

Institution: University of Surrey		
Unit of Assessment: 3 Allied Health Professions, Dentistry, Nursing and Pharmacy		
Title of case study: Innovations in the NHS Bowel Cancer Screening Programme: Introduction of the Faecal Immunochemical Test (FIT)		
Period when the underpinning research was undertaken: 2012-2018		
Details of staff conducting the underpinning research from the submitting unit:		
Name(s):	Role(s) (e.g. job title):	Period(s) employed by submitting HEI:
Prof Stephen Halloran	Honorary Professor of Clinical Biochemistry, School of Biosciences & Medicine; Post-Graduate Medical School	01/08/1999 – 24/04/2014
	Emeritus Professor of Clinical Biochemistry	25/04/2014 – present
	Director, NHS Bowel Cancer Screening Programme (Southern Hub)	2006-2015
Period when the claimed impact occurred: 2015 – 2020		
Is this case study continued from a case study submitted in 2014? N		
1. Summary of the impact (indicative maximum 100 words) <p>Research conducted by Professor Stephen Halloran into the Faecal Immunochemical Test (FIT), including a pilot of FIT within the national bowel cancer screening programme (NHS BCSP), was instrumental in the UK National Screening Committee's recommendation for the UK-wide adoption of FIT as the primary test for bowel cancer screening replacing the previously used guaiac-based Faecal Occult Blood Test (gFOBT). The introduction of FIT has influenced healthcare policy in Scotland, Wales and England, with updates to NICE Guidelines made in 2017 and is expected to contribute savings compared with gFOBT of £26m per year. Since its introduction, FIT has increased Bowel Cancer Screening uptake by up to 10%, particularly for previous non-responders and first-timers, as well as hard to reach groups.</p>		
2. Underpinning research (indicative maximum 500 words) <p>Colorectal cancer (CRC) is the second highest cause of cancer deaths in developed countries (1.8 million cases, 896,000 deaths worldwide, 2017). The aim of population-based screening for bowel cancer is to reduce incidence and mortality through prevention by the removal of adenomas and earlier diagnosis. The National Health Service Bowel Cancer Screening Programme (NHS BCSP) utilising the guaiac-based Faecal Occult Blood Test (gFOBT) was rolled out in the UK in 2006.</p> <p>In 2012, a study by Professor Halloran (in collaboration with the University of Sheffield) was undertaken on behalf of the NHS Cancer Screening Programme to inform future bowel cancer screening policy in England. This work concluded that comprehensive screening data would improve understanding of the disease and allow identification of optimal screening modalities [R1]. At that time, uptake for gFOBT was lower than for other cancer screening programmes due to the multiple faecal samples required. Professor Halloran (in collaboration with University College London) also identified that socio-economic deprivation was consistently associated with lower</p>		

gFOBT uptake [R2] therefore a test involving a simpler single sample approach was needed to help improve uptake overall and within these harder to reach groups.

The Faecal Immunochemical Test (FIT) specifically recognises human haemoglobin (Hb) in faeces and thus the presence of bleeding bowel cancers and pre-cancerous polyps. Unlike gFOBT, FIT results are not influenced by the presence of other blood in stools (e.g., animal blood ingested through diet) or drugs that have oxidising or reducing properties. FIT therefore reduces the chance of false positives. In addition, FIT detects human blood at much lower concentrations, analysis is automated and only requires a single faecal sample (compared to the 6 samples required for gFOBT). FIT also provides a quantitative result facilitating the setting of appropriate thresholds to support optimal use of 'post-test' investigation resources.

In 2012, to further develop the evidence-base for the potential introduction of FIT in the UK, Professor Halloran led a study undertaken by the Guildford Medical Device Evaluation Centre (GMEC) based at the University of Surrey. This work evaluated four quantitative FIT products [R3] generating essential data on the pros and cons of the potential testing products that would be needed for rollout of FIT screening services. The evaluation also investigated standardisation issues including sample stability, sample mass, traceability and cross reactivity.

In 2014, Professors Halloran and Moss (Queen Mary University, London) led a large comparative study of FIT and gFOBT within the existing NHS BCSP at two Screening Hubs (Southern; Midlands & North West). Over a 6-month period, 40,930 (1 in 28) participants were sent a FIT instead of a gFOBT. Overall uptake was 66.4% for FIT compared with 59.3% for gFOBT, a greater increase than had been achieved previously in any established screening programme. Importantly, uptake by previous non-responders almost doubled (FIT 23.9% vs gFOBT 12.5%) and an increase was observed across all deprivation quintiles with a 7.8 percentage point increase in the most deprived quintile (FIT 54.3% vs 46.5% gFOBT). Furthermore, and most critically, with FIT cancer detection increased two-fold and advanced adenoma detection nearly five-fold [R4].

Professor Halloran collaborated with Health Economists from University of Oxford to explore the cost-effectiveness of FIT at a range of positivity thresholds. It produced the first published economic analysis of FIT screening in England using data directly comparing FIT with gFOBT. Results for a cohort starting screening aged 60 years demonstrated that FIT is highly cost-effective at all thresholds, results in quality-adjusted life years (QALYs) gains compared to gFOBT and that a population screened with FIT would result in a total estimated cost saving of £26 million per year compared with gFOBT [R5]. In a further study involving Professor Halloran (funded by the NIHR Collaboration for Leadership in Applied Health Research and Care), it was demonstrated that including routinely available risk predictors in the screening algorithm alongside FIT improves both the risk prediction model performance and test accuracy [R6].

3. References to the research (indicative maximum of six references)

[R1] Whyte, S., Chilcott, J. and **Halloran, S.**, 2012. Reappraisal of the options for colorectal cancer screening in England. *Colorectal Disease*, 14(9), pp. e547-e561. [doi:10.1111/j.1463-1318.2012.03014.x](https://doi.org/10.1111/j.1463-1318.2012.03014.x)

[R2] Lo, S.H., **Halloran, S.**, Snowball, J., Seaman, H., Wardle, J. and von Wagner, C., 2015. Colorectal cancer screening uptake over three biennial invitation rounds in the English bowel cancer screening programme. *Gut*, 64(2), pp. 282-291. [doi:10.1136/gutjnl-2013-306144](https://doi.org/10.1136/gutjnl-2013-306144)

[R3] Carroll MRR, Piggott C, Pearson S, Seaman HE, **Halloran SP**. Evaluation of quantitative faecal immunochemical tests for haemoglobin. Guildford, UK: Guildford Medical Device Evaluation Centre (GMEC), 2013. Available at: https://www.worldendo.org/wp-content/uploads/2018/07/gmec_fit_evaluation_report_update-final.pdf

[R4] Moss, S., Mathews, C., Day, T.J., Smith, S., Seaman, H.E., Snowball, J. and Halloran, S.P. 2017. Increased uptake and improved outcomes of bowel cancer screening with a faecal immunochemical test: results from a pilot study within the national screening programme in England. *Gut*, 66(9), pp.1631-1644. [doi:10.1136/gutjnl-2015-310691](https://doi.org/10.1136/gutjnl-2015-310691)

[R5] Murphy J., Halloran S., Gray A. Cost-effectiveness of the faecal immunochemical test at a range of positivity thresholds compared with the guaiac faecal occult blood test in the NHS Bowel Cancer Screening Programme in England. *BMJ Open* 2017; 7:e017186. [doi:10.1136/bmjopen-2017-017186](https://doi.org/10.1136/bmjopen-2017-017186)

[R6] Cooper, J.A., Parsons, N., Stinton, C., Mathews, C., Smith, S., Halloran, S.P., Moss, S. and Taylor-Phillips, S., 2018. Risk-adjusted colorectal cancer screening using the FIT and routine screening data: development of a risk prediction model. *British journal of cancer*, 118(2), pp.285-293. [doi: 10.1038/bjc.2017.375](https://doi.org/10.1038/bjc.2017.375)

4. Details of the impact (indicative maximum 750 words)

On the 19th November 2015, as a direct result of the outcomes of the 2014 study conducted by Professor Halloran, University of Surrey [R4], the UK National Screening Committee (UK NSC) recommended the adoption of FIT within the NHS Bowel Screening Programme as the primary test for bowel cancer [S1]. Following this recommendation, on the 7th June 2016 the Department of Health issued their media statement “**New bowel screening test to save hundreds of lives**” announcing that FIT would replace the current gFOBT used in the NHS Bowel Screening Programmes in England, Scotland and Wales [S2]. Public Health Minister, Jane Ellison, stated “**This new test is an exciting game changer for helping us beat bowel cancer. It is easier to use, will increase the number of tests and help us tackle cancer earlier**”.

In July 2017, NICE issued their guidance on the use of FIT testing for patients with low-risk symptoms [S3]. Subsequent work commissioned by the UK National Screening Committee (NSC) to consider the cost-effectiveness of a variety of different screening options and thresholds and directly citing Professor Halloran’s research outcomes [R1, R2, R4, R5] concluded in September 2017 that a FIT strategy is indeed more effective and less expensive than gFOBT [S4]. The roll out of FIT commenced in Scotland on 20th November 2017, Wales on 28th January 2019 and England in June 2019.

In Scotland, latest figures show, that following the introduction of FIT, the uptake of bowel cancer screening had already increased from 55.9% (2016/17) to 63.9% (2017/18). Moreover, the largest improvement in participation has been amongst those living in the most deprived areas (42.0% to 51.8%) where survival outcomes are often poorer. The number of men participating increased by more than 9 percentage points (52.6% to 61.8%) and there was an even greater increase in uptake (8.2% to 18.4%) amongst those who had never participated before, but previously had the opportunity to [S5].

Wales began their phased introduction of FIT on 28th January 2019 with 1 in 28 random screening participants issued with FIT, mirroring the approach used in Professor Halloran’s research [R4]. Although it is too early for a full statistical analysis to be reported regarding the effect, the most recent data available from Public Health Wales Screening Division (for the year 2018/19) has already shown performance improvements compared to gFOBT. For example, the percentage of spoilt or rejected tests appears lower with FIT (0.0%/0.2% FIT vs 1.1%/2.3% gFOBT) [S6].

Prior to the Welsh roll-out, and in support of it, in December 2018 Cancer Research UK (CRUK) issued their “Engaging Primary Care in bowel screening GP good practice guide for Wales” [S7]; this cites Professor Halloran’s research [R4] as the primary underpinning evidence for the replacement of gFOBT with a FIT screening pathway. They reinforced the replacement of gFOBT by FIT in their Insights Brochure for GPs (Insights Brochures are CRUK’s expert guides on prevention and early diagnosis of cancer for health professionals) [S8] again citing the University of Surrey’s crucial work [R4] showing superior uptake associated with FIT. Further, it states that

“The switch to FIT provides a great opportunity to raise screening with your patients” and through achieving diagnosis “at the earliest stage [ensure] more than 9 in 10 people will survive bowel cancer for more than 5 years” [S8].

In summary, as a direct result of research conducted by Professor Halloran at the University of Surrey, national bowel cancer screening policy has changed to include the adoption of FIT as the primary screening test used in the NHS BCSP. Moreover, since its recent introduction, utilisation of FIT is radically increasing bowel cancer screening uptake across England, Scotland and Wales and is clearly already reducing inequalities in screening rates across Scotland. Given that early diagnosis is the most effective route to reducing deaths from colorectal cancer, this change in screening technology will directly contribute to lives saved.

5. Sources to corroborate the impact (indicative maximum of 10 references)

[S1] UK National Screening Committee Meeting Minutes, 19th November 2015 Pg. 14 Section 9 refers to “the pilot” meaning our study **[R4]**. Available at:

<http://qna.files.parliament.uk/qna-attachments/632459/original/20161110%20-%20HL3125%20-%20UK%20NSC%20Minutes%20-%2019%20November%202015.pdf>

[S2] Public Health Minister Jane Ellison announcement “New bowel screening test to save hundreds of lives”. 7th June 2016. Available at: <https://healthmedia.blog.gov.uk/2016/06/07/new-bowel-screening-test-to-save-hundreds-of-lives/>

[S3] NICE Quantitative faecal immunochemical tests to guide referral for colorectal cancer in primary care, Diagnostics guidance [DG30]. July 2017. Available at: <https://www.nice.org.uk/guidance/dg30>

[S4] Optimising Bowel Cancer Screening Phase 1: Optimising the cost effectiveness of repeated FIT screening and screening strategies combining bowel scope and FIT screening. National Screening Committee, 22nd September 2017. Available at: <https://core.ac.uk/download/pdf/157834144.pdf>

[S5] Bowel Cancer UK, Press Release “New bowel screening test leads to increase in uptake in Scotland”. February 2019. Available at: <https://www.bowelcanceruk.org.uk/news-and-blogs/news/new-bowel-screening-test-leads-to-increase-in-uptake-in-scotland/> using data derived from <https://www.isdscotland.org/Health-Topics/Cancer/Bowel-Screening/>

[S6] Bowel Screening Wales Annual Statistical Report 2018-19. February 2020. Available at: <http://www.bowelscreening.wales.nhs.uk/sitesplus/documents/1121/Bowel%20Screening%20Wales%20Annual%20Statistical%20Report%202018-19%20v1.0.pdf>

[S7] Engaging Primary Care in bowel Screening: GP good practice guide for Wales. Cancer Research UK, December 2018. Available at: https://www.cancerresearchuk.org/sites/default/files/wales_gp_good_practice_guide_2019_final.pdf

[S8] Faecal Immunochemical Test GP Insight. February 2019. Available at: https://publications.cancerresearchuk.org/sites/default/files/publication-files/G1504_CRUK_FIT_INSIGHT_GP_WAL_FINAL.pdf