

# Fifteen years of bowel cancer screening policy in Australia: putting evidence into practice?

Kathy L Flitcroft, Glenn P Salkeld, James A Gillespie, Lyndal J Trevena and Les M Irwig

Over 4000 Australians die from bowel cancer each year, making it the second biggest cause of cancer death in Australian men, after prostate cancer, and in Australian women, after breast cancer.<sup>1</sup> Meta-analysis of randomised controlled trial (RCT) evidence has shown a reduction in relative risk of dying from bowel cancer of 25% for those who attended at least one round of faecal occult blood test (FOBT) screening.<sup>2</sup> In addition, FOBT screening has the potential to reduce morbidity from bowel cancer through earlier diagnosis and treatment, and prevent bowel cancer by the removal of precancerous lesions, identified through colonoscopic follow-up of positive FOBTs.<sup>3</sup> FOBT screening is the only mode of bowel cancer screening with RCT evidence of efficacy.

Here, we describe the history of bowel cancer screening policy development and implementation in Australia, based on semi-structured interviews with key informants and document analysis (Box 1). Research evidence appears to have played a major role in the development of bowel cancer screening policy proposals. However, policy decisions about how best to implement the program, given considerable external constraints, have not been based on evidence and reflect a lack of understanding of the importance of research evidence in population screening programs, where some people will inevitably be harmed and a few will benefit.

## The development of bowel cancer screening policy proposals: following the evidence

The development of bowel cancer screening policy proposals from the late 1980s to October 2005 was largely evidence based (Box 2). Clinicians made a case for considering FOBT screening, after publication of the first RCT evidence,<sup>7</sup> and the federal government agreed to establish an expert group (the Australian Health Technology Advisory Committee [AHTAC] Working Party on Colorectal Cancer Screening)<sup>4</sup> to specifically review the benefits, risks and costs of bowel cancer screening in Australia. This review comprised a detailed examination of literature, including evidence from recently published RCTs<sup>7,12,13</sup> and cost-effectiveness analysis.<sup>11</sup>

After the AHTAC's report was published in December 1997,<sup>4</sup> the federal government allocated funding in the 2000–01 budget for a pilot program of FOBT screening, which ran from November 2002 to June 2004. Invitations were sent to 57 000 people in three states, with households randomly allocated to receive one of two immunochemical FOBT kits. The Bowel Cancer Screening Pilot Implementation Committee commissioned a range of qualitative and quantitative studies, including an unpublished literature review and cost-effectiveness analysis, and concluded that an FOBT screening program would be feasible, acceptable and cost-effective in the Australian setting.<sup>5</sup> The final report on the pilot program included a proposed framework for implementing a national program with biennial screening using an immunochemical FOBT for the initial target age group of 55–74-year-olds and a review of the age range once the program was fully operational.<sup>5</sup>

## ABSTRACT

- Bowel cancer kills over 4000 Australians each year.
- From the late 1980s to October 2005, research evidence guided the development of bowel cancer screening policy proposals, but political, financial and institutional constraints restricted implementation options.
- Since 2006, the Australian Government has provided a limited bowel cancer screening program, based on what the government deems it can afford, rather than on evidence of what is required to implement a successful population-based screening program.
- Even a partial program can be implemented in an evidence-based way, and failure to do so threatens to undermine the potential public health gains of a national bowel cancer screening program.
- To realise the expected public health gains from a national bowel cancer screening program, bowel cancer screening policy should return to its evidence-based beginnings, starting with an analysis of Australian age-specific cost-effectiveness data.

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## Timing of the evidence: the 2004 federal election

The methodical approach to examining evidence on bowel cancer screening was out of kilter with the 3-year electoral cycle in Australia and the more practical demands on policymakers. Despite the expert review of evidence by the Bowel Cancer Screening Pilot Implementation Committee, the final report was not published until October 2005 (16 months after the pilot program was completed) and so was not publicly available in time to inform policy proposals on this issue. Advisers of then Health Minister Tony Abbott had already identified bowel cancer screening as one of a suite of cancer-related options for inclusion in their 2004 election campaign document *Strengthening cancer care*,<sup>17</sup> published before the election held on 9 October. The pressure of an upcoming federal election left little time for considered reflection of the evidence by the politicians responsible for making the decisions, and the government's campaign promises reflected this lack of evidence.

In *Strengthening cancer care*, the Howard government pledged to “work to phase in a national, coordinated, population-based screening programme based on the pilots, with the ultimate aim that, by 2008, every Australian aged over 55 and Indigenous Australians aged over 45 will be screened for bowel cancer at least every two years”.<sup>17</sup> This election commitment indicates that there was sufficient political will to fund a national program of bowel cancer screening, but it also reflects the lack of understanding of screening issues by those making the commitment. For example, it set no upper age limit on those to be screened, advocated an earlier starting age for Indigenous Australians, unrealistically assumed

## 1 Methods used to analyse bowel cancer screening policy development and implementation in Australia

### Interviews

Semi-structured interviews with 34 key informants were conducted between August 2007 and August 2009. Interviewees included representatives from cancer organisations, academics, clinicians, former and current federal bureaucrats, industry lobbyists, political advisers and state bureaucrats. Although this article is based primarily on analysis of published documents, interviewees were helpful in identifying relevant published documents, and providing copies of background correspondence as well as unpublished and out-of-print materials, which enabled a thorough historical analysis.

### Document analysis

All relevant publicly available documents on bowel cancer screening in Australia were reviewed, beginning with the two major government reviews: the Australian Health Technology Advisory Committee report, published in 1997,<sup>4</sup> and the final evaluation report of the Bowel Cancer Screening Pilot Program, published in October 2005.<sup>5</sup> Subsequent searching was an iterative process, following up references from these initial reports and subsequent publications until all available relevant documents had been reviewed. These included published reports from government committees, reports commissioned by government committees, published bowel cancer guidelines, information on government and cancer organisation websites, consumer information produced by the government, press releases, election campaign documents, papers from workshops on bowel cancer screening, federal government budget papers and publications of relevant research evidence, such as randomised controlled trials of faecal occult blood testing and cost-effectiveness analyses.

### Ethics approval

Ethics approval for this project was granted by the Human Research Ethics Committee of the University of Sydney. ◆

that a full roll-out was possible within a short time frame, and proposed a budget of only \$25.5 million over 4 years<sup>17</sup> — a small fraction of the likely estimated cost,<sup>17</sup> given the Rudd government's subsequent allocation of \$29 million per year for just three age groups.<sup>18</sup>

Abbott's policy advisers were not the only ones to get the figures so drastically wrong. Once a federal election has been called in Australia, a set of caretaker conventions limits the access that political parties have to the Australian Public Service.<sup>19</sup> However, both the Prime Minister and the Leader of the Opposition have the right, under the *Charter of Budget Honesty Act 1998* (Cwlth), to request costings of publicly announced election commitments. The Department of Finance and Administration, at the request of the then Prime Minister, costed the entire *Strengthening cancer care* package at \$130.1 million over 4 years, with \$34.5 million allocated to "cancer prevention (bowel cancer, smoking and skin cancer)" over 3 years — again a major underestimate of probable costs.<sup>20</sup> Ironically, costings for the proposed national bowel cancer screening program had already been prepared by M-TAG as part of the pilot process. Although this report — *Cost-effectiveness evaluation of a national bowel cancer screening program* — was not published, bureaucrats working in the Department of Health and Ageing would have known about the costings, and the Secretary to the Department of Finance and Administration would have been within their rights to request the information. Yet, there appears to have been no sharing of these costings between departments.

All new major federal policy proposals are vetted by the Expenditure Review Committee, a subcommittee of Cabinet, which includes senior representatives from Treasury, the Department of Finance and Administration and the Department of the Prime Minister and Cabinet. Despite 2004 being a time of economic surplus, once the inaccurate Department of Finance and Administration costings had been approved by the Expenditure Review Committee, and the rest of the budget had been allocated to other programs, the institutional constraints of this system made subsequent budgetary allocations of the magnitude required virtually impossible. The opportunity for a fully funded national bowel cancer screening program, as outlined in the election promises, had passed.

## Implementing a national program: deviating from the evidence

In the May 2006 federal budget, \$35.6 million over 3 years was allocated to fund the first phase of the National Bowel Cancer Screening Program.<sup>16</sup> This was around \$10 million more than the figure costed in the election campaign document, but fell far short of the real costs of a full program and was a major constraint on program implementation options. For example, there was no federal funding for the states to cover the costs of follow-up colonoscopies for those with positive FOBTs performed in the public sector, so additional colonoscopies were to be incorporated into the "usual care" model and the number of participants who could be screened was limited. From August 2006 to June 2008, the Howard government offered screening to those turning 55 and 65 years of age and to those who were invited to participate in the pilot program but declined, and offered rescreening to those who were screened in the pilot.<sup>21</sup>

Official justification for the choice of these age groups was, and continues to be, based on the need to manage the capacity of health services given the expected increased demand for colonoscopy and treatment services.<sup>21,22</sup> Although this is a valid argument for a staged roll-out, it does not justify the choice of these two particular age cohorts, which appears to have been based primarily on cost — we were unable to find any published cost-effectiveness analysis data on screening at particular ages, rather than age ranges. Existing international evidence and practice suggests that screening people older than 60 years is likely to be the most cost-effective strategy, as more cancers and precancerous lesions would be detected in an older population, and 60-year-old men have been shown to have much higher cumulative 10-year mortality benefits than men aged 40 or 50 years.<sup>2</sup> According to recent findings from the United Kingdom, 61% of bowel cancers occur in those aged 70 years or over.<sup>23</sup> The English program screens those between 60 and 69 years of age, and plans have been made to extend this age range to 75 by 2010. A comparison of Australian, English and other national FOBT programs is shown in Box 3. Economic modelling of a potential bowel cancer screening program in Australia, published in 2004, showed that extending the age range for screening upwards to the 75-years-and-older age group was likely to be cost-effective, but extending it downwards to the 50–54-year age group was significantly less likely to be cost-effective.<sup>29</sup> However, no-one over 65 years is included in the Australian national program, and this mismatch between the evidence and choice of ages was compounded by the Rudd government's announcement in the May 2008 budget of \$87

## 2 Development of bowel cancer screening policy proposals in Australia, late 1980s to 2005

Event	Comment
<b>Making a case to consider to the evidence</b>	
Late 1980s: Growing interest among Australian clinicians, particularly gastroenterologists, in bowel cancer screening using FOBTs, because of its potential to save lives and reduce morbidity	Based on clinicians' own research and progress reports from international RCTs
1990: World Congresses of Gastroenterology held in Sydney, with a major symposium on bowel cancer screening	Working party report published in 1991 <sup>6</sup>
1993: Results of Minnesota Colon Cancer Control Study published; <sup>7</sup> showed a 33% relative risk reduction in bowel cancer mortality from annual FOBT screening, but only 6% from biennial screening	This was the first of three international RCTs with published mortality outcomes
November 1994: Revised Australian bowel cancer screening guidelines published by Gastroenterological Society of Australia and Australian Cancer Society (now Cancer Council Australia) <sup>8</sup>	Stopped short of recommending population-based FOBT screening, but advocated a pilot study
Early 1995: Australian Cancer Network organised a series of consensus meetings for clinicians in Sydney	Most clinicians supported an investigation into the potential of FOBT screening
April 1995: Australian Cancer Network deputation met with Hal Swerissen, adviser to then Health Minister Carmen Lawrence	Resulted in an agreement to examine the possibility of FOBT screening
<b>Examining the evidence</b>	
July 1995: Working Party on Colorectal Cancer Screening, a subcommittee of the AHTAC, was established to specifically review evidence on the benefits, risks and costs of bowel cancer screening	Took a rigorous and systematic approach to reviewing evidence, referring to the NHMRC's levels of evidence <sup>9</sup> and the WHO's 10 principles for screening programs <sup>10</sup>
April 1996: A cost-effectiveness analysis <sup>11</sup> showed that, compared with breast and cervical cancer screening, bowel cancer screening was similarly cost-effective	A need for pilot projects to assess whether benefits of bowel cancer screening outweighed harms and costs was noted
November 1996: Results of biennial FOBT screening from two other RCTs published: one reported a relative mortality risk reduction of 18% (Funen, Denmark), <sup>12</sup> and the other reported a 15% reduction (Nottingham, United Kingdom) <sup>13</sup>	Results of both trials published in the same edition of <i>The Lancet</i>
December 1997: Final report of AHTAC's Working Party on Colorectal Cancer Screening published <sup>4</sup>	Recommended establishing pilot studies using FOBT on individuals who are at average risk and aged over 50 years
February 1998: Meta-analysis of four RCTs showed 16% relative mortality risk reduction from biennial FOBT screening, and 23% when adjusted for attendance <sup>14</sup>	Included unpublished mortality data from RCT in Gothenburg, Sweden
March 1999: Data from 18-year follow-up of Minnesota Colon Cancer Control Study published; showed 21% relative mortality risk reduction from biennial FOBT screening, and marked reduction in incidence of Dukes' stage D cancers <sup>3</sup>	All three RCTs with published mortality data now had similar estimates of relative mortality risk reduction, and the incidence reduction that had been presumed was shown
1999: NHMRC released revised clinical practice guidelines for prevention, early detection and management of bowel cancer <sup>15</sup>	Recommended at least biennial, but preferably annual, FOBT screening for individuals over 50 years of age
<b>Testing the evidence in the local context</b>	
May 2000: Budget approval for a bowel cancer screening pilot program was announced, with \$7.4 million allocated over 4 years; 63% of this budget was spent on establishing the Bowel Cancer Screening Pilot Register <sup>5</sup>	A further \$7.8 million was allocated from the 2004–05 budget to make up the shortfall in funding for the pilot program <sup>16</sup>
2001: DoHA established the Bowel Cancer Screening Pilot Implementation Committee to advise on the design and implementation of the pilot program (the committee was divided into four main task groups, to specifically advise on policy, quality, communication and education, and monitoring and evaluation issues); terms of reference were to determine whether bowel cancer screening was acceptable, feasible and cost-effective in the Australian setting <sup>5</sup>	Decisions about age groups, the screening interval, the type of FOBT, use of a central registry run through the Health Insurance Commission (now Medicare Australia), and choice of pilot sites were informed by consultation with members of the task groups, <sup>5</sup> but ultimately made by DoHA
2001 to 2004: In 2001, the Monitoring and Evaluation Task Group developed a framework of 10 feasibility, acceptability and cost-effectiveness objectives; <sup>5</sup> DoHA then commissioned several projects and consultancies to assess these criteria	Findings of some consultancies, such as the M-TAG cost-effectiveness analysis, were not made publicly available
October 2005: Final report of the pilot program published; <sup>5</sup> it concluded that overall bowel cancer screening in Australia was acceptable, feasible and cost-effective, and proposed an implementation framework involving biennial screening with immunochemical FOBT for individuals aged 55–74 years	Provided a proposed framework for a national bowel cancer screening program, rather than recommendations to the government

AHTAC = Australian Health Technology Advisory Committee. DoHA = Department of Health and Ageing. FOBT = faecal occult blood test. NHMRC = National Health and Medical Research Council. RCT = randomised controlled trial. WHO = World Health Organization.

### 3 Comparison of national faecal occult blood test (FOBT) programs

Country	Type of FOBT	Age (years)	Frequency	Follow-up of positive FOBT result	Roll-out status
Australia	Immunochemical	50, 55, 65	One-off	Colonoscopy	Expected to be completed by June 2010 <sup>24</sup>
England <sup>25</sup>	Guaiaac (no dietary restriction)	60–69	Biennial	If 5 or 6 out of 6 windows are positive, a nurse clinic appointment is made to discuss colonoscopy; if result is unclear (1–4 windows positive), guaiaac FOBT is repeated. If second result is unclear or abnormal, a nurse clinic appointment is made to discuss colonoscopy; if second result is normal, guaiaac FOBT is repeated again to confirm the result <sup>26</sup>	99.4% complete; <sup>27</sup> plans have been made to extend the target population to include 70–75-year-olds from 2010 <sup>23</sup> and pilots of the extended age range are underway <sup>27</sup>
France <sup>25</sup>	Guaiaac	50–74	Biennial	Colonoscopy	Eighty of 99 districts covered by end of 2007; full coverage was scheduled for late 2008
Israel <sup>25</sup>	Guaiaac	50–74	Annual	Colonoscopy	Not stated (target population, 1.1 million)
Japan <sup>25</sup>	Immunochemical preferred, but guaiaac may also be used	40 +	Annual	Not stated	Not stated (target population, 35 million people with national insurance)
South Korea <sup>25</sup>	Immunochemical or HemoQuant	50 +	Annual	Double-contrast barium enema and/or colonoscopy	Not stated (target population, 4.4 million)
Scotland <sup>25</sup>	Guaiaac (no dietary restriction)	50–74	Biennial	As per England	Completed 2010 <sup>28</sup>

million over 3 years to continue the existing program and extend screening to 50-year-olds from 1 July 2008.<sup>18</sup>

Commencing bowel cancer screening at age 50 years is in line with the most recent National Health and Medical Research Council (NHMRC)-approved guidelines,<sup>30</sup> and would be a welcome policy decision if resources were less scarce and could allow for biennial screening (as the guidelines stipulate). However, Health Minister Nicola Roxon has since made it clear that there will be no biennial screening under the second phase of the national program, which runs until June 2011.<sup>31</sup> This means that 50-year-olds will be rescreened in 5 years, 55-year-olds will be rescreened in 10 years, and 65-year-olds will not be rescreened at all. In February 2009, perhaps in recognition of the lack of biennial screening, the government placed an FOBT kit on the Medicare Benefits Schedule, so some reimbursement from the government is now possible.<sup>32</sup> Results from kits used by individuals outside the national program will not be incorporated into the National Bowel Cancer Screening Program Register, and so will not contribute to ongoing data collection on how many people have been screened and the outcomes.

The latest report on the National Bowel Cancer Screening Program, which provides information for 2008, revealed a drop in overall participation rates to an estimated 39.3%, from the 45.4% achieved in the pilot program.<sup>33</sup> Although some of this drop might be explained by the late inclusion, from July 2008, of 50-year-olds — who are less likely to participate<sup>33</sup> (another reason to possibly focus on an older age range) — it also reflects continuing problems with obtaining follow-up data, an issue that is not confined to FOBT results. Although 64.5% of those with a positive FOBT result were recorded as having colonoscopic follow-up, this figure may underestimate the true rate because of under-reporting by clinicians and the use of positive FOBT results as a substitute denominator for colonoscopy referrals (a consequence of the low

return rate of colonoscopy report forms).<sup>33</sup> In May 2009, the roll-out of the program had to be temporarily suspended following a modification by the manufacturers to the buffer solution used in the FOBT kit, which increased the likelihood of a false-negative result. Routine evaluation of test results showed a noticeable decline in the rate of positive results from the modified kits that were distributed between 1 December 2008 and 8 May 2009. The Department of Health and Ageing estimated that around 600 000 replacement kits had to be issued, including 108 000 kits sent to people for whom negative results were returned during this period and who needed to repeat the FOBT.<sup>34</sup> As a result, the roll-out of the program has been significantly delayed.

#### Implications of deviating from the evidence

It may seem a reasonable policy option to start a public health program by doing what you can afford first and hoping to expand it later. A staged roll-out is a sensible approach, provided the selection of age cohorts and the frequency of screening are based on evidence. Given that the final report of the Australian pilot program concluded that FOBT screening was feasible, acceptable and cost-effective, based on biennial screening of 50–74-year-olds,<sup>5</sup> one must question whether the current program — one-off screening of individuals aged 50, 55 and 65 years — is justifiable. It seems likely to result in fewer benefits compared with other more evidence-based age and interval options that are possible within the budgetary constraints (such as the English model).

A related concern is that if the benefits side of the equation is reduced, then the benefits may no longer outweigh the downsides of bowel cancer screening, which include anxiety due to false positives, inappropriate reassurance due to false negatives, morbidity and the remote possibility of mortality due to follow-up colonoscopies. The absolute mortality risk reduction figures for bowel cancer screening are modest — for example, it is estimated

that biennial screening over a 10-year period saves one life for every 1000 men aged 55–74 years who are at average risk, and one life for every 1000 women aged 65–74 years who are at average risk.<sup>35</sup> On the flip side, many more will not benefit and may be harmed.<sup>36,37</sup>

Finally, as there are no published data on the cost-effectiveness of one-off screening of individuals aged 50, 55 and 65 years, we do not know how cost-effective this strategy is. An independent cost-effectiveness analysis by the Cancer Institute NSW,<sup>38</sup> published in August 2008 (around the same time as Roxon's announcement that there would be no biennial screening under the current program), stated that the National Bowel Cancer Screening Program represented value for money for the Australian health care system, based on a model in which people turning 55 or 65 years of age were first invited to participate, and invitations to rescreen were repeated biennially thereafter until 75 years. Other eligibility scenarios, with first invitation at 45 and 50 years of age, were also shown to be cost-effective, provided that screening was offered biennially and over a specified age range.<sup>38</sup>

## Conclusion

Although there is solid RCT evidence that bowel cancer screening can contribute to a reduction in the 80 deaths a week from this disease in Australia, policy decisions about implementation of the Australian program to date have not been based on the full extent of available research evidence, but on selected parts of the evidence. Political, financial and institutional constraints combined to shape and limit the National Bowel Cancer Screening Program. Given these constraints, the most useful basis for making evidence-based decisions about who to screen and how often to screen is age-specific cost-effectiveness analysis of Australian cost data. To our knowledge, no such analysis has been published. Fifteen years on from the government's first involvement in bowel cancer screening, policies concerning age cohorts and screening intervals seem to be based on what the government deems it can afford, and not on firm evidence of what is required for a screening program to obtain worthwhile mortality and morbidity benefits. To realise the expected public health gains from a national bowel cancer screening program, the government needs to return this important public health policy to its evidence-based beginnings. An age-specific cost-effectiveness analysis would be a good start.

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## Competing interests

Glenn Salkeld was a member of the AHTAC Working Party on Colorectal Cancer Screening, the Bowel Cancer Screening Pilot Implementation Committee, the Pilot's Monitoring and Evaluation Task Group and the Pilot's Monitoring and Evaluation Steering Committee. Les Irwig was a member of the Bowel Cancer Screening Pilot Executive Committee, the Pilot's Policy Task Group and the Pilot's Monitoring and Evaluation Steering Committee.

## Author details

Kathy L Flitcroft, BBS, MA(Govt), GradCertHealthPolicy, Research Fellow (Health Policy) and NHMRC Scholar, Screening and Test Evaluation Program

Glenn P Salkeld, GDipHealthEconomics, MPH, PhD, Professor (Health Economics), Screening and Test Evaluation Program  
 James A Gillespie, PhD, Senior Lecturer (Health Policy), Menzies Centre for Health Policy  
 Lyndal J Trevena, MBBS(Hons), MPhilPH, PhD, Associate Professor (General Practice)  
 Les M Irwig, MB BCh, PhD, FPPHM, Professor (Epidemiology), Screening and Test Evaluation Program  
 Sydney School of Public Health, University of Sydney, Sydney, NSW.  
 Correspondence: [kathy.flitcroft@sydney.edu.au](mailto:kathy.flitcroft@sydney.edu.au)

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