

## Introduction

The Australian Government announced funding for an Australian bowel cancer screening Pilot in the 2000-01 Budget. The Pilot contained a long period of careful design work informed by medical and other experts, with screening offered to eligible people in three Pilot sites from November 2002 to June 2004. This report provides an overall evaluation of the Pilot. This chapter provides background information on the Pilot and descriptions of how it was established and how it operated. It also describes the approach taken to the overall evaluation. This information sets the context for the evaluation discussion and findings presented in the remaining chapters of this report.

### 1.1 Screening for bowel cancer

Screening is the performance of tests on apparently well people in order to detect a medical condition at an earlier stage than would otherwise be the case. Screening is only beneficial if treatment of the screen detected condition results in a better long-term outcome (in terms of reduced morbidity or mortality) than treatment of the same condition presenting clinically (AHMAC 1990). Australia uses criteria which have been adopted by the World Health Organizations to determine whether a new population screening program should be introduced. These are:

- the condition sought should be an important health problem;
- the natural history of the disease should be well understood;
- there should be a recognisable early stage;
- treatment of the disease at an early stage should be of more benefit than treatment started at a later stage;
- there should be a suitable test;
- the test should be acceptable to the population;
- there should be adequate facilities for the diagnosis and treatment of abnormalities detected;
- for diseases of insidious onset, screening should be repeated at intervals determined by the natural history of the disease;
- the chance of physical or psychological harm to those screened should be less than the chance of benefit; and
- the cost of a screening program should be balanced against the benefit it provides (Wilson and Jungner 1968).

## **Why screen for bowel cancer?**

Bowel cancer is a malignant tumour that starts in the bowel and is confined locally for a relatively long period before spreading through the bowel wall and into other parts of the body. Australia has one of the highest rates of bowel cancer in the world, which imposes a significant burden of disease on the Australian community. It is the most common cancer affecting both men and women and the second most common cause of cancer-related death after lung cancer (AIHW 2003). Based on current trends, one in 21 Australians will develop bowel cancer in their lifetime. Currently around 91 people die from the disease each week. In 2000, 12,405 new cases were diagnosed, and 4,725 people died from the disease. Annual costs of treating the disease are estimated at \$235 million (AIHW 2005).

The risk of bowel cancer increases from the age of 40 years onwards, rising sharply from the age of 50 (AIHW 2003). One particular feature of bowel cancer is that few, if any, symptoms are exhibited until the cancer has reached a relatively advanced stage. However, death can be prevented and survival rates can significantly improve in cases where the disease is treated early. Consequently, screening for bowel cancer before symptoms develop has the potential to reduce morbidity and mortality significantly.

## **How to screen for bowel cancer?**

The presence of blood in faeces may indicate the presence of abnormalities of the bowel, including pre-cancerous conditions or bowel cancer. The blood may be in microscopic amounts – often referred to as ‘occult’ blood. Faecal occult blood tests (FOBTs) are designed to detect the presence of blood in faeces. Where an FOBT is positive, that is, it shows the presence of blood, this indicates further diagnostic follow-up tests are necessary. Evidence from clinical trials has shown that regular screening using faecal occult blood testing can reduce mortality from bowel cancer by 15-33% (Hardcastle 1996, Kronborg 1996, Mandel 1993).

In 1997, the then Australian Health Technology Advisory Committee (AHTAC) conducted a systematic review of the evidence for screening for bowel cancer, culminating in a report that concluded that the efficacy for screening for bowel cancer with faecal occult blood testing had been demonstrated. However, the AHTAC report noted that Pilot studies were required to identify the best method of screening Australian populations, particularly with regard to recruitment strategies, compliance, quality assurance, assessment and adverse effects (AHTAC 1997).

Despite the recommendations of AHTAC, debate amongst international and Australian health professionals continued around the most appropriate and effective method of screening for bowel cancer. In particular, there was debate about the role of flexible sigmoidoscopy and colonoscopy as screening tests. These screening methods are still undergoing evaluation, however, results of randomised controlled trials using these methods are not yet available.

During 1998 and early 1999, professional opinion about the use of faecal occult blood testing to screen for bowel cancer began to coalesce. This was further strengthened by the release of the National Health and Medical Research Council Guidelines (‘NHMRC Guidelines’) on the prevention, early detection and management of colorectal cancer in 1999 (NHMRC 1999).

This was followed in late 1999 by a proposal from the National Cancer Control Initiative (NCCI) to conduct Pilot feasibility studies for bowel cancer in Australian subjects aged over 50 years.

## **1.2 An overview of the Bowel Cancer Screening Pilot**

### **Establishing the Pilot**

In the 2000-01 Budget the Australian Government announced an investment of \$7.2 million over four years to improve knowledge about the early detection of bowel cancer through a Bowel Cancer Screening Pilot Program (the Pilot) using faecal occult blood tests as the screening test. The Pilot was *not* a clinical trial of the effectiveness of faecal occult blood testing in reducing mortality and morbidity from bowel cancer. International randomised controlled trials have already demonstrated that screening using faecal occult blood testing can reduce mortality from bowel cancer by between 15%- 33%. Rather, the Pilot sought to assess the acceptability, feasibility and cost-effectiveness of bowel cancer screening, aiming to inform consideration of whether, and how, to introduce a national, organised population based bowel cancer screening program using faecal occult blood testing in Australia.

In April 2001, a Bowel Cancer Screening Pilot Implementation Committee (the Implementation Committee) was established to provide advice to the Department on the design and implementation of the Pilot. The Implementation Committee and its Task Groups met from April 2001 and developed<sup>1</sup>:

- an evidence based screening pathway;
- criteria to assist with the selection of Pilot sites;
- key policy parameters, including target population age range, screening interval, and type of FOBT;
- central, national screening register arrangements to manage the invitation and recall of the target population for screening, and monitoring activities;
- communication and education materials for encouraging the target population and health professionals to participate in the Pilot;
- quality protocols to operate across the screening pathway; and
- a monitoring and evaluation framework for the Pilot.

The Pilot aimed to assess the feasibility, acceptability and cost effectiveness of bowel cancer screening using faecal occult blood testing, in both urban and rural settings. The Monitoring and Evaluation Task Group (METG), a committee of experts that reported to the Implementation Committee, developed a monitoring and evaluation framework against ten Pilot objectives to support this assessment.

**Chapter 2 discusses the findings of the Pilot against these objectives.**

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<sup>1</sup> Membership of the Implementation Committee and its Task Groups is given in Appendix B.

## Key Pilot design features

The Implementation Committee proposed a number of key Pilot design principles, which were endorsed by the then Ministers for Health and Ageing, the Hon Michael Wooldridge MP and the Hon Senator Kay Patterson. These were:

- (1) **An age range of 55-74.** The risk of developing bowel cancer rises sharply and progressively from age 50. NHMRC Guidelines (NHMRC 1999) recommend screening from age 50 years and a previous AHTAC report also recommended that Pilot studies should investigate the effects of varying the upper age limit for screening. The Implementation Committee considered an expert epidemiological assessment of options for an age range for the Pilot with a view to maximise the power of the Pilot and the capacity to use Pilot outcomes to inform the development of a national program within available resources. On the basis of this assessment, the Implementation Committee recommended a Pilot age range of 55-74 years on the basis that this would maximise detection of cancer and its precursors.
- (2) **A biennial screening interval.** NHMRC guidelines recommend that the minimum effective program is screening at least every second year, but preferably annually. The screening interval for the Pilot was nominally<sup>2</sup> biennial (every two years) because:
  - there was limited evidence at the time of Pilot establishment, with the results of only one randomised controlled trial that compared screening outcomes of an annual or biennial screening interval; and
  - annual screening was not seen to be significantly more effective than biennial screening, and biennial screening was seen as more cost effective.
- (3) **The preferred use of immunochemical FOBT.<sup>3</sup>** Immunochemical FOBTs detect human haemoglobin and/or its degradation products. The Implementation Committee considered that immunochemical FOBTs had more advantages for the Australian population than the more commonly used guaiac FOBTs. These included:
  - the suitability of immunochemical FOBTs with a biennial screening interval due to their higher sensitivity;
  - that they do not require dietary or medication restrictions, as for guaiac tests, which could affect the participation rate negatively;
  - the potential for automated analysis of immunochemical FOBTs, which could reduce the training requirements for pathology laboratory staff, increase the volume of tests which could be analysed in a timely fashion and reduce the likelihood of human reading errors in analysis; and
  - the potential to alter the test positivity rate.

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<sup>2</sup> In practice, at the time of preparing the overall evaluation, there had only been one screening cycle for each participant.

<sup>3</sup> The tender process for the Pilot did not specifically exclude guaiac tests but noted a preference for immunochemical tests.

- (4) **Using Health Insurance Commission (HIC) to develop the Bowel Cancer Screening Pilot Register.** Experience with existing population screening programs for other conditions (cervical and breast cancer) had highlighted the difficulties in transferring data to other State and Territory registers when people move, particularly between States and Territories, and in ensuring nationally consistent data collection and definitions. The Implementation Committee advised that there would be benefits in developing a national population screening register. Furthermore, other program arrangements for identifying the target population, generally via electoral roll, have significant limitations. Departmental analysis identified that Medicare enrolment files were likely to provide the best method for identifying the target population for the purposes of inviting them to screening. A register could also be adapted to meet the needs of future population screening programs if required.

### 1.3 Description of the Pilot design

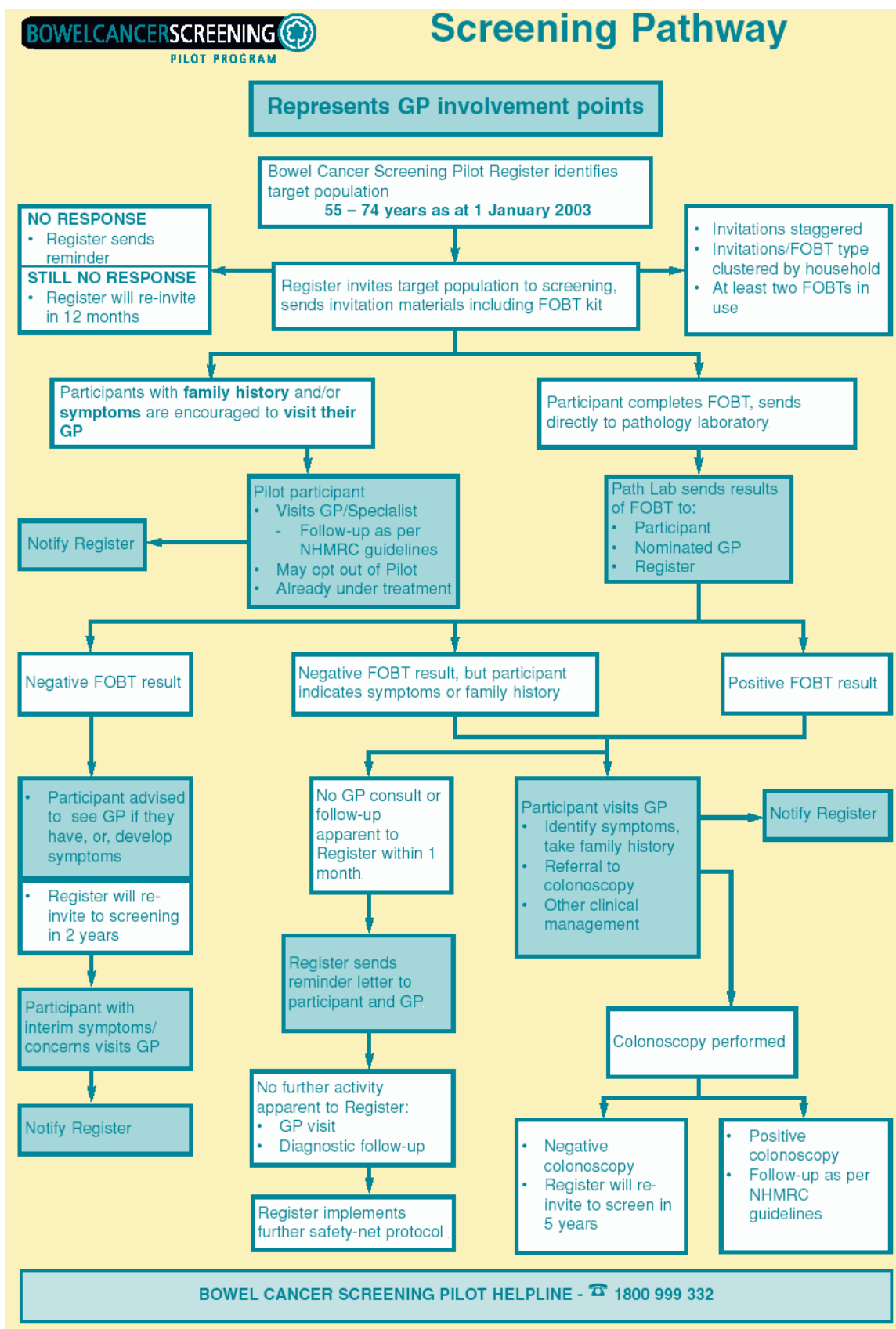
The operations of the Pilot encompassed the following key components:

- direct mail of invitations to the target population to participate in screening, including information material and a FOBT for each invitee;
- participants using FOBT and forwarding the completed tests to a pathology laboratory;
- pathology analysis of completed FOBTs and the notification of results;
- GP referral of participants with positive screening tests to further diagnostic investigation;
- diagnostic investigation by colonoscopy unless otherwise clinically indicated;
- management and treatment of disease where it is identified, noting that the screening pathway ends at the point of definitive diagnosis; and
- recall of the target population to re-screening, as appropriate.

The proposed interval for FOBT screening was biennial, however only one round of screening took place during the Pilot.

The major components of the screening pathway are shown in Figure 1.1.

Figure 1.1 Pilot Screening Pathway



## **The Bowel Cancer Screening Register**

A key feature of the Pilot was the development of a Bowel Cancer Screening Pilot Register (the Register), maintained by the Health Insurance Commission (HIC).<sup>4</sup> The Register performed two key functions:

- a service function to facilitate participation by eligible people in screening, follow-up and re-screening at appropriate intervals; and
- an epidemiological and monitoring function to assist in data collection, monitoring and evaluation of Pilot outcomes.

The service function of the Register included identifying and inviting members of the target population to participate in the Pilot. The Register began sending invitations to Pilot sites in November 2002 and ceased invitations in June 2004, although follow-up of participants continued after this time. The Australian Institute of Health and Welfare (AIHW) undertook regular monitoring based on analysis of Register data.

**Chapter 3 discusses the operation of the Register.**

### **Pilot target population**

The criteria for the selection of Pilot sites were developed by the Department in consultation with the Implementation Committee. It was agreed that the preferred sites should:

- ‘include a mixture of men and women, urban and rural residents, and diverse socioeconomic and ethnic groups to reflect the Australian screening target population;
- be organised around present, mainstream structural units of health service delivery;
- have the cooperation and involvement of the GPs providing services to the screening population;
- have the capacity to be involved in a Pilot screening program; a high proportion of GPs working in practices which are Practice Incentives Program registered; and demonstrated capacity to support and train GPs in population health activities;
- have the co-operation and involvement of the relevant specialists; and
- have commitment from all participating health service providers or their representatives to adhere to nationally agreed Pilot protocols and processes, including quality standards, quality assurance processes and necessary data collection and monitoring.’ (DoHA 2003).

Three sites from around Australia were selected for the Pilot with a defined number of postcodes for each site. The Pilot sites, announced in October 2001, were based around four divisions of general practice, located in:

- Mackay (the Mackay Division of General Practice);
- Adelaide (part of the Adelaide Southern and Western Divisions of General Practice); and
- Melbourne (part of the North East Valley Division of General Practice).<sup>5</sup>

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<sup>4</sup> The Register was established after a determination by the Minister for Health and Ageing on 12 September 2002 allowing HIC to perform additional functions required to administer the Register.

<sup>5</sup> Mackay Postcodes: 4740, 4741, 4750 and 4751; Melbourne: 3070, 3071, 3078, 3079, 3081, 3083, 3084, 3085, 3087 and 3088; Adelaide: 5011, 5012, 5022, 5023, 5024, 5040, 5044, 5045 and 5048.

The Pilot target population was men and women aged 55 to 74 years within selected postcodes at these three sites. Medicare and Department of Veteran’s Affairs (DVA) enrolment data was used to identify the target group within the sites. Table 1.1 shows the number of eligible people invited to participate in each site over the duration of the Pilot.

**Table 1.1: Number of eligible invited people by Pilot Site**

Pilot Site	Rurality	Total Invited Eligible Population
Mackay	Rural	11,045
Adelaide	Urban	18,431
Melbourne	Urban	27,431
<b>Total Pilot</b>	<b>NA</b>	<b>56,907</b>

Source: AIHW (2004)

Invitations to participate in the Pilot were sent alphabetically and staggered over 15 months in the Mackay and Melbourne sites, and over 12 months in the Adelaide site, so that demand on service providers was spread evenly over the period that the Pilot operated. Invitations were first sent to Mackay participants in November 2002, Adelaide participants in February 2003 and Melbourne participants in March 2003. The invitation of new people was completed in June 2004, although people who were invited prior to that date continued to be followed up using standard Pilot protocols.

The Register sent an invitation pack, including an FOBT, to people in the target age group by mail. People were randomly allocated one of the two FOBTs. People living in the same households were sent the same brand of FOBT. The FOBTs were self-administered tests, completed in the person’s home then mailed to a specified pathology laboratory for analysis. People who required help completing their FOBT or had difficulty understanding the test instructions could contact a dedicated telephone helpline for assistance. People who completed the test and posted it to a pathology laboratory were then participants in the Pilot.

**Chapter 4 discusses the impact of the Pilot on the target population.**

### Screening test

The Pilot used immunochemical FOBTs to identify participants that required further investigation for the presence of bowel cancers or pre-cancerous polyps or adenomas by virtue of detection of occult (hidden) blood in their faeces. An FOBT detects microscopic amounts of blood which may be released from bowel cancers or their precursors into the bowel motion. The Pilot used two immunochemical FOBTs:

- (1) ***Bayer Detect* produced by Bayer (also known as Magstream HemSp).** For this test, a participant places a biodegradable cellulose sheet above the water in the toilet bowl and passes a bowel motion. The participant then inserts the tip of a collection probe into the stool and passes it along the stool several times. The probe is then inserted into a collection tube. A sample is collected from two separate bowel motions.

- (2) ***!inform (now known as InSure) produced by Enterix.*** This product uses a brush to collect material from the stool which is then pressed onto a test card. A sample is collected from two separate bowel motions.

**Chapter 5 discusses the FOBTs and FOBT pathology processing.**

### **The role of general practitioners and specialists**

Eligible people who were invited to participate in screening were encouraged to visit their GP if they were concerned about symptoms or a family history. GPs were asked to explain the purpose of the Pilot, provide information on bowel cancer and screening and advice on how to complete the FOBT. Pilot participants were asked to nominate the GP to whom their test results were to be sent. The pathology laboratories then sent results to the participant, their nominated GP and the Register within two weeks of receiving the FOBT. Participants who returned a positive FOBT were advised to visit their GP to discuss the result of the FOBT. GPs were responsible for referring participants for investigation after a positive FOBT result. GPs were encouraged to follow their usual specialist referral arrangements/patterns. Two Pilot sites established funding agreements with specialist facilities to provide colonoscopy at no cost to the participant and GPs were informed of these arrangements. GPs were requested to provide specific information on Pilot participants to the Register by returning a *GP Assessment Form*. GPs were paid an information payment by the Register for the return of these forms.

**Chapter 6 discusses the impact of the Pilot on general practitioners.**

The Pilot also required information from colonoscopists and histopathologists, again supported by payments from the Register on receipt of information on participants. Colonoscopists undertook follow-up diagnostic procedures on referral from GPs. They also provided appropriate clinical management of Pilot participants in accordance with the NHMRC guidelines (NHMRC 1999). Colonoscopists and histopathologists were also encouraged to provide information to the Register about procedures and results for Pilot participants.

**Chapter 7 discusses the impact of the Pilot on follow-up colonoscopy services.**

### **Pilot organisation and governance**

The Pilot was administered through the Screening Section of the Department of Health and Ageing (referred to either as ‘the Department’ or ‘DoHA’). The Section was responsible for providing Pilot support services, including:

- secretariat and administrative support;
- policy development and advice to the Minister for Health on Pilot operations; and
- contract/ service agreement negotiation and administration with HIC, Divisions of General Practice, FOBT suppliers and State governments.

In April 2001, the Implementation Committee and supporting Task Groups were established to provide advice to the Department on Pilot policy issues, quality, communication and education, and monitoring and evaluation. The Implementation Committee and its Task Groups comprised experts from a broad range of disciplines including epidemiology, gastroenterology, health economics, statistics, and representatives from relevant medical colleges, peak cancer bodies and consumers.

The Bowel Cancer Screening Pilot Monitoring and Evaluation Steering Committee was established in June 2004 to oversee the evaluation of the Pilot.<sup>6</sup>

Several other organisations/entities were involved in the administration of the Pilot. These comprised:

- State Health Departments in the three States in which Pilot sites operated (South Australia, Queensland and Victoria);
- Divisions of General Practice within each Pilot site; and
- State Cancer Councils.

The three Pilot sites each formed local implementation committees prior to the commencement of the Pilot. These committees typically included representatives from the local Division, State Health Department, the Australian Government Department of Health and Ageing, State Cancer Councils, consumer representatives, universities, GPs and expert advisors.

Another feature of the Pilot was the inclusion of duty of care and ‘safety net’ provisions as they should be applied to a bowel cancer screening program. The safety net provisions for the Pilot were modelled on those of Australia’s National Cervical Screening Program. The underlying philosophy of these provisions is the assurance that either: each woman with a positive Pap smear who appears not to have received necessary management knows that the smear was abnormal, what management is appropriate, and how she could obtain that care; or, that all possible avenues for communication to that effect with a woman with a positive Pap smear have been followed without success.

Ethics approval for the implementation of the Bowel Cancer Screening Pilot was given by the DoHA Ethics Committee and the Department of Veterans’ Affairs Human Research Ethics Committee.

**Chapter 8 discusses the organisation, governance arrangements and quality assurance for the Pilot.**

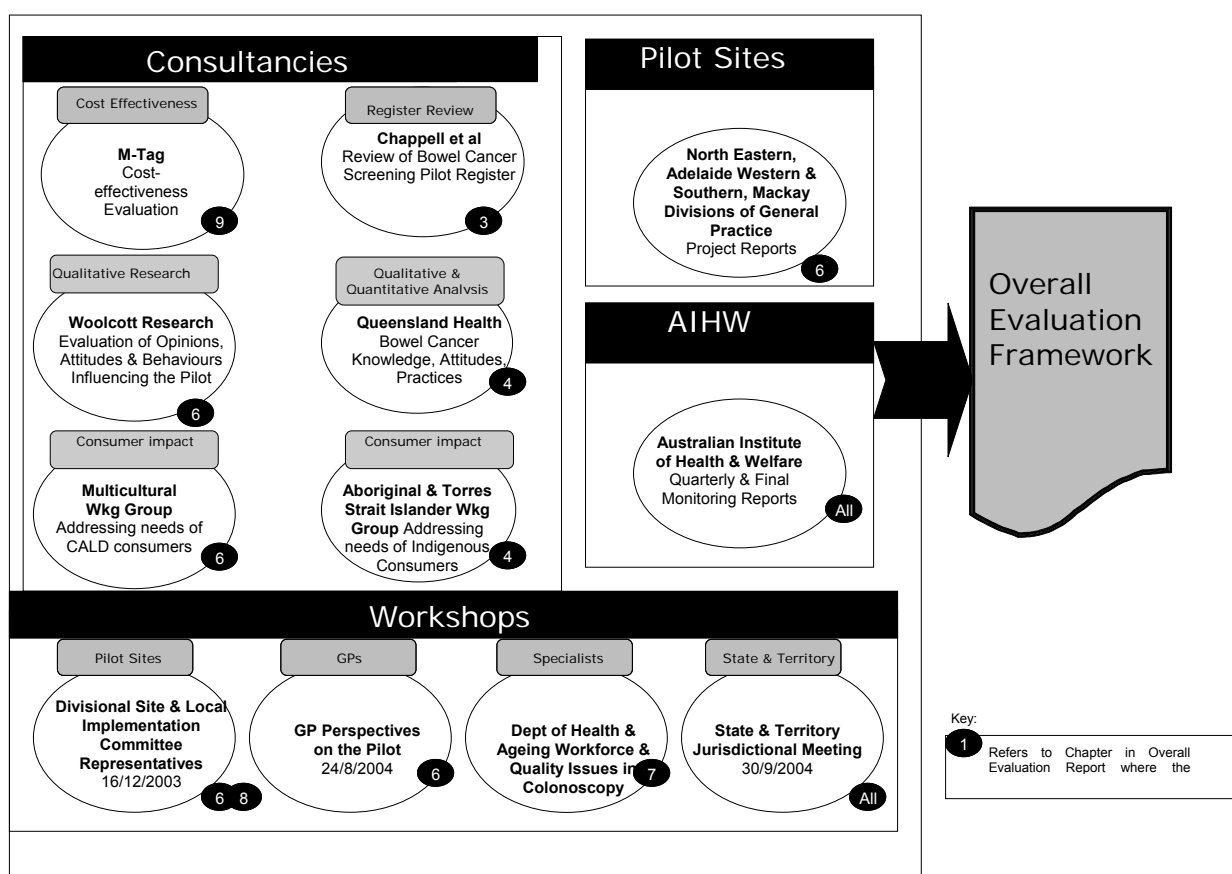
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<sup>6</sup> The membership and terms of reference of the committee are at Appendix B.

## 1.4 Approach to the Pilot evaluation

During the initial Pilot planning phase, the Monitoring and Evaluation Task Group developed a monitoring and evaluation framework that addressed the ten *feasibility*, *acceptability* and *cost effectiveness* objectives. Based on that framework, the Department commissioned a number of projects and consultancies to assist in assessing the feasibility, acceptability and cost-effectiveness of a national program. The data and information from those projects were major inputs into the preparation of this report.<sup>7</sup> Additional detail on these projects is provided at Appendix C. Findings from the evaluation projects were complemented by workshops held with representatives of the Pilot sites, GPs, colonoscopists, and State and Territory health departments. A summary of each of the projects, consultancies and workshops that informed the different components of the overall evaluation is shown in Figure 1.2.

**Figure 1.2: Projects, consultancies and workshops informing the overall evaluation**



<sup>7</sup> A complete list of those contributing projects and their associated documentation is provided at Appendix C.

Refinements to the initial Monitoring and Evaluation Task Group evaluation approach were made in June 2004. This included incorporating evaluation criteria specified by the Department of Finance and Administration for program reviews. A summary of the framework is presented in Figure 1.3. This shows the relationship between the screening pathway, the overall program logic and the key Pilot evaluation areas.

The aim of the overall evaluation report is to bring together information which evaluates the Pilot, to determine whether the Pilot was successful in meeting its objectives and to consider whether there were any gaps in knowledge gained through the Pilot which could usefully be addressed in considering a possible national bowel cancer screening program.

## **1.5 Structure of this report**

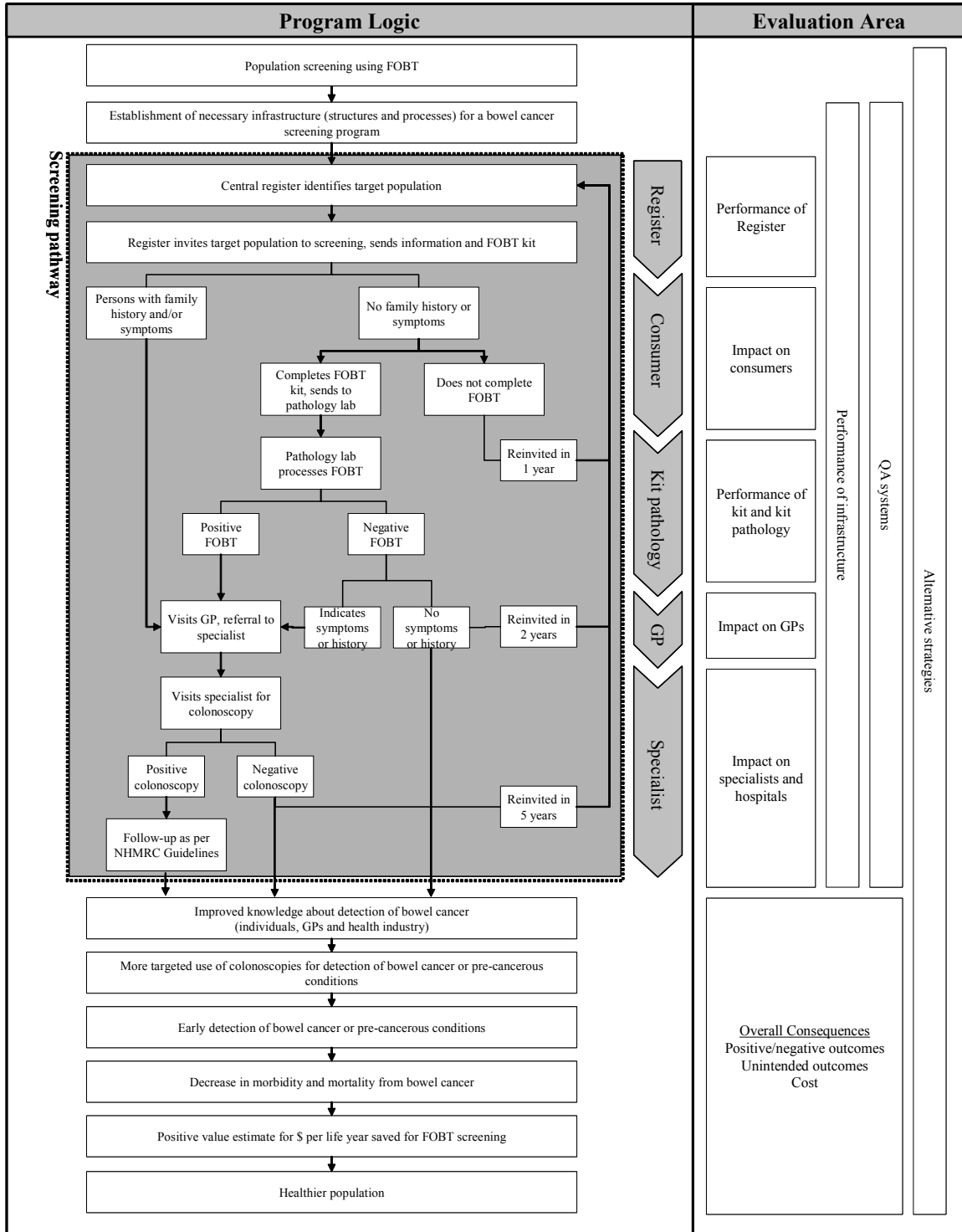
This report is referred to as the overall evaluation because it synthesises all the evaluation activities undertaken during the Pilot and identifies key findings. Based on those findings the report also includes a framework for the implementation and operation of a national program, prepared in consultation with the Bowel Cancer Screening Pilot Monitoring and Evaluation Steering Committee.

The structure of the report is based on the key evaluation areas shown in Figure 1.3. The overall findings are presented in the following chapters:

- Chapter 1 (this chapter) provides background information on the Pilot, a description of its operational structure and the activities undertaken to design and implement screening in the Pilot, and the approach to the overall evaluation;
- Chapter 2 provides a summary assessment of the performance of the Pilot against its original evaluation objectives;
- Chapters 3 to 7 provide a description and evaluation of each component of the Pilot - the Register, the FOBTs and FOBT pathology, and the impact of the Pilot on its target population, GPs involved in the Pilot, and colonoscopy follow-up services;
- Chapter 8 evaluates Pilot organisation and governance and Pilot-wide quality assurance systems;
- Chapter 9 discusses the cost-effectiveness of screening for bowel cancer; and
- Chapter 10 presents a framework to inform a possible national bowel cancer screening program.

Chapters 2 to 9 commence with a summary of key findings and close with a summary of questions and issues raised during the evaluation which require further investigation and analysis to inform a possible national bowel cancer screening program.

**Figure 1.3: Pilot program logic and key evaluation areas<sup>8</sup>**



<sup>8</sup> Note that the Pilot screening pathway illustrated in this diagram has been simplified to highlight the key components of the Pilot.

## Overall evaluation findings

### Key evaluation findings

- The means of inviting eligible people, through direct mail, and the type of FOBTs used were acceptable – the overall participation rate of 45.4% and the analysis of surveys carried out before and after the Pilot and focus group research supported this.
- The additional work for GPs in referring participants with a positive FOBT was not seen to be onerous. GPs were generally positive in their experience of screening and supportive of the FOBT as an effective screening tool.
- There was some pressure on colonoscopy services as a result of the Pilot. These were generally well managed by having an identified nurse coordinator and designated colonoscopy sessions for participants.
- There remained some questions about the impact of large numbers of colonoscopies on current health system structures in the event of a national bowel cancer screening program, particularly with regard to the number of skilled colonoscopists to support follow-up assessment of participants with a positive FOBT.
- Bowel cancer screening was shown to be cost-effective.
- There was significant loss to follow-up with incomplete records for many Pilot participants. For many Pilot participants with a positive FOBT, the register held no record of follow-up colonoscopy. It is not known what proportion of these people had a colonoscopy but their information was not provided to the Register. In addition, there were many cases where the person had a colonoscopy and had a suspected abnormality removed where the Register did not hold confirmation of their diagnosis. That is, no histopathology records were sent to the Register.

### 2.1 Feasibility

**Objective 1:** To pilot processes for providing screening information and support to the target population and service providers to facilitate informed participation in screening.

The Pilot successfully provided information on screening for bowel cancer to the target population and service providers:

- Direct mail was successfully used as the mechanism for distributing the FOBTs. The invitation packages that were mailed to the target population included an FOBT as well as information on bowel cancer and the importance of screening. This included a booklet on bowel cancer and the Pilot, as well as the *Eat Well for Life: Dietary Guidelines for Older Australians* leaflet published by NHMRC. Invitee feedback suggested that there were mixed views on the value of the supporting educational material and the privacy information that was included.

- Key Pilot information was translated into the most commonly spoken languages used in the Pilot sites in the 55-74 age bracket, to take account of culturally and linguistically diverse community groups. The translated materials were part of a broader collection of communication and educational resources used to inform health service providers and other stakeholders about the Pilot, bowel cancer and screening. The Pilot demonstrated the need to keep educational support material and the FOBT instructions simple and concise. It also demonstrated that written material is more effective if supplemented by a public awareness campaign in the local press, radio and TV (including local distribution channels).
- The majority of people in the eligible Pilot population raised no concerns regarding their selection on the basis of Medicare enrolment file information. There were no major privacy concerns raised throughout the Pilot on processes or use of personal information.
- A public telephone helpline (the Pilot Helpline) was established to provide ongoing support and further information during the Pilot. The Pilot Helpline received 11,242 calls (11 November 2002 to 15 October 2004), of which 66% were from Pilot participants, 23% were from the general public and 8% were from GPs. Calls predominately related to opting out of the Pilot (19%), general information (18%) or FOBT results (15%). The Hobart office of the HIC operated a separate helpline to field enquiries on the Register from participants and medical practitioners. Calls were first triaged through the general helpline and transferred to the HIC helpline if required. The HIC helpline received a total of 2,875 calls, primarily from Pilot participants.
- Further information was available on the website established for the Pilot.
- The six-weekly reminder letters had a substantial effect on subsequent participation. There was no significant difference in subsequent participation following the reminder letter with or without the inclusion of an additional FOBT.
- GP information kits were developed and distributed to GPs involved in the Pilot by the divisions of general practice at each Pilot site. Further on-site presentations at GP practices were also undertaken, providing background information on the Pilot and the nature of GP involvement. In general, GP feedback indicated that this information was comprehensive and thorough.
- Similarly, specialist information kits were developed and distributed to specialists involved in the Pilot. There were limited on-site presentations that described the requirements of follow-up colonoscopy services for the Pilot. Specialist feedback indicated that this process provided adequate background information and met their requirements for the Pilot.

**Objective 2:** To compare costs and performance of at least two immunochemical FOBTs in detecting bowel cancers and significant adenomas in the Australian target population in order to determine which test(s) to use in a subsequent national program.

The Pilot successfully collected sufficient data to compare the cost and performance of two types of FOBTs (*Bayer Detect* and *!nform*) and the pathology processing arrangements for each:

- The pathology laboratories received 27,064 completed FOBTs from eligible Pilot participants (12,821 *!nform* and 14,243 *Bayer Detect*), of which 25,688 (95%) were correctly completed.
- The participation rate was significantly higher for people receiving the *Bayer Detect* FOBT (47.2%) than for people receiving the *!nform FOBT* (43.6%). Invitee feedback suggested that the *Bayer Detect* FOBT was viewed as ‘more professional’, however its instructions were seen as complicated, containing a lot of text and difficult to follow (even in English), whereas the *!nform* FOBT was viewed as easier to use, but some participants and non-participants queried its efficacy (because of an apparent perception that the use of a brush to collect a faecal sample may not be effective). Additional reassurance in the instructions was probably required to indicate that use of a brush was effective.
- Of the correctly completed valid FOBTs there was an overall positivity rate of 9.0%. Specifically, 10.5% of the tests completed by men had a positive result, while 7.7% of tests completed by women were positive. Positivity rates increased with age and there were noticeable changes in the positivity rate for the *!nform* FOBTs throughout the Pilot.
- The positive predictive value for suspected cancers or advanced adenomas was 19.2% across both FOBTs. That is, for people who had a positive FOBT and proceeded to colonoscopy there was nearly a one in five chance that an advanced adenoma or suspected cancer would be identified.
- According to the records held in the register, colonoscopies performed on participants with a positive FOBT found 67 suspected cancers (of which 20 were confirmed as cancers), and 176 advanced adenomas.
- There were also 2 suspected cancers, 19 advanced adenomas and 21 small or diminutive adenomas identified for Pilot participants who were not recorded as having a positive FOBT. A proportion of these people are highly likely to have had symptoms or a family history.
- Overall, pathology laboratories stated that the Pilot FOBT processing model worked well,. However it was suggested that greater use of electronic data transfer between the laboratories and HIC would lead to a significant improvement in administrative processing.

**Objective 3:** To monitor the impact of bowel cancer screening on the primary health care sector (GP screening role; education and training; GP knowledge, attitudes and satisfaction with screening; GP financing; workforce issues) and the implications of this for a national program.

General practitioners involved in the Pilot were generally satisfied with the operation of the Pilot, the provision of materials and education, and the screening pathway:

- GPs supported key design features of the Pilot pathway, notably the central invitation and Register arrangements and the role of GPs along the pathway.
- The estimated total number of GP consultations resulting from the Pilot was 4,558, of which 96% occurred after the laboratory had sent participants' FOBT results to participants.
- GPs referred a total of 1,457 participants to colonoscopy or other examination after receipt of a positive FOBT and 994 participants without a positive FOBT. GPs' reactions to the referral for colonoscopy process were mixed, with many stating that the waiting time for follow-up colonoscopy was excessive (median = 30 days).
- GPs were satisfied with the efficacy of using immunochemical FOBTs to screen for bowel cancer. Their knowledge of screening was facilitated through the provision of detailed information kits and support from local divisions of general practice, which had dedicated Pilot program officers to support the implementation process.
- The general view of GPs was that the workload arising from the Pilot on their day-to-day practice was minimal. There appeared to be a broad willingness to comply with the overall processes of the Pilot, although this was not necessarily reflected in the completion and return of *GP Assessment* forms. GPs strongly supported the use of electronic forms for collection and transfer of patient information.

**Objective 4:** To monitor the impact of bowel cancer screening on tertiary services (specialist consultations, referral patterns, waiting times, costs, colonoscopy provision, workforce issues, satisfaction with screening service) and the implications of this for a national program.

In general, colonoscopy providers reported very positive feedback on the operations of the Pilot:

- Follow-up colonoscopy services played a fundamental role in the screening pathway. At the time of data download for the analysis used in this report, there were a 1,833 follow-up colonoscopies recorded in the Register, of which 525 were performed on people who had a negative FOBT, and another 5 on people who had no FOBT result recorded.
- The actual number of cancers and adenomas detected as a result of the Pilot are likely to be significantly higher than is recorded in the Register due to the incomplete return of follow-up colonoscopy and histopathology data to the Register.
- Pilot sites reported a substantial increase in staff workload as a result of the Pilot. These workload changes would need to be effectively managed in a national program. The useful role that nurse coordinators can fulfil as the link between GPs, patients and facilities was highlighted at some colonoscopy services. These services employed a dedicated Pilot nurse coordinator to oversee the management of colonoscopy services for Pilot participants, which was seen as integral to the success of the Pilot at those sites.
- Waiting times over the Pilot were variable. The median waiting time was 30 days.

- Workforce capacity to meet increases in demand for colonoscopy services will be dependent on the FOBT positivity rate. Workforce modelling would be a useful mechanism to further assess potential workforce impacts of a national program, with sensitivity analysis undertaken in relation to FOBT positivity rates.
- Funding based on activity targets and purchase of additional or dedicated services was generally supported by specialists. Observers highlighted the need to establish funding mechanisms to support the provision of quality colonoscopy services, for example, through accreditation of facilities and credentialing of proceduralists.
- Participant feedback reported that the follow-up process for those requiring colonoscopies generally worked well.
- Tracking a participant through the entire screening pathway is integral for monitoring the outcomes of screening. The limited data collected on histopathology highlights the difficulty of this process. Histopathology data may not have been recorded on the Register for a number of reasons, including that:
  - the polyps were identified at colonoscopy were recorded but no pathology was taken;
  - the polyps were removed but lost;
  - the pathology was performed but not forwarded to the Register; or there were errors in data entry.
- It is possible that in a national program electronic data transfer between service providers and to the register may improve the rate of data completeness.

**Objective 5:** To develop and trial during the Pilot a national bowel cancer screening register within the Health Insurance Commission (HIC). Functions of the register will include invitation of the target population, register recall, reminder and clinical data functions, capacity for monitoring of screening clinical and cost indicators.

The Pilot successfully developed and trialled a centralised, national bowel cancer screening Register within the Health Insurance Commission. The Register was generally successful at meeting its desired functions. However, there were a number of areas of concern:

- The Register’s identification and invitation process worked well. Of a total of 60,792 people invited, 56,907 are recorded as ‘eligible’ on the Pilot register. This equated to a successful identification rate of 94% of all invitations. A potential improvement to the identification process would be the ability for the Register to exclude those who had a recent colonoscopy by referencing other Medicare data. A number of people were invited who were not appropriate for a population based FOBT screening program, for example because of a previous diagnosis of bowel cancer.
- The sending out of six-weekly reminder letters was generally satisfactory. However, there were some instances where inappropriate reminder letters were sent out. For example, six-weekly reminders were sent to some participants who had already responded. The frequency of this occurrence during the Pilot was unclear.
- In addition, it was intended that some reminder letters would include an additional FOBT to test whether this increased the response rate. The process of randomly including an

FOBT with the reminder letter was not completed as intended. The HIC randomised over the 3 sites combined, rather than within each. This increases the potential for statistical bias in comparative analyses.

- There was a data incompleteness issue, particularly in relation to participants' follow-up colonoscopy results, which were not consistently and comprehensively sent to the Register. Similarly, histopathology data in the Register was substantially incomplete and there were some initial delays in recording histopathology data that was provided to the Register.
- This data is fundamental for accurately determining the status of second round participants, program specificity, and cost-effectiveness.
- The Pilot did not trial electronic data transfer between different service providers involved in the Pilot.
- There were no specific direct cost indicators collected in the Register. These could be derived by applying estimates of costs to components of the screening pathway recorded in an individual's Register record.
- The cost of the Register was a further area of significant concern, with a substantial increase in estimated development and operational cost for the Pilot.

## 2.2 Acceptability

**Objective 6:** To evaluate the acceptability of FOBT screening to a representative cross-section of the Australian target population, and equitable access within that sample.

The overall evaluation examined the acceptability of FOBT within the three Pilot sites around Australia. The three Pilot sites were specifically chosen to include a mixture of men and women, urban and rural residents, and diverse socioeconomic and ethnic groups to reflect the Australian screening target population:

- Invitations were sent to 56,907 eligible members of the target population, of which 25,840 responded by returning a completed FOBT, giving an overall participation rate of 45.4%.
- Pilot participation was higher among women (47.4%) than men (43.4%).
- Pilot participation was higher for the two least disadvantaged quartiles.
- Participation in Mackay (57.5%) was higher than in Adelaide (46.3%) and in Melbourne (39.9%).
- Participation appeared to be lower for Aboriginal and Torres Strait Islander people compared to the general eligible population, and for people who spoke a language other than English than for English speakers. However, it should be noted that many people did not respond to these questions so it is not clear that this is the case. Any lower participation that occurred possibly arose from a combination of factors including: language barriers, for example, the testing procedure was too complex; cultural barriers, for example, felt uncomfortable with any tests involving the bowel region and/or discussing the screening process; and, practical barriers, for example difficulty with postal contact.
- There were also difficulties in developing strategies for particular target groups within the population given the limited time available to implement the Pilot.

- The Pilot noted difficulties in postal contact with some members of the target population. The use of direct mail as the primary distribution channel of the invitation package requires a person to have a fixed address. Those in the community most at risk of not having fixed addresses, for example Aboriginal and Torres Strait Islander people and people from low socio-economic groups, particularly homeless people, would appear to require an alternative distribution mechanism where possible.
- The evaluation of the Pilot included substantial research on participants and non-participants views on bowel cancer and bowel cancer screening. The research was conducted at the outset of the Pilot (baseline data) and at its conclusion (post intervention data). The baseline survey demonstrated that awareness among Australians of FOBT screening aimed at early detection was relatively low, with only 43% of those surveyed having heard of an FOBT and only 26% of them ever using such a test. However, after the Pilot, 85% of people reported having heard of an FOBT.
- In addition, after the Pilot, only 2% of participants said they would be unlikely or very unlikely to participate in an FOBT screening program in the future. The research carried out in association with the Pilot found that the likelihood of future participation if an FOBT was mailed out was almost as high as if a doctor recommended the completion of the test.

**Objective 7:** To evaluate screening knowledge, attitudes and satisfaction with service delivery amongst those invited to participate, especially factors associated with not participating.

Two mechanisms were used to assess this objective. These included a Knowledge, Attitudes and Practices Survey undertaken pre and post intervention through the Pilot, and a large scale qualitative evaluation research exercise combining mini-group discussions and one-on-one in-depth interviews. The analysis of these two activities found:

- In general, people with the following characteristics were more likely to participate in bowel cancer screening through the Pilot:
  - a biological family history of bowel cancer
  - greater awareness of bowel cancer and the need for screening
  - experience with other screening programs.
- The major reasons reported for taking part in bowel cancer screening were ‘precaution/prevention/early detection/health check important’ and ‘wanted to know whether had bowel cancer/peace of mind’.
- The major reasons reported for not taking part in bowel cancer screening were having ‘already had other bowel tests’ and having a ‘lack of symptoms’ or ‘feeling well’. Non-participants were usually less aware of the screening process and, therefore, less likely to consider participating.

**Objective 8:** To agree minimal acceptable and achievable quality standards along the screening pathway and set up quality assurance systems for the Pilot which can be expanded into a national quality assurance system.

The overall evaluation examined quality assurance systems established for each component of the Pilot screening pathway, as well as overall Pilot quality assurance. There was a minimum quality data indicator set developed for the Pilot and reported by the Australian Institute of Health and Welfare through quarterly reports. Quality indicators were also built into contracts with FOBT suppliers, FOBT pathology and colonoscopy providers. The Quality Task Group operating during the design phase of the Pilot noted that there was a considerable lead time required for the development of quality processes and performance indicators.

Key Performance Indicators for the program need to be introduced and carefully monitored. For example, there needs to be careful analysis of the performance of colonoscopists to ensure quality standards are maintained.

## 2.3 Cost-effectiveness

**Objective 9:** To determine the costs of all services provided along the screening pathway in order to provide estimates of screening cost-effectiveness and funding required for a national program.

The Department commissioned M-TAG Pty Ltd to undertake an evaluation of the cost-effectiveness and financial impact of establishing a national screening program, largely based on the preliminary data from the Pilot:

- For a target population aged 55–74 years, at the Pilot participation rate of 45.4%, the estimated cost per additional life year saved was \$24,000.
- For a target population aged 50-74 years, at the Pilot participation rate of 45.4%, the estimated cost per additional life year saved was \$20,000.
- These estimates can be considered conservative because there will be a further cost saving due to the reduction in current *ad hoc* ‘screening colonoscopies’ currently conducted in the average-risk population. They are also based on the outcome data collected during the Pilot, which can be considered the minimum number of cancers and advanced adenomas detected in the Pilot, as the Register data included only 50% of referred follow-up colonoscopies at the time of the overall evaluation.
- This analysis was carried out based on a set of assumptions about how a national program might be implemented. The actual cost-effectiveness of the program may vary depending on how a national program is delivered.

**Objective 10:** To compare the impact (and anticipated impact) of bowel cancer screening in the Australian health care environment with results achieved in international screening trials.

The findings from the Pilot have been compared with findings from published results for three major Randomised Control Trials (RCTs) of population screening for bowel cancer using FOBTs, a major study of participation in FOBT screening, and the results from the recently completed Pilot test of FOBT based population screening for colorectal cancer in the United Kingdom (UK).

Compared with the UK Pilot and major international RCTs, a lower rate of participation was achieved. However, if the RCT and UK reported rates were adjusted for their exclusion of people in the target age group who were judged unsuitable for screening, their rates are likely to be comparable to the Australian Pilot rates (where no such exclusions were made).

The Australian test positivity rates are higher than those for both the RCTs and the UK Pilot. The Australian test positive predictive value is lower than those for both the RCTs and the UK Pilot. The likely consequence is that more participants will be subjected to unnecessary colonoscopy in Australia than in the UK or the RCTs but that the UK pilot and the RCTs missed more cancers and adenomas than were missed in the Australian Pilot. Detection of advanced adenomas is particularly important because they are the polyps with a high risk of progressing to cancer, so their detection is what mainly allows the screening program to prevent cases of colorectal cancer.

This implies that the mortality outcomes for people responding to a screening invitation in the Australian Pilot should be at least as good, if not considerably better, than the analogous outcomes for people participating in either the RCTs or the UK Pilot. Similar mortality reductions to those achieved in the RCTs can therefore be expected to be achievable.

## **2.4 Summary of Pilot participation activity levels**

Information collected through the overall evaluation enabled the preparation of a comprehensive analysis of the participation and data incompleteness rates along the screening pathway. A system-wide presentation of the activity along the Pilot screening pathway facilitates a drill-down analysis that identifies the following (see Figures 8.2 and 8.3 for additional detail):

- 56,907 eligible people were invited to participate in the Pilot;
- 121 (0.2%) of eligible participants visited a GP prior to receiving an FOBT result;
- of the 56,907 eligible participants, 25,840 (45.4%) participated in the Pilot by completing the FOBT;
- 2,308 of these returned a positive result;
- of the FOBTs that were positive, a significant number did not have a GP visit recorded, but were still recorded as proceeding to follow-up colonoscopy (n=517); and
- of the 1,273 colonoscopies recorded in the Register for participants with a positive FOBT, there were a total of 176 advanced adenomas and 67 suspected cancers. Some additional cancers and adenomas were also detected in people who proceeded to colonoscopy without a positive FOBT (see section 7.2).

The Monitoring and Evaluation Steering Committee suggested that further work should be undertaken to investigate data incompleteness across the screening pathway. The data shown above identify the importance of establishing the reasons for the missing data across the screening pathway. In particular, for each step of the clinical pathway, it will be important to determine whether the data incompleteness rate was due to:

- service providers' failure to return Pilot reporting forms; or
- differences in participants' behaviour once they entered the screening pathway, for example, failure to attend follow-up colonoscopy post-GP referral.

Chapter 8 discusses this issue in more detail.

## Performance of the Register

### Key evaluation findings

- The Pilot successfully trialled a central, national bowel cancer screening Register.
- The Register's identification and invitation process worked well, with a total of 56,907 invitations sent to eligible people in the Pilot population (94% of all invitations).
- The issuing of six-weekly reminder letters was generally satisfactory, but, there were some instances where inappropriate reminder letters were sent out.
- There were some concerns about data integrity, particularly in relation to missing information on the follow-up of participants who had positive FOBT results.
- The issue of missing data, particularly of follow-up of people with a positive FOBT is a critical issue that would need to be addressed as a high priority item within a national bowel cancer screening program.
- The cost of the Register was an area of significant concern, with a substantial increase over estimated development and operational cost for the Pilot.
- Electronic data transfer from pathology providers, GPs and specialists to the Register would assist in maintaining timely and accurate participant data.

### 3.1 Background

A key feature of the Pilot was using a single national register to invite people in the eligible target population, based on the use of individuals' Medicare enrolment files, to participate in screening and to follow-up participants based on capture and storage of data for each participant at each point along the screening pathway. The Register was distinctive because of this national and centrally-managed approach. The national population breast cancer and cervical screening programs, both established in 1991, use State and Territory developed and operated registers to manage and monitor screening services along the screening pathway. A recent exception to this approach has been the development of national registers within HIC to support childhood immunisation and organ donation.

#### Rationale for a central register

A national, central register was adopted, on advice from the Implementation Committee, as the preferred register option because of:

- the relative ease of identifying and recruiting the target population at a national level using an identifier that is constant across State and Territory borders, i.e., a person's Medicare enrolment file;
- the ease of collecting and monitoring outcomes of the Pilot at a national level, avoiding the need to collate data from multiple registry databases;
- the capacity to link national register data to payment and provider data;

- the potential to scale up the Register infrastructure to implement a possible future national program; and
- its capacity to serve as a building block or model for other possible future population screening initiatives for other conditions (Implementation Committee 2001b).

The Implementation Committee also considered that a more co-ordinated national approach could result in better data on clinical performance, and assist in developing strategies to improve clinical practice and better services for those participating in the Pilot.

### **Building and maintaining the Register**

The Register was developed and maintained by the Health Insurance Commission (HIC).<sup>9</sup> HIC was selected as the preferred provider for the following reasons:

- HIC had some experience in developing national registers;
- HIC had experience in developing database structures, with similar performance requirements as the bowel cancer screening register;
- Departmental analysis identified that the Medicare enrolment file, which is maintained by HIC, was the best method of identifying the target population (DoHA 2002); and
- HIC was a Government-preferred provider of services.

HIC began building the Register in 2001 and implementation was introduced over six phases. The Register build was completed to the stage where implementation could commence in late 2002, with final development completed in August 2003. The front-end data collection functions for the Register were maintained on a HIC intranet that interfaced to a back-end written in COBOL with DB2 data storage.

### **Role of the Register during the Pilot**

The Register performed two key functions in the Pilot:

- a *service function* to facilitate participation by eligible people in screening, follow-up and re-screening at appropriate intervals; and
- an *epidemiological and monitoring function* to assist in data collection, monitoring and evaluation of Pilot outcomes.

Within the service function, the Register was used to:

- identify and invite people in the eligible target population to participate in bowel cancer screening;
- provide a system of communication with participants and their medical practitioners to allow for appropriate and timely follow up and investigation;
- record participants' screening and assessment histories;
- provide information to medical practitioners to assist them in advising their patients about options for their clinical management; and

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<sup>9</sup> The Register was established after a determination by the Minister for Health and Ageing on 12 September 2002 allowed the HIC to perform additional functions required to populate the Register with data.

- make payments on behalf of the Australian Government to medical professionals for the transfer of data to the Register for Pilot participants (HIC 2004).

HIC also had responsibility for:

- arranging storage and mailing house functions for the invitations, including FOBTs, reminders to participants, and advice to GPs that were sent out by the Register; and
- running a Register information helpline (note that this was a dedicated Register helpline, different and separate from the public helpline run by the Department).

### **Organisational arrangements of the Register**

The contents of the Register were negotiated between HIC and the Department. Specifications for the Register are contained in a statement of business requirements (HIC 2004). The statement also specified the Register business processes and data fields.

## **3.2 Performance of Register functions**

The Department commissioned a review of the Register ('Register Review') in March 2004. The Register Review assessed the capacity of the Register to achieve its desired functions, the operations of the Register and Register quality assurance systems (Chappell 2004).

### **Identification and invitation of participants**

Mackay was the first site to begin receiving invitations from the Register in November 2002, with weekly mailing commencing on 24 February 2003. The total number of invitations issued increased dramatically from March 2003 as the Register commenced issuing invitations to the South Australian and Victorian Pilot sites, with more than 1,000 invitations being sent out per week. The final invitations were sent out during the first week of June 2004. In total, 60,792 people were sent an invitation to participate in the Pilot (see Table 3.1 below for breakdowns).

The Register Review found that the Register's identification of participants was excellent. Medicare and DVA enrolment files were used to identify the ages and addresses of eligible people within the Pilot sites. The currency of this data was advantageous, with address details updated nightly and vital statistics updated weekly (Chappell 2004). Nevertheless, there were some instances where people outside the target population were invited to participate. AIHW data (Table 3.1 below) indicates that 3,885 invitations (6% of all invitations) were sent to people ineligible or inappropriate to participate in a population based FOBT screening program.

**Table 3.1: People sent invitations by the Register**

	Adelaide		Mackay		Melbourne		All Sites		
	Inform	Bayer Detect	Inform	Bayer Detect	Inform	Bayer Detect	Inform	Bayer Detect	All FOBTs
Total number of people sent an invitation	9,909	9,939	6,049	5,823	14,533	14,539	30,491	30,301	60,792
Total number of people sent an invitation – eligible participants only	9,189	9,242	5,655	5,390	13,746	13,685	28,590	28,317	56,907

Source: AIHW (2004)

Of the people who were classified as ineligible or inappropriate for the program, 168 were outside the target age group and 568 had moved outside of the Pilot site prior to being invited to participate. That is, they were invited due to inaccurate or out of date Medicare data. A further 3,149 people were classified as inappropriate or ineligible for screening for other reasons. These reasons included being deceased; being diagnosed with bowel cancer or having a recent colonoscopy. People who were invited to participate and their GPs were able to advise the register that an individual was not appropriate for the program (AIHW 2004).

The pathology laboratories stressed the need to effectively identify the target population for invitation for screening. The pathology laboratories reported receiving some letters from people whose partner had been invited to participated but their ‘partner had passed away’ or who reported that ‘they already had cancer’. It was suggested that the use of a pre-invitation letter that stated that the person is going to receive a FOBT shortly would help more accurately identify appropriate potential participants. Improved data matching against death records and cancer registries may also assist to address this issue.

The proportion of excluded participants should reduce in a national program as there would not be geographical constraints that existed in the Pilot (i.e. people cannot move outside the ‘Pilot site’). However, the identification process could be further improved with the ability for the Register to exclude those who had had a recent colonoscopy by referencing other HIC data.<sup>10</sup>

Improved communication between HIC Central office and local Pilot sites on the timing and volume of invitation mail outs may have facilitated better management of clinical workloads in the Pilot sites.

### Reminder invitations

The Register Review found that issuing of reminder letters was generally satisfactory (Chappell 2004). There were some instances where inappropriate reminders were issued, for example, six-weekly reminders were sent to participants who had already responded. The frequency of this occurrence during the Pilot was unclear. Sending out inappropriate letters has the capacity to damage the public image of the program.

<sup>10</sup> The Determination under subsection 8AA(4) of the Health Insurance Commission Act 1973 did not allow the checking of claims histories of potential participants.

One aim of the Pilot was to test the effect on subsequent participation of including a replacement FOBT kit with the reminder letter sent at six weeks to non-participants. The intention was to have an FOBT randomly included with half of the reminder letters within each Pilot site. However, the process of allocating FOBTs to reminder letters was not undertaken in accordance with this objective. HIC randomised over the 3 sites combined, rather than within each. The Melbourne Pilot site received primarily reminder letters with a replacement FOBT and Adelaide received primarily reminder letters only. Although closer, Mackay still had a ratio of 1 letter with a replacement FOBT to 3 letters without an FOBT. Some adjustment to the allocation process was made after this was discovered, but possibly not to the full extent necessary to achieve a statistically comparable result. This may increase the potential for bias in a comparative analysis.

### **Pathology laboratories' data transfer**

Pathology laboratories provided data in hard copy form and the Register relied on manual processing and entry of this information which related to test results and participants' details. The timeframe for completion of the Pilot did not allow for development of the technical requirements required to upload the data electronically.

### **Follow-up colonoscopy results**

The Register Review found that collection and entering of the result of participants' assessment following a positive FOBT was an area of significant concern (Chappell 2004). Colonoscopy results were not available from the Register at the time of the Register Review in March 2004. Similarly, it appeared that histopathology results were not entered in to the Register at this time.

Some colonoscopy and histopathology results had been entered into the Register by the time of the overall evaluation. The Register had records of histopathology data for 17 surgically resected cancers and a further 6 locally resected cancers. This means that 20 of the 67 suspected cancers have been confirmed as cancers. It was not possible to tell the stage of the surgically resected cancers (AIHW 2004). It should be noted that this is a data definition and data capture issue rather than a gap in the performance of the Register.

The Pilot also indicated that the system for collecting histopathology results was not satisfactory.

### **Payment processing**

The Register Review found that the payments to GPs, colonoscopists and histopathologists were performed adequately. A suggested improvement would be to tie payment to quality of data provided to the Register. This could create an incentive to maximise Register data integrity.

### **Monitoring of indicators**

A key role of the Register was to provide the data required to monitor and evaluate screening program performance to the AIHW. HIC provided AIHW with data downloads from the Register on a quarterly basis.

The Register Review found that there should be greater capacity for HIC staff entering the data into the Register to interrogate the database to ensure quality and completeness of the data entered. During the Pilot, the AIHW was the only area working to identify data inconsistencies and errors. The HIC Central Office relied on the AIHW to identify problems and suggest solutions.

### **3.3 Register operations**

The Register Review also examined the Register's operations during the Pilot.

#### **Data collection, entry and extraction**

Standardised, paper-based forms were used for data collection. Information was collected from participants, GPs, pathology laboratories, specialists and pathologists. The completed forms were forwarded via facsimile in most cases to HIC for data entry. An exception was *Inform* pathology information which was provided electronically. HIC staff undertaking data entry were based in Hobart, Tasmania. Approximately 90% of participants returned a negative FOBT result and thus only their *Participant Details* and FOBT pathology forms were required to be completed and processed.

The Register Review reported that the processing time of *Participant Details* and FOBT pathology forms appeared to be a minimum five days. They did not report a maximum, but a check late in 2003 showed that there was a six week backlog in data entry. There were also some noticeable gaps in data provided to the AIHW. The data entry time did improve towards the end of the Pilot. It is suggested that as much data as possible should be transferred electronically to support timelier data and decrease processing error rates. The acceptability of electronic data transfer would need to be considered in the event of a national rollout of the program. Further, it is suggested that standards on data entry and processing times should be specified.

Routine data extraction from the Register was restricted to AIHW quarterly monitoring reports. The data was de-identified prior to transfer. HIC also provided *ad hoc* reports to the Department of Health and Ageing upon request.

#### **Systems structure and administration**

The HIC office in Hobart undertook data entry and Helpline functions whilst the HIC Office in Canberra managed system development, mailing and reporting. The Register was web-based, located on a server at HIC in Canberra. Access to the Register and relevant data was controlled through security levels and passwords. The Register appeared to have good basic functionality. The Register Review identified a number of suggested improvements relating to system functionality and design modifications.

#### **Reporting data accuracy**

Data from the Register formed the basis of the AIHW reporting, as well as *ad-hoc* reporting for the Department of Health and Ageing. AIHW identified some apparent inconsistencies in the Register data; for example, AIHW analysed the minimum and maximum waiting times from data as it was stored in the Register.

AIHW reported that ‘in some cases these waiting times appear implausible and should be treated with caution’. There were in excess of 60 negative waiting times, presumably as a result of inconsistent dates stored in the Register (AIHW 2004). This highlights again the importance of review mechanisms and quality assurance to ensure data integrity.

### **Relationships with other stakeholders**

The Register Review reported that the relationship between HIC and AIHW could have been more collaborative and that their respective roles should have been clearer. AIHW was responsible for data analysis while HIC was responsible for data collection and integrity. The Register Review found that HIC had taken little overall responsibility for data quality beyond a basic level.

## **3.4 Register quality assurance**

This section outlines the use of quality assurance systems for the Register’s operations during the Pilot.

### **System implementation and maintenance**

HIC established protocols and quality control measures for development of the Register, including functionality testing. It is suggested that a formalised issues tracking system could support quality improvement of the Register.

### **Data integrity**

There were no routine quality control processes for data collection, except for reminder letters issued by the Register.

Data entry quality assurance systems were adequate. Register software included in-built data validation checks, but these could have been more comprehensive. There was manual cross-checking of most data entry (one in six *Participant Details* forms and 100% of other forms). There was also a reconciliation of lists of people invited to participate and letters issued. Data validation was adequate, and participants’ details were checked against Medicare enrolment files to ensure only eligible people were invited and that the correct address was used. Nevertheless, HIC issued invitations to people who had moved out of the Pilot sites. This problem only became apparent in AIHW reports and the Department requested a check of current address be included in procedures to overcome the problem.

There were no quality assurance systems for data extracted from the Register. The Register Review recommended a comparison of data collected at the pathology laboratories with corresponding data from the Register to assess extent of agreement.

It is suggested that formalised interrogation and data review could ensure completeness and validity of data.

## Help-line advice

The Department developed a manual to guide people answering help-line queries which was provided to HIC Helpline staff. However, the Register Review found that there was no formal ongoing quality assurance process in relation to help-line advice or the recording of outcomes.

## Risk management and contingency planning

Although there were no formal risk management strategy or contingency plans in place, the Register Review was reasonably confident that risk management would have been satisfactory (Chappell 2004).

## 3.5 Register cost

The cost of the Register was a significant component of the overall cost of the Pilot. The total cost of the Register represented approximately 63% of the initial funding allocation for the Pilot. This was a significant increase in the original Register cost estimates provided by HIC. The Register Review concluded that the cost increase resulted from unclear understanding of Register requirements at the outset.

The unique nature and functionality of the Register makes it difficult to accurately compare its cost to other population screening registers. However, other Australian population screening program registers can provide rough benchmarking estimates for a fully operational national program.

- (1) **National Cervical Screening Program.** The cost for all State and Territory registry functions (State-based registers), education, recruitment and related functions was 9% of public expenditure on cervical screening (Chappell 2004).
- (2) **BreastScreen Australia.** Coordination and evaluation of the Program by States and Territories, including register costs, was 5% of public expenditure on breast cancer screening.

These are rough comparisons, and provide only indicative estimates. A comparison with other population screening registers is difficult because the Register is unique in its scope and functionality, amongst other things. For example, while the State and Territory screening registers do not undertake a payment function, the State and Territory BreastScreen registers have more complex and complete clinical management functions across the whole screening pathway.

**Areas for further exploration**

- Referencing other HIC data to exclude those who have a recent colonoscopy to better identify people in the eligible target population to be invited to participate in screening.
- Better planning and communication around the invitation mail out process to support planning at the local level. This could include feedback mechanisms for the various stakeholders, including ensuring necessary supply of FOBTs from manufacturers, and advising colonoscopy facilities and GPs of mail out schedules.
- Examine mechanisms for reducing issuing of inappropriate reminder letters.
- There is a precedent for the transfer and loading of laboratory data electronically in the National Cervical Screening Program, where pathology laboratories transfer data on the outcomes of Pap smears to State and Territory Pap Test Registers. Explore this model as a means of building Register capacity to accept an electronic upload of pathology laboratory data and electronic transmission of data from clinical service providers.
- Consider mechanisms for follow-up of incomplete colonoscopy and histopathology data, with reference to processes established within State and Territory BreastScreen and Pap Test Registers for investigating where data is missing for an individual moving across the screening pathway.
- Identify options for tying incentive payments to GPs, colonoscopists and histopathologists to completeness and quality of data provided to the Register.
- Determine routine and regular reporting and data integrity checks to assist: quality data collection and recording; and in minimising data processing errors and missing data. This may include a role for the Australian Institute of Health and Welfare.
- Consider possible tendering of development and implementation of a national Register to contain costs.