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Non-physicians Performing Screening Flexible Sigmoidoscopy: Clinical Efficacy and Cost-effectiveness

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Non-physicians Performing Screening Flexible Sigmoidoscopy: Clinical Efficacy and Cost-effectiveness

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January 2006

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As lead author, Chuong Ho led the project protocol development, supervised the literature review, wrote the draft, revised the report, and prepared the report for publication.

Philip Jacobs and Gurpal Sandha provided economic expertise and clinical expertise respectively; and contributed to the draft document and its subsequent revisions.

Hussein Noorani worked with Chuong Ho to evaluate the articles' relevance, assess their quality, extract data, and revise the report.

Becky Skidmore was responsible for the design and execution of the literature search strategies; writing the section and associated appendix on literature searching; and verifying and formatting the bibliographic references.

Conflicts of Interest

No conflicts of interests were declared by the authors.

REPORT *IN BRIEF*

January 2006

Non-physicians Performing Screening Flexible Sigmoidoscopy: Clinical Efficacy and Cost-effectiveness

Technology

Flexible sigmoidoscopy (FS) performed by non-physicians for colorectal cancer screening (CRC).

Disease

In Canada, CRC is the fourth most common cancer in terms of incidence, and the second leading cause of cancer-related death. Individuals with a family history of cancer, and those with chronic inflammatory bowel disease are at a high risk for developing CRC. Other individuals, older than 50, have an average risk of developing CRC. CRC screening programs target this average risk category.

Issue

Only 30% of individuals older than 50 undergo FS for CRC screening. This may partly be due to its limited availability. As the number of Canadians older than 50 grows, there will be additional requirements for FS. In some jurisdictions, FS is performed by non-physicians to increase the availability of CRC screening. To better inform decision making about non-physician FS as a suitable alternative, the effectiveness and economic impact of this approach needs to be examined.

Methods and Results

Relevant clinical literature was systematically reviewed; 17 studies were selected. Polyp detection rates, depth of endoscope insertion, complication rates and patient satisfaction were comparable between non-physician endoscopists (NPE) and physician endoscopists. Through a cost-minimization analysis, the utilization of NPEs was found to be favourable only at relatively low polyp detection rates. Polyps detected by NPEs, however, need to be removed by physicians, whereas endoscopies performed by physicians serve the dual purpose of identifying and removing the polyp at the same time.

Implications for Decision Making

- **Clinically, non-physician endoscopy and physician endoscopy are comparable.**
- **Cost considerations are dependent on polyp detection rates**. Because polyps detected by NPEs need to be removed by physicians, the NPE model will cost less than the physician-based model, at low polyp detection rates.
- **Patient satisfaction with endoscopies performed by physicians and non-physicians is comparable.**
- **Capacity issues are an important consideration.** If limited access to physician-endoscopists is an issue at a 30% rate of participation in CRC screening, the increase in the population of Canadians >50 will make it even more difficult to improve the participation rate. The non-physician endoscopy model may help to meet the challenge of screening this large and growing segment of the population.

This summary is based on a comprehensive health technology assessment available from CCOHTA's web site (www.ccohta.ca): Ho C, Jacobs P, Sandha G, Noorani HZ, Skidmore B. *Non-physicians performing screening flexible sigmoidoscopy: clinical efficacy and cost-effectiveness.*

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EXECUTIVE SUMMARY

The Issue

The incidence of colorectal cancer (CRC) and its high mortality rate are of concern. Even though early diagnosis by screening sigmoidoscopy has led to improved survival, only 30% of those eligible for screening undergo the procedure. This may, partly, be due to its limited availability. Canadian guidelines state that everyone 50 years of age and older should be screened for colorectal cancer, thus increasing the pressure to make screening more widely available. To meet this growing need and to reduce costs, some jurisdictions are using non-physician endoscopists (NPE) to provide flexible sigmoidoscopy (FS). Safety and accuracy are essential if the NPE model is to be incorporated into CRC screening guidelines.

Objectives

The primary aim of providing endoscopy examinations by non-physicians is to improve access to CRC screening, and thereby reduce the waiting time for diagnostic investigations. This report reviews the evidence to determine the clinical efficacy, safety, and cost-effectiveness of the NPE model for screening sigmoidoscopy, thus helping health care decision makers and others who are involved in the planning and delivery of CRC screening services.

Methods

Published and unpublished literature was identified through systematic searches of multiple databases and resources. Abstracts of conference proceedings and bibliographies of selected papers were also searched. Studies that reported clinical outcomes from non-physician endoscopy, and those performed by physicians were systematically reviewed. The clinical outcomes investigated were the rate of polyps detection, rate of cancer detection, mean depth of endoscope insertion, and mean procedural time. Safety endpoints included the incidence of perforation, bleeding, infection, death, and the number of patients withdrawn because of adverse events. Patients' satisfaction was also examined. Comparisons were made whenever possible between non-physician and physician endoscopy. The cost-effectiveness of the two approaches was also examined.

Results

A total of 663 citations were identified through the original searches, with 112 full reports retrieved. After excluding reports that did not satisfy the selection criteria, 17 studies, including one survey, were retained to form the basis of the clinical review.

Clinical Review

Seven studies (five prospective and two retrospective cohorts) reported the detection of polyps and cancers by NPE in patients with an average risk of developing CRC and in patients with CRC symptoms. In patients with an average risk of developing CRC (i.e., >50 years of age, asymptomatic, and no hereditary predispositions), the rates of polyp and cancer detection by NPE varied from 8% to 21% and from 0.1% and 2.4% respectively. In patients with colorectal symptoms, the rates of polyp and cancer detection range from 16% to 47% and from 2% to 6% respectively. Comparisons between non-physician endoscopy and physician endoscopy in five

studies (one randomized controlled trial and four prospective cohorts) did not show any statistically significant difference in rates of polyp detection. There are no data comparing the rates of cancer detection by NPE and physicians. Eleven studies (eight prospective, one retrospective cohort, and two randomized controlled trials) reported the comparable depth of endoscope insertion by NPE and physicians, both ranging from approximately 50 cm to 60 cm. Twelve studies (seven prospective, three retrospective cohorts, and two randomized controlled trials) reported rates of complications from endoscopies by NPE or physicians. These rates were modest, and no differences in harmful outcomes were observed between NPE, gastroenterologists, and non-gastroenterology physicians. The mean procedural time, which was reported in two prospective cohorts and one randomized controlled trial, was <15 minutes for both NPE and physician endoscopists. Patients' satisfaction was reported in three prospective cohorts, one randomized controlled trial, and one survey. NPE provided a comparable level of satisfaction to patients as physician endoscopists; a majority of patients were content to have the procedure performed by non-physicians.

Economic Review

A cost minimization analysis was used, because clinical outcomes between the alternative modes of delivery of the procedure were considered to be the same. The basic cost of sigmoidoscopy performed by a non-physician was about $62.50 less than one conducted by a physician. When polyps are detected by non-physicians, cases must then be referred to a physician for a polypectomy. This is not the case with a sigmoidoscopy conducted by a physician. Taking into account this added cost, NPE will be favourable only at relatively low polyp detection rates. The number of sigmoidoscopies needed annually in Canada, based on CRC Screening Guidelines, is estimated to be more than two million. Whether NPE achieve savings depends on the polyp detection rate.

Conclusions

No clinically significant differences between NPE and physician endoscopists performing FS were found, as measured by the depth of insertion of the endoscope, identification of polyps, mean procedural time, and patients' satisfaction. Complication rates are modest, and no differences in harmful outcomes were observed between NPE and physicians.

The cost minimization analysis in this report showed that the cost of a sigmoidoscopy performed by a non-physician was C$62.50 less than one conducted by a physician. This translates into a 16% reduction in the total cost of the screening program, if all sigmoidoscopies were done by NPE. This difference will be reduced, and perhaps reversed, because of the costs of physician therapeutic polypectomies.

Given the information available, it would appear that non-physician endoscopy is a viable model for Canada, because it might lead to increased screening availability and reduced waiting times. The NPE model would help meet the challenge of screening people at an average risk of CRC – a large and growing segment of the population. This alternative to endoscopies, done solely by physicians, can provide economical CRC screening if proficiency is established and patients' satisfaction is assured. There is a need to standardize the training protocol for NPE.

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1 INTRODUCTION

1.1 Background

In 2004, there were 19,100 new cases of colorectal cancer (CRC) in Canada. This represents about 13% of the total number of new cancer cases.[1] CRC ranked as the fourth most common cancer, after lung, breast, and prostate cancers. CRC is the second leading cause of cancer-related death. Out of 68,300 cancer deaths in Canada, in 2004, 8,300 were a result of colorectal cancer. While most deaths from colorectal cancer occurred in people older than 60, about 22% occurred in younger people. Colorectal cancer can occur sporadically or may appear with a high incidence in individuals with a hereditary predisposition. Genetic abnormalities have a significant role in the development of cancer in both categories. Individuals at high risk for developing colorectal cancer are those who have a family history (first-degree relatives) of cancer or polyposis (e.g., familial adenomatous polyposis) and non-polyposis [e.g., hereditary non-polyposis colon cancer (HNPCC)] syndromes, and those predisposed because of chronic inflammatory bowel disease. All other individuals older than 50 are classified as having an average risk of developing colon cancer. It is the average risk category that is the target for colon cancer screening guidelines, which strive to identify the safest, most effective modality to use.

The process of colorectal carcinogenesis is a complex multi-step process.[2] Genetic alterations, inherited and acquired, are instrumental in this process, in addition to environmental factors such as a high-fat, low-fibre diet. The genetic factors can be categorized as alterations in proto-oncogenes, loss of tumor suppressor genes, and defects in genes involved with DNA mismatch repair. The normal colonic mucosa is transformed into hyperproliferative epithelium and further into adenomatous tissue before developing into dysplasia and cancer. The annual conversion rate of polyps into cancer is estimated to be 0.25%.[3] The cancer risk is higher in adenomas that are large, that have a villous architecture, and that have the presence of high-grade dysplasia.[4] Identification and removal of these polyps in a timely fashion are associated with a reduced rate of cancer formation and mortality.[5,6]

Screening asymptomatic individuals for a disease is relevant if the disease is a health issue; effective therapy is available if the disease is found; and a cost-effective, safe, and acceptable screening test is available.

Of the recommended modalities for colorectal cancer screening, fecal occult blood testing (FOBT) is the only one that demonstrates a reduction in mortality, probably because of the follow-up colonoscopy and polypectomy done for a positive test. Because it is an inexpensive and safe test that can be administered by the primary care physician, FOBT is a frequently employed screening modality in Canada, although there are no data to support this assertion. Because a negative FOBT cannot rule out every carcinoma or adenoma, flexible sigmoidoscopy (FS) is advocated for people older than 50 with no CRC symptoms. FS is performed primarily by physicians. Only 30% of individuals age 50 or older undergo sigmoidoscopy. This may partly, be a result of restricted access to the limited pool of resources. Compliance is higher for FOBT than for FS, with rates of 50% to 80%,[7-9] and 15% to 30%[10] respectively.[11]

The safety and accuracy of screening sigmoidoscopy performed by non-physician endoscopists (NPE) have been studied in some jurisdictions to determine whether this would increase screening availability and reduce costs.

1.2 Technology

Endoscopy refers to the passage of an instrument into one of the orifices of the human body to observe specific internal organs for the presence or absence of disease. Gastrointestinal endoscopy is defined as the visualization of the digestive tract with flexible or rigid diagnostic tools. Flexible sigmoidoscopy (FS), or sigmoidoscopy, refers to the examination of the lower half of the large intestine, or colon, using a flexible endoscope. The specific parts of the colon that can be viewed with FS are the rectum, sigmoid colon, and descending colon. This fibre optic technology allows for the direct viewing of these organs in real time.

FS is usually performed in the endoscopy unit of a hospital, as it requires a special set-up for the equipment, although it is also performed in settings such as ambulatory endoscopy clinics or physician offices. The patient is usually given a rectal enema shortly before the procedure to evacuate the lower half of the colon, thereby facilitating visualization. Dedicated sigmoidoscopes are generally not used. The majority of centres use a colonoscope for the procedure, with the only difference from a sigmoidoscope being the length of the endoscope. The patient may experience mild discomfort, but sedation is rarely required, because the procedure lasts a few minutes. Patients are then generally discharged with no impairment to their ability to drive or work.

Traditionally, physicians undergo special training to perform endoscopic procedures including FS. These physicians include gastroenterologists, general and colorectal surgeons, general internists, and family physicians. The level of experience usually depends on each individual's duration of training. Experience and training determine an individual physician's ability to conduct specific therapeutic interventions. A diagnostic endoscopy, performed with the sole intent to visualize the colon, is easier than a therapeutic endoscopy, as the latter involves additional skill.

The effectiveness of FS for CRC screening is determined by the demonstrated impact on outcomes of clinical benefit and harm. These include the rate of detection of polyps; rate of detection of cancers; mean depth of endoscope insertion; mean procedural time; incidence of perforation, bleeding, infection, and death; and number of patients withdrawn because of adverse events.

1.3 Indications

Screening for cancer prevention involves diagnostic testing. Canadian and American CRC screening guidelines have identified the general population, older than 50, for diagnostic testing to identify polyps in the colon.[12,13] FOBT, air-contrast barium enema, and endoscopic examination of the colon are the technologies available. The latter includes FS (examination of the lower half of the colon) and colonoscopy (examination of the entire colon). These endoscopic procedures are not only capable of

diagnosing polyps, but also allow endoscopists to remove them in a safe and controlled manner, something other modalities cannot do. Other emerging technologies, such as virtual colonoscopy and stool markers, are also laudable considering their safety profile.

The proportion of individuals found to have polyps in the general population with individuals older than 50, varies according to the population studied, but is related to increasing age. Two studies in a North American population base found the prevalence of polyps to be 23% and 25% respectively.[14,15] The labour and financial resources needed to perform diagnostic screening endoscopy in this group of average risk individuals are tremendous. Mathematical models have examined this issue. A comparison of screening programs for average risk individuals found that FOBT alone was the most cost-effective modality (US$225,000 per death prevented, at 100% compliance), but it prevented fewer deaths compared with FS+FOBT (US$250,000 per death prevented). A colonoscopy was most expensive (US$274,000 per death prevented), but it had the greatest impact on mortality with 68% of cancers prevented.[16] This has led to the concept of training non-physician endoscopists to perform diagnostic endoscopy and to refer patients with polyps to trained medical professionals to perform therapeutic polypectomy (the removal of a polyp). As FS is technically easier to perform than colonoscopy, it has been the subject of clinical studies that have assessed efficacy and patient acceptance when performed by non-physicians.

2 THE ISSUE

The incidence of CRC and its mortality rate are of concern. Although early diagnosis and treatment have been shown to improve survival and screening sigmoidoscopy is recommended for all persons age 50 or older, only 30% of eligible patients undergo this procedure. The imbalance between the large and growing number of people age 50 or older, and the number of available gastroenterologists may partly limit access to sigmoidoscopy testing. Some jurisdictions are providing FS by non-physicians to increase its availability and reduce costs. There remains a need to review the clinical and economic implications of adopting NPE-based screening programs in Canada to determine the effectiveness and economic impact of this approach.

3 OBJECTIVES

This report is intended to help health care decision makers and others who are involved in the planning and delivery of CRC screening services. This report reviews the evidence of clinical and cost-effectiveness of the NPE model compared with the physician endoscopist model for screening sigmoidoscopy. The budget impact of non-physician endoscopy programs for CRC screening in a Canadian setting will also be determined.

The objectives were achieved by addressing the following questions:

- What is the evidence of clinical effectiveness when non-physician endoscopists perform screening sigmoidoscopy compared with physician endoscopists?
- What is the demonstrated economic impact and impact on health budgets when screening sigmoidoscopy is performed by non-physicians versus physicians?

4 METHODS

4.1 Literature Search

Published literature was identified by searching databases (Appendix 1). MEDLINE®, EMBASE®, BIOSIS Previews®, and INSPEC® were searched on DIALOG®. Parallel searches were run on PubMed and CINAHL. Duplicates were removed using the OneSearch® feature in DIALOG and through the use of Reference Manager®, a bibliographic reference management software. DIALOG searches were updated regularly, throughout the project, on all databases except INSPEC. Where possible, all search results were limited to the human population, and there were no language restrictions. DIALOG and PubMed searches were restricted to the publication years 1980 onward. The Cochrane Library and HEED: health economic evaluations database were also searched, and the results updated as new issues arrived.

Grey literature was obtained by searching the web sites of health technology assessment and related agencies and their associated databases. Sources for clinical practice guidelines were also searched. Google™ and other Internet search engines were used to search for additional web-based materials and information. These searches were supplemented by hand searching the bibliographies of selected papers and conference proceedings and through contacts with appropriate experts and agencies.

4.2 Selection Criteria and Method

4.2.1 Selection criteria

Included studies satisfied each of the following criteria:

- study design [randomized controlled trials (RCTs), prospective cohorts, retrospective cohorts, surveys]
- population group (patients undergoing endoscopy for CRC screening)
- interventions [flexible sigmoidoscopy (FS) performed by NPE]
- comparators (endoscopy performed by physicians)
- outcomes (rate of detection of polyps and cancers, depth of endoscope insertion, mean procedural time, complication rate, and patients' satisfaction).

Abstracts, letters, editorials, short notes, and duplicate publications were excluded.

4.2.2 Selection method

Selection was done in two stages: screening using the title and abstract, then a full text review of those citations identified as relevant.

Two reviewers (CH and HN) independently selected the relevant clinical trials, and two reviewers (CH and PJ) independently selected the relevant economic studies. Disagreements were resolved by discussion in both cases.

4.3 Data Extraction Strategy

After relevant trials were selected, two reviewers (CH and HN) extracted the clinical outcome data using a form that was designed a priori to capture information on trial and publication characteristics [first author, year of publication, journal, publication status, time period and country of study, number of centres, source(s) of funding, study design, sample size]; patient characteristics (age, gender, smoking status, comorbidities, previous treatments); intervention characteristics (treatment, concomitant medications); outcomes related to clinical benefit (rate of polyps detection, rate of cancer detection, mean depth of endoscope insertion, mean procedural time); and outcomes related to harm (perforation, bleeding, infection, death, number of patients withdrawn because of adverse events). The reviewers verified the accuracy of this information.

The same form, created a priori, captured information on economic data (first author, year of publication, sponsor, year, and country); the evaluation type (methods and design of model, if appropriate); results of the base case analysis; and the sensitivity to changes in the assumptions and parameters of the evaluation. Data were extracted by two reviewers (CH and PJ), and verified for accuracy.

4.4 Strategy for Quality Assessment

A quality appraisal assessment form was used to assess the quality of all included studies (Appendix 2).[17] The form, based on the work of Hailey *et al.*, takes account of study design and study performance.

4.5 Data Analysis Method

When possible, the comparisons of outcomes were made between non-physicians and physicians. GraphPad QuickCalcs was used to calculate p values, using Fisher's exact test when the total sample size is approximately <20 to 40, or the expected number of counts in any cell is <5; and using chi-square with Yates' correction when the values were large (thousands). Statistical significance was defined as $p<0.05$.

According to the economic framework used by health economists, alternative interventions should be compared based on health outcomes and costs. If outcomes are the same, then a cost minimization analysis, which focuses on costs, can be used.[18] Because this report found that clinical findings did not differ between physician and non-physician interventions, a cost minimization analysis was conducted with the summary measure of cost based on Alberta data for physician fees and facility costs. Nurse costs were based on procedure times found in the literature.

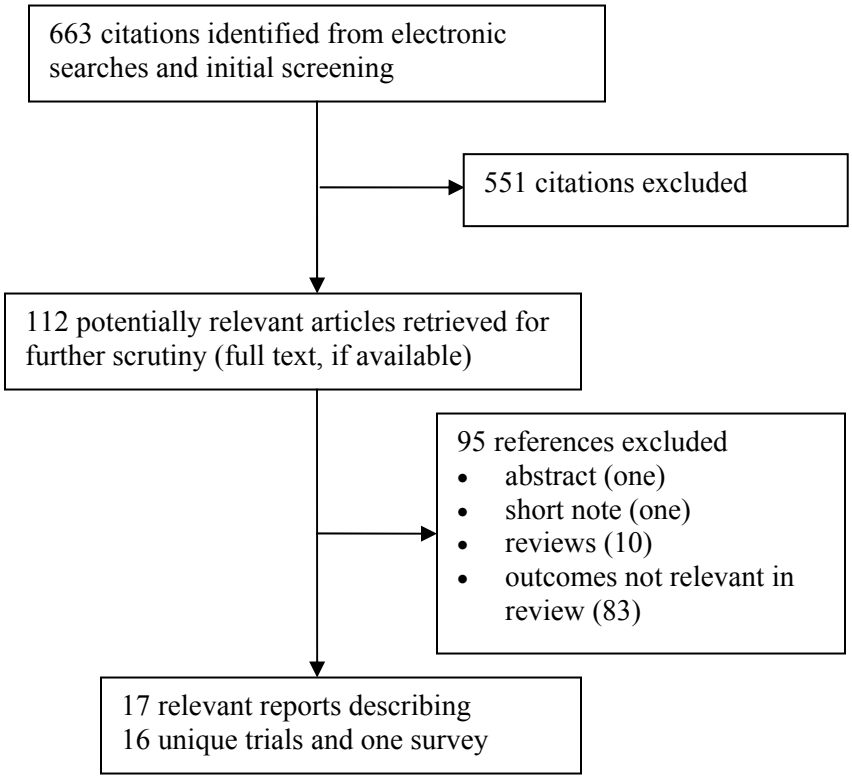
In the health services impact analysis, it was assumed that all screening would be done by FS. The total number to be screened annually, current and needed capacity, and the budget impact of a national screening program were estimated. The target number to be screened was based on the recommendations of the Canadian guidelines.

5 RESULTS

5.1 Quality and Quantity of Research Available

A total of 663 citations were identified in our original searches of multiple databases with 112 full reports retrieved. After eliminating reports that did not satisfy the selection criteria, there were 17 studies: 14 cohort studies, two RCTs and one survey (Figure 1). The average quality score[17] was 7.0±2.58, corresponding to category D (poor to fair quality – substantial limitations in the study; findings should be used cautiously) (Appendix 2). The literature search did not identify any systematic reviews or health technology assessments that addressed the report objectives.

Figure 1: Selected reports



5.2 Study Characteristics

5.2.1 Clinical studies

Of the 17 reports[19-35] that were included, one study was conducted in Canada,[34] four in the UK,[19,21,23,25] and 12 in the US.[20,22,24,26-33,35] There were two RCTs,[22,31] 11 prospective cohorts,[19,21,23-25,29,30,32-35] three retrospective cohorts,[26-28] and one survey.[20] Five of the 11 prospective cohorts,[19,29,30,32,35] one retrospective cohort,[28] the survey[20] and the two RCTs[22,31] reported on endoscopies performed by both NPE and physicians. Eight studies were based on

endoscopies performed only by NPE.[21,23-27,33,34] Details of the 16 included studies are shown in Table 1. More than 200,000 patients were enrolled in the included studies. Most of the trials recruited patients with an average risk of developing CRC [i.e., >50 years of age, asymptomatic, no hereditary predispositions (Appendix 3)]. Training programs for NPE range from two to three months, with the number of supervised complete examinations varying from 20 to >50 endoscopies (Appendix 4).

5.2.2 Economic studies

Three studies, with a total of 4,895 patients, provided cost estimates.[21,34,35]

Table 1: Characteristics of included clinical studies

Study	Setting	Design	Study Group (number of patients)	Quality Score (maximum of 15)
Arumugam[19]	UK	prospective cohort	130 by NPE; 262 by MD	6
Basnyat[21]	UK	prospective cohort	706 by NPE	6
DiSario[22]	US	RCT	106 by NPE; 106 by MD	9
Duthie[23]	UK	prospective cohort	215 by NPE	6
Eisemon[24]	US	prospective cohort	745 by NPE	4
Goodfellow[25]	UK	prospective cohort	282 by NPE	5
Gruber[26]	US	retrospective cohort	100 by NPE	2
Jain[27]	US	retrospective cohort	5,017 by NPE	6
Levin[28]	US	retrospective cohort	107,704 by NPE and MD	7
Maule[29]	US	prospective cohort	1,881 by NPE; 730 by MD	10
Palitz[30]	US	prospective cohort	14,988 by NPE; 62,258 by MD	4
Schoen[20]	US	survey	668 by NPE; 528 by MD	N/A
Schoenfeld[31]	US	RCT	151 by NPE; 162 by MD	13
Schoenfeld[32]	US	prospective cohort	114 by NPE; 269 by MD	6
Schroy[33]	US	prospective cohort	100 by NPE then video reviewed by MDs	6
Shapero[34]	Canada	prospective cohort	488 by NPE	6
Wallace[35]	US	prospective cohort	2,323 by NPE; 1,378 by MD	8

N/A=not applicable.

5.3 Data Analysis and Synthesis

5.3.1 Results of clinical studies

a) Non-comparative studies – rates of polyps and cancers detection by NPE

Of the 17 studies included in this review, seven[21,23-27,34] reported on the detection of polyps and cancer by NPE. Three of these[21,23,25] involved patients with colorectal symptoms, such as rectal bleeding. Basnyat *et al.*[21] reported that the highest proportion of patients in whom polyps and cancers were detected (47% and 6% respectively), was in patients between the age of 40 and 70 years, presenting with rectal bleeding. In the two other trials of symptomatic patients, Duthie *et*

al.[23] reported detecting polyps and cancer in 16% and 2% of participants respectively. Goodfellow *et al.*[25] reported values of 39% and 3% for the detection of polyps and cancer respectively. The four remaining studies[24,26,27,34] included asymptomatic people who had an average risk for developing CRC. As expected, the proportion of participants in whom polyps or cancer was detected was lower among those of average risk than in patients with colorectal symptoms. For those with an average risk, the rates of polyp and cancer detection varied from 8% to 21% and from 0.1% to 2.4% respectively. In patients with symptoms, the rates of polyp and cancer detection range from 16% to 47% and from 2% to 6% respectively.

Table 2: NPE detection of polyps and cancers

Study	Patient Characteristics	Polyps Detected (number of patients)	Cancers Detected (number of patients)
Basnyat[21]	between 40 and 70 years of age with rectal bleeding	90/189 (47%)	12/189 (6%)
Duthie[23]	presenting with colorectal symptoms	32/199 (16%)	4/199 (2%)
Eisemon[24]	average risk of CRC*	63/745 (8%)	1/745 (0.1%)
Goodfellow[25]	presenting with colorectal symptoms	46/121 (39%)	4/121 (3%)
Gruber[26]	average risk of CRC*	>21/100 (>21%)	>2/100 (2.4%)
Jain[27]	average risk of CRC*	666/5017 (13%)	15/5017 (0.3%)
Shapero[34]	average risk of CRC*	75/488 (15%)	4/488 (0.8%)

* Patients at average risk of developing CRC are >50 years of age, asymptomatic, and have no hereditary predispositions for CRC.

b) Comparative studies–rates of polyps detection by NPE and physicians

Five studies[30-33,35] compared the detection of polyps by NPE with that by physicians in patients at an average risk for CRC (Table 3). Two of the five studies reported statistically significant differences in the number of polyps detected, with both studies favouring NPEs.

Table 3: Rates of polyp detection by NPE and physicians

Study	Patient Characteristics	Number of Polyps Detected by NPE (number of polyps/ number of patients)	Number of Polyps Detected by Physicians (number of polyps/number of patients)	p value
Palitz[30]	average risk of CRC*	3,806/14,988 (25.4%)	gastroenterologist 5,288/24,415 (21.7%); generalist 8,739/37,833 (23.1%)	<0.0001
Schoenfeld[31]	average risk of CRC*	rate of missed polyps 22/118 (17%)	gastroenterologist: rate of missed polyps 41/139 (29%)	0.0615
Schoenfeld[32]	average risk of CRC*	8/114 (7%)	General surgeons 11/139 (8%); gastroenterology fellow 12/130 (9%)	0.6929
Schroy[33]	average risk of CRC* or >40 years of age with family history	28/100 (28%)	gastroenterologist 32/100 (32%)	0.6434
Wallace[35]	average risk of CRC*	619/2,323 (27%)	gastroenterologist 321/1,378 (23%)	0.0260

* Patients at average risk of developing CRC are >50 years of age, asymptomatic, no hereditary predispositions for CRC

c) Mean depth of endoscope insertion

The depth of endoscope insertion is an important criterion for a successful endoscopic examination. A successful passage of the scope allows for a complete and accurate diagnosis of polyps while not causing discomfort.

Five studies[21,23,26,33,34] reported the mean depth of endoscope insertion by NPE, and six studies[22,29-32,35] reported the mean depth of insertion by NPE and physicians (Table 4). Most studies reported a comparable depth by NPE and physicians, ranging from approximately 50 cm to 60 cm. The shortest mean depth of insertion by NPE (~40 cm) was reported in a study by Schroy *et al.*[33] in which the NPE had performed the least number of examinations (25) before the study. The NPE had experience with a 35 cm scope, but not with the 40 cm scope used in the study. In comparative studies, the mean depth of endoscope insertion by NPE is less than that by gastroenterologists, but more than by general practitioners. The difference between NPEs and gastroenterologists is statistically significant.

Table 4: Mean depth of endoscope insertion

Study	Mean (±SD) Depth of Insertion by NPE	Mean (±SD) Depth of Insertion by Physicians	p Value
Basnyat[21]	58.6 cm	NR	NA
Duthie[23]	55.5 cm	NR	NA
Gruber[26]	60 cm	NR	NA
Schroy[33]	37.8±4.7 cm	NR	NA
Shapero[34]	52.9±12.1 cm	NR	NA
DiSario[22]	46±15 cm	44±17 cm	>0.05
Maule[29]	46 cm for men; 38 cm for women	48 cm for men; 41 cm for women (gastroenterologist)	.003 (men); .002 (women)
Palitz[30]	52.6 cm	54.1 cm (gastroenterologist) 53.9 cm (general practitioner)	NR
Schoenfeld[31]	55±11 cm	61±10 cm (gastroenterologist)	<.00001
Schoenfeld[32]	53±9 cm	50±11cm (general surgeons) 54±9 cm (gastroenterology fellows)	>0.05 >0.05
Wallace[35]	52±10 cm	55±9 cm (gastroenterologist)	<.001

SD=standard deviation; NA=not applicable; NR=not reported.

d) Complications

Two trials[28,34] reported complications (i.e., perforation, bleeding, infection, diverticulitis, infection, and death) from endoscopies. Ten trials showed no complications,[22-27,29,31,32,35] whether the endoscopy procedure was done by NPE or physicians. One trial[34] showed one case of bleeding by NPE, and one trial[28] showed a complication rate of 19.3 per 100,000 for NPE, 16.5 per 100,000 for gastroenterologists and 27.5 per 100,000 for non-gastroenterologist physicians.

Table 5: Complications by NPE and physicians

Study	NPE	Physician
Duthie[23]	0/215	NR
Eisemon[24]	0/745	NR
Goodfellow[25]	0/282	NR
Gruber[26]	0/100	NR
Jain[27]	0/5,017	NR
Maule[29]	0/2,611	NR
Shapero[34]	1/488	NR
DiSario[22]	0/106	0/106
Levin[28]	19.3/100,000	16.5/100,000 (gastroenterologists) 27.5/100,000 (other physicians)
Schoenfeld[31]	0/123	0/126
Schoenfeld[32]	0/114	0/269
Wallace[35]	0/2,323	0/1,378

NR=not reported.

e) Patient satisfaction

Two studies[21,24] reported patient satisfaction when endoscopies were performed by non-physicians. The level of satisfaction between NPE and physician endoscopies were compared in three other studies.[20,22,32] Out of 249 participants in the study by Basnyat *et al.*,[21] 99% of the participants were satisfied with the service by NPE. Of the 37 patients who had non-physician endoscopies, and were studied by Eisemon *et al.*,[24] 80% reported a "very good" level of satisfaction.

In the three trials that compared patient satisfaction between non-physician and physician endoscopies, the results were comparable.[20,22,35] The RCT by DiSario et al[22] did not observe a difference in tolerance levels among patients examined by NPE and those examined by physicians. The survey (n=1,221) by Schoen *et al.*[20] reported a significantly better overall satisfaction with NPE as compared with internists or gastrointestinal specialists ($p<0.001$). This survey also showed that approximately 70% of individuals who undergo screening sigmoidoscopy are satisfied, and find the procedure more comfortable than expected, regardless of who performed the examination.

Table 6: Patient satisfaction with NPE and physicians

Study	Method Used to Rate Satisfaction	Patient Satisfaction with Non-Physician Endoscopies	Patient Satisfaction with Physician Endoscopies
Basnyat[21]	questionnaire survey	246/249 (99%) satisfied	NR
Eisemon[24]	patient call-back tool	very good 80%; good 20%	NR
DiSario[22]	questionnaire survey	procedure tolerance: 24% good; 58% fair; 18% poor	procedure tolerance: 24% good; 58% fair; 18% poor
Schoen[20]	questionnaire survey	1.7*	gastroenterologist ranked 1.8*; internists ranked 1.9*
Schoenfeld[32]	questionnaire survey	1.66±0.52†	general surgeons 1.70±0.57+; gastroenterologist fellows: 1.73±0.54+

NR=not reported; *Rated on a scale of 1 to 5. The lower the score, the more favourable the response; †Rated on a scale of 1 to 5; 1 being very satisfied and 5 being not satisfied.

f) Mean procedural time

Schroy[33] and Shapero[34] reported a mean (±SD) procedural time of 13.7±10.2 minutes and 8.4±3.9 minutes respectively, for non-physician endoscopies. Schoenfeld[31] reported mean procedural times for both NPE and physicians of <15 minutes in their RCT, while in their cohort study,[32] the mean (±SD) duration of the procedure was 8.3±3.2 minutes for NPE, 7.6±6 minutes for general surgeons; and 6.8±3.4 minutes for gastroenterologist fellows). Although these differences were statistically significant, the clinical significance is not of concern because all procedural times were less than 15 minutes, regardless of who performed the procedure.

g) Summary of clinical findings

This review of clinical studies showed that there are no clinically significant differences between NPE and physician endoscopists performing FS, as measured by the identification of polyps, depth of insertion of the endoscope, and patients' satisfaction. The rates of cancer detection by NPE varied from 0.1% to 2.4% in patients with average risks, and from 2% to 6% in patients with CRC symptoms. There are no data comparing rates of cancer detection between NPE and physicians. The complication rates are modest, and no differences in harms were observed between NPE, gastroenterologists, and non-gastroenterology physicians. The significant difference between the groups performing the procedure was in terms of the procedural time. This finding needs to be considered when examining the economic implications of the models of FS screening.

5.3.2 Results of economic studies

Because the clinical outcomes did not differ in a clinically significant manner between the interventions, the relevant costs are that which differ between interventions. This includes the cost of health services (e.g., doctors, NPE, facility costs, supplies) and costs that are incurred privately by patients (e.g., costs for waiting). The analysis should begin at the time of the patient's referral for endoscopy and continue beyond the procedure to include any post-endoscopy events that result from differences in interventions (e.g., differences in the number of incorrect diagnoses). The events would not include downstream diagnostic procedures (e.g., follow-up colonoscopies) or treatment, as these are assumed to be similar between the alternative screening methods.

The costs from all sources were of interest, including paid labour, supplies, equipment, and unpaid time of patients. Training costs were not considered. In addition, the quality of the estimates was of relevance to our analysis with estimates that were based on direct observation to be of higher quality than those that were generated by speculation and professional opinion.[36]

a) Results

Three studies provided cost estimates: Wallace *et al.*,[35] Shapero *et al.*,[34] and Basnyat *et al.*[21] (Table 7). Of these, Wallace *et al.*[35] included observations for physician and non-physician endoscopies. Shapero *et al.*[34] and Basnyat *et al.*[21] included observations for non-physician endoscopy, and based their estimates of physician endoscopy on speculation.

Table 7: Components of economic studies

Study	Number in Sample	Type of Patients Referred	Costs Included and Excluded	Results
Wallace[35]	physician endoscopy 1,378, non-physician endoscopy 2,323	age >50, negative fecal blood, no relatives with CRC before age 55	includes compensation, support staff, supplies, and equipment; excludes waiting time; MD review not mentioned	total costs: NPE US$183 per test; MD US$283 per test; direct labour costs US$30 for NPE, and US$112 for MD
Shapero[34]	non-physician endoscopy 488	all referrals	includes compensation for NPE; excludes waiting time and MD review	direct labour cost per procedure: C$30 for NPE, and C$73 for MD
Basnyat[21]	non-physician endoscopy 706	between 40 and 70 years of age with rectal bleeding	includes salary and fee; biopsy in 15% of cases; excludes physicians' review of videotapes and patient time; currency not identified, assumed to be $US; no follow-up visit by nurses identified	NPE US$81, MD US$171 ($112 fee and US$59 follow-up visit)

In terms of identifying costs, the study by Wallace *et al.*[35] was the most comprehensive. It incorporated the cost of supplies, equipment and support items, and compensation to the service provider and fringe benefits. The procedure costs were US$183 for NPE and US$283 for physicians. This $100 difference was largely the result of the discrepancy in compensation between NPE and physicians.

Wallace *et al.* did not consider patient wait time, which may not be an issue in the US where waits for endoscopies are minimal. No mention was made of additional resources that would be needed for a physician to review the results of NPE. The other two economic studies did mention that a subsequent review took place, which would take extra physician time.

Although it was not stated, the British study by Basnyat *et al.*[21] presented their results in dollars, presumably US dollars. The assumptions behind their analysis were not stated. The authors estimated that there was a small cost differential between NPE and physicians ($81 versus $112), but that the total differential between the two was increased, because there was a follow-up visit for physician endoscopy. No such follow-up visit was mentioned for non-physician endoscopy.

In the Canadian study, Shapero *et al.*[34] estimated that the cost of a non-physician endoscopy was $30 (direct compensation only) and that endoscopy by a physician was $73. Because both NPE and physicians were assumed to take 30 minutes per procedure, the smaller cost differential in this study, compared with Wallace *et al.*,[35] must be due to differences in compensation for NPE and physicians between Canada and the US. This implies that Wallace *et al.*'s results[35] may be less applicable to Canada. Shapero *et al.*[34] stated that a physician reviewed all non-physician procedures, but this is not reflected in their cost estimates. Such a review would take physician resources, and would narrow the differential between NPE and physician endoscopies.

b) Conclusions

A cost minimization analysis was used because outcomes between the alternative therapies were comparable. The economic analysis is based on a small number of studies, none of which are particularly robust.

Basnyat *et al.*[21] did not provide the underlying assumptions of their analysis, so it is difficult to use their study as a comparison.

Although the Canadian study by Shapero *et al.*[34] is of poor quality, relative to that by Wallace *et al.*, the indicators of physical resources are similar. Shapero *et al.*[34] omitted several resources in their analysis, including physician review of non-physician examinations, and patient wait times. The former reduces the differential between the two, depending on the polyp detection rate. If endoscopies by non-physicians reduced waiting times for patients, the costs to society would be reduced, thereby making this option more favourable.

The approximate values for time to conduct a screening FS (15 minutes for a gastroenterologist and 10 minutes for a nurse practitioner) are based on Schroy[33] and Schapero.[34] Other values were based on Alberta statistics. An FS would cost $403 if done by a physician, and $340.50 if done by a nurse practitioner – a difference of $62.50 (Table 8).

Table 8: Budget impact analysis of a nationwide colorectal screening program using FS

Screenings	Gastroenterologist	Nurse Practitioner
Target annual number of screenings according to national guidelines	2,800,000	2,800,000
Number of screenings (see text)	556,000	556,000
Additional screenings needed to meet national guidelines	2,244,000	2,244,000
Unit cost (see Table 9)	$403.00	$340.50
Additional physician screenings for 18% detected cases by NP		403,290
Total budget needed to meet national guidelines	**$904,332,000**	**$764,082,000*+ $162,525,870+ $926,607,870**

*$764,082,000=2,244,000x$340.50;+$162,525,870=403,290x$403.00.

This difference will be reduced, and perhaps reversed, because of the costs of physician therapeutic polypectomies. Polyp detection by NPE can range from 8% to 47% (Table 2). It is reasonable to assume that these cases will be referred to physicians for therapeutic polypectomy, while those sigmoidoscopies initially done by physicians will not require a referral. If the detection rate were 8%, this would add $32 per case (0.08 x $403), and narrow the difference to $30. The difference of $62.50 would become zero at a polyp detection rate of 15.5% (=62.50/403).

Table 9: Estimated cost of a flexible sigmoidoscopy screening

Item	Gastroenterologist	Nurse Practitioner
Compensation	$73.00*	$10.50†
Facility fee	$330.00‡	$330.00
Other (physician review)		N/A
Total direct costs	**$403.00**	**$340.50**

*Alberta Health Insurance Plan, Schedule of Medical Benefits 2005,[37] Flexible sigmoidoscopy.
†Average hourly rate for a nurse practitioner ($35) plus 20% benefits, applied to one FS procedure each 15 minutes.
‡Health costing in Alberta, 2004 Annual Report,[38] Schedule 4, Ambulatory care cost results, item 28.1, Endoscopy GI Low, direct cost $330.

6 HEALTH SERVICES IMPACT

6.1 Screening Target

The Canadian colorectal cancer screening guidelines recommend screening using colonoscopy, FOBT, FS, and air-contrast barium enema.[39] A colonoscopy is recommended for a positive result on any of the latter three tests.[12] In this analysis, it is assumed that all screening is done with FS.

In a modelling exercise, Flanagan *et al.*[40] studied the economic impact of a screening package consisting of FOBT plus colonoscopy. According to Flanagan *et al.*,[40] if 67% of the target Canadian population between the ages of 50 and 75 were screened biannually (i.e., 8.35 million people with one half of these, 4.179 million, eligible to be screened annually), and this was averaged over 25 years, 2.8 million persons (4.179 x 0.67 screening rate) would need to be screened with FOBT annually. Flanagan *et al.*'s assumptions were applied to this analysis whereby all screening was assumed to be carried out by FS. There is an assumed annual need for 2.8 million screenings with FS. In addition, using Flanagan *et al.*'s assumptions, this level of follow-up screening would result in a need for 55,845 colonoscopies (1.336% of the population who are on target for screening, or 1.994% of all persons screened).

6.2 Capacity Issues

To achieve the target level of screenings, certain labour requirements need to be considered. The number of FS procedures that can be done by a physician in one hour is six (10 minutes each),

and by a nurse practitioner is four (15 minutes each). These assumptions are based on Schroy[33] and Schapero.[34] Assuming a work schedule that includes a six-hour day, a five-day week, and a 48-week year, then a full-time equivalent (FTE) gastroenterologist could perform 8,640 FS's annually, and a nurse practitioner could perform 5,760. To meet the national target of 2.8 million screenings annually, 324 gastroenterologists or 486 nurse practitioners would be needed.

There is little evidence on the extent of colorectal cancer screening in Canada. According to an Ontario study, roughly 20% of all persons aged 50 to 59 were screened for colorectal cancer between 1995 and 2000.[40] If this is conservatively assumed to be the biannual screening rate, and it is applied to the Canadian population that is assumed in Flanagan *et al.* (i.e., the entire population aged 50 to 74), then 556,000 persons (0.20 x 0.5 screens annually x 8.35 million population x 0.6667 screening rate) are being screened annually. This number of FS procedures could be done by 64 FTE gastroenterologists or 96 FTE nurse practitioners. This would mean 260 more full-time gastroenterologists (324 – 64) are needed to meet Canadian CRC screening targets. Alternatively, 486 nurse practitioners could be trained. There are between 25 and 30 trainees graduating from gastroenterology training programs in Canada annually. According to the Canadian Association of Gastroenterology, there are 475 registered gastroenterologists. The requirement of an additional 260 gastroenterologists would represent a sizeable increase. In addition to the increase in labour capacity, dedicated ambulatory endoscopy centres catering to screening colonoscopy would favourably affect wait times for the FS procedure.

The wait time for colonoscopies is from three to 10 months.[12] More than 260 additional gastroenterologists would be needed to reduce waits and serve the national screening program.

The alternative to training additional specialists is to train nurse practitioners. In the United Kingdom, one program successfully trained nurses during a three-week period.[23] Although nurses are in short supply in Canada, the resource commitment that would be needed to deploy nurses would seem to be more realistic than for specialists. Because nurses and doctors can provide the same number of sigmoidoscopies, more than 20 nurses would have to be trained, which would not require a major commitment of resources.

6.3 Impact of NPE on System-Wide Costs

According to the model by Flanagan *et al.*,[40] a screening program targeting Canadians between the ages of 50 and 74 using FOBT would cost $112 million annually. In 2004, this would represent 7.6 million people.[41] The number of colonoscopies that would be performed would depend on whether screening was conducted annually or biannually. In the case of biannual screening, and with 67% of the population accepting the screening, there would be 2.8 million screenings annually.

As demonstrated in Table 8, a target of screening 2.8 million people annually will require that 2,244,000 additional persons be screened annually. If the additional screening is done using the FS method alone, and all FSs are done by physicians, then based on the costs in Table 9, the additional costs would be $904 million. It was assumed that all detected polyps by physicians would receive therapeutic polypectomy.

All polyps detected by non-physicians would have to be re-screened by physicians, at a cost of $403 per screen. If the same procedures were done entirely by NPEs, then the costs would be $764 million plus the re-screens by the physicians for polypectomy ($162 million), for a total of $926 million. In this case, the NPE approach would cost $21 million more than the physician approach. This conclusion is based on an assumed 18% rate for polyp detections. If the rate of polyp detection was at the lower end of the observed range (e.g., 8%), the non-physician option would cost $836 million, which is $68 million less than the physician option. Thus, the total budget impact depends on the polyp detection rate.

The key difference between these results and those of Flanagan *et al.*,[40] are due to Flanagan *et al.'s*[40] reliance on FOBT screening, which is cheaper than sigmoidoscopies. The Flanagan *et al.* study[40] does not question whether resources will be available. The already long waits translate into delayed diagnoses and perhaps the use of extra resources. Considerations related to delays and waits have not been explicitly considered in any analysis.

In view of the labour force and financial strain of CRC screening in Canada, average risk screening (asymptomatic individuals aged 50 to 74) should be undertaken by modalities that do not employ the services of a physician endoscopist.[42,43]

7 DISCUSSION

7.1 Clinical Review

Markers of effective endoscopy examinations include adequate depth of endoscope insertion, accurate identification of polyps, low frequency of complications, and acceptable levels of patients' satisfaction. Non-physicians need appropriate training to achieve each of these markers.

An inherent difficulty in assessing mean depth of insertion is the discrepancy between the actual length of colon examined to the corresponding length of endoscope insertion. Because of the possibility of looping the endoscope in the lower colon, the length of the endoscope inserted does not necessarily correspond to an equivalent length of colon examined. This may vary depending on the experience of the endoscopist, physician or non-physician, and may not be readily recognizable to the operator. Therefore, 50 cm of endoscope may be inserted, but only 25 cm of actual colon examined.

In this report, NPE and physicians achieved similar depths of insertion, with a slight but statistically significant deeper insertion by gastroenterologists. This difference may be minimized with the increasing experience of the NPE. The differences in insertion depth between clinical physician specialties should be considered in training programs for CRC screening. The mean depth of insertion also varies between men and women of all ages, with generally greater insertion in men. This may be explained by the different anatomic structure at the junction of the rectum and the sigmoid colon, and the different levels of tolerance between the genders.

The primary purpose of FS is to detect adenomatous polyps, which are non-malignant precursors of CRC. Detecting and removing polyps before they become malignant is therefore a marker for a successful endoscopy. The detection rate of polyps and cancers by NPE varies according to the patient's baseline characteristics. The detection rate is lower in patients with an average risk of developing CRC than in patients with CRC symptoms. When rates of polyp detection by NPE and physicians were compared in studies of persons at average risk, Palitz *et al.,*[30] and Wallace *et al.*,[35] found the NPE had a better rate of detection that was statistically significant.

Potential gastrointestinal complications of FS include colitis from the chemical used to sterilize the endoscope, bowel perforation, bleeding, and infection. Findings from this report show that the rate of complications from non-physician endoscopies is modest and that limited evidence showed that NPEs perform FS as safely as gastroenterologists and other physicians.

Patients' satisfaction is critical if screening strategies for cancer are to succeed in the long term, particularly screening for CRC by FS. A more comfortable examination experience, combined with information about how to reduce the risk of cancer, should encourage patients to undergo future screening at recommended intervals. Although sigmoidoscopy has been in clinical practice for many years, little is known about patients' satisfaction. This report found no statistically significant difference in patients' satisfaction relative to the background of the endoscopist. The majority of patients are also satisfied with endoscopy performed by non-physicians.

Given the information available, non-physician endoscopy is a viable model for people at average risk of developing CRC and it helps meet the challenge of screening a large and growing segment of the population. This approach would have to be coupled with another technique that would assess the right side of the colon, such as a barium enema. Colonoscopy is also a viable option, even though there are concerns with its use. Colonoscopy would entail more training for the NPE, and it would have an increased risk of complications, albeit infrequently. If a polyp is identified, a physician endoscopist, trained in polypectomy, would need to be available. This may be worth exploring, but studies are required to document the safety and efficacy of this approach.

Other considerations include the possibility of employing emerging technologies such as virtual colonoscopy and stool markers; both have notable safety profiles. There are issues regarding these techniques that would limit their generalizability to the population at large. This discussion is beyond the scope of this report.

Meeting national guidelines for CRC screening poses challenges for health care providers, especially as the population ages. The burden of providing widespread screening has prompted a closer look at alternatives rather than relying solely on physicians to provide the screening service. To ensure that other health care professionals, such as nurses, are effective in this capacity, it is vital that they receive appropriate training. The training programs described in the studies that we examined varied. There is a need to standardize training protocols while still providing different levels of training, according to the specific needs of trainees. The available evidence suggests that the majority of non-physicians are competent in providing the screening after completing the didactic component of a training session, and then independently performing approximately 35 sigmoidoscopic examinations.

7.2 Economic Analysis

This economic analysis focused on specific economic aspects, such as the difference in cost between the alternative interventions. In order for the cost minimization approach to be a valid indicator of the economic efficiency of sigmoidoscopy by NPE, certain conditions must be met. The diagnostic accuracy of NPE and physician-led endoscopies should be similar, and all other cost-generating factors should be the same. Events such as repeat procedures, additional procedures due to misdiagnosis, and adverse events should also be comparable. No evidence was found to suggest that these other outcomes or events differed between interventions so a cost minimization analysis was used. The basic cost of sigmoidoscopy performed by a non-physician was about $62.50 less than one conducted by a physician. When polyps are detected by non-physicians, cases must then be referred to a physician for a polypectomy. This is not the case with a sigmoidoscopy conducted by a physician. Taking into account this added cost, NPE will be favourable only at relatively low polyp detection rates. The number of sigmoidoscopies needed annually in Canada, based on CRC Screening Guidelines, is estimated to be more than two million. Whether NPE achieve savings depends on the polyp detection rate.

This report was based on a small number of studies, only one of which provided direct observation of both sides of the analysis. In addition, none of the studies addressed the costs that are borne by the patients, such as transportation or other incidentals. A full economic assessment should contain all relevant costs, including these.

The introduction of sigmoidoscopy by NPE in Canada might reduce patient wait times, although it is unknown by how much. A reduction in wait lists reduces patients' anxiety, and it means that pathologies can be detected at an earlier stage. No literature exists that addresses the wait list reduction issue.

8 CONCLUSION

There are no clinically significant differences between NPE and physician endoscopists performing FS, as measured by depth of insertion of the endoscope, identification of polyps, mean procedural time, and patients' satisfaction. The rate of cancer detection by NPE varied from 0.1% to 2.4% in patients with average risks, and from 2% to 6% in patients with CRC symptoms. Complication rates are modest, and no differences in harmful outcomes were observed between NPE and physicians.

The cost minimization analysis in this report showed that the cost of a sigmoidoscopy performed by a non-physician was C$62.50 less than one conducted by a physician, which translates into a 16% reduction in the total cost of the screening program, if all sigmoidoscopies were done by NPE. This difference will be reduced, and perhaps reversed, because of the costs of physician therapeutic polypectomies.

Given the information available, it would appear that non-physician endoscopy is a viable model in Canada because it could lead to increased screening availability and reduced waiting times. The NPE model would help meet the challenge of screening people at an average risk of developing CRC, which is a sizeable and growing segment of the population. The NPE alternative to endoscopies, performed solely by physicians, can provide economical CRC screening if proficiency is established and patients' satisfaction is assured. There is a need to develop a standardized training protocol for NPE.

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APPENDIX 1: Literature Search Strategies

?	Truncation symbol, one character only
*	Truncation symbol, any number of characters
!	Explode (i.e., subject heading/descriptor)
n	Near/next (i.e., terms are near/next to one another, any order)
s	Same (i.e., terms are in the same field as one another)
w	With (i.e., terms are next to one another, same word order)
l	Link (i.e., to subheading)
ti	Title
ab	Abstract
au	Author
de	Descriptor
dt	Publication type
tw	Text word

DATABASES	**LIMITS**	**KEYWORDS/DESCRIPTORS**
DIALOG® MEDLINE® EMBASE® BIOSIS Previews® INSPEC®	1980- Human *(MEDLINE, EMBASE®, BIOSIS, only)*	Clinical Search: MEDLINE: Endoscopy(l)nursing/de All Databases: (nurse(2n)endoscop* OR non(w)physician(2n)endoscop* OR nonphysician(2n)endoscop* OR nurse(2n)colonoscop* OR non(w)physician(2n)colonoscop* OR nonphysician(2n)colonoscop* OR nurse(w)sigmoidoscop* OR non(w)physician(2n)sigmoidoscop* OR nonphysician(2n)sigmoidoscop*)/ti,ab *OR* [MEDLINE: (Colonoscopes OR Colonoscopy)/de (colonoscop* OR sigmoidoscop* OR endoscop*)/ti,ab *AND* MEDLINE: Nurses Role/de OR Nurse Practitioners/de (nurse*(2n)role* OR nursing(2n)role* OR nurse*(2n)led OR nurse*(2n)administer* OR nurse(w)practitioner*)/ti,ab (non(w)physician* OR nonphysician* or health(w)practitioner* OR health(w)care(w)practitioner? OR healthcare(w)practitioner*)/ti,ab] *OR* [EMBASE: (intestine endoscopy OR sigmoidoscope)/de

		AND (nurse OR nurse practitioner OR health practitioner)/de (nurse*(2n)role* OR nursing (2n)role* OR nurse*(2n)led OR nurse*(2n)administer* OR nurse(w)practitioner* OR non(w)physician* OR nonphysician* OR health(w)practitioner* OR health(w)care(w)practitioner* OR healthcare(w)practitioner*)/ti,ab] *AND* MEDLINE: (controlled clinical trials! OR epidemiologic research design! OR meta-analysis)/de OR dt=(multicenter study OR randomized controlled trial OR controlled clinical trial OR meta-analysis) EMBASE: (major clinical study OR multicenter study OR controlled study! OR randomized controlled trial OR evidence based medicine! OR meta analysis)/de BIOSIS: (multicenter study OR randomized controlled trial OR randomized clinical trial OR randomized trial OR evidence-based medicine OR meta-analysis)/de All Databases: singl*(w)(blind* OR dumm* OR mask*)/ti,ab OR doubl*(w)(blind* OR dumm* OR mask*)/ti,ab OR tripl*(w)(blind* OR dumm* OR mask*)/ti,ab OR trebl*(w)(blind* OR dumm* OR mask*)/ti,ab OR (random* OR sham* OR placebo*)/ti,ab control*(w)(study OR studies OR trial*)/ti,ab OR RCT? ?/ti,ab OR comparative(w)(study OR studies)/ti,ab (meta(w)analy* OR metaanaly* OR met(w)analy* OR metanaly*)/ti,ab (meta(w)regression* OR metaregression* OR mega(w)regression*)/ti,ab (systematic*(w)literature(w)review* OR systematic*(w)review* OR systematic*(w)overview*)/ti,ab (methodologic*(w)literature(w)review* OR methodologic*(w)review* OR methodologic*(w)overview*)/ti,ab quantitative(w)(review* OR overview* OR synthes*)/ti,ab OR research(w)(integration* OR overview*)/ti,ab integrative(2w)(review* OR overview*)/ti,ab OR collaborative(w)(review* OR overview*)/ti,ab (pool*(w)analy* OR data(w)synthes* OR data(w)extraction* OR data(w)abstraction*)/ti,ab

		Performed 25 Oct 2004 *133 unique records* MEDLINE – 32 records EMBASE – 93 records BIOSIS – 8 records INSPEC - 0 records
		Safety/Adverse Events Search: *Same descriptors and keywords from clinical search, excluding clinical trial/systematic review filter* *AND* MEDLINE: (Adverse Effects OR Complications OR Ethics! OR Harm Reduction OR Intraoperative Complications! OR Morbidity! OR Mortality!)/de (Postoperative Complications! OR Psychology! OR Risk! OR Safety! OR Treatment Outcome!)/de EMBASE: (Complication! OR Ethics! OR Morbidity! OR Mortality! OR Psychology! OR Risk! OR Safety! OR Side Effect! OR Treatment Outcome!)/de BIOSIS: (Adverse Effects OR Adverse Events OR Complications OR Ethics OR Morbidity OR Morbidity Rate OR Mortality OR Mortality Rate)/de (Mortality Risk OR Postoperative Complications OR Postoperative Mortality OR Postoperative Nausea OR Postoperative Pain OR Postoperative Vomiting)/de (Psychological Factors OR Psychological Well-Being OR Psychology OR Risk OR Risk Management OR Risk Perception OR Risk Reduction)/de (Safety OR Treatment Failure OR Treatment Outcome)/de INSPEC: (Risk Management! OR Safety!)/de ALL DATABASES: (adverse(w)effect* OR adverse(w)event* OR adverse(w)incident* OR complication* OR harm* OR injurious(w)effect* OR morbidity OR mortality OR risk* OR side(w)effect* OR treatment(w)outcome* OR undesirable(w)effect*)/ti,ab *Performed 25 Oct 2004* *129 unique records (excludes overlap with clinical search)* MEDLINE – 102 records

		EMBASE – 22 records BIOSIS – 5 records INSPEC - 0 records
		Economic Search: *Same descriptors and keywords from clinical search, excluding clinical trial/systematic review filter* *AND* MEDLINE: (economics OR costs and cost analysis! OR value of life OR economics, medical! OR economics, hospital! OR economics, nursing OR fees and charges! OR budgets)/de (models, economic! OR markov chains OR monte carlo method OR decision trees OR quality of life OR patient satisfaction OR quality-adjusted life years)/de OR economics (subheading) EMBASE: (Health economics! OR economic evaluation! OR pharmacoeconomics! OR pharmacoeconomics)/de BIOSIS: (economic impact OR economic value OR health care cost OR economic factors OR economics OR cost analysis OR economic analysis OR cost OR cost-effectiveness OR cost effectiveness)/de (costs OR quality of life OR health care cost OR cost savings OR cost-benefit analysis OR hospital costs OR medical costs OR quality-of-life)/de All Databases: (econom* OR cost OR costly OR costing OR costed OR price OR prices OR pricing OR priced OR discount OR discounts OR discounted OR discounting OR expenditure OR expenditures OR budget* OR afford* OR pharmacoeconomic* OR pharmaco(1n)economic*)/ti,ab (cost*(1n)(util* OR effective* OR efficac* OR benefit* OR consequence* OR analy* OR minimi* OR saving* OR breakdown OR lowering OR estimate* OR variable* OR allocation OR control OR illness OR sharing OR life OR lives OR affordabl* OR instrument* OR technolog* OR day * OR fee OR fees OR charge OR charges))/ti,ab (unit(1n)cost OR unit*(1n)costs OR drug(w)cost OR drug(w)costs OR hospital(w)costs OR health(1n)care(w)costs OR medical(1n)cost OR medical(1n)costs OR markov OR markow OR monte(w)carlo)/ti,ab (decision (1n)(tree* OR analy* OR model*))/ti,ab ((value OR values OR valuation)(2n)(money OR monetary OR life OR lives))/ti,ab

		(QOL OR QOLY OR QOLYs OR HRQOL OR QALY OR QALYs OR quality(1n)life OR willingness(1n)pay OR quality(1n)adjusted(w)life(w)year*)/ti,ab *Performed 25 Oct 2004* *37 unique records (excludes overlap with clinical and safety searches)* MEDLINE – 23 records EMBASE – 11 records BIOSIS – 3 records INSPEC - 0 records
		Program Overview Search: *Same descriptors and keywords from clinical search, excluding clinical trial/systematic review filter* MEDLINE: Canada!/de EMBASE: Canada/de BIOSIS: (Canada OR British Columbia OR Alberta OR Saskatchewan OR Manitoba OR Ontario OR Quebec OR Nova Scotia OR New Brunswick OR Prince Edward Island OR Newfoundland)/de All Databases: (Canada OR British(w)Columbia OR Alberta OR Saskatchewan OR Manitoba OR Ontario OR Quebec OR Nova(w)Scotia OR New(w)Brunswick OR Prince(w)Edward(w)Island OR Newfoundland OR Yukon OR Northwest(w)Territories OR Nunavut)/ti,ab *Performed 25 Oct 2004* *2 unique records (excludes overlap with clinical, safety and economic searches)* MEDLINE – 1 record EMBASE – 1 record BIOSIS – 0 records INSPEC - 0 records
CINAHL*direct*® CINAHL		(nurse*(w)endoscop* OR nurse*(w)practitioner*(w)endoscop* OR non(w)physician*(w)endoscop* OR nonphysician*(w)endoscop* OR nurse*(w)colonoscop* OR nurse*(w)practitioner*(w)colonoscop* OR non(w)physician*(w)colonoscop* OR nonphysician*(w)colonoscop* OR nurse*(w)sigmoidoscop* OR nurse*(w)practitioner*(w) sigmoidoscop* OR non(w)physician*(w)sigmoidoscop* OR nonphysician*(w)sigmoidoscop*)/ti,ab,tw *OR* [colonoscopy!

		(colonoscop* OR sigmoidoscop* OR endoscop*) *AND* (nurse*(w)role* OR nursing(w)role* OR nurse*(w)led OR nurse*(w) administer*)/ti,ab (nurse*(w)practitioner*(s)role* OR nonphysician*(n)role* OR nonphysician*(n)led* OR nonphysician*(n)administer*)/ti,ab] *Performed 1 Nov 2004* *81 records*
PubMed	1980- Human	Clinical Search: *Same descriptors and keywords as per DIALOG MEDLINE search, adjusting syntax where necessary* *Performed 19 Oct 2004* *131 records*
		Safety/Adverse Events Search: *Same descriptors and keywords as per DIALOG MEDLINE search, adjusting syntax where necessary* *Performed 19 Oct 2004* *255 records (excludes overlap with clinical search)*
		Economic Search: *Same descriptors and keywords as per DIALOG MEDLINE search, adjusting syntax where necessary* *173 unique records (excludes overlap with clinical and safety searches)*
		Program Overview Search: *Same descriptors and keywords as per DIALOG MEDLINE search, adjusting syntax where necessary* *Performed 19 Oct 2004* *6 unique records (excludes overlap with clinical, safety and economic searches)*
The Cochrane Collaboration & Update Software Ltd.	1980-	Clinical Search: *Same descriptors and keywords as per DIALOG MEDLINE search, adjusting syntax where necessary*

The Cochrane Library, 2004, Issue 4		*16 records* CENTRAL = 13 references; HTA database = 1 record; The NHS Economic Evaluation Database = 2 records
		Safety/Adverse Events Search: *Same descriptors and keywords as per DIALOG MEDLINE search, adjusting syntax where necessary* *5 unique records (excludes overlap with clinical search)* CENTRAL = 5 references
		Economic Search: *Same descriptors and keywords as per DIALOG MEDLINE search, adjusting syntax where necessary* *9 unique records (excludes overlap with clinical and safety searches)* CENTRAL = 7 references; HTA database = 1 record; The NHS Economic Evaluation Database = 1 record
		Program Overview Search: *Same descriptors and keywords as per DIALOG MEDLINE search, adjusting syntax where necessary* *0 unique Records (excludes overlap with clinical, safety and economic searches)*
Office of Health Economics Health Economic Evaluations Database (HEED) 2004, Oct issue		colonoscop* OR sigmoidoscop* OR endoscop* *AND* nurse OR nurses OR nursing OR nonphysician* OR non-physician* *28 records*
Websites of health technology assessment (HTA) and near-HTA agencies; clinical trial registries; other databases		e.g. NZHTA; AHRQ; National Research Register; University of York NHS Centre for Reviews and Dissemination – CRD databases; etc.

APPENDIX 2: Trial Quality Assessment Form

Reference: _____

Reviewer: _____

Study Characteristics	Score
Study Design Large RCT (>50 in each arm): 5 points Small RCT: 3 points Prospective: 2 points Retrospective: 1 point If it is a RCT*: • randomized? • randomization appropriately described? • blinded? • blinding appropriately described? • withdrawals described?	
Study Performance Patient selection Description or specification of the intervention Specification and analysis of study Patient disposal Outcomes reported Score (information missing=0 points; information limited=1 point; information satisfactory=2 points)	
Overall Score	
Category A (overall score 11.5 to 15.0): high quality (high degree of confidence in study findings) B (overall score 9.5 to 11.0): good quality (some uncertainty regarding the study findings) C (overall score 7.5 to 9.0): fair to good quality (some limitations that should be considered in any implementation of study findings) D (overall score 5.5 to 7.0): poor to fair quality (substantial limitations in the study; findings should be used cautiously) E (overall score 1.0 to 5.0): poor quality (unacceptable uncertainty for study findings).	

* An RCT receives full points if it addresses all five characteristics. One point is deducted for each characteristic that is not addressed.

APPENDIX 3: Patients' Characteristics and Inclusion Criteria at Baseline for Included Trials

Study	Endoscopist	Patient Characteristics and Inclusion Criteria
Arumugam[19]	NPE physicians	age >45 with fresh rectal bleeding (non-physician endoscopy); rectal bleeding, weight loss, altered bowel habit, positive family history (physician endoscopy)
Basnyat[21]	NPE	between 40 and 70 years of age with rectal bleeding
DiSario[22]	NPE physician	persons at average risk for CRC*
Duthie[23]	NPE	patients with colorectal symptoms
Eisemon[24]	NPE	persons at average risk for CRC
Goodfellow[25]	NPE	patients with colorectal symptoms
Gruber[26]	NPE	persons at average risk for CRC
Jain[27]	NPE	persons at average risk for CRC
Levin[28]	NPE physicians	persons at average risk for CRC
Maule[29]	NPE physicians	>45 years of age, asymptomatic
Palitz[30]	NPE physicians	persons at average risk for CRC
Schoen[20]	NPE physicians	persons at average risk for CRC
Schoenfeld[31]	NPE physicians	persons at average risk for CRC
Schoenfeld[32]	NPE physicians	persons at average risk for CRC
Schroy[33]	NPE	persons at average risk for CRC, or >40 years of age with family history
Shapero[34]	NPE	persons at average risk for CRC
Wallace[35]	NPE physicians	persons at average risk for CRC

* Persons at average risk: >50 years of age, asymptomatic, no hereditary predispositions for CRC

APPENDIX 4: Training Program for Non-Physician Endoscopists

Study	Training Program
Arumugam[19]	Nurse practitioners; didactic sessions, observations of FS examinations, competence on the colon models, 35 supervised sigmoidoscope withdrawals, 35 supervised full examinations
Basnyat[21]	An experienced nursing sister with 13 years experience in the endoscopy unit: 40 supervised complete examinations and 40 examinations performed independently
DiSario[22]	Gastrointestinal assistants; didactic sessions, written and video materials, familiarity with plastic colon models; 10 minutes permitted for insertion and 10 minutes for withdrawal; deemed proficient when on two consecutive occasions, study completed beyond 45 cm within 20 minutes, all anatomic landmarks and pathologic lesions identified (objective criteria), thoroughness achieved, and no assistance needed (subjective criteria)
Duthie[23]	Nurse practitioners; didactic sessions, observations of FS examinations, competence on colon models, 35 supervised sigmoidoscope withdrawals, 35 supervised full examinations
Eisemon[24]	Registered nurse; didactic sessions, supervised examinations, 50 independent complete examinations
Goodfellow[25]	Nurse practitioner; didactic sessions, 35 observations, 35 withdrawals, and 35 supervised full procedures
Gruber[26]	Clinical nurse specialist; deemed competent for independent examinations after 20 supervised sigmoidoscopic procedures
Jain[27]	Registered nurses; minimum of 50 supervised FS before independent examinations
Levin[28]	Nurses and physician assistants; training unreported
Maule[29]	Registered nurses and nurse practitioners; 35 observation trials, 30 withdrawal, and 35 supervised complete examinations during three to five weeks
Palitz[30]	Nurse practitioners: from 50 to 100 supervised examinations
Schoen[20]	Nurse practitioners: training unreported
Schoenfeld[31]	Registered nurse of gastrointestinal units: 100 supervised, insert ≥50 cm, complete within 15 minutes, ≥50 independent full examinations
Schoenfeld[32]	Registered nurses: 100 supervised examinations
Schroy[33]	Nurse practitioners: 25 examinations
Shapero[34]	Gastrointestinal assistants: supervised examinations (no number reported); 50 independent examinations
Wallace[35]	Nurse practitioners, physician assistants: minimum 100 supervised examinations