

Security classification: In-Confidence

File number: AD62-14-2017

Action required by: 31 January 2018

Ministry of Health

16 JAN 2018

National Bowel Screening Programme and the choice between the Faecal Immunochemical Test and Flexible Sigmoidoscopy

To: Hon David Clark, Minister of Health

RECEIVED

16 JAN 2018

Office of Hon David Clark

Purpose

This report provides you with information about using the faecal immunochemical test (FIT) rather than flexible sigmoidoscopy (FS) in the National Bowel Screening Programme (NBSP).

Key points

- Bowel screening detects bowel cancer at an early stage where treatment is more effective. It can also detect pre-cancerous polyps (adenomas) that if not removed have the potential to develop into bowel cancer.
- When the Ministry of Health (the Ministry) developed the New Zealand bowel screening pilot that has led to the NBSP, it considered the benefits, harms, costs, and available screening or testing methods used internationally.

The major test used internationally in population based bowel screening programmes is the faecal occult blood test (FOBT). This test detects blood in faeces and are undertaken at home by the participant. If positive participants are referred to colonoscopy. This is an invasive procedure which is more resource intense, but only 5% of those screened will require colonoscopy. More recently, there has been adoption of the more sensitive faecal immunochemical test (FIT). The NBSP uses the newer test which only requires one sample.

- In 2011, based on the available international evidence and recommendations from the colorectal cancer screening advisory group, the Ministry adopted the FIT for the pilot.
- Screening with FIT followed by diagnostic colonoscopy for test results over a defined threshold of blood was chosen because:
 - clear evidence of benefit
 - it is a more acceptable test for participants
 - there was a work programme in place to improve colonoscopy wait times to meet the needs of the programme
- Another type of screening test is flexible sigmoidoscopy (FS). The FS is an invasive procedure to undertake a visual examination of the lower two-thirds of the colon. FS is also generally undertaken in a hospital setting.
- More recent evidence continues to support the decision made in 2011. While both FIT and SF are cost-effective ways to reduce bowel cancer mortality, the impact is greater for FIT.
- Because it is repeated every two years, the test is more acceptable to participants and it has a lower impact on endoscopy services. The Ministry has not ruled out the introduction of FS as an additional screening test, as has occurred in England, in the future.
- Health Report number: H20171632

Recommendations

The Ministry recommends that you:

This report is for your information only and does not request any decisions.



Jill Lane
Director
Service Commissioning



Minister's signature:

Date: 14/2/18

Released under the Official Information Act 1982

National Bowel Screening Programme and the choice between the Faecal Immunochemical Test and Flexible Sigmoidoscopy

Background

1. In late 2010, during the design phase of the bowel screening pilot, the Ministry concluded that the plan to proceed with bowel screening using the faecal immunochemical test (FIT) was strongly supported by the available evidence.
2. Flexible sigmoidoscopy (FS) was not considered a favourable option at the time because of: the limited evidence of its benefits; concerns regarding lower participation rates; and insufficient endoscopic workforce to undertake FS as a primary screening test as well as colonoscopies that would also be required subsequently.
3. The Ministry issued a position paper about FS in 2011 following its decision. This health report draws on evidence that was considered in the early decision making for the programme and more recent publications.

Description of the two tests

Faecal Immunochemical Test for haemoglobin

4. A FIT screens for tiny amounts of blood in faeces. A small sample is collected by participants, usually at home. No bowel preparation is needed. People send their sample to a laboratory for analysis. If the amount of blood is above the predetermined threshold the screening test is considered positive. Screening needs to be repeated at regular intervals.
5. The results are sent to the participants' GP. The GP refers participants with a positive result for colonoscopy, an invasive procedure which examines the entire bowel for cancers and pre-cancerous polyps. During this procedure polyps can be removed and sent for laboratory testing.
6. About five percent of NBSP participants require a colonoscopy because they have a positive screening FIT.
7. Screening can also use a guaiac faecal occult blood test (gFOBT) which also tests for blood in the faecal specimen. The original randomised control trials on bowel cancer screening used this test. However, FIT has the benefits of being more sensitive, easier to use for participants and needs only a single sample.

Flexible Sigmoidoscopy

8. A flexible sigmoidoscopy (FS) is an examination that can identify cancers and polyps in the lower (distal) portion of the bowel where a large proportion of bowel cancers develop. It is undertaken by the insertion of a flexible fibre-optic scope through the rectum and then guided through the lower portion of the large bowel. If polyps are located they can usually be removed during the procedure. The patient is awake throughout the procedure, which takes up to 30 minutes. Mild sedation may be administered. FS is usually undertaken as a one off screening test.
9. The FS is usually carried out in a hospital setting as it requires a suitable facility, endoscopy equipment, cleaning technicians and endoscopists. The individual also needs to prepare their bowel before the procedure can take place.
10. About five percent of participants who undergo FS screening and are identified to have bowel polyps will also be sent on for a colonoscopy to view the entire bowel.

Clinical evidence for FIT and FS screening

11. Both FIT and FS could offer cost-effective programmes which reduce bowel cancer mortality in populations invited to screening.
12. The earliest trials for bowel cancer screening used gFOBT. These showed a 16% mortality reduction for populations invited to screening¹. The Subsequent move to use the newer

¹ Hewitson P, Glasziou P, Irwing L, Towler B, Watson E. (2007) Screening for colorectal cancer using the faecal occult blood test, Hemocult. *Cochrane Database of Systematic Reviews*; (1): CD001216.

immunochemical faecal occult blood test are expected to result in a greater mortality reduction because their increased sensitivity will result in the detection of more cancers and adenomas.

13. By 2011, two randomised controlled trials (RCTs) had reported on the effectiveness of a once only FS as a screening tool for bowel cancer^{2,3} and the European Union (EU) published a guideline on colorectal cancer screening⁴ observing that there was increasing evidence that FS could reduce mortality from bowel cancer. However the size of the reduction was uncertain. The appropriate interval between tests and the suitable age range were also unknown. The EU guideline did not recommend FS as a screening tool.
14. Since 2009, four main international trials using FS as a screening test have been published. Three of the four trials were able to demonstrate a reduction in bowel cancer mortality of 20-31% for invited groups and all showed a reduction in the incidence of bowel cancer⁵. Critically however, the studies used groups that had already indicated an interest in bowel screening and therefore more likely to agree to having an invasive procedure as the screening test, an important bias when considering a population based screening programme.
15. Latest research in 2017 indicates that a single screening FS continues to provide substantial protection from colorectal cancer diagnosis and death, with protection lasting at least 17 years⁶.
16. Many authorities have reviewed the wide body of evidence around bowel cancer screening, including the US Preventative Services Task Force⁷. The group reviewed a range of screening modalities and concluded that no approach is superior to each other in the context of individual patient choice. The best screening test is considered to be the one that people do.

International screening programmes

17. Organised screening programmes weigh up a number of factors when making decisions. With consideration of the advantages and limitations of all bowel screening options, there are no national screening programmes that have introduced FS as their main or only screening test. However, FS provides additional benefits when used in conjunction with FIT. This is an option for programmes with additional resources.
18. Ireland and the Netherlands decided to use FIT as the primary test for their bowel screening programmes based on reasons similar to New Zealand. Before choosing to implement a FIT screening programme, the Netherlands undertook a rigorous evaluation of guaiac FOBT, immunochemical FOBT and FS. The decision to use FIT was based its higher detection of cancers, the impact on mortality, higher participation and the impact on endoscopy facilities.
19. NHS England has a two-year faecal occult blood test screening programme, using the older guaiac FOBT for those aged 60-74. In early 2013, the National Health Service (NHS) in England began a six centre bowel screening pilot for participants aged 55 using FS. Participants in the pilot will also continue to be invited to the NHS two-yearly bowel screening programme from 60 to 74 years using a FOBT.

² Atkin et al (2010) Once-only flexible sigmoidoscopy screening in prevention of colorectal cancer: a multicentre randomised controlled trial. *Lancet* 357(9726) 1624-1633.

³ Hoff et al (2009) Risk of colorectal cancer after flexible sigmoidoscopy screening: randomised control trial. *British Medical Journal* 338:b1846.

⁴ Segnan et al (2011) *European guidelines for quality assurance in colorectal cancer screening and diagnosis*. International Agency for Research on Cancer, Luxembourg.

⁵ Sarfati D, Shaw C, McLeod M, Blakely T, Bisset I (2016) Screening for colorectal cancer: spoiled for choice? *NZMA* 129 120-128.

⁶ Atkin W, Wooldrage K, Parkin MD, Kralj-Hans I, MacRae E, Shah U, Duffy S, Cross AJ (2017) Long-term effects of once-only flexible sigmoidoscopy screening after 17 years of follow-up: the UK Flexible Sigmoidoscopy Screening randomised controlled trial. *Lancet* 2017; 389: 1299-311

⁷ US Preventative Service Task Force (2016). Screening for Colorectal Cancer US Preventative Services Task Force Recommendation Statement. *Journal of the American Medical Association* 315(23) 2564-2575.

20. The uptake of FS in NHS England over the first 14 month period from March 2013 to May 2014 was 43.1 percent, lower than the participation levels of the FIT type screening offered to those aged 60 to 74 years⁸.
21. Based on the pilot findings above, the programme has adopted and is gradually rolling out a one-off FS at the age of 55 as an addition to the gFOBT programme. They also propose to move to use the newer FIT test.

New Zealand context and FS in the bowel screening pilot and NBSP

22. An important consideration in the NBSP is to achieve equity in the programme for Māori and other priority populations. To be able to maximise participation in the programme having the most acceptable test to participants is critical. While data for New Zealand on uptake is limited, international experience shows that FIT is the preferred test to do. It can be completed at home, requires no preparation and only if it is positive is an invasive procedure required.
23. The Ministry's decision has been challenged publically by Associate Professor (Assoc Prof) Brian Cox based at the Dunedin Medical School at the University of Otago. The Otago Daily Times, The Press and the Dominion Post have published opinion pieces by him, advocating that the NBSP should use a one-off FS rather than FIT. The opinions held by Assoc Prof Cox have been rebuffed by a number of leading academics and clinicians in New Zealand with the NBSP approach consistent with international evidence^{9,10}.
24. A review of evidence, in 2016, relating to FS and FIT by New Zealand based academics, most of whom are members of the Ministry's Bowel Screening Advisory Group, concluded that the Ministry's decision to proceed with FIT, screening every two years was consistent with international evidence.

End.

⁸ McGregor L, Bonello B, Kerrison RS, Nickerson C, Baio G, Berkman L, Rees CJ, Atkin W, Wardle J, von Wagner C (2015) Uptake of Bowel Scope (Flexible Sigmoidoscopy) Screening in the English National Programme: the first 14 months. *Journal of Medical Screening*. 23(2): 77-82

⁹ Frankish P, Hulme-Moir M, Walmsley R (2016) Flexible sigmoidoscopy and bowel cancer screening: reply to Professor Cox. *New Zealand Medical Journal* 129(1435) 90-91.

¹⁰ Sarfati D, Shaw C, McLeod M, Blakely T, Bissett I (2016) Response to Cox letter. *New Zealand Medical Journal* 129(1446) 116-118.