



PILOT PROGRAM

An Australian Government Initiative

Progress Report

April 2004

Overview

The Australian Government is conducting a Bowel Cancer Screening Pilot. The primary aim of the Pilot is 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 will also compare the performance of two types of immunochemical Faecal Occult Blood Tests (FOBTs)—Inform and Bayer Detect. The results of the Pilot will inform government decisions about whether, and how, to introduce a national bowel cancer screening program.

The Pilot is being 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.

Implementation of the Pilot commenced in Mackay in November 2002, with screening starting in the other two sites in early 2003. Eligible members of the Pilot population have been randomly allocated to one of the two FOBT types. Invitation packs, including the allocated FOBT, are being sent out over an 18 month period to all people living in each site who were aged from 55 to 74 years on 1 January 2003. Participants are requested to post their completed FOBT to the pathology laboratory for analysis. Results of this analysis are 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, are advised to consult their GPs to discuss further testing. In most cases this will be colonoscopy. Responses to invitations and the outcomes for those who complete the screening tests will be monitored to the point of definite diagnosis for those who are found to have bowel cancer.



Launch of the Adelaide Pilot site – February 2003. Consumer representative Mrs Dorothy Fagg who was diagnosed with and successfully treated for bowel cancer that was detected in its earliest stages through an FOBT and follow-up colonoscopy.



*Pilot site workshop
December 2003. Representing the
Queensland site: Bottom row L to R*

*Ms Rosemary Young
Dr Fiona Millard
Ms Karen Andrew
Ms Jennifer Muller.*

*Back row L to R
Ms Robyn Nikolsky
Dr David Parker
Mr Craig Margetts
Mr Bel Lui.*

Photo: Craig Margetts

Feedback

Mr and Mrs B used the test kit for the Pilot and said the screening program might have been a life saver for Mrs B. Mr B. tested negative but his wife tested positive and was treated for early stages of bowel cancer. Mr B. said, "I believe the fact that my wife and I chose to participate in this screening program has very likely saved her life".

Monitoring data are 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 are collected on forms completed by participants, general practitioners, pathologists and other specialists.

The Australian Institute of Health and Welfare has produced three quarterly monitoring reports. These reports analyse data extracted from the Bowel Cancer Screening Pilot Register to provide an

overview of screening participation and outcomes, the additional workload that screening is placing on general practitioners, and waiting times for key periods in the screening pathway.

Preliminary Pilot outcomes

A summary of highlights from the third Pilot quarterly monitoring report is set out below. It covers all screening activity relating to invitations sent in the period 6 November, when the first invitations were sent out in Mackay, to 5 January 2004. There needs to be some caution taken in interpreting the data contained in the summary. This report presents monitoring indicators and should not be used to assess or evaluate the effectiveness of the Pilot

- 38, 228 invitations were sent out to eligible members of the target population between 6 November 2002 and 5 January 2004. As of 5 January 2004, 15,250 (39.9%) people responded by returning a Participant Details form and/or a completed FOBT. This is an under representation of the true participation rate in the Pilot. Using the Kaplan-Meier method¹ a truer rate of participation is 45.4% at 38 weeks following invitation.
- At 38 weeks following invitation, the participation rate in Mackay (56.2%) was higher than the rate in either Adelaide (46.4%) or Melbourne (38.4%). The result for Melbourne is particularly encouraging as the target population in the site is made up primarily of people from non-English speaking backgrounds.
- Almost all of returned FOBTs were correctly completed.

Feedback

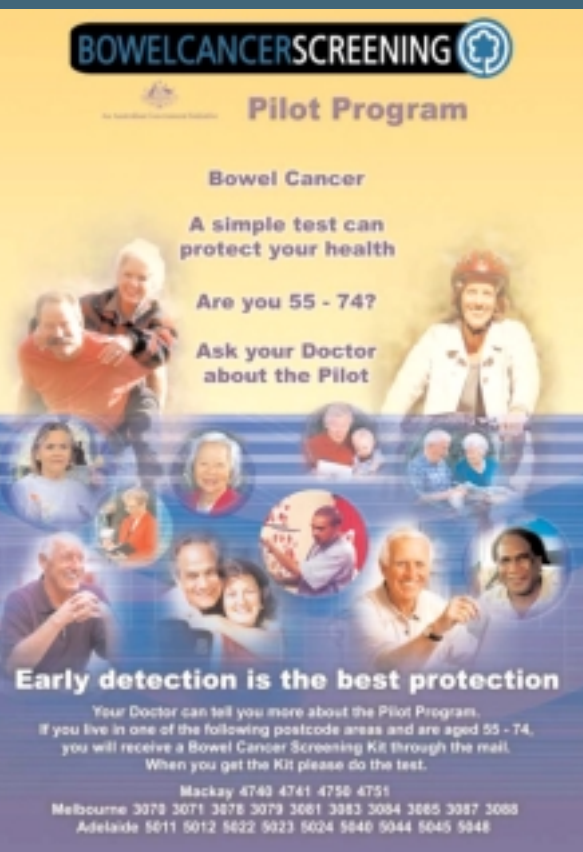
Mr F. wrote to the Chief Medical Officer, "In August I received a bowel cancer screening kit...blood had shown up in the sample...I had a colonoscopy...I had an operation to remove part of the bowel and cancer...I am recovering at a fast rate. I had no pain and nothing to show that I had cancer and only for the test I would have never known until it was too late...I would like to say thank you to all those involved in the programme - for me it was a life saver. The test is so simple that anyone who doesn't do it is a fool. So to all a very warm Thank You for all you did. Keep up the good work as it is saving many people..."

- The proportion of positive results out of all valid results, referred to as the positivity rate, was significantly higher for Inform FOBTs than for Bayer Detect FOBTs. The proportion of positive results out of all valid Inform results was 14.3% for males and 10.9% for females. The corresponding positivity rates for Bayer Detect FOBTs were 10.3% for males and 7.3% for females.²
- GPs reported 2,023 consultations in relation to the Bowel Cancer Screening Pilot for the period 6 November 2002 to 5 January 2004.
- Of the 2,023 GP consultations in relation to the Bowel Cancer Screening Pilot, 851 (42.1%) were with participants that had a positive FOBT. A referral for colonoscopy or other examination was made in 93.8% of these consultations. Of the 1,172 consultations with participants that did not have a positive FOBT, 30.6% resulted in a referral for colonoscopy or other examination. This was largely due to the Pilot Participant having either symptoms or a strong family history of bowel cancer.
- The median waiting time between an FOBT being processed by the pathology laboratory and the result being sent to the Pilot was 8 days for Inform FOBT results and 7 days for Bayer Detect FOBT results.
- The waiting time between a GP consultation in relation to a positive FOBT result and colonoscopy ranged from 0 to 237 days. The median waiting time was 27 days.
- There was no statistically significant difference between the positive predictive value of the Bayer Detect FOBT (14.5%) and that of the Inform FOBT (13.7%).
- As at 5 January 2004 a total of 731 colonoscopies had been performed for Pilot Participants. Thirty two cases of suspected bowel cancer and 328 cases of bowel polyps (potentially precancerous conditions) have been detected. In the majority of cases, the suspected cancers were found in people who had no symptoms of disease.

Pilot activities

Local implementation committees

Each Pilot site has established an implementation committee, all of which have met regularly. These committees are all working closely with the local stakeholders to educate, promote and implement the Pilot at the local level. All three Pilot sites have coordinated and delivered very broad and comprehensive community mobilisation strategies to influence participation in the Pilot.



BOWELCANCERSCREENING 

Pilot Program

Bowel Cancer

A simple test can protect your health

Are you 55 - 74?

Ask your Doctor about the Pilot

Early detection is the best protection

Your Doctor can tell you more about the Pilot Program.
If you live in one of the following postcode areas and are aged 55 - 74,
you will receive a Bowel Cancer Screening Kit through the mail.
When you get the Kit please do the test.

Mackay 4740 4741 4750 4751
Melbourne 3070 3071 3078 3079 3081 3083 3084 3085 3087 3088
Adelaide 5011 5012 5022 5023 5024 5040 5044 5045 5046

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5044 5045 5048

Early detection is
the best protection

Pilot Helpline 1800 999 332 Website www.cancerscreening.gov.au

Materials

Posters for general practitioners and community groups have been developed. These have been distributed to Pilot sites.

Key Pilot materials have been translated into thirteen community languages. The translations are available on line at <http://www.cancerscreening.gov.au/bowel/contacts/lote.htm>

Pilot site workshops

Two workshops were held in Canberra in May and December 2003 for representatives from the Pilot sites and Department of Health and Ageing staff. Both workshops have been very successful and provided an opportunity for discussion and clarification of local implementation issues for the Pilot.

Following the May 2003 Pilot site workshop, an Aboriginal and Torres Strait Islander Pilot Cross Site Working Group has been formed. This group provides a network opportunity between the Pilot sites to address issues for Aboriginal and Torres Strait Islander peoples. The Working Group has developed a poster to encourage participation by Aboriginal and Torres Strait Islander people in the Pilot. Members are currently examining issues in relation to Aboriginal and Torres Strait Islander participation in screening in the event of a possible national bowel cancer screening program.

Evaluation

An interim evaluation of the Pilot undertaken in October 2003 by an external independent evaluator has concluded that all the necessary processes to achieve the desired outcomes of the Pilot have been put in place and that the Pilot is on target to achieve these desired outcomes within the planned time period. The review report notes that the Pilot is on track to provide information on the aims and objectives of the Pilot.

A number of key activities have commenced to inform the final evaluation of the Pilot. These include:

- A baseline survey of knowledge, attitudes and practices (KAP) of potential Pilot participants to bowel cancer and screening has already been conducted in each Pilot site. A follow-up KAP across the three Pilot sites is in progress.
- A qualitative research project titled Qualitative Research with General Practitioners and Consumers Aged 55 to 74 Years to explore Attitudes, Opinions and Behaviours that Influenced Participation in the Three Bowel Cancer Screening Pilot Sites to be conducted by the Research

and Marketing Group, Information and Communication Division, Department of Health and Ageing. The component of this research dealing with consumers will include representation from Aboriginal and Torres Strait Islander people, people from four different culturally and linguistically diverse backgrounds, South Sea Islander people (Mackay) and mainstream groups. It will take into account the two different FOBT test kits used and include people who chose not to participate.



- The Australian Institute of Health and Welfare (AIHW) is undertaking monitoring on a quarterly basis throughout the course of the Pilot. This monitoring is based on data from the Pilot Register, established by the Health Insurance Commission. The Register contains all details in relation to participants' data, including invitation and follow-up, FOBT kit usage and associated pathology, contacts with all health practitioners and histopathological data. The first monitoring report was released by the AIHW in August 2003. Monitoring also takes place through the Pilot Helpline and through the Pilot pathology analysis providers. A detailed monitoring report will be produced at the end of September, with an interim version

due at the end of August, which will cover all the monitoring indicators contained in the Bowel Cancer Screening Pilot Monitoring and Evaluation Framework.

- A cost effectiveness study of the Pilot is being sponsored by the Medical Services Advisory Committee. The work is being undertaken by the Medical Technology Advisory Group (MTAG) an independent research company. MTAG is close to finalising the cost-effectiveness analysis model. Final monitoring data from the Pilot will be used to ensure that the model is run using real data to set probabilities.
- A requirement for reporting against agreed outcomes is part of contract arrangements with State health departments and local GP Divisions in Pilot sites. This will provide some information on the effectiveness of local level activities.
- Two cross Pilot site working groups have been established to consider ways to assess the effectiveness of communication strategies between General Practitioners and Aboriginal and Torres Strait Islander people and people from culturally and linguistically diverse backgrounds.

XVIIIth World Conference on Health Promotion and Health Education

A poster presentation on the Pilot, focussing on recruitment strategies, has been accepted for this conference to be held in April 2004 in Melbourne. Pilot sites are collaborating on the development of the poster presentation.

- 1 The participation rate which is a simple algorithm of numbers of responses received in the numerator and numbers of responses sent in the denominator represents an under estimate of the true screening participation rate. This is because the number of invitations in the rate denominator covers all invitations sent up to 5 January 2004. However, the number of responses in the rate numerator only covers people who have received the invitation and had time to respond. This means that the absolute levels of participation are understated.

An alternative approach is to follow each individual invitee and, for those who respond, to record the time it takes them to respond. This allows the calculation of a response rate over time from the date of invitation. The 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 (either by returning a completed FOBT test kit or test kit form) 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 participation rates.

- 2 There has been a higher than expected rate of positive faecal occult test results in the Pilot. This means that a significant number of people have been required to have a follow up colonoscopy. It is possible to adjust the cut off points of the tests so that fewer people unnecessarily undergo colonoscopy. A meeting of experts held in December 2003 to discuss the issue of the higher than expected positivity rate. Experts advised that it would be preferable not to adjust the cut off point at what would have then been the mid point of the Pilot. They suggested that it would be preferable to wait until the end of the Pilot when there would be a sufficient quantum of data available for analysis on clinical outcomes against FOBT results.