

# Registered Nurse-Performed Flexible Sigmoidoscopy

**2013** Implementation and Outcomes  
of the Ontario Pilot Project



*Institut national  
de santé publique*

Québec 



**Ontario**

Cancer Care Ontario  
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# Foreword

Colorectal cancer (CRC) is the second leading cause of mortality from cancer in Québec and in Ontario. In both provinces, population-based screening programs have been established to address this silent killer.

The Ontario program, known as ColonCancerCheck (CCC), was launched in April 2008 and is administered by Cancer Care Ontario (CCO). In Québec, the Ministry of Health and Social Services (MSSS) is working on implementing the Programme Québécois de dépistage du cancer colorectal (PQDCCR). CCC recommends biennial screening in average risk people aged 50 to 74 using the guaiac fecal occult blood test (gFOBT), followed by colonoscopy for those with an abnormal FOBT. For those at increased risk because of a family history, colonoscopy is advised. For the Québec program, the modalities will be similar, but the screening test chosen will be the fecal immunochemical test (FIT). CCC is also evaluating implementation of FIT.

New screening technologies must also be appraised as they become available and clinical trial results are published. Recently, the results of multicentre randomized controlled trials on flexible sigmoidoscopy (FS) as a CRC screening procedure generated strong interest in Québec. The Québec Ministry of Health mandated the Institut national de santé publique du Québec (INSPQ) to provide a policy assessment on the use of screening flexible sigmoidoscopy. Such assessment includes a comparative analysis with other provinces.

Under CCO's leadership, a pilot project of registered nurse-performed screening FS was initiated in 2007. Based on the evaluation of this pilot, it will be potentially expanded and integrated into CCC. INSPQ approached CCO in 2011 to better understand the Ontario experience using screening flexible sigmoidoscopy. INSPQ's interest was to secure documentation relevant to successful implementation of registered nurse-performed flexible sigmoidoscopy to assist in planning in Quebec. As a result, a formal agreement between INSPQ and CCO was reached in 2012. It included a financial contribution from INSPQ to assist CCO to assemble and summarize relevant materials that would help inform a series of questions that would be of interest for a Quebec audience composed of policy-makers, health administrators, health professionals and nurses. These questions fit seamlessly with CCO's desire to more fully document what was learned and have served to enrich the dialogue on nurse-led FS.

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# Abbreviations

<b>CCO</b>	Cancer Care Ontario
<b>CHC</b>	community health centre
<b>CMPA</b>	Canadian Medical Protective Association
<b>CNO</b>	College of Nurses of Ontario
<b>CPSO</b>	College of Physicians and Surgeons of Ontario
<b>CSGNA</b>	Canadian Society of Gastroenterology Nurses and Associates
<b>CRC</b>	colorectal cancer
<b>FIT</b>	fecal immunochemical test
<b>FOBT</b>	fecal occult blood test
<b>FS</b>	flexible sigmoidoscopy
<b>gFOBT</b>	guaiac fecal occult blood test
<b>ICES</b>	Institute for Clinical Evaluative Sciences
<b>INSPQ</b>	Institut national de santé publique du Québec
<b>NP</b>	nurse practitioner
<b>OHIP</b>	Ontario Health Insurance Plan
<b>OCR</b>	Ontario Cancer Registry
<b>OMA</b>	Ontario Medical Association
<b>MOHLTC</b>	Ministry of Health and Long Term Care
<b>PCP</b>	primary care providers
<b>RPN</b>	registered practical nurse
<b>RN</b>	registered nurse
<b>RNAO</b>	Registered Nurses' Association of Ontario
<b>RNFS</b>	registered nurse-performed flexible sigmoidoscopy

# Executive Summary

## BACKGROUND

Screening is one of the most effective means to reduce the burden of colorectal cancer (CRC). In Canada this burden is particularly high and CRC represents the second greatest cause of cancer-related deaths. There are several different modalities that may be used for CRC screening that allow for detection of cancer at an earlier and more treatable stage, thereby reducing mortality. Some screening modalities further permit detection and removal of lesions before they become cancerous, thereby reducing incidence as well; flexible sigmoidoscopy (FS) is one of these. FS is an endoscopic procedure which allows direct visualization of the rectum and the distal portion of the colon, allowing for detection of polyps and tissue sampling. This screening modality is highly effective and empirical evidence suggests that FS may reduce the incidence and mortality of CRC by approximately 33% and 43%, respectively. Furthermore, FS may be performed out-of-hospital and by non-physicians, thereby presenting valuable opportunities to potentially reduce costs and improve endoscopic capacity for screening.

Based on formative work from 2005 to develop a nurse flexible sigmoidoscopy training program, a registered nurse-performed flexible sigmoidoscopy (RNFS) pilot project was launched in 2007 by Cancer Care Ontario (CCO). The experience of planning and implementing this project has been highly informative, and has provided a number of key lessons. The purpose of this report is to document the history, key issues, main outcomes and costs of the RNFS pilot project in Ontario. Findings will be used to support new and ongoing initiatives in Canada to deliver FS and reduce the burden of CRC.

## METHODS AND SCOPE

This report was developed by Cancer Care Ontario, in collaboration with the Institut national de santé publique du Québec, and was informed by the analysis of project documents and interviews with individuals in the RNFS pilot project and Cancer Care Ontario. The scope of this document covers the history of the project from 2005 to 2012.

## KEY FINDINGS

There have been a number of valuable findings that have been drawn from Ontario's experience in piloting RNFS.

**These findings have been consolidated into a series of considerations for developing FS programs:**

- 1 Alignment with broader federal and/or provincial strategic plans can help facilitate the process of designing and implementing a new model of care.
- 2 Seeking a wide range of stakeholder input early on in the process can help improve acceptability of the project, and facilitate a smooth transition from project planning to project implementation.
- 3 Clear and consistent messaging regarding colorectal cancer screening to both the public and providers (in particular family physicians) can help ensure appropriate and adequate use of registered nurse-performed flexible sigmoidoscopy.

- 4 Because many providers still prefer to refer patients for colonoscopy, in the absence of clear guidelines, consideration of local capacity for colonoscopy can help improve uptake of RNFS by choosing sites based on local need (i.e., choosing sites with limited access to other screening services can effectively target areas of need and improve the overall screening capacity of the community with implementation of RNFS).
- 5 Leveraging existing relationships with primary care providers and/or existing referral mechanisms can be effective ways of improving RNFS referral rates.
- 6 Careful consideration of the methods used to refer patients to the project can help ensure adequate volumes by focusing on reducing the impact on the workflow and workload of the referring primary care providers.
- 7 If RNFS is to be offered in hospitals, strong and committed host hospital leadership is necessary to support the ongoing success and maintenance of RNFS.

## CONCLUSIONS

Ontario's RNFS pilot project has demonstrated the feasibility of an expanded role for registered nurses to improve the province's screening capacity for colorectal cancer. The first of its kind in Canada, the RNFS pilot project can provide guidance to other jurisdictions considering similar programs.

# Purpose of the Report

The purpose of this report is to document the history, design and lessons learned from the registered nurse-performed flexible sigmoidoscopy (RNFS) pilot project in Ontario.

This report was developed by Cancer Care Ontario (CCO) in collaboration with the Institut national de santé publique du Québec (INSPQ). Data collection and analysis were qualitative, and conducted through key informant interviews and document analysis. Documents were selected based on the authors' knowledge of the RNFS pilot project, key informant recommendations and follow-up of references contained within other documents. Interview data were collected from stakeholders involved in the development or management of the project.

**The scope of this report includes the various stages of implementation of Ontario's pilot project from the year 2005 to 2012, including:**

- 1 The initial pilot study funded by the Change Foundation in 2005 to examine registered nurse-performed FS and develop a training program (hereinafter referred to as the "Change Foundation study")
- 2 Development of the design of CCO's RNFS pilot project (hereinafter referred to as the "RNFS pilot")
- 3 Implementation of the RNFS training program and setting up of the operational sites
- 4 Evaluation of the RNFS pilot and lessons learned

Specific areas of focus for this work include consideration of legal issues, training and regulatory requirements, remuneration matters, endoscopic interventions, social factors, costs, success factors and barriers.

This work was conducted for the purpose of sharing experiences and lessons learned in developing flexible sigmoidoscopy pilot programs. The information may be used to support initiatives related to nurse-led flexible sigmoidoscopy and support ongoing efforts to reduce mortality due to colorectal cancer in Canada.

# History of the Project

Colorectal cancer (CRC) represents a significant burden of disease in Ontario. In 2012, an estimated 8,700 Ontarians were diagnosed with colorectal cancer and an estimated 3,450 died from the disease<sup>1</sup>. Fortunately, there is strong evidence to support population-based screening for colorectal cancer to detect the disease at an early stage and improve prognosis<sup>2</sup>.

A number of different screening options are available, including guaiac fecal occult blood test (gFOBT), fecal immunochemical test (FIT), flexible sigmoidoscopy (FS), and colonoscopy. In 2001, the Canadian Task Force on Preventive Health Care released a recommendation stating that asymptomatic individuals with average risk of developing colorectal cancer should be screened by either fecal occult blood testing (grade A recommendation) or flexible sigmoidoscopy (grade B recommendation)<sup>3</sup>.

Flexible sigmoidoscopy has a number of distinct advantages over other screening options. Unlike fecal-based tests, FS allows for the direct visualization of the rectum and distal portion of the colon. Similar to colonoscopy, it also allows for direct polyp detection and tissue sampling (biopsy). Unlike colonoscopy, however, FS involves less patient preparation, does not require sedation and is associated with fewer risks to the patient, including reduced risk of bowel perforation<sup>4</sup>. Non-physicians, such as nurses, may also effectively perform the procedure in an office or out-of-hospital setting. Nurse-led flexible sigmoidoscopy

programs have been in place for many years in several jurisdictions around the world, including the United States and the United Kingdom (UK). Studies conducted at these sites have demonstrated no clinically significant differences between nurses and physicians performing FS in terms of missed polyps or complication rates<sup>5-10</sup>. These studies have also found FS performed by nurses to be cost-effective and acceptable to patients<sup>7, 10-12</sup>.

Building on the recommendation from the Canadian Task Force on Preventive Health Care, the Institute for Clinical Evaluative Sciences (ICES) released a report in 2004 examining practice patterns for colonic evaluation procedures and their associated resources to help inform the discussion on implementing a population-based CRC screening program in Ontario<sup>13</sup>. Like many jurisdictions, Ontario faced issues of limited capacity for endoscopy services, particularly for organized screening, which was highlighted in the report. As such, one of the recommendations from ICES was to investigate the feasibility of FS performed by non-physicians<sup>13</sup>. In response to this, the Cancer Quality Council of Ontario established the Ontario Task Force on Large Bowel Endoscopic Services. After an evaluation of the existing regulatory framework (i.e., the Regulated Health Professions Act and the Nursing Act), the Task Force found FS to be within the scope of practice for registered nurses<sup>14</sup>. The final outcome of the task force report was a recommendation that the Ministry of Health and Long-Term Care (MOHLTC) support Ontario in developing a pilot project to evaluate the uptake, access, and performance of registered nurse-performed flexible sigmoidoscopy (RNFS)<sup>14</sup>.

In 2005, grant funding to develop and evaluate a nurse flexible sigmoidoscopy training program in Ontario was obtained from the Change Foundation. The Change Foundation study involved experts from Cancer Care Ontario (CCO), the University of Toronto, Princess Margaret Hospital, and what was then called Sunnybrook and Women's College Health Sciences Centre. Feedback from international experts in RNFS in the United States and the United Kingdom helped refine the training curriculum and assessment criteria, which were piloted with six nurses from two sites<sup>15</sup>. The Change Foundation study was clearly formative, laying the foundation for implementation of a provincial RNFS pilot. Details of the training program are provided under the Training Considerations section of this report.

Near the end of the Change Foundation study, HealthForceOntario, a collaborative initiative involving the MOHLTC and the Ministry of Training, Colleges and Universities, was established to help address Ontario's health human resource. A key component of the HealthForceOntario strategy is "establishing innovative, new health care professional roles in areas of high need," including expanded roles for nurses<sup>16</sup>. This initiative, along with the growing evidence and increasing demand for colorectal cancer screening, created an opportunity for change and, at the end of 2006, the MOHLTC and CCO entered into an agreement to establish an RNFS pilot in Ontario<sup>17</sup>.

It should be noted that at the beginning of the RNFS pilot, CCO was already developing a new organized population-based colorectal cancer screening program utilizing FOBT as the screening tool for average risk Ontarians, supported by high-quality evidence. At this point in time, evidence for the efficacy of FS was still building, and CCO, in partnership with the MOHLTC, had successfully piloted opportunistic colorectal cancer screening with primary care providers using FOBT<sup>18</sup>. Because there had been pressure on the system to develop a population-based colorectal screening program for some time<sup>19, 20</sup>, the MOHLTC and CCO moved ahead with ColonCancerCheck in 2008. The timing of this program alongside the RNFS pilot project introduced challenges to the success of the pilot project. These challenges will be discussed in further detail in the last section of this report.

Ontario's RNFS pilot project has now been in place since 2005. In 2009, a request was made to the MOHLTC for funding to continue the pilot project and expand the number of sites. Another expansion was then made in 2010. Currently, the RNFS pilot is in a state of transition. Efforts to support and strengthen the pilot are underway (e.g., by focusing on certifying nurses at current sites) with the expectation that the pilot may expand the number of sites and transition into the ColonCancerCheck program in the coming years. Additionally, since 2009, the results of four FS randomized controlled trials have also been released, which have made significant contributions to the FS evidence base<sup>21-24</sup>. This includes the landmark trial by Atkin and colleagues in the UK, which found a 23% reduction in colorectal cancer incidence and a 31% reduction in colorectal cancer mortality at 11 years of follow-up

after once-only FS<sup>21</sup>. CCO's Program in Evidence-Based Care (PEBC) is reviewing the evidence base on CRC screening to develop practice guidelines for colorectal cancer screening, including the role of FS.

**Since its inception, the RNFS pilot has undergone two evaluations for the purposes of:**

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- 1 Evaluating the educational component of the training program from the perspective of the participating nurses
- 2 Assessing the feasibility and acceptability of implementing and operating nurse-led FS clinics through interviews with local project teams
- 3 Evaluating the processes used to refer patients to the RNFS pilot
- 4 Assessing the needs of nurses with regards to maintenance of competency<sup>17,25</sup>

The results of these evaluations and the experience of designing and implementing this project provide valuable insight into the benefits and challenges of RNFS in a Canadian context. Based on the experience in Ontario, it is apparent that RNFS may also be a feasible option to reduce the burden of colorectal cancer in other provinces.

# Pilot Design

The registered nurse-performed flexible sigmoidoscopy (RNFS) pilot project is a partnership between Cancer Care Ontario (CCO) and the Ministry of Health and Long-Term Care (MOHLTC) Nursing Secretariat. Building on the Change Foundation study that developed the training program, the RNFS pilot was formally launched in 2007 with a goal of testing the feasibility of introducing an expanded role for registered nurses within an interdisciplinary care model<sup>17</sup>.

The objectives of the pilot project were to<sup>26</sup>:

- 1 Increase screening capacity for colorectal cancer
- 2 Develop a distributed training program for RNFS (i.e., the majority of the training program takes place at the nurses' home sites)
- 3 Identify and understand the factors that contribute to the success of establishing RNFS sites
- 4 Develop strategies to ensure that FS screening is sustainable after the pilot project is completed
- 5 Develop a plan to roll out RNFS sites in other areas of the province

## OVERVIEW OF THE RNFS PILOT PROJECT DESIGN

Ontario's RNFS pilot has evolved to meet the various needs associated with the development, implementation, and ongoing maintenance and evaluation of the project. The RNFS pilot has been managed by CCO, with support from the MOHLTC Nursing Secretariat, and the Health Services Branch<sup>27</sup>. Because the pilot was the first of its kind in Canada, there were unique challenges to be addressed in relation to governance and stakeholder involvement.

Early in the pilot, a CCO Leadership Team was assembled to monitor the progress of the pilot and resolve issues as they arose. For instance, operational decisions, such as what polyp size nurses should be able to biopsy, or how to effectively promote the pilot to family physicians were topics that were addressed through this forum. Membership on the Leadership Team varied over the years, starting with representatives from CCO, the MOHLTC, clinical nursing and gastroenterology<sup>28</sup>, and later evolving to include the vice-president of Prevention and Cancer Control, the director of Integrated Cancer Screening, an educational lead, the provincial head of nursing and psychosocial oncology, and the RNFS pilot project manager<sup>27</sup>. Originally the Leadership Team met monthly to discuss the RNFS pilot. Because the pilot is past the development stage, the meetings have ceased.

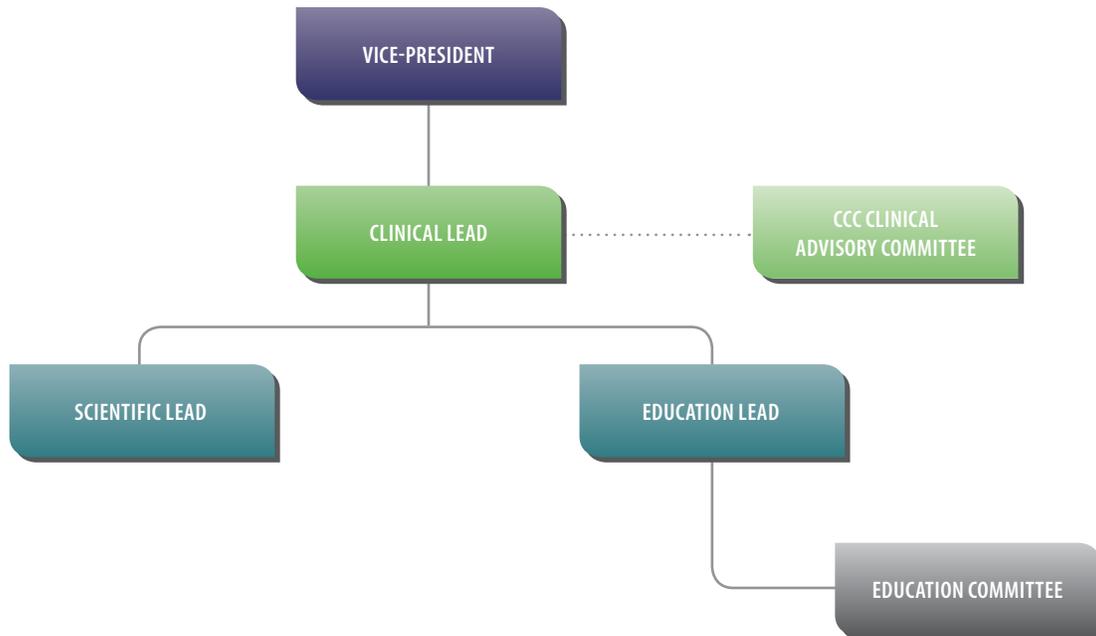
Also during the initial development of the RNFS pilot, the CCO Leadership Team regularly collaborated with a multidisciplinary stakeholder advisory committee, including representatives from The College of Nurses of Ontario, the Registered

Nurses' Association of Ontario (RNAO), the Canadian Society of Gastroenterology Nurses and Associates (CSGNA), the Institute for Clinical and Evaluative Sciences (ICES), the Ontario Association of Gastroenterology, the Ontario Medical Association (OMA), the Canadian and Ontario Associations of General Surgeons, and primary care physicians. The advisory committee provided advice, information and expertise for the implementation and operation of the RNFS pilot<sup>29</sup>. Ongoing collaboration with external stakeholders was also used to discuss and address concerns, and keep all interested parties updated on the status of the pilot and problems as they arose. For instance, expertise and feedback was sought from the advisory committee in regards to the implementation of medical directives within the

hospitals. Involvement of the external stakeholders was also crucial for generating the engagement essential for this multidisciplinary initiative. Because the pilot sites are now established, and all initial stakeholder concerns have been addressed, the multidisciplinary stakeholder advisory committee no longer has a formal role.

As the RNFS pilot moves to become a formal program, a clinical team consisting of the vice-president of Prevention and Cancer Control, a colonoscopy clinical advisor, as well as an education lead and a scientific lead, with support and feedback from the ColonCancerCheck Clinical Advisory Committee will be responsible for oversight and expansion of the program (Figure 1).

FIGURE 1 | Clinical Governance Structure of the registered nurse-performed flexible sigmoidoscopy (RNFS) program

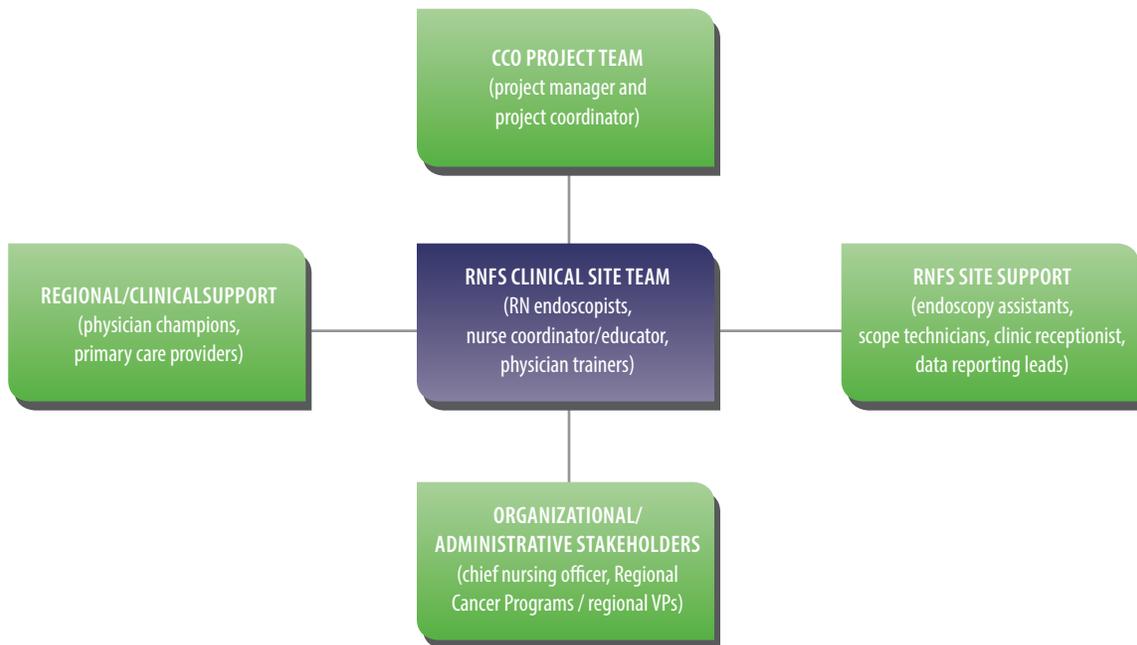


Within CCO there is also a project team consisting of the project manager and the project coordinator, who provides support to the sites for the ongoing maintenance of the project (Figure 2). CCO’s RNFS project team provides support for new sites with a standard tool kit, including a step-by-step guide to launching the project within their own site<sup>26</sup>. The tool kit also includes information on processes, clinical algorithms for referrals, and examples of letters and forms, along with position descriptions for hiring necessary staff, sample letters to primary care providers, sample referral forms, information brochures for patients and sample medical directives<sup>26</sup>. The RNFS project team also coordinates the use of a secure online website to share project information with and between RNFS sites. Information contained on this website includes

educational materials for physicians and patients, invitation and referral templates, published articles and abstracts, marketing materials and a calendar to organize meetings. Regular meetings are held with nurses via teleconference or videoconference, allowing for sharing of experiences and discussion of questions. The project team also coordinates bimonthly meetings with nurse educators/ coordinators and nurse endoscopists to support them in their activities. During these meetings, the coordinators are encouraged to update others on progress at their sites. Patient recruitment methods are also discussed in depth. The CCO project team also facilitates mentoring opportunities for new sites to learn from experiences of operational sites.

Additionally, CCO has facilitated the development

FIGURE 2 | RNFS organizational structure



of two communities of practice that focus on RNFS priorities. Within both communities of practice, a select number of registered nurses (RNs) from the RNFS sites are invited to collaborate and address key issues and improvement opportunities to enhance the RNFS pilot project. These two groups are focusing on improving the Patient Experience survey and standardizing operational tools respectively.

Within each site, the RNFS team itself is collaborative and multidisciplinary. It is comprised of three main roles, which are: (1) a nurse coordinator/educator to oversee the administration of the project and patient recruitment; (2) registered nurse endoscopist to perform flexible sigmoidoscopy procedures; and, (3) physician trainers who guide nurses' training and provide back-up clinical support. Additionally, sites are expected to employ a range of support staff necessary for the usual functioning of an endoscopy facility<sup>15</sup>. The activities of each pilot site are further supported by a broader base of stakeholders: physician champions and primary care providers to support patient recruitment; data reporting leads; chief nursing officers; and administrative officials within the Regional Cancer Program, who provide guidance and institutional support (Figure 2).

**The RNFS nursing roles are comprised of three primary functions<sup>25</sup>:**

- 1 Project coordination
- 2 Patient education
- 3 Performing FS

Nurses' roles vary depending on the organizational

preference of the site, such that some may be involved in all three functions, while in other sites these roles may be split by different nurses. In the majority of cases, nurses' roles are divided between the RN endoscopist and the nurse coordinator (either an RN or RPN) who focuses exclusively on outreach, coordination and patient education<sup>25</sup>. Additionally, some sites may choose to split the nurse coordinator role into 0.6 FTE coordinator and 0.4 FTE educator<sup>26</sup>. CCO funds the nurse coordinator/educator role at 1.0 FTE for the first year and at 0.8 FTE for following years<sup>26</sup>.

As the cornerstone of RNFS, the RN endoscopist must be strongly motivated and bring to the site a willingness to expand his/her role and take on new challenges. It has been standard practice to recruit RNs' with a minimum of five years' experience in acute care and two years' endoscopy experience (e.g., as an endoscopist assistant), with the majority of RNs recruited from their hospital's endoscopy unit<sup>25</sup>.

Nurse coordinator/educators are responsible for a variety of tasks, including administrative support, community outreach, marketing, patient recruitment and patient education. These individuals arrange and lead meetings with primary care providers, nurse practitioners and other stakeholders to encourage support for screening with flexible sigmoidoscopy (FS). They also liaise with coordinators at other sites, as well as CCO's project manager to contribute ideas and information and to participate in data sharing as part of the site's evaluation strategy.

The nurse coordinator/educator is responsible for recruitment of eligible patients and advises the RN endoscopist within the site of a patient's eligibility. Finally, coordinator/educators

are responsible for the education of patients booked for FS.

The physician trainer role is highly important at each site. Physician trainers are either gastroenterologists or surgeons. They supervise the nurses as they assume increasing independence in performing FS and provide valuable feedback to improve performance. Furthermore, as each RNFS site becomes operational, the trainer assumes the role of the back-up physician for the RNs during all FS procedures, and must be available to provide immediate advice or support if needed. These physicians act as mentors for nurse endoscopists.

Each site is also required to appoint a data reporting lead. In some cases this has been the nurse coordinator/educator, while in other cases hospitals have given this role to a person who was already responsible for providing data. All elements of required data collection are outlined in the agreements between each site and CCO. These include details of the site's recruitment activities relating to eligible patients, the number of nurses participating at the site in the project, financial reports, clinical activity reports detailing the volume of procedures for both the independent and training phases, such as duration of the procedure, polyp detection and the occurrence of complications<sup>30</sup>. See **Appendix A** for a full list of data reporting elements. At this point in time, sites do not report follow-up data or cancer detection rates.

Upon becoming part of the RNFS pilot project, data reporting leads have been required to participate in training sessions with the Informatics Department at CCO to review the reporting process. CCO

collects RNFS data on a monthly basis. A summary of the site-level data is shared with all sites for benchmarking purposes on the secure online site hosted at CCO. This information includes the number of training and independently-performed FS procedures by site. The Informatics Department also reports summary information to the MOHLTC on a quarterly basis, including the number of RN endoscopists and the status of training per site, the number and types of procedures (training or independent) per RN endoscopist, the total volume per site, the average rate of polyp detection per site, the average duration of the procedure per site, the occurrence of complications per site, the insertion depth by site, and description of "other" findings<sup>31</sup>.

Only sites with existing endoscopy facilities have been selected for the RNFS pilot. In addition to the above roles, it is expected that these sites also employ the necessary support staff to run an endoscopy facility safely and efficiently. This includes an endoscopy assistant who assists the RN endoscopist during the procedure, playing an important role in the efficient and effective handling of the sigmoidoscope. Endoscope technicians are also necessary to reprocess the sigmoidoscopes in automated scope washing machines. Clinic receptionists may also be required to schedule procedures and receive patients upon arrival at the hospital<sup>15</sup>. The number of support staff required varies among sites depending on available clinic space, patient volumes and clinic organization.

Finally, sites are encouraged to appoint physician champions who are responsible for marketing and promoting the project to primary care providers, both within their organizations and within the

broader regions. This may include attending lunch-and-learn sessions and site visits to family physician offices organized by the RN coordinator. Physician champions are highly valuable to engage the community with the RNFS pilot project and support patient recruitment for RNFS screening. Physician champions may be gastroenterologists or surgeons within the host institutions who support the project by encouraging other providers to refer to the program, or may be primary care providers within the regions themselves. The RNFS pilot project was also able to leverage the Regional Primary Care Leads (RPCLs) as physician champions. The RPCLs represent a network of family physicians supported by CCO to promote screening activities within their respective regions and so were ideally poised to be leveraged to support the RNFS pilot project.

## IMPLEMENTATION AND TIMELINE

In terms of implementation, Ontario's RNFS pilot project was phased-in. Recruitment for the first six pilot sites began in late 2006 and early 2007. At each site, one to three nurses were recruited for the project, for a total of 13 nurses in the first cohort of trainees in 2007<sup>17</sup>. The initial six sites were chosen based on past collaborations. CCO delivered a presentation and provided information on the proposed pilot project to sites that had expressed interest in the initiative. Those sites interested in RNFS were then interviewed by the CCO RNFS team and invited to participate.

By 2009, nurses from two sites had completed their training targets and had begun performing independent FS. At that point it was decided that only those sites that had nurses who had completed their clinical evaluation and had medical directives in place would continue to be funded<sup>17</sup>. Of the six initial sites, three sites were eligible and interested in maintaining involvement in the project. These sites received additional funding to continue activities for one year<sup>17</sup>. The other three sites discontinued activity as of June, 2009<sup>17</sup>. The main reason why sites were discontinued was lack of adequate referrals.

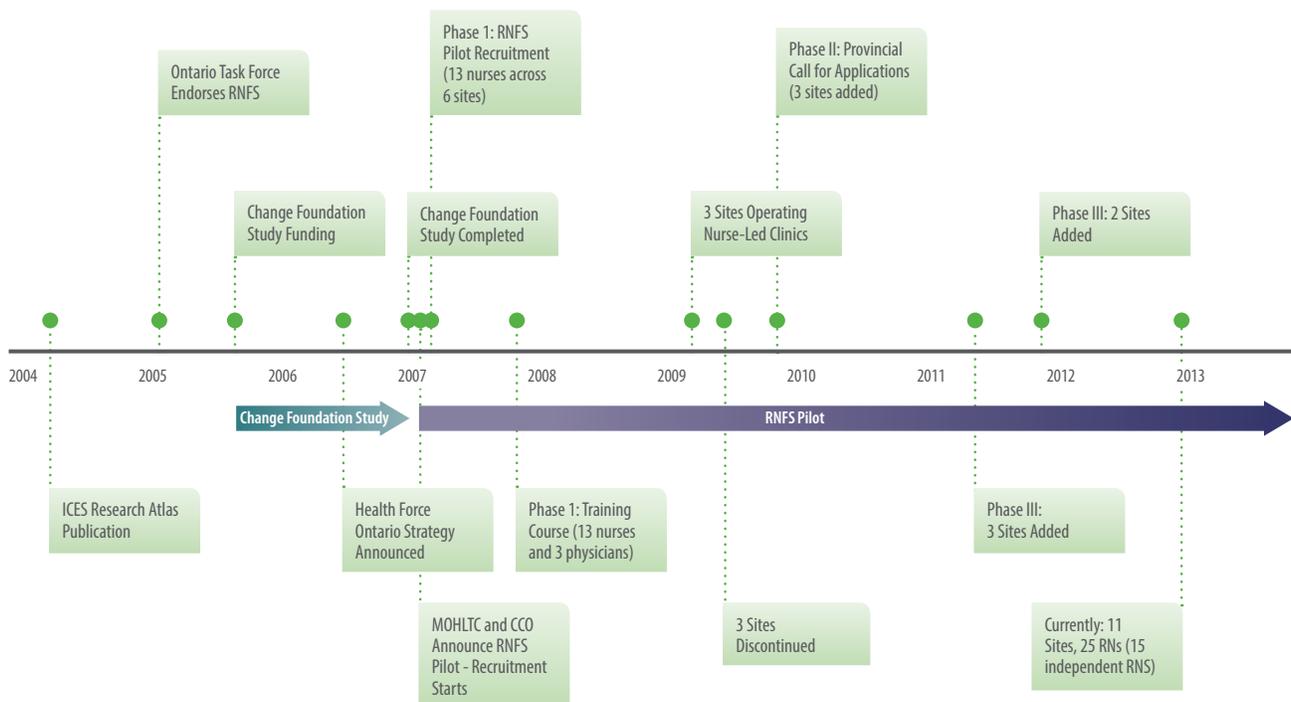
Learning from the successes and challenges experienced by the first six sites, a provincial call for applications was then made to add sites to the pilot project using a more formal evaluation process. Site readiness assessment templates were developed to help guide this process. The templates included questions regarding organizational vision, physician leadership, senior administrative support, availability of nurses, foreseeable challenges in recruiting

nurses, plans for ensuring key positions were filled (physician trainer, coordinator, endoscopy assistant, scope technicians, clinic reception), strategies/volumes/anticipated problems in recruiting patients, process to be used to register patients, process for patient follow-up, equipment availability, anticipated timelines and in-kind contributions. As a result of this process, three additional sites were chosen. Since 2009, five additional sites have been recruited to participate (see **Figure 3** and **Figure 4**). Further to this, the Regional Cancer Programs are now involved in identifying appropriate RNFS sites where increased access to screening can be provided in communities

with low screening rates. Sites were evaluated by CCO’s Provincial Head, Nursing and Psychosocial Oncology and asked to fill out the Site Readiness Assessment Templates. CCO is also in the process of establishing additional site eligibility criteria for further expansion based on the lessons learned.

As of November 2012, 11 sites are operational. Within these sites there are 11 registered nurse coordinator/educators, 25 registered nurses performing flexible sigmoidoscopy (of which 15 are independent) and 30 physician trainers/back-up support physicians.

FIGURE 3 | Timeline of registered nurse-performed flexible sigmoidoscopy (RNFS) pilot in Ontario

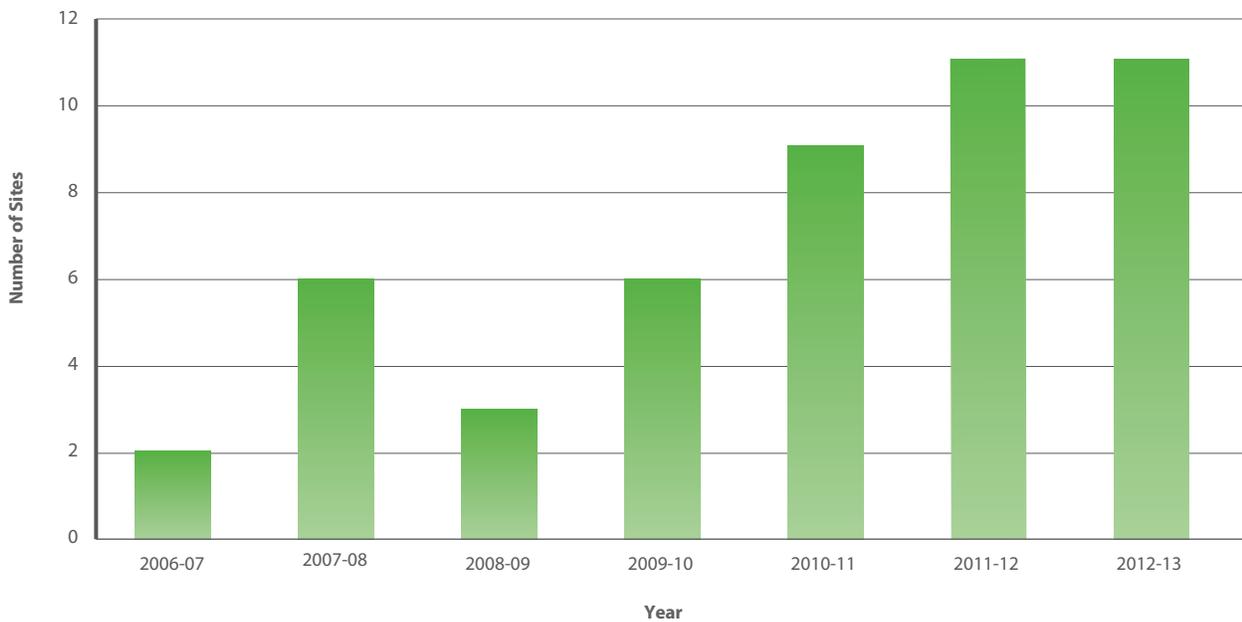


**Within the pilot sites themselves, a three-stage process of implementation is used:**

- 1** The planning stage
- 2** The training stage
- 3** The 'operational' stage

During the planning phase, each site must recruit the members of the multi-disciplinary FS team, initiate clinical training by scheduling observation of FS procedures and develop a program infrastructure. Efforts also begin in this phase to recruit patients. When the planning phase is complete, RNs and physician leads proceed to introductory clinical training, which, to date, has been hosted at the Michener Institute for Applied Health Sciences in Toronto. During this week-long course, nurses are introduced to FS using simulators. Physicians receive a day-long “train-the-trainer” course. Training then continues at the pilot sites with

**FIGURE 4 | Registered nurse-performed flexible sigmoidoscopy (RNFS) pilot project site participation**



nurses performing 25 partial (scope withdrawals only) and 50 full FS procedures under physician supervision. The clinical training phase is complete when nurses complete a minimum of 100 procedures (25 observations, 25 withdraws and 50 full procedures) and pass an independent assessment of competency (see Training Phase section below for further details). Additionally, in accordance with the College of Nurses of Ontario's (CNO's) *Decisions about Procedures and Authority* practice standard, the nurses must be able to reflect on their own practice to ensure that “they are competent in both the cognitive and technical aspects of a procedure prior to performing it.”<sup>32</sup> After meeting these requirements, the nurses are then considered competent for independent performance of FS and sites then move into the operational phase.

In the operational phase, registered nurses perform FS without direct supervision by the physician trainer. However, the physician trainer is required to be available (i.e., in the building and accessible at all times) should the nurse require any assistance during the procedure. Indications for requesting assistance from the physician are taught to nurses during the week-long training course. In general, a nurse may request assistance from the back-up physician if he/she is having technical difficulty with the procedure. The back-up physician must be summoned if a significant complication has occurred, such as bowel perforation or severe bleeding. **Appendix B** provides a high-level overview of three phases of implementation.

# Pilot Implementation

## LEGAL CONSIDERATIONS

### Regulatory Framework and Delegated Medical Acts

Before implementing the registered nurse-performed flexible sigmoidoscopy (RNFS) pilot project, the 2005 Ontario Task Force on Large Bowel Endoscopic Services examined whether nurses were able to perform flexible sigmoidoscopy (FS) within the current regulatory framework in Ontario. Ultimately this group determined that under the Ontario Regulated Health Professions Act (1991) and the Nursing Act (1991), FS is within the scope of practice for registered nurses (general class) in Ontario (Table 1)<sup>33, 34</sup>.

The Nurse Flexible Sigmoidoscopy Site Agreement, which must be signed by Cancer Care Ontario (CCO) and the participating site, stipulates that the site must

provide a medical directive to authorize designated nurses (i.e., those who have completed the program and have demonstrated the required knowledge and skills) to perform flexible sigmoidoscopy, in accordance with the Regulated Health Professions Act (RHPA) (1991). This agreement also contains an official consent form for physicians, which outlines a requirement to participate in training, supervisory and back-up activity as per the project requirements.

At the start of the pilot, CCO developed a medical directive template for pilot sites. Sites could adapt this template or draft a directive to meet their own internal requirements<sup>34</sup>. The medical directives had to be developed in accordance with the policies of the participating institutions and are necessary in order for nurses participating in FS training to advance to an operational stage<sup>17</sup>.

TABLE 1 | Summary of regulatory framework for RN-performed FS

CRITERIA	RN PERFORMING FLEXIBLE SIGMOIDOSCOPY
<b>Authority to Perform Controlled Acts</b>	RNs have the authority through the current regulatory framework (RHPA, Nursing Act) to perform flexible sigmoidoscopy for assessment purposes.
<b>Communicating Assessment Findings</b>	FS and biopsy through the screening program will be performed for assessment purposes. RNs do not have the authority to communicate a diagnosis under the RHPA. All patients in whom a biopsy is performed would be referred to a physician who would communicate the results.
<b>Physician Availability</b>	To ensure the safety of patients undergoing these procedures, a physician must be available within the appropriate short time frame to assess and intervene as necessary. The RN would need to be knowledgeable about when and how to request the physician's assistance, and about necessary and appropriate interventions while awaiting the physician's arrival.
<b>Medical Directives</b>	A medical directive is a written order that may be implemented for a number of patients when specific conditions are met and when specific circumstances exist. Medical directives facilitate provision of care in the absence of direct assessment and order by a physician. A medical directive will be required for RNs to initiate and carry out both flexible sigmoidoscopy and biopsy (section 5(1) of the Nursing Act).
<b>Professional Liability Protection</b>	RNs working in a hospital setting and some other facilities (e.g., Community Health Centres) are covered under Healthcare Insurance Reciprocal of Canada (HIROC). Those RNs who are members of the RNO have \$1 million of occurrence-based liability coverage through the Canadian Nurses Protective Society (CNPS) and can obtain additional insurance through Nurse Insure or CNPS Plus.

Source: Ontario Task Force on Large Bowel Endoscopic Services. Increasing Colorectal Cancer Screening in Ontario through RN-Performed Flexible Sigmoidoscopy. Toronto, ON. Cancer Quality Council of Ontario, Cancer Care Ontario, 2005.

**The components of the medical directives are as follows<sup>35</sup>:**

- ▶ The name and description of the procedure(s)/ treatment(s)/intervention(s) being ordered
- ▶ Specific client clinical conditions and situational circumstances that must be met before the procedure(s) can be implemented
- ▶ Clear identification of the contraindications for implementing the directive
- ▶ The name and signature of the physician approving, and taking responsibility for, the medical directive
- ▶ The date and signature of the administrative authority approving the directive; for example, the Nursing Practice Council, the Professional Advisory Committee and/or the Medical Advisory Committee

The process for finalizing an institution's medical directive varies, and may create delays in progressing to the operational stage of the project<sup>17</sup> if not considered early in the site's pilot project involvement.

**Professional Liability and Legal Implications**

Over the course of the implementation of the RNFS pilot project, some physicians expressed concern over liability issues pertaining to nurse-performed FS and signing the medical directive at their institution without specific malpractice insurance<sup>17</sup>.

Cancer Care Ontario in conjunction with the MOHLTC's Nursing Secretariat sought guidance on liability issues from sources with relevant knowledge and background, including the Canadian Medical Protective Association (CMPA) and the Health Care Insurance Reciprocal of Canada (HIROC). Further, to help alleviate concerns and clarify roles and responsibilities, CCO and the MOHLTC collaborated with the Ontario Medical Association (OMA) to produce a document that provides guidance to physicians in the RNFS pilot about their roles and responsibilities and to assist in the understanding of liability concerns<sup>36</sup>. Physicians were also encouraged to inquire directly with the CMPA or their personal insurers if they had any additional concerns.

**Patient Consent and Withdrawal**

As the original Change Foundation study was considered a research project, ethics approval required that consent be obtained from all patient participants. This process was merged with the central patient booking system which was established specifically for this project. A study coordinator was responsible for contacting all patients referred to the RNFS pilot project to assess their eligibility. Patients meeting the eligibility requirements were invited to Cancer Care Ontario to review all aspects of the study, obtain written consent, and schedule the procedure. These meetings took place in person with the study coordinator. This was in addition to the procedural consent required at the actual time of procedure<sup>33</sup>. Patients were also informed that participation in the study was voluntary and they could choose to withdraw at any point and without consequence.

Once the RNFS pilot moved beyond the research project stage, the process for consent and withdrawal changed. In terms of consent, practices vary among sites. When a physician refers a patient to the RNFS pilot project, an initial consultation appointment with the nurse educator is booked to determine patient eligibility. The initial consultation may take place either in person or over the phone, depending on the site. All patients are provided with information regarding the procedure, as well as the risks and benefits, and informed that the procedure itself will be performed by a nurse. At this time, sites may request either oral or written consent from the patient, which is then documented. If written consent is not obtained at this time, however, it must be obtained by the registered nurse (RN) at the time of the procedure. Because the RNFS pilot is no longer a research project, there is no formal process for withdrawal; however, participants are able to cancel their appointment at any time and/or choose not to participate in screening FS.

In terms of data collection, CCO is a prescribed entity under the Personal Health Information Protection Act (PHIPA) under subsection (ss.) 18(1) PHIPA Regulation 329/04 and under ss. 45(1) and is permitted to collect, use and disclose personal health information (PHI) without consent for the purposes of management and planning of the health system as long as information practices are regularly approved by the Ontario Information and Privacy Commissioner (OIPC)<sup>37</sup>.

## TRAINING CONSIDERATIONS

Drawing from established training programs in the United States (US) and the United Kingdom (UK), the initial grant from the Change Foundation was used to develop a training, assessment and certification process for non-physician endoscopists<sup>33</sup>.

The resulting program is multifaceted, with comprehensive and collaborative training provided for nurse endoscopists, physician trainers and nurse coordinator/educators<sup>17</sup>.

### Training the Nurse Endoscopists

During the development of the original Ontario Task Force on Large Bowel Endoscopic Services report, the College of Nurses of Ontario was consulted to determine the necessary competencies RNs must possess to perform flexible sigmoidoscopies (see **Appendix C** for competency profile of RNs performing flexible sigmoidoscopy). Taking into consideration these required competencies, as well as other similarly developed training programs a curriculum was developed by Dr. Mary Anne Cooper (Sunnybrook Health Sciences Centre), Ms. Karen Gayman (Princess Margaret Hospital) and Ms. Angela Cuddy (The Michener Institute for Applied Health Sciences)<sup>15</sup>. The curriculum consists of an observational phase, a didactic education phase, a clinical training phase and a certification component (**Table 2**).

In the observational phase, nurses observe 25 flexible sigmoidoscopy procedures conducted by physician trainers at their home sites. This is followed by a

TABLE 2 | Overview of Ontario’s registered nurse-performed flexible sigmoidoscopy training program

TRAINING COMPONENT	DESCRIPTION	EVALUATION
<b>Observational</b>	Nurses must observe 25 pre-course FS procedures conducted by physician trainers at their home site.	No formal evaluation
<b>Didactic</b>	<p>A 1-week in-class training program at The Michener Institute for Applied Health Sciences. Course content includes:</p> <ul style="list-style-type: none"> <li>• Description of the expanded role for nurse endoscopists</li> <li>• Principles of effective patient education</li> <li>• Anatomy/physiology</li> <li>• Pathology of the colon</li> <li>• Flexible sigmoidoscopy (indications, contraindications, complications)</li> <li>• Patient education and follow-up</li> <li>• Dictation</li> <li>• Technical skills (hands-on practice with high-fidelity simulator)</li> </ul>	<p>Written examination</p> <p>Simulator feedback</p>
<b>Clinical training</b>	Nurses must complete at least 25 procedures in which they perform the withdrawal portion only, and 50 full FS procedures in which the nurse assumes increasing independence performing the entire procedure under physician supervision.	Feedback from physician trainer
<b>Certification</b>	Nurses must complete 5 full FS procedures assessed by two independent assessors contracted by CCO’s RNFS Project Team.	Observational assessment (clinical assessment for FS procedure and global rating scale/checklist)

week-long didactic and simulation training session, which, to this point, has been hosted at the Michener Institute for Applied Health Sciences in Toronto. The content of the didactic portion of the training includes an overview of the expanded role for nurses performing flexible sigmoidoscopy, general principles for effective patient education, anatomy of the gastrointestinal tract, pathophysiology related to the polyps-to-cancer sequence, common pathological

conditions of the colon, flexible sigmoidoscopy, patient education and follow-up, dictation, technical skills development using low-fidelity and high fidelity (Immersion Medical®) simulators, and a simulated patient experience<sup>38\*</sup>.

After completing this one-week course, RNs return to their home sites to continue clinical training. At this stage, nurses work closely with physician trainers and must perform 25 partial procedures

\* Course content reprinted with permission from: Cooper, M.A. & Gayman, K. *Flexible Sigmoidoscopy for Ontario Registered Nurses. Course Syllabus September 2007.* The Michener Institute for Applied Health Sciences. Course content and syllabus are property of Dr. Mary Anne Cooper and Ms. Karen Gayman and should not be reprinted in part or in whole without express written permission from the authors.

(endoscope withdrawals). In line with the current Society for Gastroenterology Nurses and Associates (SGNA) *Guideline for Performance of Flexible Sigmoidoscopy by Registered Nurses for the Purpose of Colorectal Cancer Screening*<sup>39</sup> and the *Ontario Medical Association's Statement on Nurse Sigmoidoscopist*<sup>40</sup>, nurses then perform 50 full procedures (insertion and withdrawal) under direct supervision of their physician trainer<sup>17</sup>.

The approach of having the nurse first observe 25 procedures, perform 25 FS withdrawals and perform 50 full FS, represents a combination of factors, including recommended numbers by professional organizations and the need for RNs to become comfortable with their new role. Nurses in the RNFS program at Kaiser Permanente California who were interviewed by the education lead during a site visit in 2004 highlighted the latter aspect. This need and these numbers were emphasized further during the Change Foundation study.

Once the clinical training goals are achieved, physician assessors with contracts from CCO visit the nurses' sites to evaluate them as they perform five procedures. There are two independent

physician assessors who are the education leads, Dr. Mary Anne Cooper and Dr. Catherine Walsh. Nurses are assessed based on the following criteria: their pre-procedure assessment, informed consent practice, preparation for the procedure, technical skills (insertion, handling, passage of scope, posture, visualization, insertion depth, biopsy or referral for colonoscopy as appropriate, etc.), knowledge (visualization and identification of polyps and other pathology, etc.), patient comfort and post-procedure care. A global rating checklist was developed to help guide this process. The nurse being evaluated meets with the evaluators directly following the assessment to receive feedback and his/her results. Nurses who pass this assessment receive a certificate of completion from the Michener Institute for Applied Health Sciences. While most nurses pass the independent assessment on their first attempt, this has not been true of all nurses, with some requiring additional supervised training before being re-evaluated and considered competent for independent practice.

For the first cohort of nurses, the median length of time required to complete the practical training (100 procedures) was 396 days<sup>17</sup> (Table 3). In the cases

TABLE 3 | Length of training period for first cohort of nurses

MILESTONE	LENGTH OF TIME (TOTAL DAYS)			
	MEAN	MEDIAN	MINIMUM	MAXIMUM
Completed 100 procedures (n=8)	439	396	193	876
Completed independent assessment (n=6)	511	467	354	807

Source: Rabeneck, L. et al. RN-Performed Flexible Sigmoidoscopy in a Pilot Project of Colorectal Cancer Screening - Evaluation Report 2007-2010. Cancer Care Ontario: 2010.

in which more time was required, progress was limited by patient recruitment, and the availability of both physician trainers and endoscopy time. After training, the median length of time required to arrange for assessment was 72 days due to challenges in scheduling the clinical assessment and arranging for travel to the project sites<sup>17</sup>.

From the beginning of the Pilot to November 2012, each RN has spent an average of 20 months in the training phase of the project before certifying for independent practice. The number of training procedures performed by RNs (withdrawal-only and full-procedures) ranges from 77 to 231, with an average of 140 procedures<sup>25</sup>.

### Training the Trainers

In order to promote standardized training across the sites, all physician trainers are required to participate in a training session, which occurs at the end of the nurses' week-long didactic and simulation course. The first two physician trainers in the Change Foundation study were also part of the curriculum development team and required no further training because they had a full understanding of all the components in the training program<sup>15</sup>. Recognizing that new physician trainers may not have experience training others (such as training and supervising medical residents), it was decided that these physicians must be supported in their role as mentors to enable them to enhance their teaching skills, share knowledge with other physicians in the program, and promote standardized training across all the sites<sup>17</sup>. The education lead of the RNFS pilot project, Dr. Mary Anne Cooper, attended a "train-the-endoscopic-trainer" course in the UK, which has

a well-established program to teach endoscopists to train others. Based on this experience, and an understanding of the Ontario context of the RNFS pilot project, Dr. Cooper developed a condensed version of the curriculum for the half-day "train the trainer" workshop with new physician trainers. The classroom component of the curriculum includes information on the RNFS pilot project, basic teaching skills and an overview of the physician trainers' role. At the end of the classroom component, physician trainers apply their newly gained teaching skills in drills with the nurse trainees. No evaluation or assessment of skills is required to complete physician training.

### Training the Nurse Coordinators

RNs or registered practical nurses (RPN) who are recruited to the role of nurse coordinator must attend a workshop in advance of the nurse endoscopists' one-week course. This workshop focuses on recruitment strategies, change management, physician engagement and lessons learned from existing sites<sup>41</sup>. At this workshop, RN coordinators are presented with a tool kit that contains resources for coordinators to get started on setting up the RN flexible sigmoidoscopy site. The tool kit includes useful information such as site readiness assessment checklists, a project plan, overviews of the various project phases, communication tools for patients and physicians, job description templates, and a number of other resources that have been developed over the life of the pilot project<sup>26</sup>.

### Continuing Medical Education

At the end of 2012, clear requirements for continuing education and maintenance of competency had

not yet been established. In a statement on nurse sigmoidoscopists, the OMA recommended that nurse competency be subject to annual review by an approved preceptor, and that annual updating of skills under the supervision of a physician trainer should be expected<sup>40</sup>. In addition, the College of Nurses of Ontario (CNO) encourages continuing competence of all nurses through their mandatory quality assurance (QA) program. The QA program requires that nurses assume responsibility for their own professional development through self-assessments, seeking peer input, developing and implementing a learning plan, and evaluating the outcomes of the plan<sup>42</sup>. CCO's Program in Evidence-Based Care (PEBC) is working with an expert panel to develop standards for colorectal cancer screening. As well, the RNFS Education Committee will be developing pedagogical guidelines and an educational plan for certification of the maintenance of competence. Once these new guidelines are released, CCO will develop a quality assurance program that will recommend quality standards for ongoing competency among nurses as well as other endoscopists performing flexible sigmoidoscopy. In the meantime, the educational lead for the pilot project is developing quarterly online refresher training courses for nurse endoscopists that began in November of 2012. Future continuing education strategies may also include online courses; participation in Canadian Society of Gastroenterology Nurses and Associates (CSGNA) conferences; participation in team meetings; and annual refresher sessions that coincide with the annual training program<sup>25</sup>.

## REMUNERATION CONSIDERATIONS

### Nurses' Remuneration

Initial deliberation on compensation models for nurses participating in this project involved consideration of international experience. In the UK, nurses are provided a 40% to 60% salary increase compared to general RNs to acknowledge their additional training and skill, while at Kaiser Permanente in the United States, no additional compensation is provided to nurses<sup>15</sup>. Ultimately, within the context of Ontario, it was determined that nurse endoscopists would remain full-time employees at their host institution throughout the training program and participate in the training program as an educational endeavour within their role as an RN. The hospital provides the salaries for the nurse trainees, as well as 0.2 FTE salary support for RNs to replace these nurses while they participate in the project<sup>15</sup>. Nurse endoscopists in Ontario do not receive additional remuneration beyond their full-time salary.

CCO provides funding for a nurse coordinator/educator role at each participating site. Given the effort required in setting up an RNFS site, funding for this position is provided at 1.0 FTE for first year. After this time, this may be altered to 0.8 FTE as the operation of the site becomes routine.

### Physician Incentives for Training and Supervision

When developing the RNFS pilot project, CCO and the Ministry of Health and Long-Term Care (MOHLTC) recognized the need to reimburse physicians for their participation. Physicians act in leadership roles for training, post-training and on-site support, in addition to follow-up and communication

of findings<sup>34</sup>. As a result, the MOHLTC collaborated with the OMA and established two models of reimbursement: a per diem model (Model 1) and an OHIP reimbursement model (Model 2). In Model 1, the physician is paid a daily rate, pro-rated for the number of hours worked. In Model 2, the physician is paid a percentage of the value of the Physician Schedule of Benefits code Z555 for each FS procedure the nurse performs.

Billing and remuneration was initially managed by the MOHLTC. However, as of April 1, 2010, CCO assumed responsibility for this by way of contracts with participating physicians<sup>34</sup>.

In addition, physicians are paid a monthly stipend for the first six months of their participation in the pilot project to cover their additional administrative duties, review of reports, and time allocated to the project outside of the direct training and direct oversight supervision hours<sup>30</sup>.

Upon signing the agreement between CCO and the sites, physicians must choose one model of reimbursement for the training and one for the post-training phase. In 2010, a preliminary evaluation of project costs revealed that Model 2 (the OHIP reimbursement model) is likely less costly in the training phase, whereas Model 1 (the per-diem model) is likely less costly in the post-training phase<sup>17</sup>.

**Because OHIP billing data were not available, this costing exercise was based on two scenarios:**

- 1 If all physician trainers had opted for the per diem model
- 2 If all physician trainers had opted for the OHIP reimbursement model

## ENDOSCOPIC INTERVENTION CONSIDERATIONS

### Procedures Performed by Nurses

As the cornerstone of the RNFS pilot project, nurses have a wide range of responsibilities. Before the procedure, nurse coordinators are responsible for recruiting patients, and confirming eligibility and appropriateness of screening with FS. For this, nurses must also consider the indications for the procedure, risks and contraindications as outlined in the medical directive. On the day of the procedure, patients are registered as out-patients under the name of the back-up physician (as required by the Public Hospitals Act). Although the performance of FS, including the biopsy of polyps on the mucous membrane, is within the scope of practice for nurses, the act of initiating FS is not within scope and therefore requires a medical directive. Once the pilot site puts a medical directive in place, including the initiation of FS, nurse endoscopists are responsible for performing FS and for the biopsy of polyps that are judged appropriate. If the patient requests sedation, the RN must transfer care to the physician (either immediately or by scheduling a new appointment at a later date). CCO and the College of Nurses of Ontario do not support the practice of conscious sedation because nurse endoscopists are not specifically trained to manage patients under sedation.

During the procedure, the nurse endoscopist will insert the flexible sigmoidoscope up to the point of the splenic flexure. Once the scope reaches this point, and nurses have adequate visualization upon withdrawal from this point, the insertion is considered complete. If the endoscope is not introduced this far (e.g., due to poor patient

preparation, patient discomfort), the nurse may consider retrying the procedure after the patient has been given an additional enema or rescheduling the procedure at a later date. Nurses may also consider referring patients to colonoscopy<sup>43</sup>.

Nurses are trained to perform cold biopsies (i.e., incisional biopsies) on polyps roughly 5 mm in size or smaller regardless of morphology<sup>44</sup>. Although additional polypectomy techniques may be employed during flexible sigmoidoscopy procedures under other circumstances, nurses do not perform electrocautery (i.e., hot biopsies), snaring or endoscopic mucosal resections (EMR).

Indications for requesting assistance from the physicians are taught to nurses through the training program. In general, the goal of the program is to have nurses independently perform FS with limited occasion to request support from the back-up physicians. In cases with polyps larger than 5 mm in size, or other findings such as diverticulosis or hemorrhoids, the nurse will generally take a photograph and document the findings for physician review. Although registered nurses may not make diagnoses, they are able to provide patient education and recommendations for management of non-malignant diseases (i.e., diverticulosis and hemorrhoids) based on their own clinical judgment. Nurses are taught about common non-malignant findings they may encounter when performing FS.

In general, nurses are taught to contact physicians for immediate assistance in cases of bowel perforation, severe bleeding or acute patient distress. In some cases, if the physician is readily available, nurses may also ask the back-up physician to confirm clinical findings, although in the majority

of cases, a photograph of the suspicious finding and documentation of the encounter will suffice.

### Referral Criteria

**Patient eligibility was defined in the pilot project as an insured person who is:**

- 1 Between the ages of 50 to 74
- 2 Has no first-degree family history of colorectal cancer
- 3 Is not symptomatic

In 2012, CCO provided additional clarification to sites regarding contraindications for RN-performed flexible sigmoidoscopy, which included a previous positive FOBT or positive FS; a colonoscopy within the last 10 years; a history of inflammatory bowel disease; a history of large bowel symptoms, such as rectal bleeding; previous polyps, with the exception of hyperplastic polyps; a personal history of colorectal cancer; or on anticoagulant therapy<sup>44</sup>.

Depending on the recruitment model, either the patient's primary care provider will review patient eligibility (including contraindications) before referring that patient to FS, or the nurse coordinator, on behalf of the primary care provider will contact patients directly to confirm eligibility. Once referred to the program, in either case, the nurse coordinator will assess eligibility during an initial consultation and health assessment, which may occur in person or over the phone. If it appears during this consultation that the patient is eligible for FS screening, nurses will then provide patients with information on screening for colorectal cancer,

flexible sigmoidoscopy and preparation instructions. She/he will schedule the procedure and may obtain the consent.

On the day of the procedure, the RN endoscopist is responsible for reviewing the indications, reviewing/obtaining the consent and performing the procedure. If the results are normal (i.e., no polyps are detected), or if only diverticulosis or hemorrhoids are detected, the patient will be informed of the results and recommended follow-up instructions. A copy of the results is also sent to the referring primary care provider. Patients are recommended to follow-up with their primary care provider to ensure ongoing surveillance.

If patients are found to have a polyp 3 mm to 5 mm in size, and the polyp is deemed appropriate for biopsy by the RN endoscopist, the nurse will perform a cold biopsy and submit the specimen to pathology for analysis. If the polyp is over 4 mm to 5 mm and should be excised, or findings of the procedure are otherwise suspicious, the nurse will take a photograph and document findings for later review by the physician. After the procedure, the results of the pathology report will be sent to the back-up physician and RN who performed the procedure. Reading and interpreting the results of the pathology report is the responsibility of the back-up physician; however, the physician and RN endoscopist generally review the reports together. Once results are sent to the back-up physician, he or she assumes responsibility for the patient. For patients who have a negative pathology report, results are sent to the patient and referring primary care provider and the patient is advised to continue normal surveillance practices. If the results are

positive (e.g., greater than 10 hyperplastic polyps detected or any histologically verified adenomas or carcinomas) the patient will be referred to the back-up physician for consultation and/or colonoscopy, with follow-up notification of results sent to the referring primary care provider. Although referral process may differ somewhat among sites, a sample flow map is provided in **Appendix D**.

As noted above, in Ontario, the RNFS program is currently in transition and has not yet been incorporated into the ColonCancerCheck program. As such, recommendations for referral and follow-up practices for fecal occult blood test (FOBT), FS and colonoscopy vary among sites and individual primary care providers. Initially, in line with the recommendation from the Canadian Association of Gastroenterology, some sites recommended that patients undergo either annual or biennial FOBT with or without FS every 10 years<sup>45</sup>, while other sites recommended annual or biennial FOBT with FS every five years. At this point in time, however, all sites have adopted a five-year recall process with FS.

## Volumes

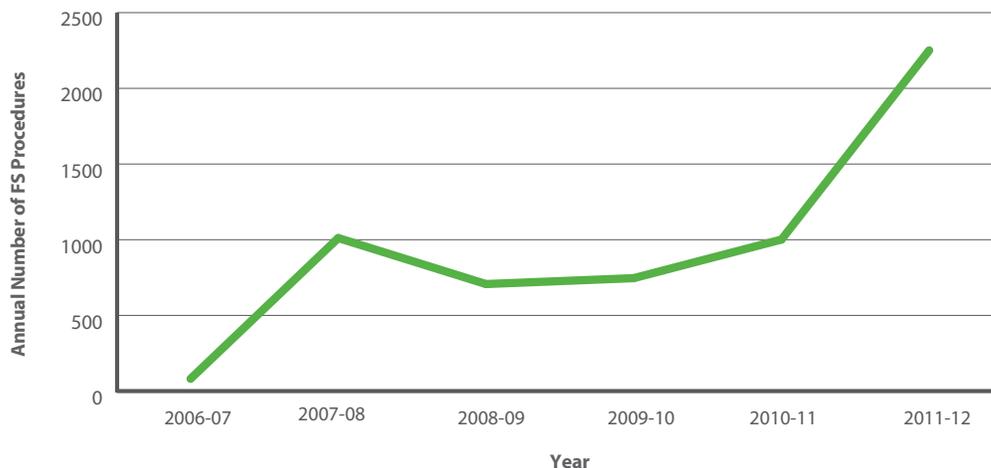
From the start of the RNFS project to October 2012 a total of 7,192 flexible sigmoidoscopies were performed (including procedures performed during the Change Foundation funded study in 2006). The project has experienced a trend towards increased growth in referrals for RNFS since its inception (**Figure 5**), indicating a general increase in acceptance and awareness of the project and its capacity for expansion.

As of July 1, 2009, Cancer Care Ontario implemented capacity targets for each of the sites based on projected year-end funding. The target is the same for all sites: between 24 and 48 procedures per month<sup>17</sup>. These monthly targets are used as general guidelines to provide sites with an indication of

where they stand relative to capacity targets.

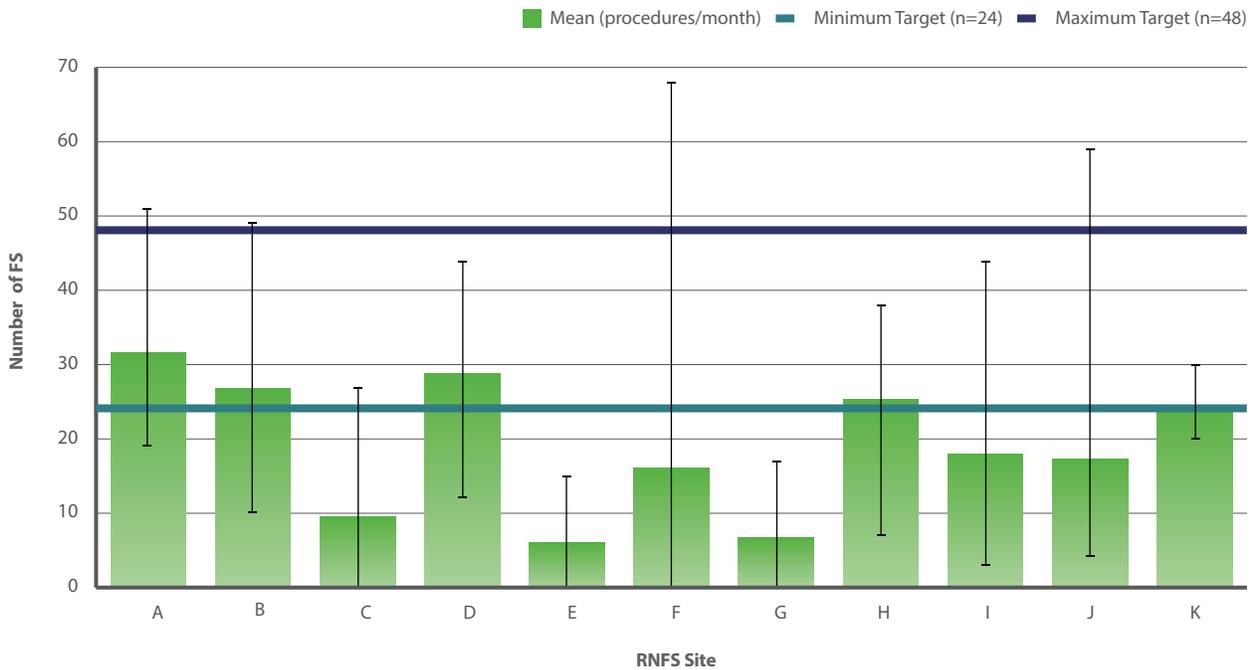
The target is based on a number of variables, including expected volumes, historical volumes and consideration of some site-specific variables (e.g., the number of available nurse endoscopists). For example, if a site falls below the minimum target in one or more months, they will need to work to increase their volumes in later months to meet their year-end funding target. In the fiscal year April 2011 to March 2012, the range of monthly volumes was highly variable, likely reflecting each site's attempt to balance volumes to stay within year-end capacity targets (**Figure 6**).

FIGURE 5 | Number of registered nurse-performed flexible sigmoidoscopies annually (fiscal year) in Ontario (2006/07 to 2011/12)



Source: 2012\_09 NFS Regional Reporting Package. Fiscal year is from April 1 to March 31.

FIGURE 6 | Average volumes per month by site for 2011/12 fiscal year (April 2011 to March 2012)



Source: 2012\_09 NFS Regional Reporting Package. Prior to July 1, 2009, no targets were in place. Sites J and K were not added until October and November 2011 respectively, and as such, reporting for these two sites is inclusive of October 2011 to March 2012, and November 2011 to March 2012, respectively. Bars reflect range of volumes per month for each site.

### Safety

Patient safety is carefully monitored within each pilot site as part of the terms of agreement with CCO. Each site is required to report immediately occurring complications, including the number of gastrointestinal (GI) bleeds, the number of perforations and other variances/complications, which include patient discomfort, technically difficult procedures, vasovagal response and inadequate patient preparation. Of the 6,261 training

or independent FS done between October 1, 2007 and October 1, 2012, there have been a total of eight patients who experienced GI bleeding (0.1% of patients) and no cases of perforation<sup>†</sup>.

### Effectiveness

In general, nurses conducting full procedures while in the training phase have shown relatively consistent polyp detection rates. On average, during this phase, 36% of patients were found to have

<sup>†</sup> Data extracted by Informatics March 12, 2013. Data do not include the Change Foundation grant as these data were collected by the study investigators independent of CCO Informatics. This analysis is based on the total number of procedures performed between October 1, 2007 and October 31, 2012 excluding duplicates (i.e., procedures with the same Health Care Number, referral date, procedure date and participating site). Additionally, there are no data available for the 'Training Observations' for all six Phase 1 sites, or the 'Training Withdrawal' procedures for three additional sites. Please note that these figures also include physician-performed procedures within the RNFS pilot.

polyps, with 33% undergoing an actual biopsy (Table 4). The average number of biopsies performed by nurses in the clinical training phase of the program was 1.5 per patient.

The number of biopsies performed by nurses in the training phase varied from 20 to 110, reflecting the wide range of actual FS procedures performed

by nurses in this stage (from 55 full FS training procedures up to 207 procedures). As mentioned above, the final assessment of competency may have been hindered by challenges in scheduling the clinical assessment and arranging for travel to the project sites. This may account for some of the nurses in the initial cohort who had completed well over the target of 50 full procedures.

TABLE 4 | Polyp detection rates for nurses in training phase completing the full procedure

NURSES	NUMBER OF TRAINING FS WHERE RN ADVANCED AND WITHDREW SCOPE	PATIENTS WITH POLYPS PER NURSE		PATIENTS WITH BIOPSY PER NURSE			POLYPS BIOPSIED PER NURSE			AVERAGE POLYPS BIOPSIED PER PATIENT PER NURSE
		N	%	N	% OVERALLS	% BIOPSIED†	N	MIN	MAX	
RN4	207	71	34.3	70	33.8	98.6	110	1	9	1.6
RN15	177	46	26	43	24.3	93.5	53	1	4	1.2
RN14	129	58	45	56	43.4	96.6	72	1	3	1.3
RN9	126	52	41.3	49	38.9	94.2	109	1	6	2.2
RN10	123	40	32.5	39	31.7	97.5	62	1	5	1.6
RN29	92	32	34.8	30	32.6	93.8	49	1	6	1.6
RN22	92	25	27.2	24	26.1	96	29	1	2	1.2
RN11	72	26	36.1	25	34.7	96.2	34	1	3	1.4
RN31	70	39	55.7	32	45.7	82.1	48	1	4	1.5
RN32	70	42	60	30	42.9	71.4	41	1	3	1.4
RN12	65	19	29.2	19	29.2	100	32	1	4	1.7
RN23	60	20	33.3	18	30	90	26	1	3	1.4
RN27	55	16	29.1	14	25.5	87.5	25	1	5	1.8
RN28	55	16	29.1	16	29.1	100	20	1	3	1.3
<b>Average (Total)</b>	<b>100 (1393)</b>	<b>35.9 (502)</b>	<b>36.7</b>	<b>33.2 (465)</b>	<b>33.3</b>	<b>92.7</b>	<b>50.7 (710)</b>	<b>1</b>	<b>9</b>	<b>1.5</b>

Notes: Data inclusive of nurses who have reached independent status (i.e., nurses who have successfully completed training and completed at least one 'independent' FS as of October 31, 2012). Data extracted: November 26, 2012; Data source: RN Flexible Sigmoidoscopy (RNFS); Data range: October 1, 2007 to October 31, 2012; Prepared by: Informatics; †Percentage based on flexible sigmoidoscopies for nurse advanced and withdrew sigmoidoscopy independently with physician trainer present; ‡Percentage based on total number of patients with polyp.

### Patient Recruitment and Invitation Process

Patient recruitment is a critical component of the RNFS pilot project. Because nurses are required to perform 75 procedures as part of the curriculum, a lack of patient referrals for FS can be a significant barrier to reaching the operational phase of the site. As such, sites are strongly encouraged to begin patient recruitment in the planning phase of implementation, at least eight to 10 weeks before practical training is scheduled to begin. A number of different mechanisms are used to recruit patients to the RNFS pilot (Table 5).

In Ontario, there is no direct method to refer patients to nurses. For the Change Foundation study, a central referral intake was set up at CCO to facilitate the organization of referrals and arrange

for informed consent<sup>33</sup>. Within the toolkit provided by CCO, sites are now provided with materials to aid in developing an easy-to-use referral system (i.e., minimal impact on the referring primary care provider). Materials include process flow maps to understand the referral processes set up at other sites, sample referral forms, participant eligibility checklists, and sample confirmation and procedure preparation forms<sup>26</sup>.

Given that patients are recruited into the project through their family physicians, it is important that physicians in the area are aware of the project. The primary strategy for increasing awareness during the Change Foundation study was through lunch and learn sessions held with local family physicians. It was noted that this method is resource-intensive

TABLE 5 | Patient recruitment mechanisms

TARGET	STRATEGY	DESCRIPTION	CONSIDERATIONS
<b>Patients (directly)</b>	Marketing directly to patients to raise awareness	Using print, radio, website, or door-to-door strategies	<ul style="list-style-type: none"> <li>• Consistent messaging and “branding” are important to consider</li> <li>• May not lead to significant number of referrals since patients must complete the extra step of getting referral from their PCP by booking a non-urgent appointment</li> </ul>
<b>Patients (indirectly)</b>	Family Physician Model (FPM)	Ask primary care providers (PCPs) for their patient roster. Contact patients directly using the roster.	<ul style="list-style-type: none"> <li>• Help gain early engagement of physicians</li> <li>• Helps physicians identify patients eligible for screening</li> <li>• Little impact on work of PCPs</li> <li>• Allows for in-person or telephone education of patient before procedure date (patients required to attend extra visit to RNFS site or hospital before procedure)</li> <li>• Highly resource intensive – coordinator is responsible for reviewing all patient charts</li> </ul>
<b>Providers</b>	Peer-to-peer education (e.g., lunch and learn sessions) and local physician champions	Gastroenterologist and/or RN visit PCP office to provide overview of RNFS project	<ul style="list-style-type: none"> <li>• The number of “champions” available and the amount of time they can devote to the project</li> <li>• Peer-to-peer influence may help establish credibility of the project</li> <li>• Provides significant support to nurses in coordinator roles by promoting referrals</li> <li>• Consistency in messaging is important</li> </ul>

and as such may not be feasible to reach all of the local family physicians<sup>33</sup>. Since the initial Change Foundation study, a number of additional recruitment models have been developed, including the Family Physician Model (FPM), which is also used in some regions to recruit patients to the Ontario Breast Screening Program. In this model, family physicians provide their patient rosters directly to the nurse coordinator/educator<sup>17</sup>. The nurse coordinator/educator then compiles a list of eligible patients and drafts an invitation letter, which is sent by the RNFS pilot project staff on behalf of the primary care physician. In this letter, the patient is invited to call the RN to discuss screening. This model has been found to be one of the most successful means of recruiting patients<sup>17</sup>. The toolkit provided to sites also includes a number of materials to help sites implement this model, including a sample letter to primary care providers to inform them about the RNFS pilot project, a sample script for cold calls to primary care offices inviting them to an educational lunch and learn session, and a sample presentation for primary care physician recruitment<sup>26</sup>. During the workshop for RN coordinators/educators, it was recommended that larger family practices be approached first by identifying the family health teams (FHTs) in the region. After identifying the FHTs, a letter may be sent to the physicians' offices requesting to have a lunch and learn. Because physician-to-physician communication seems to work best, the role of the physician lead is also important. Involving the gastroenterologist or surgeon in the outreach efforts can be an effective means of improving referrals.

Additionally, the involvement of family physicians as spokespersons for the project has aided referrals at

several sites<sup>17</sup>. For instance, after the introduction of the RNFS pilot project in 2006/07, regions introduced the role of the Regional Primary Care Lead (a family physician supported by Cancer Care Ontario as of 2009) to support cancer screening efforts in Ontario. As part of this role, the Regional Primary Care Leads also helped build the profile of the RNFS pilot project and promote referrals among peers<sup>17</sup>.

Overall, an integrated and consistent approach to patient recruitment is critical. While there are a variety of strategies available, each site must find effective ways to engage local stakeholders and build support for screening using whatever approaches are best for that site. A number of success factors for patient recruitment have been identified as particularly important, including the presence of engaged physician champions, face-to-face meetings with primary care providers to provide screening education, and an easy-to-use process for primary care providers to refer patients to nurses.

## SOCIAL CONSIDERATIONS

### Professional Acceptability

Since the start of the RNFS pilot project, the acceptability of RNFS among healthcare providers has grown. In July 2007, the OMA released a *Statement on Nurse Sigmoidoscopists* stating, "The OMA supports the role of RNs performing flexible sigmoidoscopy with significant conditions/criteria."<sup>40</sup> Details of the conditions and principles outlined by the OMA are available in **Appendix E**.

This position is also held by the Registered Nurses' Association of Ontario (RNAO), and RNFS was included as one of the strategic policy

recommendations to the government of Ontario prior to a provincial election in 2010<sup>46</sup>. The CSGNA has also released a position statement officially advocating the nurse endoscopist role<sup>47</sup>.

In the 2010 project evaluation, participants in the RNFS pilot project noted that acceptability among their colleagues had grown over time<sup>17</sup>. In the training phase of the pilot sites, some team members noted skepticism among both nurses and physician colleagues. However, in the operational phase of these sites, nurses reported increased respect and acceptance from their colleagues. Furthermore, family physicians have become more engaged in supporting the project and interested to support nurses in their new role. Physician trainers and Cancer Care Ontario clinical experts have been extremely important in this evolution by promoting colorectal cancer screening and FS among healthcare providers.

### Population and Patient Acceptability

In 2009 a survey was administered as part of CCO’s project evaluation to assess the acceptability of RNFS to patients<sup>17</sup>. The survey was administered during the training phase of pilot sites when participating nurses had completed their withdrawal procedures and had begun full FS procedures. A validated instrument known as the Patient Satisfaction Questionnaire III (PSQ III) was used and focused on five domains of satisfaction and pain. Patients were also able to submit written comments<sup>17</sup>.

A total of 184 surveys were received from patients at four project sites. All patients who were surveyed had undergone an FS procedure performed by a nurse and supervised by a physician trainer. Results (Table 6) indicated that patients were satisfied with the procedure overall (average general satisfaction score of 25.7 out of 30) and experienced a low degree of pain (average pain score 2.4 out of 10)<sup>17</sup>.

TABLE 6 | Patient satisfaction survey results (October 1, 2007 to June 30, 2009)

PSQ III SUBSCALE	DESCRIPTIVE STATISTICS							POSSIBLE SCORE	
	N	MEAN	MEDIAN	SD	MIN	MAX	MEAN SCORE AS % OF MAX POSSIBLE	MIN	MAX
<b>General Satisfaction</b>	177	24.7	25	3.5	14	30	82.4	6	30
<b>Technical Quality</b>	179	43.6	45	5.0	30	50	87.2	10	50
<b>Interpersonal Aspects</b>	182	32.6	34	3.3	23	35	93.3	7	35
<b>Communication</b>	182	22.9	24	2.5	16	25	91.5	5	25
<b>Time Spent with Nurse</b>	181	9.1	10	1.2	6	10	91.4	2	10
<b>Pain</b>	173	2.4	1.8	2.3	0	10	24.4	0	10

Notes: Data extracted: July 23, 2009; Date range: October 1, 2007 to June 30, 2009; Data Source: Nurse Flexible Sigmoidoscopy (NFS) Patient Satisfaction Survey; Prepared by: ColonCancerCheck Source: RN-Performed Flexible Sigmoidoscopy in a Pilot Project of Colorectal Cancer Screening - Evaluation Report 2007-2010. Cancer Care Ontario; 2010.

Patients reported highest satisfaction for non-technical aspects of their experience, including the “interpersonal aspect” (average score of 24.7 out of 30), “communication” (average score of 22.9 out of 25) and “time spent” (average score of 9.1 out of 10). Patients appeared to value highly the comfort and support that was provided by the nurse endoscopists<sup>17</sup>.

The scores that were obtained on the technical quality of nurses were also high, although some patients found it challenging to make judgments in this area<sup>17</sup>.

This is an ongoing survey used to continually monitor patient satisfaction with the project. As mentioned above, the RNFS community of practice is currently working to improve the survey with the intent to deploy the revised survey within the next few years.

Since the implementation of the RNFS pilot, patient satisfaction has remained high. An evaluation among seven pilot sites in 2011 found a mean general satisfaction score of 80.9% as a percentage of the maximum possible score<sup>48</sup>. This compares favourably with previous findings and illustrates that RNFS in the context of this pilot project is acceptable and satisfactory to patients.

### **RNFS Pilot Project Team Members’ Satisfaction and Preferences**

In 2010, Cancer Care Ontario conducted an evaluation of acceptability and satisfaction of the RNFS pilot project among project members. This evaluation included a survey and series of interviews with RNs, physician trainers and course instructors. An additional series of interviews with project team

members was conducted at two RNFS sites in the operational stage<sup>17</sup>.

The survey was administered to assess nurses’ satisfaction and the ability of training to meet nurses’ needs after the initial cohort of nurses completed didactic and simulator training. The response rate for the survey was 100%. When asked to rate their satisfaction with the education week hosted at the Michener Institute for Applied Health Sciences on a scale from 1 to 5 (1= very dissatisfied, 5= very satisfied), nurses gave highly favourable responses, with a mean response rating of 4.7. Participants responded positively to opportunities for further education, training sessions and communication with other nurse endoscopists<sup>17</sup>.

In addition to this survey, a series of interviews was conducted with some team members from each site, as well as the course instructors. This sample included a total of six nurses, six coordinators, five physician trainers and two course instructors<sup>17</sup>. The outcome of this qualitative evaluation found that, overall, nurses were satisfied with the training they received. Nurses felt that their instructors were highly knowledgeable, and enjoyed the opportunity to collaborate with peers and learn from one another. Physician trainers who were interviewed as part of this evaluation similarly expressed satisfaction with the training course. Those who participated described it as a positive experience and would recommend RNFS to other physicians<sup>17</sup>.

When asked to reflect on why they participated in FS training, nurses expressed a strong interest in expanding their role, acquiring new skills and developing professionally. Several of the nurses were also interested in being involved in a new initiative

for colorectal cancer screening. Nurses expressed satisfaction with didactic and clinical training, and felt that the training was extremely valuable in building their skills and confidence. Nurses rated the feedback that they received from their physician trainers and patients highly, and recognized the importance of having a good relationship with their physician trainer to support skill development. It was also recognized that this relationship would continue to be important during the operational phase of the project, to address complications and properly communicate findings.

Characteristics that were identified as necessary to improve nurse training included more training sessions and time for simulator training, more one-on-one time with instructors, ongoing opportunities for education and ongoing communication among peer trainees. Low availability of physician trainers and inadequate clinical time were identified as barriers to adequate training. Patient recruitment was also identified as a major factor because low procedural volumes negatively impact nurses' confidence and ability to maintain their skills.

When physicians were asked for their views on nurses' training, most expressed satisfaction with the required volume of 75 scopes in order to determine nurses' competence. However some indicated that individual nurses may require more or less time to become competent, depending on their previous experience. One physician suggested that 100 full scopes would be preferable to determine competency in FS<sup>17</sup>. Another stated that there may be complications that do not appear during the 50 practice scopes, but may occur when the nurse is independent, posing problems for nurses.

In general, however, physicians were supportive of nurses and viewed them as "team players."<sup>17</sup> Physicians expressed that it was important to develop productive long-term relationships with nurses to support the success of the project. Finally, physicians expressed positive views about the nurses' independent assessment and described it as "fair, appropriate and valid."<sup>17</sup>

In March 2010, an evaluation was conducted of the acceptability of the RNFS pilot project in the first two sites in which nurses were able to operate independently. Interviews were held with team members, including the nurse endoscopists, physician trainers and nurse educators/coordinators<sup>17</sup>. This evaluation found that nurse endoscopists who were performing independent FS were highly confident in their ability to perform flexible sigmoidoscopy and manage their patients. They indicated that their skills had significantly improved over the course of training and that having sufficient numbers of patients was critical to maintaining skills and their comfort in performing the procedure. This was supported by physician trainers who also expressed a high degree of trust and confidence in nurses' capabilities. In particular, physicians valued the nurses' ability to provide a high level of support for patients before and after the procedure<sup>17</sup>.

# Pilot Project Costs

The registered nurse-performed flexible sigmoidoscopy (RNFS) pilot project was funded by the Ministry of Health and Long-Term Care (MOHLTC) through Cancer Care Ontario (CCO). To determine the initial funding requirement for the RNFS pilot project, the Ontario Task Force for Large Bowel Endoscopy Services produced an a priori estimate in 2005 for start-up/training costs and one year operating costs<sup>14</sup> (Table 7).

In 2010, actual costs were calculated for the first three years of the RNFS pilot project<sup>17</sup>. This analysis focused on the direct costs of training nurses and physicians, and post-training clinical operations. The analysis was conducted for the first six sites that entered the pilot project, including 13 registered nurses (RNs).

Because Ontario Health Insurance Plan (OHIP) billing data were not available, the cost estimates were calculated based on two scenarios: if all physician trainers had opted for the per diem remuneration model or if all physician trainers had

opted for reimbursement as a proportion of OHIP fees (Table 8). Based on these models, the total estimated cost for the first three years of the project (including training and operation), with 6 sites participating, was just over \$2.3 million.

The initial estimates from the Ontario Task Force on Large Bowel Endoscopy Services were based on a number of assumptions. It was estimated that a total of 14 nurse endoscopists would participate in the first phase of the pilot (six from the original Change Foundation study and eight other nurses from six additional sites). The initial estimate also reflected the assumption that RN endoscopists would perform a total of 1,248 procedures per year (eight procedures/half day and three half days/week)<sup>14</sup>.

Thirteen nurses actually participated in the first phase of the RNFS pilot project across six sites. Three sites discontinued their involvement as of April 1, 2009. In the first years of the RNFS pilot, operational costs for the pilot sites were covered by a global budget, regardless of volumes<sup>17</sup>. This was altered in the third year of the project (2009/10) when a new model of funding was adopted. Each site was then allocated \$185 per procedure to

TABLE 7 | Estimated costs (*a priori*) associated with training and ongoing operation of the RNFS pilot project

PHASE	ESTIMATED COSTS
Start-Up/Training Phase*	\$803,338 (\$200,834/site <sup>§</sup> )
Operation Phase <sup>¶</sup> (1 year)	\$1,926,802 (\$321,133.67/site <sup>¶¶</sup> )
<b>Total</b>	<b>\$2,730,140 (\$521,968.17/site)</b>

Notes: \*start-up training phase includes site-specific human resource training costs and central start-up costs including endoscopic equipment (for one site), information systems, and program coordination and marketing; <sup>§</sup> estimate based on 4 sites participating in training (2 sites had already undergone training through the Change Foundation study); <sup>¶</sup>operation phase costs include site-specific annual operating costs for human resources (based on the assumption that a fully-trained RN endoscopist will perform 1,248 procedures/year), endoscopy supplies, and CCO operation costs; <sup>¶¶</sup>estimate based on 6 operational sites

cover clinical and human resource-related costs (i.e., salary and benefits for nurse endoscopists, endoscopy assistants, scope technicians, as well as any associated supplies and equipment as outlined in the site agreements)<sup>17</sup>. A target volume was set at a minimum of six procedures per week per site. This change in funding led to a distinct decrease in costs associated with the RNFS pilot project<sup>17</sup>. Funding for the nurse coordinators, physician trainers/back-up physicians, as well as administrative costs associated with patient recruitment, communications, and additional education is in addition to the \$185/procedure (Table 9).

Upon entering into an agreement with a site, CCO provides each site with variable funding based on the actual volumes of procedures in addition to fixed

funding for recruitment, which includes salary and benefits of a 1.0 FTE RN coordinator/educator and for other associated recruitment expenses (Table 9). Sites are able to use the variable funding for salary and benefits of staff who participate in the project (e.g., nurse endoscopists, endoscopy assistants, scope technicians and administrative staff), education expenses, supplies and equipment (not including capital equipment, such as the purchase of sigmoidoscopes or colonoscopes), operational expenses and associated travel costs (e.g., for nurse coordinators to travel within their region to promote patient recruitment)<sup>30</sup>.

TABLE 8 | Pilot project costs (2007/08 to 2009/10)

	TRAINING PHASE	POST-TRAINING PHASE	TOTAL
<b>Education Costs*</b>	\$113,291.39	-	\$113,291.39
<b>Site Operating Costs<sup>5</sup></b>	\$1,434,147.78	\$233,771.32	\$1,667,919.10
<b>Physician Compensation Costs<sup>†</sup></b> Scenario a: per diem remuneration model Scenario b: OHIP reimbursement model	\$152,267.58a to \$110,819.60b	\$13,600.00a to \$18,833.28b	\$165,867.58a to \$129,652.88b
<b>CCO Operating Costs<sup>™</sup></b> (Project Management and Evaluation)	\$312,482.53	\$120,564.63	\$433,047.17
<b>Total</b>	\$2,012,189.28a to \$1,970,741.30b	\$367,935.95a to \$373,169.23b	\$2,380,125.25a to \$2,343,910.54b

Notes: above figures assume: 6 initial sites, involving 13 nurses and 13 physicians in training/back-up role; 3 sites discontinued as of April 1, 2009; of the 3 sites that continued, 1 entered post-training phase on December 1, 2008, 1 entered post-training phase on May 1, 2009, and 1 was still in training as of May 2010.

\* Education costs relate to 2007 training course (including cost for using the Michener facility; low- and hi-fidelity simulators; standardized patients; course materials; faculty; travel, meals and lodging for nurses; and support for physicians to attend train-the-trainer course); nurse-coordinator collaboration workshop (held in March, 2008) and independent assessment of the nurses. † Physicians were remunerated for the time they spent in direct supervision of nurses and in other activities such as team meetings and activities to promote the project; ‡ CCO costs have been pro-rate to training / post-training based on how many months project sites spent in each phase. 2007/08:100% training; 2008/09: 94% training; 2009/10: 36% training. § Operating costs for 2007/08 and 2008/09 include actual spending; 2009/10 figures include allocation based on minimum required volumes.

TABLE 9 | Registered nurse-performed flexible sigmoidoscopy (RNFS) site operating costs

SITE OPERATING COSTS	TOTAL (\$)
<b>Cost per Case</b> (e.g., nurse endoscopist salary, endoscopy assistant salary, scope technicians salary, supplies and equipment, etc.)	\$185 / case
<b>RN Coordinator/Educator</b>	\$85,000 - \$106,000 / annum
<b>Administration</b> (e.g., communications, continuing education expenses, patient recruitment)	\$6,000 - \$7,500 / annum

Note: Physician trainers/back-up physicians are remunerated separately, and in addition to the above funding.

# Success Factors and Lessons Learned

Understanding how organizational change and innovation occur requires an understanding of the context, meanings and actors involved. There are a number of strategies and milestones that have contributed to the success of the registered nurse-performed flexible sigmoidoscopy (RNFS) pilot project over the years, as well as a number of lessons learned. The following section highlights a number of these.

## I. THE POLITICAL CONTEXT

### Alignment with Governmental Health and Human Resources Strategies

In 2005/06, the Government of Canada launched the Pan-Canadian Health Human Resources Strategy (HHRS) to “support effective coordination and collaborative health human resources planning across the country” in response to recommendations made by the Commission on the Future of Health Care in Canada (2002), the Standing Senate Committee on Social Affairs, Science and Technology (2002), and the First Ministers’ 2003 and 2004 Accord<sup>49</sup>. This renewed focus on human health resources was based on a number of principles and recommendations:

- To “address the need to change the scopes and patterns of practice of health care providers to reflect changes in how health care services are delivered, particularly through new approaches to primary health care... This suggests new roles for nurses, family physicians, pharmacists, case managers and a host of new and emerging health professions”<sup>50</sup> (p. 28).

- To ensure access to the appropriate health care provider when needed. First ministers agreed to “immediately accelerate primary health care initiatives and to make significant annual progress so that citizens routinely receive needed care from multi-disciplinary health care organizations or teams.”<sup>51</sup>
- And, the recommendation that “an independent review of scope of practice rules and other regulations affecting what individual health professionals can and cannot do be undertaken for the purpose of developing proposals that would enable the skills and competencies of diverse health care professionals to be utilized to the fullest and enable health care services to be delivered by the most appropriately qualified professionals.”<sup>52</sup>

On May 3, 2006 Ontario’s implementation of this new focus on health human resources took the form of HealthForceOntario (HFO), a strategy to ensure that Ontarians have access to the right number and mix of qualified healthcare providers. One of the key components of the HFO strategy involves establishing innovative new healthcare professional roles.

The purposes of the RNFS pilot project were to examine the acceptability and feasibility of RNFS in the context of a new service delivery model for colorectal cancer screening, and its potential to increase colorectal cancer detection in Ontario; these closely aligned with one of the priorities of the HFO strategy. As a result, the Ministry of Health and Long-Term Care (MOHLTC) Nursing Secretariat and Cancer Care Ontario (CCO) created and launched the RNFS pilot project in 2007. The timing of this project in relation to broader government strategic initiatives is likely a key factor in its early success.

## II. THE CANCER SYSTEM CONTEXT

### Early Stakeholder Input and Engagement

Early on in the project, the need for stakeholder input became apparent. Because each stakeholder group has a unique perspective, a multidisciplinary stakeholder advisory committee, including representatives from The College of Nurses of Ontario, the Registered Nurses' Association of Ontario (RNAO), the Canadian Society of Gastroenterology Nurses and Associates (CSGNA), the Institute for Clinical and Evaluative Sciences (ICES), the Ontario Association of Gastroenterology, the Ontario Medical Association (OMA), the Canadian and Ontario Associations of General Surgeons, and primary care physicians, was convened.

The purpose of this committee was to provide advice, information, knowledge and expertise to assist the leadership team and CCO in implementing a nurse endoscopist project in Ontario. Although RNFS is not a new concept, this project was the first of its kind in Canada. Expanding the role of nurses to include skills typically performed by specialist physicians required careful consideration of such nuances as how the expanded role would fit within the scope of nursing practice, and how it would affect physicians, the healthcare system and patients.

This multidisciplinary stakeholder committee was instrumental in considering the details involved in implementing a new multidisciplinary model of care. For instance, it provided input on how best to develop medical directives, the necessary elements to include and the process to be used to implement them. Additionally, practice issues that arose were dealt with by consulting with the College of Nurses

of Ontario with careful consideration of implications for other groups.

It is likely that an iterative process is required to ensure that all potential stakeholder concerns are addressed. Although this process is lengthy with much deliberation, it has been considered one of the great successes of this project. Without the acceptance of all stakeholders, it is unlikely that a multidisciplinary project of this type could succeed.

### Clear and Consistent Messaging

During the initial Change Foundation study, family physicians indicated that the provincial colorectal cancer screening program messaging seemed to conflict with the goals of the RNFS project. At that point in time, CCO had just launched the ColonCancerCheck program, a population-based colorectal cancer (CRC) screening program with biennial fecal occult blood test (FOBT) as the recommended screening method for average-risk patients. In addition, as a tool to improve screening rates, the province was providing physicians with financial incentives for screening patients with FOBT<sup>53</sup>. Concurrently, the RNFS pilot project, also funded by the MOHLTC through CCO, was reaching out to local primary care providers to promote referrals for average-risk individuals. This conflict likely impeded referral rates to the RNFS sites. When considering implementation of RNFS, it is essential to consider how such a program fits within the broader screening program to ensure clear and consistent messaging to providers. An expert panel supported by CCO's Program in Evidence-Based Care (PEBC) is reviewing the evidence concerning CRC screening tests to determine, in part, how flexible sigmoidoscopy should be incorporated into the ColonCancerCheck program.

### III. THE REGIONAL CONTEXT

#### Regional Capacity for Colonoscopy and Awareness of the Evidence for Flexible Sigmoidoscopy

Another enabler of a flexible sigmoidoscopy (FS) pilot project is having a strong evidence base<sup>54</sup>. Evidence has amassed for FS over the past several years, including recent publications from large randomized controlled trials demonstrating the efficacy of FS screening, with a 21% reduction in the incidence of CRC after a median follow-up of 11.9 years<sup>23</sup>. At the inception of the RNFS pilot project, however, the evidence for the efficacy of FS as a population-based CRC screening tool was still building. As noted in the original Institute for Clinical and Evaluation Sciences (ICES) Research Atlas investigating the use of large bowel procedures in Ontario, the rates of flexible sigmoidoscopy declined between 1992 and 2001, in contrast to increasing rates of colonoscopy, likely the result of both patient and physician preferences for colonoscopy<sup>14</sup>. This trend has also been observed over the life of RNFS in Ontario. During the Change Foundation study, both study sites were located in large urban areas with established specialist bases; this contributed to difficulty in obtaining the volume of referrals to nurse endoscopists necessary for success<sup>33</sup>.

With the introduction of CCO's RNFS pilot, which involved a larger number of both urban and rural sites, the variability in access to colonoscopy across the province was seen to influence referrals to the project. In communities with widespread access to specialists, many family physicians and patients seemed to prefer colonoscopy, while in communities where access to specialists was limited, family

physicians recognized RNFS as a way to have their average risk patients screened<sup>53</sup>. These findings have implications for the future implementation and selection of RNFS sites. Significant educational efforts may be necessary to improve provider awareness of the evidence and benefits for screening with FS. It is important to monitor and disseminate this evidence to increase support for appropriate screening from healthcare providers and the public. Additionally, while this evidence is building and educational efforts are underway, it may be prudent to limit the implementation of RNFS sites to regions with limited capacity for colonoscopy and/or in areas that are currently under-screened.

#### Leverage Existing Relationships with Primary Care Providers

Given that sufficient volumes are critical to the success of the project, the role of good working relationships with regional primary care providers cannot be underestimated. Within the context of the RNFS pilot project, some sites were successfully able to leverage existing relationships between CCO and local primary care providers.

The Ontario Breast Screening Program (OBSP) was launched in 1990 as a partnership between the MOHLTC and CCO. The purpose of this program is to reduce mortality from breast cancer by screening average risk women aged 50 to 74, with recently expanded screening for high-risk women as young as 30 years. Screening services are delivered within dedicated sites, affiliated hospitals and independent health facilities across the province. Patients may be referred to the program by their family physician or nurse practitioner, or they may self-refer. To improve referrals to the program and increase breast

cancer screening rates, an innovative recruitment model was implemented within some sites: OBSP staff members took on a supportive role for primary care physicians by assisting them with a variety of the administrative activities involved in ensuring their eligible patients got screened. OBSP staff help determine which patients are eligible for screening based on physicians' rosters, send personalized letters of invitation to eligible patients on behalf of the physicians, and ensure proper follow-up with the primary care providers and the patients<sup>55</sup>. This model, referred to as the Family Physician Model (FPM), has been associated with increased uptake of breast cancer screening<sup>55</sup>.

In general, administrative staff from the RNFS pilot project noted that volumes of referrals to RNFS sites within the same regions as OBSP sites using the FPM were greater than volumes experienced by sites without local OBSP FPM referrals. Utilizing this same recruitment model, some RNFS sites have been able to leverage the existing relationships between family physicians and the OBSP because many of the family physician practices in these regions have had first-hand experience of the process and benefits of this recruitment model.

## IV. INSTITUTIONAL CONTEXT

### Committed and Strong Hospital Leadership

Support from the medical leadership is essential to ensure the ongoing success of RNFS sites<sup>17</sup>. Support includes not only a commitment to provide clinic space and staff time, but also a commitment to support nurses within this expanded role. Administrators within the RNFS pilot project have highlighted the critical role that hospital leadership plays, especially the chief nursing officer, who can influence decisions at senior levels. The RNFS physician trainers also have an influential role in the operations of the project given their direct and ongoing involvement. Although sites were initially chosen based on prior collaborations, learning from the experience with the initial sites, a site readiness assessment template was developed, which included elements that CCO could use to assess the level of hospital commitment to the project. CCO's provincial head of nursing and psychosocial oncology plays an important role by meeting with potential sites to gauge the level of commitment.

Additionally, nursing unions within hospitals can influence the success of RNFS. In one instance, a nurse who had been fully trained as an endoscopist was redeployed elsewhere within the organization when union officials moved a more senior nurse into the endoscopy unit, effectively "bumping"<sup>‡</sup> the registered nurse endoscopist out of her role.

<sup>‡</sup>Bumping' refers to the contractual right of a senior employee being laid-off to replace a junior employee as long as she/he is qualified for the position. Bumping rights are generally defined in collective bargaining agreements.

### **Easy-to-Use Referral Mechanisms**

In Ontario, there is no direct method for referring patients to nurses. This lack of existing referral mechanisms may have hindered patient recruitment<sup>33</sup>. For the Change Foundation study, a central referral intake was set up at Cancer Care Ontario to facilitate the organization of referrals and arrange for informed consent. For the RNFS pilot, a toolkit was provided to the sites by CCO and included materials to aid in developing an easy-to-use referral system. This includes process flow maps to understand the referral processes set up at other sites, sample referral forms, participant eligibility checklists and sample confirmation/procedure preparation forms<sup>26</sup>. In general, an easy-to-use referral mechanism is one that would not negatively impact the workload of the referring physician. The Family Physician Model, where patients are automatically referred to the project based on eligibility as determined by the RNFS site staff, is an example of a successful easy-to-use referral process.

# Conclusion and Future Directions

The registered nurse-performed flexible sigmoidoscopy (RNFS) pilot project has demonstrated the feasibility of an expanded role for nurses to improve Ontario's screening capacity for colorectal cancer. The first of its kind in Canada, the RNFS pilot project provides key lessons and considerations for other jurisdictions considering similar programs.

Because the pilot project accomplished its goals, it is now entering a new and exciting phase. Within the next few years, all RNFS sites will be accountable to their respective Regional Cancer Programs, which will take on a more significant role and more responsibility for supporting the RNFS program. During the 2012/13 fiscal year, the program has focused on strengthening the current structure, with additional resources for central support, data collection, evaluation and reporting, as well as a focus on assessing the current registered nurses (RNs) in the training program to build the base of qualified RN endoscopists in the province. With a strong base, subsequent years will focus on expanding the program to increase capacity for colorectal cancer screening in the province.

Additionally, the Education Committee will re-evaluate and update the educational program, including a review of the skills taught in the curriculum and whether or not the repertoire of interventions might be expanded. It will validate the rating scales used to evaluate nurses, and will re-examine the minimum number of procedures required by nurses before consideration for

assessment noting that, pedagogically, evaluation methods in general are moving toward competency-based assessments. Understanding how this may impact the RNFS educational program will be a key consideration for the future. Additionally, given the infrastructure for the RNFS training that exists in Ontario (i.e., in that it is already a distributed program and does not rely on the core trainers having privileges at any specific hospital), there may be some consideration to expand the program to offer training to other provinces. Furthermore, as the program matures with a firm base of trained and involved RNs, it is hoped there will be a role for experienced RN endoscopists to be involved in the education of new RNs entering the program.

Finally, with new evidence mounting about the effectiveness of flexible sigmoidoscopy as a population-based screening tool for colorectal cancer and the positive results of the RNFS pilot project in Ontario, we also await the results of the expert panel evidence review currently underway, supported by Cancer Care Ontario's Program in Evidence-Based Care, to help guide the potential integration of flexible sigmoidoscopy into the ColonCancerCheck program.

# Appendix A

## DATA REPORTING ELEMENTS

ID	DATA ELEMENT	DEFINITION
FS1	Master Institution Number	Four-digit MOHLTC uniquely assigned facility number.
FS2	Patient Chart Number	Patient identifier code that is unique within the healthcare facility.
FS3	Health Card Number	Patient's most recent health insurance number assigned by their provincial government of residence.
FS5	Date of Receipt of Referral	The date when the referral for sigmoidoscopy is received at the clinic.
FS6	Date of Procedure	The date that the sigmoidoscopy was performed.
FS7	Depth of Insertion	Depth of insertion of sigmoidoscopy (in cm).
FS8	Duration of Procedure	Duration of sigmoidoscopy (in minutes).
FS9	Polyp(s) Found	Were there one or more polyps found during the sigmoidoscopy?
FS10	Polyps Biopsied	Number of polyps biopsied.
FS11	Other Findings	Aside from polyps, describe any other (abnormal) findings.
FS12	Other Findings – Other	Description of "other" Other Findings. <b>Complete only when "Other Findings" is "0."</b>
FS13	Complications	Occurrence of a complication during the procedure.
FS14	Complications – Other	Description of "Other" Complications. <b>Complete only when "Complications" is "0."</b>
FS15	Splenic Flexure Reached	Was the splenic flexure reached during the procedure?
FS16	Adequate Bowel Preparation	Was the patient's bowel properly prepared for the procedure?
RN1	Nurse Provider Number	The Nurse Provider Number identifier code for the nurse who performed this activity. This code is unique to the submitting healthcare facility.
RN2	HCP Number	The healthcare professional (HCP) identifier code for the physician who performed this activity. This code is unique to the submitting healthcare facility. It is not the physician's billing number.
RN3	Level of Independence	Degree of independence with which the nurse performed the sigmoidoscopy.
RN4	Type of Endoscope Used for Training	Was the procedure performed with a sigmoidoscopy or a colonoscope?
RN5	Duration of Assistance	How long was the back-up physician needed (in the room) for the procedure, in minutes.
RN6	Type of Assistance	What was the nature of the back-up assistance provided
RN7	Type of Assistance – Other	Description of "Other" Type of Assistance.

# Appendix B

## SHORT-TERM IMPLEMENTATION PLAN FOR NEW SITES

(Adapted from the RNFS Toolkit)

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WEEK 1-4



- Recruit/appoint project coordinator and clinic receptionist
  - Post nurse endoscopist position
  - Recruit physician trainer
  - Start patient recruitment activities
  - Coordinator to plan and prepare lunch & learns
  - Determine recruitment process and identify office to be contacted
  - Identify equipment needs
  - Identify project budget
- 

WEEK 5-8



- Hire nurses
  - Continue patient recruitment activities and book patients
  - Ensure equipment available
  - Finalize appointments of physician trainers
  - Hire/appoint staff
  - Prepare clinic space
  - Develop methods for patient follow-up
  - Schedule nurses for observation experiences
- 

WEEKS 8-10

- Continue booking patients
  - Orient staff
  - Classroom components to start
-

# Appendix C

## COMPETENCY PROFILE FOR NURSES PERFORMING FLEXIBLE SIGMOIDOSCOPY

Developed for the Ontario Task Force on Large Bowel Endoscopic Services (OTFLBES) by College of Nurses of Ontario, March 2005

	PRE	DURING	POST
<p><b>Legal / Ethical</b></p> <p><b>Practices in a manner consistent with professional standards, quality standards, guidelines, legislation and scope of practice.</b></p> <p><b>Works within the boundaries of education, training and experience.</b></p>		<ul style="list-style-type: none"> <li>• Required authority</li> <li>• Medical directive to perform controlled acts related to insertion of instrument beyond anal verge</li> <li>• Medical directive to perform biopsy</li> <li>• Medical directive for immediate management (if appropriate) of potential complications while awaiting arrival of physician</li> </ul>	<ul style="list-style-type: none"> <li>• Required authority</li> <li>• Medical directive for post-procedure care</li> <li>• Medical directive to send tissue specimen to the lab for pathology testing</li> <li>• Decision tree or algorithm and process for referral of clients who undergo biopsy to a physician for diagnosis and treatment</li> </ul>
<p><b>Health and Technical Knowledge to Provide Holistic Care</b></p> <p><b>Conducts assessment relevant to endoscopy procedure to determine client needs, including internal (attitudes, values, beliefs and perceptions) and external (family, social, environmental and political) influences on health and health care.</b></p>	<ul style="list-style-type: none"> <li>• Anatomy, physiology, pathophysiology, relevant to flexible sigmoidoscopy and biopsy</li> <li>• Purpose, indications, contraindications, performance, benefits, risks, alternatives, and complications of flexible sigmoidoscopy and biopsy</li> <li>• Preparation of the patient for flexible sigmoidoscopy specific intra- and post-procedure care</li> <li>• Communication skills appropriate to the individual client (range and variety)</li> <li>• Patient education principles</li> <li>• Management of actual and potential outcomes</li> <li>• Obtaining informed consent protection measures for staff, patients and environment</li> <li>• Health and safety concerns for patients &amp; staff in endoscopy suite (chemical, ergonomics, latex, radiology, electrical, lifting, hazardous substances, etc.)</li> </ul>	<ul style="list-style-type: none"> <li>• In depth knowledge of anatomy and physiology of sigmoid colon</li> <li>• Assessment and accurate identification of normal and abnormal bowel tissue</li> <li>• Knowledge skill and judgement relating to removal of tissue</li> <li>• Ability to identify signs and symptoms of complications during procedure</li> <li>• Management of complications</li> <li>• Assessment of findings and their implications regarding patient's condition</li> <li>• Knowledge about the construction, function and application of flexible sigmoidoscopes and accessories</li> <li>• Preparation and handling of instruments and equipment, including function testing and problem solving during use</li> <li>• Technical skills related to insertion, advancement, manoeuvring and withdrawal of scope; biopsy and any potential therapeutic interventions</li> </ul>	<ul style="list-style-type: none"> <li>• Knowledge of normal recovery</li> <li>• Capability to integrate findings into clinical practice (e.g., potential for complications, knowing when to refer, resources)</li> <li>• Ability to manage immediate complications</li> <li>• Provide patient education regarding post-procedure monitoring and action</li> <li>• Use therapeutic communication skills re: procedure, findings and follow-up care</li> <li>• Collaborate with client to develop a plan of care</li> </ul>

## COMPETENCY PROFILE FOR NURSES PERFORMING FLEXIBLE SIGMOIDOSCOPY

Developed for the Ontario Task Force on Large Bowel Endoscopic Services (OTFLBES) by College of Nurses of Ontario, March 2005 (continued)

	PRE	DURING	POST
<b>Hygiene, infection control, patient and staff safety</b>	<ul style="list-style-type: none"> <li>• Applies knowledge of infection prevention and control measures</li> <li>• Takes action to address patient safety issues</li> <li>• Ensures equipment safety prior to use</li> </ul>	<ul style="list-style-type: none"> <li>• Takes appropriate action to protect patients, self and other members of the team from potential harm including:               <ul style="list-style-type: none"> <li>• infection risks and transmission of infection from flexible sigmoidoscopy and biopsy</li> </ul> </li> <li>• Demonstrates knowledge about the construction, function, application and potential malfunction and hazards of flexible sigmoidoscopy equipment</li> <li>• Troubleshoots equipment problems and takes action to resolve</li> </ul>	<ul style="list-style-type: none"> <li>• Identifies potential risks to staff and patients during decontamination and reprocessing of equipment</li> <li>• Ensures appropriate decontamination, reprocessing and storage of flexible sigmoidoscopy and biopsy equipment to prevent infections and damage to equipment</li> <li>• Meets applicable infection prevention and control standards</li> <li>• Maintains, uses and disposes of flexible sigmoidoscopy and biopsy equipment and supplies according to guidelines, regulations, laws and manufacturer's instructions</li> </ul>
<b>Continuing competence</b>	<ul style="list-style-type: none"> <li>• Maintains current knowledge and competence relating to:               <ul style="list-style-type: none"> <li>• care of patients before, during, and after flexible sigmoidoscopy and biopsy procedures</li> <li>• performance of flexible sigmoidoscopy and biopsy procedures</li> </ul> </li> <li>• Teaches and trains new staff</li> </ul>	<ul style="list-style-type: none"> <li>• Maintains current knowledge and competence relating to:               <ul style="list-style-type: none"> <li>• care of patients before, during, and after flexible sigmoidoscopy and biopsy procedures</li> <li>• performance of flexible sigmoidoscopy and biopsy procedures</li> </ul> </li> <li>• Teaches and trains new staff</li> </ul>	<ul style="list-style-type: none"> <li>• Maintains current knowledge and competence relating to:               <ul style="list-style-type: none"> <li>• care of patients before, during, and after flexible sigmoidoscopy and biopsy procedures</li> <li>• performance of flexible sigmoidoscopy and biopsy procedures</li> </ul> </li> <li>• Teaches and trains new staff</li> </ul>
<b>Research</b> <b>Critically evaluates and applies research</b>	<ul style="list-style-type: none"> <li>• Identification of researchable questions</li> <li>• Read and critique research reports</li> <li>• Interpret and integrate research findings into practice</li> </ul>	<ul style="list-style-type: none"> <li>• Evidence-based practice</li> </ul>	<ul style="list-style-type: none"> <li>• Applies research skills to evaluate effectiveness of care and treatment</li> <li>• Participates in the testing of new equipment</li> </ul>
<b>Relationships with healthcare team and others</b>	<ul style="list-style-type: none"> <li>• Understands the role of other healthcare team members</li> <li>• Collaborates with other members of the healthcare team</li> <li>• Uses conflict resolution skills when appropriate</li> <li>• Provision of appropriate health and disease education to patients, their relatives and families, and healthcare providers</li> </ul>	<ul style="list-style-type: none"> <li>• Understands the role of other healthcare team members</li> <li>• Collaborates with other members of the healthcare team</li> <li>• Uses conflict resolution skills when appropriate</li> <li>• Provision of appropriate health and disease education to patients, their relatives and families, and healthcare providers</li> </ul>	<ul style="list-style-type: none"> <li>• Understands the role of other healthcare team members</li> <li>• Collaborates with other members of the healthcare team</li> <li>• Uses conflict resolution skills when appropriate</li> <li>• Provision of appropriate health and disease education to patients, their relatives and families and healthcare providers</li> </ul>
<b>Record-keeping</b>	<ul style="list-style-type: none"> <li>• Meets legal and professional requirements for documentation</li> <li>• Different formats and systems for documentation</li> </ul>		<ul style="list-style-type: none"> <li>• Maintains accurate documentation, including record of use, reprocessing and maintenance of equipment</li> <li>• Ensures use of an audit trail to track equipment use, decontamination, maintenance and reprocessing</li> </ul>

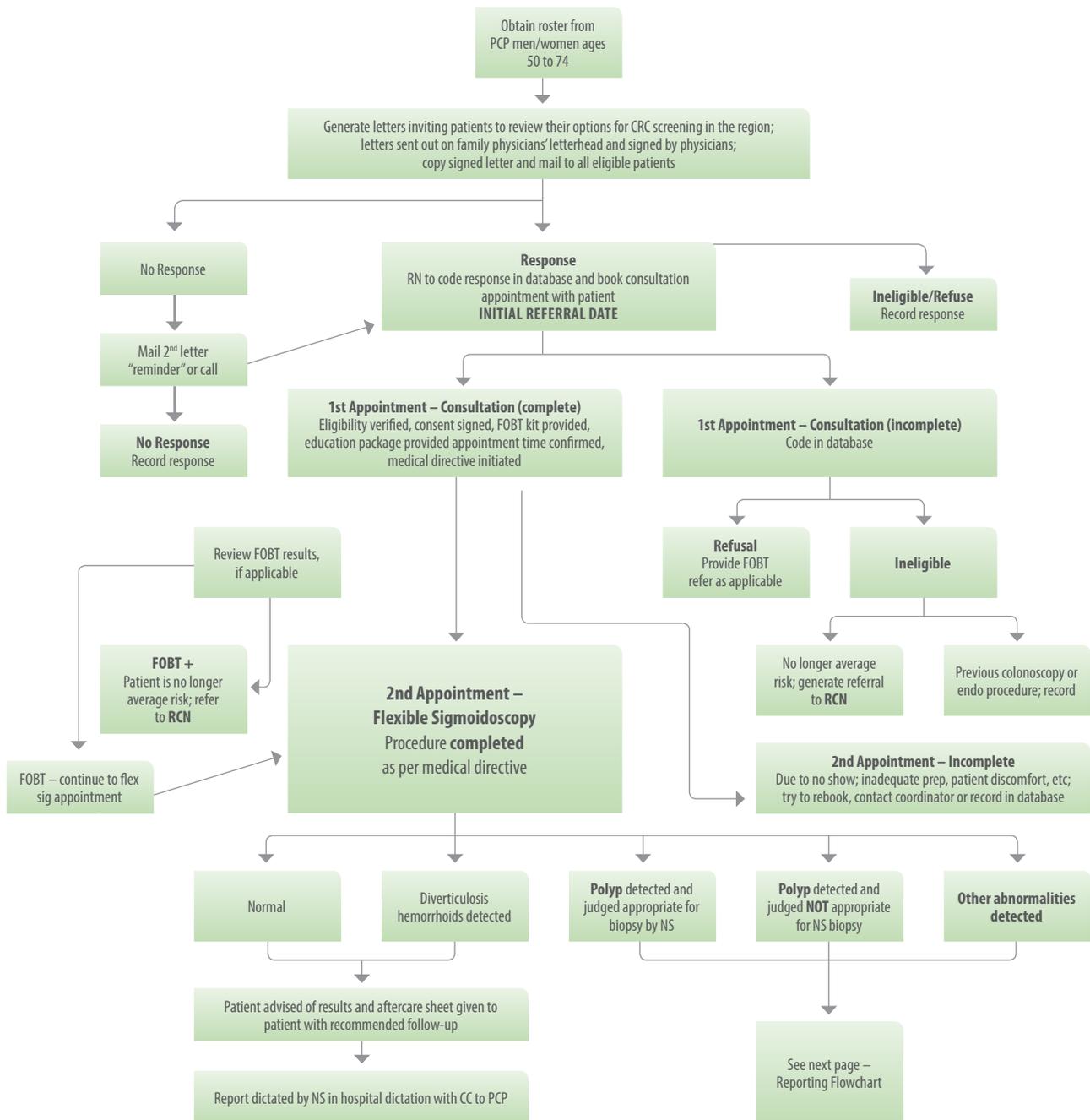
Source: Cancer Care Ontario and the Cancer Quality Council of Ontario. Increasing Colorectal Cancer Screening in Ontario through RN-performed Flexible Sigmoidoscopy. Report and Recommendations from the Ontario Task Force on Large Bowel Endoscopic Services. July 2005.

# Appendix D

## RNFS PROGRAM PROCESS FLOW MAP (EXAMPLE)

### Recruitment Model Registered Nurse-Performed Flexible Sigmoidoscopy

Last Updated December 2011

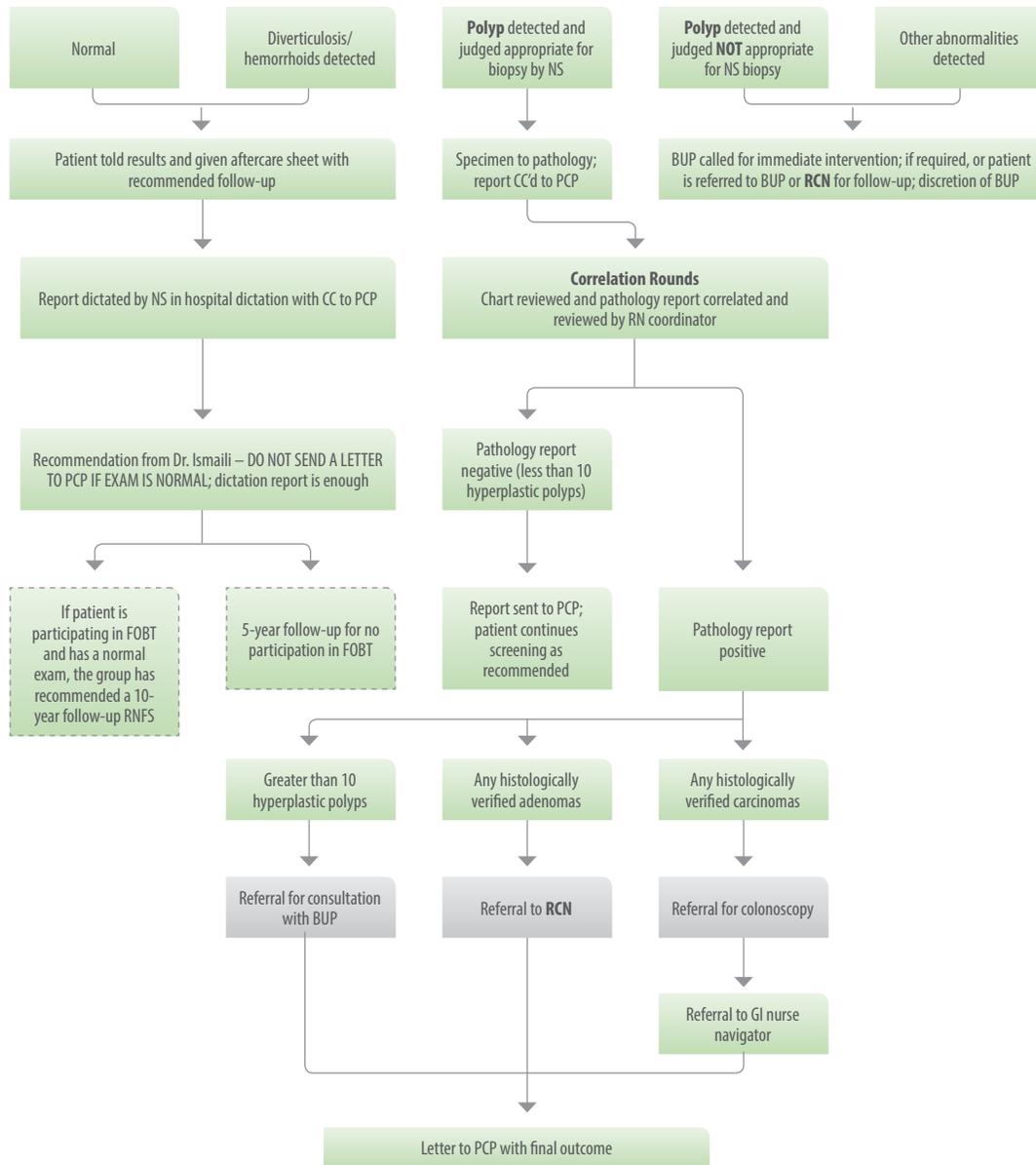


#### Legend

<b>BP</b>	back-up physician	<b>CRC</b>	colorectal cancer	<b>NS</b>	nurse sigmoidoscopist	<b>RN</b>	registered nurse
<b>CC</b>	carbon copy	<b>FOBT</b>	fecal occult blood test	<b>RCN</b>	Regional Colonoscopy Network	<b>PCP</b>	primary care physician

## Recruitment Model Registered Nurse-Performed Flexible Sigmoidoscopy (continued)

Last Updated December 2011



### Legend

<b>BUP</b>	back-up physician	<b>NS</b>	nurse sigmoidoscopist	<b>RNFS</b>	RN flexible sigmoidoscopy	---	recommendation from
<b>CC</b>	carbon copy	<b>RCN</b>	Regional Colonoscopy Network	<b>PCP</b>	primary care physician		BUP for normal follow-up
<b>FOBT</b>	fecal occult blood test	<b>RN</b>	registered nurse				

# Appendix E

## ONTARIO MEDICAL ASSOCIATION CONDITIONS/CRITERIA AND PRINCIPLES NECESSARY FOR A NURSE SIGMOIDOSCOPIST TO CARRY OUT FLEXIBLE SIGMOIDOSCOPY

### Conditions/Criteria

- 1 The Ontario Medical Association (OMA) believes that it is important for nurse sigmoidoscopists to work with physicians as part of an interprofessional care team.
- 2 There must be a systematic approach to the training introduction of nurses performing flexible sigmoidoscopy with input from physicians and general surgeons already experienced in the procedure.
- 3 Physician access to current needed resources and hospital times to provide endoscopy examinations must not be compromised by the introduction of nurse sigmoidoscopists. These resources include access time to endoscopy suites, access to equipment to perform the procedure, medications and the staff required to perform full endoscopy, including registered nurses, RNAs, secretarial support and cleaning personnel.

### Principles

- 1 Flexible sigmoidoscopy can be performed by nurse sigmoidoscopists for the purpose of colon cancer screening, but not as part of a therapeutic procedure, such as polypectomy, controlling lower gastrointestinal bleeding, diagnosis or treatment of colonic disorders.
- 2 There must be an appropriate and approved training program for nurse sigmoidoscopists to be certified to perform flexible sigmoidoscopy. This includes the didactic training, as well as completion of 50 independent procedures with a gastroenterologist or general surgeon preceptor present. An annual review of competency by an approved preceptor will be required. Annual ongoing updating of skills would be expected continuing medical education with supervision by a gastroenterologist or general surgeon.
- 3 The institution, the physician and the nurse must be satisfied that the nurse sigmoidoscopist has the required knowledge, skill and judgement to perform flexible sigmoidoscopy.
- 4 The nurse sigmoidoscopist must work in the same location at the same time as the team physician so that the physician is readily available for backup. Backup may be required for an adverse event (bowel perforation, bleeding), to carry out a needed biopsy or for consultation on certain findings.
- 5 Nurse sigmoidoscopists will report the sigmoidoscopy findings to physicians in a timely manner.

- 6 Nurse sigmoidoscopists should **not** perform a flexible sigmoidoscopy under sedation without an anaesthetist available and providing such anaesthesia.
- 7 Patients should be informed that flexible sigmoidoscopy does not examine the full length of the colon and is not a complete or as sensitive a screening procedure for significant colonic neoplasm as colonoscopy.
- 8 The appropriate resources must be in place for all procedures at all times, including high-quality video sigmoidoscopy, high-quality viewing monitors, and computer image capture and storage for quality control. These resources should be in addition to present OMA negotiated resources.
- 9 Physician compensation and resources for leadership for nurse sigmoidoscopists, backup and consultation must be included and be appropriate for the time and skill required by the physician team member.
- 10 Appropriate institutional and professional malpractice issues should be addressed, including those related to physician leadership for nurse sigmoidoscopy.

Source: The Ontario Medical Association's Statement on Nurse Sigmoidoscopist. July 2007.

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