

## Impact on the target population

### Key evaluation findings

- The overall participation rate was 45.4%.
- Participation in Mackay (57.5%) was higher than in Adelaide (46.3%) and in Melbourne (39.9%).
- Participation was higher among women (47.4%) than men (43.4%), and for the two least disadvantaged quartiles.
- People with the following characteristics were more likely to participate in bowel cancer screening:
  - greater awareness of bowel cancer and the need for screening
  - a biological family history of bowel cancer
  - experience with other population screening or testing programs.
- The major reasons reported for taking part in the Pilot were 'precaution/prevention/early detection/health check important' and 'wanted to know whether had bowel cancer/peace of mind'.
- Direct invitation of eligible people through the mail was successful – indeed, 38% of people reported using and returning the FOBT because they received it in the mail.
- The major reasons reported for not responding to the invitation to participate in 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.
- There were mixed views on the supporting health promotion material provided with the invitation letter, with many indicating there was too much information provided.
- The six-weekly reminder letters had a substantial effect on subsequent participation. Whether or not the six-weekly reminder letter included an FOBT made no significant difference.
- Participants with a nominated GP who tested positive were advised to consult their GP, yet no timeframe was specified. Without a date specified, many felt the referral must not have been too important, whilst others were prone to put off the visit to a later date, only to forget to visit their GP at all.
- Participants reported that the follow-up process for colonoscopies generally worked well.
- A baseline survey conducted in each Pilot site prior to issuing invitations indicated 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% ever using such a test.
- A comparison of people's views expressed in a follow-up 2004 survey suggested that the Pilot successfully increased people's understanding and awareness of bowel cancer, FOBTs and the need for screening, and increased their intention to participate in screening.
- Participation tended 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.
- Lower participation arose from combination of factors, including language, cultural and practical barriers.

## **4.1 Background**

The impact on the target population needs to take into account the entire screening pathway, from invitation to participation, through to follow-up assessments with GPs and specialists where clinically indicated. The screening pathway for the Pilot tracked outcomes for participants from the initial invitation to participate in the Pilot through to colonoscopy results. Any participants diagnosed with bowel cancer were considered to have exited the screening program.

### **Community mobilisation**

Community mobilisation for the Pilot was undertaken at the local level primarily by health promotion officers. Each site used a variety of strategies and activities to promote bowel cancer screening through the Pilot. Awareness campaigns included the use of media releases, articles in newsletters, local radio interviews, television interviews on local news networks, information in local newspapers, and general awareness activities such as information booths at local shows and shopping centres. An example of a local media release used in the Mackay Pilot site is shown in Figure 4.1. These community mobilisation strategies are discussed in more detail in Chapter 8.

Community mobilisation also included strategies to encourage people from Aboriginal and Torres Strait Islander and culturally and linguistically diverse communities within the target population to participate in the Pilot (see Section 4.8).

### **Distribution mechanism**

Direct mail was successfully used as the mechanism for distributing the FOBTs and the means for participants to return their completed FOBT. The decision to proceed with direct mail as the distribution mechanism was based on an Australian and international study of effective invitation-to-screen methods (Implementation Committee 2001a).

In the initial design phase of the Pilot, consideration was given to the possibility of GPs distributing FOBTs. The Implementation Committee considered a range of factors including ensuring a uniform approach to invitation, the specific identification of the target population for the Pilot, demographics of the target population, the requirement to follow-up participants, cost issues, the amount of educational material required, and the potential impact on GP workload (Implementation Committee April 2001). After considering these issues, it was concluded that direct mail was the most appropriate method of invitation for the Pilot. This decision has been supported by the findings of the evaluation and further endorsed at the *National GP Workshop* held in August 2004 (see Chapter 6).

Figure 4.1: Example local media advertisement of Pilot



## MEDIA RELEASE

### MACKAY BOWEL CANCER SCREENING PILOT CONTINUES

Mackay is the only Queensland site involved in the National Bowel Cancer Screening Pilot Program. This pilot program aims to encourage early detection of the most commonly diagnosed cancer in Australia for men and women.

The pilot, which started late last year, is a joint initiative of the Commonwealth Department of Health & Ageing, Mackay Division of General Practice and Queensland Health.

Mackay's Bowel Cancer Screening Pilot Program involves more than 13,000 people aged between 55-74 years living in the postcode areas of 4740, 4741, 4750 and 4751.

Invitations to participate in the pilot are being sent alphabetically to residents, with invitations currently being sent to people with surnames GR-HA. The invitation contains information about the pilot and a bowel cancer screening test kit. The test kit can be undertaken by the participant at home and posted back to the laboratory at no cost to the participant.

Dr. David Parker said "if the results are positive participants will be advised to make an appointment with their GP for follow-up. If a follow up colonoscopy is required this will be arranged through the public or private sector at no cost to the participant as part of the pilot study."

"Many bowel cancers are preventable", Dr. David Parker said "To minimise the risk of bowel cancer, people should include plenty of breads, cereals, vegetables and fruits in their diet, do regular moderate exercise and maintain a healthy weight."

"However identifying bowel cancer early is also important, and that is where bowel cancer screening is vital" Dr. Parker said. "Early detection is the best protection, by finding bowel cancer early or before it is fully developed can significantly reduce your chances of dying from bowel cancer."

For further information about the pilot or if your community group caters for people aged 55-74 and would like a guest speaker, please phone **Jane Paine, the Bowel Cancer Pilot Health Promotion Officer** at Queensland Health's Mackay Community Health Centre on telephone 4968 3823.

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For further information contact

Rosemary Young BSCPP Project Officer at the Mackay Division of General Practice on 49534491 (all day Monday or Tuesday and Wednesday morning) or Dr David Parker at his surgery on 49577800.

## **Invitation package contents**

The invitation package that people were sent contained the following material:

- letter inviting people to participate in the Pilot;
- covering letter from HIC providing information on privacy issues;
- booklet on bowel cancer, bowel cancer screening and the Pilot;
- *Eat Well for Life: Dietary Guidelines for Older Australians* leaflet published by NHMRC;
- *Participant Details* form; and
- randomly allocated FOBT and its accompanying instructions.

A return reply-paid envelope was provided for participants to send their completed FOBT and *Participant Details* form to the pathology laboratory for processing.

## **Evaluation of Pilot impact on the target population**

The AIHW analysed Register data on the Pilot participation by personal characteristics, for example age and sex, across the three Pilot sites. There were additional key research projects commissioned by the Department that investigated people's views on bowel cancer, screening, and the impact of the Pilot on the target population.

### *Knowledge, Attitudes and Practices survey*

The Department commissioned Queensland Health to conduct computer assisted telephone interviews of the general population to ascertain their views on bowel cancer and bowel cancer screening. Queensland Health conducted two surveys across the three pilot sites to assess the knowledge, attitudes and practices of participants and non-participants in relation to bowel cancer and bowel cancer screening ('KAP Research'). The target population was randomly selected households in the Pilot postcode areas with at least one individual aged between 50 and 74 years. The first KAP survey was conducted in 2002 prior to the commencement of the Pilot (2,789 people interviewed), providing baseline data from which to evaluate the post-Pilot survey data gained from the second survey in 2004 (2,984 people interviewed) (Queensland Health 2004a, 2004b).

The KAP Research also included a specific survey of Pilot participants. The target population was households in the selected postcode areas with at least one individual who reported receiving an FOBT as part of the Pilot, completing the test and returning it to the laboratory for testing. There were 347 participants interviewed in total.

### *Qualitative research of the target population*

A qualitative study was also conducted through interviews with people invited to participate in the three Pilot sites ('Woolcott's Qualitative Research'). The key objectives of the study were to assess the relevant attitudes, opinions and behaviours that influenced participation in the Pilot, reactions to the invitation package material, and the factors affecting participation. The research was conducted as a large scale qualitative exercise, combining mini-group discussions and one-on-one in-depth interviews.

The research targeted three groups:<sup>11</sup>

- people who participated in the Pilot;
- people who were invited but did not participate; and
- Aboriginal and Torres Strait Islander people and people from culturally and linguistically diverse backgrounds.

Participants and non-participants were recruited at random from within each Pilot site, as follows:

- eight mini-groups were conducted amongst participants;
- four face-to-face in-depth interviews were conducted amongst participants who had been referred for a colonoscopy; and
- six mini-groups and seven face-to-face in-depth interviews were conducted with non-participants.

The research sought to understand the impact of the Pilot on knowledge, attitudes and behaviours regarding bowel cancer screening. This involved assessing people's:

- knowledge of and attitudes towards bowel cancer;
- response to the FOBTs;
- process of decision making about participation;
- perceived triggers and barriers to participation; and
- suggested improvements to the screening program.

#### *Specific community group research*

The Department established working groups to investigate issues arising from the Pilot for Aboriginal and Torres Strait Islander people (Aboriginal and Torres Strait Islander Working Group 2004) and people from culturally and linguistically diverse background (Multicultural Working Group 2004).

The Qualitative Research also included specific interviews with Aboriginal and Torres Strait Islander people and people from culturally and linguistically diverse backgrounds to obtain their perspectives on the Pilot (Cultural Perspectives 2004). A series of 60 in-depth interviews were conducted amongst people from culturally and linguistically diverse backgrounds and Aboriginal and Torres Strait Islander people in each of the Pilot sites (34 participants and 26 non-participants). These interviews included a mix of the language and cultural groups in each of the Pilot sites. (See Section 4.8)

## **4.2 Pilot participation rates**

### **Overall Pilot participation rates**

The Register issued 56,907 invitations to people in the eligible target population (excludes data from people invited who fell outside the target population or who were ineligible or inappropriate for the program).<sup>12</sup>

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<sup>11</sup> The research also targeted GPs involved in the Pilot, which is addressed separately in Chapter 6.

<sup>12</sup> See section 3.2

The data on the Pilot participation across the three Pilot sites are shown in Table 4.1 below, as at 1 October 2004.

Participation rates shown below are age-standardised to ensure comparisons between Pilot sites are not confounded by differences in the ages of people in the areas.

**Table 4.1: Number of participants by Pilot site**

Pilot Site	Males	Females	Persons
Adelaide	3,847	4,715	8,562
Mackay	3,076	3,270	6,346
Melbourne	5,030	5,902	10,932
Total	11,953	13,887	25,840

**Table 4.2: Age standardised participation rates by Pilot site (Rate per 100 invitations)**

Pilot Site	Males		Females		Persons	
	Participation Rate	95% Confidence Interval	Participation Rate	95% Confidence Interval	Participation Rate	95% Confidence Interval
Adelaide	44.2	42.9-45.7	48.3	46.9-49.7	46.3	45.4-47.3
Mackay	54.3	52.4-56.3	60.9	58.9-62.8	57.5	56.0-58.9
Melbourne	38.1	37.0-39.1	41.5	40.5-42.6	39.9	39.1-40.6
Total	43.4	42.6-44.2	47.4	46.6-48.2	45.4	44.9-46.0

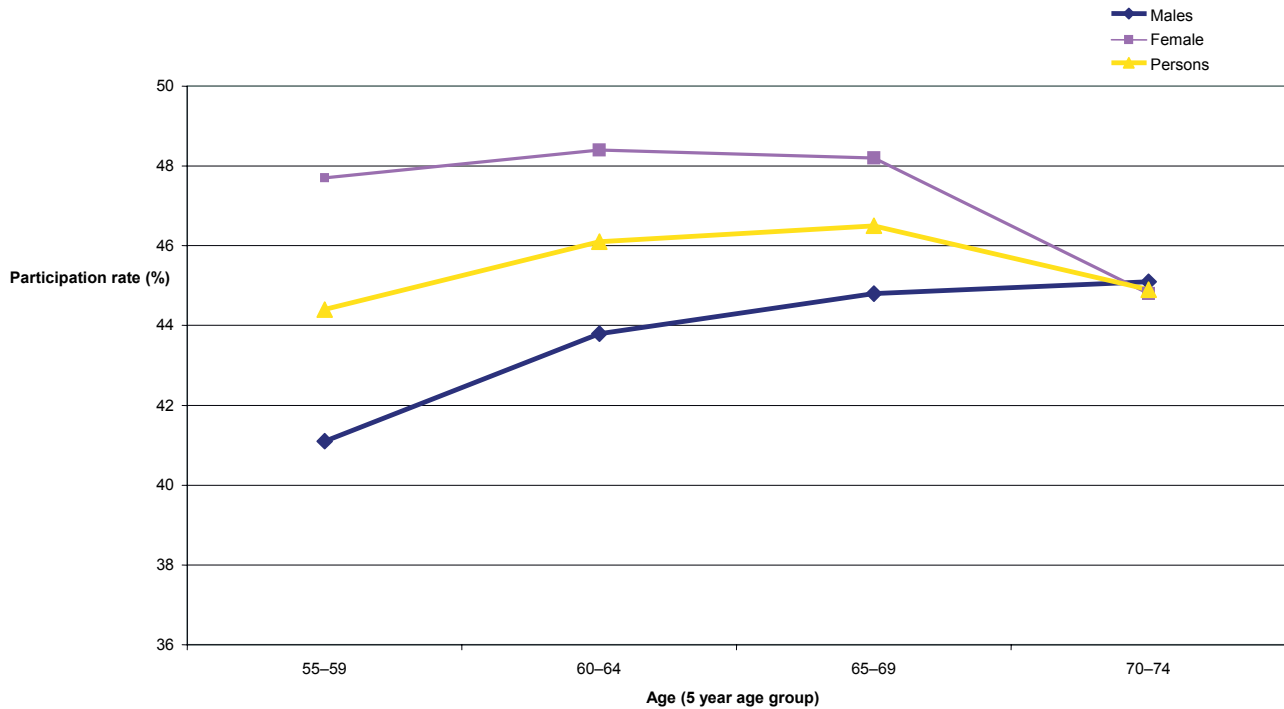
Source: AIHW (2004)

**Table 4.3: Participation rate by age and sex**

	Males	Females	Persons
Age Group	Rate per 100 invitations	Rate per 100 invitations	Rate per 100 invitations
55-59	41.1	47.7	44.4
60-64	43.8	48.4	46.1
65-69	44.8	48.2	46.5
70-74	45.1	44.8	44.9
Total	43.4	47.3	45.4
ASR	43.4	47.4	45.4
95% confidence interval	42.6-44.2	46.6-48.2	44.9-46.0

Source: AIHW (2004)

**Figure 4.2 Participation rate by age and gender**

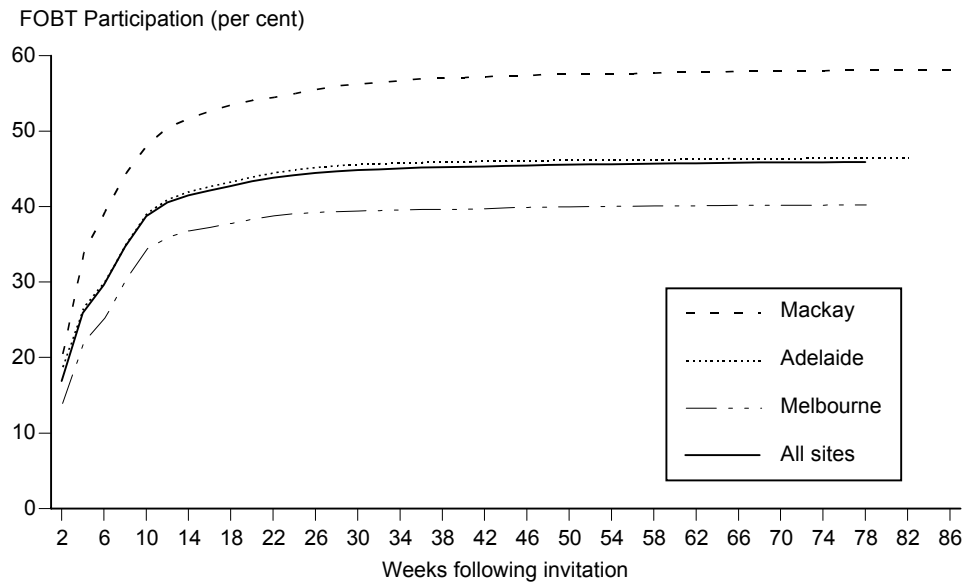


The key observations from these data are:

- a total of 25,840 eligible invited people responded by returning a completed FOBT, giving an overall participation rate of 45.4%;
- participation was significantly higher among women than men ( $p < .0001$ ), with 47.4% of invited women participating compared to a participation rate of 43.4% for men; and
- the participation rate in Mackay (57.5%) was higher than the rate in Adelaide (46.3%) and in Melbourne (39.9%).

The overall participation rate over the course of the Pilot is shown in Figure 4.2. The figure shows that participation reached a virtual plateau at around 24 weeks after invitation, with a subsequent increase of less than two percentage points after this time.

**Figure 4.2 Participation rate by weeks since invitation**



Source: AIHW (2004)

### 4.3 Factors influencing participation

The Knowledge, Attitudes, Practices (KAP) survey undertaken before and after the Pilot investigated the reasons for participation and non-participation in screening through the Pilot (Queensland Health 2004b). It found that people with the following characteristics were more likely to participate in the Pilot:

- a biological family history of bowel cancer;
- greater awareness of bowel cancer and the need for screening;<sup>13</sup> and
- experience with other screening programs.<sup>14</sup>

These findings suggest that greater awareness and discussion of bowel cancer in the community had a positive impact on promoting participation in bowel cancer screening.

The major reasons reported for participating in the Pilot were:

- ‘precaution/prevention/early detection/health check important’ (48%); and
- ‘wanted to know whether had bowel cancer/peace of mind’ (36%).

Only 2% of participants said that they would be unlikely or very unlikely to participate in FOBT screening in the future (Queensland Health 2004b).

<sup>13</sup> For example, participants could name and describe a sign or symptom of bowel cancer, identify bleeding, blood and/or mucus in bowel motions as a symptom of bowel cancer would strongly agreed with the statements ‘It is important to check for bowel cancer even if I have no symptoms’, ‘Treating bowel cancer in the early stages increases a person’s chance of survival’, ‘If bowel cancer is treated early a person may need less extensive treatment and may not need a colostomy bag’, strongly disagreed with the statement ‘Having a test like FOBT seems like more trouble than it’s worth’, knew of tests to check for bowel cancer, named and described the FOBT without interviewer prompting, recalled that they had heard of FOBT after interviewer descriptions and prompting.

<sup>14</sup> This included men who had had a prostate screening test in the last 2 years (however those who nominated bowel cancer as one of the two most prevalent male cancers were not more likely than others to have returned the FOBT) and women who had had a screening mammogram test in the last 2 years (however those who nominated bowel cancer as one of the two most prevalent female cancers were no more likely to have returned the FOBT).

The KAP Research also found that people aged 55-59 and those employed full-time were slightly less likely than others to have returned the FOBT. The proportion of people likely to return an FOBT did not differ significantly across different sex, marital status and education levels.

The major reasons reported for not taking part in the Pilot were:

- ‘already had other bowel tests’ (24%); and
- ‘lack of symptoms or ‘feeling well’ (16%).

Non-participants were less likely to recall having seen or heard information about FOBT than participants. The majority of non-participants reported that they would participate in FOBT screening in the future (84%), with a doctor’s recommendation a key consideration for non-participants. The likelihood of future participation in FOBT screening increased dramatically if a doctor’s recommendation was mentioned, compared to a screening program without promotion (whereas for Pilot participants the likelihood of future participation if a FOBT was mailed out was almost as high as with a doctor’s recommendation).

These findings were supported by Woolcott’s Qualitative Research of GPs and the target population in the Pilot sites which explored influencing factors in more depth and identified some common characteristics of Pilot participants (Woolcott 2004). It found that participants tended to be:

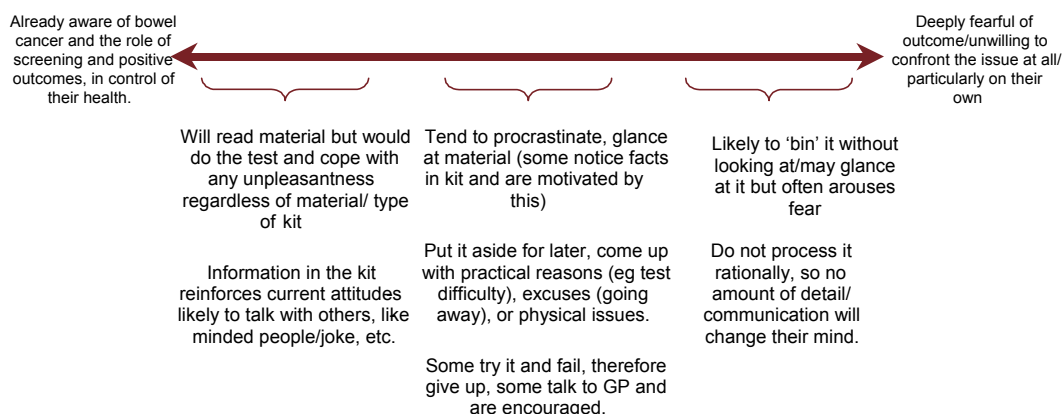
- people who felt they were more informed, involved and in control of their health;
- female, who tended to be more open and knowledgeable and more likely to visit their GP regularly;
- people with more active lifestyles; and
- people with a family history of bowel cancer and those whose close friends have suffered from bowel cancer.

The research also investigated views of people invited who chose not to participate. It found that non-participants tended to be:

- males, who were more likely to resist any screening due to a perceived ‘ruggedly independent’ persona, and relied more on their female partner to manage their health;
- people who relied on specific instructions from their GP (or relevant authority figure) to undertake testing;
- people with illnesses, disabilities and depression, due to a general feeling of being unable to cope with and confront potentially additional ‘bad news’; and
- Aboriginal and Torres Strait Islander people and people from culturally and linguistically diverse backgrounds, due to a combination of language barriers, i.e. the testing procedure was too complex, and cultural barriers, i.e. felt uncomfortable with any tests involving the bowel region and/or discussing the screening process with a GP and/or other family members and friends. (See Section 4.8).

The decision about whether or not to participate in the Pilot was examined to develop a clearer understanding of the acceptability to people of the screening process and contents of the invitation package. People’s attitudes to participation can be summarised on a continuum, shown in Figure 4.3.

**Figure 4.3: Continuum of attitudes regarding participation**



Source: Woolcott (2004)

In general, Woolcott's Qualitative Research found that the most powerful trigger to participate in the Pilot was a pre-existing attitude and desire to participate in screening and do whatever was necessary to ensure good health. People with such an attitude viewed the FOBT as a convenient and opportune means to take control and manage one's health better.

The research indicated that not all people invited to participate necessarily had such strong attitudes towards preventative health. This group of people had not formed strong opinions on screening (i.e. they fell in the centre of the continuum in Figure 4.3 above). There were a number of triggers for, and barriers to participation for this group:

- knowledge and attitudes regarding bowel cancer, including feelings of healthiness and infallibility as well as the amount of time available to be concerned about it;
- social norms, acceptance and support;
- the notion that by taking action one can make a positive difference to one's life and that of one's family and friends;
- general awareness of the range of health issues to address and look out for;
- encouragement of others to take tests and be more proactive (eg GP, wife, friends, authority figures, 'celebrity effect');
- breadth and depth of family bowel cancer history (many families worry about other types of cancer, with little prominence given to bowel cancer);
- number of other health, physical and personal problems already requiring attention; and
- perceived convenience, intrusiveness and relative efficacy of FOBT (a much stronger barrier than trigger) versus preference to leave it to medical professionals to conduct any tests.

The group of people at the right extreme of the continuum in Figure 4.3 was the least committed to screening.

The main barrier to participation was based on a fear of finding cancer and the subsequent belief that, despite the positive outcomes from screening:

- once found, ‘it’s all downhill’ based on knowledge of family and friends that died within a short timeframe (seen to be up to six months) of diagnosis;
- ‘it’s better not to know’; and
- fatalism – ‘it’s too late at 65’ (Woolcott 2004).

## **4.4 Views on the invitation package and FOBTs**

### **Initial response to receiving an FOBT**

A person’s initial reaction to the invitation package seemed to be a strong determinant of their willingness to participate in screening.<sup>15</sup> General reactions to the invitation pack from participants, and those people who indicated that they were intending to participate, included:

- the invitation was not a surprise as participants were more likely to have noticed publicity, particularly localised publicity such as local papers;
- they believed it was an easy solution to an issue some had already thought about;
- the testing process seemed relatively easy to follow, hence, many thought ‘why not’;
- they were more likely to have discussed the testing with their friends, hence helping to demystify bowel cancer and build up a social norm to participate in screening; and
- did not view the screening process as an intrusion on their privacy (Woolcott 2004).

General reactions to the invitation pack from non-participants included the following:

- usually less aware of the screening process and, therefore, less likely to consider participating;
- concerned that mail was used as the means of distributing and returning the tests and the size of the pack, which stuck out of some letterboxes causing embarrassment;
- concerned about the sheer volume of educational support material, which put them off completing the FOBT;
- any reference to ‘bowel’ on mail received was enough for some people to discard the FOBT without reading it;
- single people and some from culturally and linguistically diverse and religious backgrounds had nobody to talk to about the FOBT or felt uncomfortable doing so;
- the Pilot Helpline was not perceived as a personal contact point that provided a compelling face-to-face encouragement to do the test (unlike visiting a GP);
- the invitation immediately sparked thoughts of unpleasantness (illness, discomfort, death), providing an incentive to avoid the test; and
- concerned as to why they - and not someone else - had received the FOBT (Woolcott 2004).

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<sup>15</sup> This was generally the case. However, for some people there was a strong positive correlation between attitude and participation; these people were knowledgeable about bowel cancer and/or had a positive attitude to screening were likely to participate, irrespective of their reaction to the invitation package.

## Views on the FOBTs

The Pilot found that the overall reaction to the two FOBTs was mixed. As each person received only one of the two FOBTs the provision of explicit views on the relative merits of both FOBTs were not obtained. 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). The *Inform* FOBT was viewed as easier to use, but this posed some questions about its efficacy. There seemed to be a view that ‘if it’s not complex, it mustn’t be effective’ (Woolcott 2004). Table 4.4 summarises reactions to the FOBTs.

**Table 4.4: Specific reaction to the FOBTs**

DETECT		INFORM	
Positive	Negative	Positive	Negative
Looked more like a “proper” test/clearly identifiable/medical/more substantial/sample.	Instructions look marginally amateurish in presentation “photocopied” sheet, not official.	Instructions are easy to follow/relatively lighthearted and friendly in tone.	Does not look like a “kit”, more like a piece of direct mail.
The paper collecting sheet was thought a practical idea (quite a few men would squat onto it).	Looks more complicated/more difficult to do.	Looks easier/less close contact with stool/less complex.	Concern about efficacy of just a smear.
	Concern about having to urinate first.	Easy to use in practice/long brushes.	Difficult to reach stool - prefer the sheet.
			Concerns raised in the instructions about how to clean the toilet/ensure no BLU, etc.

Source: Woolcott (2004)

These views were consistent with the findings of the post-Pilot KAP (Queensland Health 2004b). The majority of participants interviewed (94%) found the FOBTs easy to use. The ‘brush’ *Inform* FOBT was found to be slightly easier to use than the ‘stick’ *Bayer Detect* FOBT. Ease of FOBT use was not associated with age or sex. Only 73 of the 1,269 participants interviewed reported not finding the test easy to use. The most commonly reported problem was that the paper became wet, sank or disintegrated (26 participants). Nearly all of these participants (n=23) had used the ‘stick’ (i.e. *Bayer Detect*) FOBT.

However, these findings were not consistent with the Pilot participation rates when analysed by type of FOBT. The data indicated that participation was significantly higher for people receiving the *Bayer Detect* FOBT (47.2%) than for those receiving the *Inform* FOBT (43.6%) (p<.0001).

Attitudes to the FOBTs were influenced to a degree by what people had heard and the articles that they had read (Woolcott 2004). Some people said that they were aware of new, more efficacious tests that had been developed in the last five years, and had questioned their GP as to the relative value of the FOBT received through the Pilot. This would suggest that information on the efficacy of FOBTs may increase the likelihood of participation in screening. Whilst many stated that they had received too much support material on the

screening program, which may have made it seem overly-complicated, education on the efficacy of the tests appeared to have a greater impact on participation.

### Views on support material contained in the invitation package

Educational information about bowel cancer appears to have equivocal effects on participation, be it through postal invitation or when distributed during an ‘opportunistic’ GP invitation (Implementation Committee 2001a). Feedback on the pros and cons of the supporting material included in the Pilot invitation pack is summarised in Table 4.5.

**Table 4.5: Specific reaction to supporting material**

ENVELOPE	LETTER	HIC LETTER	FORM	BOOKLET	DIETARY GUIDELINES
<p>Relatively innocuous and clear</p> <p>Looks “governmenty” and official</p> <p>A little too large for some</p>	<p>Main piece of communication</p> <p>Most likely element to be read</p> <p>Personal</p> <p>Around 90 die each week, an impactful fact/ but confronting</p> <p>Clear and to the point</p>	<p>Glanced at</p> <p>Unnecessary information, privacy not a concern</p> <p>Could be briefly referred to in the letter</p>	<p>Straightforward and predictable, no alarm or concern</p> <p>Normal government form</p> <p>The pressure of family history reinforces however that this has an impact and may suggest less relevance for those without family history</p> <p>Some symptoms “unexplained tiredness” quite common and causes concern</p>	<p>Good source of information for the more committed</p> <p>Non participants tended to only glance at it</p>	<p>Interesting information, but available elsewhere</p> <p>Extraneous</p>

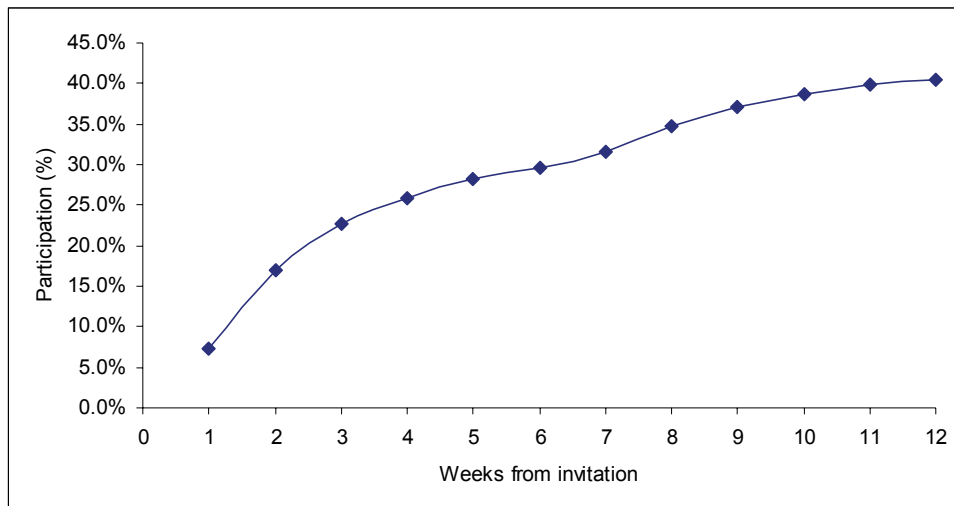
Source: Woolcott (2004)

## 4.5 Effect of reminder letters

The Register issued reminder letters to people for whom it had no FOBT result at six weeks after invitation to encourage them to participate in screening. The Register data indicated that reminder letters had a significant impact on participation. Figure 4.4 shows a rise in participation at 7-8 weeks, most likely caused by the reminder letter sent at six weeks.

It was not possible to directly measure the effect of the reminder letter as there was no control group which did not receive the letter for comparison. However, the AIHW modelled participation rates up to six weeks and projected these forward to calculate an estimate of participation without the reminder letter. If the trends in participation up to six weeks had continued, the final participation was projected to be around 30%. This compares with the actual participation of 45.4%, suggesting that the reminder letters had a substantial effect on subsequent participation.

**Figure 4.4: Participation since time of invitation**



Source: AIHW, discussions with HMA (5 November 2004)

The Pilot also sought to examine whether the reminder letter was more effective at increasing subsequent participation if it included another FOBT. The AIHW data indicated that there was no significant difference in subsequent participation following the reminder letter with or without the inclusion of an FOBT.

Woolcott's Qualitative Research suggested that the reminder letters appeared to have motivated a small proportion of non-participants, and those who had tried but failed to submit an initial test, to use and return an FOBT (Woolcott 2004). Some participants told their GP that they were sent reminder letters, even though some had already posted back their completed FOBT (see Chapter 3). Others reported incorrect details contained in the reminder letter.

## **4.6 Views on the referral process**

Follow-up of participants depended on their FOBT result. Participants posted their sample to the pathology laboratory for processing (see Chapter 5 for FOBT pathology processing times). Participants with a negative FOBT and no symptoms nor family history of bowel cancer were informed that they would receive another invitation 'when their next screening is due'. If participants suspected a family history and/or symptoms of bowel cancer, the invitation information recommended that they visit their GP as a precaution or contact the Pilot Helpline for further information. Participants returning a negative FOBT result who indicated that they had the symptom of rectal bleeding or indicated a family history of bowel cancer were sent a reminder letter informing them that they should attend their GP for advice.

Participants with a positive FOBT were advised of their FOBT result in a letter from the pathology laboratory. The letter advised them to visit their GP for advice and a likely referral to a specialist for a follow-up colonoscopy.

Those participants who required follow-up colonoscopy reported that the referral process generally worked well. However, some GPs reported that their patients had told them about high levels of anxiety, and feared that there were not enough specialists to cope with demand.

Similarly, GPs reported that patients felt that waiting times for colonoscopies were at times excessive (Woolcott 2004).

In Woolcott's Qualitative Research, some participants reported being uncomfortable with the lack of clarity in the referral process (Woolcott 2004). For example, some participants who had received a positive FOBT result and who had not nominated a GP claimed that they were not followed-up and/or did not have their GP providing suitable encouragement to visit a specialist for a follow-up colonoscopy. Others who had nominated a GP were advised to consult their GP, yet no timeframe was specified. Without a date specified, many felt the referral must not have been too important, whilst others were prone to put off the visit to a later date, only to forget to visit their GP at all.

## **4.7 Knowledge about bowel cancer pre and post Pilot**

The KAP Research baseline survey, conducted prior to commencement of invitations to participate in screening, suggested that awareness among Australians of bowel cancer and FOBT screening aimed at its early detection was relatively low.<sup>16</sup> In 2002, only 43% of those surveyed had heard of an FOBT and only 26% had ever used such a test (Queensland Health 2004b). Woolcott's Qualitative Research also suggested that bowel cancer had a low profile, even though many people interviewed had known somebody who had died from the disease (Woolcott 2004). This low profile was further compounded by a lack of 'celebrities' that have spoken out about bowel cancer, in combination with the relative taboo of speaking about the bowel. In general bowel cancer was assumed by the focus group participants to be:

- rarer than breast/cervix/brain (tumours)/prostate cancer;
- relatively final and unpleasant once discovered;
- associated with males;
- an older persons (65+) disease;
- strongly associated with family history; and
- easily identified by 'obvious' symptoms.

Furthermore, focus groups considered the appearance of symptoms to be the time to seek help, usually at the encouragement of a GP or close family member.

The KAP Research 2004 follow-up survey undertaken near the completion of the Pilot assessed changes in views and behaviours since the 2002 baseline survey. A comparison of people's views expressed in the 2004 survey with those interviewed in the 2002 baseline survey suggests that the Pilot successfully increased people's understanding and awareness of bowel cancer, the need for screening and the use of FOBTs. For example, the 2004 respondents were more likely to:

- report a biological family history of bowel cancer and to have had bowel tests other than FOBT;
- identify bleeding/blood/mucus from bowel motions as a symptom of bowel cancer;
- perceive that they thought it was 'very likely' or 'likely' that they would develop bowel cancer in their lifetime;

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<sup>16</sup> There was a total of 2,984 responses to the surveys with an overall response rate of 75.9% and contact rate of 86.2%.

- recognise the importance of screening for bowel cancer;<sup>17</sup> and
- be aware of tests to check for bowel cancer.

The likelihood of participation in a future FOBT screening program also increased substantially between 2002 and 2004. Most of the shift was from the ‘highly likely’ category to the ‘very highly likely’ category. The percentage of respondents who would be ‘very highly likely’ to participate regardless of screening method/approach used more than doubled from 24% in 2002 to 56% in 2004 (Queensland Health 2004b).

Among non-participants in the Pilot, 23.7% reported not completing the test due to already completing other bowel tests. A further 15.5% reported no symptoms and 10.5% said it was due to embarrassment or distaste with stool collection. However, 39.8% indicated they were either likely or very likely to participate in a future FOBT based screening program, increasing to 52.6% if the kit was mailed out or 83.5% if a doctor recommended they complete the test.

Among Pilot participants, 90.6% indicated that they were either very likely or likely to participate in an FOBT based screening program in the future. This increased to 96.9% if the kit was mailed to them.

A summary of survey responses for 2002 and 2004 for some key awareness indicators is shown in Table 4.6.

**Table 4.6: KAP Survey data indicators, 2002 compared with 2004**

KAP area	2002	2004
Aware of FOBT	41%	81%
Completed FOBT	26%	43%
Proportion of respondents who named or described FOBT without prompting from the interviewer	30%	69%
Proportion of respondents who recalled having heard of FOBT after interviewer descriptions	43%	84%
Proportion of men who named bowel cancer as one of the two most common male cancers	42%	50%
Proportion of women who named bowel cancer as one of the two most common female cancers	20%	25%
Proportion of respondents that are ‘very likely’ or ‘likely’ to participate in bowel cancer screening in the future	47%	74%
Proportion of respondents that are ‘very likely’ or ‘likely’ to participate in bowel cancer screening in the future if it were known the tests were recommended by the Health Department	82%	87%
Proportion of respondents that are ‘very likely’ or ‘likely’ to participate in bowel cancer screening in the future if the recommendation came from their doctor	93%	94%

Woolcott’s Qualitative Research reported that the general consensus from the focus groups was that the role of government (State and Federal) should be to inform and provide options for health management. However, they also recognised that active participation in such health management programs should ultimately rest with the individual. In relation to bowel cancer

<sup>17</sup> For example, 2004 respondents were more likely to strongly agree with the statements ‘It is important to check for bowel cancer even if I have no symptoms’, ‘Treating bowel cancer in the early stages increases a person’s chance of survival’, ‘If bowel cancer is treated early a person may need less extensive treatment and may not need a colostomy bag’, and to strongly disagree with the statement ‘Having a test like FOBT seems like more trouble than it’s worth’.

screening, the majority were in favour of government initiated screening, with many supportive of free screening, viewing this as a positive contribution to the community.

## **4.8 Participation by specific Population Groups**

An Aboriginal and Torres Strait Islander Working Group was established to provide a mechanism to facilitate Aboriginal and Torres Strait Islander participation in the Pilot. This Working Group provided expert advice on Aboriginal and Torres Strait Islander related issues within the Pilot, and strategies to address these issues in the event of a national program (Aboriginal and Torres Strait Islander Working Group 2004).

A Multicultural Working Group, with representatives from each Pilot site who had direct experience working with people with culturally and linguistically diverse backgrounds, was also established. This Working Group provided expertise on issues associated with mobilising people from culturally and linguistically diverse backgrounds and addressing their specific needs (Multicultural Working Group 2004). They also communicated pilot findings to people from culturally and linguistically diverse backgrounds. The research included information sessions, surveys and telephone interviews, feedback from bilingual health educators, and a multi-lingual cancer information help-line to target culturally and linguistically diverse communities during the Pilot program.

Woolcott's Qualitative Research also included 60 focussed, in-depth, interviews with Aboriginal and Torres Strait Islander people and people from culturally and linguistically diverse backgrounds who did and did not participate in screening, to obtain their views on the Pilot and on bowel cancer screening in general.

The monitoring of the Pilot examined participation rates for people: of Aboriginal and Torres Strait Islander descent; and who speak a language other than English (self-identified). Analysis was also carried out to assess whether there was any significant variations in participation or outcomes for people by socioeconomic disadvantage.

### **Materials translated for the Pilot**

Key Pilot information was translated into the most commonly spoken languages used in the Pilot sites in the 55-74 year age bracket. An analysis of the Pilot site composition by age group and languages spoken at home indicated that the requisite languages for translation were Arabic, Chinese, Croatian, Dutch, German, Greek, Italian, Khmer, Macedonian, Maltese, Polish, Tagalog, and Vietnamese. The objectives of translating documents and posting them on the Pilot web site were to:

- support site specific community mobilisation strategies by providing resources in languages relevant to that community;
- demystify bowel cancer, FOBT, colonoscopy and the Pilot for culturally and linguistically diverse target population who were not comfortable/familiar with the English language;
- provide a direct, user friendly, on-line service to the culturally and linguistically diverse population of the Pilot sites; and
- assist relevant community groups, for example, migrant resource centres, in the Pilot sites to inform and empower their clients by providing access to Pilot information in other languages.

The translated materials were part of a broader collection of communication and educational resources being used to inform health service providers and other stakeholders about the Pilot, bowel cancer and screening. The resources translated included:

- invitation letter: invitation to participate in the Pilot, explanation of the Pilot and screening process;
- participant booklets (part of the invitation pack): an overview of the Pilot, bowel cancer, FOBT screening and colonoscopy;
- the *Participant Details* form: agreement to participate in the Pilot, availability of test results, pertinent medical questions on symptoms and family history of bowel cancer;
- bookmarks: directed people from diverse cultural backgrounds to the appropriate points of contact for further information in their chosen language;
- Pilot brochure: a précis of information on bowel cancer, screening and the Pilot;
- colonoscopy brochure: a pamphlet to empower the participant with a positive FOBT to obtain further information about the colonoscopy procedure from their GP or specialist;
- patient fact sheet on colonoscopy and patient fact sheet on bowel cancer: two single pages to inform participants about bowel cancer and colonoscopy to be provided by the GP to the Pilot participant during consultation; and
- presentations for community meetings on the Pilot, bowel cancer and colonoscopy.

All relevant stakeholder organisations were informed that the materials were available on-line to ensure access to these resources by the target group and community organisations.

### **Pilot participation rate by indigenous status**

The number of participants identifying as Aboriginal or Torres Strait Islander people was too small to allow analysis adjusted by Pilot site. However, the overall response rate was significantly lower for Aboriginal and Torres Strait Islander people than the general population after adjusting for age and sex ( $p < 0.0001$ ). This result should be treated with caution as it relies on self identification on the participant form and there are difficulties in obtaining reliable population data to use in calculation of rates.

There was no significant difference in the participation rate between Aboriginal and Torres Strait Islander men and women ( $p = 0.99$ ).

### **Pilot participation rate by language group**

Participants were asked to self identify on their *Participant Details Form* if they spoke a language other than English.

The participation rates in Mackay were significantly higher for people who spoke a language other than English, taken as a single group, than for English speakers (87.4% versus 55.7%). However, this result was based on small numbers and may be affected by a mismatch between the numerator and denominator of the rate estimates.

In the Adelaide Pilot site, the participation rates were significantly lower for people who spoke a language other than English, taken as a single group, than English speakers (49.9%).

For Greek speakers, the participation rate was estimated at 27%, compared with 31.6% for Italian speakers and 41.3% for other non-English speakers.

In the Melbourne Pilot site, participation rates for Greek speakers (20.9%) and Italian speakers (38.1%) were significantly lower than for speakers of another non-English language (43.0%), after adjusting for confounders. Participation rates for speakers of other non-English languages were not significantly different from rates for English speakers (42.2%).

### **Pilot participation rate by quartile of socioeconomic disadvantage**

Analysis of socioeconomic factors was carried out by allocating postcodes against the Australian Bureau of Statistics Index of Relative Socio-Economic Disadvantage (ABS 2003).

The participation rate in Adelaide was higher for the two least disadvantaged quartiles (48.5% and 50.6%) than the two most disadvantaged quartiles (37.1% and 39.5%). Similarly, the participation rate in Melbourne was higher for the least disadvantaged quartile (46.1%) than for the other three quartiles of socioeconomic disadvantage (37.3%, 24.9% and 36.6%). The very low participation for quartile 3 is based on limited data and should be treated with caution.

There was no significant difference between participation rates by quartile of socioeconomic disadvantage in Mackay, but this result is based on limited data and should be treated with caution. However, there was a higher participation rate overall for Mackay which may in part explain the lack of difference, as typically early adopters of screening programs are the least disadvantaged groups.

### **General attitudes towards cancer and cancer screening**

Cultural beliefs play an important role in whether people seek early diagnosis, how they understand disease and the kind of support they are willing to accept. The interviews with Aboriginal and Torres Strait Islander people and people from culturally and linguistically diverse backgrounds demonstrated a lower level general awareness of bowel cancer, particularly amongst the Aboriginal and Torres Strait Islander group (Woolcott 2004). This was often dependent on personal experiences of bowel cancer, usually through friends and family.

#### *Fatalism and cancer*

Fatalism, or the belief that death is inevitable when cancer is detected, has been found to be more prevalent among some members of a culturally and linguistically diverse community. Research suggests that those who believed life events such as cancer are fated were less likely to participate in screening programs for the detection of breast and cervical cancer (Multicultural Working Group 2004). The Multicultural Working Group found that members of the culturally and linguistically diverse community interviewed tended to speak about cancer as a *cause that they could not control* rather than a risk that they could seek to avoid.

### *Fear of cancer*

Fear of cancer was another theme in the research with culturally and linguistically diverse communities that seemingly acts as a barrier to screening and detection (Multicultural Working Group). Two kinds of fears were commonly discussed. The first is fear of a cancer diagnosis (more common with Australian born participants). Some culturally and linguistically diverse people interviewed said that they did not want to associate with bowel cancer (eg 'when I saw the words bowel cancer... I didn't want to open the pack, I put it aside') (Woolcott 2004). The second fear relates to the 'taboo' about discussing cancer. Many non-Western cultures believe that the spoken word has the power to create as well as describe reality (i.e. it is best not to pre-empt any bad luck).

### *Perceptions of 'health'*

Many people from culturally and linguistically diverse backgrounds view health in the context of fostering and maintaining family relationships, rather than viewing their own wellbeing as separate from that of other family members (Multicultural Working Group 2004). Women in particular may be predisposed due to cultural factors to put the well being of the entire family group before their own health.

Aboriginal and Torres Strait Islander health traditionally includes spiritual and social wellbeing, with sickness often attributed to a spiritual or external cause. Many see the health system as a place to go when one is sick or about to die. There is an associated belief that cancer equates to death, and the concept of population screening is totally foreign (Aboriginal and Torres Strait Islander Working Group 2004). The Aboriginal and Torres Strait Islander people who were invited to participate and interviewed tended to be the least proactive about their health (Woolcott 2004).

### *Other research findings from the Victorian Pilot site*

During the Pilot, the Cancer Council of Victoria used its Community Language Program to deliver free, multilingual information sessions about bowel cancer and the Pilot to multicultural community groups (Multicultural Working Group 2004).<sup>18</sup> Results from the research (a simple, one-page survey covering awareness, knowledge and attitudes about bowel cancer and intent to undertake a FOBT) found:

- support for the Pilot was high with 95% indicating that they thought the program was a 'good' or 'very good' idea and 74% indicating that they would be 'likely' or 'very likely' to complete a test if it involved taking a small sample of their bowel motion;
- there was a generally low level of knowledge of bowel cancer and screening processes at the initial survey;
- before the information session, Greeks were more likely than the other groups to think that a bowel cancer test would be difficult to complete; and
- English and Greek speakers reported they had learnt more from the sessions.

Participants were positively disposed toward bowel cancer screening and gained some knowledge of the process and the disease by attending the education sessions. The relatively small numbers completing the follow-up survey and the low overall participation rate meant

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<sup>18</sup>A full report of the Bowel Program Information Session Study (Greek, Italian and English) is available from the Cancer Council Victoria.

that in most cases it was not possible to measure any change in knowledge or attitude following the information session, nor make comparisons between language groups.

### **Reactions to the FOBT invitation**

The invitation letter and accompanying material, which were written in English, appeared to be problematic for people from culturally and linguistically diverse backgrounds. Whilst evidence is anecdotal, this group repeatedly mentioned difficulties such as:

- inability to understand the letter of invitation because nothing was translated;
- inability to access information in appropriate language;
- frustration, anxiety and fear; and
- inability to follow FOBT instructions because they were not translated (Multicultural Working Group 2004).

Generally, Aboriginal and Torres Strait Islander people or people from culturally and linguistically diverse backgrounds interviewed felt that there was too much supporting information material in the invitation pack. This resulted in confusion and difficulty in identifying what to send back. Some people from culturally and linguistically diverse backgrounds commented that the translated material was not presented clearly. A few people from culturally and linguistically diverse backgrounds would have liked to have seen more culturally specific foods listed in the dietary guidelines. There was very little interest in the web-based information. It appears that in some respects the Pilot was unable to effectively address specific needs of these groups, particularly in relation to implementing suitable models of communication.

Aboriginal and Torres Strait Islander people and people from culturally and linguistically diverse backgrounds did not have any concerns regarding privacy, that is, the use of Medicare details to identify prospective participants or their GP receiving a copy of their test result (Woolcott 2004).

### **Triggers for participation**

In Melbourne, many of the Chinese and Greek participants interviewed had seen or heard promotion on the Pilot prior to receiving their invitation package, and those that had seen promotional material were more likely to participate. Italian and Vietnamese participants were less likely to have seen promotional material on the Pilot. Italian participants were initially apprehensive that they were specifically targeted because there was something wrong with them, however, these concerns were allayed by subsequent media, and discussions with GPs and/or family members (Woolcott 2004).

The Aboriginal and Torres Strait Islander participants were more likely to have seen promotional material prior to receiving the FOBT (Woolcott 2004). They reacted positively to the invitation and appreciated the opportunity to check their health free of charge, in the privacy of their own home. Participants also tended to be more literate and more likely to ask for third party support.

A number of Aboriginal and Torres Strait Islander people interviewed reported regretting not completing the FOBT after subsequently talking to a health worker, seeing television advertising or talking to friends.

Interviews with Aboriginal and Torres Strait Islander people and people from culturally and linguistically diverse backgrounds identified a number of factors that triggered participation in the Pilot. These included:

- media, which helped raise awareness and acted as a reminder to complete the FOBT;
- consultation with GPs, which provided confidence in the process;
- contact and encouragement from community health workers (Aboriginal and Torres Strait Islander participants);
- family support, particularly for assistance in translating the information in the invitation pack;
- information sessions (Greek participants);
- the fact that the test was free of charge (Chinese and Aboriginal and Torres Strait Islander participants in particular); and
- little effort required (Italian).

‘Peace of mind’ and a sense of privilege associated with participation (particularly Aboriginal and Torres Strait Islander and Chinese participants) were also mentioned as motivational influences for participating in the Pilot. Culturally and linguistically diverse participants also acknowledged the benefits of preventative medicine. This was not a motivating influence for Aboriginal and Torres Strait Islander participants (Woolcott 2004).

### **Practical barriers to screening**

There were a number of specific issues that acted as barriers to Aboriginal and Torres Strait Islander and culturally and linguistically diverse community participation in the Pilot, and other population screening programs.

#### *Language and literacy issues*

Language and literacy constraints across all cultural groups are a common barrier to perceived self-efficacy and participation in cancer screening programs (Multicultural Working Group 2004). The FOBT was a self-administered test, unlike many other health professional administered screening procedures, so language and literacy issues stand to considerably impede participation. Language and literacy issues may also impact on knowledge about disease relevance, symptoms and progression, which has implications for screening behaviour.

Language appeared to be the most significant barrier to participation for these groups. Interviews with Aboriginal and Torres Strait Islander people and people from culturally and linguistically diverse backgrounds discovered that many opened the invitation, but put it aside because of language difficulties (Multicultural Working Group 2004). They remembered its arrival in the mail, but found the information too difficult and did not complete the FOBT. Further, many people from culturally and linguistically diverse backgrounds also asked for third party assistance in understanding the information. Aboriginal and Torres Strait Islander people were the least likely to seek third party assistance.

Low level of literacy is an important and frequently overlooked factor influencing cancer screening behaviours among people from culturally and linguistically diverse backgrounds and Aboriginal and Torres Strait Islander people. Low literacy levels have been linked to

poor health status, a general lack of knowledge about health and problems with instructions given by healthcare providers, including instructions on screening programs and materials.

Some Aboriginal and Torres Strait Islander people interviewed raised literacy as an issue, stating that they were unable to comprehend the invitation pack (Woolcott 2004).

#### *Lack of experience with the concept of health screening*

There is a general lack of understanding about the benefits of population screening within some communities. Some culturally and linguistically diverse communities find cancer or cancer screening a particularly shameful or embarrassing prospect. A number of studies have demonstrated some culturally and linguistically diverse groups have a tendency to perceive the doctor as the originating source of all health treatment (Multicultural Working Group 2004).

A lack of awareness of bowel cancer and an inability to understand the purpose and/or the nature of screening was identified as a significant barrier to participation in the Pilot for Aboriginal and Torres Strait Islander people (Woolcott 2004). Some Aboriginal and Torres Strait Islander women were embarrassed by the thought of the process. Some people from culturally and linguistically diverse backgrounds commented that they felt healthy, so they did not see the need for screening (Multicultural Working Group 2004).

#### *Lack of understanding of the Australian health care system*

Many people from culturally and linguistically diverse backgrounds hold a culture of suspicion and fear of 'officialdom' and of people in 'authority', which is exacerbated by a lack of understanding of policymaking, the bureaucracy, services, and service providers (Multicultural Working Group 2004). For example, there is a widespread lack of knowledge about services and how they operate, which leads to marginalisation and the lack of a sense of ownership and participation in services and service provision. Similarly, some Aboriginal and Torres Strait Islander people report being afraid of the health system as they had seen so many of their people die within it (Aboriginal and Torres Strait Islander Working Group 2004).

#### *Difficulties with postal contact*

A further difficulty for screening in Aboriginal and Torres Strait Islander populations is postal contact, used as the invitation distribution mechanism in the Pilot. Some Aboriginal and Torres Strait Islander people do not have a fixed address or are at a given address on an infrequent basis (Aboriginal and Torres Strait Islander Working Group 2004). This is also a problem more generally for some people in lower socioeconomic groups. This makes delivering an FOBT invitation problematic.

#### *Different demographic features*

There are difficulties in screening for Aboriginal and Torres Strait Islander populations arising from the demographic profile of these groups (Aboriginal and Torres Strait Islander Working Group 2004). Social and economic deprivation is associated with poor health, particularly prevalent in Aboriginal and Torres Strait Islander communities. This results in a different age profile in relation to health problems. Many Aboriginal and Torres Strait Islander people develop health problems at an earlier age, which would be under the target age level of 55 years.

### *Relationship with GPs*

Culturally and linguistically diverse people generally saw their doctor as the expert and would defer responsibility to their GP if they were worried about their health. Some reported that they did not participate in the Pilot because their GP did not say that it was compulsory (Multicultural Working Group 2004).

Some Aboriginal and Torres Strait Islander people experience difficulties in accessing GPs, or do not tend to use GPs (Aboriginal and Torres Strait Islander Working Group 2004). In the Aboriginal and Torres Strait Islander community there is a far greater reliance on community health services and local hospitals, particularly in rural and remote areas.

#### **Issues for possible further exploration**

- Assessment of how negative perceptions of FOBTs can be better addressed in written and media communication messages about FOBT.
- Simplification of instructions for completion of FOBTs, with inclusion of information about the science and accuracy of FOBTs.
- Inclusion of more specific information in relation to visiting a GP in the event of a positive FOBT result. For example, by including a recommended maximum waiting time before visiting a GP for referral.
- Exploration of the use of a spokesperson or public face for bowel cancer screening.
- Education for GPs on their important role in preparing their patients for receiving an FOBT and for encouraging them to participate in organised bowel cancer screening.
- Simplification of invitation letter to a lower level reading age, consideration of the amount of material sent to eligible people, and assessment of the usefulness of including a very brief amount of material translated into key community languages.
- Explore more flexible methods of invitation to support participation of people with no fixed address, for example possible recruitment of Aboriginal and Torres Strait Islander people through Aboriginal Medical Services.
- Investigate options for the provision of telephone information and support in languages other than English.

## Performance of screening tests and pathology

### Key evaluation findings

- Two types of FOBTs (Bayer Detect and Inform), and the pathology processing for each, were used successfully in the Pilot.
- The Register sent out a total of 79,192 FOBTs to eligible Pilot participants, 39,698 Inform and 39,494 Bayer Detect FOBTs.
- Pathology laboratories received 27,064 completed FOBTs from eligible Pilot participants (12,821 Inform and 14,243 Bayer Detect), of which 25,688 (95%) were correctly completed.
- Of the 25,688 correctly completed FOBTs, 2,317 returned a positive result, giving an overall positivity rate for the Pilot of 9.0%, with a higher rate in men and amongst older participants.
- Available colonoscopy results for participants with a positive FOBT indicated that there were 67 suspected or confirmed cancers and 176 advanced adenomas (See Chapter 7 for clinical outcomes of colonoscopy).
- This results in a positive predictive value for suspected cancers and advanced adenomas across both FOBTs of 19.2%.
- This compares with a positive predictive value of 7.5% for people who proceeded to colonoscopy without a positive FOBT for family history and/or symptoms of bowel cancer.
- Overall, pathology laboratories thought that the Pilot FOBT processing model worked well. However greater use of electronic data transfer to the Register would be a significant improvement.

### 5.1 Background

Randomised controlled clinical trials at the population level have indicated that screening using FOBTs, in populations selected on the basis of age, can reduce overall mortality from bowel cancer by 15-33% (Hardcastle 1996, Kronborg 1996 & Mandel 1993). In screening programs a person with a positive FOBT result was shown to have a 30-45% chance of having an adenoma, and a 3-5% chance of bowel cancer (NHMRC 1999). An FOBT is an aid to early diagnosis of bowel cancers and significant adenomas in the target population. It is not a diagnostic test. An FOBT is designed to detect the presence of microscopic amounts of occult or hidden blood in faeces. Where blood is detected, the FOBT result is positive and further diagnostic tests are required to determine whether there is a cancer or other abnormality present in the bowel. Pilot participants with a positive FOBT were identified for further assessment, which was usually colonoscopy.

## **Rationale for immunochemical FOBT**

There are two main types of FOBT; immunochemical tests and traditional chemical (guaiac) tests. Immunochemical FOBTs use antibodies against human haemoglobin, whereas the guaiac test is based on detection of the pseudoperoxidase activity of haem. (UK CRC Evaluation Team 2003). Immunochemical FOBTs were selected as the preferred testing method for the Pilot as, in contrast to guaiac FOBTs, they have no potential for interference by diet or medication.

When using guaiac FOBTs, a person should not consume red meat, specific fruit and vegetables (for example, raw broccoli) vitamin C supplements, aspirin or anti-inflammatory drugs for three days prior to taking their first test sample and throughout the testing period (UK CRC Evaluation Team 2003). The immunochemical FOBTs were therefore seen to be less intrusive, more reliable, more acceptable and more likely to achieve higher participation rates. Further, there are advantages in the automated technology processing available for several immunochemical FOBTs (DoHA 2002).

## **FOBT suppliers for the Pilot**

As a result of a competitive tender process, the two FOBTs used in the Pilot were:

- (1) **Bayer's *Bayer Detect* product (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) **Enterix's *Inform* product.** This product uses a brush to collect material from the stool which is then pressed on a test card. A sample is collected from two separate bowel motions.

People within the target population were randomly allocated one of the two FOBTs. The Register sent an invitation pack that included an FOBT to people in the eligible target population by mail. Eligible people in the same household were sent the same type of FOBT and were invited to participate at the same time. With both types of FOBTs, samples were collected by the participant at home. Participants who required help completing their FOBT or had difficulty understanding the test instructions could contact a dedicated freecall telephone helpline for assistance.

## **Pathology processing arrangements**

Pathology analysis of the completed *Inform* FOBTs was undertaken by Enterix Australia based in Sydney. Pathology analysis of the completed *Bayer Detect* FOBTs was undertaken by Mayne Dorevitch Pathology based in Melbourne. Participants posted their completed FOBT, together with their *Participant Details* form, to the relevant pathology laboratory for analysis using the return post paid envelope provided. Completed FOBTs were analysed in accordance with manufacturers' specifications. The results of the analysis of the FOBT were either negative/no blood detected, positive/blood detected or inconclusive.

The pathology laboratory mailed written results of the participant’s FOBT pathology to:

- the participant;
- the participant’s nominated GP; and
- the Register.

Pilot participants with a positive FOBT were advised to see their GP without delay for referral for assessment, usually a colonoscopy. Pilot participants with a negative result were advised they would be invited to do the test again in the future, but to visit their GP if they developed symptoms or became aware of a family history in the interim.

In cases where the results of the FOBT analysis were the sample was unsatisfactory or the results were inconclusive, the pathology laboratory contacted the participant and advised them to complete another FOBT. The pathology laboratory then contacted the Register to arrange for a replacement FOBT to be sent to the participant. The pathology laboratory also contacted participants in the following circumstances, either directly or via HIC:

- if the participant<sup>19</sup> had not nominated a GP;
- if the participant had not signed the *Participant Details Form*; and/or
- if the participant had not provided all details on the *Participant Details Form*.

Laboratories recorded both qualitative and quantitative results for both FOBTs to support future analysis of the impact of adjusting positivity cut-off points.

## 5.2 FOBT supply during the Pilot

The Department ordered FOBTs direct from each FOBT supplier in batches of 5,000. The FOBT suppliers delivered the FOBTs to HIC, where they were stored until they were mailed out. FOBT suppliers were contracted to provide FOBTs within six weeks of order. Throughout the Pilot, HIC provided FOBT stock level reports to the Department, which monitored the stock levels and ordered FOBTs as required, allowing enough time for the delivery of the kits. The total number of FOBTs sent out by the Register was 84,259, of which 79,192 were sent to eligible participants (Table 5.1). These figures include the additional FOBTs that were resent to participants upon request and FOBTs sent with the six-weekly reminder letters.

**Table 5.1: Number of FOBTs sent out by FOBT type**

	<b>Inform</b>	<b>Bayer Detect</b>	<b>All</b>
All FOBTs sent out by Register	42,175	42,084	84,259
FOBTs sent out by Register to eligible people	39,698	39,494	79,192

Source: AIHW

Each supplier was responsible for providing instructions for completion of their FOBT in a range of languages, which were provided to the HIC for distribution to Pilot participants as required.

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<sup>19</sup> See section 3.2 for more information on those people who were sent kits but are not classified as eligible.

There was an initial issue in the availability of *Bayer Detect* FOBTs towards the beginning of the Pilot (there was a two month supply lag as the FOBTs needed to be imported from Japan). Otherwise both FOBT suppliers effectively met supply demand from the Pilot. In a national program there would need to be accurate forecasting of demand for FOBTs, which should be communicated to FOBT suppliers so that they can effectively manage FOBT manufacture and supply arrangements.

### 5.3 Pathology analysis of FOBTs

#### Number of FOBTs received

The data held by the Register shows that of the total 84,259 FOBTs sent out to the target population, 28,438 were returned to the pathology laboratories (34%). Similarly, of the 79,192 FOBTs sent to eligible Pilot participants, 27,064 were returned and processed by the pathology laboratories (34%).<sup>20</sup>

#### Proportion of returned FOBTs correctly completed

Pathology laboratories categorised returned FOBTs into four groups: ‘correctly completed’, ‘incorrectly completed’, ‘damaged’ or ‘unsatisfactory’. The results of the FOBTs processed by the pathology laboratories for eligible Pilot participants during the Pilot are shown in Table 5.2 below.

**Table 5.2: FOBTs received status by FOBT type**

Kit Type	% of kits returned by eligible participants				Total Number
	Correctly Completed	Incorrectly Completed	Damaged	Unsatisfactory	
Inform	97.1	2.5	0.1	0.3	12,821
Bayer Detect	93.0	1.8	0.3	4.9	14,243
Total	94.9	2.1	0.3	2.7	27,064

Source: AIHW (2004)

The majority of returned FOBTs were correctly completed. The data indicated that overall 25,688 FOBTs were completed correctly (94.9%). The proportion of correctly completed and satisfactory *Inform* FOBTs (97.1%) was noticeably higher than the rate of correctly completed and satisfactory *Bayer Detect* FOBTs (93.0%). There was an issue with return of Bayer Detect kits from the Adelaide Pilot site at the commencement of screening, as Australia Post was initially holding back returns and batching them to send to the pathology laboratory. FOBTs are meant to be analysed within a certain period after completion and due to these delays they did not always reach the laboratory in time. Woolcott’s Qualitative Research also indicates that differences between the packaging of the two tests may have contributed to differences in the rates of the two tests found to be satisfactory (see section 4.4).

If the pathology laboratories found an FOBT to be incorrectly completed, damaged or unsatisfactory, they would notify HIC (by email, phone and/or spreadsheet list) to send another FOBT to the participant.

<sup>20</sup> A further 1,307 pathology returns were excluded from the analysis in this section. This includes 906 returned FOBTs for people previously diagnosed with bowel cancer, 48 from people outside the target age group and 420 from people who had moved outside the pilot areas prior to being sent an invitation to screen.

Similarly, if the returned *Participant Details* form was incomplete, the pathology laboratories would notify HIC. One pathology laboratory suggested that there could have been more promotion for using the Freecall helpline to walk people through completion of their FOBT. This would help avoid incorrectly completed FOBTs. It also highlights the importance of clear, effective instructions for completing the FOBT, especially for people from culturally and linguistically diverse backgrounds.

### FOBT processing and waiting times

The time between the FOBT being processed and the result sent to the participant was measured, and is shown in Table 5.3 below. It is unclear whether the maximum waiting times for notification of results represents an error in the Register or a true waiting time.

**Table 5.3: Waiting times for notification of FOBT results (Days)**

	Mean	Median	Maximum
<b>Inform</b>	3	2	391
<b>Bayer</b>	4	2	144

Source: AIHW

The median waiting time between an FOBT being processed by the pathology laboratory and the result being sent to the participant was 3 days for *Inform* FOBT results and 4 days for *Bayer Detect* FOBT results. This is in line with contractual agreements with the suppliers to send FOBT results to participants within seven days. The Register data indicated that there were no cases where a completed FOBT was received by the pathology laboratories and the results were not sent.

### Overall views on the FOBT pathology processing model

FOBT suppliers and pathology laboratories found that the Pilot FOBT processing model worked well during the Pilot. However, pathology laboratories stated that the process was very manual. That is, reliant on double data entry and mailing hard copies of forms to HIC.

Pathology laboratories also commented that they received numerous unused FOBTs that were ‘returned to sender’ by people who chose not to participate in the Pilot. In a national program, it should be made clear to people that choose not to participate to dispose of the unused FOBT, rather than return it to FOBT suppliers.

## 5.4 Positivity rates

The pathology results for the valid FOBTs (i.e. excluding kits that were incorrectly completed, inconclusive or damaged) are shown in Table 5.4. Of the 25,688 correctly completed FOBTs analysed, 2,317 (9.0%) were positive and 23,371 (91.0%) were negative. The positivity rate was higher for *Inform* FOBTs (9.9%) than for *Bayer Detect* FOBTs (8.2%).

**Table 5.4: FOBT results for valid FOBTs**

Kit Type	FOBT Positive	FOBT Negative	Total Number
!inform	9.9	90.1	12,446
Bayer Detect	8.2	91.8	13,242
Total	9.0	91.0	25,688

The positivity rate is defined as the proportion of positive results out of all valid results, that is, all positive and negative results. This is presented for each FOBT type, categorised by age and sex, in Table 5.5 below.

**Table 5.5: Positivity rates by sex, age and FOBT type (all eligible participants)**

Age Group	Males		Females	
	!inform	Bayer	!inform	Bayer
55–59	9.9	7.1	6.3	5.2
60–64	9.2	8.6	7.4	6.4
65–69	14.2	10.7	9.5	7.4
70–74	13.9	13.1	11.7	10.4
<i>Total</i>	<i>11.6</i>	<i>9.6</i>	<i>8.4</i>	<i>7.0</i>

Source: AIHW (2004), includes valid and conclusive tests only

The proportion of positive results out of all valid *!inform* results was 11.6% for males and 8.4% for females. The corresponding positivity rates for *Bayer Detect* FOBTs were 9.6% for males and 7.0% for females. Overall, 10.5% of the tests completed by men had a positive result, while only 7.7% of tests completed by women were positive. Positivity rates increased with age.

Participants were asked to report any rectal bleeding within the last six-months on their *Participant Details* form. The positivity rates for participants who reported no rectal bleeding are shown in Table 5.6. The data indicate that the overall positivity rate for the Pilot, excluding those that reported rectal bleeding, was 8%.

**Table 5.6: Positivity rates by sex, age and FOBT type for participants without rectal bleeding**

Age Group	Males		Females	
	!inform	Bayer	!inform	Bayer
55–59	8.3	5.9	5.5	4.9
60–64	7.8	7.3	6.6	5.5
65–69	13.1	9.6	8.7	6.8
70–74	12.2	12.0	10.7	9.5
<i>Total</i>	<i>10.1</i>	<i>8.4</i>	<i>7.6</i>	<i>6.4</i>

Source: AIHW (2004)

## 5.5 Positive predictive value of FOBT

The positive predictive value of a screening test is measured as the proportion of outcomes of interest out of all outcomes. In the case of FOBT, this is the proportion of FOBTs with cancers and advanced adenomas detected out of all positive FOBTs that are followed up with a colonoscopy (see Chapter 7 for clinical outcomes of colonoscopy).<sup>21</sup> The positive predictive value of the two FOBTs for cancers and advanced adenomas is shown in Table 5.7.

**Table 5.7: Positive Predictive Value - participants with a positive FOBT  
Rate of cancer and advanced adenoma detection**

	Suspected cancer		Advanced adenoma <sup>21</sup>		Total		All investigated positive FOBTs
	Number	Rate per 100 investigated positive FOBTs	Number	Rate per 100 investigated positive FOBTs	Number	Rate per 100 investigated positive FOBTs	
!nform	37	5.5	87	12.9	124	18.5	672
Bayer Detect	30	5.1	89	15.0	119	20.1	593
All	67	5.3	176	13.9	243	19.2	1,265

Source: AIHW (2004)

The positive predictive value for suspected cancers and advanced adenomas across both tests was 19.2%. That is, 19.2% of people who proceeded to colonoscopy following a positive FOBT had a suspected cancer or advanced adenoma detected. In comparison, the positive predictive value for significant family history and/or symptoms of bowel cancer in the absence of a positive FOBT was 0.5% for cancer, 4.3% for advanced adenoma and 7.5% for cancer or any adenoma.

There was no significant difference between this positive predictive value for the *Bayer Detect* FOBT (20.1%) and the *!nform* FOBT (18.5%,  $p = 0.47$ ).

The positive predictive value of the two FOBTs for cancers and advanced adenomas (including small and diminutive adenomas) is shown in Table 5.8 below.

**Table 5.8: Positive Predictive Value - participants with a positive FOBT – cancers and all adenomas (including small and diminutive adenomas)**

	All cancers and adenomas		All investigated positive FOBTs Number
	Number	Rate per 100 investigated positive FOBTs	
!nform	162	24.1	672
Detect	156	26.3	593
All	318	25.1	1,265

Source: AIHW (2004)

<sup>21</sup> The majority of bowel cancers develop from adenomas (polyps) that are tiny growths inside the colon or rectum and look like small spots or cherries on stalks. If these adenomas are removed, the risk of bowel cancer is reduced. Not all adenomas will lead to cancer. Advanced adenoma are classified as such if any of the following indicators are met: Adenoma multiplicity – three or more adenomas present at examination.; Adenoma size - 10mm or greater; High grade dysplasia; or significant villous change or serrated as indicated on pathology reports (AIHW 2004).

The positive predictive value for all cancers and adenomas (including small and diminutive adenomas) across both tests was 25.1%. There was no significant difference between the positive predictive value for the *Bayer Detect* FOBT (26.3%) and the *Inform* FOBT (24.1%,  $p = 0.37$ ).

The high rate of missing colonoscopy data (see section 7.5 for discussion) indicates that there are likely to be a large number of cancers and adenomas detected as a result of the Pilot on which the Register holds no data.

## 5.6 Pilot sensitivity

The sensitivity of a screening test for a disease or condition is the proportion of people who truly have that disease or condition who are identified by the screening process as having the disease or condition. The sensitivity of the Pilot could be defined with regard to all adenomas and cancers, advanced adenomas and cancers or only cancers. The difficulty in calculating sensitivity is that it is not known how many participants have cancers or adenomas that were missed by FOBT. In theory, it would be possible to match participants with the cancer registers in the three states containing the Pilot sites to see how many subsequently develop bowel cancer in a sufficiently small time after participation in the Pilot to allow the assumption that the cancer was present at that time. This would give the sensitivity of the screening program to bowel cancer, though the results would not be available for some time after the Pilot (2-4 years). There is no practical method of determining the number of adenomas which were missed by the FOBT.

## 5.7 FOBT and pathology quality assurance

The contractual agreements with the FOBT suppliers specified Key Performance Indicators (KPIs) on expected standards of performance and provision of data. The contracts also specified standards for waiting times, with results to be sent to participants within seven days of receipt of the completed FOBT at the laboratory. The KPIs specified in the contractual agreements were adequately monitored during the Pilot. There appeared to be adequate systems established to measure FOBT processing times. The FOBT suppliers and pathology laboratory successfully achieved these standards.

The pathology laboratories established adequate systems to monitor inadequately completed FOBTs, to follow-up with participants where required and to report this information to the Register.

### Areas for possible further work

- Consider expansion of the role of the freecall helpline to walk people through completion of their FOBT if they have any questions, to help avoid incorrectly completed FOBTs.
- Explore use of a pre-invitation letter that states that the person is going to receive a FOBT shortly as a means for more accurately identifying appropriate potential participants.
- Consider inclusion of a note to participants asking them to contact the freecall helpline if they have not received their FOBT pathology results within a specified time period. This would provide a means for checking that the FOBT had actually been received by the laboratory and not gone astray in the mail.