The Newfoundland and Labrador colorectal cancer screening program for the average risk population: A pre-implementation study of the family physician and target population perspective on fecal occult blood testing.

by

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ABSTRACT

Background

Newfoundland and Labrador (NL) has the highest incidence and mortality rates of colorectal cancer (CRC) in North America. In March 2010, funding was announced for a fecal occult blood test (FOBT) screening program for those aged 50 – 74 years and at average risk for CRC. The main goal of this program is to reduce mortality from CRC through the detection of pre-cancerous polyps or early-stage cancer. Research was undertaken prior to program implementation to survey the average risk population regarding their intention to participate in screening and to ascertain family physicians' knowledge of screening guidelines, current screening practices and level of support for an organized screening program.

Methods

Average risk individuals living in three different areas of the province were surveyed (n = 959): a rural area with a familial cluster of high genetic risk CRC, and a rural and an urban area without familial clusters of high genetic risk CRC. It was hypothesized that those living in the area with a presence of high genetic risk CRC would be most likely to report positive intention to participate in screening. It was further hypothesized that between the two areas without any familial clustering of CRC, urban respondents would be more likely to report a positive intention to screen.

The intent of the family physician survey (n = 274) was to enhance understanding of FOBT screening practices and level of physician support for an organized screening program. It was posited that the majority of physicians would be supportive of an organized FOBT screening program but would not necessarily be screening their average risk patients according to recommended guidelines.

Results

No significant association was found between intention to screen and a) presence of a familial cluster of high genetic risk CRC ($p = 0.17$), or b) residing in a rural versus urban region ($p = 0.30$). In multivariate analysis, prior awareness of FOBT [OR = 1.92, 95% CI 1.32 – 2.77, $p = 0.001$] and prior use of FOBT [OR = 1.87, 95% CI 1.18 – 2.97, $p = 0.008$] were significant predictors of positive screening intention.

Almost all family physicians indicated support for an organized screening program (n = 256, 94.8%). Despite this, colonoscopy was the most commonly recommended procedure for screening average risk patients. Most physicians were compliant with the guideline-recommended age to start screening, (n = 228, 83.5%), but fewer were compliant with the recommended age for stopping (n = 66, 25%).

Conclusions

Presence of a familial cluster of high genetic risk CRC did not appear to positively impact the screening intention of average risk individuals. Based on previous research, a higher than expected level of positive intention to screen was reported across all regions that were sampled. Similarly, it was unanticipated that almost all family physicians would be supportive of an organized screening program. Follow-up research, post-implementation of the screening program, will provide an opportunity to determine whether reported intention and support translate into high rates of participation and physician referral for screening.

ACKNOWLEDGEMENTS

DEDICATION

This thesis is lovingly dedicated to my parents ***Doreen and Richard McCrate.*** Thank you for, quite simply, Everything.

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ASIR	Age-standardized incidence rate
ASMR	Age-standardized mortality rate
AJCC	American Joint Committee on Cancer
AFAP	Attenuated Familial Adenomatous Polyposis
ARR	Average risk rural
ARU	Average risk urban
BCSQ	Bowel Cancer Screening Questionnaire
BC	British Colombia
CAG	Canadian Association of Gastroenterology
CCHS	Canadian Community Health Survey
CIHI	Canadian Institute for Health Information
CPAC	Canadian Partnership Against Cancer
CRC	Colorectal cancer
FAP	Familial Adenomatous Polyposis
FIT	Fecal immunochemical test
FOBT	Fecal occult blood test
gFOBT	Guaiac fecal occult blood test
HNPCC	Hereditary non-polyposis colon cancer
HRR	High risk rural
NCCSN	National Colorectal Cancer Screening Network
NL	Newfoundland and Labrador
NLCCSP	Newfoundland and Labrador Colon Cancer Screening Program
POHEM	Population Health Model

PPV	Positive predictive value
PSA	Prostate specific antigen
RCT	Randomized controlled trial
RHA	Regional Health Authority
SEER	Surveillance Epidemiology and End Results
TNM	Tumour, nodes, metastases

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Chapter one

Introduction

1.1 Context - The Provincial Colorectal Cancer Screening Program

In March 2010, funding was announced for the Newfoundland and Labrador (NL) Colorectal Cancer Screening Program. The main goal of this program is to reduce mortality in the province due to colorectal cancer (CRC), through the detection of pre-cancerous polyps or early-stage CRC. The program will be phased in over a three-year period starting with an initial dissemination of 2000 home fecal immunochemical test kits in the first year. The second year will see dissemination of kits increase to 10,000 home kits, with full provincial implementation planned for the third year.

This home-based screening program is intended for the population at average risk of developing CRC. The risk of developing CRC is broadly categorized into two groups, the average risk population and the high risk population. Approximately 80% of people with CRC appear to have sporadic disease with no evidence of inheriting the disorder (average risk), and the remaining 20% appear to have familial or hereditary risk[1] (high risk). A proportion of the high risk cases are related to two main genetic predispositions, namely familial adenomatous polyposis / attenuated familial adenomatous polyposis (FAP/AFAP) which constitutes approximately 1% of cases and hereditary non-polyposis colon cancer (HNPCC or Lynch Syndrome) which constitutes around 5% of cases. The remaining 15-20% of the high risk population has a family history of CRC in close relatives without an identified genetic predisposition[2].

A higher incidence of familial and hereditary related risk for CRC is found in NL compared with many other populations[3,4] and high risk screening clinics have been

established at multiple sites across the province. Correspondingly, a body of research into this population exists and stratification of the risk of developing CRC in NL is well described[3,4,5,6]. Although there is a higher prevalence of high genetic risk CRCs in NL compared with other populations, the absolute number of these cases is smaller than the number who were at average risk before developing the disease. Therefore, it is crucial that an organized program be put in place to screen the average risk population. For the purposes of the screening program, an average risk individual will be defined as someone with no personal history of CRC or adenomatous polyps; no personal history of inflammatory colitis or Crohn's disease; and no first degree relatives (parent, sibling, offspring) with CRC or adenomas.

In addition to the average risk inclusion criteria, individuals targeted for this screening program will be between 50 and 74 years of age. It is well-established that the vast majority of sporadic CRCs, (over 90%), occur in those aged 50 or older[7]. The upper age limit is in keeping with the Canadian Association of Gastroenterology's (CAG) recommendations on screening individuals at average risk for CRC[8]. CAG recommends that programmatic CRC screening should cease at 75 years of age and that the decision to screen individuals aged between 75 and 86 should be made on a case by case basis. The reason for this age cut-off is that the risk of harm from screening is increased in the elderly population. The risks of screening include complications related to bleeding, perforation and cardiorespiratory events. Primary benefits of screening relate to number of life years saved. This decreases with increasing age. The additional benefit to individuals who have been enrolled in a screening program beyond 76 years of age is not

favourable[9].   All other Canadian provinces with average risk screening programs have targeted the 50-74 age range.

1.2 Burden of Colorectal Cancer Nationally and Provincially

According to the Canadian Cancer Statistics projections for 2014, an estimated 24,400 Canadians (13,500 men and 10,800 women) will be diagnosed with CRC this year and 9,300 (5,100 men and 4,200 women) will die from it[10]. The lifetime probability of developing CRC is 7.5% for men and 6.3% for women. It is the second most common cause of cancer death for males and the third most common cause of cancer death for females. These statistics illustrate the extent of the national burden of this disease.

Focusing on NL specifically, 320 new cases of CRC are projected for men in 2014 (17.2% of all new cancer cases) and 230 new cases are projected for women (15.3% of all new cancer cases)[10]. While projected counts are important and serve a variety of purposes, such as facilitating health care planning; age-standardized incidence and mortality rates also provide meaningful and useful information. Age-standardization is a process that adjusts for differences in age distributions among populations allowing for inter-jurisdictional comparisons. In Canada, the calculation of these rates is usually carried out using the 1991 Canadian population as the reference standard. Table 1.1 shows the 2014 estimated age-standardized incidence rate (ASIR) of CRC by gender, for Canada and each of the provinces. ASIRs are presented per 100,000 of the population. The ASIR of CRC for men and women in NL is higher than for other provinces.

Table 1.1 Estimated ASIRs for CRC by Gender and Province, Canada 2014 (Cases per 100,000)

	Canada	NL	PEI	NS	NB	QC	ON	MB	SK	AB	BC
Male	59	86	60	71	65	65	56	66	62	57	51
Female	40	53	44	48	39	42	39	44	42	37	35

Source. Canadian Cancer Statistics 2014.

In addition to incidence, mortality is an important indicator of the extent of cancer burden in a population. The number of estimated deaths in NL in 2014 from CRC is 140 for men (16.5% of all cancer deaths) and 100 for women (14.9% of all cancer deaths)[10]. Estimated age-standardized mortality rates (ASMRs) are also available for 2014 and are presented in Table 1.2. Men and women in NL have a higher mortality rate due to CRC when compared with other provinces.

Table 1.2 Estimated ASMRs for CRC by Gender and Province, Canada 2014 (Cases per 100,000)

	Canada	NL	PEI	NS	NB	QC	ON	MB	SK	AB	BC
Male	22	39	23	29	21	24	21	23	22	20	20
Female	14	22	18	17	14	16	13	15	13	12	13

Source. Canadian Cancer Statistics 2014.

Data in the Canadian Cancer Statistics publication, as outlined above, are very useful for supplying a description of projected cancer incidence and mortality rates. However, it must be acknowledged that the statistics reported are projections or estimates and are descriptive of the provincial population as a whole, as opposed to providing further breakdowns, such as cancer incidence and mortality by age. Reporting these statistics by age sub-group can elucidate differing trends in CRC burden across the lifespan.

An analysis that was carried out using NL provincial cancer registry data for CRC (analysis was carried out 'in-house') provides a more in-depth look at the extent of CRC incidence in the province between 1983 and 2006 by age sub-group. Mortality data were, unfortunately, unavailable. Table 1.3 includes ASIRs by four age sub-groups and for all

ages combined, for select years between 1983 and 2006. As with the previous tables, rates are given per 100,000 of the population.

Table 1.3 ASIR of CRC in NL by Age Subgroup for Select Years Between 1983 and 2006

Age Group	Year	Female	Male	Total Population
15-29	1983	4.5	0.9	2.8
	1994	0	0	0
	2006	0	0	0
30-49	1983	26.4	21.8	24
	1994	18.3	14.6	16.4
	2006	20.3	14.7	17.6
50-74	1983	176.5	199.1	187.8
	1994	159	237.6	196.9
	2006	170.3	276	222.3
75+	1983	426.4	477.8	438.5
	1994	280.5	392.7	332.9
	2006	438	707.5	539.7
All ages (including 0-14)	1983	64.5	69.2	66.2
	1994	50.7	70.7	60.2
	2006	60.9	92.9	75.2

A benefit of examining CRC incidence by age sub-group is to enable the identification of those who are most at risk. The increase in CRC ASIRs from age 50 onward suggests that 50 is an acceptable age to start screening in the NL population.

Overall, the data in tables 1.1, 1.2, and 1.3 illustrate that CRC is a particularly salient health issue for this province, and that as age increases, so does the risk of developing CRC. These data support the decision to implement a CRC screening program in this province for the average risk, 50-74 year old population.

1.3 The NL Target Population

Given that NL has the highest median age in Canada at 44.2 years[11], there is a substantial proportion of the population that fits into the target age range for the screening program. While it is not possible to determine the exact size of the average risk screening population, it is possible to obtain an approximation of its size via census data. According to the 2006 census there are 245,735 males and 259,735 females in the province for a total of 505,470 people. Of this total population, there are 75,030 men and 76,995 women aged between 50 and 74[12], which constitutes 30%, or almost one-third, of the full population. For the purposes of the screening program there are individuals who would be excluded from this total number for various reasons. For example, individuals at high genetic or familial risk for CRC should be targeted by the high risk screening program. The high risk program involves a provincial network of outreach offices in Grand Falls-Windsor, Corner Brook and St. John's that work together to identify families at high risk of CRC. Members of high risk families, or carriers of gene mutations, are entered into this colonoscopy screening program. Other reasons for exclusion from the average risk screening program include receipt of a screening colonoscopy within the last five years which would render an individual ineligible to enroll in the screening program until a later date; or the presence of morbidities that make follow-up colonoscopy unfeasible. However, despite some ineligible individuals, it is likely that the majority of those aged 50-74 belong to the average risk population.

1.4 Current Practices of CRC Screening in NL

In attempting to ascertain the status of CRC screening practices prior to implementation of an organized program, it became clear that no single data source could provide a robust picture. It was, therefore, necessary to triangulate information from various sources in an effort to understand the pre-program implementation state of CRC screening in this province. Sources of information included a research thesis, a provincial endoscopy access report, regional health authority laboratory databases and self-report data from the Canadian Community Health Survey (CCHS). It is acknowledged that the end result of collating these various sources of information does not provide a comprehensive summary of the screening practices in NL. Nonetheless, it does provide a triangulated snapshot of CRC screening activity.

A Master's thesis carried out in 2009[13] aimed to determine whether gastroenterologists and general surgeons, the two clinical specialty areas responsible for performing endoscopy in NL, were knowledgeable about familial and hereditary CRC and associated risk factors and whether they followed best practice screening guidelines. Although this project largely focused on screening those in the high risk category, it also provided insight into specialist screening practices for the average risk population. The sampling frame for the study was all the gastroenterologists and general surgeons in NL registered with the College of Physicians and General Surgeons. Out of the eligible population of 43 physicians, 36 (83.7%) responded to the survey. Results showed that colonoscopy every ten years was the most commonly reported screening test and screening interval used for the average risk population. Almost 70% of physicians reported using this screening modality for those at average risk. Fecal occult blood test

(FOBT) use for the average risk population was reported by 38.9% of physicians while flexible sigmoidoscopy or flexible sigmoidoscopy plus FOBT were each used by 5.6% of physicians (numbers do not add up to 100% as physicians could choose more than one option). These results suggest that colonoscopy may be the main screening modality that specialists use for screening the average risk population, which is not in accordance with the CAG guidelines[8]. FOBT, on the other hand, may be under-utilized. The proportion of average risk patients that were screened using each type of screening test cannot be determined from this thesis, rather, just the proportion of specialist physicians that report using each type of test in this population.

Colonoscopies and flexible sigmoidoscopies are recorded in the various Meditech systems around the province making it possible to obtain the total number of procedures done in a given time period. This information is not entirely useful because indications as to whether the endoscopic procedure was performed for the purpose of screening, diagnosis or surveillance and whether it was performed on an average risk or high risk individual are not recorded. Similarly, when FOBT results are tested in the laboratory, neither the individual's CRC risk status, nor indications for the test, are recorded. The guaiac fecal occult blood test (gFOBT) is still the most frequently used FOBT in the province. The fecal immunochemical test (FIT) will be broadly introduced with the advent of the screening program. There are two main pathways by which the gFOBT is distributed and analyzed. One is through the laboratory, whereby a physician will instruct their patient to obtain a gFOBT from the laboratory, complete it, and return it to the laboratory for testing. These results are recorded in a laboratory database. The other pathway is through physicians' offices, for those physicians who keep gFOBTs in their

clinic and distribute them directly to patients. Because a result for gFOBT is obtained using a manually applied reagent, physicians can carry out this testing process in their own clinic environment. The results of gFOBTs that are tested in the clinic setting are not recorded in any administrative database. Essentially, there is no way of ascertaining the total number of gFOBTs that are distributed and subsequently tested in this province.

With the above caveats considered, limited information on the volume of endoscopy and gFOBT carried out in NL is available through administrative databases. In 2010, a province-wide assessment of the current state of the endoscopy system was undertaken[14]. This assessment, done to evaluate the demand and capacity of the existing endoscopy sites, reported on the total number of colonoscopies and sigmoidoscopies that were carried out in the province over a six-month period. The total number of colonoscopies was 7,898 and the total number of flexible sigmoidoscopies was 183. However, there were also categories listed for 'sigmoidoscopy' and 'rigid sigmoidoscopy' in the report although the distinction between flexible/rigid sigmoidoscopy and solely 'sigmoidoscopy' was not clarified. The count was 42 for rigid sigmoidoscopy and 1001 for sigmoidoscopy over the six-month period. Thus, the total number of sigmoidoscopies carried out was 1,226. If the assumption is made that an approximately equivalent number of scopes are carried out in any six-month period, then the total number of colonoscopies in a year would be 15,796 and the total number of sigmoidoscopies of any type would total 2,452. Thus, a year's worth of colonoscopy and sigmoidoscopy would approximate 18,248 procedures.

Ascertaining the number of laboratory-tested FOBTs was not as straightforward due to the fact that different regions of the province capture their data in different ways.

The following numbers were obtained from various laboratory databases by an Eastern

Health employee and were provided in the following way:

Table 1.4 Total FOBTs Analyzed in Laboratories, 2010

Provincial Area	Site	Number	Total
Eastern Health	Health Sciences	5584	10702
	St. Clare's	1818	
	Rural Avalon	3300	
Central Health	Twillingate (73 @ 3 per person)	219	1857
	Buchans (152 @ 3 per person)	456	
	Green Bay (394 @ 3 per person)	1182	
Western Health	Inpatient	678	13309
	Outpatient	12631	
Labrador City		3456	3456
TOTAL			**29324**

As seen in Table 1.4, not all regions reported the data in the same way. For

example, Central Health clarified that the total number of tests performed did not

correspond to the total number of individuals tested. One gFOBT consists of 3 separate

smear cards and each card was recorded as a separate test although it was completed by

the same person. It is not known for the other regions whether each documented test

result corresponds to a unique individual or whether tests are recorded in a similar way to

Central Health. If the latter is true then the number of FOBT results reported could

correspond to up to two-thirds fewer people than tests.

Other sources, including the 2008 iteration of the CCHS provide an alternative perspective on the status of CRC screening in Canada and in NL; that of self-report. A Statistics Canada publication[7] reported on up-to-date CRC testing practices for screening or diagnosis in Canadians aged 50 and over and determinants of screening, using data from the CCHS. Up-to-date testing was defined as FOBT in the past two years or colonoscopy / sigmoidoscopy in the past five years. The analysis showed that approximately 40% of Canadians ≥ 50 years reported that they had had up-to-date CRC testing according to the above definition. The reported rate for NL was 34%, which was not the lowest in the country, but ranked below the national average. Greater inter-jurisdictional variability was observed for FOBT (10% - 42%) as opposed to endoscopy (11% - 30%). When the results for FOBT and endoscopy were looked at separately for NL, it was found that a higher percentage of respondents had undergone endoscopy (24.8%) compared with FOBT (15.6%).

It seems counterintuitive to find higher self-reported endoscopy rates than FOBT rates given that the average risk population is larger in size than the high risk population and that FOBT is the recommended screening modality for average risk individuals. However, this finding reflects the responses of gastroenterologists and general surgeons in NL, more of whom preferred colonoscopy for screening average risk patients[13.]

Possible implications of the CCHS findings are that only a small percentage of the average risk, screening eligible population are currently being screened (15.6% using FOBT), or that a higher number of the average risk population are being screened (up to 34%), but potentially with an inappropriate screening modality given their risk level. Unfortunately, the risk status of respondents was not recorded in the CCHS database.

Regardless, it is concerning to find that only 34% of the 50+ population in NL report being up to date with CRC screening, and of those, only 15.6% were screened using FOBT. It is anticipated that the population-based average-risk screening program in NL will increase this percentage.

In summary, the status of CRC screening by CRC risk level using FOBT or endoscopy is not well documented in NL, but from available information, endoscopy appears to be the preferred method. The precise number of FOBTs tested by the laboratory cannot be ascertained and there are currently no data available on the number of FOBTs distributed directly by family or specialist physicians that are returned to the clinic for testing. In the case of endoscopy procedures, it is possible to obtain a count of the total number of procedures for a given time period, but whether they were done for screening, diagnosis or surveillance and whether the patient was high risk or average risk is not known. A definitive evaluation plan with clear quality determinants and indicators as part of the CRC screening program should begin to rectify the paucity of information available on screening practices, at least for those in the average risk population who are tracked by the program.

1.5 Recommended Quality Determinants and Indicators for CRC Screening Programs

Quality determinants and quality indicators are vital components of any screening program. Tracking activity at all points along the screening pathway will provide valuable information about how the program is operating and can highlight successes as well as areas where there may be room for improvement.

In November 2008, the Canadian Partnership Against Cancer (CPAC) and the National Colorectal Cancer Screening Network (NCCSN) mandated a Working Group to identify quality determinants (including quality indicators) to be delivered in a formal report for use by organized CRC screening programs in Canada. These determinants / indicators were meant to consist of principles, processes and activities essential for maximizing the benefits of organized CRC screening in Canada while minimizing the potential risks[15].

The quality determinants identified in this report are based on a conceptual CRC screening pathway and are comprised of five key domains within the screening pathway: participation, screening, diagnostic follow-up, case management and program outcomes. This report focused on the average risk population, using a model of entry-level FOBT with colonoscopic diagnostic follow-up for those with abnormal FOBT results.

Quality determinants were proposed within each of the five domains for a total of the 20 indicators: a) Participation: participation, screening retention and utilization; b) Screening Test: positivity, positive predictive value for CRC and positive predictive value for adenoma; c) Diagnostic Follow-Up: colonoscopy completion, wait time to colonoscopy, wait time to pathological diagnosis, colonoscopy CRC detection,

colonoscopy adenoma detection, 30-day non-CRC-related hospitalization after follow-up colonoscopy and 30-day non-CRC mortality after follow-up colonoscopy; d) Case Management: wait time from screen-detected CRC diagnosis to initiation of treatment program; e) Outcomes: program CRC detection rate, interval CRC incidence, CRC stage distribution, CRC incidence, CRC mortality and non-CRC mortality.

Each of these quality determinants are important and reflect significant points at which evaluation may occur along the screening pathway. One area that is not addressed in the context of this report is the pre-implementation phase of a screening program. It may be posited that pre-implementation does not comprise a part of the screening pathway because this pathway truly begins once a person is invited to participate in a screening program. However, it can also be argued that the pre-implementation phase of a screening program does constitute a part of the screening pathway and that it represents a key opportunity to understand more about the population that will be targeted for screening as well as the perspective of other stakeholders such as family physicians, nurse practitioners and relevant specialists. Developing a greater understanding of the target population, such as their knowledge about screening methods and intention to participate in the screening program, may identify particular issues or specific population subgroups that could benefit from interventions such as education, promotion or more practical support. Identifying issues at this stage could allow for a more efficacious use of resources and may help to enhance screening participation.

Other jurisdictions have developed evaluation plans for their screening programs, albeit with a significant degree of variation in the detail. A selection of these will be described in the next section with particular attention paid to evaluation activity occurring

prior to the distribution of the screening test, and / or evaluation that focused on the screening target population's perspective or other key stakeholders' perspectives.

1.6 Program Evaluations from Other Jurisdictions

1.6.1 Ontario

Ontario was the first Canadian province to begin implementation of a population-based CRC screening program. This entailed carrying out a pilot study followed by a broader program of implementation and evaluation. The Ontario FOBT Program was a twelve-month pilot program, carried out in 12 regions in Ontario between 2004 and 2005. It was designed to inform provincial policy on CRC screening[16].

A number of evaluative processes were undertaken prior to the distribution of FOBTs including a survey of FOBT awareness and behaviour administered to a sample of the target population in an effort to determine the decision-making stage of respondents about utilizing FOBT. Respondents were classified into one of five mutually exclusive stages of screening: never heard of FOBT, not considering FOBT, decided against FOBT screening, undecided about FOBT screening, and decided not to have FOBT screening. Random digit dialing was used to recruit survey respondents. A survey about direct mailing of FOBT kits was also carried out to ascertain the acceptability to potential screening program participants of the fundamental components of a centralized FOBT screening program. Primary care physicians were surveyed regarding their knowledge and behaviour with respect to FOBT screening and semi-structured open-ended interviews explored practice barriers and facilitators regarding FOBT screening from the physician perspective.

1.6.2 Manitoba

The Manitoba CRC Screening Program was established in 2007 and subsequently carried out a 2.5 year pilot project (Phase 1) to assess the feasibility and acceptability of

an organized approach to CRC screening using the FOBT. The population targeted for Phase 1 was average risk individuals, 50 to 74 years of age, living in two selected RHAs and not up to date with CRC screening.

No data collection occurred prior to implementation of the program; however, a survey was conducted after the administration of FOBTs. This was done to explore issues related to FOBT acceptability and factors that affected screening participation in Manitoba. Other evaluation activities included focus groups with people who received an FOBT from the program and interviews with key stakeholders to collect feedback on the first phase and implications for future phases of the program[17].

Like Ontario, Manitoba's evaluation plan included an element of eliciting both the average risk population's and physicians' perspectives. However, in Manitoba, all activities were scheduled to occur after FOBT administration.

1.6.3 United Kingdom

The UK carried out an FOBT pilot screening program between 2000 and 2002 prior to national roll-out of FOBT screening in 2006. The pilot took place in two English health authorities and three Scottish health boards. Target participants were men and women aged 50 to 69[18].

Evaluation activities included tracking participation rates and acceptability of screening according to various demographic characteristics (gender, ethnicity etc.); a psychosocial survey administered to both responders and non-responders in an effort to understand beliefs and attitudes about FOBT amongst the two groups; and, focus groups to qualitatively explore beliefs and views about CRC. Other evaluation activities focused

on further steps along the screening pathway including uptake and acceptability of colonoscopy, workload and impact on routine services. Like Manitoba, no data collection occurred until after administration of the FOBT kits.

1.6.4 Australia

Australia began administration of an FOBT pilot in 2002, targeting those aged 55 to 74. This program sought to assess the acceptability and feasibility of CRC cancer screening with the aim of informing whether and how to introduce a national, organized FOBT screening program[19]. Three sites from around Australia were selected for participation in the pilot.

A number of diverse activities were undertaken as part of the evaluation process including a telephone-administered survey of knowledge, attitudes and practices of the target population in relation to CRC and CRC screening. The first administration of the survey was conducted prior to the commencement of the pilot, providing a baseline from which to evaluate the post-pilot survey data. A qualitative study was also carried out through interviews with people invited to participate at the three pilot sites. Objectives were to assess the relevant attitudes, opinions and behaviours that influenced participation or non-participation in the pilot. Focus groups and interviews were conducted with family doctors to explore the impact of the pilot program including the impact on GP satisfaction with their role in the pilot and strengths and weaknesses and possible barriers to participation in the pilot. Other quality determinants such as screening uptake, positivity rate, colonoscopy follow-up and impact on colonoscopy services were also measured.

1.6.5 Summary

Many of these evaluation plans contain an element of assessing the average risk population's perspective on CRC in general and on FOBT screening. Topics covered include knowledge of CRC and CRC screening, attitudes towards screening, barriers and facilitators to screening and intention to engage in screening. Each of the screening programs captured different elements of this information and measured it in varying ways. Most programs also attempted to capture the family physician and / or other stakeholders' perspectives, but like the average risk population perspective, it was captured via different means and at various time points along the screening pathway. The final sections of this chapter will provide an overview of the aims and rationale for carrying out similar work at the pre-implementation phase of the screening pathway in NL and an outline for the remainder of the thesis.

1.7 Study Description and Rationale

1.7.1 Study Aims

Overview: This is a two-tiered study. Study one consists of a telephone survey of individuals at average risk for CRC, 50 - 74 years of age, and living in the following geographical areas: 1) New-Wes-Valley region, Lumsden, Greenspond 2) St. John's 3) Marystown, Burin, and Grand Bank. Study two consists of a mail-out survey to all family physicians in the province.

The primary aim of study one is to compare the screening intention of average risk individuals living in three distinct geographical regions: 1) a rural region with the presence of a familial cluster of high genetic risk CRC (high risk rural or HRR); 2) a rural geography without the presence of a familial cluster of high genetic risk CRC (average risk rural or ARR); and 3) an urban geography without the presence of a familial cluster of high genetic risk CRC (average risk urban or ARU). Secondary analysis will involve examining the relationship between other factors and reported screening intention of the average risk population. The primary aim of study two is to determine the level of family physician support for a population-based FOBT screening program for the average risk population in NL. Secondary objectives include describing the physician population and their CRC screening practices. The results of both studies will be used to gain a better understanding of potential uptake and support for the NL Colorectal Cancer Screening Program (NLCCSP).

1.7.2 Study Rationale

The broad rationale for studying both the average risk population's and family physicians' perspectives prior to implementation of the screening program is that it may provide insight into how to administer the program to optimize screening uptake . The higher the level of screening participation, the more likely it is that the program will have an impact on reducing mortality due to CRC. There are possibly several points along the screening pathway at which opportunities to enhance screening uptake may occur, but the pre-implementation phase may present the best opportunity to be proactive as opposed to reactive about enhancing screening uptake.

According to the screening evaluation reports of other more established programs[16,17,18,19], efforts to elicit both the average risk population and family physician perspective are a standard practice in evaluation, regardless of the stage at which this endeavour occurs. In some evaluation plans, these activities occurred after the pilot round of screening was completed, before moving onto broader implementation, while in others it was done before any screening activity had started.

A statistical modeling exercise using the Population Health Model (POHEM) projected that a screening program with a 67% participation rate would reduce the CRC ten-year mortality rate by 16.7%, with an estimated cost effectiveness of $11,907 per life-year gained[20]. These results led the authors to conclude that CRC screening would be beneficial and cost-effective under the condition of achieving a 67% participation rate. However, a participation rate of 67% is a very high ideal to strive for with respect to population-based screening uptake.

Ascertaining how current participation rates measure up to this proposed standard is not straightforward, because, as Coombs et al. (2002)[21] reported, it is difficult to synthesize the literature regarding CRC screening uptake due to differences in study methodologies and settings. Nonetheless, based on available information, they report that compliance rates typically range between 40% and 50%. In the case of NL, it is probable that participation rates will begin below of this range and increase over time, as the program becomes more established.

If no attempt is made to understand the average risk population's intention to engage in screening, then the probable screening uptake rate cannot be estimated. Furthermore, in the absence of pre-implementation research, there will be no means of identifying vulnerable sub-populations within the average risk population, for example, those who report being less likely to engage in screening or those that report significant barriers to screening. Although certain demographic characteristics and other factors that impact screening have been studied, it is not known whether these barriers and facilitators are relevant in NL. Additionally, given the propensity to use endoscopy to screen for CRC in NL, as reported by gastroenterologists and general surgeons[13], and by self-report data from the CCHS[7], it is possible that awareness of FOBT as a screening test for CRC is quite low in the province, which could negatively impact uptake. By engaging the target population for screening it may be possible to understand more about these issues and to help develop interventions to address issues that exist.

A similar rationale is proposed for eliciting the family physician perspective. There is considerable evidence to support the positive role that family physicians can play in screening uptake[22,23]. Even if screening kits are not administered through family

physicians' clinics, physician attitude toward screening and their endorsement of it as a beneficial activity can impact the likelihood that their patients will engage in screening[24,25]. Additionally, doctors' belief in the effectiveness of cancer screening tests has been shown to predict their use in clinical practice[26]. Collecting data on family physicians' CRC screening practices in NL, their attitude toward whether FOBT is an effective screening test and their knowledge of current guidelines will not only generate new knowledge for this province in terms of the current state of FOBT screening, but may also act as a litmus test of how likely family physicians are to be supportive of the screening program. Depending on the outcome of this data collection, continuing medical education or other exercises in awareness-raising around the effectiveness of FOBT in reducing CRC mortality may be conducted.

A final reason for conducting these investigations at the pre-implementation stage is that it allows for follow-up rounds of data collection at later stages, as the screening program is phased in. This leaves open the possibility for future research, beyond the scope of this thesis, on the intention-behaviour pathway and whether intention to screen or physician support for FOBT are reflected in actual screening participation and physician referral to screening.

1.8 Outline of Thesis

Chapter one has provided an introduction to this thesis. The proposed screening program for the population at average risk for CRC in NL has been described along with the eligibility criteria for taking part in this program. The burden of CRC both nationally and provincially has been elucidated, as has the percentage of the provincial population that may comprise the average risk population. Furthermore, current screening practices in NL have been highlighted according to the best available information, and other screening evaluation plans have been reviewed. Finally, a broad overview of the study aims has been outlined and a rationale has been provided for carrying out a piece of research at the pre-implementation phase of the NLCCSP. The remaining chapters of the thesis will include a literature review (chapter two), research questions (chapter three), a description of the methodology and analysis plan (chapter four), results of the target population survey (chapter five), results of the physician mail-out survey (chapter six), and the discussion and conclusions (chapter seven).

Chapter Two

Literature Review

2.1 Overview of CRC

2.1.1 Risk Factors

Chapter one highlighted increasing age and familial or genetic predisposition as significant risk factors for CRC. In addition to these, there are a number of other risk factors for CRC, many of them modifiable. Each of these is briefly elaborated: a) Personal history of colorectal polyps or cancer: the polyp-carcinoma sequence in the development of CRC has been supported by several studies[27,28,29,30]. In addition, recurrence of polyps and CRC in those who have had previous occurrences has been highlighted as an issue[21,31,32,33,34,35,36]; b) History of inflammatory bowel disease: patients with long-standing inflammatory bowel disease have an increased risk of developing CRC[37] c) Racial and Ethnic Background: varying rates of CRC may be seen in different racial and ethnic groups. For example, in the United States, blacks have higher incidence and mortality rates of CRC when compared with whites[38]; d) Personal History of Other Cancers: women diagnosed with uterine or ovarian cancer before age 50 are at increased risk of CRC, and women with a personal history of breast cancer have a slightly increased risk of colorectal cancer[39]; e) Diet: CRC appears to be associated with diets that are high in fat and calories, red and processed meats and low in fiber, vegetables and fruits. Researchers have also suggested that methods of cooking meats at very high temperatures (frying, broiling or grilling) create chemicals that might increase cancer risk[21]. In NL, pickled red meat (or salt meat) has been found to be significantly associated with an increased risk of CRC[40]; f) Sedentary Lifestyle / Physical Inactivity: physical

activity has been shown to reduce the risk of CRC[41]. It has been estimated that 12-14% of CRC could be attributed to lack of frequent involvement in vigorous physical activity[42]; g) Type II Diabetes: people with type 2 diabetes may have an increased risk of developing CRC. Both type 2 diabetes and CRC share some of the same risk factors (such as excess weight), but even after controlling for these, people with type 2 diabetes still appear to have an increased risk[43]; h) Obesity: a meta-analysis of 31 studies illustrated a higher estimated relative risk of CRC for those who were obese compared with those who were in the normal weight range[44]. The same study showed evidence of a dose-response relationship between body mass index and CRC; i) Smoking: long-term smokers are more likely than non-smokers to develop colorectal adenomas and cancer[45]. A recent case-control study carried out in NL found that former and current smokers were at a significantly elevated risk for CRC compared with non-smokers[46]; j) Alcohol Consumption: a meta-analysis of 61 studies looking at the association between alcohol consumption and CRC concluded that there is strong evidence for an association between alcohol drinking of >1 drink per day and CRC risk[47].

These risk factors compounded with age and genetic factors likely play a role in contributing to the high burden of CRC found in NL. Lifestyle factors may be of particular relevance in this province.

2.1.2 Natural History of CRC

Most CRCs, regardless of etiology, arise from adenomatous polyps. A polyp is a grossly visible protrusion from the mucosal surface of the colon and may be classified pathologically as a non-neoplastic hamartoma (juvenile polyp), a hyperplastic mucosal proliferation (hyperplastic polyp), or an adenomatous polyp[48]. Only adenomas are clearly pre-malignant and only a minority of such lesions ever develops into cancer[49].

The adenoma-carcinoma sequence in the development of CRC has been supported by several studies and is generally well accepted[2,27,28,29,30]. This sequence has a long natural history of approximately ten years[28,30,49]. Colonic mucosa undergoes an orderly progression from the initial development of a polyp to the development of frank carcinoma. The evolution of normal colonic mucosa from a benign adenoma to invasive carcinoma has been associated with a series of genetic events, in which sporadic point mutations cause activation of proto-oncogenes and loss of tumor suppressor genes[30]. These progressive molecular genetic changes and resultant deregulation of cell growth and proliferation eventually lead to the development of invasive carcinoma.

The lifetime risk of developing CRC in Canada is about 1 in 14 (7.1%) in men and 1 in 16 (6.3%) in women[50]. The rate of recurrence of adenomas among patients who have had a previous adenoma is generally higher than the prevalence of adenomas at initial colonoscopy[31,51]. Between 15% and 60% of patients who have had a polyp removed, develop a recurrence[31,32,33,34,35,36]. With respect to metastases, cancers of the large bowel generally spread to regional lymph nodes or to the liver via the portal venous circulation. The liver represents the most frequent visceral site of metastatic

dissemination[50]. In general, CRC rarely metastasizes to other sites without prior spread to the liver.

2.1.3 Staging and Survival

Cancer staging plays an integral role in cancer treatment. It forms the basis for the understanding of the disease at initial presentation. The American Joint Committee on Cancer (AJCC) utilizes a system that classifies the extent of the disease based on the extent of the primary tumor, the degree of lymph node involvement and whether there are distant metastases. The AJCC publish a cancer staging handbook that is revised every 6-8 years to reflect advances in cancer care. The most recent cancer staging handbook was published in 2010[52].

Staging is discussed in terms of clinical staging and pathologic staging. Clinical staging includes any information obtained about the extent of cancer before initiation of definitive treatment. It incorporates information from symptoms; physical examination; endoscopic examinations; imaging studies of the tumor, regional lymph nodes and metastases; biopsies of the tumor; and surgical exploration without resection. Pathologic staging is defined by the same diagnostic studies used for clinical staging, supplemented by findings from surgical resection and histologic examination of the surgically removed tissues[51].

Tumors, nodes and metastases (TNM) are grouped into anatomic stage / prognostic groups commonly referred to as stage groups. Groups are classified by roman numerals from I – IV with increasing severity of disease. Stage I denotes cancers that are smaller or less deeply invasive with negative nodes. Stage II and III define cases with

increasing tumor or nodal extent, and Stage IV identifies those with distant metastases at diagnosis.

Stage at diagnosis has a significant impact on CRC survival. The overall relative survival rate for CRC has increased over the past twenty years mainly due to screening and treatment advances[53,54]. Relative survival compares the observed survival for a group of cancer patients to the survival that would be expected for members of the general population who have the same characteristics such as sex, age and province of residence as the cancer patients. Relative survival rates in Canada for those with CRC are 56% for men and 59% for women[55].

Although population-level relative survival broken down by stage is not available for the Canadian population at the current time, it is available for the US population. It is likely that Canadian trends would follow a comparable pattern as those in the US given that both are similarly developed countries with Westernized cultures and lifestyles. Surveillance Epidemiology and End Results (SEER) is a program of the National Cancer Institute which provides information on population-based cancer statistics in the US. They report the following distributions of stage at diagnosis and relative survival rates by stage for CRC from 2002-2008[56]:

Table 2.1 Stage Distribution and 5-year Relative Survival by Stage at Diagnosis for 2001-2007, All Races, Both Sexes

Stage at Diagnosis	Stage Distribution (%)	5-Year Relative Survival (%)
Localized (Stage I and II)	39	89.9
Regional (Stage III)	36	69.6
Distant (Stage IV)	20	11.9
Unknown	5	33.9

The SEER data demonstrate that under half of all CRCs are currently diagnosed at Stage I or II (39%), when the disease is at its most curable. Five year relative survival for those diagnosed at Stage I or Stage II is very high at 89.9%. A similar percentage of cases are diagnosed at Stage III (36%), when the cancer has progressed to the regional lymph nodes. Five-year survival for Stage III is approximately 70% or twenty percentage points lower than when the disease is found at Stage I or II. Twenty percent of CRCs are diagnosed at Stage IV when distant metastases are involved. The five-year relative survival rate for those diagnosed with metastatic CRC is very low at around 12%.

The large drop in five-year survival rate from Stage I / II to Stage IV illustrates the importance of detecting CRC early. Screening offers the opportunity to detect cancer at an earlier stage, or as can be the case with CRC, before pre-malignant polyps develop into cancer.

2.2 Rationale for Screening for CRC

Preceding sections of this thesis have, in part, provided a rationale for why it is important to screen for CRC. However, while enhanced survival due to early detection and a considerable decrease in burden of disease are key factors supporting CRC screening, there are other elements to consider when determining the feasibility and efficacy of a screening program. There are many diseases for which one or more screening tests exist but for which evidence does not support screening on a programmatic, population-based level. One example of this is prostate cancer. The prostate specific antigen (PSA) test is a blood test used to screen for prostate cancer and there are contexts in which its use is both appropriate and beneficial. On a population-based level, however, the evidence does not support the benefit of a PSA screening program. A Cochrane Review of a meta-analysis of five RCTs concluded that prostate cancer screening did not significantly decrease all-cause or prostate cancer-specific mortality[57].

In 1968, a document entitled *Principles and Practice of Screening for Disease* was published by the World Health Organization[58]. The content of this document is still relevant today and usefully outlines ten criteria for early disease detection which would render a disease appropriate for programmatic, population-based screening (pp26-27). Each criterion is listed below with a corresponding explanation of how CRC fits that criterion.

1) **The condition sought should be an important health problem.**

Chapter one established that CRC is a significant health burden. The incidence and subsequent mortality rates from CRC in NL are very high and show no indication of lowering.

2) **There should be an accepted treatment for patients with recognized disease.**

There are a number of treatments available for individuals with CRC. These include surgical resection to remove the tumour, chemotherapy, and radiation. The latter two can be offered on an adjuvant or palliative basis. Treatment options depend on, amongst other things, the severity of disease at diagnosis and the site of the disease within the colon / rectum.

3) **Facilities for diagnosis and treatment should be available.**

Facilities for diagnosis and treatment of CRC in NL are available at various sites across the province. Endoscopy is the main mechanism by which the presence of CRC is diagnostically confirmed. Endoscopy suites, where flexible sigmoidoscopy and colonoscopy are performed, are located in twelve different regions of the province. Treatments for CRC including chemotherapy, radiation, supportive care and palliative services are delivered by the Cancer Care Program. The program is responsible for four cancer centers, including the Dr. H. Bliss Murphy Cancer Center in St. John's; and three regional centers in Gander, Grand Falls and Corner Brook. Varying treatments are available at each of these sites.

4) There should be a recognizable latent or early symptomatic stage.

CRC does have a latent or early symptomatic stage in that the vast majority of tumours develop from adenomatous polyps. This implies that there is opportunity for primary prevention via the discovery and removal of pre-cancerous polyps. Additionally, there is scope for secondary prevention through the detection of early stage cancer, prior to regional lymph node involvement or distant metastases.

5) There should be a suitable test or examination.

Unlike many other diseases, which have only one main screening modality, several screening options exist for CRC. Flexible sigmoidoscopy and colonoscopy, which are used in the diagnosis of CRC, can also be used for screening purposes. Additionally, FOBT, a less invasive method that tests for the presence of hidden blood in the stool, is a well-established option in some provinces / countries. Less commonly used modalities for screening include computed tomographic colonography which images the colon, and the fecal DNA assay panel which tests the stool for the presence of genetic mutations linked to CRC. According to the 2010 CAG recommendations[8], only FOBT (using either the FIT or high sensitivity gFOBT) or flexible sigmoidoscopy are proposed for programmatic screening.

6) The test should be acceptable to the population.

Availability of a screening test that is acceptable to the target population is a vital part of any screening program. Acceptability of a screening test is dependent on many factors including personal preference, invasiveness of the test, perceived accuracy of the test, costs of the test (including costs in terms of time to prepare for and perform the test) and perceived benefits of the test. It is not likely that one test will suit all individuals in a

population. Yet, due to the number of options available for CRC screening, it may be more likely that an individual will find a test that is acceptable to them. The non-invasive nature of fecal occult blood testing may be an attractive feature to some individuals.

7) **The natural history of the condition, including development from latent to declared disease, should be adequately understood.**

As explained in section 2.1.2, the natural history of the development of CRC is reasonably well understood. Polyps generally arise from the colonic mucosa or the innermost layer of the colon. Progressive molecular genetic changes and resultant deregulation of cell growth and proliferation eventually lead to CRC. The time line between the start of a pre-malignant polyp and its subsequent development into frank carcinoma can take up to ten years[14,18,38].

8) **There should be an agreed policy on whom to treat as patients.**

Any screening program should target those who are most at risk for the disease in order to maximize the impact of the program and to ensure the most efficient use of resources. CRC screening efforts in the average risk population usually target those aged 50 to 74. This decision is supported by available evidence and guidelines[7,8]. All provinces that have implemented screening programs to date have focused on this age range.

9) **The cost of case-finding (including diagnosis and treatment of patients diagnosed) should be economically balanced in relation to possible expenditure on medical care as a whole.**

The cost-effectiveness of CRC screening has been well-studied. A 2010 review by Lansdorp-Vogelaar et al.[59] of all of the major screening modalities reported that the cost-effectiveness ratios for all established screening strategies (defined in the paper as colonoscopy, flexible sigmoidoscopy and gFOBT) were less than $50,000 per life year

gained. An intervention that provides an additional life year at an incremental cost of $50,000 or less is deemed acceptable in most industrialized countries.

When the established strategies were compared against each other, no strategy was consistently found to be the most effective or to have the best incremental cost ratio. When the newer immunochemical-based test was compared to the guaiac-based test, the results were mixed. Approximately half of the studies concluded that the immunochemical test was a cost-effective strategy, while the other half suggested that the guaiac test was superior. This result was mainly dependent on the price difference because the guaiac test is less expensive. Fecal DNA was shown to be cost effective compared to no screening but less effective than established tests, while computed tomographic colonography was been estimated to be more expensive, and in many cases, less effective than colonoscopy.

10) Case-finding should be a continuing process and not a "once and for all" project.

Guidelines exist for the appropriate interval between screenings for most of the modalities available. With respect to programmatic screening, the CAG recommends annual or biennial screening, (dependent on available resources), if using FOBT and screening at ten year intervals if using flexible sigmoidoscopy. The CRC screening program for the average risk population in NL will offer biennial fecal immunochemical testing to those aged 50 – 74, who fit the average risk criteria.

Based on the ten comprehensive criteria listed above, a case can be made for the feasibility of screening for CRC, and more specifically, screening for CRC using FOBT.

2.3 Review of Fecal Occult Blood Testing

The screening test that will be used in the NL average risk screening program is the FIT. FIT belongs to a category of tests called FOBTs which are designed to detect hidden or small quantities of blood in a stool sample. FOBTs are not diagnostic for cancer; rather they are used to select individuals for more definitive diagnostic procedures including colonoscopy[60]. There are two main types of FOBT, the FIT and the gFOBT. A systematic review of CRC screening carried out for CPAC provides a thorough description of both tests[61].

Guaiac tests detect hemoglobin peroxidase activity in the feces. It is not specific to the activity of human hemoglobin and requires dietary and medicinal restrictions for testing. For example, red meat or fruits and vegetables high in peroxidase activity can result in false positive tests. Aspirin and other medications can also lead to false positives due to other sources of gastrointestinal bleeding. Conversely, high doses of vitamin C may lead to false negatives. In order to complete a gFOBT, samples from two to three different bowel movements are smeared onto test cards using a spatula. If any of the samples turn blue when mixed with a reagent, the test is positive. Exact definitions of positivity may vary.

FITs detect the globin component of human hemoglobin using a monoclonal or polyclonal activity. They are specific to human hemoglobin, eliminating the need for diet or medicinal restrictions. Some FITs use a spatula method while others involve pushing a brush or a probe into the stool and sealing it in a tube. Both gFOBTs and FITs can be processed in a physician's office or a laboratory. FIT analysis may be carried out with automated instrumentation and the cut-off value or threshold for positive tests may be user-defined.

CAG endorses the use of either type of FOBT for programmatic screening of average risk individuals, but states that FIT is preferred[8]. A review of the literature around both types of FOBT reveals that gFOBT has been in existence substantially longer than FIT. Three large-scale randomized controlled trials (RCTs) on the gFOBT have demonstrated that CRC is detected at an earlier and more curable stage among patients screened by gFOBT than among unscreened patients[62,63,64]. Over an eight to thirteen year period these studies were able to demonstrate a 14% to 18% reduction in CRC deaths with biennial screening[62,63] and a 33% reduction in deaths with annual screening[64]. A further follow up to one of these trials[65] found that the use of either annual or biennial FOBT screening significantly reduced, not only mortality, but incidence of CRC. The reduction in incidence likely resulted from the detection and removal of pre-malignant adenomatous polyps.

The three major RCTs that demonstrated the effectiveness of FOBT in reducing CRC mortality were initiated between 1975 and 1985. The main type of FOBT test available at that time was the gFOBT, and thus, the strongest evidence for a reduction in mortality of CRC through FOBT screening is based on utilization of the gFOBT. Since that time, several advances have been made in fecal occult blood testing including the development of the FIT which was described earlier. For many researchers and clinicians, the FIT may have more desirable properties when compared with the gFOBT; including the fact that only one bowel movement may be necessary to obtain an adequate sample, no dietary restrictions are required, and results can be analyzed via an automated instrument. The fact that there are currently no RCTs published demonstrating the effectiveness of the FIT in reducing mortality from CRC is a limitation of this test.

Nonetheless, it may be posited, based on the properties of the FIT, and given that its mechanism of use is analogous to that of the gFOBT, that population screening for CRC using the FIT test would result in a reduction in mortality and perhaps also in the incidence of CRC.

Despite the lack of RCT-level evidence on the impact of FIT on CRC mortality, studies have been carried out comparing the performance of the gFOBT and the FIT. Characteristics compared include positivity rate, sensitivity, specificity, positive predictive value and participation rate. A study performing both gFOBT and FIT in parallel on the same stool samples found an overall positivity rate of 6.7% for the gFOBT and 11.8% for the FIT[66]. Patients in this trial were followed up with diagnostic colonoscopy and a sensitivity of 74.2% was reported for the gFOBT compared with a significantly higher sensitivity of 87.1% for the FIT ($p = 0.02$). Sensitivities for screening advanced adenomas and early stage cancers specifically (which would be the primary foci of a screening initiative) were also significantly different at 23% for gFOBT and 40.5% for FIT ($p < 0.001$). With regard to specificity, gFOBT was found to have a significantly higher specificity compared to FIT for cancers of all stages (95.7% vs. 91%, $p < 0.001$) and for advanced adenomas (97.4% vs. 94.2%, $p < 0.001$).

An RCT comparing gFOBT, FIT and flexible sigmoidoscopy as screening modalities in an average risk population found varying rates of participation for each type of test[67]. The FIT had the highest participation rate at 61.5%, followed by 49.5% for gFOBT, and 32.4% for flexible sigmoidoscopy. Positivity rates showed a similar trend as in the previously reported study with the lowest positivity rate observed for gFOBT (2.8%), followed by 4.8% for FIT and 10.2% for flexible sigmoidoscopy. After adjusting

for age and sex, FIT detected more advanced adenomas than gFOBT, [OR = 2.0, 95% CI 1.3 - 2.3]. Diagnostic yield of advanced neoplasia per 100 invited subjects was significantly higher for FIT [1.5, 95% CI 1.2 - 1.9] than for gFOBT [0.6, 95% CI 0.4 - 0.8], $p < 0.0001$.

Hoffman et al. (2010)[68] also found a significantly higher rate of screening or participation for patients assigned to FIT (68%) compared with those who were assigned to gFOBT (55%) $p = 0.01$. Stepwise regression showed that adherence to screening was associated only with receiving FIT versus gFOBT [OR = 1.56, 95% CI 1.04 – 2.32]. For patients who completed both tests, 62% reported a preference for the FIT, 12% preferred the gFOBT and the remainder were neutral. Respondents indicated problems with the dietary and medication restrictions for gFOBT and the majority found it easier to perform FIT.

An RCT of average risk patients, in addition to finding that FIT had favourable characteristics when compared to gFOBT, (participation, positivity, detection rates for advanced adenoma and cancer), found that five patients with a negative gFOBT had an interval cancer, detected within two years of testing[69]. This was discovered by conducting a review of cancer registry data. These cancers were likely missed by gFOBT. Tumours were found in various anatomic sites in the colon including the sigmoid colon, the descending colon, the ascending colon and the cecum. The registry review did not yield any missed cancer results in those with a negative FIT. Overall, FIT detected cancer and advanced adenomas better than gFOBT by both intention to screen analysis [OR = 2.9, 95% CI 1.59 - 4.57, $p = 0.001$] and per protocol analysis [OR = 3.16, 95% CI 1.8 -5.4, $p < 0.001$].

Based on the CAG endorsement for the FIT and the available evidence supporting

its higher sensitivity, PPV and screening adherence rates, it was decided that this test

should be utilized in the NL screening program. Lower specificity rates on the FIT

compared with the gFOBT are acknowledged, however, on balance, the FIT appears to be

the more effective test. Almost all Canadian provinces use the FIT test in their respective

average risk screening programs (i.e. Alberta, British Colombia, New Brunswick, Nova

Scotia, Prince Edward Island, Quebec and Saskatchewan).

2.4 Screening Behaviour

Establishing that CRC is an appropriate disease for which to screen on a population-level is an important element of making the case for the feasibility of launching a screening program for the average risk population in NL. Demonstrating that the FIT screening test is an appropriate and effective test for this purpose is equally important. These two points can be made relatively empirically and according to a set of discrete criteria. However, it is insufficient to focus solely on the nature of the disease or the screening test in question. The population for whom the screening program is intended must also be investigated. Desirable results may be achievable (i.e. a reduction in incidence or mortality) by using a certain test, and administration of the test may be easy and straightforward, but if no one has heard of the test or has any intention of using it, the screening program will not be successful. A logical place at which to start this investigation of the target population for screening is before the screening program has been implemented. This offers the opportunity to learn about and address possible barriers and challenges before they occur, as opposed to trying to rectify them in hindsight. This is not to say that additional issues will not arise as full implementation gets underway, but allows for a proactive approach to implementation.

Initiating this investigation at the pre-implementation stage, to a certain extent dictates the way in which questions must be asked. This is not seen as a shortcoming of the investigation, rather it simply provides a focus for the way in which the study must be framed. Due to the unavailability of information regarding the average risk population's familiarity with fecal occult blood testing or prior CRC screening behaviour using FOBT, these questions must be asked. Whether a person intends to complete an FOBT is not a

valid enquiry if they do not know what it is; it cannot be assumed the participant has any prior knowledge. Consequently, awareness and previous participation in fecal occult blood testing will also be explored in the average risk population, along with intention to participate in screening.

2.4.1. Behavioural Theory

There exists extensive literature on the subject of behaviour and behavioural intention, for example, whether individuals engage in a host of health preserving or safety-enhancing behaviours and whether they abstain from a variety of negative or risky behaviours. Health behaviour related fields have several examples of this type of research, often utilizing a theory-based approach in an attempt to better understand health behaviour and to develop behaviour change interventions. The Health Belief Model[70,71,72], the Theory of Planned Behaviour[73,74,75] and the Transtheoretical Model[76,77,78] are all theories commonly utilized in this type of research.

A useful review on theoretical behavioral change models and their relationship to either participation in CRC screening or intention to participate in CRC screening was done by Kiviniemi et al. (2010)[79]. The objectives of the report were to provide an assessment of which theoretical models and their related constructs have and have not been studied, to explore the sufficiency of the examination of the constructs in relation to CRC screening, and to summarize the association between these constructs and CRC screening behaviour. Constructs examined that related to one or more behaviour change models included severity, susceptibility, benefits, barriers, self-efficacy, attitude, social norms, perceived behavioural control, response efficacy, decisional balance and processes of change. Of the constructs examined, it was found that benefits, barriers and

perceived susceptibility have been relatively well-examined, while less evidence was available for the other constructs. The Health Belief Model was the only theory that had all its underlying constructs investigated in a single study, suggesting that the underlying constructs of most theories were only partially investigated.

This review also examined how well the evidence in the literature supported the predictions made by the theoretical models. It was found that for each of the *investigated* constructs, the majority of the studies supported the hypotheses derived from the models. In some cases no relationship was found between the construct and behaviour or behavioural intentions, however, it was uncommon to find that the relationship observed was opposite to what was predicted.

The review concluded that there are limitations to this body of literature, including relative scarcity of research coverage for some decision-making constructs, and piecemeal selection of constructs from models. Additionally, it was observed that there was variation in how concepts were conceptually and operationally defined. Thus, it can be said that behavioual theories do make an important contribution to the understanding of screening participation or intention to participate in CRC screening, but that there is still work to do in this field.

2.4.2 Search Strategy

In acknowledging the contribution of behavioural theories to CRC screening, it is essential to highlight that other factors also play a role in screening participation and screening intention. For example, demographic, socio-economic, geographical, and awareness/knowledge factors. This thesis will focus on these latter types of factors and

their relationship to reported screening intention in the target population for FOBT screening in NL.

A detailed literature review of these types of studies was conducted to provide a rationale for the content of the questionnaire developed for the average risk population survey as well as to generate hypotheses regarding the characteristics that may make individuals in the average risk population more likely to report an intention to engage in screening. A search was conducted through the Memorial University Health Sciences Library 'Health Databases' journal repository. PubMed and CINAHL were the primary databases that returned relevant articles. Search terms pertinent to studies on CRC screening intention and articles written in English language only were included in the search. It is possible that this may have introduced language bias into the search and selection of articles[80]. Of particular concern is that papers reporting negative results are more likely to be published in non-English-language journals[81]. However, the research examining this issue is conflicting in that this bias is not consistently found[82,83]. Article abstracts were read to determine whether the study reported one or more demographic, socio-economic, geographical or awareness/knowledge factors in relation to intention to participate in CRC screening. The reference section for all relevant articles was hand searched for additional relevant studies. The literature search was not restricted by date to ensure the research reviewed would give a comprehensive overview of the topic but the main focus was on more recent articles (2000 onwards). It was found that there was literature available on demographic, socio-economic and awareness factors, and to a lesser extent geographical factors, however availability for of these all factors was

somewhat limited. For this reason, relevant studies that looked at these factors in relation to actual participation in screening, in addition to intention to screen, were included.

2.4.3 Determinants of Intention to Screen

1. An Australian study by Duncan et al. (2009)[84] looked at demographic associations with stage of readiness to screen for CRC using either FOBT or colonoscopy in an urban population aged 50-74 (n = 664) via mail-out survey. This survey was sent to 1,250 individuals randomly selected from the Australian electoral roll residing in specific urban areas. The response rate was 55%. The majority of respondents reported being either in the pre-contemplation stage, 'have not thought about screening' (35%), or the action stage, 'have prepared to screen for CRC or have already screened for CRC' (31.1%). The remainder were distributed amongst the contemplation stage, 'have thought about screening but have not made a decision', (18%), the rejection stage, 'have thought about screening for CRC and decided not to' (4%), and colonoscopy intention, 'have decided to screen with a modality other than FOBT' (11.9%). The author reported that women and those in younger age subgroups of the survey population were less likely to be in the action phase than men and those in older age subgroups [$\chi^2(4) = 9.59$, $p < 0.05$] and [Fishers exact test= 16/042, $p < 0.001$] respectively. There was a larger proportion of the survey population between the ages of 60 and 64 in the rejection stage but a considerably smaller proportion between the ages of 65 and 70. These findings do not indicate a linear association between increasing age and likelihood of screening rejection. In fact, the total proportion of those who reported rejecting CRC screening was very low.

The generalizability of this study was somewhat limited by the sub-group sizes (broken down by screening intention). The rejection stage was only selected by 4% of individuals. Because the survey was conducted on a mail-out basis, the number of true

rejecters may have been underestimated due to their lack of participation. Sampling from an urban population only may also have imposed limitations on the generalizability of the results to the broader Australian population. The random sampling of participants for this study is a strength.

2. Weinberg et al. (2009)[85] surveyed 318 American women aged 50+ who were at average risk for CRC and non-compliant with screening. All women fitting the eligibility criteria were selected from an electronic medical record and contacted by telephone. After consent was obtained, respondents were asked to complete a 75-item survey; the response rate was 49%. Respondents demonstrated a high level of basic knowledge about CRC and CRC screening, however, 65.7% stated they had no need and / or no plans to undergo CRC screening while 34.3% reported plans to be screened. This study found no significant association between screening intention and CRC knowledge. An association was found between increased age and lower intention of being screened [OR = 1.12, 95% CI = 1.00 - 1.24, p <0.03]. This trend differed from the finding of the previous study, as did the finding that the majority of respondents reported no intention to undergo screening. Sampling for this survey was not random and the sample was comprised largely of employed and well-educated women. It is not known whether it is possible to extrapolate these results to other population sub-groups or to men.

3. Indigenous Australians ≥ 35 years of age[86], (n = 93), were recruited by convenience sampling and administered a face-to-face interview regarding CRC knowledge and screening intention. It was found that neither gender nor age were associated with intention to undergo FOBT screening. Marital status was associated with the intention to undergo screening in that those who were married or de facto married

were more likely to report an intention to screen than those who were widowed or divorced [OR = 5.96, p <0.0001]. Those who were employed [OR = 3.14, p = 0.022], were more educated [OR = 2.62, p = 0.043], had an income higher than $20,000 [OR = 2.79, p = 0.048], who had participated in any cancer screening in the past [OR = 3.83, p = 0.003], knew someone in their family with cancer [OR = 2.71, p = 0 025], had ever heard of CRC before [OR = 2.72, p = 0.048] and had ever heard of a CRC screening test [OR = 3.3, p = 0.027] were also more likely to report an intention to undergo screening. Awareness of FOBT was low in this study with only 14% knowing what an FOBT was. Even after being given a detailed explanation and description of the FOBT, only 30% said they had heard of the test. However, unlike the Weinberg study, knowledge or awareness of CRC was positively associated with intention to undergo screening and unlike the Duncan study; no differences were found between gender and intention to screen. Limitations of this study include a fairly small sample size and a non-random sampling strategy. Recruitment occurred in urban centres only, so viewpoints of Indigenous people living more remotely may not be not be represented.

4. Data from the Korean National Cancer Screening Survey yielded differing results when compared with the previous studies on intention, illustrating that different factors appear to affect CRC screening intention in different populations. This was a population-based, interview-administered survey of a nationally representative sample of Koreans. Results on screening intention were reported for the subset of respondents aged ≥ 50 years (n = 955)[87]. In this study, positive intention to screen was reported by 34.1% of respondents. The odds ratio for intention to screen was significantly higher in younger adults, [OR = 4.96, 95% CI 2.41 − 10.21] for those aged 50-59 and for those aged 60-69

[OR = 2.77, 95% CI 1.37 – 5.61] when compared with respondents aged 70+ years. Findings were non-significant for gender, education level, household income, marital status, residence (towns, middle & small sized cities, large cities) and family cancer history. Sampling this study was random and representative on a national level.

5. Sifri et al. (2010)[88] conducted a telephone survey in the US with respondents aged 50 -74 years (n = 1515); the response rate was 58.7%. Survey items included sociodemographic background, perceptions about CRC screening and decision stage for screening. Screening decision stage was distributed among participants as follows: 'decided against' (2%), 'never heard of' (8%), 'not considering or undecided' (41%) and 'decided to do' (51%). Compared with other studies there was only a small population that had never heard of the screening test and over half of the population reported that they had decided to get screened. Multivariate analysis showed that participants who were female [OR = 2.18, 95% CI = 1.39 - 3.42, p = 0.001] and had prior cancer screening [OR = 2.81, 95% CI = 1.67 - 4.71, p < 0.001] were more likely to be in the 'not considering or undecided stage' as opposed to the 'never heard of' stage. Participants who were younger (<60 versus 60+) [OR = 0.64, 95% CI = 0.51, 0.81, p < 0.001] and had prior cancer screening [OR = 1.43, 95% CI = 1.14, 1.79, p = 0.002] were more likely to be in the 'decided to do' stage than the 'not considering or undecided' stage. All respondents for this survey were recruited from a single family practice clinic, implying that there could be a degree of homogeneity in this sample which would limit generalizability.

6. Tong et al. (2000)[89] carried out a randomly sampled telephone survey in Queensland, Australia. Respondents were aged 40 to 80 years (n = 884). Questions were

asked about screening intention in the context of whether or not respondents would intend to participate in screening if a recommendation to screen was made by a doctor or health authority. The response rate was 77.8% and positive intention to screen was reported by 77.5% of the sample. Bivariate analysis showed that younger age (40-59), being married or de facto married, being more highly educated, employed and having a higher household income were all associated with a greater likelihood of screening intention. Significant associations were not found between screening intention and knowledge of a friend or relative with CRC, nor number of first degree relatives with CRC. In a multivariate analysis using multinomial logistic regression likelihood ratio chi-squared tests it was found that only age [χ^2 (6) = 15.0, p = 0.02] and education [χ^2 (8) = 19.4, p = 0.01] remained significant. The high reported positive screening intention in this study could have been influenced by the way the question was worded. Respondents were queried about whether they would screen in the setting having received a recommendation by a doctor or health authority. This may have biased the responses toward positive intention.

7. A second publication by Tong et al.[90] (2006) explored screening intention in the same study sample. However, this time they considered the association between screening intention and knowledge, attitudes, beliefs and behaviours. Findings relevant in the context of this thesis included that only 28% of respondents reported an awareness of FOBT and these respondents were more likely to express a positive intention to screen (p = 0.04). Additionally, only 7.6% of respondents reported prior participation in FOBT. Those who had previously participated in FOBT were much more likely to express an intention to screen than those who had not ($p < 0.01$).

8. A demonstration project on utilizing FOBT screening in a rural setting was conducted by Janda et al. (2003)[91]. The target population included men and women aged 50-74 living in a rural area of Northern Australia (n = 604). The survey was conducted via telephone. When asked how likely they were to participate in FOBT screening in the future 89 (15%) participants responded 'very likely' and an additional 231 (38%) indicated that they were 'likely'. Univariate analysis found that intention to screen was similar for men and women and for those living with or without a partner. Those aged 70 years or older were significantly less likely to report an intention to screen than those younger (p = 0.008). Those with college or university education were more likely to state that they would 'very likely' participate in future FOBT screening when compared to participants with lower educational levels (p = 0.01). Just over half of participants had heard of FOBT (52%), only 18% had ever had an FOBT. Participants with a family history or knowledge of someone with CRC were more likely to express positive screening intent. Multivariate logistic regression analyses found that prior use of FOBT [OR = 3.2, 95% CI = 1.8 - 5.5] was the strongest independent significant correlate of intention to screen. Age showed the strongest inverse relationship with older people (70-74 years) less likely to express an intention to screen [OR = 0.5, 95% CI = 0.3 - 0.9]. Compared to those knowing no one with CRC, knowing someone, whether family or not, increased the likelihood of screening intention [OR = 1.5, 95% CI = 1.0 - 2.2]. Phone numbers for this study were randomly sampled from a database of listed residential numbers. Those with an unlisted number or without a telephone would not have been reached using this methodology and, as such their views were not represented. The target population for this survey was rural-dwelling respondents.

9. Gregory et al.[92] (2011) looked at demographic and social cognitive predictors of intention to screen for CRC and actual screening participation. People aged 50 to 74, residing in an urban area of South Australia, were surveyed via mail-out using the Bowel Cancer Screening Questionnaire (BCSQ). The BCSQ was designed to determine a participant's intention to screen using FOBT and to collect information on demographic, social cognitive and social ecological measures. The response rate was 56% and positive intention was reported by 7.6% of respondents. People who returned the questionnaire were sent a FIT four weeks after the questionnaire had been received. Intention to screen was measured by six stages of readiness to screen. Only those who were in the pre-contemplation, contemplation and preparation stages were included in the analyses. Those in the action, rejection or colonoscopy intention groups were excluded because the study was interested in a relatively naïve sample with respect to screening intention. The sample size was 376 individuals with full survey data who were able to complete the FIT (pre-contemplation n = 215, contemplation n = 110, and preparation n = 51). Of the entire sample, 192 completed a FIT and 184 did not. In the univariate analysis, intention to screen was significantly associated with gender [$\chi^2 = 7.77$, $p < 0.05$], past screening for cancer [$\chi^2 = 11.82$, $p < 0.01$], knowing someone who has had CRC [$\chi^2 = 12.68$, $p < 0.01$], born in Australia [$\chi^2 = 13.15$, $p < 0.05$] and English speaking [$\chi^2 = 6.78$, $p < 0.05$]. Actual participation in the screening offer was significantly associated with just two demographic variables, past screening for cancer [$\chi^2 = 6.35$, $p < 0.05$] and knowing someone with CRC [$\chi^2 = 8.22$, $p < 0.01$]. Age, marital status, employment status, education level and socio-economic status were not found to be significant factors in stage of readiness to screen or screening participation in the univariate analysis. In a

multivariate analysis for intention to screen there were five significant predictors of stage

of readiness to screen for CRC. People who been screened for cancer in the past [OR =

1.38, 95% CI = 1.04 - 1.81, p = 0.02], perceived low barriers and high benefits to

screening [OR = 0.78, 95% CI = 0.70 - 0.94, p = 0.01], believed that good health was not

due to chance [OR = 0.84, 95% CI = 0.75 - 0.94, p = 0.01], people who believed

themselves to be susceptible to CRC [OR = 1.28, 95% CI = 1.15 - 1.42, p = 0.01], and

had higher perceived knowledge about CRC and screening [OR = 1.11, 95% CI = 1.01 -

1.24, p = 0.05] were more likely to be in a higher stage of readiness to screen. There were

only two significant predictors of actual participation in a multivariate model. People

who had known someone with CRC [OR = 1.26, 95% CI = 1.02 -1.57, p = 0.04] and

perceived low barriers and high benefits to screening [OR = 0.86, 95% CI = 0.79 - 0.95, p

= 0.01] were more likely to participate in the screening offer. While there was some

overlap between predictors, this study supports the proposition that predictors of intention

to screen for CRC and actual CRC screening are not the same.

10. A Canadian study by Ritvo et al.[93] (2009) conducted a telephone survey of

people in Ontario aged 50+ to test awareness of FOBT for CRC screening and readiness

to be screened using FOBT. In total, 1013 people were surveyed for a response rate of

69%. It was found that awareness of FOBT was low with 46% of women and 55% of

men never having heard of it. Univariate analysis showed that women were more likely

to have heard of FOBT [z = -2.90, p = 0.0045], as were people who were married or

living as married [z = -1.67, p = 0.11], and those who had completed college or higher

level education [z = 3.96, p = 0.13]. Overall, only 17.1% of the sample reported a

positive intention to screen. Of the 45% of men who had heard of FOBT, over half (26%)

were not considering screening. The same was true of women with 54% having heard of the test and 26% not currently considering FOBT. Among those who had heard of FOBT, men [$z = 2.20$, $p = 0.35$] and married people [$z = -2.14$, $p = 0.27$] were more likely to be actively considering screening. Multiple logistic regression showed that women with college-level or higher education were far more likely to have heard of FOBT than men with a similar education level [OR = 2.20, 95% CI = 1.5, 3.3] or less educated women. Among those who had heard of FOBT, evidence indicated that men and married people were more likely to be considering FOBT than women and single people. Results of this survey suggested that many people in this Canadian province had not heard of FOBT and among those who had heard of it; many were not considering screening. Because of the relatively low awareness of FOBT, the sample size and statistical power of the analysis on intention to screen were reduced.

Considerable variability exists across populations with regard to the socio-demographic and awareness factors that have an impact on screening intention. This underscores the importance of treating each population as distinct when attempting to determine factors that may or may not influence intention to participate in CRC screening. It is clear that no two populations are identical in terms of what drives or influences their reported intention to take part in screening. Table 2.2 summarizes each of the studies on CRC screening intention that were described previously.

Table 2.2 Summary of Articles on Intention to Screen (2000-2012)

First Author	Publication Year	Country	Population	Results	
				Significant Factors	N.S. Factors
1. Duncan, A.	2009	Australia	Age 50-74 Urban Men and women n = 664 Method: Mail-out survey Response rate: 55% Positive intention: 31.1%	**Age, Gender** – youngest and oldeest age groups and men more likely to in action phase of screening intention **(univariate analysis)**	Not reported
2. Weinburg, DS.	2009	U.S.	Age 50+ Women Average risk and non-compliant with screening n = 318 Method: Telephone survey Response rate: 49% Positive intention: 35%	**Age** – older age associated with higher intention of being screened **(multivariate analysis)**	Employed Married / Partnered Level of education Knowledge of CRC
3. Christou, A.	2012	Australia	Age 35+ Aboriginal or Torres Straight Islanders Men and women n = 93 Method: Interview-administered survey Response rate: Convenience sample Positive intention: 63%	**Marital Status** (married or defacto married), **Employed** (vs. unemployed), **Education** (more highly educated), **Income** (higher income), **Other screening** (participated in any cancer screening in past 2 years), **Awareness** (someone in family with CRC, ever heard of a CRC screening test) were more likely to report an intention to participate in screening **(univariate analysis)**	Gender Age

					Age (older age), **Other screening, Marital Status** (married) and **CRC awareness** were predictors of intent to participate in screening **(multivariate analysis)**	
4. Han, MA.	2011		Korea	Age 50+ Men and women n = 955 Method: Interview-administered survey Response Rate: 17.5% Positive intention 34.1%	**Age** – Intention to screen was significantly higher in younger adults (50-59 and 60-69 vs ≥ 70) **(multivariate analysis)**	Gender Education Income Marital Status Residence (town, middle & small sized cities, large cities) Family cancer history
5. Sifri, R.	2010		U.S.	Age 50-74 Average risk for CRC Primary care patients Men and women n = 1515 Method: Telephone survey Response rate: 58.7% Positive intention: 51%	**Age** – Intention to screen was significantly higher in younger adults (<60 yrs) **Other screening** - more likely to intend to screen if participated in any cancer screening **(multivariate analysis)**	Gender Marital Status
6. Tong, S.	2000		Australia	Age 40-80 Men and women n = 884 Method: Telephone survey Response rate: 77.8% Positive intention: 77.5%	**Age** – Intention to was significantly higher in younger adults (40-59 yrs), **Marital Status** (married or de facto married), **Education** (more highly educated), and **Income** (higher household income) **(univariate analysis)**	Knowledge of a friend or relative with CRC Number of first degree relatives with CRC

					Age (younger age) and Education (more highly educated) (multivariate analysis)	
7. Tong, S.	2006	Australia	Age 40-80 Men and women n = 884 Method: Telephone survey Response rate: 77.8% Positive intention: 77.5%		Awareness of FOBT (more likely to express a positive intention to screen) and Prior use of FOBT (more likely to express a positive intention to screen) (univariate analysis)	Not reported
8. Janda, M.	2003	Australia	Age 50-74 Men and women n = 604 Method: Telephone survey Response rate: 79.4% Positive intention: 53%		Age (<70 more likely to report positive intention), Education (more highly educated), and Awareness (family history or knowledge of someone with CRC) (univariate analysis) Prior use of FOBT(more likely to express a positive intention to screen), Age (70-74 yrs less likely to report positive intention, Awareness (knowledge of someone with CRC) (multivariate analysis)	Gender Without or without a partner
9. Gregory, TA.	2011	Australia	Age 50-74 Men and women n = 376 Method: Mail-out survey Response rate: 56% Positive intention: 7.6%		Gender (male) Past Cancer Screening Awareness (knowledge of someone with CRC), Place of birth (Australia), English	Age Marital Status Employment Status Education Level Private Health Insurance Socio-economic Status

				Speaking more likely report readiness to screen **(univariate analysis)** **Other Screening, Awareness** (higher perceived knowledge about CRC) **(multivariate analysis)**	
10. Ritvo, P.	2009	Canada	Age 50+ Men and women (Intention or readiness analysis focused on those who were aware of FOBT) n = 1013 Method: Telephone survey Response rate: 69% Positive intention 17.1%	**Gender** (men more likely to report readiness to screen), **Marital status** (married people) **(univariate analysis)** **Gender** (men more likely to report readiness to screen), **Marital status** (married people) **(multivariate analysis)**	

2.4.4 The Intention – Behaviour Pathway

Intention has been found to be reliably correlated with many screening behaviours including participation in CRC screening[94]. It would be an oversight within the scope of this review, however, to omit acknowledging that it is not solely intention that determines whether an individual will carry out a given behaviour. In some instances, predictors of intention can be analogous to predictors of actually performing the behaviour, while in other instances this is not the case. A previous review found that across a variety of health-related actions, average compliance among 'intenders' was only 56%[95]. Follow-up work, beyond the scope of this thesis, should be done to determine the strength of the correlation between reported intention and screening participation in the NL population.

Among the studies of screening intention described in the previous section, only one included a follow-up phase that examined whether people went on to participate in FOBT screening[92]. This study found that gender (male), past cancer screening and knowing someone with cancer were positively associated with readiness to screen. Only two of these three factors were significantly associated with screening participation (past cancer screening and knowing someone with CRC).

A more cogent illustration of intention-behaviour differences is found in a study by Power et al. (2003)[96]. The sampling frame for this study was all patients aged 55-64 registered with 53 general practices in Scotland. All eligible patients were sent a letter and information sheet from their general practitioner describing the screening test and inviting them to complete an enclosed questionnaire on screening intention. For the analysis, participants were categorized by their initial intention and their subsequent attendance at screening creating three groups: 1) non-intenders: participants who said they would 'probably not' or 'definitely not' take up the

offer of screening (this group was not invited for screening), 2) 'attenders': those who responded

'yes definitely' or 'yes probably' to the intention question *and* attended screening, and 3) non-

attenders: those who responded 'yes definitely' or 'yes probably' to the intention question but

did not attend screening. In total, 6,383 people responded to the screening intention

questionnaire. Differences between non-attenders and attenders are of particular interest here as

predictors that strengthen or weaken the intention-behaviour pathway may be identified through

these differences. Attenders were more likely to be married or co-habiting, 73.1% vs. 66.7% [χ^2

= 35.17, $p < 0.001$], and in full time employment, 24.6% vs. 17% [$\chi^2 = 73.89$, $p < 0.001$]. On a

composite measure of socio-economic deprivation, (components included car ownership, level of

education and housing tenure), attenders were more likely to be affluent (27.7% vs 16.1%) and

less likely to be experiencing deprivation (8.9% vs. 18.2%) than non-attenders [$\chi^2 = 124.23$, $p <$

0.001]. Perceived stress was higher in non-attenders, 9.1 vs. 8.6, [$F = 6.59$, $p < 0.001$], while

social support, 24.1 vs. 23.2, [$F = 12.17$, $p < 0.001$], and ratings of health as excellent, 12.6% vs

7.7% [$\chi^2 = 52.9$, $p < 0.001$], were higher in attenders.

A strong association between intention strength and attendance was observed in this

study, 72% of those who said 'yes definitely' attended for screening, compared with 45% of

those who said 'yes probably' [$\chi^2 = 113.15$, $p < 0.001$]. When data were stratified by intention

strength ('yes definitely' and 'yes probably'), analyses showed that socioeconomic deprivation

remained an important predictor of action. Social cognition conceptualizations (associated with

behavioural theory) successfully distinguished between those who intended to come for

colorectal screening and those who did not intend to come, but showed less capacity to

discriminate between those whose intentions were successfully translated into actions and those

who failed to act.

Findings such as those reported in the Power et al.[96] study support the approach of this thesis. Focusing on the pre-implementation stage of a screening program as one component of program evaluation appears to be of value. Pre-implementation work can identify challenges or vulnerable populations prior to program implementation by affording the opportunity to ask about intention to participate which has been shown to have predictive value for action or behaviour. Furthermore, there is empirical support in the literature for socio-economic, demographic and knowledge/awareness factors as predictors of both intention[84,,85,86,87,88,89,90,91,92,93] and action[96,97,98,99,100,101,102].

2.4.5 Geography

Geography, specifically urban and rural differences in CRC screening, are considered separately. The primary reason for this is that the relationship between geography and CRC screening intention is a key feature of this thesis and warrants specific attention. Secondarily, geography did not appear to be explored as a predictor of CRC screening intention as per the articles reviewed in section 2.4.3. NL is a province made up primarily of rural and remote communities. It is important to consider the unique needs and perspectives of those who reside in rural areas of NL when conducting research on a program that will be provincial in scope. All too often the perspectives and experiences of those who live outside the urban region of St. John's are not incorporated into research, and sometimes the views of the urban dwelling population are portrayed as provincial views. Efforts to include rural dwelling individuals were consciously and consistently made in this study, not only to elicit a diversity of perspectives on intention to screen, but to better understand the role that geography itself may play in shaping screening intention. This endeavor is supported by the assertion of the Canadian Health

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Commission that geography is a determinant of health[103]. Might geography also be a determinant of *intention* to engage in healthy behaviours such as CRC screening?

In 2006, the Canadian Institute for Health Information (CIHI) released a pan-Canadian report on the health of rural populations[104.] The report summarized that rural areas generally showed a health disadvantage on many health-related measures when compared with urban areas; although there were some areas where differences were not pronounced and some adverse health measures were found to be higher in urban areas. Rural areas reported higher proportions of people with low income and less than secondary education level. These factors have been linked with lower screening intention and screening action in several populations. Furthermore, the report detailed that health-related factors such as smoking and obesity were more prevalent in rural areas, as were poorer dietary practices and lower levels of physical activity. These factors have been identified as risk factors for developing many types of cancer.

Kulig and Williams reiterate these findings in a more recent publication titled Health in Rural Canada[105]. These authors/editors report that rural Canadians experience a greater number of population health risks compared with urban Canadians. Rural Canadians generally have lower economic status due to higher unemployment rates and lower education rates than do urban Canadians. They also have a shorter life expectancy and higher mortality and infant mortality rates than the Canadian average. In addition to socio-demographic contributors, Kulig and Williams report that poorer rural health is partially due to the result of shortcomings in overall, general health care services. Ongoing challenges in recruiting and retaining health professionals in rural geographies mean that rural residents experience many obstacles in obtaining care due to lack of available services and personnel. There are also geographical and transportation limitations.

In the realm of cancer care, NL-specific analyses have been carried out to determine whether the degree of rural / remoteness of a geography has an impact on various aspects of the cancer care experience. National findings can be found in a pan-Canadian report published by CPAC[106]. Province-specific findings are available in tabular format on the *cancerview* website[107]. Geographic disparities in NL, with a marked disadvantage for those living in rural / remote regions, were found in a number of areas. These included wait time from an abnormal breast screen to resolution of that screen (whether or not the resolution required a tissue biopsy to be carried out), radiation therapy utilization and the percentage of breast cancer resections that were mastectomies.

The wait time for resolution of an abnormal breast screen increased along the urban / rural gradient from 12.9 weeks to 15.9 weeks for those who did not require a tissue biopsy and from 19.3 weeks to 22 weeks for those who did require a biopsy. Radiation therapy utilization within two years of diagnosis decreased from 32.5% of cancer cases diagnosed in a given year to 27.8% of cases as geography became more remote. Lastly, the percentage of breast cancer resections that were mastectomies increased from 37.5% for urban areas up to 52.3% for rural / very remote areas.

In the literature on geography as an influencer of CRC screening, living in a rural area generally appears to be negatively correlated with having participated in screening. Several American studies comparing cancer screening between urban and rural dwelling populations provide evidence of lower participation rates and lower likelihood of being up to date with CRC screening[108,109,110,111] in the latter population.

There is less literature available in the Canadian context, however, one Canadian-based study conducted a data linkage / secondary data analysis study using provincial and national administrative databases[112]. The target population were those aged 50 - 74 and six years of cohorts were examined from 2005 – 2011, for a sample of 12, 824, 179. Fourteen percent of this sample were living in rural areas. Analyses found that there were significant inequities in FOBT participation by geography. Those living in rural areas were consistently less likely to participate in FOBT screening, 6.1% versus 7.9% in urban areas, for a difference of -1.8% (95% CI -1.9% - -1.7%). Similarly, those living in rural areas were consistently less likely to be up-to-date with CRC screening than those living in urban regions, 25.1% versus 27.6%, for a difference of -2.5% (95% CI -2.7% - -2.3%).

Research on outcomes associated with other events along the cancer trajectory has also shown a disadvantage for rural dwelling residents with CRC. For example, rurality was associated with a later stage at diagnosis[113], lower odds of receiving chemotherapy[114], increased risk of local recurrence of cancer[115] and decreased survival time[114,115].

2.5 Hypothesis and Summary of Study 1: Target Population Survey

Although literature is available for various aspects of CRC in relation to place of residence, including diagnosis, treatment, prognosis, and screening participation, there appears to be a paucity of literature on rurality as it is related to reported *intention* to engage in screening. Based on evidence of less desirable health behaviours and outcomes for rural dwelling individuals, of particular relevance to this study, their lower likelihood of having participated in CRC screening, it is hypothesized that those at average risk for CRC living in rural areas of NL will be less likely to report an intention to participate in the FOBT screening program than those at average risk living in an urban area. Identification of groups with differing intention may lead to opportunities to influence intention and subsequently enhance screening uptake. The opportunity will also be taken in this study to extend the scope and impact of the novel data that will be collected. This will be done by including two rural populations in data collection. As discussed in chapter one, NL has regions with familial clusters of high genetic risk CRC,[3,4,5,6] and there is interest gaining a better understanding of whether the presence of a population such as this has any impact on the screening intention of average risk individuals that reside in these regions. Knowing that awareness of others with CRC can positively impact the intention to participate in screening[86,91,92] has led to the question: Does the presence of a familial cluster of high genetic risk CRC mediate the potential health disadvantage of living rurally and strengthen the likelihood of positive screening intention for those at average risk for CRC?

In order to answer this question, samples from three distinct areas of the province will be surveyed – an urban area with no familial clustering of high risk CRC, a rural area with no familial clustering of high risk CRC and a rural area with a familial cluster present. Respondents at average risk for CRC from each of these areas will be compared on reported intention to

participate in FOBT screening. This is the primary research question of this study. It is hypothesized that individuals 50 to 74 years of age, who are at average risk for CRC, and who are residing in a rural region with a presence of high genetic risk CRC will have the highest proportion of reported positive screening intention; the next highest proportion will be those who live in an urban region; and those who live in a rural region without a significant presence of high genetic risk CRC will have the lowest reported proportion of positive screening intention. Secondary analyses will involve the examination of other socio-demographic characteristics in relation to screening intention, comparing each of the geographies and considering the study population as a whole.

2.6 Primary Care and CRC Screening

The method of entry into the NLCCSP will be through participant self-referral or physician referral. Access to provincial, population-wide databases, such as the MCP database, would present the best available method to equitably reach all members of the target population with an invitation to screen. Unfortunately, access to these databases is restricted due to provincial privacy legislation. In order to enhance screening uptake as the program is phased in across the province, various communication and awareness-raising efforts are planned. These efforts focus mainly on the target population for screening and on family physicians. It is quite possible that potential participants may consult with their family physician about whether or not the screening program is right for them. It is also likely that some family physicians may refer patients to the program; if those physicians are aware of the program and endorse it. There is considerable evidence to support the positive association between family physician knowledge and support of FOBT and patient participation in screening[22,23,24,25]. Thus, a second part of pre-implementation work will be to gather information from family physicians across the province on their current screening practices, knowledge of FOBT and support for an organized screening program.

2.6.1 Eliciting the Family Physician Perspective

Several studies exist that endeavor to elicit the physician perspective on CRC screening, personal screening preferences, and / or screening practices. The findings illustrate a variety of attitudes toward FOBT screening and a range of responses about the use of FOBT in clinical practice in several physician populations. Methodological components of two of these studies will form the basis for eliciting the family physician perspective on CRC screening in NL.

Young et al. (1998)[116] surveyed a national random sample of Australian general practitioners about the effectiveness of several cancer screening tests including breast self-examination, clinical breast examination, mammography, annual chest radiology, clinical skin examination, FOBT, flexible sigmoidoscopy, digital rectal exam, and the PSA assay. For each screening test, respondents were asked to indicate if it was effective in reducing premature mortality from the specific cancer site. Belief in mammography outranked the other tests, which was consistent with compelling evidence of mammography effectiveness from seven RCTs that were available at the time that the survey was carried out. However, despite the effectiveness of FOBT in reducing mortality also being demonstrated in RCTs, belief in the effectiveness of this test was outranked by seven other screening tests. With respect to CRC screening methods specifically, physicians were more likely to believe in flexible sigmoidoscopy despite weaker available evidence. Given that belief in the effectiveness of a test will influence whether or not it is actually used in practice, it would seem that FOBT would not be readily used by the physician population surveyed.

Another Australian study explored general practitioners' knowledge, attitudes and practices with respect to CRC screening in order to determine GP support for population-based screening[117]. Only half of physician respondents reported that they would support a population based screening program utilizing FOBT for persons over 50 years of age. Approximately 15% said they would not support such a program and 34% were unsure. Various reasons were given by supportive physicians including; FOBT is non-invasive, CRC incidence is high, FOBT is simple and quick to use, population-based FOBT reduces mortality rates and FOBT is less expensive than other screening options. Reasons given for not supporting a population-based screening program included the perception that FOBT yields a high proportion of false positives

and false negatives, FOBT is not cost-effective, and patients are unwilling to comply with FOBT. The majority of respondents (84.3%) thought it was important that GPs be involved in any future screening programs and two-thirds (64.4%) were unsure or disagreed with the statement that populations screened with FOBT have lower mortality from CRC than those who have not been screened. A similar percentage (64.7%) reported always or often asking patients over 50 years old about symptoms or risk factors for CRC, 80% reported that they have used FOBT for their patients, and 50% that they were not confident in instructing patients about FOBT. Close to three-quarters reported a desire for more education and training about CRC screening.

The underlying message from this study is that there appears to be a great deal of uncertainty amongst the physician population about the effectiveness of FOBT as a screening test and about the benefit of FOBT screening on a population level. Overwhelming support for population-based screening with FOBT was not apparent, with only 50% of physicians indicating their support. It is, therefore, not surprising that a high percentage of physicians were unsure of, or disagreed that, screening populations using FOBT resulted in a reduction in mortality from CRC. Lack of familiarity with the test seems to be significant, with half of physicians reporting that they were not confident in instructing patients on how to use FOBT. It is encouraging, however, that there was a high level of interest in receiving further education and training about screening.

Taking a somewhat different perspective, an Ontario study surveyed family physicians about their personal choices of CRC screening modalities, as well as about their perception of the preferred screening choices of their patients[118]. Decennial colonoscopy and biennial FOBT were the two most popular screening methods, accounting for more than 90% of both the physicians'

personal preferences and their perceptions of patient preferences. Interestingly, personal preferences and perceived patient preferences differed. Sixty-four percent of physicians thought their average-risk patients would prefer FOBT screening and only 29% thought their patients would prefer colonoscopy. In contrast, 40% of family physicians would want FOBT for themselves with 50% preferring colonoscopy. The difference in physicians' personal screening choices and their perceptions of patients' preferences was statistically significant [$\chi^2 = 150.5$, $p < 0.001$]. It is not clear why physicians would choose one test for themselves but perceive another to be more desirable to their patients. While causality for these preferences could not be determined from this study design, personal screening choice of physician was significantly associated with physician-estimated FOBT sensitivity [$\chi^2 = 14.75$, $p < 0.005$], perception of mortality reduction [$\chi^2 = 113.3$, $p < 0.001$] and cost-effectiveness [$\chi^2 = 87.12$, $p < 0.001$].

Screening practices, as opposed to preferences, were examined in another Canadian setting (Calgary) in a survey of family physicians, gastroenterologists, general and colorectal surgeons and general internal medicine specialists[119]. Physicians were asked whether they had a screening policy for asymptomatic individuals with and without a family history of CRC. Those patients without a family history would correspond to an average risk population, while those with a family history would represent higher risk. Approximately 60% of respondents reported having a screening policy for asymptomatic individuals without a family history of CRC, while the remaining proportion had no policy for this subgroup. Of those who reported having a screening policy for family history negative patients, 63.6% initiated screening at 50 years of age and FOBT was the most commonly used screening test either alone or in combination with other modalities. For patients with a family history of CRC, almost all physicians (96.4%) reported

that they employed a screening policy. Colonoscopy was the most common screening modality chosen.

It would appear in this physician population that having a screening policy in place is a much higher priority for patients with a family history of CRC. While it is reassuring that a policy was almost universally in place for this group, screening of the average risk population appeared to be less structured. This was particularly so amongst family physicians and internal medicine specialists of which 59% and 38% respectively reported having a screening policy for asymptomatic patients with no family history. Primary care would likely be the portal through which asymptomatic average risk patients would enter a screening pathway and it is concerning that almost 40% of family physicians did not have a tangible approach or policy to starting people on this pathway.

The final study elaborated on is a comprehensive, province-wide, cancer screening needs assessment carried out in British Colombia (BC) which contained a considerable amount of data on the primary care physician (terminology used in the assessment) perspective of cancer screening in that province[120]. Although screening modalities for several cancer sites were included in the assessment, the CRC screening components of the survey will mainly be discussed. The survey covered knowledge and attitudes towards cancer screening, attitudes towards educational approaches aimed at increasing the overall prevalence of cancer screening, barriers towards engaging in cancer screening discussions with well patients, and self-reported practices on screening for cancer. Demographic information and practice characteristics were also collected.

The majority of primary care physicians (94%) felt that screening for cancer in well

patients was advantageous, and 85% felt that they effectively communicated screening strategies

to their patients. Slightly fewer (79%) felt that their patients followed their recommendations for

cancer screening. Sixty-three per cent reported that their patients either 'never' or 'seldom'

requested FOBT and 6% reported that their patients either 'often' or 'always' asked for FOBT.

The remaining 31% chose the 'sometimes' category. The breakdown was different for

colonoscopy where only 28% of physicians reported that their patient never or seldom requested

colonoscopy, 20% reported that their patients often or always requested colonoscopy and 51%

chose sometimes. This illustrates that in the primary care physician experience in BC, patients

infrequently request FOBT.

Only 34% of physicians reported having CRC screening educational materials available

for patients. Most physicians preferred conferences as the educational format for learning about

cancer screening (73%) and their preferred sources of accessing cancer screening guidelines

were web-based resources (58%) and paper-based resources (49%).

Several barriers were identified in relation to discussing cancer screening with patients

including having to deal with other co-morbidities in a clinical consult, the time it takes to

explain the pros and cons of cancer screening options, physician financial compensation, patients

with language barriers, level of comfort with knowledge to help patients decide on cancer

screening options, and ability to address patient's fear about the screening procedure (e.g.

radiation exposure, pain, embarrassment).

In addition to screening attitudes and knowledge, physician screening practices were also

investigated in this needs assessment. The majority of physicians reported starting to recommend

CRC screening in their well patients in the 50-54 age range, which is consistent with Canadian CRC screening guidelines. However, the most frequent response given for patient age range at which the physician stopped recommending screening was 'I don't stop recommending CRC screening' (40%), followed by 80-84 age range (23%). Neither one of these responses are consistent with screening guidelines for the recommended stop age of 74 years. The procedures most commonly recommended were colonoscopy (87%), digital rectal exam with FOBT (82%) and FOBT completed at home (82%), (numbers do not sum to 100% because respondents could choose more than one response).

This needs assessment provides a useful summary of BC primary care physicians' knowledge, attitudes and behaviours about CRC screening. It would appear that physicians think that cancer screening is advantageous and feel that they effectively communicate cancer screening information to their patients. Overall, patient awareness of FOBT, or possibility patient belief in the effectiveness of FOBT does not seem to be high with a reported 6% of patients 'often' or 'always' asking about FOBT. With respect to the patient population, physicians were asked to answer these questions in the context of thinking about their 'well' patients. The study therefore, did not make any distinction between physicians' attitudes and screening practices for their average risk versus high risk patients. Additionally, several of the questions referred to cancer screening in general, as opposed to CRC screening specifically.

2.7 Summary of Study Two

Eliciting NL family physicians' knowledge, attitudes and practices around CRC screening will be the second major component of this thesis. Elements of the BC needs assessment survey will be utilized to collect this information; however, some adaptations will be made to the survey before it is used in NL. Adaptations will focus on extracting the CRC screening questions and re-wording the general screening questions to have a CRC screening-specific focus. Permission has been granted from the relevant sources at the BC Cancer Agency to do so (email correspondence with co-investigator Ms. Laura Swaré, Februray 7th, 2012, Appendix A).

While the BC Cancer Agency Needs Assessment instrument does address many areas relevant to this thesis, there is no content on attitudes toward FOBT screening on a population basis or physician belief in the effectiveness of FOBT as a viable screening modality. These will be important areas to address in the context of doing a pre-implementation assessment of physician support for the program. Therefore, the measure used by Tong et al. (2004)[117], as described previously, will also be administered to physicians. Further information and detail on survey content and methodology will be provided in chapter four.

It is hoped that the two major components of this PhD thesis, an average risk population survey and a family physician survey will yield valuable data which will inform and support more efficacious implementation of the CRC screening program in NL. Little is currently known about rural residents' screening intentions compared with their urban counterparts. Moreover, it is not known whether the presence of a high genetic risk for CRC population might have an impact on CRC awareness and intention to participate in preventive behavior for those who are

at average risk for the disease. Similarly, little is known about family physicians' attitudes toward FOBT screening or about their screening practices in this province. The concept of an organized CRC screening program is still in its infancy in NL and the pre-implementation phase provides an opportunity to proactively facilitate the best possible operation of this program. This research is supported by a framework central to the field of epidemiology called the Measurement Iterative Loop[121].
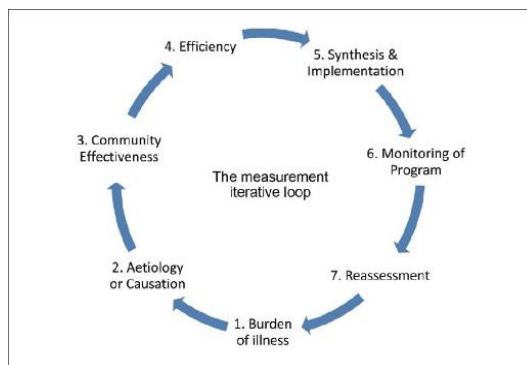
Figure 2.1 The Measurement Iterative Loop (CC-BY-NC-SA 3.0)
Source: http://www.jcd.org.in/viewimage.asp?img=JConservDent_2012_15_1_5_92598_u3.jpg

The main aim of implementing a screening program is to reduce the burden of disease in a population. FOBT screening has been shown to reduce incidence of and mortality from CRC. Screening can also detect disease at an earlier stage, possibly leading to less invasive treatment requirements and enhanced quality of life. Thinking of screening program implementation as an iterative process provides a useful framework for how this work can be carried out in a standardized and rigorous manner. An understanding of the burden and aetiology of the disease, along with evidence to support the effectiveness and efficiency of an intervention are integral parts of implementation. Monitoring progress and re-assessing practices provide a means to recalibrate and improve processes where necessary. Conducting pre-implementation work to better understand the target population and the broader primary care context fits with this model

of health intervention implementation and will hopefully lead to better outcomes for those which

the program is meant to serve.

Chapter Three

Study Summary

3.1 Target Population Survey

3.1.1 Problem Statement

NL has the highest ASIR and ASMR of CRC in Canada. Screening using FOBT has been shown to reduce mortality and lower disease incidence. In order for screening to have an impact on the burden of disease, sufficient uptake of screening must occur. NL is in the early stages of implementing an FOBT screening program for those at average risk for CRC. This pre-implementation stage of screening may provide an opportunity to better understand the NL average risk population's intention to engage in screening, and to intervene if potential challenges are detected.

3.1.2 Study Purpose and Hypothesis

The primary objective of the study is to compare intention to participate in CRC screening amongst three distinct geographic regions. Exploring screening intention by geography may yield new information on how various geographical features including rurality and presence of high risk populations may impact or mediate intention to screen. Secondary objectives of the target population survey are to determine the overall target populations' intention to participate in an FOBT screening program and to explore various socio-demographic variables that may be associated with intention to screen.

It is hypothesized that individuals at average risk for CRC living in a rural area with the presence of a familial cluster of high genetic risk CRC will be proportionally more likely to report positive screening intention than those living in an urban area without a familial cluster of high genetic risk CRC. Following from this, it is also hypothesized that those living in the urban area will be proportionally more likely to report positive screening intention that those living a rural area, without a familial cluster of high genetic risk CRC.

3.2 Family Physician Survey

3.2.1 Problem Statement

Little is currently known about NL family physicians' attitudes toward FOBT screening or about their practice patterns with respect to CRC screening of the average risk population. Better established is that the use of endoscopy surpasses use of FOBT in this province. There is evidence that highlights the positive role that family physicians can play in endorsing CRC screening uptake. Furthermore, it is known that family physicians are more likely to recommend a test if they believe in its efficacy. Therefore, it is beneficial to better understand the knowledge of and attitudes toward FOBT screening, and the average risk screening practices of the family physician population in NL prior to full implementation of a CRC screening program.

3.2.2 Study Purpose and Hypothesis

The primary purpose of the family physician survey is to determine family physician support for a population-based FOBT screening program in NL, to assess knowledge about and attitudes towards CRC screening, and to gather information on current CRC screening practices in primary care. It is hypothesized that the majority of family physicians will express support for an organized CRC screening program for the average risk population, but reported screening practices will not adhere current to screening guidelines.

Chapter Four

Methods

4.1 Average Risk Population Telephone Survey

4.1.1 Study Population

This survey targeted individuals at average risk for developing CRC aged 50 to 74. Eligibility criteria for average risk included no prior history of colorectal cancer or polyps; no presence of inflammatory bowel disease such as Crohn's disease or ulcerative colitis; and no first degree relatives (mother, father, child, brother or sister) diagnosed with CRC before age 60.

Based on the intent of the study, and more broadly, the intent of the average risk CRC screening program in NL, the lack of precise documentation about familial history of the screenees was not viewed as problematic. Participation in the screening program can be initiated either by participant self-referral or family physician referral. Either way, contact is ultimately made with the interested individual and a review of the average risk eligibility criteria, as described previously, is conducted. This is done by a clerical person and the intent is neither to thoroughly verify all family history of CRC, nor to document a familial pedigree. Eligibility criteria are in place to attempt to stratify individuals according the screening strategy that is optimal for their level of risk. However, there is no mechanism to ensure that what is reported is entirely accurate. For a population-wide program, it would not be feasible to conduct such an intensive validation process with each screenee. In the real-world screening program, the eligibility criteria are reviewed and if the person reports fitting the eligibility criteria, they are sent a screening kit, regardless of whether they may have an unknown family history or may be

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incorrect about their family history. This approach was also followed for the thesis work, i.e., if a person fit the eligibility criteria of average risk and completed a survey, their result was included. The desire was to mirror, as much as possible, operation of the screening program. Thus, it is entirely possible that people who have an unknown or incorrect perception about their family history for CRC will be included in the average risk screening program and were included in the target population survey. This possibility exists for all regions sampled and is not regarded as a bias because if a person is unaware of an increased risk for CRC, they are likely to respond to questions and approach screening activity with the mindset of an average risk person. The intent of the survey was to better understand whether the presence of high risk families in an area would impact the screening intent of those at average risk. A person who considers themselves to be at average risk according to the best of their knowledge about their family history is considered an eligible person for the study and for screening. Although no literature is available comparing urban and rural populations on accuracy of reporting familial incidence of CRC, a population-based study reported a positive predictive value (PPV) of 53.5% [95% CI = 33.0 - 72.8] and a negative predictive value (NPV) of 98.1% [95% CI = 96.6 – 98.9] on reports of family incidence CRC by study participants compared to a reference standard[122]. Furthermore, reports on first degree relatives had a significantly higher PPV, and thus greater accuracy, than reports on second degree relatives [85.8% versus 43.5%, p = 0.04]. A second study found a PPV of 79.8% [95% CI = 73.9 – 84.9], a NPV of 98.6% [95% CI = 97.9 – 99.2] and a probability of agreement of having CRC between the reporting individual and a reference standard of 89.7%[123]. The false negative rate for CRC was 10.3% for first degree relatives, followed by 42.4% for second degree relatives and 63.6% for third degree relatives. Thus, although some

misclassification is possible, it would appear that individuals are able to reliably report on the family history of CRC for their first degree relatives.

Three distinct geographies or regions in Newfoundland were selected: one urban without the presence of a familial cluster of high genetic risk CRC, one rural with the presence of a familial cluster of high genetic risk CRC and one rural without the presence of a familial cluster of high genetic risk CRC. The three regions initially targeted were: St. John's, capital city of the province and home to major tertiary health care centres (ARU); the New-Wes-Valley Region (Badger's Quay, Pool's Island, Brookfield, Wesleyville, Pound Cove, Newtown, Valleyfield and Templeman), Lumsden and Greenspond (HRR). This region is approximately 375km from St. John's. The closest major centre is Gander which is 75km to the west of the New-Wes-Valley region and has a population of roughly 10,000; and Burin and surrounding communities (Fox Cove – Mortier, Port au Bras, Salmonier), Marystown and surrounding communities (Jean de Baie, Rock Harbour, Spanish Room) and Grand Bank (ARR). The Burin region is 320 km from St. John's. The largest centre in the Burin region is Marystown with a population of roughly 5,400 people.

The region with a presence of high risk hereditary CRC was chosen under advisement from Dr. Jane Green, Memorial University, a leading researcher in the area of high risk CRC. The "Family C" cluster of 15 large HNPCC or Lynch Syndrome families with a known mutation is originally from Swain's Island of Wesleyville. Many members of this family cluster live in communities in New-Wes-Valley region along with Lumsden and Greenspond (Appendix B email correspondence from Dr. Jane Green January 22, 2012 and February 20, 2012).This decision was corroborated by others with expertise in this area, including the supervisory

committee members. Figure 4.1 shows a map of the province depicting the various regions

targeted.

Figure 4.1. Regions of the Province Targeted for Average Risk Population Survey

According to Community Accounts[124], which makes use of census data to provide population counts for various levels of geography in NL, the population of those aged 50-74 in St. John's or the ARU region is 26,835. In the HRR it is 1,245, and in the ARR, it is 2,890.

4.1.2 Study Methods

Phone numbers for the relevant communities were purchased from InfoCanada. InfoCanada is a company that houses databases of contact information based on the latest census data. The phone numbers provided to purchasers are randomly selected from the available universe of all numbers that fit the desired criteria. Telephone surveying has a number of advantages over face-to-face interviewing allowing greater ease of access to geographically remote areas and lower costs. Furthermore, because of anonymity, telephone surveys may be useful in collecting data of a sensitive nature[125]. Limitations of this methodology include lack of representativeness because households with no landline are not represented. In an age where cellular phone ownership is commonplace, this may be an increasing possibility. However, telephone survey is frequently used and was found to be an effective recruitment strategy in other surveys on screening as reviewed Chapter Two of the thesis[85,88,89,90,91,93]. Telephone survey was utilized in six of the ten screening intention surveys reviewed and response rates ranged from 49% to 79.4%. Additionally, a case-control study conducted in NL employed random digit dialing as the recruitment method and achieved a response rate of 45.1%[126]. Although this response rate is at the lower end in comparison with the response rate of the studies reviewed, telephone surveys, in general, achieve a higher response rate than self-completion and mail-back surveys[127,128] and, as such, this methodology was chosen for this study.

Trained staff members of the Primary Research Healthcare Unit of the Discipline of Family Medicine, Memorial University of NL were contracted to carry out the calls. Training was provided to ensure that standardized methodology was utilized when conducting the telephone surveys. When contact was made with the resident of a household, a telephone script that was incorporated into the average risk population survey (Appendix C) was followed to determine whether the person on the line was interested in taking part in the study and if they were not interested, whether there was anyone else in the household who was within the appropriate age range who might be interested. If no one in the household was interested and/or of the appropriate age range, the person on the line was thanked for their time and the call was ended. If there was someone in the household who was within the appropriate age range and interested in taking part in the study, further questions were asked to determine eligibility with respect to risk level for developing CRC. If the respondent fit the criteria for eligibility, the interviewer proceeded with the survey. Participants were told that participation was voluntary, that they could refuse to answer any questions, that they could stop the survey at any time, and that their responses would be kept confidential.

4.1.3 Modification to Average Risk Population Survey Methodology

Early in the administration of the telephone survey it became apparent that telephone calls were not going to be an efficacious modality to yield the required sample size. The telephone survey was initiated in January 2013 and after logging 52 hours of calling, only 41 surveys were successfully completed. A detailed account of the telephone survey process is as follows: 869 unique numbers were called; 41 completed the survey; 115 were not in service; 100 declined to participate; 208 did not meet the eligibility criteria; 404 did not answer and 1 refused to continue.

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Based on these results, a decision was made to change the survey administration modality to a mail-out strategy. An amendment form requesting this change was submitted to the Health Research Ethics Board and was approved (Appendix D). An information letter was drafted (Appendix E) and the survey was formatted for mail-out (Appendix F).

Round one of the mail-out survey used address contact information from the same database purchased from InfoCanada for the telephone survey. This mail-out was impacted by the poor quality of the information provided. Addresses were only included for a portion of the numbers listed in the database and many of those addresses were incorrect. The response rate was still low after the first mail-out attempt, particularly in the rural areas. A decision was made to switch to Canada Post's unaddressed admail method to distribute the surveys to the selected communities.

4.1.4 Sample Size and Analysis Plan

In estimating the sample size for the average risk population survey, the parameters were set of no more than a 5% margin of error and a confidence level of at least 95%. The sample size calculation was driven by the percentage of proposed respondents who would report an intention to participate in the FOBT screening program. Fifty per cent was chosen as the assumed response distribution for this outcome as this would give the largest required sample size. If the response distribution was greater than 50% or less than 50%, the sample size would still be large enough to ensure representativeness of the populations from which sampling was taking place. Using the known population estimates outlined in the above section, a sample size was calculated for each of the three study sites. In St. John's, or the ARU region, the sample size required was 379; in New-WesValley / Lumsden / Greenspond, or the HRR region, it was 294 and in Burin / Marystown / Grandbank, or the ARR region, it was 340. This equals a total sample size of 1013.

With respect to analysis comparing each of the three geographies on the proportion of respondents that report intending to participate in the screening program, it was hypothesized that the HRR region would have the highest proportion of people reporting 'yes' they are intending to participate in an FOBT screening program, followed by the next highest proportion in the ARU region, and the lowest proportion of people reporting that they intend to participate in screening being found in the ARR region. It was predicted that 60% of people in the HRR region would say they intended to engage in screening compared with 45% in ARU region. A sample size of 173 was required at each site to test this prediction. It was then predicted that those in the ARR area would be 15% less likely to participate than those in St. John's, in other words, that 30% would report an intention to participate. This comparison required a sample size of 163 for each group. Thus, assuming a required sample size of 173 at each site, the total

required sample size would be 519. Due to the larger sample size required to ensure representativeness of the populations under study, there will be a sufficiently large sample to conduct the comparative analysis.

Beyond comparing the three regions of interest, analysis focused on determining predictors of intention to engage in screening for the total population. This was done by first carrying out bivariate chi square analysis to ascertain which predictors were significantly associated with reported intention to screen. Those that were significant at the $p = 0.1$ level in the chi square analysis were retained for inclusion in multivariate analysis. Multivariate analysis was done using binomial logistic regression.

4.2 Family Physician Survey

4.2.1 Study Population

All family physicians in Newfoundland and Labrador. The sampling frame was developed from two sources: the database of the Office of Continuing Medical Education at the Faculty of Medicine and the database of the NL College of Physicians and Surgeons. Although, nurse practitioners (NPs) often play a key role in primary care delivery, there are very few NPs practicing in a primary care role in NL. For confidentiality reasons, this small number of individuals was not targeted in the study as their survey responses would not have been reportable as a distinct group.

4.2.2 Study Methods

A questionnaire (Appendix G) was developed based on two existing measures. The first source was a comprehensive, province-wide, cancer screening needs assessment that was carried out by the BC Cancer Agency and which provided a great deal of useful data on the primary care physician perspective of cancer screening in that province[120]. Although screening modalities for several cancer sites were included in the assessment, only select CRC screening components of the survey were included for this study. Permission was granted from the BC Cancer Agency to do so.

While the BC Cancer Agency Needs Assessment instrument did address many relevant areas for this study, it did not include content on attitudes toward FOBT screening on a population level or physician belief in the effectiveness of FOBT as a viable screening modality. These issues were important areas to address in the context of doing a pre-implementation assessment of physician support for the program. Therefore, items adapted from a measure used

by Tong et al. (2004)[117] were also administered to physicians. Questions focused on whether or not the physician would support a population-based screening program utilizing FOBT for persons aged ≥ 50 years; reasons for support or lack of support; and whether or not it was important for physicians to support screening programs. This measure was not administered in its entirety due to repetition of some questions that were already included on the BC Cancer Agency assessment.

The physician survey was administered on a mail-out basis and the Dillman Method[129] was used to enhance response rate. The Dillman method recommends second and third mail-outs to survey non-responders. Three weeks after the first mailing, all non-responders were sent a second questionnaire; 8 weeks after the first mailing a third questionnaire was sent to the remaining non-responders. In order to ensure anonymity and track responses, a post card was sent each time a questionnaire was sent that could be returned separately from the completed questionnaire. This provided a way to record who had responded without being able to identify individuals from their questionnaire results. An information letter describing the study was also included with each survey package, in each round (Appendix H).

4.2.3 Sample Size and Analysis Plan

The proposed sample for this survey was family physicians currently practicing in NL. Descriptive analysis was carried out for all questions in the survey. The percentage of respondents choosing each response category was provided, and where appropriate, the mean response was also calculated. According to the BC Cancer Agency analysis plan for the physician survey[120], for the Likert scale responses (scale 1 to 6), weighted means instead of arithmetic means were reported. The weighted mean is calculated by summing the products for

each step on the rating scale and the number of respondents choosing the scale (Rating Scale x Response Count) and dividing this by the total number of respondents. This procedure was followed for the NL analysis. Descriptive analysis was done to provide an overview of the sample characteristics and to set the context in which further bivariate and multivariate analyses were conducted.

The primary question of interest was question 11: "Would you support a population-based fecal occult blood test screening program for all eligible persons in the province over 50 years of age?" Analysis were planned to determine which variables were significantly associated with physician support for population-based FOBT screening and which might play a predictive role in determining support. Select questions from the survey were highlighted for this analysis including attitude, knowledge and current practice variables, along with certain demographic variables. All analyses were conducted using the PASW Statistical Package Version 18.

4.3 Ethical Approval and Funding

Full ethical approval for this study was granted by the Health Research Ethics Authority on July 23, 2012 (Appendix I). Funding in the amount of $27,000 was awarded by the Department of Health, Provincial Government of Newfoundland through the Provincial Cancer Prevention and Awareness Grant program.

Chapter Five

Results: Average Risk population Survey

5.1 Sample

As outlined in chapter four, telephone contact was the initial methodology proposed for the average risk population survey. This did not prove to be an effective method of recruitment. The decision was made to transition to a mail-out survey, and although this method also had challenges at the outset, ultimately it resulted in an acceptable response rate. A detailed description of the recruitment pathway follows:

5.1.1 Telephone Survey

A total of 869 unique numbers were called. Of these, 38 completed the survey (10 average risk urban, 26 average risk rural, 2 high risk rural); 115 numbers were not in service; 100 individuals declined to participate; 208 did not meet eligibility criteria; 404 did not answer and 1 refused to continue. Based on these results, the methodology was changed, and the average risk survey was conducted using a mail-out strategy.

5.1.2 Round One Mail-Out Survey

For the first round mail-out, the address information utilized came from the same database that had been purchased to complete the telephone survey. This information was of poor quality. Addresses were included in the database for only a portion of the phone numbers listed and many of the addresses provided were incorrect.

In the ARU area, 658 survey packages were mailed out. Ninety completed, eligible (according to the target population inclusion criteria) surveys were returned, 42 ineligible

surveys were returned and 62 packages were returned to sender due to an incorrect address. This represented a response rate of 22.8% for all returned surveys and a response rate of 15.1% for eligible surveys, out of a denominator of 596 after the 'return to sender' survey packages were discounted.

In the ARR area, 321 packages were mailed. No surveys were completed and returned, either eligible or ineligible, for a 0% response rate. This was because all 321 packages were returned to sender due to an incorrect address.

In the HRR area, 175 survey packages were mailed, 28 completed eligible surveys were returned and 16 completed ineligible surveys were returned. Seven packages were returned unopened due to incorrect address. This yielded a response rate of 26.1% for all surveys returned and response rate of 16% for eligible surveys returned, out of a corrected denominator of 168.

While the response rate remained low using this method, it was a much less time and labour intensive process compared with the telephone survey method. The decision was made to continue using a mail-out strategy, however, survey distribution was switched to Canada Post's unaddressed admail method to mail the surveys to the selected communities. This was done to increase the accuracy of the addresses. This method had the added advantage of greatly reduced postage rates.

5.1.3 Round Two Mail-Out Survey

The response rate for returned eligible surveys in the round one mail-out was used to determine the approximate number of packages that would need to be sent to each study area in the second round to achieve the desired sample size. Because there was no reference response

rate for the ARR area based on round one, the ARU response rate was used. It was lower than the HRR response rate and, therefore, felt to be the more cautious estimate.

For the ARU area, based on a prior response rate of 15%, 1927 packages were required to meet the remaining desired sample size of 289. In total, 2586 packages were sent using the unaddressed admail method. The overage was due to the number of households located on mail routes. Using Canada Post's method, it was compulsory to send enough packages for each household on the selected mail routes. In total, 395 packages were completed and returned for a response rate of 15.3%. Eligible surveys constituted a response rate of 10.3%.

Using the same expected response rate of 15% for the ARR sample, 2267 packages were required to achieve a desired sample size of 340. As with the urban sample, there was an overage on packages sent due to the requirement of the admail method to deliver packages to all households on all selected routes. In total, 2794 packages were mailed out. Twelve percent of the surveys sent out to the ARR population were returned, of these, 6.3% were eligible for inclusion in the analysis.

A response rate of 17% was assumed for the HRR population based on the round one mail-out. The remaining sample size to achieve for this group was 266. The number of mailed packages required, based on a 17% response rate, was 1565. In this area, the number of packages required to achieve the necessary sample size was greater than the number of possible households in this area. Thus, 1209 packages were mailed out in this area using the unaddressed admail method. In other words, a package was sent to every possible household. The total response rate combining eligible and ineligible packages was 16%. The number of eligible

packages returned was 112 (9.3%). Table 5.1 depicts the attained sample versus the required

sample for each region at the end of the aborted telephone survey and two rounds of mail-outs.

Table 5.1 Attained Sample Size versus Required Sample Size by Region

	Average Risk Urban	Average Risk Rural	High Risk Rural
Survey Sample Size Required	379	340	294
Number of Useable Completed Surveys	366 10 by telephone 356 by mail	201 26 by telephone 175 by mail	142 2 by telephone 140 by mail
Number Outstanding	13	139	152

After the round two mail-out was completed, it was found that the required sample sizes

had not been realized for any of the targeted areas. Because study funds were still available, it

was decided that a third and final round of mail-outs would be attempted for each type of area.

Given the small population sizes of the two rural regions, it was thought that saturation had been

reached in each of these areas due to the high volume of packages that had been sent out. It was

not considered an effective use of remaining resources to resend packages to each of these two

regions, possibly duplicating households with a probable low return rate. Rather, it was

determined that new areas should be approached that fit the criteria for the ARR and HRR

populations.

Additional rural communities without the presence of a cluster of high genetic risk CRC

were identified for the round three mail-out survey. These communities are located on the

Connaigre Peninsula / South Coast of the province and include McCallum, Milltown, Head of

Bay d'Espoir, Morrisville, Conne River, St. Alban's, St. Joseph's-St. Veronica's, Harbour

Brenton, Belleoram, Pool's Cove, Rencontre East, St. Jacque's, Coomb's Cove, Hermitage,

Sandyville, Seal Cove, Gaultois, Burgeo, Francois, Grey River, La Poile, and Ramea. This constellation of small communities is located approximately 600km from St. John's. According to Community Accounts these communities totaled about 10,640 people. Assuming four people per household, this constituted approximately 2600 households to sample from. An additional 139 responses were required to achieve the necessary sample size of 340. Additionally, to ensure less wastage of research resources and unreturned surveys, a $10 incentive was offered to each person who returned a completed survey. Doing this required a slight variation in methodology from the original mail-out design. In order to receive the $10 incentive, respondents first had to return the survey. A postcard on which the respondent could provide their mailing address was also included in the package. This card was placed in a separate envelope, which was inserted into the survey package. A different person was responsible for opening the envelopes that contained the respondent address than the person who compiled the surveys and entered the data. By doing this, the respondent address could be retained for remuneration without being able to associate the respondent with their survey responses. This was done to maintain confidentiality. When a survey was returned, a cheque in the amount of $10 was sent to each respondent, whether or not their survey was eligible for inclusion in the sample. An amendment form detailing these proposed changes was submitted to the ethics board and approved (Appendix J) The cover letter included with the survey packages was also amended to provide instructions to respondents, and to detail how their contact information would be kept confidential and separate from their survey responses (Appendix K).

With respect to sampling further regions with a presence of high genetic risk for CRC, it was determined through consultation with Dr. Jane Green, an expert in the area of high genetic risk CRC in the province of NL, that there were no further communities that fit the required

description that could be sampled. The only remaining region of the province that had a familial cluster of high risk genetic CRC was the Twillingate / New World Island area. This region has familial clusters of AFAP. However, it was advised by Dr. Green that a pilot FOBT screening program had been running in that region for many years and a significant amount of research activity had also been conducted in this area. The high level of awareness of CRC in this region due to the screening program and previous research activity, coupled with the fact many residents were potentially already undergoing regular programmatic FOBT screening, rendered this an inappropriate region to survey.

Final efforts were made through methods other than unaddressed admail to reach people in the original HRR region. Through a regional website, contact information was available for various groups that would likely have members in the desired age range. Letters, or where possible, emails, were sent to Anglican Church Women's groups, United Church Women's groups, the New-Wes-Valley 50+ club, the Royal Orange Lodge and the Lion's Club. This did not lead to any further recruitment in this region.

5.1.4 Round Three Mail-Out Survey

Round three mail-out activities were conducted in St. John's and in the new ARR rural communities, as described above. Due to the $10 monetary incentive associated with round three, the projected response rate was higher. To account for this, the anticipated response rates for each region in round two were doubled and applied to the corresponding region in round three to calculate the number of packages that had to be sent to achieve the desired sample size. The outstanding sample size for the ARU region was 29, and with a proposed response rate of 21%, 138 packages were required. Due to the overage, 148 packages were actually sent.

Seventeen completed, eligible surveys were returned for an 11.5% response rate, and seven completed ineligible surveys were returned for a total response rate of 18.1%.

The response rate from the round two mail out for the ARR area was 6%. Consequently, a projected 12% response rate was applied to round three. The remaining sample size was 165, requiring 1375 packages to be sent. With the overage, 1378 were mailed out. A total of 233 completed, eligible surveys and 27 completed, ineligible surveys were returned for respective response rates of 16.9% (eligible) and 18.9% (total).

Combining both the telephone survey recruitment and all three mail-outs, there were 383 ARU respondents, 434 ARR respondents and 142 HRR respondents in the total sample. The average response rates across all iterations of the mail-out survey process were 12.3%, 11.6% and 12.6% for ARU, ARR and HRR respectively. The response rate for all respondents over all mail-outs was 12.2%. Required sample sizes were achieved for the ARU and ARR areas, but not the HRR area. Figure 5.1 portrays the recruitment process for the target population for screening survey.

Telephone Survey: 869 unique numbers called
- 38 Completed the survey
- 115 were not in service
- 100 declined to participate
- 208 did not meet eligibility criteria
- 404 did not answer

Round 1 Mail-Out (Info Canada)
- Average Risk Urban Area
  - 596 eligible surveys mailed, 90 eligible returned, 15.1% response rate
- Average Risk Rural Area
  - 321 mailed, 321 returned to sender, 0% response rate
- High Risk Rural Area
  - 168 eligible surveys mailed, 28 eligible returned, 16% response rate

Round 2 Mail-Out (Canada Post, Unaddressed Admail)
- Average Risk Urban Area
  - 2586 surveys mailed, 266 eligible returned, 10.3% response rate
- Average Risk Rural Area
  - 2794 surveys mailed, 175 eligible returned, 6.3% response rate
- High Risk Rural Area
  - 1209 surveys mailed, 112 eligible returned, 9.3% response rate

Round 3 Mail-Out (Canada Post, Unaddressed Admail)
- Average Risk Urban Area
  - 148 surveys mailed, 17 eligible returned, 11.5% response rate
- Average Risk Rural Area
  - 1378 surveys mailed, 233 eligible returned, 16.9% response rate

Totals
- **Average Risk Urban Area = 383**
- **Average Risk Rural Area = 434**
- **High Risk Rural Area = 142**

Total Sample Size: n = 959

Figure 5.1 Recruitment Process for the Average Risk Population Survey

5.2. Total Sample

5.2.1 Demographics

Table 5.2 describes the demographic characteristics of and survey responses given by the total sample (n = 959). Women comprised slightly over half of the sample, 55.4%, and the mean age was 61 years, (SD = 6.5). The proportion of respondents in four of the five-year age subgroups was relatively similar, but was slightly lower in the 70-74 years subgroup at 11.8%. The majority of the sample were married, 70.3%, and 87% of respondents rated their health as good, very good or excellent.

Table 5.2 Demographic Characteristics of the Total Sample

Characteristic	% (n)
Gender	Men: 43.9% (421)
	Women: 55.4% (531)
Five-year Age Groups	50-54 years: 20.2%
	55-59 years: 22.5%
	60-64 years: 25%
	65-69 years: 19.6%
	70-74 years: 11.8%
Marital Status	Married: 70.3%
	Living as married: 5.3%
	Never married: 7.4%
	Divorced: 7.3%
	Separated: 1.4%
	Widowed: 7.3%
Health Status	Excellent: 13.8%
	Very Good: 39.3%
	Good: 33.8%
	Fair: 11.2%
	Poor: 1.3%

5.2.2 FOBT Awareness and Prior Use

Approximately two-thirds of the sample (67.3%) reported that they had heard of an FOBT test prior to reading a description of this test as a part of the survey. Approximately two-thirds of the sample reported that they not been screened using FOBT in the past (67.5%).

5.2.3 Intention to Screen Using FOBT

Respondents were asked about their intention to screen using two different approaches. First they were asked: *Which statement best describes how you feel about using the fecal occult blood test when it becomes available in your region?* Possible response categories were: *'I would not complete a fecal occult blood test if one were sent to my home'*, *'I am unsure if I would complete a fecal occult blood test if one were sent to my home'* or *'I would definitely complete a fecal occult blood test if one were sent to my home'*.

A positive intention to screen if an FOBT were sent to their home was reported by 79.2% of respondents (definitely screen), followed by 14.9% who were uncertain if they would screen, and 4.5% who reported that they would not complete the test.

Secondly, respondents were asked to circle how likely is was that they would complete a FOBT if one were sent to them at home. Respondents could choose a numerical value between 1 and 10, where 1 represented *'I would definitely not complete a fecal occult blood test'* and 10 represented *'I would definitely complete a fecal occult blood test'*. Table 5.3 displays the response distribution for this question. Responses to both questions on intention to screen demonstrated that there was high positive intention to screen among the sample.

Table 5.3 Response Distribution for 10-Point Scale *Intention to Screen* Question

Response	Frequency	Percent
1	50	5.2
2	10	1.0
3	6	0.6
4	15	1.6
5	53	5.5
6	35	3.6
7	31	3.2
8	77	8.0
9	66	6.9
10	602	62.8
Missing	14	1.5
Total	**959**	**100**

5.3 Sample Characteristics and Survey Responses by Presence / Absence of High Risk CRC

Sample characteristics and survey responses were examined by the three distinct populations. Table 5.4 compares the sample characteristics and survey responses by the ARU, ARR and HRR areas.

The sample from each region had a similar gender breakdown ($p = 0.79$) and mean age ($p = 0.59$). The highest proportion of respondents were aged 60-64 for all regions. Fewer respondents in the ARU area were married, and more were divorced compared with the other two areas ($p = 0.00$). Urban respondents were more likely to report their health status as 'Excellent' or 'Very Good' ($p = 0.02$). The most frequently chosen response to health status in the ARR and HRR regions was 'Good'.

Those in the ARR region were most likely to have heard of FOBT before (75.3%), followed by the ARU population (62%) and then the HRR population (57%), $p = 0.00$. Additionally, those in the ARR population were approximately twice as likely as those in the other two areas to have previously screened using FOBT, 41.2%, versus 23.4% and 19% in ARU and HRR populations, respectively ($p = 0.00$). Overall, 30.9% of respondents reported previous screening activity using FOBT, indicating that many respondents had not used the test before.

With respect to intention to screen using FOBT, a high proportion responded 'yes' to the intention to screen question in each of the three areas. As with prior awareness of FOBT, the ARR sample had the highest proportion of positive intention (82.9%), followed by the ARU sample (79.6%) and the HRR sample (77.1%). All three regions had very low proportions of respondents who said they would not complete an FOBT if one were sent to their home ($< 7\%$ in total). The HRR group was more likely to report uncertain intention to participate in FOBT

screening (20.7%) when compared with the other two groups (ARU = 15% and ARR = 13.3%),

$p = 0.05$.

Table 5.4 Sample Characteristics and Survey Responses by Geography/Risk Level

Survey Item	Response					Significant
Gender (%)	**Gender**	**ARU**	**ARR**	**HRR**	**Total**	**No**
	Male	45.3	43	45.1	44.2	$p = 0.79$
	Female	54.7	57	54.9	55.8	
	Missing: 7 cases					
Mean Age (years)	**Mean Age**	**ARU**	**ARR**	**HRR**	**Total**	**No**
		61	61.1	60.3	60.9	$p = 0.59$
	Missing: 7 cases					
Age Group (%)	**Age Group**	**ARU**	**ARR**	**HRR**	**Total**	**No**
	50-54	22	18.2	22.5	20.4	$p = 0.15$
	55-59	22.5	22.9	23.2	22.7	
	60-64	23.1	26.4	27.5	25.2	
	65-69	17.3	22.4	18.3	19.8	
	70-74	15.2	10	8.5	11.9	
	Missing: 9 cases					
Marital Status (%)	**Marital Status**	**ARU**	**ARR**	**HRR**	**Total**	**Yes**
	Married	61.3	78.9	73.2	71	$p = 0.00$
	Living as Married	5.5	4.9	6.3	5.4	
	Never Married	11.3	4.0	7.7	7.5	
	Divorced	12.6	3.7	4.2	7.4	
	Separated	2.4	0.7	0.7	1.4	
	Widowed	6.8	7.7	7.7	7.4	
	Missing:10 cases					
Health Status (%)	**Health Status**	**ARU**	**ARR**	**HRR**	**Total**	**Yes**
	Excellent	18.8	10.3	11.3	13.9	$p = 0.02$
	Very Good	40.7	40.3	34.5	39.6	
	Good	29.5	36.1	40.1	34	
	Fair	9.9	11.9	12.7	11.2	
	Poor	1.0	1.4	1.4	1.3	
	Missing: 7 cases					
Heard of FOBT Before Survey (%)	**Heard of FOBT**	**ARU**	**ARR**	**HRR**	**Total**	**Yes**
	Yes	62	75.3	57.9	67.5	$p = 0.00$
	No	38	24.7	42.1	32.5	
	Missing: 3 cases					
Prior Use of FOBT (%)	**Prior FOBT**	**ARU**	**ARR**	**HRR**	**Total**	**Yes**
	Yes	23.4	41.2	19	30.9	$p = 0.00$
	No	76.6	58.8	81	69.1	
	Missing: 23 cases					
Intention to Screen	**Intent**	**ARU**	**ARR**	**HRR**	**Total**	**Yes**
	Definitely	78.6	82.9	76.1	79.2	$p = 0.05$
	Unsure	15	13.1	20.4	14.9	
	No	6.3	3.7	2.1	4.5	
	Missing: 13 cases					

5.4 Univariate Analysis

5.4.1. Data Amalgamation Considerations – Average Risk Populations

Before further analysis was undertaken, a chi square test was performed to determine if the two average risk populations differed from each other on their reported screening intentions. Based on prior findings of lower engagement in preventive health behaviours in rural populations, the secondary study hypothesis stated that individuals residing in an ARU region would be more likely to report a positive intention to screen than ARR dwelling individuals. If no significant difference was found between these two groups, this hypothesis would not be supported and the two populations with no familial clusters of high risk CRC would be collapsed into one group called 'average risk' for the remainder of the analysis. Table 5.5 shows the results of the cross-tabulation comparing the ARU and ARR populations on intention to screen. No significant difference was detected between these groups on intention to screen, [$\chi^2 = 3.56$ (2), $p = 0.17$]. This does not support the hypothesis of a significant difference on reported screening intention between these two groups.

Table 5.5 Average Risk Populations by Intention to Screen 2x3 Table

Region of Province	Intention n (%)			Total
	No	Unsure	Yes	
Average Risk Urban	24 (6.3)	57 (15)	298 (78.6)	379
Average Risk Rural	16 (3.7)	57 (13.3)	354 (82.9)	427
Total	40	114	652	806

5.4.2 Data Amalgamation Considerations – Intention to Screen Response Categories

The option was also explored of grouping the 'unsure' and 'no' responses to the screening intention question into one response category for remaining analysis. Very small numbers of respondents chose the 'unsure' and particularly the 'no' categories in each region leading to small cell sizes that could impact the validity of univariate and multivariate analyses. Given that the study's principal focus was on whether or not those living in areas where there was a familial cluster of high risk CRC differed on positive screening intention from those living in areas where there was no such cluster, it was felt that collapsing the 'unsure' and 'no' categories warranted examination to see if it would alter the results. If a similar relationship was found using two response categories compared with the original three, then 'yes' and 'unsure / no' would be used going forward for parsimony of analyses.

Tables 5.6 and 5.7 demonstrate the cross-tabulation and chi-square analysis for presence / absence of high risk CRC by screening intention, retaining the original three response categories. Tables 5.8 and 5.9 demonstrate the same statistics, excepting that screening intention is a dichotomous variable.

Table 5.6 Presence / Absence of High Risk CRC by Screening Intention 2x3 Table

Region of Province	Intention n (%)			Total
	No	**Unsure**	**Yes**	
Average Risk	40 (5.0)	114 (14.1)	652 (80.9)	806
High Risk	3 (2.1)	29 (20.7)	108 (77.1)	140
Total	43	143	760	946

Table 5.7 Presence of High Risk CRC by Screening Intention (Three Response Categories) Chi Square Analysis

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	5.70	2	0.06

Table 5.8 Presence of High Risk CRC by Screening Intention 2x2 Table

Region of Province	Intention		Total
	Unsure / No	Yes	
Average Risk	154 (19.1)	652 (80.9)	806
High Risk	32 (22.9)	108 (77.1)	140
Total	186	760	946

Table 5.9 Presence of High Risk CRC by Screening Intention (Two Response Categories) Chi Square Analysis

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	1.06	1	0.30

Based on non-significant findings on screening intention using either two or three response categories, and the very small number of participants reporting a negative intention to screen (5% in the combined average risk region and 2.1% in the high genetic risk region), it was decided that collapsing the 'no' and 'unsure' response categories into one category for comparison against those reporting a positive intention to screen was a methodologically justifiable decision. The combined average risk regions (cAR) and the HRR region had high and similar rates of reported positive screening intention (80.9% and 77.1% respectively), $p = 0.30$. This finding refutes the study hypothesis that those living in an area with the presence of a familial cluster of high genetic risk of CRC would be more likely to report positive screening intention than those living in areas where high genetic risk CRC familial clustering was not found. Further analyses were conducted to determine if other demographic factors played a significant role in impacting screening intention in the NL population.

5.4.3 Ten-Point Screening Intention Variable

An additional item on the average risk population survey that addressed screening intention was also examined in relation to presence / absence of familial clusters of high genetic risk CRC to determine whether asking about screening intention an alternative way yielded the same or different outcomes. This question asked respondents to choose on a scale of 1 to 10 how likely they would be to complete an FOBT if one were sent to them. As the independent variable was nominal and the dependent variable was ordinal, non-parametric tests other than chi-square were used for analysis.

A Kruskal-Wallis test was first run, keeping the independent variable of 'Region' as three distinct groups. As seen in Table 5.10, no significant difference was found between ARU, ARR and HRR respondents on the response distribution for screening intention.

Table 5.10 Kruskal-Wallis Test of Screening Intention by Region (Three Categories)

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distribution of q0009_0001 is the same across categories of Region of Province.	Independent-Samples Kruskal-Wallis Test	.150	Retain the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

Subsequent to this, the two average risk regions were collapsed into one category, making the independent variable two-category. A Mann-Whitney U test was then run comparing the two groups on screening intention. No significant difference was found in response distributions between the two groups.

Table 5.11 Mann-Whitney U Test of Screening Intention by Region (Two Categories)

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distribution of q0009_0001 is the same across categories of Regions Collapsed.	Independent-Samples Mann-Whitney U Test	.128	Retain the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

5.4.4 Intention to Screen by Socio-Demographic Characteristics and FOBT Awareness /Prior Use

Following the chi square analyses run for the primary outcome of interest: relationship of presence / absence of a familial cluster of high genetic risk CRC and intention to screen, chi-square analyses were run for each socio-demographic variable by reported screening intention and for responses on FOBT awareness and prior use by reported screening intention to determine if any of these factors had a significant relationship with intention to screen. All chi square analyses that were significant at the $p \leq .10$ level were retained for inclusion in multivariate analysis.

There was no significant difference in screening intention by gender, $[\chi^2 = 0.01\ (1), p = 0.91]$. The proportion of respondents choosing each response category were similar for men and women. This variable was not retained for multivariable analysis.

Table 5.12 Gender by Intention to Screen 2x2 Table

Gender	Intention n (%)		Total
	Unsure / No	Yes	
Male	83 (20)	333 (80)	416
Female	103 (19.7)	421 (80.3)	524
Total	186	754	940

Age was collapsed into five-year subgroups for the purpose of analysis by age. No significant difference was found on screening intention by five-year age group, [$\chi^2 = 4.23$ (4), $p = 0.38$]. All age groups were likely to report a positive screening intention, although those in the 50-54 age group were slightly less likely to choose 'yes' on screening intention than those in the older groups. Age group was not retained for multivariable analysis.

Table 5.13 Five-Year Age Group by Intention to Screen 5x2 Table

	Intention n (%)		
Age Group	**Unsure / No**	**Yes**	**Total**
50-54	47 (24.5)	145 (75.5)	**192**
55-59	41 (19.2)	173 (80.8)	**214**
60-64	43 (18.2)	193 (81.8)	**236**
65-69	31 (16.7)	155 (83.3)	**186**
70-74	22 (19.8)	89 (80.2)	**111**
Total	**184**	**755**	**939**

Health status was reduced from five response categories down to three by grouping 'poor' / 'fair' into one category and 'very good' / 'excellent' into one category. This was done to avoid cells containing counts < 5 in the chi square analysis because very few respondents chose 'poor' or 'fair' to represent their health status. The majority of respondents reported a positive intention to screen despite their health status. A slightly higher proportion of those whose considered their health 'Very Good' or 'Excellent' answered in the 'Yes' category compared with those who considered their health 'Good'. In turn, those who considered their health 'Good' were slightly more likely to report a positive intention to screen than those in the 'Poor / Fair' health status category. Chi square analysis was significant at $\leq$ the 0.10 level, so health status was retained for multivariate analysis, [$\chi2 = 4.64$ (2), $p = 0.09$].

Table 5.14 Health Status by Intention to Screen 3x2 Table

Health Status	Intention n (%)		Total
	Unsure / No	Yes	
Poor/Fair	29 (24.8)	88 (75.2)	**117**
Good	70 (21.8)	251 (78.2)	**321**
Very Good / Excellent	87 (17.3)	416 (82.7)	**503**
Total	**186**	**755**	**941**

Marital status was grouped into two categories of 'married' / 'living as married' and 'never married' / 'separated' / 'divorced' / 'widowed' to distinguish those who were living in partnership from those who were not. A number of the available response categories for marital status were chosen infrequently, which was an additional reason to collapse across categories. Individuals who were currently in a partnership chose a positive intention to screen slightly more often than those who were un-partnered. This difference was not significant, $[\chi^2 = 1.74\ (1), p = 0.19]$, and this variable was not retained for multivariate analysis.

Table 5.15 Marital Status by Intention to Screen 2x2 Table

Marital Status	Intention n (%)		Total
	Unsure / No	Yes	
Married/Living as Married	134 (18.7)	583 (81.3)	**717**
Not married	50 (22.7)	170 (77.3)	**220**
Total	**184**	**753**	**937**

Those who had heard of FOBT before were more likely to report a positive intention than those who had not heard of it, 85.3% versus 70.2%. Prior awareness of FOBT appeared to reduce uncertainty and increase positive intention to complete FOBT in this sample. The difference on intention to screen between those who had heard of FOBT and those who had not was significant, $[\chi^2 = 30.05\ (1), p = 0.00]$. This variable was retained for multivariate analysis.

Table 5.16 Prior FOBT Awareness by Intention to Screen 2x2 Table

Prior Awareness of FOBT	Intention n (%)		Total
	Unsure / No	Yes	
No	92 (29.8)	217 (70.2)	**309**
Yes	93 (14.7)	541 (85.3)	**634**
Total	**185**	**758**	**943**

Those who had used FOBT in the past were less likely to report uncertainty or negative intention about completing an FOBT if one were sent to them. Almost 90% of those who completed an FOBT prior to taking the survey said they would definitely complete an FOBT if they received one compared with 15% less of those who had never used FOBT (76.7%). The association between prior FOBT use and intention to screen was significant, [$\chi^2 = 19.99$ (1), $p = 0.00$], and thus this variable was also retained for multivariate analysis.

Table 5.17 Prior FOBT Use by Intention to Screen 2x2 Table

Prior Use of FOBT	Intention		Total
	Unsure / No	Yes	
No	149 (23.3)	490 (76.7)	**639**
Yes	31 (10.8)	257 (89.2)	**288**
Total	**180**	**747**	**927**

5.4.5 Univariate Analysis Summary

Analyses conducted at the univariate level suggested rejecting the study hypothesis. The majority of respondents reported a positive intention to engage in screening regardless of the presence or absence of a familial cluster of high genetic risk CRC in the region in which they were residing. Rurality of geography did not appear to make a difference, given that there was no significant difference in intention to screen between those residing in urban or rural regions where there was no cluster of high risk CRC. Those variables that were significant at the $p \leq 0.1$ level were retained for multivariate analysis and included health status, prior awareness of FOBT and prior use of FOBT. As the primary predictor of interest, presence or absence of high risk CRC was also retained for multivariable analysis, even though it did not meet the significance criteria. Table 5.18 provides a summary of all univariate analysis conducted and which variables were retained for multivariable analysis.

Table 5.18 Summary of Univariate Analysis Conducted on the Relationship between Target Population Survey Variables and Intention to Screen

Variable	Statistic	Value [df]	Significance Level	Retained
Presence / Absence of High Risk CRC	χ^2	1.06 [1]	p = 0.30	√
Gender	χ^2	0.01 [1]	p = 0.91	X
Age Group	χ^2	4.23 [4]	p = 0.38	X
Health Status	χ^2	4.64 [2]	p = 0.09	√
Marital Status	χ^2	1.74 [1]	p = 0.19	X
Prior Awareness of FOBT	χ^2	30.05 [1]	p = 0.00	√
Prior Use of FOBT	χ^2	19.99 [1]	p = 0.00	√

5.5 <u>Multivariate Analysis</u>

5.5.1 Logistic Regression

Because the dependent variable (screening intention) was treated dichotomously, (yes or no/unsure), binomial logistic regression was used to conduct multivariate analysis. Logistic regression was chosen over discriminant analysis because it requires fewer assumptions and is more statistically robust[130]. Logistic regression employs binomial probability theory in which there are only two values to predict: that probability (p) is 1 rather than 0. It forms a best fitting equation of function using the maximum likelihood method, which maximizes the probability of classifying the observed data into the appropriate category given the regression coefficients. Each independent variable has a β-coefficient that measures each independent variable's contribution to changes in the dependent variable. A minimum of 50 cases per independent variable is recommended[130]. Binomial logistic regression produces an odds ratio which estimates the change in the odds of membership in the target group for a one unit increase in the predictor. In the case of this analysis, predictor values that were significant at the $p \leq 0.1$ level using chi-square analysis, were retained for inclusion in a multivariate model. These included health status, prior awareness of FOBT and prior use of FOBT. Although, not significant in univariate analysis, the presence / absence of high genetic risk was maintained for multivariate analysis given that it was the primary predictor variable of interest.

5.5.2 Model Summary

The overall significance of the model was tested using the Model Chi Square. This is derived

from the likelihood of observing the actual data under the assumption that the model that has

been fitted is accurate. The null hypothesis is that the model is a good fit without any predictors

added. Table 5.19 shows that the model chi-square has a value of 37.18, three degrees of

freedom and a probability of $p < 0.00$. Thus, the indication is that the model has a poor fit when

it contains only the constant, and the inclusion of predictors does have a significant effect and

create a different model.

5.19 Model Chi-Square

		Chi-square	df	Sig.
Step 1	Step	37.25	4	0.00
	Block	37.25	4	0.00
	Model	37.25	4	0.00

5.5.3 Logistic Regression Results

Table 5.20 shows the logistic regression output when prior awareness of FOBT, prior use of FOBT, health status and presence or absence of high genetic risk are entered into the logistic regression model. The Wald statistic shows that all variables included make a significant contribution to the prediction except presence or absence of high genetic risk. P-values for the three significant predictors were prior awareness ($p = 0.001$), prior use ($p = 0.008$) and health status ($p = 0.05$). The Exp(B) column shows the odds ratio for each variable. The odds of reporting a positive screening intention were more likely if the person had heard of FOBT before, [OR = 1.92, 95% CI 1.32 - 2.77]; if the person had used FOBT before [OR = 1.87, 95% CI 1.18 - 2.97] and, as self-reported health status improved [OR = 1.27, 95% CI 1.00 - 1.60]. The confidence intervals for both prior awareness and prior use of FOBT were narrow and did not cross one, which indicates reasonable reliability and significance of the estimate. The lower limit of the confidence interval for health status approached one, which calls into question the significance of this predictor in the model. When presence or absence of high genetic risk was removed and the model rerun, the results for the remaining three variables remained almost the same.

Table 5.20 Logistic Regression Output

Variable	B	S.E.	Wald	df	Sig.	Exp(B)	95% C.I.for EXP(B)	
							Lower	Upper
Prior Awareness FOBT	0.65	0.19	11.84	1	0.001	1.92	1.32	2.77
Prior Use FOBT	0.63	0.24	7.13	1	0.008	1.87	1.18	2.97
Health Status	0.24	0.12	3.92	1	0.05	1.27	1.00	1.60
Presence of Risk	0.07	0.24	0.07	1	0.79	1.07	0.67	1.70
Constant	0.28	0.32	0.78	1	0.38	1.32		

Chapter Six

Results: Family Physician Survey

6.1 Sample Recruitment and Response Rate

The intended population for the family physician survey was all family physicians practicing in NL. The Primary Health Research Unit of the Faculty of Medicine, Memorial University maintains a family physician database that is updated frequently. This database was accessed for the mail-out. As explained in the methodology chapter, the Dillman[129] method was used to enhance response rate. This involved three iterations of survey mail-outs in which non-responders in each round were sent a survey in the subsequent round.

6.1.1 Round One Mail-Out

In the first mail-out, 586 surveys were mailed to the individuals included in the family physician database. Of these, 15 were returned unopened as 'return to sender' and two were returned with notes stating that the physician to which the survey was sent was not practicing in the primary care setting. Out of an eligible denominator of 569 then, 140 completed or partially completed surveys were returned for a response rate of 24.6%.

6.1.2 Round Two Mail-Out

It was recognized that surveys from some physicians who had responded to the round one mail-out would not have been received by the time the round two mail out was initiated. Thus, some physicians would receive a second survey package even though they had already sent a response. This was acknowledged in the information letter that was sent in the round two survey

package. Those who had already returned a survey were asked to disregard the second mailing. In total, 482 surveys were mailed out in round two. Four packages were returned unopened and three were returned with notes explaining why the physician to which the survey was sent was not in the correct target group. Eighty-one surveys were returned out of an eligible 475 mailed for a response rate of 17.05%.

6.1.3 Round Three Mail-Out

A total of 409 survey packages were sent out in round three. A similar message was included in the round three information letter acknowledging that some physicians had possibly already returned a survey and, if so, asking them to disregard the follow-up mail-out. Five surveys were returned unopened and an additional four were returned with note stating that the physician was not involved in primary care. These nine surveys were discounted from the denominator total. Round three resulted in a response rate of 13.25% (53/400).

6.1.4 Response Rate Summary

Table 6.1 summarizes the response rates attained over the three rounds of survey mail-outs. After discounting all surveys sent back as 'return to sender' or sent back indicating that the survey had been received by an individual who was not practicing primary care (33), the final denominator of eligible individuals was 553. Over the three rounds of mail outs, 274 surveys were returned either completed or partially completed. This resulted in a final response rate of 49.6% for the family physician survey.

Table 6.1 Family Physician Survey Response Rate Summary

Mail Out	Surveys Sent	Surveys Eligible	Surveys Returned	Response Rate
1	586	569	140	24.6%
2	482	475	81	17.1%
3	409	400	53	13.3%
Total				49.6%

6.2 Survey Results

6.2.1 Sample Demographics

Of the 274 family physicians who responded to the survey, 158 (57.7%) were male. The mean age of respondents was 47.6 (SD = 11.5) years of age and the median year of graduation was 1991. The majority of respondents graduated from a Canadian medical school, (70.8%), and 62.8% had their practice located in the Eastern Regional Health Authority. The split between urban and rural practices was almost equal and most physicians were practicing full-time. Physicians saw a mean of 131.2 (SD = 61.7) patients per week and 72.6% were practicing in a family physician office / clinic spending on average 40.7 (SD = 12.3) hours per week in direct patient care. The mean number of additional physicians per office was 3.57 (SD = 3.67). Table 6.2 and Figures 6.1-6.5 provide a description of the family physician sample.

Table 6.2 Family Physician Respondent Characteristics

Survey Item	Response
Gender	**Female:** 114 (41.6%)
	Male: 158 (57.7%)
	Missing: 2
Median Age	45 years (range: 23-73 years)
	Missing: 6
Median Year of Graduation	1991 (range: 1966-2011)
	Missing: 9
Medical School	**Canadian:** 194 (70.8%)
	International: 69 (25.2%)
	Missing: 11
Location of Practice by RHA	**Eastern Health:** 172 (62.8%)
	Central Health: 48 (17.5%)
	Western Health: 33 (12%)
	Labrador-Grenfell Health: 20 (7.3%)
	Missing: 1
Time Spent in Practice	**Full-Time:** 223 (81.4%)
	Part-Time: 38 (13.9%)
	Locum: 5 (1.8%)
	Other: 5 (1.8%)
	Missing: 3
Location of Practice by Urban / Rural	**Urban:** 135 (49.3%)
	Rural: 134 (48.5%)
	Missing: 6
Median Number of Patients per Week	122.5 (range: 15-350 patients)
	Missing: 6
Clinic Setting	**Family Practice Office/Clinic:** 199 (72.6%)
	Long Term Care: 1 (0.4%)
	Emergency Room: 19 (6.9%)
	In-patient Based: 5 (1.8%)
	Walk-In: 5 (1.8%)
	Other: 13 (4.7%)
	Missing: 32
Mean Hours / Week in Direct Patient Care	40.7 (range: 6-100 hours)
	Missing: 6
Mean Number of Physicians in Practice	3.57 (range: 0-30 physicians)
	Missing: 25
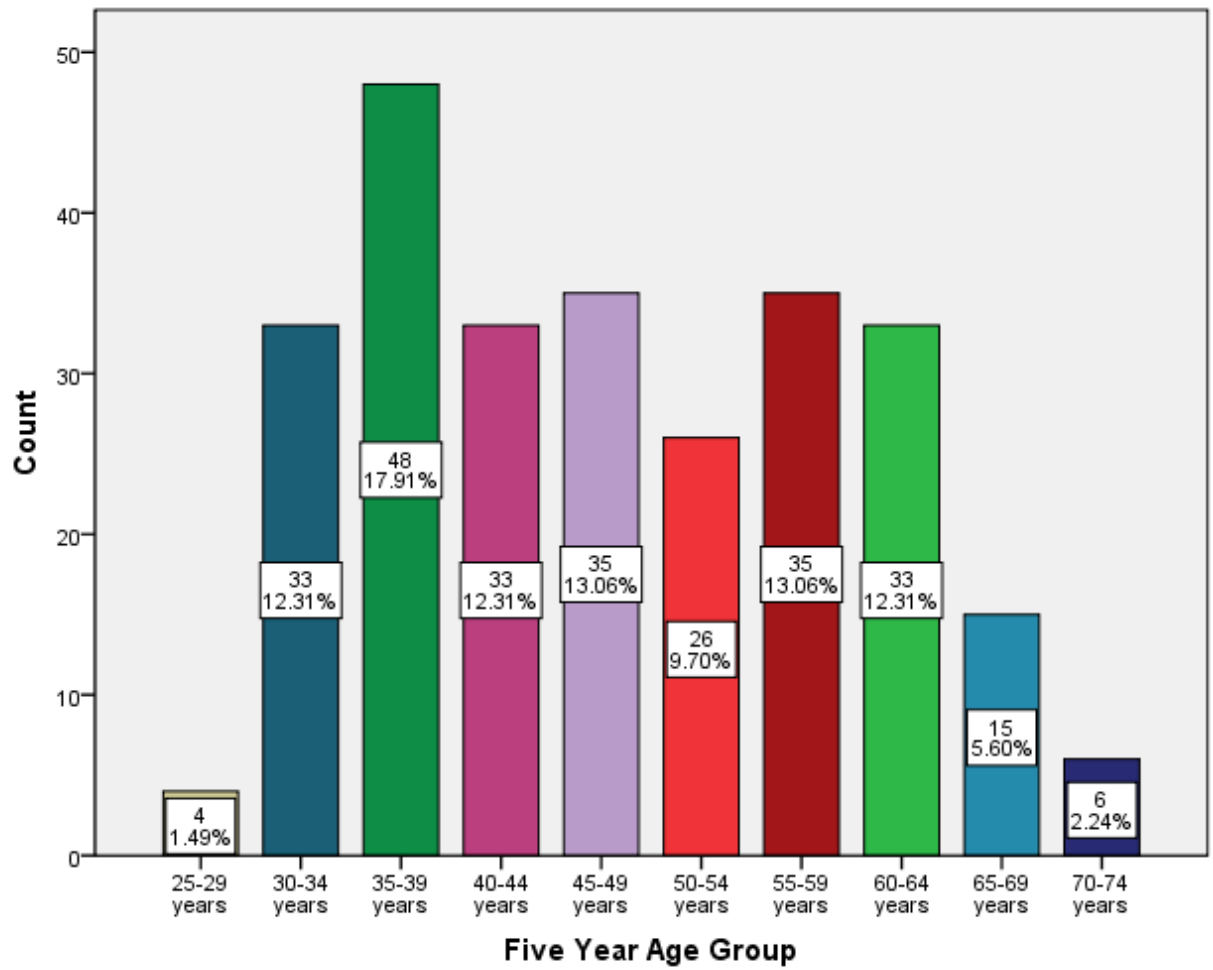
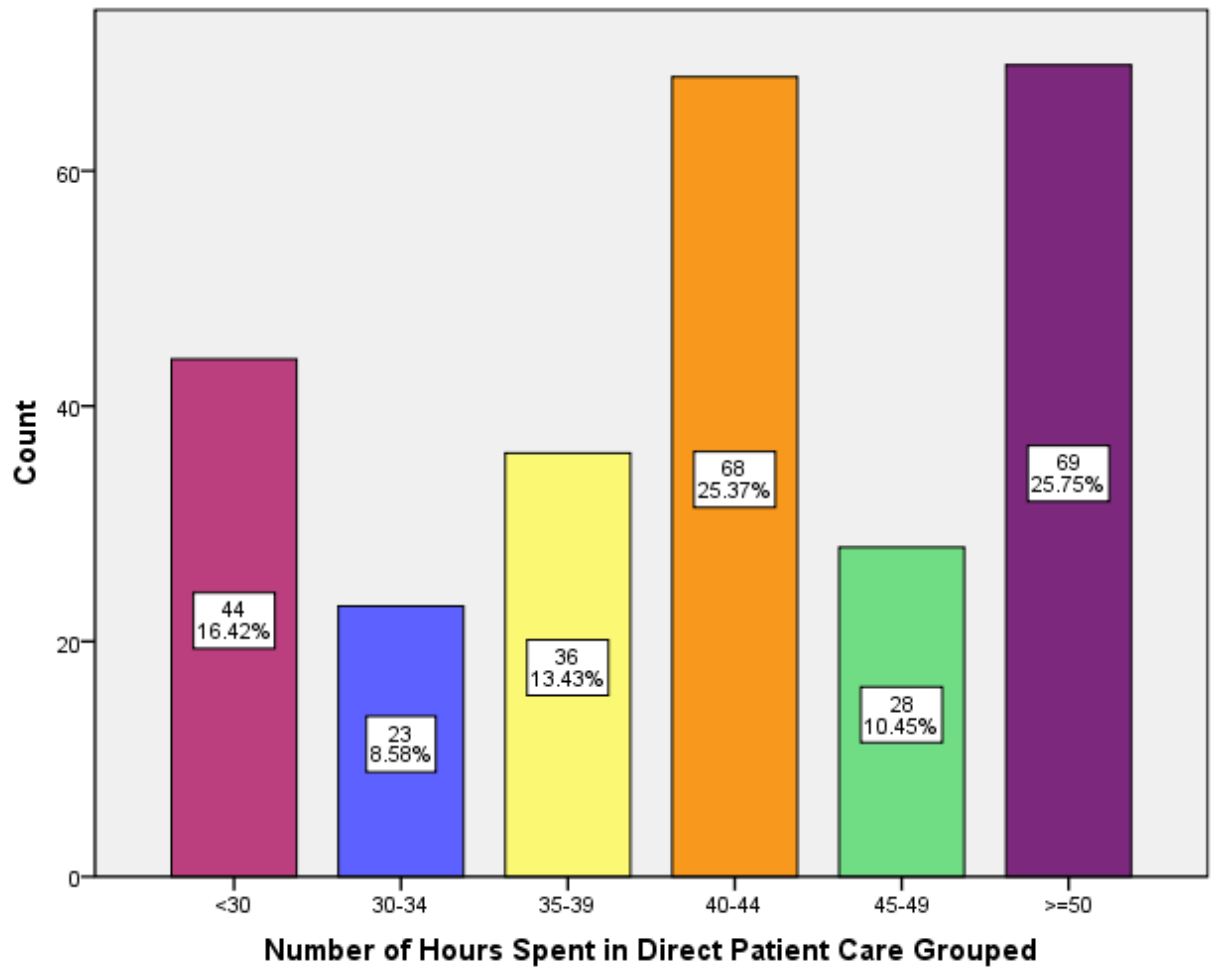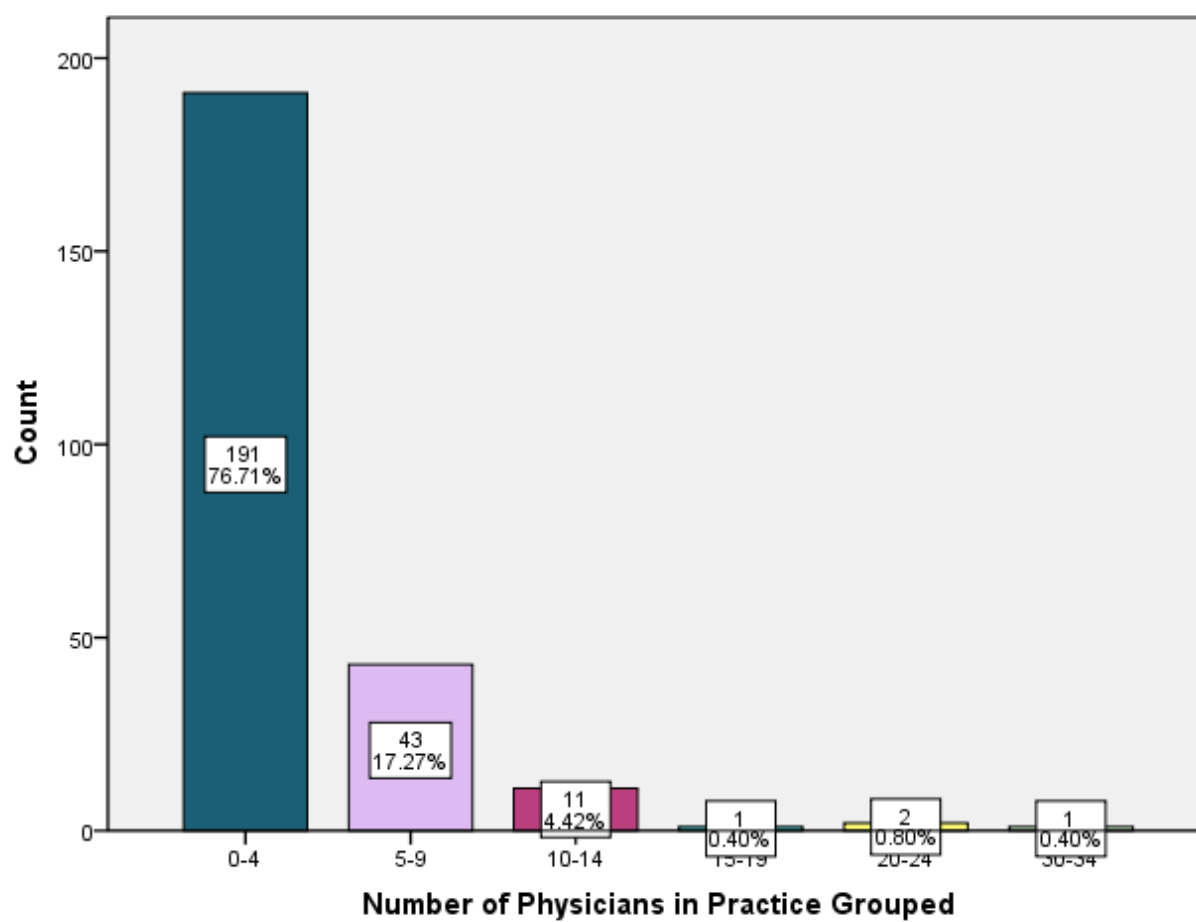**Figure 6.1 Physician Age Group**
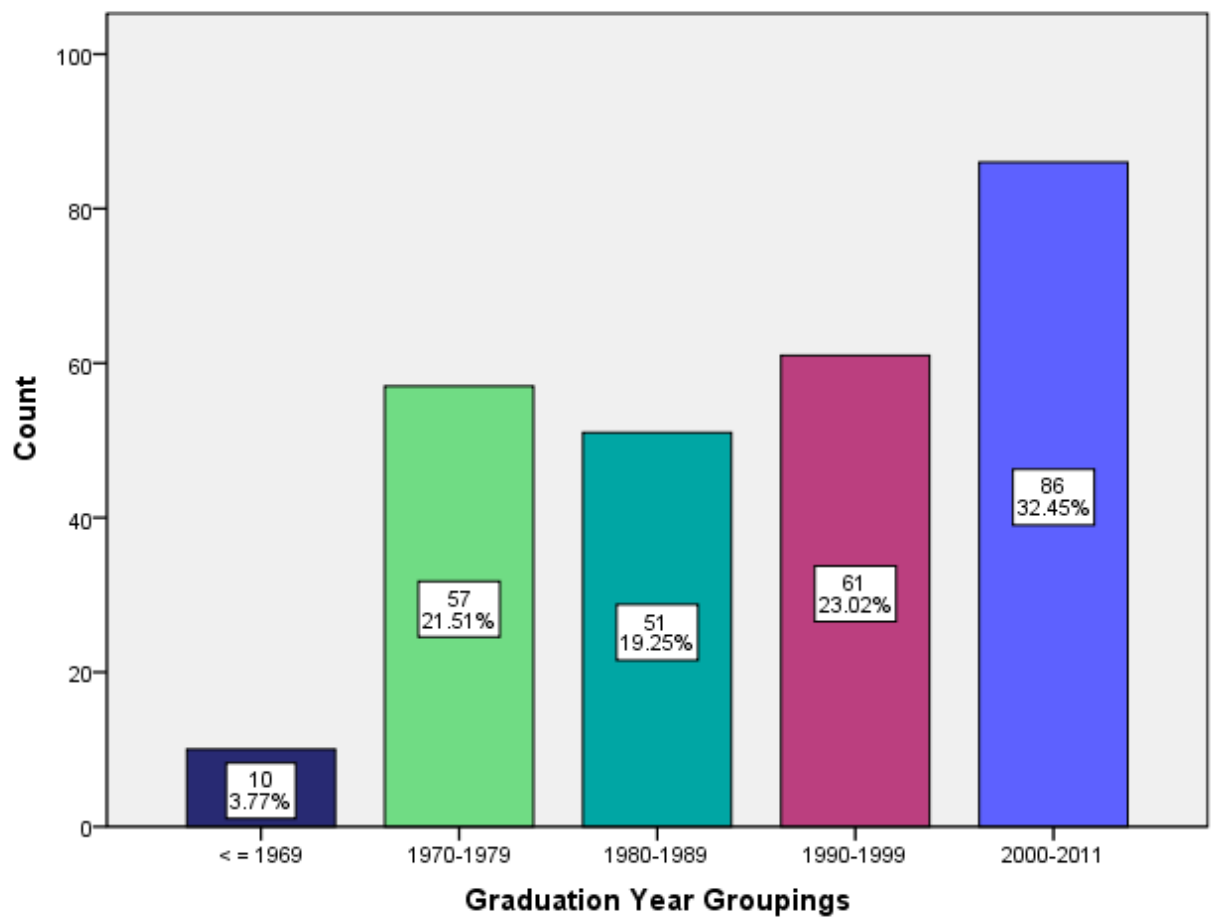
Figure 6.2 Year of Graduation from Medical School
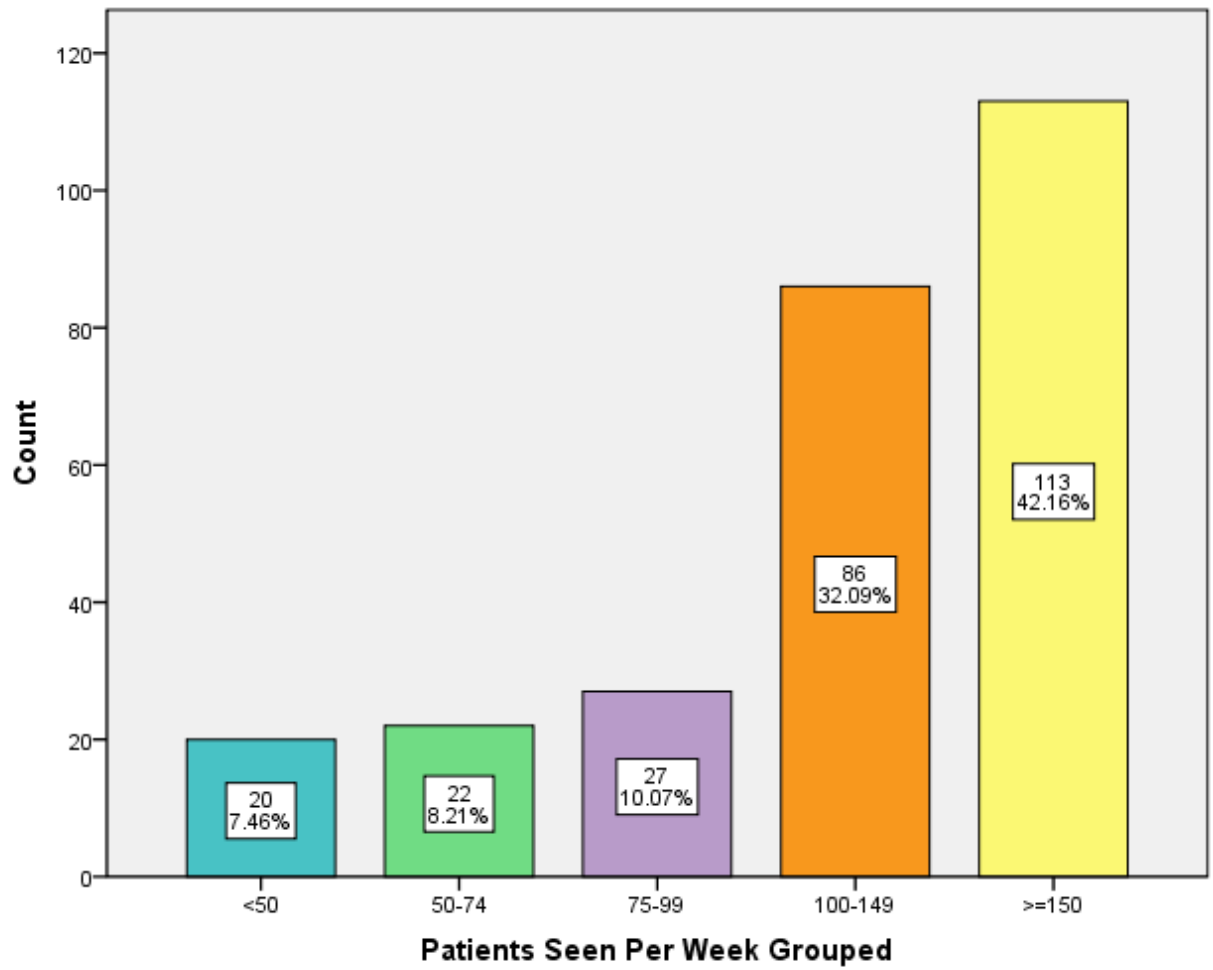
Figure 6.3 Number of Patients Seen Per Week

Figure 6.4 Number of Hours Spent in Direct Patient Care Per Week

Figure 6.5 Number of Physicians in Practice

6.2.2 Responses to Screening Questions

Physicians were asked a variety of questions regarding their knowledge, beliefs and practices with respect to FOBT screening for CRC. These are described in the various tables and figures below. Question 1 asked 'Before receiving this information letter and survey, were you aware of fecal occult blood testing (FOBT) as a screening modality for colorectal cancer?' All respondents reported having awareness of FOBT prior to receiving the survey.

The mean levels of agreement for questions 2a and 2b, 5.79 and 5.11 respectively, indicated a high level of agreement with both statements. Family physicians felt particularly strongly about having a role to play in support and advocacy for CRC screening. They also agreed that they effectively communicated with their patients about CRC screening, with 75% choosing response categories 5 or 6. However, there was more variability over categories 4, 5 and 6 in response to question 2b when compared with question 2a. This suggests more uncertainty is felt by physicians in how effectively they communicate with their patients regarding CRC screening.

Table 6.3 (Questions 2a and 2b.) Please indicate your level of agreement with the following statements: 2a. Family Physicians have a responsibility to support and advocate for colorectal cancer screening &2b. I effectively communicate colorectal cancer screening strategies to my patients.

Question	n	Strongly Disagree 1	2	3	4	5	Strongly Agree 6	Agreement 5+6	Weighted Mean
2a	273	0%	0%	0.7%	3.3%	16.8%	79.1%	95.9%	5.79
2b	273	0%	1.1%	1.5%	22.3%	35.5%	39.6%	75.1%	5.11

Question 3 explored various potential barriers to discussing CRC screening in the family practice environment. Combining the 'often', 'most of the time' and 'always' categories clearly demonstrated that many of these items were not perceived to be barriers for the family physicians responding to this survey. In particular, physician financial compensation, comfort level with knowledge of CRC screening options and perceived patient fear or embarrassment about the screening procedure did not appear to be significant barriers.

The time required to explain the pros and cons of screening options was reported to be a barrier 'often', 'most of the time' or 'always' by almost 20% of physicians, however, almost half (48.9%) felt this was a barrier 'never' or 'rarely' and 31.6% reported that it was a barrier 'sometimes'. The presence of co-morbid conditions in patients at average risk for CRC was seen to be the biggest barrier to discussing screening with 40.9% of physicians choosing 'often', 'most of the time' or 'always' in response to this question. Nonetheless, the remaining 60% chose one of the lower three response categories. Of the barriers listed in the survey, none emerged as being a frequent barrier by the majority of the physician sample.

Table 6.4 (Question 3.) The following factors are barriers to discussing colorectal cancer screening with my average risk patients.

Factors	n	Never 1	2*	3±	4‡	5^	Always 6	4 + 5+ 6	Weighted Mean
Physician financial compensation	270	61.5%	17.5%	13.5%	4.0%	1.5%	1.5%	7.0%	1.70
Level of comfort with my knowledge to help patients decide pros/con of CRC screening options	271	43.2%	37.3%	14.4%	2.6%	2.2%	0.4%	5.2%	1.85
Time it takes to explain the pros/cons of CRC screening options	272	26.1%	22.8%	31.6%	12.5%	5.5%	1.5%	19.5%	2.54
Patients with multiple health issues	271	16.2%	12.9%	29.9%	28.0%	11.8%	1.1%	40.9%	3.10
Patients fear/embarrassment about the screening procedure	271	39.5%	28.8%	19.2%	8.9%	2.6%	1.1%	12.6%	2.10

* Rarely   ± Sometimes   ‡Often   ^Most of the Time

Question 3 also included an 'other' category that invited respondents to specify other barriers not listed in the survey and to indicate the frequency with these impacted the ability to discuss CRC screening. Only 13 physicians identified additional barriers and some of these related to the barriers already listed in the survey. It is unknown why the barriers, as they were worded, did not adequately capture the experience for certain physicians. Responses from this small number of respondents revealed that financial compensation, competing patient issues, time available with the patient, availability of FOBT kits in the physician's office, patient uptake of colonoscopy, and health system inability to cope with increased colonoscopy demand were all barriers.

Examples of physician quotes are provided below:

"Too many other more important issues"

"Have so many issues to address on visit and not compensated for time with patient"

"Must have kits ready and available"

"Physical restraints, not having testing available"

"Very poor response for booking patient for screening colonoscopy"

"The system in Labrador could not handle the one of three positive screens that would be generated in a 10-year follow-up / screening program. Access to endoscopy etc."

Question 4 on the survey asked physicians about the age at which they started screening their patients who are average risk for CRC. This question was designed to understand whether physicians were practicing according to screening guidelines which recommend beginning screening at age 50 for individuals at average risk for CRC. Table 6.5 displays these results which demonstrate that almost 85% of respondents reported practicing according to the recommended guideline for beginning CRC screening at age 50. Only 5.1% reported that they did not routinely recommend CRC screening.

Table 6.5 (Question 4) I routinely start recommending colorectal cancer screening to my average risk patients when they are:

Age	Percentage Reporting (n)
<50	8.8 (24)
50	83.5 (228)
>50	2.6 (7)
I do not routinely recommend CRC cancer screening	5.1 (14)

For those who reported that they did not routinely recommend CRC screening (14 respondents), Question 5 provided an opportunity to explain the rationale behind this. Again, time available during the patient visit was cited to be a factor, as was the health system's inability to cope with follow-up colonoscopy demand. Three physicians mentioned that they preferred not to screen their patients unless they were symptomatic or otherwise at an increased risk for CRC (which is counter to the recommendation of FOBT screening for average-risk, asymptomatic patients), and one physician stated that very few of their patients would qualify as average risk, rendering FOBT inappropriate for most of their patient population. Two physicians reported being unsupportive of FOBT as a screening modality. Examples of reasons for not routinely recommending CRC screening to average risk patients included:

"Do not have time to get occult blood on all patients over age 50. We have so much colon cancer that our medical services (scopes) is over loaded now. Mass screening with occult blood would make the colonoscope wait time laughable. So need to select the patients I ask to get occult blood. Also not comfortable with occult blood screening but do support scope every 5 years."

"I ask if there is any family history or colon cancer / polyps or in the patient has any lower GI symptoms. If no family history of colon cancer, colonic polyps, no change in bowel habit, no per rectum blood and CBC and LFTs normal I don't pursue any further."

"I discuss colorectal cancer screening with most of my patients starting around 45 years old, but most have some clinical risk factors justifying referral for colonoscopy. The few that don't I would probably request FOB testing."

"Referral for colonoscopy is extremely unreliable in this area."

"Whereas stools for occult blood are available, I have little faith in it. Colorectal scoping is not easily obtainable and it is a source of endless grief!!"

"Generally there is a focused agenda around each of the visits and often you remember to discuss colorectal screening after the patient has left."

Following from enquiry about the patient age at which screening is started, Question 6 asked physicians to provide the age at which they routinely stopped recommending CRC screening to their average risk patients. As with Question 4, this question was designed to investigate whether physicians were following the recommendation to stop average risk screening at age 74. Table 6.6 displays the distribution of responses. Ages 74 and 75 were both accepted as correct responses given that the recommended screening age range is 50-74 years. Stopping screening at age 75 could imply that the physician stopped screening at the end of a patient's 74th year of age, which would be appropriate. It was clear from responses that adherence to the recommendation that screening be terminated at age 74 was relatively low. Roughly half of physicians reported that they did not stop screening at a particular age, and only a quarter complied with the recommend guideline.

Table 6.6 (Question 6.) I routinely stop recommending colorectal cancer screening to my average risk patients when they are:

Age	Number Reporting (%)
<74	17 (6.4)
74 or 75	66 (25)
>75	53 (20)
I do not routinely stop CRC screening	128 (48.6)

Question 7 explored the types of CRC screening testing that physicians were utilizing with their average risk patients and the frequency with which they utilized each type of test. A summary of responses is illustrated in table 6.7. Responses to Question 7 show that colonoscopy was the most frequently used screening method for average risk patients by family physician respondents in NL. This is counter to the 2010 CAG position paper which recommends FOBT annually or biennially, or flexible sigmoidoscopy every five years for programmatic screening of the average risk population. Only half of respondents reported using FOBT 'often', 'most of the time' or 'always', while approximately 40% and 34% chose these response categories cumulatively for digital rectal exam with home FOBT and digital rectal exam with office FOBT respectively. Surprisingly, just over a quarter of the sample chose the highest three response categories for digital rectal exam only. One-fifth of respondents used flexible sigmoidoscopy, 'often', 'most of the time' or 'always', and double-contrast barium enema and CT colonography were used infrequently. Percentages across the different screening modalities did not sum to100% as an answer could be provided by each physician for each type of procedure.

Table 6.7 (Question 7.) I recommend the following procedures to my average risk patients for colorectal cancer screening:

Procedures	n	Never 1	2*	3±	4‡	5^	Always 6	4 + 5+ 6	Weighted Mean
Digital Rectal Exam Only	237	37.1%	18.1%	12.8%	9.1%	10.6%	6.2%	25.9%	2.64
Digital Rectal Exam with office FOBT	239	32.2%	13.8%	20.1%	14.6%	12.6%	6.7%	33.9%	2.82
Digital Rectal Exam with home FOBT	241	18.7%	14.1%	27.4%	14.5%	17.8%	7.5%	39.8%	2.80
FOBT completed at home only	238	19.7%	12.2%	16.8%	16.8%	24.4%	8.8%	50%	3.44
Double-contract barium enema	237	29.1%	42.6%	23.2%	3.8%	1.3%	0%	5.1%	2.05
Flexible sigmoidoscopy	237	19.4%	27.0%	32.9%	13.5%	5.1%	1.8%	20.4%	2.64
Colonoscopy	251	6.8%	11.6%	21.1%	25.5%	23.9%	11.2%	60.6%	3.82
CT colonography	236	23.3%	28.8%	35.6%	10.2%	2.1%	0%	12.3%	2.39

* Rarely   ± Sometimes   ‡Often   ^Most of the Time

Question 8 offered respondents the opportunity to articulate whether they recommended any other screening procedures for CRC to their patients. Only four family physicians provided a response to this question. Two of these listed procedures from the aforementioned list in Question 7, and two mentioned blood work (complete blood count and carcinoembryonic antigen).

The frequency with which family physicians recommended FOBT screening was explored in Question 9. The recommended frequency of programmatic screening using FOBT, as mentioned above, is annually or biennially, which were the frequencies chose by almost 90% of

physicians. This implies that almost all family physicians who are using FOBT screening with their patients are aware of and practicing according to an appropriate screening interval.

Table 6.8 (Question 9.) With what Frequency do you Recommend Fecal Occult Blood Test Screening?

Frequency Recommended	Percentage (n)
Not at all	2.6 (7)
Once a year	58.3 (158)
Every two years	28.8 (78)
Every 3-5 years	7.4 (20)
Not sure	3 (8)

Table 6.9 demonstrates the responses to Question 10 which posed a variety of situations to physicians in which they might encounter difficulties in encouraging screening for their average risk patients. As with prior questions, respondents could indicate how frequently they encountered these situations on a six-point Likert scale. All of the weighted means were in the three or below range signifying that the three lower-frequency response categories were chosen most often for each situation listed. As such, none of the issues appeared to be encountered frequently by most family physicians. Availability of colonoscopy was the most problematic issue with almost 40% of the sample reporting that this posed a difficulty in encouraging screening 'often', 'most of the time', or 'always'. Patient discomfort due to colonoscopy was reported as a difficulty 'often', 'most of the time' or 'always' by 21.8% of the sample. The other

screening modalities addressed (DRE and FOBT) and anxiety about screening did not frequently pose difficulties to physicians in encouraging screening.

Question 10 also offered an 'other' category where respondents could provide input on the difficulties encountered in encouraging CRC screening for their average risk patients. Only five physicians supplied additional information in the 'other' category. Example of difficulties expressed were: "D*ietary"* and *"I had not previously considered the patient description on page 1* (of the survey) *as 'average risk'."*

Table 6.9 (Question 10.) I have difficulty encouraging colorectal cancer screening for my average risk patients when:

Procedures	n	Never 1	2*	3±	4‡	5^	Always 6	4 + 5+ 6	Weighted Mean
Colonoscopy is not readily available	258	21.3	18.6	20.5	19	15.1	5.4	39.5	3.04
My patient expresses anxiety about results of the screening procedures and / or treatment for CRC	262	15.6	32.4	39.7	9.9	1.9	0.4	12.2	2.51
My patient expresses discomfort with colonoscopy	261	12.3	19.5	46.4	18.0	3.4	0.4	21.8	2.37
My patient expresses discomfort with DRE	256	14.5	31.6	37.9	12.9	1.6	1.6	16.1	2.60
My patients expresses disgust with FOBT done at home	256	22.7	35.5	31.3	7.8	1.6	1.2	10.6	2.34

* Rarely   ± Sometimes   ‡Often   ^Most of the Time

The key question in this survey asked respondents whether they would support a population-based FOBT screening program for all eligible persons in the province over 50 years of age. The response to this question was overwhelmingly positive with 256 (94.8%) of family physicians saying that they would support such a program.

Physicians who responded in the affirmative to Question 11 were provided with a list of reasons why they might support population-based screening and were asked to select all reasons that applied to them. An open 'other' category was also included in this question. The percentage of physicians in support of an FOBT screening program that selected each of the reasons provided is shown in Table 6.10. Percentages do not sum to 100% as each respondent could choose more than one category. The non-invasive nature of FOBT and that it is quick and simple to do were the reasons most often chosen by physicians. Cost-effectiveness of FOBT and the incidence of CRC seen in NL were the next most common reasons, each chosen by roughly three-quarters of the sample. A higher level of acceptability and mortality reduction were the least commonly chosen reasons. Nonetheless, over half of the sample selected each of these reasons.

Table 6.10 (Question 12.) Reasons for Supporting a Population-Based FOBT Screening Program

Reason	Percent Selecting
Non-invasive	91.0%
Quick and simple to do	89.8%
Cheaper than other screening options	78.9%
High incidence of CRC in NL	75.0%
Reduces CRC mortality	66.0%
Higher level of acceptability than other screening options	60.5%
Other	9.4%

Almost 10% of physicians also selected the 'other' category and some provided qualitative information to articulate these other reasons. Reasons included the role that programmatic screening could play in taking the onus off physicians to remember to offer screening to all their patients aged 50+; the easy availability of FOBT; convenience for patients in that they could take the test at home; and decreased risk of an adverse event when compared with some other screening modalities. Some of examples of other reasons for supporting a population-based FOBT screening program are listed below.

"Available to everyone."

"Doesn't depend on office-based recall systems etc. which only addresses patients who visit their family doctor."

"Easiest initial screen for average risk patients".

"I'm up to my neck in my practice. To do screening properly it needs more than just an individual GP's resources."

"It doesn't take up my time in an office visit that is already overburdened with the three other issues that patient came in with!"

"It is the second most common cause of cancer and a very high cause of cancer deaths. Demographic shift with population aging."

"Less risk of complications, geographic reasons."

"No patient travel out of the community."

"Risks associated with colonoscopy and high dose radiation with CT colonography."

*"Simple way to prevent an awful death."*

Physicians who were not supportive of a population-based FOBT program (n = 14) were asked to respond to Question 13 which provided a list of reasons why they did not support such a program. An 'other' category was provided for this question. Table 6.11 displays the percentage of non-supportive physicians selecting each reason. A perceived high proportion of false positives and false negatives was the reason most commonly chosen, followed by patient unwillingness or inability to comply and lack of cost-effectiveness. The potential reasons for non-support provided on the survey were not as commonly endorsed as many of the reasons for support. However, the sample of non-supportive physicians comprised only a very small portion of the whole sample.

Table 6.11 (Question 13.) Reasons for Not Supporting a Population-Based FOBT Screening Program

Reason	Percent Selecting (n)
High proportion of false positives and false negatives	85.7% (12)
Patient unwillingness or inability to comply	57.1% (8)
Not cost-effective	42.9% (6)
Other	14.3% (2)

Only two physicians provided other reasons for non-support. One physician stated that, *"Bleeding is often a late sign - polyps need to be removed earlier."* Presumably the bleeding this physician is referring to the presence of occult blood in the stool that is detected by FOBT. The other comment was, *"We do not have ability to follow up on in the province!"* This is likely referring to the increased demand that an FOBT screening would place on endoscopy resources. This physician appears to feel that the endoscopy capacity in NL cannot cope with more referrals.

The final survey question asked physicians to indicate their level of agreement with the guideline recommendation that people at average risk for CRC be screened every two years starting at age 50 years. Reponses ranged from 'strongly disagree' to 'strongly agree' on a six-point Likert scale. Figure 6.6 shows the response distribution. Over 75% of respondents chose 5 or 6 on the Likert scale and over 90% selected one of the top three response categories (4, 5 or 6), indicating a relatively high level of agreement for the average risk screening guideline from this physician population.
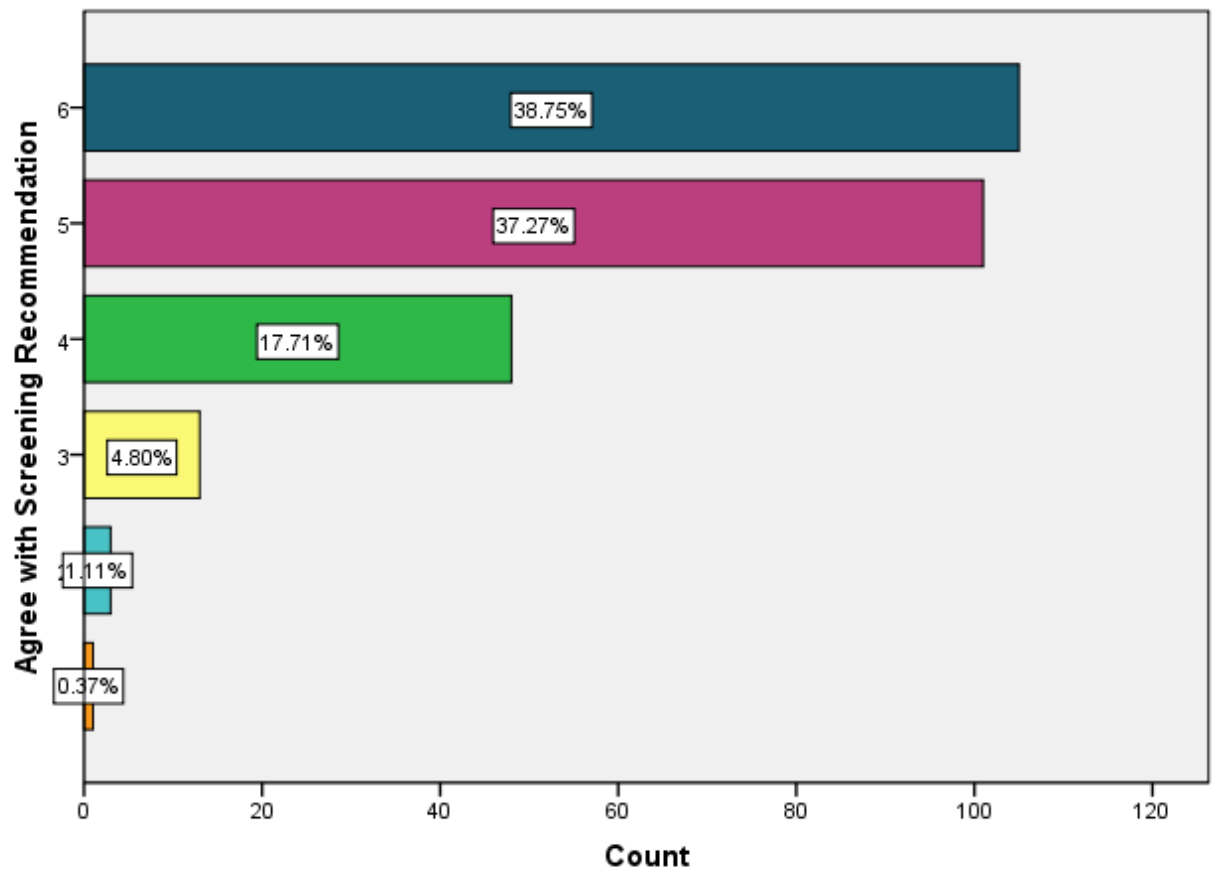
Figure 6.6 Agreement with Average Risk CRC Screening Guideline Recommendation

6.2.3 Summary of Screening Questions

All physicians reported being aware of FOBT prior to taking the survey. Most felt they had a responsibility to advocate for CRC screening and that they did a good job communicating with their patients about screening strategies. The biggest barrier to discussing CRC screening was having patients with co-morbidities, which was chosen 'often', 'most of the time' or 'always' by 40% of physicians. Other barriers listed on the survey were reported to a lesser extent. Most physicians commenced CRC screening with their average risk population at the recommended age, however, only a quarter reported stopping screening at the recommended age. Colonoscopy was the most commonly recommended screening test for average risk patients, followed by FOBT completed at home. Almost all of those using FOBT in their practice knew the correct screening interval. The most common difficulty encountered in encouraging screening was the lack of availability of colonoscopy (which would impact both colonoscopy and FOBT screening). All but 5% of physicians said they would support a population-based FOBT screening program if one were available, and the most common reasons for endorsing a program were that FOBT was non-invasive, cost-effective and simple to do, and because of the high incidence of CRC in NL. Of the small proportion of the sample that said they would not be supportive of a population-based FOBT screening program, the most common reason for non-support was the high proportion of false positives and false negatives obtained with FOBT screening. Finally, most physicians were supportive of the guideline recommendation to begin FOBT screening at age 50 in their average risk patients.

Further analyses of the physician survey are not presented due to the high level of family physician support expressed for a population-based FOBT screening program. Physician support was the primary question of interest. With only 14 (5.2%) respondents indicating they would not

support a screening program, analysis of supporters and non-supporters at the univariate or multivariate level was not found to make a meaningful contribution to understanding predictors of support for an FOBT screening program. Future research and analysis will provide an opportunity to explore whether stated support at the pre-implementation phase is reflected in family physician referral patterns to the screening program, once it is implemented

Chapter Seven

Discussion

7.1 Target Population Survey

7.1.1 Primary Hypothesis

The primary hypothesis of this study was that those at average risk for CRC who resided in a region of the province with the presence of a familial cluster of high genetic risk CRC would be more likely to report a positive screening intention than those living in regions without such a presence. Counter to the study hypothesis, no significant difference in intention was found between areas with and without a familial cluster of high genetic risk CRC. Comparison of the three regions at the univariate level showed those living in the HRR area were proportionally more likely to feel uncertain about whether or not they would undergo FOBT screening than individuals in the other two regions. This was an unexpected finding, given the hypothesis. In light of the finding that individuals in the ARR region were significantly more likely to have heard of FOBT and to have used it previously, one possible explanation for increased uncertainty in the HRR region individuals might be that living in an area with a familial cluster of high genetic risk for CRC could bring about heightened awareness of people who are screened and surveilled using colonoscopy – which is the appropriate modality for those at increased risk. It may be that due to this awareness, colonoscopy is the more recognized and preferred method for individuals in this area, regardless of their risk level.

7.1.2 Secondary Hypothesis

Hypothesized differences in screening intention by urban versus rural area of residence was a secondary question of interest. Geography, in particular rurality, has been shown to be a predictor of poorer health outcomes and increased risk factors for chronic disease, including cancer[106,107]. As such, a lower rate of reported positive screening intention was hypothesized in the ARR population when compared with the ARU population. Within NL, certain disparities have been noted in the cancer diagnosis and treatment trajectories for rural-dwelling residents including longer wait times to resolution of an abnormal breast screen and lower rates of radiation therapy use[108,109]. US studies comparing urban and rural dwelling residents on CRC screening-related outcomes found lower screening participation rates and lower likelihood of being up to date with CRC screening in rural residents[110-114.] In this study, however, no significant difference was found between urban and rural populations on intention to screen. The ARR population had the highest proportion of reported positive screening intention, although this was not significant. It is not known what the influencers of positive intention might be in this group.

Comparing the groups on intention as either three distinct regions or collapsing the two average risk regions into one average risk category did not reveal any significant differences. Screening intention was also examined using a ten-point scale. This analysis was also run keeping the three distinct regions and collapsing the two average risk groups into one. Neither test showed a significant difference. It can be stated that, in NL, neither the presence of a familial cluster of high genetic risk CRC nor rurality appear to play a significant role in influencing intention to participate in CRC screening.

7.1.3 Total Sample Analyses

The majority of those who responded to the average risk population survey reported a positive intention to participate in FOBT programmatic screening if a kit were sent to their home (70.3%). A small proportion of the sample reported a negative intention and slightly more reported being uncertain about participation. This was an unanticipated finding. It was expected that there would be a greater degree of variation across the intention response choices, as has been the case in other studies of screening intention. Duncan et al.(2009)[84] found that only 35% of their respondent population (Australia) reported being prepared for screening or had already screened, over 65% of respondents (US) in Weinburg et al.[85] (2009) reported no plans/no need to undergo CRC screening, and in both Sifri et al.[88] (2010) and Janda et al.[91] (2010), US and Australia, approximately half of respondents reported being ready or likely to screen. In the Sifri study, an additional 41% reported feeling unsure about screening participation. In no other studies was there the overwhelmingly positive response rate found as for the respondent sample in this study. It is unclear why positive intention to engage in screening is so high in this sample of Newfoundlanders. Perhaps the high prevalence of CRC in this province may play a role.

For the total sample, no differences were found in intention to screen by several demographic variables that had been reported as significant in some other studies. These included gender, marital status and age group. While self-rated health status did not show a significant association with intention at the univariate level, the significance level observed did fit the criteria for retention in multivariate analysis. Awareness of FOBT as a screening test and prior screening were more important influencers of future screening behaviours in this population than any of the demographic variables studied. The inconsistency, from one study to

the next, of which variables act as predictors for positive screening intention lend support to the endeavor to examine distinct populations prior to implementing a screening program as opposed to assuming a 'one size fits all' approach. In this case, only the FOBT awareness and prior screening variables remained significant in multivariate model.

7.1.4 Limitations

One limitation of the average risk population survey is that considerable challenges were encountered with sample recruitment. The method of data collection was changed early on from telephone survey to mail-out survey due to a very low response rate. Despite other studies on screening intention achieving a much higher response rate via telephone survey, this was not true for this population. Although mail-out yielded a better response rate, it was still relatively low at 12.1%. Ultimately, the sample size for the HRR area was not realized. This challenge persisted despite attempts to reach respondents in this area via other means including, phone calls and emails to community groups. The full population from which to sample average risk individuals living in an area with a cluster of individuals at high genetic risk CRC was considerably smaller than the available populations for the ARR and ARU populations. Nonetheless, the response rate achieved for the HRR region was disappointing and somewhat surprising. Given the potentially higher prevalence of people with CRC in this area, it was expected that these individuals would be the most motivated to respond. Due to the reduced sample size of the HRR area, the power to be able to detect certain group differences may have been lost. Had the full sample size been attained, perhaps different results would have observed. However, of the responses obtained, a higher proportion of respondents from the HRR reported uncertain intention to screen compared

with respondents from the two average risk areas. Thus, the data that were obtained from HRR did not indicate a tendency toward the predicted hypothesis.

Restrictions of the Personal Health Information Act (PHIA), a piece of provincial legislation that governs privacy, were prohibitive to taking a more targeted and population-based approach for recruitment of the average risk survey. Use of the province's client registry, an up-to-date population database, would have allowed for more rigor to be applied to the sampling strategy and would have opened up the possibility of reminder letters being issued to non-responders. This may have potentially increased the sample size and allowed for a better use of financial resources relating to the mail-out. Restrictions under PHIA are also likely to impact the implementation of the screening program. Work is ongoing to attain a special designation under PHIA that would lift some these restrictions for the Cancer Care Program, but this designation has not yet been realized.

Required samples sizes were realized for the ARU and ARR areas, although this also proved to be somewhat challenging until a $10 incentive was offered to each respondent during the third round mail-out. Perhaps if a $10 incentive had been used from the outset, the HRR sample might have been attained. The extent of recruitment challenges, however, were only made apparent after the second mail-out. It was assumed that the low response rate when the survey was attempted by telephone was a methodology issue, perhaps respondent discomfort with speaking directly to someone about CRC screening and cancer. Similarly, the issue with the poor quality of address information used in the first round mail-out was thought to be the major influencer of low response rate on that iteration. Nevertheless, the second round mail-out, using the better quality Canada Post's unaddressed admail system did not yield the response rate

desired. For the third mail-out it was not possible go back and do another round in the HRR because all households in the relevant communities had already been sent a survey package in the second mail-out. Surveys were returned anonymously, so there was no way of knowing who had already responded. Resending surveys to households in the HRR area during the third mail-out would have introduced severe contamination into the study as it was entirely possible that some of the same individuals would have returned a second survey in order to avail of the $10 incentive. As described in the Methods chapter, it was not possible to approach other areas of the province to increase the sample size for this distinct population. With respect to the ARR and ARU areas, the $10 incentive assisted in reaching the necessary sample sizes. It is not known whether the $10 incentive might have biased the make-up of the respondent population in some way. It is possible that those individuals who were motivated to screen were more likely to participate in a phone conversation or respond to the survey than those were not interested in screening for CRC. This could have introduced bias into the sample and may, in part, account for the very high positive screening intention reported by the total sample. If this is the case, it could imply that non-respondents were not as likely to have a positive intention to engage in screening. Given the low response rate, this may mean there is a large proportion of individuals in these regions who do not intend to participate in FOBT. Program implementation will reveal participation rates in each of the surveyed areas.

Finally, the relatively high level of awareness of FOBT in the overall population, when compared to other study's findings[92,95], likely contributed to the high rate of positive intention to engage in screening. The two variables were strongly associated. The high degree of positive intention, while encouraging, made comparative analysis between the groups on screening intention challenging.

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7.1.5 Future Considerations

Follow-up work in this area could focus on whether the high level of positive intention is reflected in the rate of actual participation in the FOBT screening program. This analysis could be done for the overall provincial population and by subgroups, for example, by region of the province or by demographic factors. Empirically, intention to be screened is one the strongest and most consistent factors associated with future cancer screening. This has been found to be the case for various disease sites[131,132,133,134,135,136,137,138]. Follow-up work would present an ideal opportunity to further explore the intention - behaviour relationship on a population level. While prior screening behaviour cannot be modified, awareness of FOBT has also been shown to be a predictor of screening intention in the NL target population. If actual participation in FOBT screening is found to be lacking, strategies to heighten awareness of the FOBT test may prove to be a feasible way to enhance screening uptake, which ultimately will enhance positive patient outcomes.

Almost half of all family physicians in NL responded to the survey, which was considered an acceptable response rate. Responses by gender were reflective of the gender breakdown for all family physicians in the province. All respondents reported being aware of FOBT as a screening modality for CRC and there were high levels of agreement that family physicians had a responsibility for supporting and advocating screening. There did not appear to be significant challenges to CRC screening encountered by family physicians as evidenced by the responses to questions on barriers to and difficulties associated with CRC screening.

7.2.1 Screening Practices and Screening Support

With respect to screening practices, almost all physicians reported that they initiated screening with their average risk patient at age 50, in accordance with recommended guidelines. Very few reported that they did not routinely recommend screening. Interestingly, physicians were much less compliant with the recommended guideline for the age to discontinue screening. Almost half of the respondent population reported not routinely stopping screening at any age, and an additional 25% reported an incorrect age. This calls into question the degree of awareness of this recommendation and perhaps an unclear interpretation of the principles of screening; particularly the importance of having a defined target population that stands to garner the most benefit from screening. Furthermore, physicians also reported using colonoscopy most frequently as the screening method for their average risk population, which is not supported by the guidelines.

The primary variable of interest in the family physician survey was reported support for a population-based CRC screening program. Physicians were almost unanimously supportive of

programmatic screening using FOBT, a finding which was not anticipated, particularly given the reported preference to use colonoscopy. Moreover, other studies of family physician knowledge and attitudes toward screening showed more variability in their physician populations[118, 119]. Perhaps physicians in NL who were supportive of FOBT screening were more likely to respond to the survey or perhaps the way the question was asked, providing only yes / no response choices led to such a high proportion responding in the affirmative. However, these response choices were selected deliberately to avoid a majority of physicians choosing an 'uncertain' category.

The level of reported family physician support for population-based programmatic FOBT screening in NL is encouraging, as is the high level of reported agreement with the guideline recommendation that people at average risk for CRC be screened every two years starting at age 50. However, these findings are divergent with reported screening practices in that most physicians did not cease FOBT screening at 74 years of age and, as such, were not practicing in accordance with the recommendation. Furthermore, the majority of physicians reported using colonoscopy to screen their average risk patients which does not mirror their reported support for, and agreement with, FOBT screening and FOBT screening guidelines. It is not known why this disparity exists in attitude versus practice. Although gFOBT had long been available for use by physicians at the time of administration of this survey, utilization did not appear to be high and available statistics on FOBT were not of good quality. It may be that the launch of CRC screening on an organized, programmatic basis will bring physicians' screening practices more in line with their reported support for this screening method and its guidelines for use.

7.2.2 Limitations

As with the average risk population study, such a high proportion of respondents choosing the same response category on the primary question of interest rendered analysis and interpretation challenging. It is unknown if this was due to the binary structure of the response categories for the support question; if the level of support for programmatic screening is genuinely that high; or if there were other reasons. Providing a broader range of response categories or using a Likert type scale might have yielded a different result.

7.2.3 Future Considerations

Because this study was conducted at the pre-implementation phase of the CRC screening program, there is now opportunity to follow-up and examine the family physician referral rate to the program. Enrollment into the screening program can either happen by patient self-referral or physician referral. Implementation of the program is being conducted on a phased-in basis by Regional Health Authority, starting with Western Health, then Central Health, followed by Labrador-Grenfell Health and lastly, Eastern Health. This means that, in addition to examining physician referral patterns at the provincial level, intra-provincial comparisons can also be made. With the launch of the program in each region, there is a plan to educate family physicians about the screening program and to provide information materials for use in clinics. Follow-up research could focus on whether education efforts will result in physician buy-in into the program. Given that family physician support has been demonstrated to positively impact screening uptake[18,19,20,21], investigation of referral patterns when the program is operational is a logical next step that may help to enhance screening uptake in the target population, thus ensuring maximum benefit of the program.

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APPENDIX A

Farah McCrate

Hi Farah,
We would be very happy for you to use the surveys as a starting point for your work. We would appreciate receiving a copy of your results as well, if this is possible and ask that if published to cite the survey info.
I hope this will work for you.
Let me know if you have further questions.
Laura.

APPENDIX B

Farah McCrate

hi Farah

i agree that three sites is a good idea and I think that St John's; and Burin, Marystown, Grand Bank are good choices. The Twillingate/New World island is a high CRC risk area but they have had a Pilot FOBT population screening program for several years run by Dr Hewitt, Tony Richardson and Kim Osmond so they have had various 'teaching sessions' about this.

Bonavista North (Brookfield Hospital area) is also a high risk CRC area - Lynch Syndrome or HNPCC rather than familial adenomatous polyposis like in Twillingate/NWI. The 'Family C' cluster of 15 large Lynch Syndrome families with a known mutation is originally from Swain's Is off Wesleyville but have lived in communities from Greenspond to Lumsden for many years, and there are other big families without a known mutation in the area. Maybe this would be a good substitute.

let me know if you would like any more information

Jane Green
███████

Farah McCrate

Hi Farah

I apologize for not writing much sooner. You may have chosen your communities for the Bonavista North area already. Many of the communities have combined as New-Wes-Valley and this actually includes many of the original towns I would include, ie, Wesleyville, Brookfield, Badger's Quay, Newtown, Pound Cove, but also Greenspond, and Lumsden which are probably outside of N-W-V but areas with excess Hereditary/familial colon cancer. If not too late I hope this helps

jane

APPENDIX C

Participant Survey

Section 1. Introduction

[Read] Hello, my name is_____ and I am a research assistant working with Eastern Health. Today I am looking to conduct a survey about screening or testing for colorectal cancer, also known as colon cancer, rectal cancer or bowel cancer. I am wondering if there is someone in your household between the ages of 50 and 74 who would be willing to participate in this ten minute survey?

     Yes   No

If "NO" is chosen:

- **Thank participant for their time**
- **End phone call**

If "YES" is chosen:

- **Skip to next section**

Section 2.

a) [Read] Thank you for agreeing to participate. Before we proceed to the main survey there are certain criteria that I would like to review with you to see if you are eligible to take part in our survey. Please answer yes or no to the following questions:

- Just to confirm: are you aged between 50 and 74 years of age?   **Yes**   **No**

- Have you ever had colorectal cancer or polyps?   **Yes**   **No**

- Have you ever been diagnosed with inflammatory bowel disease? Examples of inflammatory bowel disease are Chron's disease and ulcerative colitis.

  Yes   No

- Do you have any first-degree blood relatives, for example, your mother, father, a sister, brother or child who have been diagnosed with colorectal cancer or polyps?

  Yes   No

- Do you have two or more second degree blood relatives, for example aunts, uncles, cousins or grandparents with colorectal cancer or polyps before age 60? (Prompt: And this person is a blood relative?)

  Yes   No

- Have you had a colonoscopy within the last ten years? A colonoscopy is a test that provides an inside look at your colon and rectum. A doctor uses a flexible tube called a colonoscope that he or she inserts into a person's rectum to look at the inside of the colon and rectum.

  Yes   No

b) If the participant is NOT between the ages of 50 and 74 or responds with a "YES" to any of the other questions, they are ineligible to take part in the study:

- ➢ **[Read]** Thank you very much for your time. Unfortunately we cannot proceed any further with this survey today because the rest of the survey questions are only relevant to people who....... [provide reason to participant] e.g. are aged between 50 and 74; do not have a history of colorectal polyps or cancer; do not have inflammatory bowel disease; do not have any first degree relatives with colorectal cancer; do not have two or more second degree relatives with colorectal cancer; have not had a colonoscopy in the last ten years. If you would like further information about the study I can give you a number to call. Would you like that number? **If "YES", provide number, if "NO", exit interview. *Phone number is principal investigators number.**

- ➢ **[Read]** Is there anyone else in your household aged between 50 and 74 who might be willing to speak with me today?

If yes to the above question, when the person comes on the line, skip back to Section 1 and introduce yourself and describe the survey. If the new participant is not interested in taking part, thank them for their time and end the survey.
If they are interested in taking part, go to Section 2a and go through the remaining eligibility criteria to determine if they are eligible to take part. If the person is ineligible to take part, go to Section 2b to provide an explanation as to why they are ineligible. Thank them for their time and offer the study phone number.

2c) If the original person or another person who comes on the line are have indicated their interest in taking part and are eligible to take part:

➤ **[Read]** Thank you for agreeing to take part. Your participation is very important to this survey. Your responses will be kept completely confidential and your participation is voluntary. I would like you to answer the questions as accurately as possible, so please feel free to take as much time as you need before answering. If there are any questions you would rather not respond to, just say so.

➤ **[Read]** As I mentioned earlier, the questions in this survey have to do with colorectal cancer, which is also known as colon cancer, rectal cancer or bowel cancer. Screening for colorectal cancer means having tests to check for colon cancer when you do not have any symptoms or problems. A fecal occult blood test, or stool blood test, is a test to check for colorectal cancer. It is done at home using a set of cards. You smear a sample of your fecal matter or stool on a card from 2 or 3 separate bowel movements and return the cards to be tested for blood that is not visible to the naked eye.

3. Before I read the description, had you ever heard of a fecal occult blood test? [Provide participant with possible response categories of Yes or No]

Yes   No

[If "YES" to question 3 go to question 4. If "NO" to question 3, skip question 4 and go to question 5].

4. **Have you used a fecal occult blood test to be tested for colorectal cancer in the past? [Provide participant with possible response categories of Yes or No]**

Yes   No

5. As you may already know, the provincial government and Cancer Care Program have recently started a screening program for colorectal cancer for those who are at average risk for the disease. They plan on having the screening test available to all eligible people in the province aged between 50 and 74 in the next number of years. The test that will be used is the fecal occult blood test as described above. The test will be sent to people at home where they will be asked to collect a small sample of their own stool and return it for testing. Which of the following statements best reflects your intention to participate in screening for colorectal cancer using fecal occult blood testing when it becomes available in your region: [Read all response options to the participant before they provide an answer].

   a) I would not complete a fecal occult blood test if one were sent to my home ☐

   b) I would feel undecided about whether or not to complete a fecal occult blood test if one were sent to my home ☐

   c) I would definitely complete a fecal occult blood test if one were sent to my home ☐

6. On a scale of 1 to 10, how likely is it that you would complete a fecal occult blood test if one were sent to you at home? [Zero represents "I would definitely not complete a fecal occult blood test" and ten represents "I would definitely complete a fecal occult blood test"].

   0   1   2   3   4   5   6   7   8   9   10

Demographic Information

Before finishing the survey, I would like to ask you a few final questions about yourself. I would like to know this information so that I may better describe the population of people who take part in the survey. None of your information will be used individually and your confidentiality will be protected at all times.

7. What is your age? _____

8. Are you male or female?   Male   Female

9. **What is your marital status? [Read all options to participant before they provide an answer].**

Married	☐
Living as married	☐
Never Married	☐
Divorced	☐
Separated	☐
Widowed	☐

10. **What is the highest level of education that you have attained? [Read all options to participant before they provide an answer].**

Less than a high school diploma	☐
High School Diploma	☐
Some Post-Secondary Education	☐
College or Trade Certification	☐
University Degree	☐

11. **Do you know anyone who has colorectal cancer at the moment or who has had it in the past?**

Yes   No

12. **Would you say your health is: [Read all options to participant before they provide an answer].**

Excellent	☐
Very Good	☐
Good	☐
Fair	☐
Poor	☐

Thank you very much for taking part in this survey. Your answers will help us to better understand people's intention to take part in fecal occult blood testing for colorectal cancer. If you would like more information about this study or would like a copy of the results of the survey when they become available, there is a number you can call for that information. Would you like that number? If "YES", provide number of the principal investigator to participant.

APPENDIX D

Ethics Office
Suite 200, Eastern Trust Building
95 Bonaventure Avenue
St. John's, NL
A1B 2X5

February 19, 2013

Ms. Farah McCrate
Cancer Care Program
Eastern Health
Building 532, Pleasantville
P.O. Box 13122
St. John's, NL A1B 4A4

Dear Ms. McCrate:

Reference #12.154

RE: The Newfoundland and Labrador Colorectal Cancer Screening Program for the
Average Risk Population: A Pre-Implementation Study of the Family Physician and Target
Population Perspective on Fecal Occult Blood Testing.

This will acknowledge receipt of the correspondence dated **February 18, 2013** wherein you request
an amendment to the above noted research.

The co-chair of the Health Research Ethics Board has reviewed your correspondence and has
approved:
1. The amendment dated February 18, 2013 (change in methodology for the survey)
2. Cover letter, approved
3. Survey, approved

It is **your responsibility to seek the necessary approval from the Regional Health Authority or**
other organization as appropriate.

This Research Ethics Board (the HREB) has reviewed the amendment for the study which is to be
conducted by you as the qualified investigator named above at the specified study site. This
approval and the views of this Research Ethics Board have been documented in writing. In addition,
please be advised that the Health Research Ethics Board currently operates according to the Tri-
Council Policy Statement and applicable laws and regulations.

email: info@hrea.ca   Phone: 777-8949   FAX: 777-8776

Sincerely,

Dr. Fern Brunger
Chair, Non-Clinical Trials
Health Research Ethics Board
Notification to: VP Research c/o Office of Research, MUN
                         VP Research c/o Patient Research Centre, Eastern Health

For office use only: March 7, 2013, 2013

APPENDIX E

<Memorial University Letterhead>

Date

<Participant Address>

Dear <insert Participant name>

Please find enclosed a survey about screening or testing for colorectal cancer, also known as colon cancer, rectal cancer or bowel cancer. This survey is being done as part of a PhD project. As you may already know, the provincial government and Cancer Care Program in Newfoundland and Labrador have started a screening program for colorectal cancer for those who are at average risk for the disease. They plan on having the screening test available to all eligible people in the province aged between 50 and 74 in the next number of years. Therefore, we are looking for people **aged between 50 and 74 to complete the survey.**

The purpose of this survey is to better understand how people feel about this screening program and whether they would take part if invited to do so. Funding for this project is through a Provincial Cancer Prevention and Awareness Grant from the Department of Health and Community Services.

The survey can be returned in the self-addressed stamped envelope provided. It will not be possible to identify you from your survey. Participation in this survey is completely voluntary and your responses will be kept confidential. It is understood that you give your consent to participate by filling out the survey.

Taking part in this project will provide valuable information that will help us better understand people's willingness to taking part in a new screening program for colorectal cancer. If you have any questions please do not hesitate to contact either one of us. You can also talk to someone who is not involved with the study at all. They can tell you about your rights as a participant in a research study. This person can be reached through the Ethics Office at 709-777-6974 or by email: info@hrea.ca

Many thanks.

_____

Farah McCrate, BSc (Hons), MSc, PhD (candidate)
PhD Student / Epidemiologist
Memorial University / Cancer Care Program
Tel. (709) 752-6716
Email. farah.mccrate@easternhealth.ca

_____

Marshall Godwin, MD
Director
Primary Healthcare Research Unit
Tel. (709) 777-8373
Email. godwinm@mun.ca

APPENDIX F

Colorectal Screening Survey

This is a survey about <u>screening</u> or testing for colorectal cancer, also known as colon cancer, rectal cancer or bowel cancer. **We would like people between the ages of 50 and 74 to complete this survey. If you do not fall in this age group, please feel free to give this survey to someone who is in this age group.** Your participation is appreciated.

<u>Section 1: History</u>

1. Have you ever had colorectal cancer or polyps?
   - ☐ Yes
   - ☐ No

2. Have you ever been diagnosed with an inflammatory bowel disease? Examples of inflammatory bowel disease include Chron's disease and ulcerative colitis.
   - ☐ Yes
   - ☐ No

3. Do you have any first-degree blood relatives, for example, your mother, father, a sister, brother or child who were diagnosed with colorectal cancer <u>before age 60</u>?
   - ☐ Yes
   - ☐ No

<u>Section 2: Screening History</u>

Screening for colorectal cancer involves having tests to check for colon cancer when you <u>do not</u> have any symptoms or problems.

A fecal occult blood test, or stool blood test, is a test to check for colorectal cancer. It is done at home using a set of cards. You smear a sample of your fecal matter or stool on a card from 2 or 3 separate bowel movements and return the cards to be tested for blood that is not visible to the naked eye.

1. Before reading the description, had you ever heard of a fecal occult blood test?
   - ☐ Yes
   - ☐ No

2. Have you used a fecal occult blood test <u>to be tested for colorectal cancer</u> in the past?
   - ☐ Yes

Colorectal Screening Survey

☐ No

Section 3: Screening Program for Colorectal Cancer

The provincial government and the Cancer Care Program have recently started a screening program for colorectal cancer for those who are at <u>average risk</u> for the disease.
They plan on having the screening test available to all eligible people in the province aged between 50 and 74 in the next number of years.
The fecal occult blood test that was just described will be sent to people at home where they will be asked to collect a small sample of their stool and return it for testing.

1. Which statement best describes how you feel about using the fecal occult blood test when it becomes available in your region?
   ☐ I would not complete a fecal occult blood test if one were sent to my home
   ☐ I am unsure if I would complete a fecal occult blood test if one were sent to my home
   ☐ I would definitely complete a fecal occult blood test if one were sent to my home

2. Please circle how likely is it that you would complete a fecal occult blood test if one were sent to you at home?

      1   2   3   4   5   6   7   8   9   10

   I would definitely   I would definitely
    not complete a   complete a fecal
   fecal occult blood   occult blood test
        test

Colorectal Screening Survey

Section 4: Questions about you.

The following section contains a few questions about you. This information will allow researchers to better describe the population of people who take part in the survey. None of the information provided will be used individually and your confidentiality will be protected at all time.

1. What is your age?   _____

2. Are you male or female?

   ☐ Male
   ☐ Female

3. What is your current marital status?

   ☐ Married   ☐ Divorced
   ☐ Living as Married   ☐ Separated
   ☐ Never Married   ☐ Widowed

4. How would you rate your current level of health?

☐ Poor   ☐ Fair   ☐ Good   ☐ Very Good   ☐ Excellent

Thank you for participating! Your answers will help us better understand people's intention to take part in the fecal occult blood testing for colorectal cancer. If you would like more information about this study, or a copy of the results when they become available, please contact the principal investigator, Farah McCrate, at (709) 752-6716

APPENDIX G

Physician Survey

Please respond to the questions below in relation to patients who are at average risk for colorectal cancer. The following criteria constitute an average risk individual.

1. Aged between 50 and 74;
2. No significant family history of colorectal cancer or a personal history of adenomas or colorectal cancer;
3. Non-symptomatic of bowel disease;
4. No inflammatory bowel disease.

Thank you very much for your participation.

Q1. Before receiving this information letter and survey, were you aware of fecal occult blood testing (FOBT) as a screening modality for colorectal cancer?

Yes ☐   No ☐

[If you answered 'No' to the above question, there is no need to respond to any further questions. Please return your questionnaire in the envelope provided. Thank you.].

Q2. Please indicate your level of agreement with the following statements:

a) **Family physicians have a responsibility to support and advocate for colorectal cancer screening.**

| 1 | 2 | 3 | 4 | 5 | 6 |

Strongly Disagree   Strongly Agree

b) **I effectively communicate colorectal cancer screening strategies to my patients.**

| 1 | 2 | 3 | 4 | 5 | 6 |

Strongly Disagree   Strongly Agree

Q3. The following factors are barriers to discussing colorectal cancer screening with my average risk patients. [Please choose a response for each factor].

Factors	Never	Rarely	Sometimes	Often	Most of the Time	Always
a) Physician financial compensation						
b) Level of comfort with my knowledge to help patients decide pros/cons of colorectal cancer screening options						
c) Time it takes to explain the pros/cons of the colorectal cancer screening options						
d) Patients with multiple health issues						
e) Patient's fear/embarrassment about the screening procedure						
f) Other _____ [please specify]						

Q4. I routinely <u>start</u> recommending colorectal cancer screening to my average risk patients when they are:

_____ years of age

I do not routinely recommend colorectal cancer screening ☐

Q5. If you <u>do not</u> routinely recommend colorectal cancer screening, please explain?

[ ]

[If you answered Q4 and you do not recommend colorectal cancer screening, go to Q11]

Q6. I routinely stop recommending colorectal cancer screening to my average risk patients when they are:

_____ years of age

I do not routinely recommend stopping colorectal cancer screening ☐

Q7. I recommend the following procedures to my average risk patients for colorectal cancer screening: [Please choose a response for each procedure].

Procedures	Never	Rarely	Sometimes	Often	Most of the Time	Always
a) Digital Rectal Exam (DRE) only						
b) DRE with office fecal occult blood test (FOBT)						
c) DRE with home FOBT						
d) FOBT completed at home only						
e) Double-contrast barium enema						
f) Flexible sigmoidoscopy						
g) Colonoscopy						
h) CT colonography						

Q8. If you recommend colorectal cancer procedures other than those listed above, please explain.

Q9. With what frequency do you recommend fecal occult blood test screening?

☐ Not at all   ☐ Once a year   ☐ Every 2 years   ☐ Every 3-5 years   ☐ Not sure

Q10. I have difficulty encouraging colorectal cancer screening for my average risk patients when: [Please choose a reponse for each situation].

Situations	Never	Rarely	Sometimes	Often	Most of the Time	Always
a) Colonoscopy is not readily available						
b) My patient expresses anxiety about results of the screening procedures and / or treatment for colorectal cancer						
c) My patient expresses discomfort with colonoscopy						
d) My patient expresses discomfort with DRE						
e) My patient expresses disgust with FOBT done at home						
f) Other _____ [please describe]						

Q11. Would you support a population-based fecal occult blood test screening program for all eligible persons in the province over 50 years of age?

Yes ☐   No ☐

Q12. If yes to Q11, what are your reasons for supporting a population-based fecal occult blood test screening program? (Check all that apply).

☐ Cheaper than other screening options

☐ Non-invasive

☐ Quick and simple to do

☐ Higher level of acceptability than other screening options

☐ Population based fecal occult blood test screening reduces colorectal cancer mortality

☐ There is a high incidence of CRC in the province

☐ Other _____

Q13. If no to Q11, what are your reasons for not supporting a population-based fecal occult blood test screening program?

☐ High proportion of false positive and false negatives

☐ Not cost-effective

☐ Patient unwillingness or inability to comply

☐ Other _____

Q14. FOBT screening has been shown to detect colorectal cancer earlier and to lower mortality. The current Canadian guidelines recommend that average risk people be screened for colorectal cancer with FOBT every two years starting at age 50 years. Please indicate your level of agreement with this recommendation.

1	2	3	4	5	6

Strongly Disagree   Strongly Agree

Demographics

The following information will help us better understand your context of care and will enable more effectual analysis of the survey results. None of this information is being collected to identify any individual physician. Your confidentiality will be maintained at all times.

Q15. I am: ☐ Female   ☐ Male

Q16. My age is: _____ [years]

Q17. Year of graduation from medical School: _____

Q18. Medical School of Graduation: _____

Q19. My primary practice is located in or under the following NL Regional Health Authority:

[ ] Eastern   [ ] Central   [ ] Western   [ ] Labrador-Grenfell

Q20. My primary region of practice is: ☐ Rural   ☐ Urban

Q21. I currently practice:

☐ Full-time   ☐ Part-time   ☐ A locum   ☐ Retired   ☐ Other _____

Q22. I see the following number of patients in a typical week:

☐ Approximately _____ [# of patients / week]

☐ Not applicable

Q23. I primarily work in the following clinical setting: [check only one]

☐ Walk-in clinic

☐ Family practice in office / clinic

☐ Long-term care facility

☐ Emergency room

☐ In-patient based

☐ Not in clinical practice

☐ Other _____   [please specify]

Q24. I spend the following number of hours per week in direct patient care:_____
[#hrs/week]

Q25. The number of other physicians in my practice is:

☐ Solo practice

☐ _____   [# of other physicians]

☐ Not applicable

THE END

APPENDIX H

<Memorial University Letterhead>

Date

<Physician Address>

Dear Dr. <Insert Physician Name>

Please find enclosed a survey regarding colorectal cancer screening. This survey is being carried out as part of a PhD project whose purpose is to better understand family physicians' attitudes and perceptions towards colorectal cancer screening, particularly fecal occult blood testing. Additionally we would like to gain insight into current primary care screening practices for colorectal cancer. We are hoping to receive responses from all family physicians in the province, as this will enhance the validity of the results that are reported. Funding for this project is through a Provincial Cancer Prevention and Awareness Grant, which is an initiative of the Department of Health and Community Services.

The survey can be returned anonymously in the self-addressed stamped envelope provided. We ask that you also mail the enclosed postcard and return it to us separately. This way we can have a record of who has completed the survey without being able to identify any individual from their survey answers. As a gesture of thanks, all those who respond to the survey will have their name entered in a draw to receive a complementary lunch for their clinic staff.

Participation in this survey is completely voluntary and confidentiality will be ensured through the procedure outlined above. Consent to participate is implied via completion and return of the survey.

Completing this survey will provide valuable information that may ultimately be used to improve uptake of a new screening program for colorectal cancer. If you have any questions please do not hesitate to contact either one of us. You can also talk to someone who is not involved with the study at all. They can tell you about your rights as a participant in a research study. This person can be reached through the Ethics Office at 709-777-6974 or by email: info@hrea.ca

Many thanks.

_____	_____
Farah McCrate, BSc (Hons), MSc, PhD (candidate)	Marshall Godwin, MD
PhD Student / Epidemiologist	Director
Memorial University / Cancer Care Program	Primary Healthcare Research Unit
Tel. (709) 752-6716	Tel. (709) 777-8373
Email. farah.mccrate@easternhealth.ca	Email. godwinm@mun.ca

Primary Healthcare Research Unit
Room 426, Janeway Hostel, Health Science Centres
300 Prince Philip Drive, St. John's, NL A1B 3V6
Tel: 709 777 6645 Fax: 709 777 6118
Email: Phru@med.mun.ca
Website: www.med.mun.ca/phru

September 28, 2012

«AddressBlock»

Dear Dr. «Last_Name»,

Please find enclosed a survey regarding colorectal cancer screening. This is a second round of survey administration for those who did not have an opportunity to respond to the first iteration. If you have already returned the survey, please do not complete it a second time. This survey is being carried out as part of a PhD project whose purpose is to better understand family physicians' attitudes and perceptions towards colorectal cancer screening, particularly fecal occult blood testing. Additionally we would like to gain insight into current primary care screening practices for colorectal cancer. We are hoping to receive responses from all family physicians in the province, as this will enhance the validity of the results that are reported. Funding for this project is through a Provincial Cancer Prevention and Awareness Grant, which is an initiative of the Department of Health and Community Services.

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Many thanks.

Farah McCrate, BSc (Hons), MSc, PhD (candidate)
PhD Student / Epidemiologist
Memorial University / Cancer Care Program
Tel. (709) 752-6716
Email. farah.mccrate@easternhealth.ca

Marshall Godwin, MD
Director
Primary Healthcare Research Unit
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Faculty of Medicine

Primary Healthcare Research Unit

Janeway Hostel, 4th Floor
Health Sciences Centre
300 Prince Philip Dr
St. John's NL A1B 3V6
Canada

Phone: (709) 777-6645
Fax: (709) 777-6118
Email: phru@mun.ca
Web: www.med.mun.ca/phr

<Date>

<Physician Address>

<Physician Name>,

Please find enclosed a survey regarding colorectal cancer screening. This is a third round of survey administration for those who did not have an opportunity to respond to previous iterations. If you have already returned the survey, please do not complete it a third time. This survey is being carried out as part of a PhD project whose purpose is to better understand family physicians' attitudes and perceptions towards colorectal cancer screening, particularly fecal occult blood testing. Additionally we would like to gain insight into current primary care screening practices for colorectal cancer. We are hoping to receive responses from all family physicians in the province, as this will enhance the validity of the results that are reported. Funding for this project is through a Provincial Cancer Prevention and Awareness Grant, which is an initiative of the Department of Health and Community Services.

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Completing this survey will provide valuable information that may ultimately be used to improve uptake of a new screening program for colorectal cancer. If you have any questions please do not hesitate to contact either one of us. You can also talk to someone who is not involved with the study at all. They can tell you about your rights as a participant in a research study. This person can be reached through the Ethics Office at 709-777-6974, or by email at info@hrea.ca.

Many thanks,

Farah McCrate, BSc (Hons), MSc, PhD (candidate)
PhD Student/Epidemiologist
Memorial University/Cancer Care Program
Tel: (709) 752-6716
Email: farah.mccrate@easternhealth.ca

Marshall Godwin, MD
Director
Primary Healthcare Research Unit
Tel: (709) 777-8373
Email: godwinm@mun.ca

APPENDIX I

Health Research
Ethics Authority

Ethics Office
Suite 200, Eastern Trust Building
95 Bonaventure Avenue
St. John's, NL
A1B 2X5

July 23, 2012

Ms. Farah McCrate
Cancer Care Program
Eastern Health
Building 532, Pleasantville
P.O. Box 13122
St. John's, NL A1B 4A4

Dear Ms. McCrate:

<u>Reference #12.154</u>

RE: The Newfoundland and Labrador Colorectal Cancer Screening Program for the Average Risk Population: A
Pre-Implementation Study of the Family Physician and Target Population Perspective on Fecal Occult Blood Testing.

This will acknowledge receipt of your correspondence.

This correspondence has been reviewed by the Chair under the direction of the Board. *Full board approval* of this
research study is granted for one year effective **July 18, 2012.**

This is to confirm that the Health Research Ethics Board reviewed and approved or acknowledged the following
documents (as indicated):

- Application, approved
- Physician Information Letter, approved
- Physician Survey, approved
- Study Proposal, approved
- Budget, acknowledged

Please Note: As discussed, you are not to proceed with any part of the telephone survey until ethics approval of the
instrument is approved. Once this document in available, you can send it as an addendum to the Health Research
Ethics Board.

MARK THE DATE

This approval will lapse on **July 27, 2013.** It is your responsibility to ensure that the Ethics Renewal form is forwarded
to the HREB office prior to the renewal date. *The information provided in this form must be **current to the time of
submission** and submitted to HREB **not less than 30 nor more than 45 days** of the anniversary of your approval date.*
The Ethics Renewal form can be downloaded from the HREB website http://www.hrea.ca.

email: info@hrea.ca   Phone: 777-8949   FAX: 777-8776

The Health Research Ethics Board advises THAT IF YOU DO NOT return the completed Ethics Renewal form prior to date of renewal:

- *Your ethics approval will lapse*
- *You will be required to stop research activity immediately*
- *You may not be permitted to restart the study until you reapply for and receive approval to undertake the study again*

Lapse in ethics approval may result in interruption or termination of funding

It is your responsibility to seek the necessary approval from the Regional Health Authority or other organization as appropriate.

Modifications of the protocol/consent are not permitted without prior approval from the Health Research Ethics Board. Implementing changes in the protocol/consent without HREB approval may result in the approval of your research study being revoked, necessitating cessation of all related research activity. Request for modification to the protocol/consent must be outlined on an amendment form (available on the HREB website) and submitted to the HREB for review.

This research ethics board (the HREB) has reviewed and approved the research protocol and documentation as noted above for the study which is to be conducted by you as the qualified investigator named above at the specified site. This approval and the views of this Research Ethics Board have been documented in writing. In addition, please be advised that the Health Research Ethics Board currently operates according to *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans; ICH Guidance E6: Good Clinical Practice* and applicable laws and regulations. The membership of this research ethics board is constituted in compliance with the membership requirements for research ethics boards as defined by *Health Canada Food and Drug Regulations Division 5; Part C.*

Notwithstanding the approval of the HREB, the primary responsibility for the ethical conduct of the investigation remains with you.

We wish you every success with your study.

Sincerely,

Patricia Grainger, Acting Chair
Health Research Ethics Board

C C   VP Research c/o Office of Research, MUN
VP Research c/o Patient Research Centre, Eastern Health
HREB meeting date: August 9, 2012

email: info@hrea.ca   Phone: 777-8949   FAX: 777-8776

Health Research Ethics Authority

Ethics Office
Suite 200, Eastern Trust Building
95 Bonaventure Avenue
St. John's, NL
A1B 2X5

August 17, 2012

Ms. Farah McCrate
Cancer Care Program
Eastern Health
Building 532, Pleasantville
P.O. Box 13122
St. John's, NL A1B 4A4

Dear Ms. McCrate:

<u>Reference #12.154</u>

RE: **The Newfoundland and Labrador Colorectal Cancer Screening Program for the Average Risk Population: A Pre-Implementation Study of the Family Physician and Target Population Perspective on Fecal Occult Blood Testing.**

This will acknowledge receipt of the correspondence dated **August 15, 2012** wherein you request an amendment to the above noted research.

The co-chair of the Health Research Ethics Board has reviewed your correspondence and has approved:
1. The amendment dated August 15, 2012
2. Telephone Survey

It is **your responsibility to seek the necessary approval from the Regional Health Authority or other organization as appropriate**.

This Research Ethics Board (the HREB) has reviewed the amendment for the study which is to be conducted by you as the qualified investigator named above at the specified study site. This approval and the views of this Research Ethics Board have been documented in writing. In

addition, please be advised that the Health Research Ethics Board currently operates according to the Tri-Council Policy Statement and applicable laws and regulations.

Sincerely,

Patricia Grainger

Patricia Grainger, Acting Chair
Health Research Ethics Board

Notification to: VP Research c/o Office of Research, MUN
                      VP Research c/o Patient Research Centre, Eastern Health

For office use only: August 23, 2012

APPENDIX J

Health Research Ethics Board
777-6974 (Phone)
777-8776 (Fax)

Version June 2013

Request for Amendment to an Approved Application

HREB #: 12.154		Current Date: February 25th, 2014

Title of study: Include protocol number, if any.

The Newfoundland and Labrador Colorectal Cancer Screening Program for the Average Risk Population: A Pre-Implementation Study of the Family Physician and Target Population Perspective on Fecal Occult Blood Testing.

Amendment Date: February 25th, 2014	Version # (if applicable):

Are these changes editorial and/or administrative?		No
Will there be any increase in risk, discomfort or inconvenience to the participants?		No
Are there changes to inclusion or exclusion criteria?		No
Is a modification to the consent form required?		No

1

HREB #: 12.154	Amendment Date: Feb 25, 2014	Version:

Health Research Ethics Board
777-6974 (Phone)
777-8776 (Fax)

Summarize the significant changes being requested. It is not necessary to itemize editorial, administrative and similar changes.

I am requesting approval to recruit from additional communities as part of the target population survey portion of my PhD thesis work. The original study proposed to survey three regions of the province. All targeted respondents are between 50-74 years of age, and at average risk for colorectal cancer. (CRC) The three geographies targeted to date are: St. John's (urban area), Burin/Marystown/Grandbank (rural area with no significant presence of a population at high genetic risk for CRC) and the New-Wes-Valley, Lumsden, Greenspond area (rural with a significant presence of a population at high risk for CRC). The response rate in the two rural areas has not been adequate to date and I have not reached my required sample size in either of these areas – after several iterations of survey mail outs. Data collection is starting to lag to a point where my supervisor and I have agreed that additional measures will be required to complete data collection for the thesis.

In order to attain the required sample size for the rural area with no significant presence of a population at high genetic risk for CRC, I am proposing to survey additional communities in the province. These communities are located on the Connaigre Peninsula / South Coast and include McCallum, Milltown, Head of Bale d'Espoir, Morrisville, Conne River, St. Alban's, St. Joseph's-St. Veronica's, Harbour Brenton, Belleoram, Pool's Cove, Rencontre East, St. Jacque's, Coomb's Cove, Hermitage, Sandyville, Seal Cove, Gaultois, Burgeo, Francois, Grey River, La Poile, Ramea. According to Community Accounts these communities total about 10,640 people. Assuming four people per household, this constitutes 2600 households to sample from. An additional 166 responses are required to achieve the necessary sample size of n = 340. These communities should provide more than adequate numbers for this purpose. Additionally, to ensure less wastage of research resources and unreturned surveys, I am proposing to offer a $10 incentive to each person who returns a completed survey. Doing this will require a slight variation in methodology from the original study design. In order to receive the $10 incentive, people must first return the survey. Thus, we are proposing to include a postcard on which the respondent can provide their mailing address. This card will go in a separate envelope, which will be inserted into the larger survey return envelope. A different person will be responsible for opening the envelopes that contain participant information than the person who will be compiling the surveys and entering data. This way, respondent confidentiality can be maintained. The cover letter will be amended (see attached) to provide instructions to respondents and to detail how their contact information will be kept confidential and separate from their survey responses.

For the rural area with a significant presence of a population at high genetic risk for CRC, I am proposing to re-survey the same communities as were targeted in the first phase. These communities include the New Wes Valley Region (Badger's Quay, Pool's Island, Brookfield, Wesleyville, Pound Cove, Newtown, Valleyfield and Templeman), Lumsden and Greenspond. After an extensive conversation with Jane Green, one of the province's leading experts in high genetic risk CRC, it is clear that there are very few communities where clusters of high genetic risk for CRC populations exist. In fact, there only appear to be three significant areas in the province. One area is the one I have already targeted, another is the Twillingate area which has already received CRC screening intervention for a number of years and is likely contaminated in that awareness of CRC screening is very high. The third area is Western Health, where the provincial screening program has already been launched for well over a year and awareness of CRC screening is also likely very high. Thus, it will likely be most efficacious to continue recruitment efforts in the geography I have already targeted. I propose to offer the $10 incentive in this region as well, in an effort to increase response rate. I also plan to contact groups in the community (50+ groups, Knights of Columbus etc) to determine whether they would be willing to assist with survey administration to recruit more intensively. The total sample size required is n = 294 of which 137 have been obtained.

What is the rationale for the amendment(s)?

To achieve the sample size required for my study.

Other pertinent information – List ALL documents, including version dates, to be reviewed:

2

HREB #:	Amendment Date:	Version:
12.154	Feb 25, 2014.	

Health Research Ethics Board
777-6974 (Phone)
777-8776 (Fax)

Amended information letter (see attached).

Farah McCrate   _Jarah McCrate_   _Feb 25, 2014_
Printed Name of Principal Investigator   Signature of Principal Investigator   Date

This Health Research Ethics Board (the HREB) has reviewed the amendment as noted above for the study which is to be conducted by you as the qualified investigator named above at the specified study site. This approval and the views of this Research Ethics Board have been documented in writing. In addition, please be advised that the Health Research Ethics Board currently operates according to Tri-Council Policy Statement (TCPS2) and applicable laws and regulations. The membership of this research ethics board complies with the membership requirements for research ethics boards defined in TCPS2.

Full Board Review and Approval granted at _____N/A_____ Meeting

_____
Signature Chair   (Dr. Fern Brunger)   Date

_____
Signature Vice-Chair (Patricia Grainger)   Date

OR

Reported to Full Committee at _march 6, 2014_____ Meeting
Approved by:

_____   APPROVED   FEB 2 5 2014
Signature Chair   (Dr. Fern Brunger)   Date

_____
Signature Vice-Chair (Patricia Grainger)   Date

3

HREB #:	Amendment Date:	Version:
12.154	Feb 25, 2014	

APPENDIX K

<Memorial University Letterhead>

Date

<Participant Address>

Dear <insert Participant name>

Please find enclosed a survey about screening or testing for colorectal cancer, also known as colon cancer, rectal cancer or bowel cancer. This survey is being done as part of a PhD project. As you may already know, the provincial government and Cancer Care Program in Newfoundland and Labrador have started a screening program for colorectal cancer for those who are at average risk for the disease. They plan on having the screening test available to all eligible people in the province aged between 50 and 74 in the next number of years.

The purpose of this survey is to better understand how people feel about this screening program and whether they would take part in screening if invited to do so. Funding for this project is through a Provincial Cancer Prevention and Awareness Grant from the Department of Health and Community Services.

The survey can be returned in the self-addressed stamped envelope provided. We are offering a $10 incentive as a way to thank those who return a completed survey. If you would like to receive the $10 incentive, please write your name and address on the card provided. Put this card in the smaller envelope provided. When you are ready to return the survey, place the smaller envelope containing the card inside the larger envelope, along with the completed survey. When the survey is received at our offices, one person will remove the card and oversee sending you a cheque for $10. A different person will remove your survey from the envelope. This way, it will not be possible to know which survey you completed and your answers can be kept confidential and private. Participation in this survey is completely voluntary and your responses will be kept confidential. It is understood that you give your consent to participate by filling out the survey.

Taking part in this project will provide valuable information that will help us better understand people's interest in taking part in a new screening program for colorectal cancer. If you have any questions please do not hesitate to contact either one of us. You can also talk to someone who is not involved with the study at all. They can tell you about your rights as a participant in a research study. This person can be reached through the Ethics Office at 709-777-6974 or by email: info@hrea.ca

Many thanks.

Farah McCrate, BSc (Hons), MSc, PhD (candidate)
PhD Student / Epidemiologist
Memorial University / Cancer Care Program
Tel. (709) 752-6716
Email. farah.mccrate@easternhealth.ca

Marshall Godwin, MD
Director
Primary Healthcare Research Unit
Tel. (709) 777-8373
Email. godwinm@mun.ca