3

FOBT participation

3.1 Introduction

Analyses

This section analyses the proportion of people invited to participate in the screening program who are recorded on the register as having returned a completed test kit. Invitations sent by mistake to people outside the target population are excluded from this analysis. The excluded invitations comprise people outside the target age group of 55 to 74 years, people either deceased or ineligible for screening (for example, because of a recent colonoscopy or previous diagnosis of bowel cancer) and people who moved out of the Pilot site after selection but prior to being sent a screening invitation.

The majority of invitations were sent by the end of May 2004, with only 64 late invitations (0.1% of all invitations) sent after this date. Hence all but a small number of people will have had four months or longer to respond to the screening invitation by 1 October 2004. This means that the UK approach of assuming that sufficient time has passed between the screening invitation and the final data download can be taken to apply here.

So for the purposes of modelling the data, those who have not yet responded may be neglected. The participation rates are calculated using the Kaplan-Meier method but logistic regression modelling is used to examine differences in participation between population groups. The logistic regression results are reported with the tables on which they are based. They are also reported with the relevant figure presenting the Kaplan-Meier estimates as an aid in interpreting the figure.

The exception to this is FOBT undertaken in response to a reminder letter with and without inclusion of a test kit. The reminders were sent six weeks after the initial invitation. Hence there is insufficient time since the last of these were sent and the date of data download to assume that all those who intend to respond have done so.

The non-parametric test of survival curves was used to adjust for confounders for this comparison. Because of the significant confounding introduced by incomplete randomisation of participants to the groups with and without test kits in the reminder, which was different for different Pilot sites, this analysis was done separately for each site.

Confounding variables

Pilot site, age, sex and test kit type are all used as potential confounding variables in the logistic model. For example, the analysis of the significance of the relationship between test kit type and FOBT participation is adjusted for Pilot site, sex and age.

In addition, all significance tests involving Pilot site, test kit type, age, and sex are adjusted for the number of months since the commencement of the Pilot. This allows for confounding arising from the fact that slightly different numbers of each test kit type were distributed in each month and for the possibility that practices in each site may have evolved during the course of the Pilot.

Finally, those months where only one test kit type was distributed (November 2002 and May 2003) were excluded from the logistic model.

Significance tests applied to Indigenous status and language spoken were only adjusted for age, sex and Pilot site. The sourcing of the denominator population data from ABS Census tables classified only by site, age and sex did not allow for the inclusion of other potential confounders in the logistic model.

Anomalous and excluded data

Invitations sent to people outside the target population have been excluded from this report. The excluded invitations were sent to 168 people outside the target age group of 55 to 74 years, 3,149 people either deceased or ineligible for screening (for example, because of a recent colonoscopy or previous diagnosis of bowel cancer) and 568 people who moved out of the Pilot site prior to being invited to participate in the screening program.

Some rates for participation by language group in Mackay are greater than 100%. There are two reasons for this:

- The denominator and numerator are drawn from different sources—the ABS 2001 Census and the HIC invitation list respectively. The ABS introduces small random changes to census counts where the counts are small to protect confidentiality. Also the time difference between the conduct of the census and the compilation of the invitation list may mean that there was some movement of non-English language speakers into or out of the Pilot site between the census and the compilation of the invitation list. Both of these may lead to a small mismatch between the numerator and denominator in the FOBT response rate.
- The questions defining the numerator and denominator are different. The Pilot participant form asks ‘Do you speak a language other than English?’ The Census question is ‘Do you speak a language other than English *at home*?’ People who speak a language other than English as a second language may answer yes to the Pilot question and no to the Census question.

The observed rate is reported in the tables, but rates larger than 100% were assumed to be equal to 100% for the purposes of the logistic modelling.

As noted in section 2.2 above, detailed examination of participation rates for South Sea Islanders is not possible. The ABS Census identified 22 men and 26 women as being South Sea Islanders in the age group 55 to 74 in Mackay. Of those participants in Mackay who returned a completed FOBT kit, 12 men and 11 women identified as South Sea Islanders. Hence the overall estimated participation rates for South Sea Islanders in Mackay were 55% for men (95% confidence interval 34%– 75%) and 42% for women (95% confidence interval 26%–66%).

3.2 Tables, figures and analyses

Table 3.1.a: Participation by Pilot site and test kit type – all sites

	!nform FOBT		Bayer Detect FOBT		All tests		All invitations
	Number responding	Rate per 100 !nform invitations	Number responding	Rate per 100 Bayer Detect invitations	Number responding	Rate per 100 invitations	Number of invitations
Males							
55–59	1,795	39.2	1,955	43.0	3,750	41.1	9,124
60–64	1,422	41.2	1,577	46.4	2,999	43.8	6,851
65–69	1,322	43.2	1,420	46.3	2,742	44.8	6,126
70–74	1,159	42.9	1,303	47.2	2,462	45.1	5,464
Total	**5,698**	**41.3**	**6,255**	**45.4**	**11,953**	**43.4**	**27,565**
ASR	**. .**	**41.3**	**. .**	**45.5**	**. .**	**43.4**	**. .**
95% CI	**. .**	**40.3–42.4**	**. .**	**44.3–46.6**	**. .**	**42.6–44.2**	**. .**
Females							
55–59	2,079	45.5	2,266	49.9	4,345	47.7	9,111
60–64	1,673	46.2	1,826	50.6	3,499	48.4	7,230
65–69	1,581	47.3	1,589	49.1	3,170	48.2	6,583
70–74	1,430	44.0	1,443	45.6	2,873	44.8	6,418
Total	**6,763**	**45.7**	**7,124**	**49.0**	**13,887**	**47.3**	**29,342**
ASR	**. .**	**45.7**	**. .**	**49.0**	**. .**	**47.4**	**. .**
95% CI	**. .**	**44.7–46.8**	**. .**	**47.9–50.2**	**. .**	**46.6–48.2**	**. .**
Persons							
55–59	3,874	42.3	4,221	46.5	8,095	44.4	18,235
60–64	3,095	43.7	3,403	48.6	6,498	46.1	14,081
65–69	2,903	45.3	3,009	47.8	5,912	46.5	12,709
70–74	2,589	43.5	2,746	46.3	5,335	44.9	11,882
Total	**12,461**	**43.6**	**13,379**	**47.2**	**25,840**	**45.4**	**56,907**
ASR	**. .**	**43.6**	**. .**	**47.3**	**. .**	**45.4**	**. .**
95% CI	**. .**	**42.8–44.3**	**. .**	**46.5–48.1**	**. .**	**44.9–46.0**	**. .**

- 56,907 invitations were sent out to eligible people. As at 1 October 2004, 25,840 (45.4%) invitees responded by returning a completed FOBT.

- Participation was significantly higher among women (47.3%) than men (43.4%) after adjusting for confounding variables (p<.0001)[1]. Participation was also significantly higher for people receiving the Bayer Detect FOBT (47.2%) rather than the !nform FOBT (43.6%) (p<.0001).

Table 3.1.b: Participation by Pilot site and test kit type - Mackay

	!nform FOBT		Bayer Detect FOBT		All tests		All invitations
	Number responding	Rate per 100 !nform invitations	Number responding	Rate per 100 Bayer Detect invitations	Number responding	Rate per 100 invitations	Number of invitations
Males							
55–59	509	49.9	551	53.9	1,060	51.9	2,043
60–64	400	53.8	423	58.1	823	55.9	1,472
65–69	350	54.4	332	58.0	682	56.1	1,215
70–74	247	50.6	264	57.8	511	54.1	945
Total	**1,506**	**52.0**	**1,570**	**56.5**	**3,076**	**54.2**	**5,675**
ASR	**..**	**52.0**	**..**	**56.7**	**..**	**54.3**	**..**
95% CI	**..**	**49.4–54.7**	**..**	**53.9–59.6**	**..**	**52.4–56.3**	**..**
Females							
55–59	561	59.0	575	63.1	1,136	61.0	1,862
60–64	418	60.7	434	65.1	852	62.8	1,356
65–69	376	63.1	334	62.5	710	62.8	1,130
70–74	294	56.2	278	55.7	572	56.0	1,022
Total	**1,649**	**59.8**	**1,621**	**62.1**	**3,270**	**60.9**	**5,370**
ASR	**..**	**59.8**	**..**	**62.0**	**..**	**60.9**	**..**
95% CI	**..**	**57.1–62.5**	**..**	**59.2–64.9**	**..**	**58.9–62.8**	**..**
Persons							
55–59	1,070	54.3	1,126	58.3	2,196	56.2	3,905
60–64	818	57.1	857	61.4	1,675	59.2	2,828
65–69	726	58.6	666	60.2	1,392	59.4	2,345
70–74	541	53.5	542	56.7	1,083	55.1	1,967
Total	**3,155**	**55.8**	**3,191**	**59.2**	**6,346**	**57.5**	**11,045**
ASR	**..**	**55.8**	**..**	**59.2**	**..**	**57.5**	**..**
95% CI	**..**	**53.8–57.8**	**..**	**57.1–61.3**	**..**	**56.0–58.9**	**..**

- The first invitations were sent out in Mackay on 6 November 2002. By 1 October 2004, 11,045 invitations had been sent to eligible people in Mackay. The participation rate as at 1 October 2004 in Mackay (57.5%%) was higher than the rate in either Adelaide (46.5%) or Melbourne (39.9%) (see Tables 3.1c and 3.1d).
- In Mackay, participation was higher among women than men for both test types. Overall, 60.9% of invited women responded compared with a participation rate of 54.2% for men[2].

[1] Data for those months where only one type of test kit was distributed were excluded from the logistic regression modeling but are included in the table.

[2] Data for those months where only one type of test kit was distributed were excluded from the logistic regression modeling but are included in the table.

- For both sexes, participation rates were higher for people sent the Bayer Detect FOBT (56.5% for men, 62.1% for women) than those sent an !nform FOBT (52.0% and 59.8%).

Table 3.1.c: Participation by Pilot site and test kit type - Adelaide

	!nform FOBT		Bayer Detect FOBT		All tests		All invitations
	Number responding	Rate per 100 !nform invitations	Number responding	Rate per 100 Bayer Detect invitations	Number responding	Rate per 100 invitations	Number of invitations
Males							
55–59	514	37.9	594	43.3	1,108	40.6	2726
60–64	412	40.8	461	47.2	873	44.0	1986
65–69	451	46.7	502	48.3	953	47.5	2006
70–74	445	45.8	468	47.8	913	46.8	1950
Total	**1,822**	**42.4**	**2,025**	**46.4**	**3,847**	**44.4**	**8668**
ASR	**..**	**42.2**	**..**	**46.3**	**..**	**44.2**	**..**
95% CI	**..**	**40.3–44.2**	**..**	**44.3–48.4**	**..**	**42.9–45.7**	**..**
Females							
55–59	595	43.3	699	50.8	1,294	47.0	2752
60–64	537	47.1	608	52.0	1,145	49.6	2309
65–69	529	47.7	561	50.2	1,090	48.9	2227
70–74	616	48.7	570	47.1	1,186	47.9	2475
Total	**2,277**	**46.6**	**2,438**	**50.0**	**4,715**	**48.3**	**9763**
ASR	**..**	**46.3**	**..**	**50.2**	**..**	**48.3**	**..**
95% CI	**..**	**44.4–48.3**	**..**	**48.2–52.3**	**..**	**46.9–49.7**	**..**
Persons							
55–59	1,109	40.6	1,293	47.1	2,402	43.8	5478
60–64	949	44.2	1,069	49.8	2,018	47.0	4295
65–69	980	47.2	1,063	49.3	2,043	48.3	4233
70–74	1,061	47.5	1,038	47.4	2,099	47.4	4425
Total	**4,099**	**44.6**	**4,463**	**48.3**	**8,562**	**46.5**	**18431**
ASR	**..**	**44.4**	**..**	**48.3**	**..**	**46.3**	**..**
95% CI	**..**	**43.0–45.8**	**..**	**46.9–49.8**	**..**	**45.4–47.3**	**..**

- The first invitations were sent out in Adelaide on 24 February 2003. By 1 October 2004, 18,431 invitations had been sent to eligible people in Adelaide.
- In Adelaide, participation was higher among women than men for both test types. Overall, 48.3% of invited women responded. This compares with a participation rate of 44.4% for men[3].
- For both sexes, participation rates were higher for people sent the Bayer Detect FOBT (46.4% for men, 50.0% for women) than those sent an !nform FOBT (42.4% and 46.6%).

[3] Data for those months where only one type of test kit was distributed were excluded from the logistic regression modeling but are included in the table.

Table 3.1.d: Participation by Pilot site and test kit type - Melbourne

	!nform FOBT		Bayer Detect FOBT		All tests		All invitations
	Number responding	Rate per 100 !nform invitations	Number responding	Rate per 100 Bayer Detect invitations	Number responding	Rate per 100 invitations	Number of invitations
Males							
55–59	772	35.1	810	37.6	1,582	36.3	4355
60–64	610	35.9	693	40.9	1,303	38.4	3393
65–69	521	35.9	586	40.4	1,107	38.1	2905
70–74	467	37.5	571	43.1	1,038	40.4	2569
Total	**2,370**	**35.9**	**2,660**	**40.2**	**5,030**	**38.0**	**13222**
ASR	**. .**	**35.9**	**. .**	**40.2**	**. .**	**38.1**	**. .**
95% CI	**. .**	**34.5–37.4**	**. .**	**38.7–41.8**	**. .**	**37.0–39.1**	**. .**
Females							
55–59	923	41.1	992	44.1	1,915	42.6	4497
60–64	718	40.0	784	44.3	1,502	42.1	3565
65–69	676	41.2	694	43.8	1,370	42.5	3226
70–74	520	35.5	595	40.9	1,115	38.2	2921
Total	**2,837**	**39.7**	**3,065**	**43.4**	**5,902**	**41.5**	**14209**
ASR	**. .**	**39.7**	**. .**	**43.4**	**. .**	**41.5**	**. .**
95% CI	**. .**	**38.3–41.2**	**. .**	**41.9–45.0**	**. .**	**40.5–42.6**	**. .**
Persons							
55–59	1,695	38.1	1,802	40.9	3,497	39.5	8852
60–64	1,328	38.0	1,477	42.6	2,805	40.3	6958
65–69	1,197	38.7	1,280	42.1	2,477	40.4	6131
70–74	987	36.4	1,166	41.9	2,153	39.2	5490
Total	**5,207**	**37.9**	**5,725**	**41.8**	**10,932**	**39.9**	**27431**
ASR	**. .**	**37.9**	**. .**	**41.8**	**. .**	**39.9**	**. .**
95% CI	**. .**	**36.8–38.9**	**. .**	**40.8–42.9**	**. .**	**39.1–40.6**	**. .**

- The first invitations were sent out in Melbourne on 24 March 2003. By 1 October 2004, 27,431 invitations had been sent to eligible people in Melbourne.
- In Melbourne, participation was higher among women than men for both test types. Overall, 41.5% of invited women responded. This compares with a participation rate of 38.0% for men[4].
- For both sexes, participation rates were higher for people sent the Bayer Detect FOBT (40.2% for men and 43.4% for women) than those sent an !nform FOBT 35.9% and 39.7%).

[4] Data for those months where only one type of test kit was distributed were excluded from the logistic regression modeling but are included in the table.

Table 3.2: Participation by Indigenous status

	Indigenous		Non-Indigenous		All Participants	
	Number responding	Rate per 100 population	Number responding	Rate per 100 population	Number responding	Rate per 100 population
Males						
55–59	14	31.5	3,736	41.1	3,750	41.1
60–64	4	19.2	2,995	43.8	2,999	43.8
65–69	6	23.9	2,736	44.8	2,742	44.8
70–74	4	22.3	2,458	45.1	2,462	45.1
Total	**28**	**25.8**	**11,925**	**43.4**	**11,953**	**43.4**
ASR	**. .**	**24.8**	**. .**	**43.5**	**. .**	**43.4**
95% CI	**. .**	**16.2–36.1**	**. .**	**42.7–44.2**	**. .**	**42.6–44.2**
Females						
55–59	11	19.4	4,334	47.9	4,345	47.7
60–64	10	29.8	3,489	48.5	3,499	48.4
65–69	8	36.3	3,162	48.2	3,170	48.2
70–74	5	23.5	2,868	44.8	2,873	44.8
Total	**34**	**25.4**	**13,853**	**47.4**	**13,887**	**47.3**
ASR	**. .**	**26.6**	**. .**	**47.5**	**. .**	**47.4**
95% CI	**. .**	**18.0–37.7**	**. .**	**46.7–48.3**	**. .**	**46.6–48.2**
Persons						
55–59	25	24.7	8,070	44.5	8,095	44.4
60–64	14	25.8	6,484	46.2	6,498	46.1
65–69	14	29.7	5,898	46.6	5,912	46.5
70–74	9	23.0	5,326	45.0	5,335	44.9
Total	**62**	**25.6**	**25,778**	**45.5**	**25,840**	**45.4**
ASR	**. .**	**25.7**	**. .**	**45.5**	**. .**	**45.4**
95% CI	**. .**	**19.6–33.1**	**. .**	**44.9–46.1**	**. .**	**44.9–46.0**

- By 1 October 2004, 62 respondents had identified themselves as Indigenous.
- The numbers of people identifying as Indigenous were too small to allow analysis adjusted by Pilot site. However the response rate was significantly lower for Indigenous people compared to non-Indigenous after adjusting for age and sex ($p < 0.0001$). This result should be treated with caution as it relies on Indigenous people identifying themselves as such on the participant form.
- There was no significant difference in participation rates between Indigenous men and Indigenous women ($p = 0.99$).

Table 3.3: Participation by Pilot site and language group - 3.3a: Mackay

	Maltese		Italian		Other non-English		English	
	Number responding	Rate per 100 population	Number responding	Rate per 100 population	Number responding	Rate per 100 population	Number responding	Rate per 100 population
Males								
55–59	25	96.2	13	108.3	32	91.4	990	50.3
60–64	20	111.1	9	69.2	40	102.6	754	53.8
65–69	16	72.7	10	58.8	34	121.4	622	54.2
70–74	26	113.0	14	70.0	16	66.7	455	51.8
Total	**87**	**97.8**	**46**	**74.2**	**122**	**96.8**	**2,821**	**52.3**
ASR	**..**	**98.4**	**..**	**79.6**	**..**	**95.8**	**..**	**52.3**
95% CI	**..**	**78.4–121.8**	**..**	**56.7–108.2**	**..**	**79.4–114.5**	**..**	**50.4–54.3**
Females								
55–59	28	116.7	7	77.8	38	102.7	1,063	59.3
60–64	28	93.3	8	57.1	34	87.2	782	61.4
65–69	22	95.7	11	57.9	19	79.2	658	61.8
70–74	26	152.9	11	52.4	11	55.0	524	54.4
Total	**104**	**110.6**	**37**	**58.7**	**102**	**85.0**	**3,027**	**59.4**
ASR	**..**	**113.4**	**..**	**62.9**	**..**	**83.9**	**..**	**59.4**
95% CI	**..**	**93.3–136.6**	**..**	**40.2–92.0**	**..**	**67.6–102.8**	**..**	**57.5–61.4**
Persons								
55–59	53	106.0	20	95.2	70	97.2	2,053	54.6
60–64	48	100.0	17	63.0	74	94.9	1,536	57.4
65–69	38	84.4	21	58.3	53	101.9	1,280	57.9
70–74	52	130.0	25	61.0	27	61.4	979	53.1
Total	**191**	**104.4**	**83**	**66.4**	**224**	**91.1**	**5,848**	**55.7**
ASR	**..**	**104.6**	**..**	**71.9**	**..**	**90.4**	**..**	**55.7**
95% CI	**..**	**90.2–120.7**	**..**	**55.7–90.9**	**..**	**78.8–103.1**	**..**	**54.3–57.2**

- By 1 October 2004, 498 respondents had identified themselves as speaking a language other than English in Mackay. Of these, the two largest language groups were Maltese (191) and Italian (83).
- Participation rates were significantly higher for people who spoke a language other than English, taken as a single group, than English speakers ($p < 0.0001$) after adjusting for confounders. However, several of the estimated participation rates for speakers of a non English language are over 100% which suggests significant discrepancies between the numerator and denominator, so this result should be treated with caution.
- The large number of rates over 100% for Maltese speakers and speakers of non-English languages other than Maltese or Italian suggests that rate estimates for these groups in particular should be treated with caution.
- Rates for Italian and English speakers were marginally significantly higher ($p = 0.02$) after adjusting for confounders.

Table 3.3: Participation by Pilot site and language group - 3.3b: Adelaide

	Greek		Italian		Other non-English		English	
	Number responding	Rate per 100 population	Number responding	Rate per 100 population	Number responding	Rate per 100 population	Number responding	Rate per 100 population
Males								
55–59	20	20.2	49	32.0	106	45.9	933	41.6
60–64	26	29.5	71	34.6	75	37.3	701	47.0
65–69	33	28.7	78	31.0	88	41.7	754	52.8
70–74	19	25.3	68	34.2	99	47.1	727	49.6
Total	**98**	**26.0**	**266**	**32.9**	**368**	**43.1**	**3,115**	**47.0**
ASR	**..**	**25.5**	**..**	**32.9**	**..**	**43.0**	**..**	**47.0**
95% CI	**..**	**20.6–31.2**	**..**	**28.8–37.4**	**..**	**38.7–47.7**	**..**	**45.4–48.7**
Females								
55–59	33	28.4	69	39.2	103	40.7	1,089	49.3
60–64	29	31.5	82	32.2	106	40.2	928	54.7
65–69	20	20.4	62	30.8	96	39.5	912	54.1
70–74	17	37.0	38	19.7	106	38.5	1,025	52.3
Total	**99**	**28.1**	**251**	**30.4**	**411**	**39.7**	**3,954**	**52.4**
ASR	**..**	**29.2**	**..**	**31.6**	**..**	**39.9**	**..**	**52.4**
95% CI	**..**	**24.3–34.9**	**..**	**27.5–36.1**	**..**	**35.5–44.5**	**..**	**50.7–54.0**
Persons								
55–59	53	24.7	118	35.9	209	43.2	2,022	45.4
60–64	55	30.6	153	33.3	181	38.9	1,629	51.1
65–69	53	24.9	140	30.9	184	40.5	1,666	53.5
70–74	36	29.8	106	27.0	205	42.3	1,752	51.1
Total	**197**	**27.0**	**517**	**31.6**	**779**	**41.3**	**7,069**	**49.9**
ASR	**..**	**27.3**	**..**	**32.3**	**..**	**41.3**	**..**	**49.8**
95% CI	**..**	**23.5–31.4**	**..**	**29.5–35.4**	**..**	**38.4–44.4**	**..**	**48.6–51.0**

- By 1 October 2004, 1,493 respondents had identified themselves as speaking a language other than English in Adelaide. Of these, the two largest language groups were Italian (517) and Greek (197).
- Participation rates were significantly lower for people who spoke a language other than English, taken as a single group, than English speakers ($p < 0.0001$) after adjusting for confounders.
- Participation rates for Greek speakers (27.0%) and Italian speakers (31.6%) were marginally significantly different ($p = 0.04$). Both were significantly lower than rates for speakers of another non English language (41.3%%, $p < 0.0001$) after adjusting for confounders.
- Participation rates for speakers of other non English languages were significantly lower than rates for English speakers (49.9%, $p < 0.0001$) after adjusting for confounders.

Table 3.3: Participation by Pilot site and language group - 3.3c: Melbourne

	Greek		Italian		Other non-English		English	
	Number responding	Rate per 100 population	Number responding	Rate per 100 population	Number responding	Rate per 100 population	Number responding	Rate per 100 population
Males								
55–59	77	22.8	94	41.2	188	42.9	1,223	36.5
60–64	75	18.8	132	36.8	164	41.9	932	41.5
65–69	79	22.3	145	37.3	144	37.2	739	41.6
70–74	43	19.1	169	43.2	108	43.4	718	42.1
Total	**274**	**20.8**	**540**	**39.5**	**604**	**41.2**	**3,612**	**39.8**
ASR	**. .**	**20.9**	**. .**	**39.6**	**. .**	**41.5**	**. .**	**40.1**
95% CI	**. .**	**18.5–23.6**	**. .**	**36.0–43.4**	**. .**	**38.3–45.0**	**. .**	**38.8–41.4**
Females								
55–59	87	23.0	113	38.2	205	51.3	1,510	44.1
60–64	82	19.5	164	37.2	179	43.0	1,077	47.1
65–69	70	22.3	181	41.6	167	43.7	952	45.4
70–74	30	17.6	103	29.1	103	39.6	879	41.1
Total	**269**	**21.0**	**561**	**36.8**	**654**	**44.9**	**4,418**	**44.4**
ASR	**. .**	**20.8**	**. .**	**36.8**	**. .**	**45.1**	**. .**	**44.6**
95% CI	**. .**	**18.4–23.5**	**. .**	**33.3–40.6**	**. .**	**41.8–48.6**	**. .**	**43.3–45.9**
Persons								
55–59	164	22.9	207	39.5	393	46.9	2,733	40.3
60–64	157	19.1	296	37.0	343	42.5	2,009	44.3
65–69	149	22.3	326	39.6	311	40.4	1,691	43.7
70–74	73	18.5	272	36.5	211	41.5	1,597	41.6
Total	**543**	**20.9**	**1,101**	**38.1**	**1,258**	**43.0**	**8,030**	**42.2**
ASR	**. .**	**20.9**	**. .**	**38.3**	**. .**	**43.3**	**. .**	**42.4**
95% CI	**. .**	**19.1–22.8**	**. .**	**35.9–40.7**	**. .**	**40.9–45.7**	**. .**	**41.4–43.3**

- By 1 October 2004, 2,902 respondents had identified themselves as speaking a language other than English in Melbourne. Of these, the two largest language groups were Italian (1,101) and Greek (543).
- Participation rates were significantly lower for people who spoke a language other than English, taken as a single group, than English speakers ($p < 0.0001$) after adjusting for confounders.
- Participation rates were significantly lower for Greek speakers (20.9%) than Italian speakers (38.1%, $p < 0.0001$) and both were significantly lower than rates for speakers of another non English language (43.0%%, $P < 0.0001$ and $p = 0.005$) after adjusting for confounders.
- Participation rates for speakers of other non English languages were not significantly different from rates for English speakers (42.2%, $p = 0.50$) after adjusting for confounders.

Table 3.4: Participation by Pilot site and quartile of disadvantage - 3.4a: Mackay

	Quartile 1 (least disadvantage)		Quartile 2		Quartile 3		Quartile 4 (most disadvantage)	
	Number responding	Rate per 100 population	Number responding	Rate per 100 population	Number responding	Rate per 100 population	Number responding	Rate per 100 population
Males								
55–59	–	–	52	56.5	1,008	51.7	–	–
60–64	–	–	32	59.3	791	55.8	–	–
65–69	–	–	22	52.4	660	56.3	–	–
70–74	–	–	23	65.7	488	53.6	–	–
Total	–	–	**129**	**57.8**	**2,947**	**54.1**	–	–
ASR	–	–	**..**	**58.2**	**..**	**54.1**	–	–
95% CI	–	–	**..**	**48.4–69.4**	**..**	**52.2–56.1**	–	–
Females	–	–					–	–
55–59	–	–	49	64.5	1,087	60.9	–	–
60–64	–	–	25	55.6	827	63.1	–	–
65–69	–	–	23	57.5	687	63.0	–	–
70–74	–	–	19	51.4	553	56.1	–	–
Total	–	–	**116**	**58.6**	**3,154**	**61.0**	–	–
ASR	–	–	**..**	**58.0**	**..**	**61.0**	–	–
95% CI	–	–	**..**	**48.2–69.2**	**..**	**59.0–63.0**	–	–
Persons	–	–					–	–
55–59	–	–	101	60.1	2,095	56.1	–	–
60–64	–	–	57	57.6	1,618	59.3	–	–
65–69	–	–	45	54.9	1,347	59.5	–	–
70–74	–	–	42	58.3	1,041	54.9	–	–
Total	–	–	**245**	**58.2**	**6,101**	**57.4**	–	–
ASR	–	–	**..**	**58.0**	**..**	**57.4**	–	–
95% CI	–	–	**..**	**50.8–65.8**	**..**	**56.0–58.9**	–	–

- By 1 October 2004, 245 respondents had been grouped in quartile 2 and 6,101 in quartile 3. The Mackay Pilot site had no postcodes which were assigned to quartiles 1 or 4.
- There is no significant difference between response rates for quartile 2 (58.2%) and quartile 3 (57.4%, p = 0.87) after adjusting for confounders.

Table 3.4: Participation by Pilot site and quartile of disadvantage - 3.4b: Adelaide

	Quartile 1 (least disadvantage)		Quartile 2		Quartile 3		Quartile 4 (most disadvantage)	
	Number responding	Rate per 100 population	Number responding	Rate per 100 population	Number responding	Rate per 100 population	Number responding	Rate per 100 population
Males								
55–59	287	41.4	570	43.7	69	38.8	182	33.0
60–64	173	41.3	493	49.7	47	35.1	160	36.2
65–69	200	51.3	507	53.1	40	28.0	206	39.8
70–74	201	48.1	441	49.5	67	48.6	204	40.6
Total	**861**	**44.8**	**2,011**	**48.6**	**223**	**37.6**	**752**	**37.3**
ASR	**..**	**44.9**	**..**	**48.5**	**..**	**37.4**	**..**	**36.8**
95% CI	**..**	**41.9–48.0**	**..**	**46.4–50.7**	**..**	**32.7–42.7**	**..**	**34.2–39.6**
Females								
55–59	321	51.8	675	49.8	67	37.2	231	38.8
60–64	230	47.0	597	55.7	56	35.9	262	44.3
65–69	270	53.7	518	52.6	70	41.7	232	40.6
70–74	302	52.0	558	52.2	61	33.3	265	41.2
Total	**1,123**	**51.2**	**2,348**	**52.4**	**254**	**37.0**	**990**	**41.2**
ASR	**..**	**51.0**	**..**	**52.4**	**..**	**37.1**	**..**	**41.1**
95% CI	**..**	**48.0–54.1**	**..**	**50.3–54.6**	**..**	**32.3–42.3**	**..**	**38.4–43.8**
Persons								
55–59	608	46.3	1,245	46.8	136	38.0	413	36.0
60–64	403	44.4	1,090	52.8	103	35.5	422	40.8
65–69	470	52.6	1,025	52.9	110	35.4	438	40.2
70–74	503	50.4	999	51.0	128	39.9	469	40.9
Total	**1,984**	**48.2**	**4,359**	**50.6**	**477**	**37.3**	**1,742**	**39.4**
ASR	**..**	**48.0**	**..**	**50.5**	**..**	**37.2**	**..**	**39.2**
95% CI	**..**	**45.9–50.2**	**..**	**49.0–52.1**	**..**	**33.9–40.7**	**..**	**37.3–41.1**

- By 1 October 2004, 1,984 respondents had been grouped in quartile 1, 4,359 in quartile 2, 477 in quartile 3 and 1,742 in quartile 4.
- Response rates for quartile 1 (48.2%) are significantly lower than those for quartile 2 (50.6%, $p = 0.005$) but both rates are significantly higher than those for quartile 3 (37.3%, $p < 0.0001$) after adjusting for confounders.
- Response rates for quartiles 3 and 4 (37.3%, 39.4% respectively) are not significantly different ($p = 0.21$) after adjusting for confounders.

Table 3.4: Participation by Pilot site and quartile of disadvantage - 3.4c: Melbourne

	Quartile 1 (least disadvantage)		Quartile 2		Quartile 3		Quartile 4 (most disadvantage)	
	Number responding	Rate per 100 population	Number responding	Rate per 100 population	Number responding	Rate per 100 population	Number responding	Rate per 100 population
Males								
55–59	928	40.4	505	35.1	74	21.1	75	27.7
60–64	739	44.1	434	36.6	72	20.7	58	31.5
65–69	596	43.7	355	34.5	75	23.1	81	43.5
70–74	574	46.7	307	36.1	84	28.0	73	38.6
Total	**2,837**	**43.2**	**1,601**	**35.5**	**305**	**23.1**	**287**	**34.6**
ASR	**. .**	**43.4**	**. .**	**35.6**	**. .**	**22.8**	**. .**	**34.3**
95% CI	**. .**	**41.8–45.0**	**. .**	**33.8–37.4**	**. .**	**20.3–25.6**	**. .**	**30.5–38.6**
Females								
55–59	1,090	46.5	623	40.3	98	29.3	104	37.8
60–64	844	49.2	477	39.2	94	24.1	87	36.0
65–69	736	49.8	424	37.6	110	29.2	100	41.0
70–74	642	45.1	291	32.8	70	22.5	112	37.1
Total	**3,312**	**47.6**	**1,815**	**38.0**	**372**	**26.3**	**403**	**37.9**
ASR	**. .**	**47.7**	**. .**	**37.9**	**. .**	**26.5**	**. .**	**37.9**
95% CI	**. .**	**46.1–49.3**	**. .**	**36.2–39.7**	**. .**	**24.0–29.2**	**. .**	**34.0–42.1**
Persons								
55–59	2,018	43.5	1,128	37.8	172	25.1	179	32.8
60–64	1,583	46.7	911	37.9	166	22.5	145	34.0
65–69	1,332	46.9	779	36.1	185	26.4	181	42.1
70–74	1,216	45.9	598	34.4	154	25.2	185	37.7
Total	**6,149**	**45.5**	**3,416**	**36.8**	**677**	**24.7**	**690**	**36.5**
ASR	**. .**	**45.5**	**. .**	**36.8**	**. .**	**24.7**	**. .**	**36.1**
95% CI	**. .**	**44.4–46.7**	**. .**	**35.6–38.0**	**. .**	**22.9–26.7**	**. .**	**33.4–38.9**

- By 1 October 2004, 6,149 respondents had been grouped in quartile 1, 3,416 in quartile 2, 677 in quartile 3 and 690 in quartile 4.
- Response rates for quartile 1 (40.5%) are significantly higher than those for quartile 2 (33.4%, $p < 0.0001$) and those for quartile 2 and quartile 4 (33.8%) are significantly higher than those for quartile 3 (22.5%, $p < 0.0001$) after adjusting for confounders.
- Response rates for quartiles 2 and 4 are not significantly different ($p = 0.83$) after adjusting for confounders.

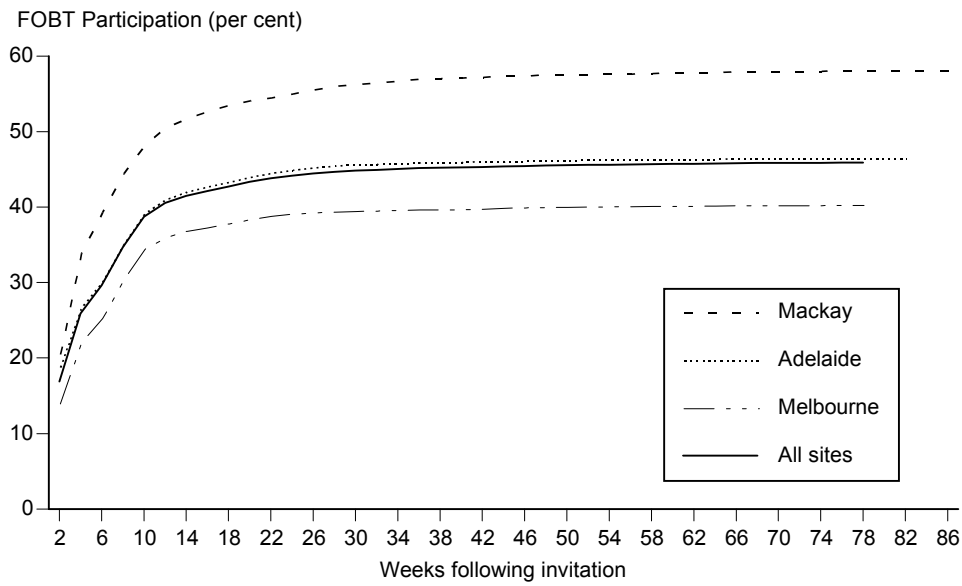


Figure 3.1: Participation by weeks since invitation and Pilot site

Table 3.5: Participation rates at 78 weeks since invitation by Pilot site

	Mackay	Adelaide	Melbourne	All sites
Rate	58.2	46.6	40.3	45.9
95% CI	57.3-59.2	45.8-47.3	39.7-40.9	45.5-46.3

- The table provides estimates of FOBT participation at 78 weeks, which is the longest period for which all three sites contributed data. However, those sites that continued beyond 78 weeks showed an increase in participation rate of less than one percentage points.
- Overall participation reaches a plateau at around 24 weeks, with a subsequent increase of less than two percentage points.
- All differences between the rates for the different Pilot sites are significant after adjusting for confounders.
- There is a rise in participation at 7 to 8 weeks largely caused by the reminder letter which was sent to non participants at 6 weeks. As results from previous overseas trials of bowel cancer screening have shown the efficacy of a single reminder letter in increasing response rates, the Australian Pilot was not designed to test this. However, it is possible to model participation rates up to 6 weeks and project these forward to calculate an estimate of what participation would have been without the reminder letter. If the trends in participation up to 6 weeks had continued, the final participation was projected to be 30% (compared to the observed participation of 46%). While this estimate is indicative only, it suggests that the reminder letter had a substantial effect on subsequent participation.

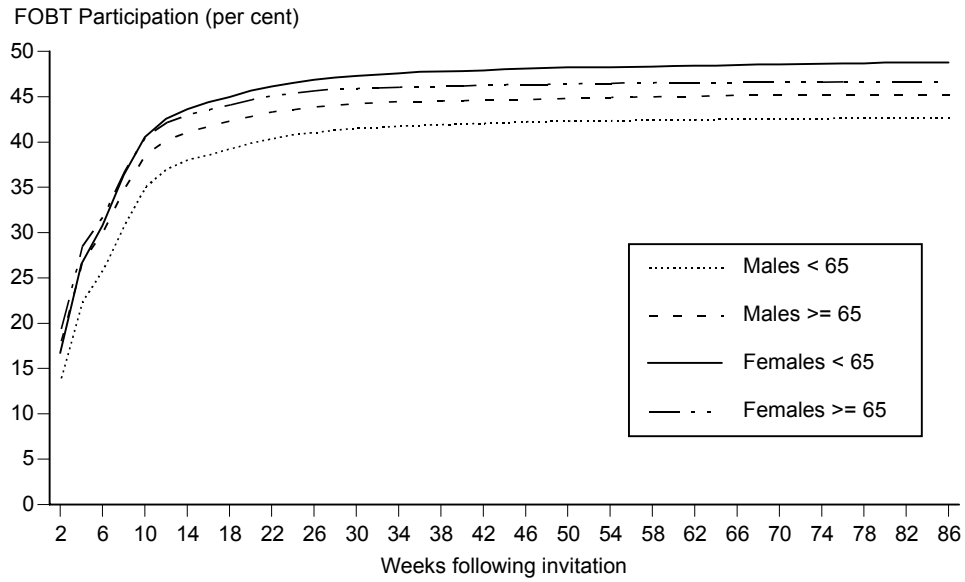


Figure 3.2: Participation by weeks since invitation and sex and age group

Table 3.6: Participation rates at 86 weeks since invitation by Pilot site

	Males under 65	Males 65 and over	Females under 65	Females 65 and over
Rate	42.8	45.3	48.8	46.8
95% CI	42-43.6	44.4-46.2	48-49.6	45.9-47.7

- The participation rates in the table are drawn from data pooled across all three Pilot sites. Data from Melbourne did not contribute to these estimates after 78 weeks, and data from Adelaide did not contribute after 82 weeks.
- The age groups have been further grouped into two (under 65 years and 65 years and over) for greater clarity in the graph. The age is taken to be the person's age at 1 January 2002, when the Pilot target population was selected.
- Participation rates for men rise consistently with age, so that the rates for under and over 65 are significantly different. Participation rates for women rise between age groups 'under 60' and '60 to 64', and then fall again between age groups '65 to 69' and '70 to 74'. The fall for older age groups is higher than the rise for younger age groups so that participation is lowest for the '70 to 74' group.
- The participation rate for men across all age groups (43.8%) is lower than that for women (47.9%).

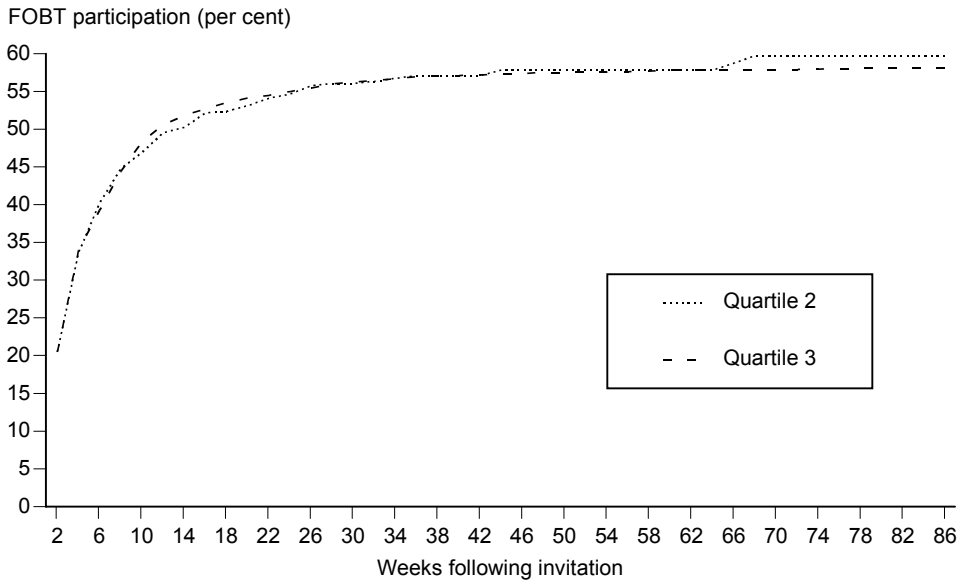


Figure 3.3a: Participation by weeks since invitation and SES quartile - Mackay

Table 3.7: Participation rates at 86 weeks since invitation by quartile of disadvantage - 3.7a: Mackay

	Quartile 1 (least disadvantage)	Quartile 2	Quartile 3	Quartile 4 (most disadvantage)
Rate	NA	59.9	58.2	NA
95% CI	NA	54.6-65.2	57.2-59.2	NA

- No postcodes in the Mackay site were coded to quartiles 1 or 4.
- There is no significant difference between response rates for quartile 2 and quartile 3 after adjusting for confounders.
- Data for quartile 2 was drawn from only one postcode in the Pilot site.

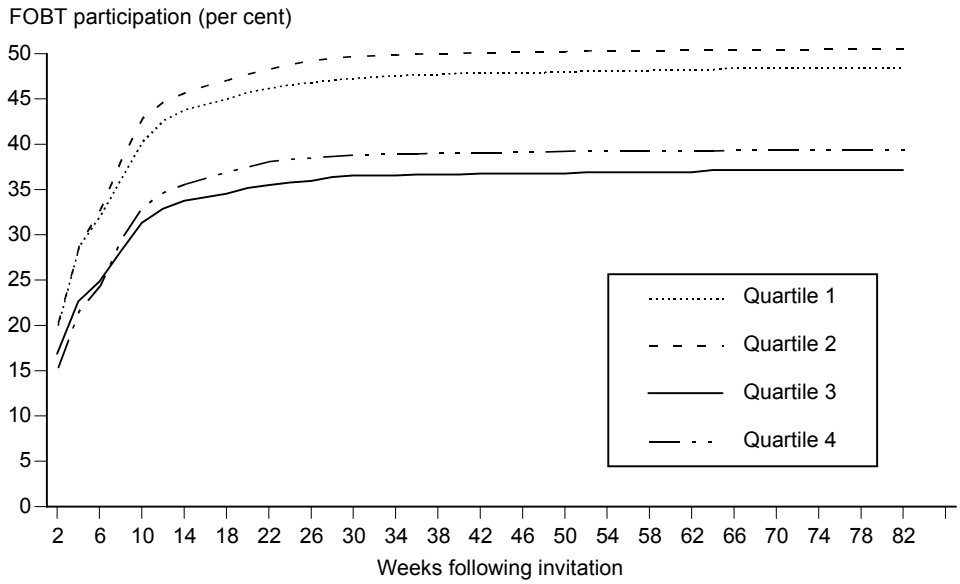


Figure 3.3b:Participation by weeks since invitation and SES quartile - Adelaide

Table 3.7: Participation rates at 82 weeks since invitation by quartile of disadvantage - 3.7b: Adelaide

	Quartile 1 (least disadvantage)	Quartile 2	Quartile 3	Quartile 4 (most disadvantage)
Rate	48.5	50.6	37.1	39.5
95% CI	47-50.1	49.5-51.7	34.5-39.8	38.1-41

- Response rates for quartile 1 are significantly lower than those for quartile 2 (p=0.005) but both rates are significantly higher than those for quartile 3 ($p < 0.0001$) after adjusting for confounders.
- Response rates for quartiles 3 and 4 are not significantly different after adjusting for confounders ($p = 0.22$).
- Data for quartile 3 was drawn from only one postcode in the Pilot site.

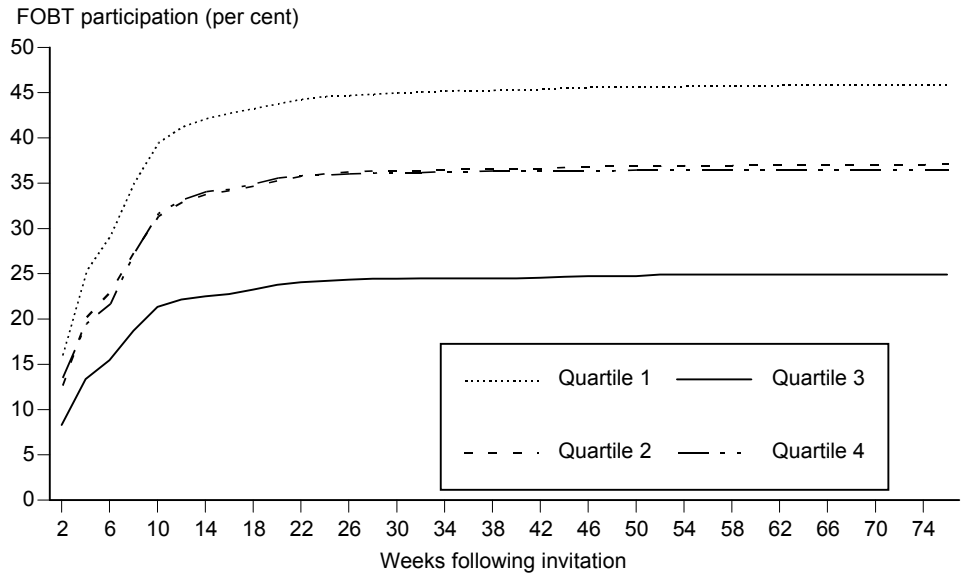


Figure 3.3c: Participation by weeks since invitation and SES quartile - Melbourne

Table 3.7: Participation rates at 78 weeks since invitation by quartile of disadvantage - 3.7c: Melbourne

	Quartile 1 (least disadvantage)	Quartile 2	Quartile 3	Quartile 4 (most disadvantage)
Rate	46.1	37.3	24.9	36.6
95% CI	45.2-46.9	36.2-38.3	23.3-26.6	34.4-38.8

- Response rates for quartile 1 are significantly higher than those for quartile 2 and those for quartile 2 and quartile 4 are significantly higher than those for quartile 3 after adjusting for confounders ($p < 0.0001$).
- Response rates for quartiles 2 and 4 are not significantly different after adjusting for confounders ($p = 0.83$).
- Data for quartile 3 was drawn from only one postcode in the Pilot site.

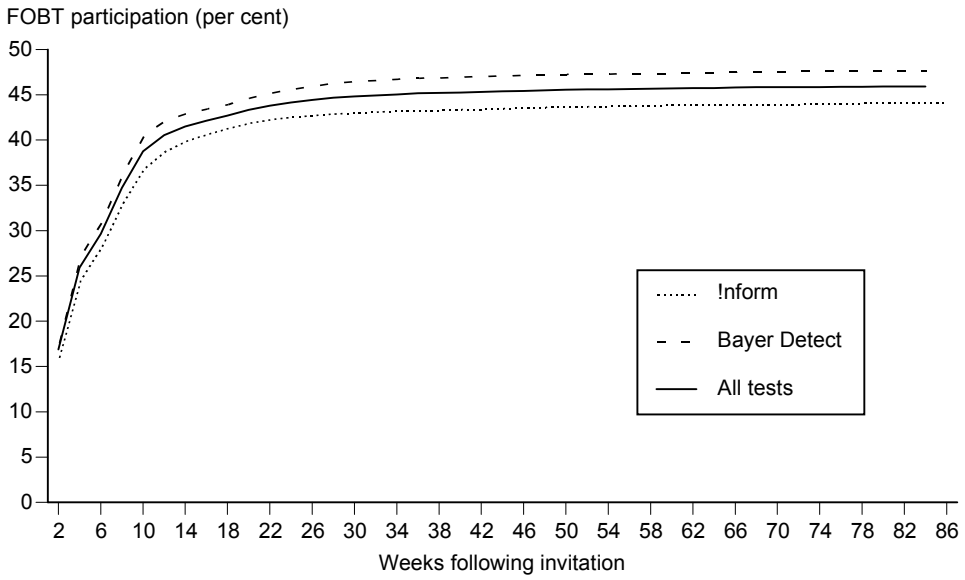


Figure 3.4: Participation by weeks since invitation and test kit type

Table 3.8: Participation rates at 84 weeks since invitation test kit type

	!nform	Bayer Detect	All tests
Rate	44.2	47.7	45.9
95% CI	43.6-44.8	47.1-48.3	45.5-46.3

- The participation data past 78 weeks does not include Melbourne. The data past 84 weeks (which only covers !nform kits) comes from Mackay. All participation rates increased by less than 0.1 percentage points after 78 weeks.
- Participation was significantly higher for people receiving the Bayer Detect FOBT than for people receiving the !nform FOBT after adjusting for confounders.

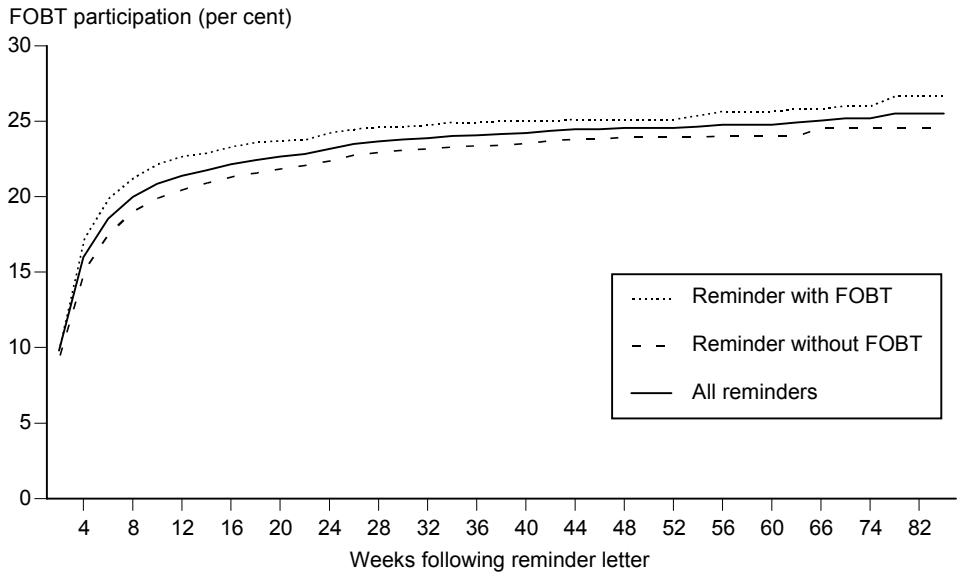


Figure 3.5: Participation by weeks since reminder letter - Mackay

Table 3.9: Participation rates at 86 weeks since reminder sent - Mackay

	Reminder letter with replacement FOBT	Reminder letter without replacement FOBT	All reminders
Rate	26.7	24.7	25.5
95% CI	24.5-29	22.9-26.4	24.2-26.8

- There is no significant difference between the participation curves following the reminder letters with and without the FOBT kit (p = 0.62) after adjustment for confounders.

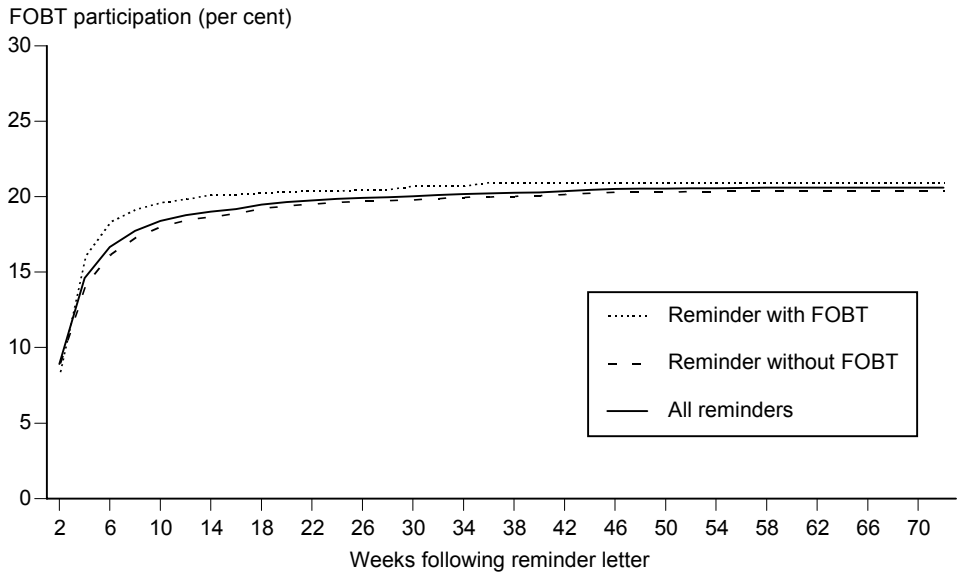


Figure 3.6: Participation by weeks since reminder letter - Adelaide

Table 3.10: Participation rates at 72 weeks since reminder sent - Adelaide

	Reminder letter with replacement FOBT	Reminder letter without replacement FOBT	All reminders
Rate	21.0	20.5	20.6
95% CI	19.3-22.7	19.7-21.2	19.9-21.3

- There is no significant difference between the participation curves following the reminder letters with and without the FOBT kit (p = 0.27) after adjustment for confounders.

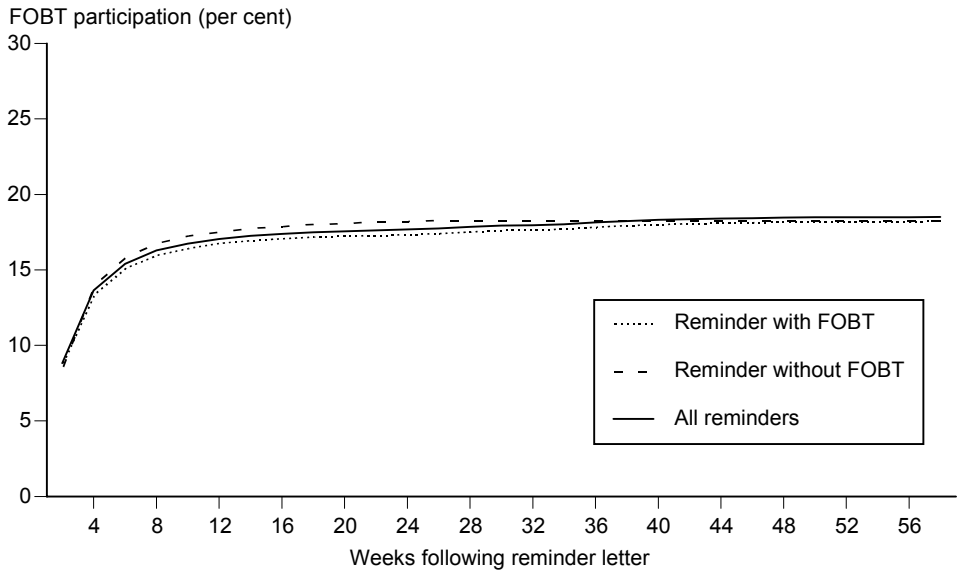


Figure 3.7: Participation by weeks since reminder letter - Melbourne

Table 3.11: Participation rates at 58 weeks since reminder sent - Melbourne

	Reminder letter with replacement FOBT	Reminder letter without replacement FOBT	All reminders
Rate	18.3	18.4	18.5
95% CI	17.6-18.9	17.4-19.3	18-19.1

- There is no significant difference between the participation curves following the reminder letters with and without the FOBT kit (p = 0.34) after adjustment for confounders.

4

FOBT outcomes

4.1 Introduction

Analyses

Tables in this section cover all FOBT results that have been returned to the Register. In some cases participants have returned more than one FOBT. In these cases all of their results have been included.

Pathologists categorise the returned FOBT into one of four groups: correctly completed, incorrectly completed, damaged and unsatisfactory. Participants are provided with specific instructions as to how to complete the FOBT. Any tests not completed according to these instructions are classified as incorrectly completed. Damaged FOBTs are any tests that have arrived spoiled or damaged and unsatisfactory tests refers to those tests that could not be processed due to an inadequate sample (for example, too much or too little faecal matter).

The classification of FOBT by return status (correctly completed etc.) and positivity is based only on returned kits. Hence the issue of kits not yet returned is irrelevant to the analyses. This means that the rates can be directly tabulated without using Kaplan-Meier estimation and the analyses done using logistic regression. In analysing return status, the dependent variable is whether or not the test was correctly completed. That is, the categories incorrectly completed, damaged and unsatisfactory were collapsed into one. This allows sufficient numbers in each category for the analysis. In analysing positivity rates, only correctly completed FOBTs were included and the dependant variable was whether or not the result was positive (i.e. whether or not blood was detected).

Confounding variables

The analysis focuses on differences between test kit types, with Pilot site, age and sex and months since the commencement of the Pilot all used as potential confounding variables in the logistic model. As before, those months where only one test kit type was distributed (November 2002 and May 2003) were excluded from the logistic model.

Anomalous and excluded data

A total of 1,374 FOBT results for ineligible participants were excluded from this section of the report. Of these, 906 results were for participants who had either undergone a colonoscopy within the last 18 months or had previously been diagnosed with bowel cancer. Another 48 results were excluded because the participants were outside the target age range of 55 to 74 years.

Finally 420 were excluded because the participants had moved outside the Pilot areas prior to being sent an invitation to participate in the screening program.

4.2 Tables, figures and analyses

Table 4.1: FOBT received status by test type - 4.1a: !nform

	FOBT correctly completed		FOBT incorrectly completed		FOBT damaged		FOBT unsatisfactory		All tests
	Number	Rate per 100 tests	Number	Rate per 100 tests	Number	Rate per 100 tests	Number	Rate per 100 tests	Number
Males									
55–59	1,793	97.1	45	2.4	5	0.3	3	0.2	1,846
60–64	1,418	97.4	35	2.4	1	0.1	2	0.1	1,456
65–69	1,314	97.3	33	2.4	2	0.1	2	0.1	1,351
70–74	1,162	97.0	32	2.7	0	0.0	4	0.3	1,198
Total	**5,687**	**97.2**	**145**	**2.5**	**8**	**0.1**	**11**	**0.2**	**5,851**
ASR	**. .**	**97.2**	**. .**	**2.5**	**. .**	**0.1**	**. .**	**0.2**	**. .**
95% CI	**. .**	**94.7–99.8**	**. .**	**2.1–2.9**	**. .**	**0.1–0.3**	**. .**	**0.1–0.3**	**. .**
Females									
55–59	2,079	97.3	49	2.3	3	0.1	6	0.3	2,137
60–64	1,670	96.3	56	3.2	3	0.2	6	0.3	1,735
65–69	1,579	97.5	35	2.2	1	0.1	4	0.2	1,619
70–74	1,431	96.8	40	2.7	2	0.1	6	0.4	1,479
Total	**6,759**	**97.0**	**180**	**2.6**	**9**	**0.1**	**22**	**0.3**	**6,970**
ASR	**. .**	**97.0**	**. .**	**2.6**	**. .**	**0.1**	**. .**	**0.3**	**. .**
95% CI	**. .**	**94.4–99.5**	**. .**	**2.2–3.0**	**. .**	**0.1–0.3**	**. .**	**0.2–0.5**	**. .**

- The majority of returned !nform FOBTs for the period 6 November 2002 to 1 October 2004 were correctly completed. Overall, 97.1% of the 12,821 returned tests were correctly completed. Of the remaining tests, 325 (2.5% of all tests) were incorrectly completed, 17 (0.1% of all tests) were damaged and 33 (0.3% of all tests) were unsatisfactory.
- Of all the people with a kit which was not correctly completed (ie. incorrectly completed, damaged or unsatisfactory), 69% correctly completed their next kit, 5% took 2 or more further kits to achieve a correctly completed kit and 26% had not yet returned a correctly completed by 1 October 2004.

Table 4.1: FOBT received status by test type - 4.1b: Bayer Detect

	FOBT correctly completed		FOBT incorrectly completed		FOBT damaged		FOBT unsatisfactory		All tests
	Number	Rate per 100 tests	Number	Rate per 100 tests	Number	Rate per 100 tests	Number	Rate per 100 tests	Number
Males									
55–59	1,939	94.4	34	1.7	9	0.4	71	3.5	2,053
60–64	1,571	94.6	25	1.5	6	0.4	58	3.5	1,660
65–69	1,419	93.7	19	1.3	4	0.3	73	4.8	1,515
70–74	1,293	92.8	26	1.9	5	0.4	70	5.0	1,394
Total	**6,222**	**94.0**	**104**	**1.6**	**24**	**0.4**	**272**	**4.1**	**6,622**
ASR	**..**	**94.0**	**..**	**1.6**	**..**	**0.4**	**..**	**4.1**	**..**
95% CI	**..**	**91.7–96.4**	**..**	**1.3–1.9**	**..**	**0.2–0.5**	**..**	**3.6–4.6**	**..**
Females									
55–59	2,247	94.5	42	1.8	4	0.2	85	3.6	2,378
60–64	1,811	93.4	37	1.9	9	0.5	81	4.2	1,938
65–69	1,557	90.3	38	2.2	3	0.2	127	7.4	1,725
70–74	1,405	88.9	33	2.1	8	0.5	134	8.5	1,580
Total	**7,020**	**92.1**	**150**	**2.0**	**24**	**0.3**	**427**	**5.6**	**7,621**
ASR	**..**	**92.2**	**..**	**2.0**	**..**	**0.3**	**..**	**5.5**	**..**
95% CI	**..**	**89.9–94.5**	**..**	**1.7–2.3**	**..**	**0.2–0.5**	**..**	**5.1–6.1**	**..**

- The majority of returned Bayer Detect FOBTs for the period 6 November 2002 to 1 October 2004 were correctly completed. Overall, 13,242 (93.0%) of the 14,243 returned tests were correctly completed. Of the remaining tests, 254 (1.8% of all tests) were incorrectly completed, 48 (0.3% of all tests) were damaged and 699 (4.9% of all tests) were unsatisfactory.
- The rate of correctly completed FOBTs was significantly higher for !nform FOBTs (97.0%) than for Bayer Detect FOBTs (92.1%) after adjusting for confounders ($p<.0001$).
- An unsatisfactory test is a test that could not be processed due to an inadequate sample (for example, too much or too little faecal matter). Results from a separate qualitative study of Pilot participants suggest that differences between Bayer Detect and !nform in the packaging of the tests may have contributed to differences in the rates of the two tests found to be unsatisfactory.
- Of all the people with a kit which was not correctly completed (ie. incorrectly completed, damaged or unsatisfactory), 66% correctly completed their next kit, 6% took 2 or more further kits to achieve a correctly completed kit and 28% had not yet returned a correctly completed by 1 October 2004.

Table 4.2: FOBT positivity rates by test type

	!nform FOBT			Bayer Detect FOBT	All FOBTs
	Rate per 100 valid !nform results prior to 22/10/04	Rate per 100 valid !nform results after 22/10/04	Rate per 100 valid !nform results	Rate per 100 valid Bayer Detect results	Rate per 100 valid results
Males					
55–59	14.1	7.1	9.9	7.1	8.5
60–64	10.2	8.5	9.2	8.6	8.9
65–69	20.5	9.7	14.2	10.7	12.4
70–74	19.1	10.2	13.9	13.1	13.5
Total	**15.7**	**8.6**	**11.6**	**9.6**	**10.5**
ASR	**15.5**	**8.7**	**11.5**	**9.5**	**10.4**
95% CI	**13.9–17.2**	**7.7–9.7**	**10.6–12.4**	**8.8–10.3**	**9.9–11.0**
Females					
55–59	9.9	3.9	6.3	5.2	5.7
60–64	10.7	5.0	7.4	6.4	6.9
65–69	11.8	7.8	9.5	7.4	8.5
70–74	16.5	7.5	11.7	10.4	11.1
Total	**12.1**	**5.8**	**8.4**	**7.0**	**7.7**
ASR	**11.9**	**5.8**	**8.4**	**7.0**	**7.7**
95% CI	**10.3–13.5**	**4.8–6.8**	**7.5–9.3**	**6.3–7.8**	**7.1–8.3**

- The positivity rates presented here are the proportion of positive results out of all valid results (ie. all positive and negative results) for each FOBT type and overall.
- Positivity rates were significantly higher for !nform FOBTs than for Bayer Detect tests after adjusting for confounders ($p<.0001$). 11.6% of all valid !nform results for males were positive and 8.4% of all valid !nform results for females were positive. The corresponding positivity rates for Bayer Detect FOBTs were 9.6% for males and 7.0% for females.
- The overall positivity rate was 9.0% (9.9% for !nform and 8.2% for Bayer Detect).
- There was a change in the !nform FOBT in either the test kit or the test analysis on 24 October 2003. The overall positivity rate for !nform fell from 13.7% prior to this date to 7.1% after this date. For kits analysed after 24 October 2003, positivity rates for !nform kits were significantly lower than those for Bayer kits (7.1% and 8.3% respectively, $p = 0.01$).

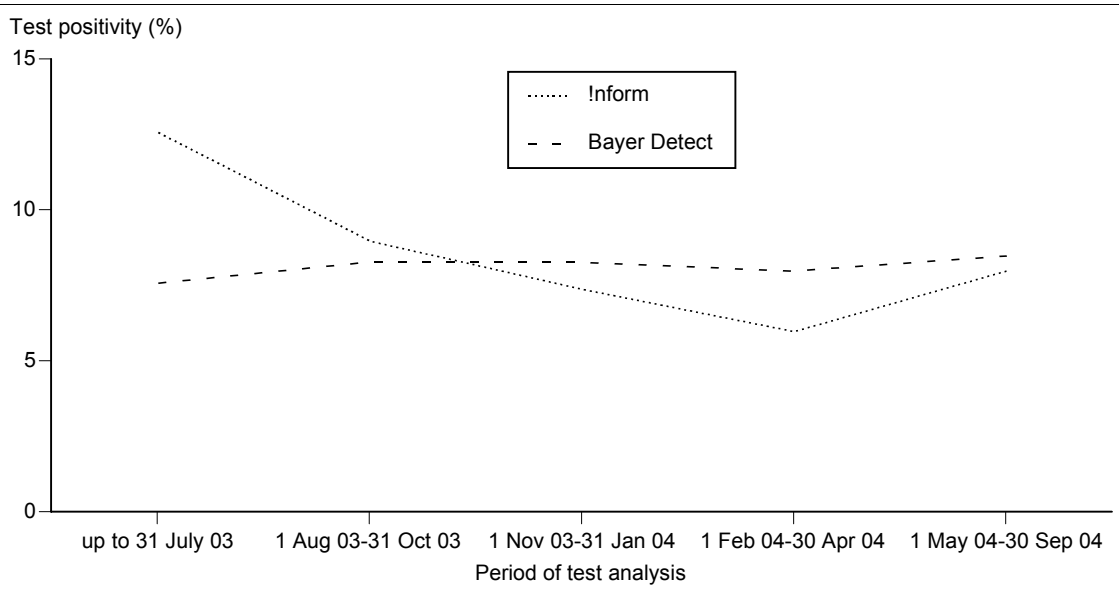


Figure 4.1: FOBT positivity rates by test type and time of processing

Table 4.3: FOBT positivity rates by test type and time of processing (%)

	Prior to 1 Aug 2003	1 Aug 03 –31 Oct 03	1 Nov 03 –31 Jan 04	1 Feb 04 –30 Apr 04	1 May 04 –30 Sep 04
!nform	12.6	9.0	7.4	6.0	8.0
Bayer Detect	7.6	8.3	8.3	8.0	8.5

- The positivity rates for Bayer Detect do not vary significantly between time periods ($p = 0.90$).
- The positivity rates for !nform fall significantly across the first four periods, with each positivity rate statistically significantly lower than the previous one. The last rate is statistically significantly higher than the previous one. The nature of the test or its analysis changed on 24 October 2003, which supports the difference between the second and third periods. However, the results presented here suggest that the !nform positivity rate was variable across the whole Pilot period.

5

GP visits

5.1 Introduction

Analyses

Participants with symptoms or a significant family history were encouraged to visit their general practitioner as soon as possible. Following the NHMRC guidelines for the prevention, early detection and management of colorectal cancer, these people should be referred direct to diagnostic assessment (generally colonoscopy). In recognition of the fact that some people at increased risk may not seek the assistance of a medical professional (e.g. those who are symptomatic but reluctant to act on their symptoms), all invited people were able to complete the FOBT if they chose to do so. Participants were also advised to visit their general practitioner on receiving a positive FOBT result to discuss further testing. General practitioners were requested to complete forms for all these consultations and for any consultations with Pilot participants who present with general concerns or queries about bowel cancer screening.

There are likely to be people who have received a positive FOBT result who intend to visit their GP but who have not yet done so. Hence the appropriate analysis technique for estimating GP visits is the Kaplan-Meier estimate and the appropriate technique for comparisons between groups is the non-parametric test of survival curves. However, the proportion of people referred for colonoscopy following a GP visit is not subject to this lag effect and so logistic modelling is the most suitable technique for the comparisons.

Four people identifying as Indigenous visited a GP following a positive FOBT result, which is insufficient to allow detailed analysis for this point on the screening pathway.

In the table presenting counts of GP visits prior to receiving an FOBT result, the GP visits were identified by comparing the date of consultation with the date that the pathology laboratory sent the FOBT result.

Confounding variables

Pilot site, age and sex are all used as potential confounding variables in the statistical comparison model. In addition, all significance tests involving Pilot site, age, and sex are adjusted for the time since the commencement of the Pilot. This variable has been collapsed from month (as used in the analysis of FOBT participation) to quarter to increase the number of respondents in each classification.

Significance tests applied to language spoken were only adjusted for age and sex because of the small numbers of people speaking a language other than English at this point on the screening pathway.

Anomalous and excluded data

Seventy four patients visiting their GP prior to receiving an invitation to participate in the Bowel Cancer Screening Pilot were recorded on the Register. These 74 GP visits have been excluded from this section of the report. 738 GP visits were also excluded from this section of the report as the participants had either undergone a colonoscopy within the last 18 months or had previously been diagnosed with bowel cancer and were therefore ineligible for screening. Four further visits were excluded as the participants were outside the target age group of 55 to 74 years and 43 were excluded as the participants had moved out of the Pilot site prior to receiving their invitation to participate in the screening program.

5.2 Tables, figures and analyses

Table 5.1: GP visits prior to receiving an FOBT result

	GP visits prior to receiving an FOBT result		All GP visits
	Number	Rate per 100 GP visits	Number
Males			
55–59	14	2.9	486
60–64	19	4.6	412
65–69	11	2.3	487
70–74	15	3.6	420
Total	**59**	**3.3**	**1,805**
ASR	. .	**3.3**	. .
95% CI	. .	**2.5–4.3**	. .
Females			
55–59	19	2.7	698
60–64	20	3.3	606
65–69	24	4.0	597
70–74	29	4.5	638
Total	**92**	**3.6**	**2,539**
ASR	. .	**3.5**	. .
95% CI	. .	**2.7–4.5**	. .

The number of visits to general practitioners in relation to the Bowel Cancer Screening Pilot Project for the period 6 November 2002 to 1 October 2004 was 4,344. Of these, 151 (3.5%) GP visits were prior to the participant receiving an FOBT pathology result. Of the people making these 151 visits, 121 went on to complete an FOBT kit while 30 had not completed a kit by 1 October 2004.

- There was no significant difference between men and women in the rate of participants visiting the GP prior to receiving an FOBT result.

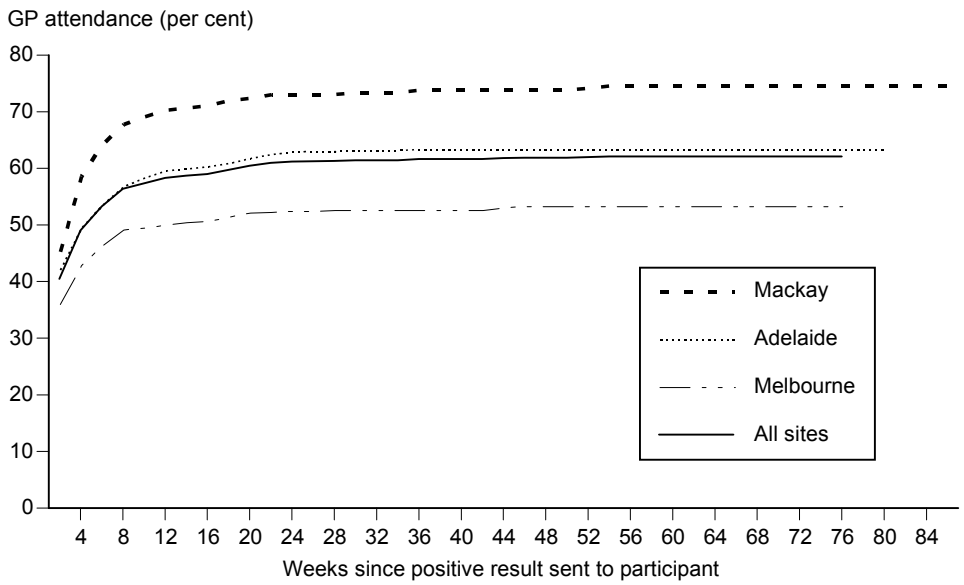


Figure 5.1: GP attendance by weeks since positive result sent and Pilot site

Table 5.2: GP attendance rates at 76 weeks since positive result sent by Pilot site

	Mackay	Adelaide	Melbourne	All sites
Rate	74.7	63.5	53.4	62.1
95% CI	70.9-78.5	60.1-66.8	50.1-56.7	60.1-64.1

- The GP attendance rates varied significantly across all three Pilot sites (p = 0.0001), with Mackay having the highest rate of 74.7%.
- Figure 7.4 (in section 7, page 61) shows significant numbers of people attending colonoscopy without previously attending a GP for a colonoscopy referral. This is possible where, for example, a person had been under the prior care of a specialist. However the large number of people apparently proceeding straight to colonoscopy without a prior GP referral suggests that some data about Pilot related GP visits were not provided to the register. Hence the attendance rates shown here may represent an underestimate of the true GP attendance rates.
- The regional nature of the Mackay site with its limited number of GPs means that most Pilot participants who visit a GP will do so within the Pilot site. Hence there is limited scope for leakage outside the pilot site and consequent loss to follow-up. In contrast, there is greater scope for loss to follow-up in the Melbourne and Adelaide sites. This may partly explain the differences in reported GP attendance rates between the sites.
- It is possible that some people contacted their GP by phone only to discuss a positive FOBT result. In this case, the register would have no record of the contact and so these people would not be included in the estimated GP attendance rates.
- All people who had not had a GP visit recorded on the register within one month of being sent a positive FOBT result were sent a reminder letter.

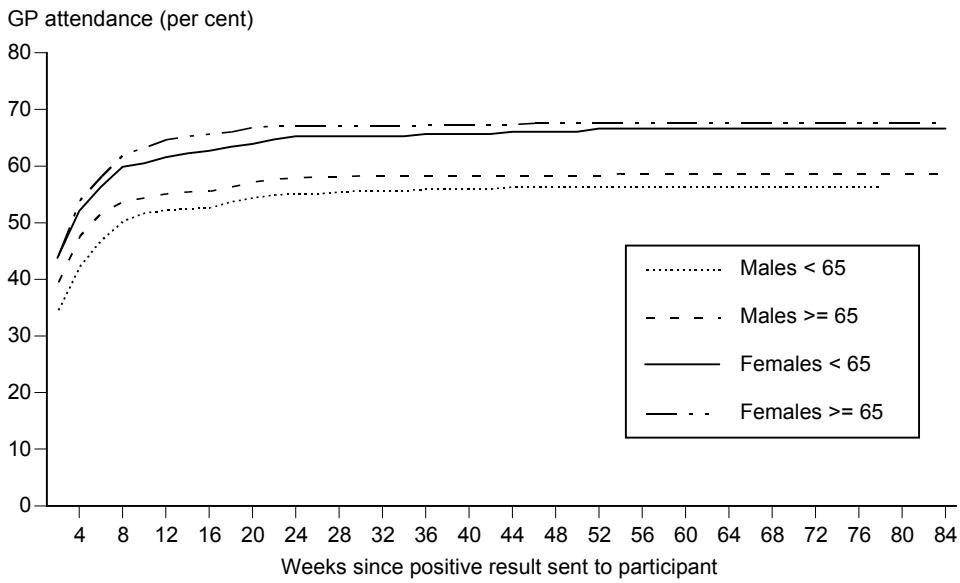


Figure 5.2: GP attendance by weeks since positive result sent and sex and age group

Table 5.3: GP attendance rates at 16 weeks since positive result sent by sex and age group

	Males under 65	Males 65 and over	Females under 65	Females 65 and over
Rate	56.5	57.5	65.9	65.2
95% CI	52.1-60.9	53.6-61.5	60.1-71.7	61.1-69.3

- Attendance rates for men (57.8%) were significantly lower than those for women (67.2%), after adjusting for age and other confounders ($p < 0.0001$).
- Attendance rates did not vary significantly by age after adjusting for sex and other confounders ($p = 0.54$).

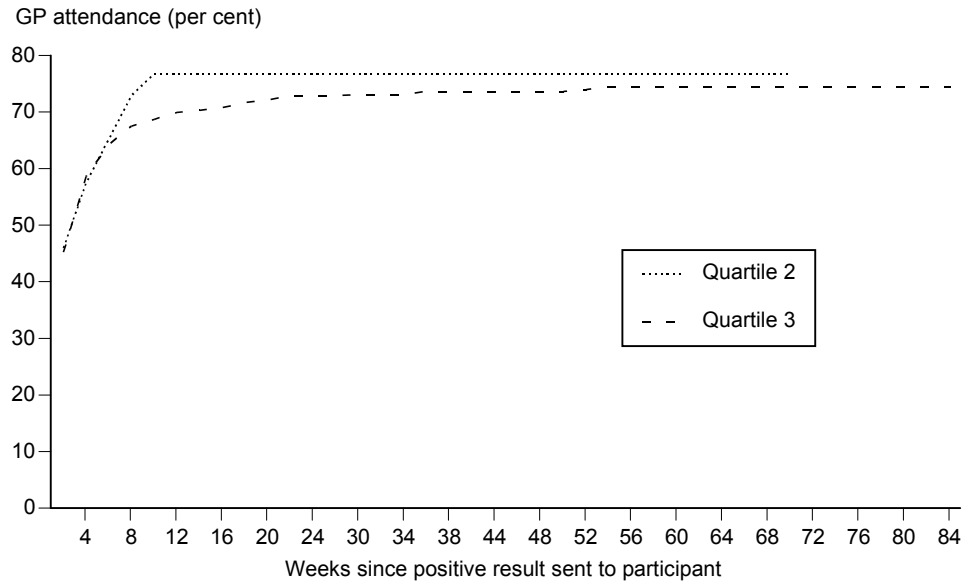


Figure 5.3a: GP attendance by weeks since positive result sent and SES quartile - Mackay

Table 5.4: GP attendance rates at 70 weeks since positive result sent by quartile of disadvantage - 5.4a: Mackay

	Quartile 1 (least disadvantage)	Quartile 2	Quartile 3	Quartile 4 (most disadvantage)
Rate	NA	76.9	74.6	NA
95% CI	NA	60.7-93.1	70.7-78.5	NA

- There is no significant difference between attendance rates for quartile 2 and quartile 3 after adjusting for confounders (p = 0.52).
- Data for quartile 2 was drawn from only one postcode in the Pilot site.

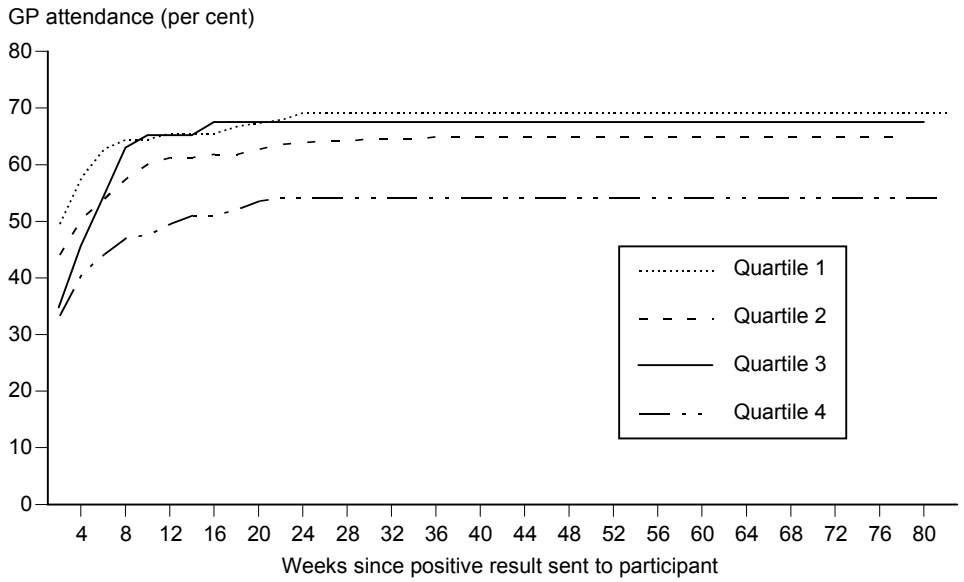


Figure 5.3b:GP attendance by weeks since positive result sent and SES quartile - Adelaide

Table 5.4: GP attendance rates at 76 weeks since positive result sent by quartile of disadvantage - 5.4b: Adelaide

	Quartile 1 (least disadvantage)	Quartile 2	Quartile 3	Quartile 4 (most disadvantage)
Rate	69.4	65.1	67.5	54.3
95% CI	62.6-76.2	60.2-70	54-81.1	47.5-61.2

- The attendance rate for quartile 4 is significantly below those for quartiles 1, 2 and 3, after adjusting for confounders (p = 0.0005).
- attendance rates for quartiles 1, 2 and 3 are not significantly different from each other after adjusting for confounders (p = 0.39).
- Data for quartile 3 was drawn from only one postcode in the Pilot site.

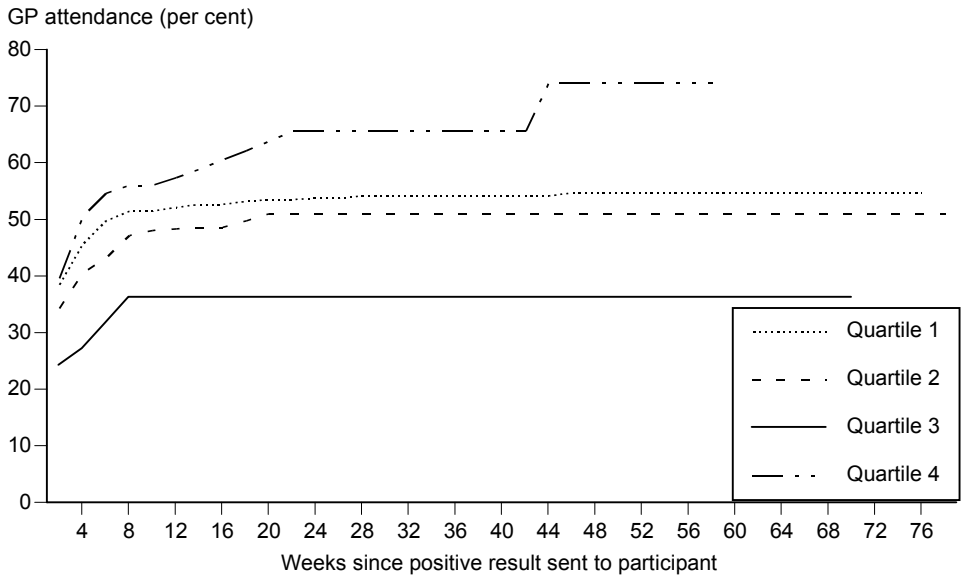


Figure 5.3c: GP attendance by weeks since positive result sent and SES quartile - Melbourne

Table 5.4: GP attendance rates at 56 weeks since positive result sent by quartile of disadvantage - 5.4c: Melbourne

	Quartile 1 (least disadvantage)	Quartile 2	Quartile 3	Quartile 4 (most disadvantage)
Rate	54.8	51.1	36.3	74.4
95% CI	50.2-59.5	45.8-56.5	24.9-47.7	61.1-87.6

- Attendance rates do not vary significantly across the four quartiles after adjusting for confounders ($p = 0.50$).
- Data for quartiles 3 and 4 were each drawn from only one postcode in the Pilot site.
- The apparent jump in attendance for quartile 4 at 44 weeks is based on small numbers of participants and should be regarded as a chance fluctuation in the rate.

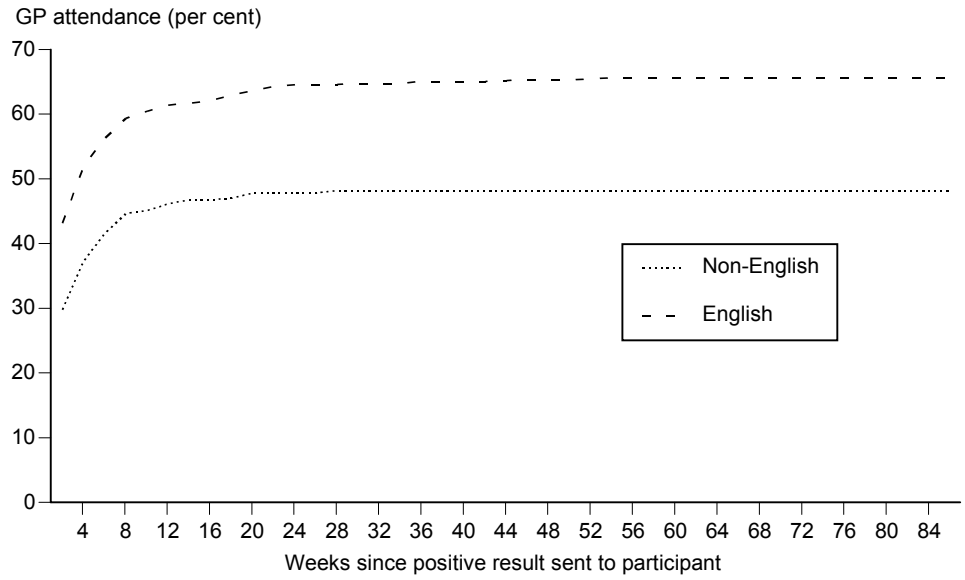


Figure 5.4: GP attendance by weeks since positive result sent and language spoken

Table 5.5: GP attendance rates at 86 weeks since positive result sent by language spoken

	English only	Language other than English
Rate	65.8	48.3
95% CI	63.5-68	43.8-52.8

- Attendance rates were significantly lower for people speaking a language other than English compared to English speakers ($p < 0.0001$).

Table 5.6: Referral by GP for colonoscopy - 5.6a: Participants with a positive FOBT

	Referral for colonoscopy		Referral for other examination		No referral		All GP visits
	Number	Rate per 100 GP visits	Number	Rate per 100 GP visits	Number	Rate per 100 GP visits	Number
Males							
55–59	175	95.1	3	1.6	6	3.3	184
60–64	138	92.6	4	2.7	7	4.7	149
65–69	195	92.4	4	1.9	12	5.7	211
70–74	175	93.6	2	1.1	10	5.3	187
Total	**683**	**93.4**	**13**	**1.8**	**35**	**4.8**	**731**
ASR	**. .**	**93.6**	**. .**	**1.8**	**. .**	**4.6**	**. .**
95% CI	**. .**	**86.5–101.1**	**. .**	**1.0–3.2**	**. .**	**3.1–6.4**	**. .**
Females							
55–59	155	95.7	2	1.2	5	3.1	162
60–64	151	93.8	4	2.5	6	3.7	161
65–69	178	94.7	6	3.2	4	2.1	188
70–74	196	91.2	5	2.3	14	6.5	215
Total	**680**	**93.7**	**17**	**2.3**	**29**	**4.0**	**726**
ASR	**. .**	**94.1**	**. .**	**2.2**	**. .**	**3.7**	**. .**
95% CI	**. .**	**87.0–101.6**	**. .**	**1.3–3.5**	**. .**	**2.3–5.6**	**. .**

- The proportion of people with a positive FOBT who were referred for colonoscopy did not vary significantly by Pilot site, age, sex, quartile of socioeconomic status or whether or not the person spoke a language other than English.
- More people had a colonoscopy than were referred for a colonoscopy (see figure 7.4, section 7, page 61). Although this is technically possible, it is unlikely and suggests that some data about Pilot related GP visits were not provided to the register.

Table 5.6: Referral by GP for colonoscopy - 5.6b: Participants without a positive FOBT

	Referral for colonoscopy		Referral for other examination		No referral		All GP visits
	Number	Rate per 100 GP visits	Number	Rate per 100 GP visits	Number	Rate per 100 GP visits	Number
Males							
55–59	99	32.8	13	4.3	190	62.9	302
60–64	94	35.7	7	2.7	162	61.6	263
65–69	82	29.7	7	2.5	187	67.8	276
70–74	55	23.6	11	4.7	167	71.7	233
Total	**330**	**30.7**	**38**	**3.5**	**706**	**65.7**	**1,074**
ASR	**..**	**31.0**	**..**	**3.6**	**..**	**65.4**	**..**
95% CI	**..**	**27.7–34.6**	**..**	**2.5–4.9**	**..**	**60.6–70.4**	**..**
Females							
55–59	177	33.0	24	4.5	335	62.5	536
60–64	159	35.7	19	4.3	267	60.0	445
65–69	112	27.4	17	4.2	280	68.5	409
70–74	92	21.7	26	6.1	305	72.1	423
Total	**540**	**29.8**	**86**	**4.7**	**1,187**	**65.5**	**1,813**
ASR	**..**	**30.2**	**..**	**4.7**	**..**	**65.1**	**..**
95% CI	**..**	**27.4–35.1**	**..**	**3.3–6.0**	**..**	**59.1–69.8**	**..**

- The proportion of people without a positive FOBT who were referred for colonoscopy did not vary significantly by sex or whether or not the person spoke a language other than English.
- The referral rate was higher for younger people than older people ($p < 0.0001$).
- The referral rate was significantly higher in Mackay (44.0%) then either Adelaide (21.5%) or Melbourne (25.6%, $p < 0.0001$).
- The referral rate in Adelaide was significantly higher for SES quartile 2 (27.0%) than each of quartiles 1, 3 and 4 (16.4% ($p = 0.002$), 12.8%, ($p=0.04$), 17.8% ($p = 0.01$)).
- Of the 994 people referred for a follow-up examination, 837 (84.2%) were referred for a family history and/or symptoms of colorectal cancer and 33 (3.3%) were referred because of a positive FOBT result even though no such result was recorded on the register. No reason for referral was recorded for the remaining 124 people.
- Of the 837 people referred for a family history and/or symptoms of colorectal cancer, 538 were referred only for family history, 233 were referred only for symptoms and 66 were referred with both symptoms and family history.

6

Colonoscopy

6.1 Introduction

Analyses

A colonoscopy is taken to have visualised the whole colon if the depth of insertion is recorded as reaching the caecum. An adequate colonoscopy is defined as any colonoscopy where the proceduralist was confident that all polyps had been removed.

There are likely to be people who have been referred for a colonoscopy and who intend to have a colonoscopy but who have not yet done so. Hence the appropriate analysis technique for estimating colonoscopy follow-up is the Kaplan-Meier estimate and the appropriate technique for comparisons of participation between groups is the non-parametric test of survival curves.

Seven people identifying as Indigenous had a colonoscopy, which is insufficient to allow detailed analysis for this point on the screening pathway. The number of people identifying as Indigenous at colonoscopy appears to be inconsistent with the numbers visiting a GP (as reported in section 5) because the analyses in section 5 primarily focussed on GP visits following a positive FOBT result. The analyses reported here cover all colonoscopies, whether or not they followed a positive FOBT result.

Confounding variables

Pilot site, age and sex are all used as potential confounding variables in the statistical comparison model. In addition, all significance tests involving Pilot site, age, and sex are adjusted for the time since the commencement of the Pilot. This variable has been collapsed from month (as used in the analysis of FOBT participation) to quarter to increase the number of participants in each classification.

Significance tests applied to language spoken were only adjusted for age and sex because of the small numbers of people speaking a language other than English at this point on the screening pathway.

Anomalous and excluded data

Forty nine colonoscopies have been excluded from this section of the report as the participants had previously been diagnosed with bowel cancer and were therefore ineligible for screening. Two further visits were excluded as the participants were outside the target age group of 55 to 74 years and 49 were excluded as the participants had moved out of the Pilot site prior to receiving their invitation to participate in the screening pathway.

Nine participants had histopathology details recorded for polyps found at colonoscopy but had no details of the colonoscopy recorded on the register. The analyses presented here require details of the colonoscopy, including the colonoscopy date, which are missing for these 9 people. Hence they have been excluded from the tables in this section but the polyp results are included in the tables in section 7.

Participation data by quartile of disadvantage have not been plotted or analysed for Mackay because the single postcode assigned to quartile 2 had very small numbers so that no reliable comparison could be made between quartiles 2 and 3.

6.2 Tables, figures and analyses

Table 6.1: Colonoscopies which visualised the whole colon

	Visualised whole colon		Did not visualise whole colon		All colonoscopies
	Number	Rate per 100 colonoscopies	Number	Rate per 100 colonoscopies	Number
Males					
55–59	234	98.7	3	1.3	237
60–64	192	98.0	4	2.0	196
65–69	248	97.3	7	2.7	255
70–74	201	95.3	10	4.7	211
Total	**875**	**97.3**	**24**	**2.7**	**899**
ASR	..	**97.5**	..	**2.5**	..
95% CI	..	**91.0–104.3**	..	**1.6–3.7**	..
Females					
55–59	265	96.0	11	4.0	276
60–64	206	96.7	7	3.3	213
65–69	195	92.9	15	7.1	210
70–74	214	91.1	21	8.9	235
Total	**880**	**94.2**	**54**	**5.8**	**934**
ASR	..	**94.5**	..	**5.5**	..
95% CI	..	**88.0–101.3**	..	**4.5–6.6**	..

- There are insufficient numbers of colonoscopies classified as not visualising the whole colon to allow comparisons between Pilot sites. However, the proportion not visualising the whole colon increased significantly with age ($p = 0.0008$) and was lower for males (97.3%) than females (94.2%, $p = 0.0008$) after adjusting for age.

Table 6.2: Adequate and inadequate colonoscopies

	Adequate colonoscopies		Inadequate colonoscopies		All colonoscopies
	Number	Rate per 100 colonoscopies	Number	Rate per 100 colonoscopies	Number
Males					
55–59	227	95.8	10	4.2	237
60–64	171	87.2	25	12.8	196
65–69	211	82.7	44	17.3	255
70–74	172	81.5	39	18.5	211
Total	**781**	**86.9**	**118**	**13.1**	**899**
ASR	**..**	**87.8**	**..**	**12.2**	**..**
95% CI	**..**	**81.7–94.4**	**..**	**10.0–14.6**	**..**
Females					
55–59	252	91.3	24	8.7	276
60–64	190	89.2	23	10.8	213
65–69	192	91.4	18	8.6	210
70–74	195	83.0	40	17.0	235
Total	**829**	**88.8**	**105**	**11.2**	**934**
ASR	**..**	**89.1**	**..**	**10.9**	**..**
95% CI	**..**	**82.9–95.6**	**..**	**8.8–13.4**	**..**

- The proportion of colonoscopies identified as adequate decreased significantly with age ($p < 0.0001$).
- The proportion of colonoscopies identified as adequate did not differ significantly by Pilot site, sex, SES quartile or speaking a language other than English.

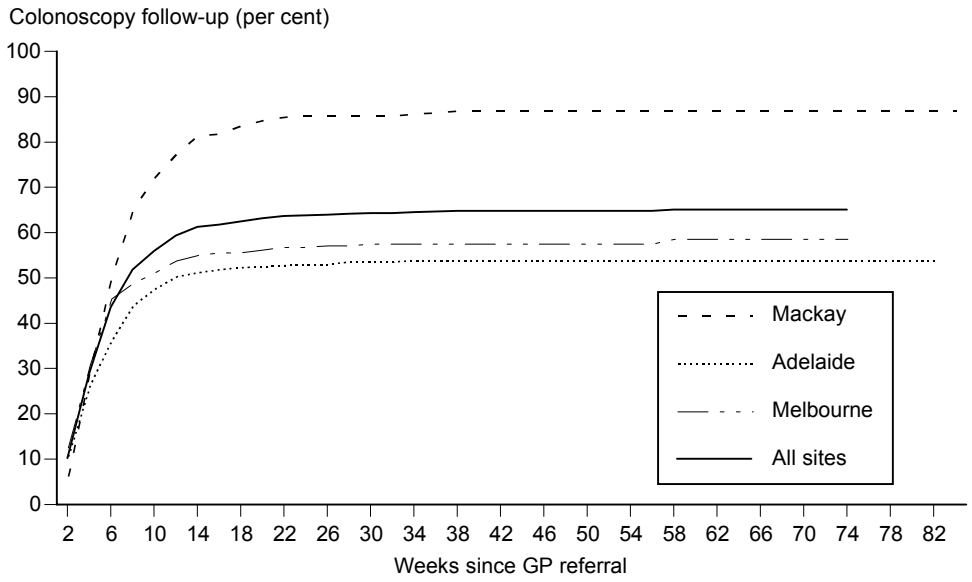


Figure 6.1: Colonoscopy follow-up by weeks since GP referral by Pilot site

Table 6.3: Colonoscopy follow-up rates at 74 weeks since GP referral by Pilot site

	Mackay	Adelaide	Melbourne	All sites
Rate	87.1	54.0	58.8	65.1
95% CI	83.5-90.6	49.5-58.5	53.8-63.7	62.4-67.8

- The proportion of people proceeding to colonoscopy following referral by a GP across the three Pilot sites was 65.1%.
- The proportion of people proceeding to colonoscopy did not differ significantly between Adelaide (54.0%) and Melbourne (58.8%) but both were significantly lower than Mackay (87.1%, $p < 0.0001$).
- The regional nature of the Mackay site enabled access to the contracted follow-up colonoscopy services within a definable area with limited leakage to services outside the pilot site. This was not the case in the Melbourne and Adelaide sites. Hence more participants in the Adelaide and Melbourne sites may have been lost to follow-up than in Mackay. Because of this, no inference can yet be drawn on the impact on follow-up rates of the different arrangements in each site for the provision of Pilot colonoscopies. Further work is required to follow up participants with positive FOBT results in all three sites to ascertain their true colonoscopy status.

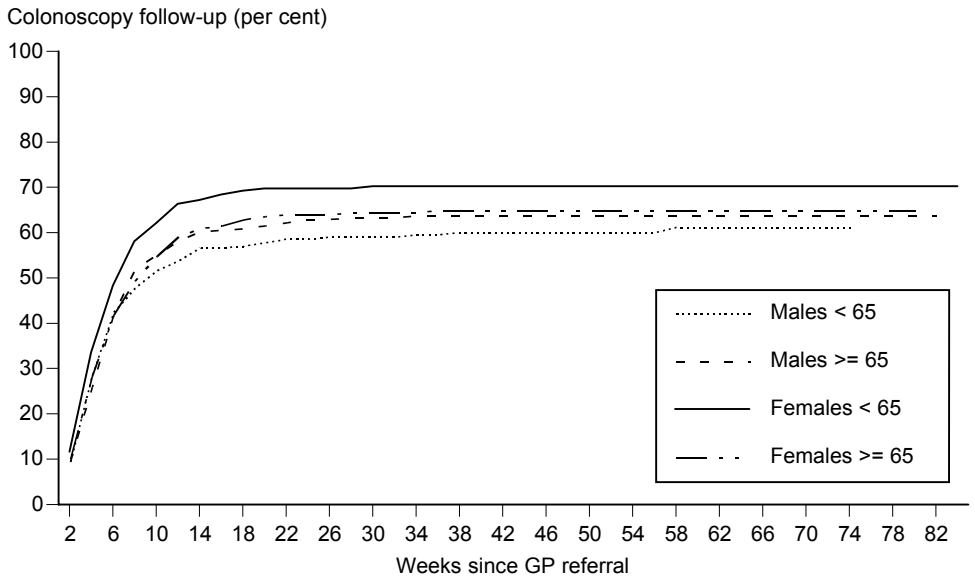


Figure 6.2: Colonoscopy follow-up by weeks since GP referral and sex and age

Table 6.4: Colonoscopy follow-up rates at 74 weeks since GP referral by sex and age

	Females under 65	Females 65 and over	Males under 65	Males 65 and over
Rate	61.5	63.9	70.3	65.1
95% CI	55.5-67.4	58.9-68.9	64.8-75.7	60-70.2

- The proportion of people proceeding to colonoscopy did not differ significantly between sex or age group.

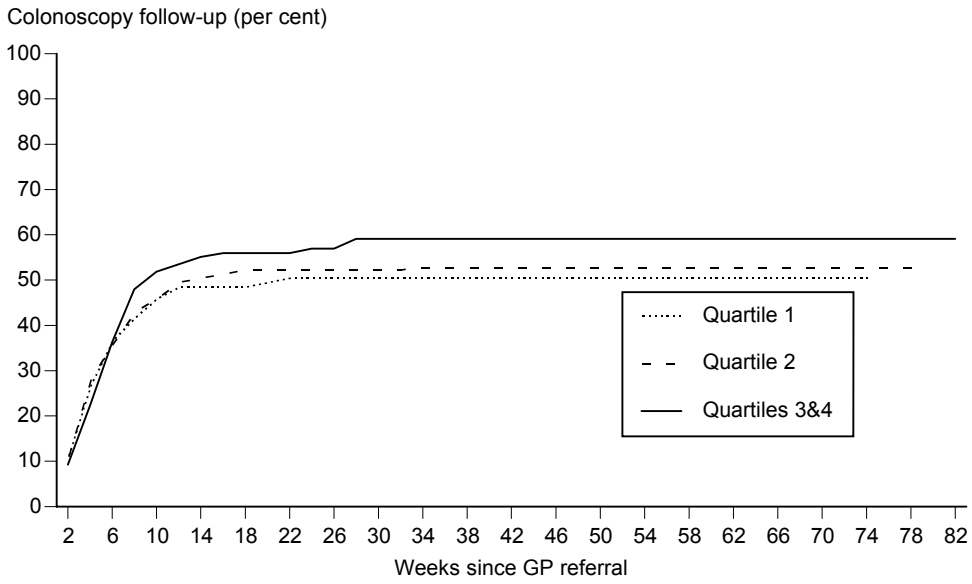


Figure 6.3a: Colonoscopy follow-up by weeks since GP referral and SES quartile - Adelaide

Table 6.5: Colonoscopy follow-up rates at 74 weeks since GP referral by SES quartile - 6.5a: Adelaide

	Quartile 1 (least disadvantaged)	Quartile 2	Quartiles 3 & 4 (most disadvantaged)
Rate	50.6	53.0	59.1
95% CI	41.6-59.6	46.6-59.5	50.4-67.8

- The proportion of people proceeding to colonoscopy did not differ significantly between quartiles ($p = 0.38$).

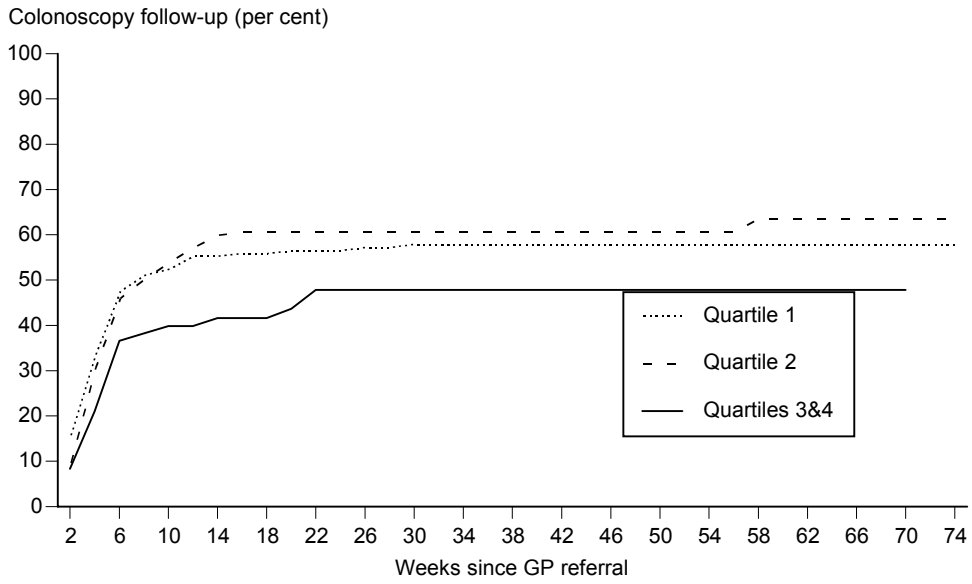


Figure 6.3b:Colonoscopy follow-up by weeks since GP referral and SES quartile - Melbourne

Table 6.5: Colonoscopy follow-up rates at 56 weeks since GP referral by SES quartile - 6.5b: Melbourne

	Quartile 1 (least disadvantaged)	Quartile 2	Quartiles 3 & 4 (most disadvantaged)
Rate	58.2	63.9	47.8
95% CI	51.6-64.7	54.9-72.8	35.4-60.2

- The proportion of people proceeding to colonoscopy did not differ significantly between quartiles ($p = 0.08$).

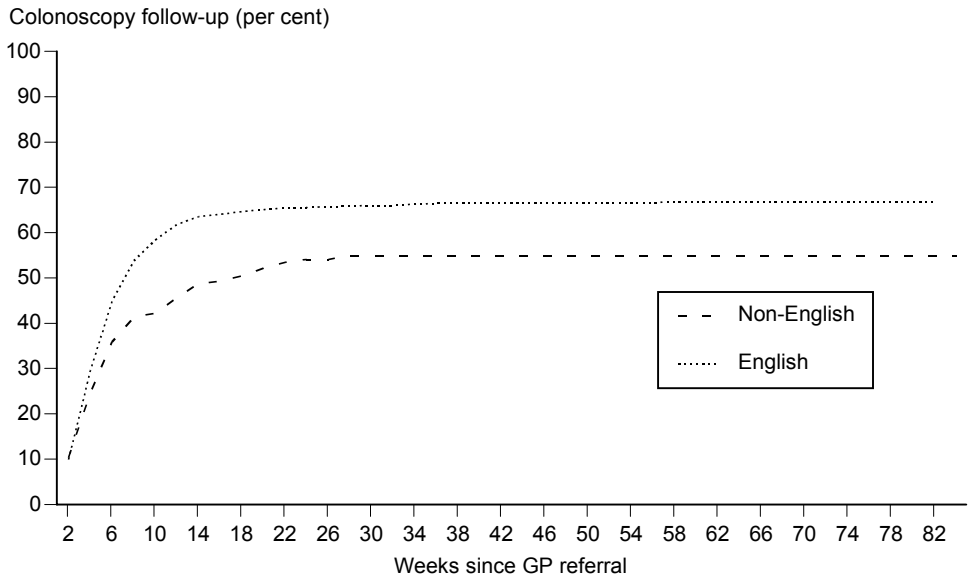


Figure 6.4: Colonoscopy follow-up by weeks since GP referral and language spoken

Table 6.6: Colonoscopy follow-up rates at 82 weeks since GP referral by language spoken

	English only	Language other than English
Rate	67.1	55.1
95% CI	64.2-70.1	48.2-61.9

- The proportion of people proceeding to colonoscopy was significantly lower for people who spoke a language other than English than for English speakers (p = 0.0006) after adjusting for confounders.

7

Overall screening outcomes

7.1 Introduction

Analyses

This section presents the overall outcomes from the Pilot. The first set of analyses focuses on people who returned a positive FOBT and estimates the proportion who proceeded to colonoscopy. This gives an estimate of the overall proportion of people with a positive FOBT result who complete the entire screening pathway. The second set of analyses tabulates the current screening outcomes for all people invited to participate in the screening program. For participants who returned more than one FOBT, the result counted in these analyses was selected according to the following order of precedence: a positive result was selected over any other result, and a negative result was selected over an inconclusive result. For participants with more than one polyp or cancer found at colonoscopy, the most serious result was counted. Adenoma classifications are described in Appendix B.

The polyps reported in tables 7.4 and 7.5 are those which have been confirmed histopathologically as adenomas. Eighty eight people were found to have only hyperplastic polyps at colonoscopy. These polyps have a very low risk of proceeding to cancer. A further 383 people had a record of polyps found at colonoscopy but no details of histopathology for these polyps. They have been excluded from the tables presented in this section. Nine participants had histopathology details recorded for polyps found at colonoscopy but had no details of the colonoscopy recorded on the register. They have been excluded from tables and figures 7.1, 7.2 and 7.3 (which require the date of the colonoscopy procedure) but they have been included in all other tables and figures in this section.

One important outcome indicator for bowel cancer screening is the stage at detection of each screen detected cancer. The Australian Pilot ran over too short a period to allow a direct assessment of its impact on bowel cancer mortality. However, if the cancers detected have a similar stage profile to those detected in the randomised controlled trials then we can be confident that screening in Australia would lead to similar mortality reductions to those demonstrated by the RCTs. Further, data on the stage profile of cancers detected in the Australian Pilot would allow a direct comparison with the outcomes of the UK pilot.

As at 1 October 2004, 16 of the people with suspected cancers found at colonoscopy had been recorded on the register as having cancers confirmed by histopathology following surgical resection . However, no staging information had been recorded for any of these cancers. A further 4 cancers were confirmed by histopathology following local resection. These could be presumed to be provisionally stage A cancers, though it is possible that some of these may proceed to surgical resection and be classified as a more serious stage. Hence no analyses of cancer stage at detection were possible in this report.

Confounding variables

Pilot site, age and sex are all used as potential confounding variables in the statistical comparison model. In addition, all significance tests involving Pilot site, age, and sex are adjusted for the time since the commencement of the Pilot. This variable has been collapsed from month (as used in the analysis of FOBT participation) to quarter to increase the number of respondents in each classification.

7.2 Tables, figures and analyses

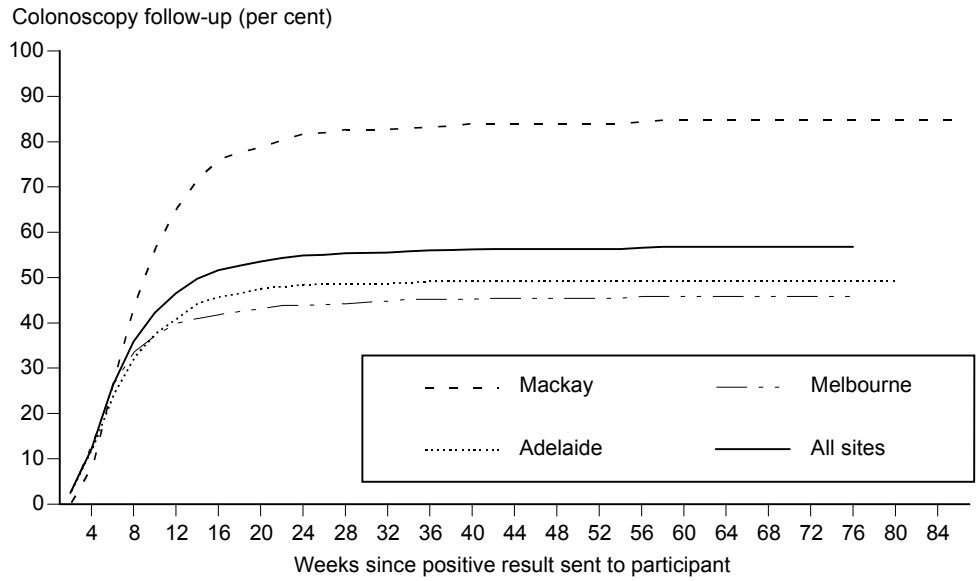


Figure 7.1: Colonoscopy follow-up by weeks since positive result sent to participant and Pilot site

Table 7.1: Colonoscopy follow-up rates at 76 weeks since positive result sent to participant by Pilot site

	Mackay	Adelaide	Melbourne	All sites
Rate	85.0	49.4	46.1	56.8
95% CI	81.7-88.3	46-52.9	42.6-49.5	54.6-58.9

- The follow-up rates are significantly higher in Mackay than Adelaide and Melbourne ($p < 0.0001$) after adjustment for confounders.
- The follow-up rates do not differ significantly between Melbourne and Adelaide ($p = 0.61$) after adjustment for confounders.
- The regional nature of the Mackay site enabled access to the contracted follow-up colonoscopy services within a definable area with limited leakage to services outside the pilot site. This was not the case in the Melbourne and Adelaide sites. Hence more participants in the Adelaide and Melbourne sites may have been lost to follow-up than in Mackay.

- More people had a colonoscopy than were referred for a colonoscopy by a GP (see figure 7.4, section 7, page 61). Although this is technically possible, it is unlikely and suggests that some data about Pilot related GP visits are not being provided to the register.

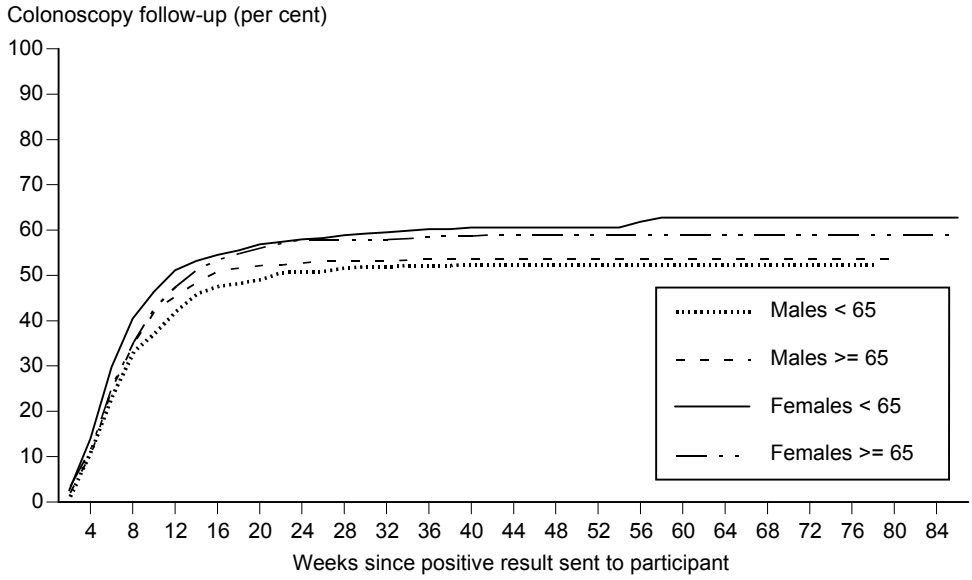


Figure 7.2: Colonoscopy follow-up by weeks since positive result sent to participant and sex and age group

Table 7.2: Colonoscopy follow-up rates at 78 weeks since invite and sex and age group

	Males under 65	Males 65 and over	Females under 65	Females 65 and over
Rate	52.7	53.8	62.7	59.2
95% CI	48.5-57	49.9-57.7	57.8-67.7	55.1-63.4

- There is no significant difference in follow-up by age group ($p = 0.78$) but the rates for men are significantly below those for women ($p = 0.008$) after adjustment for confounders.

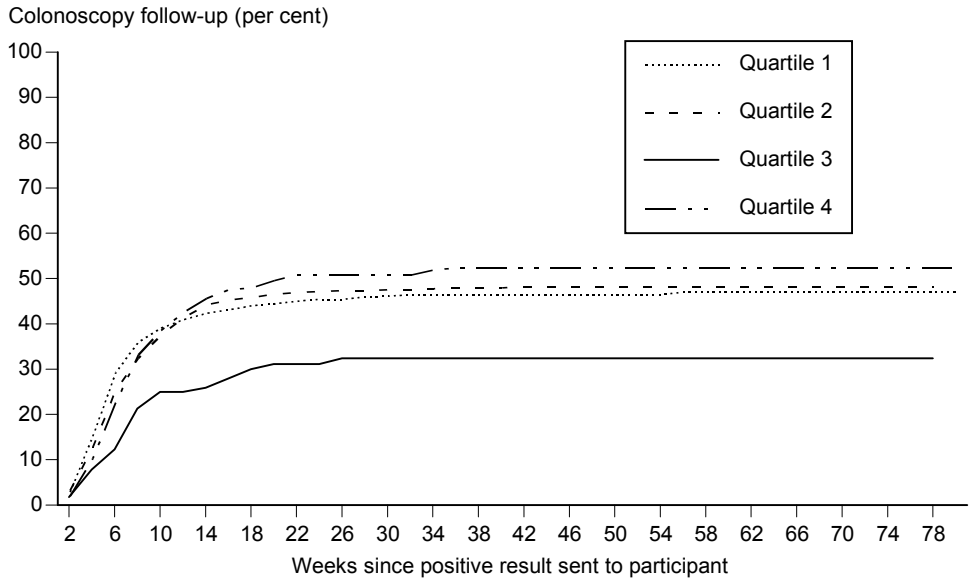


Figure 7.3: Colonoscopy follow-up by weeks since positive result sent to participant and SES quartile - Adelaide and Melbourne.

Table 7.3: Colonoscopy follow-up rates at 78 weeks since positive result sent to participant by quartile of disadvantage - Adelaide and Melbourne

	Quartile 1 (least disadvantaged)	Quartile 2	Quartile 3	Quartile 4 (most disadvantaged)
Rate	47.2	48.4	32.4	52.6
95% CI	43.1-51.3	44.7-52.1	23.4-41.3	46.5-58.6

There is no significant difference in follow-up by quartile of socioeconomic disadvantage ($p = 0.81$) after adjustment for confounders.

Table 7.4: Overall summary outcomes

	All invitations	Colonoscopy without positive FOBT		FOBT not received, no colonoscopy	FOBT inconclusive, no colonoscopy	FOBT negative, no colonoscopy	FOBT positive										
		No FOBT	Negative FOBT				Colonoscopy not done or not recorded	No cancers or adenoma	Diminutive adenoma	Small adenoma	Advanced adenoma	Cancer suspected at colonoscopy	Cancer confirmed by histopathology				
													Stage				
													A	B	C	D	Not reported
Mackay	11,045	3	381	4,696	68	5,347	100	288	21	19	91	33	..	..	..	..	..
Adelaide	18,431	0	38	9,869	107	7,614	407	311	10	8	51	18	..	..	..	..	..
Melbourne	27,431	2	106	16,497	149	9,722	536	348	11	10	38	16	..	..	..	..	..
Total	**56,907**	**5**	**525**	**31,062**	**324**	**22,683**	**1,035**	**947**	**42**	**37**	**180**	**67**	**..**	**..**	**..**	**..**	**..**

- Of the 56,907 invitations packs sent to eligible people in the Pilot population since 6 November 2002, 25,840 people (45.4%) had returned a completed FOBT by 1 October 2004.
- Of these 25,840 participants, 2,308 (8.9%) had a positive result, 23,208 (89.8%) had a negative result and the results for 324 (1.3%) were inconclusive. People who received an inconclusive FOBT test result were also sent another FOBT kit. The 324 people listed as having an inconclusive result are those who have not yet returned this second kit.
- Overall, 326 (0.6%) of the 56,907 invitations led to a positive FOBT followed by the finding of a cancer or adenoma by 1 October 2004.
- 530 participants did not have a positive FOBT but still underwent colonoscopy. Of these, 525 had a negative FOBT while the remaining 5 participants did not have an FOBT pathology result recorded in the Register before undergoing colonoscopy. See Table 7.5 for the results of these colonoscopies.
- Of the 2,308 participants that had a positive FOBT result, 1,035 (44.8%) were not recorded as having a colonoscopy by 1 October 2004. There were 67 suspected cancer cases and 259 confirmed adenomas among the 1,273 participants that had a record of a colonoscopy or pathology results for polyps.

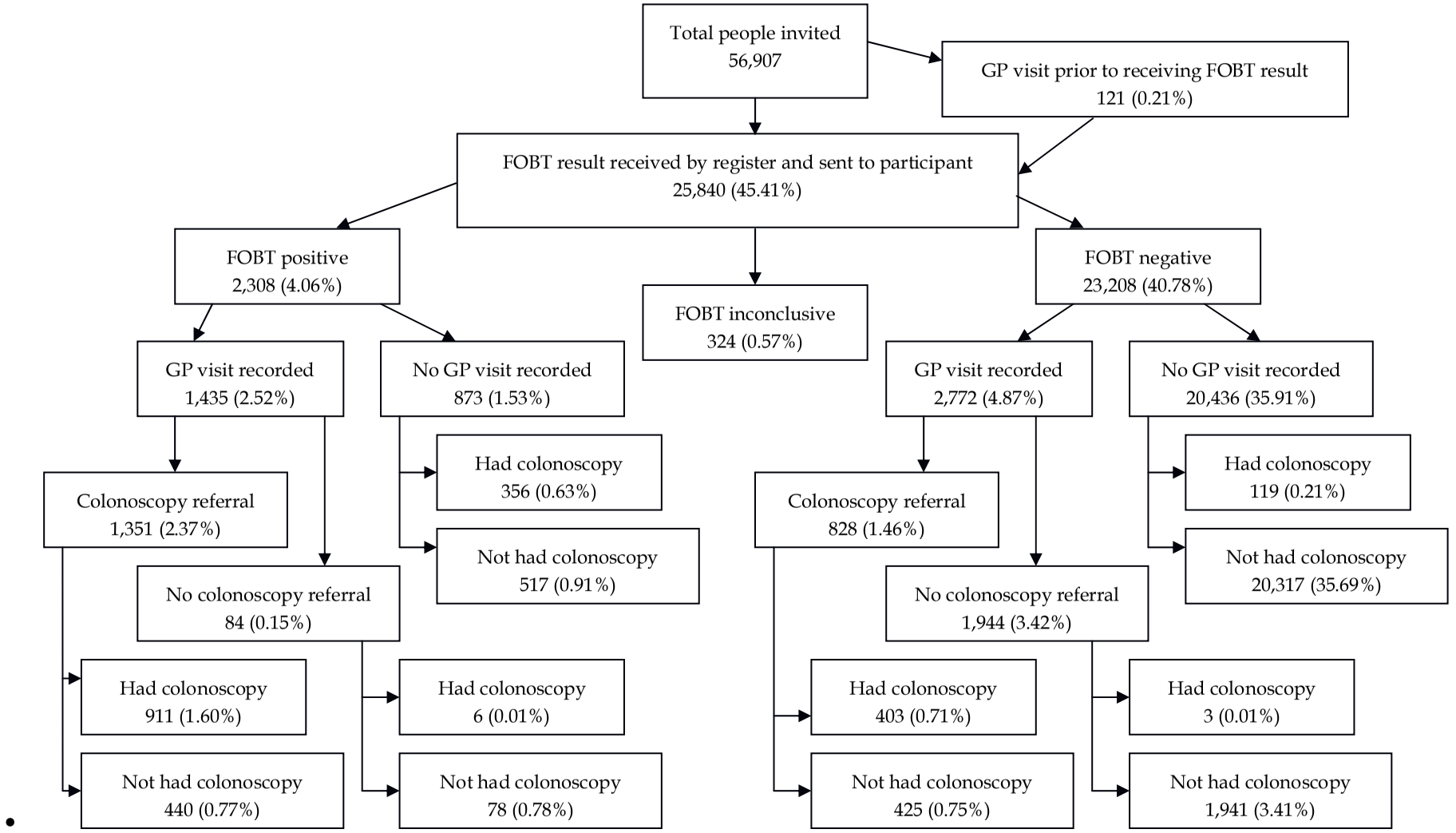
- Some of the 1,035 participants with a positive FOBT and no recorded colonoscopy have not had time to proceed to colonoscopy by 1 October 2004. Further, some of these 1,035 participants—particularly in Adelaide and Melbourne—have been lost to follow-up. That is, they may have had a colonoscopy but the details of that colonoscopy have not yet been recorded in the register (see table 6.3).
- In general there should be around twice as many small or diminutive adenomas found as advanced adenomas (see, for example, Lieberman et al. 2000). The fact that there were fewer small or diminutive adenomas found than advanced adenomas suggests that either significant numbers of these small adenomas are not being found at colonoscopy or that they are not being reported.

Table 7.5: Colonoscopy outcomes for participants without a positive FOBT

	No cancers or adenoma	Diminutive adenoma	Small adenoma	Advanced adenoma	Cancer suspected at colonoscopy	Cancer confirmed by histopathology				Total
						Stage				
						A	B	C	D	
Mackay	349	13	4	16	2	..	..	..	..	384
Adelaide	35	2	0	1	0	..	..	..	..	38
Melbourne	103	3	0	2	0	..	..	..	..	107
Total	**487**	**18**	**4**	**19**	**2**	..	..	..	..	**530**

- Of the 530 colonoscopies on participants that did not have a positive FOBT result, there were 2 suspected cancer cases. Adenomas were found in 41 participants and 487 participants had neither adenomas nor cancer.
- The GP reason for referral to colonoscopy was a significant family history of bowel cancer and/or bowel cancer symptoms for 399 participants. For another 8 participants, the GP reason for referral was a positive FOBT. However, the FOBT pathology result recorded in the Register for these 8 participants was negative. There was no record of a GP referral for the remaining 123 participants.

Figure 7.4: Numbers of people at key screening pathway points - 7.4a: People who have returned a FOBT kit



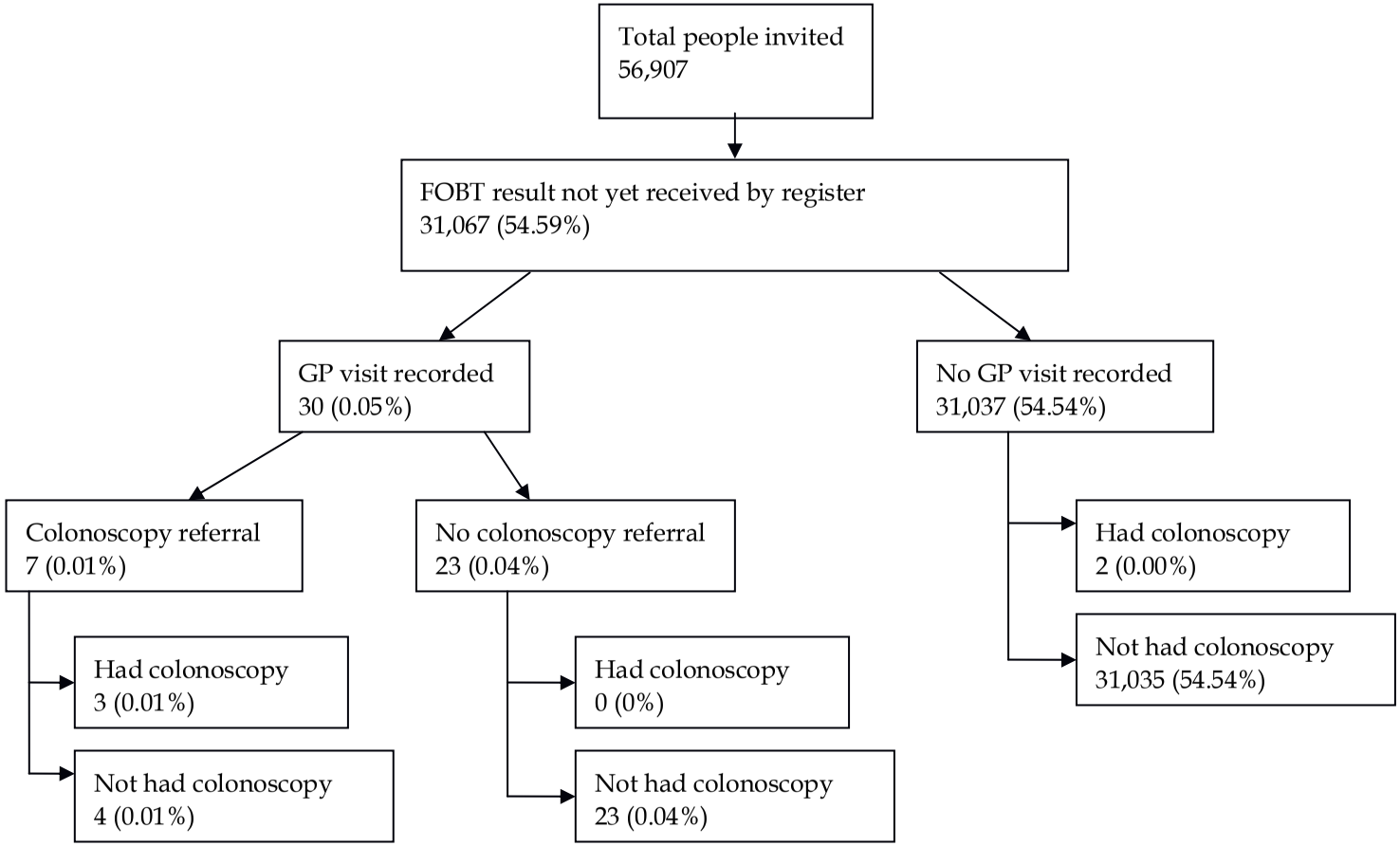


Figure 7.4: Numbers of people at key screening pathway points - 7.4b: People who have not yet returned a FOBT kit

- 4,353 (7.65%) people visited a GP in connection with the Pilot. Of these, 30 (0.05%) people visited the GP but did not complete an FOBT kit and 121 (0.21%) visited a GP prior to receiving their FOBT result. Of these 121, 11 visited the GP a second time following receipt of their result, 30 were referred directly for colonoscopy prior to receiving their FOBT result and 4 had no record of a subsequent GP visit despite receiving a positive FOBT result.
- A total of 4,213 (7.40%) visited the GP following either a positive or negative FOBT result.
- 1,803 (3.17%) people had a colonoscopy. Of these 477 had a colonoscopy with no record of a GP visit. It is unlikely that this many people proceeded straight to colonoscopy without first consulting a GP, so this result is likely to be due to data not being provided by the GP.
- 9 people had a colonoscopy despite having a prior GP visit where the GP did not refer them for colonoscopy.

Table 7.6: Positive predictive value of FOBT - 7.6a: Cancers and advanced adenomas

	Suspected cancer	Rate per 100 investigated positive FOBTs	Advanceda denoma	Rate per 100 investigated positive FOBTs	Total	Rate per 100 investigated positive FOBTs	All investigated positive FOBTs
!nform	37	5.5	90	13.3	127	18.8	676
Bayer Detect	30	5.0	90	15.1	120	20.1	597

Table 7.6: Positive predictive value of FOBT - 7.6b: All neoplasms (cancers and all adenomas)

	All cancers and adenomas	Rate per 100 investigated positive FOBTs	All investigated positive FOBTs
!nform	166	24.6	676
Bayer Detect	160	26.8	597

- There were 383 polyps detected at colonoscopy with no histopathology recorded on the register. There is no way of knowing how many of these were adenomas, so they do not appear in this table. This means that the positive predictive values for adenomas and all neoplasms are likely to be underestimates.
- Of the 676 participants that have undergone colonoscopy following a positive !nform FOBT result, 37 (5.5%) suspected cancer cases were found and 90 (13.3%) participants were found to have an adenoma. Of the 597 participants that have undergone colonoscopy following a positive Bayer Detect FOBT result, 30 (5.0%) suspected cancer cases were found and 90 (15.1%) participants were found to have an adenoma.
- 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 FOBTs, this is the proportion of FOBTs with cancers and adenomas detected out of all positive FOBTs that are followed up with a colonoscopy. The positive predictive value for cancers and advanced adenomas across both tests was 19.4%. There was no significant difference between the positive predictive value for the Bayer Detect FOBT (20.1%) and the !nform FOBT (18.8%, $p = 0.36$).
- The positive predictive value for all cancers and adenomas (including small and diminutive adenomas) across both tests was 25.6%. There was no significant difference between this positive predictive value for the Bayer Detect FOBT (26.8%) and the !nform FOBT (24.6%, $p = 0.37$).

- As a comparison, the colonoscopy outcomes for the 399 participants referred for colonoscopy for significant family history and/or symptoms but without a positive FOBT were: 2 suspected cancers, 15 advanced adenomas and 13 small or diminutive adenomas. This means that the positive predictive value of significant family history and/or symptoms of bowel cancer in the absence of a positive FOBT result was 0.5% for cancer, 4.3% for cancer or advanced adenoma and 7.5% for cancer or any adenoma.

8

Comparison of Australian Pilot results with those of international colorectal cancer screening studies

8.1 Background

There are published results for five major randomised controlled trials (RCTs) of population screening for bowel cancer using FOBTs. These studies are:

The Minnesota RCT

This study recruited 46,551 participants age 50 to 80 years from volunteers from the American Cancer Society and fraternal, veterans and employee groups in Minnesota. They were randomised to screening once a year or screening every two years, using FOBT with colonoscopy follow-up of positive screens, or to a control group (Mandel et al. 1993).

The Nottingham RCT

This study recruited 152,850 participants aged 45 to 74 years who lived in the Nottingham area of the UK. Individuals were identified according to the general practice at which they were registered. Family Health Service Authority and general practice registers were used to compile a list of men and women in the target age range associated with each general practice. After removal of people judged unsuitable for the study (for example because of a previous diagnosis of colorectal cancer), the remaining individuals were randomised to a study group for screening using FOBT every two years or to a control group. Controls were identified but not told about the study, received no intervention and continued to use healthcare facilities as usual. Screening group members were sent a Haemoccult FOBT kit, together with instructions and an explanatory letter from their family doctor inviting them to complete and return the test. For most of the study period people who did not accept the first invitation for screening were not reinvited for subsequent screens (Hardcastle et al. 1996).

The Funen RCT

This study recruited 140,000 people age 45 to 75 years living in Funen, Denmark. The study design was similar to that of the Nottingham study except that participants were selected from the population register of the county (Kronborg et al. 1996).

The Göteborg RCT

This study recruited 51,325 people aged 60 to 64 years from Göteborg, Sweden. Again the study design was similar to that of Funen and Nottingham except that all members of the screening group were invited for rescreening regardless of whether or not they participated in the first screen (Kewenter et al. 1991). This study's focus on a narrow age group limits its comparability with the Australian results, so it shall not be considered further in this report.

The Burgundy RCT

This study recruited 91,199 people aged 45 to 74 years from 12 administrative districts in Burgundy, France. The objective of the first publication from this study was to investigate the effect on compliance of demographic variables and of the way of proposing an FOBT in a colorectal cancer mass screening programme. Two recruitment strategies were trialled provision of the Haemoccult test kit by a medical practitioner during a consultation and direct mailing of the test kit (Tazi et al. 1997). A subsequent publication reported on the outcomes of screening with comparison to a control group (Faivre et al. 2004).

The only country other than Australia to have a completed pilot test of FOBT based population screening for colorectal cancer is the United Kingdom. The UK pilot was conducted at two sites—Tayside, Grampian and Fife in Scotland and the West Midlands in England. Screening began at the Scottish site on 31 March 2000 and at the English site on 6 September 2000. In each site, men and women aged between 50 and 69 who were registered with a participating General Practitioner were offered a faecal occult blood test (FOBT) to screen for bowel cancer. By the end of October 2002 (the time of the last data download available for UK final evaluation report) 486,355 people had been offered screening (The UK CRC Screening Pilot Evaluation Team 2003).

This section presents a comparison of results from the Australian and UK pilots, the RCTs and the participation study. These comparisons should be treated with caution, as there are significant methodological differences between these studies. These methodological differences are described below, along with the tables of comparison data.

8.2 FOBT participation

Table 8.1 presents the age specific participation rates from the RCTs (most of these studies did not report age specific rates separately by sex). Table 8.2 presents the age-sex specific participation rates for the UK pilot and the Australian Pilot by Pilot site.

The Minnesota study recruited participants from a pool of people who had volunteered for screening. Hence its high participation rate does not reflect the difficulties of recruiting participants from the general population. The Nottingham and Burgundy studies had similar compliance rates despite the trialling of different recruitment strategies in the latter study. The main difference in recruitment strategies between Funen and Nottingham is that participants in Nottingham received only one follow-up letter while those in Funen received two.

The Mackay recruitment rates are slightly higher than those reported for both Burgundy and Nottingham but lower than those reported for Funen. The recruitment rates for Adelaide and Melbourne are lower than the reported rates from all three studies. However, methodological differences between these studies and the Australian Pilot make direct comparison of these rates misleading. Both the Nottingham and Funen studies removed ‘unsuitable’ participants from the study population prior to recruitment. In Nottingham this exclusion was at the discretion of the doctor with whom the person was registered and in Funen the exclusion was done via data linkage with hospital inpatient files and other relevant registration systems.

The Australian Pilot invited all people resident in the Pilot site in the relevant age groups. While people could identify themselves as unsuitable for screening and remove themselves from the program, no systematic attempt was made to identify and remove such people from the target population prior to inviting people to take part in the screening program.

Table 8.1: Percent response rate to the first screen by age at study entry for the Minnesota, Burgundy, Nottingham and Funen studies

Age	Minnesota	Burgundy	Nottingham	Funen
45–49	—	49.1	—	76.0
50–54	85.4	54.4	51.5	73.0
55–59	86.9	57.4	55.3	72.0
60–64	86.0	58.2	55.9	71.0
65–69	85.9	55.0	53.5	64.0
70 and over	79.1	46.5	47.2	50.0
All ages	**84.9**	**54.0**	**52.9**	**67.0**

Note: The rate for the Minnesota study for age 50 to 54 includes participants younger than age 50 years.

Source: Adapted from Table 4 of Thomas et al. 1995.

Table 8.2: FOBT participation (%) in the Australian and UK Pilot studies by age and sex

		UK Pilot	Australian Pilot			
			Mackay	Adelaide	Melbourne	All sites
Males	50-54	47.2	—	—	—	—
	55-59	51.2	51.9	40.6	36.3	41.1
	60-64	55.0	55.9	44.0	38.4	43.8
	65-69	57.3	56.1	47.5	38.1	44.8
	70-74	—	54.1	46.8	40.4	45.1
	Total	**52.1**	**54.2**	**44.4**	**38.0**	**43.4**
Females	50-54	58.2	—	—	—	—
	55-59	62.6	61.0	47.0	42.6	47.7
	60-64	64.9	62.8	49.6	42.1	48.4
	65-69	61.7	62.8	48.9	42.5	48.2
	70-74	—	56.0	47.9	38.2	44.8
	Total	**61.4**	**60.9**	**48.3**	**41.5**	**47.3**
Persons	50-54	53.1	—	—	—	—
	55-59	57.4	56.2	43.8	39.5	44.4
	60-64	60.4	59.2	47.0	40.3	46.1
	65-69	59.7	59.4	48.3	40.4	46.5
	70-74	—	55.1	47.4	39.2	44.9
	Total	**56.8**	**57.5**	**46.5**	**39.9**	**45.4**

Source: UK Pilot data taken from The UK CRC Screening Pilot Evaluation Team 2003.

There is no way of knowing what proportion of the otherwise eligible population was excluded in the Nottingham and Funen studies and there are no data on how many such people were in the Australian Pilot sites. However, the best opinion of Australian experts in colorectal cancer is that as many as 20% to 25% of the target age range may be identified as 'unsuitable' for a population screening program due to a prior diagnosis of bowel cancer, a recent diagnostic bowel examination, a close family history of colorectal cancer or active symptoms of colorectal cancer. If this figure also applied to the Nottingham and Funen populations, then the effective participation rates of the Nottingham and Funen studies relative to the whole target age group are close to the participation rates achieved in Adelaide and Melbourne and below that achieved in Mackay.

Direct comparison with the Burgundy study is made difficult by the different recruitment strategies trialled in Burgundy. However, Tazi et al do report separately on recruitment rates achieved using only direct mailout of a test kit, which is the closest strategy to that used in the Australian Pilot. Using direct mailout of a test kit, the Burgundy study achieved participation rates of between 26% and 34%, which is well below the rates achieved in all three Australian Pilot sites (Tazi et al. 1997, p151).

A similar situation applies to comparisons between the Australian and UK pilot tests. The Mackay participation rates are also similar to those reported by the UK Pilot, while the Melbourne and Adelaide rates are lower that those reported by the UK. The UK pilot recruited participants from rolls of people registered with selected medical practices. However, the members of these practices undertook 'checking' of these rolls to avoid 'inappropriate' screening invitations (The UK CRC Screening Pilot Evaluation Team 2003, chapter 5). Again there is no way of knowing what proportion of the otherwise eligible population was removed via this checking, but if the 20% to 25% figure also applies to these exclusions then the effective UK participation rates would be reduced to close to those achieved in the Melbourne and Adelaide sites.

A critical issue in comparing participation rates between these studies is whether or not the Australian Pilot achieved participation rates which would lead to similar mortality reductions as those achieved by the RCTs. As noted above, a major difficulty in assessing this is the different basis on which the RCTs report their participation rate. A further complication is the different type of test used in the RCTs.

The RCTs used a guaiac-based FOBT while the Australian Pilot study used an immunochemical FOBT. One critical difference between the two test types is that immunochemical tests have a higher sensitivity to colorectal neoplasia (cancers and adenomas) than the guaiac-based tests (St John et al. 1993). Hence the Australian Pilot should be able to detect similar levels of colorectal neoplasia as the RCTs even with slightly lower participation rates. Given the relatively small difference between the participation rates achieved in Australia and the effective participation rates for the RCTs relative to the whole target age range, then it is likely that the Australian Pilot did achieve a participation rate at least consistent with the mortality outcomes achieved in the RCTs.

8.3 Screening outcomes

The lack of stage specific cancer data for the Australian Pilot means that no direct comparison can be made with the stage distribution of cancers detected either in the RCTs or the UK Pilot study. However, the outcomes can be compared in terms of the test positivity rates and positive predictive values (see tables 4.2 and 7.3).

The Burgundy reported a test positivity of 2.1% for its first screening round (Faivre et al. 2004, table 2). For the two RCTs which were most comparable to the Australian Pilot, the Nottingham study reported a test positivity rate of 2.1% for the first screening round, while the Funen study reported an analogous test positivity rate of 1.0%. The UK pilot reported similar test positivity rates of 1.6% in England and 2.1% in Scotland.

The positive predictive value of a positive FOBT was reported as:

- 11.5% for cancer and 16.8% for large adenomas in the Burgundy study (the rate for all neoplasia combined was not reported);
- 9.9% for cancer and 47.1% for all neoplasia in the Nottingham study;
- 17% for cancer and 32% for large adenomas in the Funen study (the rate for all neoplasia was not reported);
- 11.6% for cancer and 53.7% for all neoplasia in the UK pilot England pilot site; and
- 12.7% for cancer and 53.6% for all neoplasia in the UK pilot Scotland pilot site.

The Australian Pilot results are considerably different to these data. The test positivity rates for the Bayer Detect test were relatively stable over the life of the Pilot. The positivity rates for the !nform test were higher in the early part of the Pilot but fell to levels comparable to those of the Bayer Detect kit in the later part of the Pilot. If we take the later part of the Pilot (kits analysed after 1 March 2004), the positivity rate across both test kits was 7.8% considerably higher than those reported in the RCTs and in the UK pilot. A higher test positivity rate is likely to lead to lower test positive predictive values and this can be seen in the Australian data. The positive predictive values for cancer were 5.5% for !nform and 5.1% for Bayer Detect. The positive predictive values for all neoplasia were 24.1% for !nform and 26.3% for Bayer Detect, though as noted in section 7 above, these are likely to be underestimates

There are differences between the UK Pilot, the Nottingham and Funen RCTs and the Australian Pilot in what constitutes a positive FOBT which make direct comparison of these figures difficult. For example, both the RCTs and the UK pilot allowed a ‘weakly’ positive result which required further testing with dietary restriction whereas the Australian Pilot, which used a different type of test, did not require a retest of positive results. However, even allowing for these differences, there is still a large apparent difference in test outcomes between the Australian study and the international studies.

One possible difference in the test positivity could be due to different rates of colorectal cancer in the UK, France, Denmark and Australia. The test positivity would be expected to be higher in a country with a higher colorectal cancer incidence.

Table 8.3 presents the age standardised colorectal cancer incidence rate (standardised to the world standard population) for each country for the year 2002. These are taken from a data base maintained by the International Agency for Research on Cancer (Ferlay et al. 2004). They show that, although Australia has a higher colorectal cancer incidence rate than either the UK, France or Denmark, this difference is not enough to explain the differences in test positivity.

Table 8.3: Age standardised colorectal cancer incidence rates for Australia, Denmark and the United Kingdom, 2002

	Males	Females
Australia	47.4	35.9
Denmark	41.0	33.0
France	40.8	25.9
United Kingdom	39.2	26.5

Note: Rates are per 100,000 population and standardized to the World Standard Population.

Source: Ferlay et al. 2004

The advantage of a low test positivity rate is that the test is likely to have a high positive predictive value and hence fewer participants will be subjected to unnecessary follow-up colonoscopy. However, the disadvantage of a low test positivity rate is that some cancers and large adenomas will be missed by the testing procedure - that is, the test will have a false negative outcome.

The FOBT used in the Australian Pilot produces a quantitative result for the amount of blood in the faeces. A positive test is defined as one which detects a specific level of blood. So the test positivity rate can be varied by increasing the amount of blood which has to be present in order to identify a test result as positive. Data are available on the exact level of blood in the Bayer Detect tests, so we can investigate the effect of varying the cutoff level for positivity, which in turn varies the test positivity rate. If the Bayer Detect test cutoff level had been increased to achieve a positivity rate close to that of the UK pilot, then the test would have missed 40% of the cancers detected with the current positivity rate. Further, the test would have missed 51% of the advanced adenomas. Detection of advanced adenomas is particularly important because they are the polyps with a high risk of progressing to cancer, so their detection is what mainly allows the screening program to prevent cases of colorectal cancer.

This suggests that while both the RCTs and the UK pilot may have had fewer false positive results than the Australian Pilot, and hence subjected fewer people to unnecessary follow up colonoscopy, this was achieved at the expense of missing significant numbers of cancers and advanced adenomas. Hence that the mortality outcomes for people responding to a screening invitation in the Australian Pilot should be at least as good, if not considerably better, than the analogous outcomes for people participating in either the RCTs or the UK Pilot.