had a very different way of deciding if patients should be brought to clinic or straight to test so for convenience, we posted those sample kits out directly to the patients, but still got a reasonable return rate.

Which patient cohorts were offered a FIT test?

We have targeted directly the patients documented in the NICE guideline, so the pathway that has been issued to all of the GP's is anyone that has an unexplained change of bowel habit of any adult age who would not fit in the NICE criteria to be automatically on the 2ww pathway.

Unexplained weight loss and abdominal pain in the over 40yr olds, over 50yr with unexplained rectal bleeding, under 50yr with rectal bleeding AND change of bowel habit OR iron-deficiency anaemia OR unexplained weight loss OR abdominal pain, and over 60yr with iron-deficiency anaemia or change of bowel habit, all fit the criteria for the 2ww referral pathway. FIT should be performed on any adult with abdominal symptoms, who does not already warrant a 2ww referral on these criteria. As a result, we are investigating a very specific cohort of patients, but our take-up of the assay has been good despite this.

What support was required for clinicians and partner laboratories?

The training itself was really just making clinicians aware that the service was imminent, what would be involved in providing that service and how we were going to support them in that. We had lots of discussions with GP's, in terms of this is the pathway to follow, the service and the meaning of results reported back.
I spoke to a large group of GP's, showed them the test kit and patient guidance sheet and clarified any issues that we had found in the pilot study eg. wrong sample container. Following our very quiet launch of the service in November, I spoke to them again in December.

The 'How to collect your FIT Sample' animation supplied by Mast Group was incredibly useful and has been utilised by our Communications Lead who thought that it was excellent and put it on Knowledge Norfolk making sure GP's were aware to inform patients to watch the animation if there was any confusion how the sample should be taken correctly.

Stage 3:
FIT Sample logistics

We were lucky in that because the Eastern Pathology Alliance (EPA) Lab provides pathology to the whole of Norfolk we are doing multiple pick-ups every day from every GP surgery in Norfolk. When it was the pilot study, regardless of whether the patient was posted a test kit if they were coming to NNUH or had been seen at James Paget Hospital or QEH and given a test kit to take home, everyone had the advice, followed the instructions, take the sample, label the tube and pop it back to your GP.

As we are covering the whole of Norfolk, all of our GP's request on ICE, so all of the requests that we get in are on a printed ICE form and all of the samples that we receive are usually pre-labelled with the FIT test label with the bar code already attached. The Norwich catchment GP's and some of the James Paget catchment GP's also request their Pathology consumables on ICE and we've put FIT kits on to that page, so not only do they request the tests on ICE and also request the kits on ICE.

For the outlying GP's around the King's Lynn area, they already had a system in place that copied the ICE requesting system. It is just a paper form that is emailed to our Stores Manager and again the FIT kits were just added to that so everyone just sends in a request and they go out on the next delivery.

Stage 4:
What feedback have you had?

Patients vastly prefer the FIT test to colonoscopy, which is not surprising!

GP's seem to like it. They appreciate that they have got a very clear pathway of who they should test and at what point they should refer. We also set up our request system so that if the patient hasn't had a full blood count within the last four weeks, and FIT is required the system will automatically print two forms, one for FIT and one for a full blood count.This means that we are also satisfying the failsafe part of the pathway of unexplained anaemia. If the patient hasn't already been assessed for anaemia, we are looking for that at the same time, so they are not lost to follow up on the anaemia part of the pathway. GP's are happy that this is a clearly defined set of instructions and then the result comes back and tells them exactly what to do for the patient.

Secondary care teams seem to be happy that they are getting better triaged referrals but it's early days yet because we are not that far in from launch.

Where are you now?

We went live with symptomatic FIT testing on 12 November 2018. While we've seen a massive increase in the numbers of samples that we received and had feedback from patients, GP's and our Gastroenterology team, it has been a bit too soon to see if there has been an obvious impact on the referral pathway. We are still going through the pilot study data and I would hope that following the hard launch of the service on Monday 4th February 2019 we will then absolutely see the impact of the service on the 2ww referral. I think we will probably have to give that a couple of months to bed in and then we will have to review around May and look back at 6 months of the service and see exactly what happened in terms of numbers of referrals and what the outcomes of those referrals were. Ideally, what we want to demonstrate, is that we are picking up more cancer diagnoses, or adenomatous polyps, and seeing fewer late-stage cancer referrals or emergency admissions. Identifying colorectal cancer at the earliest possible stage is the goal of this service.

Do you have any advice for Trusts and Laboratory teams that would like to introduce FIT testing?

The main advice from this project is definitely to have the right team for planning. Make sure that you have representation from every part of the patient pathway. I think that was the key to the success of our implementation of FIT. We met regularly, had email contact between meetings as well and we had enthusiastic and very positive people on that team who were really keen to see the service work and really keen to see better patient outcomes.

I think if you are looking to introduce a FIT service that is what you need, because then you've hopefully already identified any issues before they arise. Everyone is aware of what that impact might be and has raised their concerns at a very early stage. So we were able to look at our project plan, look at our proposed outcomes and revise them quite stringently, eliminating them or changing them on the basis of what realistically we could provide in terms of outcome data. Where there was an unrealistic goal we were able to change that and say that we were not going to be able to report back on that particular outcome measure, let's make it something we can report back on. That was really helpful because all of these projects require so much buy in from the Trust, from the Primary Care clinicians, from the STP and the CCG leads. Everyone has to have the same goal and outcome measures become incredibly important when they have put a lot of funding into the provision of the service. Ensuring that outcome measures are right for the service you are going to provide is really important otherwise you are constantly being measured against something that you could never achieve, or something you can't even quantitate.

So we found that by having the team together right from the beginning we had some lovely blue sky goals, which we then had to break down into quantifiable outcome measures. The main goal of the service is to identify colorectal cancer at an earlier stage, to improve the outcome for the patient. That won't be a measurable outcome for many departments for several years, due to the number of patients required for it to be statistically significant. What we have to do is have some goals that we can actually quantitate in the next year or two years, and having everyone involved from the start has made that possible. I think that has been the biggest success of this project - everyone involved has been really positive and enthusiastic.

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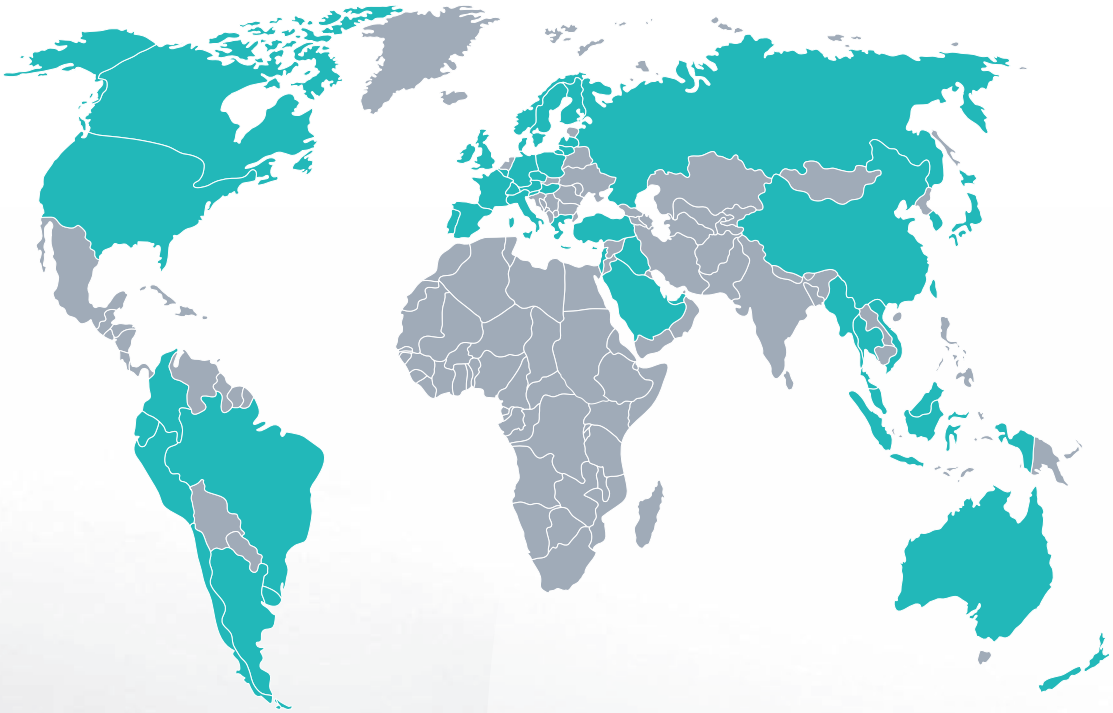

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