Ontario FOBT Project

Final Report

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Cancer Care Ontario
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EXECUTIVE SUMMARY

In 2003, The Ontario Fecal Occult Blood Test (FOBT) Project was undertaken as a joint effort of Cancer Care Ontario (CCO) and the Ontario Ministry of Health and Long-Term Care (MOHLTC), in collaboration with the Institute for Clinical Evaluative Sciences (ICES), and the Ontario Association of Medical Laboratories (OAML). It was intended primarily to inform colorectal cancer screening policy by comparing the effectiveness of two methods of promotion and recruitment for opportunistic screening—one through primary care physicians alone and one through local public health units. As well, the pilot was designed to assess the knowledge, attitudes, and screening behaviours of the public, physicians, and public health unit staff through several surveys, focus groups, and key informant interviews.

The project did not examine the impact of true population-based promotion and recruitment to screening, but rather examined the effectiveness of two methods of opportunistic screening, largely relying on primary care providers (opportunistic screening refers to a system that relies on screening to occur during encounters with the health care system that are not for the purpose of screening or preventive health care). The Primary Care physician study arm was meant to represent the current “status quo”, while the Public Health Unit arm was intended to creatively increase local promotion of screening, both directly to the public and to physicians.

A random sample of 12 public health unit regions was chosen from the 37 public health unit regions in Ontario. The first six were designated for primary care provider recruitment, and the next six regions were designated for public health unit recruitment. The intervention period lasted 15 months duration from March 2004 – May 2005 and there was an additional 6 month period of follow-up to allow for the tracking of follow-up procedures which ended November, 2005.

Key Findings of the Project:

- Over the 15-month intervention period, very low uptake of FOBT screening was observed across all 12 participating pilot regions with a total of 6,972 individuals or 0.86% of the eligible population participating in the project. Recruitment in the Public Health unit arm was slightly higher at 1% (ranging from 0.59% to 1.42%) compared to 0.7% in the Primary Care arm (ranging from 0.5% to 0.92%).

- The overall utilization of FOBT through the project was only a small proportion of the total FOBT utilization occurring in the 12 regions. Over a 12-month period during the pilot, there were 6,554 pilot project participants completing an FOBT, and 64,440 other individuals (non-participants) in the pilot regions completing an FOBT. While some of the testing in individuals not in the study may have been for diagnostic purposes and not screening, the study’s small proportion of all regional FOBT activity does make it important to evaluate background rates in the regions when assessing the impact of the pilot recruitment interventions. A comparison between two time periods: 12 months pre-pilot and 12 months within the pilot showed that in both the Primary Care regions and Public Health regions, increases of over 40% in total FOBT utilization occurred (participants and non-participants). In contrast, in the 25 non-pilot regions of the province there was an increase in FOBT utilization in the same time period of only 18%. Within the 12 pilot regions, non-participants experienced a 38% increase in uptake of FOBT. Thus, despite the low study participation rates, a notable impact appears to have occurred on FOBT utilization in the pilot regions, plausibly due to efforts of the pilot project.
• Screening rates in both arms tended to be lower in men versus women, younger versus older individuals, and lower income versus higher income regions.

• Screening rates were observed to be slightly higher across all ages and both sexes in the public health unit recruitment arm, but still orders of magnitude below ideal rates. Compared to the primary care recruitment strategy, the multi-pronged public health unit recruitment strategies appeared to perform better in screening persons who had not recently been screened, rural persons, and lower and middle incomes persons. Interventions implemented in the Public Health arm that were perceived by the health units to increase screening included:
  o Mass media awareness and promotion strategies,
  o Detailing of primary care physicians
  o Enlisting physician “champions” of FOBT screening
  o Improving the public’s access to FOBT kits beyond the physician’s office or laboratory.

• Among the regions in both intervention arms, the percent of results that were positive for occult blood varied from 0 to 4.8% (median 2.8%) (1). Regions with percentages higher than 3% were predominantly served by one laboratory network whose procedures diverged from the others.

• Among persons whose FOBT result was positive for occult blood in the stool, 30.6% (primary care arm) and 35.5% (public health unit arm) underwent large bowel endoscopy (primarily colonoscopy) within 12 weeks after the date of the positive FOBT. Overall, 64.6% of the 192 persons who tested positive underwent large bowel endoscopy by the end of the six month follow-up period.

• There is a great need for awareness raising and education about FOBT and colorectal screening in the community. A survey mailed from CCO to Ontario primary care physicians found that 67% of respondents reported recommending FOBT to their age-eligible patients. However, a survey of the age-eligible screening population of Ontario revealed that about half (45% of women and 54% of men) said they had never heard of FOBT. Results of a survey of the age-eligible screening population of Ontario indicate that three-quarters (75%) would find it “OK” to receive personally-addressed invitations for FOBT in the mail. However, receiving an FOBT specimen collection kit along with the mailed invitation would not be acceptable to 39%. Qualitative interviews with physicians practicing in the six primary care recruitment PHU regions revealed that 91% (10 of 11) of participant physicians (i.e. physicians who recruited their patients to the study) favoured population-based colorectal cancer screening with mailed invitations and reminders. A majority of non-participating primary care physicians in these same regions (i.e. those who did not recruit any of their patients to the study) agreed with them.

**Recommendations:**

From the results and experience of this project and additional information gathered by CCO on population-based colorectal screening programs in other jurisdictions around the world, it is clear that opportunistic screening alone will not achieve the population screening rates needed to reduce colorectal cancer mortality. The recommendations from the pilot are focused on moving forward with an organized colorectal screening program for Ontario, with population-based promotion, recruitment, follow-up and monitoring. They have not changed from those in the interim report of June 30, 2005, aside from an additional recommendation regarding the engagement of primary care providers in program development.
A detailed proposal for a provincial colorectal cancer screening program was submitted to the Ontario MOHLTC in the summer of 2005, based on the recommendations below.

1. We recommend that the Ontario MOHLTC establish a provincial population-based organized Colorectal Cancer Screening Program.

2. We recommend that the program be phased-in over 4 or more years, based on meeting pre-defined program goals of recruitment and follow-up, and that the program continue to roll out once these critical success factors have been achieved.

3. We recommend that Cancer Care Ontario, in conjunction with the Ontario MOHLTC, implement a major mass media awareness campaign for primary care providers and age-eligible residents of Ontario (age 50 or older), and individual health promotion messages regarding Fecal Occult Blood Test (FOBT) screening, in order to maximize the effectiveness of a population-based colorectal cancer screening program using FOBT.

4. We recommend the establishment of a central program office at Cancer Care Ontario for the population-based Colorectal Cancer Screening Program, to plan and implement the regional phase-in of the program, including contracting with laboratories to ensure consistent and high-quality FOBT, and to contract with endoscopists and hospitals to guarantee timely access to quality-controlled investigative colonoscopy. The central program office will also support an information system appropriate for monitoring quality and measuring critical success factors of the program. This program structure would readily accommodate an evidence-based change of screening method in the future, be it a different stool assay, or some form of large bowel endoscopy or imaging for a larger subset of the eligible population.

5. We recommend the creation and automatic updating of a population-based list of persons eligible for biennial screening invitations, and necessary information structures to support this. Initial invitations will be phased-in by regions, over time.

6. We recommend that Cancer care Ontario work with the Ontario MOHLTC and other stakeholders to consult with primary care providers during the planning and implementation phases of the provincial program to ensure that their concerns and needs are understood and met. As well, collaborative relationships between primary care providers and the program should be fostered.

7. We recommend that the Ontario MOHLTC solicit bids from laboratories to provide the following comprehensive services:
   - To send invitation letters and reminders with numerically unique coded FOBT specimen collection kits to age-eligible residents of Ontario, according to the phase-in schedule.
   - To receive by mail the FOBT kits and analyze them.
   - For unsatisfactory specimens, to send a letter and additional kit to the participant to repeat the test.
   - To transmit the results of negative tests by mail to the participant and, if requested, to their primary care provider, and electronically to the central office of the Colorectal Cancer Screening Program.
   - To transmit the results of positive tests by mail to the participant and, if requested, to their primary care provider, and electronically to the central office of the Colorectal Cancer Screening Program, and to the Colorectal Cancer Screening Program regional office.
8. We recommend the establishment of regional offices of the Colorectal Cancer Screening Program. Regional offices will provide toll-free telephone assistance for those requesting further information/direction for completing the FOBT kit. Regional offices will rapidly contact participants who have tested positive, for the following functions: discussion, counselling, and arranging for diagnostic colonoscopy.

9. We recommend that critical success factors for the program be established and monitored:
   - 65% of the age-eligible population will participate in the biennial program.
   - 75% of participants testing positive will undergo diagnostic colonoscopy within 12 weeks from the test date.
   - 60% of invasive cancers detected will be stage I.
   - 95% of advanced non-invasive neoplasms will be resected by polypectomy.
   - The rates of serious complication from colonoscopy will be lower than 3/1000 for bleeding, 1/1000 for perforation, and 1/15,000 for death.
1.0 Introduction & Pilot Rationale

In 2003, Cancer Care Ontario (CCO), under the direction of the Ontario Ministry of Health and Long-Term Care (MOHLTC), and in collaboration with the Institute for Clinical Evaluative Sciences (ICES), and the Ontario Association of Medical Laboratories (OAML) planned and subsequently conducted a one-year pilot project of opportunistic screening for colorectal cancer using the Fecal Occult Blood Test (FOBT). No other Canadian province or territory has yet implemented a comprehensive population-based colorectal cancer screening program, however, several are considering the option of instituting pilot projects, consistent with the National Committee’s recommendations (7). Ontario is the first province where an initiative has been taken to implement an FOBT pilot project for opportunistic FOBT screening for colorectal cancer.

Figure 1. Colorectal cancer incidence rates* for selected geographic areas, 1993-1997

Source: Parkin et al., 2002.
* Standardized to the 1991 Canadian population
** “White” population in the 5 states and 4 metropolitan areas in the original Surveillance, Epidemiology and End Results (SEER) Program
1.1 Quick Facts about Colorectal Cancer

- Colorectal Cancer (CRC) is an extremely significant health issue in Ontario. Incidence and mortality rates in Canada are among the highest in the world (8). Figure 1 illustrates CRC incidence rates in selected countries.

- Colorectal cancer is the most common cause of cancer death in non-smokers in Ontario, significantly exceeding breast and prostate cancer (8).

- Yet, CRC is easily treated if it is diagnosed early. The probability of curing CRC is 90 percent when it is detected early compared to just 10 percent for advanced-stage disease (9).

- Studies have shown that FOBT performed every two years reduces death from colorectal cancer by an average of 16% over 10 years of screening (10).

- The Canadian Task Force on Preventive Health Care (11), the Canadian Association of Gastroenterology (29), the Ontario Expert Panel on Colorectal Cancer Screening (12), and the U.S. Preventive Services Task Force (13) agree that performing biennial FOBT on average-risk persons 50-74 years old is a “Level A” Recommendation.

- According to a recent survey, Ontarians are not aware of FOBT: only about 50% of Ontarians 50 years and older have ever heard of FOBT (3); but they would like information about colorectal cancer and its prevention (14).

- Focus groups in Ontario and elsewhere reveal that FOBT is an acceptable test to patients (14).

- Although more than 2/3 of Ontario Family Physicians reported routinely recommending FOBT to their eligible patients (2), records indicate that in 2001, only 6% of eligible persons received FOBT (billed through OHIP) (15).
As the potential for primary prevention, particularly through diet modification and physical activity, is likely to have only limited effectiveness in the near future, secondary prevention, by early detection and early intervention, is the most effective way to reduce CRC mortality. However, despite strong evidence about early detection and prevention of colorectal cancer deaths through screening with the fecal occult blood test (FOBT) (10), a recent survey indicates screening participation rates in Ontario of only 15% in eligible individuals (3). Similarly, Ontario Health Insurance Plan (OHIP) billing records indicate that CRC screening is severely underused. For example, OHIP billing data reveal that just over 6% of the eligible target population received FOBT in 2001 (15).

While FOBT utilization rates remain suboptimal, colonoscopy rates have risen across Ontario. Yet, recent evidence suggests that access to timely colonoscopy is markedly constrained, and varies substantially throughout Ontario. Section 2 of this report examines these issues. Appendix A describes the various types of CRC screening tests currently available in Ontario (i.e. FOBT, colonoscopy, flexible sigmoidoscopy, double-contrast barium enema).

Colonoscopy may be performed for a variety of reasons, including screening, diagnosis, treatment, and follow-up. Although colonoscopy performed by trained professionals demonstrates excellent accuracy and cancer detection rates, and it offers a therapeutic advantage (in that suspicious areas can be biopsied and polyps can be removed during the procedure), several characteristics make it a less than ideal first-line screening test in asymptomatic individuals at average risk for CRC:

- there is no “Level A” evidence for its use,
- Ontario lacks the capacity to deliver it to the eligible population,
- it is a resource-intensive and relatively expensive procedure,
- it can be uncomfortable and is a time-consuming procedure for the participant,
- it carries a risk of complications, including perforation and hemorrhage.

1.2 History of Colorectal Screening Recommendations in Ontario

A population-based CRC screening program using FOBT has been repeatedly recommended by several expert committees over the past several years. The following is a description of those recommendations. In addition, Appendix B contains a summary table of these and other expert recommendations.

Ontario Expert Panel Report on Colorectal Cancer Screening (April 1999)
The Colorectal Cancer Screening Panel was established by CCO in May 1998 to develop recommendations for CRC screening in Ontario (12). The Expert Panel was funded by the Ontario MOHLTC, and it also received support from Health Canada and the National Cancer Institute of Canada. The panel, with representation from health care providers and consumers, conducted a stakeholder consultation regarding CRC screening.

The Expert Panel Report focused only on individuals who are at average risk of developing CRC (that is, individuals who do not have a personal history of CRC, inflammatory bowel disease, certain genetic conditions, or a strong family history of CRC). The following were suggested as policy recommendations to CCO:

- develop and introduce a program of CRC screening for average-risk individuals
• establish a representative multi-stakeholder advisory structure to provide ongoing direction regarding the design and operation of the CRC screening program
• consider implementing a program for CRC screening if the following conditions are met:
  o Screening must be comprehensive
  o Public and provider education must be a priority
  o All residents of Ontario must have reasonable access to screening
  o Participants should volunteer and do so with informed consent
  o Screening must be of high quality
  o All aspects of screening must be subject to continuous monitoring and evaluation
  o There must be a commitment to modify screening standards, guidelines and best practices based on new scientific evidence
  o The program must accommodate the needs for confidentiality and information sharing
  o There must be provision of adequate resources to support all aspects of screening
  o Screening should be accommodated within the existing patterns of practice and referral of the Ontario health care system.

The Expert Panel advised that the program screen men and women, aged 50 and above, with FOBT as the primary screening method, and in those with an abnormal FOBT, follow-up with colonoscopy or Double Contrast Barium Enema (DCBE) and flexible sigmoidoscopy.

Canadian Task Force on Preventive Health Care Report (February 2001)
The Canadian Task Force on Preventive Health Care (CTFPHC) conducted an evidence-based review of available screening modalities (11). CTFPHC graded the evidence and issued the following recommendation statement:

Recommendations for Normal (Average) Risk Individuals:
• There is good evidence to support the inclusion of annual or biennial fecal occult blood testing (FOBT) in the periodic health examination of asymptomatic individuals over age 50 years (Level A recommendation)
• There is fair evidence to include flexible sigmoidoscopy in the periodic health examination of asymptomatic individuals over age 50 years (Level B recommendation)
• There is insufficient evidence to make recommendations about whether only one or both of FOBT and sigmoidoscopy should be performed (Level C recommendation)
• There is insufficient evidence to include or exclude colonoscopy as an initial screen in the periodic health examination (Level C recommendation).

Specifically, the CTFPHC based its recommendations on landmark randomized controlled trials that have demonstrated reductions in mortality from CRC of 15 to 30% in populations screened with FOBT (16-21).

National Committee on Colorectal Cancer Screening (May 2002)
In 1998, Health Canada established a National Committee on Colorectal Cancer Screening, comprising members from provincial ministries of health and key organizations from across the country. The National Committee’s mandate was to explore the issues surrounding population-based CRC screening, thereby developing a set of recommendations which were based upon the principles of early disease detection. During its two years of deliberations, the Committee examined evidence about CRC screening, and reviewed recommendations and reports from other countries as well as information from experts in the field. From available randomized controlled trials, strong evidence indicated that FOBT could reduce CRC mortality by 15% to 33% in individuals aged 50 - 74 years. In December, 2002 the Committee released its final report containing the key recommendation that:
“Colorectal cancer screening should be made available to Canadians. In order to ensure quality screening which maximizes benefits and minimizes potential risks, ideally screening should be within an organized and structured environment, with the following elements in place:

- clear, concise, and understandable information for patients and physicians on the risks and benefits of screening and on the administration of the test.
- informed consent following personal consultation with family practitioner or equivalent
- standardized protocols and procedures with a single entry test and options for follow-up
- systematic tracking and evaluation of all screening invitations (if used), testing frequency, results (including false positive and false negative rates), follow-up, and outcomes” (7).

Because the disease-specific mortality was highest in Canada among those aged 50 years and older, the National Committee further recommended that FOBT be offered at least every 2 years to those aged 50 – 74 years old, and that abnormal results be followed with colonoscopy or DCBE and flexible sigmoidoscopy.

1.3 Objectives of the Pilot Project

Given this backdrop of significant burden of CRC in Ontario, strong evidence of a mortality reduction with timely screening, but poor uptake of screening and secondary prevention, the Ontario FOBT Pilot was designed to inform provincial policy on CRC screening. The 12-month Pilot was conducted over 2004 and 2005, in 12 randomly selected regions in Ontario.

The main goal of the project was to determine the best way to encourage Ontario residents aged 50 – 75 years and at average-risk of colorectal cancer, to be screened opportunistically. The pilot compared the effectiveness of two methods of recruitment:

- through recommendations from the family doctor to be screened, and
- through promotion and activities of the local Public Health Unit.

The project had several specific objectives, as follows:

1. To compare participation rates, as measured by the submission to a participating laboratory of a completed FOBT kit, including a signed project consent form, between two distinctly different approaches to recruitment (supported usual primary care compared to public health unit strategy).
2. To describe variation in these rates among the diverse geographic, sociodemographic, and linguistic communities of Ontario, including the North and among non-English speakers.
3. To determine which strategies for recruitment appeared to be well-received by the community, and demonstrated effectiveness in recruitment to screening.
4. To describe attitudes about screening with FOBT compared to other approaches, which lack the strength of evidence underpinning FOBT, among primary care physicians, public health units, and persons eligible for screening.
5. To determine the compliance with follow-up medical investigations for those who test positive, and their ultimate outcomes.
6. To describe selected indicators of system-capacity and resource-utilization, such as colonoscopy follow-up rates for those who test positive on FOBT, waiting times for follow-up investigation, and cost of promotion and recruitment.
7. To examine the feasibility of using the existing administrative databases at ICES to evaluate CRC screening.
8. To describe any other implementation and feasibility issues.
The results of the project will be used to inform the development of a provincial colorectal cancer screening policy, enhancing the potential for high-quality, accurate, and timely population-based colorectal cancer screening and follow-up program in Ontario.
2.0 Background

2.1 Epidemiology of Colorectal Cancer

2.1.1 Incidence and Prevalence

The burden of colorectal cancer (CRC) in Ontario is considerable. CRC is the 4th most commonly diagnosed cancer in Ontarians, after prostate, female breast, and lung cancers (see Figure 2). The prevalence of colorectal cancer is about 0.3%; in 2001 approximately 35,000 Ontarians had been diagnosed with colorectal cancer in the preceding 15 years (8).

![Figure 2: Annual number of deaths and new cases for the most common cancers in Ontario, 2001.](source)

2.1.2 Trend over Time

Although the rates have fluctuated over the past 20 years, a trend of slowly-declining incidence has been evident (see Figure 3). Although the cause for this decrease is unknown, several complementary hypotheses have been advanced:

- Better detection of pre-malignant lesions and treatment of these lesions with polypectomy and resection,
- Waves of immigration of persons at lower risk of colorectal cancer, thereby populating Canada and Ontario with persons of lower incidence, and “diluting the denominator”,
- Improved diet, consisting of fewer carcinogenic foods, more fibre, fruit, and vegetables, and lower alcohol consumption (8),
- Consumption of potentially preventive agents, vitamins and trace elements (calcium, selenium, folate, Vitamins A, D, and E) and medications (e.g. acetylsalicylic acid and other non-steroidal anti-inflammatory drugs, and hormone replacement therapy and oral contraceptives in women),
• Decreased tobacco use (8).

In some jurisdictions, a slight increase in incidence rates has been noted since 1997, and this has been attributed to improved early detection through screening, including an artifactual increase secondary to detecting prevalent cases of CRC rather than incident cases. This increase corresponds well with the increased use of screening/diagnostic procedures such as FOBT and colonoscopy (see below, Rates of Screening and Use of Large Bowel Procedures).

However, although the incidence rates appear to be falling in the long-term, as the population both grows and ages, the absolute number of cases is rising, contributing to the burden of CRC in Ontario.
• Approximately 7500 Ontarians were diagnosed with colorectal cancer in 2005, and
• Approximately 3050 Ontarians died from it in 2005 (8).

2.1.3  Sex

Figure 3 illustrates the male and female rates of CRC over time. In 2005, the rate of newly diagnosed cases of CRC in Ontario is estimated to be 61/100,000 in males, and 42/100,000 in females (8). These rates mirror the Canadian rates, at 62 and 41/100,000 respectively (8). It is noteworthy that since 1997 the incidence in men has risen about 2% per year. Female incidence rates have also risen somewhat since 1997 after a slight steady fall from the early 1980s. The reasons for these trends are not well understood, although changes in diet and social habits likely contributed to the decline in the 1980s. There is no obvious, or proven, explanation for the recent small rise.
2.1.4 **Age**

CRC is uncommon before age 50, accounting for only 7% of cases. The incidence increases from less than 20 per 100,000 in the age group 35-49 years old, to 55 per 100,000 in those aged 50–54, and to 423 per 100,000 in those aged 85 and older (see Figure 4) (22). However, CRC mortality is much lower and increases less steeply, from 16 per 100,000 in the age group 50–54 to 351 per 100,000 aged 85 and older (22). Figures 5 and 6 illustrate the trends in incidence and mortality respectively according to age. The long-term incidence and mortality trends are toward decreasing rates in all age groups, particularly for mortality. The median age at diagnosis was 70, and median age at death was 74, during the period 1997–2001 (22).

**Figure 4: Colorectal cancer incidence and mortality rates by age, 1997-2001**

Source: Cancer Care Ontario (Ontario Cancer Registry, 2003)
Figure 5. Colorectal cancer incidence rates by age group males and females combined, 1981-2001

Figure 6: Colorectal cancer mortality rates by age group males and females combined, 1981-2001
It is important to note that although the age-standardized incidence rates are lower than those of 1985, the growth and aging of the Canadian population has caused the absolute number of new cases to rise steadily and significantly in recent years among both men and women.

2.1.5 **Geographic Variation**

The incidence of colorectal cancer in Ontario is among the highest in the world, along with Australia, New Zealand, the U.S., and several European countries. Surprisingly, incidence rates in several Asian countries (e.g. Singapore, Japan, China) have risen substantially over the last decade, approaching rates in high-risk countries (8). Incidence trends in most other high-risk countries stabilized or decreased during the mid 1990s.

Rates within Canada show a west-to-east increasing gradient in incidence. Incidence rates in 2005 were estimated to be lowest in B.C. (54/100,000 males, 37/100,000 females) and highest in Newfoundland (79/100,000 males) and PEI (59/100,000 females) (8). Canadian incidence rates are highest among men in Newfoundland. This may represent a “founder’s effect” (i.e. amplification of a genetic trait within a small, isolated, and inbreeding population). As well, known lifestyle risk factors such as diet, physical activity, tobacco, and alcohol consumption may play a role in regional variation.

In Ontario, the Northeast, Northwest, and Southwest regions all have incidence rates above the provincial average of 51.4 per 100,000. The Northeast region appears to have the highest incidence rate, whereas the Central East region appears to have the lowest. This regional difference is likely attributable in part to the substantial presence of lower-risk groups created by ethnic diversity in the Greater Toronto Area (22).

2.1.6 **Mortality**

With respect to cancer deaths in Ontario, colorectal cancer is second only to lung cancer, and resulted in an estimated 3050 deaths in 2005 (8). The 2005 Ontario estimated male and female mortality rates are 26/100,000 and 17/100,000 respectively, comparable to the estimated male and female Canadian rates of 27 and 17/100,000 (see Figure 3). In Canada, the probability of dying from CRC is about 3.4%, or one in 1 in 30 (8).

Colorectal cancer ranks second, behind only lung cancer, for potential years of life lost to cancer (PYLL), accounting for 11% of PYLL (see Figure 7) (22). Note that although many more deaths occur from colorectal cancer than from breast cancer, the PYLL is only slightly higher because people generally are older when diagnosed with CRC versus breast cancer.

Mortality rates from CRC have demonstrated a steady and definitive decline over the past several decades, from 1976 rates of 32/100,000 males and 25/100,000 females, to 2005 estimated rates of 27 and 17/100,000 respectively (8). In the 20-year interval from 1981 to 2001, CRC mortality declined by 20% for males and 27% for females. These falls in mortality may reflect the decline in incidence in the 1980s and early 1990s, as well as improvements in treatment techniques, and diagnosis of CRC at earlier stages, when treatment is more effective.
The chance of dying from CRC increases dramatically with advancing age; however, all age groups have experienced a decline in mortality over recent years. Mortality for the age groups 80+ and 65-79 fell slightly, at an average of 1% per year, over the 1980s and 1990s. Over the same time period, mortality rates among those aged 50-64 fell an average of 2% per year, and 3% per year for those aged 35-49 (see Figure 6) (22).

**Figure 7: Potential years of life lost (PYLL) due to cancer (Ontario, 2001)**

<table>
<thead>
<tr>
<th>Cancer Type</th>
<th>Years Lost</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung</td>
<td>86,390</td>
<td>25%</td>
</tr>
<tr>
<td>Colorectal</td>
<td>37,670</td>
<td>11%</td>
</tr>
<tr>
<td>Female breast</td>
<td>35,210</td>
<td>10%</td>
</tr>
<tr>
<td>Pancreas</td>
<td>35,210</td>
<td>10%</td>
</tr>
<tr>
<td>Other cancers</td>
<td>121,100</td>
<td>33%</td>
</tr>
<tr>
<td>Leukemia</td>
<td>13,090</td>
<td>4%</td>
</tr>
<tr>
<td>Central nervous system</td>
<td>13,210</td>
<td>4%</td>
</tr>
<tr>
<td>Non-Hodgkin lymphoma</td>
<td>15,810</td>
<td>5%</td>
</tr>
<tr>
<td>Prostate</td>
<td>12,180</td>
<td>3%</td>
</tr>
<tr>
<td>Non-cancers</td>
<td>121,100</td>
<td>33%</td>
</tr>
</tbody>
</table>

*Mortality rates do not vary substantially by region, but the Northeast and Southwest regions experience higher than average rates, whereas the Central East region (comprising a large proportion of persons originating from lower-risk countries) has lower incidence and mortality rates than Ontario as a whole (22).*

### 2.1.7 Survival

In general, a steady increase in survival for both men and women has occurred over the past several decades (see Figure 8). Estimated five-year relative survival for CRC has improved steadily and significantly over the past two decades. Survival rose from 45% for males followed during 1981-1985, to 57% for males followed during 1996-2000. The corresponding increase for females was from 49% to 59% (22). In Canada, the current CRC death-to-case ratio is 0.43 and is higher than those for female breast (0.24) and prostate (0.21) cancers (8).
2.2 Screening In Ontario

2.2.1 Objectives of Screening

The objectives of screening are to decrease the incidence and mortality of cancer. Effective screening should:

- detect cancers at an earlier stage with a better prognosis than those detected because of symptoms, thereby decreasing mortality
- detect pre-malignant lesions, which when removed, lead to a decrease in incidence of the disease
- ideally, lead to an improved quality of life in that a cure can be effected with less invasive measures, resulting in improved post-treatment functionality (e.g. polypectomy vs. bowel resection; shorter bowel resection; less radiotherapy).

Organized screening programs have additional benefits to both the population and the health system, and these are listed below.

2.2.2 Advantages of Organized Screening Programs

Organized screening programs using population-based personal invitations have several crucial advantages over the sorts of opportunistic screening that occur through usual visits to the primary care practitioner. The reason for the improved performance of organized programs is largely due to dedicating human and information technology resources toward the critical components of successful screening. These include:

- creation of awareness in the general population and health care practitioners of the importance of screening, leading to earlier diagnosis and treatment.
- promotion / support of a culture of prevention, including primary prevention.
population-based recruitment of the entire target population, rather than only those who present to the health care system. This includes invitations to screening, reminders, and recall during appropriate screening intervals.

- assurance of timely, evidence-based screening and follow-up practices.
- assurance of thoroughness and consistency in practice.
- quality assurance programs
- monitoring and evaluation of processes and outcomes (e.g. accessibility of services, screening and diagnostic test utilization, screening and diagnostic test yield, wait times, disease incidence and mortality, lives saved).

2.2.3 Rationale for FOBT Screening

Colorectal cancer (CRC) may bleed in amounts that are grossly undetectable, but detectable by laboratory methods such as fecal occult blood testing (FOBT). The natural history of CRC is such that it is preceded by the development of non-cancerous adenomatous polyps, which although infrequently detectable by FOBT (because polyps generally do not bleed) are detectable and resectable during colonoscopy, thereby substantially diminishing the chance of developing CRC in the future (23). Therefore, if occult blood is detected by FOBT, it can be followed by a diagnostic/therapeutic procedure, such as colonoscopy, to investigate the source and cause of bleeding. The sensitivity of FOBT to detect pre-cancerous polyps and frank cancer is greatly enhanced by serial screening every one to two years.

Screening men and women over age 50 who have no symptoms of colorectal disease can lower mortality from colorectal cancer, particularly if it is carried out with quality control and timely diagnostic follow-up. An estimated 6,000 deaths could be prevented by 2030 if Ontario successfully implemented an FOBT screening program (22). CRC survival is markedly improved with detection at an early or at a pre-cancerous stage. Unlike other screening maneuvers, FOBT has been shown in randomized trials to be effective in reducing CRC mortality (16-21).

All screening tests have both risks and advantages. Risks associated with FOBT screening include anxiety, unnecessary investigations or false reassurance because of the FOBT’s lack of sensitivity and specificity. Although colonoscopy performed by trained professionals demonstrates excellent accuracy and cancer detection rates, and it offers a therapeutic advantage (in that suspicious areas can be biopsied and polyps can be removed during the procedure), several characteristics make it a less than ideal first-line screening test in asymptomatic individuals at average risk for CRC:

- It lacks the high level of evidence for its efficacy (unlike FOBT)
- Ontario lacks the capacity to deliver it to the eligible population
- It is a resource-intensive and relatively expensive procedure
- It is an uncomfortable and time-consuming procedure for the participant, requiring purgative bowel preparation prior to the procedure and sedation during the procedure. A person undergoing colonoscopy generally misses two days of work.
- It carries a risk of complications, such as colonic perforation (1/1000), hemorrhage (3/1000), and death (1/15,000). Such risks may be acceptable from an individual’s perspective, but when one considers that a whole population 50-74 years of age in Ontario should undergo screening (e.g. almost 2.8 million individuals), the risks become more tangible.

FOBT has been accepted as the primary screening test for colorectal cancer for the large majority of the age-eligible population at average risk for the development of advanced non-invasive colorectal neoplasia and of invasive colorectal cancer.
2.2.4 Rates of Screening and Use of Large Bowel Procedures

Colorectal cancer screening rates in Ontario are low. Moreover, knowledge of FOBT is low in Ontario. These observations are corroborated by a variety of sources:

- Only about 20% of Ontarians aged 50–65, and followed over 6 years, have had any bowel investigations, most of which would not be for screening purposes (24). Figure 9 illustrates the rates of all colonic evaluation procedures (excluding FOBT) in Ontarians by age group and sex.
- Although the use of FOBT (estimated through OHIP billings) increased substantially in the age-eligible population over the years 1992 to 2001 (a 20-30% increase), at only approximately 6% of Ontarians aged 50-74 years old having FOBT in 1992, the proportion was dramatically below screening recommendations (15). Figure 10 illustrates the rates of FOBT in Ontarians by age group and sex.
- A 1999 health survey in Durham Region revealed that only about 20% of respondents aged 50–69 said they had ever had FOBT as part of a check-up or for routine screening. Just 15% of those aged 50–69 reported having the test in the previous two years (22).
- A 2004 survey of Ontarians aged 50 and older found that half of respondents had never heard of FOBT, and 22% were not considering FOBT screening. Only 17% had decided to have FOBT screening (3). This is in contrast to a similar survey of a family practice population in Philadelphia (25) revealing that only 15% of respondents had ever heard of FOBT, less than 45% were not considering FOBT screening, and 37% had decided to be screened with FOBT.

On the whole, most Ontarians appear to be poorly informed about CRC screening in general and about FOBT in particular.
While knowledge of FOBT and its use remain low in Ontario, the patterns of use of other colonic evaluation procedures are changing. In 2004, ICES undertook an in-depth examination and evaluation of the use of large bowel procedures, such as FOBT and colonoscopy in Ontario up to the end of the year 2001. Note that these large bowel procedures may be employed for several reasons, including screening, investigation, treatment, and follow-up. Key findings from this work include (15, p. 2):

- Half of the more than 359,000 non-FOBT (fecal occult blood test) colonic evaluation procedures performed in Ontario in 2001 were colonoscopies. This represents an approximate 3-fold increase over the number in 1992, and the rate of growth also increased steadily throughout the decade. The year-over-year increase in 1993 was only 8%; in 2001, it was almost 17%.
- Rates for colonoscopy varied widely from county to county, based on availability.
- There is a relationship between the type of hospital(s) in a county and the colonoscopy procedure rate. Relative to total hospital volume, in small community hospitals, on average, more colonoscopies are performed than in large teaching hospitals.

A critical observation from this body of work is that the regional variation in colonoscopy largely stems from the financial disincentive for performing colonoscopy experienced by hospitals, in that the majority of the cost of colonoscopy is borne by the hospital’s global budget rather than by other mechanisms such as OHIP.

The significance of these findings is that access to colonoscopy in Ontario currently is constrained and inequitable throughout the province, and is related to the supply and activity level of endoscopists, as well as the funding structure of colonoscopy. A successful population-based FOBT screening program will require consistent and assured access to timely...
endoscopic evaluation in quality-controlled settings. This will include colonoscopy, but may also involve flexible sigmoidoscopy as further evidence mounts to support its benefit.

2.3 State of Screening Nationally and Internationally

Awareness of the need for and benefit of screening for CRC continues to grow in Canada. Notably, no other Canadian jurisdiction has yet implemented a population-based CRC screening program. However, many of the provinces and territories are working towards implementing population-based CRC screening programs. In particular, Quebec and British Columbia are planning to implement pilot FOBT screening programs. Ontario is a leader in Canada, having completed a CRC screening pilot project. Many Canadian jurisdictions will be observing the strategies used in Ontario as a model for other provincial CRC screening programs. With that said, in the absence of a funded program, other strategies will emerge to fill the policy vacuum, and strategies other than FOBT, such as colonoscopy and CT colonography (“virtual colonoscopy”), are being examined and/or advanced in Canada (26-28).

Internationally, several countries have implemented FOBT screening programs on an ongoing or pilot basis. In particular, five countries – England, Italy, Finland, Australia, and Israel – have experience with population-based FOBT programs. These programs and pilots are “population-based” in that the screen-eligible population is systematically invited to screening through the use of central databases to generate invitations, reminders, and recalls, and track results and outcomes of screening. Each of the four programs below utilizes mailed FOBT kits, sent directly to the screen-eligible person’s home, along with a waterproof, postage-pre-paid envelope to return the kit to a participating laboratory.

Some of the salient features of these programs will be highlighted in brief.

- the primary screening maneuver is FOBT (a variety of types of FOBT, including guaiac and immunochemical, are being used), followed by colonoscopy when an abnormal result is received,
- the programs generally are being phased-in by age and/or geographic region,
- the programs target men and women within the age range of 50 to 74 years old,
- the frequency of screening is biennial to annual (Israel),
- the programs are promoted through a variety of mass media and community-collaborative techniques, including primary care and occupational settings,
- FOBT testing occurs in a limited number of designated laboratories, and follow-up colonoscopy occurs in designated centres,
- communication of results to patients and health care practitioners is a function of the screening program, as is the scheduling and coordination of any necessary follow-up investigation (in Australia, the family physician does this),
- wait times for investigative colonoscopy are reported to be less than 30 days,
- the reported participation in 1st round screening ranges from 43% to 75%,
- the reported rates of positive FOBT are around 2% (up to 10% with immunochemical rather than guaiac tests),
- England and Scotland respectively report cancer detection rates of 1.26 and 1.99 per 1000 of their screened population aged 50-69 years old, while Australia reports a rate of 2.3 per 1000 screened (ages 55-70 years) and Italy reports 2.8 per 1000 screened (ages 50-69 years),
- the programs operate within various quality assurance systems and will be evaluated.
Excellent participation rates have been reported from these programs, and can largely be attributed to the mailed FOBT specimen collection kit. This method offers the tremendous advantage of eliminating the barriers of visits to the physician’s office and the lab (usually twice) to receive the screening test. Although new and unique, both the public and physicians have received this method well. In the UK, this method was found not only to be acceptable, but was even welcomed by time-pressured primary care physicians. An organized program frees them from this time and resource-consuming aspect of their practice, activities that often are overlooked or delayed, as are many health promotion and disease prevention activities, in the context of a busy office practice.
3.0 Methodology

OVERVIEW

Intervention:

<table>
<thead>
<tr>
<th>Primary Care Arm (PC)</th>
<th>Public Health Arm (PHU)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 regions</td>
<td>6 regions</td>
</tr>
<tr>
<td>-Project Announcement and Invitation to Participate mailed to primary care physicians (containing physician and patient educational material regarding FOBT)</td>
<td>-Recruitment of PHU regions</td>
</tr>
<tr>
<td>-Follow-up project reminder mailed to primary care physicians</td>
<td>-Central development of promotional material</td>
</tr>
<tr>
<td>-Written and mailed project updates</td>
<td>-Information sharing and motivational meetings (1 in-person and monthly telephone)</td>
</tr>
</tbody>
</table>

-Regional Efforts (adaptation of central resources, physician detailing, mailings, health fairs, Public Service Announcement)

Ethical approval for the project was obtained from Sunnybrook & Women’s College Research Ethics Board on May 7, 2003 (Project Identification Number: 149-2003).

The Pilot Project Steering Committee met throughout the duration of the project on a monthly basis to review the progress of the project, and address any challenges that occurred. An initial start-up period of 3 – 4 months occurred in 2003-2004, during which time Primary Care (PC) and Public Health Unit (PHU) regions were identified, project materials were developed (e.g. patient and physician information packages, educational materials and consent forms – see Appendices), PHU recruitment strategies were developed, and all participating groups were oriented. The recruitment interventions and data collection took place over a period of 12 months, commencing on March 1, 2004.

The Pilot Project comprised two study arms – the Primary Care (PC) arm and the Public Health Unit (PHU) arm. Each arm contained six Ontario regions, corresponding to public health unit boundaries.

Twelve study regions were chosen randomly from Ontario’s 37 public health unit (PHU) regions. The first 6 PHU regions were assigned to the PC arm but, one region was deemed ineligible to participate because of their “Alternate Payment Plan” for primary care physicians (i.e. as physicians were not paid by the usual OHIP fee-for-service arrangement, the intermediate outcomes of FOBT, such as colonoscopy, would not be measurable), so the next randomly selected area was substituted. The Medical Officer of Health in the next 6 PHU regions was approached for agreement to participate, however, one refused to participate. The next randomly chosen region was approached, and agreed to participate, totalling 12 regions across the province. The PHUs comprised a mix of urban and rural communities, and Algoma was the furthest North. Both arms of the pilot included a major Ontario city with an academic health sciences centre, at least one mainly rural region, and at least one other mainly urban region.

The pilot regions were as follows:

In terms of the new system of Local Health Integration Networks (LHINs), the following were included in one or both categories: South West, Waterloo Wellington, Hamilton Niagara Haldimand Brant, North Simcoe Muskoka, South East, Champlain and North East. Excluded were Erie St Clair, Central West, Mississauga Halton, Toronto Central, Central East, Central, and North West.

3.1 Surveys and Focus Groups

Copies of all survey instruments and focus group questions are contained in Appendix C

3.1.1 Age-Eligible Screening Population

Survey of FOBT Awareness and Behaviour

The survey employed was based on an instrument adapted from one validated by Vernon, Myers, and Tilley (25) that attempted to determine the decision-making stage of respondents about FOBT screening. Respondents are classified into one of five mutually exclusive stages of decision-making: never heard of FOBT, not considering FOBT, decided against FOBT screening, undecided about FOBT screening, and decided not to have FOBT screening. The sampling process of this random digit dialling survey of 1013 (69% response rate) English-speaking Ontario residents, 50 years and above, was performed using the Canada Survey Sample (CSS), a selection engine that generates random samples of residential telephone numbers. The survey’s initial questions identified whether any household residents were aged 50 years or above. If a household did not have members in the target range, there was no further contact. If a household did have members in the target range, the resident whose birthday was next during the calendar year was first contacted and surveyed. Then a request was made to survey additional household members who were 50 years and above. If they were willing, further surveys were undertaken. If they were unwilling, there was no further contact with the household. This approach provided some assessment of whether a positive influence was exerted (in terms of screening uptake) within a household when one member (50 yrs. and above) was screened on the screening uptake of other residents (50 yrs. and above), as evaluated by the probability that one resident’s decision-making stage or screening status predicted the other resident’s decision-making stage or screening status. These analyses are not ready for this report, but surprisingly, the number of households with two or more members greater than 50 years old was reported to be relatively modest.

Survey of Opinion About Direct Mailing

The purpose of this brief survey was to explore the acceptability to potential screening program participants of the fundamental components of a centralized FOBT screening program. Questions included whether or not it would be OK to receive health promotion information (such as screening information) and an FOBT specimen collection kit in the mail, and whether participants would prefer to receive their test results in the mail or from their family doctor. The sampling process of this random digit dialling survey of 1000 Ontarians aged 50 – 74 years old was virtually identical to the previously-describes Survey of FOBT Awareness and Behaviour, with the exception of cluster sampling, which was not employed in this second survey.
3.1.2 **Primary Care Physicians**

*Survey regarding Knowledge and Behaviour about FOBT Screening (Ontario Cervical Screening Survey)*

In February 2004, as part of the Physician Survey of Cervical Cancer Screening in Ontario, a sample of primary care physicians were asked five questions about their attitudes and behaviour regarding FOBT. Questionnaires were mailed to 3,063 general and family practitioners listed in the Canadian Medical Directory. Of this number, 612 were ineligible and 936 (38% response rate) returned their completed survey to CCO.

*Survey about Practice, Barriers, Facilitators regarding FOBT Screening FOBT Pilot Project PC Arm Physicians*

The purpose of this sub-study was to thoroughly understand the FOBT screening encounter, using telephone-based, semi-structured, open-ended interviews. We surveyed both physicians in the PC arm who were active in recruiting their patients to the study (N=11) and physicians who did not recruit their patients to the study (N=10), though they may offer their patients FOBT through usual (non-pilot) routes. These interviews were designed to elicit specific information and idiosyncratic perspectives on FOBT screening. Questions asked were a combination of specific questions about participation in the pilot, and generic, open-ended questions about their views of a future provincial CRC FOBT screening program.

3.1.3 **Public Health Unit Project Staff**

*Structured Interviews about Recruitment Strategies and Outcomes*

*Focus Group about Project Experience*

These two studies are grouped together because of their similar intentions, interview/focus group respondents, and convergent results. The individual interviews (N = 6) with key staff members in the FOBT promotion in each pilot PHU region were semi-structured and open ended, tape-recorded and transcribed. The focus group was undertaken, face-to-face with the same personnel and again, tape-recorded and transcribed verbatim.

3.2 **Laboratories**

The OAML, with a lead role provided by MDS Laboratories, was engaged to provide laboratory services for the project. Services of MDS, Gamma-Dynacare, CML, and some CLS labs were used. More than 100 labs participated in kit distribution and specimen collection and processing. Lab staff was trained to facilitate compliance with study procedures. The lab coordinator for the study (MDS Laboratories) assisted in addressing difficulties with the protocol.

Patients were provided with one of two Guaiac-based FOBT specimen-collection kits (Hemoccult II (Beckman Coulter) or Hema-Screen (Immunostics)), each comprising 3 slides (and each with two specimen collection windows, totalling six specimen collection windows), and written instructions on specimen collection technique and diet/medication restrictions necessary to reduce false results and increase the accuracy of the test. Both commercially
available test kits are currently in use in the community labs and have been shown to have similar test characteristics.

To ensure the reliable distribution and pick up of test kits and specimens, special arrangements with laboratories were required in several regions (particularly geographically dispersed regions), for example – delivery of test kits to physician offices, and pick-up of completed specimens by courier. Subsequent FOBT testing was carried out in multiple labs according to standard laboratory operating procedures (Appendix D).

3.3 Eligible Population & Participants

The study population comprised persons aged 50-74 years. This age group was targeted for recruitment, data collection, and analysis; however, some recruitment messages invited persons aged 50 and above to participate (because there is no upper age limit on FOBT use in Ontario). Persons who were at increased risk of CRC were not specifically eliminated from recruitment and analysis, and it is unknown whether primary care physicians may have either recruited more of these patients to screening or fewer (opting instead for screening by more invasive but reliable measures such as colonoscopy). Persons were eligible to participate if the postal code of the requisitioning physician was in the catchment area of the designated region. The patient’s postal code was not examined.

3.4 Primary Care (PC) Arm

The recruitment strategy was developed in conjunction with the Ontario College of Family Physicians, the Ontario Medical Association (Section of Family and General Practice), and the Ontario MOHLTC. The strategy was considered to be “usual care” in that it involved no particular intervention beyond dissemination of information to primary care family physicians through usual routes (e.g. mailout of information from government agencies and/or professional associations, scientific publication, educational presentations).

3.4.1 Physician Identification and Selection

A database of Ontario physicians was purchased from MDSelect, and project staff refined it to yield Primary Care (PC) physicians (i.e. Family Physicians and General Practitioners) in the study regions. The list was imported into an MS Access database. The list was supplemented and refined by information obtained from searching the College of Physicians and Surgeons of Ontario web-based database (an additional 175 physicians were identified). In some cases, the project material was returned to CCO unopened, or a request was received to remove the address from the database (e.g. physician had moved, retired, died, did not practice in that area of medicine, did not want to participate or receive communications), and they were removed from the database (n=156). Non-physician primary care providers (e.g. nurse practitioners, naturopaths) in the PC arm were not targeted for inclusion in the study, but it is possible, and even likely in some regions (for example rural regions under-supplied by PC physicians and urban practices such as Community Health Centres with multi-disciplinary health teams) that non-physicians were the instigators of the FOB test. However, a physician signature was required on every lab requisition for processing by the lab.

3.4.2 Intervention

The primary intervention strategy in the PC arm was to attempt to inform PC physicians of the latest scientific information and recommendations for colorectal screening using FOBT, and to
provide them with some tools to screen patients easily through the project. This information (available in both English and French) included:

- A “physician package” containing an explanatory cover letter (see Appendix E), project Question and Answer sheet, screening recommendations from the Canadian Task Force on Preventive Health Care, a summary of up-to-date information about colorectal screening, a list of participating labs, a sample “patient package” (see below) and a re-order form for patient educational materials.
- 25 “patient packages” containing a plain-language, pilot-tested explanatory pamphlet (about colorectal cancer, early detection through FOBT, instructions on how to participate in the pilot project) a special study laboratory requisition, a consent form for participation and future data linkage, a 1-800 number to connect with the project office for questions about the test or the project, and a list of participating labs from which to obtain and drop off the specimen kit. (see Appendix E)

In a personalized cover letter, PC physicians were asked to recommend FOBT to eligible patients during office visits scheduled for care or for other purposes and to provide eligible patients with a patient package. To minimize the work of their office staff, physicians were provided with their own pre-printed address labels to affix to FOBT project requisitions.

In February/March 2004, all PC physicians (N=1339) were couriered a physician package and 25 patient packages. They were provided with an order form to obtain more patient packages, and the phone number and email addresses of project staff, including the Medical and Project Coordinators of the project.

PC physicians were asked to advise their patients to complete the test at home and return the specimen along with the signed consent form to the laboratory or doctor’s office for processing. Subsequently, copies of the patient’s result were sent to both the patient’s PC physician who signed the requisition and to CCO for entry into the study database, along with the patient’s consent form. Responsibility for follow-up of positive results was left solely with the PC physician, and CCO did not follow-up any patient. The occurrence of follow-up investigations subsequent to a positive FOBT will be monitored by a search for relevant billing claims in the OHIP and CIHI records held at ICES.

Additional strategies employed in the PC arm are follows:

- Through a series of regional visits, we attempted to personally present the project to groups of PC physicians in communities. Ultimately, the Medical Coordinator of the FOBT project delivered three presentations to a small number of PC physicians (two presentations in Middlesex-London, one in Wellington-Dufferin-Guelph) about the project.
- We attempted to identify and engage local family practice opinion leaders (e.g. specialists, respected practitioners, chiefs of staff), groups, and organizations by contacting local hospitals, departments of Family Practice, universities, public health departments, the Ontario Medical Association, Ontario Family Health Networks, and the Canadian College of Family Physicians.
- We provided PC physicians by mail on four occasions with project updates, thanks, and encouragement for participation.

3.4.3 Chronology of Primary Care Strategies

All materials are contained in the Appendix F.

- Letter #1 (early February 2004) – a personalized letter of introduction and study notification
• Initial Mailout (late February – early March 2004) – an initial mailout to 1339 selected physicians in the 6 regions (PCs) comprising the “physician package” and 25 “patient packages”.
• Presentations – where possible, physicians were offered an in-person presentation regarding the project by the Medical Coordinator of the project.
• Postcard #1 (July 2004) – a reminder/encouragement postcard, advising of the status of the project through a histogram of the rate of returned FOBTs in each of the 6 regions (with only the physician’s own region labelled).
• Letter #2 (October 2004) – a letter reiterating the high burden of colorectal cancer in Ontario, low rates of screening, and recommendations for FOBT, as well as a project status update.
• Family Medicine Forum (November 2004) – Cancer Care Ontario and the Canadian Cancer Society jointly staffed a booth at a national conference for Family Medicine, held in Toronto. The booth was staffed by experts in cancer screening, and written information about the prevention and early detection of colorectal, cervical and breast cancers was distributed to interested visitors.
• Postcard #2 (January 2005) – a reminder/encouragement postcard, with a histogram of the rate of returned FOBTs in each of the 6 regions (with only the physician’s own region labelled).
• Letter #3 (February 2005) – a letter of thanks and request to discard existing study materials and information about how to obtain more patient fact sheets.

3.5 Public Health Unit (PHU) Arm

There was general support and interest from PHUs regarding the pilot project (both voiced at a consultation meeting held in December, 2001 and through the Association of Local Public Health Agencies (aLPHA) by way of a letter of support and resolution passed by its Board supporting the pilot project (Appendix G).
• The Medical Officer of Health in six randomly selected PHUs was contacted by Dr. Verna Mai (Cancer Care Ontario, Director of Screening) and invited to participate. Due to concerns about staffing and financial constraints, one Medical Officer of Health refused, so a seventh randomly-selected PHU was invited, and agreed to participate.
• The PHUs were sent a letter of agreement detailing the terms and conditions of involvement.
• Each PHU was provided $40,000 for promotion and $75,000 for staffing for the 12 month duration of the project.

However, to engage the full participation of the six selected PHUs, several common concerns needed to be addressed. For example, each PHU was concerned about:
• “orphan patients” who did not have a primary care physician,
• whether they would be required legally or ethically to communicate results to patients, and to investigate and be responsible for ensuring followup for patients with positive results.
As well, several regions had specific issues with provision of laboratory services that needed tailored solutions (e.g. the usual use of hospital and other non-project labs; long distances between physician offices, patients’ homes, and participating labs). One region (Hamilton-Wentworth) required additional funding in order to engage their large volume of physicians and specialists in their region.

Monthly teleconferences were held with the group of participating PHUs to identify and solve problems, and share information and strategies. As well, an in-person meeting was held at Cancer Care Ontario in June of 2004, just as PHUs were developing their strategies. Finally, an
an in-person “wrap-up” meeting was held at Cancer Care Ontario in February 2005, to communicate the experiences of the PHUs to CCO and each other. All of these meetings were well-attended.

3.5.1 Intervention

PHUs were encouraged to use whatever intervention strategies they felt were feasible and appropriate in their communities, including direct promotion to physicians, the community, and mass media campaigns. PHUs were provided with the same educational materials as were physicians in the PC arm. However, additional promotional materials were developed and provided, as below.

3.5.2 Centrally-Developed Promotional Material

Each PHU developed and implemented its own strategy, consistent with the mission of the local PHU and the community it serves. However, PHUs started with some resources developed centrally by project staff, including:
- patient pamphlets promoting FOBT screening through the pilot project, in plain-language, translated into eight languages commonly-spoken in Ontario (Arabic, Cantonese, Italian, Portuguese, Punjabi, Spanish, Urdu, and Vietnamese)
- physician packages and patient packages, virtually identical to the ones used in the PC arm containing all the necessary materials for physician / patient participation in the project and regional contact information.
- an educational PowerPoint presentation for general public
- an educational PowerPoint presentation for physicians
- small & large print Public Service Announcements
- radio Public Service Announcements (30 and 60 sec)
- a sample press release (for regional adaptation)
- media relations tips
- bilingual versions of all materials.

Media materials are in Appendix H.

3.5.3 Regional PHU Strategies

The project office provided PHUs with suggested recruitment strategies (based on a review of the literature regarding effective recruitment), however each PHU was responsible for developing a recruitment plan for its area. Each PHU drew on existing broadly-based community networks, including PC physician leaders and groups, local screening and prevention advocacy groups, service clubs, and community cultural and social organizations to educate physicians and the community, and promote colorectal screening by FOBT. The specific strategies of each PHU were developed with support and input from the project office, and often involved an expansion of existing promotional approaches for breast screening and healthy lifestyles promotion. Recruitment strategies were implemented over the study period and generally included elements of the following:
- notification of PC physicians, general surgeons, gastroenterologists, and oncologists about the project and current screening recommendations through several ways, including individual face-to-face meetings, phone meetings, mail notifications, fax notifications, presentations, vaccine bag inserts. In some cases, presentations were given by PHU pilot project staff, the local Medical Officer of Health, and physician specialists such as a gastroenterologist.
- distribution of study materials such as physician packages and patient brochures.
• provision of project updates to PC physicians by mail, email, fax, departmental meetings, rounds.
• mass media campaigns (newspaper, magazine, community paper, transit, billboard, radio, TV, website).
• promotion at community sites (e.g. brochures/booths at senior’s residences and agencies, health fairs, flu immunization sites, medical offices, pharmacies & labs, OBSP sites, hair salons/barbers, health/recreation clubs, service clubs, voluntary and professional associations, civic centres, public libraries, shopping centres, banks, religious centres, workplaces, unions, payroll inserts).
• presentations to community groups, physicians and other health professionals.
• collaborative screening initiatives with other community stakeholders such as hospitals, pharmacies, community health centres, and voluntary associations (e.g. Canadian Cancer Society, Colorectal Cancer Association of Canada).
• facilitation of FOBT kit delivery between patients and laboratories.
• partnering of “orphan” patients without a primary care physician with community physicians.

Five of the six PHUs distributed physician packages directly to their community physicians (often in person), but one region (Hamilton-Wentworth) found it unwieldy and untenable to contact their many physicians, and requested that the study office (CCO) mail packages directly to physicians. In general, PHUs distributed only information to patients, and advised them to follow-up with their PC physician to have the laboratory requisition signed, and obtain the FOBT. One PHU (Eastern Health Unit) handed out FOBT laboratory requisitions that were already signed by the local Medical Officer of Health, and the patient was instructed to pick up the FOBT kit directly from either a participating lab or PHU, bypassing the need for a patient to visit his/her physician’s office prior to obtaining the FOBT kit (results of the test were to be copied to the PC physician if the patient requested so).

As in the PC arm, patients were advised to complete the test at home and return the specimen and signed consent form to the laboratory (and in specific cases, the doctor’s office or PHU) for processing. Subsequently, copies of the patient’s result were sent to both the patient’s PC physician of record (who usually had signed the requisition) and to CCO for entry into the study database, along with the patient’s consent form. Responsibility for follow-up of positive results was left solely with the PC physician, and CCO did not follow-up any patient. The occurrence of follow-up investigations subsequent to a positive FOBT will be monitored by a search for relevant billing claims in the OHIP and CIHI records held at ICES.

3.6 Data Collection, Storage, and Security

The laboratories returned all submitted consent forms and all FOBT test results to the CCO project office on a monthly basis, initially in electronic format (password-protected MS Excel files), and hard copies were sent later and stored in a locked cabinet upon receipt. Consent forms and requisition forms were matched against the paper result and an indication was made on the main data file that the forms were received. All three (consent form, requisition form, and paper result) were stapled together and filed in a locked cabinet. Date of birth, sex, and study arm (as indicated on the requisition form) were entered into the main database.

A secure database was constructed at ICES based on encrypted OHINs of all participants. Preliminary data (up to and including results from November 2004) were transferred to ICES in April 2005, as a password-protected MS Access database. The password was conveyed to ICES separately from the database. The fields transferred were:
• Ontario Health Insurance Number (OHIN)
• date and results of FOBT test,
• public health region of Ontario they reside in,
• postal code of requisitioning physician.
Following the stringent ICES data security and confidentiality procedures, upon receipt, ICES encrypted OHINs and deleted unencrypted numbers. Follow-up procedures that are carried out following the completion of the FOBT were identified by linkage of this secure database with the OHIP billing and hospitalization files held at ICES. Additional data transfers to ICES, relating to tests processed up to the end of May 2005, occurred June 30 and October 24, 2005.
4.0 Results

4.1 Surveys and Focus Groups
Copies of all surveys are contained in Appendix C.

4.1.1 Age-Eligible Screening Population

Survey of FOBT Awareness and Behaviour

The telephone survey was administered to 1013 persons aged 50 to 74 years old (69% response rate) to determine their stage of decision-making about FOBT screening. As can be seen in Table 1, a large proportion of males (55%) and females (46%) had never heard of FOBT. In those reporting awareness of FOBT, about 26% of females vs. 17% of males were not considering obtaining FOBT screening. Only 17% of the females and 17% of males had decided to obtain FOBT screening, although only very low percents of respondents of both genders had decided against FOBT screening. These data indicate that, from a decisional stage perspective, females may manifest a reluctance relative to males to undertake FOBT screening.

Our population-based data may be compared with data obtained from a patient sample of primary care practice attendees in the Philadelphia, PA, previously surveyed by Myers et al. in 2002. While the samples are not equivalent (general public vs. enrollees in a primary care medical practice), interesting contrasts are obvious. One important contrast is the relatively modest proportion of the Philadelphia primary care sample who have never heard of FOBT (20% males and 12% females) versus the considerably larger proportion (of the Ontario sample) who have not heard of FOBT (55% males and 46% females). This information suggests that the Ontario population is not well-informed about FOBT compared to other communities.

Table 1. Stage of Decision Making about FOBT, Ontario vs. Philadelphia Residents

<table>
<thead>
<tr>
<th>Decision Stage</th>
<th>Ontario Males</th>
<th>Ontario Females</th>
<th>Philadelphia Males</th>
<th>Philadelphia Females</th>
</tr>
</thead>
<tbody>
<tr>
<td>I: Never heard of FOBT</td>
<td>54.6% (272/498)</td>
<td>45.6% (235/515)</td>
<td>19.8%</td>
<td>12.0%</td>
</tr>
<tr>
<td>II: Not considering FOBT screening</td>
<td>17.4% (87/498)</td>
<td>26.2% (135/515)</td>
<td>37.7%</td>
<td>44.5%</td>
</tr>
<tr>
<td>III: Decided against FOBT screening</td>
<td>0.1% (1/498)</td>
<td>0% (0/515)</td>
<td>0.78%</td>
<td>0.69%</td>
</tr>
<tr>
<td>IV: Undecided about FOBT screening</td>
<td>10.4% (52/498)</td>
<td>11.2% (58/515)</td>
<td>4.1%</td>
<td>5.9%</td>
</tr>
<tr>
<td>V: Decided to have FOBT screening</td>
<td>17.3% (86/498)</td>
<td>16.9% (87/515)</td>
<td>36.5%</td>
<td>36.9%</td>
</tr>
<tr>
<td>Total</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>
This random digit dial survey of Ontario residents aged 50 –74 years old (N=1000) indicates that:

- respondents are supportive of receiving health promotion information in the mail (75% yes, 25% no)
- a majority (58%) of respondents are supportive of receiving a mailed FOBT kit, 39% are not, and 3% did not know or refused the question.
- the majority (86%) thought it would be “OK” to receive their test results from their family doctor, and 64% thought it would be “OK” to receive them by mail.

4.1.2 Survey of Primary Care Physicians regarding Knowledge and Behaviour about FOBT Screening (Ontario Cervical Screening Survey)

Our mailed, self-report survey of randomly-selected Ontario primary care physicians (N = 2154, with 940 respondents, response rate = 44%) found only 67% reported usually recommending annual FOBT to their age-eligible patients. A sizeable proportion (48%) thought FOBT generated too many false results and that explaining FOB testing to patients required a ‘lot of time’ (46%). Table 2 details these results.

<table>
<thead>
<tr>
<th>Agree</th>
<th>Disagree</th>
<th>Missing</th>
</tr>
</thead>
<tbody>
<tr>
<td>I do not usually recommend annual FOBT for colorectal cancer screening in my asymptomatic patients, age 50 and over</td>
<td>32.0%</td>
<td>67.0%</td>
</tr>
<tr>
<td>I think that FOBT has too many false positive and false negative results to be a useful test for colorectal cancer screening</td>
<td>47.6%</td>
<td>51.3%</td>
</tr>
<tr>
<td>I think that explaining to patients what is involved in FOBT takes a lot of physician time</td>
<td>45.0%</td>
<td>53.7%</td>
</tr>
<tr>
<td>The availability of follow up testing for patients with abnormal FOBT is limited in my community</td>
<td>27.0%</td>
<td>71.4%</td>
</tr>
<tr>
<td>I think that asymptomatic patients age 50 and over are unlikely to do FOBT for colorectal cancer screening</td>
<td>25.2%</td>
<td>73.7%</td>
</tr>
</tbody>
</table>

4.1.3 Survey about Practice, Barriers, Facilitators regarding FOBT Screening

Actively-Recruiting Physicians in the PC Arm

Interview results indicated that all 11 physicians surveyed who were actively recruiting their patients to participate in the pilot were currently offering FOBT to average-risk patients, 50 years and above, although there was disagreement about the upper age limit for FOBT screening (some physicians stopped screening at 75 years of age while most screened all willing, elderly patients). All actively-recruiting physicians believed FOBT was a good test that could reduce morbidity/mortality in patients screened. Nearly all the physicians reported offering FOBT at annual exams although most believed only a minority of patients received screening regularly in this way. The patients who did regularly receive “annual” exams (or periodic health exams) typically received them at intervals ranging from 16 – 24 months. Most physicians reported providing patients with specimen collection kits, or lab requisitions for kits, that were then picked up at local laboratories, a modest distance from their medical offices. Most physicians required patients to return specimens to these local laboratories although a few received specimens at their offices.
Most of these physicians were aware of their participation in the provincial pilot, although they pointed out that since they were already offering FOBT, the pilot had only a modest influence on practice. A few physicians reported liking the materials and requisitions they received for patients – they found them useful and helpful. Only 1 of 11 physicians could not recall receiving or using pilot materials.

All physicians who we interviewed planned to offer and encourage FOBT screening in the future. They felt the following items would be useful in promotion:

- patient materials on FOBT
- a website on FOBT to which they could direct patients, and
- peer-reviewed scientific articles and guidelines about FOBT screening
- none felt that a video on FOBT was worthwhile.

All but one physician in the actively-recruiting group (N = 10 out of 11) favoured a provincial screening program, centrally organized to provide reminder/recalls facilitating periodic screening and timely, high-quality follow-up investigations of screen-positives, as well as central collection/analyses of trends/outcomes associated with FOBT. The great majority felt this program should be combined with the Ontario Breast Screening Program (OBSP) and the Ontario Cervical Screening Program (OCSP) and, if possible, with cardiovascular risk screening, thereby creating a central mechanism addressing all evidence-based screening modalities. The one dissenting physician, unfavourable to a centralized system, was concerned that patients would object to the ‘intrusion of privacy’ involved in such a system. When asked if these views would change if individuals could ‘opt out’ of the centralized system, he was not convinced that his patients would respond well to a centralized system and felt he wanted to be involved, as their physician, in all aspects of screening.

In contrast, most physicians welcomed the movement of FOBT screening out of their practice domain. They were ‘so busy’ that they felt a centralized system would efficiently increase screening rates and effectively reduce their responsibilities to a more reasonable level.

Although most physicians were satisfied with being informed about the screening of their patients, several wanted to communicate results to patients and refer them for colonoscopy screening if positive test results were found. They also wanted to be involved if patients were found to have colorectal cancer and to refer them to an oncologist or oncolgical surgeon. Most physicians supported a United Kingdom-type system that included kits directly mailed to age-eligible, average-risk citizens. Their primary reservation with such a system was ‘whether it would work’ in Canada. When told it appeared to be working in the UK, most indicated a willingness to test its feasibility but had to be convinced that people would accept it and comply with specimen collection. Physicians did not voice opposition, but rather, scepticism. If such a system was enacted, about one-half of physicians would be satisfied with having their offices ‘copied’ with screening results. Another one-half wanted direct collaboration with their office, enabling them to provide services to eligible patients who preferred the involvement of their physician.

Non-Recruiting Physicians in the PC Arm
All 10 non-recruiting physicians (those who practised in the PC arm, but did not recruit their patients to be screened through the FOBT pilot) who we interviewed reported currently offering FOBT to average-risk patients, 50 years and above. All believed FOBT was a good test that could reduce morbidity/mortality in patients screened. Nearly all reported offering FOBT at annual exams which most believed only a minority of their patients received regularly. The patients who did regularly receive “annual” exams (or periodic health exams) typically received them at intervals, again ranging from 16 – 24 months. Most physicians provided patients either
FOBT kits, or requisitions for kits, that were picked up at local laboratories a modest distance from their medical offices. Most physicians required patients to return specimens to local laboratories although a few received specimens at their offices.

All non-recruiting physicians planned to offer and encourage FOBT screening in the future. They felt the following items would be useful in promotion:

- patient materials on FOBT
- a website on FOBT to which they could direct patients (most said as long as it is included in patient education materials), and
- peer-reviewed scientific articles and guidelines about FOBT screening.

These physicians comprised a more mixed sample with respect to their opinions about a provincial program, centrally organized to provide a reminder/recall system facilitating periodic screening and timely, high-quality follow-up of screen-positives, as well as central collection/analyses of trends and outcomes associated with FOBT screening. The great majority felt that central organization was a positive step but a strong minority felt the reminder system should ‘flow through’ the primary-care physician office.

Still, a majority welcomed the movement of FOBT screening out of the domain of their practice. While most were satisfied with just being informed about the screening of their patients, the strong minority wanted to communicate results and refer for colonoscopy the individuals with positive test results. They wanted to be involved with patients found to have colorectal cancer and to refer them to an oncologist or oncological surgeon for further treatment.

Most physicians in the non-recruiting group supported a United Kingdom-type system that included kits directly mailed to age-eligible average-risk citizens as an interesting and possibly effective ‘step’ in screening but were more sceptical about ‘it working’ in Canada. When told it appeared to be working in the UK, most indicated a willingness to test its feasibility but remained unconvinced that people would accept it and comply in specimen collection. If such a system was enacted, however, the same strong minority wanted their offices ‘copied’ with results and wanted direct collaboration with the screening program, enabling them to provide services to those eligible patients who preferred the involvement of their physician.

4.1.4 Public Health Unit Project Staff

Structured Interviews about Recruitment Strategies and Outcomes

Focus Group about Project Experience

What follows is a summary of themes and issues articulated by PHU staff who were responsible for implementing the FOBT pilot project in their PHU. The convergent themes in the data collected were not surprising as the individuals involved were identical. The fact that two different forms of data collection were involved (in two separate events) confirms the validity of the themes articulated below.

- Physician Resistance
  The physicians with whom these PHU staff members communicated during the FOBT pilot did not seem bothered by the FOBT screening promotion and information provision that was occurring outside their practices. In most cases, they were very supportive of it. However, resistance was encountered in some situations:
    - physicians who advocated colonoscopy as first-line screening,
• physicians who were concerned about flooding the system with requests for follow-up colonoscopies, and thereby increasing wait times for diagnostic colonoscopy,
• physicians who were concerned about the length of time required to explain the FOBT, and obtain informed consent for the pilot.

• Physician Support
Most barriers presented by physicians were overcome with personal visits by regional staff. Although this method was time and resource consuming, PHU staff felt that visits were effective in getting doctors on board and enthusiastic about the FOBT pilot.

PHU staff felt that physician ‘buy-in’ was enabled by the presence of a few important physician ‘opinion leaders’ to champion the cause of FOBT. One region found that by performing comprehensive physician outreach in the beginning, there was not as much opposition as experienced in other regions. Again, although this method was time consuming, they found it effective in getting the doctors on board.

• Patient Barriers
PHU staff reported that in some regions of the province, patient access to participating laboratories was restricted, and required novel solutions (e.g. courier service, recruitment of additional labs). Having patients pay for parking while picking up or dropping off FOBT kits at the lab was also mentioned as a negative point of the pilot.

The PHU staff reported that the screen-eligible population, for the most part, was happy to pick up FOBT kits from public health sites. However, there was some confusion about where patients should be picking up or dropping off kits (i.e. the laboratory, the health unit, the doctor’s office). One of the public health districts provided FOBT kits directly to the general public. The health units, generally, seemed very good at giving out the kits and organizing follow-up for “orphaned” patients (persons without a primary care physician).

PHU staff felt that patient instructions about how to correctly perform FOBT (diet and medication restriction and specimen collection particularly) should be clearer than are the written instructions usually provided by the laboratories.

• System Barriers
Some reasons for the slow start of the FOBT pilot included administrative barriers, such as a delay in receipt of pilot materials and the need to increase laboratory accessibility. As well, the PHUs required a fair amount of time to plan their interventions and prepare the necessary materials (e.g. media advertisements, community events).

PHU staff felt that momentum was built in terms of response to FOBT promotion. Consequently, it would be unfortunate to lose momentum by allowing a long interval to elapse between the end of the pilot and the advent of a screening promotion program.

• PHU staff reported that the number of FOBTs being undertaken is actually higher than the data demonstrate. This was observed to be true for several reasons:
  o Some doctors who already use FOBT did not participate in the study. Thus more people in the targeted age-range are being screened than numbers show.
  o Some participating physicians did not fill out requisition forms properly, and some consent forms were not signed or even included in packages to laboratories, and hence, were excluded from analysis. Other kits were lost between labs and offices.
Some patients who lived in one region, had a family doctor in another region. Thus, these patients, who might have undertaken FOBT as a result of PHU promotion strategies, were not picked up in the outcomes.

Similarly, due to promotional efforts of the PHUs, some doctors may have increased their use of FOBT, but not enrolled their patients in the pilot by using pilot laboratory requisitions.

Altogether these interviews and focus group findings suggest that the PHU arm project staff felt that the FOBT pilot was successful in increasing uptake of FOBT. They felt that there was little insurmountable resistance to increasing uptake. However, as the baseline awareness was very low, they felt that some time would be required to ‘build up’ awareness in the promotion effort.

4.2 Recruitment

Recruitment Over Time and by Region and Recruitment Arm.

After excluding 150 OHIP beneficiaries who had participated in the project but had a previously-recorded diagnosis of colorectal cancer in the Ontario Cancer Registry, the laboratories had analysed FOBT kits from a total of 6,972 OHIP beneficiaries by May 31, 2005 (out of an age-eligible population of 811,219 persons). Figure 11 shows recruitment over time in the two pilot arms. Recruitment in the Primary Care arm remained relatively stable over time, while recruitment in the PHU arm required a “ramp up” period, and demonstrated increased recruitment corresponding to peak times of promotional efforts (e.g. October, November, 2004). Once recruitment efforts in the Public Health Arm (PH) started to show results, monthly numbers of completed FOBT’s consistently surpassed those of the Primary Care Arm (GP).

Figure 11. Recruitment per Month by Pilot Arm

(total n=6967)
As a caveat to the presentation and interpretation of results, the very low recruitment rates in the pilot project make comparisons between the two recruitment arms difficult. However, in some cases trends are apparent, and these are noted and discussed.

Table 3 shows screening participation by pilot region and recruitment arm. Screening uptake in the eligible population was much lower than expected, with total uptake of 0.86% of the eligible population across all 12 pilot regions (ranging from 0.27% to 1.72% across regions). The Public Health Unit recruitment strategy performed slightly better than did the Enhanced Primary Care strategy (1.00% versus 0.70% uptake). Participation rates did not vary by size of the community. Of note, the region with the highest participation (region 10) also employed the most intensive outreach, including the provision of FOBT laboratory requisitions directly to age-eligible persons, allowing them to complete screening without needing a visit to their family physician to get the requisition.

Table 3. Number and Percent Participation of Participants by Pilot Region and Recruitment Arm.

<table>
<thead>
<tr>
<th>Region</th>
<th>Number of Participants</th>
<th>% Participation</th>
<th>Number Eligible*</th>
<th>Region</th>
<th>Number of Participants</th>
<th>% Participation</th>
<th>Number Eligible*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>126</td>
<td>0.47</td>
<td>26,891</td>
<td>7</td>
<td>390</td>
<td>0.99</td>
<td>39,202</td>
</tr>
<tr>
<td>2</td>
<td>90</td>
<td>0.27</td>
<td>33,058</td>
<td>8</td>
<td>144</td>
<td>0.37</td>
<td>39,342</td>
</tr>
<tr>
<td>3</td>
<td>334</td>
<td>0.70</td>
<td>47,712</td>
<td>9</td>
<td>590</td>
<td>1.19</td>
<td>49,834</td>
</tr>
<tr>
<td>4</td>
<td>286</td>
<td>0.47</td>
<td>61,439</td>
<td>10</td>
<td>958</td>
<td>1.72</td>
<td>55,666</td>
</tr>
<tr>
<td>5</td>
<td>1,154</td>
<td>1.06</td>
<td>108,169</td>
<td>11</td>
<td>863</td>
<td>0.82</td>
<td>104,883</td>
</tr>
<tr>
<td>6</td>
<td>738</td>
<td>0.66</td>
<td>111,046</td>
<td>12</td>
<td>1,299</td>
<td>0.97</td>
<td>133,977</td>
</tr>
<tr>
<td>Total</td>
<td>2,728</td>
<td>Avg. = 0.70</td>
<td>388,315</td>
<td>Total</td>
<td>4,244</td>
<td>Avg. = 1.00</td>
<td>422,904</td>
</tr>
</tbody>
</table>

Total participants = 6,967. Total eligible population = 811,219. Median participation = 0.76%

*Eligible population derived from Statistics Canada population projections, adjusted for ineligible persons.

Age and Sex of Ontario FOBT Project Participants compared to non-participants in study regions, and to OHIP beneficiaries in all other non-pilot public health regions.

The age and sex distributions of the 12 pilot regions were virtually identical to the 25 non-pilot regions in Ontario. Table 4 details the uptake of FOBT (measured by percent participating of those eligible). FOBT uptake was lowest in the 50 – 54 year old age group, which is the largest age group. Uptake of FOBT was better in the older age groups, and was highest in those aged 65 – 69 years old. Uptake of FOBT was higher among women than men (1.00% versus 0.71%). This may be due to the increased likelihood of women to attend appointments with a primary care provider compared to men. Again, participation rates across all age groups and both genders were higher in the Public Health Unit recruitment arm.
Table 4. Number and Percent Participation of Participants by Age Range, Sex, and Pilot Arm.

<table>
<thead>
<tr>
<th>Age</th>
<th>6 Primary Care Recruitment Regions</th>
<th>6 Public Health Unit Recruitment Regions</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of Participants</td>
<td>% Participation</td>
<td>Number Eligible*</td>
</tr>
<tr>
<td>50-54</td>
<td>598</td>
<td>0.50</td>
<td>118,543</td>
</tr>
<tr>
<td>55-59</td>
<td>629</td>
<td>0.68</td>
<td>92,922</td>
</tr>
<tr>
<td>60-64</td>
<td>573</td>
<td>0.82</td>
<td>69,400</td>
</tr>
<tr>
<td>65-69</td>
<td>506</td>
<td>0.92</td>
<td>55,116</td>
</tr>
<tr>
<td>70-75</td>
<td>422</td>
<td>0.80</td>
<td>52,334</td>
</tr>
<tr>
<td>Total</td>
<td>2,728</td>
<td>Avg. = 0.70</td>
<td>388,315</td>
</tr>
</tbody>
</table>

Male  | 1,022 | 0.53 | 190,587 | 1,805 | 0.87 | 208,100 |   |
| Female | 1,706 | 0.86 | 197,728 | 2,439 | 1.14 | 214,804 |   |
| Total  | 2,728 | Avg. = 0.70 | 388,315 | 4,244 | Avg. = 1.00 | 422,904 |   |

Total participants = 6,972, Total eligible population = 811,219
*Eligible population derived from Statistics Canada population projections, adjusted for ineligible persons.

Table 5 shows that the age distribution of pilot participants was older than the age structure of the regions as a whole, with a higher relative proportion of persons aged 60 and above participating. The percentage of participants who were female (59.4%) was greater than the percentage of non-participants who were female (50.8%). Both the age and sex distributions of the 12 regions were similar to those of the non-pilot regions (25 public health unit regions).

Table 5. Age Distributions of Participants and of the Eligible Population in the 12 Pilot Regions.

<table>
<thead>
<tr>
<th>Eligible OHIP beneficiaries</th>
<th>Pilot Regions Participants*</th>
<th>Pilot Regions Non-Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ontario FOBT project data participants from 12 PHU Regions</td>
<td>Administrative data on 12 PHU Regions MINUS [Ontario FOBT project participants]</td>
</tr>
<tr>
<td>Number</td>
<td>Distribution of Participants %</td>
<td>Number</td>
</tr>
<tr>
<td>50-54</td>
<td>1,326</td>
<td>19.0</td>
</tr>
<tr>
<td>55-59</td>
<td>1,519</td>
<td>21.8</td>
</tr>
<tr>
<td>60-64</td>
<td>1,546</td>
<td>22.2</td>
</tr>
<tr>
<td>65-69</td>
<td>1,403</td>
<td>20.1</td>
</tr>
<tr>
<td>70-75</td>
<td>1,178</td>
<td>16.9</td>
</tr>
<tr>
<td>Total</td>
<td>6,972</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Male  | 2,827 | 40.6 | 395,860 | 49.2 |
| Female | 4,145 | 59.4 | 408,387 | 50.8 |
| Total  | 6,972 | 100.0 | 804,247 | 100.0 |

*Participants = primary care arm participants + public health unit recruited participants

Primary care providers, Urban/rural residence, and FOBT History of Ontario FOBT project participants, non-participants, and OHIP beneficiaries in all other non-pilot public health regions.

Participants in both recruitment arms were very likely to have a single provider of most primary care visits rather than to have no such provider, or multiple providers with none providing care for >50% of any one beneficiary’s primary care visits (see Table 6). This is expected, given that
the design of the study encouraged the delivery of the intervention through a primary care provider. The majority of participants were urban residents, however the percent of rural participants was higher in the public health recruitment regions than in the primary care arm, perhaps indicating better reach by PHU promotion into rural communities.

The percentage of Primary Care recruitment participants with a history of one or more FOBTs during the five years immediately prior to the start date of the study was 33.5% compared to 20.1% among the Public Health recruitment regions, suggesting that Public Health recruitment was more successful in recruiting unscreened and underscreened persons.

Table 6. Number and Percent of Participants with a Primary Care Provider, Urban vs. Rural Residence, and FOBT History by Recruitment Arm.

<table>
<thead>
<tr>
<th>Primary Care Recruitment Regions</th>
<th>Number</th>
<th>%</th>
<th>6 Public Health Unit Recruitment Regions</th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes &gt; 50% primary care visits with one provider</td>
<td>2,592</td>
<td>95.0</td>
<td>3,796</td>
<td>89.4</td>
<td></td>
</tr>
<tr>
<td>No = no provider or &lt; 50% of visits with any one provider</td>
<td>136</td>
<td>5.0</td>
<td>448</td>
<td>10.6</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>2,728</td>
<td>100.0</td>
<td>4,244</td>
<td>100.0</td>
<td></td>
</tr>
<tr>
<td>Urban</td>
<td>2225</td>
<td>81.6</td>
<td>3,100</td>
<td>73.0</td>
<td></td>
</tr>
<tr>
<td>Rural</td>
<td>503</td>
<td>18.4</td>
<td>1,144</td>
<td>27.0</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>2,728</td>
<td>100.0</td>
<td>4,244</td>
<td>100.0</td>
<td></td>
</tr>
<tr>
<td>History of FOBT in the 60 months prior to study participation</td>
<td>913</td>
<td>33.5</td>
<td>851</td>
<td>20.1</td>
<td></td>
</tr>
</tbody>
</table>

Table 7 illustrates that more participants (91.6%) had access to a single primary care provider than did non-participants (79.6%) or persons residing in non-pilot regions (71.9%). Project participants and non-participants among the 12 recruitment regions were very similar in the percentage of those who are urban residents (76.4% vs. 76.0%). The underlying age-eligible population in the remaining 25 non-pilot regions is overwhelmingly composed of urban residents (89.5%); this is because none of the public health units serving the three largest cities in Ontario (Toronto, Mississauga, Ottawa) were selected in the random sample. The preponderance of urban residents without a single primary care provider may be a reflection of the diversity of care that urban residents have access to, relative to rural residents, such as after-hours and walk-in clinics, emergency departments, and multiple community primary care providers.

Table 7. Participants, Non-Participants, and Persons in Non-Pilot Regions with a Primary Care Provider, having Urban vs. Rural Residence.

<table>
<thead>
<tr>
<th>Primary Care Provider</th>
<th>Participants</th>
<th>%</th>
<th>Non-Participants</th>
<th>%</th>
<th>Non-Pilot Regions</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes &gt; 50% primary care visits with one provider</td>
<td>6,388</td>
<td>91.6</td>
<td>640,331</td>
<td>79.6</td>
<td>1,770,366</td>
<td>71.9</td>
</tr>
<tr>
<td>No = no provider or &lt; 50% of visits with any one provider</td>
<td>584</td>
<td>8.4</td>
<td>163,916</td>
<td>20.4</td>
<td>691,544</td>
<td>28.1</td>
</tr>
<tr>
<td>Total</td>
<td>6,972</td>
<td>100.0</td>
<td>804,247</td>
<td>100.0</td>
<td>2,461,910</td>
<td>100.0</td>
</tr>
<tr>
<td>Urban</td>
<td>5,325</td>
<td>76.4</td>
<td>611,406</td>
<td>76.0</td>
<td>2,202,175</td>
<td>89.5</td>
</tr>
<tr>
<td>Rural</td>
<td>1,647</td>
<td>23.6</td>
<td>192,841</td>
<td>24.0</td>
<td>259,735</td>
<td>10.6</td>
</tr>
<tr>
<td>Total</td>
<td>6,972</td>
<td>100.0</td>
<td>804,247</td>
<td>100.0</td>
<td>2,461,910</td>
<td>100.0</td>
</tr>
</tbody>
</table>

*Participants = primary care arm participants + public health unit recruited participants
Income Quintiles and Comorbidity of Ontario FOBT project participants, non-participants, and OHIP beneficiaries in all other non-pilot public health regions.

No direct information about participants' incomes was collected in the pilot project; however indirect, ecological-level information was sought by correlating participants' postal codes with data collected in the Canadian census (1996). Participants in both recruitment arms tended to live in higher rather than lower income areas (see Table 8). This is partly explained by the proportion of the 50 to 75 year-old age group who are enjoying the most prosperous period of their lives, but is also consistent with the higher adoption of health promotion behaviours among wealthier people wherever this has been studied. The PHU arm did reach more low and middle income people, whereas more than 50% of participants in the PC arm resided in the two highest income regions.

Table 8. Income Quintile of Ontario FOBT Project Participants by Recruitment Arm

<table>
<thead>
<tr>
<th>Income Quintile</th>
<th>6 Primary Care Recruitment Regions</th>
<th>6 Public Health Unit Recruitment Regions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>%</td>
</tr>
<tr>
<td>Missing</td>
<td>53</td>
<td>1.9</td>
</tr>
<tr>
<td>1 (low)</td>
<td>361</td>
<td>13.2</td>
</tr>
<tr>
<td>2</td>
<td>438</td>
<td>16.1</td>
</tr>
<tr>
<td>3</td>
<td>486</td>
<td>17.9</td>
</tr>
<tr>
<td>4</td>
<td>640</td>
<td>23.5</td>
</tr>
<tr>
<td>5 (high)</td>
<td>750</td>
<td>27.5</td>
</tr>
<tr>
<td>Total</td>
<td>2,728</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Table 9 shows that participants, non-participants, and the eligible population in the 25 non-pilot regions have similar patterns of income distribution. According to CIHI (Canadian Institute of Health Information) hospital separation data (back to 1988), the occurrence of serious comorbid illness was similar among participants, non-participants, and non-pilot regions of Ontario. This is reflected in the distribution of the Charlson Comorbidity score in these groups.

Table 9. Number and Percent of Ontario FOBT Project participants, non-participants, and persons in non-pilot regions by Income Quintile and Charlson Comorbidity.

<table>
<thead>
<tr>
<th>Income Quintile</th>
<th>Participants*</th>
<th>%</th>
<th>Non-Participants</th>
<th>%</th>
<th>Non-Pilot Regions</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Missing</td>
<td>156</td>
<td>2.2</td>
<td>16,366</td>
<td>2.0</td>
<td>64,235</td>
<td>2.6</td>
</tr>
<tr>
<td>1 (low)</td>
<td>986</td>
<td>14.1</td>
<td>140,912</td>
<td>17.5</td>
<td>422,126</td>
<td>17.2</td>
</tr>
<tr>
<td>2</td>
<td>1,208</td>
<td>17.3</td>
<td>158,001</td>
<td>19.7</td>
<td>460,867</td>
<td>18.7</td>
</tr>
<tr>
<td>3</td>
<td>1,495</td>
<td>21.4</td>
<td>162,706</td>
<td>20.2</td>
<td>475,509</td>
<td>19.3</td>
</tr>
<tr>
<td>4</td>
<td>1,612</td>
<td>23.1</td>
<td>161,670</td>
<td>20.1</td>
<td>489,383</td>
<td>19.9</td>
</tr>
<tr>
<td>5 (high)</td>
<td>1,515</td>
<td>21.7</td>
<td>164,592</td>
<td>20.5</td>
<td>549,790</td>
<td>22.3</td>
</tr>
<tr>
<td>Total</td>
<td>6,972</td>
<td>100.0</td>
<td>804,247</td>
<td>100.0</td>
<td>2,461,910</td>
<td>100.0</td>
</tr>
</tbody>
</table>

| Charlson Comorbidity** | | | | | |
|------------------------| | | | | |
| 0                      | 6,375 | 91.4 | 718,728 | 89.4 | 2,233,139 | 90.7 |
| 1                      | 297   | 4.3  | 44,008  | 5.5  | 114,946   | 4.7  |
| 2                      | 220   | 3.2  | 26,430  | 3.3  | 70,825    | 2.9  |
| 3 or higher            | 80    | 1.1  | 15,081  | 1.8  | 43,000    | 1.7  |
| Total                  | 6,972 | 100.0| 804,247 | 100.0| 2,461,910 | 100.0|

*Participants = primary care arm participants + public health unit recruited participants ** as of 2004/3/01.
4.3 FOBT Results

Pilot Project FOBT Results.

Overall, 192 participants had positive tests (85 in the Primary Care recruitment arm and 107 in the Public Health recruitment arm). The percentage of positive FOBT results was 2.8% (3.1% among participants in the primary care recruitment regions compared to 2.5% among the public health unit recruitment regions). This difference can be partially attributable to the distribution of results in one of the three laboratory networks, which showed a higher positive rate (5.4%) due to technique. This laboratory was a significant provider in several of the primary care recruitment regions, relative to other regions (see Table 10, Laboratory 3). It is also possible that there was provider and participant selection bias in proceeding with the FOBT (for example, some persons with symptoms or signs such as some rectal bleeding may have completed and submitted project-related FOBT kits). As well, one laboratory network (Laboratory 2) experienced a higher proportion of tests (3.5%) deemed unsuitable for interpretation.

Table 10. FOBT Results by Laboratory Network.

<table>
<thead>
<tr>
<th>Lab</th>
<th>Laboratory 1 (Hemoccult II)</th>
<th>Laboratory 2 (Hema-Screen)</th>
<th>Laboratory 3 (Hema-Screen)</th>
<th>All Labs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>63 (1.9%)</td>
<td>45 (2.2%)</td>
<td>84 (5.4%)</td>
<td>192 (2.8%)</td>
</tr>
<tr>
<td>Negative</td>
<td>3,304 (97.9%)</td>
<td>1,932 (94.3%)</td>
<td>1,456 (94.0%)</td>
<td>6692 (96.0%)</td>
</tr>
<tr>
<td>Other</td>
<td>6 (0.2%)</td>
<td>72 (3.5%)</td>
<td>9 (0.6%)</td>
<td>87 (1.2%)</td>
</tr>
<tr>
<td>Total</td>
<td>3373 (100%)</td>
<td>2049 (100%)</td>
<td>1549 (100%)</td>
<td>6971*</td>
</tr>
</tbody>
</table>

* Note: lab code was missing for 1 report

Table 11 shows the age distribution of those with positive tests. A clear trend toward increasing positivity with advancing age was evident, with 4.7% of tests positive in the oldest age group compared to 1.8% in the youngest group. Men had a higher rate of positivity than did women (3.5% vs. 2.2%).

Table 11. FOBT Positivity by Age and Sex.

<table>
<thead>
<tr>
<th>Age</th>
<th>Number Testing Positive</th>
<th>Number of Participants</th>
<th>Percent Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>50-54</td>
<td>24</td>
<td>1,326</td>
<td>1.8%</td>
</tr>
<tr>
<td>55-59</td>
<td>41</td>
<td>1,519</td>
<td>2.7%</td>
</tr>
<tr>
<td>60-64</td>
<td>35</td>
<td>1,546</td>
<td>2.3%</td>
</tr>
<tr>
<td>65-69</td>
<td>37</td>
<td>1,403</td>
<td>2.6%</td>
</tr>
<tr>
<td>70-75</td>
<td>55</td>
<td>1,178</td>
<td>4.7%</td>
</tr>
<tr>
<td>Total</td>
<td>192</td>
<td>6,972</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>93</td>
<td>4,145</td>
<td>2.2%</td>
</tr>
<tr>
<td>Male</td>
<td>99</td>
<td>2,827</td>
<td>3.5%</td>
</tr>
<tr>
<td>Total</td>
<td>192</td>
<td>6,972</td>
<td></td>
</tr>
</tbody>
</table>
Background rates of Large Bowel Procedures in the 12 months prior to the Ontario FOBT Project and during the 12 months of Ontario FOBT Project recruitment.

In order to examine the effects on colorectal cancer screening, and FOBT in particular, that the pilot project may have had on screening that occurred outside of the pilot (for example, physicians in the Primary Care recruitment arm who may have increased their screening behaviour, but did not enrol their patients in the pilot), we examined OHIP billing records for potential screening procedures. Comparisons were made between a 12-month time period prior to the start of the intervention period (March 01, 2003 – Feb 28, 2004) and a 12-month time period during the intervention period (April 1, 2004 – March 31, 2005). Tables 12 and 13 detail these results. Endoscopy procedures included all billings pertaining to examination of the colon. The OHIP feecodes used for endoscopy were: Z580 – Endoscopy (using 60 cm. flex scope) and Z555 – Endoscopy – sigmoid/descending colon. This background analysis provides valuable data on what was happening in the regions, since the number of pilot participants completing FOBT screens represented only 9% of all FOBTs (pilot-related and outside of the pilot) completed in the pilot regions over 12 months of the intervention period (6554/70,994).

For all OHIP beneficiaries aged 50 to 75 years old who resided in the pilot project regions, there was a modest increase in FOBT. The FOBT rate was slightly higher in Primary Care versus Public Health recruitment regions during the 12-month period of the pilot (9.8% vs. 6.9%), but the pre-pilot rate was also marginally higher in these regions (6.8% Primary Care regions vs. 4.9% in Public Health regions), suggesting a possible imbalance in the two arms despite randomization. There was a slight increase in endoscopy and polypectomy from the year prior to the pilot to the year of the pilot in regions of both recruitment arms.

Table 12. Number and Rate of Large Bowel Investigations billed for pilot participants and non-participants in the 12 months prior to (01 March 2003 to 28 Feb 2004) and the 12 months during (01 April 2004 to 31 March 2005) the Ontario FOBT Project.

<table>
<thead>
<tr>
<th>Investigation</th>
<th>6 Primary Care Recruitment Regions*</th>
<th>6 Public Health Unit Recruitment Regions*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre-Pilot (n, %)</td>
<td>Pilot (n, %)</td>
</tr>
<tr>
<td>FOBT</td>
<td>26,586 (6.8%)</td>
<td>37,930 (9.8%)</td>
</tr>
<tr>
<td>Barium enema</td>
<td>5,082 (1.3%)</td>
<td>4,853 (1.3%)</td>
</tr>
<tr>
<td>Endoscopy no polypectomy</td>
<td>11,173 (2.9%)</td>
<td>12,262 (3.2%)</td>
</tr>
<tr>
<td>Polypectomy</td>
<td>3,547 (0.9%)</td>
<td>4,184 (1.1%)</td>
</tr>
</tbody>
</table>

*Includes investigations performed on both Participants and Non-Participants in the Pilot Project Regions.

Overall, pilot participants from the 12 regions were more likely to have had FOBT before the pilot project than were non-participants (10.6% vs. 5.8% in the 12 months prior to the pilot). Of note, the rate of FOBT in non-participants increased slightly during the pilot period over background rates (from 5.8% pre-pilot to 8.0% during the pilot), perhaps indicating a regional impact of the educational and awareness-raising activities of the pilot project. In non-pilot regions, background FOBT rates were 7.4% and 8.8% before and during the pilot periods.
Table 13. Number and Rate of Large Bowel Investigation billed for participants, non-participants, and OHIP beneficiaries in non-pilot regions in the 12 months prior to (01 March 2003 to 28 Feb 2004) and 12 months during (01 April 2004 to 31 March 2005) the Ontario FOBT Project.

<table>
<thead>
<tr>
<th>Investigation</th>
<th>Participants</th>
<th>Non-Participants</th>
<th>Non-pilot regions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre-Pilot n (%)</td>
<td>Pilot n (%)</td>
<td>Pre-Pilot n (%)</td>
</tr>
<tr>
<td>FOBT</td>
<td>736 (10.6)</td>
<td>2,840 (43.3)*</td>
<td>46,596 (5.8)</td>
</tr>
<tr>
<td>Barium enema</td>
<td>70 (1.0)</td>
<td>102 (1.5)</td>
<td>9,131 (1.1)</td>
</tr>
<tr>
<td>Endoscopy no polypectomy</td>
<td>154 (2.2)</td>
<td>205 (2.9)</td>
<td>23,032 (2.9)</td>
</tr>
<tr>
<td>Polypectomy</td>
<td>30 (0.4)</td>
<td>73 (1.1)</td>
<td>7,610 (1.0)</td>
</tr>
</tbody>
</table>

*Due to the alternate (non-OHIP) payment arrangement established with pilot project laboratories, a different methodology was used to calculate this number. The number of pilot project FOBTs in this 12-month period was actually 6,554, however, only 2,840 (43.3% of the known total) tests had been billed to OHIP by the time of writing.

Examining more closely the trends in the regions of the pilot and the non-pilot regions, there is an obvious difference in the experience of the pilot regions compared to non-pilot regions. Overall, all groups showed an increase in FOBT screening. However, in both arms of the pilot, there was an increase in FOBT testing of greater than 40%, while there was only an 18% increase in the non-pilot regions.

Table 14. Comparison of the change in FOBT and endoscopy utilization prior to (01 March 2003 to 28 Feb 2004) and 12 months during (01 April 2004 to 31 March 2005) the Ontario FOBT Project.

<table>
<thead>
<tr>
<th>Investigation</th>
<th>6 Primary Care Regions</th>
<th>6 Public Health Regions</th>
<th>Non-Participants in 12 Regions</th>
<th>25 Non-Pilot Regions</th>
</tr>
</thead>
<tbody>
<tr>
<td>FOBT (pre-pilot)</td>
<td>26,586</td>
<td>20,746</td>
<td>46,596</td>
<td>181,745</td>
</tr>
<tr>
<td>FOBT (pilot)</td>
<td>37,930</td>
<td>29,350</td>
<td>64,440</td>
<td>214,645</td>
</tr>
<tr>
<td>% Increase</td>
<td>42.7%</td>
<td>41.5%</td>
<td>38.3%</td>
<td>18.1%</td>
</tr>
<tr>
<td>Endoscopy (pre-pilot)</td>
<td>11,173</td>
<td>12,013</td>
<td>23,032</td>
<td>73,296</td>
</tr>
<tr>
<td>Endoscopy (pilot)</td>
<td>12,262</td>
<td>13,664</td>
<td>25,721</td>
<td>85,562</td>
</tr>
<tr>
<td>% Increase</td>
<td>9.8%</td>
<td>13.7%</td>
<td>11.7%</td>
<td>16.7%</td>
</tr>
</tbody>
</table>

4.4 Follow-up Investigations

Active FOBT recruitment by primary care providers and public health units continued until February 28, 2005. Laboratories continued to distribute FOBT kits on presentation of FOBT Project requisitions with consent forms until late May 2005, and kit analysis was performed until May 31, 2005. OHIP billings for follow-up investigations such as barium enema, endoscopy (i.e. colonoscopy, sigmoidoscopy, and polypectomy) were collected up to November 30, 2005, thus allowing 6 months follow-up time from the last FOBT submitted.

Time to Endoscopy.

Overall, 124 / 192 (64.6%) of participants with positive FOBT had large bowel endoscopy by November 30, 2005, with a slightly higher proportion of those from the Primary Care arm receiving endoscopy (71% versus 60%). The rate of follow-up by large bowel endoscopy within 12 weeks following the date of the test was very low amongst participants with a positive FOBT (30.6% among the Primary Care recruitment regions and 35.5% among the Public Health recruitment regions). However, for those who eventually underwent large bowel endoscopy, 50% did so by 12 weeks. Overall, 90% of those who had endoscopy did so by 228 days (more
than 7.5 months) after testing positive on FOBT. Figure 12 illustrates the time to endoscopy for participants who underwent the procedure.

In addition, 270 / 6780 (4.0%) of participants with negative or un-assessable FOBT proceeded to large bowel endoscopy by November 30, 2005.

**Figure 12.** Time from date of positive FOBT to date of large bowel endoscopy for participants who underwent the procedure (n=124).

Follow-up Endoscopy by Sex.
Among participants with positive results, a gender bias in follow-up was evident. Males were more likely to proceed to endoscopy than were females – 73% of males with a positive FOBT had endoscopy compared to 56% of females with a positive FOBT. Moreover, males had the endoscopy sooner than did females; 50% of all male participants with positive FOBT had endoscopy by 121 days, but 50% of females had endoscopy by 202 days (nearly 3 months longer).
5.0 Discussion

In 2003, The Ontario Fecal Occult Blood Test (FOBT) Project was undertaken as a joint effort of Cancer Care Ontario (CCO) and the Ontario Ministry of Health and Long-Term Care (MOHLTC), in collaboration with the Institute for Clinical Evaluative Sciences (ICES), and the Ontario Association of Medical Laboratories (OAML). It was intended primarily to inform colorectal cancer screening policy by comparing the effectiveness of two methods of promotion and recruitment to opportunistic screening – one through primary care physicians alone and one through public health units.

5.1 Awareness

Both public and physician awareness of the efficacy of FOBT as a colorectal screening test is low. Our survey mailed to Ontario primary care physicians found that 67% reported recommending FOBT to age-eligible patients (2). However, among the age-eligible population of Ontario, 45% of women and 54% of men have never heard of FOBT (3). Interpreted jointly, these surveys indicate that many Ontario physicians may not have discussed FOBT screening to a degree necessary for patients in the screen-eligible population to recall having ‘heard of’ FOBT. Furthermore, the fact that a large proportion of the citizenry who report having heard of FOBT are ‘not considering’ FOBT screening indicates that more effort is needed in screening promotion. The lack of awareness of FOBT is also underlined by our interviews with physicians who indicated some confusion about the appropriate age groups to screen, as well as the best modalities for mass screening.

Moreover, although physicians reported that they knew of and used FOBT for CRC screening, this finding was inconsistent with the actual screening data collected from the project. For example, according to OHIP physician and laboratory billing records, FOBT had not been performed in the 12 months preceding the pilot for 93% of age-eligible persons in the Primary Care regions and 95% in the Public Health regions.

Our survey of Ontario primary care physicians revealed that 45% felt that explaining FOBT to patients takes “a lot of physician time”, and almost half of physicians felt that FOBT has too many false results to be useful.

It is absolutely imperative that any future colorectal cancer screening program that is implemented in Ontario have a strong focus on public and health care provider education, to ensure that the most up to date information is readily available. To support screening behaviour change, additional organized screening program components, such as personal invitations and recall, and effective promotional campaigns will also need to be implemented – to ensure movement from “not knowing” to “knowing” and ultimately, to “doing”.

5.2 Recruitment

We observed very low uptake of FOBT screening among participating regions in both intervention arms (0.70% in the primary care physician-based recruitment arm versus 1.0% in the public health unit-based recruitment arm) throughout the 15 months of data collection. The low recruitment rates make comparisons between the groups difficult, but certain differences between the two recruitment arms are plausible. Recruitment in the Primary Care arm remained relatively constant throughout the pilot, whereas recruitment in the Public Health arm corresponded with major outreach initiatives. The highest recruitment occurred in urban regions with prominent academic health science centres and with strong and wide PHU outreach, including the distribution of kits directly to the community. Comparatively, the lowest rates of
recruitment were found in more rural regions characterized by relatively few and socio-geographically isolated medical practices.

In comparison to the Primary Care recruitment strategy, the Public Health recruitment strategy had slightly higher uptake across all age groups and both sexes, screened more people in rural areas, screened more lower and middle income people, and screened more people who had not been screened recently or perhaps ever screened. We postulate that this difference may be attributable to more intensive outreach efforts to physicians and the community, including one-on-one personal interactions and mass media campaigns in the Public Health regions.

The slightly lower rates of screening in men compared to women, younger versus older age groups (i.e. 50-54 vs. 65-69), rural compared to urban residents, and the poor compared to the wealthy perhaps reflects these demographic groups’ access to and use of primary care. Indeed, we found a high preponderance among participants in both recruitment arms of having a primary care provider (92% versus 80% in non-participants and 72% in persons residing in non-pilot regions). This again underscores the necessity of improving access to FOBT through novel routes in the community.

The low overall rates of uptake indicate that the current state of best practices alone will not yield adequate participation to impact the population burden of colorectal cancer. Interventions that were felt to be high-yield by PHUs include:

- mass media awareness and promotion strategies,
- “detailing” of physicians in the catchment area,
- enlisting physician leaders as “champions” of FOBT screening,
- engaging the area’s physicians in discussions on recruitment before the intervention was implemented,
- improving patient/public access to the test kits by making them available at locations other than the laboratory (e.g. PHUs, health fairs, flu immunization clinics).

Our interviews with participating and non-participating physicians revealed that the majority appreciated some of the educational materials provided in the pilot, such as patient pamphlets, peer-reviewed scientific articles regarding screening, and a patient website on FOBT and colorectal screening.

One of the drawbacks of the project was the requirement for a comprehensive informed consent process for potential participants to enable health record linkage. While consent was ethically necessary for record linkage in the study, physicians perceived it to be an additional barrier to participation in screening due to the time and effort required to inform participants. Indeed, we noted an increase in FOBT screening of non-participants over the pilot period, perhaps indicating that promotional efforts resulted in increased screening, but outside of the pilot. This impact is noteworthy as the initiation of screening promotion strategies by screening programs has the potential to reach the whole population in the target region. The much lower increase in background FOBT rates in non-pilot regions compared to pilot regions underscores this effect (18% vs. 40%).

5.3 FOBT Results and Follow-up Rates

Among the 12 regions in both recruitment arms, the percentage of results that were positive for occult blood was slightly higher than expected at 2.8%, and varied across regions from 0 to 4.8%. Regions with percentages higher than 3% were predominantly served by one laboratory network whose procedures diverged from the others. Higher than average rates of positive FOBT may also be explained in part by a prevalence effect that is commonly noted in a first
round of screening. As well, a bias toward screening those who had symptoms (e.g. rectal bleeding) may have occurred. As expected, positivity increased with advancing age, and with male gender.

Compliance with follow-up diagnostic procedures after an abnormal (positive FOBT) screening result is an important issue that affects the outcome and utility of screening. It has been noted in many jurisdictions that organized breast-screening programs have resulted in increased awareness of and attention to appropriate follow-up for screen-detected abnormalities. While compliance with follow-up was high in the randomized controlled trials of FOBT, it has been found to be lower in settings where follow-up is not organized. One of the objectives of this pilot project was to examine compliance with follow-up in real-life settings. Of the 192 persons with positive FOBTs, only 30.6% (Primary Care) and 35.5% (Public Health) had undergone large bowel endoscopy (primarily colonoscopy) within 12 weeks after the positive test date. Overall, only 64.6% of those with a positive FOBT underwent endoscopy by the end of our follow-up period (November 30, 2005). This rate of investigative colonoscopy following a positive FOBT is well below our expectations, and must be contrasted with rates and times to follow-up of organized screening programs in other countries such as England, Australia, Italy, Finland, and Israel, where reported follow-up rates are approximately 80% and average times to colonoscopy after a positive FOBT are around 30 days. The delay and low uptake of follow-up in this study is likely due to several factors, including access to colonoscopy, lack of recommendations for follow-up colonoscopy by physicians and patient non-compliance with recommendations. These same factors likely underlie the surprising preponderance of follow-up endoscopy in males compared to females (73% versus 56%) and delay in endoscopy for those females who undergo the procedure (202 days for women versus 121 days for men). Further research in this area is needed to understand the facilitators and barriers to follow-up colonoscopy for an abnormal screen result.

5.4 Policy Issues

5.4.1 Recruitment

Start-up and Awareness

The intervention period for the project was 12 months. However, the actual offering of FOBT in the public health arm was delayed by a period of approximately 3 months, compared to the physician arm. This was due to the necessary steps of start-up planning by the public health units, recruitment of program staff and engagement of the physicians in the public health unit area. One of the significant concerns in all six health units was the potentially negative implications of implementing new colorectal screening strategies without prior stakeholder engagement. For example, introducing the handout of kits at locations such as the PHU or local hospital required that the physicians, institutions, and laboratories were supportive, and that the logistics could be worked out for handling kits and completed specimens. In the start-up of a provincial colorectal cancer screening program, it will be important to build in adequate time and resources to allow for this type of planning and stakeholder engagement to occur.

Invitations to Screening

Neither of our opportunistic screening recruitment strategies involved the method of “invitation to screening” (i.e. mailed personal invitations) used in the three randomized controlled trials performed in Europe, or in the population-based pilot projects and organized screening programs implemented abroad, and described earlier in this report.
The province of Ontario has high quality data from which to create a continuously-updated invitation list which would omit persons who have recently died, have already received a diagnosis of colorectal cancer, or whose burden of chronic illnesses is associated with high short-term mortality and would prohibit any investigation of occult bleeding in the stool or surgical treatment of an underlying resectable cause of the bleeding. Furthermore, the Privacy Commissioner allows personal information to be used for generating personal letters of invitation to screening.

The qualitative interviews with physicians practicing in the six Primary Care arm regions revealed that 91% (10 of 11) of participant physicians (i.e. physicians who recruited their patients to the study) favoured population-based colorectal screening with mailed invitations and reminders. A lesser majority of non-participating primary care physicians in these regions (i.e. those who did not recruit any of their patients to the study) agreed with them (6). Although physicians supported the idea of a provincial screening program such as the Ontario Breast Screening Program (OBSP) or Ontario Cervical Screening Program (OCSP), some preferred that a screening program flow through their office rather than entirely “remove” FOBT from their practice.

With respect to the age-eligible screening population, a personally-addressed invitation for FOBT would be acceptable to three-quarters of the age-eligible population (4). However, receiving an FOBT specimen collection kit along with the invitation currently would not be acceptable to 39%. With respect to receiving test results, more respondents thought it would be “OK” to be informed of their result through their doctor rather than through the mail; but still, a majority thought that receiving an abnormal test result in the mail (accompanied by instructions of how to contact a designated nurse to discuss and follow-up) was “OK”.

These findings suggest that while there is support for direct mailing of screening invitations and even mailed test kits, much groundwork needs to be done to build awareness of colorectal screening and to set a precedent for and normalize the idea of mailed kits. The experience of jurisdictions abroad highlights the importance of creating a screening system that does not place additional (and unnecessary) requirements on participants and their primary care providers – as these are barriers to effective screening. It will be necessary and advantageous for a provincial screening program to liaise with Family Health Team initiatives in Ontario to maximize recruitment.

Personal invitations to screening that are issued through the mail have been determined by the Information and Privacy Commissioner’s Office in Ontario to be an acceptable practice for the Ministry of Health and Long Term Care. In the case of breast screening, the report of an investigation of a privacy complaint from 1994 stated, “It is our view that “health promotion” (from section 6(2) of the Ministry of Health Act) is compatible with health planning and coordination. In “promoting health”, the Ministry disclosed the personal information to Canada Post so that the OBSP letter could be sent to targeted individuals. It is our view that these individuals could have reasonably expected such a disclosure of their personal information. Therefore, the Ministry’s disclosure of the personal information to Canada Post was for a consistent purpose, in accordance with section 42 of the Act” (5).
Testing and Follow-up

FOBT.
The major community-based private laboratory companies participated in the Ontario FOBT project and were very cooperative in adapting specimen pick up times and locations, and in general, in providing timely data. However, despite extensive collaboration among the laboratories and the project steering committee, it was discovered near the end of the recruitment period that one laboratory was following a different procedure than the others, which likely contributed to a FOBT “positive” rate that was more than double that of the other two laboratories. Moreover, another of the laboratory networks had a much higher rate of specimens deemed unsuitable for interpretation, which would result in the patient needing to re-submit another sample. Discrepancies such as these may result in inefficiencies typical of opportunistic screening utilization, such as repeat testing and variable colonoscopy referral rates. Jurisdictions with organized screening programs have found it advantageous to limit their programs to a single FOBT product and limited number of designated laboratories for processing specimens. Standard (and shared) procedures must be used, standard equipment (if any) must be used, and standard criteria for test interpretation must be followed.

Colonoscopy.
Among the regions in both intervention arms, the percent of results that were positive for occult blood varied from 0 to 4.8%. Among those participants testing positive, only 64.6% underwent colonoscopy by the end of our follow-up period. Moreover, only 30.6% in the Primary Care recruitment regions, and 35.5% in the Public Health recruitment regions, underwent colonoscopy within 12 weeks following the test date at the laboratory. These low rates of overall and 3-month follow-up are major weaknesses. It is generally accepted that a screening program must achieve a high rate of follow-up of positive results, and that access to subsequent procedures must be timely, in order to attain the benefits of screening as achieved in randomized controlled trials. The results of this study support the need for a colorectal screening program to provide both screening and follow-up assessment components in an organized program setting.

There is ample evidence that the utilization of large bowel investigative procedures in Ontario up to the end of 2001 varied among counties and did not approach a level consistent with a rate of screening required to achieve the mortality reductions demonstrated in the trials (15).
6.0 Recommendations

From the results and experience of this project and subsequent research carried out in 2005 by CCO to examine population-based colorectal screening programs in other jurisdictions around the world, it is clear that opportunistic screening alone will not achieve the population screening rates needed to reduce colorectal cancer mortality. The recommendations from the pilot are focused on moving forward with an organized colorectal screening program for Ontario. They have not changed from those in the interim report of June 30, 2005, aside from an additional recommendation regarding the engagement of primary care providers in program development. Effective April 1, 2006, physicians in family health teams will receive bonus payments for reaching set practice targets for FOBT screening. As of March, 2006, over 5,000,000 Ontarians are enrolled with Family Health Teams.

A detailed proposal for a provincial colorectal cancer screening program was submitted to the Ontario MOHLTC in the summer of 2005, based on the recommendations below. The proposal identified the first step towards program implementation to be the formation of a Colorectal Screening Program Working Group involving all key groups.

1. We recommend that the Ontario MOHLTC establish a provincial population-based organized Colorectal Cancer Screening Program.

2. We recommend that the program be phased-in over 4 or more years, based on meeting pre-defined program goals of recruitment and follow-up, and that the program continue to roll out once these critical success factors have been achieved.

3. We recommend that Cancer Care Ontario, in conjunction with the Ontario MOHLTC, implement a major mass media awareness campaign for primary care providers and age-eligible residents of Ontario (age 50 or older), and individual health promotion messages regarding Fecal Occult Blood Test (FOBT) screening, in order to maximize the effectiveness of a population-based colorectal cancer screening program using FOBT.

4. We recommend the establishment of a central program office at Cancer Care Ontario for the population-based Colorectal Cancer Screening Program, to plan and implement the regional phase-in of the program, including contracting with laboratories to ensure consistent and high-quality FOBT, and to contract with endoscopists and hospitals to guarantee timely access to quality-controlled investigative colonoscopy. The central program office will also support an information system appropriate for monitoring quality and measuring critical success factors of the program. This program structure would readily accommodate an evidence-based change of screening method in the future, be it a different stool assay, or some form of large bowel endoscopy or imaging for a larger subset of the eligible population.

5. We recommend the creation and automatic updating of a population-based list of persons eligible for biennial screening invitations, and necessary information structures to support this. Initial invitations will be phased-in by regions, over time.

6. We recommend that Cancer care Ontario work with the Ontario MOHLTC and other stakeholders to consult with primary care providers during the planning and implementation phases of the provincial program to ensure that their concerns and needs are understood and met. As well, collaborative relationships between primary care providers and the program should be fostered.
7. We recommend that the Ontario MOHLTC solicit bids from laboratories to provide the following comprehensive services:
   - To send invitation letters and reminders with numerically unique coded FOBT specimen collection kits to age-eligible residents of Ontario, according to the phase-in schedule.
   - To receive by mail the FOBT kits and analyze them.
   - For unsatisfactory specimens, to send a letter and additional kit to the participant to repeat the test.
   - To transmit the results of negative tests by mail to the participant and, if requested, to his/her primary care provider, and electronically to the central office of the Colorectal Cancer Screening Program.
   - To transmit the results of positive tests by mail to the participant and, if requested, to his/her primary care provider, and electronically to the central office of the Colorectal Cancer Screening Program, and to the Colorectal Cancer Screening Program regional office.

8. We recommend the establishment of regional offices of the Colorectal Cancer Screening Program. Regional offices will provide toll-free telephone assistance for those requesting further information/direction for completing the FOBT kit. Regional offices will rapidly contact participants who have tested positive, for the following functions: discussion, counselling, and arranging for investigative endoscopy.

9. We recommend that critical success factors for the program be established and monitored:
   - 65% of the age-eligible population will participate in the biennial program.
   - 75% of participants testing positive will undergo diagnostic colonoscopy within 12 weeks from the test date.
   - 60% of invasive cancers detected will be stage I.
   - 95% of advanced non-invasive neoplasms will be resected by polypectomy.
   - The rates of serious complication from diagnostic colonoscopy will be lower than 3/1000 for bleeding, 1/1000 for perforation, and 1/15,000 for death.
7.0 References


