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The Australian Bowel Cancer Screening Pilot Program:

Analysis of Routinely Collected Screening Data

November 2004

**The Australian Bowel Cancer Screening Pilot Program:
Analysis of routinely collected screening data**

**Bowel Cancer Screening Pilot
Monitoring and Evaluation Steering Committee
November 2004**

Reports on the Bowel Cancer Screening Pilot were coordinated by the Bowel Cancer Screening Pilot Monitoring and Evaluation Steering Committee with support from the Screening Section, Targeted Prevention Program Branch, Australian Government Department of Health and Ageing. This report was prepared by the Australian Institute of Health and Welfare.

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Executive Summary

This report presents analyses of monitoring data from the Australian Bowel Cancer Screening Pilot Program. This program piloted population screening at three sites (in Mackay, Adelaide and Melbourne) using Faecal Occult Blood Testing (FOBT) with follow up of positive results by colonoscopy. Two FOBT kits were trialled—!nform (Enterix Australia Pty Ltd) and Bayer Detect (Bayer Australia Ltd). The purpose of the analyses in this report is to support the overall evaluation of the Pilot and to inform the planning of the proposed national bowel cancer screening program. The main results are:

FOBT Participation

All estimated FOBT participation rates are adjusted for the lag between an invitation to screen being sent to a Pilot participant and the return by that participant of a completed FOBT kit, with the exception of the rates for Indigenous people and people speaking a language other than English where the data did not allow this adjustment. The way this adjustment is made is described in Section 2.1.

- 56,907 invitations were sent out to eligible people between 6 November 2002 and 1 October 2004. As at 1 October 2004, 25,840 (45.4%) people responded by returning a completed FOBT. After adjustment for the lag between invitation and response, the overall estimated participation rate was 45.9%.
- Participation was significantly higher among women than men. Overall, 47.9% of invited women responded and 43.8% of invited men.
- Participation was significantly higher for people receiving the Bayer Detect FOBT (47.7%) than for people receiving the !nform FOBT (44.2%).
- The participation rate as at 1 October 2004 in Mackay (58.2%%) was higher than the rate in Adelaide (46.6%) and the rate in Adelaide was higher than that in Melbourne (40.3%).
- The response rate was significantly lower for Indigenous people compared to non-Indigenous. This result should be treated with caution as it relies on Indigenous people identifying themselves as such on the Pilot participant form and anecdotal evidence suggests that many Indigenous participants may not have done so.
- Participation rates in Mackay were significantly higher for people who spoke a language other than English, taken as a single group, than English speakers (87.4% vs 55.7%). However, this result is based on small numbers and may be affected by a mismatch between the numerator and denominator of the rate estimates.
- Participation rates were significantly lower for people who spoke a language other than English, taken as a single group, than English speakers in both Adelaide and Melbourne (35.1% vs 49.9%, Adelaide; 34.5% vs 42.2%, Melbourne).
- Interpretation of the data for socioeconomic disadvantage is difficult because it is based on postcode. Some quartiles of disadvantage in some sites had only one postcode and Mackay had only postcodes in the second and third quartiles of disadvantage. However, in general participation was better among people living in less disadvantaged postcodes.

- There was no significant difference between participation rates by quartile of socioeconomic disadvantage in Mackay, but this result is based on limited data and should be treated with caution.
- Participation in Adelaide was higher for the two least disadvantaged quartiles (48.5% and 50.6%) than the two most disadvantaged quartiles (37.1% and 39.5%).
- Participation in Melbourne was higher for the least disadvantaged quartile (46.1%) than for the other three quartiles of socioeconomic disadvantage (37.3%, 24.9% and 36.6%). The very low participation for quartile 3 is based on limited data and should be treated with caution.
- The Pilot incorporated a test of whether a reminder letter sent to non-participants at 6 weeks after invitation was more effective at increasing subsequent participation if it included another FOBT kit. There was no significant difference in subsequent participation following the reminder letter with or without the inclusion of a test kit.

FOBT outcomes

- Completed FOBT kits are classified as either correctly completed or incorrectly completed, damaged or unsatisfactory. The rate of correctly completed FOBTs was significantly higher for Inform FOBTs (97.0%) than for Bayer Detect FOBTs (92.1%).
- Results from a separate qualitative study of Pilot participants suggest that differences between Bayer Detect and Inform in the packaging of the tests may have contributed to differences in the rates of the two tests found to be unsatisfactory.
- The test positivity rate is the proportion of positive results out of all valid results (ie. all positive and negative results). The overall positivity rate was 9.0% (9.9% for Inform and 8.2% for Bayer Detect).
- There was a change in the Inform FOBT in either the test kit or the test analysis on 22 October 2003. The overall positivity rate for Inform fell from 13.7% prior to this date to 7.1% after this date. For kits analysed after 22 October 2003, positivity rates for Inform kits were significantly lower than those for Bayer kits (7.1% and 8.3% respectively, $p = 0.01$).
- The positivity rates for the Bayer Detect test do not vary significantly by quarter. However, the positivity rates for Inform for each quarter differ significantly from the previous quarter, suggesting that the Inform rates had more variability than could be accounted for by the change on 22 October 2003.

GP visits

GP attendance rates are the proportion of participants who were sent a positive FOBT result who subsequently visited a GP. All the estimated GP attendance rates are adjusted for the lag between a positive result being sent to a Pilot participant and that participant's visit to a GP. The number of people visiting a GP prior to being sent an FOBT result and the GP's colonoscopy referral patterns are not subject to a lag and so require no adjustment.

- 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. These 151 are not included in the estimate of the GP attendance rate.

- 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.
- The GP attendance rate was 62.1%. This rate varied significantly across the Pilot sites (Mackay 74.7%, Adelaide 63.5%, and Melbourne 53.4%).
- Significant numbers of people had a colonoscopy without a record of a previous visit to 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 being 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.
- The GP attendance rate did not vary significantly with the age of the participant but was lower for men than for women (57.8% vs 67.2%).
- There was no significant difference between GP attendance rates by quartile of socioeconomic disadvantage in Mackay, but this result is based on limited data and should be treated with caution.
- GP attendance in Adelaide was lower for the most disadvantaged quartile (54.3%) than for the other three quartiles (69.4%, 65.1%, and 67.5%).
- There was no significant difference between GP attendance rates by quartile of socioeconomic disadvantage in Melbourne.
- GP attendance was significantly lower for people speaking a language other than English compared to English speakers (48.3% vs 65.8%).
- The proportion of people visiting a GP 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.
- The proportion of people visiting a GP for Pilot related reasons but 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. It was significantly higher in Mackay (44.0%) than either Adelaide (21.5%) or Melbourne (25.6%) and in Adelaide it was significantly higher for SES quartile 2 (the second least disadvantaged quartile 27.0%) than each of quartiles 1, 3 and 4 (16.4%, 12.8%, and 17.8% respectively).
- There were 994 people who visited a GP without a positive FOBT and who were referred for a follow-up examination. Of these 994 people, 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.

Colonoscopy

Colonoscopy follow-up rates are the proportion of participants who were referred by a GP for colonoscopy and who subsequently had a colonoscopy. All the estimated colonoscopy follow-up rates are adjusted for the lag between the referral and colonoscopy.

The number of colonoscopies which were complete and/or adequate are not subject to a lag and so require no adjustment.

- The overall colonoscopy follow-up rate was 65.1%. The colonoscopy follow-up rate did not differ significantly between Adelaide (54.0%) and Melbourne (58.8%) but both were significantly lower than Mackay (87.1%). However, 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. 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.
- The colonoscopy follow-up rate did not differ significantly between sex and age group.
- The colonoscopy follow-up rate did not differ significantly by quartile of socioeconomic disadvantage in either Adelaide or Melbourne. There were insufficient data to test this in Mackay.
- The colonoscopy follow-up rate was significantly lower for people speaking a language other than English compared to English speakers (55.1% vs 67.1%).
- The proportion of colonoscopies classified by the colonoscopist as visualising the whole colon decreased significantly with age and was higher for males (97.3%) than females (94.2%).
- The proportion of colonoscopies identified as adequate by the colonoscopist decreased significantly as age increased but did not differ significantly by Pilot site, sex, quartile of socioeconomic disadvantage or speaking a language other than English.

Overall screening outcomes

The proportion of people who were sent a positive FOBT result who went on to have a colonoscopy is an estimate of the proportion of these people who completed the entire screening pathway. All these estimated proportions are adjusted for the lag between the sending of a positive FOBT result and the colonoscopy. The overall counts of people at each stage of the screening pathway are not subject to a lag and so require no adjustment.

- Of the 25,840 persons returning a completed FOBT by 1 October 2004, 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.
- Of the 2,308 participants that had a positive FOBT result, 1,035 (44.8%) were not recorded as having gone on to 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.
- 530 participants did not have a positive FOBT but still underwent colonoscopy. Of these, 399 were referred for colonoscopy for a family history of bowel cancer and/or bowel cancer symptoms. The reason for the referral of the remainder is not clear.
- The positive predictive value of a test is the proportion of followed-up positive results which resulted in finding either a cancer or an adenoma. The positive predictive value for cancers and advanced adenomas across both tests was 19.4% (ie. 19.4% of those who had a colonoscopy following a positive FOBT had a finding of a cancer or advanced adenoma). There was no significant difference between this positive predictive value for the Bayer Detect FOBT (20.1%) and the Inform FOBT (18.6%).

- 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 Inform FOBT (24.6%).
- As a comparison, 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.
- 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 were excluded from the calculations involving adenomas. This means that the positive predictive values for adenomas are likely to be underestimates.

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

- The Australian Pilot achieved participation rates which are below those reported for the major international Randomised Controlled Trials (RCTs) and the UK pilot test of colorectal cancer screening. However, if the RCT and UK reported rates were adjusted for their exclusion of people in the target age group who were judged unsuitable for screening, their rates are likely to be comparable to the Australian Pilot rates (where no such exclusions were made).
- The use in Australia of a more sensitive FOBT than that used in the RCTs means that even if the Australian participation rates are slightly below those of the RCTs, they should still be high enough to be consistent with screening in Australia achieving similar mortality reductions to those reported by the RCTs.
- The FOBT positivity rate is the proportion of completed FOBTs which have a positive result. The positive predictive value is the proportion of FOBTs with cancers and adenomas detected out of all positive FOBTs that are followed up with a colonoscopy. A lower test positivity is likely to lead to a higher positive predictive value.
- The Australian test positivity rates are higher than those for both the RCTs and the UK Pilot. The Australian test positive predictive value is lower than those for both the RCTs and the UK Pilot. The likely consequence is that more participants will be subjected to unnecessary colonoscopy in Australia than in the UK or the RCTs but that the UK pilot and the RCTs missed more cancers and adenomas than were missed in the Australian Pilot.
- Data are available for the Bayer Detect test which allow for modelling of the likely numbers of cancers missed if the test had given similar positivity rates to the UK pilot and the RCTs. If the Bayer Detect test had been set to a comparable positivity rate to the RCTs and the UK, it would have missed 40% of the cancers detected with the current positivity rate and 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 implies that the mortality outcomes for people responding to a screening invitation in the Australian Pilot should be at least as good, if not considerably better, than the analogous outcomes for people participating in either the RCTs or the UK Pilot.

Introduction

The purpose of this report is to present analyses of monitoring data from the Australian Bowel Cancer Screening Pilot Program to support the Pilot evaluation. The first section outlines the aims and broad structure of the report. Subsequent sections present analyses of the monitoring data covering successive key points on the screening pathway. The final section presents a comparison of the results of the Australian Pilot with those of the international randomised controlled trials of bowel screening and the results of the United Kingdom bowel screening pilot.

The analyses presented in this report are based on data downloaded from the Pilot screening register on 1 October 2004. Hence they represent the performance of the Pilot from its commencement in late 2002 and early 2003 to that point.

1.1 Background

The Australia Bowel Cancer Screening Pilot program was conducted by the Australian Government Department of Health and Ageing. The primary aim of the Pilot was to provide information about the feasibility, acceptability and cost effectiveness of bowel cancer screening amongst the Australian population in both rural and urban areas. The Pilot also compared the performance of two types of immunochemical Faecal Occult Blood Tests (FOBTs)—Inform and Bayer Detect. The Pilot is designed to inform decisions about the planning and introduction of a national bowel cancer screening program.

The Pilot was conducted at three sites—in Melbourne (part of the North East Valley Division of General Practice), Adelaide (part of the Adelaide Southern and Western Divisions of General Practice), and Mackay (part of the Mackay Division of General Practice). The population living in these areas includes a mixture of urban and rural residents and diverse socioeconomic and ethnic groups to reflect the broader Australian population.

The Pilot commenced in Mackay in November 2002, with screening starting in the other two sites in early 2003. The eligible Pilot population consisted of all people living in each Pilot site who were aged from 55 to 74 years on 1 January 2003. Members of the Pilot population were randomly allocated to one of the two FOBT types. Invitation packs, including the allocated FOBT, were sent out over an 18 month period to all Pilot population members. Participants were requested to post their completed FOBT to the pathology laboratory for analysis. Results of this analysis were sent to the participant, the participant's nominated general practitioner and the Bowel Cancer Screening Pilot Register. Participants with a positive result, indicating blood in their faeces, were advised to consult their general practitioner to discuss further testing—in most cases this will be a referral for colonoscopy. A complete representation of the screening pathway from invitation to diagnosis is in Appendix A.

Responses to invitations and the outcomes for those who complete the screening tests will be monitored to the point of definite diagnosis for all participants who are found to have a histologically confirmed bowel cancer or polyp or to the point of a negative FOBT result or a negative colonoscopy result.

Monitoring data were collected about participants and their screening outcomes from a variety of sources throughout the screening pathway. These data are stored in the Bowel Cancer Screening Pilot Register maintained by the Health Insurance Commission. The data were collected on questionnaires completed by participants, general practitioners, pathologists and other specialists.

1.2 Report aims and broad structure

The aims of the analyses presented in this report are:

- to describe what proportion of participants progressed past each key point on the screening pathway and to investigate where possible what characteristics of the Pilot subjects influenced this progress;
- to describe any differences between test kit types in the performance and outcomes of the FOB tests; and
- to describe the final screening outcomes in terms of cancers and polyps detected and to investigate where possible what characteristics of the Pilot subjects influenced these outcomes.

The analyses focus on the following key screening pathway points:

- Sending the letter of invitation;
- Receipt of a completed FOBT kit;
- Sending of the FOBT result to the participant;
- Attendance by the Pilot subject at a GP consultation (with or without a prior FOBT result);
- Attendance by the Pilot subject for colonoscopy, and
- The result of the colonoscopy.

The report has a section corresponding to the transition between each of these key screening pathway points and a section on overall screening participation and outcomes. There is also a final section which places the Pilot outcomes in the context of the major international bowel cancer screening studies.

Statistical analyses

2.1 Participation

The term participation is taken in this report to refer to participation in the screening test. Hence the FOBT participation rate is the proportion of the eligible people invited to participate in the screening program who return a completed FOBT. The proportion of people who were sent a positive FOBT result and who subsequently visit a GP is referred to as the GP attendance rate. The proportion of people with a positive FOBT who were referred by a GP for a colonoscopy and who subsequently had a colonoscopy is referred to as the colonoscopy follow-up rate.

The *crude participation/attendance/follow-up rate* is the proportion of people who have proceeded to a key point on the screening pathway at the date of data download out of those eligible to proceed to that point. For example, the crude FOBT participation is the proportion of eligible people who return a completed FOBT kit by 1 October 2004. The crude colonoscopy follow-up is the proportion of people with a positive FOBT result and referred for colonoscopy who proceeded to having a colonoscopy by 1 October 2004.

The crude proportions will generally underestimate the true proportions of the Pilot population who will participate in the program. This is because at any point in time there will be members of the population who are eligible to proceed to the next point on the screening pathway but who have not yet had time to do so. For example, a person who has just received an invitation to screen may intend to participate in screening but may not have had time to do so. They will be counted in the denominator of the crude FOBT participation, but not in the numerator. Similarly, there will be a time lag between when a person with a positive FOBT result is referred for colonoscopy and when they can actually have the colonoscopy. A colonoscopy follow-up calculated during this lag will include them in the denominator but not in the numerator.

The approach taken to this by the evaluators of the UK colorectal cancer screening pilot study was to exclude from the analyses people who had recently entered the eligible population. For example, FOBT participation excluded all people invited less than four months prior to the data download on which the analyses were based (The UK CRC Screening Pilot Evaluation Team 2003). The difficulty with this approach is that it excludes information on people who did respond in the recent period, which decreases the power of any statistical comparisons. This is not a major issue for FOBT participation because of the large number of eligible people and the relatively large number of completed test kits. However, it is a potential problem for analyses at later points in the pathway or for small population sub-groups where there are smaller numbers in the eligible population.

Kaplan-Meier estimates of participation, attendance or follow-up

The approach taken in this report is to calculate a modelled rate based on the time it takes each individual invited for screening to move between points on the screening pathway. For example, FOBT participation is calculated by following each invited person and, for those who respond, recording the time it takes them to respond. This allows the calculation of a response rate over time from the date of invitation. The modelled response rates have been calculated using the Kaplan-Meier methods. These are standard methods used to model the time to an event and the changes in the rates of an event over time. In this case, the event is a person's response (by returning a completed FOBT kit) and the time to the event is measured in weeks from the date the invitation was sent. These Kaplan-Meier estimates represent valid estimates of the true FOBT participation.

In principle, the Kaplan-Meier estimate only gives us a result at a specific point in time. The estimate is likely to grow for later points in time. However, inspection of these estimates shows that they reach a plateau after which they have only a negligible increase. Further, preliminary analyses based on modelling the survival time with both a Weibull and an exponential distribution shows that the latest observed Kaplan-Meier estimate differs from the long term modelled estimate by less than one percentage point. Hence we can take the latest Kaplan-Meier estimate as an approximate estimate of the overall rate.

The Kaplan-Meier estimates require that classifying variables be known for the Pilot population. Hence they can be calculated for FOBT participation classified by age, sex, FOBT kit type and Pilot site. However, they cannot be used for FOBT participation classified by Indigenous status or language group which are not known for all the invited population. These variables are only known for those participants who identify themselves as a member of these groups on their returned FOBT kit form. In these cases, a crude participation can be calculated by using known population counts (from the Australian Bureau of Statistics census data) in the denominator. However, neither the Kaplan-Meier estimates nor the UK approach of excluding recently invited people can be applied. In these cases, all analyses will be based solely on the crude participation. This does mean the FOBT participation presented in this report for Indigenous people and people with a language other than English may represent slight under estimates of the true proportions.

Indigenous status and language group will be known for all people completing FOBT kits (at least to the extent that people self-identify as members of these groups). Hence in principle Kaplan-Meier estimates can be calculated for these groups for participation at subsequent points on the screening pathway. In practice, these calculations depend on sufficient numbers of people self-identifying as group members to allow the calculation of reliable estimates.

2.2 Comparisons and tests of statistical significance

This report includes statistical tests of the significance of comparisons of rates between population groups. Any statistical comparison applied to one variable must take account of any other potentially relevant variables. For example, any comparison of participation by test kit type must also take account of differences in the distribution of age, sex and Pilot site between the two test kit types. These other variables are known as 'confounding' variables.

Age standardisation

The simplest method of allowing for age as a confounding variable is to use age standardisation. This can be applied to both the crude rates and the Kaplan-Meier estimates. Confidence intervals can be constructed for these standardised estimates and simple tests of statistical significance used to compare them for different population groups. All tables specified below with a classification of age and sex include an age standardised estimate. This estimate is labelled as 'ASR'.

The AIHW usually uses the Australian 2001 standard population for age standardisation. An alternative for the Pilot could be to use the total Pilot study population as the standard population. Using the total Pilot study population would result in estimates with an easier interpretation in the context of the Pilot. For example, the age standardised FOBT participation for a particular Pilot site could be interpreted as the hypothetical total Pilot FOBT participation if that site's age specific rates had applied to the whole Pilot population. Using the Australian 2001 standard population would result in estimates with an easier interpretation in the context of a national screening program. For example, the age standardised FOBT participation for a particular site could be interpreted as the hypothetical FOBT participation for a national program if that site's age specific rates had applied across a national program. Since this report is to be used to support planning for a national screening program, this report uses the Australian 2001 standard population for age standardisation.

Modelling the participation, attendance and follow-up rates

Age standardised estimates are suitable for simple pairwise comparisons where age is the only confounder. Where comparisons are to be made across a variable with several levels (eg testing whether FOBT participation varies across the three Pilot sites) and where the comparisons must be adjusted for several confounders (e.g. adjusting the comparison of FOBT participation across the sites for age, sex and test kit type), the usual approach is to base the test on a statistical model of the data. This section outlines the major approaches available for this statistical modelling. Not all of these approaches proved suitable for the analyses presented in this report.

Logistic regression

Logistic regression modelling can be applied to relate crude rates to predictor variables. All possible combinations of the confounding variables are incorporated into a logistic regression model using the crude rate as the dependent variable. Then the variable of interest is added to the model to assess its significance after confounding variables have been accounted for.

The problem with using logistic regression is that it applies to the crude rate, not the rate adjusted for the lag between becoming eligible to proceed to a point on the screening pathway and actually proceeding to that point. There may be systematic differences between groups in the time taken to respond even where those groups have the same final response rates. Hence the crude rate may incorrectly identify some groups as having higher response rates than other groups. For example, if one population group takes longer to respond to an invitation to screen than another, then the crude participation for the first group may be lower than that for the second even if ultimately similar numbers of each group intend to respond.

This could lead to the logistic regression identifying a spurious association between these groups and FOBT participation.

The UK pilot evaluation used logistic regression as its primary analysis tool in investigating differences in participation between population groups. As noted above, this was done by excluding from the analyses people who had recently entered the eligible population for the rate under study.

Cox proportional hazards model

The Kaplan-Meier curves can be adjusted for confounders by use of the Cox proportional hazards model. The ‘hazard’ associated with screening is the probability of responding to a screening invitation at a specific point in time. The proportional hazards model is a regression-like approach which models the ratio of hazards between different population groups. For example, it can be used to model how much more likely men are to respond to a screening invitation than women or older people compared to younger people. The proportional hazards model allows more than one variable to be assessed at a time, in the same way as more than one variable may be entered into a regression equation at a time. So the model can also adjust for confounding variables by incorporating them into the model first and then adding the variable of interest.

One difficulty with the proportional hazards model is that it relies on the assumption that the hazard ratio is constant over time. For example, if men were 50% more likely to respond to a screening invitation than women in the first week after the invitation is sent, then they will remain 50% more likely to respond in all subsequent weeks. This assumption may be violated if there are population groups that are more likely than other groups to respond quickly to an invitation. In this case the hazard ratio in the weeks immediately following an invitation may be higher than in subsequent weeks.

It is possible to test this assumption and, if necessary, adjust for departures from it by applying time-varying coefficients to the models in effect applying a different coefficient for each different time period. However, the use of time-varying coefficients requires modelling of the form of the time dependence and the results are often difficult to interpret. Where the assumption fails for confounding variables but not for variables of interest, then the confounding variables can be entered into the model as ‘strata’. The model adjusts for these strata but does not produce estimated hazard ratios or tests of statistical significance for them.

Initial examination of the participation strongly suggested that the proportional hazards assumption could not be relied on for these data. For this reason, the proportional hazards model was not used in this report.

Parametric survival models

It is possible to use a standard regression approach which takes account of censored data. Such models are called *parametric survival models* or *accelerated failure models*. In these cases, the model depends on identifying a suitable probability distribution for the event times being modelled. Common distributions used include the exponential, Weibull and log-normal

distributions. Variables of interest can be tested and confounders adjusted for in an analogous way to the logistic and proportional hazards models described above.

In addition, regression coefficients can be interpreted, in the same way as for standard regression, as specifying differences in the parameters of the predicted event time distribution.

A critical part of using these models is correctly specifying the underlying distribution of the times to an event. This can be a lengthy and inexact process. Further, inferences drawn from these models may be sensitive to departures from these distributional assumptions. For these reasons, parametric survival models were not used in this report.

Non-parametric test of survival curves

Where the proportional hazards assumption does not hold, there are non-parametric tests of homogeneity across times to events which can be used to test for the significance of covariates. The SAS procedure LIFETEST implements the log-rank test and the Wilcoxon test. Potential confounders are entered into the tests as ‘strata’. Then the variable (or variables) of interest is added using the TEST statement. The result will be tests of the significance of the association between the variable of interest and the response rate adjusted for the variables in the strata. These non-parametric tests were used in this report where logistic regression was considered unsuitable.

Comparisons for socioeconomic disadvantage

The UK pilot study analysis included a measure of economic deprivation based on the person’s address. The Australian data can include a similar measure based on the person’s postcode using the ABS Index of Relative Socio-economic Disadvantage (IRSD) (ABS 2003). Table 2.1 shows the distribution of Pilot invitees by quartile of the IRSD index, where quartile 1 represents the least disadvantaged 25% of the population and quartile 4 the most disadvantaged 25%. These are based on the person’s postcode of residence.

Table 2.1: Numbers of people in each Pilot site by quartile of disadvantage

	Quartile of disadvantage				Total
	1 (least disadvantage)	2	3	4 (most disadvantage)	
Mackay	0	421	10,624	0	11,045
Adelaide	4,113	8,621	1,280	4,417	18,431
Melbourne	13,522	9,280	2,736	1,893	27,431
Total	17,635	18,322	14,640	6,310	56,907

Mackay has most of its population in quartile 3, with only one postcode identified as belonging to quartile 2 and none belonging to quartiles 1 or 4. In both Adelaide and Melbourne only one postcode was identified as belonging to quartile 3 and in Melbourne only one postcode was identified as belonging to quartile 4. In Adelaide close to half the Pilot population are in quartile 2, while in Melbourne close to half the Pilot population are in quartile 1. This means that any analysis of participation by level of disadvantage which combines results from all sites will be confounded by differences in overall participation

between the sites. So analysis of participation by level of disadvantage will be done separately for each site. These analyses should still be treated with caution, as any specific features of the postcode allocated to quartile 2 in MacKay, quartile 3 in Melbourne and Adelaide and quartile 4 in Melbourne may confound the results.

Comparisons for Indigenous people

One focus of the Pilot was to assess participation by Indigenous people. Further, the Mackay Pilot site also had a focus on participation of South Sea Islander people. Table 2.2 presents the number of people who identified as either Indigenous or South Sea Islander people at key points on the screening pathway. Table 2.3 presents the number of people who returned a completed FOBT kit and identified as either Indigenous or South Sea Islander people in each Pilot site.

The analyses of FOBT participation includes detailed analyses for Indigenous people. However, based on tables 2.2 and 2.3, there are insufficient respondents identifying as Indigenous or South Sea Islander people to allow for detailed analyses of participation at later points on the screening pathway.

Table 2.2: Indigenous and South Sea Islander people at key points of the screening pathway as at 1 October 2004

	Aboriginal and/or Torres Strait Islander	South Sea Islander
Number returning FOBT kit	62	33
Number with FOBT positive	7	5
Number with colonoscopy*	7	4

* This number represents all colonoscopies, irrespective of whether or not the participant had a positive FOB test result.

Table 2.3: Indigenous and South Sea Islander people returning a completed FOBT kit in each Pilot site as at 1 October 2004

	Aboriginal and/or Torres Strait Islander	South Sea Islander
Mackay	35	23
Adelaide	13	5
Melbourne	14	5
Total	62	33

The calculation of FOBT participation rates for Indigenous and South Sea Islander people depends of the availability of ABS census data for use as the rate denominator (see section 2.1 above). Age-sex specific population counts are available from the census for Indigenous people in each Pilot site. However, the ABS census only identifies 48 people as South Sea Islanders aged 55 to 74 in the Mackay Pilot site (22 men and 26 women). Because of the small numbers and the associated confidentiality issues, census counts for South Sea Islanders were not available for the Pilot age and sex groups. Hence no detailed analyses were possible for South Sea Islander participation in the Pilot.

Comparisons for people speaking other languages than English

People are identified as speaking another language by answering the question “Do you speak a language other than English?” and identifying the language (or languages).

This raises an issue of interpretation, since it is possible to speak a language (by, for example, having studied it at school or university) without belonging to any particular ethnic or community group. However, in terms of numbers of people identifying as speaking another language, table 2.4 shows that reasonably detailed analyses of participation is possible. All analyses are done within each Pilot site because the main language groups are different for each site.

Table 2.4: People identifying as speaking a language other than English at key points on the screening pathway as at 1 October 2004

	Mackay		Adelaide		Melbourne	
	Males	Females	Males	Females	Males	Females
Number returning FOBT kit	255	243	732	761	1418	1484
Number with FOBT positive	23	31	90	69	174	104
Number with colonoscopy*	32	36	43	35	51	45

* This number represents all colonoscopies, irrespective of whether or not the participant had a positive FOB test result.