Colorectal Cancer Screening Participation and Medical Advice Seeking for Symptoms in Australia

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Submitted for fulfilment of the award of:
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(Behavioural Science in Relation to Medicine)

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Priority Research Centre for Health Behaviour, School of Medicine and Public Health,
University of Newcastle
Statement of originality

This thesis contains no material which has been accepted for the award of any other degree or diploma in any university or other tertiary institution and, to the best of my knowledge and belief, contains no material previously published or written by another person, except where due reference has been made in the text. I give consent to this copy of my thesis, when deposited in the University of Newcastle Library*, being made available for loan and photocopying subject to the provisions of the Copyright Act 1968.

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Acknowledgement of authorship

I hereby certify that this thesis is in the form of a series of published papers of which I am a joint author. I have included as part of the thesis a written statement from each co-author, endorsed by the Faculty Assistant Dean, Research Training, attesting to my contribution to the joint publications.

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Synopsis

The contents of this thesis by publication include an introduction, a critical review, five data-based manuscripts and a general discussion providing implications and conclusions. The papers examined the early detection and prevention of colorectal cancer (CRC) in the community-based setting and among first-degree relatives of CRC patients. At timing of thesis submission, three papers (two data-based and one review paper) had been accepted for publication. The remaining three are under editorial review.

The burden of disease, early detection and prevention of colorectal cancer (CRC) is presented in the Introduction. It provides a general overview of CRC-related global burden of disease, its aetiology and the efficacy of screening in reducing incidence and mortality. It also examines current levels of CRC screening uptake and the populations currently experiencing inequality in CRC screening. This chapter also provides an overview of the current state of medical consultation and delay in seeking medical advice for primary symptoms of CRC (i.e. rectal bleeding and change in bowel habit).

Paper One (accepted for publication, Cancer Forum): "Community approaches to increasing colorectal screening uptake: A review of the methodological quality and strength of current evidence" provides a critical review of methodically sound community-based approaches to increasing CRC screening levels. This review identified (i) the number of community-based interventions published between 2002 and 2011, (ii) the proportion of intervention studies that had adopted a community-based approach and met basic Cochrane Effective Practice and Organisation (EPOC) study design criteria and (iii) the effectiveness of community-based studies with at least a moderate level of methodological rigour at increasing
CRC screening rates. Eighty-six intervention studies were identified, 21 of which adopted a community- or population-based approach to increasing CRC screening levels. Overall, the methodological rigour of such studies was moderate. Of the 21 intervention studies, 15 had used an accepted EPOC study design. Only one methodologically robust Australian community-based study was identified. Based on findings from studies with moderate methodological rigour, a number of potential options which the National Bowel Cancer Screening Program may consider using to increase screening rates are discussed. This review highlighted the urgent need for further methodologically rigorous community-based CRC screening intervention research in Australia.

Paper Two (accepted for publication, Medical Journal of Australia):
“Colorectal (bowel) cancer screening in Australia: A community-level perspective” is a cross-sectional study which identified the current levels of CRC screening uptake and screening in accordance with National Health and Medical Research Council (NHMRC) screening guidelines among an at-risk community cohort of persons aged 56-88 years. A total of 1592 participants were selected from the Hunter Community Study (HCS), Hunter Region, New South Wales, Australia. Of these, 1117 respondents returned a completed questionnaire (response rate, 70%). Of this group, 777 persons were deemed asymptomatic and eligible for analysis. Overall, 63% of respondents had ever received any CRC testing in their lifetime. Forty-three percent of respondents had ever had a faecal occult blood test (FOBT), with a screening rate of 20% in the previous two years. Thirty percent of respondents had ever had a colonoscopy, with 16% screened in the previous five years. Seven percent of respondents had ever had a sigmoidoscopy, with a screening rate of 1% in the previous five years. Rates of adherence to screening guidelines were 21% for respondents “at or slightly above average risk” and 45% for respondents at “moderately
increased risk” or “potentially high risk”. This study indicated that rates of CRC screening in Australia remain low. The screening rate for colonoscopy was high among persons “at or slightly above average risk”, despite such screening not being endorsed in the NHMRC guidelines. Effective strategies to improve rates of CRC screening and appropriate use of colonoscopy are required across the entire at-risk population.

Paper Three (under editorial review, *BMC Public Health*): “Individual- and provider-level factors associated with colorectal cancer screening in accordance with guideline recommendation: A community-level perspective across varying levels of risk” is a cross-sectional cohort study using the aforementioned sampled population which assessed the socio-demographic and provider-level factors associated with ever receiving CRC testing and CRC screening in accordance with guideline recommendations. A secondary analysis was conducted to examine National Bowel Cancer Screening Program eligibility on each aforementioned outcome. Ever receiving CRC testing was significantly more likely for persons aged 65-74 years and for those who had discussed their family history of CRC with a doctor or had ever received screening advice from a doctor. For respondents “at or slightly above average risk”, screening in accordance with guideline recommendation was significantly more likely for persons aged 65-74 years, those with higher household income and those who had ever received screening advice. For respondents at “moderately increased risk” or “potentially high risk”, screening in accordance with guideline recommendations was significantly more likely for persons with private health insurance and for those who had discussed their family history of CRC with a doctor. Colonoscopy screening in the previous five years was significantly more likely for persons who had ever smoked, those who had discussed their family history of CRC with a doctor and those who had ever received screening advice. Public education programs that target population
groups less likely to engage in CRC screening are pivotal for decreasing screening inequalities. Interventions are also required to increase CRC screening rates.

**Paper Four: (Under editorial review, *British Medical Journal*):** “A population-based examination of colorectal cancer screening practices of first-degree relatives of colorectal cancer patients” is a population-based study among first-degree relatives (FDRs) of CRC patients examining across varying levels of risk, the proportion of FDRs (i) ever receiving any CRC testing in their lifetime and (ii) screened in accordance with NHMRC screening guidelines. Socio-demographic and provider-level predictors of (i) and (ii) were also evaluated. Index case patients were selected from the Victorian Cancer Registry, Victoria, Australia. Seven hundred and seven first-degree relatives completed telephone interviews. Of these, 405 FDRs were deemed asymptomatic and eligible for analysis. Sixty-nine percent of FDRs had ever received any CRC testing in their lifetime. This rate did not differ statistically across level of risk. Older FDRs, those with private health insurance, siblings and those who had ever been asked about their family history of CRC by a doctor were significantly more likely to have ever received CRC testing. Twenty-five percent of FDRs “at or slightly above average risk” were screened in accordance with screening guidelines. For this group, male FDRs and those with a higher level of education were significantly more likely to have been screened in accordance with guidelines. For persons at “moderately increased risk” or “potentially high risk”, 47% and 49% respectively, were screened in accordance with screening guidelines. For this group, FDRs living in major cities or metropolitan areas, siblings, those married or partnered and those who were ever asked about family history of CRC by a doctor were significantly more likely to be screened in accordance with guideline recommendations. A significant level of non-compliance to screening guidelines among a population at elevated relative risk was evident. There is substantial room for improved screening of FDRs of CRC patients.
and an urgent need to address individual- and provider-level barriers to screening. Effective systematic interventions that reach this vulnerable population group are needed.

Paper Five: (Accepted for publication, Colorectal Disease): “The current state of medical-advice-seeking behaviour for primary symptoms of colorectal cancer: Determinants of failure and delay in medical consultation” reports on a cross-sectional study examining, for two primary symptoms of colorectal cancer (i.e. rectal bleeding and change in bowel habit), rates of (i) non-consultation and (ii) delay in seeking medical advice for both symptoms. Additionally, the reasons for non-consultation and delay in seeking medical advice for each symptom as well as the triggers for consulting a doctor following symptom episode were investigated. A total of 1592 persons aged 56-88 years were randomly selected from the Hunter Community Study and sent a questionnaire. Of these, 1117 persons returned completed questionnaires (response rate, 70%). Eighteen percent (60/332) of respondents experiencing rectal bleeding and 20% (39/195) of those reporting change in bowel habit had never consulted a doctor for the symptom. Rates of delay (> one month) for each symptom were 18% and 37% respectively. Reasons for delay included assumptions about symptom seriousness and benign nature. Various triggers for seeking medical advice were identified. Healthcare-seeking behaviour for rectal bleeding had not significantly improved, compared with a previous community-based data set. The seriousness of symptoms, importance of early detection, and prompt medical consultation must be articulated in health messages to at-risk persons.

Paper Six: (Under editorial review, BMC Gastroenterology): “Factors associated with consultation behaviour for primary symptoms that potentially indicate colorectal cancer: A cross-sectional study on response to symptoms”.

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The purpose of this study using the aforementioned Hunter Community Study cohort was to identify the socio-demographic and provider-related characteristics associated with (i) ever seeking medical advice for primary symptoms of CRC and (ii) early medical-advice-seeking behaviour for primary symptoms of CRC. Males and those who had received screening advice from a doctor were significantly more likely to ever seek medical advice for rectal bleeding. Persons who had private health coverage, those who consulted a doctor because the “symptom was serious” or who did not wait to consult a doctor for another reason were significantly more likely to seek early medical advice. Persons with lower income, those within the healthy weight range and those who had discussed their family history of CRC, irrespective of whether they were informed of “increased risk”, were significantly more likely to ever seek medical advice for change in bowel habit. Persons frequenting their general practitioners less often and those seeing their doctors because the symptoms persisted were significantly more likely to seek early medical advice. This study identified modifiable factors at individual and provider levels related to consultation behaviour and delay. Effective health promotion efforts must heed these factors and target sub-groups less likely to seek early medical advice.

Discussion and implications for future research and practice

In conclusion, this dissertation has provided insight into the current levels of CRC screening in compliance with NHMRC screening guideline recommendations at a community level and among an increased-risk population (i.e. first-degree relatives of CRC patients). Previously, little was known about community CRC screening levels across varying levels of risk. The low rates of screening in accordance with guidelines and the identified screening inequalities across individual and socio-demographic characteristics highlights the need for systematic population-based approaches to increase the rate of risk-appropriate CRC screening. This thesis also highlighted the
poor receptivity of community members to prompt medical advice seeking for potential symptoms of CRC. Both high rates of delay and non-consultation for primary symptoms were evident, with little appreciable improvements indicated through a direct comparison with an earlier at-risk community data set. The current work highlights the need for systematic population-based approaches that are tested in methodically rigorous interventions, if improvements in the earlier presentation of primary symptoms and the level of risk-appropriate CRC screening are to occur. The direction of future research stemming from this dissertation and the possible pathways for future research initiatives are discussed.
Statement of Contributions of Others
Statement of contribution

I, Associate Professor Christine Paul, attest that Research Higher Degree candidate, Ryan Courtney, contributed substantially in terms of study concept and design, data collection and analysis, and preparation of the manuscripts to meet British Medical Journal authorship guidelines for the following manuscripts:


A population-based examination of colorectal screening practices of first-degree relatives of colorectal cancer patients. Ryan J Courtney, Christine L Paul, Mariko L Carey, Robert W Sanson-Fisher, Finlay Macrae, Catherine D'Este, David Hill, Daniel Barker, Jody Simmons.


Statement of contribution

I, Laureate Professor Robert Sanson-Fisher, attest that Research Higher Degree candidate, Ryan Courtney, contributed substantially in terms of study concept and design, data collection and analysis, and preparation of the manuscripts to meet British Medical Journal authorship guidelines for the following manuscripts:


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Statement of contribution

I, Professor David Hill, attest that Research Higher Degree candidate, Ryan Courtney, contributed substantially in terms of study concept and design, data collection and analysis, and preparation of the manuscript to meet British Medical Journal authorship guidelines for the following manuscript:

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INTRODUCTION

Colorectal cancer, its early detection and prevention: The clear need for adherence to screening guidelines and improved medical-advice-seeking behaviour for primary symptoms
Introduction

Aetiology of colorectal cancer

Colorectal cancer (CRC) is a malignant tumour that occurs in either the colon or rectum, often remaining localised for several years.\(^1\) If left untreated, it may spread through the bowel wall and into blood or lymph systems of the body.\(^1\) The natural history of CRC is known as the adenoma-carcinoma sequence.\(^2\) Colorectal cancer, for the most part, occurs from small benign growths (adenomatous polyps) that gradually transform to irregular or uncontrollable cell growths.\(^1\) In the majority of CRC cases, progression from benign pre-cursors (adenoma) to carcinoma takes between five and ten years.\(^3\) The targeting of these adenomas through routine CRC screening is argued to be an effective method of reducing CRC rates.\(^4\)

Burden of illness associated with colorectal cancer

It is estimated that worldwide in 2008 1,234,000 persons were diagnosed with CRC, with CRC being the third most common cancer in men (663,000, 10% of total cases) and the second most common cancer in women (571,000, 9.4% of total cases).\(^5\) In this same year, CRC accounted for approximately 608,000 deaths (7.6% of all cancer-related deaths) worldwide, making it the fourth most common cause of cancer death.\(^5\) In Australia, there is a one in 12 risk of developing CRC by age 85 years, for both males and females.\(^6\) The crude incidence of CRC is increasing in Australia and is expected to continue to rise with an ageing population.\(^7\) In Australia, CRC is the second most commonly diagnosed cancer after prostate cancer and the second most common cause of death from malignant disease after lung cancer, with over 14,000 diagnoses and over 4,000 deaths annually attributable to CRC.\(^8\) Colorectal cancer is a leading cause of premature death, second only to lung cancer in Australia as a cause of years of life lost, resulting in 55,000 years of life lost in 2010.\(^8\) Australia has among the highest incidence and mortality rates for CRC in the world, higher than for the United Kingdom (UK), United States (US) and Canada (See Table 1.1).\(^9\)
Table 1.1: Age-standardised incidence and mortality rates (per 100,000) for colorectal cancer by selected countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Incidence</th>
<th>Mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>38.7</td>
<td>12.6</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>30.8</td>
<td>11.3</td>
</tr>
<tr>
<td>United States</td>
<td>29.2</td>
<td>8.8</td>
</tr>
<tr>
<td>Canada</td>
<td>38.1</td>
<td>11.7</td>
</tr>
</tbody>
</table>

The Australian age-standardised mortality rate is 54% higher than that of the estimated world average. Although the age-standardised incidence rate has remained relatively constant in Australia over the last two decades, the mortality rate from 1982 to 2007 has decreased by 41% for males and 47% for females. The reasons for a continued decline in mortality are not clear, although advances in treatment and earlier detection of precancerous polyps are thought to be key contributing factors.

Economic cost of colorectal cancer

On recent trends, it is expected that in Australia CRC will be the most costly malignancy in economic terms by 2012. Its cost to the healthcare system has increased four-fold over the past decade. Australia’s annual CRC bill is set to exceed $1 billion in 2012, with increases in costs associated with Medicare and Pharmaceutical Benefit Schemes expected to continue unless cost offsets from screening accrue. Most of the costs associated with CRC (over 80%) are primarily treatment costs, with only 3% of the annual CRC expenditure related to screening. The cost of treating CRC increases substantially with disease progression, varying from $1250 for the removal of pre-cancerous polyps to over $23,000 for the treatment of...
late-staged carcinoma.\textsuperscript{14} The benefits of removal of pre-cancerous polyps appear to be evident in economic terms and also in improved prognosis for individuals.\textsuperscript{14}

**Colorectal cancer staging and survival**

Early diagnosis of cancer can result from either screening or improved recognition of symptomatic cancers.\textsuperscript{15} A key prognostic factor for survival is stage at the time of treatment.\textsuperscript{16} Staging is a measure of how far the disease has spread through the body.\textsuperscript{17} The longer that CRC goes undetected, the greater the likelihood that the cancer will spread throughout the body.\textsuperscript{17} Thus, diagnosis at an early stage is of great importance.\textsuperscript{18} A commonly used method of staging is the Tumour Node Metastasis (TNM) classification system.\textsuperscript{19} The TNM system is based on the extent of the tumour (T), the extent of spread to the lymph nodes (N) and the presence of distant metastasis (M). A number is added to each letter to indicate the size or extent of the primary tumour and the extent of cancer spread (See Table 1.2).\textsuperscript{19, 20} Alternatively, the “Duke’s” method of staging may be used (See Table 1.3).\textsuperscript{20}

**Table 1.2: Tumour Node Metastasis colorectal cancer staging system\textsuperscript{20}**

<table>
<thead>
<tr>
<th>Primary tumour (T)</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>TX</td>
<td>Primary tumour cannot be assessed</td>
</tr>
<tr>
<td>T0</td>
<td>No evidence of primary tumour</td>
</tr>
<tr>
<td>Tis</td>
<td>Carcinoma \textit{in situ}: intra-epithelial or invasion of \textit{lamina propria}</td>
</tr>
<tr>
<td>T1</td>
<td>Tumour invades \textit{submucosa}</td>
</tr>
<tr>
<td>T2</td>
<td>Tumour invades \textit{muscularis propria}</td>
</tr>
<tr>
<td>T3</td>
<td>Tumour invades through the \textit{muscularis propria} into pericolorectal tissues</td>
</tr>
<tr>
<td>T4a</td>
<td>Tumour penetrates to the surface of the visceral peritoneum</td>
</tr>
<tr>
<td>T4b</td>
<td>Tumour directly invades or is adherent to other organs or structures</td>
</tr>
<tr>
<td></td>
<td>Description</td>
</tr>
<tr>
<td>---</td>
<td>-------------</td>
</tr>
<tr>
<td><strong>Regional Lymph Nodes (N)</strong></td>
<td></td>
</tr>
<tr>
<td>NX</td>
<td>Regional lymph nodes cannot be assessed</td>
</tr>
<tr>
<td>N0</td>
<td>No regional lymph node metastasis</td>
</tr>
<tr>
<td>N1</td>
<td>Metastasis in 1-3 regional lymph nodes</td>
</tr>
<tr>
<td>N1a</td>
<td>Metastasis in one regional lymph node</td>
</tr>
<tr>
<td>N1b</td>
<td>Metastasis in 2-3 regional lymph nodes</td>
</tr>
<tr>
<td>N1c</td>
<td>Tumour deposit(s) in the subserosa, mesentry, or nonperitonealised pericolic or perirectal tissues without regional nodal metastasis</td>
</tr>
<tr>
<td>N2</td>
<td>Metastasis in 4 or more regional lymph nodes</td>
</tr>
<tr>
<td>N2a</td>
<td>Metastasis in 4-6 regional lymph nodes</td>
</tr>
<tr>
<td>N2b</td>
<td>Metastasis in 7 or more regional lymph nodes</td>
</tr>
</tbody>
</table>

| **Distant Metastasis (M)** |   |
| M0 | No distant metastasis |
| M1 | Distant metastasis |
| M1a | Metastasis confined to one organ or site |
| M1b | Metastases in more than one organ/site or the peritoneum |
Table 1.3: Tumour Node Metastasis stage groupings, Duke’s stage, and degree of spread*

<table>
<thead>
<tr>
<th>TNM stage</th>
<th>TNM group</th>
<th>Duke’s stage</th>
<th>Degree of spread</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Tis, N0, M0</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>I</td>
<td>T1, N0, M0</td>
<td>A</td>
<td>Local</td>
</tr>
<tr>
<td></td>
<td>T2, N0, M0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IIA</td>
<td>T3, N0, M0</td>
<td>B</td>
<td>Local</td>
</tr>
<tr>
<td>IIB</td>
<td>T4a, N0, M0</td>
<td>B</td>
<td>Local</td>
</tr>
<tr>
<td>IIC</td>
<td>T4b, N0, MO</td>
<td>B</td>
<td>Local</td>
</tr>
<tr>
<td>IIIA</td>
<td>T-T2, N1/N1c, M0</td>
<td>C</td>
<td>Regional</td>
</tr>
<tr>
<td></td>
<td>T1, N2a, M0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IIIB</td>
<td>T3-4a, N1/N1c, M0</td>
<td>C</td>
<td>Regional</td>
</tr>
<tr>
<td></td>
<td>T2-T3, N2a, M0</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>T1-T2, N2b, M0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IIIC</td>
<td>T4a, N2a, M0</td>
<td>C</td>
<td>Regional</td>
</tr>
<tr>
<td></td>
<td>T3-T4a, N2b, M0</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>T4b, N1-N2, M0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IVA</td>
<td>Any T, Any N, M1a</td>
<td>-</td>
<td>Distant</td>
</tr>
<tr>
<td>IVB</td>
<td>Any T, Any N, M1b</td>
<td>-</td>
<td>Distant</td>
</tr>
</tbody>
</table>

* Source: Adapted from American Joint Committee on Cancer. Colon and rectum cancer staging (7th Edition)²⁰

Five-year survival estimates for CRC are stage-based. Across Australia, the UK, the US and Canada, early-stage detection of disease has a five-year relative survival rate of approximately 90%.⁵ This figure, however, diminishes significantly for later-stage presentation, with less than 10% five-year survival rate for advanced metastatic disease.⁵ Few, if any, symptoms manifest until CRC reaches an advanced stage, thus making CRC screening an invaluable tool for prevention.²¹ Worldwide, less than 40% of CRCs are diagnosed at the earliest stage of
disease. In Australia, the overall five-year survival rate for CRC is 61.8%, with the majority of CRC cases not detected at an early stage. In 1999, approximately 15% of CRCs in South Australia were diagnosed at the earliest possible point (i.e. Stage A, confined to the bowel wall). Most recent state-wide data from the New South Wales (NSW) Cancer Registry indicate that approximately 33% of CRCs are diagnosed at a localised stage. This suggests that screening to enable early detection would have a positive impact on survival rates and reductions in CRC mortality.

**Efficacy and effectiveness of colorectal cancer screening in reducing incidence and mortality**

Colorectal cancer is an ideal candidate for screening, as it has high prevalence, a long natural history and demonstrated clear benefits from early-stage disease detection. Colorectal cancer is largely clinically asymptomatic in its early stages, thus making it a prime target for early detection and prevention through screening. Colorectal cancer screening reduces both CRC incidence through the removal of pre-cancerous polyps, and CRC deaths through early detection and treatment. Widely-used screening tests for CRC include the faecal occult blood test (FOBT), colonoscopy and sigmoidoscopy.

*Faecal occult blood test (FOBT)*

There are two main types of faecal occult blood test (FOBT): guaiac-based FOBT (gFOBT) and immunochemical-based (iFOBT), also sometimes given the term Faecal immunochemical test (FIT). The faecal occult blood test is based on the premise that CRCs or polyps often bleed microscopic amounts of blood into the bowel, with subsequent bleeding detected through testing. Both iFOBT and gFOBT have an important role in CRC screening as these tests can identify persons who may have either early staged CRC or pre-cancerous polyps. Both tests are used to detect the presence of blood in the stool but differ in their biological and
technological characteristics used to detect gastrointestinal bleeding. The gFOBT uses the chemical guaic to identify heme in stool. Heme is the iron-containing part of the blood protein haemoglobin. While the iFOBT alternative uses antibodies to detect the haemoglobin protein in stool. Several randomised controlled trials (RCTs) have indicated it is possible to reduce mortality from CRC by 15% to 33% with FOBT screening on either an annual or biennial basis. Screening with FOBT also has the potential to reduce incidence and prevent CRC through the removal of precancerous lesions, identified through colonoscopic follow-up of positive FOBTs. Randomised controlled trials have demonstrated that the likelihood of detection of CRC following positive FOBT is 12-40 times greater than following a negative FOBT. Research findings suggest that 11% of patients presenting with symptomatic CRC have a Duke’s stage A tumour, the least severe cancer grading, compared with 51% of all CRCs detected by FOBT screening. At present, population-based randomised trial evidence largely favours the FOBT. However, more recently research support has been provided for flexible sigmoidoscopy. On a population basis, CRC screening programs using FOBTs are comparable to, if not superior than, current breast and cervical screening programs (on a cost-effectiveness basis).

**Colonoscopy**

Colonoscopy is a preferred screening modality endorsed by authorities such as the US Preventive Services Task Force, due to its preventive potential for detection and removal of adenomatous polyps, thus reducing CRC incidence. Although colonoscopy remains untested in randomised trials, some organisations and societies advocate this test as a preferred screening modality on a population level. Case control and cohort studies using large-bowel endoscopy have shown a CRC mortality reduction rate ranging from 60% to 76% and incidence reduction of 76% to 90%. The usefulness of colonoscopy for detecting right-sided carcinoma has been questioned, as there is a substantial identified miss-rate and a lessened
mortality reduction rate for right-sided CRCs. However, a recent study has indicated benefits for detection of right-sided carcinoma. Further, while considered generally safe, colonoscopy is a procedure that requires both full bowel preparation and patient sedation, and is associated with a serious complication risk of 1 in 1000. This rate of complication is much higher than that for other cancer screening tests. The evidence base for colonoscopy as a screening tool relies on indirect case control evidence. Until future RCT evidence is available, caution has been suggested when interpreting the benefits and risks of colonoscopy.

**Sigmoidoscopy**

Flexible sigmoidoscopy can locate adenomas or carcinomas in the rectum and sigmoid colon, the location of approximately two-thirds of presenting CRCs. The risk of perforation is half that of colonoscopy. Case control research has indicated a CRC mortality reduction of between 59% and 79% for carcinomas accessible to the sigmoidoscope. Recent RCT evidence of once-only flexible sigmoidoscopy for persons 55-64 years of age provides strong evidence for the substantial and long-term benefit of this procedure. This study indicated a one-third reduction of incidence and 40% reduction in mortality for persons undertaking sigmoidoscopy screening. Potentially greater reduction in incidence and mortality associated with sigmoidoscopy screening may be witnessed in the near future, with results of several randomised trials soon to be released.

**Colorectal cancer screening guidelines**

Reduction in CRC mortality relies on screening that takes place with minimal cost and harm. For CRC screening, a number of testing modalities are present, with screening programs quite complex compared with other cancers. Quality in CRC screening is not restricted to the number of screening procedures, but rather refers to the appropriate use, under-use, over-use or misuse of screening procedures. While under-use of screening has been evident for some decades, a
newer investigation of over-use (i.e. screening procedures where little net benefit is possible) or misuse (i.e. screening which reduces the net benefit of screening) has started to evolve in the literature.\textsuperscript{49} Clinical practice guidelines have been implemented worldwide to encourage the adoption of risk-appropriate CRC screening.\textsuperscript{50} Periodic CRC screening of people at varying levels of risk is recommended by several healthcare organisations worldwide, including the United States Preventive Services Task Force (USPSTF), the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, and the National Health and Medical Research Council (NHMRC).\textsuperscript{51} In Australia, the NHMRC clinical practice guidelines separate level of risk into three categories: “at or slightly above average risk”; “moderately increased risk”; and “potentially high risk” (See Table 1.4 for Australian CRC screening guidelines).\textsuperscript{51} Asymptomatic individuals aged over 50 years of age with no pre-existing history of CRC, advanced adenoma, chronic ulcerative colitis or first-degree relative (i.e. parent, sibling or child) diagnosed with CRC before the age of 55 years are deemed “at or slightly above average risk” of developing CRC.\textsuperscript{51} Factors which place individuals at increased risk of CRC in accordance with guidelines include personal history of advanced adenoma or CRC, family history of CRC or inflammatory bowel disease, and the presence of a genetic mutation, e.g. Lynch’s Syndrome or Familial Adenomatous Polyposis (FAP).\textsuperscript{51} This thesis will include a focus on age and family history of CRC as two of the most common non-modifiable risk factors for developing CRC.
Table 1.4: Levels of risk in accordance with National Health and Medical Research Council colorectal cancer screening guidelines\textsuperscript{51}

Individuals can be placed in one of three categories of relative risk based on their family history:

<table>
<thead>
<tr>
<th>Risk Category</th>
<th>Description</th>
</tr>
</thead>
</table>
| At or slightly above average risk | • No personal history of bowel cancer, advanced adenoma or chronic ulcerative colitis  
• Either no close relative with bowel cancer or one first-degree or second-degree relative with bowel cancer diagnosed at 55 years or older |
| Moderately increased risk         | • One first-degree relative diagnosed before the age of 55 years (without the potentially high-risk features listed below), or  
• Two first-degree or one first- and one second-degree relative(s) on the same side of the family with bowel cancer diagnosed at any age (without the potentially high-risk features listed below) |
| Potentially high risk             | • Three or more first-degree or a combination of first-degree and second-degree relatives on the same side of the family diagnosed with bowel cancer (suspected HNPCC\textsuperscript{*}), or  
• Two or more first-degree or second-degree relatives on the same side of the family diagnosed with bowel cancer, including any of the following high-risk features:  
  - multiple bowel cancers in the one person  
  - bowel cancer before the age of 50 years  
  - at least one relative with cancer of the endometrium, ovary, stomach, small bowel, renal pelvis, ureter, biliary tract or brain (suspected HNPCC\textsuperscript{**}), or  
  - at least one first-degree relative with a large number of adenomas throughout the large bowel (suspected FAP)\textsuperscript{**}  
  - somebody in the family in whom the presence of a high-risk mutation in the adenomatous polyposis coli (APC) gene or one of the mismatch repair (MMR) genes has been identified. |

\textsuperscript{*}HNPCC (Hereditary non-polypsis colorectal cancer), also known as Lynch's Syndrome.  \textsuperscript{**} FAP (Familial Adenomatous Polyposis).

Colorectal cancer screening recommendations

Recommendations regarding test type and schedules for repeat testing vary across countries, although the risk features which place persons at increased risk, e.g. number and type of affected relatives and age of onset of CRC, are generally consistent.\textsuperscript{50} Table 1.5 presents
Australian clinical practice guideline recommendations for screening of asymptomatic persons across varying levels of risk.\textsuperscript{51} It should be noted that in the Australian context, colonoscopy screening of asymptomatic at-risk persons (i.e. those aged over 50 years) is only endorsed for persons at elevated levels of risk (i.e. “moderately increased risk” and “potentially high risk”).\textsuperscript{51} This contrasts with the US health system where colonoscopy screening is endorsed for all at-risk persons and every 10 years for the “average risk” population.\textsuperscript{36, 37} Further, FOBT screening in Australia is endorsed every two years for persons “at or slightly above average risk”, compared with annually for persons in the US.\textsuperscript{37} Additionally, persons aged 50-74 years are recommended to receive FOBT screening in the US,\textsuperscript{36, 37} in comparison to Australian guidelines which do not specify an upper age-limit.\textsuperscript{51}

\textbf{Table 1.5:} Australian colorectal cancer screening guideline recommendations across varying levels of risk\textsuperscript{51}

<table>
<thead>
<tr>
<th>Risk category</th>
<th>Screening recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>At or slightly above average risk</td>
<td>• FOBT every two years from the age of 50 years</td>
</tr>
<tr>
<td></td>
<td>• Consider sigmoidoscopy (preferably flexible) every five years</td>
</tr>
<tr>
<td>Moderately increased risk</td>
<td>• Offer colonoscopy every five years starting at age 50, or at an age ten years younger than the age of first diagnosis of bowel cancer in the family, whichever comes first. Flexible sigmoidoscopy and double contrast barium enema or computed tomography (CT) colonoscopy may be offered if colonoscopy is contraindicated for some reason.</td>
</tr>
<tr>
<td>Potentially high risk</td>
<td>• Endoscopy screening recommendations (commencement age and timing of repeat testing for this risk group vary dependent on the family-specific mutation identified).</td>
</tr>
</tbody>
</table>

\textbf{Australia’s National Bowel Cancer Screening Program and current screening rates}

Australian guidelines recommend that asymptomatic persons “at or slightly above average risk” receive either FOBT screening biennially or sigmoidoscopy (preferably flexible) every five years commencing at age 50 years.\textsuperscript{51} The National Bowel Cancer Screening Program (NBSCP) offers
immunochemical faecal occult blood test (iFOBT) screening to persons turning 50, 55 or 65 years of age.52 Selected age-brackets were chosen for this program as a staged roll-out of the program is being adopted. Further, there were concerns that colonoscopy services may not cope if the program was made available to the whole at-risk population at one time.53 The selected age brackets offered CRC screening however is in contrast to existing studies which have provided estimates of costs and outcomes from full implementation of biennial FOBT screening for adults in the at-risk population (50-74 years), including one study which established a likely mortality reduction of 25% and saving of 500 deaths per year.35 On a cost-effectiveness basis, such a program is comparable to breast and cervical cancer screening programs.33, 35 The current program’s restriction of screening to persons in selected age brackets is not consistent with the NHMRC recommendation of biennial screening of all Australians in the at-risk population.51 Further, the NBCSP has excluded persons aged over 65 years of age from screening.52

Screening programs similar to the NBCSP have been implemented in several countries, with variations in reach, cost to patients and scheduling of repeat screening.54 In the US, a national population-based screening program is not available, although it is a requirement of private and public health insurers to provide coverage for preventive health services given an A or B recommendation by the USPSTF.55, 56 In Canada, some progress has been made since the inception of the National Colorectal Cancer Screening Network, with ten provinces now involved, to some extent, in organised screening programs.57

Participation rates in Australia’s national screening program appear to have reached a plateau since the pilot program’s introduction.58-61 The pilot program received a response rate of 45%, with the roll-out of the national program in 2006 receiving a slightly lower rate of 41% (August 2006 to July 2007).59 The rate of participation only marginally increased during phase 2 (with
screening also offered to persons aged 55 years of age) in 2008 to 42.9%.\textsuperscript{58} Most recent estimates (January 2008 to January 2010) suggest a similar rate of low participation (40.1%).\textsuperscript{61} The experience in other countries with national screening programs suggests that much higher screening rates are achievable. For example, FOBT screening rates in the UK and Finnish screening programs are currently 52% and 71% respectively.\textsuperscript{62, 63}

**Inequality in colorectal cancer screening participation**

The ultimate aim of healthcare is to increase equality in access, utilisation, treatment and outcomes, including morbidity and mortality.\textsuperscript{64} In numerous parts of the world there is growing evidence that CRC survival differs across socio-economic groups.\textsuperscript{65, 66} Such disparities are still found in countries with universal healthcare, thus raising questions about the origins of such disparities.\textsuperscript{65} The NBCSP monitoring reports and community-based evaluations have indicated low rates of screening participation among a number of population groups.\textsuperscript{58-61, 67, 68} Screening inequalities have consistently been identified for the following socio-demographic variables: age; geographical location; socio-economic status; ethnicity; and language group (i.e. Indigenous and non-English-speaking persons).\textsuperscript{58-61, 64, 68} An inverted U-relationship is observed in relation to CRC screening among the at-risk age-group, with the lowest rates of participation found among persons 50-55 years and 70-80 years of age.\textsuperscript{64, 69} Data from both the NBCSP monitoring reports and Australian community-based studies are inconclusive regarding whether males or females are more likely to engage in CRC screening.\textsuperscript{58, 60} Colorectal cancer screening among Non-English-speaking persons and migrant groups is significantly lower, compared with Australian-born and English-speaking persons.\textsuperscript{58, 60} The NBCSP monitoring reports indicate a low rate of participation (17%) among Indigenous persons, almost half that of the non-Indigenous population.\textsuperscript{58} Findings related to geographical location and CRC screening are mixed. A population-based assessment of at-risk persons aged over 50 years in NSW revealed that persons from remote or disadvantaged locations were less likely to engage in screening.\textsuperscript{68}
Figures from the NBCSP monitoring reports have been mixed, with the proportion of persons participating from remote and very remote areas at a significantly lower level than the national level in the 2009 report, while in 2008 participation was shown to be significantly higher in regional compared with other areas.\textsuperscript{58, 60} Persons from lower socio-economic background tend to have less interest in and uptake of screening, compared with persons from higher socio-economic backgrounds.\textsuperscript{64} Examination of the preliminary round of the NBCSP indicated that participation was lowest among persons from the most socio-economically disadvantaged quintile.\textsuperscript{59} A cross-sectional analysis of participation in the NBCSP in South Australia identified inequalities in access for disadvantaged persons, whereby significantly higher rates of participation were identified among less disadvantaged persons.\textsuperscript{70} These findings are consistent with other studies that have identified persons with lower incomes as less likely to engage in CRC screening.\textsuperscript{68, 71}

**Impact of colorectal cancer screening on incidence and mortality reduction**

If screening programs are to be efficient in lowering CRC mortality and increasing the rate of early detection, high levels of uptake across all population groups and continued adherence to scheduled screening must be achieved.\textsuperscript{72} While the likely impact of the NBCSP program on mortality and incidence reduction in Australia and the UK is still too early to gauge, it appears that both programs are having appreciable impacts on earlier detection of CRC, with substantial downgrading of cancers detected in the screened population.\textsuperscript{12, 73-75} A recent review of CRC cases detected within 19 Australian hospitals during May 2006 and June 2008 indicated that 40 cases (3.2\%) were detected through the NBCSP.\textsuperscript{12} This study also indicated that NBCSP-detected cancers were staged at an earlier point, compared with symptomatic cases (i.e. Stage 1, 40\% \textit{versus} 14\% respectively; and Stage IV, 3\% \textit{versus} 15\% respectively).\textsuperscript{12} Latest figures from the annual NBCSP monitoring report also indicate a higher rate of earlier detection of disease (with approximately 58\% of participants detected at an early stage), compared with
state-wide Registry-based estimates. In the UK, the National Health Service Bowel Cancer Screening Programme implemented in 2006 (offering biennial screening to persons aged 60-74 years) is estimated to save 20,000 lives from CRC over the next two decades if a participation rate of 60% is achieved. Further, simulation modelling using a participation rate of 60% estimated a 13% to 17% reduction in mortality for men and 12% to 15% for women over the next 20 years. The UK program, similar to Australia’s program, is experiencing low levels of participation, with screening rates tapering off since the program’s implementation. To date, little is known about community-wide screening rates for CRC in relation to level of risk, particularly in the Australian context.

**Importance of early detection of colorectal cancer through prompt medical advice seeking when relevant symptoms appear**

**Primary symptom episode and clinical presentation of colorectal cancer**

While the pattern of CRC detection is slowly changing towards more asymptomatic cancers being detected through screening (5% to 20% of all cancers), the majority of cases in the US, UK and Australia present symptomatically to primary care or through medical emergency. For those cases presenting through emergency (20% to 40% of all CRC cases), the post-operative mortality rate is higher and cancer-specific five-year survival rate inferior, compared with non-emergency cases. In the UK it is estimated that up to 75% of patients with CRC present initially to their general practitioners with non-emergency symptoms, including rectal bleeding, abdominal pain and change in bowel habit. Even after the introduction of a national screening program in the UK in 2006, it is likely that the majority of patients will continue to present symptomatically. In Australia, with a low coverage of the at-risk population (i.e. persons turning 50, 55 and 65 years of age) within its National Screening Program and most patients diagnosed over the age of 70 years, the high numbers of symptomatic presentation of patients with CRC are also likely to continue in the foreseeable future. Further, the low
participation rates in this program and other programs worldwide strongly suggest that symptomatic presentation is likely to continue to be the predominant pathway for the diagnosis of CRC. Therefore, it is important to examine the early detection of CRC, not just in the confines of screening, but also in the context of symptomatic CRC presentation.

With the exception of rectal bleeding, possible symptom indicators of CRC are non-specific to CRC and have poorly defined parameters as potential CRC indicators. These ill-defined and non-specific symptoms include change in bowel habits, abdominal pain, fatigue, anaemia and weight loss. Most CRC symptoms have similar overlap to those for benign gastro-intestinal symptoms, e.g. haemorrhoids and irritable bowel syndrome. Although rectal bleeding and change in bowel habit are common symptoms in presenting CRC patients, they are also highly prevalent in the wider population. For those diagnosed with CRC, rectal bleeding is a common presenting symptom and frequently the first symptom experienced. Approximately 37% to 84% of all symptomatic cases of CRCs present with rectal bleeding, while change in bowel habit presents in approximately 48% to 77% of all CRCs.

**The paradoxical relationships among symptom duration, colorectal cancer staging and survival**

Patient delay generally refers to the time period between a person’s first awareness of a symptom and first consultation with a doctor. Early treatment, i.e. minimising delay in receiving treatment in symptomatic patients, has long been assumed to lead to improved prognosis for CRC. The diagnosis and treatment of CRC are complicated by numerous factors, including the biology of tumours, patient behaviour, the conduct of health professionals and the operation of the healthcare system. Intuitively, a reduction in diagnostic and therapeutic delay should be accompanied by an improved survival rate. While this has been heavily supported for breast cancer, with delays of 3-6 months associated with poorer survival, the evidence for other
cancers does not appear to be as strong.\textsuperscript{98} In CRC, it is axiomatic that reduced diagnostic and treatment delay will be accompanied by earlier-stage detection and improved prognosis.\textsuperscript{83} However, several studies have indicated that symptom duration is unrelated to pathological stage at diagnosis.\textsuperscript{82, 93, 99-102} A potential explanation for this paradoxical finding may be the limited potential benefit of early detection and treatment for those persons with particularly aggressive tumour biology.\textsuperscript{15} Conversely, other studies have indicated that patients with symptom duration equal to or greater than 3 months are less likely to have Stage 1 tumours.\textsuperscript{103, 104} Although inconclusive, other studies have indicated an inverse relationship, whereby a shorter symptom duration period is associated with poorer staging and survival.\textsuperscript{95, 105}

Despite the lack of a clear consensus, the importance of reduction in delay is highlighted in a recent UK National Health Service review of the “Two Weeks” program which indicated that reduction in delay can have the important patient outcome of minimising complications, e.g. bowel obstruction, which may have an effect on survival.\textsuperscript{106} Ideally, a large public health gain may be achieved for the late-presenting patient group if medical intervention occurs at an earlier stage and the proportion of admitted cases is decreased.\textsuperscript{82} Although recent Australian data are not available, previous research suggests that such public health gains are not being achieved in this area. Studies examining symptomatic persons presenting to medical emergency indicate a lengthy symptom duration period (median 3 months) prior to emergency admission, with symptoms not necessarily previously presented to primary care before admission.\textsuperscript{102, 107}

\textit{Theoretical framework: CRC screening and medical advice seeking behaviour.}

Numerous models of human behaviour have been used to predict health behaviour. The theory of planned behaviour (TPB) and its predecessor, the theory of reasoned action (TRA) have been used to explain the behaviour of individuals such as screening attendance \textsuperscript{108-110} and medical advice seeking behaviour.\textsuperscript{111, 112} Meta-analytic reviews have supported the utility of both the TPB
and TRA to predict a wide range of behaviours and behavioural intentions. Figure 1.1 presents the theoretical framework for the TPB.

**Figure 1.1**: Theory of Planned Behaviour framework. Adapted from Azjen 1991.

![Theory of Planned Behaviour framework](image)

Both theories posit that the most important predictor of intention to perform a behaviour is a person's intention. Despite some variation across behaviours, it is well founded that intention is correlated with many health behaviours, including CRC screening. Behavioural intention is conceived as a function of several factors including: attitudes (positive or negative), subjective norms (perception of social approval), and perceived behavioural control (amount of control an individual perceives over a behaviour). Existing literature suggests that perceived behavioural control has a direct relationship with intentions to undertake CRC screening. Further, attitudes have been consistently shown to be a reliable predictor of intentions and behaviour in the TPB, TRA and several other theoretical models. This model is appropriate to the thesis given its focus on individuals’ decisions and subsequent actions. Along with a recognition of social determinants of health frameworks, which suggest the importance of also exploring factors such as socio-demographic characteristics and the behaviour of health care providers.
The theory of planned behaviour provides a general framework for survey development and interpretation of findings.

**Closing the knowledge gap: Existing challenges and research aims**

**Colorectal cancer screening**

Despite recommendations from several healthcare organisations and international peak bodies, low screening rates and inequality in uptake are evident across several population groups in Australia.\(^{58-61}\) Since the introduction of the NBCSP in 2006, no community- or population-based assessments outside the annual monitoring reports (confined to selected age brackets) have been conducted. Further, since the NHMRC guidelines’ implementation in 1999,\(^ {121}\) only one previous study has assessed the level of risk-appropriate screening, across varying levels of risk, in accordance with national guideline recommendations.\(^ {67}\) The identification of current CRC screening practices and individual and provider factors associated with risk-appropriate screening is of critical importance for future planning and implementation of tailored CRC screening programs. Further, little is known about risk-appropriate screening for those persons at increased risk owing to positive family history of CRC. To date, only one study in Australia has examined rates of CRC testing among first-degree relatives of CRC patients in Australia.\(^ {122}\) This study, however, did not differentiate between CRC testing undertaken for symptomatic purposes and that undertaken for asymptomatic purposes. Thus, the levels of CRC screening uptake and CRC screening undertaken in accordance with guideline recommendations for first-degree relatives of CRC patients are unknown in Australia.

**Medical-advice-seeking behaviour for primary symptoms of colorectal cancer**

The literature indicates a substantial gap in our knowledge of medical advice seeking related to symptoms of CRC. For change in bowel habit, the time taken to seek medical advice, the reasons for delay in seeking or failure to seek medical advice, and the triggers for medical consultation are yet to be examined among an at-risk population. For rectal bleeding, while
previous studies have investigated delay in seeking medical advice, the investigation of reasons for delay has been confined to persons waiting longer than three months, rather than across the entire delay trajectory.\textsuperscript{87, 88} For both symptoms, the present investigation explores in unison the reasons for delay in seeking or failure to seek medical advice, as well as the triggers for medical consultation among an at-risk population. Little data exists on the the factors associated with medical-advice-seeking behaviour for primary symptoms potentially indicating CRC. The literature has been largely restricted to a few community- and population-based studies that have focused on rectal bleeding. Australian community-based studies have indicated that divorced, separated and retired persons were more likely to ever consult a doctor for this symptom.\textsuperscript{123} International studies have identified that the following factors predict ever seeking care for CRC symptoms in the community setting: age (> 45 years); not smoking; employment; and symptom-specific characteristics including concern about severity and frequency of symptoms.\textsuperscript{124, 125} In relation to early medical advice seeking for rectal bleeding, the literature has largely focussed on those delaying more than three months with no studies examining the predictors of prompt medical consultation.\textsuperscript{123, 126} Previous studies have indicated persons delay greater than 3 months due to a perception that the symptom may not be serious. In relation to change in bowel habit, even less is understood about medical advice seeking behaviour. Only a handful of studies have examined this symptom and more generally examined medical consultation rather than time taken to seek medical advice or the factors associated with prompt help-seeking behaviour.\textsuperscript{124, 127, 128}

Specifically, in summary each paper comprising this thesis will examine:

Paper 1: The methodological rigour of Australian community-based approaches to increasing CRC screening uptake and their levels of effectiveness.

Paper 2: The current uptake of CRC testing and the level of CRC screening in accordance with screening guidelines across each level of risk at a community level.
Paper 3: The individual- and provider-related factors associated with ever receiving CRC testing and CRC screening in accordance with guidelines across each level of risk at a community level.

Paper 4: Colorectal cancer patients’ first-degree relatives’ current uptake of CRC testing and level of screening in accordance with guidelines across each level of risk.

Paper 5: Current rates of non-consultation and delay in seeking medical advice for primary symptoms of CRC at a community-level: Reasons for failure and delay in seeking medical advice and the triggers for seeking medical advice.

Paper 6: The individual- and provider-related factors associated with ever seeking medical advice and prompt medical consultation for primary symptoms that potentially indicate CRC at a community level.

To my knowledge, this work is the first Australian attempt to obtain a clear understanding of:

- Community-wide levels of CRC screening in accordance with guideline recommendations across each level of risk and, in particular, the level of risk-appropriate colonoscopy screening.
- The level of risk-appropriate screening in accordance with guideline recommendations among first-degree relatives of persons diagnosed with CRC, using a population-based approach.
- The individual- and provider-level factors associated with CRC screening in accordance with guideline recommendations on a community level and among first-degree relatives of CRC patients.
- In unison, the reasons for non-consultation and delay in seeking medical advice for primary symptoms of CRC (i.e. rectal bleeding and change in bowel habit), and the triggers for medical consultation.
- The factors associated with medical consultation and prompt medical advice seeking for primary symptoms that potentially indicate CRC.
References


PAPER ONE

Community approaches to increasing colorectal screening uptake: A review of the methodological quality and strength of current evidence

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Community approaches to increasing colorectal screening uptake: A review of the methodological quality and strength of current evidence

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Abstract

In Australia, colorectal cancer (CRC) screening rates are sub-optimal and considerably lower than those of other countries. The purpose of the current review was to identify in relation to CRC screening (i) the number of Australian and international community-based intervention studies published between 2002-2011, (ii) the proportion of intervention studies that had adopted a community-based approach and met the Cochrane Effective Practice and Organisation of Care (EPOC) study design criteria, and (iii) the effectiveness of community-based interventions with at least a moderate level of methodological rigour at increasing CRC screening rates. Electronic database searches identified 86 intervention studies, of which 21 used a community-based approach and 15 met EPOC study design criteria. Overall, the methodological rigour of community-based intervention studies using EPOC-accepted study designs was moderate. Only one methodologically robust Australian community-based study was identified. Based on findings from studies with moderate methodological rigour, a number of potential options which the National Bowel Cancer Screening Program may consider to increase screening rates are discussed. The current review highlights the urgent need for further methodologically rigorous, community-based CRC screening intervention research in the Australian setting.
Background

Why addressing colorectal cancer is essential to Australia’s health

Worldwide, colorectal cancer (CRC) accounts for 9.4% of all cancer diagnoses and ranks as the fourth leading cause of cancer-related deaths.¹ Australia has one of the highest age-standardised rates for CRC in the world, with the crude incidence set to increase as a consequence of an ageing population.² In Australia, as in other countries, fewer than 40% of cases are diagnosed at an early localised stage.³⁻⁵ Screening for CRC has demonstrated effectiveness in reducing its incidence through the identification and removal of precancerous adenomatous polyps ⁶⁻⁷ and increasing the rate of detection of early-stage disease.⁸⁻⁹

Colorectal cancer screening participation in Australia

In Australia, the National Bowel Cancer Screening Program (NBCSP) takes a community-based approach by offering a mailed one-off immunochemical faecal occult blood test (iFOBT) to persons turning 50, 55 and 65 years of age.¹⁰ Participation rates in Australia’s NBCSP have remained at a consistent rate of approximately 40 per cent.¹⁰⁻¹³ These rates, however, are only reflective of participation among the selected age brackets incorporated in the program. Australian community- and population-based assessments of persons aged over 50 years have consistently demonstrated low levels of CRC screening participation.¹⁴⁻¹⁸ Two population-based studies among at-risk persons (aged 50 years and over) prior to the NBCSP indicated that less than 20% of the at-risk population undertook faecal occult blood test (FOBT) screening in the previous five years.¹⁵⁻¹⁸ A recent evaluation following the NBCSP’s inception found that 20% of persons aged over 55 years had undertaken FOBT screening within the guideline-recommended two-year period.¹⁹ The Australian CRC screening rate compares poorly with that of other countries. For example, FOBT screening rates in the United Kingdom (UK) and Finnish screening programs are currently 52% and 71% respectively.²⁰⁻²¹
Need to increase colorectal cancer screening participation rates in Australia

It is too early to identify the likely impact of the NBCSP program on mortality and incidence reduction in Australia. Nonetheless, the most recent data on a small number of histologically confirmed NBCSP cases suggest a high rate of early-staged CRC detection (58.3%).\textsuperscript{10} Further, an earlier review of CRC detection methods (i.e. NBCSP-screened \textit{versus} symptomatic presentation) across 19 Australian hospitals highlighted a significant downgrading in staging of disease among NBCSP-detected CRCs.\textsuperscript{22} While these results show promise, there is a need for expansion of this program (i.e. extending the offering of FOBT screening to all persons aged between 50 and 75 years biennially) if the high rate of mortality reduction (15% to 33%) reported in screening randomised controlled trials (RCTs) is to be achieved.\textsuperscript{6, 9, 23, 24}

Effective interventions to increase colorectal cancer screening

The most comprehensive review of intervention studies aimed at increasing CRC screening was confined to studies conducted in the United States (US) during 1998-2009.\textsuperscript{25} In Australia, relatively little is known about the effectiveness of methodologically robust community-based interventions, although the NBCSP has adopted a community-based approach. It is crucial to identify robust evidence of effective strategies for increasing screening rates at a community level in order to maximise the effectiveness of the program. The Cochrane Effective Practice and Organisation of Care Group (EPOC) checklist, which provides valuable criteria against which to judge the methodological rigour of intervention studies, has been used in this review.\textsuperscript{26} The purpose of this review was to identify, in relation to increasing CRC screening uptake, (i) the number of Australian and international community-based intervention studies published between 2002 and 2011, (ii) the proportion of intervention studies that adopted a community-based approach and met EPOC study design criteria and (iii) the effectiveness of community-based interventions with at least a moderate level of methodological rigour.
Methods

Inclusion criteria

Intervention studies published in English aimed at increasing rates of CRC screening (e.g. by FOBT, colonoscopy or sigmoidoscopy) were included in this review. Studies that examined solely knowledge or intention to screen, or compared compliance rates across CRC testing modalities were excluded. Studies that evaluated CRC testing solely among the following population groups were excluded: CRC patients; persons with advanced adenoma or bowel-related disease; and those persons at high risk due to familial predisposition to CRC.

Literature searches

An electronic database search of Medline was conducted to identify relevant intervention studies published between 1 January 2002 and 11 October, 2011. This time period was considered appropriate, given that the National Health and Medical Research Council (NHMRC) CRC screening guidelines were established in 1999 and that the wider adoption of supporting programs and interventions would take time to evolve. The Medline search included three search themes (colorectal cancer, screening and interventions) combined using the Boolean operator, “AND”. For a complete list of MeSH headings and search terms see Appendix 1.A. The Cochrane Clinical Trial database was also searched for relevant intervention studies using the following search terms, “colorectal neoplasms AND mass screening”.

Data extraction and coding for design and methodological rigour

All abstracts were reviewed independently by authors RJC and CLP to determine whether studies met the eligibility criteria. All relevant intervention studies were categorised based on the setting for recruitment or sampling: (i) primary care; (ii) community; or (iii) other. Intervention studies conducted in the primary care setting or recruiting persons directly from general practice
registers were coded as “primary care”. Intervention studies sampling participants from an electoral roll or population register, using a broad sampling technique, e.g. state driver’s licence databases, or directly recruiting participants from a community setting, e.g. seniors’ centres, were coded as “community”. Each intervention study coded as “community” was assessed against basic EPOC study design criteria: randomised controlled trial (RCT); controlled clinical trial (CCT); controlled before and after study (CBA); and interrupted time series (ITS). Intervention studies not meeting any of the above study designs were excluded.

**Methodological rigour**

Intervention studies coded as “community” and meeting EPOC-specified study design criteria (i.e. RCT, CCT, CBA or ITS) were evaluated for methodological strength using the following EPOC criteria.²⁷ For each criterion, a score of “Yes” was assigned if the study met the criterion, “No” if it did not and “Unclear” if there was insufficient information in the paper. For RCTs, CCTs and CBAs, these criteria included the following: 1) whether the allocation sequence was adequately generated (i.e. the random component in the sequence generation process was described); 2) whether there was concealment of allocation (e.g. units were allocated by the institution or team, a centralised randomisation scheme, an on-site computer system or sealed opaque envelopes); 3) whether baseline outcome measurements were similar in intervention and control groups (i.e. the study reported whether baseline measurement was similar in the two groups and, if not, whether appropriately adjusted analysis was performed); 4) whether baseline characteristics of study participants were reported and whether they differed between experimental groups; 5) whether incomplete outcome data were adequately addressed (i.e. missing data were unlikely to bias the results and the proportion of missing data was less than the effect size); 6) whether there was blinded allocation of intervention and control groups (i.e. the primary outcome was assessed blindly or by using an objective outcome); 7) whether the study was adequately protected against contamination (i.e. it randomised by practice or
institution, or it was unlikely for the control group to receive the intervention); 8) whether the study was free from selective reporting (i.e. all relevant outcomes were reported); and 9) whether the study was free from other risks of bias (i.e. no evidence of other risk of bias). As a quality assurance measure, independent coding of intervention studies was conducted by two reviewers (RJC and SY). All differences were resolved by mutual discussion between coders and with a third-party (CLP), where necessary.

Results
Number of community-based intervention studies aimed at increasing colorectal cancer screening
The Medline search found 1436 separate articles. Of these, 1350 articles were excluded as they were either descriptive studies or were not relevant to increasing CRC screening. Of the remaining articles, 86 were intervention studies aimed at increasing CRC screening rates. A search of the Cochrane Clinical Trial database (n = 195) between 2002 and October 20, 2011 found no further intervention studies. The majority of intervention studies (79%, 68/86) were conducted in the US. Few studies (9%, 8/86) had been undertaken in Australia, with the remainder of interventions (12%, 10/86) from the UK, Canada, Europe or Asia. Most studies (70%, 60/86) had sampled participants from either general practice registers or directly through primary care sites. Of the remaining interventions, participants were either recruited using a community- or population-based sampling technique (24%, 21/86) or “other” sampling method (6%, 5/86). Of the eight studies conducted in Australia, only four had adopted a community- or population-based sampling approach.
Community intervention studies which met EPOC study design criteria

Of the 21 community-based intervention studies only 15 (71%) met EPOC criteria related to research design; all of these studies were RCTs. The remaining six articles did not use an accepted EPOC study design. Overall, 10 out of 15 (66%) of the RCTs scored at least five points or higher on methodological rigour (see Table 2.1). These studies were deemed to be of at least moderate methodological rigour and were evaluated for effectiveness at increasing CRC screening.

Effectiveness of strategies trialled in methodologically rigorous studies

An overview of the ten intervention studies which scored five or more on the EPOC criteria for methodological rigour grouped by intervention type: mail; non-mail strategies (e.g. telephone, audiovisual and computer); and multiple-component strategies are presented in Tables 2.2, 2.3 and 2.4 respectively. As shown in Table 2.2, mail-based strategies with FOBT invitation can achieve participation rates of 51% to 59%, with increased participation evident in two studies that had adopted pre-notification prior to the screening invitation. Tailoring of the screening invitations appeared to have a modest effect on screening participation. As described in Table 2.3, non-mail-based strategies, including the use of an interactive electronic tool or video education, appeared to increase the rate of CRC screening significantly, compared with the usual care or standard condition. Studies of telephone-based outreach had mixed findings with samples drawn from private healthcare funds. Multiple-component interventions (See Table 2.4) that involved education or self-empowerment of cultural groups showed modest improvements in CRC screening. An Australian study among lower socio-economically disadvantaged persons, contrary to expectation, indicated that the adoption of a decision-making aid (i.e. booklet plus DVD) significantly decreased FOBT completion, compared with controls who received a standard NBCSP information package. Study findings from Powe et al.’s intervention should be considered with caution, given substantial limitations related to
sample size and an under-representation of male persons. Further, the authors report the primary outcome (return of FOBT samples) as significant across group membership, despite not meeting the widely accepted statistically significant cut-point of \( p < .05 \).
Table 2.1: Methodological rigour assessment of community- and population-based intervention studies using accepted EPOC study designs

<table>
<thead>
<tr>
<th>First author, Year</th>
<th>Allocation sequence adequately generated</th>
<th>Concealment of allocation</th>
<th>Baseline outcome measurements similar*</th>
<th>Baseline characteristics similar</th>
<th>Incomplete data addressed</th>
<th>Knowledge of interventions prevented</th>
<th>Selective outcome reporting</th>
<th>Protection against contamination</th>
<th>Other risk of bias</th>
<th>Total</th>
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<tbody>
<tr>
<td>Powe, 2004 31</td>
<td>?</td>
<td>✓</td>
<td>x</td>
<td>x</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>6/9</td>
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<tr>
<td>Braun, 2005 32</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>x</td>
<td></td>
<td>8/9</td>
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<tr>
<td>Ruffin, 2007 39</td>
<td>?</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>8/9</td>
</tr>
<tr>
<td>Morgan, 2010 42</td>
<td>?</td>
<td>✓</td>
<td>x</td>
<td>x</td>
<td>?</td>
<td>✓</td>
<td>✓</td>
<td>x</td>
<td></td>
<td>3/9</td>
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<tr>
<td>Simon, 2010 44</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>?</td>
<td>x</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>x</td>
<td>6/9</td>
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<tr>
<td>Smith, 2010 45</td>
<td>✓</td>
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<td>✓</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>x</td>
<td>8/9</td>
</tr>
</tbody>
</table>

Key: ✓ = Yes; ? = Unclear; x = No.

*Studies specifying strict CRC screening eligibility criteria for participation scored ✓.
<table>
<thead>
<tr>
<th>First author, Year, Country</th>
<th>Design and intervention description</th>
<th>Participants (Sample size (n), Gender, Age)</th>
<th>Primary outcome</th>
<th>Results for primary outcome</th>
<th>Differences among population sub-groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marcus, 2005 34 United States</td>
<td>RCT</td>
<td>4,014 callers to the Cancer Information Service (CIS) over 50 years of age, eligible for CRC screening and not calling the CIS about CRC or CRC screening</td>
<td>Self-reported FOBT, sigmoidoscopy or colonoscopy at 6- (short-term) and 14-month (long-term) follow-up</td>
<td>6-month follow-up: SU = 22% compared with combined intervention groups (ST, MT, MRT) = 26%. No statistically significant difference 14-month follow-up: SU group doubled CRC screening rate (20% baseline to 42% at 14-month follow-up) Overall, significant* trend across groups, suggesting higher rates of CRC screening associated with tailoring Nested comparison: SU (42%) vs MT (51%) significant**; SU (42%) vs MRT(48%) not significant</td>
<td>Test for moderator variables at 14-month follow-up Age: Among participants aged 50-59 years, all three tailored interventions showed significant improvement compared with SU (SU vs ST*, SU vs MT and SU vs MRT)** Gender: Female participants Significant trend in prediction for females*** (SU vs MT **, SU vs MRT **). No statistically significant difference between (SU vs MT and MT vs MRT)</td>
</tr>
<tr>
<td>Libby, 2011 ** Scotland</td>
<td>RCT</td>
<td>N = 59,953, aged 50-74 years, randomly selected from population register Randomisation produced comparable baseline characteristics and equivalent</td>
<td>Return of FOBT sample</td>
<td>Uptake significantly higher in both pre-notification (59%) and letter + booklet (58.5%) interventions, compared with usual method of invitation</td>
<td>Significant trend found across all age, gender and deprivation categories***</td>
</tr>
</tbody>
</table>
Intervention groups received pre-notification two weeks prior to invitation date. 

Across groups:
- Intervention (i) = 19,975, (ii) = 19,991, (iii) = 19,987  
- Males: (i) = 49.2%, (ii) = 49%, (iii) = 48.6%  

Return of faecal immuno-chemical test (FIT) kit sample  

Advanced notification letter (58%) was significantly associated with higher adherence compared with invitation letter (52%)***

Age (less than 60 years), gender (male), SES (low) were independent predictors of non-adherence. No significant interactions between groups.

Table 2.3: Characteristics of non-mail based interventions with at least moderate methodological rigour

<table>
<thead>
<tr>
<th>First author, Year, Country</th>
<th>Design and intervention description</th>
<th>Participants (Sample size (n), Gender, Age)</th>
<th>Primary outcome</th>
<th>Results for primary outcome</th>
<th>Differences among population sub-groups</th>
</tr>
</thead>
</table>
| van Roon ** 2011 Netherlands | RCT: Standard invitation + advanced notification letter sent two weeks beforehand  
Control: Standard invitation | N = 4784, aged 50-74 years, randomly selected from population registers;  
(i) = 2507, (ii) = 2493  
Males: (i) = 40%, (ii) = 49%  
Age (mean): (i) and (ii) = 60 years | Receipt of CRC screening within 6 months of randomisation (FOBT, sigmoidoscopy, colonoscopy or barium enema)  
Medical claims and records reviewed | Percentage screened for CRC at 6-month follow-up:  
Intervention 27% vs control 6%  
Screening rates were 4.4 times higher for the intervention group |  

*P<0.05; **P<0.01; ***P<0.001
<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Country</th>
<th>Intervention</th>
<th>Control</th>
<th>n = (equal groups control and intervention) aged 50-70 years</th>
<th>Self-reported CRC screening (FOBT/ endoscopy)</th>
<th>Participants contacted 2, 8 and 24 weeks post-intervention</th>
<th>Return of FOBT sample</th>
<th>Not significant result for age, gender, race or geographical residence in logistic model</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ruffin, 2007</td>
<td>RCT</td>
<td>United States</td>
<td>(i) Intervention: interactive electronic tool (Colorectal Web)</td>
<td>Control: standard website</td>
<td>n = 174</td>
<td>Self-reported CRC screening (FOBT/ endoscopy)</td>
<td>Participants contacted 2, 8 and 24 weeks post-intervention</td>
<td>89/174 (51%) of participants received CRC screening: 56/89 (63%) intervention group vs 33/89 (37%) control group. Participants in intervention group significantly more likely to be screened than control group*</td>
<td>No significant result for age, gender, race or geographical residence in logistic model</td>
</tr>
<tr>
<td>Gimeno-Garcia, 2009</td>
<td>RCT</td>
<td>Spain</td>
<td>(i) Intervention: brief educational video (3.5 mins) providing overview of CRC prevention</td>
<td>Control: non-medical documentary</td>
<td>n = 158 (control and intervention equal), aged 50-79 years</td>
<td>Return of FOBT sample</td>
<td>Significantly higher rate of FOBT sample return (within 2 weeks) in the intervention group (70%) compared with control group (54%)*</td>
<td>Participants returning FOBT were older than non-compliant individuals.* Elderly age independent factor significantly associated with FOBT return*</td>
<td>hochvoltage</td>
</tr>
<tr>
<td>Simon, 2010</td>
<td>RCT</td>
<td>United States</td>
<td>(i) Intervention: automated telephone outreach with speech recognition (ATO-SR), including targeting knowledge deficits, addressing attitudes and self-efficacy, and emphasising importance of screening; (ii) Control: usual care</td>
<td>Control: usual care</td>
<td>N = 20,938, aged 50-64 years, randomly selected from the Harvard Pilgrim Health Care</td>
<td>Self-reported CRC screening in the year following intervention (FOBT, double-contrast barium enema, flexible sigmoidoscopy, colonoscopy)</td>
<td>No significant difference in CRC screening (intervention = 30.6%; control = 30.4%)</td>
<td>Not assessed</td>
<td>hochvoltage</td>
</tr>
</tbody>
</table>

*p<0.05; **p<0.01; ***P<0.001
Table 2.4: Characteristics of multi-component-based interventions with at least moderate methodological rigour

<table>
<thead>
<tr>
<th>First author, Year, Country</th>
<th>Design and intervention description</th>
<th>Participants (Sample size (n), Gender, Age)</th>
<th>Primary outcome</th>
<th>Results for primary outcome</th>
<th>Differences among population sub-groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Powe, 2004 <strong>United States</strong></td>
<td>RCT Intervention: (i) Cultural and self-empowerment group (video, calendar, poster, brochure and flier) (ii) Modified cultural group (video) Control: Traditional group (usual care)</td>
<td>n = 134, aged 50 and over recruited from 15 senior centres (i) n = 54, (ii) n = 39, (iii) n = 41 Males: (i) = 18%, (ii) = 8%, (iii) = 7% Age (mean): (i-ii) = 75, (iii) = 73</td>
<td>Return of FOBT sample</td>
<td>Return of FOBT sample: (i) = 61%, (ii) = 46%, (iii) = 15% Significant differences not reported</td>
<td>Group membership and knowledge of CRC** reported as significant predictors of FOBT return N.B. p-value for group membership higher than arbitrary .05 cut-point (p = .13)</td>
</tr>
<tr>
<td>Braun, 2005 <strong>United States</strong></td>
<td>RCT (i) Control group: Culturally targeted educational presentation, free FOBT kit and reminder call (ii) Intervention group: receiving above in line with social learning theory + education delivered by Native Hawaiian physician and CRC survivor, FOBT demonstration, and multiple telephone calls to address change-related emotions and barriers</td>
<td>121 persons aged 50 and over recruited via 16 Hawaiian Clubs (i) = 52, (ii) = 69 Males: (i) = 25%, (ii) = 30% Age (mean): 66 years across both groups</td>
<td>Return of FOBT sample</td>
<td>Return of FOBT sample: (i) = 40%, (ii) = 33% No significant difference between groups</td>
<td>Not assessed</td>
</tr>
<tr>
<td>Smith, 2010 <strong>Australia</strong></td>
<td>RCT (i) Intervention 1: Patient decision aid comprising paper-based interactive booklet and DVD, presenting risk information on</td>
<td>572 participants aged 55-64 years randomly selected from the NSW electoral register using the Australian Bureau of</td>
<td>Return of FOBT sample (up to 3 months post-intervention).</td>
<td>Significant difference in return of FOBT sample between interventions (59%) and control</td>
<td>Not assessed</td>
</tr>
<tr>
<td>Intervention 1</td>
<td>Intervention 2</td>
<td>Control</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------------</td>
<td>----------------</td>
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<tr>
<td>(i) = 196, (ii) = 188, (iii) = 188</td>
<td>(i) = 196, (ii) = 188, (iii) = 188</td>
<td>(i) = 196, (ii) = 188, (iii) = 188</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Male: (i) = 51%, (ii) = 51%, (iii) = 50%</td>
<td>Male: (i) = 51%, (ii) = 51%, (iii) = 50%</td>
<td>Male: (i) = 51%, (ii) = 51%, (iii) = 50%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age: not reported</td>
<td>Age: not reported</td>
<td>Age: not reported</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Statistics codes to target socio-economically disadvantaged persons

(75%)*

*p<0.05; **p<0.01; ***P<0.001
Discussion

Number of community-based intervention studies
The review indicated that most CRC screening intervention studies occurred in the US. Given that the Australian setting differs from the US in terms of health system and population sub-groups, US findings may not be generalisable to the Australian setting. Only eight intervention studies were conducted in Australia, four of which adopted a community-based approach. Of these studies, only two used EPOC-accepted study designs. The lack of robust research with relevance to the community-based approach taken by the NBCSP is surprising.

Methodological rigour of community-based studies
The degree to which study findings are indicative of a high level of evidence is dependent on methodological rigour. Of the 21 intervention studies in this review adopting a community-based approach, 15 had used EPOC-accepted study designs, and 10 had at least moderate methodological rigour. However, only one methodologically robust community-based study was undertaken in Australia, providing scant evidence to base decisions regarding how to approach the crucial issue of maximising screening rates for CRC in Australia.

Increasing the effectiveness of community-based interventions
The NBCSP adopts a pre-notification strategy shown to be effective at increasing FOBT participation rates. Based on the studies with at least moderate experimental rigour, it would appear that there are a number of additional options which the NBCSP may consider to increase screening rates for the age groups included in the program. First, the relative value of co-ordinated advocacy from other respected organisations, including Cancer Councils and other public health organisations, should be further examined. In addition, it should be noted that Australian studies, although not using an EPOC-accepted study design, have indicated that FOBT participation is improved one-off and over time if a letter of invitation includes general practitioner endorsement. Further, in the UK, for non-
responders to CRC screening invitations, final letters are sent to non-responders’ general practitioners. Given that direct linkage of the patient to his or her general practitioner is not easily attainable in Australia for community-based recruitment approaches, it is important to consider how the active endorsement of the NBCSP by general practitioners may be co-ordinated with NBCSP initiatives. In addition, the timing of reminder letters following non-response in the Australian screening program is at 8 weeks, much longer than that adopted in the UK screening program, which is achieving higher rates of participation. Therefore, it is worthwhile to explore whether a shorter follow-up interval may increase participation rates. Finally, it is important to consider the unexpected study findings among an Australian cohort of lower socio-economic persons aged 55-64 years sent FOBT kits, where a particularly high rate of FOBT test return was identified among the control group (75% of those receiving standard NBCSP booklets), a rate higher than that in the intervention group (59% of those receiving a decision aid and accompanying DVD). It is noteworthy that two weeks following mail-out, participants received follow-up telephone interviews assessing other primary outcomes, i.e. knowledge, attitudes and informed choice. It is possible that this follow-up call lifted participation rates across both groups. The incorporation of a telephone-based reminder system may be worth consideration in the NBCSP. Additionally, for the control group the FOBT return rate of 75% among a wide age-bracket of 55-64 years was achieved, much higher than the consistent return rate of approximately 40% achieved in the NBCSP. Overall, in addition to the above opportunities for increasing screening rates among those invited into the NBCSP, it should also be noted that a dominant rate-limiting factor for population-based screening uptake in Australia appears to be the limited age- brackets invited to screen in the NBCSP. The greatest opportunity for future increases in FOBT screening participation largely relies on opening the program to the entire at-risk population (all those aged 50-74 years) for repeated screening.
Effectiveness of community-based strategies in improving screening rates among population sub-groups experiencing inequality

With the exception of age and gender, there were relatively few data in this review about responses to interventions among population groups known to experience lower rates of CRC screening participation, i.e. Indigenous persons, non-English speaking persons and those from lower socio-economic backgrounds. Some studies indicated that younger persons in the at-risk group had a considerably lower rate of screening participation compared with older age groups.\textsuperscript{35, 40} A few studies used targeted approaches for certain cultural groups, e.g. African Americans.\textsuperscript{31} However, findings for socio-cultural groups in the US may not generalise to the Australian context. In Australia, relatively little robust research has been directed towards population sub-groups less likely to participate in CRC screening, although the NBCSP has focussed efforts towards reaching these groups, particularly through state-based initiatives. The present review identified only one Australian intervention that targeted CRC screening among lower socio-economic groups.\textsuperscript{45} It is important that future interventions pay close attention to population groups experiencing lower rates of CRC screening, to maximise broad participation and avoid increasing health inequality.

Limitations, future research and areas for improvement

Searching grey literature and non-English language studies was beyond the scope of the current review. Therefore, it is possible that some studies were missed. The generalisability of international study findings to the Australian setting should be considered with caution, given differing healthcare systems and CRC screening provisions across countries. The NBCSP currently offers one-off iFOBT screening to just three selected age groups. This is in contrast to the evidence base for the benefits and cost-effectiveness of CRC screening, which is predicated on biennial screening of those aged 50-74 years.\textsuperscript{52} In addition, it is important to monitor CRC screening rates across the entire at-risk population, as NBCSP monitoring reports are only reflective of participation among the selected age brackets. Unfortunately, given the low number of Australian community-based intervention studies
identified in this review, few data are available to indicate the most effective approach for improving population-level CRC screening participation rates to an optimal level. The current review highlights the urgent need for more methodologically rigorous community-based CRC screening intervention research in the Australian setting.
References


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Cancer Screening: an evaluation of the second round. Edinburgh: The Institute of
Cancer Research 2006. Available from:

52. Pignone MP, Flitcroft KL, Howard K, Trevena L, Salkeld GP, St John J. Costs and cost-
effectiveness of full implementation of a biennial faecal occult blood test screening
Appendix 1.A

Search terms used for Medline search

<table>
<thead>
<tr>
<th>Type of search term</th>
<th>Mesh headings/keywords</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colorectal cancer terms</td>
<td>colorectal neoplasms colorectal cancer bowel cancer colonic neoplasms OR colon cancer rectal cancer</td>
</tr>
<tr>
<td>Screening terms</td>
<td>mass screening faecal occult blood test faecal immunochemical testing stool test fobt occult blood OR DNA stool colonoscopy sigmoidoscopy sigmoidoscopes</td>
</tr>
<tr>
<td>Intervention terms</td>
<td>intervention studies evaluation studies randomised control trial as Topic / randomised control trial controlled clinical trial clinical trial OR random$ intervention$</td>
</tr>
</tbody>
</table>

*Limited to English language, humans, period 2002-2011.*
PAPER TWO

Colorectal (bowel) cancer screening in Australia: A community-level perspective
Introduction to Paper Two

Periodic screening of at-risk persons is recommended by several national healthcare organisations worldwide, including the National Health and Medical Research Council (NHMRC) in Australia.\textsuperscript{1} Despite this, worldwide the level of colorectal cancer (CRC) screening remains sub-optimal.\textsuperscript{2, 3} Paper One highlighted the fact that participation rates in Australia’s National Bowel Cancer Screening Program (NBCSP) have remained low at approximately 40% since the program’s roll-out in 2006. Paper One also indicated that in Australia there is scant literature to gauge the effectiveness of methodologically robust community approaches to increasing CRC screening uptake. This review identified only one study in Australia that had adopted an accepted EPOC study design with at least a moderate level of methodological rigour.\textsuperscript{4} This study, however, was unsuccessful at increasing CRC screening uptake in the intervention group. Of the potentially useful strategies that emerged from the literature described in Paper One (i.e. mail, non-mail and multiple-component strategies), only a mail-based strategy is currently being used in Australia. Since the NBCSP’s implementation, the knowledge of population-level screening uptake in Australia is limited to program monitoring reports released annually by the NBCSP. These reports, however, only provide rates of screening participation among the limited portion of the at-risk population offered screening (i.e. persons turning 50, 55 and 65 years of age during the year of screening). Further, this program does not cater for the screening needs of persons at elevated levels of risk (i.e. “moderately increased risk” or “potentially high risk”) who, in accordance with guideline recommendations, require scheduled colonoscopy screening rather than population-level FOBT screening. This suggests a need for a broader assessment of screening uptake and the level of CRC screening undertaken across varying levels of risk in accordance with NHMRC screening guidelines.\textsuperscript{1}

The current study is the first cross-sectional analysis of CRC screening rates since the initiation of the NBCSP. In Australia, relatively little is know about the uptake of CRC
screening in population groups at higher-than-average risk on a community or population level. Before the current study, only one population-based evaluation of CRC screening participation among persons at varying levels of risk had been conducted (prior to the NBCSP implementation). The current paper describes the population-level effects of current approaches, including the NBCSP, on screening participation in Australia, and the level of CRC screening undertaken in accordance with NHMRC screening guidelines for persons at varying levels of risk in the community.

Aims and purpose
The aim of this paper was to identify on a community-level (i) the proportion of at-risk persons (aged 56-88 years) ever undertaking CRC testing and (ii) the current level of CRC screening undertaken in accordance with Australian screening guidelines across varying levels of risk. A secondary evaluation was also undertaken to compare the levels of screening uptake and screening in accordance with guideline recommendations among persons who were eligible for NBCSP participation, compared with those not eligible for NBCSP participation.

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Manuscript ID: MJA-201110661R1.
References


Colorectal (bowel) cancer screening in Australia: A community-level perspective

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² Department of Colorectal Medicine and Genetics, The Royal Melbourne Hospital, Victoria, Australia
³ Centre for Clinical Epidemiology and Biostatistics, Faculty of Health, University of Newcastle, New South Wales, Australia
⁴ Hunter Medical Research Institute, New South Wales, Australia
Abstract

Objectives: To determine current CRC screening rates and the level of adherence to screening guidelines at a community level.

Setting: A cross-sectional cohort of at-risk persons aged 56-88 years randomly selected from the Hunter Community Study (HCS), Australia.

Main outcome measures: Proportion ever reporting undertaking any CRC testing; Current screening rates for each CRC screening modality; Level of screening in accordance with screening guidelines.

Results: 1117 participants (70%) returned a questionnaire. 777 persons were deemed asymptomatic and eligible for analysis. Overall, 63% of respondents had ever received any CRC testing. 43% of respondents had ever had a Faecal Occult Blood Test (FOBT); with a screening rate of 20% in the previous two years. 30% of respondents had ever had a colonoscopy; with a screening rate of 16% screened in the previous five years. 7% of respondents had ever had a sigmoidoscopy; with a screening rate of 1% in the previous five years. Rates of adherence to screening guidelines were 21% for respondents “at or slightly above average risk” and 45% for respondents at “moderately increased/ potentially high risk”.

Conclusions: Rates of CRC screening remain low. The screening rate for colonoscopy was particularly high among persons “at or slightly above average risk” despite such screening not being endorsed in the guidelines. Effective strategies to improve rates of CRC screening and appropriate use of colonoscopy are required across the entire at-risk population.
Introduction

One in 12 Australians is likely to develop CRC in their lifetime.\textsuperscript{1} In Australia, CRC is the second leading cause of cancer-related mortality.\textsuperscript{2} Survival from CRC is stage-dependent, yet fewer than 40\% of individuals are diagnosed at a localised stage.\textsuperscript{3} Several randomised controlled trials (RCTs) have demonstrated that CRC mortality can be reduced by 15\%-33\% through Faecal Occult Blood Testing (FOBT).\textsuperscript{4-7} A recent RCT of once-only flexible sigmoidoscopy for persons 55-64 years of age found a 40\% reduction in mortality for persons offered a screening invitation.\textsuperscript{8} Although the use of colonoscopy to detect right-sided CRCs is under debate\textsuperscript{9,10} indirect evidence suggests a CRC mortality reduction ranging from 60\% to 76\%\textsuperscript{11} and incidence reduction of 76\% to 90\%.\textsuperscript{12}

Screening recommendations for those aged 50 years or over vary internationally.\textsuperscript{13} Australian guidelines recommend that asymptomatic persons “At or slightly above average risk” receive FOBT screening biennially commencing at age 50 years with sigmoidoscopy (preferably flexible) considered every five years.\textsuperscript{14} Colonoscopy screening is endorsed only for asymptomatic persons at “Moderately increased risk” or “Potentially high risk” due to risk features including: personal or family history of CRC; adenoma; or chronic ulcerative colitis. The recently re-funded NBCSP offers one-off immunochemical FOBT screening to persons turning 50, 55 or 65 years of age. Implementation of biennial CRC screening in Australia for all those aged between 50-74 years could prevent up to 500 deaths per year,\textsuperscript{15} with cost effectiveness comparable to breast and cervical cancer screening programs.\textsuperscript{15,16}

Participation rates in phase one of the NBCSP (persons aged 55 and 65 years sent FOBT) were 43\%.\textsuperscript{17} Roll out of the second-phase from July 2008 included those turning 50 years of age. In the United States, findings from the National Health Interview Survey\textsuperscript{18} indicated that 50\% of persons had undertaken colonic screening within the recommended time interval (FOBT within one year or endoscopy within 10 years). In Australia, previous community and
population-based studies have consistently indicated a low uptake of CRC screening, with less than 20% of at-risk individuals ever undergoing FOBT.\textsuperscript{19-22} More recent population-based data indicated that 36% of persons aged over 50 years of age had ever undertaken CRC testing with 18% undertaking FOBT in the last five years.\textsuperscript{23} This latter study however did not differentiate between CRC testing for screening and diagnostic purposes.

Given the recent announcement of the NBCSP’s continuation and the associated need for future planning and implementation of CRC screening programs, an evaluation of CRC screening practice in the community is timely. The purpose of this community-based study among at-risk persons (aged 56-88 years) was to assess the following for those at each level of risk: (1) the proportion ever undertaking CRC testing (2) the level of uptake for each screening modality (FOBT, sigmoidoscopy and colonoscopy); and (3) the proportion screened in accordance with screening guidelines.

\textbf{Methods}

\textbf{Ethics approval}

The University of Newcastle Human Research Ethics Committee, in partnership with the Hunter New England Population Health, granted ethical approval (H-820-0504).

\textbf{Study population}

The Hunter Community Study (HCS) is a longitudinal cohort of community-dwelling men and women aged 55-85 years at baseline from the Hunter Region, NSW), Australia.\textsuperscript{24} Participants were randomly selected from the NSW State electoral roll between December 2004 and 2007. The HCS cohort population profile reflects that of the Hunter Region state and national Australian profiles for gender and marital status, but is slightly younger in age.\textsuperscript{24} A randomly selected sub-sample of HCS participants (n = 1592) aged 56-88 years were
mailed a questionnaire during November, 2009. Reminder telephone calls were made to non-responders four weeks after initial mail out.

**Questionnaire**

Questionnaire items are presented in Appendix 2.A. Respondents were asked whether they had ever undertaken FOBT, colonoscopy or sigmoidoscopy. Respondents indicating “Yes” to any were asked to specify the timing of most recent testing and whether this procedure was undertaken as a consequence of a symptom. All respondents were asked about family history of CRC and age at which any first- or second-degree relative may have been diagnosed (see Appendix 2.B). Respondents’ self-reported family history of CRC was used to allocate each respondent to a level of risk (see Table 3.1) in accordance with National Health and Medical Research Council (NHMRC) guidelines.  

**Table 3.1:** Respondents’ risk allocation in accordance with national screening guidelines

<table>
<thead>
<tr>
<th>Risk category*</th>
<th>Details</th>
</tr>
</thead>
</table>
| At or slightly above average risk | • No personal history of bowel cancer  
  • Either no close relatives with bowel cancer or one first-degree or second-degree relative with bowel cancer diagnosed at age 55 years or older |
| Moderately increased risk | • One first-degree relative diagnosed before the age of 55 years (without potentially high-risk features listed below), or  
  Two first-degree relatives or one first- and one second-degree relative(s) on the same side of the family (without potentially high-risk features listed below) |
| Potentially high risk | • Three or more first-degree or a combination of first-degree and second-degree relatives on the same side of the family diagnosed with bowel cancer (suspected HNPCC**), or  
  Two or more first-degree or second-degree relatives on the same side of the family diagnosed with bowel cancer, including the following risk feature: bowel cancer before the age of 50 years or at least one relative with cancer of the endometrium, ovary, stomach, small bowel, renal pelvis, ureter, biliary tract or brain |

---

*Risk features potentially placing persons at possible increased risk, including personal history of adenoma, inflammatory bowel disease or suspected familial adenomatous polyposis (FAP) were not assessed in the survey.**HNPCC (Hereditary non-polyposis colorectal cancer), also known as Lynch’s Syndrome.
Statistical analysis

Each outcome was assessed overall and according to familial level of risk. The proportion of respondents screened in accordance with screening guidelines was assessed across familial level of risk as follows: “At or slightly above average risk” (FOBT < two years; consider sigmoidoscopy, preferably flexible, every five years) and “Moderately increased risk”/“Potentially high risk” (colonoscopy every five years). Data were analysed using STATA 11 (STATA, Texas, USA).

Results

Sample characteristics

Of the 1592 mailed surveys, 1117 respondents completed and returned a survey (response rate, 70%). Respondents previously diagnosed with CRC (n = 24) or reporting they had undergone major abdominal surgery (n = 8) were excluded from analysis, leaving a total sample of 1085 participants with data. A total of 777 persons were deemed asymptomatic and eligible for CRC screening analysis (see Figure 2.1). Socio-demographic characteristics of asymptomatic persons are presented in Table 3.2.
**Figure 2.1:** Flowchart representing selection of asymptomatic respondents
Table 3.2: Socio-demographic characteristics of the asymptomatic study population

(n = 777)

<table>
<thead>
<tr>
<th>Characteristic</th>
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<th>Census (Hunter Region)</th>
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</tr>
</thead>
<tbody>
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<td></td>
<td>n</td>
<td>%*</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Gender</td>
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</tr>
<tr>
<td>Male</td>
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<td>14782</td>
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</tr>
<tr>
<td>Female</td>
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<td>Age (years)</td>
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<td>56-64</td>
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<td>65-74</td>
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</tr>
<tr>
<td>Secondary schooling (not completed)</td>
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<tr>
<td>Secondary schooling (completed)</td>
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</tr>
<tr>
<td>Trade qualification or TAFE</td>
<td>193</td>
<td>26</td>
<td></td>
<td></td>
</tr>
<tr>
<td>University or other tertiary study</td>
<td>183</td>
<td>25</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other or not applicable</td>
<td>34</td>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Household income before tax ($)</td>
<td></td>
<td></td>
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<tr>
<td>≤ 39,999</td>
<td>398</td>
<td>57</td>
<td></td>
<td></td>
</tr>
<tr>
<td>40,000 – 69,999</td>
<td>155</td>
<td>22</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥ 70,000</td>
<td>148</td>
<td>21</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk category</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At or slightly above average risk</td>
<td>707</td>
<td>93</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderately increased risk</td>
<td>34</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Potentially high risk</td>
<td>19</td>
<td>3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Percentage of responses (excluding any missing values). Census data reported includes grouped data for persons aged 85-89 years; age-specific data (56-88 years) for gender and age not obtainable.
Proportion ever undertaking colorectal cancer testing

Overall, 63% (475/760) of respondents had ever received any CRC testing (FOBT, sigmoidoscopy or colonoscopy). The proportions of persons ever undertaking CRC testing within each risk category were: “At or slightly above average risk” (61%); “Moderately increased risk” (82%); and “Potentially high risk” (84%).

Level of uptake for each screening modality

**Faecal occult blood test screening**

Table 3.3 presents the results for FOBT screening. Of the 749 respondents providing FOBT screening information, 43% had ever received this test; 20% reported having had an FOBT within the previous two years (with 94% of these persons being “At or slightly above average risk”).

<table>
<thead>
<tr>
<th>Table 3.3: Timing of most recent faecal occult blood test by risk category</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>At or slightly above average risk</td>
</tr>
<tr>
<td>Moderate increased risk</td>
</tr>
<tr>
<td>Potentially high risk</td>
</tr>
</tbody>
</table>

*95% Confidence Interval reported for proportions.

**Sigmoidoscopy screening**

Of the 740 respondents providing sigmoidoscopy screening information, 7% (53/740) had ever received this test in their lifetime; 1% of respondents had undertaken this procedure within the previous five years. All persons who had undertaken this test in the previous five years were “At or slightly above average risk”.

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**Colonoscopy screening**

Table 3.4 presents the rate of colonoscopy screening. Of the 752 respondents providing colonoscopy screening information, 30% had ever received this test; 16% of respondents had a colonoscopy within the previous five years, of which 81% were “At or slightly above average risk”. Over one-third (33%) of respondents “At or slightly above average risk” who had undertaken colonoscopy screening within the previous five years had never undertaken recommended FOBT or sigmoidoscopy screening. Further, 58% of such persons had no family history of CRC. For persons “At or slightly above average risk”, the number of colonoscopies resulting from positive FOBT was not obtainable.

**Table 3.4**: Timing of most recent colonoscopy by risk category (n/%)

<table>
<thead>
<tr>
<th></th>
<th>&lt; 5 years</th>
<th></th>
<th>&gt; 5 years</th>
<th></th>
<th>Not sure</th>
<th></th>
<th>Never</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>95% CI</td>
<td>n (%)</td>
<td>95% CI</td>
<td>n (%)</td>
<td>95% CI</td>
<td>n (%)</td>
<td>95% CI</td>
</tr>
<tr>
<td>At or slightly above average risk</td>
<td>100 (14)</td>
<td>11.8-17.1</td>
<td>91 (13)</td>
<td>10.6-15.7</td>
<td>11 (2)</td>
<td>.0-2.7</td>
<td>497 (71)</td>
<td>67.6-74.4</td>
</tr>
<tr>
<td>Moderately increased risk</td>
<td>14 (41)</td>
<td>24.6-59.3</td>
<td>9 (26)</td>
<td>12.9-44.4</td>
<td>0</td>
<td>0</td>
<td>11 (32)</td>
<td>17.4-50.5</td>
</tr>
<tr>
<td>Potentially high risk</td>
<td>10 (52)</td>
<td>28.9-75.6</td>
<td>4 (21)</td>
<td>.0-26.0</td>
<td>1 (5)</td>
<td>6.0-45.6</td>
<td>4 (21)</td>
<td>.0-26.0</td>
</tr>
</tbody>
</table>

*95% Confidence Interval reported for proportions.

**Colorectal cancer screening in accordance with national screening guidelines**

Table 3.5 presents the proportion of respondents screened in accordance with national CRC screening guidelines. Of the 697 respondents “At or slightly above average risk” and providing screening information on either FOBT or sigmoidoscopy screening, 21% were screened in accordance with NHMRC screening recommendation (FOBT < 2 years, consider sigmoidoscopy every five years). Of the 53 respondents at “Moderately increased risk” or “Potentially high risk” who provided colonoscopy screening information, 45% (95%, CI 31.6-59.6) were screened in accordance with NHMRC screening recommendation.
Table 3.5: Proportion of respondents screened in accordance with national screening guidelines (n/%)

<table>
<thead>
<tr>
<th>Screened in accordance with guidelines</th>
<th>n (%)</th>
<th>95% CI*</th>
</tr>
</thead>
<tbody>
<tr>
<td>At or slightly above average risk</td>
<td>145 (21)</td>
<td>14.0-27.2</td>
</tr>
<tr>
<td>Moderately increased risk</td>
<td>14 (41)</td>
<td>15.3-66.9</td>
</tr>
<tr>
<td>Potentially high risk</td>
<td>10 (56)</td>
<td>24.8-86.4</td>
</tr>
</tbody>
</table>

*95% Confidence Interval reported for proportions.

Screening in accordance with guidelines for respondents eligible and not eligible for NBCSP participation

For persons “At or slightly above average risk”, 11% (73/690) of respondents were aged 56, 65 or 66 at time of study commencement and eligible for FOBT screening in the previous two years. Of such persons, 47% (34/73) had undertaken FOBT screening in accordance with CRC screening guidelines. For persons not eligible for NBCSP participation, 17% (105/617) had undertaken screening in accordance with CRC screening guidelines. Comparison between eligible and ineligible NBCSP participants “At or slightly above average risk” using Pearson’s chi-square found a significantly higher proportion of respondents in the eligible group were screened in accordance with CRC screening guidelines ($\chi^2 = .35.5; \text{df} = 1; \ p < .001$).

Discussion

This study examined CRC screening practices among at-risk persons within an Australian community sample. Previous state-wide and community-based studies of at-risk persons aged over 40 years have indicated a relatively low rate of screening participation using FOBT, commonly reported at less than 20 per cent. In contrast, the present study indicated a substantially higher FOBT participation rate with 47% of respondents indicating they had ever undertaken FOBT. This increase is plausible given the difference in age
distribution of respondents examined in the current study (aged 56-88 years) compared to previous studies. However, of concern is the low rate of screening in accordance with national CRC screening guideline recommendation. In this study, only 21% of respondents “at or slightly above average risk” and 45% of persons at “moderately increased risk” or “potentially high risk” were screened in accordance with national screening guidelines.

Screening in accordance with national guidelines

Comparison of FOBT screening rates with other national programs is difficult as recommendations on the frequency of testing vary between programs: US (annual), Canadian (every one to two years) and Australian (every two years). Nonetheless, national and population based surveys in North America have commonly reported comparable low utilisation of FOBT, often less than 20% within one-year and two-year periods. The rate of sigmoidoscopy screening (1% previous 5 years) identified in this study is concerning, especially given robust evidence indicating its effectiveness in reducing mortality and incidence. However, a potential lack of infrastructure for such screening in Australia may be a contributory factor. In relation to screening of persons at “moderately increased risk” or “potentially high risk”, the finding that 45% of such respondents were screened in accordance with national screening guidelines is an apparent increase compared to a previous state-wide evaluation that identified 30% of persons at above average risk had received endoscopy in the previous 5 years.

Colonoscopy screening

The appropriate use of colonoscopy has been assessed in several studies using multi-disciplinary expert panels to investigate appropriateness of procedures. These studies have generally required experts to independently rate indications on the basis of expected health benefits outweighing the negative consequences by a sufficiently wide margin. Using such criteria, rates of inappropriate use have been previously estimated at between 14 and 37 per cent. The present study indicated that 16% of asymptomatic persons had a colonoscopy
in the previous five years with a majority (81%) of such respondents “at or slightly above average risk”. Colonoscopy screening for persons at this level of risk is not endorsed by Australian screening guidelines. In interpreting this study finding, it should be acknowledged that information about previous adenoma (where follow-up using colonoscopy is recommended) was not ascertained from study respondents. Consequently whether colonoscopy was undertaken for this purpose, or for screening, is largely indistinguishable. Nonetheless, one-third of most recent colonoscopy screening for persons ‘at or slightly above average risk’ in the previous five years was conducted in persons who had no other screening procedure beforehand, which reduces the likelihood that prior adenoma detection might account for the colonoscopy screening rate.

Currently, over 500,000 colonoscopies are conducted in Australia per year with this number increasing 40,000 annually. In the absence of symptoms, approximately 500 colonoscopies would need to be conducted on persons 50-75 years old to identify one cancer. Colonoscopy is associated with a serious complication risk of 1 in 1000. This contrasts with data that has suggested one cancer is found for every 20 colonoscopies following positive FOBT in the NBCSP. Inappropriate use of colonoscopy may divert resources unnecessarily. Improvements in appropriate testing may reduce the risk of lengthy colonoscopy waiting times for persons testing positive for FOBT. An opportunity exists for future research to define ways to improve adherence to guideline recommendations and appropriate referral for colonoscopy.

**Study limitations**

Some limitations should be considered in the interpretation of the study findings. The CRC screening data obtained were self-reported. Nonetheless, self reported history of CRC testing and physicians’ report has been shown to have reasonable agreement, with high levels of sensitivity and specificity. Eligibility for participation in the NBCSP (turning age 55 or 65 years) was estimated based on respondents age provided at baseline HCS study.
recruitment not on exact date of birth. For respondents at “moderately increased risk”/“potentially high risk”, level of risk may have been over-estimated for a small minority of respondents. Validation of first-degree relations diagnosed with CRC e.g. mother, father, sibling or child was not ascertained. For respondents indicating that both a first-degree relative and second-degree relative were diagnosed with CRC an assumption was made that both relatives were diagnosed on the same side of the family.

Conclusions and implications
Future interventions are needed that modify physician and individual factors influencing CRC screening decisions across the entire at-risk population and selection of screening modalities. In Australia, the NBCSP currently offers FOBT screening only on a one-off basis to those aged 50, 55 or 65 years, with no repeat biennial testing. At present within Australia the NBCSP strategy reaches less than 15% of the at-risk population each year and there is no commitment to re-screen. Future public health gain from the NBCSP largely rests on the ability to maximise screening rates for appropriate groups through the widening of this program and the provision of repeat screening.
References


Appendix 2.A: Items and response options (verbatim) of colorectal cancer test items*

FOBT*

“Have you ever had an FOBT, FIT or iFOBT? These tests, faecal occult blood test (FOBT), faecal immunochemical test (FIT) and immunochemical faecal occult blood test (iFOBT) involve you providing samples of faeces or poo. The samples would have been sent to a laboratory to test for tiny amounts of blood.”

☐ Yes
☐ No
☐ Not sure

Colonoscopy

“Have you ever had a colonoscopy? This is usually a day procedure in hospital where the inside of your colon is examined while you are sedated.”

Response options as above

Sigmoidoscopy*

“Have you ever had a sigmoidoscopy? In this procedure only the rectum and lower part of the colon are examined. This is a short procedure which lasts about 5-10 minutes. Sedation is usually not required and you can usually go home straight after the procedure.”

Response options as above

Timing of most recent testing

“How long ago was your most recent X**?”

☐ Less than a month ago
☐ One month to less than twelve months ago
☐ Twelve months to less than two years ago
☐ Two years to less than five years ago
☐ Five years or longer ago
☐ Not sure

Reason for testing

“Did you have your last X because you had a symptom?”

☐ Yes
☐ No

*Survey responses did not allow for differentiation between chemical and immunochemical FOBT and different type of sigmoidoscopy, e.g. flexible or rigid. **Insert test type.
Appendix 2.B: Items and response options (verbatim) used to assess respondents’ family histories

First-degree relatives
“How many of your close relatives (mother, father, brother, sister or child) have ever been diagnosed with bowel cancer?”
☐ None
☐ One
☐ Two
☐ Three or more

Second-degree relatives
“Have any of your second-degree relatives (grandparents, uncles, aunts, nephews, nieces or half-siblings) ever been diagnosed with bowel cancer? This includes only biological/blood relatives, not those related to you through marriage. Please select all that apply.”
☐ None of these relatives has ever been diagnosed with bowel cancer
☐ Yes, mother’s mother
☐ Yes, father’s mother
☐ Yes, mother’s father
☐ Yes, father’s father
☐ Yes, mother’s sister
☐ Yes, father’s sister
☐ Yes, mother’s brother
☐ Yes, father’s brother
☐ Yes, nephew
☐ Yes, niece
☐ Yes, grandchild
☐ Yes, half-sibling (mother’s side)
☐ Yes, half-sibling (father’s side)

Age at diagnosis (asked separately for both first- and second-degree relatives)
How many of these relative(s) were diagnosed at the following ages? (Please write number of relatives diagnosed in each age category)
___ 50 or less
___ Between 51 and 55
__ 56 or over
__ Don’t know

Other cancers (high-risk feature)
Has your mother, father, brother, sister, child, grandparent, uncle, aunt, nephew, niece, or half-sibling ever been diagnosed with any of the following cancers: endometrium, ovary, stomach, renal pelvis, ureter, biliary tract or brain?
☐ Yes
☐ No
☐ Don’t know
PAPER THREE

Individual- and provider-level factors associated with colorectal cancer screening in accordance with guideline recommendation: A community-level perspective across varying levels of risk
Introduction to Paper Three

Paper Two highlighted the fact that among an at-risk community-based cohort there was a low level of colorectal cancer (CRC) screening uptake in accordance with screening guidelines across varying levels of risk: “at or slightly above average risk” (21%); “moderately increased risk” (41%); and “potentially high risk” (56%). At the cornerstone of health policy in Australia and internationally is the reduction of health inequalities through equality of access to healthcare. However, disparities in CRC screening participation among varying population sub-groups worldwide have been identified. Rates of CRC screening have been shown to be related to numerous factors, including socio-economic status, ethnicity, age and gender. In Australia, the National Bowel Cancer Screening Program (NBCSP) monitoring reports have consistently indicated discrepancies in CRC participation across numerous socio-demographic variables, including gender, age, socio-economic status and geographical location. While such reports are highly relevant for future healthcare planning and policy decisions on a national level, they do not provide the necessary detail at local and state-based levels to enable informed service planning and to guide the adoption of interventions or programs aimed at increasing the rates of CRC screening. Further, the current monitoring reports only indicate the factors associated with screening participation among the select portion of the entire at-risk population offered FOBT screening. In Australia, little research has examined the population characteristics related to CRC testing across varying levels of risk. At present in Australia, with the exception of one prior study, relatively little is known about the socio-demographic or provider-level factors associated with CRC screening in accordance with national guideline recommendations.

Aims and purpose

This paper examined at a community level the types of persons and the sub-groups of the at-risk population less likely to engage in CRC screening practices and at levels in accordance with national screening guideline recommendations. Specifically, this paper identified among
a large community-based cohort of at-risk persons (aged 56-88 years of age) the individual- and provider-level factors related to (i) ever receiving CRC testing and (ii) CRC screening compliance in accordance with guideline recommendations across varying levels of risk.

This manuscript is currently under editorial review at *BMC Public Health*. Citation: Ryan J Courtney, Christine L Paul, Robert W Sanson-Fisher, Finlay A Macrae, Mariko L Carey, John Attia, Mark McEvoy. Individual- and provider-level factors associated with colorectal cancer screening in accordance with guideline recommendation: A community-level perspective across varying levels of risk. *BMC Public Health*, under editorial review.

Manuscript ID - MS: 1523827841638039.
References


Individual- and provider-level factors associated with colorectal cancer screening in accordance with guideline recommendation: A community-level perspective across varying levels of risk

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2 Department of Colorectal Medicine and Genetics, Royal Melbourne Hospital, Victoria, Australia
3 Centre for Clinical Epidemiology and Biostatistics, Faculty of Health, University of Newcastle, New South Wales, Australia
4 Hunter Medical Research Institute, New South Wales, Australia
Abstract

Background: Participation rates in colorectal cancer screening (CRC) are low. Relatively little is known about screening uptake across varying levels of risk and across population groups. The purpose of the current study was to identify factors associated with (i) ever receiving colorectal cancer (CRC) testing; (ii) risk-appropriate CRC screening in accordance with guidelines; and (iii) recent colonoscopy screening.

Methods: 1592 at-risk persons (aged 56-88 years) were randomly selected from the Hunter Community Study (HCS), Australia. Participants self-reported family history of CRC was used to quantify risk in accordance with national screening guidelines.

Results: 1117 participants returned a questionnaire; 777 respondents were eligible for screening and analysis. Ever receiving CRC testing was significantly more likely for persons: aged 65-74 years; who had discussed with a doctor their family history of CRC or had ever received screening advice. For respondents “at or slightly above average risk”, guideline-appropriate screening was significantly more likely for persons: aged 65-74 years; with higher household income; and who had ever received screening advice. For respondents at “moderately or potentially high risk”, guideline-appropriate screening was significantly more likely for persons: with private health insurance and who had discussed their family history of CRC with a doctor. Colonoscopy screening was significantly more likely for persons: who had ever smoked; discussed their family history of CRC with a doctor; or had ever received screening advice.

Conclusions: The level of risk-appropriate screening varied across populations groups. Interventions that target population groups less likely to engage in CRC screening are pivotal for decreasing screening inequalities.
Background

Worldwide, colorectal cancer (CRC) is a significant health burden with over one million persons diagnosed annually. The five-year survival rate for localised disease is high, yet few CRCs (less than 40%) are detected at this stage. Many CRC deaths are preventable as screening can reduce incidence through the identification and removal of precancerous polyps and increase early detection of disease. Australian National Health and Medical Research Council (NHMRC) screening guidelines recommend that asymptomatic persons “at or slightly above average risk” receive either FOBT screening biennially or sigmoidoscopy (preferably flexible) every five years commencing at age 50 years. For persons at “moderately increased risk”, colonoscopy is endorsed every five years starting at age 50 or at an age ten years younger than the age of first diagnosis of bowel cancer in the family, whichever comes first. Endoscopy screening for persons at “potentially high risk” is recommended at least on a five-yearly basis in the NHMRC screening guidelines. However, age at screening commencement, test type and repeat testing interval are dependent on the type of family-specific mutation identified.

Australia’s National Bowel Cancer Screening Program

In Australia, Medicare administers the National Bowel Cancer Screening Program (NBCSP) Register. Medicare selects eligible participants from either the Medicare enrolment records or the Department of Veterans’ Affairs. The NBCSP Register is responsible for mailing of screening invitations and FOBT kits, the recording of participants’ details and the issuing of reminder letters. As part of the NBCSP, participants are encouraged to nominate their usual primary care provider on their participants details form; however, this is not compulsory. The recently re-funded NBCSP offers persons turning 50, 55 and 65 years of age via mail a one-off immunochemical Faecal Occult Blood Test (FOBT) screening invitation. It is important to note that the limited format of the NBCSP (restriction of screening to persons in selected age brackets across the at-risk population), is not consistent with the NHMRC recommendation
of biennial FOBT screening of all Australians in the at-risk population. A recent study examining the costs and outcomes from full (rather than limited) implementation of a biennial FOBT screening for adults in the at-risk population (50-74 years) identified a likely mortality reduction of 25% and saving of 500 deaths per year.\textsuperscript{10}

**Screening participation in Australia**

Participation rates in Australia’s NBCSP appear to have reached a plateau since the pilot program’s introduction.\textsuperscript{9, 11-13} The pilot program received a response rate of 45%, with the roll-out of the NBCSP (with screening offered to persons 50 and 65 years of age) in 2006 receiving a slightly lower rate of 41%.\textsuperscript{12} The rate of participation only marginally increased in 2008 to 42.9% when the program widened to offer screening to persons aged 55 years of age.\textsuperscript{11} Most recent estimates suggest a similar rate of low participation (40.1%).\textsuperscript{9} The experience in other countries with national screening programs offering repeated FOBT screening to a wider section of the at-risk population suggests that much higher screening rates are achievable. For example, FOBT screening rates in the United Kingdom and Finnish screening programs are currently 52% and 71% respectively.\textsuperscript{14, 15} In Australia, previous community-based evaluations have also indicated low rates of CRC screening, with 5 to 20% of individuals ever undertaking FOBT.\textsuperscript{16-18} The most recent assessment in New South Wales (NSW) indicated that 18% of persons aged over 50 years had undertaken FOBT in the previous five years.\textsuperscript{19} In relation to colonoscopy screening in Australia, two population-based assessments in NSW have suggested under screening among persons at elevated levels of risk.\textsuperscript{16, 19}

Given low rates of CRC screening, it is important to identify factors which may influence screening uptake. Previous studies have indicated that the following factors influence CRC screening behaviour: *socio-demographic characteristics* (e.g. older age, higher education, higher income); *lifestyle factors* (e.g. smoking history, chronic disease); *family history* (e.g. personal or family history of CRC); *awareness* (e.g. knowledge of CRC and perceived risk of
developing CRC) and health care utilisation (e.g. usual source of care, number of GP visits, and health care coverage). In the Australian context, a small number of studies have explored determinants of CRC screening uptake with little known about predictors of screening behaviour for persons at varying levels of risk. Since the introduction of the NBCSP in 2006, no community- or population-based assessments in Australia have been conducted. Recent evidence pertaining to FOBT screening uptake and inequalities in participation have been confined to annual NBCSP monitoring reports, which report screening rates among a limited section of the at-risk population (persons 50, 55 and 65 years of age). Further, since the NHMRC guidelines’ implementation in 1999, only one study has assessed the predictors of risk-appropriate screening for persons at each level of risk in accordance with guideline-recommendation. The identification of factors associated with risk-appropriate screening is of critical importance for future planning and implementation of tailored CRC screening programs.

This study aimed to assess among a large community-based cohort of at-risk persons (aged 56-88 years), the factors associated with: (1) ever receiving any CRC testing; (2) receiving screening in accordance with screening guidelines; and (3) recent use of colonoscopy screening.

**Methods**

The University of Newcastle and Hunter New England Population Health Human Research Ethics Committees granted ethical approval.

**Study population**

The Hunter Community Study (HCS) is a longitudinal community cohort aged 55-85 years at baseline in the Hunter Region, New South Wales (NSW), Australia. HCS participants were randomly selected from the NSW State electoral roll between December 2004 and
December 2007. A modified Dillman recruiting strategy was used for this study, whereby two letters of introduction and an invitation to participate were posted to selected persons. Persons not speaking English and living in a residential aged-care facility were deemed ineligible. Following consent to participate, individuals were asked to complete two self-reported questionnaires and were asked to return these when they attended the HCS data collection centre, at which time a series of clinical measures were obtained. For further details on the HCS cohort and an exhaustive list of measures obtained from HCS participants, see the cohort profile. The HCS cohort profile reflects state and national profiles for gender and marital status but is slightly younger in age. For the current study, a randomly selected sub-sample of the HCS (n = 1592) aged 56-88 years were mailed a questionnaire during November, 2009.

**Questionnaire**

Questions and response options are presented in Appendix 3.A. Respondents were asked whether they had ever undertaken FOBT, colonoscopy or sigmoidoscopy. Those ever undertaking each test were asked to specify timing of most recent testing and “Did you have your last X test because you had a symptom” (Yes/ No). All respondents were asked about their family history of CRC [See Appendix 3.A] to allocate each respondent to a level of risk (see Table 4.1) in accordance with screening guidelines.
Table 4.1: Respondents’ risk allocation in accordance with colorectal cancer screening guidelines

<table>
<thead>
<tr>
<th>Risk category*</th>
<th>At or slightly above average risk</th>
<th>Moderately increased risk</th>
<th>Potentially high risk</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• No personal history of bowel cancer</td>
<td>• Either no close relatives with bowel cancer or one first-degree or second-degree relative with bowel cancer diagnosed at age 55 years or older</td>
<td>• One first-degree relative diagnosed before the age of 55 years (without potentially high-risk features listed below), or • Two first-degree relatives or one first- and one second-degree relative(s) on the same side of the family (without potentially high-risk features listed below)</td>
</tr>
<tr>
<td></td>
<td>• Either no close relatives with bowel cancer or one first-degree or second-degree relative with bowel cancer diagnosed at age 55 years or older</td>
<td>• Two first-degree relatives or one first- and one second-degree relative(s) on the same side of the family (without potentially high-risk features listed below)</td>
<td>• Three or more first-degree or a combination of first-degree and second-degree relatives on the same side of the family diagnosed with bowel cancer (suspected HNPCC**), or • Two or more first-degree or second-degree relatives on the same side of the family diagnosed with bowel cancer, including the following risk feature: bowel cancer before the age of 50 years or at least one relative with cancer of the endometrium, ovary, stomach, small bowel, renal pelvis, ureter, biliary tract or brain</td>
</tr>
</tbody>
</table>

* Risk features potentially placing persons at possible increased risk, including personal history of adenoma, inflammatory bowel disease or suspected familial adenomatous polyposis (FAP) were not assessed in the survey.
** HNPCC (Hereditary non-polyposis colorectal cancer), also known as Lynch’s Syndrome.

Predictors of colorectal cancer screening behaviour

Based on existing literature, the following items selected from the HCS databank, assessed at HCS baseline were investigated: Socio-demographic characteristics: age, gender, education, marital status, country of birth, household income, retirement, private health insurance status, tobacco or alcohol use; Clinical characteristics: number of general practice visits over the past 12 months, previous cancer diagnosis (excluding CRC), body mass index, and presence of a chronic health-condition; and Psychosocial characteristics: physical health (SF-36) and mental health (K-10 Kessler Scale). Predictors ascertained at survey completion included: risk category, discussion of family history of CRC with doctor and notification of any “increased risk” (Never discussed/ discussed and informed of possible “increased risk”/ discussed and not informed of any possible “increased risk”), and ever received screening advice from doctor (Yes/No).
Statistical analysis

“Ever received CRC testing” was calculated by the proportion of respondents indicating “Yes” to undertaking any of the following CRC tests (i.e. FOBT, sigmoidoscopy or colonoscopy) divided by the total number of respondents. Respondents who had not provided any information on any of these CRC tests were excluded from analysis. The proportion of respondents screened in accordance with screening guidelines was assessed by risk category as follows: “at or slightly above average risk” (FOBT within two years or sigmoidoscopy preferably flexible within five years) and “moderately increased risk/potentially high risk” (colonoscopy within 5 years). Self reported family history of CRC was used to allocate respondents to a risk category in accordance with screening guidelines. Respondents with missing values relating to type or number of relative(s) diagnosed or age at their diagnosis were excluded from analysis. Multiple logistic regression modelling was used to assess the association between socio-demographic, clinical and psychosocial characteristics and each study outcome. Variables with a \( p < .25 \) following simple logistic regression analysis [See Appendix 3.B] were entered into a multiple logistic regression model (both forward and backward stepwise elimination were used to check consistency of results). Stepwise logistic regression was used to determine the final set of predictor variables associated with each study outcome. Variables that met the significance cut point (\( p \) value < .05) were included in the final model.

Results

Characteristics of the sample

Of the 1592 mailed surveys, 1117 respondents completed and returned a survey (response rate = 70%). Respondents previously diagnosed with CRC (\( n = 24 \)) or reporting they had undergone major abdominal surgery (\( n = 8 \)) were excluded from analysis, leaving a total sample of 1085 participants with data. Responder bias was assessed on the following key
characteristics (i.e. age, gender and education). Pearson’s χ² test found no significant differences relating to gender (χ² = .09; df = 1; p = .76) or education (χ² = 8.75; df = 4; p = .07). However, for age, respondents were significantly more likely to be of a younger age compared to non-respondents (χ² = 11.12; df = 1; p < .01).

**Inclusion and exclusion for colorectal cancer screening**

Respondents were classified as asymptomatic and eligible for screening if they had not reported the following: undertaking FOBT, sigmoidoscopy or colonoscopy due to a symptom episode in the previous five years; any bowel related condition; previous history of CRC; or consulting a doctor for their first primary symptom episode of CRC (rectal bleeding or change in bowel habit) in the previous five years. Following exclusion of such persons, a total sample of 777 asymptomatic persons were identified. Table 4.2 describes the characteristics of the study population. 17 persons were excluded from analysis due to insufficient family history information available to derive a level of risk. A total of 760 asymptomatic respondents were allocated to a level of risk in accordance with screening guidelines and eligible for analysis.

**Table 4.2:** Socio-demographic, clinical and psychosocial characteristics of the asymptomatic study population (n = 777)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Socio-demographic</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>368</td>
<td>47</td>
</tr>
<tr>
<td>Female</td>
<td>409</td>
<td>53</td>
</tr>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>56-64</td>
<td>323</td>
<td>42</td>
</tr>
<tr>
<td>65-74</td>
<td>273</td>
<td>35</td>
</tr>
<tr>
<td>75-88</td>
<td>174</td>
<td>23</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In relationship</td>
<td>587</td>
<td>79</td>
</tr>
<tr>
<td>Not in relationship</td>
<td>159</td>
<td>21</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Secondary schooling (not completed)</td>
<td>168</td>
<td>23</td>
</tr>
<tr>
<td>Secondary schooling (completed)</td>
<td>167</td>
<td>23</td>
</tr>
<tr>
<td>Trade qualification or TAFE</td>
<td>193</td>
<td>26</td>
</tr>
<tr>
<td>Category</td>
<td>Count</td>
<td>Percentage</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>-------</td>
<td>------------</td>
</tr>
<tr>
<td>University or other tertiary study</td>
<td>183</td>
<td>25</td>
</tr>
<tr>
<td>Other or not applicable</td>
<td>34</td>
<td>5</td>
</tr>
<tr>
<td>Household income before tax ($)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 39,999</td>
<td>398</td>
<td>57</td>
</tr>
<tr>
<td>40,000 – 69,999</td>
<td>155</td>
<td>22</td>
</tr>
<tr>
<td>≥ 70,000</td>
<td>148</td>
<td>21</td>
</tr>
<tr>
<td>Country of birth</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Australian</td>
<td>631</td>
<td>89</td>
</tr>
<tr>
<td>Other</td>
<td>80</td>
<td>11</td>
</tr>
<tr>
<td>Retired</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>464</td>
<td>62</td>
</tr>
<tr>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Private health insurance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No coverage</td>
<td>195</td>
<td>26</td>
</tr>
<tr>
<td>Coverage</td>
<td>543</td>
<td>74</td>
</tr>
<tr>
<td>Alcohol</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drinking days per month</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean =11 SD =11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoking</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ever</td>
<td>352</td>
<td>47</td>
</tr>
<tr>
<td>Never</td>
<td>391</td>
<td>53</td>
</tr>
<tr>
<td>Clinical</td>
<td></td>
<td></td>
</tr>
<tr>
<td>General practitioner visits per year</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None to twice</td>
<td>191</td>
<td>25</td>
</tr>
<tr>
<td>3 - 6</td>
<td>414</td>
<td>55</td>
</tr>
<tr>
<td>&gt; 6</td>
<td>145</td>
<td>19</td>
</tr>
<tr>
<td>Previous cancer (excluding CRC)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>164</td>
<td>22</td>
</tr>
<tr>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk category</td>
<td></td>
<td></td>
</tr>
<tr>
<td>At or slightly above average risk</td>
<td>707</td>
<td>93</td>
</tr>
<tr>
<td>Moderately increased risk</td>
<td>34</td>
<td>4</td>
</tr>
<tr>
<td>Potentially high risk</td>
<td>19</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>529</td>
<td>70</td>
</tr>
<tr>
<td>Discussion of family history of CRC with doctor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never discussed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Discussed, informed of “increased risk”</td>
<td>137</td>
<td>18</td>
</tr>
<tr>
<td>Discussed, not informed of “increased risk”</td>
<td>93</td>
<td>12</td>
</tr>
<tr>
<td>Ever received screening advice from doctor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>197</td>
<td>28</td>
</tr>
<tr>
<td>BMI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 18.5</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>18.5 - 25</td>
<td>135</td>
<td>19</td>
</tr>
<tr>
<td>&gt; 25</td>
<td>564</td>
<td>80</td>
</tr>
<tr>
<td>Chronic health condition</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>569</td>
<td>77</td>
</tr>
<tr>
<td>Psychosocial</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SF-36 (physical health score)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean = 52 SD = 9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>K-10 (mental health score)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low or no risk (10-15)</td>
<td>565</td>
<td>75</td>
</tr>
<tr>
<td>Medium to high risk (16 +)</td>
<td>190</td>
<td>25</td>
</tr>
</tbody>
</table>

*Percentage of responses (excluding any missing values).*
Ever received colorectal cancer testing

Overall, 63% (475/ 760) of respondents allocated to a level of risk had ever received any CRC testing (FOBT/ sigmoidoscopy or colonoscopy). The proportion ever undertaking CRC testing by risk category were: “at or slightly above average risk” (61%), “moderately increased risk” (82%) and “potentially high risk” (84%). Simple logistic regression analyses identified items with a p value < .25 which were entered into multiple logistic regression modelling. Table 4.3 presents the results of this analysis. Persons significantly more likely to have ever been tested for CRC were aged between 65- 74 years of age and had ever received screening advice from a doctor. Persons who had discussed their family history of CRC with a doctor, irrespective of whether they were informed of any possible “increased risk”, were significantly more likely to be tested than those never having discussed their family history with a doctor.

Table 4.3: Multiple logistic regression analysis of factors associated with ever receiving colorectal cancer screening

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>N (%)</th>
<th>OR (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>56-64</td>
<td>184 (57)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>65-74</td>
<td>194 (71)</td>
<td>2.08 (1.41, 3.06)</td>
<td>.000</td>
</tr>
<tr>
<td>75-88</td>
<td>104 (60)</td>
<td>1.30 (.84, 1.99)</td>
<td>.234</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Discussion of family history of CRC with doctor</th>
<th>N (%)</th>
<th>OR (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never discussed</td>
<td>274 (52)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Discussed and informed of possible &quot;increased risk&quot;</td>
<td>122 (89)</td>
<td>4.07 (2.13, 7.78)</td>
<td>.000</td>
</tr>
<tr>
<td>Discussed and not informed of possible &quot;increased risk&quot;</td>
<td>76 (82)</td>
<td>4.02 (2.16, 7.48)</td>
<td>.000</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ever received screening advice from doctor</th>
<th>N (%)</th>
<th>OR (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>278 (54)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>173 (88)</td>
<td>3.43 (2.03, 5.77)</td>
<td>.000</td>
</tr>
</tbody>
</table>
Colorectal cancer screening in accordance with national screening guidelines

Of the 707 respondents “at or slightly above average risk”, 697 provided information on either FOBT or sigmoidoscopy screening, with 21% (145/697) of respondents screened in accordance with national screening recommendation (see Table 4.4). Screening in accordance with guideline recommendation was significantly more likely to occur for “at or slightly above average risk” persons: aged 65-74 years of age; with a higher household income (> $70,000 compared to <= $39,999); and who had ever received screening advice from a doctor.

Table 4.4: Multiple logistic regression model (n = 586*) of factors associated with screening in accordance with guidelines for persons “at or slightly above average risk”

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n (%)</th>
<th>OR (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>56-64</td>
<td>46 (17)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>65-74</td>
<td>59 (29)</td>
<td>2.71 (1.64, 4.49)</td>
<td>.000</td>
</tr>
<tr>
<td>75-88</td>
<td>21 (18)</td>
<td>1.57 (.83, 2.20)</td>
<td>.166</td>
</tr>
<tr>
<td>Annual household income before tax ($)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;= 39,999</td>
<td>60 (18)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>40,000 – 69,999</td>
<td>27 (21)</td>
<td>1.28 (.74, 2.21)</td>
<td>.380</td>
</tr>
<tr>
<td>&gt;= 70,000</td>
<td>39 (30)</td>
<td>2.59 (1.50, 4.49)</td>
<td>.000</td>
</tr>
<tr>
<td>Ever received screening advice from doctor</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>69 (16)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>53 (37)</td>
<td>3.00 (1.95, 4.64)</td>
<td>.000</td>
</tr>
</tbody>
</table>

* Respondents excluded from model due to missing values (n = 121).

Of the 53 respondents at “moderately increased risk/potentially high risk” and providing colonoscopy screening information, 45% (24/53) were screened in accordance with screening recommendation. Screening in accordance with guideline recommendation (colonoscopy within 5 years) was significantly more likely to occur for persons who had
private health insurance and who had discussed their family history of CRC with a doctor (see Table 4.5).

**Table 4.5**: Multiple logistic regression model (n = 50) of factors associated with screening in accordance with guidelines for persons at “moderately increased risk/ potentially high risk”

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n (%)</th>
<th>OR (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Private health insurance</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No-coverage</td>
<td>3 (17)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Coverage</td>
<td>19 (58)</td>
<td>8.46 (1.58, 45.39)</td>
<td>.013</td>
</tr>
<tr>
<td><strong>Discussion of family history of CRC with doctor</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never discussed</td>
<td>3 (14)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Discussed/ informed of ‘increased risk’</td>
<td>17 (68)</td>
<td>16.34 (3.19, 83.55)</td>
<td>.001</td>
</tr>
<tr>
<td>Discussed/ not informed of increased ‘risk’</td>
<td>2 (67)</td>
<td>17.50 (.83, 368.04)</td>
<td>.066</td>
</tr>
</tbody>
</table>

* Respondents excluded from model due to missing values (n = 3).

**Recent colonoscopy screening irrespective of level of risk**

Of the 760 respondents allocated to a level of risk, 752 respondents provided colonoscopy screening information, with 16% (124/752) of respondents receiving a colonoscopy within the previous five years. Table 4.6 presents the multiple logistic regression model for recent colonoscopy screening (within 5 years) irrespective of level of risk. Recent colonoscopy screening was significantly more likely for persons: that had ever smoked; discussed their family history of CRC with a doctor regardless of whether informed of “increased risk”; and who had ever received screening advice from a doctor.
Table 4.6: Multiple logistic regression model (n = 659)* for colonoscopy screening (within 5 years) irrespective of level of risk.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n (%)*</th>
<th>OR (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoking</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>53 (14)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Ever</td>
<td>66 (19)</td>
<td>1.89 (1.15, 3.10)</td>
<td>.012</td>
</tr>
<tr>
<td>Discussion of family history of CRC with doctor</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never discussed</td>
<td>37 (7)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Discussed/ informed of 'increased risk'</td>
<td>67 (51)</td>
<td>7.20 (3.95, 13.09)</td>
<td>.000</td>
</tr>
<tr>
<td>Discussed/ not informed of increased 'risk'</td>
<td>18 (20)</td>
<td>2.30 (1.11, 4.76)</td>
<td>.0025</td>
</tr>
<tr>
<td>Ever received screening advice from doctor</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>36 (7)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>80 (41)</td>
<td>4.60 (2.65, 8.00)</td>
<td>.000</td>
</tr>
<tr>
<td>Private health insurance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No-coverage</td>
<td>18 (9)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Coverage</td>
<td>99 (19)</td>
<td>1.84 (.97, 3.50)</td>
<td>.062</td>
</tr>
</tbody>
</table>

* Respondents excluded from model due to missing values (n = 101).
Discussion

The behaviour of health care providers including discussing family history of CRC and making a CRC screening recommendation were predictors of CRC screening uptake, screening in accordance with guideline recommendation and recent colonoscopy screening. Individual and lifestyle characteristics associated with some but not all of the above CRC screening outcomes included: higher household income, age, private health insurance and smoking.

Factors associated with colorectal cancer screening behaviour

Healthcare-provider recommendation for colorectal cancer screening

The variable most strongly associated with CRC testing and screening was receiving screening advice from a health care provider. This finding is consistent with previous literature which identified physician encouragement as an important predictor of CRC screening. Strategies such as general practitioner screening invitations sent to patients and provider reminder/ prompt systems are effective in increasing the likelihood of screening participation. Relatively little is known about how well CRC screening is included within practice-based reminder systems. Improvement in the systematic delivery of CRC screening advice and implementation of effective primary-care based interventions are likely to be beneficial.

Discussion of family history of colorectal cancer with doctor

Persons who had discussed their family history of CRC regardless of whether they were informed of possible “increased risk” were more likely to be ever tested, screened in accordance with guideline recommendation (“moderately/ potentially high risk” persons) and screened recently using colonoscopy. Such findings highlight the importance of family history of CRC assessment in the primary care setting. Studies of cancer risk assessment tools suggest that such an approach is feasible and effective for collection of family history of
cancer information, automation of familial risk stratification and risk-appropriate screening advice.\textsuperscript{36, 37}

\textbf{Age}

Among persons who were “at or slightly above average risk”, those who were older were more likely to ever be tested and screened in accordance with CRC screening guidelines, as per previous studies.\textsuperscript{19, 24, 38, 39} The literature suggests that an inverted U-relationship is observed, with the lowest rates of CRC screening participation found among persons 50-55 years and 70-80 years of age.\textsuperscript{24, 40} Further, it has also been demonstrated that non-adherence to repeat FOBT screening is evident for persons aged less than 65 years.\textsuperscript{41} Given the rapid increase in CRC risk after age 50, the targeting of those aged 50-65 years is of particular importance if optimal screening rates are to be achieved.

\textbf{Household income}

A gradient in CRC screening participation has been identified worldwide related to socio-economic status.\textsuperscript{20, 24, 40} Patient screening preference is sensitive to out of pocket expenses\textsuperscript{42} with lower participation among disadvantaged persons.\textsuperscript{21, 24} In the current study, persons “at or slightly above average risk” with household incomes above >$70,000 were more likely to be screened in accordance with guideline recommendation, suggesting a need for interventions facilitating CRC screening among low income households. In Australia, annual NBCSP monitoring reports and cross-sectional analysis of participation in this program have also indicated significantly lower levels of CRC screening participation among persons from the most deprived socio-economic quintiles in the population.\textsuperscript{9, 11-13, 43} It is important to consider that this disparity in participation among differing socio-economic groups in Australia and the United Kingdom (UK) occurs in the presence of universal programs offering FOBT screening at no cost.\textsuperscript{43} A similar socio-economic gradient in screening participation has also been identified for cervical and breast cancer screening programs.\textsuperscript{21} These findings, lend support to the suggestion that direct economic barriers alone do not explain the socio-
economic differential in participation. Previous studies have indicated that the provision of universal healthcare or re-imbursement for the cost of screening has little appreciable effect on eliminating equality in screening participation. It appears that some health service access hurdles appear to dominate among disadvantaged persons. Additionally, it is argued that there are distinct differences in healthcare-seeking behaviour and beliefs among persons from lower socio-economic groups, compared with those from higher socio-economic groups. Taken together, this suggests that strategies to improve equality in screening must recognise factors other than financial coverage. It is paramount that future formative research examines the beliefs and barriers to CRC screening participation among lower socio-economic persons, to assist in the development of effective interventions.

When considering future decisions about Australia’s NBCSP, it is critical that policy makers consider the reasons for non-screening compliance among persons from lower socio-economic status if increased equality in participation is to eventuate.

Private health insurance

Persons with private health insurance were marginally more likely to have recent colonoscopy screening. Previous literature indicates that private health insurance is a strong predictor of CRC screening. Importantly, the current finding that private health insurance is a predictor for all colonoscopies but not for colonoscopies in accordance with guidelines casts some doubt on the process by which colonoscopies are decided. There is a pressing need to identify ways to improve guideline-appropriate use of colonoscopies.

Smoking

Previous studies have indicated that smokers tend to be less compliant with CRC screening. The increased likelihood of recent colonoscopy screening among persons who had ever smoked in the current study may be due to health providers’ identification of this risk factor and provision of colonoscopy screening. Alternatively, ex-smokers who have already made a
health behaviour change in their lives may have an increased motivation for health screening compared to persons who had never smoked.

Limitations
It should be acknowledged that sample representativeness and responder bias place some limitations on the interpretation of findings and their generalisability. For the most part, the HCS is a representative sample of the Hunter Region and NSW in comparison to Census data on a number of demographic characteristics, at the exception of age. Analysis of responders’ bias identified that responders were more likely to be younger than non-responders from the HCS cohort. For respondents undertaking FOBT, type of test undertaken (guaiac or immunochemical) and the outcome of testing (negative/positive) was not assessed. In relation to positive FOBT testing, this caveat should be considered in the interpretation of the rate of colonoscopy screening (previous five years).

Screening behaviour was self-reported, however this has shown to have reasonable agreement with physician report and relatively high levels of sensitivity and specificity. Although two new studies and a recent meta-analysis have indicated high levels of sensitivity and specificity for self-reported screening behaviour, it is important to recognise that accuracy of self-reported screening varies across patient characteristics and test modalities. A meta-analysis of validation studies on self-reported CRC cancer screening use in the United States found that self-report versus documented history of screening had a high level of specificity (endoscopy .90 and FOBT .78) and sensitivity (endoscopy .82 and FOBT .79).

To enhance recall, the current study adopted descriptions of CRC tests to increase the accurate recall of CRC testing. Self-reported family history of CRC was used to assign level of risk. Previous studies have indicated self-reported family history of CRC has relatively high levels of sensitivity and specificity for reporting of affected first-degree relatives. However, the level of accuracy is substantially reduced for affected second-degree relatives. The
accuracy of reporting of age at diagnosis in CRC-affected relatives has not been identified in the literature. Further, the extent to which misleading family history information reorients risk classification for relatives following verification is largely unknown. Therefore, it is possible that the classification of risk may be inaccurate for a small proportion of study respondents given the limitation of no objective verification of self-reported family history. For respondents at “moderately increased/potentially high risk”, level of risk may have been overestimated for a small minority of respondents. For respondents indicating that both a first-degree relative and second-degree relative were diagnosed with CRC, an assumption was made that both relatives were diagnosed on the same side of the family. This assumption may have over-estimated the level of risk for some respondents.

Finally, the current study is subject to limitations associated with stepwise regression analysis including: parameter estimation, error rate estimation and reliance on a single best model. Conducting stepwise regression models with a large number of independent variables and a small sample size, may over-estimate model fit. However, this limitation is difficult to overcome when applying statistical modelling techniques to identify predictors associated with rare occurrences in the population i.e. persons at increased familial risk of disease. It is conceivable that future large scale population-based studies examining CRC screening behaviour across varying levels of familial risk will assist in further defining the predictors of risk-appropriate CRC screening.

Conclusions
Empirical randomised controlled trial evidence suggests that the offering of repeated (annual or biennial) FOBT screening to the at-risk population is effective in reducing mortality and incidence associated with CRC. In Australia, there is a pressing need for expansion of the NBCSP and offering of repeated screening to the at-risk population, if the CRC-related disease burden and economic cost is to be reduced. Multiple strategies and messages targeting specific demographic groups as well as healthcare provider factors are needed if
increases in overall screening participation are to be achieved. A pressing issue is the reduction of inequalities in CRC screening participation to reduce inequality in health outcomes. High quality research is required to unravel the barriers to CRC screening, as well as the mechanisms by which screening inequalities are maintained.
References


Appendix 3.A: Wording of questionnaire items

Table 1: Items and response options (verbatim) of colorectal cancer test items*

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Description</th>
<th>Response Options</th>
</tr>
</thead>
</table>
| FOBT      | “Have you ever had an FOBT, FIT or iFOBT? These tests, faecal occult blood test (FOBT), faecal immunochemical test (FIT) and immunochemical faecal occult blood test (iFOBT), involve you providing samples of faeces or poo. The samples would have been sent to a laboratory to test for tiny amounts of blood.” | □ Yes  
□ No  
□ Not sure |
| Colonoscopy | “Have you ever had a colonoscopy? This is usually a day procedure in hospital where the inside of your colon is examined while you are sedated.” | Response options as above |
| Sigmoidoscopy | “Have you ever had a sigmoidoscopy? In this procedure only the rectum and lower part of the colon are examined. This is a short procedure which lasts about 5-10 minutes. Sedation is usually not required and you can usually go home straight after the procedure.” | Response options as above |
| Timing of most recent testing | “How long ago was your most recent X**?” | □ Less than a month ago  
□ One month to less than twelve months ago  
□ Twelve months to less than two years ago  
□ Two years to less than five years ago  
□ Five years or longer ago  
□ Not sure |
| Reason for testing | “Did you have your last X** because you had a symptom?” | □ Yes  
□ No |

*Survey responses did not allow for differentiation between chemical and immunochemical FOBT and different type of sigmoidoscopy, e.g. flexible or rigid. **Inset test type.
**Table 2:** Items and response options (*verbatim*) used to assess respondent’s family history

First-degree relatives

“How many of your close relatives (mother, father, brother, sister or child) have ever been diagnosed with bowel cancer?”

- None
- One
- Two
- Three or more

Second-degree relatives

“Have any of your second-degree relatives (grandparents, uncles, aunts, nephews, nieces or half-siblings) ever been diagnosed with bowel cancer? This includes only biological/blood relatives, not those related to you through marriage. Please select all that apply.”

- None of these relatives has ever been diagnosed with bowel cancer
- Yes, mother’s mother
- Yes, father’s mother
- Yes, mother’s father
- Yes, father’s father
- Yes, mother’s sister
- Yes, father’s sister
- Yes, mother’s brother
- Yes, father’s brother
- Yes, nephew
- Yes, niece
- Yes, grandchild
- Yes, half-sibling (mother’s side)
- Yes, half-sibling (father’s side)

Age at diagnosis (asked separately for both first- and second-degree relatives)

“How many of these relative(s) were diagnosed at the following ages?” (Please write number of relatives diagnosed in each age category)

- 50 or less
- Between 51 and 55
- 56 or over
Don’t know

Other cancers (high-risk feature)

“Has your mother, father, brother, sister, child, grandparent, uncle, aunt, nephew, niece, or half-sibling ever been diagnosed with any of the following cancers: endometrium, ovary, stomach, renal pelvis, ureter, biliary tract or brain?”

□ Yes
□ No
□ Don’t know
Appendix 3.B: Simple logistic regression analysis of study outcomes

Table 1: Simple logistic regression analysis for socio-demographic, lifestyle, clinical and psychosocial characteristics associated with screening outcomes

<table>
<thead>
<tr>
<th>Socio-demographic characteristics</th>
<th>Ever received CRC test</th>
<th>Screening in accordance with guideline (&quot;At or slightly above average risk&quot;)</th>
<th>Screening in accordance with guideline (&quot;Moderately increased risk&quot;/&quot;Potentially high risk&quot;)</th>
<th>Recent colonoscopy screening (irrespective of risk category)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>.73 (.54, .97)</td>
<td>.033</td>
<td>.63 (.18, 2.23)</td>
<td>.89 (.60, 1.31)</td>
</tr>
<tr>
<td>Male</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>56-64</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>65-74</td>
<td>1.86 (1.32, 2.61)</td>
<td>.000</td>
<td>1.02 (.30, 3.44)</td>
<td>1.26 (.82, 1.94)</td>
</tr>
<tr>
<td>75-88</td>
<td>1.12 (.77, 1.63)</td>
<td>.546</td>
<td>.20 (.36, 1.16)</td>
<td>.073</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In relationship</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Not in relationship</td>
<td>.70 (.49, .99)</td>
<td>.050</td>
<td>.26 (.05, 1.39)</td>
<td>.116</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Secondary schooling (not completed)</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Secondary schooling (completed)</td>
<td>1.12 (.73, 1.74)</td>
<td>.606</td>
<td>.44 (.08, 2.46)</td>
<td>.90 (.49, 1.65)</td>
</tr>
<tr>
<td>Trade qualification or TAFE</td>
<td>1.11 (.73, 1.74)</td>
<td>.606</td>
<td>.83 (.15, 4.63)</td>
<td>.86 (.48, 1.55)</td>
</tr>
<tr>
<td>University or other tertiary study</td>
<td>1.54 (.99, 2.39)</td>
<td>.054</td>
<td>1.00 (.19, 5.07)</td>
<td>1.33 (.77, 2.32)</td>
</tr>
<tr>
<td>Other or not applicable</td>
<td>1.09 (.52, 2.34)</td>
<td>.808</td>
<td>.50 (.03, 7.45)</td>
<td>1.12 (.42, 3.00)</td>
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<tr>
<td>Household income before tax ($)</td>
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<tr>
<td>≤ 39,999</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>40,000 – 69,999</td>
<td>1.29 (.87, 1.90)</td>
<td>.199</td>
<td>1.07 (.23, 4.84)</td>
<td>.933</td>
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</table>
1.31 (.88, 1.96)  .175  1.84 (1.17, 2.92)  .009  1.07 (.23, 4.84)  .933  1.05 (.63, 1.74)  .850

Country of birth
- Australian 1  1  1  1
- Other  .56 (.35, .90)  .016  .76 (.41, 1.44)  .409  1.23 (.16, 9.43)  .844  .77 (.39, 1.51)  .448

Retired
- Yes  1.32 (.98, 1.79)  .071  1.15 (.79, 1.70)  .465  .88 (.28, 2.74)  .829  1.10 (.73, 1.65)  .642
- No  1  1  1  1

Private health insurance
- No coverage  1  1  1  1
- Coverage  1.49 (1.07, 2.08)  .018  1.36 (.87, 2.13)  .173  5.91 (1.43, 24.43)  .014  2.23 (1.31, 3.79)  .003

Alcohol
- Drinking days per month  1.01 (1.00, 1.03)  .017  1.02 (1.00, 1.04)  .006  1.00 (.96, 1.05)  .824  .99 (.98, 1.01)  .762

Smoke
- Never  1  1  1  1
- Ever  1.11 (.82, 1.49)  .509  1.12 (.77, 1.62)  .557  3.15 (.98, 10.14)  .054  1.54 (1.04, 2.27)  .032

Clinical characteristics
General practitioner visits per year
- None to twice  1  1  1  1
- 3-6  1.28 (.90, 1.82)  .167  .84 (.54, 1.29)  .418  4.92 (.89, 27.32)  .068  1.96 (1.16, 3.27)  .011
- > 6  1.30 (.83, 2.03)  .249  .76 (.43, 1.34)  .336  3.42 (.52, 22.80)  .202  1.46 (.77, 2.78)  .245

Previous cancer (excluding CRC)
- Yes  1.34 (.93, 1.94)  .117  .95 (.61, 1.48)  .822  1.39 (.30, 6.30)  .670  1.58 (1.02, 2.45)  .041
- No  1  1  1  1

Risk category
- At or slightly above average risk  1  1  1  1
- Moderately increased risk  2.98 (1.22, 7.31)  .016  -  -  4.19 (2.05, 8.57)  .000
- Potentially high risk  3.41 (.99, 11.83)  .053  -  -  6.66 (2.64, 16.79)  .000

Discussion of family history of CRC with doctor
- Never discussed  1  1  1
Discussed and informed of “increased risk”  7.56 (4.32, 13.28)  .000  1.52 (0.92, 2.51)  .098  10.69 (2.74, 41.74)  .001  12.25 (7.66, 19.59)  .000
Discussed and not informed of “increased risk”  4.16 (2.39, 7.23)  .000  2.37 (1.43, 3.92)  .001  9.5 (0.68, 132.00)  .094  3.07 (5.61, 13.42)  .000
Ever received screening advice from doctor
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BMI
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<th>&lt; 18.5</th>
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<td>.47 (.10, 2.18)</td>
<td>.84 (.09, 7.57)</td>
<td>.879 -</td>
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<td>.47 (.10, 2.18)</td>
<td>.84 (.09, 7.57)</td>
<td>.879 -</td>
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Comorbidity
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Psychosocial characteristics
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<tr>
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<th>SF-36 (physical health score)</th>
<th>K-10 (mental health score)</th>
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<tbody>
<tr>
<td></td>
<td>1.01 (.99, 1.03)</td>
<td>.269</td>
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<td>1.02 (.99, 1.04)</td>
<td>.058</td>
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<td>1.01 (.96, 1.07)</td>
<td>.654</td>
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<td></td>
<td>1.01 (.99, 1.03)</td>
<td>.486</td>
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<tr>
<td></td>
<td>Low or no risk (10-15)</td>
<td>Medium to high risk (16 +)</td>
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* p values < .25 included in multiple regression model bold.
PAPER FOUR

A population-based examination of colorectal screening practices of first-degree relatives of colorectal cancer patients
Introduction to Paper Four

Papers Two and Three identified at a community level across varying levels of risk (i) low levels of colorectal cancer (CRC) screening in accordance with guideline recommendations and (ii) several socio-demographic characteristics and provider-level factors associated with adherence to guideline-recommended screening. Paper Two highlighted at a community-level a low level of colorectal cancer (CRC) screening in accordance with screening guidelines across varying levels of risk: “at or slightly above average risk” (21%); “moderately increased risk” (41%); and “potentially high risk” (56%). Family history is a common risk factor for the development of CRC, with approximately 20% of persons who develop CRC having a first-degree relative (i.e. parent, sibling or child) affected by the disease. The risk of developing CRC is at least doubled in first-degree relatives of CRC patients, with the risk three- to six-fold in the presence of a first-degree relative diagnosed under the age of 55 years or where there are multiple CRCs in a relative, or multiple relatives affected. The presence of genetic-based familial syndromes, e.g. Lynch’s Syndrome and Familial Adenomatous Polyposis (FAP), further increases the risk of CRC among first-degree relatives (FDRS). Worldwide, healthcare organisations and other professional societies advocate the need for screening of FDRs of CRC patients. Although recommendations for screening vary slightly across peak bodies, there is consensus that screening should commence at an earlier age for those at increased risk of CRC. While persons with family history of CRC are more likely to participate in CRC screening, the level of compliance in individuals with family history of CRC remains low. Scant research has examined CRC screening participation in this population group, with relatively few studies assessing CRC screening participation in terms of accordance with screening guidelines. In Australia, a single population-based study has previously been undertaken among FDRs of CRC patients, with patients selected through the New South Wales Cancer Registry. This study,
however, examined CRC testing and did not differentiate between testing undertaken for screening and that undertaken for symptomatic purposes, thus preventing extrapolation of accurate screening rates. The present study is the first study of its kind in Australia to evaluate the level of CRC screening compliance among FDRs of CRC patients on a population level.

**Aims and purpose**

This paper identified, among a population-based sample of first-degree relatives of CRC patients and across level of risk, the proportion of first-degree relatives (i) ever receiving any CRC testing and (ii) receiving CRC screening in accordance with guideline recommendations. The socio-demographic and provider-level factors associated with ever receiving CRC testing and CRC screening in accordance with guideline recommendations were also evaluated.

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Manuscript ID: BMJ.2012.003743
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A population-based examination of colorectal screening practices of first-degree relatives of colorectal cancer patients

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2 Department of Colorectal Medicine and Genetics, The Royal Melbourne Hospital, Australia
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4 Hunter Medical Research Institute
5 University of Melbourne
6 Cancer Council Victoria
Abstract

Objectives: To determine the proportions and predictors of first-degree relatives (FDRs) of colorectal cancer (CRC) patients (i) ever receiving any CRC testing and (ii) receiving CRC screening in accordance with CRC screening guidelines.

Design: Colorectal cancer patients and their FDRs were recruited through the population-based Victorian Cancer Registry, Victoria, Australia.

Participants: Seven hundred and seven FDRs completed telephone interviews. Of these, 405 FDRs were deemed asymptomatic and eligible for analysis.

Main outcome: The first-degree relatives’ levels of adherence to screening guidelines across varying categories of risk.

Results: Sixty-nine percent of FDRs had ever received any CRC testing. First-degree relatives of older age, those with private health insurance, siblings and FDRs who had ever been asked about family history of CRC by a doctor were significantly more likely than their counterparts to have ever received CRC testing. Twenty-five percent of FDRs “at or slightly above average risk” were adherent to CRC screening guidelines. For this group, adherence to guideline-recommended screening was significantly more likely to occur for male FDRs and those with a higher level of education. For persons at “moderately increased risk” and “potentially high risk”, 47% and 49% respectively adhered to CRC screening guidelines. For this group, guideline-recommended screening was significantly more likely to occur for FDRs who were living in metropolitan areas, siblings, those married or partnered and those ever asked about family history of CRC.

Conclusions: A significant level of non-compliance with screening guidelines was evident. Improved risk-appropriate screening of FDRs and effective systematic interventions to increase screening rates among population groups experiencing inequality are needed.
Introduction

Worldwide, colorectal cancer (CRC) is diagnosed in over one million persons annually and is the fourth leading cause of cancer death.\(^1\) Staging of disease at diagnosis is a critical factor affecting survival. When discovered early, CRC is highly treatable, with a relative five-year survival rate of 90% for localised CRC.\(^2\) Several randomised controlled trials have demonstrated that CRC mortality can be reduced by 15% to 33% through Faecal Occult Blood Test (FOBT) screening,\(^3\)\(^-\)\(^6\) with fewer advanced CRCs detected, compared with patients presenting with symptoms, in population-based screening.\(^7\) Although the use of colonoscopy to detect right-sided CRCs is under debate,\(^8\)\(^,\)\(^9\) case control and cohort studies of colonoscopy screening suggest a CRC mortality reduction ranging from 60% to 76\(^%\)\(^10\) and incidence reduction of 76% to 90%.\(^11\)

Approximately 15% to 25% of persons who develop CRC will have a first-degree relative (FDR), i.e. a parent, sibling or child, also affected by the disease.\(^12\)\(^,\)\(^13\) Persons with one FDR diagnosed under the age of 55 years or with two FDRs diagnosed at any age have a three- to six-fold increased risk of developing CRC.\(^14\) The relative risk of developing CRC is further increased where a known genetic mutation has been identified.\(^15\) For persons where a known genetic mutation has been identified, both earlier onset of CRC and much higher risk are apparent. Given the increased risk imposed on FDRs of CRC patients, screening for CRC assumes major importance. Screening strategies targeting FDRs of affected cases could contribute to the prevention or early detection of 15% to 20% of CRCs.\(^16\)\(^,\)\(^17\) Healthcare authorities and professional societies have published guidelines for the appropriate screening of FDRs of persons affected with CRC.\(^18\)\(^-\)\(^20\) International approaches to risk classification vary slightly, but all follow the same pattern, with risk level determined by the number and type of relatives diagnosed (i.e. first- or second-degree), the age
at diagnosis and the presence of other high-risk features, i.e. mutation status for cancer-predisposing genes if present in the family.\textsuperscript{18-20} Screening guidelines for persons at higher risk generally recommend additional types of testing (e.g. colonoscopy rather than, or in addition to, FOBT), more frequent testing and commencement of testing at an earlier age, compared with their average risk counterparts.\textsuperscript{18-20} Australian National Health and Medical Research Council (NHMRC) guidelines recommend that asymptomatic persons “at or slightly above average risk” commence screening at the age of 50 years and receive FOBT screening every two years or consider sigmoidoscopy (preferably flexible) every five years.\textsuperscript{18} In Australia, contrary to other international guidelines,\textsuperscript{19,20} colonoscopy screening is endorsed only for asymptomatic persons at higher levels of risk (i.e. “moderately increased risk” or “potentially high risk”). For persons at “moderately increased risk”, colonoscopy is endorsed every five years starting at age 50 years or at ten years earlier than first diagnosis in the family, whichever comes first.\textsuperscript{18} Endoscopy screening for persons at “potentially high risk” is recommended at least on a five-yearly basis in the Australian guidelines. However, age at screening commencement, test type and repeat testing interval are dependent on the type of family-specific mutation identified.\textsuperscript{18}

Despite the elevated risk associated with having a family history of CRC, the little available evidence suggests that adherence to recommended screening for FDRs of CRC patients is low.\textsuperscript{18} While FDRs of CRC patients are more likely to be screened, compared with those without a family history of CRC\textsuperscript{21,23}, screening compliance for this group is sub-optimal, at between 21% and 78%.\textsuperscript{16,21,24-27} Scant literature exists related to screening participation in terms of published screening guidelines and across level of risk.\textsuperscript{28-30} Further, relatively little is known about the factors associated with FDRs of CRC patients’ guideline-recommended screening compliance.\textsuperscript{21} The
aim of this study was to examine among FDRs of persons diagnosed with CRC and at each level of risk (“at or slightly above average risk”, “moderately increased risk” and “potentially high risk”), the proportions (i) ever receiving any CRC testing in their lifetime and (ii) screened in accordance with Australian CRC screening guidelines.

The individual- and provider-level factors associated with FDRs ever receiving CRC testing and guideline-recommended screening were also evaluated.

**Methods**

**Setting and design**

Index cases (i.e. persons diagnosed with CRC) and their FDRs were recruited through the population-based Victorian Cancer Registry (VCR), Victoria, Australia. Human research ethics approval was obtained from The University of Newcastle and The Cancer Council Victoria.

**Procedure**

Index cases (ICs) aged 18 years or older, within 9 months of CRC diagnosis, registered with the VCR and English-speaking were eligible to participate in this study. The VCR checked the Familial Adenomatous Polyposis (FAP) Register to exclude persons with FAP. The VCR wrote to the clinicians of eligible patients to advise them of the study and request consent to approach the index cases. Clinicians were asked to notify the VCR if there was any reason why a person should not be invited to participate in the study. Patients for whom the treating clinicians did now allow consent to patient approach from the VCR were not contacted. The VCR wrote to the remaining patients seeking permission to release their contact details to the research team. Index cases who agreed to provision of their contact details to the researchers were contacted by the research team via mail and asked to participate in
the study. To accommodate index case preferences about the mode of approach to their relative, consenting index cases provided the details of FDRs aged 18 years or older for the purposes of contacting them via either (i) the research team (with their permission) who sent a study invitation by post on their behalf or (ii) a study invitation mailed to the patient who passed this invitation on to the relative(s). Eligibility criteria for FDRs’ participation were (1) English-speaking, aged 18 years or older, and (2) no previous history of advanced adenoma, CRC, ulcerative colitis, Crohn’s disease, inflammatory bowel disease or FAP. First-degree relatives meeting these criteria were eligible to complete the baseline telephone interviews. They were classified as asymptomatic and eligible for CRC screening if they had not undertaken FOBT, sigmoidoscopy or colonoscopy due to a symptom episode in the previous five years. A diagrammatic representation of the recruitment protocol is presented in Figure 3.1.
Figure 3.1: Flowchart representing selection and recruitment of asymptomatic first-degree relatives of colorectal cancer patients
Quantifying risk based on family history of colorectal cancer

Index cases were asked about family history of CRC, including all first- and second-degree relatives and their ages at diagnosis, if relevant. Index cases’ ages at diagnosis were obtained from VCR data. The FDRs of index cases were allocated to a level of risk in accordance with screening guidelines (See Table 5.1).
Table 5.1: Description of risk categories and their respective screening recommendations in accordance with National Health and Medical Research Council colorectal cancer screening guidelines

<table>
<thead>
<tr>
<th>Risk category</th>
<th>Risk features</th>
<th>Screening recommendation</th>
</tr>
</thead>
</table>
| At or slightly above average risk| • No personal history of bowel cancer  
  • Either no close relatives with bowel cancer or one first-degree or second-degree relative with bowel cancer diagnosed at age 55 years or older. | FOBT every second year from the age of 50 years.  
Consider sigmoidoscopy (preferably flexible) every five years. |
| Moderately increased risk        | • One first-degree relative diagnosed before the age of 55 years (without potentially high-risk features listed below), or  
  • Two first-degree relatives or one first- and one second-degree relative(s) on the same side of the family (without potentially high-risk features listed below). | Colonoscopy every five years starting at age 50, or at an age 10 years younger than the age of first diagnosis of CRC in the family, whichever comes first. |
| Potentially high risk            | • Three or more first-degree or a combination of first-degree and second-degree relatives on the same side of the family diagnosed with bowel cancer (suspected HNPCC*), or  
  • Two or more first-degree or second-degree relatives on the same side of the family diagnosed with bowel cancer, including any of the following high-risk features: | Dependent on presence and type of familial cancer.  
At least colonoscopy every 5 years. |
- bowel cancer before the age of 50 years
- multiple bowel cancers in the one person
- at least one relative with cancer of the endometrium, ovary, stomach, small bowel, renal pelvis, ureter, biliary tract or brain
- at least one first-degree relative with a large number of adenomas throughout the large bowel (suspected FAP)**
- somebody in the family in whom the presence of a high-risk mutation in the adenomatous polyposis coli (APC) gene or one of the mismatch repair (MMR) genes has been identified.

*HNPCC: Hereditary non-polyposis colorectal cancer or Lynch’s Syndrome. ** FAP: Familial Adenomatous Polyposis.
Colorectal cancer screening history

FDRs were asked separately whether they had ever undertaken any of the following CRC tests: FOBT/ Faecal Immunochemical Test (FIT); sigmoidoscopy; or colonoscopy. Respondents indicating “Yes” to any of these tests were asked to specify how long ago their most recent test was undertaken and the reason for the test, to establish whether the respondent was asymptomatic at the time of testing.

Eligibility for screening

Asymptomatic FDR respondents “at or slightly above average risk” were eligible for screening if they were aged 50 years or older. For respondents at “moderately increased risk”, in accordance with guidelines, eligibility for CRC screening was determined on the basis of “starting at age 50 years or at an age 10 years younger than the age of first diagnosis of bowel cancer in the family, whichever comes first”. Asymptomatic respondents at “potentially high risk” were eligible for screening if they were aged 18 years or older.

Statistical analysis

The proportions of FDRs ever receiving CRC testing (i.e. FOBT, sigmoidoscopy or colonoscopy) overall and by level of risk (i.e. “at or slightly above average risk”, “moderately increased risk” and “potentially high risk”) were calculated by the number of FDRs reporting receiving any CRC test, divided by the total number of FDRs. The proportion of FDRs screened in accordance with Australian screening guidelines was assessed according to level of risk as follows: “at or slightly above average risk” (FOBT every two years, consider sigmoidoscopy, preferably flexible, every five years); and “moderately increased risk” or “potentially high risk” (colonoscopy every five years). Over-screening was not assessed in this study as information was only obtained on the most recent testing for each test type. Associations between ever-
tested and guideline-recommended screening were explored for the following items: socio-demographic characteristics (i.e. age, gender, education, marital status, Australian born, employment situation, private health insurance); geographical location (Accessibility/Remoteness Index of Australia); relationship to index case (parent, child, sibling); quality of life (Euro-Qol EQ-5D, VAS score); worry about bowel cancer (Worried/Not worried); and ever asked about family history of bowel cancer by doctor/health professional (Yes/No). Logistic regression modelling in a generalised estimation equation framework was used to adjust for multiple FDRs within families. Simple associations were examined first before all covariates were added to a multiple logistic regression model. Variables with \( p \)-value < .10 were retained in the final model. Parents of index cases were excluded from multiple regression models in all analyses due to the small number of parents recruited in the sample.

**Results**

Of the 748 index cases interviewed, 98% had living FDRs. Of the index cases with living FDR(s), 88% gave consent for the research team to send a study invitation to at least one FDR. A total of 2398 study invitations were sent to FDRs, with 707 (30%) FDRs participating in the study. A total of 405 FDRs were deemed asymptomatic and eligible for analysis. The proportions of asymptomatic FDRs recruited per family were as follows: 56% (107) of families had one FDR recruited; 23% (43) had two FDRs recruited; 15% (29) had three FDRs recruited; and 6.3% (12) had more than three FDRs recruited. Table 5.2 describes the characteristics of the asymptomatic study population.
Table 5.2: Characteristics of asymptomatic first-degree relatives of colorectal cancer patients (n = 405)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Risk category</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At or slightly above average risk</td>
<td>166</td>
<td>41</td>
</tr>
<tr>
<td>Moderately increased risk</td>
<td>43</td>
<td>11</td>
</tr>
<tr>
<td>Potentially high risk</td>
<td>195</td>
<td>48</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>165</td>
<td>41</td>
</tr>
<tr>
<td>Female</td>
<td>240</td>
<td>59</td>
</tr>
<tr>
<td><strong>Highest level of education</strong></td>
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<td></td>
</tr>
<tr>
<td>University degree</td>
<td>164</td>
<td>41</td>
</tr>
<tr>
<td>Trade or TAFE Certificate/Diploma</td>
<td>72</td>
<td>18</td>
</tr>
<tr>
<td>Secondary schooling completed</td>
<td>44</td>
<td>11</td>
</tr>
<tr>
<td>Secondary schooling not completed</td>
<td>123</td>
<td>31</td>
</tr>
<tr>
<td><strong>Marital status</strong></td>
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<tr>
<td>Married/partnered</td>
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<td>78</td>
</tr>
<tr>
<td>Not partnered</td>
<td>90</td>
<td>22</td>
</tr>
<tr>
<td><strong>Born in Australia</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>33</td>
<td>8</td>
</tr>
<tr>
<td>Yes</td>
<td>372</td>
<td>92</td>
</tr>
<tr>
<td><strong>Employment situation</strong></td>
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</tr>
<tr>
<td>Full-time</td>
<td>172</td>
<td>42</td>
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<tr>
<td>Part-time</td>
<td>87</td>
<td>21</td>
</tr>
<tr>
<td>Not working</td>
<td>114</td>
<td>28</td>
</tr>
<tr>
<td>Other</td>
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<td>8</td>
</tr>
<tr>
<td><strong>Private health insurance</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>----------------</td>
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<td>Geographical location (ARIA)</td>
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<tr>
<td>Major cities (urban)</td>
<td>211</td>
<td>54</td>
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<tr>
<td>Regional/remote</td>
<td>182</td>
<td>46</td>
</tr>
<tr>
<td>Relationship to index case</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parent*</td>
<td>22</td>
<td>5</td>
</tr>
<tr>
<td>Sibling</td>
<td>212</td>
<td>52</td>
</tr>
<tr>
<td>Child</td>
<td>171</td>
<td>42</td>
</tr>
<tr>
<td>Worry about bowel cancer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not worried</td>
<td>175</td>
<td>43</td>
</tr>
<tr>
<td>Worried</td>
<td>230</td>
<td>57</td>
</tr>
<tr>
<td>Ever asked about family history of bowel cancer by doctor/health professional</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>258</td>
<td>64</td>
</tr>
<tr>
<td>Yes</td>
<td>147</td>
<td>36</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>56.5</td>
<td>13</td>
</tr>
<tr>
<td>Quality of life (EQ-5D VAS score)</td>
<td>80.8</td>
<td>13</td>
</tr>
</tbody>
</table>

*Parents removed from further regression analyses due to small cell size (n = 22).

**Ever received colorectal cancer testing**

Overall, 69% (278/405) of FDRs had ever received any CRC testing (i.e. FOBT, sigmoidoscopy or colonoscopy) in their lifetime. The proportions of FDRs ever undertaking CRC testing within each risk category were as follows: “at or slightly above average risk” (70%, 116/166); “moderately increased risk” (70%, 30/43); and “potentially high risk” (67%, 131/195). No significant differences in CRC testing across risk category were identified ($\chi^2 = 0.3$, $df = 2$, $p = .86$). Multiple logistic
regression analyses (see Table 5.3) revealed that older FDRs, those with private health insurance, siblings of the index case and FDRs who had ever discussed family history of CRC with a doctor were at significantly greater odds of ever receiving CRC testing.

**Table 5.3:** Multiple logistic regression analysis of factors associated with ever receiving colorectal cancer testing

<table>
<thead>
<tr>
<th></th>
<th>N (%)</th>
<th>OR (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Private health insurance</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>201 (71)</td>
<td>2.05 (1.26, 3.33)</td>
<td>0.0039</td>
</tr>
<tr>
<td>No</td>
<td>77 (63)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td><strong>Relationship to index case</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sibling</td>
<td>166 (78)</td>
<td>2.19 (1.32, 3.63)</td>
<td></td>
</tr>
<tr>
<td>Child</td>
<td>92 (54)</td>
<td>1</td>
<td>0.0024</td>
</tr>
<tr>
<td><strong>Ever asked about family history of bowel cancer by doctor/health professional</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>125 (85)</td>
<td>4.78 (2.80, 8.18)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>No</td>
<td>153 (59)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td><strong>Mean (SD)</strong></td>
<td></td>
<td>OR (95% CI)</td>
<td>p value</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>58.8 (11.01)</td>
<td>1.04 (1.02, 1.07)</td>
<td>0.0002</td>
</tr>
<tr>
<td>No</td>
<td>51.3 (15.64)</td>
<td>1</td>
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</tbody>
</table>
Colorectal cancer screening in accordance with guideline recommendations

First-degree relatives “at or slightly above average risk”

Of the 166 FDRs “at or slightly above average risk”, 25% (42/166) were screened in accordance with NHMRC screening guideline recommendation (See Figure 3.2). All respondents screened in accordance with guidelines had undertaken FOBT screening. Thirty percent (50/166) of persons “at or slightly above average risk” had never undertaken any CRC testing in their lifetime. The remaining persons “at or slightly above average risk” (45%, 74/166) had either undertaken FOBT screening outside the recommended guideline timeframe (i.e. every two years) or had undertaken colonoscopy screening, a test type not endorsed in screening guidelines for persons “at or slightly above average risk”. For persons “at or slightly above average risk”, the number of colonoscopies resulting from positive FOBT was not obtainable, although the number of such cases is likely to be small, as 59% (37/63) of respondents “at or slightly above average risk” who had undertaken colonoscopy screening in the previous five years had previously never undertaken guideline-recommended FOBT or sigmoidoscopy testing.

First-degree relatives at “moderately increased risk”

Of the 43 respondents at “moderately increased risk”, 47% (20/43) were screened in accordance with NHMRC screening recommendation (i.e. colonoscopy screening every five years). Thirty percent (13/43) of respondents had never undertaken any CRC testing (see Figure 3.2). Of the remaining 23% (10/43), half (5/10) had undertaken FOBT screening in the previous two years.

First-degree relatives at “potentially high risk”

Of the 195 respondents at “potentially high risk”, 49% (95/195) were screened in accordance with NHMRC screening recommendation (i.e. colonoscopy screening
every five years). Thirty-three percent (64/195) of respondents had never undertaken any CRC testing. The remaining 18% (36/195) of respondents had undertaken CRC screening not in accordance with guideline recommendation (see Figure 3.2). Of these, 61% (22/36) had undertaken FOBT screening in the previous two years.

Figure 3.2: First-degree relatives’ colorectal cancer screening status in accordance with guidelines by level of risk

Factors associated with screening in accordance with guidelines

Multiple logistic regression models for factors associated with screening guidelines across level of risk are presented in Table 5.4. FDRs “at or slightly above average risk” with higher levels of education were significantly more likely to be screened in accordance with guideline recommendations, compared with FDRs with lower levels of education. Further, male FDRs “at or slightly above average risk” were significantly more likely to be screened in accordance with guidelines, compared with female FDRs. Due to the small number of respondents in the “moderately increased risk”
group (n = 43), both “moderately increased risk” and “potentially high risk” groups were combined in the analysis of screening in accordance with screening guidelines. Persons at “moderately increased risk” and “potentially high risk” who were married or partnered, living in a major city or urban area, sibling of the index case and ever asked about family history of CRC by a doctor were significantly more likely to be screened in accordance with guideline recommendations.

Table 5.4: Multiple logistic regression model of factors associated with first-degree relatives’ screening in accordance with guidelines

<table>
<thead>
<tr>
<th>“At or slightly above average risk”</th>
<th>N (%)</th>
<th>OR (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>27 (35)</td>
<td>2.74 (1.32, 5.68)</td>
<td>.0068</td>
</tr>
<tr>
<td>Female</td>
<td>15 (17)</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Highest level of education</th>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Secondary schooling completed</td>
<td>3 (19)</td>
<td>0.34 (0.09, 1.20)</td>
<td>0.0941</td>
</tr>
<tr>
<td>Secondary schooling not completed</td>
<td>10 (18)</td>
<td>0.41 (0.18, 0.91)</td>
<td>0.0288</td>
</tr>
<tr>
<td>Trade or TAFE Certificate/Diploma</td>
<td>4 (14)</td>
<td>0.21 (0.07, 0.65)</td>
<td>0.0070</td>
</tr>
<tr>
<td>University degree</td>
<td>25 (38)</td>
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</table>

<table>
<thead>
<tr>
<th>“Moderately increased risk” and “Potentially high risk”</th>
<th>N (%)</th>
<th>OR (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married/partnered</td>
<td>97 (55)</td>
<td>3.68 (1.72, 7.88)</td>
<td>0.0008</td>
</tr>
<tr>
<td>Not partnered</td>
<td>18 (30)</td>
<td>1</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Geographical location (ARIA)</th>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Major cities (urban)</td>
<td>68 (56)</td>
<td>2.26 (1.27, 4.03)</td>
<td>0.0056</td>
</tr>
<tr>
<td>Regional/remote</td>
<td>41 (39)</td>
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</table>
Relationship to index case

<table>
<thead>
<tr>
<th>Relationship</th>
<th>Count (Percentage)</th>
<th>Odds Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sibling</td>
<td>74 (62)</td>
<td>5.15 (2.28, 11.67)</td>
</tr>
<tr>
<td>Child</td>
<td>29 (30)</td>
<td>1</td>
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</tbody>
</table>

Ever asked about family history of bowel cancer by doctor/health professional

<table>
<thead>
<tr>
<th>Response</th>
<th>Count (Percentage)</th>
<th>Odds Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>65 (71)</td>
<td>5.08 (2.55, 10.11)</td>
</tr>
<tr>
<td>No</td>
<td>50 (34)</td>
<td>1</td>
</tr>
</tbody>
</table>

**Discussion**

Rates of ever receiving CRC testing for FDRs of CRC patients were relatively high in the current study, with approximately 70% of FDRs across each level of risk ever receiving CRC testing. The rate of FDRs ever receiving CRC testing was not found to be significantly higher among population groups at higher relative risk of CRC (i.e. persons at “moderately increased risk” and “potentially high risk”, compared with persons “at or slightly above average risk”). In an Australian context, rates of participation in CRC testing or testing undertaken in adherence to guidelines among FDRs of CRC have previously only been evaluated in one study recruiting index cases through the New South Wales Cancer Registry. That study, however, recruited one FDR per CRC patient, resulting in a relatively small sample size (n = 225), and did not differentiate between CRC testing for screening and diagnostic purposes, thus not allowing estimation of true screening rates.

The current study highlighted low levels of CRC screening in accordance with guideline recommendations across varying levels of risk: “at or slightly above average risk” (25%); “moderately increased risk” (47%); and “potentially high risk”
(49%). International comparisons of risk-appropriate screening in accordance with
guideline recommendations are difficult to ascertain, given that healthcare authorities’
endorsement of screening modality and timing of repeat testing vary across
countries.  Few studies have assessed CRC screening in accordance with
guideline recommendations for persons with an affected FDR with CRC. This
study, to our knowledge, is the first Australian population-based examination of CRC
screening participation among FDRs of CRC patients.

Screening of first-degree relatives “at or slightly above average risk” in
accordance with guidelines

The low rate of screening in accordance with guideline recommendation for FDRs “at
or slightly above average risk” identified in this study is comparable to that of the
general population in Australia. Two separate population-based evaluations
among persons over 50 years of age have indicated that 33% of respondents at
“average risk” had undertaken FOBT screening in the previous five years and
18.4% in the previous two years. The most recent investigation of CRC screening
participation among at-risk persons (i.e. those aged over 55 years) since the National
Bowel Cancer Screening Program’s introduction in 2006 indicated that screening in
accordance with guideline recommendation for persons “at or slightly above average
risk” was 20 per cent. Although community-based studies in the United States (US)
have generally established rates of FOBT screening in accordance with guideline
recommendations among FDRs of CRC patients of between 9% and 42%, the
studies with the highest screening rates had recruited participants through
advertisements. Such samples are unlikely to be representative of FDRs of CRC
patients in general, and are likely to be biased as they include participants more likely
to engage in screening, thus reducing the findings’ relevance for indicating
population-based estimates.
Screening of first-degree relatives at elevated risk ("moderately increased risk" and "potentially high risk") in accordance with guidelines

Current study findings indicated that 47% of FDRs of CRC patients at "moderately increased risk" and 49% of persons at "potentially high risk" were screened in accordance with the Australian guideline recommendation (i.e. colonoscopy screening every five years). This is much higher than the only other Australian data on risk-appropriate CRC testing among FDRs, which had identified three FDRs among 225 who were screened in accordance with Australian guidelines. The rate of screening in accordance with guideline recommendations for FDRs of CRC patients at elevated levels of risk (i.e. "moderately increased risk" and "potentially high risk") in the current study is similar to rates identified in the general population.

The most recent Australian community-based study of CRC screening participation found that among persons over 55 years of age, 45% of those at "moderately increased risk" and "potentially high risk" were screened in accordance with guideline CRC screening recommendation (i.e. colonoscopy screening every five years).

Another population-based investigation among persons aged over 50 years at "above average risk" indicated that 30% had undertaken endoscopy (colonoscopy or sigmoidoscopy) in the previous five years. This study, however, did not investigate colonoscopy screening independently. Rather, it examined endoscopy (i.e. sigmoidoscopy and colonoscopy combined), thus not allowing for the identification of colonoscopy screening in accordance with guideline recommendations. Data available from a US population-based National Health Interview Survey sample of persons 41-75 years of age with a FDR diagnosed with CRC indicated that 28% of FDRs had undertaken colonoscopy screening in the previous ten years. For this study, direct compliance with guideline screening recommendation was not ascertained. Another study recruiting siblings of CRC patients diagnosed younger
than 56 years of age through four cancer centres in the US indicated that 57% of siblings older than 34 years were screened in accordance with guidelines (i.e. they had undertaken both flexible sigmoidoscopy in the past three to five years and FOBT within the past year, or undertaken colonoscopy within the past 10 years). Study findings from an investigation of FDRs of CRC patients participating in a free FOBT screening program indicated that 22% of respondents also met the aforementioned screening guideline. In Canada, the most recent evaluation of CRC screening among FDRs of CRC patients aged over 40 years selected through the Alberta Cancer Registry indicated that 60% were appropriately screened for CRC screening (i.e. FOBT within one year, barium enema or sigmoidoscopy within five years, or colonoscopy within 10 years). In this study, however, the authors used a broad definition of appropriate screening among FDRs of CRC patients, as guideline recommendations for CRC screening of individuals with a first-degree family history of CRC vary across healthcare organisations in North America. In summary, the available evidence suggests that, worldwide, the screening rates of FDRs of CRC patients in accordance with guideline recommendations rarely exceed 50 percent, well short of rates likely to be necessary for reducing CRC incidence and mortality on a population basis.

**Factors associated with colorectal cancer testing and adherence to colorectal cancer screening guidelines**

The present study identified a number of socio-demographic and provider-level factors impacting upon CRC testing and screening in accordance with guideline recommendations. It is well-established that older age is a consistent predictor of CRC screening. The current study identified that the odds of receiving CRC testing increased with increasing age of FDRs. This finding is consistent with previous literature among the FDR population. For persons “at or slightly above
average risk”, adherence to screening guidelines was significantly more likely to occur for male compared with female FDRs. This is contrary to other studies of FDRs that have, on the whole, largely indicated no association between gender and screening behaviour.\(^{23}\) The wider literature on the general population contains mixed findings related to gender and CRC screening behaviour.\(^{41}\ ^{42}\) Therefore, efforts to improve CRC screening among FDRs of CRC patients must target both men and women.

Previous literature has indicated that having medical insurance is significantly correlated with CRC screening adherence.\(^{35}\ ^{42}\ ^{44}\) Consistent with this literature, the current study identified that the likelihood of ever receiving CRC testing was at significantly higher odds for FDRs with private health insurance. This suggests that the costs of medical consultation or screening itself represent significant barriers to CRC screening rates among persons without private health insurance.

The current study also found that siblings compared with children of the index case were at significantly increased likelihood of ever receiving CRC testing and receiving CRC screening in accordance with screening guideline recommendations for persons at “moderately increased risk” and “potentially high risk”. Previous literature has largely analysed either CRC screening among siblings only\(^{28}\ ^{45}\) or FDRs combined and not separated into type of FDRs (i.e. parent, child or sibling).\(^{36}\ ^{40}\ ^{46}\) A previous Australian investigation found that being a sibling of a CRC patient, consistent with current study findings, was significantly associated with increased likelihood of previous participation in CRC testing.\(^{30}\) Further, a multi-centre nation-wide study in Spain identified a higher rate of adherence to colonoscopy screening for siblings and children, compared with parents, when offered screening by a gastroenterologist.\(^{26}\) Current data suggest that screening compliance may be lower among CRC patients’
children who are deemed eligible for screening in accordance with screening guidelines compared to their siblings. There is a pressing need to ensure equality in CRC screening uptake across at-risk FDRs e.g. children, siblings and parents.

This study also found that persons “at or slightly above average risk” with a higher level of education were at significantly increased odds of receiving screening in accordance with guideline recommendations. Previous findings related to CRC testing and educational attainment for persons with a family history of CRC are mixed, with some studies indicating a positive trend\textsuperscript{28} 29 47 and others indicating no association between CRC testing and level of education.\textsuperscript{30} 37 46 For persons at “moderately increased risk” and “potentially high risk”, screening according to guideline recommendations was significantly more likely to occur for FDRs who were married or partnered, compared with those not partnered. For the most part, marital status has been identified as a significant factor influencing screening participation in the general population\textsuperscript{42} 48-50 and among FDRs of CRC patients,\textsuperscript{21} 46 with increased screening compliance commonly found for married and partnered persons.

The role of geographical barriers to CRC screening was also evident in the current study, as screening in accordance with guideline recommendations for persons at “moderately increased risk” and “potentially high risk” was significantly more likely to occur for persons residing in metropolitan areas, compared with regional or remote areas. This finding is plausible, given the high concentration of colonoscopy services in major hospitals in large cities in Australia.\textsuperscript{51} Future attention to equality in access to CRC screening services for those at increased levels of risk (i.e. “moderately increased risk” and “potentially high risk”) is clearly required.
The FDRs of CRC patients in the current study who had ever been asked about their family history of CRC by a doctor were also at significantly higher odds of ever undertaking CRC testing and undertaking testing in accordance with guideline recommendations for persons at “moderately increased risk” and “potentially high risk”). This finding highlights the need for assessment and on-going monitoring of family history of CRC within both the primary and specialist healthcare settings. Although physicians have been found to follow appropriate guideline recommendations for CRC screening once increased risk has been identified, the family history information gathered is often insufficient for risk stratification purposes.\textsuperscript{52-54} The wider incorporation of recently developed cancer risk assessment tools, showing both feasibility and effectiveness in the collection of family history information, automation of familial risk stratification and risk-appropriate screening advice,\textsuperscript{55,56} should be considered in the primary and secondary healthcare systems.

Despite the evidence that physician recommendation to screen has a powerful motivating effect on CRC screening uptake,\textsuperscript{57} FDRs are most often not informed by physicians about the need for CRC screening.\textsuperscript{58} A significantly higher rate of colonoscopy screening can result among those siblings where the index cases were aware of their FDRs’ increased risk.\textsuperscript{27} Improvements in CRC screening among the higher-risk populations (i.e. persons at “moderately increased risk” and “potentially high risk”) rely on physicians’ active involvement in discussions with index cases and their FDRs surrounding their families’ increased risk and need for CRC screening.

**Strengths and limitations of the study**

In interpreting study findings, several limitations should be considered. The response rates among index cases and FDRs were low. Given that people interested in their health are more likely to participate in health research, it is likely that this has
resulted in an over-estimate rather than an under-estimate of the true screening rates. It should be noted that the index case response rate achieved in the current study is comparable to the only other Australian-based investigation of CRC screening among FDRs that had adopted a Cancer Registry based recruitment method.\textsuperscript{30} The low response rates achieved in both Australian studies are due primarily to the multiple-stage consenting process required using Registry-based recruitment (i.e. doctor consent to approach patient, consent for Registry to release contact details of the index case to the research team, and index case consent to research team study invitation). It is possible that the response options for “main reason” for undertaking each CRC test included items which may have been correlated: “my GP recommended it” and “I had symptoms”. Subsequently, this limitation is likely to underestimate the number of persons classified as “asymptomatic”.

Personal history of adenomatous polyps was not investigated in this study, making it difficult to calculate precisely the proportion of persons “at or slightly above average risk” undertaking inappropriate colonoscopy screening (i.e. in the previous five years) not in accordance with guideline recommendation. Nonetheless, the available data are suggestive of significant over-use of colonoscopy, given that a large proportion of persons “at or slightly above average risk” had received recent colonoscopy without any other CRC screening (i.e. FOBT or sigmoidoscopy) beforehand.

Family history and CRC screening behaviour were self-reported, rather than objectively assessed. Nonetheless, studies have indicated that self-reported family history of CRC is moderately accurate.\textsuperscript{59, 60} Further, patients’ self-reported history of CRC testing and physicians’ report have been shown to have reasonable agreement, with high levels of sensitivity and specificity.\textsuperscript{51, 62} The level of risk obtained for FDRs
was allocated on the basis of index case self-reported information about family history, thus allowing only a potential estimate. It was not practical to obtain a full family history from each FDR of CRC patients for this study. The family history risk-algorithm used to allocate FDRs of CRC patients was devised and extensively piloted with an expert advisory group, comprising experts from a leading Familial Cancer Clinic in Australia. It is noteworthy that a high proportion of FDRs were categorised at “potentially high risk”. This proportion is higher than that expected on a population-level and it is important to consider that this categorisation is performed on an “index of suspicion” basis. Subsequently, in accordance with guideline recommendations, such respondents were asked to consult a Familial Cancer Clinic or doctor to discuss tailored screening regimes.

Implications and conclusions

In summary, the current study identified a significant level of under-screening among a high-risk population and a substantial level of inappropriate colonoscopy screening of persons “at or slightly above average risk”, with such screening not endorsed in screening guidelines. There is an urgent need for enhanced physician and patient education about risk-appropriate screening for FDRs of CRC patients, and for descriptive research to identify the barriers to CRC screening among this population group. Effective systematic interventions on a population basis are required to improve CRC screening participation of FDRs of CRC patients.
References


### Appendix 4.A: Simple logistic regression analysis of study outcomes

**Table 1:** Simple logistic regression analysis for characteristics associated with CRC test/screening outcomes

<table>
<thead>
<tr>
<th></th>
<th>Ever received CRC test</th>
<th>Screening in accordance with guideline (&quot;At or slightly above average risk&quot;)</th>
<th>Screening in accordance with guideline (&quot;Moderately increased risk&quot;/&quot;Potentially high risk&quot;)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OR (95% CI)</td>
<td>p-value*</td>
<td>OR (95% CI)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>1.00 (.68, 1.49)</td>
<td>.987</td>
<td>2.58 (1.24, 5.34)</td>
</tr>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At or slightly above average risk</td>
<td>1</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Moderately increased risk</td>
<td>1.02 (.46, 2.24)</td>
<td>.965</td>
<td>-</td>
</tr>
<tr>
<td>Potentially high risk</td>
<td>.85 (.54, 1.35)</td>
<td>.498</td>
<td>-</td>
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<tr>
<td>Highest level of education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>University degree</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Trade or TAFE Certificate/Diploma</td>
<td>.93 (.51, 1.71)</td>
<td>.821</td>
<td>.25 (.08, .80)</td>
</tr>
<tr>
<td>Secondary schooling completed</td>
<td>.41 (.20, .81)</td>
<td>.001</td>
<td>.37 (.10, 1.38)</td>
</tr>
<tr>
<td>Secondary schooling not completed</td>
<td>.82 (.49, 1.37)</td>
<td>.451</td>
<td>.34 (.16, .73)</td>
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<td>Marital status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not partnered</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Married/ partnered</td>
<td>1.55 (.92, 2.60)</td>
<td>.099</td>
<td>.48 (.20, 1.12)</td>
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<tr>
<td>Born in Australia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>No</td>
<td>.70 (.32, 1.52)</td>
<td>.366</td>
<td>2.9 (1.05, 8.00)</td>
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<td>Employment situation</td>
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<tr>
<td>Category</td>
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<td>----------------------------------------------</td>
<td>--------</td>
<td>--------</td>
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<tr>
<td>Full-time</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Part-time</td>
<td>1.52 (.84, 2.74)</td>
<td>.164</td>
<td>.56 (.20, 1.58)</td>
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<tr>
<td>Not working</td>
<td>1.73 (1.02, 2.94)</td>
<td>.042</td>
<td>1.03 (.47, 2.28)</td>
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<tr>
<td>Other</td>
<td>1.38 (.23, 8.29)</td>
<td>.722</td>
<td>.71 (.28, 1.83)</td>
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<td>Private health insurance</td>
<td>No</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Yes</td>
<td>1.46 (.96, 2.21)</td>
<td>.077</td>
<td>1.21 (.51, 2.87)</td>
</tr>
<tr>
<td>Geographical location (ARIA)</td>
<td>Regional/remote</td>
<td>1</td>
<td>1</td>
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<tr>
<td>Major cities (urban)</td>
<td>1.18 (.75, 1.85)</td>
<td>.480</td>
<td>1.33 (.66, 2.67)</td>
</tr>
<tr>
<td>Relationship to index case</td>
<td>Child</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Sibling</td>
<td>3.21 (2.07, 5.00)</td>
<td>.000</td>
<td>.59 (.30, 1.18)</td>
</tr>
<tr>
<td>Worry about bowel cancer</td>
<td>Not worried</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Worried</td>
<td>.67 (.41, 1.09)</td>
<td>.107</td>
<td>.72 (.36, 1.47)</td>
</tr>
<tr>
<td>Ever asked about family history of bowel cancer by doctor/health professional</td>
<td>No</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Yes</td>
<td>3.83 (2.29, 6.41)</td>
<td>.001</td>
<td>1.01 (.49, 2.06)</td>
</tr>
<tr>
<td>Quality of life (EQ-5D VAS score)</td>
<td>1.01 (1.00, 1.03)</td>
<td>.135</td>
<td>1.01 (.98, 1.03)</td>
</tr>
</tbody>
</table>

* p values < .25 included in multiple regression model bold.
PAPER FIVE

The current state of medical-advice-seeking behaviour for primary symptoms of colorectal cancer: Determinants of failure and delay in medical consultation
Introduction to Paper Five

The early detection of cancer is important because of the link between staging of disease and survival outcomes.\(^1\)\(^2\) Earlier diagnosis can arise from either screening or improved recognition of symptomatic cancers.\(^1\) Papers Two, Three and Four identified low levels of colorectal cancer (CRC) screening in accordance with screening guidelines, as well as inequalities in CRC screening participation. The final two papers of this thesis examine responses to symptoms. Paper Five explores the rates of (i) medical consultation and (ii) delay in seeking medical advice for primary symptoms of CRC (i.e. rectal bleeding and change in bowel habit) among an at-risk community-based cohort. In Australia, State-wide Cancer Registry data indicate that an overwhelming majority of CRC patients (90\%) present with symptomatic CRC.\(^3\) While National Bowel Cancer Screening Programs (NBCSPs) in Australia and the UK aim to reduce the incidence of symptomatic CRC, such programs have attracted low levels of screening participation. Approximately 60\% of those invited to screen in the UK and approximately 40\% of persons invited to screen in Australia actually participate in such screening programs.\(^4\)\(^5\) Papers Two and Four also reflected the low participation of the Australian community in CRC screening. In addition, most CRCs are diagnosed in persons aged over 70 years,\(^6\) with a small proportion of the at-risk population in Australia (persons 50, 55 and 65 years of age) offered population-level faecal occult blood test (FOBT) screening. Subsequently, such figures indicate the likelihood that screening will only identify a quarter of total CRC cases.\(^6\) In Australia, with a low proportion of the at-risk population offered FOBT via the NBCSP, it is plausible that the present high proportion of persons diagnosed after symptoms develop will continue in the foreseeable future.

While there are some data about the prevalence of primary symptoms of CRC in the general population, few population-based investigations have been undertaken.\(^7\)\(^9\)
Few community-based studies have assessed delay in seeking medical advice for rectal bleeding,\(^7\)\(^8\) with no studies directly assessing medical-advice-seeking behaviours for changes in bowel habit (i.e. constipation and diarrhoea).

**Aim and purpose**

This study is the first to examine delay in seeking medical advice for change in bowel habit and to explore in unison the reasons for delay and triggers for seeking medical advice for both primary symptoms of CRC in an at-risk population (> 55 years of age) in Australia. The current study also evaluates the reasons for delay in seeking medical advice for rectal bleeding across a wider delay trajectory (from one week upwards), compared with previous studies that have only examined reasons for delay greater than three months.\(^7\)\(^8\) This study is also innovative in its assessment of the current state of medical-advice-seeking behaviour in the community and its direct comparison with a previous community-based data set.\(^8\)

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References


The current state of medical-advice-seeking behaviour for primary symptoms of colorectal cancer: Determinants of failure and delay in medical consultation

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⁴ Hunter Medical Research Institute, New South Wales, Australia
Abstract

Aim: Little data exists on the factors associated with health care seeking behaviour for primary symptoms of colorectal cancer (CRC). This study described the determinants of failure and delay in seeking medical advice for rectal bleeding and change in bowel habit.

Methods: 1592 persons (56-88 years) were randomly selected from the Hunter Community Study (HCS) and mailed a questionnaire.

Results: 18% (60/332) of respondents experiencing rectal bleeding and 20% (39/195) reporting change in bowel habit had never consulted a doctor. Rate of delay (> one month) for each symptom was 18% and 37%. Reasons for delay included assumptions about symptom seriousness and benign nature. Triggers for seeking medical advice varied. Health care seeking behaviour for rectal bleeding had not significantly improved compared to a previous community-based data set.

Conclusion: The seriousness of symptoms, importance of early detection, and prompt medical consultation must be articulated in health messages to at-risk persons.
Introduction

Colorectal cancer (CRC) and primary symptom presentation

Internationally, CRC is diagnosed in over one million persons annually (9.4% of all cancer diagnoses) and ranks as the fourth leading cause of cancer related death. [1] Five-year relative survival rate for early-stage CRC is 90%, compared to less than 10% for distant metastatic CRC. [2] However, approximately 40% of CRCs are diagnosed at a localised stage. [2] Rectal bleeding and change in bowel habit are common symptoms experienced in the general population. [3, 4] It is estimated that 37-84% of all CRCs present with rectal bleeding, [5-7] while change in bowel habit presents in approximately 48-77% of CRCs. [5-7] The majority of CRC cases present symptomatically to primary care, while 20-40% of cases present to emergency. [8-11]

Current debate: Symptom duration and staging of disease

It is axiomatic that, for an individual patient, the earlier the presentation and diagnosis, the greater likelihood that a tumour will be detected at an early curable stage. [12] There is however, a paradoxical relationship between symptom duration, earlier diagnosis and survival, which continues to be debated in the literature. [13-16] Some studies suggest symptom duration of 3 months or more are less likely to have early-stage tumours, [17-19] while other studies have indicated no relationship between symptom duration, pathological stage at diagnosis and survival. [15, 20, 21] This would suggest that the public health message should be to engage in screening for CRC, before symptoms develop. However, it would be unwise to diminish the importance of prompt medical advice for CRC symptoms, particularly given the high rate of symptomatic presentation (approximately 80% of CRC cases) and the present low rate of asymptomatic presentation. [22, 23] Studies examining emergency admissions have indicated a median symptom duration of 3 months prior to admission, without patients necessarily presenting at any earlier point to primary...
A lack of knowledge about current symptom presentation

Our knowledge of medical advice seeking behaviour for rectal bleeding is limited to a few population and community based evaluations. [4, 29, 30] Australian community-based studies [29, 30] have indicated that a third of persons following their first symptom episode of rectal bleeding will either delay longer than three months or fail to seek medical advice, potentially due to perceptions that the condition is not serious [3, 29-31] or a lack of pain or discomfort. [3, 31] For change in bowel habit (constipation or diarrhoea), little is known about medical advice seeking behaviour, with studies generally examining overall medical consultation rates [32-34] rather than time taken to seek medical advice. The present study is novel in its assessment of the current state of medical advice seeking behaviour within an at-risk community (56-88 years of age) and its exploration of not just the reasons of delay but also factors associated with earlier presentation times for both primary symptoms of CRC. The aims of the study were to identify for each primary symptom of CRC: (i) the proportion ever experiencing a symptom in their lifetime, and (ii) non-consultation rate - the proportion failing to ever seek medical advice and reason for non-consultation. For those who sought medical advice for their first symptom episode in the previous five years: (iii) the time taken to seek medical advice, the reason for delay and perceived triggers for seeking medical advice were identified. Results for the time taken to seek medical advice and non-consultation rate for rectal bleeding were compared to a previous study data set in a similar geographic area to assess whether medical advice-seeking behaviour had changed over time.
Methods

Design and sample descriptions

**Hunter Community Study (HCS)**

A cross-sectional sample of community dwelling men and women aged 56-88 years in the Hunter Region of New South Wales (NSW), Australia, were extracted from the Hunter Community Study (HCS) cohort. [35] The HCS sample is a longitudinal cohort of community dwelling men and women aged 55-85 years at cohort baseline from the Hunter Region, NSW, Australia. [35] Participants were randomly selected from the NSW State electoral roll between December 2004 and 2007. The HCS cohort provides a population profile reflecting that of the Hunter Region, state and national Australian profiles for gender and marital status but is slightly younger in age. [35]

**Comparative study**

The comparative study [30] was a cross-sectional survey of NSW men and women aged over 40 years of age conducted between June and August, 2000. This study used a computer assisted telephone interview (CATI) method of data collection with free-recall provision. Participants were randomly selected from the NSW telephone directory. Compared with NSW census data, this sample was representative for age and marital status, with females slightly over-represented. [30]

**Exclusion criteria**

Persons previously identified on the HCS databank as diagnosed with CRC or self-reporting undergoing major abdominal surgery were excluded from analysis.

**Procedure**

A randomly selected sub-sample of HCS participants (n=1592) were mailed an information statement and a pen and paper questionnaire in November, 2009. A
reminder telephone call was made to non-responders at 4-6 weeks following initial mail out.

**Questionnaire**

**Symptom episode**

The pen and paper questionnaire asked whether participants had “ever noticed blood in bowel motions, in the toilet bowl or on the toilet paper?” or “a persistent change in your normal bowel habits that lasted longer than two weeks? This may include looser bowel motions/ needing to go to the toilet more than usual (diarrhoea) or an inability to pass bowel motions (constipation)”. These items were used to determine the proportion of respondents ever experiencing either symptom episode and are referred to hereafter as [Symptom X]. The item concerning rectal bleeding had been used in two previous Australian studies [29, 30] while the change in bowel habit item was devised for this study.

**Non-consultation rate**

For both symptoms, respondents indicating ‘yes’ to ever experiencing a symptom were asked “have you ever seen a doctor about: [Symptom X]? These items were used to identify the proportion experiencing either symptom who had never consulted a doctor. Respondents ever experiencing each symptom and never having sought medical advice were asked: “What is the main reason you did not seek medical advice about [Symptom X]? Please circle only one response.”

**Time taken to seek medical advice: Reason for delay and triggers for seeking medical advice**

Respondents indicating they had ever sought medical advice were asked “did you first notice [Symptom X] in the last five years?” and “Did you see a doctor about it?” To reduce recall bias only those experiencing their first symptom episode in the last five years and consulting a doctor were included in the analyses of time taken to
seek medical advice, reason for delay and triggers for seeking medical advice. Such respondents were asked to specify the time taken to seek medical advice: “How long after you first noticed [Symptom X] did you see a doctor about it? Please specify the amount of time.”; reason for delay: “What is the main reason you did not seek medical advice about [Symptom X] sooner? Please circle only one response”; and trigger(s) for seeking medical advice: “What in particular prompted you to consult a doctor about [Symptom X]? Please circle all that apply.” Closed response options were provided relating to reasons for delay/failure to seek medical advice and triggers for seeking medical advice with an “Other (Please specify)” option included. The questions asked were identical to those asked in the comparative study [30] except for triggers to seeking medical advice which was not assessed in the former study.

**Comparison between data sets**

Cross-study comparisons are an insightful mechanism to track improvement in health outcomes overtime. Such a technique has been successfully adopted in previous studies assessing health behaviour change. [36] Comparisons between the existing survey and the comparative study data (a similar population group) were made to identify whether medical advice-seeking behaviour for rectal bleeding had improved. The comparative study data set contained participants aged 40 years and over. The data were re-analysed for respondents aged 55 years or older to provide a comparable data set on the following outcomes: proportion ever experiencing rectal bleeding, non-consultation rate, and the time taken to seek medical advice.

**Statistical analysis**

Proportion of respondents ever experiencing each symptom episode (Yes/No) and ever consulting a doctor about each symptom episode (Yes/No) were assessed.
Frequency distribution was used to examine: the time taken to seek medical advice (95% confidence interval reported), reason for delay, reason for failure to consult a doctor, and triggers for seeking medical advice. A shorter cut-point (> one month) was adopted in this study to constitute “delay” compared to previous studies [29, 30] that have adopted a cut-point > 3 months. This tighter cut-point was used to assess reasons for delay across a wider trajectory with consideration that any “delay” in this studied cohort is of critical importance given that the entire cohort is at increased-risk of developing CRC (> 55 years of age). It should be acknowledged that delay cut-points used within previous studies [29, 30] are arbitrary with no empirical evidence suggesting any critical “delay” cut-point. Pearson chi-square tests were used to detect any significant differences across data sets for the non-consultation rate and time taken to seek medical advice for rectal bleeding. Data were analysed using STATA 11 (STATA, Texas, USA).

**Ethics approval**

The University of Newcastle in partnership with the Hunter New England Population Health Human Research Ethics Committee granted ethical approval (H-820-0504).

**Results**

**Characteristics of the sample**

Of the 1592 mailed surveys, 1117 completed and returned (consent rate, 70%). Respondents previously diagnosed with colorectal carcinoma (n = 24), as listed on the HCS databank, or reporting they had undergone major abdominal surgery (n = 8), were excluded from analysis, leaving a total sample of 1085 eligible participants for analysis. For those persons (n = 475) not participating in the study:, 19% (90/475) indicated an intention of returning survey with no subsequent return, 13% (63/475) refused to participate, 7% (33/475) were too ill, 2% (8/475) were deceased, and for
59% (281/475) a reason for non-participation was not given. Demographic characteristics of the sample are presented in Table 6.1.

Table 6.1: Demographic characteristics of study respondents (n = 1085)

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>508</td>
<td>47</td>
</tr>
<tr>
<td>Female</td>
<td>577</td>
<td>53</td>
</tr>
<tr>
<td><strong>Age (years)</strong></td>
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<td>65-74</td>
<td>382</td>
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<td>237</td>
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<td>Australia</td>
<td>885</td>
<td>89</td>
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<td>Other</td>
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<tr>
<td><strong>Marital status</strong></td>
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<tr>
<td>In relationship</td>
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<td>77</td>
</tr>
<tr>
<td>Not in relationship</td>
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<td>23</td>
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<td><strong>Highest level of education</strong></td>
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<td></td>
</tr>
<tr>
<td>Secondary schooling (not completed)</td>
<td>229</td>
<td>22</td>
</tr>
<tr>
<td>Secondary schooling (completed)</td>
<td>241</td>
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<td>Trade qualification or TAFE</td>
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<td>25</td>
</tr>
<tr>
<td>University or other tertiary study</td>
<td>256</td>
<td>25</td>
</tr>
<tr>
<td>Other or not applicable</td>
<td>53</td>
<td>5</td>
</tr>
</tbody>
</table>

*Percentage of responses (excluding any missing values).

Proportion ever experiencing a primary symptom of colorectal cancer

Of the 1075 respondents to the rectal bleeding question, 332 (31%) reported ever experiencing this symptom. For change in bowel habit, 1049 respondents answered this question, with 195 (19%) reporting ever experiencing this symptom. Overall, 609 (59%) respondents had never experienced either symptom, 235 (23%) rectal bleeding only, 101 (9.7%) change in bowel habit only and 94 (9.1%) had ever experienced both symptoms. Pearson’s $\chi^2$ test found that the proportion of
respondents experiencing rectal bleeding in the HCS cohort (31%) was significantly higher than that found in the comparative study sub-sample ($\chi^2 = 16; \text{df} = 1; p < .001$).

**Non-consultation rate**

For respondents ever experiencing rectal bleeding or change in bowel habit, 60 (18%) and 39 (20%) respectively had never consulted a doctor in their lifetime. Pearson’s $\chi^2$ test found that the rate of non-consultation for rectal bleeding in the comparative study (19/85, 22%) was not significantly different from the HCS cohort ($\chi^2 = .8; \text{df} = 1; p < .369$).

**Reason for never seeking medical advice following primary symptom episode**

Reasons for failure to ever seek medical advice for rectal bleeding or change in bowel habit are listed in Table 6.2. The most common reason for non-medical consultation for rectal bleeding was a perception that the symptom was from a benign cause (“Thought it was haemorrhoids/piles”, 66%). For change in bowel habit, reasons were mixed, including an under-estimation of the seriousness of the symptom (“Thought it wasn’t serious”, 37%) and an attitude towards wait for the symptom to subside (“Decided to wait and see”, 23% and “Cleared up itself”, 23%).
Table 6.2: Respondents’ reasons for never seeking medical advice following primary symptom episode

<table>
<thead>
<tr>
<th>Response options (verbatim)</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rectal bleeding (n=60)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thought it was haemorrhoids/piles</td>
<td>38</td>
<td>66</td>
</tr>
<tr>
<td>Cleared up itself</td>
<td>9</td>
<td>15</td>
</tr>
<tr>
<td>Thought it wasn’t serious</td>
<td>8</td>
<td>14</td>
</tr>
<tr>
<td>Decided to wait and see</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Didn’t want to worry family or friends</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Change in bowel habit (n = 39)**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thought it wasn’t serious</td>
<td>13</td>
<td>37</td>
</tr>
<tr>
<td>Cleared up itself</td>
<td>8</td>
<td>23</td>
</tr>
<tr>
<td>Decided to wait and see</td>
<td>8</td>
<td>23</td>
</tr>
<tr>
<td>Thought it was haemorrhoids/piles</td>
<td>4</td>
<td>11</td>
</tr>
<tr>
<td>Thought doctor couldn’t do anything</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Put it out of my mind; chose not to think about symptom</td>
<td>1</td>
<td>3</td>
</tr>
</tbody>
</table>

*2 missing values; **4 missing values.

Delay in seeking medical advice

For those ever experiencing rectal bleeding and change in bowel habit, 101 (30%) and 72 (37%) respondents reported consulting a doctor and experiencing their first symptom episode in the previous five years. For rectal bleeding (Figure 4.1) and change in bowel habit (Figure 4.2), 18% and 37% of respondents respectively delayed greater than one month before seeking medical advice. Comparison between data sets indicated a greater proportion of respondents in the comparative study sought medical advice within one week (71% versus 53%) and lesser proportion delayed between one to four weeks (17% versus 29%) and greater than one month (12% versus 18%) in the comparative study. Such differences across data sets using Pearson’s $\chi^2$ test were not found to be statistically significant ($\chi^2 = 5; df = 2; p = .072$).
One missing value; proportions and 95% Confidence Interval displayed.

N.B. Participants circling response option (e.g. days, weeks, months or years) and not specifying exact time taken to seek medical advice were allocated to the following categories: Days circled placed in “one week” category, weeks circled placed in “> one week or ≤ one month” category, months circled placed in “> one month” category, years circled placed in “> one year” category.

Figure 4.1: Rectal bleeding: Time taken to seek medical advice following first symptom episode in previous five years
Four missing values; proportions and 95 % Confidence Interval displayed.

N.B. Participants circling response option (e.g. days, weeks, months or years) and not specifying exact time taken to seek medical advice were allocated to the following categories: Days circled placed in “one week” category, weeks circled placed in “> one week or ≤ one month” category, months circled placed in “> one month” category, years circled placed in “> one year” category.

Figure 4.2: Change in bowel habit: Time taken to seek medical advice following first symptom episode in last five years

Reason for delay in seeking medical advice

For rectal bleeding (see Table 6.3), the predominant reason for delay (76%) was the perception of a benign cause (“Thought it was haemorrhoids/piles”). For change in bowel habit (see Table 6.3), more than half of respondents either indicated that they wanted to wait before seeking treatment (“Decided to wait and see”, 32%) or that they thought the symptom was not serious (“Thought it wasn’t serious”, 24%).
Table 6.3: Respondents' reasons for delay (> one week) in seeking medical advice following the first primary symptom episode in the previous five years

<table>
<thead>
<tr>
<th>Response options (verbatim)</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rectal bleeding (n = 47)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thought it was haemorrhoids/piles</td>
<td>32</td>
<td>76.2</td>
</tr>
<tr>
<td>Difficulty making an appointment</td>
<td>3</td>
<td>7.1</td>
</tr>
<tr>
<td>Cleared up itself</td>
<td>2</td>
<td>4.8</td>
</tr>
<tr>
<td>Thought it wasn't serious</td>
<td>1</td>
<td>2.4</td>
</tr>
<tr>
<td>Decided to wait and see</td>
<td>1</td>
<td>2.4</td>
</tr>
<tr>
<td>Worried or scared it might be serious</td>
<td>1</td>
<td>2.4</td>
</tr>
<tr>
<td>Not confident in discussing symptoms/doctor hard to talk to</td>
<td>1</td>
<td>2.4</td>
</tr>
<tr>
<td>No time/busy/other things to think about</td>
<td>1</td>
<td>2.4</td>
</tr>
<tr>
<td><strong>Change in bowel habit (n=49)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decided to wait and see</td>
<td>13</td>
<td>31.7</td>
</tr>
<tr>
<td>Thought it wasn't serious</td>
<td>10</td>
<td>24.4</td>
</tr>
<tr>
<td>Other</td>
<td>7</td>
<td>17.0</td>
</tr>
<tr>
<td>Thought it was haemorrhoids/piles</td>
<td>5</td>
<td>12.2</td>
</tr>
<tr>
<td>Difficulty making an appointment</td>
<td>3</td>
<td>7.3</td>
</tr>
<tr>
<td>Seeing a doctor would be unpleasant/embarrassing</td>
<td>1</td>
<td>2.4</td>
</tr>
<tr>
<td>Worried or scared it might be serious</td>
<td>1</td>
<td>2.4</td>
</tr>
<tr>
<td>No time/busy/other things to think about</td>
<td>1</td>
<td>2.4</td>
</tr>
</tbody>
</table>

*5 missing values; **8 missing values.

**Triggers for seeking medical advice**

Triggers for rectal bleeding included: “Thought the symptom was serious” (27%); “Symptom didn’t go away” (15%); “Opportunity to talk during doctor visit for other reason” (14%); “Family history of cancer” (9%); “Partner or family member suggested it” (8%). For change in bowel habit, the most common reported trigger was the persistence and duration of symptom episode: “Symptom didn't go away” (40%), followed by “Thought the symptom was serious” (13%), and “Opportunity to talk during doctor visit for other reason” (9%).
Discussion

Both rectal bleeding and change in bowel habit are common symptoms experienced in the community, with 31% and 23% of respondents respectively ever reporting a symptom episode. Across both symptoms approximately one in five persons ever experiencing a primary symptom episode had never sought medical advice. For those consulting a doctor following their first symptom episode in the previous five years, a sizeable minority - 18% for rectal bleeding and 37% for change in bowel habit - delayed greater than one month. For both symptoms, the reason for delay in seeking medical advice was consistent with a tendency to underestimate the potential serious nature of symptom episode. Accordingly, the triggers for seeking medical advice for both symptoms related to perceived seriousness and persistence of the symptom. Comparison with data from an earlier comparative study [30] suggest that no significant change had occurred in either the rate of medical consultation or time taken to seek medical advice for rectal bleeding in the community.

Comparison with other studies

The higher reported rate of rectal bleeding experienced in the current study compared to previous studies is likely due to the older age demographic under investigation compared to previous studies. Study findings indicate that approximately one in five persons will experience at least one primary symptom episode without ever seeking medical advice. The direct comparison of the rate of non-consultation with a previous data set in the current study and figures from other Australian community-based studies [29, 30] suggest little improvement in two decades. Data from the United States [4] and England [37] suggest similar rates of poor consultation. Respectively 18% of respondents experiencing rectal bleeding and 37% change in bowel habit for their first time in the previous five years delayed
longer than one month before seeking medical advice. If the time elapsed to consult a doctor is averaged across both symptoms and extrapolated to the community setting, over one in four persons will delay greater than one month. Unfortunately, similar to the rate of medical consultation, the figures relating to timely access to medical advice for rectal bleeding in Australia has improved little if at all [29, 30]. Studies outside of Australian communities are scant. A very small (n=30) study from England indicated a median delay of two months in seeking medical practitioner advice. [3]

The current study, to our knowledge is the first to evaluate time taken to seek medical advice for change in bowel habit (constipation/ diarrhoea). Reason given for delay and not seeking medical advice following rectal bleeding episode appear to be similar to the underestimation of symptom seriousness elucidated previously in the literature. [3, 29-31] In the current study, underestimation of symptom seriousness with a benign perception – “Thought it was haemorrhoids/ Piles” was often cited. The decision to consult was due to a perception of the symptom’s serious nature. For change in bowel habit, the reason for delay/ failure to seek medical advice for a large proportion was consistent with a tendency to underestimate the serious nature of the symptom. For a significant proportion of respondents the decision to consult was due to the persistence of the symptom.

Limitations and strengths of study

The present study is the first to assess both the reason for delay and triggers for seeking medical advice for primary symptoms of CRC in an at-risk community sample (56-88 years of age). This study importantly provides an across-time comparison of medical advice seeking behaviour for rectal bleeding. A large sample size was obtained with a response rate (70%) comparable to previous community-
based studies. [4, 29, 30] It should be acknowledged that sample representativeness and methodological differences between the present and comparative study place some limitations on the interpretation of findings. While the delay data suggests a trend towards no change or negligible improvement in prompt reporting of rectal bleeding, two truly representative samples and identical methodology may have provided a more accurate depiction. It must be noted that the method of investigation of non-consultation differed slightly across the current and comparative study [30] for rectal bleeding. Non-consultation was only assessed in those experiencing their first symptom episode in the previous five years in the comparative study compared to assessment of all respondents that had ever experienced rectal bleeding (irrespective of symptom onset) in the current study. Further, data obtained was self-reported and may be subject to recall error. This limitation however is inherent to studies throughout the wider literature that have assessed retrospective recall of symptoms. In the interpretation of study findings it is important to consider whether persons in the current study who may have had only one symptom would behave in a similar way to symptomatic CRC patients, who sometimes present with symptom complexes. [38] Given the importance of symptom persistence and severity as triggers for action, the experience of a symptom complex may reduce rates of delay or rates of non-consultation. The influence of symptom complexes on patient delay in both groups requires future consideration.

Conclusions and implications

While the likely impact of specific delay times on disease outcomes cannot be estimated, the data suggest that a sizeable proportion of those at-risk (55 years +) do not promptly seek medical advice for CRC symptoms. Currently a general lack of awareness of CRC symptoms and understanding of the importance of CRCs early detection is present in communities. [30, 39, 40] One of the challenges for those
charged with public education surrounding cancer is the need to provide consistent
and concrete recommendations regarding what may constitute ‘prompt’ advice
seeking. [41] It is also crucial that future public education messages highlight the
potential seriousness of CRC symptoms and the need for prompt medical
consultation among the at-risk population. An additional approach to encourage
earlier detection of symptoms is intervention within the primary care setting, given
that 88% of persons present to a GP annually. [42] Currently the acceptability and
feasibility of systematic assessment of ovarian symptoms during GP practice visits is
being assessed in the general practice setting. [43] A similar approach for CRC
symptoms might improve symptom reporting and may be cost-effective if an efficient
mechanism is used. Systematic use of Computer Risk Assessment Tools (CRATs)
that screen for symptomatic patients and provide real-time feedback to GPs is one
such mechanism.
References


Factors associated with consultation behaviour for primary symptoms that potentially indicate colorectal cancer: A cross-sectional study on response to symptoms
Introduction to Paper Six

Paper Five indicated that among an at-risk community sample there were high rates of non-consultation and delay in seeking medical advice for primary symptoms of colorectal cancer (CRC) (i.e. rectal bleeding and change in bowel habit). Approximately one in five persons ever experiencing either symptom had never consulted a doctor regarding that symptom. For persons experiencing their first symptom in the previous five years and consulting a doctor, approximately a quarter of persons across each symptom delayed (> one month) before consulting a doctor. Direct comparison with a previous community data set indicated negligible improvements in the time taken to seek medical advice for rectal bleeding. The final paper of this dissertation examines the factors associated with medical consultation for rectal bleeding and change in bowel habit. At present, scant literature exists on the socio-demographic and provider-level factors associated with prompt/early presentation of potential symptom indicators of CRC. While previous studies have examined the factors associated with delay (> 3 months)\textsuperscript{1,2} in seeking medical advice for rectal bleeding, relatively little is known about the factors associated with early presentation for this symptom. For change in bowel habit, a largely neglected symptom in the literature, studies have more generally examined factors associated with medical consultation, rather than the time taken to seek medical advice.\textsuperscript{3} The prospective longitudinal design of the current study allows for investigation of the socio-demographic, lifestyle, clinical and psychosocial characteristics associated with medical-advice-seeking behaviour for primary symptoms potentially indicating CRC. Identification of population sub-groups or individual characteristics associated with earlier medical consultation is important in shaping future public health messages aimed at encouraging prompt medical advice seeking in the at-risk community.
Aims and purpose

This paper examined, among an at-risk (i.e. aged 56-88 years) prospective longitudinal cohort of community dwelling persons, for each primary symptom of CRC (i.e. rectal bleeding and change in bowel habit), the socio-demographic, provider and psychosocial factors associated with (i) ever seeking medical advice and (ii) prompt medical advice seeking for rectal bleeding (< 2 weeks) and change in bowel habit (< 4 weeks).

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References


Factors associated with consultation behaviour for primary symptoms that potentially indicate colorectal cancer: A cross-sectional study on response to symptoms

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² Hunter Medical Research Institute, New South Wales, Australia
³ Department of Colorectal Medicine and Genetics, The Royal Melbourne Hospital, Victoria, Australia
⁴ Centre for Clinical Epidemiology and Biostatistics, Faculty of Health, University of Newcastle, New South Wales, Australia
Abstract

Background: Little data exists on the factors associated with health care seeking behaviour for primary symptoms of colorectal cancer (CRC). This study aimed to identify individual, provider and psychosocial factors associated with (i) ever seeking medical advice and (ii) seeking early medical advice for primary symptoms of colorectal cancer (CRC).

Methods: 1592 persons aged 56-88 years randomly selected from the Hunter Community Study (HCS) were sent a questionnaire.

Results: Males and those who had received screening advice from a doctor were at significantly higher odds of ever seeking medical advice for rectal bleeding. Persons who had private health coverage, consulted a doctor because the ‘symptom was serious’, or who did not wait to consult a doctor for another reason were at significantly higher odds of seeking early medical advice (< 2 weeks). For change in bowel habit, persons with lower income, within the healthy weight range, or who had discussed their family history of CRC irrespective of whether informed of ‘increased risk’ were at significantly higher odds of ever seeking medical advice. Persons frequenting their GP less often and seeing their doctor because the symptom persisted were at significantly higher odds of seeking early medical advice (< 2 weeks).

Conclusions: The seriousness of symptoms, importance of early detection, and prompt consultation must be articulated in health messages to at-risk persons. This study identified modifiable factors, both individual and provider-related to consultation behaviour. Effective health promotion efforts must heed these factors and target sub-groups less likely to seek early medical advice.
Background

Colorectal cancer: The burden of illness
Internationally, CRC is diagnosed in over one million persons annually (9.4% of all cancer diagnoses) and ranks as the fourth leading cause of cancer related death.\(^1\) On average, 50% of CRC cases are living five years following diagnosis.\(^2\)-\(^4\) Survival rates for CRC are inversely related to stage at diagnosis with early staged-localised CRC 5-year survival rate at 90% compared to approximately 10% for distant metastatic CRC.\(^5\) The rate of early detection is relatively low with approximately 40% of CRC patients diagnosed at a localised stage.\(^5\)

Primary symptoms and clinical presentation of colorectal cancer
Rectal bleeding and change in bowel habit are common potential symptoms of CRC experienced in the population.\(^6\)-\(^9\) Past studies have estimated 37-84% of all CRCs present with rectal bleeding.\(^10\)-\(^12\) Change in bowel habit, broadly termed as diarrhoea or constipation, generally refers to a change in frequency of defecation, consistency of stool, shape of stool or difficulty in evacuation.\(^13\) Change in bowel habit is the symptom most associated with patient delay in presentation\(^14\) and presents in approximately 48-77% of CRCs, with increased frequency of defecation/diarrhoea accounting for the largest proportion of cases.\(^10\)-\(^12\)

The paradoxical relationship between symptom duration and earlier diagnosis
The paradoxical relationship between symptom duration, CRC staging and survival continues to be debated in the literature.\(^10,\,15-17\) Intuitively, a reduction in diagnostic and therapeutic delay should be accompanied by an improved survival rate.\(^17\) This has been supported for breast cancer, with delays of 3-6 months associated with poorer survival,\(^18\) however, for CRC, it is axiomatic that reduced diagnostic and treatment delay will be accompanied by earlier-stage detection and improved
Several studies have indicated that symptom duration is unrelated to pathological stage at diagnosis. A potential explanation for this paradoxical finding may be the limited potential benefit of early detection and treatment for those persons with particularly aggressive tumour biology. Conversely, other studies have indicated that patients with symptom duration equal to or greater than 3 months are less likely to have Stage 1 tumours. Although inconclusive, other studies have indicated an inverse relationship, whereby a shorter symptom duration period is associated with poorer staging and survival.

It is important however that the necessity of prompt medical advice seeking is not forgotten especially given that only a minority of CRC cases are detected asymptptomatically through screening, between 5-20% of all cases. While the pattern of presentation is slowly changing towards more CRCs being identified through screening, for the foreseeable future, the high rate of symptomatic presentation to the health care system is likely to continue. Most commonly the first step towards diagnosis is via symptomatic presentation to primary care with approximately a quarter of symptomatic cases presenting as an emergency, usually with bowel obstruction. Studies examining emergency presentation to hospital departments have indicated a median symptom duration of three months prior to admission, without patients necessarily presenting at any earlier point to primary care. For cases presenting to emergency, the mortality rate and five year-survival rate is poor, likely because of the serious state of illness across multiple organ systems that patients develop after obstruction occurs. A recent UK National Health Service review of the “Two Weeks” program indicated that reduction in delay can have the important patient outcome of minimising complications, e.g. bowel obstruction, which may have an effect on survival. Ideally, a large public health gain may be achieved for the late-presenting patient group if medical
intervention occurs at an earlier stage and the proportion of emergency admitted cases is decreased.40

Bridging the evidence-practice gap
Our understanding of the factors associated with medical advice seeking behaviour for primary symptoms potentially indicating CRC is largely restricted to a few community and population-based studies, predominantly focusing on rectal bleeding. An Australian community-based study indicated that divorced, separated or retired persons were more likely to ever consult a doctor for rectal bleeding.6 Other international studies have identified that the following predict ever seeking care for CRC symptoms in the community setting: older age (>45 years), being a non-smoker, being employed, having constipation rather than diarrhoea, and symptom specific characteristics such as greater concern, severity, and frequency of symptoms.41, 42 In relation to early medical advice seeking, the literature has largely focused on those delaying greater than three months.6, 43 Previous research suggests that adults experiencing rectal bleeding delay or fail to consult a doctor due to a perception that the condition is not serious.6, 7, 43 Identified triggers for seeking medical advice for rectal bleeding include: greater perceived seriousness, persistence and/or nuisance of the symptom, pain or discomfort, opportunity during an existing consultation to discuss the symptom, and pressure from a relative.44, 45 Previous literature relating to CRC patients health care seeking behaviour have also highlighted other key factors associated with patient delay including: patient appraisal, recognition and knowledge of symptoms, symptom characteristics, and emotional response to symptoms.46-50

Little is known about medical advice seeking for change in bowel habit, which is limited to a handful of studies more generally examining medical consultation rather
than time taken to seek medical advice.\textsuperscript{41, 51, 52} The current study seeks to identify the factors associated with medical advice seeking behaviour for primary symptoms of CRC. Identification of population or individual characteristics associated with earlier medical consultation is important in shaping future public-health messages aimed at encouraging prompt medical advice seeking in the at-risk community. Therefore, this study retrospectively examined socio-demographic, provider and psychosocial factors associated with the following practices among an at-risk (56-88 years of age) cohort of community dwelling persons: (i) ever seeking medical advice for rectal bleeding and change in bowel habit; and (ii) early medical advice seeking for rectal bleeding ($<$ 2 weeks) and change in bowel habit ($<$ 4 weeks).
Methods

Design and study population

The Hunter Community Study (HCS) is a longitudinal cohort of community dwelling men and women aged 55-85 years at baseline from the Hunter Region, NSW, Australia. Participants were randomly selected from the NSW State electoral roll between December 2004 and 2007. The HCS cohort provides a population profile reflecting that of the Hunter Region, state and national Australian profiles for gender and marital status but is slightly younger in age. A randomly selected subsample of HCS participants (n=1592) aged between 56 and 88 years at time of survey (November, 2009) were mailed a pen and paper questionnaire. A reminder telephone call was made to non-responders at 4-6 weeks following initial mail out.

Questionnaire

Respondents were asked separately whether they had ever experienced either rectal bleeding or a persistent change in bowel habit (diarrhoea/constipation) that lasted longer than two weeks. These items were used to determine the proportion of respondents ever experiencing each symptom. The item concerning rectal bleeding had been used in two previous Australian studies while the change in bowel habit item was devised for this study. Details regarding rates of medical advice seeking are provided elsewhere. Respondents indicating they had ever experienced either symptom were asked whether they had ever seen a doctor about that particular symptom. Response to this question, for both symptoms was used to identify the proportion who had ever sought medical advice from a doctor. Respondents indicating they had ever consulted a doctor were asked if they had noticed this symptom for the first time in the previous five years. To reduce recall bias only respondents experiencing their first symptom episode in the last five years and consulting a doctor were included in the analyses of early medical advice seeking.
Such respondents were asked to specify the time taken to seek medical advice and trigger(s) for seeking medical advice. The response options relating to triggers for seeking medical advice were forced choice with an “Other (Please specify)” option included. For rectal bleeding, location of bleeding, colour, frequency and level of concern were assessed. For change in bowel habit, type of irregular bowel movement, level of discomfort/pain, and frequency of symptom were assessed.

All respondents were asked about their family history of CRC and age at diagnosis across first and second degree relatives. Respondents answers to questions relating to doctor screening of family history of CRC and identification of any possible ‘increased risk’ were used to derive a family history of CRC discussed with doctor variable with three levels (never discussed, discussed and informed of possible ‘increased risk’, discussed and not informed of possible ‘increased risk’). Respondents were also asked to indicate whether a doctor or other health professional had ever provided CRC screening advice. Appendix E shows in more detail questions and response options used in this study.

**Predictors**

Based on existing literature relating to the barriers and facilitators of medical advice seeking, an *a priori* investigation of the following items selected from the HCS databank were assessed: *Socio-demographic and lifestyle characteristics*, i.e. age, gender, education, marital status, country of birth, household income, retirement, private health insurance status, tobacco or alcohol use; *Clinical characteristics* i.e. general practice visits per year, previous cancer diagnosis (excluding CRC), body mass index, and co-morbidity (e.g. high cholesterol, hypertension, asthma, diabetes); and *Psychosocial characteristics* i.e. physical health, assessed using the physical health component summary score (PCS) on the short form health survey (SF-36)\(^{55}\) and mental health, assessed using the Kessler Psychological Distress Scale (K-10).\(^{56}\)
The PCS is a physical health summary score aggregated from the physical functioning, role-physical, bodily pain and general-health scales on the SF-36.\textsuperscript{57} Predictors ascertained from respondents at the time of survey completion included: trigger for seeking medical advice, symptom characteristics, first degree relative diagnosed with CRC, family history of CRC discussed with doctor, and ever received screening advice from doctor.

**Statistical analyses**

Logistic regression analysis was used to determine independent factors associated with ever seeking medical advice (never consulted, consulted) and early medical advice seeking (<2 weeks for rectal bleeding and <4 weeks for change in bowel habit). Variables with a $p < .25$ following simple regression analysis (see Appendix 5.A) were considered for multiple logistic regression modelling (both forward and backward stepwise elimination were used to check consistency of results). Variables that met the significance cut point of $p < .05$ were retained in the final model. Data were analysed using STATA 11 (STATA, Texas, USA).

**Ethics approval**

The University of Newcastle, in partnership with the Hunter New England Population Health Human Research Ethics Committee, granted ethical approval (H-820-0504).

**Results**

**Sample demographics**

Of the 1592 mailed surveys, 1117 respondents completed and returned a survey (consent rate = 70%). Respondents previously diagnosed with colorectal carcinoma (n =24) or reporting they had undergone major abdominal surgery (n=8) were excluded from analysis, leaving a total sample of 1085 eligible participants for
analysis. For participants diagnosed with CRC or having undergone abdominal surgery information relating to the date of CRC diagnosis/ abdominal surgery was not obtained. The timing of such an event (before or after) symptom episode is critical to understanding health care seeking behaviour for such respondents. To eliminate the potential for bias in study results persons diagnosed with CRC or having undergone abdominal surgery were excluded. Demographic characteristics of the sample are presented in Table 7.1.

**Table 7.1: Demographic characteristics of study respondents (n = 1085)**

<table>
<thead>
<tr>
<th>Demographic characteristics</th>
<th>n</th>
<th>%</th>
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<td>Female</td>
<td>577</td>
<td>53</td>
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<td>75-88</td>
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</tr>
<tr>
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<td></td>
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<tr>
<td>Australia</td>
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<td>89</td>
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<td>Other</td>
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<tr>
<td>Marital status</td>
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<td>23</td>
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<tr>
<td>Annual household income before tax ($)</td>
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<td></td>
</tr>
<tr>
<td>≤ 39,999</td>
<td>574</td>
<td>58</td>
</tr>
<tr>
<td>40,000 – 69,999</td>
<td>216</td>
<td>22</td>
</tr>
<tr>
<td>≥ 70,000</td>
<td>197</td>
<td>20</td>
</tr>
<tr>
<td>Highest level of education</td>
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<tr>
<td>Secondary schooling (not completed)</td>
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<td>22</td>
</tr>
<tr>
<td>Secondary schooling (completed)</td>
<td>241</td>
<td>23</td>
</tr>
<tr>
<td>Trade qualification or TAFE</td>
<td>264</td>
<td>25</td>
</tr>
<tr>
<td>University or other tertiary study</td>
<td>256</td>
<td>25</td>
</tr>
<tr>
<td>Other or not applicable</td>
<td>53</td>
<td>5</td>
</tr>
</tbody>
</table>

*Percentage of responses (excluding any missing values).
Rectal bleeding

Of the 1075 respondents to the rectal bleeding question, 332 (31%) reported ever experiencing this symptom with 60 (18%) respondents never having consulted a doctor. Appendix 5.A, Table 1 presents the univariate (Pearson $\chi^2$) associations between socio-demographic, clinical and psychosocial characteristics and ever seeking medical advice for rectal bleeding. Multiple logistic regression modelling identified the following significant predictors of ever seeking medical advice for rectal bleeding: being male and persons that had ever received screening advice from a doctor or other health professional (See Table 7.2).

Table 7.2: Multiple logistic regression analysis of factors associated with ever seeking medical advice for rectal bleeding

<table>
<thead>
<tr>
<th></th>
<th>OR (95% CI)</th>
<th>p value</th>
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</thead>
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</tr>
<tr>
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<td>1</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>.51 (.26, .98)</td>
<td>.045</td>
</tr>
<tr>
<td>Screening advice from doctor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>4.45 (1.90, 10.41)</td>
<td>.001</td>
</tr>
<tr>
<td>No</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

OR, odds ratio; CI, Confidence Interval.
Of the 332 respondents ever experiencing rectal bleeding, 30% (101/332) had experienced their first symptom episode in the previous five years and consulted a doctor. These respondents were included in the analyses for early medical advice seeking, in which 67% of persons had consulted a doctor within two weeks. Multiple logistic regression modelling (see Table 7.3) identified that early medical advice seeking (<2 weeks) was significantly associated with private health coverage and participant trigger for seeking medical advice - 'Thought the symptom was serious'. Persons indicating the prompting factor for consultation was “Opportunity to talk during doctor visit for other reason” were less likely to seek early medical advice.

Table 7.3: Multiple logistic regression analysis of factors associated with early medical advice seeking for rectal bleeding

<table>
<thead>
<tr>
<th>Factor</th>
<th>OR (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Private health insurance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No coverage</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Coverage</td>
<td>3.96 (1.11, 14.19)</td>
<td>.034</td>
</tr>
<tr>
<td>Prompt for medical consultation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Thought the symptom was serious”</td>
<td>5.88 (1.48, 23.30)</td>
<td>.012</td>
</tr>
<tr>
<td>“Opportunity to talk during doctor visit for other reason”</td>
<td>.15 (.04, .52)</td>
<td>.003</td>
</tr>
</tbody>
</table>

OR, odds ratio; CI, confidence interval.
Change in bowel habit

For change in bowel habit, 1049 respondents answered this question; 195 (19%) reported ever experiencing this symptom, of which 39 (20%) respondents never consulted a doctor. Following multiple logistic regression modelling ever seeking medical advice for change in bowel habit was significantly more likely for persons: who had discussed their family history of CRC, irrespective of whether they were informed of possible ‘increased risk’ or not, with a lower household income, and who were within the healthy BMI weight range (See Table 7.4).

Table 7.4: Multiple logistic regression analysis of factors associated with ever seeking medical advice for change in bowel habit

<table>
<thead>
<tr>
<th>Annual household income before tax ($)</th>
<th>OR (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 39,999</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>$40,000 - $69,999</td>
<td>.36 (.13, .95)</td>
<td>.038</td>
</tr>
<tr>
<td>≥ $70,000</td>
<td>.29 (.10, .86)</td>
<td>.027</td>
</tr>
<tr>
<td>BMI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 18.5</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>18.5 - 25</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>&gt; 25</td>
<td>.12 (.03, .59)</td>
<td>.009</td>
</tr>
<tr>
<td>Family history of CRC discussed with doctor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never discussed</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Discussed/ informed of “increased risk”</td>
<td>5.68 (1.72, 18.75)</td>
<td>.004</td>
</tr>
<tr>
<td>Discussed/ not informed of “increased risk”</td>
<td>2.90 (1.06, 7.94)</td>
<td>.038</td>
</tr>
</tbody>
</table>

Of the 195 respondents ever experiencing a change in bowel habit persisting longer than two weeks, 37% (72/195) of persons had experienced this symptom for the first time in the previous five years and consulted a doctor. For this group, 63% of respondents respectively sought medical advice within four weeks. Multiple regression modelling indicated that early medical advice seeking (< 4 weeks) was
significantly associated with persons who had: identified as a prompting factor for medical consultation - “Symptom didn’t go away”; fewer GP visits per year; and discussed their family history of CRC with a doctor and were notified of a possible ‘increased risk’ (See Table 7.5).

**Table 7.5:** Multiple logistic regression analysis of factors associated with early medical advice seeking for change in bowel habit

<table>
<thead>
<tr>
<th>Factor</th>
<th>OR (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fewer general practitioner visits per year</td>
<td>.52 (.31, .88)</td>
<td>.014</td>
</tr>
<tr>
<td>Prompt for medical consultation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Symptom didn’t go away”</td>
<td>5.75 (1.42, 23.24)</td>
<td>.014</td>
</tr>
<tr>
<td>Family history of CRC discussed with doctor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never discussed</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Discussed and informed of “increased risk”</td>
<td>6.37 (1.04, 38.92)</td>
<td>.045</td>
</tr>
<tr>
<td>Discussed and not informed of “increased risk”</td>
<td>3.73 (.82, 16.97)</td>
<td>.089</td>
</tr>
</tbody>
</table>

OR, odds ratio; CI, confidence interval.

**Discussion**

To our knowledge this study is the first to assess factors associated with *early* medical advice seeking behaviour for primary symptoms potentially indicating CRC. Previous studies have generally focused on rectal bleeding and the reasons for non-consultation or delay greater than three months. For change in bowel habit, the current investigation of early medical advice seeking is timely given that research to date has generally examined factors associated with the decision to consult, rather than early medical advice seeking behaviour. Further, the current study’s adoption of a prospective longitudinal cohort has the added benefit of allowing for an extensive evaluation of socio-demographic, clinical, psychosocial and provider related factors influence on health care seeking behaviour.
Failure to seek medical advice

The present study has highlighted that for both primary symptoms approximately one in five persons who had experienced symptoms had never consulted a doctor at any stage in their lifetime. A recent Australian population-based study of persons aged over 18 years indicated that 69% of respondents experiencing rectal bleeding had not presented to their physician in the previous year. Other community-based studies have indicated that for persons aged over 40 years, approximately one-third either fail to seek, or delay (> 3 months) seeking medical advice for rectal bleeding. A community based-study conducted in the United States identified that 86% of respondents experiencing rectal bleeding had failed to seek medical care within the prior year. UK based studies have also indicated a high rate of non-consultation, between 59%-82% of respondents experiencing rectal bleeding. For change in bowel habit, the literature is less developed. A UK study indicated that 76% of persons experiencing lower gastrointestinal symptoms (including functional bowel disorders) had failed to ever consult a doctor.

Public health gain: Decreasing CRC patients admitted to acute settings

At present, an alarming rate of 20-40% of all CRC cases present as a medical emergency. Previous studies have indicated that symptomatic persons presenting to emergency departments report a median symptom duration of 3 months prior to admission, without necessarily presenting at an earlier point of intervention to primary care. For cases presenting to emergency departments, the mortality rate is higher and the cancer specific five year-survival rate is lower which indicates that a significant public health gain is achievable if cases are identified and appropriately investigated within the primary health care setting. Further, it is conceivable that improvements in earlier recognition of symptoms and immediate presentation to primary care could reduce the number of CRC cases.
requiring acute management options e.g. surgery for bowel obstruction. In theory, some emergency presentations should be prevented yet are not.\textsuperscript{33} There is considerable room for improvement, with a significant proportion of community members (approximately 20\% across both symptoms) never seeking medical advice for either potential symptom of CRC.

**Factors associated with ever seeking medical advice**

Male persons were significantly more likely to seek medical advice for rectal bleeding. This finding is inconsistent with previous literature that has indicated males are less likely to present for medical care across a wide-trajectory of health issues.\textsuperscript{64, 65} Nonetheless, previous community-based studies relating to medical consultation for bowel related symptoms have generally indicated no gender difference.\textsuperscript{6, 66} Further, a systematic review of delay in diagnosis of CRC highlighted that sex had no impact on presentation times.\textsuperscript{67} Future exploration of the barriers to help seeking for rectal bleeding among female persons and addressing such behaviours in public awareness campaigns may assist in improving overall consultation rates.

The present study identified that persons experiencing rectal bleeding who had ever received screening advice from a doctor or other health professional were significantly more likely to have ever sought medical advice. For this finding, the exact temporal sequencing of events was not ascertained, making extrapolation of exact cause and effect difficult. Intuitively persons may have experienced rectal bleeding, consulted a doctor and received screening advice after symptom episode. Alternatively persons may have received screening advice prior to symptom episode, with recollection of such a conversation prompting the increased likelihood of medical consultation. This temporal sequencing issue also relates to our finding that discussion of family history, regardless of whether the respondent was informed of increased risk, resulted in increased likelihood of ever consulting a doctor for change.
in bowel habit. Future research is required that clarifies the sequence and timing of such events.

Persons experiencing change in bowel habit with a lower household income were found to be significantly more likely to ever seek medical advice compared to persons with higher household income. In contrast, other community-based studies have found no relationship between socio-economic status and help seeking behaviour for rectal bleeding.\textsuperscript{42} Similarly, no relationship between socio-economic status and help-seeking behaviour has been identified in relation to other cancer related symptoms.\textsuperscript{42, 68} Given the scant literature examining change in bowel habit and earlier presentation time, further investigation of broader socio-economic constructs effect on help-seeking behaviour is required.

**Factors associated with early medical advice seeking**

The current study indicated that persons with private health coverage were significantly more likely to seek early medical advice for rectal bleeding. Such a finding is not surprising, given that persons without health insurance are known to have limited access to medical care\textsuperscript{69} and poorer health outcomes\textsuperscript{70, 71} compared to privately insured persons. For this group it is proposed that increased morbidity and mortality of CRC is a result of restricted access to medical and surgical care.\textsuperscript{70, 72} In relation to CRC, health insurance status heavily influences access to care, screening and long-term outcomes.\textsuperscript{70, 72, 73} Previous research has indicated that persons without health insurance are more likely to present with advanced cancer.\textsuperscript{73} For CRC, uninsured and Medicaid populations have been found to be at greater risk of developing post-operative complications and in-hospital mortality compared to those privately insured.\textsuperscript{72} More recent research also highlights longer pre- and post-presentation times for CRC patients without private health insurance.\textsuperscript{27} Restricted access to health care or more concerning, lack of any medical advice seeking for
those without private health insurance raises significant issues relating to possible
delayed diagnosis, worse overall health, and advanced disease progression.

**Triggers for early medical advice seeking**

Previous community and population-based studies have identified that perceived
symptom seriousness is an important factor in eliciting medical consultation for rectal
bleeding.44,45 Studies that have examined retrospective recall of cancer patients have
commonly identified that failure to recognise symptom seriousness is a significant
factor associated with patient delay.74 Previous population-based studies have
indicated that failure to consult or delay (> 3 months) in seeking medical advice for
rectal bleeding is due to an underestimation of symptom seriousness.6,43 A similar
finding has been demonstrated for patients recruited in the general practitioner
setting.44 The current study indicated that persons perceiving their symptom as
serious were more likely to see a doctor at an earlier time point (< 2 weeks). This
finding suggests that perception of symptom seriousness is not just an important
factor for medical consultation but also contributes to earlier presentation time.
Intuitively future health messages directed at the at-risk community must articulate
the serious nature of primary symptoms of CRC and the importance of early medical
advice seeking for improved health outcomes.

The current research also indicated that persons indicating that their trigger for
medical consultation was “Opportunity to talk during visit for other reason” were more
likely to not seek earlier medical advice. Such a finding suggests a person’s
willingness to “sit on symptoms” until another health issue or alternate reason for
medical consultation arises. Encouragingly, current health messages worldwide are
targeting this sub-group of persons with the “Don’t sit on your symptoms”
campaign.75,76 In relation to change in bowel habit, persons identifying “Symptom
didn’t go away” as a trigger for medical consultation were more likely to consult at an
earlier time point (< four weeks) compared to persons not identifying with this trigger.

The need for improved medical advice seeking behaviour in the primary care
setting
The study results suggest that there may be room for improvement in the
identification of symptomatic patients in the primary care setting. General
Practitioners (GPs) are in an ideal position to systematically offer information to
patients with 88% of persons presenting to a GP annually, 30% aged 65 years or
older.77 Routine health screening relating to bowel related health may encourage
earlier identification of symptoms. The acceptability and feasibility of systematic
assessment of ovarian symptoms during GP practice visits is currently being
assessed in the general practice setting.78 A similar mechanism could be
incorporated to monitor for potential symptom indicators of CRC, with particular
attention on those subgroups who are less likely to seek prompt medical advice for
symptoms.

Study limitations
This study includes some limitations that should be considered when interpreting
study results. The main limitation is a reliance on self-reported recall with no
objective verification of symptom episode and time taken to seek medical advice. It is
possible that recall bias may have affected some reports given that respondents
were asked to report on circumstances that had occurred up to five years previously.
To enhance respondents’ recall of the time taken to seek medical advice for primary
symptoms of CRC, analysis was restricted to persons who had experienced their first
symptom episodes in the previous five years and had consulted a doctor during this
timeframe. This technique was adopted, as in other previous studies,6 43 to reduce
the influence of potential recall bias. Nonetheless, this inherent limitation of studies using retrospective self report may be improved in the future through the adoption of a shorter recall period from symptom onset. Further, it should be considered that a conservative cut-point was used to denote early medical advice seeking for rectal bleeding (<2 weeks) and change in bowel habit (<4 weeks). Clinical practice guidelines in Australia and the United Kingdom (UK) do not specify a timeframe for at-risk persons (aged 50 years or over) to seek medical advice for primary symptoms of CRC. In relation to rectal bleeding, at-risk persons are encouraged to seek prompt medical advice following symptom episode. In relation to change in bowel habit, Australian guidelines encourage at-risk persons to seek medical advice but do not specify an exact time period. However, guidelines in the UK do specify that persons 60 years or over experiencing changed bowel habit for longer than 6 weeks with no other anal symptoms be urgently referred. Research on the predictive value of symptoms and patient delays effect on staging and prognosis of CRC should be used to inform any future amendments to guidelines or public health messages relating to “prompt” medical advice seeking behaviour. Finally, it must be noted that the relationship between the timing of discussions about family history of CRC with a doctor and provision of screening advice with symptom onset was not clearly delineated in the survey. Nonetheless, it is reasonable to assume that where health care providers have previously raised the issue of CRC, patients may subsequently feel more open about discussing potential symptoms and realise the importance of discussing symptoms.

Conclusions

The high rate of failure to ever seek medical advice for primary symptoms potentially indicating CRC is an issue requiring public health action. Education about the seriousness of symptoms, particularly rectal bleeding and change in bowel habit in
people over 50 years, and the need for early medical advice is required. Study results suggest the need for targeting of specific sub-groups in future public health messages encouraging prompt medical advice seeking. Importantly, patient delay in seeking medical advice is a modifiable factor that must be addressed if the burden of illness associated with CRC is to be reduced. Interventions within the primary health care setting are an important starting point to reach this critical endpoint.
References


75. Bowel Cancer Australia. Don't sit on your symptoms awareness campaign. Available from: http://bowelcanceraustralia.org/bca/


Appendix 5.A: Results of simple logistic regression analyses

Table 1: Simple logistic regression analyses of the factors associated with ever seeking medical advice for rectal bleeding and change in bowel habit

<table>
<thead>
<tr>
<th></th>
<th>Rectal bleeding</th>
<th>Change in bowel habit</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OR (95% CI)</td>
<td>p value</td>
</tr>
<tr>
<td><strong>Socio-demographic characteristics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>56-64</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>65-74</td>
<td>1.82 (.94, 3.49)</td>
<td>.073</td>
</tr>
<tr>
<td>75-88</td>
<td>1.12 (.52, 2.40)</td>
<td>.774</td>
</tr>
<tr>
<td>Marital status</td>
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<td>Married/ Living with partner</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Secondary schooling (not completed)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Trade qualification or TAFE</td>
<td>1.42 (.60, 3.39)</td>
<td>.421</td>
</tr>
<tr>
<td>University or other tertiary study</td>
<td>.93 (.43, 2.00)</td>
<td>.848</td>
</tr>
<tr>
<td>Other or not applicable</td>
<td>1.44 (.29, 7.22)</td>
<td>.65</td>
</tr>
<tr>
<td>Household income before tax ($)</td>
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<td></td>
</tr>
<tr>
<td>Income Range</td>
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<td>1</td>
</tr>
<tr>
<td>-------------------</td>
<td>-------</td>
<td>-------</td>
</tr>
<tr>
<td>≤ 39,999</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>40,000 – 69,999</td>
<td>1.03 (.49, 2.16)</td>
<td>.935</td>
</tr>
<tr>
<td>≥ 70,000</td>
<td>.57 (.28, 1.17)</td>
<td>.128</td>
</tr>
<tr>
<td>Country of birth</td>
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<td></td>
</tr>
<tr>
<td>Australian</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Other</td>
<td>.53 (.23, 1.21)</td>
<td>.133</td>
</tr>
<tr>
<td>Retired</td>
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<td></td>
</tr>
<tr>
<td>Yes</td>
<td>1.64 (.93, 2.88)</td>
<td>.088</td>
</tr>
<tr>
<td>No</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Private health insurance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No coverage</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Coverage</td>
<td>.76 (.37, 1.55)</td>
<td>.451</td>
</tr>
<tr>
<td>Drinking days per month (Alcohol)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.00 (.97, 1.03)</td>
<td>.828</td>
<td>1.98 (.95, 1.01)</td>
</tr>
<tr>
<td>Smoke</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Ever</td>
<td>.84 (.47, 1.52)</td>
<td>.566</td>
</tr>
<tr>
<td>Now</td>
<td>.50 (.15, 1.70)</td>
<td>.266</td>
</tr>
<tr>
<td>Clinical characteristics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>General practitioner visits per year</td>
<td>1.15 (.93, 1.43)</td>
<td>.20</td>
</tr>
<tr>
<td>Previous cancer (excluding CRC)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>.83 (.43, 1.63)</td>
<td>.592</td>
</tr>
<tr>
<td>No</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>First-degree relative diagnosed with CRC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>5.93 (1.40, 25.18)</td>
<td>.016</td>
</tr>
<tr>
<td>No</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Ever discussed family history of CRC with doctor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Category</td>
<td>Reference Value</td>
<td>p Value</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Never discussed</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Discussed and informed of “increased risk”</td>
<td>5.70 (2.31, 14.08)</td>
<td>.000</td>
</tr>
<tr>
<td></td>
<td>3.10 (1.17, 8.23)</td>
<td>.023</td>
</tr>
<tr>
<td>Discussed and not informed of “increased risk”</td>
<td>2.22 (1.09, 4.53)</td>
<td>.028</td>
</tr>
<tr>
<td></td>
<td>2.02 (.82, 4.95)</td>
<td>.125</td>
</tr>
<tr>
<td>Screening advice ever given by doctor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>4.67 (2.13, 10.25)</td>
<td>.000</td>
</tr>
<tr>
<td></td>
<td>1.23 (.57, 2.66)</td>
<td>.591</td>
</tr>
<tr>
<td>No</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>BMI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 18.5</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>18.5 - 25</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>&gt; 25</td>
<td>.87 (.40, 1.90)</td>
<td>.729</td>
</tr>
<tr>
<td></td>
<td>.28 (.08, .98)</td>
<td>.046</td>
</tr>
<tr>
<td>Comorbidity</td>
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</tr>
<tr>
<td>Yes</td>
<td>1.43 (.70, 2.94)</td>
<td>.323</td>
</tr>
<tr>
<td></td>
<td>1.53 (.59, 3.98)</td>
<td>.378</td>
</tr>
<tr>
<td>No</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Psychosocial characteristics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SF-36 (physical health)</td>
<td>.99 (.96, 1.02)</td>
<td>.642</td>
</tr>
<tr>
<td></td>
<td>1 (.97, 1.03)</td>
<td>.922</td>
</tr>
<tr>
<td>K-10 (mental health)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low or no risk (10-15)</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Medium to high risk (16 +)</td>
<td>1.28 (.66, 2.47)</td>
<td>.457</td>
</tr>
<tr>
<td></td>
<td>.83 (.40, 1.73)</td>
<td>.627</td>
</tr>
</tbody>
</table>

*Variables with p values < .25 included in multiple logistic regression model bolded.*
Table 2: Simple logistic regression analyses of socio-demographic, clinical and psychosocial factors associated with early medical advice seeking for rectal bleeding and change in bowel habit

<table>
<thead>
<tr>
<th></th>
<th>Rectal bleeding (&lt; 2 weeks)</th>
<th>Change in bowel habit (&lt; 4 weeks)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OR (95% CI)</td>
<td>p value</td>
</tr>
<tr>
<td><strong>Socio-demographic characteristics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Male</td>
<td>.55 (.23, 1.30)</td>
<td>.177</td>
</tr>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>56-64</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>65-74</td>
<td>2.05 (.80, 5.26)</td>
<td>.136</td>
</tr>
<tr>
<td>75-88</td>
<td>1.57 (.49, 5.04)</td>
<td>.443</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In relationship</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Not in relationship</td>
<td>.76 (.28, 2.09)</td>
<td>.601</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Secondary schooling (not completed)</td>
<td>1</td>
<td>.735</td>
</tr>
<tr>
<td>Secondary schooling (completed)</td>
<td>1.25 (.34, 4.56)</td>
<td>.735</td>
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<tr>
<td>Trade qualification or TAFE</td>
<td>1.31 (.37, 4.58)</td>
<td>.670</td>
</tr>
<tr>
<td>University or other tertiary study</td>
<td>.97 (.28, 3.37)</td>
<td>.965</td>
</tr>
<tr>
<td>Other or not applicable</td>
<td>2.33 (.21, 25.24)</td>
<td>.486</td>
</tr>
<tr>
<td>Household income before tax ($)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 39,999</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>40,000 – 69,999</td>
<td>1.7 (.58, 4.99)</td>
<td>.334</td>
</tr>
<tr>
<td></td>
<td>≥ 70,000</td>
<td>2.40 (.60, 9.50)</td>
</tr>
<tr>
<td>--------------------------</td>
<td>----------</td>
<td>------------------</td>
</tr>
<tr>
<td>Country of birth</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Australian</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>1.19 (.29, 4.93)</td>
<td>.704</td>
</tr>
<tr>
<td>Retired</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>1.07 (.44, 2.57)</td>
<td>.881</td>
</tr>
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<td>No</td>
<td>1</td>
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</tr>
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<td>Private health insurance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No coverage</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Coverage</td>
<td>2.29 (.85, 6.20)</td>
<td>.102</td>
</tr>
<tr>
<td>Drinking days per month (Alcohol)</td>
<td>1.03 (.99, 1.08)</td>
<td>.090</td>
</tr>
<tr>
<td>Smoke</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Ever</td>
<td>.90 (.36, 2.34)</td>
<td>.828</td>
</tr>
<tr>
<td>Now</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Clinical characteristics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>General practitioner visits per year</td>
<td>1.07 (.79, 1.47)</td>
<td>.628</td>
</tr>
<tr>
<td>Previous cancer (excluding CRC)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>.88 (.29, 2.65)</td>
<td>.824</td>
</tr>
<tr>
<td>No</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>First-degree relative diagnosed with CRC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>.44 (.15, 1.32)</td>
<td>.146</td>
</tr>
<tr>
<td>No</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Ever discussed family history of CRC with doctor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never discussed</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Discussed and informed of “increased risk”</td>
<td>1.71 (.56, 5.20)</td>
<td>.341</td>
</tr>
<tr>
<td>Description</td>
<td>Yes</td>
<td>.65 (0.23, 1.82)</td>
</tr>
<tr>
<td>-----------------------------------------------------------------------------</td>
<td>-----------</td>
<td>-----------------</td>
</tr>
<tr>
<td>Screening advice ever given by doctor</td>
<td>No</td>
<td>1</td>
</tr>
<tr>
<td>BMI</td>
<td>&lt; 18.5</td>
<td>1</td>
</tr>
<tr>
<td>18.5 - 25</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>&gt; 25</td>
<td>.89 (0.28, 2.85)</td>
<td>.845</td>
</tr>
<tr>
<td>Comorbidity</td>
<td>Yes</td>
<td>.33 (0.07, 1.60)</td>
</tr>
<tr>
<td>No</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Psychosocial characteristics</td>
<td>SF-36 (physical health)</td>
<td>1.01 (0.98, 1.06)</td>
</tr>
<tr>
<td>K-10 (mental health)</td>
<td>Low or no risk (10-15)</td>
<td>1</td>
</tr>
<tr>
<td>Medium to high risk (16 +)</td>
<td>.35 (0.14, 0.89)</td>
<td>.028</td>
</tr>
<tr>
<td>Trigger for seeking medical advice</td>
<td>Thought the symptom was serious</td>
<td>5.43 (1.87, 15.77)</td>
</tr>
<tr>
<td>Symptom didn’t go away</td>
<td>.98 (0.35, 2.72)</td>
<td>.971</td>
</tr>
<tr>
<td>Symptom was bad</td>
<td>.47 (0.06, 3.54)</td>
<td>.469</td>
</tr>
<tr>
<td>Symptom got worse</td>
<td>.63 (0.13, 3.01)</td>
<td>.568</td>
</tr>
<tr>
<td>Partner or family member suggested it</td>
<td>.98 (0.27, 3.53)</td>
<td>.979</td>
</tr>
<tr>
<td>Advertisement about bowel cancer</td>
<td>4.33 (0.52, 36.25)</td>
<td>.175</td>
</tr>
<tr>
<td>Friend diagnosed with cancer</td>
<td>.48 (0.03, 8.00)</td>
<td>.613</td>
</tr>
<tr>
<td>Family history of cancer</td>
<td>.30 (0.09, 0.98)</td>
<td>.046</td>
</tr>
<tr>
<td>Opportunity to talk during doctor visit for other reason</td>
<td>.21 (0.07, 0.58)</td>
<td>.003</td>
</tr>
<tr>
<td>Variable</td>
<td>Estimate (95% CI)</td>
<td>p value</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Had check-up or appointment already booked</td>
<td>2.58 (.29, 23.03)</td>
<td>.396</td>
</tr>
<tr>
<td></td>
<td>.36 (0.05, 2.30)</td>
<td>.279</td>
</tr>
<tr>
<td><strong>Symptom characteristics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Frequency</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Only once to less than half the time</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Half the time to every time</td>
<td>1.56 (.59, 4.15)</td>
<td>.370</td>
</tr>
<tr>
<td></td>
<td>.70 (.19, 2.52)</td>
<td>.592</td>
</tr>
<tr>
<td>Not sure</td>
<td>.43 (.12, 1.46)</td>
<td><strong>.176</strong></td>
</tr>
<tr>
<td><strong>Location of blood</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood mixed with stool</td>
<td>.79 (.26, 2.40)</td>
<td>.677</td>
</tr>
<tr>
<td>Blood on toilet paper</td>
<td>.84 (.29, 2.43)</td>
<td>.750</td>
</tr>
<tr>
<td>Blood in toilet bowl</td>
<td>.97 (.41, 2.29)</td>
<td>.955</td>
</tr>
<tr>
<td><strong>Concern</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate to high concern</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>None to minor concern</td>
<td>.33 (.13, .86)</td>
<td><strong>.022</strong></td>
</tr>
<tr>
<td><strong>Type of bowel movement</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diarrhoea</td>
<td>-</td>
<td>.78 (.28, 2.16)</td>
</tr>
<tr>
<td></td>
<td>.76 (.32, 2.30)</td>
<td>.761</td>
</tr>
<tr>
<td>Constipation</td>
<td></td>
<td></td>
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<tr>
<td><strong>Discomfort/pain</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None to mild discomfort</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>Mild to intense pain</td>
<td>1.50 (.53, 4.28)</td>
<td>.443</td>
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*Variables with p values < .25 included in multiple logistic regression model bolded.*
DISCUSSION AND IMPLICATIONS FOR FUTURE RESEARCH AND PRACTICE
Introduction

Colorectal cancer screening

Colorectal cancer (CRC) is a leading cause of preventable morbidity and mortality worldwide and will continue to be a critical challenge facing public health. The absolute numbers of cases will increase over the coming decades owing to the ageing and expansion of populations in both developed and developing countries.\(^1\) Colorectal cancer screening increases the likelihood of having a cancer diagnosed and treated at an earlier stage, when treatment may offer the prospect of lengthened life expectancy.\(^2\) Colorectal cancer screening is particularly challenging and complex, with multiple factors influencing uptake, including socio-demographic characteristics, health insurance coverage, physician-patient communication and psychosocial factors.\(^3\) Despite randomised controlled trial (RCT) evidence indicating the effectiveness of FOBT screening of the at-risk population,\(^4\)-\(^7\) low levels of screening participation at a population-level, remain a critical stumbling block to reduced CRC incidence and mortality. Similarly, for persons at elevated level of risk (i.e. those at “moderately increased risk” and “potentially high risk” according to the National Health and Medical Research Council (NHMRC) guidelines, adherence to colonoscopy screening guidelines in Australia is critical for reducing the burden of disease causes by CRC. Strategies and interventions at multiple levels are likely to be required if improvements in CRC screening uptake are to eventuate. These include policy and program modifications to remove structural and access barriers to screening. In Australia, the key elements to reducing the burden of illness associated with CRC are the expansion of the current National Bowel Cancer Screening Program (NBCSP) and increased uptake of faecal occult blood test (FOBT) screening across the entire at-risk population.\(^8\) However, expansion of this program alone will not suffice, with relatively low levels of participation identified in its current format.\(^9\)-\(^12\) There is a pressing need for the identification of individual, behavioural
and attitudinal constructs impeding CRC screening uptake. Further, the enhancing of doctors’ and other health professionals’ knowledge, awareness and encouragement of patients to undertake CRC screening is a critical factor in ensuring patient compliance with screening.

At present, the benefits of CRC screening are not equally distributed across population groups. Survival, CRC staging and life-expectancy outcomes are less favourable for persons experiencing socio-economic deprivation and for those persons from ethnic or Indigenous background. A pressing issue worldwide is the reduction of inequalities in CRC screening participation to ensure equality in health outcomes among the population. There is a clear need for high quality research to unravel the mechanisms by which such inequalities are maintained and for the implementation of methodologically rigorous intervention studies aimed at reducing such health inequalities.

**Medical advice seeking for primary symptoms of colorectal cancer**

While CRC screening programs aim to reduce the incidence of symptomatic CRCs; however, the overwhelming majority of patients present to their general practitioners with symptoms, a situation which is set to continue into the foreseeable future. A complex relationship exists between symptoms presentation and help-seeking behaviour for symptoms of CRC. The literature suggests that patients’ recognition and comprehension of the potentially serious nature of symptoms are key contributors to reductions in delay. For the most part, symptom indicators of potential CRC, e.g. rectal bleeding and change in bowel habit, will be attributable to benign, self-limiting illness, and patient perceptions of a benign cause often will prove correct. Nonetheless, for a small minority such an assumption in the presence of more severe gastrointestinal conditions e.g. CRC, may have devastating
consequences, with lengthened patient delay leading to possible advanced staging at diagnosis and diminished survival outcomes. In spite of the commonality of symptoms in the at-risk population, there is a need for continued emphasis of the potentially serious nature of these symptoms. However, for public health purposes, a critical challenge exists to find a balance between targeting the at-risk population without causing undue fear, and the overburdening of primary care providers and investigative services. While the way forward, i.e. the reduction of diagnostic and treatment delay for CRC, may seem clear, its achievement is complex.

Patient delay is only one part of the delay trajectory. For medical advice seeking, a common patient dilemma must be addressed, i.e. the correct appraisal and categorisation of specific symptoms of CRC, e.g. rectal bleeding and change in bowel habit. That is, it is important for people to recognise when to act in the presence of non-serious benign symptoms and when to act promptly in the presence of more serious symptoms potentially indicating CRC. Public education is one way to achieve this. However, such efforts require a greater effort than merely increasing a patients’ recognition of symptoms and their serious nature. Future health messages must emphasise symptom interpretation in the context of pre-existing disease, symptom complexes, patient experience, social circumstances and life priorities.

This shift in focus, away from merely ensuring recognition of symptoms and their seriousness, towards an improved understanding of symptoms, particularly those symptoms occurring in the presence of serious gastrointestinal conditions such as CRC, requires careful future consideration by the medical and research communities.
Key thesis findings

(1) Low rates of colorectal cancer screening in accordance with NHMRC screening guidelines across varying levels of risk

(2) A high rate of colonoscopy screening among persons “at or slightly above average risk”

(3) Inequality in colorectal cancer screening participation and levels of screening in accordance with guideline-recommendations across population groups

(4) Low rates of medical consultation and prompt medical-advice-seeking for primary symptoms that potentially indicate CRC.

Discussion of methodological limitations

Prior to discussion of the thesis findings, their implications and possible future research directions, it is important to consider the methodological limitations associated with the methods employed in this thesis and other studies that have examined CRC screening participation and medical-advice-seeking behaviour for primary symptoms of CRC.

Colorectal cancer screening behaviour

In common with other community- and population-based assessments of CRC screening participation within the literature, this thesis used self-report to measure CRC screening behaviour. Although two new studies and a recent meta-analysis have indicated high levels of sensitivity and specificity for self-reported screening behaviour,24-26 it is important to recognise that accuracy of self-reported screening varies across patient characteristics and test modalities.27 A meta-analysis of validation studies on self-reported CRC cancer screening use in the United States found that self-report versus documented history of screening had a high level of specificity (endoscopy .90 and FOBT .78) and sensitivity (endoscopy .82 and FOBT
Other studies comparing self-report of CRC test use to information from medical records have also found moderate-to-good agreement between the two data sources. To enhance recall, this study adopted descriptions of CRC tests to increase the accurate recall of CRC testing. Therefore, the estimates of screening behaviour provided in this thesis, while not likely to be highly precise, should provide reasonable estimates.

**Family history of colorectal cancer**

In this thesis, self-reported family history of CRC was used to assign level of risk in accordance with screening guidelines for at-risk persons. The accuracy of family history information is crucial to clinical decision-making and care provision, particularly for the management of persons with familial cancer. Correct risk assessment and subsequent screening advice provision are dependent on the accuracy of family history information obtained from the informant. This information needs to be accurate in reporting of the number of relatives (both first- and second-degree) diagnosed with CRC in a family unit and the age of affected relatives at diagnosis. Previous studies have indicated self-reported family history of CRC has relatively high levels of sensitivity and specificity for reporting of affected first-degree relatives. However, the level of accuracy is substantially reduced for affected second-degree relatives. The accuracy of reporting of age at diagnosis in CRC-affected relatives has not been identified in the literature. Further, the extent to which misleading family history information reorients risk classification for relatives following verification is largely unknown. Therefore, it is possible that the classification of risk may be inaccurate for a small proportion of the studied community and the sample of first degree relatives. As part of a larger Cancer Council Victoria (CCV) screening trial led by thesis supervisor, Laureate Professor Sanson-Fisher, a sub-study will be undertaken to assess the accuracy of CRC patients’ self-reported family history of
CRC, for the purposes of assigning risk level and providing risk-appropriate screening advice to first-degree relatives on a population-basis. See appendix L for a detailed description of this proposed study.

**Medical-advice-seeking behaviour**

Similar to previous community- and population-based studies of medical-advice-seeking behaviour, self-report was used in this thesis to assess consultation behaviour and delay in seeking medical advice.\(^{20, 21}\) It is likely to have a small-to-moderate margin for error, particularly where longer recall time frames are concerned. To enhance participants’ recall of the time taken to seek medical advice for primary symptoms of CRC, analysis was restricted to persons who had experienced their first symptom episodes in the previous five years and had consulted doctors during this timeframe. This technique was adopted, as in other previous studies, to reduce the influence of potential recall bias.\(^{20, 21}\)

**Discussion of key thesis findings**

With such caveats in mind, this thesis has uncovered a number of issues that have important implications for population health. The following sections of this thesis will provide a summary of the key findings and discuss their implications for future research and practice. For each key thesis finding, a proposed direction for future research will be suggested.

**Key Thesis Finding 1: Low rates of colorectal cancer screening in accordance with screening guidelines across varying levels of risk**

Paper Two is the first community-based evaluation of CRC screening rates since the roll-out of the NBCSP in 2006 and only the second evaluation of CRC screening in accordance with guidelines across varying levels of risk in Australia.\(^{33}\) At present in
Australia, information on the rate of population-level screening is limited to annual NBCSP monitoring reports, which only highlight screening rates for the selected range of the at-risk population offered screening (i.e. persons aged 50, 55 and 65 years). Prior to Paper Two, it was largely unknown whether persons outside the selected age brackets offered screening in the NBCSP had engaged in screening and, if so, what was their level of screening uptake in accordance with screening guidelines. Paper Two, in filling this knowledge gap, identified among a community-based cohort of at-risk persons aged 56-88 years the following rates of CRC screening in accordance with screening guidelines: “at or slightly above average risk” - 21%; “moderately increased risk” - 41%; and “potentially high risk” - 56%. Although there appeared to be higher adoption of CRC screening in accordance with guideline-recommendation for persons “at or slightly above average risk” who had been offered screening as part of the NBCSP (i.e. persons recently turning 55 or 65 years of age), in comparison with the only other previous population-based investigation, it appears there has been little improvement in screening uptake for any risk level over time.33

Paper Four presented new data on the level of screening in accordance with guidelines among first-degree relatives (FDRs) of CRC patients. Previously, only one state-wide evaluation in Australia had been conducted among FDRs.34 However, this study did not indicate whether CRC testing was undertaken in the presence or absence of symptoms, thus preventing extrapolation of true screening rates. Similar to the community-level evaluation in Paper Two, Paper Four identified low levels of screening in accordance with guidelines for first-degree relatives of CRC patients at each level of risk (“at or slightly above average risk” - 25%; “moderately increased risk” - 47%; “potentially high risk” - 49%). Both papers Two and Four highlighted
substantial under-screening across each level of risk in accordance with screening guidelines.

In Paper Two, the level of screening in accordance with guideline recommendation for persons “at or slightly above average risk” offered a screening kit by mail (i.e. persons recently turning 55 years or 65 years) as part of the NBCSP was 47%, a figure significantly higher than the corresponding 17% of persons who were not in the invited age groups. Given this finding and studies on mail-based approaches identified in Paper One, it is likely that if the NBCSP were expanded to include all persons in the at-risk population on a biennial basis, a population-level increase in CRC screening rates for those “at or slightly above average risk” would be evident. However, as the maximum screening rate achieved via mailed strategies was 59% in Paper One, it is unlikely that a mail-based strategy alone would achieve a CRC screening rate on which estimates of cost-effectiveness and potential lives saved from a fully implemented population-level FOBT screening program could be based. Therefore, alternative approaches to increasing CRC screening in accordance with guidelines for persons at varying levels of risk are required. The strong associations found between provider-level factors in Papers Three and Four and compliance with screening guidelines provide some indication of how further increases in screening rates may be achieved. Factors such as being asked about family history of CRC or ever receiving screening advice from a doctor or other health professional were associated with increased likelihood of CRC screening uptake and compliance with guideline-recommended screening. This suggests that a systematic general-practice-based approach to increasing the rate of CRC screening in accordance with guideline recommendations may be an option worth pursuing. Interventions in this setting would have a large reach, with a high proportion of the population (88%) visiting their general practitioners in any given year. Such an
approach (discussed later in Proposed Study 1), however, would have to be mindful of the competing demands for care and the often limited time available for preventive healthcare in the general practice setting.  

On a population level the NBCSP only caters for the FOBT screening needs of selected persons “at or slightly above average risk” aged 50, 55 and 65 years of age. The NBCSP’s format does not cater for the tailored screening needs of persons at elevated risk (i.e. those at “moderately increased risk” and “potentially high risk”). For persons at these respective levels of risk, more stringent CRC screening regimes involving colonoscopy screening (unless contraindicated) are required. This thesis highlighted in Papers Two and Four, low levels of CRC screening in accordance with guidelines for persons at “moderately increased risk” and “potentially high risk”, where the relative risk is at a minimum three-fold increase. In Papers Two and Four, for persons at “moderately increased risk” and “potentially high risk”, for the most part, consistently less than half of this at-risk population was screened in accordance with guideline-recommendations. This highlights the urgent need for adoption of organised and systematic approaches that are tailored to the screening needs of at-risk persons, irrespective of level of risk.

The Reach Effectiveness Adoption Implementation Maintenance (RE-AIM) framework specifies several critical components that determine the overall impact of an intervention on a targeted population including: the potential reach of the intervention; the likelihood of adoption; the ease of implementation; and the maintenance of the program. Interventions adopting a Cancer Registry approach to increasing CRC screening guideline compliance of FDRs of CRC patients appears to be, at face value, a mechanism that meets key requirements of the RE-AIM framework. The major advantage of delivering cancer control interventions using a
Cancer Registry is their potential population reach, which maximises the public health benefits of successful interventions. Registry-based screening programs can allow for the widespread dissemination of tailored screening programs to all first-degree relatives of persons diagnosed with CRC, including those at elevated levels of risk (i.e. those at “moderately increased risk” and “potentially high risk”). The Cancer Council Victoria (CCV) is currently examining the feasibility and effectiveness of an RCT adopting a Registry-based approach to increase CRC surveillance and screening in accordance with guideline recommendations, for index case patients and their first-degree relatives. As a part of this screening trial, FDRs of CRC patients in the intervention group would be sent tailored CRC screening recommendations in accordance with NHMRC screening guidelines for their respective levels of risk. However, the low response rate to this screening trial and other Registry-based cancer control initiatives in Australia is a key barrier to be overcome if the widespread implementation of Registry-based screening programs and their potentially positive effects are to be reached in Australia (personal communication, RW Sanson-Fisher). Paper Four, reported baseline findings for this CCV screening trial among FDRs of CRC patients and identified a low response rate from index case patients (26%) and their first-degree relatives (30%). This low rate is largely attributable to the ethical and legal requirements associated with how the Registry can communicate and recruit patients and their first-degree relatives. While the potential benefits of screening programs must be weighed against risk to patient privacy, it appears that the success of such programs on a population- and cost-effectiveness bases is unlikely under current constraints to patient recruitment.

In the foreseeable future, the consideration of other approaches to increase compliance with guideline-recommended screening is needed. Paper One presented a review of community-based interventions to increase CRC screening uptake and
identified (i) a paucity of intervention studies adopting EPOC accepted study designs, (ii) a low level of methodologically rigorous intervention studies that had adopted accepted EPOC study designs and (iii) only one methodologically robust study conducted in Australia. The poor rates of CRC screening and the lack of effective interventions to address this situation highlight the urgent need for the adoption of methodologically rigorous approaches to improve CRC screening rates. A proposed study to meet this requirement is outlined below.

Proposed study 1: A randomised controlled trial to improve compliance with guideline-recommended colorectal cancer screening in the general practice setting

Background
Healthcare providers play an integral role in cancer control by identifying those individuals whose behaviour, environment or family history place them at increased risk of CRC. In Australia, the NHMRC entrusts healthcare providers with preventive practices related to patient family history of CRC assessment, the notification of persons at increased risk and the provision of risk-appropriate CRC screening advice. Available information suggests that family health histories are seldom taken in primary care and are typically not sufficiently detailed to identify persons at risk. Retrospective chart audits have demonstrated that 40% to 55% of patient medical records include important family history information (i.e. the presence or absence of breast or bowel cancer). Clinicians’ self-reported rates of patient family history assessment ranges from 30% to 90%. Direct observation studies suggest discussion of family history may occur in 51% of visits by new patients and 22% of visits with established patients. Further, while general practitioners typically obtain family histories from new patients, they less commonly update such information. The failure to collect or update family history information may be due to the
competing demands for care and time factors that are placed on general practitioners.\textsuperscript{38, 51} In addition, the complexity of familial risk interpretation and the lack of systematic collection and assessment methods to assist primary care providers further compound this problem.\textsuperscript{43} Numerous references, online tools and guidelines are available related to cancer genetics. However, the time required for health care providers to search and digest such information is a critical factor.\textsuperscript{44}

There is an urgent need for more efficient protocols for obtaining, organising and interpreting family history in the primary care setting. Health care providers report the need for clear guidance on the risk stratification and referral processes with patients.\textsuperscript{44, 52} The cumbersome and time consuming nature of family history assessment has been a barrier to accurate assessment of familial risk,\textsuperscript{53-55} which may in part be overcome by the introduction of Computerised Cancer Risk Assessment Tools (CRATs).\textsuperscript{56} These tools have assisted in increasing the utility of family history assessment by standardising and simplifying the family history assessment process.\textsuperscript{57, 58} There is a need to examine the effectiveness of CRATs in allocating patients to a CRC risk level and their ability to provide risk-appropriate CRC screening information. Recent cluster randomised controlled trial evidence has demonstrated computer-based tools’ effectiveness in the management of familial breast cancer and CRC.\textsuperscript{43, 59} However, their widespread implementation in rigorous intervention trials aimed at increasing screening in accordance with guideline recommendations is yet to be investigated. The CRATs have the ability to tailor information to suit patients’ individual screening needs and the potential to integrate collected information with existing data management software (e.g. Medical Director in general practices).\textsuperscript{56} The feasibility of digital tools for collecting health information regarding patient health risk factors and providing tailored preventive health messages to general practice patients is currently being trialled by thesis supervisors.
Associate Professor Paul and Laureate Professor Sanson-Fisher, across several chronic diseases. The application of similar technology, the CRAT, to facilitate family history collection, risk allocation and the provision of risk-appropriate screening information to patients presents as a possible strategy that may be successful in increasing general practice patients’ compliance with guideline-recommended CRC screening.

**Aim**

(i) To determine the effectiveness of a computer risk assessment tool (CRAT) in increasing the proportion of general practice patients screened for colorectal cancer in accordance with NHMRC recommendations.

**Hypotheses**

(i) Patients randomly allocated to receive the CRAT and tailored risk-appropriate screening advice will have 10% and 15% higher levels of screening in accordance with NHMRC screening guidelines at one and three years post-recruitment.

(ii) The CRAT will reduce the proportion of persons “at or slightly above average risk” that may be receiving referral for colonoscopy not in accordance with guidelines.

(iii) The CRAT will increase the identification and appropriate referral of higher-risk patients to Familial Cancer Services.

**Research plan**

**Design**

A cluster-randomised controlled trial of individuals aged 25-74 years will be conducted at 12 general practice settings across New South Wales, Australia. Individuals between the age of 25-50 years will be included in the study as some gene mutations including HNPCC and FAP carry a very high lifetime risk of developing CRC. For such persons, clinical practice guidelines recommend...
screening at an earlier age than for the general population. \(^{39}\) General practice will be the unit of allocation. The primary outcome measure will be self-reported CRC screening behaviour at one and three years post-recruitment.

**Participants**

Participants in the target age group will be recruited from general practices as they attend for scheduled appointments. Each general practice clinic receptionist will generate a random list of eligible patients (i.e. those aged 25-74 and with no personal history of bowel cancer). A research assistant will approach eligible participants as they wait for their appointments and invite them to complete the CRAT using an iPad. Participant completion of the CRAT will constitute implied consent. Participants will be asked to provide contact details for follow-up at one and three year periods.

**Measure**

The CRAT will ask patients questions about family history of cancer for purposes of assigning levels of risk. Information collected would include the following: personal history of advanced adenoma or chronic ulcerative colitis; number of any first- or second-degree relatives diagnosed with CRC and their ages at diagnosis; whether multiple CRCs were detected in a relative; and family history of other cancers conveying risk for the identification of suspected Lynch Syndrome. A computer-generated algorithm would be developed to allocate each patient to their respective levels of risk in accordance with NHMRC screening guidelines. \(^{39}\) Such a purpose-built risk algorithm has been successfully implemented in a Cancer Council Victoria screening trial led by thesis supervisor, Laureate Professor Sanson-Fisher and was used in Paper Four to assign participants to levels of risk.
The intervention

The iPad used to complete the CRAT will have a wireless connection to a printer. Patients will be provided with printed risk-appropriate screening information tailored to their levels of risk. This information will include their personal NHMRC-designated risk category description, an appropriate screening recommendation and a personalised summary of this information to discuss with their general practitioners. Patients will be encouraged to discuss risk-appropriate screening with their general practitioners and provided with a copy of the tailored screening information to give to their general practitioners. Future development of the intervention could include (i) electronic transfer of this information to the patients’ electronic medical records and (ii) patient electronic medical record matching with patient data on the NBCSP.

Control group

Participants in the minimal ethical care group (control) will receive a standardised information pamphlet about CRC and standard screening recommendations for each level of risk in accordance with NHMRC screening guidelines.

Primary outcome

Five-year self-reported screening behaviour would be collected at baseline for both groups. Patients at baseline, one year and three years will be asked separately for each CRC testing modality (i.e. FOBT, sigmoidoscopy and colonoscopy) the timing of the most recent testing and the reason for testing (to ascertain whether the patient was symptomatic or asymptomatic). At one-year and three-year follow up, the patients’ allocated NHMRC risk categories would be compared with their self-reported screening behaviour to ascertain the levels of screening in accordance with guideline recommendations. Grouped data (for the intervention and control groups)
on the level of adherence to guideline recommendation would be compared at one- and three-year follow-up to identify improvements in risk-appropriate screening.

**Significance and potential benefits**

A distinctive benefit of this method is that it provides an opportunity to implement a system which could reach a high proportion of the at-risk population. This systematic approach can also help to guide improvements in appropriate referrals for colonoscopy screening in the general practice setting. If successful in reaching a high proportion of the population, this approach has the potential to lower the economic and social costs associated with CRC. If the approach proves to be effective, the relative costs and benefits of this approach versus more intensive approaches could be explored.

**Key Thesis Finding 2: A high rate of colonoscopy screening that may not be in accordance with guidelines among persons “at or slightly above average risk”**

Papers Two and Four together present as the first community and population-based study in Australia to evaluate the level of colonoscopy screening that may not be in accordance with guidelines among persons “at or slightly above average risk”. Colonoscopy screening for persons at this level of risk is not endorsed in NHMRC CRC screening guidelines. Nonetheless, in Papers Two and Four a large proportion of asymptomatic persons “at or slightly above average risk” reported having had colonoscopy screening in the previous five years. Further analysis indicated that it is plausible that much of this colonoscopy screening was not accounted for by prior FOBT screening which may have required colonoscopy follow-up, prior adenoma detection or, in relation to Paper Two, by the presence of a family history of CRC. Paper Three also identified that private health insurance was a predictor of colonoscopy screening in the previous five years, irrespective of level of risk. This
finding, that private health insurance is a predictor of all colonoscopies and not on a risk-appropriate basis, casts some doubt on how and for what purposes colonoscopy referrals are decided.

The high rate of colonoscopy screening that may not be in accordance with guidelines among persons “at or slightly above average risk” identified in Papers Two and Four is problematic. Clinical indications for colonoscopy that may not be in accordance with guidelines decrease the likelihood of detection of significant findings while increasing both the costs and risk to patients. Currently over 500,000 colonoscopies are conducted in Australia per year, with this number increasing by 40,000 annually. In the absence of symptoms, approximately 500 colonoscopies would need to be conducted on persons 50-75 years old to identify one cancer. This contrasts with data that have suggested that one cancer is found for every 20 colonoscopies following positive FOBT in the NBCSP. Colonoscopy is a procedure not without a serious risk of complication, estimated at 1 in 1000. Colonoscopy use that may not be in accordance with guidelines may divert resources unnecessarily, lengthen waiting lists for persons requiring appropriate clinical indications and further reduce the capacity of limited colonoscopy services. Improvements in appropriate clinical indications for colonoscopy screening may also reduce the risk of lengthy waiting times for persons testing positive for FOBT. There is a need to identify ways to improve guideline-appropriate use of colonoscopy. A proposed intervention is outlined in proposed study 2.
Proposed study 2: A randomised controlled trial of a decision-making aid to facilitate risk-appropriate general practice triage for colonoscopy screening in the general practice setting

**Background**
An opportunity exists to improve the number of risk-appropriate referrals for colonoscopy and the proportion of procedures that are undertaken in accordance with guideline recommendations in Australia. Few data exist on effective mechanisms to increase risk-appropriate general practice triage for colonoscopy screening. In Australia, a previous study had indicated that supervised application of screening guidelines using a nurse co-ordinator can reduce the number of surveillance colonoscopies undertaken that may not be in accordance with guidelines. Further, education programs aimed at general practitioners have shown promise in reducing colonoscopy that may not be in accordance with guidelines and its associated costs and waiting lists. Numerous leading healthcare organisations promote the engagement of patients in decisions about healthcare, with a growing importance placed on the provision of the best available evidence to guide patient decisions on their health needs. Cochrane review evidence suggests that in comparison to usual care, decision-making aids improve knowledge about clinical options, create more realistic expectations about outcomes and increase active involvement in the decision-making process. The use of decision-making aids to facilitate risk communication between patients and doctors and their ability to increase the adoption of risk-appropriate colonoscopy in accordance with guideline recommendations is yet to be examined in the literature.

**Aim**
To determine the effectiveness of a decision-making tool at increasing the proportion of patients in the general practice setting receiving risk-appropriate referral and colonoscopy screening in accordance with NHMRC CRC screening guidelines.
Hypotheses

(i) Patients allocated to receive the decision-making aid will have 10% and 15% higher levels of risk-appropriate colonoscopy screening adoption in accordance with NHMRC screening guidelines at one and three years post-recruitment.

(ii) The decision-making aid will reduce the proportion of persons “at or slightly above average risk” that may be receiving referral to colonoscopy services not in accordance with guidelines.

(iii) The decision making aid will increase the proportion of persons at elevated levels of risk (i.e. those at “moderately increased risk” or “potentially high risk”) receiving colonoscopy screening in accordance with guideline recommendations.

Research plan

Design

A clustered-randomised controlled trial of individuals aged 25-74 years will be conducted at 12 general practice settings across New South Wales, Australia. General practices will be the unit of allocation. Patient self-reported screening behaviour at one and three years post-recruitment will be used to assess the primary outcome, i.e. colonoscopy screening in accordance with guideline-recommendations.

Participants

Research assistants at participating practices will recruit participants in the target age group as they attend for scheduled appointments. Each general practice clinic receptionist will generate a random list of eligible patients (i.e. those aged 25-74 and with no personal history of bowel cancer). A research assistant will approach eligible participants as they wait for their appointments and invite them to complete a touch-screen survey on an iPad. Participant completion of this survey will constitute implied
consent. Participants will be asked to provide contact details for follow-up at one and three-year periods. The survey will ask questions about patients’ family history of CRC and other features conveying risk, for purposes of allocating patients to their respective level of risks in accordance with clinical practice guidelines. General practitioners in intervention practices would be asked to use the decision-making aid to guide any referrals of patients for colonoscopy screening and patient decisions to undertake colonoscopy screening.

The intervention
The decision-making aid would be a three-page pamphlet, which would be used in conjunction with the NHMRC and Australian Cancer Network endorsed booklet - “Familial aspects of bowel cancer: A guide for health professionals”. General practitioners would be requested to use both materials in discussions with patients about potential colonoscopy screening.

Control group
General practices in the control group and their patients would receive existing care only.

Content
The decision aid would include:

- General information on CRC screening: early detection and prevention; CRC risk factors; and familial risk of developing CRC.
- Quantitative information on colonoscopy screening: absolute mortality reduction; potential harms (e.g. perforation and risk of complication); and probability of test outcomes using an alternative screening procedure to colonoscopy, e.g. FOBT.
**Pamphlet lay-out**

Plain language and basic design would be used in the pamphlet to meet the needs of low-literacy patients and reduce cognitive effort of readers. The following strategies would be adopted: reducing the amount of text; using lay person language to replace technical terms and jargon; and using the active rather than the passive voice to communicate information. Illustrations would be used to highlight key facts and figures indicated in the text. The decision aid tool would be developed in compliance with the International Patient Decision Aid Standard.74

**Primary outcome**

Five-year self-reported screening behaviour would be collected at baseline for both groups. Patients at baseline, one year and three years will be asked separately for each testing modality (i.e. FOBT, sigmoidoscopy and colonoscopy) the timing of the most recent testing and the reason for testing (to determine whether the patient was symptomatic or asymptomatic). At one-year and three-year follow-up, patients’ NHMRC risk categories will be compared with their self-reported screening behaviour to ascertain the presence of colonoscopy screening in accordance with guidelines (Yes, No). The total proportion of patients receiving colonoscopy screening in accordance with guidelines in the intervention and control group will be compared at one- and three-year follow-ups.

**Significance and potential benefits**

Referral to and use of colonoscopy that may not be in accordance with guidelines is a major hurdle to the delivery of efficient colonoscopy services in Australia. The decision-making aid could assist in alleviating the waiting time for colonoscopy services and ensure timely access to such services for persons with clinical
indications for this procedure. This standardised tool can be used to ensure the adequate provision and clinical indication of colonoscopy services. If effective at a local level, this strategy can be adopted on a wider level across general practice settings in Australia to ensure adherence to best evidence practice for colonoscopy screening.

**Key Thesis Finding 3: Inequality in colorectal cancer screening participation and level of screening in accordance with guideline recommendations across population groups**

The concept of equality in health and health care is important for the achievement of optimal population-wide health outcomes. Research attention is needed to close the gradient in CRC screening uptake across population groups. Both Papers Three and Four presented data on the individual- and provider-level factors associated with CRC screening uptake and adherence with guideline recommendations across varying levels of risk. Provider-level factors, including ever asked about family history of CRC and ever received screening advice, were consistently associated with an increased likelihood of compliance with CRC screening guideline recommendations. A number of individual factors were also found to be significantly associated with an increased likelihood of adherence to guideline recommendations for some but not all risk levels: higher household-income, higher education, older aged persons (65-74 years), and private health insurance.

Paper Two found that lower household income was a significant predictor of reduced likelihood of screening compliance in accordance with guidelines for persons “at or slightly above average risk”. In Australia, consistent with this finding the NBCSP annual monitoring reports and cross-sectional analysis of participation in this program have also indicated lower levels of CRC screening participation among
persons from the most deprived socio-economic quintiles in the population.\textsuperscript{9-12, 76} It must be considered that the disparity in participation among socio-economic groups in Australia and in the United Kingdom (UK) is occurring in the context of highly structured and universal screening programs offering FOBT screening free of charge.\textsuperscript{76} This socio-economic gradient in screening participation has also been identified in other cervical and breast cancer screening programs.\textsuperscript{77} Taken together, these findings provide support for the suggestion that direct economic barriers alone do not explain the socio-economic differential in participation.\textsuperscript{13} While any future widening of Australia’s NBCSP program to include the entire at-risk population may alleviate some of the out-of-pocket expenses faced by lower socio-economic status (SES) persons, it would do little to alleviate other barriers hindering participation among lower-SES persons. The psychosocial and indirect economic constraints to CRC screening participation among persons of lower SES must be addressed if equality across socio-economic groups is to be achieved.\textsuperscript{13, 77} In Australia, few data exist on the barriers and impediments to CRC screening adoption among persons from lower socio-economic groups. A qualitative study of the NBCSP pilot program indicated that non-participating persons indicated a variety of reasons for their non-participation, including lack of knowledge and awareness of CRC, fear of cancer and having more pressing concerns at the time of screening offer.\textsuperscript{78}

It is important that any future policy decisions about Australia’s NBCSP address the reasons for non-compliance and develop tailored interventions aimed at persons from lower SES if increased equality in participation is to eventuate. However, a key stumbling block in Australia, as described in Paper One, is the scant number of methodologically rigorous interventions aimed at increasing screening participation among population groups experiencing inequality. Paper One identified one Australian community-based intervention study, which targeted FOBT screening
among persons from lower SES.\textsuperscript{71} This trial, which examined the effectiveness of a decision-making tool in increasing informed choice in FOBT screening and compliance, found contrary to expectation a higher return rate of FOBT in the control group (79\%) compared with the intervention group (59\%).\textsuperscript{71} Such findings suggest there are challenges in using decision-making aids with low-SES groups. On an international scale, Paper One found that the intervention studies conducted were largely on a population level and were not targeted at specific population groups experiencing screening inequality. The few studies that had examined interventions aimed at increasing screening rates among under-served population groups, including African Americans and Native Hawaiians in the US, for the most part, did not identify any significant differences across treatment and control groups.\textsuperscript{79,80} Further, where significant differences were identified, the transferability of effective interventions among population groups experiencing inequality in the US setting to the Australian setting is highly problematic, given the differing health care systems, structures and provisions of healthcare between the two countries. Given the absence of direction provided by the literature about community-based intervention approaches which are likely to be effective, a consideration of the impediments and barriers to screening participation among population groups experiencing inequality is paramount to shaping future intervention delivery. Proposed study three seeks to identify the barriers and enablers of CRC screening participation among persons of lower socio-economic status in Australia.
Proposed study 3: A descriptive study to identify the facilitating enablers of and barriers to colorectal cancer screening participation among lower socio-economic persons experiencing inequality

Background

A clear gradient in CRC screening participation has been identified worldwide related to socio-economic status. The majority of studies have found persons with lower education and income are less likely to access and utilise CRC screening. The importance of these findings is highlighted by data indicating that survival following diagnosis of CRC is correlated with socio-economic factors. The recent introduction of screening programs in Australia and the UK could result in a narrowing of the socio-economic gap in detection of and survival outcomes for CRC. However, a narrowing of the gap is only likely to eventuate if screening participation is heightened among low-SES groups. Early indications from annual monitoring reports in Australia’s and the UK’s screening programs have consistently indicated greater participation among higher-SES persons, suggesting the future likelihood of continuing socio-economic inequality in screening participation and CRC staging and survival outcomes.

Studies have indicated that the provision of universal healthcare or re-imbursement for the cost of screening has little appreciable effect on eliminating equality in screening participation. Previous reports suggest that some health service access hurdles appear to dominate among disadvantaged persons. It is suggested that there are distinct differences in healthcare-seeking behaviour and beliefs among persons from lower socio-economic groups, compared with those from higher socio-economic groups. This suggests that strategies to improve equality in screening must recognise factors other than financial coverage. Previous studies have
consistently indicated that persons from lower SES are less likely to accept and engage in CRC screening. However, few studies have examined the barriers to screening participation among this population group. The development of effective interventions for novel settings requires formative research to examine the beliefs and barriers to change among a target population. In Australia, social and community service organisations (SCSOs) have a large throughput of disadvantaged persons, estimated at more than three million persons annually. These SCSOs present as an innovative and viable setting for improving preventive healthcare practices among socially disadvantaged and marginalised groups in Australia. These organisations provide numerous welfare services and support to socio-economically disadvantaged persons, including accommodation, emergency relief (e.g. groceries, assistance with paying bills), counselling (e.g. financial and relationship support) and family support. They are keen and aware organisations focused on reducing health disparities endured by disadvantaged groups and interested in the development of intervention programs aimed at increasing preventive health behaviours, as evidenced by their current involvement in smoking-related research involving thesis supervisor Associate Professor Paul, and others. In Australia, no previous research has examined the barriers to CRC screening participation among disadvantaged persons in the community service sector. Such formative research is paramount for the development of effective intervention strategies aimed at increasing screening participation among lower-SES persons.

**Aim**

To assess current screening practices, knowledge, beliefs and barriers related to screening among lower socio-economic attendees at social and community service organisations. This descriptive study will be a prelude to the development of an
intervention study aimed at increasing CRC screening uptake among this population group.

**Research plan**

**Design**

A mixed method (quantitative survey and qualitative focus groups) study of persons without mental or cognitive deficits aged 50-74 years from SCSOs in the Hunter Region, New South Wales, Australia will be conducted. Following a baseline survey of 300 SCSO attendees, a sub-set of participants (n = 30) who had never undertaken any CRC screening will be invited to participate in focus groups one month after initial recruitment. Focus groups are an important technique to assist in the development of tailored interventions that address the needs of persons in different settings. Focus groups allow in-depth exploration of the barriers to screening participation and its associated issues within a social context.

**Participants and procedure**

Directors of SCSOs will be approached for permission for their organisations to participate in the study. Purposeful sampling will be used to ensure the inclusion of persons across the wide spectrum of services and presenting client types. A research assistant will approach eligible participants as they wait for their appointments and invite them to complete a touch-screen survey on an iPad. This approach has been used successfully in SCSOs to explore preventive health behaviours in relation to smoking and other preventive behaviours. Participant completion of this survey will constitute implied consent.
Instrument

Survey items will assess demographic information, CRC screening behaviour, knowledge, beliefs and barriers to screening. The PRECEDE_PROCEED model of health behaviour will be used as a theoretical framework to guide the development of study materials i.e. questionnaire and discussion guide. Within this framework knowledge and beliefs are predisposing factors (antecedent to behaviour), with enabling (i.e. availability of resources) and reinforcing factors (i.e. social support) also considered in the theory. This model has been used previously to guide the development of behavioural change interventions. It has been applied to a number of health behaviours related to low socio-economic groups, including cancer screening, physical activity and nutrition. The iPad technology assists with improving the accessibility of health concepts (e.g. through the use of visual aids) and survey readability (e.g. by presenting one question per screen) for those with low literacy levels.

Screening behaviour

Participants would be asked for the following CRC tests, FOBT, sigmoidoscopy and colonoscopy whether they had ever undertaken each procedure, the timing of the most recent testing and the reason for testing (to determine whether the patient was symptomatic or asymptomatic).

Knowledge and health literacy

Participants would be asked questions about preventability of CRC; risk factors for CRC; the names and types of CRC tests, the age at recommended screening commencement, and screening recommendations. The Rapid Estimate of Adult Literacy in Medicine (REALM) scale would be used to measure health literacy.
This is a validated scale found to be predictive of health behaviour and outcomes for a variety of preventative practices including CRC screening.¹⁰³,¹⁰⁴

**Beliefs**

Participants would be asked about their beliefs regarding the following issues: personal susceptibility, i.e. age and risk of developing CRC; CRC screening and the importance of early detection of disease; fears or denial about the need for CRC screening and consulting physicians for advice; and the detection of cancer and fatalistic ideas.

**Focus groups**

After survey completion, participants would be asked by a research assistant if they had ever undertaken any CRC screening in their lifetimes. Clients who had self-reported no previous history of CRC screening would be asked if they were willing to participate in a 60-minute focus group at a later date (approximately three to four weeks post-recruitment). Focus groups would be conducted by two facilitators with experience working with disadvantaged persons in SCSOs. Three separate focus groups (n = 10 per group) would be conducted within a private room at a participating SCSO. Prior to focus group commencement, participants would be given verbal information about the study, information statements and consent forms. Participants would be informed that sessions would be audio-taped, with quotes de-identified in any reports. Participants providing informed consent would be given $50 gift vouchers to reimburse their time and travel costs. The focus group discussion guide would be developed after a critical review of the literature pertaining to the barriers to CRC screening participation among lower socio-economic persons, and viewing data from client surveys. Participants would be asked for their preferences for CRC screening, whether support from SCSOs would be welcomed, the perceived role of
such services in providing support, and the types of support that would assist in screening uptake. Transcripts would be analysed using thematic analysis techniques with emergent themes of barriers to CRC screening documented.

**Significance and potential benefits**

There is an urgent need for the development of colorectal cancer preventative screening programmes that are accessible to lower SES-groups within a wider community-based framework. To date, few preventive programmes have been developed in the community setting, particularly aimed at addressing the CRC screening disparity experienced for persons from lower socio-economic groups. This study's unique evaluation of lower socio-economic persons recruited from SCSOs will provide key insights and a foundation for the development of tailored interventions aimed at increasing CRC screening among this population group. This study will evaluate participant perceptions and potential receptivity to intervention programs conducted in the non-government community service sector. If found acceptable, the development of an effective intervention sensitive to addressing the CRC screening needs of persons from lower socio-economic status in this setting would be explored.

**Key Thesis Finding 4: Low rates of medical consultation and prompt medical advice seeking for primary symptoms that potentially indicate colorectal cancer**

Papers Five and Six presented data on the medical-advice-seeking behaviour of at-risk persons (aged 56-88 years) for primary symptoms of CRC at a community level. These studies were novel in that they involved investigating in unison the triggers for medical consultation and reasons for delay in seeking medical advice for both rectal bleeding and change in bowel habit. This series of studies is the first Australian
investigation of delay in medical advice for change in bowel habit, the reasons for delay and triggers for seeking medical advice for this symptom. Further, these studies present new data on the factors associated with prompt medical advice seeking for both symptoms.

Findings

Low rates of medical consultation and prompt medical advice seeking

Paper Five identified a high rate of delay in medical advice seeking and non-consultation for potential primary symptom indicators of CRC. In response to rectal bleeding and change in bowel habit, approximately one in five persons had never consulted a doctor. Further, for both symptoms, approximately a quarter of persons experiencing their first symptom episodes in the previous five years self-reported consulting a doctor after a delay period of longer than one month. Direct comparison with a previous community data set indicated that little improvement had occurred in time taken to seek medical advice for rectal bleeding. The only other available data in Australia, a New South Wales population-based investigation of at risk-persons (aged 40 years or older) also supports the notion of negligible improvement in medical-advice-seeking behaviour. This study found that 30% of persons experiencing their first symptoms of rectal bleeding in the previous five years had either delayed or failed to ever seek medical advice for this symptom.

Reasons for non-consultation and delay, and triggers for seeking medical advice

Paper Five identified pertinent issues related to the reasons for non-consultation and delay in seeking medical advice, and triggers for medical consultation. For rectal bleeding, symptom interpretation of a benign cause ("Thought it was haemorrhoids") was commonly reported as a reason for never seeking medical advice and delay in seeking medical advice. This finding is consistent with other studies that have indicated a tendency for patients to delay due to belief in a benign cause or minor
illness. For change in bowel habit, an under-estimation of symptom seriousness ("Thought it wasn't serious") or waiting for symptom subsidence were commonly reported reasons for failing to ever seek or delaying in seeking medical advice. Previous studies have consistently indicated that non-recognition of symptom severity is a key contributing factor to delay in seeking medical advice for abdominal symptoms. Paper Six, consistent with this literature, found that the likelihood of early medical advice seeking for rectal bleeding was significantly associated with persons who had indicated “Thought it was serious” as a trigger for seeking medical advice. Taken together, such findings suggest that the interpretation of “symptom seriousness” is a critical factor in the symptom appraisal process that affects both decisions to consult and consultation at an earlier time point for primary symptoms of CRC.

Factors associated with seeking medical advice and prompt action

Paper Six highlighted a number of individual- and provider-level factors associated with medical-advice-seeking behaviour for both symptoms. A number of factors were significantly associated with an increased likelihood of ever seeking medical advice for primary symptoms including: being male; receiving screening advice from a doctor; lower household income; body mass index within the healthy weight range; and discussion of family history of CRC with a doctor. In addition, a number of individual- and provider-level factors were associated with an increased likelihood of prompt medical advice seeking for either rectal bleeding (< 2 weeks) or change in bowel habit (<4 weeks): persons frequenting their general practitioners less often per year; discussion of family history of CRC with a doctor; perception of symptom persistence; private health coverage; and perception of symptom seriousness.
Improving medical-advice-seeking behaviour for symptoms of colorectal cancer

The steps leading from symptom occurrence to medical consultation are similar for many cancers: symptom detection; inference of potential illness; a decision to seek medical advice; and action to consult a doctor.\textsuperscript{113} Critical to improving medical-advice-seeking behaviour for CRC symptoms is an increased public knowledge and awareness of the symptoms which may indicate CRC. As the primary symptoms, such as bleeding and change in bowel habit, may be indicative of less serious conditions than CRC, an individual is required to make a judgement about whether further medical advice should be sought. Sufficient knowledge is important for the correct interpretation of symptoms.\textsuperscript{111} While not studied in this dissertation, the literature indicates that insufficient knowledge has been commonly associated with uncertainty and delayed help-seeking for symptoms of CRC.\textsuperscript{21, 109, 114} Further, strong correlations have been found among lower awareness of CRC, negative attitudes towards CRC early detection and poorer health care seeking behaviour.\textsuperscript{21, 109, 111, 115, 116}

Prior to any suggestions of future research to increase the proportion of the population who promptly seek medical advice for primary symptoms of CRC, it is important to acknowledge the paradoxical relationship between patient delay, disease staging and survival evident in the CRC literature.\textsuperscript{23, 117-122} Numerous studies have explored delay in diagnosis and treatments and its impact on stage and survival for cancers.\textsuperscript{110, 122-126} It is axiomatic that longer diagnostic delay will result in an increased likelihood of tumour growth and advanced staging of CRC disease.\textsuperscript{119, 127} Thus, any reductions in delay will lead to less advanced staging and improved patient prognosis.\textsuperscript{119, 127} For CRC the quantitative effect of delay on staging and survival outcomes remains unclear in the literature.\textsuperscript{23, 106, 110, 117-119, 122, 128-130} While it has been
suggested that these differences could be explained by the different tumour growth rates or the biological nature and aggressiveness of the tumour, it would be wise to wait for greater clarity on this issue before making major investments in changing behaviour at a population level. However, until such consensus is achieved, it is generally accepted that the public be advised to minimise the period between symptom onset and treatment for CRC, as is advised for a number of other major cancers. It is also important to consider that, aside from the potential risk delay may pose for patient morbidity and mortality, delay can impose significant distress for the patient.

For cancers where the link between delay, staging and survival is more concrete e.g. breast cancer, mass media campaigns have been used to encourage appropriate behavioural responses to symptoms and screening behaviours. In relation to CRC, health care organisations, professional bodies and consumer groups have advocated for efforts to increase public exposure to early detection of CRC health messages. Mass media campaigns have the ability to disseminate well-defined behavioural messages to a large audience repeatedly over time and at a low cost per person. A recent study investigating the effect of two mass media CRC campaigns in the US indicated that media campaigns were effective at increasing public awareness and education about CRC risk and screening. Research in the US and Australia suggests that mass media campaigns with tailored reminder letters can increase screening compliance for cervical and breast cancer. A US meta-analysis examining the effects of media-based health campaigns has also indicated a small yet significant effect of such campaigns across a number of health behaviours. In relation to CRC screening and mass media, a recent review found no studies examining mass media’s effectiveness and concluded that “evidence was insufficient to determine effectiveness” at increasing CRC screening participation.
Similarly, no evidence currently exists to indicate the effectiveness of mass media campaigns in improving the proportion of patients who respond appropriately and promptly to symptoms of cancer. The few available studies that have investigated mass media effects on response to health symptoms have been confined to an investigation of emergency health conditions e.g. heart attack.\textsuperscript{140,149} This research, however, related to acute symptom episodes has little relevance to the experience of CRC symptoms which tend to occur over days or weeks rather than hours.

The Department of Health in Australia indicated, prior to the NBCSP roll-out the need for mass media based education aimed at the at-risk population “in order to raise the profile of bowel cancer, and to correct some of the perceptions that people have which may inhibit the propensity to screen”.\textsuperscript{78} Further, the National Bowel Cancer Coalition has recently called on the Australia Government to launch a comprehensive communication program on the early symptoms of CRC and preventive measures to address the low level of awareness of the disease in the community.\textsuperscript{139} Additionally, this coalition involving key stakeholders has highlighted the urgent need for symptom and screening messages to be relayed to persons who fall outside of the selected-age brackets in the NBCSP in Australia.\textsuperscript{139}

Despite government bodies and advocacy groups actively pushing for raised awareness, the available evidence in Australia suggests that media attention related to CRC is low. The Australian National Bowel Cancer Coalition has called for a coordinated, national awareness and education campaign to raise the profile of bowel cancer, in a manner proportional to its burden of disease.\textsuperscript{139} In Australia, however, CRC has been largely neglected in media coverage, compared with other cancers. A recent study examining televised news coverage of CRC in Australia over a three-year period indicated that CRC accounted for a mere 4.1% of all cancer news,
despite accounting for 13.5% of cancer incidence and 11.5% of cancer deaths in Australia.\textsuperscript{138} In comparison with other cancers, CRC received much less television coverage.\textsuperscript{138} Further, this study found minimal coverage of reports of celebrity CRC diagnoses and no examples of support from CRC control advocacy or support groups.\textsuperscript{138} Celebrity diagnoses of cancer are suggested to be causally related to increases in screening participation.\textsuperscript{141} For example, in the US Katie Couric’s “Today” show media campaign led to a surge in demand for colonoscopy while in Australia Kylie Minogue’s diagnosis of breast cancer led to a marked increase in bookings for mammography.\textsuperscript{150, 151} While these examples relate to screening rather than symptom presentation, it is likely that media attention to symptoms of CRC would similarly improve community knowledge and influence responses to symptoms.

A critical factor identified in Paper Five influencing the decisions to consult and delay in seeking medical advice for primary symptoms was the perception of symptom seriousness and attribution to a benign cause. It is important that any future public health educations campaigns aimed at the at-risk population be based on current evidence and clarify how to make judgements about symptom seriousness. Such campaigns should emphasise the need for prompt appraisal of symptoms and medical advice seeking, with regard for individual variation in the response to the threat of serious illness.\textsuperscript{109} Such campaigns, however, must be carefully communicated. Cancer concepts and vocabulary have often been cited as difficult to understand, with a tendency for persons to get the gist but not the detail.\textsuperscript{152} It is important that any future health messages related to behavioural response to primary symptoms of CRC are co-ordinated and consistent with effective techniques identified in the cancer communication literature.\textsuperscript{153} Further, these campaigns must be developed in collaboration with key stakeholders, including consumers, CRC advocacy groups, and the medical and research communities.\textsuperscript{138} The development of
comprehensive communication programs will require key insight from an expert advisory group (comprising, for example, general practitioners and medical specialists) regarding specific recommendations for the severity and duration of symptoms which require investigation or should be considered “serious”. This is particularly important, given that a key perception associated with seeking medical advice is the view that a symptom may have been serious. Any health messages must strike a balance between overburdening of general practitioners with unnecessary symptom investigation, while still ensuring patients with symptom indicators of CRC present promptly and appropriately.

**Conclusion and the way forward**

Findings from a series of studies in this dissertation highlight the urgent need for an improvement in the at-risk population's participation in CRC screening in Australia. Significant levels of under-screening and non-compliance with CRC screening guidelines were identified at a community level and among first-degree relatives of CRC patients at varying levels of risk. There is a pressing clear need for the development of systematic approaches to increase the levels of CRC screening in compliance with screening guideline recommendations. In addition, future research efforts must address the disparity in CRC screening participation evident across individuals and population groups. The elimination of health inequalities in CRC screening is a critical challenge confronting the medical and research communities. This challenge requires both concerted action on a population level and targeted approaches at population groups with lower levels of screening participation, e.g. persons of lower SES.

Empirical RCT evidence gathered over the course of approximately two decades has indicated that biennial FOBT screening for persons in the at-risk population is
effective in reducing CRC morbidity and mortality.\textsuperscript{4-7,138} As indicated by the Cancer Council Australia the "expanding of the NBCSP is by far the most clinically and economically effective investment available to government at a federal level in terms of reducing Australia’s cancer disease and cost burden in both the immediate and longer term".\textsuperscript{61} The current series of studies adds further evidence to the existing body of literature in support of the future expansion of Australia’s NBCSP. Any expansion however, may do little to close the gap in CRC screening participation and the marginalisation that some population groups in Australia experience. Future efforts to increase screening participation must address the barriers to CRC screening experienced for some populations groups experiencing inequality and act as a prelude to the development of future targeted interventions. Colorectal cancer screening, however, is not the only area requiring decisive action. For the foreseeable future, it appears the high proportion of symptomatic CRC presentation in Australia is set to continue. Consequently, concerted efforts from the medical and research communities are necessary to improve at-risk persons’ behavioural response to primary symptoms. The findings from this series of studies have provided useful insight into the need for, and potential content of, public health efforts to increase responses to symptom episodes. The proposed future descriptive studies in this thesis indicate ways to move forward, while the proposed intervention studies, if implemented in a methodologically rigorous nature, hold promise of reducing the burden of illness associated with colorectal cancer.
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Appendices for Hunter Community Study

(study materials for Papers Two, Three, Five and Six)
Appendix A: Ethics approval, University of Newcastle

HUMAN RESEARCH ETHICS COMMITTEE

Notification of Expedited Approval

To Chief Investigator or Project Supervisor: Conjoint Professor Wayne Smith
Cc Co-investigators / Research Students: Mr Ryan Courtney
Doctor Christine Paul
Miss Rheegan McDonald
Laureate Professor Robert Sanson-Fisher
Doctor Mariko Carey
Doctor Anne Crotty
Conjoint Associate Professor Peter Schofield
Professor Catherine d’Este
Conjoint Professor Peter Gibson
Conjoint Professor David Henry
Doctor Lisa Wood
Doctor Regina Berretta
Associate Professor Pablo Moscato
Professor John Attia
Associate Professor Philip Hansbro
Professor Rodney Scott
Professor Julie Byles
Mr Mark McEvoy
Dr Sukumaran Thambar
Doctor Benjamin Ewald
Assoc Prof Michael Boyle
Mr Peter Osmotherly

Re Protocol: The Hunter cohort project: A public health, clinical
genetic, health services and pharmacologic resource

Date: 16-Nov-2009
Reference No: H-820-0504

Thank you for your Variation submission to the Human Research Ethics Committee (HREC)
seeking approval in relation to a variation to the above protocol.
Variation:
a. For a Sub-Study to examine the level of association between neck pain and the concurrent
presence of dizziness in the population;
b. For the addition of Peter Osmotherly as HCS Collaborator and Student Supervisor;
c. For the addition of Miss Rheegan McDonald as a student researcher;
d. For the Letter of Invitation for the Sub-Study;
e. For the Information Sheet for the Sub-Study (Version 1; dated September 2009);
f. For the Neck Pain and Dizziness Study Survey

g. For a Sub-Study Exploring a potential link between anti-thyroid antibodies and decreased
cognitive ability;
h. For the addition of Dr Michael Boyle as a collaborator for the sub-study;
i. For the addition of Dr Ben Ewald as an investigator on the main study.
j. For a Sub-Study examining delay in seeking medical advice for bowel-related symptoms and level
of appropriate screening for bowel cancer;
k. For the addition of Dr Chris Paul as an investigator;
l. For the addition of Professor Rob Sanson-Fisher as an investigator;
m. For the addition of Dr Mariko Carey as an investigator;

Your submission was considered under **Expedited Review of External Approval** review by the Chair/Deputy Chair. I am pleased to advise that the decision on your submission is **External HREC Approval Noted effective 10-Nov-2009.**

The full Committee will be asked to ratify this decision at its next scheduled meeting. A formal **Certificate of Approval** will be available upon request.

Associate Professor Alison Ferguson  
Chair, Human Research Ethics Committee

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<th>First named investigator</th>
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<td>The impact of Anticholinergic Activity on cognition in a population-based cohort</td>
<td>Schofield Peter,William</td>
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<td>Enabling Grants - Special Facilities</td>
<td>The Hunter Data Linkage Project: A population-based biological and information database for health and aging research.</td>
<td>Smith Wayne, Trevor</td>
<td>G0183559</td>
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<td>The Hunter Cohort Project: A population-based cohort for health services and pharmacologic resources</td>
<td>Smith Wayne, Trevor</td>
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<td>Healthy Airways and Obstructive Lung Disease (HAROLD) Is pneumococcal vaccination protective for cardiovascular disease? Elucidating the relationship between pneumococcal vaccination and protective anti-oxidised LDL antibodies</td>
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### Linked University of Newcastle administered funding:

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<tr>
<td>Project Grant</td>
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<td>Smith Wayne, Trevor</td>
<td>G0182931</td>
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<td>Project Grant</td>
<td>Healthy Airways and Obstructive Lung Disease (HAROLD)</td>
<td>Smith Wayne, Trevor</td>
<td>G0187246</td>
</tr>
<tr>
<td>Pilot Grant</td>
<td>Is pneumococcal vaccination protective for cardiovascular disease? Elucidating the relationship between pneumococcal vaccination and protective anti-oxidised LDL antibodies</td>
<td>Attia John, Richard</td>
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<td>McEvoy Mark, Anthony</td>
<td>G0187872</td>
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Appendix B: Ethics approval, Hunter New England Population Health

21 October 2009

Dr J Attia
COEB
David Maddison Building
University of Newcastle

Dear Dr Attia,

Re: The Hunter Cohort Project: A Public Health, Clinical, Genetic, Health Services and Pharmacologic Resource (03/12/10/3.26)

Thank you for submitting a request for an amendment to the above project. This amendment was reviewed by the Chair of the Hunter New England Human Research Ethics Committee under the provisions of expedited review. This Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council’s National Statement on Ethical Conduct in Human Research (2007) (National Statement) and the CPMP/ICH Note for Guidance on Good Clinical Practice. Further, this Committee has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review. The Committee’s Terms of Reference are available from the Hunter New England Area Health Service website: http://www.hnehealth.nsw.gov.au/Human_Research_Ethics.

I am pleased to advise that the Hunter New England Human Research Ethics Committee has granted ethical approval for the following amendment request:

- For a Sub-Study examining delay in seeking medical advice for bowel-related symptoms and level of appropriate screening for bowel cancer;
- For the addition of Dr Chris Paul as an Investigator;
- For the addition of Professor Rob Sosenko-Fisher as an Investigator;
- For the addition of Dr Marko Carey as an Investigator;
- For the addition of Student Researcher Mr Ryan Courtney;
- For the Invitation Letter (Version 1 dated October 2008);
- For the Information Sheet (Version 1 dated October 2009); and
- For the Early Detection of Bowel Cancer Study Survey

For the protocol: The Hunter Cohort Project: A Public Health, Clinical, Genetic, Health Services and Pharmacologic Resource

Approval from the Hunter New England Human Research Ethics Committee for the above protocol is given for a maximum of 3 years from the date of the approval letter of your initial application, after which a renewal application will be required if the protocol has not been completed. The above protocol is approved until June 2010.

Hunter New England Research Ethics & Governance Unit
(Locked Bag No 1)
New Lambton NSW 2305
Telephone (02) 49214 910 Fax (02) 49214 818
Email: hnehrea@hnehealth.nsw.gov.au
The National Statement on Ethical Conduct in Human Research (2007) which the Committee is obliged to adhere to, include the requirement that the committee monitors the research protocols it has approved. In order for the Committee to fulfil this function, it requires:

- a report of the progress of the above protocol be submitted at 12 monthly intervals. Your review date is June 2010. A proforma for the annual report will be sent two weeks prior to the due date.

- A final report be submitted at the completion of the above protocol, that is after data analysis has been completed and a final report compiled. A proforma for the final report will be sent two weeks prior to the due date.

- All variations or amendments to this protocol, including amendments to the Information Sheet and Consent Form, must be forwarded to and approved by the Hunter New England Human Research Ethics Committee prior to their implementation.

- The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
  - any serious or unexpected adverse events
    - Adverse events, however minor, must be recorded as observed by the Investigator or as volunteered by a participant in this protocol. Full details will be documented, whether or not the Investigator or his deputies considers the event to be related to the trial substance or procedure. These do not need to be reported to the Hunter New England Human Research Ethics Committee

- Serious adverse events that occur during the study or within six months of completion of the trial at your site should be reported to the Manager, Research Ethics & Governance, of the Hunter New England Human Research Ethics Committee as soon as possible and at the latest within 72 hours.


- Serious adverse events are defined as:
  - Causing death, life threatening or serious disability.
  - Cause or prolong hospitalisation.
  - Overdoses, cancers, congenital abnormalities whether judged to be caused by the investigational agent or new procedure or not.

- unforeseen events that might affect continued ethical acceptability of the project.

- If for some reason the above protocol does not commence (for example it does not receive funding), is suspended or discontinued, please inform Dr Nicole Gerrand, Manager, Research Ethics & Governance, of the Hunter New England Health as soon as possible.

Hunter New England Research Ethics & Governance Unit
(Locked Bag No 1)
(New Lambton NSW 2305)
Telephone (02) 49214 800 Facsimile (02) 49214 818
Email: hnehrec@hnehealth.nsw.gov.au
Please quote 03/12/10/3.26 in all correspondence.

Should you have any queries about your project please contact Dr Nicole Gerrand as per her contact details at the bottom of the page. The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Yours faithfully

For: Dr M Parsons
    Chair
    Hunter New England Human Research Ethics Committee
Dear ______________.

As a participant in the Hunter Community Study, you are now invited you to participate in a study examining early detection of bowel cancer. This study is being carried out by researchers from The Hunter Community Study at the University of Newcastle.

The enclosed survey consists of a number of questions asking if you have experienced bowel-related symptoms and, if so, whether you had sought medical advice. The survey also asks about family history of bowel cancer and whether you have been screened for bowel cancer.

If you agree to take part in the study you will need to complete the enclosed questionnaire on one occasion only and return it in the reply-paid envelope provided. More details concerning the study can be found in the accompanying document entitled “Information Sheet”.

Kind Regards,

Professor John Attia
Hunter Community Study
Appendix D: Information statement

<table>
<thead>
<tr>
<th>Information Sheet</th>
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<tbody>
<tr>
<td><strong>What are the aims of this Hunter Community Study, “Early detection of bowel cancer”, and what does the study involve?</strong></td>
</tr>
<tr>
<td>The study is about symptoms of bowel cancer and level of appropriate screening. We will ask whether you have ever experienced bowel-related symptoms, whether you sought medical advice for symptoms and the length of time passed before seeing a doctor. We are also interested in finding out the reasons for consulting or not consulting your doctor about bowel-related symptoms. We will also ask questions about your family history of bowel cancer and screening tests undertaken. Even if you have never had any symptoms of bowel cancer, we are still interested in your answers.</td>
</tr>
<tr>
<td>If you agree to participate, please complete the enclosed questionnaire and return it in the reply-paid envelope provided. We estimate that this questionnaire will take about 15 minutes to complete.</td>
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<tr>
<th>How to take part in the study</th>
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<tr>
<td><em>If you are interested in participating in the study, please complete the enclosed questionnaire and return it to us by post.</em></td>
</tr>
<tr>
<td>If we do not hear from you, a member of our research team may contact you by telephone within two weeks of you receiving this invitation, to determine if you are interested in participating in this important research.</td>
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<tr>
<th>Confidentiality and privacy</th>
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<tr>
<td>Any information you provide for this study will remain completely confidential. Your information will be entered on a computer and will be identified by a study number only. Your name will not be on the same file as your questionnaire or health</td>
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</table>
assessment information. No individual information will be reported; results will only be reported for groups of participants. Your name and contact details will be stored separately in locked filing cabinets in locked rooms, and will be used only to provide you with results of the study and for future contact if you agree.

Paper copies of study information, only identifiable by a study ID number, will be kept in locked filing cabinets in locked rooms, and security systems have been established for electronic information. All health information will be used, accessed and stored in accordance with the NSW Health Records and Information Privacy Act (2002).

All staff involved in the study are required to sign a confidentiality agreement, and the provisions of the Privacy Act 1988 guarantee your privacy. At the end of the study, the file containing your health information will be securely stored by the University of Newcastle in locked filing cabinets with personal identifiers removed.

<table>
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<tr>
<th>Contact details for the Hunter Community Study</th>
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<tr>
<td><strong>For questions about the study in general, the best initial contacts are</strong></td>
</tr>
<tr>
<td>Mrs. Roseanne Peel</td>
</tr>
<tr>
<td>Study Co-ordinator</td>
</tr>
<tr>
<td>Hunter Community Study</td>
</tr>
<tr>
<td>Telephone: (02) 49138276</td>
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<tr>
<td>Fax: (02) 49138148</td>
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<tr>
<td>Email: <a href="mailto:Roseanne.Peel@newcastle.edu.au">Roseanne.Peel@newcastle.edu.au</a></td>
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<th>If you have concerns or complaints about this study</th>
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<tr>
<td>This research has been reviewed and approved by the Hunter New England Human Research Ethics Committee, Reference number 03/12/10/3.26.</td>
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</table>

Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, you may contact the following person:

**Dr Nicole Gerrand**
Professional Officer
Hunter New England Human Research Ethics Committee
Hunter New England Health
Locked Bag 1
New Lambton NSW 2305
Phone: (02) 49214950
E-mail: Nicole.Gerrand@hnehealth.nsw.gov.au
Appendix E: Pen-and-paper questionnaire

All of the questions in this survey are about bowel cancer. They ask about symptoms, visiting the doctor, family history of bowel cancer and screening tests.

Please circle the number or letter that best describes your answer to each question. Some questions will require you to record numbers.

Please answer every question.

There are no right or wrong answers. The survey will take around 15 minutes to complete.

When you have completed all sections of the survey, simply put the survey in the reply-paid envelope provided and post it back within the next 7 days. No postage stamp is needed.

The return of your completed questionnaire will be taken as an indication of your voluntary consent to participate in this study.

If you have any questions or concerns about the study please do not hesitate to contact Dr Chris Paul (Study Co-ordinator) by telephone on 02 49 138143 or by email chris.paul@newcastle.edu.au

THANKS FOR YOUR TIME

If you have any concerns or complaints about the conduct of the study, you may contact:

Dr Nicole Gerrand
Professional Officer
Hunter New England Human Research Ethics Committee
Hunter New England Health
Locked Bag 1
New Lambton NSW 2305
Phone: (02) 49214950
Nicole.Gerrand@hnehealth.nsw.gov.au

Q1. Have you ever been told that you have a bowel-related condition, e.g. Inflammatory bowel disease - Ulcerative colitis or Crohn’s disease?

1. Yes
2. No

The following questions are about blood in your bowel motions

Q2. Have you ever noticed blood in your bowel motions, in the toilet bowl or on the toilet paper?

1. Yes ⇒ Go to Question 3
2. No ⇒ Go to Question 2a

Q2a. If you noticed blood or black material in a bowel motion how soon would you contact your doctor to make an appointment?

1. Less than 1 week
2. More than 1 week but less than 4 weeks
3. More than 4 weeks but less than 8 weeks
4. More than 8 weeks but less than 12 weeks
5. More than 3 months but less than 12 months
6. More than 12 months
7. Never
   Go to Question 15

Q3. Have you ever seen a doctor about blood in your bowel motions, in the toilet bowl or on the toilet paper?

Q3a. If you noticed blood or black material in a bowel motion (sign of rectal bleeding) how soon would you contact your doctor to make an appointment?

Q4. Did you first notice blood in your bowel motions, in the toilet bowl or on the toilet paper in the last 5 years?

1. Yes Go to Question 4
2. No Go to Question 3a

1. Less than 1 week
2. More than 1 week but less than 4 weeks
3. More than 4 weeks but less than 8 weeks
4. More than 8 weeks but less than 12 weeks
5. More than 3 months but less than 12 months
6. More than 12 months
7. Never
   Go to Question 14

1. Yes Go to Question 5
2. No Go to Question 4a
**Q4a.** If you noticed blood or black material in a bowel motion (sign of rectal bleeding) how soon would you contact your doctor to make an appointment?  

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<td>1.</td>
<td>Less than 1 week</td>
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<td>2.</td>
<td>More than 1 week but less than 4 weeks</td>
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<tr>
<td>3.</td>
<td>More than 4 weeks but less than 8 weeks</td>
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<tr>
<td>4.</td>
<td>More than 8 weeks but less than 12 weeks</td>
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<td>5.</td>
<td>More than 3 months but less than 12 months</td>
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<tr>
<td>6.</td>
<td>More than 12 months</td>
</tr>
<tr>
<td>7.</td>
<td>Never</td>
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**Q5.** How long ago did you notice blood in your bowel motions for the first time?  
*(Please specify the amount of time)*

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<td>b.</td>
<td>_______ Weeks</td>
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<tr>
<td>c.</td>
<td>_______ Months</td>
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<td>d.</td>
<td>_______ Years</td>
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**Q5a.** Did you see a doctor about it?  

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<td>1.</td>
<td>Yes</td>
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<tr>
<td>2.</td>
<td>No</td>
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**Q6.** How long after you first noticed blood in your bowel motions did you see a doctor about it?  
*(Please specify the amount of time)*

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<td>b.</td>
<td>_______ Weeks</td>
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<td>c.</td>
<td>_______ Months</td>
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<td>d.</td>
<td>_______ Years</td>
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**Q7.** What is the main reason you did not seek medical advice about blood in your bowel motions sooner?  
*(Please circle only one response)*

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<tr>
<td>1.</td>
<td>I consulted a doctor within one week</td>
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<tr>
<td>2.</td>
<td>Thought it wasn’t serious</td>
</tr>
<tr>
<td>3.</td>
<td>Cleared up itself</td>
</tr>
<tr>
<td>4.</td>
<td>Thought it was haemorrhoids/piles</td>
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<tr>
<td>5.</td>
<td>Decided to wait and see</td>
</tr>
<tr>
<td>6.</td>
<td>Seeing a doctor would be unpleasant / embarrassing</td>
</tr>
<tr>
<td>7.</td>
<td>Worried or scared it might be serious</td>
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<tr>
<td>8.</td>
<td>No faith in doctors/Doctor couldn’t do anything</td>
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<tr>
<td>9.</td>
<td>Couldn’t afford doctor visit</td>
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<tr>
<td>10.</td>
<td>Did not want to waste doctor’s time</td>
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<td>11.</td>
<td>Not confident in discussing symptom/doctor hard to talk to</td>
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<tr>
<td>12.</td>
<td>No time/busy/other things to think about</td>
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<td>13.</td>
<td>Difficulty making an appointment or getting transport</td>
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<td>14.</td>
<td>Didn’t want to worry family/friends</td>
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<td>15.</td>
<td>Can’t remember</td>
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<td>16.</td>
<td>Other (please specify _________________________)</td>
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<tr>
<td>Question</td>
<td>Options</td>
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| Q8. Where did you notice this blood? (Please circle all that apply) | a. Blood mixed with stool/poo  
b. Blood on toilet paper  
c. Blood in the toilet bowl |
| Q9. How would you describe the colour of the blood? | 1. Bright red  
2. Dark red  
3. Black |
| Q10. How often was there blood in bowel motion? | 1. Every time  
2. More than half of the time but not all the time  
3. About half of the time  
4. Less than half the time but more than once  
5. Only once  
6. Not sure |
| Q11. How much did the amount of blood concern you? | 1. High concern  
2. Moderate concern  
3. Minor concern  
4. No concern at all |
| Q12. What in particular prompted you to consult a doctor about blood in your bowel motions? (Please circle all that apply) | 1. Thought the symptom was serious  
2. Symptom didn't go away  
3. Symptom was bad  
4. Symptom got worse  
5. Partner or family member suggested it  
6. Advertisement about bowel cancer  
7. Friend diagnosed with cancer  
8. Family history of cancer  
9. Opportunity to talk during doctor visit for other reason  
10. Had check-up or appointment already booked  
11. Other (please specify________________________) |
Q13. What did your doctor do when you mentioned the blood in your bowel movements? (Please circle all that apply)

1. Discussed symptoms
2. Advised to make dietary change e.g. higher fibre diet
3. Told to “wait and see”
4. Digital rectal examination (DRE)/Physical examination
5. Referral to bowel specialist for screening test, e.g. colonoscopy/sigmoidoscopy
6. Sent for test to detect blood in stool/poo, e.g. Faecal Occult Blood Test (FOBT)
7. Blood test
8. Diagnosed with haemorrhoids/piles
9. Diagnosed with bowel-related condition, e.g. Irritable Bowel Syndrome. No further action taken

⇒ Go to Question 15
Q14. What is the main reason you did not seek medical advice about blood in your bowel motions? (Please circle only one response)

1. Thought it wasn’t serious ⇒ Go to Question 14a
2. Cleared up itself ⇒ Go to question 14b
3. Thought it was haemorrhoids/piles ⇒ Go to Question 15
4. Decided to wait and see ⇒ Go to Question 15
5. Seeing doctor would be unpleasant/embarrassing ⇒ Go to Question 15
6. Worried that the doctor might find something serious (scared) ⇒ Go to Question 15
7. Never see doctors/little faith in doctors ⇒ Go to Question 15
8. Thought doctor couldn’t do anything ⇒ Go to Question 15
9. Couldn’t afford doctor visit ⇒ Go to Question 15
10. Did not want to waste doctor’s time ⇒ Go to Question 15
11. Not confident in discussing symptom ⇒ Go to Question 15
12. Doctor difficult to talk to ⇒ Go to Question 15
13. No time/busy/other things to worry about ⇒ Go to Question 15
14. Put it out of my mind – chose not to think about the symptom ⇒ Go to Question 15
15. Difficulty making an appointment ⇒ Go to Question 15
16. Didn’t want to worry family/friends ⇒ Go to Question 15
17. Transport problems ⇒ Go to Question 15
18. Can’t remember ⇒ Go to Question 15
19. Other (please specify_________________________)

Q14a. Which symptom(s) would be serious enough for you to see a doctor? (Please circle all that apply)

a. Black blood
b. Blood in the stool
c. Blood every time I passed bowel movements
d. Lots of blood ⇒ Go to Question 15
Q14b. How long did it take to clear up?  
(Please specify the amount of time)  
<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>a.</td>
<td>_________ Days</td>
<td>b.</td>
<td>_________ Weeks</td>
<td>c.</td>
</tr>
</tbody>
</table>

The following questions are about a change in normal bowel habits

Q15. Have you ever noticed a persistent change in your normal bowel habits that lasted longer than two weeks? This may include looser bowel motion/need for more toilet visits (diarrhoea) or an inability to pass motions (constipation).

1. Yes ⇒ Go to Question 16  
2. No ⇒ Go to Question 15a

Q15a. If you noticed a persistent change in your bowel habits lasting longer than two weeks, how soon would you contact your doctor to make an appointment?

1. Less than 1 week  
2. More than 1 week but less than 4 weeks  
3. More than 4 weeks but less than 8 weeks  
4. More than 8 weeks but less than 12 weeks  
5. More than 3 months but less than 12 months  
6. More than 12 months  
7. Never  
⇒ Go to Question 28

Q16. Have you ever seen a doctor about a persistent change in your normal bowel habits that lasted longer than two weeks?

1. Yes ⇒ Go to Question 17  
2. No ⇒ Go to Question 16a

Q16a. If you noticed a persistent change in your bowel habits lasting longer than two weeks, how soon would you contact your doctor to make an appointment?

1. Less than 1 week  
2. More than 1 week but less than 4 weeks  
3. More than 4 weeks but less than 8 weeks  
4. More than 8 weeks but less than 12 weeks  
5. More than 3 months but less than 12 months  
6. More than 12 months  
7. Never  
⇒ Go to Question 27

Q17. Did you first notice a persistent change in your bowel habits that lasted longer than two weeks in the last 5 years?

1. Yes ⇒ Go to Question 18  
2. No ⇒ Go to Question 17a
Q17a. If you noticed a persistent change in your bowel habits lasting longer than two weeks, how soon would you contact your doctor about it to make an appointment?

1. Less than 1 week
2. More than 1 week but less than 4 weeks
3. More than 4 weeks but less than 8 weeks
4. More than 8 weeks but less than 12 weeks
5. More than 3 months but less than 12 months
6. More than 12 months
7. Never — Go to Question 28

Q18. How long ago did you notice a persistent change in your bowel habits for the first time?
(Please specify the amount of time)

| a. ___________ Days |
| b. ___________ Weeks |
| c. ___________ Months |
| d. ___________ Years |

Q19. What type of irregular bowel movements did you experience?
(Please circle all that apply)

a. Diarrhoea
b. Constipation
c. Other (please specify ____________________)

Q19a. Did you see a doctor about it?

1. Yes
2. No — Go to Question 27

Q20. How long after you first noticed a persistent change in your bowel habits did you see a doctor about it?
(Please specify the amount of time)

| a. ___________ Days |
| b. ___________ Weeks |
| c. ___________ Months |
| d. ___________ Years |
Q21. What is the main reason you did not seek medical advice about a persistent change in your bowel habits sooner?  
(Please circle only one response)

<table>
<thead>
<tr>
<th>Reason</th>
<th>Go to Question 22</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I consulted a doctor within one week</td>
<td></td>
</tr>
<tr>
<td>2. Thought it wasn’t serious</td>
<td></td>
</tr>
<tr>
<td>3. Cleared up itself</td>
<td></td>
</tr>
<tr>
<td>4. Thought it was haemorrhoids/piles</td>
<td></td>
</tr>
<tr>
<td>5. Decided to wait and see</td>
<td></td>
</tr>
<tr>
<td>6. Seeing doctor would be unpleasant/embarrassing</td>
<td></td>
</tr>
<tr>
<td>7. Worried or scared it might be serious</td>
<td></td>
</tr>
<tr>
<td>8. No faith in doctors/Doctor couldn’t do anything</td>
<td></td>
</tr>
<tr>
<td>9. Couldn’t afford doctor visit</td>
<td></td>
</tr>
<tr>
<td>10. Did not want to waste doctor’s time</td>
<td></td>
</tr>
<tr>
<td>11. Not confident in discussing symptom/Doctor hard to talk to</td>
<td></td>
</tr>
<tr>
<td>12. No time/busy/other things to think about</td>
<td></td>
</tr>
<tr>
<td>13. Difficulty making an appointment or getting transport</td>
<td></td>
</tr>
<tr>
<td>14. Didn’t want to worry family/friends</td>
<td></td>
</tr>
<tr>
<td>15. Can’t remember</td>
<td></td>
</tr>
<tr>
<td>16. Other (please specify ______________________)</td>
<td></td>
</tr>
</tbody>
</table>

Q21a. How long did it take to clear up?  
(Please specify the amount of time)

<table>
<thead>
<tr>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. _____ Days</td>
</tr>
<tr>
<td>b. _____ Weeks</td>
</tr>
<tr>
<td>c. _____ Months</td>
</tr>
<tr>
<td>d. _____ Years</td>
</tr>
</tbody>
</table>

Q22. How long did the change in bowel habits persist?  
(Please specify the amount of time)

<table>
<thead>
<tr>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. _____ Days</td>
</tr>
<tr>
<td>b. _____ Weeks</td>
</tr>
<tr>
<td>c. _____ Months</td>
</tr>
<tr>
<td>d. _____ Years</td>
</tr>
</tbody>
</table>
| Q23. Please rate how uncomfortable or painful this diarrhoea/constipation was. | 1. **No discomfort**  
2. **Mild discomfort**  
3. **Mild pain**  
4. **Moderate pain**  
5. **Intense pain** |
|---|---|
| Q24. How often did you experience diarrhoea/constipation when passing bowel motion? | 1. **Every time**  
2. **More than half of the time but not all the time**  
3. **About half of the time**  
4. **Less than half the time but more than once**  
5. **Only once**  
6. **Not sure** |
| Q25. What in particular prompted you to consult a doctor about a persistent change in your bowel habits? | 1. **Thought the symptom was serious**  
2. **Symptom didn't go away**  
3. **Symptom was bad**  
4. **Symptom got worse**  
5. **Partner or family member suggested it**  
6. **Advertisement about bowel cancer**  
7. **Friend diagnosed with cancer**  
8. **Family history of cancer**  
9. **Opportunity to talk during doctor visit for other reason**  
10. **Had check-up or appointment already booked**  
11. **Other (please specify ______________________)** |
| Q26. What did your doctor do when you mentioned a persistent change in your bowel habits? | a. **Discussed symptoms**  
b. **Advised to make dietary change e.g. higher fibre diet**  
c. **Told to “wait and see”**  
d. **Digital rectal examination (DRE)/Physical examination**  
e. **Referral to bowel specialist for screening test, e.g. colonoscopy/sigmoidoscopy**  
f. **Sent for test to detect blood in stool/poo, e.g. Faecal Occult Blood Test (FOBT)**  
g. **Blood test**  
h. **Diagnosed with Haemorrhoids/piles**  
i. **Diagnosed with bowel related condition e.g. Irritable Bowel Syndrome. No further action taken.** |

⇒ Go to Question 28
Q27. What is the main reason you did not seek medical advice about a persistent change in your bowel habits? 
(Please circle only one response)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Thought it wasn't serious ⇝ Go to Question 28</td>
</tr>
<tr>
<td>2.</td>
<td>Cleared up itself ⇝ Go to Question 27a</td>
</tr>
<tr>
<td>3.</td>
<td>Thought it was haemorrhoids/piles ⇝ Go to Question 28</td>
</tr>
<tr>
<td>4.</td>
<td>Decided to wait and see ⇝ Go to Question 28</td>
</tr>
<tr>
<td>5.</td>
<td>Seeing doctor would be unpleasant/embarrassing ⇝ Go to Question 28</td>
</tr>
<tr>
<td>6.</td>
<td>Worried that the doctor might find something serious (scared) ⇝ Go to Question 28</td>
</tr>
<tr>
<td>7.</td>
<td>Never see doctors/little faith in doctors ⇝ Go to Question 28</td>
</tr>
<tr>
<td>8.</td>
<td>Thought doctor couldn't do anything ⇝ Go to Question 28</td>
</tr>
<tr>
<td>9.</td>
<td>Couldn't afford doctor visit ⇝ Go to Question 28</td>
</tr>
<tr>
<td>10.</td>
<td>Did not want to waste doctor's time ⇝ Go to Question 28</td>
</tr>
<tr>
<td>11.</td>
<td>Not confident in discussing symptom ⇝ Go to Question 28</td>
</tr>
<tr>
<td>12.</td>
<td>Doctor difficult to talk to ⇝ Go to Question 28</td>
</tr>
<tr>
<td>13.</td>
<td>No time/busy/other things to worry about ⇝ Go to Question 28</td>
</tr>
<tr>
<td>14.</td>
<td>Put it out of my mind — chose not to think about the symptom ⇝ Go to Question 28</td>
</tr>
<tr>
<td>15.</td>
<td>Difficulty making an appointment ⇝ Go to Question 28</td>
</tr>
<tr>
<td>16.</td>
<td>Didn't want to worry family/friends ⇝ Go to Question 28</td>
</tr>
<tr>
<td>17.</td>
<td>Transport problems ⇝ Go to Question 28</td>
</tr>
<tr>
<td>18.</td>
<td>Can't remember ⇝ Go to Question 28</td>
</tr>
<tr>
<td>19.</td>
<td>Other (please specify) ____________________________</td>
</tr>
</tbody>
</table>

Q27a. How long did it take to clear up? 
(Please specify the amount of time)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>a.</td>
<td>________ Days</td>
</tr>
<tr>
<td>b.</td>
<td>________ Weeks</td>
</tr>
<tr>
<td>c.</td>
<td>________ Months</td>
</tr>
<tr>
<td>d.</td>
<td>________ Years</td>
</tr>
</tbody>
</table>
Q28. If you noticed any of the following, how soon would you contact your doctor to make an appointment? Record the answer to each question that best applies to you by circling:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Less than a week</th>
<th>More than 1 week but less than 4 weeks</th>
<th>More than 4 weeks but less than 8 weeks</th>
<th>More than 8 weeks but less than 12 weeks</th>
<th>More than 3 months but less than 12 months</th>
<th>More than 12 months</th>
<th>Never</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Unexplained weight loss</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>b. Unexplained tiredness or weakness</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>c. Abdominal pain</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>d. Loss of appetite</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
</tbody>
</table>

The following questions are about appropriate bowel cancer screening

The following questions are about whether any of your relatives have been diagnosed with bowel cancer. Bowel cancer, also called colorectal cancer, is cancer in the large bowel or large intestine. It includes both colon and rectal cancer but not anal cancer.

Q29. How many of your close relatives (mother, father, brother, sister or child) have ever been diagnosed with bowel cancer?

a. None ☐ Go to Question 31
b. One

c. Two

d. Three or more

Q30. How many of these relative(s) were diagnosed at the following ages? (Please write number of relatives diagnosed in each age category)

1. ____50 or less
2. ____Between 51 and 55
3. ____56 or over
4. ____Don’t know
### Q31. Have any of your second-degree relatives (grandparents, uncles, aunts, nephews, nieces or half-siblings) ever been diagnosed with bowel cancer? This includes only biological/blood relatives, not those related to you through marriage. (Please select all that apply)

- a. None of these relatives have ever been diagnosed with bowel cancer ⇒ Go to Question 33
- b. Yes, mother’s mother
- c. Yes, father’s mother
- d. Yes, mother’s father
- e. Yes, father’s father
- f. Yes, mother’s sister
- g. Yes, father’s sister
- h. Yes, mother’s brother
- i. Yes, father’s brother
- j. Yes, nephew
- k. Yes, niece
- l. Yes, grandchild
- m. Yes, half-sibling (mother’s side)
- n. Yes, half-sibling (father’s side)

### Q32. How many of these relatives were diagnosed at the following ages? (Please write number of relatives diagnosed in each age category)

1. ____ 50 or less
2. ____ Between 51 and 55
3. ____ 56 or over
4. ____ Don’t know

### Q33. Has your mother, father, brother, sister, child, grandparent, uncle, aunt, nephew, niece or half-sibling ever been diagnosed with any of the following cancers: endometrium, ovary, stomach, renal pelvis, ureter, biliary tract or brain.

1. Yes
2. No
3. Don’t know

The next questions are about screening tests you may have had for bowel cancer.

### Q34. Have you ever had an FOBT, FIT or iFOBT? These tests – faecal occult blood test (FOBT), faecal immunochemical test (FIT) and immunochromatographic faecal occult blood test (iFOBT) – involve you providing samples of faeces or poo. The samples would have been sent to a laboratory to test for tiny amounts of blood.

1. Yes
2. No ⇒ Go to Question 37
3. Not Sure ⇒ Go to Question 37
| **Q35. How long ago was your last FOBT, FIT or iFOBT?** | 1. Less than a month ago  
2. One month to less than twelve months ago  
3. Twelve months to less than two years ago  
4. Two years to less than five years ago  
5. Five years or longer ago  
6. Don't know/not sure |
|---|---|
| **Q36. Did you have your last FOBT, FIT or iFOBT because you had a symptom?** | 1. Yes  
2. No |
| **Q37. Have you ever had a colonoscopy? This is usually a day procedure in hospital where the inside of your colon is examined while you are sedated.** | 1. Yes  
2. No ⇒ Go to Question 40  
3. Not Sure ⇒ Go to Question 40 |
| **Q38. How long ago was your most recent colonoscopy?** | 1. Less than a month ago  
2. One month to less than twelve months ago  
3. Twelve months to less than two years ago  
4. Two years to less than five years ago  
5. Five years or longer ago  
6. Don't know/not sure |
| **Q39. Did you have your most recent colonoscopy because you had a symptom?** | 1. Yes  
2. No |
| **Q40. Have you ever had a sigmoidoscopy? In this procedure only the rectum and lower part of the colon are examined. This is a short procedure which lasts about 5-10 minutes. Sedation is not usually required and you can usually go home straight after the procedure.** | 1. Yes  
2. No ⇒ Go to Question 43  
3. Not sure ⇒ Go to Question 43 |
| **Q41. How long ago was your most recent sigmoidoscopy?** | 1. Less than a month ago  
2. One month to less than twelve months ago  
3. Twelve months to less than two years ago  
4. Two years to less than five years ago  
5. Five years or longer ago |
| **Q42. Did you have your most recent sigmoidoscopy because you had a symptom?** | 1. Yes  
2. No |
**The following questions ask about risk**

You may or may not be aware that an individual's risk of developing bowel cancer increases with the number of relatives diagnosed in a family. Sometimes doctors may ask questions about your family history of colorectal cancer and give advice on screening for you and your relatives.

| Q43. Has any health professional, e.g. your doctor, ever asked if you have a family history of bowel cancer? | 1. Yes  
2. No ☞ Go to Question 45 |
|---|---|
| Q44. Did this person discuss whether there was a possible "increased risk" of bowel cancer for you or your family members? | 1. Yes  
2. No |
| Q45. Has any health professional suggested that you or your relatives should do any of the following:  
*Please choose all that apply.* | a. Start having screening tests for bowel cancer  
b. Talk to their doctor about screening tests  
c. No advice has ever been given  
d. Take other action related to bowel cancer  
(please specify __________________________) |

**The following questions ask about internet use.**

We are interested in finding out whether people of various ages would be interested in answering surveys over the internet.

| Q46. Do you use the internet?  
 *(Please circle all that apply)* | a. Yes, at home  
b. Yes, at work  
c. Yes, at library or café  
d. No, not at all |
| Q47. Do you have access to email?  
 *(Please circle all that apply)* | a. Yes, at home  
b. Yes, at work  
c. Yes, at library or café  
d. No, not at all |
If you have any questions, concerns or worries about cancer after doing this survey, we encourage you to discuss matters with your doctor or contact the Cancer Council Helpline, on 13 11 20.

You have now finished this survey.
Thank you for your time.

Please return the completed questionnaire to the Hunter Community Study in the reply-paid envelope provided.
Appendices for Victorian Cancer Registry Study

(study materials for Paper Four)
Appendix F: Ethics approval, University of Newcastle

HUMAN RESEARCH ETHICS COMMITTEE

Notification of Expedited Approval

To Chief Investigator or Project Supervisor:  
Professor Robert Sanson-Fisher

Cc Co-investigators / Research Students:  
Professor Finlay Macrae  
Professor David Hill  
Professor Robert Thomas  
Professor Catherine D'Este  
Dr Christine Paul  
Associate Professor Chris Doran

Re Protocol:  
Increasing appropriate screening for colorectal cancer patients and their first degree relatives: A randomised controlled trial

Date:  
23-Apr-2008

Reference No:  
H-2008-0047

Thank you for your Response to Conditional Approval submission to the Human Research Ethics Committee (HREC) seeking approval in relation to the above protocol.

Your submission was considered under Expedited review by the Chair/Deputy Chair.

I am pleased to advise that the decision on your submission is Approved effective 22-Apr-2008.

The full Committee will be asked to ratify this decision at its next scheduled meeting whereupon a formal Certificate of Approval will be issued. In the interim your approval number is H-2008-0047.

If the research requires the use of an Information Statement, ensure this number is inserted at the relevant point in the Complaints paragraph prior to distribution to potential participants.
You may then proceed with the research. Best wishes for a successful project.

Professor Val Robertson
Chair, Human Research Ethics Committee

For communications and enquiries:
Ms Ruth Gibbins
Human Research Ethics Officer

Research Services
Research Office
The University of Newcastle
Callaghan NSW 2308
T +61 2 492 16333
F +61 2 492 17164
Ruth.Gibbins@newcastle.edu.au

Funding Details

<table>
<thead>
<tr>
<th>Funding body</th>
<th>Funding project title</th>
<th>First named investigator</th>
<th>Administering institution</th>
<th>Uni of Newc G Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHMRC</td>
<td>Increasing appropriate screening...</td>
<td>Prof R Sanson-Fisher</td>
<td>University of Newcastle</td>
<td>G0187633</td>
</tr>
</tbody>
</table>
Appendix G: Ethics approval, Cancer Council Victoria

Human Research Ethics Committee

10 July 2008

Professor Robert Sanson-Fisher
University of Newcastle
School of Medicine and Public Health
Room 256 David Maddison Building
Cnr King and Watt Streets
NEWCASTLE NSW 2300

Re: Increasing appropriate screening for colorectal cancer patients and their first degree relatives. A randomised controlled trial.
Project No: HREC 0810

Thank you for your letter of 12 June 2008. The Acting Chair of The Cancer Council Victoria’s Human Research Ethics Committee has considered your responses to the queries raised at the meeting held on 13 May 2008. I am pleased to advise that final ethical approval has been granted. This approval is valid until 31 December 2013, being the anticipated date of completion. Should the study not be complete by this date, please submit a request for extension.

In accordance with the National Statement on Ethical Conduct in Human Research, I would be grateful if you could advise the Human Research Ethics Committee of any changes to the protocol during the course of the study, or if the study is discontinued before the anticipated date of completion. You should also notify the Committee immediately of any adverse effects on participants or unforeseen events.

Please note that you are required to provide an annual report in respect of progress of the research, maintenance and security of records, compliance with protocol and any conditions of approval. I will write to you again closer to the time when this report is due.

Yours sincerely

Woody Macpherson
Head, Research Management Unit

CC: Prof David Hill AM
    Prof Graham Giles

Please quote Project No. for all correspondence

The Cancer Council Victoria
1 Bartra Avenue
Blacktown NSW 2148 Australia
Telephone: 02 8888 3000
Facsimile: 02 8888 3178
enquiries@cancervic.org.au
Appendix H: Invitation letters
Appendix H: Invitation letter 1

<Department Name> <Department Name>
<Department Address>
<Department Suburb/City>
<Department State> <Department Postcode>

Dear <FDR Title> <FDR Surname>,

We are trying to find better ways to help families of people with bowel cancer reduce their risk of this disease. The bowel cancer screening tests that you should have will depend on your personal medical history. So we would like to ask you a few questions by phone to find out what sort of bowel cancer information is best suited to you.

As you may know, your relative <IC Name> <IC Surname> has been diagnosed with bowel cancer. We are writing to you with <IC First Name>'s permission. We would like to phone you to ask you a few questions. Your answers to these will help us to provide you with information on bowel cancer screening that is relevant to you. If you are willing to be contacted, please phone the study co-ordinator to give your phone number. She is contactable by phone on 0395 350 350 or email Jody.Simmons@cancervic.org.au. If emailing or leaving a phone message, please provide your name, phone number and the ID number which is listed on the top of this sheet.

How can you help to improve healthcare for family members of people with bowel cancer?
In addition to providing you with information, we would also like to invite you to take part in a study we are conducting to improve bowel cancer care. The study will help us to understand the healthcare needs of family members of people with bowel cancer. It will also help us to determine the best ways to provide them with information about screening for bowel cancer to improve results of treatment for bowel cancer. We have enclosed an information sheet about the study.

What are we asking of you?
Please read the enclosed information sheet. When we phone you to find out what sort of information is suited to you, we will also ask if you are interested in participating in the study. It is your choice whether or not to take part in the study. We will not inform your relative of your decision to participate (That is left up to you).

If you have any questions about the study, please call the study coordinator, Jody Simmons, on 0306 350 350.

We hope that you will agree to be part of this project to help reduce bowel cancer in our community. Thank you for taking the time to read this letter.

Kind regards

David Hill AO PhD
Director
Cancer Council Victoria

Cancer Council
Victoria
ADN: 01 420 368 735
1 Kambaloe Street
Carlton Victoria 3053
Australia
T: +61 3 9655 5000
F: +61 3 9655 5270
E: support@cancervic.org.au

Cancer Council
Helpline 13 11 19
www.cancervic.org.au

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Appendix H: Invitation letter 2

Dear FDR Name, FDR Surname,

We are trying to find better ways to help families of people with bowel cancer reduce their risk of this disease. The bowel cancer screening tests that you should have will depend on your personal medical history. So we would like to ask you a few questions by phone to find out what sort of bowel cancer information is best suited to you.

As you may know, your relative <IC Name> <IC Surname> has been diagnosed with bowel cancer. We are writing to you with <IC First Name>’s permission. Your relative has provided the following number for us to contact you on <FDR Phone number>. We will phone you in two weeks’ time to ask you a few questions. Your answers to these questions will help us to provide you with information on bowel cancer screening that is relevant to you. If you don’t want us to contact you, please return the “Do not contact” form attached.

How can you help to improve healthcare for family members of people with bowel cancer?

In addition to providing you with information, we would also like to invite you to take part in a study we are conducting to improve bowel cancer care. The study will help us to understand the healthcare needs of family members of people with bowel cancer. It will also help us to determine the best ways to provide them with information about screening for bowel cancer to improve results of treatment for bowel cancer. We have enclosed an information sheet about the study.

What are we asking of you?

Please read the enclosed information sheet. When we phone you to find out what sort of information is suited to you, we will also ask if you are interested in participating in the study. It is your choice whether or not to take part in the study. We will not inform your relative of your decision to participate. (That is left up to you.)

If you have any questions about the study, please call the study coordinator, Jody Simmons, on 03 96 355 350.

We hope that you will agree to be part of this project to help reduce bowel cancer in our community. Thank you for taking the time to read this letter.

Kind regards

David Hill AO PhD
Director
Cancer Council Victoria
Appendix I: First-degree Relative Information Statement

First-degree Relative Information Statement

Project: Increasing appropriate screening for bowel cancer patients and their first-degree relatives: A randomised controlled trial

You are invited to take part in a research project which is being led by Professor David Hill of the Cancer Council Victoria and Professor Rob Sanson-Fisher from the School of Medicine and Public Health at the University of Newcastle. Some of the information collected in this study will form part of Mr Ryan Courtney’s PhD studies.

Why is the research being done?
The purpose of this research is to improve the follow-up care of people with bowel cancer and improve screening for bowel cancer in their relatives. This study will compare two kinds of follow-up programs to see which one is better at improving follow-up and screening. We hope this will lead to a better screening system in Victoria.

Who can participate in the research?
People who are aged 18 years or older and have had bowel cancer in the past 10 months can take part in this study. Their close relatives (parents, brothers, sisters and children) who are aged 18 years or older can also take part. Your name, contact details and approval to contact you was given to us by <insert index case name> who has recently been diagnosed with bowel cancer.

What choice do you have?
Taking part in this research is completely your choice. Only people who agree to take part and sign the consent form will be included in the study. Your choice to take part or not to take part will not affect the care you get from your doctor. If you do decide to take part, you may pull out of the study at any time without giving a reason. You can also withdraw any information which identifies you.

What would you be asked to do?
If you agree, we will ask you to answer some questions about your health by phone. This will help us to work out what sort of information about bowel cancer we should send to you. It will also tell us whether the screening programs we are testing in the study will be suitable for you. If they are, we will ask you if you would like to participate in the main study. If you agree to take part you will be asked to complete a phone interview. The interview will include questions about your knowledge of bowel cancer screening and about any bowel cancer tests you have had. Questions related to your general health will also be asked.

Together, you and any members of your family who take part will have an equal chance of being in either of the two follow-up programs. If you are placed in Group 1 we will send you information about screening (testing people without symptoms) for bowel cancer, and advice about talking to your general practitioner. You can also ring the Cancer Council Helpline if you have questions.

If you are placed in Group 2, we will send you detailed information about your risk of getting bowel cancer and the types of screening tests you can have. We will also ask your permission to contact your general practitioner to give them information on bowel cancer screening.
People in both Group 1 and in Group 2 will be asked to complete a paper and pencil survey 12, 24 and 36 months later. These surveys will ask about your health and whether you have had bowel cancer screening tests in the past 12 months. If you have had screening tests, we will ask if we can contact your doctor to find out the results.

**How much time will it take?**
The first interview will take about 20 minutes to complete. The three follow-up surveys after 12, 24, and 36 months will each take about 15 minutes to complete.

**What are the risks and benefits of participating?**
Having the latest information about screening may help you make decisions about your healthcare. There is increasing evidence that having the right screening leads to better health outcomes. It is not expected that you will be exposed to any risks by taking part in this study.

Your help with the study could help others get better follow-up and screening for bowel cancer in the future.

**How will your privacy be protected?**
All information about you and your family members, including any information from your doctors, will be kept in a secure, locked filing cabinet and as password-secured computer files. When we write reports about the study, only group data will be given, and no individuals will be identified. Therefore, you can be sure that any information that you or your family members give to our staff, which identifies you, will be kept totally confidential and used only for this research. Electronic records of any information you give us will be kept as password-protected files on a password-secured server. Paper files will be kept in a locked cabinet. Information which identifies you will be removed after the research is finished. Other information will be kept for at least 5 years to allow enough time for any publications resulting from this research to be finalised. De-identified data files may be stored for longer in archived form if additional publications are required after 5 years. You have the right to check and correct any information we have collected about you during the study (e.g. via the phone interview and check of doctors’ records).

**How will the information collected be used?**
At the end of the study, we look at which of the two groups’ follow-up programs was better at improving follow-up and screening for people with bowel cancer and their family members. The results will be reported in journal articles. A report on the findings will be on http://www.newcastle.edu.au/research-centre/health-behaviour/ for you to read. All your personal information will be kept confidential.

**What do you need to do to participate?**
Please let us know whether you would like to take part in the study by circling “Yes” or “No” on the consent form and returning it to us in the reply-paid envelope. If your relative has given us your phone number and we haven’t heard from you within two weeks, we will phone you to ask if you want to participate.

**Further information**
If you would like further information please contact the Study Co-ordinator, Jody Simmons, on 0396 355 356.

Thank you for considering this invitation.

Your time is very much appreciated.
Kind regards,

David Hill AO PhD Director
Cancer Council
Victoria

Complaints about this research
This project has been approved by the University of Newcastle Human Research Ethics Committee, Approval No. H-2008-0047, and the Cancer Council Victoria Research Ethics Committee, Approval No. 0810. Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to the Human Research Ethics Officer, Research Office, The Chancellery, The University of Newcastle, University Drive, Callaghan NSW 2308, Australia, telephone (02) 49216333, email Human- Ethics@newcastle.edu.au.

The research team
Professor Rob Sanson-Fisher, Professor Catherine D'Este, Dr Mariko Carey, Dr Chris Paul and Mr Ryan Courtney (PhD candidate), School of Medicine and Public Health, University of Newcastle
Professor Finlay Macrae, Department of Colorectal Medicine and Genetics, The Royal Melbourne Hospital
Professor David Hill, Cancer Council Victoria
Associate Professor Christopher Doran, Centre for Burden of Disease and Cost Effectiveness, University of Queensland
Professor Robert Thomas, Director of Surgical Oncology, Peter MacCallum Cancer Centre

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APPENDIX J: Consent form

Consent form

Project: Increasing appropriate screening for bowel cancer patients and their first-degree relatives: A randomised controlled trial

Researchers: Professor Rob Sanson-Fisher, Professor Finlay Macrae, Professor David Hill, Professor Catherine D’Este, Associate Professor Christopher Doran, Professor Robert Thomas, Dr Mariko Carey, Dr Chris Paul, Mr Ryan Courtney

I understand that the project will be conducted as described in the Information Statement, and I have kept a copy.

I understand that participation in this study will involve completing a questionnaire in the next few weeks and after 6, 12 and 36 months, and receiving educational material.

I understand I can withdraw from the project at any time and do not have to give any reason for withdrawing.

I understand that my personal information will remain confidential to the researchers.

I have had the opportunity to have questions answered to my satisfaction.

I agree to participate in the above research project and give my consent freely: Yes/No

Print Name: ___________________________________
Signature: ____________________________________Date: _______________
Please provide your contact details below.

Correct name and address details:

Name
Postal Address
Suburb  Postcode

<table>
<thead>
<tr>
<th>Contact telephone numbers</th>
<th>Best time to contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Home  Day</td>
<td>Hours AM  Hours PM</td>
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<tr>
<td>Mobile</td>
<td>Monday</td>
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<td>Work</td>
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<td>Friday</td>
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We also ask that you nominate an alternative contact person in case we are unable to reach you on the telephone numbers provided. (Please check with the person that is okay to give their details to us). If you would rather not nominate an alternative contact person that is okay.

Alternative Contact Person:
_____________________________________________________________________

Their Relationship to You:
_____________________________________________________________________

Contact Phone Number:
_____________________________________________________________________
Appendix K: Computer-assisted telephone interview script

First-degree relatives – screening computer-assisted telephone interview script

Good morning/afternoon. I am (interviewer name) from the Cancer Council Victoria. May I speak with (participant name), please?
(If participant not available, organise time to call back.)
We wrote to you recently with the permission of your relative, (insert name). They are participating in a study to improve bowel cancer care. As a family member of someone with bowel cancer, you may have an increased risk of developing bowel cancer. We would like to provide you with some information about screening for bowel cancer.

Module 1: Consent for screening questions

First, I would like to ask you a few questions about your health. This is necessary to ensure that any information we give you is appropriate. All information you give us will be kept private.

Is it OK for me to ask you these questions?
If no, thank the person for their time. (Provide details of the Cancer Helpline if they would like to find out information about bowel cancer screening at some time in the future.)

Exit survey
If yes:
That's great. Is now convenient, or should I call back another time. (Book a time to ring back if, appropriate.)

Module 2: Screening questions

1. Have you ever been diagnosed with bowel cancer?
   □ Yes
   □ No
2. Advanced adenoma or suspected familial adenomatous polyposis (FAP) occurs when three or more non-cancerous growths that look like small spots are found on the lining of the bowel. It can also occur when one large non-cancerous growth of at least 10mm with unusual cells is found on your bowel. Have you ever been told by a doctor that you have advanced adenoma or FAP?

- □ 1 Yes
- □ 2 No
- □ 3 Not sure

3. Ulcerative colitis, Crohn’s disease and inflammatory bowel disease are conditions where inflammation of the bowel wall can cause abdominal pain. Have you ever been told that you have ulcerative colitis, Crohn’s disease or inflammatory bowel disease?

- □ 1 Yes Go to 4
- □ 2 No Skip 4
- □ 3 Not sure Skip 4

4. Which condition do you have?

- □ 1 Ulcerative colitis
- □ 2 Inflammatory bowel disease
- □ 3 Crohn’s disease

*If the person has answered “yes” to any of the above conditions:*
Thank you for answering those questions. Because you have (insert condition), the follow-up programs that we will be testing in the study we are conducting will not be suitable for you. We would like to send you some information that may be helpful to you. It’s recommended that you see your doctor to discuss what sort of care may be suitable for you.

*If needed:* Can you please give me your address so that we can post the information to you?

*Record details*

*Exit survey*

*If the person answered “no” to all of the above screening questions:*
Thank you very much for answering those questions. We would like to send you some information about bowel cancer screening that may be helpful to you. We
recommend that you discuss what sort of screening may be suitable for you with your doctor.

If needed: Can you please give me your address so that we can post the information to you?

Record details

**Module 3: Consent for larger study**

You would have seen from the information we sent you, that we are conducting a study to improve outcomes of possible bowel cancer among relatives of people with bowel cancer. Did you get a chance to read the information?

If no: It would be great if you could read the information. There's a consent form attached where you can indicate whether you want to participate in the study. If you could send that back to us in the envelope provided, that would be great. If we haven't heard from you in two weeks, would it be OK for me to phone you again to remind you?

If yes: That's great. Would you be interested in participating in the study?

If no: That's fine. Thank you so much for your time today. I'll send you the information on bowel cancer screening.

Exit survey

If person wants to participate: That's great. The first interview doesn't take long – only about 20 minutes. Would you like to do that now?

If no: book a time to reschedule. Remind the person to send back the consent form if they haven't done so.

If yes: That's great. If the person, hasn't sent back their consent form: Your verbal consent to do the interview will be fine for this first interview. However, we will need a copy of your consent form to be sent back to cover your participation in the rest of the study. I'll give you a call to remind you if I haven't received it in the next two weeks.
OK, let’s begin the interview.

Go to Module 4.

**Module 4. Knowledge about bowel cancer**

This section asks about your knowledge of bowel cancer, and whether you have discussed bowel cancer with your doctor.

Please pick the answer that best describes you.

1. **When did you first become aware that having a family history of bowel cancer increases a person's risk of developing bowel cancer?** Read out response options
   - □ 1. Less than a month ago
   - □ 2. One month to less than 12 months ago
   - □ 3. 12 months to less than 2 years ago
   - □ 4. 2 years to less than 5 years ago
   - □ 5. 5 years or longer ago
   - □ 6. Don’t know that family history increases risk

2. **What first alerted you that family history of bowel cancer increases a person's risk of developing bowel cancer?** Read out response options
   - □ 1. The letter I received from the Cancer Council
   - □ 2. A member of my family was diagnosed with bowel cancer
   - □ 3. Information from the TV, radio or newspaper
   - □ 4. My doctor discussed the risk of bowel cancer with me
   - □ 6. Other. Please specify_____________________________________________________
   - □ 7. Don’t know/Not sure

3. **Has a doctor or other health professional ever asked you about your family history of bowel cancer?** Read out response options
   - □ 1. Yes Go to 4
   - □ 2. No Go to Module 5
   - □ 3. Don’t know/Not sure Go to Module 5
4. What sort of doctor or health professional was this? Read out response options
- □ 1 General practitioner
- □ 2 Cancer specialist
- □ 3 Genetic counsellor
- □ 4 Other. Please specify __________________________________________

5. How long ago was it that the doctor or other health professional asked you about your family history? Read out response options
- □ 1 Less than a month ago
- □ 2 One month to less than 12 months ago
- □ 3 12 months to less than 2 years ago
- □ 4 2 years to less than 5 years ago
- □ 5 5 years or longer ago
- □ 6 Don’t know/Not sure

6. How many times have you consulted that health professional about family history of bowel cancer/ screening for bowel cancer?
Record response

Module 5. Bowel cancer screening

Now I’d like to ask about any screening tests that you may have had for bowel cancer. Whether the tests are appropriate for you will depend on your age and family history.

Faecal occult blood test (FOBT), faecal immunochemical test (FIT) or immunochemical faecal occult blood test (iFOBT). For any of these tests you would have been asked to provide samples of faeces or poo. The samples would have been tested for tiny amounts of blood. Certain foods and medications can affect some of these tests. So you may have been asked not to eat red meats or large amounts of vitamin C in the days before having the test.
1. Have you *ever* had an FOBT, FIT or iFOBT?

- [ ] Yes  
  Please go to question 2
- [ ] No  
  Please go to question 5
- [ ] Not sure  
  Please go to question 5

2. How many FOBT, FIT or iFOBT tests have you had?

3. How long ago was your last FOBT, FIT or iFOBT?

- [ ] Less than a month ago
- [ ] One month to less than 12 months ago
- [ ] 12 months to less than 2 years ago
- [ ] 2 years to less than 5 years
- [ ] 5 years or longer ago
- [ ] Don’t know/Not sure

4. What was the main reason you had your last FOBT, FIT or iFOBT? *Please select only one.*

- [ ] My general practitioner recommended it
- [ ] I had symptoms that I was concerned about
- [ ] A member of my family was diagnosed with bowel cancer
- [ ] I like to keep up to date with health checks relevant to me
- [ ] It was suggested in the information I received from the Cancer Council
- [ ] I received an invitation from the National Bowel Cancer Screening Program
- [ ] Other. Please specify ____________________

5. Do you intend to have an FOBT, FIT or iFOBT in the next 12 months?

- [ ] Yes
- [ ] No
- [ ] Not sure

*Colonoscopy.* This is usually a day procedure in hospital where the inside of your colon is examined while you are sedated.
6. Have you _ever_ had a colonoscopy?

☐ 1. Yes  
☐ 2. No  
☐ 3. Not sure

   Please go to question 11

   Please go to question 15

7. How many colonoscopies have you had?

___________

8. How long ago was your _most recent_ colonoscopy?

☐ 1. Less than a month ago
☐ 2. One month to less than 12 months ago
☐ 3. 12 months to less than 2 years ago
☐ 4. 2 years to less than 5 years ago
☐ 5. 5 years or longer ago
☐ 6. Don’t know/Not sure

9. What was the _main_ reason you had your _most recent_ colonoscopy?  
   (Please select only one)

☐ 1. My general practitioner recommended it
☐ 2. I had symptoms that I was concerned about
☐ 3. A member of my family was diagnosed with bowel cancer
☐ 4. I like to keep up to date with health checks relevant to me
☐ 5. It was suggested in the information I received from the Cancer Council
☐ 6. Other, please specify

10. Did you have any days off work or days when you could not do your usual activities due to your _most recent_ colonoscopy?

☐ 1. No
☐ 2. Yes, 1 day
☐ 3. Yes, 2-3 days
☐ 4. Yes, 4-7 days
☐ 5. Yes, more than a week.
11. Are you planning to have a colonoscopy within the next 12 months?

☐ 1 Yes
☐ 2 No
☐ 3 Not sure

**Sigmoidoscopy.** In this procedure only the rectum and lower part of the colon are examined. This is a short procedure which lasts about 5-10 minutes. Sedation is not usually required and you can usually go straight home after the procedure.

12. Have you ever had a sigmoidoscopy?

☐ 1 Yes Please go to question 17
☐ 2 No Please go to question 21
☐ 3 Not sure Please go to question 21

13. How many sigmoidoscopies have you had?

_____________________

14. How long ago was your most recent sigmoidoscopy?

☐ 1 Less than a month ago
☐ 2 One month to less than 12 months ago
☐ 3 12 months to less than 2 years ago
☐ 4 2 years to less than 5 years ago
☐ 5 5 years or longer ago

15. What was the main reason you had your most recent sigmoidoscopy?

☐ 1 My general practitioner recommended it
☐ 2 I had symptoms that I was concerned about
☐ 3 A member of my family was diagnosed with bowel cancer
☐ 4 I like to keep up to date with health checks relevant to me
☐ 5 It was suggested in the information I received from the Cancer Council
☐ 6 Other. Please specify
16. Did you have any days off work or days when you could not do your usual activities due to your most recent sigmoidoscopy?

☐ 1. No
☐ 2. Yes, 1 day
☐ 3. Yes, 2-3 days
☐ 4. Yes, 3-7 days
☐ 5. Yes, more than a week

17. Are you planning to have a sigmoidoscopy in the next 12 months?

☐ 1. Yes
☐ 2. No
☐ 3. Not sure

18. How would you rate your level of worry about getting bowel cancer?

☐ 1. Not at all worried
☐ 2. Slightly worried
☐ 3. Somewhat worried
☐ 4. Very worried
☐ 5. Extremely worried

19. Have you consulted a non-medical healthcare practitioner at any time over the last 12 months, because you were worried about your risk of developing bowel cancer? If necessary, prompt that chiropractors, dieticians, naturopaths, acupuncturists, counsellors and herbalists are all non-medical practitioners.

☐ 1. Yes
☐ 2. No Go to module 6

20. Which, if any, of the following practitioners have you consulted in the last 12 months because you were worried about bowel cancer?

*Code all that apply. If the respondent has seen one of the practitioners listed, prompt for number of times consulted in last 12 months.*

☐ 1. Herbalist No. of times consulted
☐ 2. Dietician No. of times consulted
☐ 3. Acupuncturist No. of times consulted
Module 6. Your health state

Please select from the statements I read out which best describes your own health today.

1. Mobility
   - I have no problems in walking around
   - I have some problems in walking around
   - I am confined to bed

2. Personal care
   - I have no problems with personal care
   - I have some problems washing or dressing myself
   - I am unable to wash or dress myself

3. Usual activities (e.g. work, study, housework, family or leisure activities)
   - I have no problems with performing my usual activities
   - I have some problems with performing my usual activities
   - I am unable to perform my usual activities

4. Pain/Discomfort
   - I have no pain or discomfort
   - I have moderate pain or discomfort
   - I have extreme pain or discomfort

5. Anxiety/Depression
   - I am not anxious or depressed
   - I am moderately anxious or depressed
   - I am extremely anxious or depressed
To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by choosing a number from 0 to 100, describing how good or bad your health state is today.

*Record response*
Module 7. Your background

The following questions are about you and your background.

1. How old are you?
   __________ years

2. Record gender
   ☐ 1 Male
   ☐ 2 Female

3. Were you born in Australia?
   ☐ 1 Yes
   ☐ 2 No
   ☐ 3 Don’t know

4. What is the highest level of schooling you have completed? Please choose one answer from the following.
   ☐ 1 University degree
   ☐ 2 TAFE or trade certificate or diploma
   ☐ 3 Year 12 or Higher School Certificate
   ☐ 4 Year 10 or School Certificate
   ☐ 5 Primary school
   ☐ 6 Other. Please specify ________________

5. What is your current marital status?
   ☐ 1 Married
   ☐ 2 Living in a de facto relationship
   ☐ 3 Divorced
   ☐ 4 Married, but separated
   ☐ 5 Widowed
   ☐ 6 Never married

6. How would you best describe your employment situation at the moment?
   ☐ 1 Employed full-time
   ☐ 2 Employed part-time/casual
   ☐ 3 Unemployed (not retired or on pension)
   ☐ 4 Student (full-time or part-time)
   ☐ 5 Retired
   ☐ 6 Permanently unable to work/ill
   ☐ 7 Home duties
   ☐ 8 Other. Please specify ____________________
   ☐ 9 Refused
7. Do you have private health insurance? (Please select one response)

- Yes
- No
- Refused

Internet surveys are becoming increasingly popular. They allow the survey information to be transferred quickly and easily to the research team without the need to post back paper copies of the surveys. We are interested in your thoughts on whether you would have been able and willing to do this survey online.

8) Would you have been willing to do this survey on the internet?

- Yes, prefer an online survey
- Yes, but would prefer a paper and pencil survey
- No, probably wouldn't complete it as an online survey
- No, don't have internet access

Module 8. (This section is for intervention group first-degree relatives only)

This section is about the researchers contacting your doctor. We would like to send your general practitioner some specific recommendations for screening for bowel cancer.

1) Are you willing for us to contact your general practitioner?

- Yes,
- No

If no,
That's OK. Your participation is still greatly appreciated. Go to closing script
If yes,
That's great.
I'll just get some details about your general practitioner from you now.

2a) What is your general practitioner’s name?

- Record response
2b) What is the name of the practice or clinic where he/she works?

   i) Record response

2c) What is the address of the practice or clinic where he/she works?

   i) Record response

2d) What is the contact phone number for the practice or clinic?

   i) Record response

Module 9. Closing script

If this interview has raised some questions or concerns for you, you may want to contact your doctor or the Cancer Council Helpline. You can contact the Helpline on 131120. They can provide you with general information regarding bowel cancer and the recommended screening tests. If you have any further questions about the research, feel free to contact the Research Team. Our contact details are on the letter we sent you.

1) Do you still have these contact details?
   If respondent says no, provide HBRG contact details again.

   If respondent says yes:
   OK, great. Feel free to contact us at any time if questions arise.
Appendix L: Proposed study: How accurate is self-reported family history for categorising level of risk among first-degree relatives of colorectal cancer patients?

Background
Approximately 20% of persons developing colorectal cancer (CRC) will also have a first-degree relative (FDR) affected by the disease. First-degree relatives of CRC cancer patients are at increased risk of developing CRC. Individuals at increased risk, including those with positive family history, should be screened before advanced or incurable cancer develops. The Australian National Health and Medical Research Council (NHMRC) guidelines for CRC screening recommended earlier and scheduled screening for persons at “moderately increased risk or “potentially high risk”. Evidence for the benefit of screening of FDRs of CRC patients has come from both prospective and retrospective cohort studies and from a non-randomised study of relatives in a high-risk familial setting.

Family history collection is one of the most important tools healthcare providers have to facilitate risk categorisation and recommendation for type and frequency of screening. The accuracy of family history information is crucial to clinical decision-making and care provision, as a false negative equals a missed opportunity for potentially life-saving early colonoscopy, while a false positive may result in needless stress and over-estimation of risk leading to unwarranted procedures, surgeries or referrals to genetic services. Inaccurate reports influence clinical decisions unless verification occurs.

The proposed sub-study is part of a larger study using a Cancer Registry based approach to advising FDRs of CRC patients about appropriate screening. This study
relies on being able to quantify accurately the likely risk status of the family. A report of a positive family history of CRC may identify a first-degree relative at “moderately increased risk” or “potentially high risk”. For most, a positive family history confers only slightly increased risk, but for some this may be suggestive of a possible genetic predisposition warranting referral to Familial Cancer Centres. If accurate family history is reported by CRC cases on the Registry, the Registry (or Cancer Council) is in a position to then inform family members (via the index case) of their potential need for additional screening tests. The nature of the Registry allows for this to be a systematic process, potentially giving widespread access to tailored screening advice.

The NHMRC clinical practice guidelines quantify risk of CRC to asymptomatic individuals on the following basis: “at or slightly above average risk”, “moderately increased risk” and “potentially high risk”, with self-reported family history of CRC influencing risk categorisation. Adequate family history assessment relies on a comprehensive assessment of diagnoses of cancer in FDRs and their ages at diagnosis, with second-degree relatives also considered in allocating risk to an individual or family. The present study seeks to address the accuracy of CRC cases’ self-report of CRC family history and assess its affect on adequate risk categorisation for FDRs. Family history information provided by CRC patients can be vital in the clinical setting as patient’s reports on family history can indicate likely risk conferred to other family members.

Previous studies have shown the accuracy of self-reporting of family history of cancers varies as a function of the family history collection tool used, e.g. face-to-face interview and type of cancer reported. Research has indicated that medical information provided by patients about relatives is often inaccurate. Limited research has explored the accuracy of self-reported family history of CRC. Of
these studies, some have focussed on patient self-report,\textsuperscript{15,17} case control studies\textsuperscript{2,11}\textsuperscript{14,18} or high-risk persons.\textsuperscript{19} The above studies exploring the accuracy of patient-reported family history of CRC have found accuracy to fluctuate between sensitivity of 48% and 89%, dependent on the patient population and the technique used to gather the data.\textsuperscript{12,17-19} There is very limited knowledge about the accuracy of self-reported family history from CRC patients and its influence on risk categorisation for family members. Only five studies have explored reporting from CRC patients, with no comprehensive assessment of the degree to which inaccurate family history reporting affects appropriate risk categorisation for family members.\textsuperscript{2,11,14,15,17} To date, only one study has systematically analysed both positive and negative self-reports of CRC, and explored family history accuracy in both FDRs and second-degree relatives and its ramifications for risk classification.\textsuperscript{11} This study, however, was limited by a small assessment of the clinical utility of reporting, only assessing a handful of families.

Currently, there are limited data to clarify whether a strategy such as telephone-based interviews (suitable for large-scale assessment of risk status and implementation by organisations such as Cancer Councils) for documenting family history will achieve acceptable levels of accuracy. This is crucial to the Cancer Council Victoria CRC screening trial led by thesis supervisor Laureate Professor Sanson-Fisher, as a telephone-based system is being used to gather family history for the purposes of assigning risk and providing screening recommendations to FDRs of CRC patients. Only two studies have used telephone interviews as the principal collection tool for assessing the accuracy of family history of CRC.\textsuperscript{13,15} One study found high accuracy of CRC patients’ self-report but had a number of methodological shortcomings.\textsuperscript{15} The other study did not assess family history reporting of cancer by CRC patients but by lymphoma patients.\textsuperscript{13}
While numerous studies have focussed upon varying cancer sites and techniques, the utility or effectiveness of a Cancer Registry based system for collection of family history information using a Computer Assisted Telephone Interview (CATI) approach is unknown. A CATI approach towards family history collection for CRC cases is likely to be a relatively cost-efficient approach, provided it is sufficiently accurate. This study will identify whether the level of accuracy achieved by a telephone-based approach to family history reporting is similar to that achieved by more intensive methods, and the degree to which inaccurate family history reporting results in risk misclassification.

Aims
The study aims to identify each of the following for CRC patients:

1. i) The accuracy (i.e. sensitivity, specificity, positive predictive value and negative predictive validity) of self-reported family history of CRC in the first-degree relatives (FDRs) and second-degree relatives (SDRs) of CRC patients, collected by telephone interview. The CRC patients’ reports of the presence or absence of CRC in their family members will be compared with Victorian Cancer Registry (VCR) data and death certificates to establish accuracy.

   ii) The accuracy of reporting age of diagnosis of CRC in FDRs. For reported CRC in FDRs, reports will be compared with Registry data.

2. The proportion of family risk estimates which are correct when compared with data from the VCR. Estimated family risk will be allocated on the basis of index case self-reported family history information (i.e. number of FDRs diagnosed with CRC, their ages at diagnosis and the numbers of SDRs diagnosed with CRC). The risk categories used to allocate estimated family risk will be risk categories 1 (“at or slightly above average risk”), 2 (“moderately increased risk”) and 3 (“potentially high risk”) on the basis of the
NHMRC clinical practice guidelines. These will be collapsed into two larger categories: Category A – Risk category 1 (those “at or slightly above average risk”); and Category B – Risk categories 2 and 3 (those at “moderately increased risk” and “potentially high risk”) to explore the levels of agreement between self-report and Registry data.

Hypotheses

1. i) The accuracy of family history of CRC achieved by the telephone-based approach will be similar (70-80% sensitivity, 98% specificity) to that achieved in previous studies using this approach with CRC patients.

   ii) The accuracy of age of diagnosis, within five years of true diagnosis, will be high (greater than 90%).

2. The level of misclassification of risk category based on CRC patient self-reported family history will be low (less than 10%).

Research plan

Design and methods

Participants

Colorectal cancer patients over the age of 18 years and less than nine months post-diagnosis registered with the VCR with sufficient English capability and physical and mental capacity will be informed about the study by the Registry. Those who are not excluded by the doctor and allow the VCR to pass on their contact details will be invited by the researchers to participate in the main trial (which has ethical approval from Cancer Council Victoria and the University of Newcastle Human Research Ethics Committees).

Procedure

The sample for this study will include 480 CRC patients consenting to participation in the main trial CATI approach and a subsequent telephone interview gathering family
member details for VCR verification purposes. The main trial CATI approach will be used to gather family history of CRC information on first- and second-degree relatives of each CRC patient. Questions in this interview will ask whether these relatives have ever had CRC: mother, father or grandparents; uncles and aunts; siblings or half-siblings; children, nieces or nephews; or grandchildren. For reports of CRC in affected family members, their names and their relationships to the informant will be established. For each CRC diagnosis reported in FDRs, age at diagnosis will be asked. The second CATI approach will be used for the purposes of gathering sufficient family member details (e.g. name and date of birth) to allow verification of each FDR’s and SDR’s CRC status (Yes or No) self-reported during the main trial CATI approach on the VCR, and the age of CRC diagnosis self-reported by FDRs.

Prior to the second CATI approach (one month following the main trial) participants will be mailed five tables with each section of their families depicted: grandparents, uncles and aunts from the father’s side; grandparents, uncles and aunts from the mother’s side; siblings, nieces and nephews; half-siblings; children and grandchildren. Participants will be asked to complete in each table the following details of family members: relative’s name; relative’s date of birth; Victorian residency (Yes or No); and, if deceased, date of death. Participants will be asked to have these tables with them during the second interview. This interview will be used to ensure sufficient details are supplied to allow for verification of each FDR and SDR on the VCR. Those individuals who were believed to be living outside Victoria during the period of diagnosis or for much of their adult life will not be eligible to be passed on to the Registry for verification.

Victorian Cancer Registry verification

The accuracy (i.e. sensitivity, specificity, positive and negative predictive validity) of self-reported family history data of CRC cases collected in the main trial CATI approach will be cross-checked using data from the VCR. The details of every
eligible family member will be provided to the VCR to check whether there has been a diagnosis of CRC registered for that family member. Ethical clearance will be sought to verify all FDRs and SDRs notified by the participant without each family member’s prior permission. This type of consent process has been used by other non-related accuracy of self-reported family history of cancer studies using VCR data. The FDRs will be classified into NHMRC risk categories on the basis of both CRC patient self-reported family history and VCR-verified family history, to assess the degree of misclassification resulting from self-report alone.

Statistical analysis

The following components will be assessed to ascertain overall accuracy of family history in FDRs and SDRs of CRC patients, using the terminology below:

Sensitivity [TP/(TP + FN)]: the proportion of true cases identified by Victoria Cancer Registry check who were self-reported at interview.

Specificity [TN/(FP+TN)]: the proportion of true non-affected relatives confirmed with Victoria Cancer Registry check who were self-reported at interview.

Positive Predictive Value [TP/(TP + FP)]: the proportion of “true” reported colorectal cancer cases self-reported at interview who were confirmed by VCR check.

Negative Predictive Value [TN/(FN + TN)]: the proportion of individuals reported to be non-affected at interview who were confirmed as non-affected by VCR check.

Accuracy of age at diagnosis: defined as those identifying relative diagnosed with bowel cancer within five years of true diagnosis as depicted by the Cancer Registry data check. (TP within 5yrs)/(TP + FP)

Terminology

True Positive (TP): individuals who state "yes" to family member having bowel cancer and family member does have bowel cancer (Registry check)

False Positive (FP): individuals who state "yes" to family member having bowel cancer and family member does not have bowel cancer (Registry check)
True Negative (TN): individuals who state "no" to family member having bowel cancer and family member does not have bowel cancer (Registry check).

False Negative (FN): individuals who state "no" to family member having bowel cancer and family member does have bowel cancer (Registry check).

Sample size

Sample size calculations are based on the calculation of accurate risk classification in a dichotomous fashion, that is, participants will be classified either as at “average or slightly above average risk” (Category A – Risk Category 1) or “moderately/potentially high risk” (Category B – Risk Category 2 or 3). Assuming that approximately 38% of participants are truly in Risk Category 2 or 3, and approximately 80% of those will be accurately identified as being in Risk Category 2 or 3 based on self-reported family history, 400 CRC patients will need to provide a full and verifiable family history in order to assess accuracy of risk classification with confidence intervals of ± 7% for sensitivity and ± 5% for specificity. Risk categories have been collapsed into two categories (Category A and B) as it would not be possible to make reliable comparisons among the three separate categories, given that less than 5% of CRC cases fall into Risk Category 3.

Assuming approximately 10% of FDRs will be lost from the sample due to their relatives being out of Victoria (and therefore not verifiable via the VCR), and 10% will not be able to provide sufficient data for matching purposes, 480 participants will need to be approached to achieve 400 completed family histories.

Limitations of the current study

The current study will use the Victorian Cancer Registry for verifying reports from CRC patients of CRC in their FDRs and SDRs. Subsequently, reports can only be verified for those relatives who have lived in Victoria and for self-reported cancer-affected relatives living in Victoria at the time of diagnosis. Further, notification of
cancer in relatives before 1982 will not be possible due to the Registry not containing all cases of cancer diagnosed in Victoria until after this time point. The present study will only assess the influence of family history information provided by CRC patients on the adequacy of risk assessment for relatives. Factors other than family history can convey risk to an individual, e.g. personal history of advanced adenoma or chronic ulcerative colitis. Subsequently, the current study cannot make absolute risk classification of families.
References


