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From screening criteria to colorectal cancer screening: what can New Zealand learn from other countries?

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Abstract

New Zealand is currently exploring how population-based colorectal cancer (CRC) screening will be implemented. The United Kingdom (UK), Australia, France, Italy, Spain, Finland, Denmark, the Netherlands, and Switzerland have conducted or are currently conducting pilot/feasibility studies. The UK, Australia, Finland, Canada, France and Italy are all in the early stages of implementing population-based CRC screening programmes. Most of these countries have lower CRC mortality rates than New Zealand. New Zealand is in a good position to learn from this overseas experience. Some of the key areas that will require careful consideration include; the best use of a population register to identify and invite eligible participants; the type of screening test to be used; ensuring adequate colonoscopy capacity; efficient and effective information systems; the management of high-risk groups; and how to ensure that all population groups benefit from screening.

New Zealand has some of the highest rates of colorectal cancer (CRC) incidence and mortality in the world.[1] In the absence of effective primary prevention strategies, efforts have concentrated on screening and improving treatment in order to decrease mortality from CRC.[2] At least four randomised controlled trials (RCT) of CRC screening (using the guaiac faecal occult blood test Haemoccult) have been undertaken. Meta-analysis of the RCT conducted in Nottingham, Minnesota, Funen, and Goteborg show a 16% reduction in population CRC mortality can potentially be achieved by screening.[3]

New Zealand has twice considered whether a national population based screening programme would be appropriate.[4,5] The most recent review concluded that CRC screening largely met the National Health Committee screening criteria for population based screening programmes. However there were still unanswered questions, mainly relating to the type of faecal occult blood test (FOBT) to be used and the ability of the healthcare system to deliver diagnostic services (i.e. colonoscopy after a positive screening FOBT).

The advisory group considering this issue recommended that a feasibility study, involving at least a prevalence round of screening in a community setting, be conducted to examine these, and other, aspects of screening. The advisory group specifically noted that a feasibility study should be conducted prior to a final decision on a national programme. Assuming a feasibility study was deemed successful it would be followed by a pilot programme, then a full programme roll-out.[5] This advice was endorsed by other groups providing advice to the Ministry and Minister of Health.[6,7] Recently the Minister of Health announced that New Zealand will proceed with CRC screening, although specific details are yet to be announced.[8]

Establishing effective screening programmes is always demanding, but colorectal cancer screening has some particular challenges:

- The mortality reduction potentially achievable from CRC screening is modest at best; meta-analysis of the RCTs of screening shows a 16% mortality reduction, compared to 20% for breast cancer screening.[3,9]
- Participation in CRC screening appears to be lower than other screening programmes; most pilot studies have shown only moderate participation.[10–17]
- Selection of the type of screening test is problematic. There are two types of faecal occult blood tests; guaiac (FOBTg) and immunochemical (FOBTi). They use different methods to detect blood in faeces and neither test is ideal. FOBTg is the screening test for which there is RCT evidence, but it only has a sensitivity of about 55%, meaning that almost half of people with cancer will have a negative screening test.[3] FOBTi are more sensitive for detecting blood or blood products in faeces, processing can be automated and they are 'set' allowing some alteration of what constitutes positive.[18] Using FOBTi would mean more cancers are detected, but also that considerably more colonoscopies would be required. There is some research evidence suggesting higher participation compared with FOBTg,[19,20] but there is currently no RCT evidence supporting the use of FOBTi in population screening.
- Complications of the required follow up diagnostic test, colonoscopy, while rare, are potentially serious (e.g. perforation of the bowel).

While other screening tests—such as flexible sigmoidoscopy, CT colonography, and faecal DNA—are being explored, as yet evidence for these options is limited.[21–23]

This paper aims to review the feasibility and pilot studies that have been completed overseas, in order to inform planning for CRC screening in New Zealand.

International situation

Internationally, there seems to be a (slow) transition occurring in CRC screening policies. While opportunistic testing remains the most common practice in OECD countries, there is an increasing move towards adoption of population based FOBT screening, and ongoing research interest in flexible sigmoidoscopy.[24–26]

The United Kingdom (UK), Australia, France, Italy, Spain, and Finland have all conducted feasibility or pilot studies.[10–17,27–30] Denmark, the Netherlands, and Switzerland are currently conducting pilot or feasibility studies, although no details of design or results have yet been published.[25,26,31,32]

The UK, Australia, Finland, Canada, France, and Italy are all in the early stages of implementing population-based CRC screening programmes run at either a state or national level.[10,12,25,33–38] Canada does not appear to have conducted a population-based pilot or feasibility study prior to commencing implementation of a screening programme.

All of these countries, with the exception of Denmark, have lower rates of CRC mortality than New Zealand.[1]

What are the key findings from international CRC screening pilot/feasibility studies?

Conducting and evaluating a pilot or feasibility study results in a wealth of information. Table 1 summarises some of the key aspects of the design and results of pilot studies conducted in the UK, Australia, France, Spain, and Italy, and the first phase of the implementation of the Finnish screening programme which was explicitly designed to assess the feasibility of screening.[12,28]

The terms feasibility study and pilot study are largely synonymous in the literature. The design of these studies is also identical, involving (at least) a prevalence round of screening in a community setting. The intent of studies also seems similar; to test the viability of screening in the community and to inform planning for any national programme.

Design of the screening pathway—Screening for colorectal cancer involves a pathway of activities, from inviting people to be screened through to ensuring they receive best practice treatment if they are diagnosed with the condition. The details of this specific pathway must be determined before screening can be commenced. Despite different health systems, there are a number of commonalities in the details of screening pathway design of the pilot studies discussed in Table 1.

All studies had biennial screening and used a population register to identify and invite people to participate in screening. Colonoscopy was the diagnostic investigation in all pilot studies, although second-line investigation protocol (e.g. double contrast barium enema) varied slightly. Most countries had exclusion criteria for those at high risk of colorectal cancer (as they are not suitable for population screening), although these varied slightly.[10–17,28]

Some of the differences between pilots included:

- *Age ranges*—these varied slightly, although all were within 50–74 years. No rationale for particular age range selected was stated.
- *Type of screening test*—Spain, France, Finland, and the UK used guaiac faecal occult blood tests (FOBTg) in their pilot studies. Australia and Italy used immunochemical faecal occult blood tests (FOBTi).
- *Definition of a positive FOBTg test*—France and Finland regarded any positive result for blood on any of the six samples as requiring colonoscopy follow up. Spain and the UK had a 'weakly positive' category that required repeat testing.
- *The involvement of primary care in the screening pathway*—General practitioner referral for colonoscopy was required after a positive result in the Australian, French, and Finnish programmes. The other countries had a more centralised screening programme, with colonoscopy referral occurring directly from the programme.[10–17,28]

Table 1. Results of international pilot studies of CRC screening

Country name	Australia	UK	Italy (Florence)	France	Spain	Finland
Age of eligible population	55–74	50–70	50–70	50–74	50–69	60–69
Population invited to be screened	60,792 (56,907 actually eligible)	478,250	15,235	182,981 (163,707 actually eligible)	64,886 (63,880 actually eligible)	52,994 (52,994 actually eligible)
Number (%) participated in screening	25,840 (45.4% of eligible)	276,819 (57.9% of invited)	6,418 (42.1% of invited)	90,706 (test completion) (55.4% of eligible)	10,987 (17.2% of eligible)	37,514 (70.8% of eligible)
Number (%) of positive tests	2308 (9%)	5050 (1.9%)	268 (4.2%)	3100 (3.4%)	372 (3.4%)	803 (2.1%)
Time to follow up colonoscopy	9 days (mean) from FOBT result to GP consultation: 38.5 days (mean) from GP consultation to colonoscopy	2-6 weeks average	Not stated	Not stated	41 days (median time from positive FOBT to colonoscopy)	82% had colonoscopy within 3 months of test, 91% within 4 months.
Attended colonoscopy after positive FOBT	1,265 (55%)*	4,116 (81.5%)	231 (86.2%)	2,724 (87.9%)	334 (89.8%)	723 (90.0%)
Colonoscopy complications	Not stated	2 perforations (0.05%) 23 admissions	Not stated	2 perforations, 4 bleeding (0.2%) 9 admissions	1 perforation , 3 bleeding	Not stated
Number of cancers detected (% of people screened)	67 (0.26%) (only 20 are confirmed by pathology)	552 (0.19%)	33 (0.51%)	206 (0.23%)	23 (0.21%)	62 (0.16%)

Country name	Australia	UK	Italy (Florence)	France	Spain	Finland
Number of adenomas detected (% of people participated in screening)	176 advanced (0.68%) (these do not appear to be confirmed by pathology)	1,388 (0.5%)	75 (1.16%)	958 (1.06%)	109 (0.99%) (high risk 79)	312 (0.83%)
Positive predictive value (denominator number of colonoscopies)	Cancer: 5.2% High risk adenoma 13.9% (note these were not pathologically confirmed cancers and adenomas)	Cancer: 10.9% Adenoma: 35.0%	Cancer: 14.3% Adenoma: 32.5%	Cancer: 7.6% High risk adenoma: 23.6%	Cancer: 6.2% High risk adenoma: 21.2%	Cancer: 8.6% Adenoma: 43.2%
Stage of cancers detected	Not known	Dukes stage A: 48%** B: 25% C: 26% D: 1%	Astler and Coller A: 39.3% B1: 33.3% B2: 12.1%	TNM stage I: 47.6% II: 23.8% III: 20.5% IV: 8.1%	TNM stage (for cancers from 2 rounds of screening) I: 41.7% II: 19.4% III: 27.8% IV: 11.1%	Not stated

*Likely to be an underestimation due to data collection issues, however many of those with positive FOBT did not attend their GPs, which was required for colonoscopy referral.

** Including polyp cancers.

All information for this table is sourced from[10–17, 28]

Participation in CRC screening programmes—Participation is a key factor in screening programme success. As detailed in Table 1, participation varied considerably in the different studies, from 17% in Spain to 70% in Finland.[11,12] The remainder of studies had participation between 42–58%.[10,13–17]

The two countries that used FOBTi did not have higher participation compared to countries using FOBTg, which is somewhat inconsistent with research evidence.[19,20]

Ongoing participation in screening programmes is crucial, particularly in a programme with low screening test sensitivity. Current information on ongoing participation is limited as only Spain and England have reported on second (incidence) rounds of screening. In Spain, participation increased from 17% to 22%, but in England it decreased from 58.5 to 51.9%.[11,39] This latter result is of particular concern.

Screening test issues—The screening test positivity rate varied considerably in the first round of screening in the studies summarised (Table 1). This is due to a number of factors, including the different test types used (FOBTg vs FOBTi), different measures of test positivity, and different underlying disease incidence. For example, in the UK using FOBTg there was a positivity rate of 1.9% while in Australia, which used FOBTi, the rate was 9%.[14,15]

Establishing an appropriate threshold for a positive test in immunochemical FOBT appeared to be a challenge in Australia where two different FOBTi were tested in the pilot study. Initially 13.7% of people were test positive on one of the immunochemical tests being trialled, however after a change in the "test kit or the test analysis" this declined to 7.1%.[15,16] Different positivity levels have implications for the sensitivity and specificity of the screening test, as well as for the numbers of diagnostic colonoscopies required.

Colonoscopy—Colonoscopy rates (the proportion of people attending for colonoscopy following a positive screening test) were over 80% in all but the Australian study (which was 55%) although data issues mean that the Australian rate is likely to be an underestimate. Over 85% of all colonoscopies were completed adequately. Few serious complications were described in those studies which reported complication rates. Perforation rates varied between 0.05% and 0.2%.[10–17,28]

Colonoscopy capacity was a concern in many of the pilots. The UK, which had the lowest test positivity rate, had to cease inviting individuals for periods while the pilot was running because colonoscopy services were unable to cope.[40] Australia does not appear to have monitored the impact of screening activities on routine colonoscopies in their pilot; however they have opted for staged implementation of their full programme to ensure that their colonoscopy capacity is adequate.[16,33]

Identifying cancer—The positive predictive value (PPV) of the screening test varied between countries (from 5.2% in Australia to 14.3% in Italy).[10–17,28] Information on PPV is essential to inform participants about their chances of having cancer after a positive test. The variation between countries shows that locally relevant information is crucial.

The stage at which cancers were detected is an important surrogate indicator of screening programme success.[41] Screening should 'down shift' cancer stage when

compared to a stage at presentation in an unscreened population. The countries that reported stage had a majority of cancers in Dukes A or equivalent, suggesting that screening was detecting cancers earlier.[10,11,13,14,17]

Lessons for CRC screening in New Zealand

This section highlights some of the areas that New Zealand will have to consider in the planning, design, implementation and evaluation of CRC screening. More thorough coverage of the issues, including quality considerations, is available elsewhere.[5,42]

Inequalities—Screening has the potential to exacerbate inequalities in health. In the studies reviewed here, there were differences in participation by sex, socioeconomic position, and age.[10–13,15 ,17] In the UK, the CRC screening programme was much less able to deliver a successful service to ethnic minorities along the entire screening pathway. This was reflected in lower participation rates, lower test completion, higher levels of psychological distress after FOBT, and lower uptake of colonoscopy after a positive result.[43]

Currently, in New Zealand, Māori are less likely to be diagnosed with CRC than non-Māori, but just as likely to die from it (i.e. Māori are less likely to survive CRC). For CRC, Māori are less likely to have stage recorded, less likely to have a localised stage at diagnosis, and more likely to be diagnosed at a later stage.[44] Despite some progress, the New Zealand breast and cervical screening programmes have not yet achieved equitable screening rates between Māori and non-Māori.[44–46]

New Zealand CRC screening should be designed to both eliminate existing inequalities in CRC (e.g. in stage at diagnosis) and avoid creating new inequalities. This will require these goals to be explicitly integrated throughout all levels of the planning and activity and evaluation. It will require strong leadership and commitment to these goals.

Ensuring adequate participation—Ensuring adequate participation in CRC screening will be one of the key challenges in New Zealand. A vital part of this is the ability to identify eligible people and invite them to participate in screening. Participation in CRC screening pilot studies was, in the main part, modest despite all countries using population based registers. The evidence of population benefit comes from trials where 60–75% of individuals invited participated in screening at least once.[3]

Recommendations that New Zealand should develop and utilise a population register to invite people to participate in screening have been made on many occasions.[47–50] It is essential that a register is developed and trialled in a CRC screening pilot — possibly based on Primary Health Organisation enrolment data which covers the majority of the population.[51]

Choosing a screening test—The CRC screening advisory group recommended that a feasibility study be conducted using FOBTi. There are obvious advantages to FOBTi, including increased sensitivity, the ability to determine the 'positive threshold', and the ability to automate processing, which could improve quality control.[5,18]

In addition, there is some evidence suggesting that participation may be better with FOBTi, although it is difficult to know how to interpret this as there was no difference in participation in the pilot studies that used FOBTi.[19,20] On the other hand, the disadvantages are higher cost—lack of RCT evidence of a mortality benefit and the potential for very high positivity rate which could overwhelm health services due to colonoscopy demand.

Several jurisdictions have selected guaiac tests because of their lower positivity rate and thus requirement for fewer colonoscopies,[10,39,52] and it is difficult to see how NZ could cope with a positivity rate similar to that seen in Australia. For example, in Waikato DHB in the 2006 census, there were approximately 70,000 men and women aged 50–70. Assuming a 60% participation rate in screening, using an FOBTi with 9% positivity, an extra 3780 diagnostic colonoscopies would be required over 2 years for a prevalence round of screening. In contrast, a 1.9% positivity rate would result in about 800 extra colonoscopies being needed.

Service capacity—As with other countries developing CRC screening, colonoscopy capacity is probably the biggest challenge for New Zealand to implement CRC screening. A survey of endoscopy units conducted in 2005 indicated that many services could not offer diagnostic colonoscopy to symptomatic patients within 3 months of referral.[53] If services are not currently able to offer timely colonoscopy to those with symptoms, then the increased demands of a screening programme are very likely to compromise the already stretched diagnostic services. Options for increasing service capacity, such as training health professionals other than doctors to perform endoscopy, will need to be explored. It may also be necessary to restrict the age range to which screening is initially offered (for example to 60–69 as has been done in England[54]) and then look to increase this later as capacity allows.

Information systems—Information systems for a feasibility study are vital in assuring the optimal and ethical delivery of screening activities. Without such systems it is impossible to ascertain how much benefit, or otherwise, a screening programme is providing at a population level or to ensure adequate safety net provisions for individual participants. For example, in the Australian pilot, 45% of screen positive participants were 'lost to follow up', highlighting the potential consequences of inadequate information systems.[15,16]

Similar problems were faced by the groups evaluating the breast cancer screening pilots in New Zealand, where changing data systems and the lack of centralised access to data made evaluation difficult.[55] The Gisborne Inquiry also highlighted problems with correlation of histology and cytology information and the lack of centralised information in the New Zealand cervical cancer screening programme.[48] Setting up good information systems is a vital foundation for a functional screening pilot study and programme.

High-risk individuals—There are two areas to consider in relation to high-risk individuals and groups, firstly services for those already at high risk of CRC and thus not eligible for population screening and secondly those who become 'high risk' after participating in screening (e.g. through detection of high risk adenoma).

Careful consideration has to be given to individuals and groups who are already at high risk of CRC (e.g. through personal or family history). Currently, there are

clinical guidelines recommending the regular surveillance and monitoring of this group, but there is evidence that not all public hospitals are able to offer the recommended level of service.[53,56]

Individuals who have high-risk adenomas detected through screening are no longer eligible for population-based screening, which is aimed at people of 'average' risk. In the UK, people who become 'high risk' after participating in screening are then managed in a specific arm of the screening programme, allowing better assessment of surveillance colonoscopy requirements and providing them with best practice management.[39] This approach should be adopted in New Zealand.

Conclusion

New Zealand, like many other countries, is exploring CRC screening as a way to reduce mortality from CRC. Like other population-based screening programmes, CRC screening is expensive, complex, and demanding. Learning from international experiences is one way that we can minimise problems in planning and delivering screening. Additionally we need to heed the lessons from the New Zealand experience of implementing cervical and breast cancer screening programmes- they remain germane.

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