

CHAPTER 3 POPULATION SCREENING FOR COLORECTAL CANCER

The biology of Colorectal Cancer provides the opportunity for a variety of approaches to primary prevention and early detection. Progression from the precancerous phase through the various stages of cancer is normally spread over a number of years.¹ Certainly, Colorectal Cancer has a high cure rate in its early stages.¹ Effective targets for screening are curable cancer (to reduce mortality) and removable adenomas (to reduce incidence) through early detection.

3.1 Concept of screening for Colorectal Cancer

Population screening is the systematic application of a suitable screening test, to identify individuals at risk of a specific condition/disorder to warrant intervention. It is undertaken among asymptomatic individuals. Importantly, population screening is an organised process that involves call and recall of the population to regular screening, as an aid to early detection and appropriate follow up of people requiring further treatment. As such, population screening differs significantly from dealing with symptomatic patients, or even 'individual case finding' in asymptomatic patients with certain risk factors.

The World Health Organization (WHO) has endorsed nine principles of screening^{2,3} to assist in determining whether there is sufficient evidence to warrant the consideration of an organised, population-based screening program. In summary, the WHO principles specify that population screening should only be considered where:

- the condition is an important health problem
- there is a recognisable latent or early symptomatic stage
- the natural history of the condition, including the development from latent to declared disease, is adequately understood
- there is an accepted treatment for patients with recognised disease
- there is a suitable test or examination (i.e. for screening purposes)
- the test is acceptable to the population
- there is an agreed policy on who to treat as patients
- the cost of case finding (including diagnosis and treatment of patients diagnosed) should be economically balanced in relation to possible expenditure on medical care as a whole, and
- case finding is a continuing, and not a 'once and for all' project.

As specified by WHO,³ the process involves offering a simple, affordable and acceptable screening tool or test to identify whether a particular healthy individual is more likely to have a significant lesion such as an advanced adenoma or cancer (preferably early stage and curable) and in whom it is justifiable to go ahead and perform an invasive, perhaps slightly risky, diagnostic test such as colonoscopy.³ Adequate therapy must be available. The process should be acceptable to a large segment of the at-risk population and high-quality investigation and treatment should be available for those with positive findings. As screening is directed at apparently healthy people and uses expensive and sometimes scarce resources, harm must be minimised and the screening method must have been shown to offer benefit at a population level.

With Colorectal Cancer, screening applies to individuals living in a high-risk country (e.g. Australia) who have reached an age where the chance of neoplasia being present justifies engagement in screening. Any screening program should identify and redirect those with significant symptoms or those with increased risk factors towards more appropriate interventions (see subsequent chapters). It should also advise those with co-morbid conditions or other concerns to seek further medical advice before participating.

3.2 Age as a risk factor

The risk of Colorectal Cancer increases with age, as shown in Table 3.1.

Table 3.1 Absolute risk of Colorectal Cancer

If a person is aged	Risk over the next ...			
	5 years	10 years	15 years	20 years
30	1 in 7000	1 in 2000	1 in 700	1 in 350
40	1 in 1200	1 in 400	1 in 200	1 in 90
50	1 in 300	1 in 100	1 in 50	1 in 30
60	1 in 100	1 in 50	1 in 30	1 in 20
70	1 in 65	1 in 30	1 in 20	1 in 15
80	1 in 50	1 in 25		

Note: Absolute risk is the observed or calculated likelihood of the occurrence of an event in a population under study (*cf* relative risk, which is the ratio of the risk in a particular exposed group to the average risk in the population; see Table 6.1).

Source: AIHW 1996⁴

Table 3.1 gives the absolute risk for an average member of the population. If risk factors apply, then these multiply the chance. Symptoms are a risk factor and, obviously, a person's risk will be increased pending clarification of the cause.

Similarly, if a person has a relative with Colorectal Cancer, that person's risk is modified in accordance with the categories outlined in Chapter 6. For example, a 50-year-old woman with no family history of bowel cancer is at about *average risk* for her age. As shown on the table, her chance of developing bowel cancer is about 1 in 300 over the next five years, and 1 in 30 over the next 20 years. If her father were diagnosed with bowel cancer at age 68 (that is, 55 years or older), that would place her in the second part of category 1 (see Chapter 6). Her *risk approximately doubles*⁵ to 1 in 150 over the next five years and 1 in 15 over the next 20 years.

If her paternal grandmother as well as her father had bowel cancer, or if her father was diagnosed at age 48 rather than 68, that would place her in category 2. Her risk would be *three to six times average*.⁵ It would be between 1 in 100 and 1 in 50 over the next five years; and between 1 in 10 and 1 in 5 over the next 20 years.

Personal history of advanced adenoma or cancer also increases risk by the relevant multiplier (see Chapter 9).

3.2.1 Age to commence screening

Randomised controlled trials at the population level indicate that screening tests for faecal occult blood (performed once every 12 months, as shown in one trial,⁶⁻⁸ or once every 24 months, as shown in three trials,⁶⁻¹² reduce overall mortality from Colorectal Cancer in populations selected on the basis of age.⁶⁻¹³ These have shown benefit for people aged 45–50 years and upward. Cost-effectiveness

studies also demonstrate that age influences cost-effectiveness.¹⁴ Together with the observation that risk increases 4-fold between ages of 40 and 50 years (Table 3.1), these lead to the recommendation that screening of average risk people should commence at age 50 years. This is consistent with the deliberations of several major international bodies.¹⁵⁻²⁰

3.3 Evidence for benefit from population screening

Randomised controlled trials at the population level show that screening for faecal occult blood reduces overall mortality from Colorectal Cancer on the basis of intention-to-screen by 15–33%^{6,7,9-12} and reduces incidence by 20%.⁸ Case-control studies (see below) suggest an impact of screening based on sigmoidoscopy and colonoscopy as well. However, these are not population-based studies and, especially in the case of colonoscopy, suffer from several biases that make it impossible to determine the added benefit and cost derived from use of these modalities.

3.3.1 Implementation of population screening for Colorectal Cancer in Australia

The question of screening for Colorectal Cancer in Australia has been systematically reviewed in a report from the Australian Health Technology Advisory Committee (AHTAC).¹⁵ The committee's key recommendations related to population screening are listed in Box 3.1.

The pilot studies recommended in the AHTAC report commenced in November 2002 through the Bowel Cancer Screening Pilot Program (the Pilot) (in Mackay, Melbourne and Adelaide) to address issues such as recruitment, participation and compliance, assessment, choice of faecal occult blood test (FOBT), access to services, quality assurance and potential adverse effects. These are being implemented in the context of the existing health care system and should demonstrate whether such screening is feasible, what barriers exist and whether the program can be rolled out to the Australian population. The Pilot will assess the feasibility, acceptability and cost-effectiveness of faecal occult blood-based screening in the Australian population in both rural and urban areas.

Box 3.1

The first two recommendations of the Australian Health Technology Advisory Committee on Colorectal Cancer Screening,¹⁵ are

1. On the basis of published evidence, and subject to favourable preliminary testing, it is recommended that Australia develop a program for the introduction of population screening for Colorectal Cancer by faecal occult blood testing for the average risk population (well population aged over 50).
2. Given the uncertainties relating to the most effective means of implementing such a program and to the feasibility, acceptability and cost-effectiveness of such a program in the Australian setting, the program should commence with preliminary testing involving a number of pilot and feasibility studies.

3.3.2 Barriers to population screening with FOBTs

Barriers to participation in FOBT screening fall into several categories, including: inconvenience of the testing process, aversion to manipulating faeces, lack of perceived benefit of screening, fear of a diagnosis of cancer, cost, views about personal invulnerability, and cultural beliefs and attitudes.^{21,22} Recent studies have demonstrated that several of these barriers can be at least partially overcome so as to improve participation. Removal of dietary restrictions needed for certain FOBTs, simplifying the method of stool sampling and endorsement of screening by a person's own general practitioner all lead to a significant improvement in participation.²³⁻²⁵

3.3.3 Potential psychological consequences of screening

A further important consideration is the role of adverse psychological effects on individuals. These can range from the trauma of identification of disease in symptom-free, healthy individuals, to stress among people in whom cancer is suspected although later discounted, to more subtle concerns of participants during the screening process.²⁶ Health care professionals must recognise the potential adverse psychological effects of screening, although several studies have shown no evidence of long-term harm after screening.²⁷⁻²⁹

Despite the possibility of adverse psychological consequences of screening, the stress generated by diagnosis of an advanced cancer when there has been no opportunity for early detection by screening also needs to be taken into consideration.

3.4 Screening and case-finding scenarios

Two main scenarios need to be considered:

- an unsolicited offer of screening to individuals in the general population that does not involve any personalised approach (population screening)
- the individual asymptomatic person aged 50 years or over who is concerned about the possible presence of Colorectal Cancer (sometimes referred to as case-finding) due to their age, family medical history, personal medical history or symptoms.

3.4.1 Population screening for Colorectal Cancer

In this scenario the focus is on the general population and WHO criteria should be met. Feasibility, acceptability and cost-effectiveness are vital considerations as pointed out in the AHTAC report. The more people undertaking even the simplest preventive measures, the greater will be the impact at the population level.

Screening tool options could be: FOBT, sigmoidoscopy, FOBT combined with sigmoidoscopy, colonoscopy, and CT colonography. Taking into account WHO criteria, the need for high-level evidence at the population level, and the feasibility of engaging a majority of the population, a simple, affordable and acceptable screening tool could be FOBT (alone) or perhaps sigmoidoscopic examination either alone or combined with FOBT.

FOBT appears likely to be acceptable in Australian populations and the outcomes of the Pilot will establish whether this is the case. Cost-effectiveness calculations based on Australian costs demonstrate that FOBT screening is cost-effective.³⁰

It is important to advise people entering a screening program that if they develop symptoms or have a significant family history, they should seek medical advice. Also, if any new risk factors become apparent, then they should return for re-evaluation of their screening protocol. Ideally, screening is not a once-only event and continuing participation increases the likelihood of success.

3.4.2 The asymptomatic individual aged 50 or over

The individual asymptomatic person aged 50 or over, who has concerns about the possible presence of Colorectal Cancer, presents a particular situation that warrants careful consideration.

Where the issue of prevention or risk for Colorectal Cancer is raised in a subject over 50 years, the following procedure is recommended:

1. Take a thorough history focusing on risk factors, namely:
 - present age

- symptoms
- family medical history
- individual history of colorectal adenomas (note that not all polyps are adenomas and not all adenomas pose a risk)
- individual history of Colorectal Cancer
- individual history of extensive inflammatory bowel disease (eight or more years)
- cigarette smoking
- unfavourable diet and/or lifestyle.

Although it is difficult to make a simple assessment of unfavourable diet and lifestyle, body mass index (BMI) could be used as an indicator because of the greater risk for Colorectal Cancer associated with obesity.³¹

2. Perform a physical examination (including abdominal and digital rectal examination), looking for:
 - palpable abdominal masses or enlarged liver
 - low rectal cancer — note that this will detect approximately 35% of rectal cancers but less than 10% of all Colorectal Cancer.
3. Once it is clear that there are no relevant risk factors apart from age, and that the person is otherwise healthy, the following sequence is appropriate:
 - explain to the person their absolute and relative risk for Colorectal Cancer using the information provided above
 - providing the person desires to proceed with preventive measures, explain what constitutes a healthy dietary lifestyle
 - explain the nature, value, risks, and cost of all screening tools available, and indicate that it is reasonable to choose FOBT-based screening (providing testing is of high quality) as it has been shown to reduce Colorectal Cancer mortality and incidence.

3.5 Screening tests for average risk subjects or general populations

3.5.1 Faecal occult blood testing

Two main types of FOBT are available³² — guaiac tests and immunochemical tests. Guaiac tests are based on the pseudoperoxidase activity of haem. Immunochemical tests utilise antibodies against human haemoglobin.

In population screening programs, a person with a positive FOBT has a 30–45% chance of having an adenoma and a 3–10% chance of Colorectal Cancer.¹⁵

Traditional guaiac tests (e.g. Hemoccult®) will detect 40–60% of asymptomatic Colorectal Cancer.^{9,11} In other words, a Hemoccult II test will miss at least 40% of Colorectal Cancer under ideal testing conditions. However, when dietary restrictions are followed, a test such as Hemoccult II is highly specific — 97–99% of healthy subjects will have a negative FOBT.^{9,11}

The newer guaiac tests (e.g. Hemoccult SENSE[®]) and immunochemical tests (e.g. HemSp (also known as Bayer detect), OC Hemodia, Hemolex[®] and InSure (previously known as Inform)) are generally more sensitive than the earlier guaiac tests such as Hemoccult II.³² Under ideal circumstances, they may detect 60–90% of cancers and many advanced adenomas. Specificity of the more sensitive guaiac tests and the immunochemical tests tends to be lower than that of the earlier guaiac tests. The immunochemical tests are not affected by diet or medications, making dietary and drug restriction unnecessary. Immunochemical tests have now been shown to demonstrate clear population advantages in terms of participation²³ and are being evaluated in the Australian Pilot program. They are also highly selective for colonic bleeding.

FOBTs serve to refine the likelihood of cancer being present. A person with a positive FOBT is 12–40 times more likely to have a Colorectal Cancer than somebody with a negative test.^{9,11,33}

It is mandatory that any positive FOBT (even if just one of the samples is positive) be appropriately investigated by diagnostic evaluation of the colon. Colonoscopy is preferred as it allows for biopsy of lesions and therapeutic removal of adenomas. In those who have a positive FOBT, the probability that some type of neoplastic lesion will be present is 35–50%.^{9,11,33}

In the absence of iron deficiency or relevant symptoms, positive test results do not warrant follow up by upper GI endoscopy.

3.5.2 Sigmoidoscopy

Sigmoidoscopy has been shown to have value in screening.

Flexible sigmoidoscopy has a higher diagnostic sensitivity than rigid sigmoidoscopy, as more colon is examined. It is capable of reaching 50–60% of Colorectal Cancers and a similar proportion of larger adenomas (those of 6 mm or more).³⁴ Although controlled population studies of screening flexible sigmoidoscopy are in progress, final results, with mortality as the endpoint, will not be available for several years.³⁵⁻³⁷

Nonetheless, a number of case-control studies (not population-based) have demonstrated that subjects who undergo screening with flexible sigmoidoscopy do show a reduction in mortality.³⁸⁻⁴⁰ Depending on the study and the interval involved, the reduction in mortality for participants appears to be between 50% and 80% for lesions within reach of the instrument. A five-year interval between examinations should be sufficient, and even longer intervals might be satisfactory.³⁸

3.5.3 Colonoscopy and CT colonography

The place of once-only or periodic colonoscopy for population screening remains unproved as there is insufficient high-level, direct evidence to include or exclude this as the primary screening method.^{17,18} Colonoscopic resources are limited and the efficacy of colonoscopy is supported by its integral role in FOBT screening. A way of directing limited endoscopic resources to those more likely to benefit is through FOBT screening, a positive test increasing the likelihood of neoplasia being present. At an international level, many recommendations are guarded. They support individual choice of method in the context of case-finding and based on consensus rather than population evidence.^{19,20,41} It is unclear whether the increased accuracy of colonoscopy compared to alternative, less invasive screening methods offsets its cost and additional complications, especially when its acceptability to the general population is uncertain.

CT colonography is being evaluated as a diagnostic test compared to colonoscopy (see Section 8.1.5). Encouraging results are being obtained but the data are not yet conclusive. Equipment varies greatly in its usefulness and experience is highly variable. Population-based evaluation for CT colonographic screening is only just beginning^{42,43} and the approach must be considered experimental at this time. Colonoscopy will still be necessary for polypectomy and biopsy.

Should screening be recommended?

Guidelines — Screening asymptomatic individuals over 50	Level of evidence	Practice Recommendation	Refs
Organised screening with FOBT, performed at least once every two years, is recommended for the Australian population over 50 years of age.	I	Strongly recommend	6-9, 11, 13, 15
Screening with flexible sigmoidoscopy on a five-yearly basis from the age of 50 years.	III-2	Equivocal	38,39

3.6 Correct usage of screening tools

It is important that screening tests be undertaken carefully and with attention to quality assurance and quality control, and that those conducting the tests are experienced in their use.

3.6.1 FOBT — guaiac and immunochemical

At present, considerable research is being undertaken to determine the most appropriate FOBT to use. As indicated above, evidence now indicates that some immunochemical tests are easier for the subject to use than guaiac tests.²³ The manufacturer's instructions on how to use these tests should be followed, and it is recommended that the specified number of stools be tested, no matter what type of test is being used.

If a subject fails to follow dietary restrictions for guaiac tests, it is risky to assume that a positive result is due to non-compliance with diet. Dietary restrictions are not needed for immunochemical tests.

Sampling stools

Participants should be given stool sample cards/devices in order to take the faecal sample themselves. Several precautions are necessary because haem and haemoglobin degrade in moist faeces and because haemoglobin may be leached out of stools by toilet bowl water.

1. Follow the test instructions carefully to have the greatest likelihood of detecting occult bleeding from the large bowel.
2. Sample the number of stools recommended, as bleeding may be intermittent.
3. Collect samples from normally passed bowel actions, carefully following the manufacturer's instructions. For example, with guaiac tests, prepare a thin smear (which will dry quickly) on the specimen card.
4. Sample from the stool surface or where it is thought that blood might be present, or where the test manufacturer recommends.

Reading of results

The guaiac FOBTs are generally thought to be simple, but inexperienced readers may miss faintly positive results.⁴⁴ It is important to read guaiac tests with adequate illumination. Any blueness, no matter how transient, signifies a positive test. Automated development of some immunochemical tests avoids subjective aspects of interpretation of test results, thus improving quality assurance.^{45,46}

3.6.2 Performing flexible sigmoidoscopy

It is obviously important that screening endoscopic examinations be carried out under optimal conditions by appropriately experienced endoscopists. Patients should be advised that this procedure is quite simple, does not require bowel washout or elaborate preparation (although an enema is needed) and does not require sedation. It has been demonstrated to be very acceptable to participants.^{36,47}

3.7 Current status of Bowel Cancer Screening in Australia

In view of the evidence and the AHTAC recommendations (Box 3.1), a pilot feasibility program for population screening, the Bowel Cancer Screening Pilot, ran from November 2002 to June 2004. The key features of the Pilot are described in Box 3.2 and the screening pathway used is shown in Box 3.3.

Box 3.2

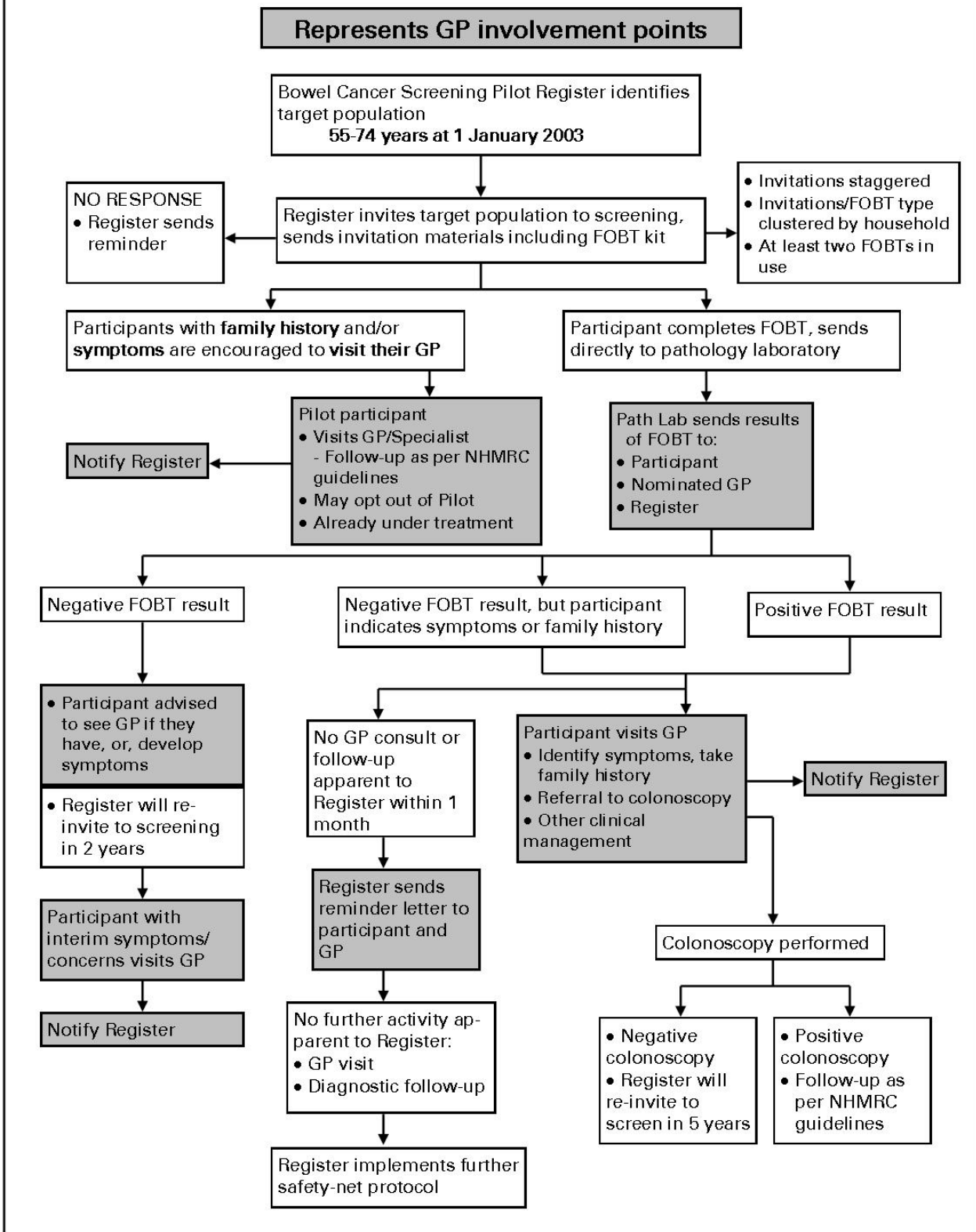
Features of the Australian Bowel Cancer Screening Pilot Program*

- 1 The Central Bowel Cancer Screening Pilot Register (the Register) was located within the Health Insurance Commission in Canberra. It utilised Medicare data to identify those eligible for inclusion in the Pilot.
- 2 There were three sites — Mackay in Queensland (November 2002 start date); nine postcodes in the western and southern suburbs of Adelaide (February 2003 start date); and ten postcodes in the north-east part of Melbourne (March 2003 start date). Invitations to participate were sent to nearly 57,000 eligible members of the target population.
- 3 Two immunochemical FOBTs were used at all three sites, with tests randomised by household.
- 4 The age range for Pilot participants was 55–74 years, as of 1 January 2003.
- 5 FOBTs were distributed by the Register, by mail, over 12–15 months, up to June 2004.
- 6 Test results were sent to the Pilot participants and, with their consent, to their general practitioners and to the Register.
- 7 The relevant state health departments, divisions of general practice, general practitioners, and cancer council education units were closely involved in the conduct of the Pilot and in providing professional and community education about the Pilot.
- 8 Specialists were involved in follow-up of positive tests.
- 9 Safety net procedures were provided by the Register to fulfil duty-of-care requirements for participants with positive FOBT results who failed to see their general practitioner about follow up, and for participants failing to have appropriate follow up investigation.

* The Pilot evaluation report is available at <www.cancerscreening.gov.au>.

Box 3.3

Screening Pathway used in the Australian Bowel Cancer Screening Pilot Program.



Following the success of the Bowel Cancer Screening Pilot Program, in the 2005-06 Federal Budget the Australian Government allocated \$43.4 million over three years to phase in a nationally coordinated, population based, bowel cancer screening program. Initially screening will be offered to people turning 55 and 65 years of age and those who participated in the Pilot program. The results will be fully evaluated in 2007-08 with the aim of extending screening, if successful on clinical grounds, to all Australians over the age of fifty five.

The National Bowel Cancer Screening Program will be run along similar lines to the Pilot Program, with an immunochemical faecal occult blood test being mailed directly to eligible participants by a National Register, to be established and maintained by Medicare Australia (formerly the Health Insurance Commission). Almost one million Australians will be offered bowel cancer screening under this initial phase of the Program, which will commence in May 2006.

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