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COLORECTAL CANCER IN THE AUSTRALIAN POPULATION - PROSPECTS FOR PREVENTION THROUGH SCREENING

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Abstract

This thesis examines Fecal Occult Blood Test (FOBT) screening as a possible means of reducing mortality from colorectal cancer in Australia. The study upon which the thesis is based consists of an evaluation of a FOBT screening program in South Australia (in terms of numbers of cancers detected, accuracy of the test used, costs of the program and characteristics of participants) and surveys of the general population and of South Australian general practitioners which provide information on knowledge, attitudes and practices in relation to colorectal cancer and its prevention. The main components of the thesis are as follows:

1. Literature reviews which provide an overview of the epidemiology of colorectal cancer, prospects for primary prevention, screening for the disease, results of previous screening programs, acceptability of and compliance with colorectal cancer screening, economic aspects and clinician-related issues such as knowledge, practice and screening guidelines.

2. An evaluation of the FOBT screening program in South Australia, including measures of performance (such as sensitivity, specificity and predicitve value) for the immunochemical screening test used in the program.

3. An examination of characteristics of participants in FOBT screening, including socioeconomic status, presence of family history/past history of colorectal cancer and presence of symptoms.

4. A cost analysis of the program. Costs measured include travel costs, time off work, costs of medical investigations and psychological distress. A distinction is made between costs which are borne by the individual and those which are borne by society as a whole, and a cost per cancer detected in the program is calculated.

5. A survey examining knowledge, attitudes and beliefs of general practitioners in relation to colorectal cancer and screening.

6. A population, interview-based survey which examines knowledge, attitudes and beliefs in relation to screening for colorectal cancer in the population.

7. Conclusions about the feasibility and desirability of conducting major FOBT screening programs in the Australian community, based on an examination of information from the various components of the study in the light of existing evidence in the literature.

Declaration

This thesis contains no material which has been accepted for the award of any other degrees or diploma in any university. It contains no material previously published or written by another person, except where due reference is made in the text.

I consent to this thesis being made available for photocopying and loan if accepted for the award of the degree.

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(David Weller, June 1994)

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For Belinda, Madeleine, Ray and Daphne

-and in memory of Gwenda-

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Chapter 1:

Colorectal Cancer and its Prevention - Background and Overview of the Literature

1.1 Introduction

Colorectal cancer is a major public health problem in the Australian population. In South Australia it is the most common cancer recorded by the Cancer Registry in both sexes combined (Bonett et al, 1992 - a), and is second only to lung cancer as a cause of death (see *Tables 1.1 & 1.2*). Approximately seven thousand new cases are detected each year in Australia (Giles et al, 1987). While major efforts have been directed towards developing better curative approaches to the disease, for most of this century there has been a consistently upward trend in age-standardized mortality rates for colorectal cancer in Australian men and women (Rohan & McMichael, 1978).

As with many cancers, prospects for both preventing the disease (primary prevention) and detecting the disease at an early stage (secondary prevention) have been examined. Secondary prevention, which is undertaken by applying screening tests to groups of asymptomatic individuals aims to bring about reductions in mortality from a disease by early detection and treatment. In the case of colorectal cancer the most commonly studied screening test is the fecal occult blood test (FOBT). While it is a relatively simple and inexpensive test, it is important to examine whether screening with the FOBT fulfills the widely accepted criteria for screening summarised in *Table 1.3.*

The research results reported in this thesis are from a study, known as the South Australian Colorectal Cancer Screening (SACCS) study, which examines FOBT screening as a possible means of reducing mortality from colorectal cancer in

Australia. In the context of the criteria for screening outlined in *Table 1.3*, it includes an examination of many of the wider issues associated with this form of screening, including expected costs and benefits, its acceptability and the role which general practitioners might play. The study consists of an evaluation of a FOBT screening programme in South Australia (in terms of numbers of cancers detected, accuracy of the test used, costs of the programme and characteristics of participants) and surveys of the general population and of South Australian general practitioners which provide information on knowledge, attitudes and practices in relation to colorectal cancer and its prevention. It is described more fully at the end of this chapter.

Before reporting the results of the study, a brief overview of the current status of epidemiological evidence in relation to colorectal cancer and its prevention is presented. Alternatives to FOBT screening as a means of reducing mortality from colorectal cancer, such as dietary interventions and use of other screening tests are also examined.

1.2 Natural history of colorectal cancer

It is widely believed that most cancers of the colon and rectum develop from benign precursor lesions, or adenomas (Tierney et al, 1990). These adenomas vary in morphological appearance from tiny nodules to huge tumours as much as 12 cm. across (Morson, 1984). Although colon and rectal cancers are identical in pathology (most are adenocarcinomas), their trends in incidence and mortality rates, risk factors and natural history are quite different, and they are often considered as separate disease entities for this reason.

Differences such as these have also been noted between right-sided and left-sided colorectal cancers. Left-sided colon cancer is the most prevalent form in western populations, and more is known about its etiology than with right-sided

cancer. There is, however, evidence that the site distribution of colon cancers is changing over time - a 20-year retrospective study in the US suggests that both benign polyps and adenocarcinoma are occurring with increasing frequency in the right colon (Greene, 1983). Other studies of site distribution have shown a similar increase in the proportion of proximal (or right-sided) cancers (Kee et al, 1992) (Beart et al, 1983), and it suggests that environmental factors that increase the risk of colon cancer may be different in proximal versus distal disease.

Evidence that adenomas can develop into carcinomas comes from a variety of sources. Greene's retrospective study (1983) showed a constant association of benign polyps within colonic cancer resections, supporting the concept of a polyp-cancer sequence. Morson (1984) has added to the evidence with his findings that about one-third of all operation specimens for colorectal cancer contain one or more adenomas. He also notes that the incidence of a benign component of large bowel carcinoma has been demonstrated to be related to the extent of spread of tumour through the bowel wall, suggesting that as a carcinoma enlarges, progressively more of the precursor adenoma is destroyed by, or is transformed into, malignant tissue.

The adenoma appears to be a useful for marker of increased cancer risk, but the evolution to cancer is slow and unpredictable. The magnitude of increased risk is greater in patients with large and/or multiple adenomas. The mechanism whereby benign neoplasms, such as adenomas, change into malignant carcinomas is not known. Furthermore, it seems likely that only between 5 and 10% of colorectal adenomas progress to cancer (Morson, 1974). It is also thought that colorectal cancer can take as long as 10 to 15 years to progress from polyps to clinically detectable stages.

Prognosis of colorectal cancer is determined by many factors, the most important of which is the histopathological stage of the cancer. In 1932 a system was developed for rectal cancer which was, subsequently, also applied to colon cancer (Dukes & Bussey, 1958). Although this system of classification has been modified and revised in subsequent years, it remains the most practical and widely used prognostic indicator (Goldberg et al, 1988). *Table 1.4* shows estimated survival from time of diagnosis based on Dukes histopathological staging and using data from the Surveillance, Epidemiology and End Results Programme of the National Cancer Institute.

1.3 Descriptive Studies of Colorectal Cancer

As in many other forms of cancer, information on the characteristics of colorectal cancer comes from two main sources; analytical studies, in which particular hypotheses in relation to risk factors for the disease can be tested, and descriptive studies (considered in this section) which provide information on a number of measures including disease incidence, prevalence and mortality and the prevalence of potential risk factors in the population. Much can be learned about the etiology of colorectal cancer from observational measurements such as these, particularly if the measures can be compared in different populations or in the same populations at different points in time.

1.31 International comparisons

Much of what is known about the epidemiology of colorectal cancer has been derived from descriptive studies of incidence of the disease in relation to various geographic, racial and other characteristics. Epidemiological research has been prompted by the finding that western countries such as Australia and the US have a particularly high incidence of colorectal cancer, whereas in less developed countries (such as those of the Asian and African continents) it is relatively rare. In the search for environmental risk factors much attention has

focused on the western diet, particularly in relation to its relatively high fat and low fibre components. There is evidence from both descriptive and experimental studies that dietary factors such as these are important factors in the etiology of colorectal cancer.

Much of the evidence linking dietary factors and colorectal cancer incidence has come from descriptive studies which incorporate international comparisons. *Figures 1.1 and 1.2* are derived from one such study (Liu et al, 1979) in which data on food consumption were collected from a number of industrialized countries for the period 1954-65, and compared with age-specific colon-cancer mortality rates over the period 1967-1973. The graphs suggest a positive association between colorectal cancer mortality and total fat consumption, and a negative association with fibre consumption. It can be seen that mortality rates from colorectal cancer in Australia are among the highest in the world.

Studies such as these are limited by the fact that various dietary factors are intercorrelated with each other, making it difficult to determine which are true risk factors. Also, there are many potential confounders of observations made in this way - factors other than those of direct interest may be responsible for the observed associations. Nevertheless, ecological evidence of this nature has provided a strong incentive for more detailed experimental research to be undertaken.

1.32 Migrant studies

Data on first generaton migrants to Australia supports the concept that migration from low-risk to high-risk countries for CRC, such as Australia, results in a transition of rates towards the risk levels of the new country (Kune et al, 1986). This has been observed in European migrants to Australia (McMichael et al, 1980), and dietary change has been suggested as a plausible explanation for this

increased risk. A comparison of British-Irish and Southern European migrants to Australia (McMichael & Giles, 1988) showed that there was a much higher consumption of fibre in Southern Europeans, and a higher consumption of animal fats in the British-Irish. These groups had lower and higher rates of colorectal cancer respectively, but there was a general pattern of convergence on the Australian-born rate with increasing duration of stay. Again, data such as these support the widely-held belief that diets high in saturated fats and low in dietary fibre are a source of increased risk of colorectal cancer.

1.33 Changing incidence, mortality and survival over time

For most of this century there has been a generally consistent increase in incidence of colorectal cancer in western countries including Australia. A review of Australian mortality rates from cancer of the colon and rectum from 1908 to 1978 revealed an upward trend in age-standardized rates for colorectal cancer for males and, to a lesser extent, females (Rohan & McMichael, 1981). Mortality data were used in this analysis, as population cancer incidence registries have only been established relatively recently in Australia.

Evidence from South Australia suggests this trend is continuing (Bonett et al, 1992 - a); an increased incidence of colonic cancers was observed between 1977-1979 and 1989-1991. The increase was greater in males than females for both colonic cancers (29% and 8% respectively) and rectal cancers (35% and 25% respectively). Evidence of a continuing increase in colonic cancer incidence is further supported by US research which has found the age-adjusted incidence rates of invasive colon cancer have continued rising in all age groups since 1976, particularly amongst white males and blacks (Devesa et al, 1987).

While it has been suggested that some of the reported increase in incidence figures in the US could be due to the more complete ascertainment of cases

brought about by recent advances in diagnostic techniques and more widespread screening (Chow et al, 1991), analysis of the overrall trends in the last three to four decades appears to be consistent with an increasing incidence. Despite this, there is now quite convincing evidence that, in contrast to the generally upward trend this century (Rohan & McMichael, 1981), mortality from colorectal cancer has been declining over recent years (Bailar & Smith, 1986). Data from the US show a recently decreasing mortality rate from colorectal cancer, despite an increasing incidence (National Cancer Institute, 1988). Similarly, in South Australia, rising incidence figures for colorectal cancer have not been accompanied by corresponding increases in mortality in the most recent period of observation (Bonett et al, 1992 - a). The decline in mortality rate from colorectal cancer appears to be particularly evident in recent years in countries such as Scotland, Canada, Australia and US where rates of colorectal cancer were high in the 1950s (Boyle et al, 1985).

The reasons for this decline in mortality are not clear, but contributing factors may include the advent of better diagnostic procedures, earlier detection of the disease (either through more widespread screening programmes, greater awareness in the population of early warning signs or increased vigilance in detecting the disease by doctors) and improvements in treatment of colorectal cancer. There is some evidence that modern treatment techniques can prolong case survival - an improvement in case-survival for cancers of the colon and rectum has been recorded in the South Australian population between 1977 and 1990 (Bonett et al, 1992 - b). Research from the UK has found that, while five year overall survival rates are less than 30%, regimes combining chemotherapy and radiotherapy can prolong survival in patients at high risk of recurrence (Begent, 1992). A meta-analysis of trials of adjuvant chemotherapy regimes has shown a small but statistically significant survival benefit (3.4%) in treated groups

(Buyse et al, 1988). Nevertheless, it is unlikely that the recent decline in mortality rates can be attributed to any single factor.

Changes in the incidence of colorectal cancer in populations over time can also provide evidence of a role for dietary risk factors if corresponding changes in dietary patterns in the population can be identified. Evidence of this nature was sought in an analysis of time trends of colorectal cancer mortality in relation to food consumption in the US, England & Wales, Australia and New Zealand, in which a protective effect of fibre was suggested. The role of fat and meat was, however, inconsistent over the period of this analysis (McMichael et al, 1979).

1.4 Analytical studies

While the descriptive epidemiology of colorectal cancer has had an important role in determining risk factors, ultimately evidence from analytical studies is required before definitive conclusions can be made. Analytical studies have focused on a range of potential risk factors, mainly linked to dietary components.

1.41 Diet

Much of the attention in this analytical research has, again, focused on the western diet. Although there is evidence suggesting that the dietary patterns of western countries lead to greater risk of colorectal cancer, efforts to develop clear dietary guidelines for primary prevention of the disease have been frustrated by the frequent inconsistencies in the research findings - there remain many areas where there is a general lack of consensus. While research has generally suggested that fruit, vegetables and other sources of dietary fibre have a protective effect (Steinmetz & Potter, 1991 - a) (Slattery et al, 1988), the evidence for clear links between specific dietary factors and colorectal cancer remains unclear.

There is some evidence from prospective studies that the increase in colon cancer incidence may be due to an increase in the prevalence of dietary risk factors in the population (Willett et al, 1990). Findings from the Melbourne Colorectal Cancer Study (Kune et al, 1992) suggest that, in the presence of a family history, the attributable risk for colorectal cancer of diet when one dietary risk factor is present is 11%, while if five or more dietary risk factors are present, the attributable risk is almost 50%.

While individual dietary components such as fibre or saturated fat are often identified and measured, another approach is to examine consumption of actual foodstuffs such as fruit and vegetables. In a recent review of case-control studies examing the relationship between fruit and vegetable consumption and colon cancer (Steinmetz & Potter, 1991 - a), eleven out of fourteen found a statistically significant negative relationship between the cancer and at least one index of vegetable and fruit consumption (one study found only positive relationships and two studies found no significant relationships). A prospective study from the US provides evidence that risk of fatal colon cancer decreases with more frequent consumption of vegetables and high-fibre grains (Thun et al, 1992). There is also evidence that risk of rectal cancer decreases with increasing intake of fibre from vegetables (Freudenheim et al, 1990).

1.42 Fibre

The role of fibre in the diet has been extensively examined in relation to colorectal cancer risk. It is widely believed that consumption of fibre may reduce the risk for colon cancer. Where it has been possible to examine total dietary fibre or components of dietary fibre, negative associations with rates of colon cancer have generally been found in the many case-control studies undertaken in recent years. Examples include the studies conducted by Slattery et al (1988), Graham et al (1978) and, more recently, the Swedish study by Arbman et al

(1992) results of which add to the body of evidence that a high intake of either cereal fibre or total fibre in relation to energy intake is associated with a reduced risk ratio of colorectal cancer.

A combined analysis of 13 case-control studies recently showed that risk decreased as fibre intake increased in 12 out of the13 studies examined. (Howe et al, 1992). On the basis of evidence of this nature, the authors estimate that the risk of colorectal cancer in the US population could be reduced by about 31% if average fibre intake increased by 70%.

A similar analysis conducted by Steinmetz & Potter (1991 - b) had more equivocal results; five out of thirteen case-control studies examined provided strong support for a protective effect, four provided moderate support, two no support and two equivocally suggested an increased risk. There is further inconsistency in the negative associations between colon cancer risk and consumption of fibre or fibre-containing foods when adjustment is made for consumption of potentially harmful foods such as fat or meats (McKeown-Eyssen, 1987).

Caution is required in the interpretation of case-control studies such as these; because it is usually necessary to retrospectively determine fibre intake there may be bias in the results. Furthermore, factors other than those of direct interest (confounding variables) may be responsible for the observed associations.

1.43 Dietary fats, meat and protein

Experimental and epidemiological studies have demonstrated a number of significant correlations between dairy fat, saturated animal fat and a range of cancers including colon cancer (Kestletoot et al, 1991). However, evidence from

case-control studies remains equivocal - many studies have shown no significant associations (Bingam et al, 1990). Armstrong and Doll (1975) found a strong correlation between meat consumption and cancer of the colon in observational studies. Protein is yet another dietary component which has been examined for its potential as a risk factor, and a study from South Australia found that diets high in protein were associated with a two- to three- fold excess risk for colon cancer (Potter & McMichael, 1986).

Correlations between diet and colorectal adenomas have also been examined. In a study which compared the relative risk for colorectal adenomas of high versus low consumption of varioius nutrients (Giovannucci et al, 1992), greater risk, after adjustment for total energy intake, was associated with a diet high in saturated fat, and low in all sources of dietary fibre such as vegetables, fruit and grains. Further evidence for a strong link between diet and colorectal adenomas comes from a US case-control study (Sandler et al, 1993) showing an inverse relationship between adenoma risk in women and intake of carbohydrate, fruit and fibre derived from vegetables and fruit. Total fat showed a positive association. The risks in men were similar in direction but not statistically significant. Cases and controls in this study were similar with respect to gender, body mass, race, marital status, education and indications for colonoscopy.

1.44 Possible mechanisms for dietary risk factors

A number of studies have shown a reduction in fecal mutagenicity, probably by dilution, with the intake of high-fibre containing foods such as bran (Venitt, 1988). It seems likely, however, that dietary fibre has a critical role in carcinogenesis - this is further supported by the finding that fibre appears to be protective against the development of potentially pre-malignant adenomas (Little et al, 1993). It has for some years been postulated that diets high in fat or low in fibre lead to an increased risk of colon cancer by producing high gut bile acid levels. In the case

of fats this is through increased cholesterol biosynthesis or high dietary cholesterol. As with most forms of cancer, however, understanding of the precise mechanisms which bring about mutagenic change is limited.

1.45 Socioeconomic Factors

With the exception of Japan, colorectal cancer is a disease of economically developed countries and it is one of the few cancers for which evidence of a link with lower socioeconomic status is lacking. Indeed, a number of individual reports have found evidence of a greater incidence of colorectal cancer in higher socio-economic groups. For example, a study based on the Cancer Registry of France found that, for males, risk for left-sided colon cancer was greatest amongst individuals of highest social classes (Faivre et al, 1989).

In Australia, mortality from colorectal cancer has been associated with residence in higher socioeconomic areas of Sydney (Burnley, 1992), and a higher incidence of cancer of the colon has been demonstrated in upper versus lower income areas of Adelaide (Esterman et al, 1988). A study which examined age-standardized cancer incidence and socioeconomic status with new cancers registered with the Victorian Cancer Registry showed a positive association between socioeconomic status and colorectal cancer incidence (Williams et al, 1991). There are, however, inconsistencies in the socioeconomic gradients for the disease in developed countries (Correa, 1975), and it appears, on the basis of evidence from the past two decades, that the relationship is not strong (Davey Smith et al, 1991).

In contrast to other diseases such as lung cancer, the known environmental risk factors for colorectal cancer do not predominate in lower socioeconomic groups. This may provide an explanation for the lack of any clear link between colorectal cancer and low socioeconomic status.

1.46 Genetic Factors: Family History and Colorectal Cancer Risk

A family history of colorectal cancer is the most reliable indicator of increased susceptibility to the disease. Its use in targeting high-risk groups within the population for activities such as screening has been advocated (Stephenson et al, 1993). When examining the role of family history, the group of inherited syndromes which are now recognized to be associated with colorectal cancer are generally considered separately; these include adenomatous polyposis coli, Gardner's syndrome, Peutz-Jeghers syndrome and the autosomal dominant cancer families. While only a small fraction of individuals who develop colorectal cancer will have one of these genetic disorders, such individuals may have a lifetime risk for colorectal cancer of greater than 50% (Lynch, 1979) and they almost certainly warrant regular surveillance.

It is well documented from family studies (see *Table 1.5*) that the risk of colorectal cancer in first degree relatives of affected individuals is two to four times the risk in the general population (Lovett, 1976). This means that such individuals have a lifetime risk in the range of 10 to 15% (Lynch, 1979). Research from the US suggests that of the approximately 140,000 cases of colorectal cancer that present in that country each year, about 25% will occur in people who have a family history of the disease (Lynch et al, 1977). Although there are no precise figures available, Eddy et al (1987) suggest, on the basis of available information, that approximately 10% of the US population have a family history of the disease.

A higher proportion of adenomatous polyps has also been documented amongst first-degree relatives of colorectal cancer patients in a controlled, prospective study (Guillem et al, 1992), adding further to the evidence that these are precursor lesions for colorectal cancer.

In an Australian study which aimed to quantify the increased risk of colorectal cancer in first-degree relatives of individuals with colorectal cancer (St. John et al, 1993), the odds ratio for developing colorectal cancer in such individuals was 1.8 (95% CI 1.2 to 2.7) with one relative affected and 5.7 (95% CI 1.7 to 19.3) for two affected relatives. This risk increased when the age of diagnosis in the relative was under 45 years.

1.47 Occupation and exercise

Colon cancer is seldom regarded as an occupational cancer, and it is difficult to exclude dietary factors as the underlying cause for any observed differences in incidence between occupational groups. Nevertheless, Lashner and Epstein (1990), who argue that industrial exposures are important but neglected risk factors for colorectal cancer, have identified a wide range of carcinogenic occupational and environmental industrial exposures with which there is some evidence of increased colorectal cancer risk.

Occupational differences in colorectal cancer incidence have been identified in South Australia (Esterman et al, 1988). *Figure 1.3* shows observed and expected rates of colorectal cancer amongst various occupational groupings in the South Australian population. It can be seen that, as with socioeconomic status, there is a trend towards higher incidence in higher income groupings.

Occupation is closely linked to the amount of daily exercise taken. Vena et al (1985) found that risk of colon cancer increased with amount and proportion of time in jobs involving only sedentary or light work. An increased risk of colorectal cancer in individuals who belong to sedentary occupational groups as opposed to occupations involving high levels of physical activity has also been observed in a New Zealand study (Fraser & Pearce, 1993). Both of these studies included potential confounders such as diet in their analyses.

The mechanism by which exercise might reduce risk of colorectal cancer is unclear, but Garabrant et al (1984) have proposed that it may be related to exercise-induced peristaltic activity which could result in a reduction in the duration of contact of the lumen with fecal carcinogens.

1.48 Other potential risk factors

The consumption of aspirin as a potential protective measure against colorectal cancer recently has received attention in the literature. Logan et al (1993) have produced evidence of a protective effect of aspirin in a case-control study of subjects participating in the Nottingham trial of FOBT screening, while Thun et al (1992) have found that the consumption of aspirin appears to add to the protective effect of vegetable consumption.

While the role of alcohol in the epidemiology of colorectal cancer has been examined in a number of analytical studies, there is evidence that beer consumption may be an independent risk factor. McMichael et al (1979) found a positive association between beer consumption and rectal cancer. Riboli et al (1991) found beer consumption has been associated with colorectal cancer in a trial which found no such link with total ethanol intake.

In women, there is some evidence that reproductive history influences risk for colorectal cancer. A US case-control study (Peters et al, 1990) found a "U-shaped" relationship between number of pregnancies and colon cancer, the risk decreasing with successive pregnancies up to four then increasing with additional pregnancies.

1.5 Implications of epidemiological evidence for primary prevention

This lack of general consensus on dietary risk factors for colorectal cancer has impeded the development of effective primary preventive strategies, although

diets which are claimed to be associated with low cancer risk are frequently promoted through various health organizations and the media.

Given that the strongest and most consistent epidemiological evidence is in relation to diet, there appears to be the potential to reduce risk of colorectal cancer through modification of traditional western dietary habits. While there is an increasingly prevalent belief in the public and the medical community that a good diet can prevent certain forms of cancer, the efficacy of most nutritional recommendations has not been proven by rigorous clinical trials. Interim guidelines, based on current data and on basic nutritional principles, have been established by the WHO Collaborating Centre for the Prevention of Colorectal Cancer (Shike et al, 1990); they include reducing fat consumption such that animal and vegetable fats constitute no more than 25% of total calories, ensuring an adequate intake of high fibre foods including vegetables, legumes, fruits and whole grain cereals (dietary fibre intake should amount to at least 25 gm/day) and balancing energy intake and expenditure to avoid excess body weight. Guidelines such as these are in accord with dietary recommendations for reducing heart disease and therefore can be regarded as forming the basis of a diet that is unlikely to do harm and may have the potential to reduce colorectal cancer rates. In Australia, similar guidelines have resulted from efforts to develop dietary recommendations for reducing colorectal cancer risk by the Better Health Commission (1986). In view of the nature of the evidence and the difficulties involved in bringing about dietary change in populations, primary prevention may only have the potential to bring about modest reductions in colorectal cancer incidence.

1.6 FOBT screening for colorectal cancer - an overview

The consistent finding that individuals in whom colorectal cancers are detected at an early stage survive longer (compared to those with late cancers) provides the

rationale for screening. While a range of screening strategies have been examined in trials of screening, only the FOBT is used by significant numbers of individuals in countries such as the US and Australia.

Van Deen is generally regarded as the pioneer of occult blood testing (Simon, 1985) - in 1864 he used gum guaiac as an indicator reagent for blood, and it remains the most widely used indicator for occult bleeding. Greegor, an Ohio internist, was the first to stimulate interest in screening healthy populations in 1967 using guaic impregnated slides for use at home, and in subsequent years many screening studies were undertaken and its use became widespread.

The FOBT requires the collection of a fecal specimen (or, more usually, sequential stool samples) and applying it to a test-kit which can detect blood. It is based on the rationale that colorectal cancers are friable and can bleed into the lumen of the bowel. Unfortunately, cancers tend to bleed intermittently, so testing for fecal blood may be inaccurate. Furthermore, there are sources of blood in the bowel other than colorectal cancer (including physiological microbleeding), and there are other substances which may also cause a falsely positive result.

When blood enters the bowel its hemoglobin is digested, leaving predominately a substance called heme. Hemoglobin is degraded to a greater degree in the proximal gastrointestinal tract. In the large bowel, heme is further degraded by bacterial action to produce substances called porphyrins. Hence, fecal material contains hemoglobin, heme and porphyrins. Bleeding from the proximal bowel will result in a predominance of the porphyrin substances.

1.61 Types of fecal occult blood tests

There are three main groups of fecal occult blood tests in common use; the guaic tests (including Hemoccult), immunochemical tests and heme-porphyrin assays. They all differ in their mechanism of action and performance characteristics.

1.611 Guaiac tests

Guaic tests for fecal occult blood are the simplest and least expensive. They detect only intact heme and hence are quite specific for large bowel blood loss.Hemoccult® (and Hemoccult 11®) are the most widely used fecal occult blood tests in Australia and overseas - they have been used in all of the major randomized control trials of FOBT screening (Hardcastle et al, 1989) (Mandel et al, 1993) (Kronborg et al, 1989) (Kewenter et al, 1988). Sensitivity of guaic tests such as Hemoccult for colorectal cancer varies between different trials. It is usually in the region of 50 to 80%, while specificity is generally over 95% (Allison, 1992) (Hardcastle et al, 1989). The sensitivity of the FOBT is also influenced by whether or not the test slide is re-hydrated, a process which increases the test's reactivity to blood.

A further problem with guaic tests is the need for dietary restrictions which may have an adverse effect on the acceptability of the tests. They are affected by red meats, plant peroxidases (such as cruciferous vegetables and radish), vitamin C and aspirin ingestion (Young & St. John, 1991), and these food substances need to be avoided prior to using the test.

The fact that Hemoccult misses a significant proportion of cancers has prompted the search for fecal occult blood tests with more favourable performance characteristics - that is, improved sensitivity for colorectal cancer without corresponding losses in specificity. HemoccultSensa® is a modified version of the standard Hemoccult test which is claimed to have a greater sensitivity for

detection of blood, and greater readability and precision (that is, lower false negative rates). Only preliminary evaluation has been undertaken on these tests in Australia (Petty et al, 1992) although initial results from overseas suggest they may be more sensitive than Hemoccult for colorectal cancers (Cleator, 1992).

1.612 Heme-porphyrin Assays

These detect all three components of fecal blood; intact hemoglobin, heme-derived porphyrins and intact hemes. The most widely used of these tests is the HemoQuant® test, which allows quantification of gastrointestinal blood loss. The Hemoquant test is relatively expensive and has not been extensively evaluated (Cleator, 1992) although there is some evidence it is more selective, depending on the "cut-off point" at which a test is declared positive (McGill, 1992). It detects heme and porphyrins originating from both upper and lower gastrointestinal bleeding as well as dietary porphyrins and animal heme. Unlike the guaic-based tests it is not affected by plant peroxidases or vitamin C, but is affected by red meat and aspirin ingestion, so dietary restrictions are required.

An initial evaluation of the HemoQuant test undertaken in Melbourne suggests it has a lower sensitivity for colorectal cancer than Hemoccult (St. John et al, 1992). A comparison of Hemoccult and HemoQuant in a group of relatives of colorectal cancer patients who underwent colonoscopy as a surveillance measure has been undertaken in the US (Ahlquist et al, 1993). The estimated sensitivity at one to three years of follow-up was, respectively, 25% to 33% by Hemoccult and 29% to 43% by HemoQuant.

1.613 Immunochemical tests

Immunochemical testing for fecal occult blood offers the promise of higher performance characteristics as the test is designed to detect only intact human hemoglobin by the development of specific antibodies. This eliminates false

positives from dietary causes and should make the test more specific for lower gastrointestinal bleeding as hemoglobin from more proximal bleeding (such as bleeding ulcers) is unlikely to remain intact. The Institute of Medical & Veterinary Science's FOBT screening programme, which is evaluated in this thesis, uses an immunochemical test known as Detectacol®. It incorporates a radial immunodiffusion technique and polyclonal antibodies directed against intact human hemoglobin (Thomas, 1992). An immunochemical test which is in wider use is HemeSelect® which, like Hemoccult, HemoccultSENSA and HemoQuant, has been developed by Smith Kline Diagnostics Inc., San Jose, CA.

Immunochemical tests require analysis in a laboratory, making them potentially less convenient than the Hemoccult slide which can be interpreted in an office setting. Research from the UK suggests that these tests are more sensitive for colorectal cancers and adenomas than chemical tests (Frommer et al, 1988). The accuracy and performance of immunochemical tests has also been the subject of Australian research - in a study of 1615 individuals who had been previously treated for colorectal cancer the positivity rate in screening with an immunochemical test was 6.1% (99 individuals) of whom 14.4% had colorectal cancer and 40.0% adenomas (Williams et al, 1987). Of the 53 occult blood negative individuals who accepted an offer of colonoscopy or barium enema, none had colorectal cancer.

While the aim in developing immunochemical tests has been to achieve greater specificity for lower gastrointestinal bleeding, the anti-hemoglobin antiserum used in these tests is not always specific for human hemoglobin (Saito et al, 1992), and other causes of lower gastrointestinal bleeding, such as hemorrhoids, may also produce false positive results.

All the randomized controlled trials of FOBT screening (described later in this chapter) have used Hemoccult. It is a matter of some debate whether it will be appropriate to use these results in deciding whether to introduce new FOBT screening programmes which use technologies other than Hemoccult.

1.62 Measures of performance of FOBTs

Sensitivity and specificity are traditionally used as quantitative measures to assess the validity of screening tests, and are the principal indicators of performance reported in comparisons of the various fecal occult blood tests available. While these measures are generally regarded as inherent properties of the test itself (independent of disease prevalence) they can be influenced by such factors as the severity of disease or the presence of concomitant illness (Mausner & Bahn, 1974). Modelling approaches, which use information from various subgroups of the population, have been advocated under certain cicumstances to obtain more accurate estimates of sensitivity and specificity (Coughlin et al, 1992).

As with most tests used for screening, the sensitivity and specificity of the FOBT can be adjusted by altering the cut-off point at which fecal blood (or its degredation products) is detected. In general, there is a trade-off between sensitivity and specificity - for example, if the sensitivity of the test is increased (meaning that less cancers will be missed) there is usually a corresponding loss of specificity - that is, there will be a higher proportion of "false positives" amongst the positive test results. It is argued that, for colorectal cancer, the trade-off between sensitivity and specificity should favour specificity as the consequence of a positive test is an expensive, uncomfortable and potentially harmful workup for colonic disease (Simon, 1985).

The most usual procedure by which sensitivity is determined is to measure the number of cancers which present clinically following a negative screening test. It is not usually practical in trials of screening to investigate all test-negative subjects to determine how many cancers have been missed by the FOBT - hence, reported sensitivities are open to interpretation. Furthermore, there is no universally accepted criteria of what denotes a "false negative" discovered in this way - should it be a cancer which appears within one year of a negative screening test or two years?

In examining ways of determining more valid measures of sensitivity Day, (1985) has suggested that basing calculations on numbers of cancers occurring in an arbitrary period of time after a screening test (usually one year) allow only crude estimations - some cancers will not have been present at the time of screening but will become clinically apparent within a year, while other cancers missed at screening will not appear within a year. He proposes estimates of sensitivity based on the incidence rate of cancers after screening and the incidence rate of cancers in a control group who are not screened.

Positive predictive value (PPV) is an important measure of performance for FOBT screening programmes. It is the percent of all positive screening tests that lead to a diagnosis of cancer (or polyps, if detection of these is also considered to be worthwhile). The PPV for a particular condition is directly related to the prevalence of the condition in the screened population and inversely related to the false positive rate. The prevalence of previously undetected disease tends to decrease as screening frequency increases - so programmes with shorter screening intervals should have lower PPVs. In the randomized controlled trials currently underway there have been declining PPVs as the trials have progressed.

Methods such as rehydration of hemoccult slides, while increasing the sensitivity to blood in the stool, tend to lower the PPV. Positive predictive value is, by itself, an insufficient measure - a screening procedure with a low PPV can still be effective if the reductions in mortality and morbidity through early detection outweigh the consequences of follow-up procedures required as a result of false positive results.

1.63 Evidence of mortality benefits from FOBT screening

1.631 Intermediate measures of benefit

As in all screening programmes, the question of most critical concern is whether or not populations who are screened have reduced mortality from the illness. Until recently, no results on mortality from randomized controlled trials of FOBT screening have been available. Most reports have focused on intermediate measures such as sensitivity, specificity and PPV of screening tests used and pathological staging of screen-detected tumours.

Evidence that screen-detected cancers have more favourable histopathological staging is, in itself, insufficient to provide a justification for undertaking widespread screening. Cancers diagnosed at earlier stages generally have better prognoses, and therefore it may be that screening leads to improvements in mortality through earlier detection of cancers. However, two forms of bias bring this conclusion into doubt; lead-time bias (although the time of diagnosis is brought forward, the course of the disease is otherwise unaltered) and length bias (slower-growing lesions have a greater chance of being detected in a periodic screening programme, and since these slower-growing tumours are not as invasive or lethal as the faster-growing tumours, the change in stage distribution will overestimate the number of cancers averted or expected life years gained).

Volunteer bias is a further potential limitation on the results of screening programmes outside of trials in which individuals are randomly allocated to screened or control groups - people who agree to participate in a screening programmes may develop cancers with a different clinical course than those who do not participate. The direction of this volunteer bias cannot be predicted.

1.632 Case-control studies

In the absence of detailed results from randomized controlled trials, the case-control approach is sometimes used to investigate potential mortality benefits from screening. In these studies, cases and controls are compared in relation to their screening histories. While lead-time and length bias can be avoided in case-control studies by appropriate study design (Sasco et al, 1986) (Moss, 1991), selection bias (the tendency for those accepting screening to be at higher or lower risk than the general population of developing the disease and/or dying from it) is difficult to exclude. This is because it is not possible to identify all the potential risk factors for the disease for which cases and controls should be similar. Difficulties with selection bias have been highlighted in case-control evaluations of mammographic screening (Moss et al, 1992).

Nevertheless, there is some evidence from Europe (based on case-control studies) that individuals who die from colorectal cancer are less likely to have been screened for the disease (Wahrendorf et al, 1993) although no conclusive evidence has come from similar case-control studies of FOBT screening in the US (Selby et al, 1993) (Newcomb et al, 1992).

1.633 Randomized control trials

As with almost all interventions, the randomized control trial provides the highest quality of evidence for examining the effect of FOBT screening on mortality from colorectal cancer. It has the potential to overcome most forms of bias provided

adequate randomization is achieved and there is rigorous collection of incidence and mortality data in both screened and non-screened groups.

A number of randomized controlled trials have been established to examine differences in mortality and morbidity between individuals underataking FOBT screening and controls. The following is a brief description of the current status of these trials.

Nottingham, UK

Hardcastle and his colleagues are conducting a randomized control trial of FOBT screening at the Queen's Medical Centre in Nottingham. Asymptomatic individuals have been recruited via their general practitioners' registers and those allocated to the study group are offered the FOBT every second year. The comparison group have been given no particular treatment. Mortality differences between the screened and unscreened groups are being measured.

The recruitment phase of the trial, which began in 1984, is now complete. The results of the first 107,349 subjects were published in 1989 (Hardcastle et al 1989) with a follow-up report in 1991 (Hardcastle, 1991). A final report with mortality data is expected in the next two to three years.

The initial tests were carried out with dietary restrictions, but since 1985 subjects with a positive test result have been asked to repeat the test over a 6 day period while excluding red meats and vegetables high in peroxidase from the diet. Subjects with a second positive test undergo full investigation by colonoscopy (although barium enema was used in the early part of the study).

At the initial screen 618 of the 27,651 completed tests were positive for faecal occult blood (2.24%), and further investigation of these subjects showed 63

cancers (a rate of 2.3 cancers per 1000 people accepting the test). The positivity rate at initial screening fell to 1.4% as the trial progressed - this is lower than the overall rate as there were no dietary restrictions in the early part of the study.

Table 1.6 shows that the proportion of Dukes stage A cancers was significantly lower in the comparison group (13/123, or 11%) than in the screen-detected group (40/76, or 53%). Conversely, the proportion of stage D tumours was significantly higher in the comparison group. Fewer tumors in the screen-detected group were fixed to other structures at the time of surgery or required operations carried out as emergencies or semi-emergencies. More of the screen-detected tumours were amenable to colonoscopic polypectomy alone. Those who declined the invitation to participate in the study had tumours with the least favourable histopathological staging.

Through the course of the study there has been a fall in the yield of cancers from 10.3 per 1000 at the first round of screening to 5.3 per 1000 at the second screening and 1.6 per 1000 at the third.

Goteborg, Sweden

Kewenter and his colleagues began a randomized controlled trial of FOBT screening in the Swedish city of Goteborg in 1982 (Kewenter et al, 1988). All inhabitants of the city aged between 60 and 64 years were randomly divided between a test and comparison group (a total of 27,700 individuals). Those in the test group were sent three Hemoccult 11 tests, a letter of instruction, a questionnaire and a postage-paid reply envelope. They were asked to perform the test with two samples from each of three consecutive stools and to mail the slides back to the hospital immediately after the last test. Two reminder letters were sent out to subjects who did not answer, and another set of Hemoccult 11

slides was included with the last letter. All subjects were offered rescreening after 16 to 22 months.

This process was repeated between January 1987 and May 1988 with rescreening 14 to 17 months later (Kewenter 1990). There were, in total, 25,655 people in the test group of the combined studies, and 25670 in the comparison group. Investigations on individuals with one or more positive tests included digital rectal examination, proctoscopy, rectosigmoidoscopy to 60 cm. and barium enema.

The test group was divided into two further groups in order to test the effects of rehydration. The positivity rate in the unrehydrated test group was 1.9%, and in the rehydrated test group it was 6.1%. The vast majority of the slides were rehydrated, as the number of false negative results with unhydrated slides was felt by the investigators to be too high - the rate of interval cancers amongst the non-rehydrated group was 77% (14 of 18 subjects with a carcinoma), and only 11% (4 out of 36 subjects) amongst the rehydrated group. The rehydration process led to a corresponding decrease in specificity. *Table 1.6* shows that, as in the UK trial, screen-detected cancers had a more favourable pathological staging than those occurring in the control group, and that non-compliers have a particularly poor prognosis.

Minnesota, US

The largest US randomized control trial of FOBT screening was initiated in 1975 at the University of Minnesota. A total of 46,622 subjects (aged 50-80 yrs) were recruited from among volunteers from a number of sources including veterans and employee groups and fraternal organizations (Gilbertsen et al, 1980). A variety of methods were used to solicit participation from the members of these groups.

Subjects were assigned to one of three groups: one was screened annually, the second biennially and the third acted as a control group. Diagnostic work-up of test-positive cases included barium enema, upper gastrointestinal barium examination and colonoscopy. The use of barium enema was ceased in 1978 due to an unacceptably high number of missed cancers, and thereafter colonoscopy was used in all subjects.

During the first phase of screening a total of 129,523 slide sets were sent to subjects in the study and 76.1% were returned and processed (Mandel et al, 1988) (Mandel et al, 1989). Six slides, two per stool from three consecutive stools, were obtained from each participant. A varying number of slides were rehydrated - the proportions varied from 0% in the first year to 100% by the last year of the study. Rehydration resulted in a a fourfold increase in the percent of positive slides, from 2.4% for the nonrehydrated slides to 9.8% for the rehydrated slides. There was an increase in sensitivity from 80.8% to 92.2% with a corresponding decrease in sensitivity from 97.7 to 90.4%.

Specificity was highest for those < 60 years of age and decreased with increasing age. The positive predictive value increased with age from 1.6% for those under 60 years to 3.6% for those in the over 70 age group. Overall, 80% of individuals with positive tests underwent colonoscopy and about 90% had some diagnostic workup of the colon or rectum (Church et al, 1991).

This randomized controlled trial recently reported mortality data (Mandel et al, 1993). In the biennially screened group there was initially a higher cumulative mortality and incidence of colorectal cancer than in the control group, although by the end of the study this trend had reversed and there was a slight reduction in mortality. A 33% reduction in mortality was noted in the group in whom annual screening was undertaken, and this result was statistically significant. The

authors caution that with the high positivity rate brought about by re-hydration of most of the Hemoccult slides used in the programme, a high proportion (38%) of those screened annually during the course of the study had at least one colonoscopy, and this in itself may have contributed to the reduction in mortality. They further suggest that the relatively high positivity rate in this study may have led to a greater probability of non-bleeding cancers being detected by chance in individuals whose positive test resulted from other causes such as hemorrhoids - in which case the mortality benefit from FOBT screening would be incidental.

Despite these reservations, publication of this data has been lauded as a significant step in assessing the worthiness of FOBT screening (Winawer, 1993) and has prompted renewed interest in the long-anticipated mortality results from other trials. Data from this study have not been published in a format that facilitates their incorporation in *Table 1.6.*

Funen, Denmark

This study was initiated in 1985 (Kronborg et al, 1989) (Bech et al, 1992). It involved the assignment of 30970 men and women to a screening group (using Hemoccult 11) and 30968 to a control group receiving no screening. The first screening ended in 1986, and rescreening was undertaken between August 1987 and October 1988.

Screening was aimed at inhabitants of the island of Funen aged beteween 45 and 74 years.The randomization procedure selected 3/14 of the 140,000 inhabitants in this age group for screening and 3/14 as controls. Only those who completed the first screening were invited for re-screening two years later. The Hemoccult 11 test was used and slides were not re-hydrated. People with positive slides were phoned by a physician to arrange further diagnostic evaluation with colonoscopy.

Written invitations were mailed to participants, with detailed instructions and explanations of possible causes of positive tests. Reminders were sent after six and ten weeks; if no answer was received within 4 weeks of the second reminder the person was considered a non-responder. Of those invited for the first screening 67% completed the test and 93% of these participated in the re-screening. The positivity rate was 1.4% over the study period.

Preliminary mortality data from this study suggest a beneficial effect of screening, although the results were not statistically significant at the time of the most recent report (Kronborg et al, 1992). A summary of results from the first year of the study is included in *Table 1.6* which again shows a greater proportion of Dukes A cancers in the screened group compared with controls.

Sloan-Kettering (New York)

This controlled trial was commenced in 1974 and is now completed (Winawer et al 1980, 1982, 1991). It differs significantly from the other trials reported here in that individuals were assigned to either screening with Hemoccult and sigmoidoscopy or sigmoidoscopy alone. Asymptomatic men and women over the age of 40 were offered screening. Investigation of positive results included double-contrast barium enema and colonoscopy. Upper gastrointestinal investigation was undertaken in patients who demonstrated no significant colonic pathology.

Subjects in this study were selected from a self-referred population who attended the Preventive Medicine Institute-Strang Clinic where people come for regular screening examinations. Hemoccult slides were sent to participating individuals by post. Single Hemoccult and Hemoccult II tests were used. Slides were rehydrated only during a selected time period. Of the 13127 study patients who were sent slides for the first time, 74% complied with the test.

The total number of patients with positive slides on first examination was 242, or 2.5 % of those that returned them. The rate of positivity for single Hemoccult slides was 1% with a positive predictive value for cancer of 12%. With use of Hemoccult II slides the rate of positivity increased to 3.7% and, when rehydrated, to 5.4%. The false positivity rate was between 0.5 and 2.1%. Rates of positivity varied with age, and the positive predictive value for cancer increased with age. Consistent with other control trials of FOBT screening, colorectal cancers detected by Hemoccult testing had a more favourable pathologic staging than those found in the control group. This study, which is now complete, recently reported a mortality improvement using FOBT plus annual sigmoidoscopy when compared with sigmoidoscopy alone, although the difference was of borderline statistical significance (Winawer et al, 1993).

Clearly, all of these trials of FOBT screening have been major research efforts, involving the recruitment and follow-up of many thousands of individuals. Indeed, the major drawback of trials such as these is their expense and the length of time the trials must run to accrue sufficient data on mortality. Nevertheless, they provide the only conclusive evidence for the worthiness of FOBT screening, and, as the remaining trials draw to a conclusion over the next few years, their final results will be followed with considerable interest by all health professionals involved in the preventive efforts against colorectal cancer.

1.7 Other methods of screening for colorectal cancer

1.71 Sigmoidoscopy

Given the limitations of FOBT screening (in terms of false negatives and false positives), interest has focused for some years on screening techniques which can directly visualize colorectal lesions. Sigmoidoscopy is the most widely used of these techniques - while it is mainly used as a diagnostic tool, its use in screening has also been examined.

Sigmoidoscopy has a high sensitvity and specificity for those rectal or colonic lesions that are within its reach. Because polyps and cancers are directly visualized in sigmoidoscopy, a positive finding is almost always a true positive. If, however, some of these findings are *clinically* insignificant then the PPV of the tests falls. For example, while polyps which are found are usually removed or biopsied, hyperplastic polyps, which do not progress to cancer are visually indistinguishable from neoplastic polyps which do.

The development of flexible fiberoptic sigmoidoscopes in the mid-1970's increased the proportion of polyps and cancers detectable with sigmoidoscopy. It appears that approximately 2.5 times as many cancers and polyps are detected using a flexible versus rigid sigmoidoscope (Katon, 1979).

While, unlike FOBT screening, there have not been major randomized controlled trials of sigmoidoscopy, a number of uncontrolled studies have provided some evidence of benefit from this form of screening. Hertz et al (1960) conducted a study of 26126 individuals who were offered annual sigmoidoscopies from 1946 to 1954 at the Strang Clinic in New York. Most were asymptomatic at the time of examination. Cancers detected in this way appeared to have favourable pathological staging - of the cancers detected, 81 percent were in stage A or B.

Probably the best known study of sigmoidoscopic screening, however, was undertaken by Gilbertsen et al (1978) in which annual sigmoidoscopy was offered to people aged 45 years and over in Minnesota between 1948 and 1974. All cancers detected on the second or subsequent screens were in stage A or B. Cancer incidence and mortality were examined and it was found that, after eliminating cancers found on the first screen, the rate of colorectal cancer detection in subsequent years was much lower than would have been expected in a similar population, implying that sigmoidoscopy and polyp removal prevented

cancer. This study was reviewed by a number of authors who questioned its findings: Miller (1987) pointed out that the cancers detected at the first screen were not prevented, but found early. His reanalysis of the data included these pre-existing cancers and he concluded that colorectal cancer detection rates in the screened and unscreened groups were similar. Selby and Friedman (1989) suggested that people in whom a diagnosis of colorectal cancer was made in the screened group may have dropped out of the study (the incidence rate in the screened group was based on the number of person-years of observation). Hence, the actual CRC incidence rate in the screened population may have been higher. Neugut et al (1985) pointed out that the Minnesota programme enrolled volunteers for the screened group, hence the findings may have been subject to volunteer bias.

While evidence from studies such as these cannot justify widespread periodic screening with sigmoidoscopy, interest has recently focused on the potential benefits of once-off sigmoidoscopic screening. Evidence that this strategy has potential benefits comes from case-control studies - no data are currently available from randomized control trials. Newcomb et al (1992) conducted a case-control study which showed a reduced risk of death from colorectal cancer in individuals who had had a single screening sigmoidoscopy (OR = 0.21, 95% CI = 0.08-0.52).

Another case-control study (Selby et al, 1992) showed that only 8.8% of individuals who had died of colorectal cancer within reach of the sigmoidoscope (eg rectum and distal colon) had undergone screening sigmoidoscopy, compared with 24.2% of the control group (OR, adjusted: 0.41, 95% C.I. 0.25 - 0.69). This protective effect of screening sigmoidoscopy was not seen for cancers above the reach of the sigmoidoscope. Interestingly, the apparent protective effect was as strong when the most recent sigmoidoscopy was up to ten years before

diagnosis as it was for more recent examinations, suggesting that screening every ten years or so may be just as effective as screening at shorter intervals. Indeed, it has been suggested that a single sigmoidoscopy at the age of 55 to 60 years may be the most cost-effective national screening strategy for Britain (Atkin et al, 1993).

Case-control studies of screening sigmoidoscopy such as these have attracted criticism, particularly in relation to the effect of confounding factors (Shapiro, 1992). However, they do raise the possibility of an alternative form of screening which need not be conducted on a periodic basis and which may have an effect on colorectal cancer mortality.

1.72 Other screening techniques

A number of other possible screening strategies for colorectal cancer have been examined. Full colonoscopy, while probably too impractical and costly as a means of mass screening, may prove to be a worthwhile measure in high-risk groups such as first-degree relatives of individuals with colorectal cancer (Guillem et al, 1992).

Another technique with potential for screening is to test for tumour-derived DNA in individuals' stools, although it has so far only been advocated in research settings (Sidransky et al, 1992). The search for genetic markers for a range of diseases is currently attracting considerable worldwide scientific interest. Genetic markers provide a great deal of promise in identifying individuals at increased risk of colorectal cancer who could be targetted in screening programmes, but a great deal more research is required in this area (Ransohoff & Lang, 1991).

1.8 The IMVS programme for colorectal cancer screening in South Australia

1.81 Background

A major component of this thesis is based on an evaluation of a FOBT screening programme in South Australia. This programme was established in 1988 by the Institute of Medical and Veterinary Science (IMVS). It uses an immunochemical fecal occult blood test, as described in Section 1.61

The programme recruits participants through a number of promotional strategies including posters in doctors' waiting rooms, media advertisements, and product information material in pharmacies and health fund offices. The test is available as a kit (called "Detectacol") which can be purchased from pharmacies, and the cost of the test kit can be claimed through certain private health funds. Funding of the programme is described more fully in Chapter 4.

Once individuals have obtained the test kits, they use them at home and then bring them to a collection point, whereupon they are returned to the IMVS laboratory. Once testing is complete, participants and their nominated doctors are informed of the results of the test. Follow-up of test-positive individuals is undertaken by participants' doctors and is outside the direct control of the programme. Information is, however, subsequently requested from the doctor who has performed follow-up investigations to determine the cause of colorectal bleeding. A twelve monthly recall system operates to invite participants to undertake re-screening.

1.82 Evaluation - The South Australian Colorectal Cancer Screening Study

The South Australian Colorectal Screening (SACCS) study was established In February 1991. The aim of this study was, firstly, to evaluate the Institute of Medical & Veterinary Science's FOBT screening programme in South Australia, to provide information on the programme's performance to the public and funding

bodies which had supported the programme, and to provide feedback to the co-ordinators of the programme. The study also undertook to examine a number of wider issues in relation to FOBT screening - this was considered to be an area of considerable public health relevance given the growing interest in FOBT screening in the 1990s. A steering committee, which included representatives from the University of Adelaide Department of Community Medicine, the South Australian Health Commission and the Institute of Medical & Veterinary Science was established to oversee the study. Ethical approval was obtained from the Committee on the Ethics of Human Experimentation of the University of Adelaide.

The aims of the South Australian Colorectal Cancer Screening Study, upon which this thesis is based, are as follows:

Aim 1. To obtain measures of performance for the screening test used in the IMVS FOBT screening programme.

Rationale:

South Australia is fortunate in having a Central Cancer Registry of a high standard of data collection which allows data sets to be imported and linked to the central data base. Hence, estimations could be made of the test's sensitivity, specificity and predictive value. Such information is of great importance - it allows comparisons to be made with the performance characteristics of tests used in other programmes, and provides feedback for clinicians whose patients are involved in the programme.

Aim 2: To examine characteristics of participants in FOBT screening.

Rationale:

A major consideration in all screening programmes is to determine whether or not those who participate are representative of the wider population. If screening only

reaches a small proportion of the population (most likely with unique characteristics), there are limitations on the generalizability of results and it may not be a clear indication of how the programme would operate in the wider population.

Socioeconomic status of screening participants is one such characteristic - there is consistent evidence from western countries that low socioeconomic status has an adverse effect on screening participation rates. The collection of postal data on IMVS screening programme participants has enabled an examination in this study of the distribution of screening participants amongst the various socioeconomic groupings of Adelaide's residential areas.

There are other important participant characteristics which are measured in this study, including the presence of a family history or past history of colorectal cancer and whether or not symptoms are present - screening should be confined to *asymptomatic* individuals, and participation in screening which is prompted by symptoms is inappropriate.

Aim 3: To examine costs in relation to potential benefits of the IMVS screening programme.

Rationale:

Cost is a critical issue in screening - even if FOBT screening is shown conclusively to produce mortality benefits, ultimately it is the costs in relation to the expected benefits of a programme which will influence decisions on whether or not it should be implemented.

Evidence from other screening programmes suggests that many of the costs to participants of screening may not be immediately evident. These include travel costs, time off work, costs of medical investigations and psychological distress. It

is important for cost calculations to screening participants to be as comprehensive as possible to make well-informed estimates of the relative costs and benefits of screening. It is also important to distinguish between costs which are borne by the individual and those which are borne by society as a whole.

In this study an attempt is made to obtain a comprehensive picture of costs of the programme and to calculate a cost per cancer detected. This information is used to examine the cost implications of introducing FOBT screening on a wider scale in Australia.

Aim 4: To examine knowledge, attitudes and beliefs in relation to screening for colorectal cancer in the population, and to assess whether FOBT screening participants are unique in relation to these characteristics.

Rationale:

Acceptability and levels of previous participation (or intended participation in the future) in the general community are critical factors in the success of any screening programme. This study therefore includes an assessment of these parameters, and how they are influenced by variables such as family history of colorectal cancer, socioeconomic status and health beliefs in relation to colorectal cancer. A comparison of these characteristics in screening participants and the general population is also included, with the aim of examining whether those who participate in FOBT screening have unique characteristics.

This information enables predictions to be made on the likely uptake of FOBT screening should such programmes be introduced on a wide scale in Australia.

Aim 5: To examine knowledge, attitudes and beliefs of general practitoners.

Rationale:

This is a critical component of any assessment of FOBT screening, as general practitioners are at the forefront of screening programmes and have a key role in providing information and co-ordinating the screening process. Should widespread FOBT screening be introduced in Australia, general practitioners will have a key implementational role. Hence, in this study, information is gathered on current screening practices of GPs and knowledge, opinions and attitudes in relation to screening for colorectal cancer. This information is of considerable importance to the screening programme in South Australia and also has implications for the implementation of widespread FOBT screening in Australia.

In the following chapters each of these aims is examined in detail. Information is then compiled from the various components of the study to draw conclusions about the feasibility and desirability of conducting major FOBT screening programmes in the Australian community.

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Table 1.1 - Cancer Incidence (for most common cancers) in South Australia, 1991

MALES

Site	no.	% of all cancers	crude incidence rate (per 100,000)*	age standardized incidence rate**
Total cancers	3134	100.0	431.8	315.0
Prostate	610	19.5	84.0	54.0
Lung	470	15.0	64.8	47.0
Colon	**297**	**9.5**	**40.9**	**30.0**
Melanoma	235	7.5	32.4	25.9
Rectum, recto-sigmoid junction & anal canal	**188**	**6.0**	**25.9**	**19.0**

FEMALES

Site	no.	% of all cancers	crude incidence rate (per 100,000)*	age standardized incidence rate**
Total cancers	2696	100.0	368.9	245.5
Breast	672	24.9	91.9	67.9
Colon	**263**	**9.8**	**36.0**	**21.5**
Melanoma	224	8.3	30.6	22.6
Lung	192	7.1	26.3	16.0
Rectum, recto-sigmoid junction & anal canal	**143**	**5.3**	**19.6**	**12.0**

(adapted from: Bonett et al, 1992 - a)

*Using SA estimated population, Australian Bureau of Statistics, 1991

**Standardized to world population

Table 1.2 - Cancer Mortality (for most common cancers) in South Australia, 1991

MALES

Site	no.	% of all cancer deaths	crude mortality rate (per 100,000)*	age standardized mortality rate**
Total deaths	1532	100.0	211.1	146.6
Lung	427	27.9	58.8	41.5
Prostate	192	12.5	26.5	16.2
Colon	**121**	**7.9**	**16.7**	**11.7**
Stomach	80	5.2	11.0	7.8
Rectum, recto-sigmoid junction & anal canal	**70**	**4.6**	**9.6**	**6.8**

FEMALES

Site	no.	% of all cancer deaths	crude mortality rate (per 100,000)*	age standardized mortality rate**
Total deaths	1282	100.0	175.4	103.4
Breast	232	18.1	31.7	20.8
Lung	167	13.0	22.9	13.4
Colon	**129**	**10.1**	**17.7**	**9.7**
Rectum, recto-sigmoid junction & anal canal	**77**	**6.0**	**10.5**	**6.3**
Lymphomas	73	5.7	10.0	5.6

*Using SA estimated population, Australian Bureau of Statistics, 1991
**Standardized to world population

Table 1.3 - Criteria of acceptability for screening tests

1. The disease should be common in the screened population, and its natural history should be well understood.

2. The screening test should be simple, inexpensive and acceptable to participants

3. An acceptable form of treatment should be available for those screening participants in whom disease is discovered

4. This treatment should favourably influence the outcome

5. The number and cost of false positive tests (and confirmatory investigations which result from these tests) should be acceptable and affordable

6. There should be adequate means of follow-up of screening participants

Adapted from: Wilson, (1976) and Mant & Fowler, (1990)

Table 1.4 - Dukes Classification of colorectal cancer with corresponding survival rates

Dukes Stage	Extent of tumour spread	5-year survival rate (%)	10-year survival rate (%)
A or B	Local	80.3%	74.0%
C	Regional	46.1%	36.0%
D	Distant	5.4%	5.0%

adapted from: Eddy et al (1987)

Table 1.5 - Lifetime risks of colorectal cancer in first degree relatives of patients with colonic cancer*

General population risk	1 in 50
One relative affected	1 in 17
One relative aged under 45 affected	1 in 10
Two first degree relatives affected	1 in 6
Dominant pedigree	1 in 2

***adapted from the Lovett series (1976)**

Table 1.6 - Stage of cancers in screened and unscreened groups in randomized control trials of FOBT screening in UK, Sweden & Denmark*

Nottingham (UK)

Stage	Screen-detected	Interval**	Non-compliers	Total	Controls
A	40(53%)	6(12%)	10(12%)	56(31%)	13(11%)
B	20(26%)	4(18%)	30(36%)	54(30%)	40(32%)
C	13(17%)	6(27%)	16(19%)	35(19%)	40(32%)
D	3(4%)	6(27%)	25(30%)	34(19%)	26(21%)
unstaged	-	-	2	2	4
Total	76	22	83	181	123

Goteborg (Sweden)

Stage	Screen-detected		Interval	Non-compliers	Total	Controls
	initial	re-screen				
A	19(50%)	8(31%)	0	1(8%)	28(30%)	4(12%)
B	7(18%)	7(27%)	6(33%)	2(17%)	22(23%)	8(24%)
C	11(29%)	6(23%)	8(45%)	4(33%)	29(31%)	13(38%)
D	1(3%)	5(19%)	4(22%)	5(42%)	15(16%)	9(26%)
Total	38	26	18	12	94	34

Funen (Denmark)

Stage	Screen-detected		Non-compliers	Total	Controls
A	19(49%)	not available	8(25%)	27(38%)	2(5%)
B	11(28%)	"	12(37.5%)	23(32%)	19(51%)
C	5(13%)	"	5(16%)	20(28%)	7(19%)
D	2(5%)	"	7(22%)	9(13%)	8(22%)
unstaged	2(5%)	"	-	2(3%)	-
Total	39	"	32	71	37

*adapted from: Hardcastle et al (1989), Kewenter et al (1988) & Kronborg et al (1989)

**there is no universally agreed upon definition for an interval colon cancer. It is usually, however, defined as one diagnosed within 12 months following a negative occult blood test

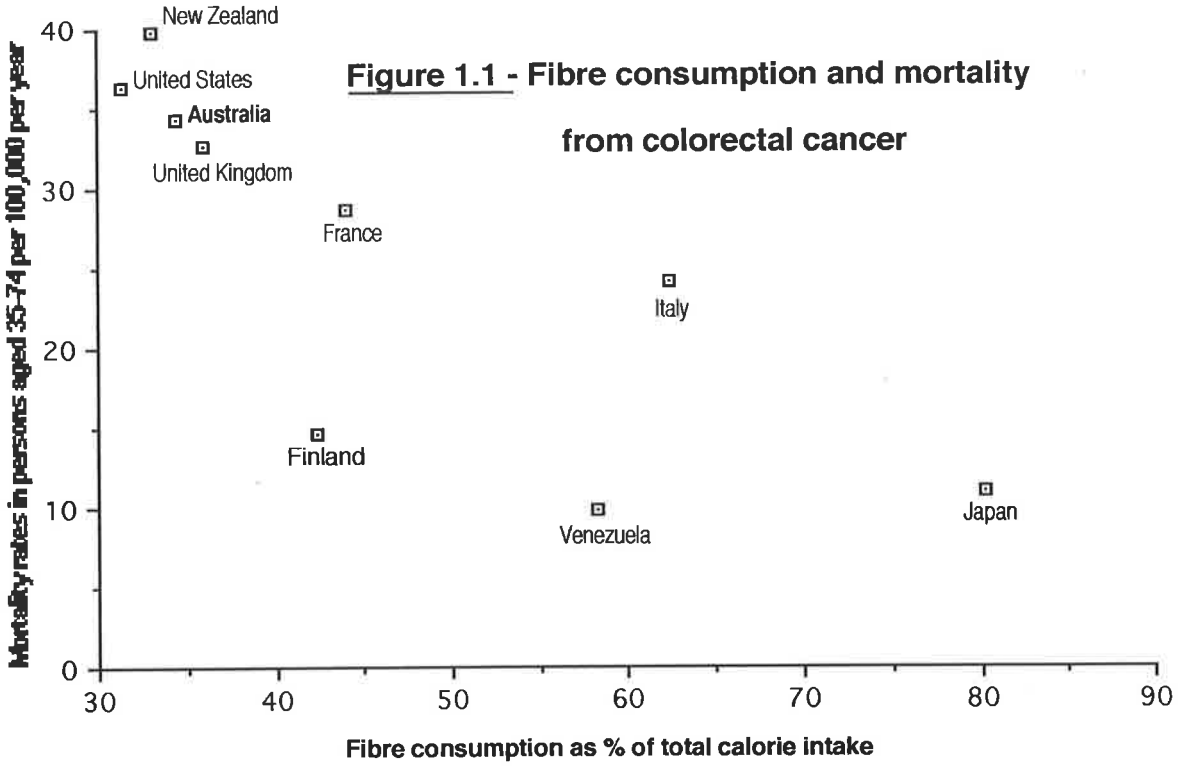
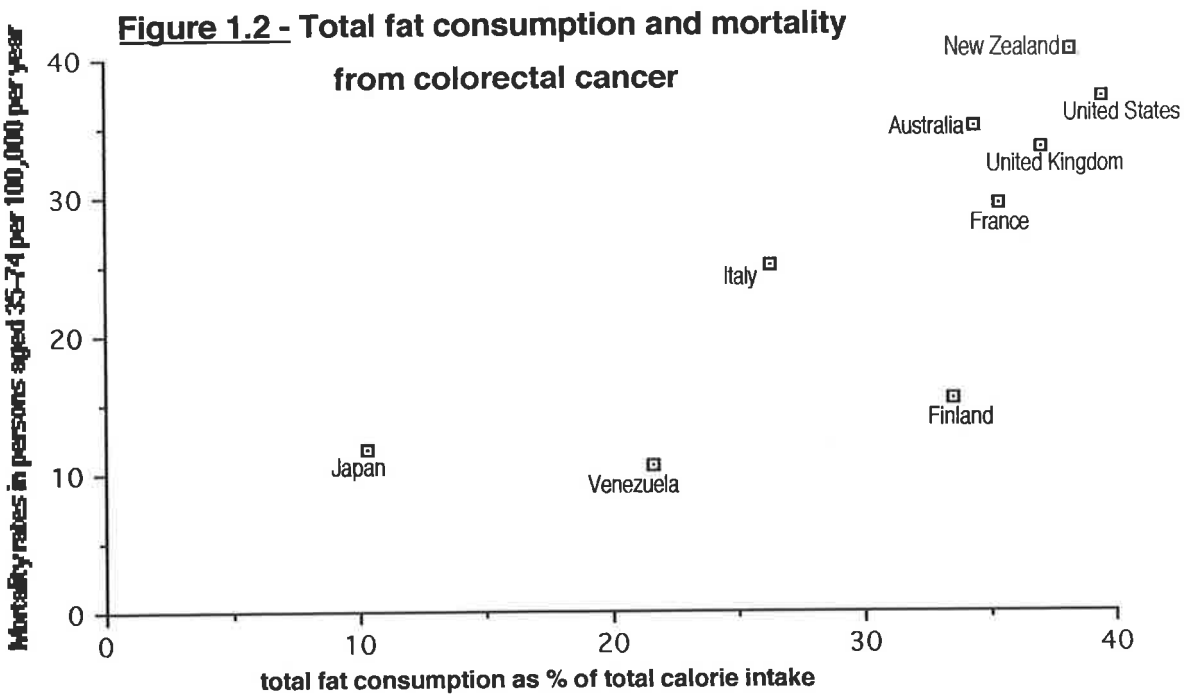


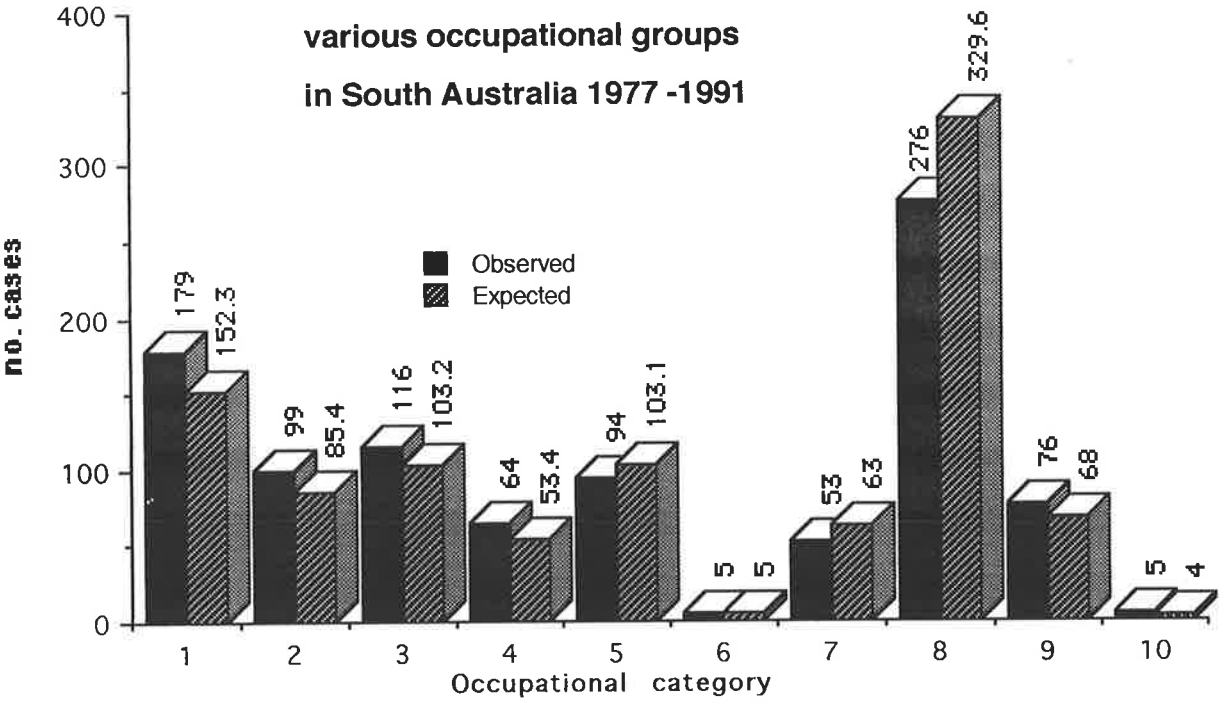
Figure 1.1 - Fibre consumption and mortality from colorectal cancer

source: Liu et al (1979)



source: Liu et al (1979)

Figure 1.3 - Observed vs expected cases of colorectal cancer for various occupational groups in South Australia 1977 -1991



1. Professional, technical and related workers
2. Administrative, executive and managerial workers
3. Clerical workers
4. Sales workers
5. Farmers, hunters, timber getters, etc.
6. Miners, quarry workers and related workers
7. Workers in transport and communication
8. Trades workers, production-process workers, labourers etc.
9. Service, sport and recreation workers
10. Members of armed services

source: Esterman et al (1988)

Chapter 2:

Profile of FOBT screening participants in South Australia, feedback on the programme and yield of cancers.

2.1 Introduction

This chapter presents information based on evaluation of the FOBT screening programme for colorectal cancer which was established in South Australia in 1988 by the Institute of Medical & Veterinary Science (IMVS). It addresses Aims 1 & 2 of the SACCS study (described in Chapter 1). In evaluating the screening programme, the three main concerns were to describe as fully as possible the participants in the programme, to obtain feedback from them on the programme and to obtain initial measures of performance of the screening test used in the programme.

The participant characteristics which are described in this chapter include the presence of a family history of colorectal cancer or of gastrointestinal symptoms which may have prompted participants to undergo screening. There is also an analysis of area-of-residence data to examine whether participants are more or less likely to come from higher-income areas of Adelaide. Feedback is sought from participants on their impressions of using the test, how they came to hear of the programme and factors which may influence their future participation.

Finally, results are presented from an analysis, using the South Australian Cancer Registry, of the numbers of screen-negative and screen-positive participants in whom a diagnosis of colorectal cancer was subsequently made. Based on these results, estimates are made of the the sensitivity and specificity of the immunochemical FOBT used in this programme, and its predictive value for colorectal cancer in the screened population.

2.2 Background

It is important to obtain a profile of screening participants in any screening programme evaluation. Basic demographic characteristics of participants can be compared, for example, with the age and sex distribution of the disease to assess whether uptake of the test is appropriately distributed according to these characteristics. Information on family history of colorectal cancer amongst participants is described in this chapter. As noted in Chapter 1, family history is a major risk factor for colorectal cancer - family studies have shown that the risk of colorectal cancer in the first degree relatives of affected individuals is two to four times the risk in the general population (Lovett, 1976). Many believe that screening programmes should focus their efforts on high-risk groups, and in the case of colorectal cancer, a positive family history is one of the most reliable indicators of increased risk. It has been estimated, on the basis of available information, that approximately 10% of individuals aged over 40 have a family history of the disease (in western populations) (Eddy et al, 1987). The presence of a family history may also prompt participation in screening programmes, and this has implications for the choice of recruitment strategies and likely participant characteristics. Hence, an important component of the SACCS study was to measure the prevalence of a positive family history for colorectal cancer in IMVS screening participants.

Similarly, enquiry about the presence of bowel symptoms in screening participants is an integral part of the evaluation. Screening tests are intended for asymptomatic individuals, and it is generally accepted that if people have symptoms they should seek medical help, not take a screening test. However, the symptoms which accompany the early stages of colorectal cancer are frequently vague and non-specific, so there is some difficulty in defining a symptomatic group in whom screening should not be undertaken.

Rectal bleeding is the most significant symptom in predicting the presence of colorectal cancer. It is estimated that, in the Australian population, approximately 10% of individuals who present to their doctors with rectal bleeding will have a colorectal cancer or adenoma (Goulston et al, 1986). However, other bowel symptoms appear to be very poor indicators of disease - in a study which aimed to determine whether there are any aspects of the history or clinical features of a patient with rectal bleeding which strongly indicate bleeding from a colorectal cancer or polyp, few (apart from family history of colorectal cancer) were related to final diagnosis (Mant et al, 1989). Nevertheless, enquiry about a range of symptoms was made in the SACCS study, and the implications of the presence of these symptoms is discussed. There is also a comparison of the prevalence of various symptoms in test-negative and test-positive individuals.

2.21 Sources of information in screening evaluation

The SACCS study relied on the recording of diagnoses of colorectal cancer by the South Australian Cancer Registry for the identification of cancers in screening participants. Population-based cancer registries in which the majority of cancers within a geographical area are recorded are ideally suited for the evaluation of cancer prevention activities such as screening. In the US state cancer registries have been used effectively to contact and counsel relatives of breast cancer patients for screening mammography (Houts et al, 1990)

With certain limitations, use of cancer registries results in ascertainment of diagnoses of cancer in screening participants without the need for individual follow-up. In particular, they provide better accounting of participants with false negative results and those lost to follow-up. Other means of follow-up, such as telephone or mail, are more costly and time-consuming, and may not be as valid.

Postal surveys of IMVS screening participants were another source of information for the SACCS study. The decision to use postal questionnaires was based on evidence that postal surveys have been found to produce similar results to other survey techniques (in terms of quality of responses) in evaluations of screening and other health programmes (Polednak et al, 1991) (Quine, 1985). IMVS screening participants are not geographically clustered, which would have made interview surveys time-consuming and expensive. Postal questionnaires, alternatively, are relatively low in cost and can reach a widely dispersed or difficult-to-reach sample simultaneously without the attendant problems of interviewer bias or variability (Schyberger, 1967) and provide the opportunity for leisurely and thoughtful reply and, potentially, more honest responses (Kanuk & Berensen, 1975) (Pederson et al, 1985). Postal questionnaires can also achieve a high rate of completeness of response, compared to other techniques (Dillman, 1978).

2.22 Socioeconomic influences on screening participation

In Chapter 1 the evidence linking socioeconomic status and colorectal cancer incidence and mortality was reviewed. On balance, the evidence suggests an association of the disease with higher socioeconomic status, although it is neither strong nor consistent. Socioeconomic differences in *survival* from a range of cancers have also been noted - significantly lower survival from colorectal cancer has been noted in lower socioeconomic groups in the South Australian population (Bonett et al, 1984). Delay in seeking care has been proposed as a major contributing cause of these observed differences in survival (Kogevinas et al, 1991).

Less is known, however, about the influence of socioeconomic status on participation in cancer screening programmes (particularly FOBT screening for colorectal cancer). As participation in such programmes may have an effect on

cancer incidence, mortality and survival, a closer examination of the effect of socioeconomic status is justified.

A number of studies from the US have examined this issue in relation to cervical and breast cancer screening, using various indicators of low socioeconomic status. One such study found that poor women have particularly low participation rates in cervical and breast cancer screening (Whitman et al, 1991). The National Health Interview Survey (Harlan et al, 1991) found that low income and educational status were associated with failure to take cervical screening tests. In another US study (Hayward et al, 1988) women who were older, uninsured, or lower in socioeconomic status were less likely to have received the three preventive measures examined (mammography, breast examination by a physician and cervical smear). The common conclusion in studies such as these is that socioeconomic factors such as income and education level can influence participation rates in screening, particularly in the absence of centrally-coordinated programmes. They are likely to be of particular relevance in programmes which rely on self-recruitment of participants, as is the case with the IMVS programme.

To provide some information on these issues, this chapter includes an examination of the association between participation in the IMVS FOBT screening programme and residence in higher-income areas of Adelaide. While it is likely, based on evidence from these other forms of screening, that such an association does exist, there is to date little published information in this area.

2.3 Methods

2.31 Postal Surveys

Information on participant characteristics, causes of bleeding in test-positive participants, and feedback on the programme was obtained by means of postal

questionnaire surveys. These questionnaires also produced information on costs (presented in Chapter 3), and knowledge, attitudes and beliefs of screening participants (presented in Chapter 4).

The questionnaires for test-negative and test-positive participants were developed as two separate instruments - while many of the questions were the same, a significant number were only relevant to one or the other group (particularly those examining costs, knowledge, attitudes and beliefs). Both questionnaires were piloted amongst twenty participants. As a result, appropriate modifications were made to the "test-negative" questionnaire, although no modifications were made to the "test-positive" questionnaire and data from the pilot survey are included in final results.

Questionnaires were only sent to individuals in whom a diagnosis of colorectal cancer had not been made subsequent to their participation in the programme. Many of the questions, particularly those reported in Chapters 3 and 4, were not relevant to participants who had developed colorectal cancer. Furthermore, the questionnaires might have caused distress to these individuals. The linkage analysis of data on screening participants and the South Australia Cancer Registry (described in Section 2.32) identified five test-negative participants and 24 test-positive participants in whom this diagnosis had been made, and hence it was possible to exclude these individuals from the surveys.

Of the remaining 5895 test-negative individuals, questionnaires were sent to a random sample of 625 participants between August and October 1991. Of the 313 individuals who had positive tests, 24 were found to have developed colorectal cancer (the predictive value of a positive test for colorectal cancer was therefore 7.5%). Questionnaires were sent to the remaining 289 test-positive individuals

between October and December 1991. Non-responders to these questionnaires after a period of 18 days were sent a second copy of the questionnaire.

Data from the questionnaires were coded and entered onto a SAS statistical programme. Analysis of results, reported in this and other chapters, included frequency tabulations, simple X^2 analyses and logistic regression. Copies of the questionnaires used in these surveys appear in *Appendices 1 & 2*.

2.32 Test/participant characteristics and Linkage Analysis with Cancer Registry

IMVS data were analysed to determine numbers of participants over the two year study period, age and gender characteristics of participants, number of tests performed and the positivity rate of the test in the screened population.

Follow-up information on FOBT screening participants was obtained using the South Australian Cancer Registry's facility to import data sets and perform "linkage analyses". This process is dependent upon the reliability and completeness of the Cancer Registry - in South Australia all new cases of cancer are notified to the Cancer Registry (Bonett et al, 1992). A system of compulsory notification operates in which pathology laboratories, medical record departments of hospitals, radiotherapists and oncologists are required to report new cases. Notification of deaths from cancer comes from the Registrar-General of Births, Deaths and Marriages, allowing calculations of relative survival rates. Strict rules of confidentiality ensure that the names of "matched" individuals from linkage analyses do not leave the South Australian Cancer Registry - only dates of diagnoses and tallies of individuals were released for this analysis.

The analysis was performed by linking a computer file of participants in the IMVS screening programme, from its commencement in November 1988 up to, and

including 30th November 1990, to the Cancer Registry data base. Only ICD codes for cancer of the colon and rectum were selected.

In order to make estimates of performance measures for the immunochemical FOBT used in the IMVS screening programme, it was first necessary to define the standard screening measures (true and false positive, true and false negatives), as there are no universally-agreed definitions. Therefore, individuals who had a positive FOBT screening test and whose names appeared on the Cancer Registry within twelve months were defined as "true positives" (the remainder being "false positives"). Individuals who had a negative test and whose names appeared on the Cancer Registry within twelve months were defined as "false negatives" (the remainder being "true negatives").

Results of the linkage analysis, using these definitions, allowed estimates of the sensitivity, specificity and predictive value of the test to be obtained.

2.33 Postcode analysis of IMVS screening participants

Information on postcode of residence of participants in the screening programme is routinely collected. These data were used to examine the influence of area of residence on likelihood of participation in the programme. It was necessary, for this analysis, to have estimates of the number of screening participants in each Local Government Area (LGA, a collection area defined by the Australian Bureau of Statistics). A measure of level of participation in the screening programme was obtained by dividing the observed numbers of screenees in each LGA by the expected number, based on population statistics (see *Table 2.2*). For example, in the 50-54 year age group in the Burnside LGA, there were 42 screening participants. On the basis of the number of residents in the Burnside LGA in this age group, the expected number of participants was 27. Hence, level of participation is calculated as observed number of participants ("O") divided by

expected number ("E") which is 46/27 x 100% = 153. In South Australia the geographical boundaries of postcodes do not correspond with LGA boundaries, so postcode-LGA conversion tables were used. This is why "observed" numbers of participants are not always whole numbers in *Table 2.2.*

The LGA's were also ranked, for each five-year age group, according to average income per person (see *Table 2.1),* in which income is expressed in multiples of $1000). Information on average income per person in each LGA was obtained from the Australia Bureau of Statistics using 1986 census data.

Having ranked the LGAs according to these criteria, the influence of area of residence on likelihood of participation in the screening programme was examined by measuring the degree of correlation, for each age-group, between the two rankings. The correlation was tested for statistical significance using Spearman's rank correlation test (Conover, 1980).

2.4 Results

2.41 Profile of screened individuals and postal survey respondent characteristics

A description of age and the gender of screening participants is shown in *Table 2.3.* Although the screening programme was recommended only to persons over 40 years of age, there were a number of participants under this age. Overall, there was a slight majority of females (53.2%).

In the postal surveys, 18 of the random sample of 625 test-negative participants, were either lost to follow-up or had died. Response rate to this survey was 75.9% (n=461). The response rate to the survey of 289 test-positive individuals (excluding 3 who had died and 11 who were lost to follow-up) was 95.3% (262 respondents).

The average age of respondents was 56.1 years for test-negative participants and 60.6 years for test-positive respondents. *Table 2.4* shows that there were more female than male test-negative respondents and more males in the test-positive group. Approximately 24% of respondents reported a family history of colorectal cancer, and this was unrelated to test-result status.

2.42 Participant feedback on the programme (test-negative participants only)

Table 2.5 shows that participants heard about the screening programme by a variety of means, most commonly through the media, in literature from their private health funds or their doctors. Respondents were also asked if they took the test on the recommendation of their doctor (not shown in *Table 2.5)* - 196 of the 461 respondents (42.5%) indicated that this was the case.

Most participants had no difficulty in following the instructions for the test, and the majority indicated they felt they completely understood the reasons for taking the test (*Table 2.6).* Respondents were asked to indicate which of a number of strategies would encourage them to continue having FOBT screening tests - all of the strategies were endorsed, but the receipt of reminder letters and not having to pay for the test were particularly favoured.

2.43 Cause of bleeding in participants with "false positive" results - Table 2.7

The most common reported cause of positive test results in individuals who did not have colorectal cancer was "bowel polyps" (39.7% of respondents). As discussed in Section 2.56, these are sometimes included amongst the yield, or benefits of colorectal cancer screening programmes, as they may progress to cancer. The next most common cause was "hemorrhoids" which occurred in 16.4% of respondents. Almost one-quarter of respondents said that no cause had been found for their positive screening test.

2.44 Bowel symptoms in screening participants - Table 2.8

Participants were asked if they had experienced gastrointestinal symptoms in the six months before taking the test. *Table 2.8* shows that "abdominal pain, discomfort or bloating" and "bleeding from the back passage" were particularly prevalent symptoms amongst test respondents. "Any change in bowel habit lasting more than two weeks" was less prevalent, although still reported by 44 (9.5%) of test-negative respondents and 35 (13.4%) of test-positive respondents. It can be seen that the proportion of participants reporting symptoms is slightly higher in the test-positive group (and particularly in the case of "bleeding from the back passage").

Of the individuals who indicated they had noticed bleeding from the back passage, 2 of the 71 test-negative individuals (2.8%) and 9 of the 99 test-positive individuals (9.1%) indicated that they only noticed the bleeding at the time of taking the test. The remainder noticed the bleeding before taking the test.

Overall, 148 test-negative individuals (32.1%) and 145 test-positive individuals (55.3%) reported they had suffered one or more symptoms in the six months before taking the test. Over two-thirds of these symptomatic participants (or, 41% of *all* participants) reported that the symptoms had prompted concern over the possibility that they may have colorectal cancer (see *Table 2.9*). Hence, a significant proportion of participants may have taken the test because of their symptoms.

2.45 Test characteristics and yield of cancers

As indicated in Section 2.31, over the two-year period of this analysis, there were 6208 participants in the programme. A total of 7249 screening tests were performed on these individuals (that is, 1041 of the tests were for re-screening).

There were 318 positive tests (in 311 individuals) over the 2 year period of this analysis, so the overrall positivity rate was 4.4%. Of the 6208 participants, 5.1% had one or more positive tests - this proportion was slightly higher in males than females (5.9% vs 4.5%), although this was not statistically significant. The occurrence of positive results was substantially higher in participants over 60 years of age (8.0% in the >60 age group compared with 3.7% in those aged 41-60 years).

An outline of the results of the linkage analysis is shown in *Tables 2.10 and 2.11.* There were 24 cancers detected as a result of the programme. Of the 68 "matched" individuals (those whose names appeared on both the IMVS and Cancer Registry data bases), 38 had their diagnosis of colorectal cancer made *before* they took the screening test. In these individuals, it appears that the FOBT was used to detect *recurrence* of disease.

The intervals between date of positive test and date of diagnosis for the 24 "true positive" individuals are shown in *Figure 2.1* - in the majority of cases the diagnosis was made within 2 months. Five of the "true positive" cases had died by December 1991 - two died within a month of diagnosis and the intervals between diagnosis and death for the remainder were 16, 13 and 12 months. One individual (not shown in *Figure 2.1*) had a positive test - diagnosis interval of 19 months, and hence was not included as a "true positive".

Of the 5 individuals with "false negative" results, two had died by Dec 1991. In one individual the negative test was followed by a positive test eight months later which led to the diagnosis of colorectal cancer.

Using results based on the first round of screening and the definitions outlined previously, estimated sensitivity of the test is 82.8% and the specificity is 95.1%.

Estimated predictive value of a positive result (for colorectal cancer) in this population is 7.7%. The total of 24 true positives (individuals in whom colorectal cancer was subsequently diagnosed within twelve months) represents a detection rate of 3.9 cancers per thousand participants.

2.46 Influence of area of residence on participation

As described in Section 2.33, Local Government Areas of Adelaide were ranked according to their average income per person, and their level of participation in the IMVS FOBT screening programme (see *Tables 2.1 and 2.2*). *Table 2.1* shows that certain Local Government Areas have consistently high rankings for average income per person across all age groups. These include Walkerville (ranked 1 to 3), Burnside (1 to 3) and Adelaide (1 to 4). *Table 2.2* , similarly, shows that higher-income areas of Adelaide appear to have higher than expected rates of participation in the screening programme.

The result of the analysis for correlation between these two sets of rankings is shown in *Table 2.12* , and confirms the high level of correlation between average income of area of residence and participation in the programme. In all age groups the correlation was statistically significant.

2.5 Discussion

An attempt has been made in this chapter to provide information on screening participants in the IMVS FOBT screening programme and numbers of cancers detected by the programme.

2.51 Comments on sources of information - postal surveys and the SA Cancer Registry

Much of the information about participants presented in this chapter is from self-reports in postal surveys. There are potential sources of bias in surveys such as these, particularly if comparisons are made between the surveyed group and the

general population. For example, IMVS FOBT screening participants (particularly those who have had positive tests) may have a heightened awareness of colorectal cancer and to be more inclined to report symptoms or personal experience of the disease through friends or relatives. In particular, interpretation of self-reports of familial cancer requires a degree of caution. There is some evidence that individuals who have themslves suffered from cancer may be more likely to recall cancer in a first- or second-degree relative (Floderus et al, 1990), and given that the prevalence of a past history of cancer in FOBT screening participants appears to be above the population average (Michalek et al, 1988), this may have given rise to a falsely high result in the SACCS study. Accurate knowledge of the exact site of cancer in a relative may also be lacking - Love et al (1985) conducted a study of 121 families in which reported cases of cancer in family members were validated from medical records. The primary site was correctly identified in 83% of cases of cancer in first degree relatives. Nevertheless, it is unlikely that potential sources of error such as these could account for a prevalence of reported family history amongst FOBT screening participants which is more than double the estimated population rate.

In the postal surveys people in whom colorectal cancer was diagnosed after participation in the programme were excluded. As this was only a relatively small proportion of screening participants over the two year study period (30 out of 6208), it is unlikely to have significantly influenced results. Furthermore, there are ethical difficulties in conducting surveys of individuals with cancer (Eardley et al, 1991), and such individuals may have found a number of questions in the postal surveys distressing. Furthermore, given that a diagnosis of cancer can cause considerable stress, there is evidence that information is unreliable in surveys of individuals with cancer in which they are required to recall details of their illness (Rimer et al, 1984).

The higher response rate in the postal surveys in test-positive participants suggests that the experience of having a positive screening test result has a compliance-enhancing effect. A similar finding was obtained in a recent survey of FOBT screening participants from France (Arveux, 1992) in which the response rate was 88.2% in participants with negative test results, and 98.0% in those with positive results.

Follow-up information in this analysis relies for its accuracy on the completeness of recording of colorectal cancer in participants in the IMVS screening programme by the South Australian Cancer Registry. The linkage process desribed in this evaluation has been used in a previous evaluation of FOBT screening from the US (Michalek et al, 1988) in which names of participants in a FOBT screening program were linked with the Western New York Tumour Registry. This study found that many participants had a previous diagnosis of cancer (that is, before they took the screening test), which is consistent with findings from the SACCS study.

Colorectal cancer in individuals who have moved away from South Australia after their screening test may not be recorded. Nine participants over the two year period of this analysis had interstate addresses. If any of these individuals had cancer there would be an underestimation of "true positives" and "false negatives" using the Cancer Registry. There was an opportunity to check on the reliability of Cancer Registry data in recording "true positives" - the IMVS carries out its own follow-up procedures of test-positive participants and this follow-up also resulted in the identification of the same 24 individuals with colorectal cancer over the two-year study period (no additional cancers were detected). Of the 24 "true positives", staging data were obtained on 14, 11 of whom (79%) had either Dukes A or B lesions. These results are summarised in *Table 2.13.*

When using cancer registries for follow-up of screening participants, the process is particularly dependent upon the reliability of the data in the registry, lag time (between date of screening test, diagnoses of cancer and entry onto the registry), and accuracy of the reported dates of both the screening test and cancer diagnosis. The South Australian Cancer Registry is seen as the best in Australia, with highly reliable data and a short lag time.

2.52 Profile of screening participants and feedback on the programme

Although the IMVS only promotes its FOBT screening programme to individuals over the age of 40, many participants were under this age. Given the extremely low prevalence of colorectal cancer in these younger age groups (and, consequently, low predictive value for cancer of positive tests), screening is likely to be of minimal benefit. One of the disadvantages of relying on self-recruitment of screening participants is that programme organizers have less control over who takes up the test.

The fact that almost one-quarter of respondents in the postal surveys reported a positive family history suggests that this is an important motivating factor for participation and that these increased-risk individuals are participating at higher-than-expected rates without being specifically targeted by the IMVS programme.

On the whole the programme appears to have been well-understood by participants. Well over half the participants made their decision to take the test independently of their doctors. This means that the majority of participants are basing their decision to be screened on knowledge and advice they are able to obtain from friends, family, other health professionals, the media or information supplied by the IMVS screening programme itself. While this information may be entirely accurate and appropriate, it is likely that it will be inconsistent in different sections of the population. This may have been one of the reasons for the major

influence of area of residence on participation rates. One of the major considerations for screening programmes is their ability to maintain involvement of participants on a periodic basis. While many different strategies have been examined in the literature, IMVS screening participants particularly endorsed the receipt of reminder letters above other strategies for this form of screening.

2.53 Significance of bowel symptoms in screening participants

Given that screening tests are not intended for individuals with symptoms which may indicate the presence of disease, it is a cause of some concern that a high proportion of screening participants reported bowel symptoms which, in all likelihood, prompted them to take the test. Nevertheless, it should be noted that there is a high prevalence of these symptoms in the general population. In an Australian study (Dent et al, 1986) which examined the prevalence of various symptoms thought to be indicative of colorectal cancer in people randomly selected from the community, 16% of respondents reported observing blood per rectum in the previous six months. A further 8% reported annoying abdominal pain that had lasted for two weeks or more in the preceding six months, while 19% reported a feeling of incomplete evacuation at least once every two weeks. In the UK, it is estimated that one in twenty four consultations in general practice are related to lower bowel symptoms (Royal College of General Practitioners, 1990).

Rectal bleeding appears to be a particularly prevalent symptom in the Australian population, and it would appear that it often goes unreported - in an Australian household survey of 1213 people aged 40 years and over (Dent et al, 1986), 239 respondents (20%) reported noticing rectal bleeding at some time in their life - 4.5% had noticed rectal bleeding for the first time in the past year. Of the individuals who had noticed rectal bleeding in the previous 3-60 months, 30% had either not sought medical advice or had only done so after a period of

considerable delay. Reasons for delay or failure included not thinking bleeding was serious (most common) and a belief that diagnostic tests would be unpleasant and/or embarrassing. Another Australian study of apparently healthy male war veterans (Chapuis et al, 1985) showed a similarly high presence of reported rectal bleeding in the previous six months (15%).

Jones and Lydeard (1992) undertook a study of the prevalence of bowel symptoms in the UK population, and found that rectal bleeding occurs in up to one-sixth of the general population each year and, furthermore, may be the only significant symptom of large bowel disease.

Despite the high prevalence of rectal bleeding in the population, there is some disagreement over appropriate guidelines for the public in dealing with this symptom. Mant et al (1989) suggest that public education should advocate general practitioner consultation and appropriate colonic investigation, for all rectal bleeding, whether or not it is accompanied by other bowel symptoms (which do not appear to be helpful in deciding whether to proceed with full investigations). This view is endorsed by other authors who advocate raising levels of awareness (in individuals and their general practitioners) of the importance of having rectal bleeding properly investigated (Goulston & Dent, 1987) (Holliday & Hardcastle, 1979), although Byles et al (1992) urge caution in initiating programmes to encourage people to seek care promptly for rectal bleeding until there is sound evidence that early detection of colorectal cancer improves prognosis.

The high prevalence of bowel symptoms, particularly rectal bleeding, in potential screening participants presents a challenge for those involved in recruitment of individuals for FOBT screening. While it would appear that not all individuals with "bowel symptoms" can be excluded (particularly with the often vague nature of these symptoms), there may be an argument for linking screening with medical

consultations so that a clinical assessment of reported bowel symptoms can be made before involvement in FOBT screening - this issue will be examined further in Chapter 5.

2.54 Measures of programme performance

Ultimately, it is the yield of cancers detected as a result of screening which is the most readily identifiable benefit of the programme. While many thousands of individuals needed to be screened in the IMVS programme for the detection of just 24 cancers, and the majority of individuals with positive tests did not not have cancer it is not clearly identifiable how this information can be used in deciding whether the programme is a worthwhile use of health resources - this issue will be discussed in Chapter 3. The basic performance parameters of the IMVS FOBT screening programme and the immunochemical FOBT used in the programme have, nevertheless, been reported in some detail - these measures are almost always included in screening programme evaluations. One of the benefits of this information is that it allows comparison of the performance parameters with those of other programmes. Such comparisons must, however, recognize that:

1. Differences in study design and differing recruitment strategies are likely to affect the composition of programme participants

2. Definitions (for example "false positives" and "false negatives") differ between studies

3. Testing procedures themselves differ

4. There are varying rates of compliance with invitations to participate in screening programmes and this also may affect the composition of programme participants. For example, if compliance is low, participants may

represent an unusually motivated group with an unrepresentative prevalence of and risk for colorectal cancer.

Data on sensitivity, specificity, predictive value for colorectal cancer and positivity rate from the five controlled trials of FOBT screening reported in Chapter 1 have been compiled in *Table 2.14.* Results from the IMVS programme are included in the table. In the case of Hemoccult screening, results are influenced by dietary restrictions, rehydration vs non-rehydration of test slides and whether the screening is initial (prevalence) or second-round (incidence).

The data suggest that the results from the IMVS programme are comparable with the overseas trials. The specificity of 95.9% is lower than that achieved in the UK and Danish trials, and this may lead to an excess of "false-positives" - there is, in any screening programme, a "trade-off" between sensitivity and specificity which is affected by the cut-off points for the detection of pathology.

There are, nevertheless, limitations on the benefits of comparing the IMVS programme with population-based randomized control trials, none of which have either used immunochemical tests or relied on self-recruitment of participants. While there are few other community-based trials of immunochemical FOBT screening, smaller-scale experimental studies have produced some information on test parameters which can be used as a basis for comparison; in a study of 79 patients with symptomatic colorectal cancer, the immunochemical FOBT HemeSelect® had a sensitivity for colorectal cancer of 95% (St. John, 1993). The Fecal Human Hemoglobin test used by the IMVS detected 100% of cancers in a similar trial amongst cancer patients (Williams et al, 1982). Recently an immunochemical test developed in Japan (Saito et al, 1985) was trialled in a group of 2066 asymptomatic individuals who subsequently underwent flexible sigmoidoscopy (Nakayama et al, 1992), and the test detected 1 out of the 4

cancers detected by the sigmoidoscope (a sensitivity of 25%). Specificity of the test was 97.3% and its positive predictive value for colorectal cancer was 1.8%. This very low predictive value, compared to the IMVS's immunochemical test, may reflect the relatively low prevalence of colorectal cancer in Japan and the small numbers in Nakayama et al's study study. A further limitation on making comparisons with other studies which have used immunochemical tests, is that the cut-off points for detection of blood by these tests can be set arbitrarily.

The initial assessment of the Fecal Human Hemoglogin test was undertaken in a group of individuals who had a past history of colorectal cancer, and therefore considered to be at "high-risk" for colorectal cancer. In this study the positivity rate was 6.1% and the predictive value for cancer was 14.4% (Williams et al, 1987). These values (which are higher than results from the SACCS study) are not unexpected in a population with an above-average prevalence of colorectal cancer.

2.55 Influence of area of residence on participation

Results from this study strongly suggest that participants in the IMVS screening programme are more likely than non-participants to reside in higher income areas of Adelaide, and support the hypothesis that screening programmes which rely on self-recruitment will attract individuals from higher socioeconomic groups.

One of the reasons for this may have been a stronger tendency for individuals from higher socioeconomic groups to have private health insurance - the programme is promoted through private health funds, many of which reimburse the cost of the test kit.

It appears that screening programmes which lack a centralized and co-ordinated recruitment strategy are particularly likely to produce socioeconomic differences in

screening participants. In a European study which examined the characteristics of participants in cervical cancer screening which was conducted in an area where there was no organized programme (although tests were free), the prevalence of women ever undergoing a Pap test was higher in women who were married, better educated and had higher incomes (Ronco et al, 1991). The authors conclude that in a population lacking organized screening programmes women of low socio-cultural status (who were also found to have less frequent contact with health services) have a markedly lower rate of pap tests.

Should the IMVS screening programme aim ultimately to reach a broader cross-section of the population, it is likely that the barriers to participation which appear to exist with the current method of recruitment will need to be addressed. Experience from other programmes suggests that satisfactory participation rates in lower socioeconomic groups are only achieved by active recruitment strategies which specifically target these groups

2.56 Detection of polyps through FOBT screening

Data presented in this analysis include information obtained from test-positive participants on the detection of adenomas and other colorectal pathology in the IMVS screening programme. It can be argued that the detection of minor conditions such as hemorrhoids is a benefit of FOBT screening if it leads to definitive treatment. A high proportion of test-positive individuals (39.7%) reported "bowel polyp" as the cause of their positive test. This information can be compared with the follow-up data which is collected routinely by the IMVS presented in *2.13* . These data show a similar proportion of bowel polyps in cancer-free test-positive participants (99 out of 271 = 36.5%) to the postal survey. Of the 58 polyps in which details of size were known, 37 (63.8%) were less than 1 cm. in diameter.

The majority of test-positive individuals in FOBT screening undergo further investigation - usually colonoscopy or barium enema and/or sigmoidoscopy (see Chapter 3). This inevitably leads to the discovery of adenomatous polyps in many individuals. The incidental identification and removal of polyps is a potential benefit of FOBT screening - there is considerable debate, however, over the appropriate management of these individuals and whether polyps discovered in this way should be included as a "true positives".

As outlined in Chapter 1, it is generally believed that most, if not all colorectal cancers arise from pre-existing adenomas. The difficulty lies in the high prevalence of adenomas in the population, particularly elderly people. In all likelihood, the vast majority of small polyps never develop a propensity to malignancy (Rickert et al, 1979). It is estimated that approximately 25% of the population in Western countries at the age of fifty years have one or more adenomas (as indicated by autopsy studies), and that this proportion increases with age (Hoff, 1987).

Many of the polyps discovered through investigation of test-positive individuals in FOBT screening programmes are less than 10 mm, and results from the multicentre National Polyp Study in the US indicate that high-grade dysplasia is very uncommon in polyps of this size (O'Brien et al, 1990). Ransohoff and Lang (1990) argue that a major proportion of adenomas less than 1cm uncovered by FOBT screening are detected merely by serendipity rather than because they are actually bleeding, in which case this would not necessarily be a benefit of FOBT screening. They suggest that there is limited rationale for colonoscopic surveillance in individuals in whom these small adenomas are detected, and this view is supported by other recent analyses (Simon, 1990).

Furthermore, although estimates of the proportion of untreated polyps larger than 10 mm which become malignant within ten years range from 5 to 10% (Stryker et al, 1987) (Morson, 1974), polyps are frequently routinely removed when discovered - a procedure which can, in itself, be hazardous. Hence, while the detection and removal of polyps which are destined to undergo malignant transformation is likely to contribute to the health benefits of FOBT screening, it would appear difficult to justify the detection and removal of all polyps in screened individuals.

The discovery of polyps in the IMVS screening programme is, therefore only a potential benefit of screening. There remains considerable debate over the management of individuals with polyps detected through screening and, in particular, the appropriate long-term follow-up of these individuals.

2.6 Summary

This chapter presents results of an evaluation of the first two years of screening in the IMVS FOBT screening programme. The programme is a major preventive initiative and, over the study period, recruited more than six thousand South Australians. On the whole, participants' feedback on the programme indicated they felt they understood the reasons for taking the test.

Results from this study suggest that the immunochemical test used in the IMVS programme has a similar accuracy to tests used in overseas controlled trials, although there are limitations to the validity of these comparisons. Some caution is also required in generalizing results from this study to the wider population of South Australia as characteristics of participants may not be typical - they are self-recruited and appear to be unrepresentative of the general population in terms of their socioeconomic status and risk factors for colorectal cancer, including family history and prevalence of bowel symptoms.

The collection of follow-up information on screening participants by using the South Australian Cancer Registry was a relatively simple and comprehensive means of determining yield of cancers and estimates of test performance parameters, although these techniques depend on the quality of data collection by both the Cancer Registry and the screening programme.

The most critical aspect of the evaluation of the IMVS screening programme presented in this chapter is the yield of cancers, as those participants in whom cancer has been detected hopefully will experience increased survival as a result of screening. The following chapter builds upon the assessment of the feasibility, and desirability, of FOBT screening in the Australian population by examining the yield of cancers in the context of the costs of the programme.

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Table 2.1 - Income by LGA

	age 40-44		age 45-49		age 50-54		age 55-59		age 60-64		age 65-69		age 70-74		age 75+	
	av.$	rank	av.$	rank	av.$	rank	av.$	rank	av.$	rank	av.$	rank	av.$	rank	av.$	rank
ADELAIDE	22.9	2	20.7	4	18.5	3	15.8	3	13.5	3	10.6	3	10.3	1	9.4	3
BRIGHTON	17.6	13	17.2	12	15.6	9	14.1	8	11.3	6	9.2	5	8.3	5	7.5	8
BURNSIDE	22.9	3	22.1	1	20.6	1	18.3	2	14.2	2	11.3	1	10	3	9.4	2
CAMPBELLTOWN	15.5	18	15	15	13.5	16	12.1	16	8.9	18	6.7	19	6.4	19	6.3	17
EAST TORRENS	19.1	9	19	5	16.6	7	15.5	4	12.6	4	7.8	10	9	4	6.2	19
ELIZABETH	12	29	11.6	28	11.2	28	10.2	26	7.5	29	6.4	23	6	26	6	25
ENFIELD PT. A	13.4	25	12.7	25	11.7	26	10.7	23	8.3	21	6.5	22	5.9	27	6	24
ENFIELD PT. B	10.6	31	9.8	31	9.4	30	8.7	30	7.3	30	5.6	31	5.5	31	5.4	31
GAWLER	15	20	13.3	24	12.4	21	11.1	22	7.9	25	6.4	24	6.2	22	6.1	22
GLENELG	18.5	11	22	2	16.7	6	14.3	7	10.8	8	8.8	6	7.8	8	7.7	7
HAPPY VALLEY	18.7	10	17.8	10	16.4	8	13.8	9	9.9	11	8.2	9	6.7	16	6.3	18
HENLEY & GRANGE	16.8	14	16.7	13	15.3	12	13	11	9.3	15	7.7	11	7	14	7.1	12
HINDMARSH	12.3	28	10.3	29	8.7	31	8.8	28	6.9	31	6	30	5.9	28	5.8	30
KENSINGTON & NORWOOD	20.2	6	17.6	11	13.9	14	12.9	12	10.5	10	7.1	15	7.6	11	7.2	11
MARION	15.5	16	14.7	17	13.4	17	12.1	17	8.8	19	6.8	18	6.4	20	6.4	16
MITCHAM	19.6	8	19	6	17.7	5	15.1	6	11.5	5	8.4	8	7.9	7	7.7	6
MUNNO PARA	13	26	12.5	26	12.1	25	9.8	28	8.1	24	6.3	25	5.9	29	5.9	27
NOARLUNGA	14.6	23	13.6	23	12.4	22	10.1	27	7.5	28	6.3	26	6.2	23	6.2	20
PAYNEHAM	14.8	22	14	19	12.3	24	11.6	19	9.2	16	6.6	21	6.5	17	6.7	14
PORT ADELAIDE	13.6	26	12	27	11.4	27	10.4	25	7.6	27	6.2	29	6	24	6	26
PROSPECT	17.9	12	15	16	13.3	18	12.3	14	9.4	13	6.9	17	7	13	7	13
SALISBURY	14	24	13.6	21	12.4	20	11.1	21	8.1	23	6.2	28	6	25	5.9	29
ST. PETERS	20	7	18.6	8	15.5	11	11.8	18	9.4	14	7.6	12	7.7	10	7.4	9
STIRLING	20.9	4	19	7	18.4	4	15.4	5	11.2	7	9.4	4	7.8	9	8.4	4
TEA TREE GULLY	16.3	15	16.2	14	14.4	13	12.6	13	9.1	17	7	16	6.4	18	6.1	23
THEBARTON	11.2	30	10.1	30	9.5	29	8	31	7.6	26	6.3	27	5.7	30	5.9	28
UNLEY	20.7	5	18.5	9	15.6	10	13.3	10	10.6	9	8.5	7	7.9	6	7.8	5
WALKERVILLE	23.6	1	21.6	3	19.6	2	19.4	1	15.9	1	10.8	2	10.1	2	9.6	1
WEST TORRENS	15.5	17	14.7	18	13.8	15	12.3	5	9.5	12	7.5	13	7	15	6.6	15
WILLUNGA	14.9	21	13.9	20	12.5	19	10.5	24	8.2	22	7.4	14	7.3	12	7.3	10
WOODVILLE	15.2	19	13.6	22	12.3	23	11.2	20	8.5	20	6.6	20	6.3	21	6.1	21
TOTAL ADELAIDE	16.3		15.2		13.8		12.2		9.3		7.4		7		7	

Table 2.2 - Participation by LGA

	age 40-44				age 45-49				age 50-54				age 55-59				
	"O"	"E"	O/Ex100%	rank	"O"	"E"	O/Ex100%	rank	"O"	"E"	O/Ex100%	rank	"O"	"E"	O/Ex100%	rank	
ADELAIDE	5	7.9	63.2911	24	15	9.31	161.199	7	9	8.3	107.833	12	13	10	130.001	11	
BRIGHTON	16.8	10.1	166.468	7	20	11	185.3	2	28	15	183.049	1	27	17	161.626	6	
BURNSIDE	34.9	23.6	148.07	10	50	26.5	190.201	1	42	27	152.689	5	46	29	159.183	8	
CAMPBELLTOWN	28.2	28.3	99.6465	18	28	38.4	72.8446	24	38	38	99.9733	15	29	34	86.5548	18	
EAST TORRENS	6.4	4.85	131.959	15	6.3	4.62	135.403	13	6	4.4	137.108	10	5.1	3	150.289	10	
ELIZABETH	4.78	14.2	33.7734	29	6.9	20.2	34.0315	29	11	25	42.9359	29	13	25	51.4561	24	
ENFIELD PT. A	14.4	25.7	56.123	26	18	32.2	54.5968	28	21	40	52.5253	27	28	44	63.12	22	
ENFIELD PT. B	1.46	7.34	19.9591	31	2.2	9.87	22.6265	30	1.6	12	13.9695	31	6.6	15	44.2611	28	
GAWLER	4.39	6.86	63.9306	23	1.8	8.29	21.1668	31	6	9.7	62.138	25	5.2	8	61.6553	23	
GLENELG	9.35	6.1	153.304	8	6.6	6.56	99.8072	17	7.5	8.1	92.4973	18	15	9	165.583	5	
HAPPY VALLEY	28.5	20.7	137.95	11	23	13.8	166.985	5	13	11	115.809	11	14	9	160.61	7	
HENLEY & GRANGE	11.4	8.43	135.786	13	15	10.5	142.446	9	18	12	154.636	4	22	12	179.915	3	
HINDMARSH	0.8	3.25	24.5614	30	2.3	4.11	56.7273	26	0.8	5.7	14.0938	30	1.9	6	31.9023	29	
KENSINGTON & NORWOOD	8.87	4.54	195.267	4	6.8	4.84	140.987	10	4.8	4.8	100.161	14	3.4	5	70.6264	20	
MARION	47.8	37.5	127.536	16	45	46.8	95.6785	18	77	54	142.768	9	70	62	112.485	12	
MITCHAM	58.8	43.2	136.343	12	75	44.7	168.431	4	68	45	152.509	6	67	44	150.86	9	
MUNNO PARA	6.18	14.3	43.2448	28	11	17.2	64.4151	25	9.4	18	51.4632	28	6.3	14	46.1128	27	
NOARLUNGA	29.9	46	65.0264	22	31	40.8	77.1066	23	20	36	55.2239	26	22	32	67.9524	21	
PAYNEHAM	10.7	6.3	169.924	6	8.7	10.3	84.4399	19	11	12	90.556	19	11	12	92.9978	16	
PORT ADELAIDE	11.4	18.5	61.4371	25	13	23	55.8212	27	21	26	81.2209	21	15	28	51.3582	25	
PROSPECT	11.3	8.46	133.022	14	12	9.63	121.587	13	9	11	80.3935	23	23	11	199.251	2	
SALISBURY	42.1	64	65.7846	21	55	67.1	81.4598	21	58	61	95.151	16	41	47	87.0405	17	
ST. PETERS	9	4.2	214.184	3	7	4.88	143.504	8	8	4.8	166.852	2	1	5	19.4416	30	
STIRLING	18.7	12.4	151.041	9	12	10.3	121.025	14	7	9.5	73.3965	24	13	7	172.013	4	
TEA TREE GULLY	45.3	58.3	77.7336	19	57	56.1	102.474	16	50	47	105.971	13	35	34	102.202	14	
THEBARTON	9	3.38	266.588	1	8	4.81	166.23	6	11	6.7	165.334	3	3	6	49.0286	26	
UNLEY	36.4	19.6	185.362	5	28	20.1	139.393	11	31	21	151.602	7	22	21	102.751	13	
WALKERVILLE	9.12	3.82	238.53	2	9.1	5.26	173.476	3	5.8	6.2	93.9861	17	17	6	285.761	1	
WEST TORRENS	17.8	23.3	76.1387	20	23	29	80.9845	22	31	35	88.8592	20	36	37	96.666	15	
WILLUNGA	2.62	5.7	45.9226	27	6.8	5.81	116.747	15	8.8	6.1	143.436	8	0.6	7	9.13277	31	
WOODVILLE	45.6	45.2	100.823	17	48	56.7	84.3606	20	50	62	80.947	22	57	66	86.4809	19	
TOTAL ADELAIDE	587				653				683				668				

Table 2.2 (continued) - Participation by LGA

	age 60-64				age 65-69				age 70-74				age 75+			
	"O"	"E"	O/Ex100%	rank	"O"	"E"	O/Ex100%	rank	"O"	"E"	O/Ex100%	rank	"O"	"E"	O/Ex100%	rank
ADELAIDE	12	10	118.3584	12	7	8	90.079	17	11	4	252.4146	1	3	5.8	51.98541	24
BRIGHTON	29	22	134.9213	10	29.9	18	163.171	4	12	9	134.9134	11	9.8	8.6	113.6422	9
BURNSIDE	78	32	243.3695	1	43.5	28	156.028	5	24	16	153.9746	8	26	16	167.6507	4
CAMPBELLTOWN	29	29	98.46558	15	19.3	21	92.3688	16	2.6	11	24.25852	28	5.5	9.6	57.1017	23
EAST TORRENS	2	2.7	73.59447	19	1.5	2	84.2407	18	1.4	1	162.5803	6	0.6	0.6	99.79433	11
ELIZABETH	8.2	23	34.88169	27	3.49	15	23.645	28	0.9	6	14.71798	30	1.3	3.3	39.10254	27
ENFIELD PT. A	28	49	57.95272	24	24.9	34	72.5191	20	14	16	88.31325	18	8.8	8.9	98.48916	12
ENFIELD PT. B	3	20	15.10824	31	3.46	13	26.0203	26	1.5	6	25.34854	26	0.8	3.4	22.91806	29
GAWLER	4.2	8.7	48.49381	25	2.63	7	38.1649	24	0.9	3	25.07219	27	0.9	2.9	30.71987	28
GLENELG	27	13	206.9456	3	16.8	12	142.674	7	12	8	156.7313	7	10	7.7	133.8869	8
HAPPY VALLEY	18	8.2	216.4094	2	9.67	5	179.046	3	4.9	2	237.2177	3	2.5	0.9	278.831	1
HENLEY & GRANGE	25	13	195.3764	6	13.5	10	130.749	9	8.1	5	152.5421	9	4.4	4.2	103.6878	10
HINDMARSH	2.2	6.5	33.44052	28	1.1	5	23.5174	15	2.1	3	71.60849	22	1.5	2.2	69.01771	22
KENSINGTON & NORWOOD	9.3	6.1	151.907	8	6.6	5	128.75	10	2.5	3	75.11458	21	3.9	4.4	87.51461	18
MARION	68	66	103.4942	14	50.5	45	111.771	14	25	21	116.0532	14	14	15	95.93133	13
MITCHAM	80	49	162.6358	7	55	38	146.491	6	24	20	120.3828	13	29	18	163.9892	5
MUNNO PARA	10	11	95.49217	16	1.49	6	24.0873	27	0.1	2	4.104971	31	0.7	1.3	51.62757	25
NOARLUNGA	30	34	90.40515	17	17.1	25	67.0439	21	1.9	12	15.80323	29	0.2	6.3	3.806696	30
PAYNEHAM	9.5	14	68.26228	21	8.81	11	78.8442	19	11	6	173.4401	5	13	8.2	163.7998	6
PORT ADELAIDE	11	33	31.78024	29	9.01	24	37.2149	25	6.7	13	52.20648	24	3.8	8.9	42.19957	26
PROSPECT	19	15	128.0933	11	15.2	12	125.229	11	7.7	7	114.9077	15	5.7	6	95.168	14
SALISBURY	14	39	35.37771	26	10.5	24	44.5779	23	6.4	11	60.43726	23	4.6	5.7	79.84619	20
ST. PETERS	4	5.6	71.50506	20	1	4	22.693	30	6	3	235.6786	4	0	3.1	0	31
STIRLING	14	7	202.3484	5	12.2	5	243.578	2	3	2	120.9223	12	3	1.6	186.305	3
TEA TREE GULLY	25	28	88.93769	18	20.2	18	111.944	13	7.4	9	85.31613	19	4	5.2	76.84939	21
THEBARTON	2	6.6	30.10538	30	1	5	21.6293	31	1	3	34.22395	25	3	2.2	138.4422	7
UNLEY	35	25	140.5855	9	29.1	22	131.564	29	19	13	151.6385	10	14	15	89.26322	16
WALKERVILLE	12	6.1	205.132	4	11.6	5	250.192	1	2.5	3	91.63056	16	5.8	3.1	189.8024	2
WEST TORRENS	47	45	104.3878	13	36.9	31	118.347	12	15	17	90.56781	17	12	13	88.1509	17
WILLUNGA	4.8	7.2	65.802	22	2.85	5	56.3239	22	5.6	2	239.2519	2	1	1.1	87.44163	19
WOODVILLE	49	75	64.75122	23	50	52	95.5046	15	22	26	82.28846	20	17	19	92.66799	15
TOTAL ADELAIDE	709				516				263				211			

Table 2.3 - Age and sex of screening participants (November 1988 to 30th November 1990)

	males	females	total
< 41	251	301	533 (8.6%)
41-50	813	943	1756 (28.3%)
51-60	834	986	1820 (29.3%)
61-70	750	785	1535 (24.7%)
> 70	257	287	544 (8.8%)
Total	2905 (46.8%)	3303 (53.2%)	**6208**

Table 2.4 - Gender and presence of family history of colorectal cancer in survey respondents

Sex

Test-negative respondents (n=461)

	male	female
no.	200	261
%	43.4%	56.6%

no. missing: 0

Test-positive respondents (n = 262)

	male	female
no.	140	121
%	53.4%	46.2%

no. missing: 1

History of colorectal cancer in first-degree relative

Test-negative respondents

yes	no	unsure
111	334	14
24.1%	72.5%	3.0%

no. missing: 2

Test-positive respondents

	yes	no	unsure
no.	62	184	15
%	23.7%	70.2%	5.7%

no. missing: 1

Table 2.5 - Means by which participants became aware of screening programme

	through friends or relatives	TV, radio or newspaper	your health fund?	your doctor	other	total
no.	63	126	149	167	31	459
%	13.7%	27.5%	32.5%	36.4%	6.8%	100

no. missing = 2

(more than one of these responses could be chosen)

Table 2.6 - Feedback from participants on the IMVS screening programme
(test-negative participants only)

Impressions of the test		completely understood	mostly understood	didn't understand at all	total
Reported understanding of the reasons for taking the test	no.	407	50	1	458
	%	88.9%	10.9%	.2	100
					no. missing = 3

		yes	no	total
Difficulty in following instructions	no.	2	451	453
	%	.4%	99.6%	100
				no. missing = 8

		yes	no	unsure	total
Reported discomfort over collecting a specimen and sending it into a laboratory	no.	72	370	12	454
	%	15.9%	81.5%	2.6%	100
					no. missing = 7

		completely understood	mostly understood	didn't understand at all	total
Reported understanding of the reasons for taking the test	no.	407	50	1	458
	%	88.9%	10.9%	.2	100
					no. missing = 3

		yes	no	unsure	total
Belief that having the test was worthwhile	no.	438	5	12	455
	%	96.3%	1.1%	2.6%	100
					no. missing = 6

Strategies which would increase intended compliance	definitely would	definitely would not	maybe	total
having the test routinely offered by GP	270	23	129	422
	64.0%	5.5%	30.6%	100
				no. missing = 39

		definitely would	definitely would not	maybe	total
being provided with more information on the test	no.	207	53	125	385
	%	53.8%	13.8%	32.5%	100
					no. missing = 76

		definitely would	definitely would not	maybe	total
receiving reminder letters to take the test	no.	351	16	64	431
	%	81.4%	3.7%	14.8%	100
					no. missing = 30

		definitely would	definitely would not	maybe	total
not having to pay for the test	no.	288	40	78	406
	%	70.9%	9.9%	19.2%	100
					no. missing = 55

Table 2.7 - Cause of test result in test-positive individuals (excluding those with colorectal cancer)

hemorr-hoids	bowel polyp(s)	medi-cations	no cause found	unsure	other	total
43	104	9	60	21	23	261
16.4%	39.7%	3.4%	22.9%	8.0%	8.8%	100%

no. missing: 1

Table 2.8 - Presence of symptoms in screening participants

abdominal discomfort, pain or bloating

Test-negative respondents

yes	no	total
96	348	444
21.6%	78.4%	100%

no. missing: 17

Test-positive respondents

yes	no	total
62	162	224
27.7%	72.3%	100%

no. missing: 38

any change in usual bowel habit lasting more than two weeks

Test-negative respondents

yes	no	total
44	392	436
10.1%	89.9%	100%

no. missing: 25

Test-positive respondents

yes	no	total
35	179	214
16.4%	83.6%	100%

no. missing: 48

bleeding from the back passage

Test-negative respondents

yes	no	total
71	386	457
15.5%	84.5%	100%

no. missing: 4

Test-positive respondents

yes	no	total
99	137	236
41.9%	58.1%	100%

no. missing: 26

Table 2.9 - Numbers of symptomatic individuals reporting that their symptoms prompted personal concern over the possibility of colorectal cancer

Test-negative respondents (n = 148)

	yes	no	total
no.	96	43	139
%	69.1%	30.9%	100%

no. missing: 9

Test-positive respondents (n = 145)

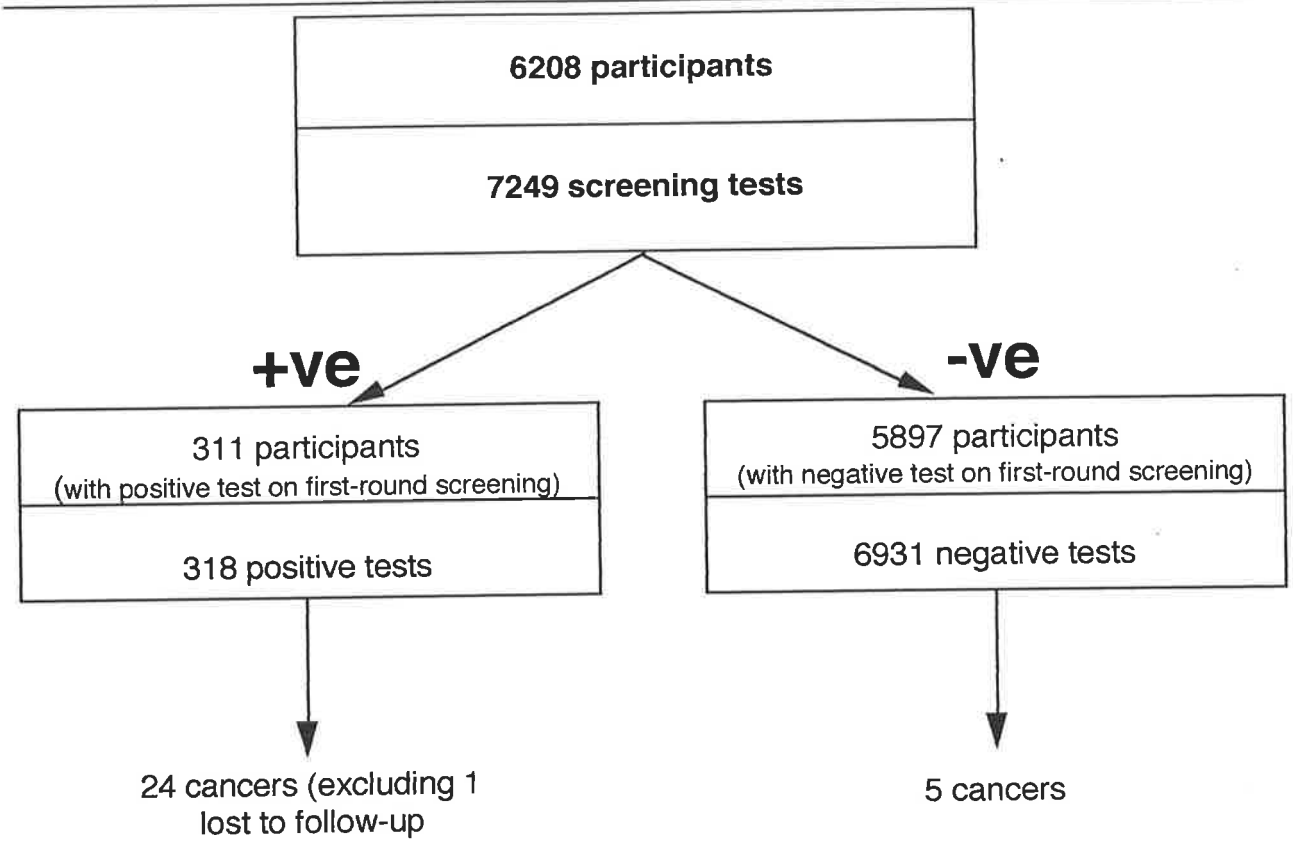
	yes	no	total
no.	98	42	140
%	70.0%	30.0%	100%

no. missing: 5

Table 2.10 - Results of linkage analysis of IMVS & SA Cancer Registry data bases

matched individuals	diagnosis of CRC made *before* screening test	"true positives"	"false negatives"	positive test/diagnosis interval > 12 months
68 (100%)	38 (56%)	24 (35%)	5 (7%)	1 (1%)

Table 2.11 - Preliminary results of first two years of IMVS FOBT screening programme



Diagnosis of colorectal cancer identified from Cancer Registry

FOBT screening test result	**+**	**-**	
+	24	287	**311**
-	5	5892	**5897**
	29	**6197**	**6208**

Sensitivity = 24/29 = **82.8%**

Specificity = 5892/6197 = **95.1%**

Positive predictive value = 24/311 = **7.7%**

Table 2.12 - Degree of correlation, in each age category, between rankings of:
1) average income per person, and
2) level of participation in the programme

age group	Spearman's rank correlation coefficient	p
40-44	.622	<.001
45-49	.742	<.001
50-54	.569	<.005
55-59	.822	<.001
60-64	.823	<.001
65-69	.646	<.001
70-74	.743	<.001
75+	.481	<.01

Table 2.13 - Results of IMVS follow-up of 295 individuals with positive tests*

Pathology detected		
CANCERS		
	stage	no.
	Dukes A	5
	Dukes B	6
	Dukes C	3
	not stated	10
		24
ADENOMA		
	size	no. (%)
	< 5mm	11 (11.1%)
	5-10mm	26 (26.3%)
	>10mm	21 (21.2%)
	not stated	41 (41.4%)
		99
MISCELLANEOUS PATHOLOGY		
		no.
	Hyperplastic polyps	8
	Haemorrhoids	23
	Diverticulosis	40
	Angiodysplasia	6
	Chronic inflammatory bowel disease	5
	Proctitis	2
	Anal fissure	2
	Carcinoid tumour	1
	Metastatic tumour	2
		89
NIL		**76**
NO FOLLOW UP		**7**

*over the period Nov. '88 - Nov. '90

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Table 2.14 - Sensitivity, specificity, predictive value and % of positive tests in trials of FOBT screening

Trial	Test used	Positivity	Sensitivity	Specificity	Positive Predictive value for cancer
Nottingham (UK)	Hemoccult	2.3% (1.4% with dietary restrictions)	79.6%	98.1%	10.4%
Minnesota (US)	Hemoccult	not rehydrated: 2.4% rehydrated: 9.8%	first (prevalence) screen: 88.0% subsequent (incidence) screen: 94.2% not rehydrated: 80.8% rehydrated: 92.2%	first (prevalence) screen: 95.8% subsequent (incidence) screen: 90.4% not rehydrated: 97.7% rehydrated: 90.4%	first (prevalence) screen: 5.5% subsequent (incidence) screen: 2.8% not rehydrated: 5.6% rehydrated: 2.2%
Goteborg (Sweden)	Hemoccult II	not rehydrated: 1.9% rehydrated: 5.8%	not rehydrated: 28% rehydrated: 93%	not rehydrated: 98.2% rehydrated: 94.7%	not rehydrated: 5.3% rehydrated: 5.3%
Funen (Denmark)	Hemoccult II	.95% (not rehydrated)	55.6% (test-diagnosis interval up to two years)	99.2%	13.7%
Sloan-Kettering (US)	Hemoccult and Hemoccult II (in combination with rigid sigmoidoscopy)	Hemoccult: 1% Hemoccult II: not rehydrated: 3.7% rehydrated: 5.4%	70%	98%	12%
IMVS (South Australia)	Fecal Human Hemoglobin test (immunochemical)	4.42%	82.8%	95.9%	7.5%

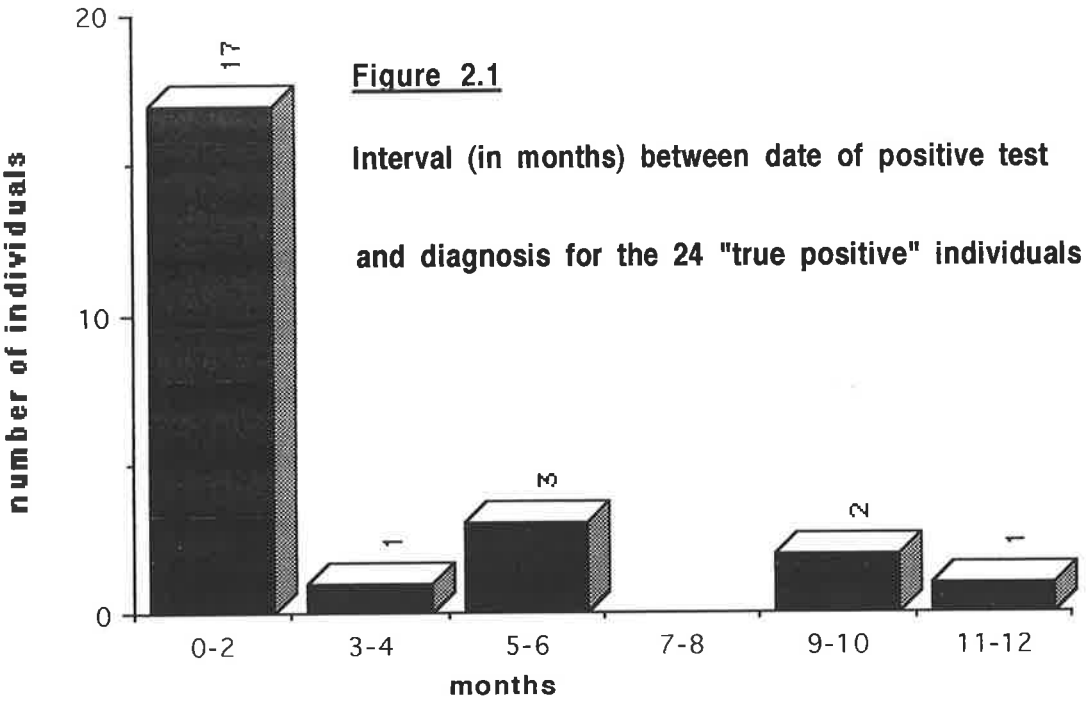

Figure 2.1

Interval (in months) between date of positive test and diagnosis for the 24 "true positive" individuals

Chapter 3:

A cost analysis of screening for colorectal cancer in South Australia

3.1 Introduction

This chapter builds upon the previous analysis of participant characteristics and yield of cancers by analysing the costs of the IMVS FOBT screening programme, and measuring these costs against potential health gains in screened individuals. The overall direct costs born by society are examined, including the cost of the tests, extra medical visits, diagnostic investigations and programme development and implementation. Individual participants' costs (such as travel and time off work) are considered as a separate component of these overall costs, as they may act as a barrier to participation. All resources (both individual and society) allocated to FOBT screening have an "opportunity cost" - that is, they become unavailable for use in other areas. Therefore, it is important to measure the likely health gains from FOBT screening against health expenditure in other areas.

3.2 Background

While screening for colorectal cancer offers the prospect of early detection and prolonged survival, increasing competition for health resources has resulted in a close examination of the costs and potential improvements in health status generated by all cancer screening programmes in Australia. An examination of existing FOBT screening programmes provides the opportunity of assessing the economic implications of this form of screening prior to the introduction of any larger-scale programmes. It was therefore considered to be an important component of the SACCS study to examine costs generated by the IMVS screening programme for colorectal cancer. Since thorough records are kept on screening participants, and screening has been undertaken in a relatively stable

population, it was possible in the SACCS study to collect, from screening participants, detailed information on costs (both individual costs and those borne by the health care system) in addition to costs borne by the programme.

3.21 Costs in the IMVS FOBT screening programme

A substantial proportion of the costs of FOBT screening programmes are likely to be "downstream" - the test used by the IMVS is, in itself, relatively simple and inexpensive (compared, for example, with mammographic examinations), but follow-up examinations for colorectal cancer involve considerable expense and inconvenience. It may be difficult for providers of FOBT screening services to maintain direct interest in downstream costs such as these, which are likely to be borne by the health care system or the participants themselves. Extra costs to individuals having follow-up investigations will include time taken off work, extra visits to doctors and travelling costs. As reported in Chapter 2, the majority of test-positive participants who undergo these investigations will not have colorectal cancer, so a significant proportion of the costs of the programme will be generated in individuals for whom the benefits of participation may be minimal.

It is important also to measure those personal costs in a screening programme which cannot be readily quantified in economic terms. These may include increased fear of cancer, greater preoccupation with ill-health and personal inconvenience. While it is not often possible to put a "dollar value" on these factors, they are an additional burden to the screening participant. Reductions in quality of life or other negative psychological sequelae resulting from participation in the programme) are therefore also presented, in a more descriptive form, in this chapter.

While not reported in this chapter, it is recognized that there are potential benefits of participation in the programme other than having a cancer detected, such as reassurance or relief from anxiety through having a negative test.

3.22 Measuring cost-effectiveness

The cost-effectiveness of screening is the measure most frequently used in determining whether or not screening should go ahead (Donaldson, 1990). A number of previous studies have examined the cost-effectiveness of screening for colorectal cancer (Lieberman, 1991) (Eddy et al, 1987). Such analyses allow comparisons to be made with other health programmes, or enable comparisons to be made of the relative cost-effectiveness of varying strategies within a particular screening programme. An example of the latter is the analysis of Neuhauser and Lewicki (1975) who examined the rationale for using six sequential stool samples in FOBT screening. Given that the majority of cases would be detected in the first two tests, they claimed that the marginal cost per cancer detected by the sixth test was close to US$50 million. Brown & Burrows (1990 - a) later reviewed this analysis and showed the cost per cancer detected was even higher when appropriate adjustments to specificity and false positive rates were made (these authors concluded that better quality data are required to develop reasonable estimates of costs in analyses of this nature).

Other analyses provide information on the relative merits of using FOBT, sigmoidoscopy and colonoscopy, (either individually or in various combinations). As an example, Lieberman (1991) compared the cost-effectiveness of screening using a combination of FOBT and sigmoidoscopy (as recommended by the American Cancer Society) with screening using colonoscopy alone - the latter strategy had a lower calculated cost per death prevented from colorectal cancer.

The cost-effectiveness of alternative work-up strategies following a positive FOBT screening test is another important issue which will be examined in this chapter. It has been the subject of previous Australian research (Brown & Burrows, 1992), and such information is of great interest to governments and private health care funds contemplating reimbursement for screening. The varying conclusions of these studies of cost-effectiveness depend on a number of factors including the screening strategy used, where the screening took place and the characteristics of the screened population. It is not possible, based on the available evidence, to conclude unequivocally that screening for colorectal cancer is a cost-effective exercise. Even in high-risk groups, such as individuals with ulcerative colitis, the value of screening is not unequivocal (Gyde, 1990).

The aim of this component of the SACCS study, therefore, is to examine the various costs generated by the IMVS screening programme, and to weigh these costs against the main potential benefit of the programme - the number of cancers detected through screening. This is an intermediate outcome measure, the final measure being an increase in survival, the determination of which is beyond the scope of this study.

3.3 Methods

Information for this analysis of costs was obtained from two different sources:

1. the postal surveys of screening participants (described in Chapter 2) - since costs were certain to depend on the results of the tests, information from the surveys of individuals with positive and negative test results was considered separately.

2. accounting information supplied by the IMVS screening programme.

Details of the questionnaire survey methodology are presented in Chapter 2. The analysis of costs in test-positive individuals did not include treatment costs of individuals who were found to have colorectal cancer (eg "true positives") - there is no widespread agreement over whether to include such costs in analyses of this nature, given that these individuals are likely to eventually incur the treatment costs when the cancers present clinically. Similarly, treatment costs of the five "false negative" individuals described in Chapter 2 were not included. In calculating travel costs, costs of diagnostic investigations, costs of medical consultations and time off work, information from respondents to the surveys of screening participants is extended to all participants - that is, it is assumed there are no differences in these costs between survey respondents and the remainder of participants (survey non-responders, those who were excluded, and non-surveyed participants). Therefore, estimates of total costs generated by the screening programme up to the point of diagnosis are based on all 6208 participants (although, as previously described, only individuals who did not have colorectal cancer were included in postal surveys).

While a total of 7247 screening tests were performed on the 6208 participants over the two year study period (that is, 14.4% of the tests were for re-screening), this analysis of costs is confined to *first-round screening* . This allows estimates to be made of the costs of screening all programme participants once. In determining annual running costs of the IMVS screening programme a number of different expenses were examined, including materials, laboratory space, salaries, specimen transport and promotion. In the case of equipment purchases of a capital nature, the initial purchase price was amortized over its estimated lifespan.

To determine the costs of investigations and extra medical visits, the government-recommended fees for consultations and procedures current at the mid-point of

the study period were used. While the actual fee charged may vary, these recommended fees are the best available estimate of medical costs.

Costs for travel by car are based on the Australian Taxation Office's claimable allowance for a 2 litre vehicle (50.48 cents per kilometer). Where public transport was used, participants were asked to provide an estimate of the return fare. In examining the costs of time off work as a result of individuals' participation in the programme, the opportunity cost of the time not worked was used, and was assumed to be the product of number of hours off work and average earnings per hour (as supplied by the Australian Bureau of Statistics).

Information on the organization of the programme itself is presented in Chapter 1. As described, participants are required to purchase test-kits, the cost of which includes subsequent laboratory testing and reporting. A proportion of participants are reimbursed for the test through private health insurance funds.

This analysis, therefore, includes a summation of the costs identified in order to calculate a cost per cancer detected. Estimates are made of the average personal cost for each test-negative and test-positive participant. All costs are presented in Australian dollars at their value in January 1990, at which time one Australian dollar was worth UK£0.48 and US$0.78.

3.4 Results

Response rates to the survey and age/sex characteristics of respondents are presented in Chapter 2 (Section 2.41 and Table 2.4).

3.41 Costs involved in obtaining and returning the test kit

The purchase price of the kit was $15.00 throughout the study period. The majority of participants (78.0%) claimed for the total cost of the kit through a

private health insurance fund. To avoid double-counting, the purchase price was not included as a separate item in the overall cost of the programme. The purchase price was, however, included when considering the personal costs borne by individuals.

In determining travel costs to obtain the kits, individuals were asked;

1) whether they had made a "special trip" to obtain the kit (if this was not the case their travel costs were not included)
2) the return distance travelled to obtain and return the kit, and
3) the form of transport used.

These costs (based on the survey of test-negative participants) are summarized in *Table 3.1*. The majority of individuals used their car to pick up and return their test kits, and a greater proportion of participants made a "special trip" to return their test kits than to collect it. The average estimated cost per participant for test kit collection and return was $5.64.

3.42 Diagnostic Investigations (test-positive participants only)

The 262 respondents to the survey of test-positive individuals were asked whether they had a colonoscopy and/or barium enema as a follow up investigation of their positive test (*Table 3.2*). In calculating the total costs of these investigations over the study period in all test-positive participants, it was assumed that equal proportions of responders and non-responders to the survey would have had the investigations.

The government recommended fee (at the mid-point of the study period) for a colonoscopy ranged from $255 to $360 depending on whether or not polyps were removed during the procedure. A telephone survey of private hospitals, pathology

laboratories and medical specialists in the Adelaide metropolitan area led to an estimate of additional costs of colonoscopy (including day theatre charges, pharmaceuticals, histological examination of biopsy specimens and above-recommended-fee payments) of $500. Assuming that approximately 25% of the population over the age of fifty have one or more adenomas (Hoff, 1987), the estimated average cost of a colonoscopy for the study period was $800. Of the respondents to the survey of test-positive participants, 79% reported having had a colonoscopy, making this investigation a significant contributor to overall costs.

A barium enema is a less expensive investigation - the recommended fee at the study mid-point was $85 and additional costs (such as bowel preparation kit) are estimated to be $10. It is almost always carried out as an outpatient procedure.

There were missing data for the questions on follow-up investigations - 21.8% of responses were coded as "missing" for the question on barium enema. If 43.1% of these individuals did, in fact, have a barium enema (a similar proportion to that in the complete responses), this would add $2,330 to the "total cost" for barium enemas shown in *Table 3.2* (most probably did *not* have a barium enema, as respondents would be more likely to leave the question blank if they had not had the investigation). In the case of colonoscopy only 8% of the data were missing - if 79% of these had had a colonoscopy this would add $13,270 to the "total cost".

3.43 Cost of medical consultations

Test-positive participants

Two hundred and five respondents (78.2%) reported that participating in the screening programme led to extra visits to their general practitioner. The average number of visits was 1.94 and given that the average recommended fee for a general practice consulation for the 1989/90 period was $20, this represents an average cost per test-positive participant over the two year study period of $30.34.

The majority of respondents to the survey of test-positive participants (74.8%) reported consulting medical specialists (it is assumed that the majority of these consultations would have been with gastroenterologists or colorectal surgeons). In this group the average number of consultations per person was 2.37 - the total reported number of consultations being 465 of which 196 were first consultations and 269 were subsequent visits. The recommended fee at the midpoint of the study period for a visit to a medical specialist was $95.00 for a first visit, and $47.50 for subsequent consultations.

Assuming no differences between the 262 responders to the survey of test-positive individuals and the remainder of the 313 test-positive individuals (survey non-responders and individuals who were excluded because they had colorectal cancer), these figures lead to an estimated average cost for specialist consultations of $108.65 for each test-positive participant over the two year study period.

Test-negative participants

Only a small proportion (3.9%) of the 461 test-negative survey respondents reported having extra visits to their GP as a direct result of participation in the programme, with an average number of extra visits of 1.7. The average cost for each of the 5895 participants with negative test results was $1.33. It was assumed that no test-negative participants would require extra visits to specialists or hospital/diagnostic facilities.

3.44 Travel costs for medical follow-up after screening

The costs to participants of travelling to doctors' rooms, hospitals and other diagnostic facilities are summarised in *Table 3.3.* As in test kit collection and return, the majority of individuals travelled by car. Average cost per visit for car

travel was derived from the product of the reported return distance travelled and the claimable allowance.

It can be seen from *Table 3.3* that individuals travelled much greater distances to visit specialists and diagnostic facilities than they did to visit GPs. This is not surprising given that most people have a GP in their local area.

3.45 Time off work

Test-positive participants

Out of the 262 respondents to the survey 65 (24.8%) reported needing to take time off work as a result of their positive test in the FOBT screening programme. The average number of hours taken off work by these individuals was 12.7 and, based on average weekly earnings of $504.40 (in January 1990), this leads to an estimate of the total opportunity cost of time off work in test-positive participants over the two year study period of $39.70 per participant.

Test-negative participants

Of the 461 test-negative participants who responded to the survey, only 2 reported needing to take time off work - one reported taking 2 hours off work, and the other 8 hours (average opportunity cost per participant of $0.27).

3.46 Intangible/psychological costs (Table 3.4)

No attempt is made to put a dollar value on the personal costs summarised in *Table 3.4*, but they are an important consideration in the evaluation of any screening programme. They have been described as "burdens" which, although not easily quantifiable, should be included when considering individuals' personal costs (Donaldson, 1990).

Test-positive participants

Clearly, having a positive bowel cancer screening test caused the majority of participants to worry that they may have cancer, and a proportion remained worried (31%) despite presumably negative confirmatory investigations. Nevertheless, although they were individuals who had had a "false positive" screening test (and had been subjected to confirmatory investigations that they otherwise would have been unlikely to have), few felt that participating in the programme had caused them unnecessary trouble, and only 4.7% wished that they had never taken the test.

Test-negative participants

It is possible that, in some individuals, participation in cancer screening programmes could increase anxiety even if the result of the test was negative. *Table 3.4* shows that although a considerable proportion of test-negative respondents (42%) felt anxious about bowel cancer before taking the test, only 10% felt more anxious as a result of participation in the programme. Indeed, as already suggested, one of the potential benefits of participating may be the reassurance of a negative test.

3.47 Costs borne by participants

Average personal costs per participant are summarized in *Table 3.5*. Costs are shown separately for positive and negative test results and whether or not the purchase price of the test-kit was claimed through a private health insurance fund. Personal costs are identified as:

1. travel costs for (a) test-kit collection and return and (b) medical follow-up
2. opportunity cost of time off work
3. medical consultation and investigation costs - personal contribution assumed to be 15% of the government-recommended fee
4. purchase price of the test-kits

Time off work may not necessarily be a "personal cost" - individuals may be paid sick pay, in which case the cost may be shared by the employer, individual or a third party. However, for the purposes of this analysis it was assumed to be borne entirely by the individual. Assuming the government recommended fee is charged for consultations and investigations, individuals can claim 85% of this fee from Medicare (Australia's national health insurance scheme). There are additional costs (such as day theatre charges for colonoscopy in a private hospital) which may not be covered under Medicare - the personal contribution to these costs will depend on where the investigation was done (eg, public versus private facility) and whether or not individuals have private health insurance. For the purposes of this analysis, personal contributions were assumed to be 15%, whether or not the items were covered by Medicare. Only 21% of participants paid for the test-kits themselves, reflecting the high level of private insurance coverage in the screened population.

3.48 Overall costs of the programme

A summary of the costs measured in this analysis is shown in *Table 3.6.* It can be seen that only $119,000 (28.5%) of the total cost of $454,000 was spent on the actual running of the programme - the remainder were "downstream" costs, generated outside of the direct control of the programme.

Cost estimates of running the screening programme are not entirely straightforward in that it is conducted by a private company which is under the overall administration of the IMVS. Many of the costs usually associated with a screening programme (such as provision of laboratory space, heating, lighting etc.) are incorporated into the IMVS budget - that is, they are not separately itemized. Nevertheless, estimates are provided of as many of the identifiable costs as possible, whether they are borne by the administering company or IMVS, and included in *Table 3.6.* Where salaries, equipment, materials or other costs are

shared between the FOBT screening laboratory and other activities in the IMVS, an attempt has been made to only include that portion of the cost attributable to the screening programme.

3.49 Sources of Funding for the IMVS Screening Programme

Table 6 shows that the total cost borne by the IMVS over the two year study period was $119,304. The principal source of funding for the programme is the sale of test-kits. For each kit sold at $15.00 through a chemist or other outlet, the IMVS receives $13.50. Over the two year test period this would have generated $83,808 of which $65,370 came from private health insurers and $18,438 from participants. Indeed, sale of the test-kits raises the possibility of the programmme ultimately running at a profit which, given that it is under the administration of a private arm of the Institute of Medical & Veterinary Science, is a desirable goal. At present, however, the shortfall in funds is covered by research grants and from the IMVS's general revenues.

3.410 Sensitivity Analysis

A sensitivity analysis was conducted to examine the impact on overall costs (per cancer detected) to society and personal costs of changes in the variables studied. Results are shown in *Table 3.7*. It is noteworthy that both the proportion of individuals having colonoscopy and the cut-off point of the FOBT test strongly influenced the overall conclusion. Colonoscopy is an expensive investigation, and its inclusion in follow up strategies for test-positive individuals has a profound influence on overall costs. The influence of positivity rate on costs is further illustrated in *Figure 3.1* which shows a linear relationship between these two variables.

Table 3.7 also shows that varying the purchase price and travel costs associated with the test-kits had a profound effect on average personal costs for test-negative

individuals, although using postage-included test-kits would likely add to IMVS costs.

At present there is spare capacity within the IMVS screening programme to screen more individuals. In calculating the costs of increasing the number of individuals screened by 25%, a number of costs incurred within the IMVS programme, including salaries and items of a capital nature, were assumed to remain constant. If such an increase in screening activity led to the discovery of 25% more cancers, this would reduce the average cost per cancer detected from $18,924 to $18,276 (a 3.4% decrease).

3.5 Discussion

Much of the information for this component of the SACCS study was obtained from surveys of screening participants who were being asked to recall events up to twelve months in the past. Hence, estimates of distances travelled, numbers of medical visits and other costs must be interpreted with some caution.

As the IMVS programme relies on self-recruitment, participants are likely to be a motivated group, and some of the responses to the survey may reflect this. Had participants been more actively recruited they may, for example, have been more likely to express dissatisfaction with the programme. A programme aimed at the wider population may require a more regulated method of enlisting participants. There is some evidence from mammographic screening in Australia that strategies which actively recruit individuals are more cost-effective than non-individualized strategies (Hurley et al, 1992).

Compliance with recruitment strategies can influence the cost-effectiveness of a programme. Walker & Whynes (1991) consider compliance-enhancement techniques to be justifiable on economic grounds in the European trials of

screening, and an analysis of different screening strategies, based on data from the Nottingham trial, has shown that higher levels of compliance generally result in a proportionate decrease in the number of cancers missed exceeding the proportionate rise in total costs (Whynes et al, 1992 - a).

Caution has been urged in performing cost-effectiveness analyses on health programmes such as FOBT-screening. Hurley (1990) argues that cost-effectiveness analyses have significant limitations in that not all aspects of individuals' costs and benefits through participating in a health programme can be included. While "life-years saved" is the most general outcome measure of cost-effectiveness analysis (Donaldson, 1990) other important aspects of outcome may be missed, such as "quality of life" issues.

It is difficult to measure all costs incurred by screening participants, and how such costs may impact on decisions to take screening tests. For example, putting a value on time spent on participating in screening programmes involves many assumptions about costs of travel, associated medical expenses and costs due to time off employment.

Hall & Mooney (1990) argue that a number of questions should be asked in any economic appraisal, including; "was a full range of benefits included?", and "whose values were used in estimating benefits?" A number of costs and benefits of participating in FOBT screening can be identified which have not been included in the current analysis. Potential costs include ongoing surveillance of individuals with bowel polyps, the cost of procedures carried out as a result of discovering other bowel pathology through screening (such as hemorrhoids), costs of confirmatory investigations other than barium enema or colonoscopy and negative psychological sequelae not considered in the surveys of participants. Potential benefits include the reassuring effect of a negative test and a raised awareness of

colorectal cancer as a major health problem in the community. The "willingness to pay" approach has been proposed as a means of valuing such intangible effects (Cairns & Shackley, 1993). Potentially positive outcomes such as these were not, however, measured in the SACCS study.

It could be argued that there is no justification for including an economic evaluation of FOBT screening as part of the SACCS study when there is only limited evidence that this form of screening can produce improvements in mortality. Existing programmes do, however, provide an opportunity to examine the wider economic implications of screening. It has been suggested that there is no point in waiting until the introduction of a health care programme is inevitable before doing an economic evaluation because many alternatives may not then be available (Brown & Burrows, 1990 - b). There are clearly limitations in generalizing from results of economic analyses of small-scale programmes, as they each have their own unique characteristics, including methods of recruitment and follow-up strategies.

3.51 Costs of medical follow-up

Given that many of the costs identified in this chapter occurred independently of individuals' participation in the screening programme, particular attention should be focussed on the diagnostic procedures which follow a positive FOBT. Colonoscopy is widely endorsed as the investigation of choice, but it is an expensive procedure - almost half of the costs in the current analysis were attributable to this investigation. Its per capita usage in Australia (along with all diagnostic techniques for investigating colonic disease) is rising (Doessel, 1986) and should FOBT screening be introduced on a wider scale, less expensive ways of providing this investigation should be examined. Possibilities include the training of non-medical specialists to perform colonoscopies or a greater provision of the service outside the hospital environment. In addition, greater use of barium

enema as a diagnostic investigation may need to be considered - while it is less accurate than colonoscopy, its lower cost may make it a more practical option for screening in the wider population. UK research (Walker et al, 1991 - a) suggests that colonoscopy is the superior in any FOBT screening programme if its sensitivity is significantly higher than that of barium enema and if the latter technique requires a large high number of follow-up colonoscopies - but given the wide range of clinical practice and reported sensitivities of investigations, it is difficult to draw definitive conclusions.

The issue of determining the most cost-effective workup strategy has been examined by a number of authors including Brown & Burrows (1990 - b) who stated, on the basis of computer modelling, that the two most efficient strategies for investigating FOBT-positive individuals (in terms of greater diagnostic yield and/or lower cost) were: 1) a combination of repeat FOBT, rigid sigmoidoscopy and barium enema, and 2) a combination of flexible sigmoidoscopy and colonoscopy. A potential advantage of the first strategy is that these investigations could be undertaken by general practitioners, hence reducing costs involved.

In a similar exercise, Barry et al (1987) used a decision analysis model to compare a number of strategies that doctors might use. They concluded that colonoscopy as an initial investigation is more effective and less costly than the combination of flexible sigmoidoscopy and barium enema. Barium enema alone had the lowest cost-effectiveness ratio. Conflicting evidence such as this contributes to the variety of strategies used by physicians to investigate a positive fecal occult blood test, and this choice of strategy will have an effect on the net costs and health benefits of screening. Maximizing cost-effectiveness must be balanced against clinical considerations - for example, on ethical grounds it may be difficult for a clinician to accept a less accurate, but less costly, investigation.

The cost of colonoscopic investigation and specialist visits added considerably to the personal burden of screening participants in the current study. Hence, despite its accuracy, the fact that colonoscopy is expensive, invasive and requires referral to a specialist may preclude its use in all test-positive individuals should mass screening be introduced in Australia. An analysis of the cost-effectiveness of colorectal cancer screening in the US came to the conclusion that "reducing colonoscopy fees would have a major effect on the cost-effectiveness of colorectal cancer screening" (Wagner et al, 1991).

Forty per cent of respondents to the survey of test-positive participants (who did not have colorectal cancer) reported that "bowel polyps" were the cause of their positive FOBT (*Table 2.7*). As discussed in Chapter 2, with current medical practice, many of these individuals are likely to undergo further investigations over the coming years to detect the development of colorectal cancer. Given that the adenoma appears to be a precursor to carcinoma in many cases, detected and excised adenomas can be taken to represent a positive outcome of a screening programme - an analysis of the likely benefits of early detection and removal of adenomas (Whynes et al, 1992 - b) has concluded that adenoma detection and removal as a result of FOBT screening is likely to off-set the total costs of the programme to some degree.

The costs of such ongoing surveillance of adenomas have not been included in this analysis. It is possible, also, that many of the specialist visits participants indicated they had as a result of their positive test were, in fact, for the treatment of other pathology detected (such as hemorrhoids), and as such should not be included in the costs of excluding cancer.

3.52 Intangible costs or reduction in quality of life

Respondents to the surveys used in this chapter's analysis of costs reported an increased fear of cancer and more general concern about their health as a result of having a positive test in the screening programme. A small proportion reported increased anxiety despite having a negative test. Similar reduction in quality of life has been examined in previous research; a UK study (Mant et al, 1990) found that of 54 patients who had false positive results, 68.5% felt some degree of distress with the initial positive test result. Many of these patients were distressed over delays in diagnostic investigations. Nevertheless, 98.1% of these patients felt that the screening process had been worthwhile, which is in keeping with our own findings.

A degree of negative psychological impact was not unexpected, given that bowel cancer is likely to be perceived as a serious health problem in the community. Marteau (1989) argues that a positive result in any screening test is invariably received with negative feelings - equally, a negative result given without explanation may itself have harmful effects such as reinforcing an unhealthy lifestyle or bolstering a pre-existing sense of invulnerability.

Harmful effects have been noted with other forms of screening - such as adverse psychosexual sequelae following an abnormal cervical smear (Campion et al, 1988). While it is difficult to accurately measure the true "cost" of these effects, they are an additional burden to the screening participant, and may act as a significant barrier to participation in screening programmes.

While effects such as increased anxiety and reduced sense of well-being are likely to be perceived as costs by participants in screening, they have not been quantified in this analysis. Donaldson (1990) argues that negative anxiety effects should not be counted as "costs" (neither should they be ignored) because

"anxiety" does not have an opportunity cost - it cannot be taken, like a resource, and used in another beneficial activity.

3.53 The overall costs of FOBT screening

Ultimately, the aim of this analysis was to examine the opportunity cost to society of the IMVS screening programme. Comparing estimates of costs per cancer detected in this study with findings from other research is difficult given differences in systems of health payment in various countries, screening strategies, size of study populations and range of costs included in the analyses. Walker et al (1991 - b) have examined data from the Nottingham trial to model the likely implications should a screening programme be introduced within a typical family practitioner committee area in the UK. They estimated the cost per cancer detected in the first round of screening would be equivalent (at the prevailing exchange rate in January 1990) to $5400 plus or minus 20% depending on the screening strategy envisaged, with a cost per person screened of approximately $10. For subsequent screening rounds, average costs would remain approximately constant although total costs might be expected to fall. These figures are considerably lower than the results reported in this chapter, but travel and medical costs are not included, the cost of investigations such as colonoscopy in the UK is reported to be considerably less, and the Nottingham trial has many times more participants.

Costs to participants were also examined as a component of the overall cost, as personal costs (such as the purchase price of the test kit and transport) may act as a barrier to participation. Evidence from mammographic screening in Australia suggests that personal costs involved in attending a screening programme may be substantial and may deter some women from attending screening (Hurley & Livingston, 1991). The cost analysis presented in this chapter demonstrates considerable personal costs to participants who have positive test results. These

costs, however, may not act as a barrier to participation as individuals are unlikely to anticipate major costs and investigations when they take what appears to be a simple test.

In examining the cost-effectiveness of this programme, it is necessary to ask whether a cost of $18,924 per cancer detected is a reasonable health expenditure. It is likely, based on the results of other FOBT screening programmes, (Hardcastle et al, 1989) (Kronborg et al, 1989) that the cancers detected in this programme will have a more favourable histopathological staging, and hence projected survival. There is, however, only evidence from one randomized control trial suggesting improvements in mortality in populations undergoing FOBT screening (Mandel et al, 1993), and widespread screening in the Australian population (outside of trial conditions) may not necessarily lead to similar mortality improvements. Furthermore, there is disagreement in the literature over whether treatment costs of screen-detected cancers are likely to be lower. Such costs probably depend on the individual characteristics and context of the screening programme. US research suggests that the pathological staging of CRC has a substantial impact on cost of care, with the more favourable staging of screen-detected cases leading to significant savings (Allison & Feldman, 1985). However, a UK study (Tuck et al, 1989) which examined three particular costs in the Nottingham trial of FOBT screening (investigation of positive test results or of bowel symptoms, the surgical treatment of colorectal cancer and inpatient stay before and after treatment), found that screened patients did not appear to be any cheaper to treat than symptomatic patients - possibly suggesting that early cases may well have a more intensive surgical input than advanced cancers, given that there are likely to be curative, rather than palliative objectives.

Other research (Kristein, 1980) suggests that properly conducted hemoccult screening for populations over the age of 55 may be a cost effective early cancer

detection procedure, (the benefits being achieved by increasing the long term survival), but the net savings in terms of medical services employed are likely to be small or negative.

3.54 Implications of Sensitivity Analysis

The sensitivity analysis demonstrates that total programme costs are likely to be dependent upon the proportion of individuals who test positive. Hence, if the organizers of the programme were concerned about the number of false negatives and lowered the threshold at which a test was declared positive (that is, increase the test's sensitivity with a corresponding loss of specificity), there would be a substantial increase in costs (more so than increasing the costs of running the programme). There have been similar results in other FOBT screening analyses - sensitivity analyses of the Nottingham FOBT screening trial (Walker et al, 1991 - a) revealed that programme costs were more sensitive to changes in clinical variables (especially detection and compliance rates) than they were to the costs of resources for the programme. In a costing model to examine results of the Nottingham and Swedish trials (Walker et al, 1991 - c) "rehydration" of the Hemoccult test kits resulted in higher sensitivity but a corresponding loss of specificity such that, although more cancers would be detected, the costs per cancer detected would be considerably higher (up 46.8%).

While variations to average personal costs have been included in the sensitivity analysis, the most critical concern is the total cost of the programme - individual participants can potentially be compensated for any increase in their costs, but society as a whole cannot escape the total costs. The variations in personal costs may, however, have an effect on demand for the test - a perception that a screening programme may involve considerable personal expense is likely to be a significant barrier to participation.

While analyses such as these contribute to the decision of whether or not to screen at all, there are other potential issues, such as marginal costing (Donaldson, 1990) which examines the decision to do more or less screening - for example changing the interval between screens, or screening more individuals. Increasing the numbers of annual participants in the IMVS programme is likely to reduce the IMVS costs per individual screened (providing salaries and costs of non-consumables remain constant) but to have only a modest impact on the overall cost per cancer detected.

Given that the investigation of FOBT-positive individuals has the most significant effect on costs, there would likely be major benefits in directing efforts towards reducing the number of false positives (either by refining the tests used or focusing on high-risk individuals), and reducing costs of medical follow-up should widespread screening be considered in Australia.

3.55 Implications for widespread FOBT screening in Australia

Should the results of randomized controlled trials unequivocally demonstrate a favourable effect of FOBT screening on mortality, a decision will need to be made on whether to introduce a national screening programme in Australia. It has been estimated that mass screening of all Australians aged between 50 and 74 would result in approximately 68,000 colonoscopies on the first round of screening (assuming only 2% positivity, and that all FOBT-positive individuals are investigated with colonoscopy) (Woodward & Weller, 1990). Under current arrangements for provision of colonoscopic investigation, this would have major resource and manpower implications in the Australian health system.

It is suggested that, even if major trials of FOBT screening do consistently demonstrate mortality improvements, "ultimately it will be policy makers and not economists who determine whether an extra case of bowel cancer detected

through screening is worth the cost" (Donaldson, 1990) - Eddy (1981) argues that the choice of an early detection protocol can only be made by patients and physicians. The final choices depend on how one values the health benefits, risks and costs of different protocols. The mammography screening programme in Australia illustrates a number of these competing values - while analyses have concluded that screening of women aged 50 to 69 every two to three years is cost-effective and "reasonable value for money" (Carter et al, 1993), other considerations including clinical preferences, individual values and political expediency continue to influence the course of the programme. Nevertheless, an examination of the economic implications of smaller, existing programmes in Australia can give an indication of the likely costs of widespread screening should it be introduced in Australia.

Screening for colorectal cancer is of particular relevance in countries where, like Australia, the population is ageing - the elderly are more likely to develop cancer, but potential gains in life years saved through cancer screening are not as great. The US Office of Technology Assessment (1990) recently analyzed the costs and effectiveness of providing colorectal cancer screening to the elderly under the US Medicare programme. They used conservative assumptions about the accuracy of the screening tests, the speed of progression of polyps to cancer and cancers from early to late stages, the stages at which cancers would be found in an unscreened elderly population, and the impact of early detection of CRC on life expectancy. It was concluded that colorectal cancer screening in the elderly (individuals aged over 65) would not reduce total health care costs, but offered "a good chance" of providing elderly people with substantial gains in health. This assessment estimated that annual FOBT beginning at age 65 would prevent approximately 23,000 cases of CRC in the 2.1 million Americans aged over 65 in 1989 at a cost per added year of life of approximately US$35,000.

A screening programme in Australia may also need to consider screening strategies apart from annual FOBT - evidence from computer modelling suggests that either annual FOBT, 5 yearly colonoscopy or 5 yearly barium enema plus annual FOBT are the strategies which are particularly likely to bring about improvements in mortality from colorectal cancer in high risk individuals who commence screening at the age of forty (Eddy et al, 1987). It is suggested that annual FOBT might reduce mortality by approximately 30% in individuals with first degree relatives with bowel cancer.

3.6 Summary

This chapter has examined the range of costs generated by the IMVS FOBT screening programme. It is of critical importance to examine costs of FOBT screening in order to assess whether it is a worthwhile use of health resources. While the initial cost of testing in a FOBT screening programme such as that run by the IMVS is not great, the results presented in this chapter suggest that the downstream costs are considerable. It appears that, in particular, investigation of FOBT positive individuals involves major expense both to society as a whole and to individuals themselves.

The costs per cancer detected in FOBT screening programmes need to be weighed against the considerable public health burden of colorectal cancer in Australia, and the fact that FOBT screening may reduce mortality from this disease. This chapter provides some insight into the costs generated by a small-scale screening programme, and how the expected value of the net benefit in screening might be maximized. Evidence presented in this chapter also suggests that the cost-effectiveness of FOBT screening programmes is profoundly

influenced by factors which influence the uptake of screening in the population (eg acceptability and compliance) and operational considerations, such as the role of doctors, in implementing widespread screening. These issues will be examined in the following two chapters.

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Table 3.1 - Costs of Specimen Kit Collection and Return

	Percentage of respondents who made a special trip	Form of transport		Estimated average cost per participant in screening programme	Estimated total costs incurred by participants over study period (6208 individuals)
		Car	Public transport		
COLLECTION	224/461 (48.6%)	191/224 (85.3%) *Av.. return journey 7.9 km*	12/224 (5.4%) *av. return fare $2.50*	$1.72	$10,670
KIT RETURN	360/461 (78.1%)	326/360 (90.6%) *Av. return journey 10.7 km*	14/360 (3.9%) *av. return fare $3.40*	$3.92	$24,350

Table 3.2 - Costs of follow-up investigations for test-positive participants

	estimated cost	no. (%) of test-positive survey respondents who reported having this investigation	estimated total cost generated over two year study period
Colonoscopy	$800	207 (79.0%)	$197,816
Barium enema	$95	113 (43.1%)	$12,816

Table 3.3 - Travel costs for medical follow-up

		General Practitioner		Specialist	Hospital/ diagnostic facility
		test-positive survey respondents (n=262)	test-negative survey respondents (n= 461)	(test-positive survey respondents only)	(test-positive survey respondents only)
extra medical visits	no. (%) of respondents who had extra visits	205 (78.2%)	18 (3.9%)	196 (74.8%)	189 (72.1%)
	average no. visits	1.94	1.7	2.37	1.85
car travel:	no. (%) using	181(88.3%)	16 (88.9%)	184 (93.9%)	176 (93.1%)
	average travel cost/visit	$7.04	$7.05	$21.66	$17.06
public transport	no. (%) using	8 (3.9%)	2 (11.1%)	9 (4.6%)	10 (5.3%)
	average travel cost/visit	$3.85	$3.86	$4.30	$9.75
other form of transport used (eg walking, bicycle) or data missing		16	0	3	3
extrapolation of survey results to estimate total travel costs in all participants over two-year study period (313 test-positive, 5895 test-negative participants).		$3023	$2617	$11395	$6806

Table 3.4 - Intangible costs or reduction in quality of life in screening participants

TEST-POSITIVE RESPONDENTS (n = 262)

		very worried	a little worried	not at all worried	not sure
Having a positive test made me worried that I might have bowel cancer (n = 259)	no.	86	138	21	14
	%	33.2%	53.3%	8.1%	5.4%
I still feel worried that I may have bowel cancer (n = 257)	no.	4	75	146	32
	%	1.6%	29.2%	56.8%	12.5%

		yes	no	not sure
Having a positive test caused me a lot of unnecessary trouble (n = 257)	no.	44	200	13
	%	17.1%	77.8%	5.1%
I wish that I had never taken the test (n = 257)	no.	12	236	9
	%	4.7%	91.8%	3.5%
Having a positive test has made me worry more about my general health (n = 258)	no.	66	175	17
	%	25.6%	67.8%	6.6%

TEST-NEGATIVE RESPONDENTS (n = 461)

		yes	no	not sure
I felt anxious about bowel cancer *before* I took the Detectacol test (n = 456)	no.	192	217	47
	%	41.7%	47.1%	10.2%
Having the Detectacol test made me feel *more anxious* about bowel cancer (n = 455)	no.	46	389	20
	%	10.0%	84.4%	4.3%

Table 3.5 - Average personal cost per individual of participating in IMVS screening programme

average cost per participant

	cost of test kit claimed through insurance	cost of test kit not claimed through insurance	all
test-positive participants	$234.60	$249.60	**$237.90**
test-negative participants	$6.55	$21.55	**$9.85**
all participants	**$17.22**	**$32.22**	**$20.52**

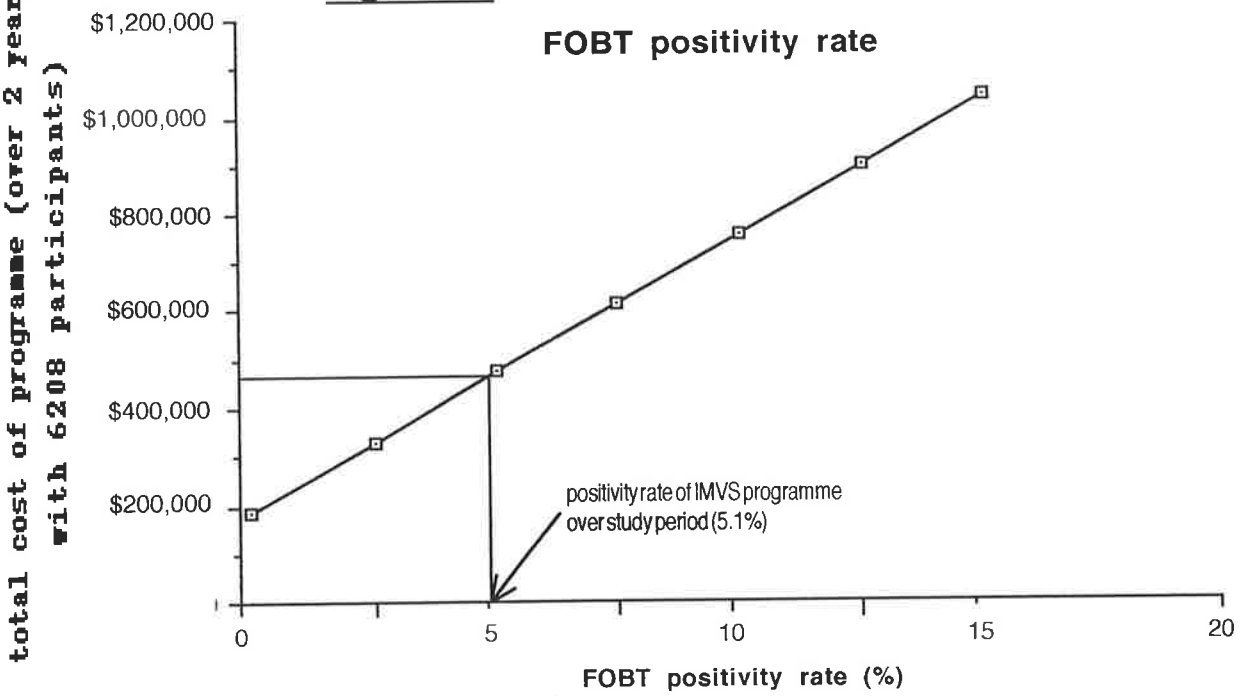
Table 3.6 - Summary of costs of IMVS FOBT Screening Programme

Description of cost (A$)	Test-positive (n = 313)	Test-negative (n = 5895)	Totals
Test-kit collection and return (n = 6208) - see *Table 1*			$35,020
Travel costs for medical follow-up - see *Table 3.3*			
1. General Practitioners	$3,023	$2,617	$5,640
2. Specialists	$11,395		$11,395
3. Diagnostic facilities	$6,806		$6,806
Medical consultation costs:			
1. General practitioners	$9,497	$7840	$17,337
2. Specialists	$34,007		$34,007
Cost of investigations - see *Table 3.2*			
1. Colonoscopy	$197,816		$197,816
2. Barium enema	$12,816		$12,816
Opportunity cost of time off work:	$12,426	$1,612	$14,038
Costs to IMVS/Health System to run the screening programme (over two-year period)			
Specimen preparation			$3,992
Assay materials (inc. antibody production, pipettes etc.)			$3,332
Salaries (technicians, programmers, consultants, other staff)			$66,900
Laboratory resources (inc. refrigerators, fume cupboard, electricity, cleaning etc.)			$7,620
Promotion			$3,200
Report generation (inc. stationary, postage, computer, phone calls)			$12,310
Test preparation& transport			$21,950
Total IMVS costs			$119,304
Estimate of total cost of programme (6208 participants over two year period 30/11/88 - 30/11/90)			**$454,179**
Overall estimate of cost per cancer detected			**$18,924**

Table 3.7 - Sensitivity analysis for costs involved in IMVS screening programme

Adjustment:	average personal cost per participant		ESTIMATED AVERAGE COST PER CANCER DETECTED OF PROGRAMME OVER TWO YEAR STUDY PERIOD
	test-positive participants	test-negative participants	
Nil	$237.90	$9.85	**$18,924**
Increase positivity rate of FOBT for first-round screening from 5% to 6% (up 20%)	unchanged	unchanged	**$21,147*** **(up 11.7%)** *assuming no extra cancers detected
Reduce purchase price of kit from $15.00 to $7.50 (50% reduction)	$236.25 (down 0.7%)	$8.20 (down 16.8%)	**unchanged**
Increase the number of individuals having first-round screening from 6208 to 7760 (25% increase).	unchanged	unchanged	**$18,276*** **(down 3.4%)** *assuming 25% more cancers detected
Eliminate travel costs for test-kit return by using kits which can be returned by mail, postage included	$233.98 (down 1.65%)	$5.93 (down 39.8%)	**$17,910 (down 5.4%)**
Increase annual running costs of IMVS screening programme by 20%	unchanged	unchanged	**$19,918 (up 5.3%)**
Follow-up scenarios:			
individuals have colonoscopy (27% crease from 79%), same proportion (43.1%) have barium enema	$263.10 (up 10.6%)	unchanged	**$21,115 (up 11.6%)**
All individuals have colonoscopy, none have barium enema	$256.96 (up 8.0%)	unchanged	**$20,581 (up 8.8%)**
All individuals have barium enema, none have colonoscopy	$151.21 (down 36.4%)	unchanged	**$11,387 (down 39.8%)**

Figure 3.1 - **Estimated effect on total costs of varying FOBT positivity rate**



Chapter 4:

Colorectal cancer and its prevention: knowledge, attitudes and beliefs in the general population and in screening participants

4.1 Introduction

This chapter examines a further determinant of the feasibility and success of FOBT screening - the knowledge, attitudes and beliefs (in relation to colorectal cancer and its prevention) of target populations for screening. This is undertaken through surveys of the general population and of FOBT screening participants. Experience from screening for other cancers suggests that, for a programme to be successful, it is important to examine the various determinants of the level of participation in screening in the target population. Complex sociodemographic factors, individual health beliefs and motivations all appear to influence how successfully a target population co-operates with a cancer detection programme (Gordon & Doty, 1987) (Montano & Taplin, 1991). Therefore, this component of the SACCS study examines, in the general population, intentions to participate in FOBT screening, actual levels of participation, beliefs in benefits of screening and awareness of the availablity of screening. It also examines the influence upon these variables of age, gender, a family history of colorectal cancer, participation in other health-related activities and various measures of socioeconomic status (SES). A number of attitudes and beliefs about colorectal cancer, derived from the Health Belief Model (HBM) (Janz & Becker, 1984), are also examined. This model is one of a number of theoretical frameworks which allow a more systematic examination of the wide range of determinants of participation in health-related activities. It proposes a set of attitudes and beliefs which are thought to influence health-related behaviour, including perceived susceptibility to an illness, the perceived seriousness of the illness and the perceived benefits and costs of taking the recommended health action. Previous research has demonstrated

relationships between attitudes and beliefs based on the HBM and participation in screening programmes (Calnan, 1984) (Lerman et al, 1990).

Those who participate in a wide range of prevention-related activities (including screening) may share many similar characteristics. Reported intentions to undertake other health-related activities (such as mammography or cervical cancer screening) are also, therefore, examined as possible determinants of participation in FOBT screening.

To further examine these issues, similar information is included from a survey of FOBT screening participants, thus allowing comparisons to be made on knowledge, attitudes, health beliefs and participation in other prevention-related activities (and how these factors are influenced by sociodemographic characteristics) with the general population survey.

4.2 Methods

Data for the general population survey were collected by including a number of questions relating to colorectal cancer in the South Australian Health Omnibus Survey, a state-wide interview survey conducted by the South Australian Health Commission which is used to examine the population prevalence of health-related behaviours (Wilson et al, 1992) (Owen et al, 1992). The survey was conducted in late 1991. Systematic, clustered area sampling was undertaken in both metropolitan and country areas, using a sampling frame from the Australian Bureau of Statistics (ABS). One interview was conducted per household in the metropolitan sample (totalling 3456 households), and if more than one individual aged 15 or over was resident, the individual whose birthday was next was chosen. For the country sample (totalling 1152 households), all towns with a population size of at least 10,000 in the 1986 census were included, and the remainder of the sample was selected from centres with a population of 1000 or more in the 1986

census with a probability of selection proportional to size. Data were weighted by the inverse of the individual's probability of selection, then re-weighted by age, sex and location to benchmarks derived from the latest .Estimated Resident Populations produced by the ABS. Missing responses to questions were followed up by telephone where possible. Given that colorectal cancer is rare under the age of 40, and screening efforts have principally targeted the over 40 age group, this section of the study used only data for individuals aged 40 or over from the Health Omnibus Survey.

Analysis of the data included frequency tabulations, simple cross-tabulations, univariate analysis and step-wise logistic regression using the SAS statistical package. Weighted data were used in all of these analyses - in all of the tables, both actual numbers of individuals and weighted frequencies are presented. All frequencies referred to in the text represent weighted frequencies. The CATMOD and LOGISTIC procedures of the SAS statistical package were used. All of the main effects identified in the univariate analysis were fitted. Analyses included the weighting factors previously described. Stepwise logistic regression was undertaken to identify possible interactions between variables.

Data for the surveys of screening participants were collected by means of postal questionnaires, as previously described in Section 2.31. A series of univariate analyses were undertaken for test-negative screening participants to examine associations between respondent characteristics (age, sex, education, salary, occupation, presence of family history and reported intentions to participate in a number of health-related activities) and responses to questions on knowledge, attitudes, beliefs and intended future participation in FOBT screening.

4.3 Results

4.31 General Population Survey (Health Omnibus Survey)

From the sampling frame of 4608, there were 3379 participants in the population survey, and 1766 (52.3%) of these were aged 40 years and over. The average age of the eligible 1766 participants was 59.0 years and 40.8% were male. Other demographic information on participants is shown in *Table 4.1.* One-tenth of respondents (176 out of 1766) reported having a first degree relative with bowel cancer. The actual questions on colorectal cancer screening used in the population survey are shown in *Appendix 3.*

4.311 Participation in FOBT Screening (Table 4.2)

Aspects of screening participation examined included awareness of FOBT screening, previous participation or intended future participation, and a belief that the test would be worthwhile. While over 60% of respondents indicated they had heard of FOBT screening, few reported having the test in the past. The majority of respondents (86%) felt that the test would be worthwhile, after an explanation of the test from the interviewer. Despite this, only 28% said they actually intended to have the test, and one-quarter stated that they were unsure.

4.312 Attitudes and Beliefs about Bowel Cancer and Screening Tests (Table 4.3)

Almost three-quarters of participants believed that bowel cancer could be cured if detected at an early stage, and most of the remainder were unsure. Those who were born in countries other than Australia or UK/Ireland were more likely to respond "not sure" ($X^2 = 31.028$, d.f. = 4, $p < .001$). Only 13.0% stated definitely that they were unlikely to ever suffer from bowel cancer, and the majority of respondents (almost half) gave a "not sure" response. A history of bowel cancer in a first-degree relative was, not surprisingly, a predictor of this response - those with a positive family history were more likely to believe they were susceptible ($X^2 = 11.515$, d.f. = 2, $p = .003$). Less than one third of respondents indicated they would

feel uncomfortable about collecting a faecal specimen and sending it into a laboratory and only a small percentage were unsure. Those age 55 years or more were more likely to indicate they were unsure (X^2 = 16.629,. d.f. = 2, $p < .001$). Over one-third of respondents indicated they would "rather not think about bowel cancer or taking a screening test".

4.313 Participation in Other Health-Screening Activities

Respondents were also asked to indicate their degree of participation in other forms of health screening, and the results are shown in *Figure 4.1.* Over two-thirds of respondents said they would get their blood pressure checked at least once a year, and this proportion rose with age. Almost one-fifth were unsure. There was a greater deal of uncertainty about cholesterol screening - over one third of respondents were unsure of their intended future participation. Those aged 65 and over were least likely to report an intention to participate.

Of the total of 1047 women who were asked about intended future participation in cervical cancer screening, 28% reported an intention of at least once a year, ranging from 55% in the 40-44 age group to 8% in the 65+ age group (the current recommendation for women of average risk between the ages of 50 and 75 in South Australia is two-yearly screening). Women in older age groups were more likely to be unsure or to indicate they did not intend to participate at all. Almost half of the total sample of women were unsure of their intended participation in mammography, and this did not vary considerably between age groups. In the 55 to 64 years age group, 44% of respondents reported an intention to participate in mammography screening, while 12% said they definitely would not.

4.314 Determinants of FOBT Screening Participation (Tables 4.4 to 4.7)

For each of the "outcome" measures (awareness of FOBT screening, previous or intended future participation and belief in worthiness), logistic regression models

were fitted which included all of the associations identified in the univariate analyses. Age and sex were included in all of the models.

There were a number of significant effects for demographic variables: Females were more likely to be aware of screening tests for bowel cancer, and to believe the test would be worthwhile. Awareness of screening tests was also more common in participants born in Australia or UK/Ireland. An intention to take the test was associated with being younger, having a first-degree relative with colorectal cancer, having a university degree and being widowed as opposed to currently married. Occupation and income had no significant effects in the models.

All of the attitudes and beliefs examined in this survey had an influence on awareness of FOBT-screening tests (particularly, a belief that colorectal cancer can be completely cured if it is found at an early stage). Those who held this belief were also more likely to consider FOBT screening tests to be worthwhile, whereas those who felt they were unlikely to ever suffer from bowel cancer were more likely to be unsure. Perceived personal vulnerability to colorectal cancer was also associated with an intention to take the test while willingness to consider the topic and acceptance of the screening procedure were associated with a past history of FOBT screening.

Reported intentions in relation to other screening activities were included in the logistic regression models to examine their influence on the participation-related variables. Reported intentions in relation to blood pressure checks had little effect on outcome variables, while a reported intention to undertake regular cholesterol testing appeared to have a marked effect. Women who intended to have pap smears at least once a year, (as opposed to 6 to 10 yearly or never) were more likely to be aware of screening tests for bowel cancer. Also, women who intended to have pap smears and/or mammograms at least every year, were more likely to

believe that FOBT screening tests would be worthwhile and to report an intention to take a test.

4.32 Survey of Screening Participants

Response rates and characteristics of respondents in the questionnaire surveys of screening participants are described in Chapter 2. Further information on socio-demographic characteristics of test-negative survey respondents (which were examined for their influence on outcome variables) is shown in *Table 4.8.*

4.321 Knowledge, attitudes and beliefs (Table 4.9)

Like participants in the general population survey, over two-thirds of respondents believed that bowel cancer can be cured if detected at an early stage. This belief was slightly stronger in test-positive participants (76.9% vs 69.9%). Approximately 38% of test-negative respondents and 21% of test-positive respondents reported a perceived personal susceptibility to bowel cancer in the future by disagreeing with the statement "I am unlikely to suffer from bowel cancer in the future" (compared with 39% in the general population survey). However, amongst the test-negative respondents only 5% indicated they frequently worried that they may have bowel cancer, although 61% indicated they occasionally worried . Less than 40% of both test-negative and test-positive respondents were sure that bowel cancer runs in families.

Bivariate analyses to examine associations between predictor variables and these responses to questions on knowledge, attitudes and beliefs were undertaken. Those in younger age categories were more likely to hold the belief that bowel cancer can be cured if detected at an early stage (X^2 = 13.04, p = .005, d.f. = 3). Respondents with higher levels of education were also more likely to report this belief (X^2 = 14.13, p = .007, d.f. = 4). Those with a family history of bowel cancer were more likely to report concern over the possibility of having bowel cancer (X^2 = 6.75,

p = ..009, d.f. = 1) and to be aware that bowel cancer runs in families (X^2 = 12.55, p < .001, d.f. = 1). Females were also more likely than males to be aware of the familial pattern of bowel cancer (X^2 = 7.65, p = .006, d.f. = 1). Occupation, which was ranked according to an occupational prestige scale (Daniel, 1984), had no effect in these analyses.

4.322 Intended future participation in FOBT screening

Participants were also asked to report their intentions to participate in FOBT screening in the future. *Table 4.10* shows that a reported intention to participate in annual FOBT screening was more common in participants with negative results (72% vs 36%), while test-positive participants were more likely to be unsure about their intentions. In total, 90.8% of test-negative participants and 58.9% of test-positive participants reported an intention to take a FOBT screening test at some time in the future, compared with 28% in the general population survey *(Table 4.2).*

Respondents were also questioned on participation in other health-related activities, in order to make comparisons with the general population survey and to examine the effect of these responses as predictors of participation in FOBT screening. Frequent participation in all of the activities examined (cervical cancer screening, mammography, cholesterol testing and blood pressure monitoring) was reported more commonly in the survey of screening participants (*Figure 4.2*) than in the general population survey (*Figure 4.1*). Amongst test-negative screening participants, intended annual FOBT screening was associated, in bivariate analyses, with reported intentions to frequently participate in these other health-related activities, particularly mammography (X^2 = 9.67, p = .002, d.f. = 1) and cholesterol testing (X^2 = 33.6, p < .001, d.f. = 1). A positive family history of bowel cancer was the only other predictor of intended annual FOBT screening identified (X^2 = 9.64, p = .002, d.f. = 1).

4.4 Discussion

The sampling strategy used in the general population survey should produce a representative sample of the South Australian population. As previously discussed, non-response levels in the screening participant surveys impose some limitations on generalizability. A number of comparisons are made in this chapter between the surveys of the general population and of screening participants. Comparisons of age and sex of respondents to these surveys are summarised in *Table 4.11,* and no major differences are seen. However, if educational status of test-negative screening participants and general population survey participants are compared *(Tables 4.1 & 4.8),* it can be seen that screening participants reported, on the whole, higher levels of educational achievement. This may, in itself, explain some of the observed differences in knowledge, attitudes, health beliefs and health practices between the two groups.

4.41 Awareness of FOBT screening, participation, and perceived worthiness (in general population)

Given the limited endorsement of FOBT screening by health professionals in Australia, it is perhaps surprising that almost two-thirds of surveyed individuals were aware of these tests, and that 15% had been tested. Awareness of available tests is a strong determinant of screening activity, as illustrated by Australian research on mammography participation (Irwig et al 1991).

Data from the 1987 National Health Interview Survey (a personal interview nationwide household survey), suggest even higher levels of awareness and usage in the US (Brown et al, 1990). Of the 9000 individuals aged over forty years in this survey, 80.9% of men and 85.0% of women had heard of FOBT screening, and 36.2% of men and 36.3% of women had had the test. Polednak (1990) found that 69% of Americans had heard of FOBT screening in a 1988 telephone survey. The proportion of Americans who had ever had a FOBT screening test is reported

to have risen by 17% between surveys carried out in 1983 and 1987 (American Cancer Society, 1988).

Reported usage of FOBT screening may, however, be overestimated - some individuals will mistake other tests for a FOBT, and in some cases the test will have been used by clinicians to investigate symptoms (case finding, not screening). Furthermore, bowel symptoms may prompt some individuals to take the test - again, using the test in the presence of symptoms cannot be classified as screening. As indicated in Chapter 2, a significant proportion of participants in the IMVS FOBT screening programme reported symptoms.

Belief in the worthiness of FOBT screening was included as an outcome measure of likely screening participation as it is so closely linked to participation. Beliefs about potential benefits of carrying out behaviours have been strongly associated with health practices (Bandura et al, 1984) (Wardle & Steptoe, 1990), and perceived test efficacy has been shown to influence participation in FOBT screening (Myers et al, 1990) (Dent et al, 1983) and breast cancer check-ups (McCusker and Morrow, 1980). The finding that most respondents considered FOBT screening to be worthwhile yet only 28% reported an intention to take the test suggests that there are many factors which influence the decision to participate. A number of these possible influences on screening participation (including family history, sociodemographic factors, participation in other health-related activities and attitudes and health beliefs) have been measured and are included in the models used in this analysis - it is likely, however, that many other complex determinants of participation in this form of screening exist, and this issue is further examined in section 4.46.

4.42 Influence of Family History on Screening Participation

Ten per cent of respondents in the population survey reported a history of colorectal cancer in a first-degree relative - this is consistent with other research in Western populations (Eddy et al, 1987). Personal experiences with cancer can profoundly influence the decision to participate in screening (Glockner & Holden, 1992) (Holt, 1991), and experience with relatives suffering from cancer appears to be a particularly motivating factor. It is likely also that first-degree relatives will be aware of their increased risk of the disease (Lovett, 1976).

Given that first-degree relatives of individuals with colorectal cancer have a two- to four-fold increased risk of the disease (Lovett, 1976), it is, perhaps, appropriate that they appear to be more inclined to participate in FOBT screening (as found in the general population survey). These findings are consistent with previous Australian research - Macrae et al (1986) demonstrated that, for women, family history positively affected initial acceptance of a take-home hemoccult test kit (although it did not influence subsequent participation). Research from the US has also shown that compliance with FOBT and endoscopic screening is significantly higher in individuals with a family history of colorectal cancer (Stephenson et al, 1993). Adherence to mammography guidelines has also been found to be significantly associated with a family history of breast cancer (Zapka et al,1991), while knowing someone with breast or other cancer has been shown to be an incentive for participation in mammography (Glockner & Holden, 1992).

Findings from the survey of participants provide additional evidence that the presence of a family history of colorectal cancer influences knowledge, attitudes and intentions in relation to colorectal cancer and related prevention activities. Furthermore, as discussed in Chapter 2, almost a quarter of screening participants reported a history of colorectal cancer in a first-degree relative

(compared to 10% in the population survey), indicating that family history is a strong motivator in FOBT screening participation.

4.43 Influence of Sociodemographic Factors on Screening Participation

Most research on FOBT screening suggests increasing compliance and participation with age (Myers et al, 1990) (Macrae et al, 1986) (Polednak, 1990) (Hoogerwerf et al, 1987), yet in the general population survey younger individuals appeared more likely to report an intention to take the test. While a stronger inclination to take preventive measures might be expected with increasing age, possible explanations for these findings may include embarrassment over FOBT screening which has been reported in the elderly (Hoogewerf et al, 1990).

Male respondents in the population survey were less likely to be aware of FOBT screening and to believe testing would be worthwhile. Better compliance in women has been noted in the Nottingham trial of FOBT screening (Hardcastle et al, 1989). FOBT screening, unlike most cancer screening tests, is aimed at both men and women and this has important implications for recruitment - men may be less accustomed, and hence more resistant, to taking screening tests which are potentially unpleasant and uncomfortable.

The statistical models used in the population survey analysis were unable to demonstrate significant associations between participation in FOBT screening and occupation and income. Similarly, no associations were found in the survey of test-negative screening participants between intended future participation or colorectal cancer-related knowledge, attitudes and beliefs and occupational prestige score and income. These findings are in contrast to the observed association between FOBT screening participation and residence in higher income areas of Adelaide described in Chapter 2, and the frequently observed influence of SES on participation in health-related activities in the literature; an

association between higher socioeconomic status and screening participation has been observed in relation to mammography (Maclean et al, 1984), and cervical smears (Hayward et al, 1988). Furthermore, a specific association between low income and poor participation rates in breast and cervical cancer screening has been demonstrated in US research (Harlan et al, 1991) (Whitman et al, 1991) (Zapka et al, 1991), although few studies have examined the individual effect of occupation.

Analyses of the socioeconomic determinants of screening participation such as these are important, as it is often those in lower socioeconomic groups who have less favourable cancer mortality experiences - while a positive association between SES and colorectal cancer incidence has been observed in Australian populations (Williams et al, 1991), significantly lower colorectal cancer survival rates have been noted in lower SES groups in the South Australian population (Bonett et al, 1984). Less is known about the influence of SES on participation in screening programmes for colorectal cancer, although Farrands et al (1984) found no evidence of a social class trend in acceptance of a FOBT screening test in the Nottingham trial of colorectal cancer screening.

The population survey did, however, show that individuals with university degrees were more likely to indicate they intended to take a FOBT screening test. An association between higher education and screening participation is frequently observed - higher levels of education have been associated with awareness and use of FOBT's (Brown et al, 1990) (Macrae et al, 1986) and participation in cervical cancer screening programmes (Ronco et al, 1991) (Harlan et al, 1991). A telephone survey conducted in the US in 1988 (Polednak, 1990) found that education level was positively associated with cancer knowledge and screening, which is consistent with the finding in the participants' survey of an association

between higher levels of education and knowledge of the curability of colorectal cancer.

4.44 Influence of reported intented participation in other health-related activities

Results from the general population and participant surveys suggest associations between FOBT screening and participation in cervical screening, mammography and cholesterol testing. In particular, it appears that FOBT screening participants are more likely to also participate in these other health-related activities. It seems plausible that there are groups within the community who have generally positive attitudes towards preventive health practices - a finding which has previously been demonstrated with FOBT screening (Farrands et al, 1984) and cervical cancer screening (Ronco et al, 1991). This has important implications for the development of recruitment strategies for screening programmes in Australia, as it suggests there may be a group in the population of who, in relative terms, are consistently neglected by all health screening initiatives.

4.45 Responses examining knowledge, attitudes and beliefs in relation to colorectal cancer

4.451 Comparison of results with other research

The population survey suggests a high level of perceived personal susceptibility to colorectal cancer in Australians - only a minority of respondents considered they were "unlikely to ever suffer from bowel cancer". This compares with a recent Australian survey on breast cancer in which 22% of women regarded themselves as being susceptible (Irwig et al, 1991).

A belief that colorectal cancer can be cured (which, indeed, it can) may be interpreted as a measure of both knowledge and attitude. Approximately one-third of respondents in both of the surveys reported in this chapter indicated they were uncertain about this question. Knowledge deficits in relation to the curability of cancer have been demonstrated in previous Australian research (Baghurst et al,

1992), while other research on colorectal cancer has demonstrated a limited understanding in the community in areas such as risk factors, lifetime risk, survival rates, dietary recommendations and preventive strategies (Dent & Goulston, 1982) (Clover et al, 1991) (Farrow et al, 1990). Conversely, the majority of respondents did believe that colorectal cancer can be cured provided it is detected early, which supports existing evidence that Australians believe preventive strategies can reduce cancer risk (Hill et al, 1991).

4.452 Ability of these Factors to Predict Health-related Behaviour

Given the complexity of determinants of health-related behaviour, it is not surprising that the Health Belief Model frequently fails, in many analyses of health-related behaviour, to fully account for the range of observed behaviours (Thompson et al, 1986) (Langlie 1977) and it is suggested that the HBM, because of its lack of predictive power, provides a useful framework rather than a true model for analysing individuals' participation in screening programmes. Statistical models which examine participation in screening activities and which include HBM components, frequently find that the HBM accounts for only a small proportion of the observed variance (Macrae et al, 1986) (Gillam, 1991) (Calnan & Rutter, 1986). It may be that alternative models which take into account a wider range of determinants of human behaviour (such as social and economic factors) should be developed if more accurate predictions are to be made about participation in cancer screening.

Nevertheless, the associations between attitudes and beliefs (particularly perceived susceptibility and a belief in the curability of colorectal cancer) and FOBT screening participation-related variables demonstrated in the population survey reported in this chapter allow comparisons with other similar research. The finding that perceived susceptibility to the disease was associated with greater awareness of FOBT screening and intention to participate has previously been

demonstrated in Australian research on compliance with FOBT screening (Macrae et al, 1984) and supports evidence that perceptions of vulnerability predict preventive health behaviour (Becker et al, 1977).

Similarly, the association between a belief in the curability of colorectal cancer and screening participation-related variables is consistent with previous research which has demonstrated associations between cancer knowledge and positive attitudes towards participation in FOBT screening (Brown et al, 1990) (Farrands et al, 1984) mammography (McCance et al, 1990) and cervical cancer screening (Nathoo, 1988). Furthermore, an optimistic attitude toward the curability of colorectal cancer has been linked with participation in FOBT screening (Brown et al, 1990) (Myers et al, 1990) (Farrands et al, 1984).

The finding that respondents who indicated they would feel uncomfortable about taking FOBT screening tests were less likely to have had a FOBT screening test is, again, consistent with previous research which suggests that embarrassment and other negative feelings about FOBT screening are barriers to participation (Macrae et al, 1984) (Hoogerwerf et al, 1990). Previous research also suggests that a significant proportion of Australians do not like to think about cancer (Dent & Goulston, 1982) - the population survey provides further evidence for this in relation to colorectal cancer, and also demonstrates the negative association of this attitude with previous participation in FOBT screening.

If factors such as perceived susceptibility and a belief in the curability of colorectal cancer are, as suggested in the survey, important determinants of participation in FOBT screening, then it is likely that the success of any future mass FOBT screening programs will depend on raising community knowledge and awareness of colorectal cancer - particularly if potential participants are to make well-informed decisions about screening. Furthermore, the acceptability of FOBT

screening and mechanisms for reducing denial in relation to colorectal cancer will need to be addressed.

4.46 Other Factors which may Influence FOBT screening participation

There are many other factors, not measured in this analysis, which may have influenced responses associated with FOBT screening participation in the population survey. For example, contact with clinical services (particularly in terms of frequency, consistency and the attitude of the health care provider) appears to strongly influence participation in screening programmes (Hobbs et al, 1992) (Mant et al, 1992) (Faivre et al, 1991). Having regular contact with a source of medical care has been associated with participation in FOBT screening (Brown et al, 1990) (Farrands et al, 1984) and mammography (Rimer et al, 1991) (Maclean et al, 1984). Furthermore, having a doctor recommend screening has been shown to be a strong incentive for participation in mammography (Glockner & Holden, 1992) (Reeder et al, 1980), FOBT screening (Myers et al, 1990) and screening sigmoidoscopy (Holt, 1991).

Anxiety is another factor which may either promote or inhibit participation in screening programmes (Kash et al, 1992). It is suggested that the most important factors for not participating in screening programmes include fear of the examination or of a positive result (Schwoon & Smoll, 1979). In a survey of women in the US, Gram & Slenker (1992) found that while having a negative screening mammogram decreases the prevalence of anxiety about breast cancer, women who elect to attend screening are still generally more anxious about breast cancer than those who do not attend. Conversely, participation in cervical screening has been found to be inhibited by high levels of anxiety about the test and cervical cancer (Nathoo, 1988).

Results of the two surveys also suggest that intended future participation in FOBT screening is strongly influenced by previous participation. Furthermore, it appears that the results of previous screening tests are important; there are a number of possible explanations for the test-positive group being less likely to report an intention of annual screening. As indicated in Chapter 3, they may have incurred a number of negative experiences, including unpleasant investigations, considerable personal expense and cancer fear arousal. Given this apparent negative effect on subsequent rounds of screening, this is a further example of the importance of keeping false positive rates in periodic screening to a minimum.

Decisions to participate in screening may be further influenced by practical issues (Maclean et al, 1984) (Schwoon & Smoll, 1979) - perceived inconvenience has been demonstrated to have a negative effect on participation in FOBT screening (Dent et al, 1983) and mammography (Rimer et al, 1989). Clearly, then, decisions to comply with an invitation for a screening test, or to more actively seek out available screening tests, have complex determinants. It is argued that individuals weigh up the costs and benefits of health interventions which are offered to them; their perceptions and the personal and social circumstances in which they live are crucial to their decision-making (Donovan & Blake, 1992).

4. 5 Summary

The survey of a random sample of the South Australian population described in this chapter examines knowledge, attitudes and beliefs in relation to colorectal cancer and its prevention. Results from the survey confirm findings from previous research that, while community awareness of FOBT screening is high, there is a lack of widespread participation in this form of screening. A number of potential barriers to the introduction of widespread FOBT screening in the Australian population are also suggested by this research - they include knowledge deficits,

denial of susceptibility to colorectal cancer and unwillingness to consider the topic in a significant proportion of the population.

A reduction in knowledge deficits and to barriers to action in relation to all forms of screening has been identified as a priority in cancer prevention in Australia (Owen et al, 1991). This chapter has attempted to identify a number of these "barriers to action" in relation to FOBT screening. While, as previously indicated, FOBT screening is not widely endorsed in Australia (and there are no plans for the introduction of mass screening), experience with programmes screening for breast and cervical cancer suggests that a careful analysis is warranted, prior to the introduction of such programmes, of the most appropriate target groups for screening, their characteristics, the potential barriers to participation and how these barriers can be overcome. Having examined the feasibility of FOBT screening in these terms, the following chapter focuses on mechanisms of delivery and co-ordination of screening - tasks in which, in the Australian context, the general practitioner is likely to have a critical role.

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Table 4.1 - Demographic information on population survey participants
(n = 1766)

	no.	weighted % of respondents
Country of birth		
Australia	1223	68.0%
UK/Ireland	282	15.7%
Other	217	16.3%
Marital status		
Married	1145	64.5%
Widowed	338	19.0%
Divorced	143	8.1%
Never married	81	4.6%
Separated	56	3.2%
De facto	13	0.7%
Schooling		
Left school age ≤ 15	733	41.3%
Left school age > 15 but no further qualification	302	17.0%
Trade qualification/apprenticeship	274	15.4%
Certificate/diploma	315	17.7%
Bachelor degree or higher	152	8.6%
Occupation		
Professionals, managers/administrators	339	19.2%
Para-professionals, students	109	6.2%
Clerks, tradespersons/personal service workers	777	43.9%
Labourers, plant & machinery operators	339	15.9%
Home duties	262	14.8%
not stated	8	
Income		
$12,000 or less	489	33.0%
$12001 - $20,000	268	18.1%
$20,001 - $30,000	173	11.7%
$30,001 - $40,000	164	11.1%
$40,001 - $50,000	142	9.6%
$50,001 - $60,000	92	6.2%
$60,001 - $80,000	86	5.8%
over $80,000	66	4.5%
not stated	292	

Table 4.2 - Participation in FOBT screening in population survey participants

n = 1766

		yes	no	not sure
Awareness of FOBT screening	no.	1098	651	17
	weighted %	61.8%	37.3%	0.9%
Previous participation	no.	257	1495	14
	weighted %	14.6%	84.7%	0.7%
Belief test would be worthwhile	no.	1497	119	150
	weighted %	85.7%	6.6%	7.7%
Intention to have test	no.	472	864	430
	weighted %	28.0%	47.8%	24.2%

4.3 - Attitudes and beliefs about bowel cancer and screening tests in population survey

		yes	no	not sure
;f that bowel cancer, if found at an 'ly stage, can be completely cured n = 1765	no.	1270	93	402
	weighted %	71.5%	5.6%	23.0%
'erceived personal susceptibility to bowel cancer n = 1766	no.	679	244	843
	weighted %	38.6%	13.0%	48.5%
Willingness to consider the topic n = 1765	no.	1022	607	136
	weighted %	58.6%	33.8%	7.7%
Reported acceptability of collecting stool specimen n = 1764	no.	1223	482	59
	weighted %	69.0%	27.8%	3.2%

Table 4.4 - Predictor variables associated with awareness of screening tests for colorectal cancer

	Odds ratio	95% confidence interval
Female gender	**2.33**	1.29 - 4.22
Birthplace Australia versus elsewhere (excluding UK/Ireland)	**2.43**	1.73 - 3.41
Birthplace UK/Ireland versus elsewhere (excluding Australia)	**2.62**	1.71 - 4.03
Belief that bowel cancer, detected at an early stage, can be completely cured	**2.30**	1.73 - 3.06
Belief in personal suceptiblity to bowel cancer	**2.06**	1.24 - 3.43
Willingness to consider bowel cancer and screening tests	**1.58**	1.09 - 2.29
Perceived acceptability of collecting stool specimen	**1.35**	1.03 - 1.77
Reported intention to participate in cervical cancer screening at least once a year (vs never)#	**1.76**	1.01 - 3.06

*n = 1766 except for those analyses marked # where n = 1052 (female participants only)

Table 4.5 - Predictor variables associated with previous participation in FOBT screening

	Odds ratio	95% confidence interval
Presence of family history of bowel cancer	**3.81**	2.49 - 5.83
Willingness to consider bowel cancer and screening tests	**2.44**	1.61 - 3.71
Perceived acceptability of collecting stool specimen	**1.59**	1.08 - 2.33
Reported intention to participate in cholesterol screening at least once a year (vs not sure)	**1.64**	1.10 - 2.42

*n = 1766

Table 4.6 - Predictor variables associated with a belief in the worthiness of FOBT screening

	Odds ratio	95% confidence interval
Female gender	**1.51**	1.04 - 2.18
Belief that bowel cancer, detected at an early stage, can be completely cured	**1.61**	1.12 - 2.31
Belief in personal suceptiblity to bowel cancer	**1.40**	1.02 - 1.92
Reported intention to participate in cervical cancer screening at least once a year (vs never)#	**2.36**	1.36 - 4.08
Reported intention to participate in mammographic screening at least once a year (vs 6-10 yrly or never)#	**3.25**	1.42 - 7.41
Reported intention to participate in cholesterol screening at least once a year (vs not sure)	**1.59**	1.12 - 2.27

*n = 1766 except for those analyses marked # where n = 1052 (female participants only)

Table 4.7 - Predictor variables associated with intention to participate in FOBT screening

	Odds ratio	95% confidence interval
Younger age (statistics for each one-year decrease)	**1.03**	1.01 - 1.05
Education to level of bachelor degree (vs school to age 15 only)	**1.40**	1.01 - 1.97
Widowed (vs married)	**1.96**	1.09 - 3.52
Presence of family history of bowel cancer	**1.89**	1.47 - 2.41
Belief in personal suceptiblity to bowel cancer	**1.44**	1.09 - 2.11
Reported intention to participate in cervical cancer screening at least once a year (vs not sure)#	**1.64**	1.09 - 2.44
Reported intention to participate in mammographic screening at least once a year (vs 6-10 yearly or never)#	**3.14**	1.69 - 5.83
Reported intention to participate in cholesterol screening at least once a year (vs 6-10 yearly or never)	**2.15**	1.38 - 3.36

*n = 1766 except for those analyses marked # where n = 1052 (female participants only)

Table 4.8 Sociodemographic information on test-negative participant survey respondents

	n	%
Age (n = 456)		
40-48	109	23.9%
49-56	115	25.2%
57-64	119	26.1%
65+	113	24.8%
Sex (n = 461)		
male	200	43.4%
female	261	56.6%
Education (n = 453)		
secondary school not completed, left school ≤ 15	94	20.8%
secondary school not completed, left school > 15yrs	95	21.0%
completed secondary school but nil else	129	28.5%
completed secondary school + diploma, TAFE/nursing qualification, tradecertificate, or completed apprenticeship	36	7.9%
completed secondary school + university/teaching/health profession degree (other than nursing)	99	21.9%
Salary (n = 420)		
no income	45	10.7%
$1 - $6000	57	13.6%
$6001 - $18,000	132	31.4%
$18,001 - $32,000	85	20.2%
$32,001 - $50,000	75	17.9%
$50,000 +	26	6.2%

Table 4.9 - Health beliefs in relation to colorectal cancer in screening participants

Attitude/belief:				
Bowel cancer, if found at an early stage, can be completely cured	TEST-NEGATIVE RESPONDENTS (n = 458)	yes	no	unsure
	no.	320	5	133
	%	69.9%	1.1%	29.0%
				missing: 3
	TEST-POSITIVE RESPONDENTS (n = 255)	yes	no	not sure
		196	3	56
		76.9%	1.2%	21.9%
				missing: 7
Reported perceived personal susceptibility to developing bowel cancer in the future	TEST-NEGATIVE RESPONDENTS (n = 453)	yes	no	not sure
		173	48	237
		38.2%	10.5%	52.3%
				missing: 8
	TEST-POSITIVE RESPONDENTS (n = 256)	yes	no	not sure
		53	27	176
		20.7%	10.5%	68.8%
				missing: 6
Reported concern about the prospect of having bowel cancer	(TEST-NEGATIVE RESPONDENTS ONLY, n = 458)	never worried	occasionally worried	frequently worried
		153	281	24
		33.4%	61.4%	5.2%
				missing: 3
Knowledge/belief that bowel cancer runs in families	TEST-NEGATIVE RESPONDENTS (n = 453)	yes	no	not sure
		180	69	204
		39.7%	15.2%	45.0%
				missing: 8
	TEST-POSITIVE RESPONDENTS (n = 259)	yes	no	not sure
		95	74	90
		36.7%	28.6%	34.7%
				missing: 3

Table 4.10 - Participants' intended future participation in FOBT screening

		once a year	every 2-5 years	every 5-10 years	never	not sure
Test-negative respondents (n = 453)	n	326	85	0	4	38
	%	72.0%	18.8%	0%	0.9%	8.4%
Test-positive respondents (n = 258)	n	92	54	6	18	88
	%	35.7%	20.9%	2.3%	7.0%	34.1%

Table 4.11 Comparitive information on survey participants

	Screening Participants Survey		Population Survey
	Test-negative	Test-positive	
% Male	43.4%	53.4%	40.8%
Average age	56.1	60.6	59.0

Figure 4.1 - **Population survey respondents' reported intentions to participate in other health screening activities**

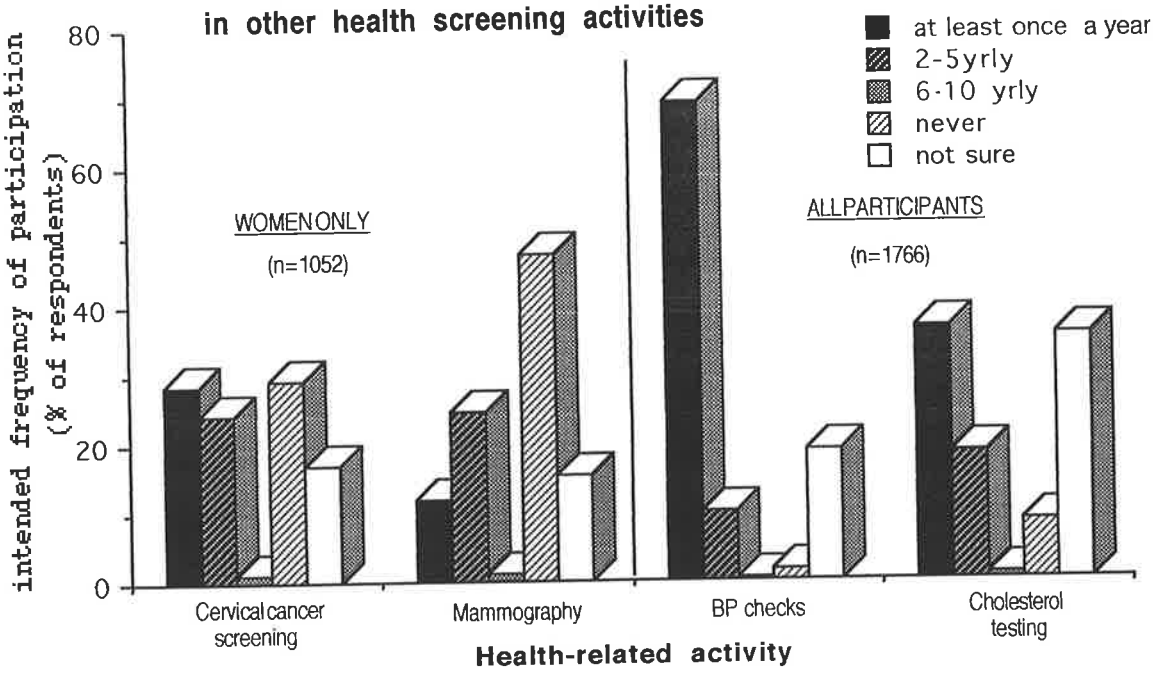
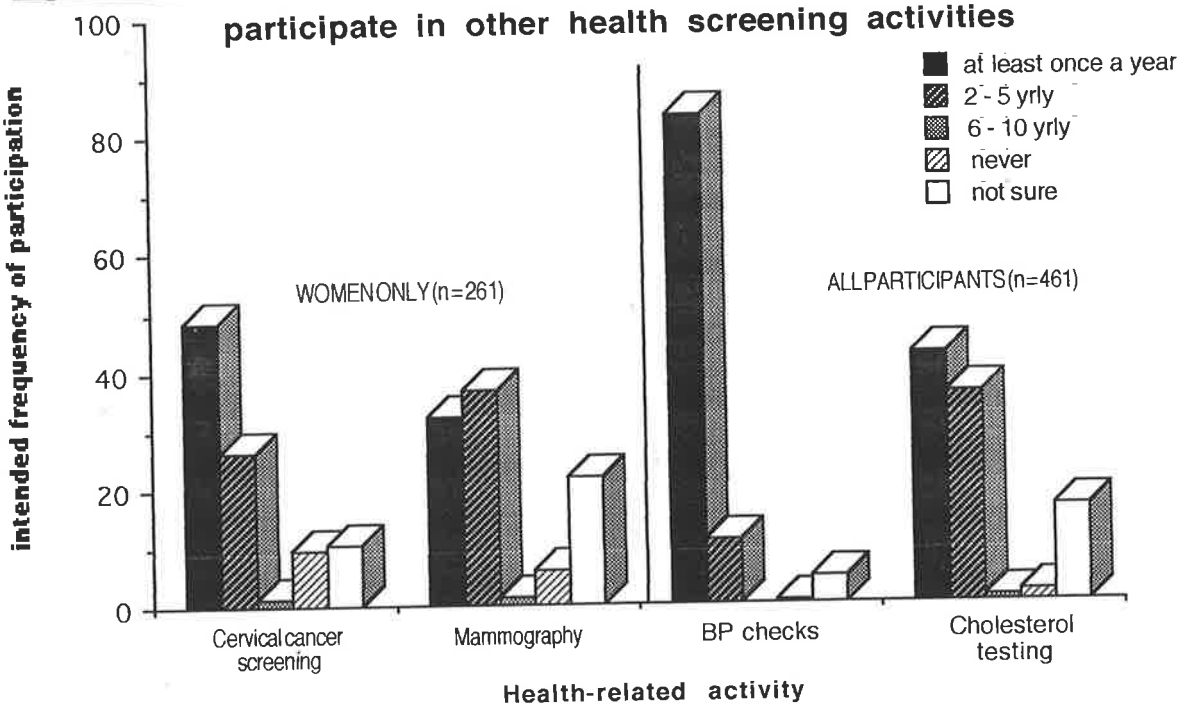


Figure 4.2 - **Test-negative screening participants' reported intentions to participate in other health screening activities**



Chapter 5:

Screening for colorectal cancer: knowledge, attitudes and practices of South Australian GPs

5.1 Introduction

This chapter examines the role of general practitioners (GPs) in screening for colorectal cancer. General practitioners are likely to be at the forefront of any future FOBT screening programmes - they are uniquely placed in the Australian health care system to co-ordinate the screening process through activities such as providing and recording relevent information and arranging follow-up of test-positive individuals. In view of this, an examination of their knowledge, attitudes and practices in relation to colorectal cancer screening was considered to be an important component of the SACCS study.

While there is evidence that Australian GPs are keen to expand their role in health screening activities (Weller et al, 1992), there are many factors which may act as barriers to the effective delivery of these services in the primary care setting. Australian evidence suggests that the population is in favour of preventive services (such as colorectal cancer prevention) being provided by general practitioners, and that general practice is a cost-effective setting for such activities (Better Health Commission, 1986).

Furthermore, if benefits from FOBT screening are consistently demonstrated in randomized trials, there is likely to be enthusiasm amongst health professionals in Australia for the rapid introduction of screening activities nationally. Experience from other screening programmes in Australia (such as cervical cancer screening) suggests that it is important to preceed this with a careful analysis of mechanisms of delivery, such as the role of the GP (Quinn, 1989). GPs have a critical role in

the success of existing screening programmes in Australia. If screening is to be successful it must achieve adequate levels of compliance in the target poulation, and general practice-based strategies (such as advice from the GP, or use of other personnel or computers in the practice) have been shown in a number of studies to have a compliance-enhancing effect on FOBT screening (Cargill et al, 1991) (Dietrich et al, 1991) (Mant et al 1992) (McPhee et al, 1991) and other preventive procedures (Pommerenke & Weed, 1991) (Harris et al, 1990). Furthermore, physician recommendation has been shown to have a strong effect on participation in screening programmes such as mammography (Howe, 1992), while Launoy et al (1993) have found that patient compliance with FOBT screening is influenced by levels of GP motivation.

Even in the absence of widespread FOBT screening in Australia, GPs have a critical role to play in early diagnosis of colorectal cancer - given that early symptoms are often vague, colorectal cancer presents a considerable diagnostic challenge. The importance of encouraging individuals and their doctors to act quickly on symptoms such as rectal bleeding has been emphasized in the literature (Dixon et al, 1990) (Holliday & Hardcastle, 1979). Widespread screening for colorectal cancer would, however, have a profound effect on the way in which general practitioners deal with the disease - a much greater proportion of their time would be spent investigating individuals with positive screening tests. Furthermore, a widespread screening programme would, in all likelihood, lead to greater community awareness of the symptoms of colorectal cancer and an associated increase in the number of consultations for these symptoms.

To undertake screening effectively, general practitioners require clear guidelines from professional organizations which provide information on areas such as appropriate target groups and follow-up procedures for test-positive individuals. In Australia two sets of guidelines on FOBT screening are available for use by GPs.

One is the "Guide to Periodic Health Examinations" produced by the Royal Australian College of General Practitioners (1990). A more recent document entitled "Guidelines for Screening for Colorectal Cancer" has been produced by the Australian Gastroenterology Institute (AGI) (1991) - this was circulated widely to GPs in Australia a few months before the current study was undertaken, and the extent to which these guidelines were known or had been adopted is, therefore, reflected in the results of this study. A revised set of AGI guidelines has been produced, in collaboration with the Australian Cancer Society, and it is planned to circulate these guidelines later in 1994.

Critical issues examined in this chapter include, therefore, GPs' knowledge and opinions in this area, the FOBT screening strategies they use, follow-up of test-positive individuals and familiarity with available guidelines. There is also an examination of the influence of a number of practitioner characteristics on many of these factors.

5.2 Methods

Data for this component of the SACCS study were collected by means of postal questionnaires. South Australian general practitioners were identified from a number of sources including the Royal Australian College of General Practitioners (RACGP) membership lists, the Medical Board of South Australia's Register of Medical Practitioners, the Health Insurance Commission's list of medical practitioners who provide general practitioner services and the telephone directory. After piloting, questionnaires were sent to 294 randomly selected GPs (208 city and 86 rural) - approximately one-fifth of all South Australian GPs (as identified in this survey). Assuming a response rate of 60 - 70%, this number was considered sufficient to allow generalization of results to the wider population of GPs, and to demonstrate differences of 10% or greater in FOBT screening knowledge, attitudes and practices amongst various groupings of GPs (at the 5%

level of statistical significance). A copy of the questionnaire used in this survey appears in *Appendix 4.*

Surveying was conducted from March 1992 to May 1992. There were three mailouts, 18 days apart. In addition, non-responders after the second mailout were contacted by telephone. All information was entered into the SAS statistical programme (1985) - frequency tabulations were undertaken, as well as univariate and logistic regression analyses.

5.3 Results

Of the 294 GPs surveyed, 15 were either no longer in practice or were not contactable. Of the remaining 279, 185 returned questionnaires - a response rate of 66.3%. There were no significant differences between responders and non-responders in terms of age or gender. Responders were more likely than non-responders to be affiliated with the RACGP ($p < .01$) and to be in rural practice ($p < .05$). The average age of respondents was 47.9 years, 81.1% were male and 78.4% obtained their medical degree in Australia. Other characteristics of respondents to this survey are shown in *Table 5.1.* For most GPs colorectal cancer appears to be a relatively rare presentation - 167 (92.3%) of the respondents estimated they would diagnose, on average, four or less cases per year. Only 26 respondents (14.1%) indicated they performed their own sigmoidoscopies.

5.31 Screening and follow-up practices

Reported preferences for screening for colorectal cancer using FOBT, colonoscopy and sigmoidoscopy are shown in *Table 5.2.* One-fifth of respondents endorsed FOBT screening for all patients over the age of forty (compared to two-fifths of respondents for screening of patients over fifty years of age). FOBT screening of first-degree relatives was widely accepted (93.5% of respondents) as

was screening of individuals with a past history of colorectal cancer or colorectal polyps (79.5% and 87.0% respectively). Almost four-fifths of GPs said they would provide FOBT screening for all patients who requested it.

Colonoscopy and, to a lesser extent, sigmoidoscopy, were strongly endorsed in individuals with a past history of colorectal cancer and/or first-degree relatives. Neither of these examinations were favoured as a form of screening for average-risk individuals. Only 14.1% of respondents indicated that they performed sigmoidoscopies themselves.

Respondents were asked how they would proceed if presented with an asymptomatic 55 year old patient with no additional risk factors for colorectal cancer who had a positive result on FOBT screening. Of the 175 respondents to this question, 120 (68.6%) said that they would repeat the test with the FOBT that they normally used. Of these, 25 (20.8%) indicated they would recommend only annual FOBT if the repeat test was negative, while the remainder advocated proceeding with further investigations despite the negative repeat test. In addition, of 183 respondents, 177 (96.7%) indicated they would perform digital rectal examination.

Reported preferences for modes of investigating the cause of the positive test in this patient are summarised in *Figure 5.1*. Respondents could choose *one or more* investigations they would use/recommend *initially* in investigating an FOBT-positive patient, and investigations they would use/recommend *only if their initial preferred investigations were inconclusive or unavailable.* Colonoscopy and barium enema were the preferred initial investigations - over 70% of respondents endorsed colonoscopy as a first-line investigation (53% in the case of barium enema), while 27.9% of respondents indicated that either of these investigations were suitable.

5.32 Prevention strategies for colorectal cancer - knowledge and attitudes

Responses to a number of statements relating to colorectal cancer screening knowledge and attitudes are shown in *Table 5.3.* A high proportion of respondents (44%) felt that there was convincing evidence that populations who are screened for colorectal cancer with FOBT have lower mortality from colorectal cancer. Over half of respondents felt they had received sufficient education in this area, and that there were adequate guidelines that they could follow for colorectal cancer screening. The majority of respondents also considered that early diagnosis of colorectal cancer improves overrall survival, and that detection and removal of adenomatous polyps decreases the incidence of colorectal cancer.

To further assess knowledge in this area, questions were included which examined familiarity with and interpretation of available evidence on primary risk factors for colorectal cancer. Results are shown in *Figure 5.2.* The majority of respondents felt that there is good evidence linking consumption of dietary fibre with a reduction in colorectal cancer risk. Almost half believed that there is good evidence in the case of reducing fat consumption. Almost one-fifth of respondents said they were unsure of the evidence in relation to fat consumption, alcohol, smoking and exercise, while 37% felt there is good evidence linking smoking and colorectal cancer. Respondents were less certain about evidence for alcohol and exercise.

Respondents were asked to select one or more strategies which they considered to hold the best prospect for a reduction in mortality from colorectal cancer. Results are summarised in *Figure 5.3.* While 32% of respondents advocated the use of mass FOBT screening (and 40% the revision/improvement of treatment regimes for colorectal cancer) there was strongest endorsement for the encouragement of GPs to be more rigorous in their follow-up of patients with

bowel symptoms (79.5%) and the encouragement of individuals to see their doctor early with bowel cancer symptoms (92.4%).

Respondents' opinions on methods of providing FOBT screening to the population (if it is to be provided at all) are summarised in *Table 5.4.* The most favoured strategy was the provision of screening by GPs to asymptomatic patients (at the *patients'* request). Two-thirds of respondents were in favour of a similar scenario in which the GP, rather than the patient, initiated the process. Centrally co-ordinated screening initiated by government or other organizations was generally not favoured - almost 40% of respondents considered this to never be acceptable, even in patients with increased risk of colorectal cancer. The provision of FOBT screening kits directly to the public (eg through pharmacies, health funds or other outlets) was considered to be acceptable for all individuals by over 60% of respondents.

5.33 Influence of GP characteristics

Most GP characteristics had little effect on outcome measures in this study. However, respondents who considered there is convincing evidence that populations who are screened with FOBT have lower mortality from colorectal cancer were more likely to recommend/endorse FOBT screening in all patients over the age of 40 ($X^2 = 7.29$, $p = .007$) and over the age of 50 ($X^2 = 7.05$, $p = .008$). When this association was examined in logistic regression models which included age, sex and country vs city practice, the belief that FOBT screening leads to mortality improvements remained a strong predictor of screening practices - for recommendation/endorsement of screening of patients over 40 the odds ratio (belief in mortality reductions vs non-belief) was 1.61 (95% C.I. 1.11- 2.24) while in the case of screening of patients over 50 it was 1.50 (95% C.I. 1.11 - 2.03). These respondents were also more likely to recommend/endorse mass FOBT screening ($X^2 = 8.647$, $p = .003$).

5.4 Discussion

This component of the SACCS study relied for its information on self-reports of attitudes, practices and opinions of general practitioners in a postal survey. Some caution is required in the interpretation of self-reports of this nature, as they can be influenced by a desire to provide answers which will be acceptable but do not reflect actual management (Dickinson et al, 1989). Respondents may wish to present the best impressions of themselves as representatives of general practice (Bucks et al, 1990). Valente et al (1986) argue that over-estimation by doctors of true levels of prevention-related activities may occur in questionnaire surveys of this kind. Nevertheless, FOBT screening is controversial, and "correct" or "acceptable" responses are not self-evident, so these effects may be minimal in this survey.

There is evidence that respondents to this study are representative of the wider population of GPs - respondents were similar in terms of age, gender and place of medical training to GPs who participated in a previous comprehensive survey conducted in South Australia (RACGP, SAHC & AMA, 1988). The response rate of 66.3% is average for postal questionnaire surveys of primary care doctors (Cartwright, 1978) (Sobal et al, 1985) and responders and non-responders had a similar demographic profile, which was consistent with other Australian GP surveys (Cockburn et al, 1988).

The over-representation of GPs affiliated with the RACGP may, however, produce an effect: these GPs are, perhaps, more likely to be involved in educational and quality-assurance activities, and this may influence screening practices. Affiliation with the RACGP was not, however, a strong predictor of any of the responses in this survey.

The finding that GP characteristics such as age, sex, RACGP affiliation and clinical exposure to colorectal cancer did not have a major influence on outcome measures is consistent with other research - while physician gender has been shown to influence the provision of women's health cancer screening, few physician characteristics appear to affect FOBT screening practices (Osborn et al, 1991). On the whole, it appears that most sociodemographic characteristics of doctors have an inconsistent influence on preventive practices (Walsh & McPhee, 1992). The effect of physician gender on the acceptability of centrally-organized health promotion activities has been examined in previous research (Cockburn et al, 1987) who found that, in contrast to the SACCS study in which no effect is demonstrated, female GPs are generally more accepting of this approach to prevention than males.

5.41 Screening practices

Although most respondents believed that efforts to detect colorectal cancer at an early stage are worthwhile, there was no widespread agreement over FOBT screening strategies (particularly for average-risk individuals). Similar inconsistencies have been demonstrated in overseas studies of primary care doctors. Coulter and Schofield (1991) have shown that while many UK general practitioners provide FOBT screening for a small proportion of their average-risk patients, they generally do not aim to provide it on a universal basis. Surveys of family physicians in the US indicate stronger endorsement of FOBT screening - its use was reported by 92% of respondents to an American Cancer Society survey (1990). Cummings et al (1984), in a survey of attitudes and opinions, found that while 95% of physicians believe that the FOBT is "useful as a first line of screening for colorectal cancer", 19% believe that it should not be promoted until there is evidence of its effectiveness in reducing mortality.

There was wider endorsement of screening for increased-risk individuals (eg those with a family history of colorectal cancer), with many respondents advocating combinations of FOBT, sigmoidoscopy and screening for this group. This is in contrast to a similar survey of Australian GPs conducted almost fifteen years ago (Macrae et al, 1982) which showed that only 23% of respondents recommended the screening of first-degree relatives (compared to 93.5% in this survey) - it would appear that screening of relatives is growing in acceptance.

Most respondents agreed with the statement that detection and removal of adenomatous polyps decreases the incidence of colorectal cancer. As indicated in Chapter 2, the benefits of detection and removal of polyps discovered as a result of screening are not consistently agreed upon in the literature, particularly in the case of small polyps. It has been argued that enthusiasm for polypectomy as a means of preventing colorectal cancer should be tempered (particularly in the case of small polyps), given that its value is unproven in clinical trials (Pollock & Quirke, 1991). A long-term follow-up study recently reported a very low incidence of colon cancer in individuals with small, tubular adenomas (4 out of 776), whether single or multiple (Atkin et al, 1992). There was a similarly low incidence of cancer in patients with only a single, small tubular adenoma that was only mildly or moderately dysplastic (4 out of 712).

It is of interest that almost all respondents endorsed digital rectal examination as part of the work-up of FOBT-positive individuals. It is suggested that only 10% of colorectal cancers will be detected on digital rectal examination (Schottenfeld & Winawer, 1980), and the findings of a digital examination are unlikely to influence the course of subsequent investigations. Macrae et al (1982) have shown that most doctors over-estimate the value of the digital examination. Nevertheless, medical training emphasises the importance of this procedure, and it may be

argued that it is a worthwhile examination, particularly if other pathology is discovered.

While colonoscopy was, in keeping with AGI Guidelines (1991), widely endorsed as a first-line investigation in FOBT-positive individuals, barium enema was also considered a first-line investigation by over half of respondents. Colonoscopy has been advocated as the initial investigation of choice in FOBT-positive individuals (despite its greater cost), as it is more accurate than barium enema in detecting polyps, and excision and biopsy of polyps can be performed during the procedure (Stroehlein et al, 1984) (Goulston & Dent, 1987) (Gryska & Cohen, 1987). It is also relatively safe - complications such as ischemic colitis and perforation are rare (Wheeldon & Grundman, 1990). Furthermore, there is evidence that it is more accurate than other modalities in evaluating the cause of rectal bleeding (Salmon, 1980) , although a degree of inaccuracy is always possible as it relies on a visual diagnosis by the physician (Neale et al, 1987). In a series of 66 patients with symptoms of colonic disease who had a negative rigid sigmoidoscopy, barium enema missed 73% of polyps - it gave the final diagnosis in 67% of patients whereas colonoscopy provided the diagnosis in 91% (Durdey et al, 1987).

Reasons that respondents to this survey did not unequivocally reject barium enema in favour of colonoscopy may include the relative ease by which barium enema can be arranged in general practice, its lesser cost and the fact that it does not require referral to a specialist. Furthermore, the barium enema is, in itself, able to provide valuable diagnostic information.

Around one-fifth of respondents supported the use of flexible or rigid sigmoidoscopy as a first-line investigation. Sigmoidoscopy does not lead to visualization of the entire lower bowel, but its cost is relatively small and it is

widely available. It is an investigation which can be undertaken by GPs (although only a small proportion of respondents to this survey performed their own sigmoidoscopies). There is no consensus in Australia on whether greater efforts should be put in to training GPs to carry out investigations such as sigmoidoscopy, or if referral of all patients with positive FOBTs for more definitive investigations should be encouraged. Concerns have been expressed over the training and skill needed, and the accuracy of such investigations if they are performed relatively infrequently - almost half the GPs in a UK survey thought that proctoscopy and sigmiodoscopy were not appropriate procedures for primary care (Jones, 1992). Nevertheless, research from the US suggests that family physicians can develop satisfactory skills in colonoscopy provided they have adequate exposure to the procedure (Rodney et al, 1993).

5.42 GP Cancer-Related Knowledge and Education

The finding that 44% of respondents believed that there is "convincing evidence that populations who are screened for colorectal cancer have lower mortality" has important implications, particularly in view of the fact that this belief had an influence on screening practices. Although Mandel et al (1993) have recently published results suggesting mortality improvements through FOBT screening, at the time of conducting the survey there was no such evidence. Similar knowledge limitations have been demonstrated in relation to the increased risk amongst first-degree relatives of individuals with colorectal cancer (Macrae et al, 1982) and awareness of risk factors and survival rates (Nichols, 1986). Previous Australian research has also demonstrated that GPs have misunderstandings over reimbursement procedures for screening activities including FOBT screening (Weller & Hiller, 1990).

The need for more accurate knowledge of breast cancer and mammography has also been suggested in Australian reasearch (Cockburn et al, 1989), particularly in

areas such as the relationship of breast cancer and age, and the knowledge of the age groups likely to experience a reduction in mortality from screening. It is essential that doctors have a clear understanding of an individual's risk for various cancers and the extent to which screening may alter the course of the disease through earlier diagnosis. Screening for colorectal cancer is particularly challenging for the GP, as evidence for its efficacy and widely accepted guidelines for its use are at an early stage of development.

Only 57% of respondents felt that they had received adequate education about strategies for the prevention of colorectal cancer - this supports the findings of an Australian study of recent medical graduates which demonstrated substantial deficits in relation to a number of areas of cancer-related knowledge, including the "existence of screening tests validly shown to reduce mortality" (Smith et al, 1991). A number of studies in the US and Australia have also demonstrated that primary care doctors feel they need more education and training in cancer prevention (Valente et al, 1986) (Orleans et al, 1985) (Bauman et al, 1989). In a US study of primary care physicians (Haber, 1992) only 13% believed they had received adequate education in preventive medicine. Furthermore, the majority believed that the effect of lack of consensus over cancer screening guidelines led to knowledge deficiencies and "arbitrary timing of tests". Despite this widely expressed need a number of obstacles have been identified in attempting to incorporate prevention into medical education and medical practice (Fried, 1990) (Weller et al, 1992) - these include time pressures on medical curriculae and poor reimbursement for preventive activities. Time constraints have been specifically identified as an impediment to physician involvement in FOBT screening (Sangster et al, 1986). Obstacles such as these need to be addressed if GPs are to improve levels of performance and knowledge in relation to cancer screening.

The wide variation in responses to the questions on primary risk factors for colorectal cancer reflect the evolving nature of the evidence in this area (much of which was outlined in Chapter 1). This lack of either consistent evidence or widespread consensus on primary prevention adds to the difficulties facing GPs who wish to provide their patients with advice on appropriate preventive measures for colorectal cancer.

5.43 Cancer-Screening Guidelines for General Practitioners

As indicated in the introduction to this chapter, one of the aims of this component of the SACCS study was to assess familiarity and compliance with AGI guidelines (1991) in South Australian general practitioners - these guidelines were widely circulated in the weeks immediately preceding the study. The guidelines include; 1) screening only recommended within the context of medical consultations, 2) if requested by the patient, FOBT screening recommended for individuals aged > 50 years, 3) doctor-initiated screening only recommended for high-risk groups (eg those with a positive family history), and 4) preferred investigation for FOBT-positive individuals is colonoscopy.

These can be compared with the recommendations and guidelines of other professional organizations for the use of FOBT screening tests in asymptomatic patients -*Table 5.5* summarizes current guidelines from North American health organizations which illustrate the fact that the recommendations often reflect the interests and preferences of their issuing organization - for example, the US Preventive Services Task Force placed a great deal of emphasis on evidence from randomized controlled trials (Smart, 1990) whereas the American Cancer Society was governed more by a desire to encourage screening if there is a chance it will do some good. The variety of recommendations in North America have recently been reviewed (Beers et al, 1991), and the consensus of a panel of experts, following an extensive review of the literature was that the evidence

supporting screening was "equivocal" - particularly in the case of elderly patients. Inconsistencies in guidelines reflect the evolving nature of the evidence in this area. As a result, however, clinicians are frequently required to base their decisions on whether or not to screen on conflicting evidence.

The majority of respondents to this survey did indicate that there were clear guidelines they could follow in deciding upon screening regimes and follow-up of test-positive individuals. Despite this, there was a wide range of screening practices (many of which were outside AGI guidelines) and knowledge in this area. This suggests either incomplete awareness of the content of the guidelines amongst respondents, or disagreement with their recommendations. While primary care physicians appear to be in favour of having specific guidelines for cancer detection (American Cancer Society, 1990), Lomas et al (1989) point out that "knowledge of recommendations does not necessarily lead to compliance of doctors with them". There are many examples of physician non-compliance with cancer prevention guidelines. In the American Cancer Society survey of US physicians (1990), which included in its aims the ascertainment of levels of agreement with their FOBT screening guidelines, almost half of the respondents did not comply with the guidelines, although 88% agreed with them. Other North American research has demonstrated limited compliance of family physicians with official cervical cancer screening guidelines (Cohen et al, 1992) and mammography guidelines (Fox et al, 1988).

It would appear, therefore, that the development of consensus guidelines is not, in itself, sufficient to ensure widespread compliance with the guidelines by primary care doctors. McPhee and Bird (1990) argue that the reasons physicians do not perform recommended tests include forgetfulness, disagreement with recommendations, lack of time and patient refusal - they also suggest that doctors tend to overestimate their own compliance rates. Furthermore, reservations have

been expressed about the guideline development process itself - Geoffrey Rose (1990), in assessing the US Preventive Services Task Force Guidelines, suggests that guidelines can encourage "labelling" of previously healthy individuals and lead to the "medicalization of prevention". He argues that there should be a "comprehensive general practitioner system such that counselling and long-term care can take place". The medical approach, he suggests, is important but "must not distract attention from the more fundamental population strategy of prevention".

Nevertheless, findings from this survey suggest that a current priority in Australian general practice should be the further development and dissemination of consensus guidelines for FOBT screening, an examination of strategies to overcome potential barriers to implementing such recommendations in primary care and an assessment of the success of the guidelines which includes measures of satisfaction of both GPs and patients.

5.44 GP Opinions on Screening Strategies

Less than one-third of respondents felt that mass-screening with FOBT was an optimal strategy for reducing mortality from colorectal cancer. Strategies which provided a more central role for the GP (eg encouragement of patients to present earlier with symptoms and for GPs to be more rigorous in their follow-up of patients with bowel symptoms) were more strongly endorsed. Other GP-based studies have suggested that strategies aimed at reducing delays from onset of symptoms to diagnosis and treatment should be encouraged (Dixon et al, 1990) (Holliday & Hardcastle, 1979), and that all patients with rectal bleeding (regardless of other symptoms) should be encouraged to consult their doctor (Mant et al, 1989). In particular, it would seem important to encourage symptomatic individuals not to take screening tests - there is evidence from Australian research that individuals with rectal bleeding frequently do not seek medical advice or only

do so after a period of considerable delay (Byles et al, 1992). Reasons for delay or failure included not thinking bleeding is serious (most common) and a belief that diagnostic tests would be unpleasant and/or embarrassing. Symptomatic individuals may find screening tests less troublesome - the distinction between screening and diagnostic tests (and when it is appropriate to use them) needs to be clearly understood by patients and their doctors.

The revision/improvement of treatment regimes was less strongly endorsed as a means of reducing mortality from colorectal cancer. This possibly indicates that the majority of respondents feel that early detection and prevention hold greater promise in the long term than curative approaches.

The lack of enthusiasm amongst respondents for a centrally-coordinated strategy in any future FOBT screening programme suggests that GPs have reservations about participating in programmes over which they have limited direct control. Proponents of centrally co-ordinated programmes point to their greater efficiency in achieving population coverage, (through centalized data collection and population-wide recall systems) while opponents question whether mass-screening programmes adequately address the needs of the individual, and suggest that screening decisions are better tailored to individuals' unique health needs through a process of negotiation between health professionals and their patients. Most research examining effects of organizational factors on screening efficiency has been undertaken in cervical cancer screening - there is strong evidence that, although mass screening for cancer of the cervix can potentially reduce morbidity and mortality, it is only likely to be effective if it is undertaken in a centralised, coordinated fashion (Day, 1989). In a collaborative study of cervical cancer screening programmes in eight countries performed by the International Agency for Research on Cancer (1986), it was concluded that centrally organised

screening programmes were, unequivocally, more effecttive than uncoordinated screening.

In the absence of central coordination, cancer screening is likely to be undertaken by health professionals in an opportunistic fashion - that is, screening tests are performed when the opportunity presents, such as a doctors visit for another health problem. Norman and Fitter (1991) have used computer-simulated models to examine the potential and limitations of opportunistic cancer screening and they conclude that in order to achieve satisfactory levels of screening, opportunistic methods alone are insufficient - they at least need to be combined with more formal methods of invitation.

Experience from cervical cancer screening in Australia suggests that the current primary care-based, predominately opportunistic approach to screening, without central registries to co-ordinate activities such as recall, leads to inadequate levels of participation in the community (Quinn, 1989). Based on the evidence from cervical cancer screening, if widespread FOBT screening is ever introduced in Australia its success is likely to depend on the degree to which GPs can conform to the need for a centrally-coordinated approach.

The greater acceptance, amongst respondents, of FOBT screening initiated by the patient, and the finding that most would provide it to "all patients who requested it" may reflect doubts about the efficacy of this form of screening. Screening involves the recruitment of healthy people in a cancer-detection programme which may end up causing more harm than good. The ethical differences between this and the usual clinical situation in which patients with symptoms consult their doctor have been described (Skrabanek 1990).

Nevertheless, while patient-initiated screening may remove some of the GPs' anxiety associated with FOBT screening, GPs are responsible for providing information and co-ordinating the screening process. In particular, they need to inform their patients of the potentially harmful effects of screening (eg through false positive and false negative results), as participants in screening programmes may only be aware of the assumed benefits of screening such as reduced mortality and relief from anxiety.

General practitioners would also have a key role in containing the cost of widespread FOBT screening, much of which is generated through confirmatory investigations such as colonoscopy. Investigation with colonoscopy of all FOBT-positive individuals in mass screening would have significant health resource implications (Woodward & Weller, 1990), and it may become necessary to involve GPs more in these diagnostic investigations, or to encourage the use of less expensive procedures which do not require referral to a specialist, such as sigmoidoscopy and barium enema. It is of interest that many respondents to this survey expressed concern over "losing control" of their patients when referring them to a specialist for colonoscopy.

5.5 Summary

This chapter has emphasised the GP's educational and coordinating role in cancer prevention programmes such as FOBT screening. While this is widely agreed upon in the literature, it is further suggested that, particularly in the case of colorectal cancer prevention where much of the evidence is conflicting, each doctor and patient should "discuss the issues and select a screening strategy to suit each patient's needs and values" (Eddy, 1990). Knight (1989) argues that "patients should be informed of the uncertainties involved in recommending screening and allowed to participate in the decision".

While colorectal cancer is one of the most common lethal cancers, results presented in this chapter are a reminder that it remains a relatively rare presentation in general practice. This has important implications for any future GP-based FOBT screening programmes - systematic screening of all eligible patients would have a major effect on practice organization, possibly for a minimal yield of cancers. This component of the SACCS study has also highlighted the need for consistent guidelines in relation to FOBT screening. At best though, only interim guidelines can be developed until further evidence is obtained on potential improvements in mortality.

There also appear to be educational needs in the area of FOBT screening. While it is difficult to anticipate the particular information needs of medical graduates for effective cancer prevention in ten or twenty years, an emphasis on areas such as disease prevalence, individual lifetime risk, anticipated risk reduction through screening, predictive values of positive tests and complication rates of confirmatory investigations would enable GPs to provide well-informed and consistent information about the risks and benefits of screening.

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Table 5.1 - Characteristics of GP respondents

(n = 185)

characteristic*:	n	%
Member/Assoc. Member of the RACGP	70	45.8%
Fellow of the RACGP	43	28.1%
Member of the AMA	142	83.5%
Involved in teaching medical students or GP trainees	86	55.8%
On Vocational Register	158	90.0%
FMP Trainee	4	2.2%
Work in General Practice Full-time	154	84.6%
Practice is in a rural area	60	32.6%
In solo practice	48	35%

**note that characteristics are not mutually exclusive*

Table 5.2 - Screening for colorectal cancer using FOBT, colonoscopy and sigmoidoscopy: respondents' reported practices/recommendations

Strategy used/recommended in.....		FOBT	Colonoscopy	Sigmoidoscopy
patients over forty	no.	38	6	7
	%	20.5%	3.9%	4.4%
patients over fifty	no.	78	17	20
	%	42.2%	10.9%	12.4%
patients over forty who have first-degree relatives with colorectal cancer	no.	173	124	102
	%	93.5%	69.3%	59.6%
patients with past history of colorectal cancer	no.	147	177	124
	%	79.5%	96.2%	72.5%

Table 5.3 - Responses to statements about screening for colorectal cancer

		agree	disagree	not sure
There is convincing evidence that populations who are screened for colorectal cancer with FOBT have lower mortality from colorectal cancer. n = 183	n	81	22	80
	%	44.3%	12.0%	43.7%
Have received adequate education about strategies for the prevention of colorectal cancer n = 183	n	105	45	33
	%	57.4%	24.6%	18.0%
There are clear guidelines that can be followed when faced with a patient with a positive FOBT n = 182	n	146	19	17
	%	80.2%	10.5%	9.3%
There are clear guidelines that can be followed in deciding who to recommend for colorectal cancer screening n = 181	n	124	30	27
	%	68.6%	16.5%	14.9%
Screening with FOBT can be helpful in diagnosing individuals with bowel symptoms (eg. change in bowel habit, rectal bleeding etc.) n = 181	n	114	55	12
	%	63.0%	30.4%	6.6%
Early diagnosis (eg. in the presymptomatic phase) of colorectal cancer improves overrall survival n = 184	n	171	2	11
	%	92.9%	1.1%	6.0%
Detection and removal of adenomatous polyps decreases the incidence of colorectal cancer n = 184	n	164	5	15
	%	89.1%	2.7%	8.2%

Table 5.4 - Opinions on FOBT screening methods

	acceptable for all individuals	only acceptable for individuals at increased risk for colorectal cancer	never acceptable
screening is part of a centrally-coordinated programme initiated by government, or other organizations (n = 141)	32 (22.7%)	53 (37.6%)	56 (39.7%)
self-testing kits are made available to the public directly, either commercially or through pharmacies (n = 146)	90 (61.6%)	19 (13.0%)	37 (25.3%)
screening is offered to asymptomatic patients by their general practitioner - on the GPs' initiative (n = 172)	124 (72.1%)	47 (27.3%)	1 (.6%)
screening is provided to asymptomatic patients (at their request) by GPs (n = 163)	136 (83.4%)	25 (15.3%)	2 (1.2%)

Table 5.5 - Recommendations for FOBT screening from North America

Source	Recommendation/guideline
NCI Working guidelines (1987)	Digital rectal examination as part of periodic health examinations Annual FOBT for age ≥ 50 Sigmoidoscopy every 3-5 years for age ≥ 50
ACS recommendations (1983)	Annual digital rectal examination for age ≥ 40 Annual FOBT for age ≥ 50 Sigmoidoscopy every 3-5 years after two negative exams performed one year apart, for age ≥ 50
US Preventive Services Task Force (Knight et al, 1989)	Insufficient evidence either for or against FOBT for age ≥ 45

Figure 5.1 - Respondents' preferred investigations for determining cause of positive FOBT

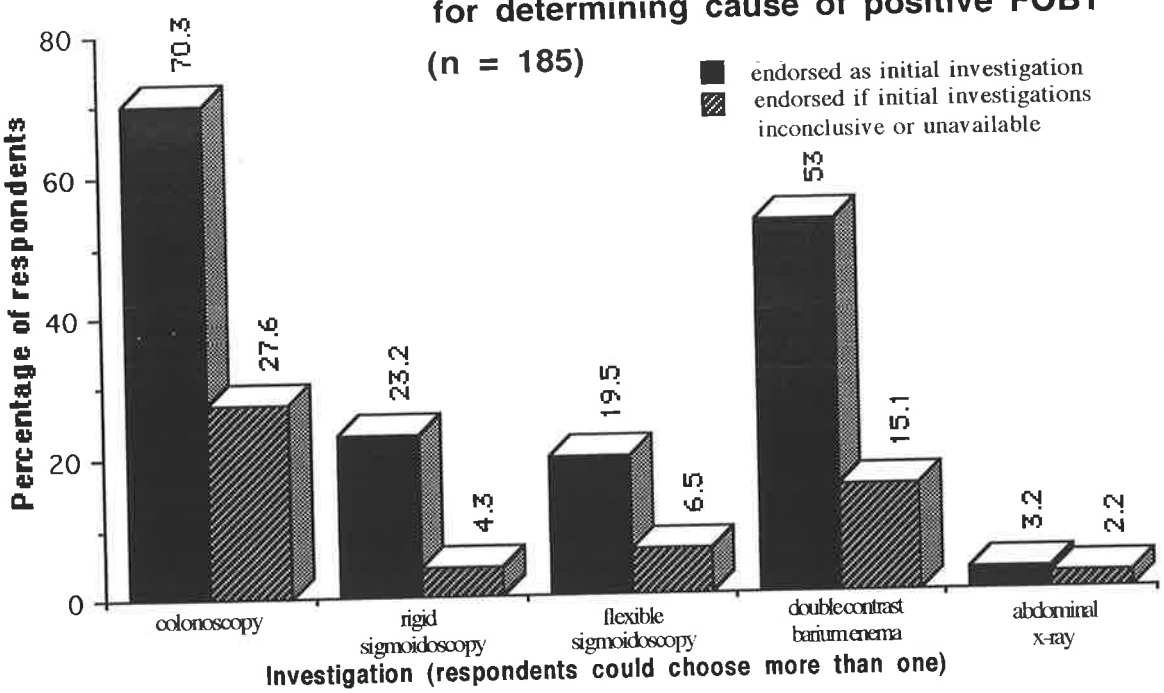


Figure 5.2 - **GP opinions on primary risk factors for colorectal cancer**

(n = 185)

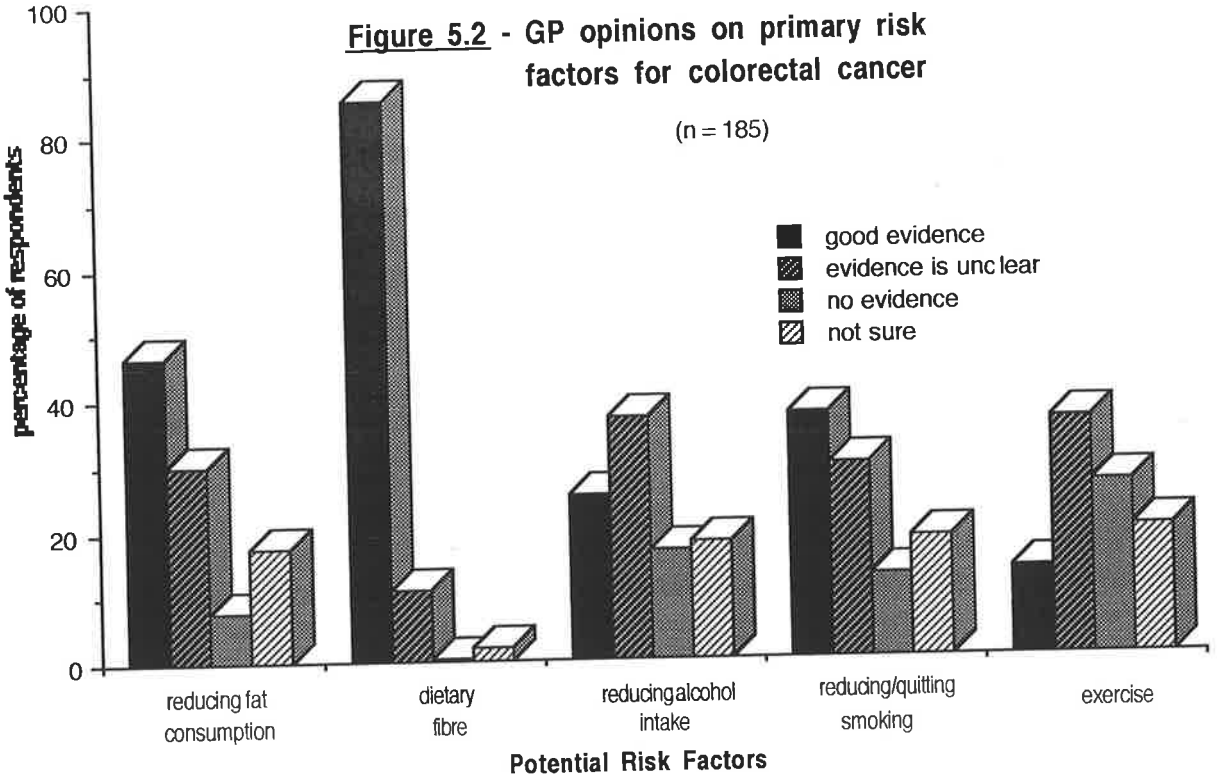
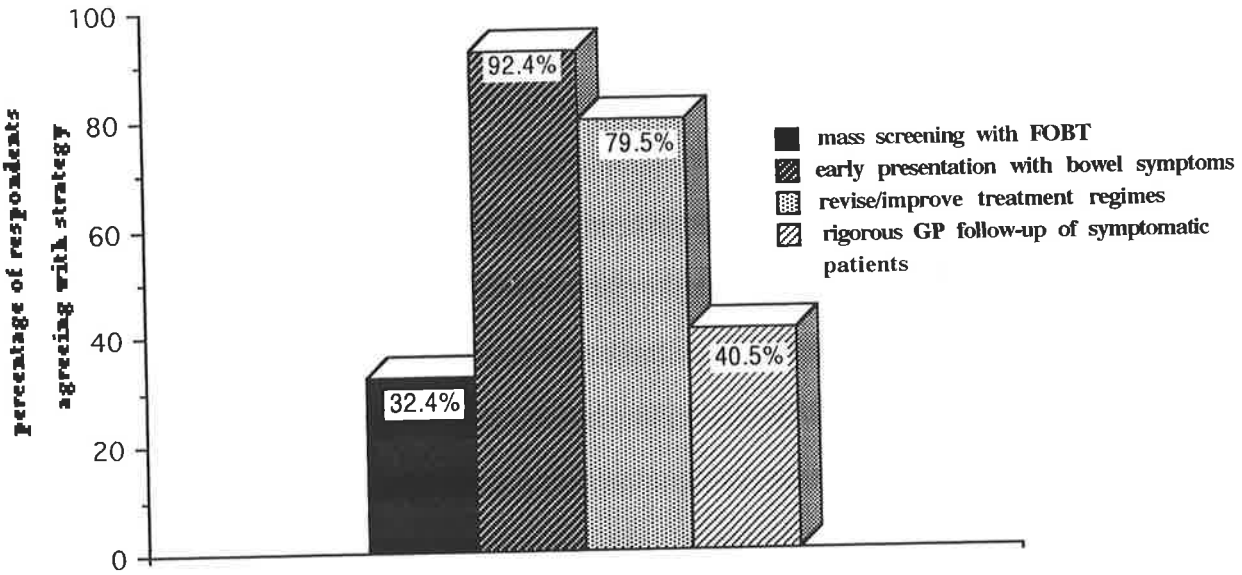


Figure 5.3 - Opinions on best methods for reducing mortality from colorectal cance

(n = 185)



Chapter 6:

Conclusions

The SACCS study has examined a number of aspects of screening for colorectal cancer in the Australian population, including costs, acceptability, compliance and implementation. This has been undertaken through an evaluation of an existing FOBT screening programme in South Australia, as well as surveys of those likely to be involved in the provision of screening, those who would be targeted in screening programmes and current screening participants. This final chapter examines the findings of the study in relation to their contribution to the debate over the future introduction of widespread screening for colorectal cancer in Australia. Over the next decade pressure is likely to mount in Australia to undertake more extensive screening for this disease. This will be driven by a number of factors, including an increased awareness of the disease in the population, a growing recognition and acceptance of cancer screening programmes as means of reducing mortality (particularly with the establishment of other cancer-prevention programmes such as mammography screening) and the perceived need in the health community to take some form of concerted action against a disease with such a major health impact. In view of this growing pressure for colorectal cancer screening, the Australian Gastroenterology Institute, in collaboration with the Australian Cancer Society, is developing screening guidelines which they hope to disseminate widely in the latter half of 1994. These guidelines will build on an earlier document issued in 1991 (Australian Gastroenterology Institute, 1991) which was referred to in Chapter 5. The consultation process for these guidelines has included clinicians, epidemiologists and health economists, and while there has been general agreement that mass screening for colorectal cancer is not justifiable (or desirable) currently in the Australian community, there has been considerable debate over issues such as

screening in high risk groups, and how screening should be undertaken (eg doctor-initiated versus patient-initiated, centrally-co-ordinated versus practise-based etc.). The complexity of the debate reflects not only the paucity of definitive evidence in this area, but the major implications for the health service in Australia of screening even if it is limited to certain high-risk groups.

6.1 The need for caution

Despite the growing enthusiasm for colorectal cancer screening, it has long been recognized that there is a possibility of well-intentioned health care providers, consumers and pressure groups leading a crusade against a particular illness and applying pressure on governments to provide screening before a thorough assessment has been made of its likely health benefits (Nuffield Trust, 1968). In these circumstances screening may acquire respectability almost by virtue of its existence. Some advocates of FOBT screening in Australia have already attracted criticism for their unqualified enthusiasm in promoting screening (Dickinson, 1992). Government-funded disease prevention programmes have frequently been undertaken in the past in the absence of convincing evidence - a recent example from the UK is the health promotion package for primary care aimed at modifying coronary risk factors which followed the 1990 White Paper (Health Departments of Great Britain, 1990) and which has been criticized for its lack of any measurable benefit (Wood et al, 1994).

Furthermore, if promotion of FOBT screening goes ahead in Australia in the absence of a coordinated and carefully evaluated strategy for its introduction, there are likely to be a number of adverse consequences. Firstly, widespread promotion is likely to increase awareness and anxiety in relation to colorectal cancer and lead to more investigations being performed, often in the absence of genuine clinical need. Secondly, uncoordinated screening results in a group of screening participants which is not representative of the wider population - this has been

demonstrated in the SACCS study and many other evaluative studies of screening programmes. Despite the finding in SACCS study that uncoordinated screening may attract high-risk individuals (such as those who are symptomatic or who have a positive family history), it is predictable that a significant proportion of available resources will be concentrated on low-risk groups such as individuals who are young or who have previously been screened. Furthermore, individuals who are at increased risk because of symptoms should seek medical advice for their symptoms in preference to taking screening tests. Finally, the introduction of widespread screening in the absence of a coordinated strategy would make the process of evaluating the relative worthiness of different screening strategies (comparing, for example, different screening frequencies and target age groups), more difficult in the future.

6.2 Ethical issues in FOBT screening

The lack of widespread consensus over the health gains of FOBT screening means that promotion of this procedure carries with it a number of particular ethical concerns. This is in contrast to programmes such as immunization, sewerage treatment and pasteurization of milk where the benefits of taking action are indisputable, and health care providers are given a clear mandate to proceed. Health promotion initiatives have attracted considerable ethical debate in recent years - a common theme in this debate is the suggestion that preventive medicine is not subjected to the same ethical scrutiny as other health initiatives (Skrabanek, 1990). Whereas the use of randomized controlled trials is widely accepted as a necessary step in evaluating new medications, it is argued that health promotion initiatives are often taken as having face validity, requiring no more than cursory evaluation, if any (Eisenberg, 1987). Indeed, it is true that FOBT screening has been undertaken in western countries for many years in the absence of evidence from randomized control trials.

In common with almost all forms of screening, FOBT screening has the potential to cause harm. Hoffmaster (1992), who argues in favour of close scrutiny of the ethical underpinnings of any health promotion programme, suggests that the potential of a health programme to actually harm individuals makes a close examination of the ethics of proceeding with the programme imperative. As an example of this, the ethical dilemmas of cervical cancer screening have been highlighted (Snadden, 1992) - women are strongly encouraged to participate, yet they are frequently provided with little information on test's potentially adverse consequences, including the risks of secondary investigations such as colposcopy and the fact that repeat tests are often required. FOBT screening is likely to attract similar ethical scrutiny should its use become more widespread.

One approach in addressing these ethical concerns is to provide individuals with as much information as possible about the screening procedure. In the case of FOBT screening this might include some of the information described in the SACCS study such as likely costs, consequences of a positive test (including adverse psychological sequelae), and accuracy of the test. Mant & Fowler (1990) argue that there is an ethical responsibility to inform individuals of the balance of risks and benefits of screening. Knight et al (1989) consider that the decision to screen should take into account individuals' preferences and their expected compliance, and that they should be informed of the uncertainties and encouraged to participate in the decision. The need to achieve a balance between making the target population aware of a screening programme and providing information which is not coercive but accurately explains the potential risks and benefits of participation in the programme is frequently expressed in the literature on screening ethics.

Promotion of screening in such a way that people at low-risk take up the screening test has, itself, ethical problems, as the balance between risks and likely benefits of screening becomes less favourable. The SACCS study has demonstrated that self-

recruitment into FOBT screening can lead to participation in extremely low-risk groups, such as those aged under 40. It is argued that approaches to health interventions are more ethically defensible if they incorporate an approach which encourages participation by those who are at highest risk (Davey Smith & Egger, 1994).

A common ethical argument against screening is that it infringes the rights of the individual. Skrabanek (1986) takes the extreme view that all screening invariably involves a loss of individuals' liberty which, in a social, political and legal climate that extols individual freedom and individual rights, is difficult to justify. This argument implies coercion of screening participants and, indeed, there are sound arguments against an indiscriminatory approach to the promotion of screening. There are, however, ethical problems in withholding information on preventive initiatives which may save lives, such as FOBT screening. A cautious, prudent approach in which all of the available evidence on the risks and likely health benefits is provided to individuals would appear to be the most widely accepted strategy. It is argued that providers of screening have a further ethical responsibility to minimize false results through the maintenance of high standards and to audit the completeness of follow-up (Mant & Fowler, 1990).

6.3 Generalizability of findings from FOBT screening research

As results from major studies of FOBT screening accumulate, there is likely to be increasing interest in their applicability to widespread screening of the population for colorectal cancer. Screening which produces favourable results in the context of a research project, may not be able to produce similar results when implemented in the wider population. It is difficult to reproduce the accuracy and quality control available in research settings. Furthermore, higher compliance rates with various stages of the screening process may be achievable in study participants compared to the population from which they are recruited. Even in the Minnesota trial which

has been undertaken with a group of volunteers and in which costs associated with travel, acommodation and medical follow-up have been provided for (Mandel, 1993), approximately one-quarter of test-positive individuals in the over-80 age group have not complied with an offer for colonoscopy (Jack Mandel, personal communication).

To some extent, the IMVS FOBT screening programme provides a better insight into how screening would take place in the Australian community, as it has not been part of a major organized trial. At present, however, only a very small percentage of the South Australian population has participated in the programme and, as the SACCS study has demonstrated, participants appear to differ from the general population in a number of important ways. Their high rate of family history and bowel symptoms gives them an increased risk for colorectal cancer, and will therefore produce an inflated positive predictive value for the FOBT used. That is, screening in more representative groups in the Australian population would almost certainly lead to higher numbers of false positive test results, and a lower predictive value for colorectal cancer of a positive test. One of the outcomes of this would be to increase the cost per cancer detected for the programme which was calculated in Chapter 3. The IMVS programme does, however, provide insights into how screening would work on a smaller scale in the absence of a community wide, centrally coordinated approach.

A further consequence of self-selection of participants into the programme is that it is not possible to draw conclusions about the likely acceptability in the wider community of the programme. While feedback from participants on the programme (see Chapter 2) provides some information on how uptake of the test might be maximized, information presented in Chapter 4 on population beliefs and attitudes suggests that widespread acceptance would require a multi-facetted approach - this is discussed further in Section 6.43.

6.4 Key issues if FOBT screening is introduced in Australia

6.41 Importance of screening strategies and test characteristics

The SACCS study is an illustration of the way in which changes in the organization of a FOBT screening programme or the test it uses can have profound public health effects. The simplest example of this is the effect of adjusting the cut-off point at which an FOBT is considered to be positive. The sensitivity analysis, described in Chapter 3 (see *Table 3.7)*, demonstrated the considerable effect on cost per cancer detected of varying the positivity rate from 5% to 6%. Test performance characteristics are of critical importance - small variations in the accuracy of the tests used in FOBT screening have profound effects in the screened population. If immunochemical tests, such as the one used in the IMVS FOBT programme, are consistently demonstrated to be more specific for colorectal cancer than the more traditional tests, then consideration should be given to their use in any national programme.

This study has also demonstrated the importance of recruitment strategies in FOBT screening. As indicated in Chapter 2, IMVS screening participants have a high rate of bowel symptoms - up to 40% may have been prompted to take the test by concern over symptoms. Self-recruitment also appears to favour participation of individuals from higher socioeconomic groups, and those who are already participating in other health-related activities. Recruitment strategies in a widespread FOBT screening programme would need to address these findings. The task of encouraging asymptomatic individuals to be screened, while at the same time discouraging symptomatic individuals (in favour of seeking medical advice for their symptoms) would be particularly difficult, requiring considerable public education efforts. Encouraging participation in lower socioeconomic groups would, in common with other health programmes, need to be tackled through a number of approaches including advice from health professionals, media campaigns and promotion through community-based organizations. This would

require a considerable allocation of health resources - in contrast to the IMVS FOBT screening programme which allocates relatively few resources toward promoting the test.

6.42 The costs and likely benefits of FOBT screening in Australia

The cost implications of the introduction of widespread FOBT screening in Australia are likely to be a principal concern for governments and health care providers. Unlike the introduction of mammography in Australia which has required the establishment of purpose-built screening centres with dedicated staff and major equipment purchases, establishing FOBT screening may appear, at first, to be relatively simple and inexpensive. The screening test is non-invasive, simple to use, inexpensive to analyse and can even be sent in the post. But it is the downstream costs of FOBT screening which have the most significant resource implications. As illustrated in Chapter 3, mosts of the costs in the IMVS screening programme have been generated outside of the direct control of the programme, and widespread screening would result in an enormous increase in the number of investigative procedures being performed, requiring a significant re-direction of resources and manpower (Woodward & Weller, 1990). It would be of critical importance in a national programme to keep a check on downstream investigations and their associated costs - either through the establishment of dedicated centres for the investigation of FOBT-positive individuals, or through changes to current arrangements in Australia for the provision and funding of investigations such as colonoscopy.

There are finite resources in health, and money spent on screening is unavailable for other health-related activities. If evidence for clear health benefits of FOBT screening remains equivocal, and health care providers remain reluctant to introduce a national programme, one approach may be to provide screening for those who wish to pay. Such an approach has been raised as a possibility in

relation to mammographic screening (Ellman, 1989) - those who are willing to pay could have a more extensive service with greater screening frequency. However, in Australia, as in many other countries, the community has expressed a desire for basic equity in health care. Particularly if evidence for health benefits of FOBT screening grows, it is unlikely that an approach such as this would be acceptable on a wide scale. Furthermore, regardless of ethical concerns, the cost of FOBT screening provided only to those whe were willing to pay would need to include all of the associated costs of investigations - at present Medicare does not provide reimbursement for FOBT screening, but does contribute towards the costs of secondary investigations for FOBT-positive individuals.

Turning to the likely benefits of FOBT screening, it is sometimes helpful to estimate the number of years of life which may have been saved as a result of screening. In common with other FOBT screening programmes (Hardcastle et al, 1989) (Kronborg et al, 1989) (Mandel et al, 1993) the 24 cancers detected in the IMVS FOBT programme appear to have a more favourable histopathological staging (and, hence, projected survival) - initial analysis suggests that approximately 80% of cancers detected in the programme are likely to be Dukes' A or B lesions (Thomas, 1992). It has been estimated that detecting a colorectal cancer in these early stages may add, on average 6.5 years to the life of an individual who is destined to develop colorectal cancer (England et al, 1989). Assuming that, in the absence of screening, approximately 40% of colorectal cancers would present in stages A & B (US Department of Health & Human Services, 1989), then an estimate of years of life saved as a result of this programme in the 6208 participants over the two year study period is 62.4 years, with a cost per life-year saved of $7280. Estimates such as these are, however, based on indirect evidence and include a number of assumptions about the natural history of colorectal cancer, the accuracy of screening, characteristics of screening particpants and life expectancy. Furthermore, caution has been urged in the use of calculations such

as these in the absence of definitive evidence that FOBT screening reduces mortality from colorectal cancer (Cher, 1993). Nevertheless, estimates such as these are likely to figure highly in decisions over the introduction of FOBT screening.

As discussed in Chapter 3, there are other potential benefits of participation in FOBT screening, such as the reassurance of a negative test result. These have not been included in comparisons of costs and potential benefits in the SACCS study. The benefit of a true negative test result is difficult to quantify (Frank, 1985 - a). Furthermore, given that an FOBT may have a false-negative rate in individuals who do have cancer in the region of 70% (Ahlquist, 1992), the value of a negative test result becomes questionable.

Arriving at a decision to introduce a national programme based on costs and likely benefits of FOBT screening is, therefore, a complex process. Available evidence from this and other studies does, however, serve as a guide to the important considerations in implementation should such a programme be introduced.

6.43 The likely acceptability and uptake of FOBT screening in Australia

Most screening programmes for cancer aim to achieve satisfactory levels of compliance, and the principal determinant of compliance is acceptability of the screening procedure. High levels of uptake in target populations for screening mean that the programme has a greater impact on health outcomes, and reduce the problems inherent in only screening a subset of the population. While it is argued that achieving high compliance rates should not, in itself, be a prime objective in screening, particularly if this requires the allocation of significant resources (Torgerson & Donaldson, 1994), the success of many programmes is gauged by their ability to achieve compliance with initial recruitment strategies, investigative procedures and subsequent rounds of screening.

The SACCS study adds to a growing body of evidence that health beliefs, knowledge and attitudes can profoundly influence participation in cancer screening. The influence of these factors on FOBT screening participation would need to be taken into account in recruitment strategies for a national screening programme in Australia. Findings presented in Chapter 4 suggest that a number of strategies might be useful - these include raising awareness of colorectal cancer, promoting an understanding of the high prevalence and seriousness of the disease (without causing panic and risking an inappropriate response), stressing that individuals are susceptible to the disease (some more than others), reinforcing the belief that colorectal cancer can be cured if detected at an early stage, and reducing inhibitions and embarrassment over performing the test.

Raising community knowledge of colorectal cancer and its prevention would be a particularly important objective in the presence of a national screening programme - knowledge clearly influences screening participation, and it is desirable that participants should base their decisions to be screened on an accurate appreciation of the relevant health information. Furthermore, educational initiatives appear to have a positive effect on compliance with, and understanding of, screening for colorectal cancer (Weinrich et al, 1993). The SACCS study examined two knowledge-related aspects of colorectal cancer - knowledge of its curability if detected at an early stage, and knowledge of its familial pattern of incidence. In both cases, informational needs were identified in significant proportions of respondents. Other areas where information and education may be required include the significance of various bowel symptoms, the distinction between screening tests and diagnostic tests and the risks and likely benefits of taking a screening test.

Experiences in the first round of screening appear to profoundly influence adherence to subsequent rounds af screening. The SACCS study demonstrated

that having a positive FOBT appears to be a deterrent to future participation in FOBT screening (see Chapter 4, *Table 4.8*). This is consistent with other research from the US which has found that having an abnormal FOBT result and exposure to first-round diagnostic interventions are significantly and negatively associated with repeat adherence (Myers et al, 1993). This has important implications for widespread, periodic screening for colorectal cancer. FOBT screening has a low positive predictive value, and the majority of test-positive individuals are unlikely to benefit from their positive test - indeed, it may cause them harm. This is a clear deterrent to continued adherence to periodic screening, and is a further incentive for the development of tests with higher specificity for colorectal cancer, and higher positive predictive value.

6.44 Integrating FOBT screening with Australia's existing system of primary medical care

It is an essential requirement for the success of FOBT screening that it has the full support of those whose responsibility it will be to recommend and implement the programme. In Australia, such a role would almost certainly filled by general practitioners. The SACCS study has demonstrated a lack of widespread agreement amongst general practitioners over screening strategies for average-risk individuals (although there is less disagreement over increased-risk individuals). General practitioners appear to be unconvinced of the health benefits of widespread FOBT screening at present, and their opinions are unlikely to change without a clear directive from professional organizations and government. Such a directive can only come when the outcome of the current debate over the mortality benefits of screening is clearer, and this may not be for some years.

Nevertheless, while opinion on the value of widespread screening is likely to remain divided, there are a number of issues raised in this study which would need to be addressed before the adoption of a national programme. Firstly, there are the apparent educational needs of GPs, discussed in Chapter 5. Undergraduate

medical education has been criticised for its lack of emphais on issues relevant to general practice, such as the provision of preventive care (Kamien, 1990). Considering that cancer screening occupies a considerable proportion of GPs' time and effort, it seems logical that medical curriculae should adequately address all of the issues relevant to screening.

Secondly, it is necessary to examine whether the current infrastructure of Australian general practice would be able to incorporate a major screening programme such as FOBT screening (in addition to other GP-based health screening efforts). Previous research has found that, while GPs indicate they are keen to participate in preventive activities, they identify a number of barriers to the effective delivery of such services, including lack of time, financial disincentives and perceived lack of self-efficacy (Weller & Hiller, 1990). Incorporating FOBT screening into general practice would require an examination of strategies for overcoming barriers such as these. For example, it has been demonstrated that organizational initiatives aimed at recording and prompting health-promoting activities can positively influence Australian general practitioners' undertaking of health promotion tasks (Crotty et al, 1993). Such initiatives may include the addition of practice staff to coordinate preventive activities.

Computers can also greatly assist primary care-based screening - particularly in the identification of target groups for screening and the provision of systematic recall. However, only 14% of GPs currently use computers to recall patients for preventive checks (Douglas & Saltman, 1991). Hence, the organizational capacity of Australian general practice to incorporate a further screening programme would need to be examined before the introduction of a national programme. This is likely to be even more important if there is an expectation that GPs will undertake a greater number of related procedures (such as flexible sigmoidoscopy), as discussed in Chapter 5.

Thirdly, it is important to address the high proportion of Australian individuals who have no stable arrangement with a GP (Veale et al, 1993) (Weller et al, 1988). This inevitably has an adverse influence on the provision and coordination of screening services. While patient enrolment is one of a number of strategies for change in Australian general practice currently being considered (National Health Strategy, 1992), the restriction of patient movements between GPs is likely to be difficult to achieve in the immediate future.

Finally, as discussed in Chapter 5, common ground would need to be found between a national, coordinated strategy and screening which is entirely practice-based and opportunistic in its organizational approach. The former approach has the advantage of greater coverage, systematic recall and less selective recruitment, whereas, in the latter approach, screening strategies can be tailored to individuals after a process of negotiation between doctor and patient. The SACCS study found that GPs are distrustful of centrally-coordinated screening. While anticipatory care and opportunistic prevention have been advocated in Australian general practice (Ellis & Leeder, 1991) it seems unlikely that a purely opportunistic approach to FOBT screening, in the absence of a centrally coordinated strategy, would produce an effective programme.

6.45 Selective screening of high-risk groups

The attraction of screening high-risk groups such as those with a family history of colorectal cancer is that the prevalence of the disease will be much higher in these groups and, hence, the positive predictive value of a positive test will be higher. The SACCS study has demonstrated the strong influence of family history on FOBT screening participation - this would, in effect, facilitate a targeted screening programme. It has been suggested that in any cancer screening programme, a major component of the effort should be directed towards identifying individuals

who have an increased risk of cancer as a consequence of a positive family history (Weber, 1993).

While the estimation of a person's risk of cancer can help focus screening efforts, a number of important issues should be addressed before a recommendation for widespread FOBT screening of individuals with a family history of colorectal cancer is made in Australia. While there is evidence that the predictive value of the FOBT is higher in increased-risk groups (Rozen et al, 1987), there is no widespread agreement that the sensitivity and specificity of currently available FOBTs are sufficiently high to justify use in these groups. Limited sensitivity would be a particular concern - standard FOBTs such as Hemoccult rarely have a sensitivity exceeding 80% in either standard-risk or increased-risk groups (Thomas et al, 1992) (Eddy et al, 1987), although techniques such as re-hydration can raise the sensitivity to over 90% (Mandel et al, 1993). Many would argue that screening in high-risk groups (such as those with a positive family history) warrants a test with virtually 100% sensitivity, such as colonoscopy; such individuals are generally aware of their greater vulnerability to colorectal cancer (see Section 4.312), and it is reasonable for them to expect a test which will not miss a significant proportion of cancers. Furthermore, identification and recruitment of those with a family history of colorectal cancer would, in itself, be a major effort. Even in the UK where most practices have computers, the recording by general practitioners of a family history of colorectal cancer on databases is a rarity. In Australia, none of the state cancer registries are currently equipped to perform this task, and a considerable investment in time and resources would be required to establish GP-based registers of individuals at increased risk through a positive family history. To complete this major effort with a screening test with limited sensitivity may not be widely acceptable.

Nevertheless, while there is so far limited evidence that population-based systematic screening of relatives of individuals with colorectal cancer can be accomplished, it is argued that systematic screening of such individuals can readily be undertaken in private medical practice settings (Stephenson et al, 1993). A strategy focused on high-risk individuals is an important alternative to mass screening in the Australian population, and further research is required into the feasibility of this approach. Furthermore, it is suggested that the identification of individuals at low risk may be equally important in focusing screening efforts, and that genetic markers may hold promise, in the future, for identifying such individuals (Ransohoff and Lang 1991). At present, however, there are limitations on the interpretation of these genetic markers in terms of absoute risk for an individual, so the benefits of counselling such individuals are doubtful.

Individuals who have polyps are also at increased risk of colorectal cancer, and, as discussed in Section 2.56, the detection of polyps as a result of FOBT screening is often included as a health gain. Consistent with most evaluations of FOBT screening, the SACCS study found a high reported prevalence of bowel polyps in screening participants with positive test results. Evidence suggests, however, that the FOBT has a very low sensitivity for polyps - hence, the majority are likely to be missed (or only discovered inadvertently), and this avenue is unlikely to result in a major impact on colorectal cancer mortality (Frank, 1985 - b). Hence, while the usefulness of detecting polyps for defining and targeting groups for whom colonoscopic screening or surveillance has been highlighted (Levi et al, 1993), the usefulness of the FOBT as a means of identifying individuals with polyps and a screening strategy for such individuals appears to be limited.

Given that the incidence of colorectal cancer increases with age, it may be argued that a national screening programme in Australia should target the elderly. The age at which screening efforts become irrational does, however, require careful

consideration. There is little doubt that risks of treatment increase in the elderly - in one series mortality from colorectal cancer surgery was four times greater among patients over the age of 70, regardless of tumour size or the extent of invasion (Fielding et al, 1989). For reasons such as these, in recent years there has been a greater emphasis on assessment and management of loss of function rather than on early detection of disease in the elderly (Taylor & Buckley, 1987).

6.5 Does FOBT screening fulfill criteria of acceptability?

In Chapter 1, *Table 1.3,* a number of widely recognized acceptability criteria were listed. Criteria such as these can be used as a guide to assessing the worthiness of a screening programme. The SACCS study provides insights into the performance of FOBT screening in relation to some of these criteria. One of the criteria states that "the screening test should be simple, inexpensive and acceptable to participants". While the fecal occult blood test is simple and inexpensive, clearly secondary investigations are not. While there was quite a high level of reported acceptability of the FOBT in the population survey of the SACCS study, this did not appear to be accompanied by an intention to take the test.

It is also stated in *Table 1.3* that "there should be adequate means of follow-up of screening participants". While the majority of true-positive IMVS screening participants received their diagnostic investigations within a month or two, responsibility for these investigations was left with individuals' doctors, and a more fail-safe method of follow-up would be required in widespread screening programmes. Given that 20% of test-positive individuals (excluding those in whom colorectal cancer had been diagnosed) did not have colonoscopy, and 8% stated they were unsure of the cause of their positive test, this study provides some support for the strategy of more coordinated follow-up, perhaps under the direct provision or control of the programme itself.

Another criteria states that "the number and cost of false positive tests (and confirmatory investigations which result from these tests) should be acceptable and affordable". Defining an acceptable rate of false positive tests involves complex judgements. The economic and personal consequences of false positive tests are well-illustrated in the SACCS study - many would argue that, in view of the adverse consequences of a positive test, a predictive value for colorectal cancer of 7.5% is unacceptably low, while others would suggest that adverse effects are outweighed by the benefits of detecting the cancers in the true-positive individuals. Clearly, there is no easily definable point at which the number of false positive tests and their associated investigations become unacceptable. Criteria such as these do, however, serve as a useful guideline in the design and implementation of screening programmes.

Elwood (1990) has compiled a number of further principles in relation to screening. They include the arguments that screening is boring, it is not the whole solution to any disease, it may appear attractive even if it is ineffective and that it is hard to evaluate at first - later it gets harder. While findings from the SACCS study provide little illustration of these principles, they are important caveats which may temper indiscriminate enthusiasm for the introduction of widespread FOBT screening in Australia.

6.6 Approaches to reducing mortality from colorectal cancer

6.61 Primary or secondary prevention?

Much of the debate in Australia in the coming years over the prevention of colorectal cancer is likely to focus on whether primary or secondary preventive strategies should be adopted. As discussed in Section 1.5, it may be possible to bring about substantial reductions in mortality through dietary change. *Table 6.1* examines the preventability of a range of common cancers in the Australian population, based on available evidence of known risk factors and the

effectiveness of screening strategies (Armstrong, 1990). Estimation of what might be achieved (preventability) is based on information on causal factors, knowledge of the association between increments of exposure and increased rates of disease, and the extent to which exposure to risk factors might be reduced.

The estimates in the table on colorectal cancer compare the likely effects of dietary modification and screening on colorectal cancer incidence (Wahrendorf, 1987). Compared to lung cancer and melanoma, where risk factors and risk-reduction strategies are well-recognized, in the case of colorectal cancer secondary preventability appears to compare well with primary preventability, and screening efforts may, therefore, be more likely to meet with success than primary risk factor reduction. Furthermore, widespread modification of dietary habits would be a major undertaking - risk reduction in the community is a difficult process, even with clearly identifiable risk factors such as smoking (Owen et al, 1992).

6.62 Screening modalities other than FOBT

As discussed in Section 1.7, there is growing interest in alternatives to FOBT in screening for colorectal cancer, such as flexible sigmoidoscopy. These alternatives are, mostly, more invasive, so it might be expected that their acceptance and uptake in the population would be lower. In a study by McCarthy & Moskowitz (1993) a number of unfavourable experiences were reported in participants in screening flexible sigmoidoscopy. These included embarassment (27% of participants), discomfort (42%) and pain (31%), although participants report less adverse experiences than they had expected. In this group of patients (belonging to an academic general internal medicine practice), compliance with the invitation for screening sigmoidoscopy was 75%. The debate over colorectal cancer prevention strategies in Australia needs to include an examination of these alternative (or, indeed, complementary) screening modalities - initial

evidence suggests, in particular, that sigmoidoscopy may have a useful role (Atkin et al, 1993).

6.7 Summary

This thesis, which is based on the SACCS study, has presented information and arguments relating to preventive strategies for colorectal cancer in the Australian population. A number of key issues, summarised in this chapter, have emerged from the SACCS study which add to the debate over the adoption of a national FOBT screening programme. These centre on organizational and implementational issues, cost and likely benefits of screening and factors affecting acceptability and compliance. Evidence from the SACCS study gives support to the view that population-based FOBT screening, if adopted in Australia, should be part of a unified national strategy for health - not undertaken by a variety of individuals in an uncoordinated fashion. Furthermore, there would appear to be clear advantages in linking it to primary preventive efforts and appropriate health education. It also needs to be linked closely with diagnostic and treatment services.

As with all new screening proposals there needs to be reasoned consideration of all of the relevant information and arguments, as well as consultancy with a wide range of health professionals before recommendations on adopting FOBT screening can be made. Such a process is currently underway in Australia. While the potential for FOBT screening to reduce mortality from colorectal cancer should maintain a keen interest in this preventive activity in the health community, there are, nevertheless, clearly identifiable risks involved in adopting this relatively new form of screening on a wide scale. Currently, the balance would appear to be in favour of waiting for evidence to accumulate before adopting widespread screening in Australia. This evidence should be able to provide answers to the following questions; 1) Is the evidence for reductions in mortality in screened groups unequivocal and, if so, are the percentage reductions which would be achievable in

population screening sufficient to warrant the costs? 2) Do we have the resources and infrastructure in the Australian health care system to adopt systematic screening of the population? 3) Are there alternative approaches which would be more cost-effective than FOBT screening in reducing mortality? 4) Would the likely acceptability of and compliance with FOBT screening (both in the general population and in health professional groups) be sufficient to make a major programme feasible?

Until such time as these questions are answered, the issue of screening for colorectal cancer is likely to remain controversial, and further evaluative research is required to advance the debate over this important public health issue.

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Woodward AJ, Weller DP. Colorectal cancer: implications of mass screening for public health. Med J Aust 1990; 153: 81-88

Table 6.1 - Estimated preventability of 8 common cancers in Australia

	Preventability			
	Primary		Secondary	
	%	modifiable risk factor	%	screening strategy
Lung	80	smoking, occupation	0	
Colon and rectum	20	diet	30	FOBT screening†
Breast	35	late first birth, obesity	40	mammography
Prostate	?		?	
Melanoma	35	exposure to sunlight	15	skin examination
Stomach	20	diet	50	gastric radiology
Bladder	40	smoking	0	
Pancreas	35	smoking	0	

source: Armstrong BK (1990)

† this estimate based on Mandel et al's mortality data (1993)

Appendix 1 - Questionnaire used in survey of test-negative screening participants

Department of Community Medicine, University of Adelaide
The South Australian Health Commission
The Institute of Medical & Veterinary Science

THE SOUTH AUSTRALIAN BOWEL CANCER STUDY - INFORMATION SHEET

Dear Participant,

We seek your involvement in a survey which is being conducted in South Australia to examine peoples' attitudes, knowledge and beliefs about bowel cancer and its prevention.

This questionnaire is being sent to a number of individuals who, like yourself, have participated in the "Detectacol" screening programme for bowel cancer.

As you are no doubt aware, bowel cancer is a major health problem in Australia. Your responses will provide important information on strategies for preventing the disease.

This study is being conducted by the University of Adelaide Department of Community Medicine, the South Australian Health Commission and The Institute of Medical and Veterinary Science.

The questionnaire should take approximately 10 minutes of your time, and we ask that you return it to us in the enclosed pre-paid envelope. ***Your responses to these questions will remain strictly confidential.*** If you would like to comment further on issues raised in this questionnaire please write your comments on the last page.

As a measure of our appreciation to all those who respond, you are invited to enter a lottery for a ***Myer Gift Voucher*** *to the value of $100. which will be drawn on Dec. 6th, 1991 in the Department of Community Medicine, University of Adelaide (details at end of questionnaire).*

If you would like further information on the study, please contact one of the organizers of the study listed below.

With thanks in anticipation,

Yours Sincerely,

(Dr. David Weller: Research Fellow, Dept. Community Medicine ph. 228 4615)

and on behalf of:
Dr. Janet Hiller (Lecturer, Dept. Community Medicine) ph. 228 4620, and
Dr. John Edwards (Head, Detectacol Laboratory, IMVS) ph. 228 7333

1. In which year were you born?

2. Sex (please tick box) male ☐ female ☐

3. What is your postcode?

4. With regard to occupation, which of the following best applies to you?
(please tick box)

- currently working ☐ → what is your occupation?
- retired/not currently working ☐ → what was your former occupation?
- your main lifelong occupation has been "domestic duties" ☐ → what is/was the occupation of your spouse?
- other (please specify) ☐ → .....

5. Regarding education, please indicate which of the following best applies to you: (tick one or more boxes)

☐ secondary school not completed
→ how old were you when you left school? .....years

☐ completed secondary school

☐ underwent further education at a university, college or institute
→ highest degree obtained.....

6. What is *your own* average annual income?

☐ no income
☐ $1-$6000
☐ $6001-$18000
☐ $18001-$32000
☐ $32001-$50000
☐ $50000+

7. When did you last take the Detectacol Test? month ☐☐ year ☐☐☐☐

8. How did you hear about the Detectacol test? (tick one or more boxes)

- ☐ *through friends or relatives*
- ☐ *TV, radio or newspaper*
- ☐ *your health fund?*
- ☐ *your doctor*
- ☐ *other (please specify) .....*

9. Did your doctor recommend that you take the Detectacol test? yes ☐ no/doctor wasn't involved ☐

10. Have any of your brothers, sisters, parents or children ever had cancer of the bowel*? yes ☐ no ☐ unsure ☐

**Bowel cancer is also known as "bowel tumour, bowel growth or colorectal cancer"*

11. Has anyone else that you have known closely suffered from bowel cancer? yes ☐ no ☐ unsure ☐

12. At the time you first took the Detectacol test (or in the few months before), did you have any of these symptoms?.....

	yes	no
discomfort, pain or bloating in your stomach/abdomen	☐	☐
any change in your usual bowel habit lasting more than two weeks	☐	☐
bleeding from the back passage	☐	☐

→ I noticed the bleeding before I took the Detectacol test ☐ / I only noticed the bleeding when I took the Detectacol Test ☐

If you answered "yes" for any of the above symptoms did they make you worry that you might have bowel cancer? yes ☐ no ☐

**questionnaire continues over the page*

13. The following questions examine your attitudes to bowel cancer and screening tests. *There are no right or wrong answers.*

Please *tick the box* which best indicates your response to the statements.

For example, if you disagree with a statement, mark as follows:

yes	no	not sure
☐	☑	☐

a. I felt anxious about bowel cancer *before* I took the Detectacol test

yes	no	not sure
☐	☐	☐

b. Having the Detectacol test made me feel *more anxious* about bowel cancer

yes	no	not sure
☐	☐	☐

c. I found it difficult following the instructions

yes	no	not sure
☐	☐	☐

d. I felt uncomfortable about collecting a specimen and sending it into a laboratory

yes	no	not sure
☐	☐	☐

e. I completely understood the reasons for taking the test

completely understood	mostly understood	didn't understand at all
☐	☐	☐

f. I feel that having the test was worthwhile

yes	no	not sure
☐	☐	☐

14. Please respond to the following statements about bowel cancer

a. Bowel cancer, if found at an early stage, can be completely cured

yes	no	not sure
☐	☐	☐

b. I have never worried that I might have bowel cancer

never worried	occasionally worried	frequently worried
☐	☐	☐

c. I am unlikely to get bowel cancer in the future

agree	disagree	not sure
☐	☐	☐

d. Health checks and screening tests are important even if I feel completely well

very important	of some importance	not important	not sure
☐	☐	☐	☐

e. By the time you know you have bowel cancer it has usually gone too far to cure

yes	no	not sure
☐	☐	☐

f. Bowel cancer tests detecting blood in stools (eg Detectacol) are always accurate.

Always	Nearly Always	Often	Occasionally	Not sure
☐	☐	☐	☐	☐

g. Bowel cancer runs in families

yes	no	not sure
☐	☐	☐

*questionnaire continues over the page

15. The following may influence whether or not people get bowel cancer:

(please tick a box)

	Yes	No	Not sure
red meat in the diet	☐	☐	☐
dietary fibre (eg bran, cereals)	☐	☐	☐
smoking	☐	☐	☐
alcohol	☐	☐	☐
physical exercise	☐	☐	☐
dietary fat	☐	☐	☐

16. Would you be more likely to continue to have screening tests for bowel cancer if.....

	Definitely would	Definitely would not	Maybe
the test was routinely offered by your GP	☐	☐	☐
you were provided with more information on the test	☐	☐	☐
you received reminder letters to take the test	☐	☐	☐
you didn't have to pay for the test	☐	☐	☐

17. Do you have private health insurance? yes ☐ no ☐

Did you claim for the cost of the Detectacol test through your private health fund? yes ☐ no ☐

18. Do you smoke cigarettes? yes ☐ no ☐

no. of cigs per day.....

19. Over the coming years, how often do you intend to take the Detectacol test....

once a year ☐ | every 2-5 years ☐ | every 6-10 years ☐ | never ☐ | not sure ☐

20. In the coming years, how often do you intend to take the following screening tests.....

a cholesterol test

at least once a year ☐ | every 2-5 years ☐ | every 6-10 years ☐ | never ☐ | not sure ☐

a blood pressure check

at least once a year ☐ | every 2-5 years ☐ | every 6-10 years ☐ | never ☐ | not sure ☐

***For women only....**

a pap smear (a test where some cells are taken from the cervix)

once a year ☐ | every 2-5 years ☐ | every 6-10 years ☐ | never ☐ | not sure ☐

a breast x-ray (mammogram)

once a year ☐ | every 2-5 years ☐ | every 6-10 years ☐ | never ☐ | not sure ☐

**questionnaire continues over the page*

21. Have you needed to take time off work as a result of your involvement in the Detectacol Programme?

yes ☐ no ☐ not working ☐

approximately how many hours?.....

22. Has your involvement in the Detectacol Programme resulted in you having extra visits to your general practitioner?

yes ☐ no ☐

Roughly how many extra visits?.....

23. How was your Detectacol test kit obtained?

- ☐ purchased from pharmacy or health fund office
- ☐ provided during visit to doctor
- ☐ sent by post
- ☐ other (please specify).....

.....

24. Did you or anyone else make a *special trip* to *obtain* your Detectacol kit?

yes ☐ no ☐

what was the form of travel?.....

public transport/ taxi ☐ car ☐ walking ☐

what was the distance travelled? ..... km

25. How did you *return* the Detectacol test kit to the laboratory?

sent in by post ☐ | brought into the IMVS laboratory ☐ | took to another collection centre ☐ | other (please specify).....

a. did this involve making a special trip? yes ☐ no ☐

b. what was the form of travel?.....

public transport/ taxi ☐ car ☐ walking ☐

c. what was the approximate *return* distance travelled? .....*km*

Do you have any other comments you would like to make about issues raised in this questionnaire?

.....

.....

.....

.....

Would you like your name to be entered into the lottery for a $100. Myer gift voucher?

yes ☐ → *name*.....

no ☐ *address*.....

.....

.....

Thank you very much for taking the time to complete this questionnaire

Appendix 2 - Questionnaire used in survey of test-positive screening participants

Department of Community Medicine, University of Adelaide
The South Australian Health Commission
The Institute of Medical & Veterinary Science

THE SOUTH AUSTRALIAN BOWEL CANCER STUDY - INFORMATION SHEET

Dear Participant,

We seek your involvement in a survey which is being conducted in South Australia to examine peoples' attitudes, knowledge and beliefs about bowel cancer and its prevention.

This questionnaire is being sent to a number of individuals who, like yourself, have participated in the "Detectacol" screening programme for bowel cancer and *have at some stage had a positive test result (even though you may have had negative test results at other times).*

As you are no doubt aware, bowel cancer is a major health problem in Australia. Your responses to this questionnaire will provide important information on strategies for preventing the disease.

This study is being conducted by the University of Adelaide Department of Community Medicine and The Institute of Medical and Veterinary Science.

The questionnaire should take approximately 10 minutes of your time, and we ask that you return it to us in the enclosed pre-paid envelope. ***Your responses to these questions will remain strictly confidential.*** If you would like to comment further on issues raised in this questionnaire please write your comments on the last page.

As a measure of our appreciation to all those who respond, you are invited to enter a lottery for a Myer Gift Voucher to the value of $100. which will be drawn on Dec. 13th, 1991 in the Department of Community Medicine, University of Adelaide (details at end of questionnaire).

If you would like further information on the study, please contact one of the organizers of the study listed below.

With thanks in anticipation,

Yours Sincerely,

(Dr. David Weller: Research Fellow, Dept. Community Medicine ph. 228 4615)

and on behalf of:
Dr. Janet Hiller (Lecturer, Dept. Community Medicine) ph. 228 4620, and
Dr. John Edwards (Head, Detectacol Laboratory, IMVS) ph. 228 7333

1. In which year were you born?

☐☐☐☐

2. Sex (please tick box)

male ☐
female ☐

3. What is your postcode?

☐☐☐☐

4. With regard to occupation, which of the following best applies to you?
(please tick box)

currently working ☐ → what is your occupation?

retired ☐ → what was your former occupation?

main lifelong occupation has been "domestic duties" ☐ → what is/was the occupation of your spouse?

other (please specify) ☐ → .....

5. Did you need to take time off work as a result of your positive test?

yes ☐ no ☐ not working ☐

approximately how many hours?.....

6. What was the cause of your positive Detectacol test? (eg hemorrhoids, polyps etc.).

☐ 1. hemorrhoids
☐ 2. bowel polyp(s)
☐ 3. caused by medications I was taking
☐ 4. no cause found
☐ 5. unsure
☐ 6. other (please specify).....

7. As a result of your positive test did you have either of the following.....

1) a ***barium enema*** (in which dye is introduced into the bowel via the back passage and an x-ray is taken)
yes ☐ no ☐ not sure ☐

2) a ***colonoscopy*** (in which a flexible tube is inserted into the back passage through which the doctor can examine the bowel)
yes ☐ no ☐ not sure ☐

8. Over the coming years, how often do you intend to take the Detectacol test....

once a year ☐ | every 2-5 years ☐ | every 5-10 years ☐ | never ☐ | not sure ☐

9. Have any of your brothers, sisters, parents or children ever had cancer of the bowel*? yes ☐ no ☐ unsure ☐

**Bowel cancer is also known as "bowel tumour, bowel growth or colorectal cancer"*

10. In the six months before you first took the Detectacol test, did you have any of these symptoms?.....

	yes	no
discomfort, pain or bloating in your stomach/abdomen	☐	☐
any change in your usual bowel habit lasting more than two weeks	☐	☐
bleeding from the back passage	☐	☐

→ I noticed the bleeding before I took the Detectacol test ☐ / I only noticed the bleeding when I took the Detectacol Test ☐

If you answered "yes" for any of the above symptoms did they make you worry that you might have bowel cancer?
yes ☐ no ☐

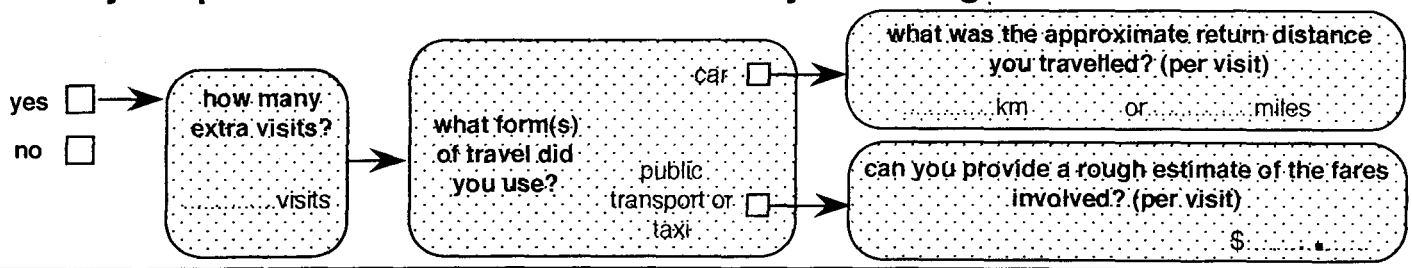
**questionnaire continues over the page*

11. The following questions examine your attitudes and beliefs about bowel cancer and screening tests. *There are no right or wrong answers*

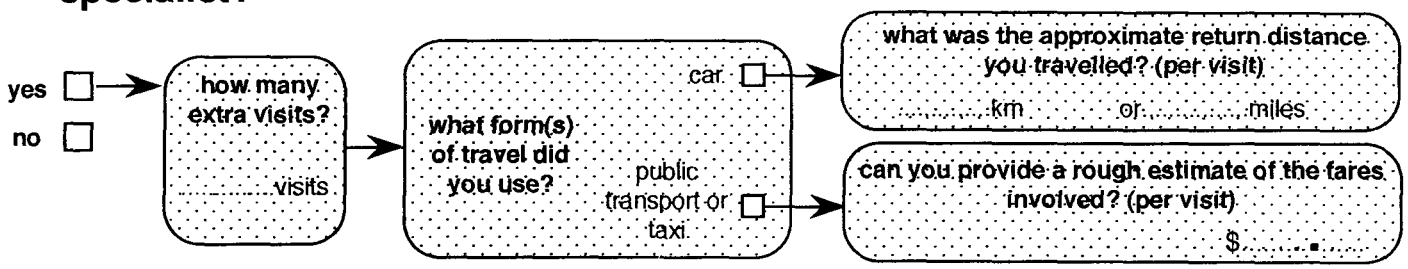
Please *tick the box* which best indicates your response

Having a positive Detectacol test made me worried that I might have bowel cancer	very worried ☐	a little worried ☐	not at all worried ☐	not sure ☐
I still feel worried that I may have bowel cancer	very worried ☐	a little worried ☐	not at all worried ☐	not sure ☐
Having a positive Detectacol test caused me a lot of unnecessary trouble	yes ☐	no ☐	not sure ☐	
Bowel cancer, if found at an early stage, can be completely cured	yes ☐	no ☐	not sure ☐	
I wish that I had never taken the Detectacol test	yes ☐	no ☐	not sure ☐	
I feel that having the test was worthwhile	yes ☐	no ☐	not sure ☐	
I am unlikely to suffer from bowel cancer in the future	yes ☐	no ☐	not sure ☐	
Having a positive Detectacol test has made me worry more about my general health	yes ☐	no ☐	not sure ☐	
Bowel cancer runs in families	yes ☐	no ☐	not sure ☐	
Bowel cancer tests detecting blood in stools (eg Detectacol) are always accurate	Always ☐	Nearly Always ☐	Often ☐	Occasionally ☐	Not sure ☐

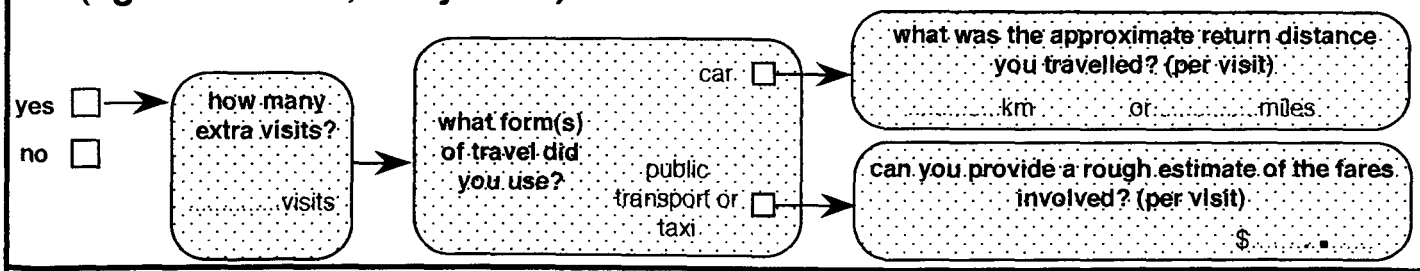
12. Did your positive Detectacol test result in you having extra visits to a GP?



13. Did your positive Detectacol test result in you having extra visits to a specialist?



14. Did your positive Detectacol test result in you having extra visits to hospitals, pathology centres, X-ray centres etc. for further investigations? (eg blood tests, x-rays etc.)



Do you have any other comments you would like to make about issues raised in this questionnaire?

.....

.....

.....

.....

Would you like your name to be entered into the lottery for a $100. Myer gift voucher?

yes ☐ → *name*.....

no ☐ *address*.....

.....

.....

Thank you very much for taking the time to complete this questionnaire

Appendix 3 - Summary of questions used in general population survey

(response categories: yes, no, not sure)

"A number of screening tests have been developed to detect cancer of the bowel at an early stage. The most common one involves collecting a specimen of faeces, applying it to a test kit which detects blood and sending/bringing the test kit to a laboratory....."

"Have you ever heard of such a test before?"

"Have you ever had such a test?"

"Do you think having such a test would be worthwhile?

"Do you intend to have this test?"

"Please respond to the following statements....."

"Bowel cancer, if found at an early stage, can be completely cured"

"I am unlikely to ever suffer from bowel cancer"

"I would rather not think about bowel cancer or taking such a test"

"I would feel uncomfortable about collecting a specimen and sending it into a laboratory"

Appendix 4 - Questionnaire used in survey of general practitioners

Department of Community Medicine
University of Adelaide

Research and Health Promotion Unit
Royal Australian College of General Practitioners

THE SOUTH AUSTRALIAN COLORECTAL CANCER SCREENING STUDY - INFORMATION SHEET

Dear Doctor,

We seek your participation in a survey of general practitioners in South Australia which is examining screening for colorectal cancer using the Fecal Occult Blood Test (FOBT). As you are no doubt aware, colorectal cancer is a major cause of mortality in Australian populations, and screening efforts are currently being directed at detecting the disease at an early stage.

As GPs are the principle health care providers who would form the front line in any widespread FOBT programme, it is important to know what you think about this form of screening.

Your considered and frank responses will greatly assist us in obtaining further information on this important health problem. *If you would like to be sent a copy of the results (which will be available in July), please indicate this in the "comments" section at the end of the questionnaire.*

The questionnaire should take approximately 10 minutes of your time, and we ask that you return it to us in the enclosed pre-paid envelope - there is a number in the left-hand corner of the envelope which is to allow for data collection and to identify those respondents who would like copies of the results. ***Your responses to these questions will remain strictly confidential.***

If you would like further information on the study, please contact us.

With thanks in anticipation,

Yours Sincerely,

Dr. David Weller MBBS (Adel) MPH FRACGP
Co-ordinator, Colorectal Cancer Screening Study. ph. 2284637 (work), 3799442 (home).

(and on behalf of)
Dr. Justin Beilby MBBS (Adel) MPH DA Dip Obs RACOG FRACGP
Assoc. Director, Research & Health Promotion Unit, RACGP (SA Faculty)
ph. 2725533 (work), 2711796 (home)

1. **Age** .....years

2. **Years since graduating from medical school** .....years

3. **Sex** male ☐ female ☐

4. **Where did you obtain your medical degree?** Australia ☐ Overseas ☐

5. **Please tick whichever of the following apply to you:**

	yes	no
a. Member/Assoc. Member of the Royal Australian College of General Practitioners (RACGP)	☐	☐
b. Fellow of the RACGP	☐	☐
c. Member of the AMA	☐	☐
d. Involved in teaching medical students or GP trainees	☐	☐
e. On Vocational Register	☐	☐
f. FMP Trainee	☐	☐
g. Work in General Practice Full-time	☐	☐
h. Work in General Practice Part-time	☐	☐
i. Principal career is General Practice	☐	☐
j. In solo practice	☐	☐
k. Practice is in a rural area	☐	☐
l. Practice is in a suburban area	☐	☐

6. **In which of the following groups of your *asymptomatic* patients would you normally recommend/perform regular FOBT for colorectal cancer?**

*please tick a box for each category of patients	yes	no	comments....
patients over forty	☐	☐	.....
patients over fifty	☐	☐	.....
patients over forty who have first-degree relatives with colorectal cancer	☐	☐	.....
patients with past history of colorectal cancer	☐	☐	.....
patients with past history of colorectal polyps	☐	☐	.....
all patients who request it	☐	☐	.....

additional comments.....

7. **Regarding *screening* tests for colorectal cancer in your *asymptomatic* patients, do you use/recommend the following procedures *(performed either by yourself or a specialist)* ?**

a. Sigmoidoscopy

in:	yes	no
patients over forty	☐	☐
patients over fifty	☐	☐
patients over forty who have first-degree relatives with colorectal cancer	☐	☐
patients with a past history of colorectal cancer	☐	☐
patients with a past history of colorectal polyp	☐	☐

b. Colonoscopy

in:	yes	no
patients over forty	☐	☐
patients over fifty	☐	☐
patients over forty who have first-degree relatives with colorectal cancer	☐	☐
patients with a past history of colorectal cancer	☐	☐
patients with a past history of colorectal polyp	☐	☐

comments.....

.....

8. An asymptomatic 55 year old patient with no past history or family history of bowel cancer presents to you with a positive occult-blood test. There is no obvious cause for the positive test on history or examination. Which of the following would you usually include in your management?

a. Reassure the patient and take no further immediate action — yes ☐ no ☐ not sure ☐

b. Perform digital rectal examination — yes ☐ no ☐ not sure ☐

c. Repeat the test with the FOBT that you normally use — yes ☐ → if this repeat test is negative, how would you proceed? *(tick one or more boxes)*
- ☐ take no further action
- ☐ recommend annual FOBT
- ☐ go ahead with further investigations
- ☐ other (please specify).....

d. **Which investigations would you use to find the cause of this individual's positive FOBT result?.....** *(please answer both parts)*

investigations you would normally use/recommend *initially* *(please tick any number of boxes)*	comments	**investigations you would normally use/recommend if your *initial* investigations were *inconclusive or unavailable*** *(please tick any number of boxes)*	comments
colonoscopy *(performed, if necessary, by medical specialist)* ☐	.....	colonoscopy *(performed, if necessary, by medical specialist)* ☐	.....
rigid sigmoidoscopy ☐	.....	rigid sigmoidoscopy ☐	.....
double-contrast barium enema ☐	.....	double-contrast barium enema ☐	.....
flexible sigmoidoscopy ☐	.....	flexible sigmoidoscopy ☐	.....
abdominal x-ray ☐	.....	abdominal x-ray ☐	.....
other (please specify).....		other (please specify).....	

further comments**.....**

.....

9. How do you prefer *FOBT screening* of your *asymptomatic patients* to take place?

- ☐ collect specimen in your surgery (or have patient bring in) and send to laboratory
- ☐ recommend your patients buy a kit which they use at home and send to laboratory
- ☐ perform and interpret the test immediately in your surgery
- ☐ other (please specify) .....
- ☐ rarely/never carry out FOBT screening

Which FOBT? IMVS's "Detectacol" test ☐ | IMVS FOBT (ordered on standard IMVS form) ☐ | Hemoccult ☐ | Gribbles FOBT ☐ | Other FOBT (please specify) ☐ .....

10. If screening for colorectal cancer using FOBT is to take place, which of the following strategies do you find acceptable?

*these strategies may overlap - for example, you may find that more than one of them is "acceptable for all individuals"	acceptable for all individuals	only acceptable for individuals at increased risk for colorectal cancer	never acceptable
Strategy1. screening is part of a centrally-coordinated programme initiated by government, or other organizations	☐	☐	☐
Strategy 2. self-testing kits are made available to the public directly, either commercially or through pharmacies	☐	☐	☐
Strategy 3. screening is offered to asymptomatic patients by their general practitioner (on the GPs' initiative)	☐	☐	☐
Strategy 4 screening is provided to asymptomatic patients (at their request) by general practitioners	☐	☐	☐

comments.....

.....

11. Please respond to the following statements about screening for colorectal cancer

	agree	disagree	not sure
There is convincing evidence that populations who are screened for colorectal cancer with FOBT have lower mortality from colorectal cancer	☐	☐	☐
I have received adequate education about strategies for the prevention of colorectal cancer	☐	☐	☐
There are clear guidelines I can follow when faced with a patient with a positive FOBT	☐	☐	☐
There are clear guidelines I can follow in deciding who I should recommend for colorectal cancer screening	☐	☐	☐
Screening with FOBT can be helpful in diagnosing individuals with bowel symptoms (eg. change in bowel habit, rectal bleeding etc.)	☐	☐	☐
Early diagnosis (eg. in the presymptomatic phase) of colorectal cancer improves overrall survival	☐	☐	☐
Detection and removal of adenomatous polyps decreases the incidence of colorectal cancer	☐	☐	☐

comments.....

.....

12. In your opinion, is there evidence that the following can reduce the risk of colorectal cancer?

	good evidence	evidence is unclear	no evidence	not sure
a. cutting down on fat consumption	☐	☐	☐	☐
b. consuming dietary fibre	☐	☐	☐	☐
c. reducing alcohol intake	☐	☐	☐	☐
d. reducing/quitting smoking	☐	☐	☐	☐
e. undertaking more exercise	☐	☐	☐	☐

comments.....

.....

13. In your opinion, how can a reduction in mortality from colorectal cancer best be achieved?

	yes	no	maybe/ not sure
mass screening with FOBT	☐	☐	☐
campaigns encouraging people to see their doctor early with bowel cancer symptoms	☐	☐	☐
revision/improvement of treatment regimes for colorectal cancer	☐	☐	☐
campaigns encouraging GPs to be more rigorous in their follow-up of patients with bowel symptoms	☐	☐	☐

comments.....

.....

14 a. How many cases of colorectal cancer would you estimate that you diagnose in an average year?

0 ☐ 1-2 ☐ 3-4 ☐ 5-6 ☐ 7-8 ☐ 9-10 ☐ >10 ☐

b. Do you usually perform sigmoidoscopies yourself? yes ☐ no ☐

Thank you very much for taking the time to complete this questionnaire. Do you have any further comments?

Appendix 5 - List of journal papers based on this thesis

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