program in evidence-based care
a cancer care ontario program
programme de soins fondé sur des preuves
un programme de action cancer ontario

Cancer Care Ontario Colonoscopy Standards: Standards and evidentiary base

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Colorectal cancer (CRC) is the most common cause of non-tobacco-related cancer deaths in Canadian men and women, accounting for 10% of all cancer deaths. An estimated 7800 men and women will be diagnosed with CRC, and 3250 will die from the disease in Ontario in 2007. Given that CRC incidence and mortality rates in Ontario are among the highest in the world, the best opportunity to reduce this burden of disease would be through screening. The present report describes the findings and recommendations of Cancer Care Ontario's Colonoscopy Standards Expert Panel, which was convened in March 2006 by the Program in Evidence-Based Care. The recommendations will form the basis of the quality assurance program for colonoscopy delivered in support of Ontario's CRC screening program.

Key Words: *Cancer Care Ontario; Colonoscopy; Colonoscopy standards; Colorectal cancer screening*

Les normes de coloscopie d'Action cancer Ontario : Fondées sur les normes et les preuves

Le cancer colorectal (CCR) est la principale cause de décès par cancer non relié au tabac chez les hommes et les femmes du Canada. En effet, il représente 10 % de tous les décès par cancer. On estime que 7 800 hommes et femmes recevront un diagnostic de CCR et que 3 250 en mourront en Ontario en 2007. Puisque l'incidence et le taux de mortalité du CCR en Ontario font partie des plus élevés dans le monde, le dépistage représenterait le meilleur moyen de réduire le fardeau de cette maladie. Le présent rapport décrit les observations et les recommandations du comité d'experts des normes de coloscopie d'Action cancer Ontario, convoqué en mars 2006 par le programme de soins fondé sur des preuves. Les recommandations formeront la base du programme d'assurance de la qualité des coloscopies effectuées en appui au programme ontarien de dépistage du CCR.

Colorectal cancer (CRC) is the most common cause of non-tobacco-related cancer deaths in Canadian men and women, accounting for 10% of all cancer deaths (1). An estimated 7800 men and women will be diagnosed with CRC, and 3250 will die from the disease in Ontario in 2007 (1). Given that CRC incidence and mortality rates in Ontario are among the highest in the world (1), the best opportunity to reduce this burden of disease would be through screening.

The two CRC screening methods recommended by the Canadian Task Force on Preventive Health Care for men and women 50 years of age and older are the fecal occult blood test (FOBT) and flexible sigmoidoscopy (FS) (2). Screening with FOBT (coupled with colonoscopy for those who test positive) is associated with a decrease in CRC mortality and an increase in the proportion of detected tumours that are stage 1 cancers (3-6). In 1999, Cancer Care Ontario (CCO) convened an expert panel to develop recommendations for a CRC screening program in Ontario. The panel recommended a province-wide FOBT-based CRC screening program for average-risk individuals 50 years of age or older (7). In 2002, this recommendation was echoed at the national level by a Health Canada committee (8).

*See Appendix A

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In June 2003, a one-year pilot study to evaluate implementation models for FOBT was funded by the Ministry of Health and Long-Term Care (MOHLTC) (9). In June 2005, CCO submitted a proposal for an FOBT-based CRC screening program to the MOHLTC. Funding for the program was announced by the MOHLTC in January 2007. In this program, colonoscopy will be used to investigate the 2% to 3% of screenees who have a positive FOBT. To support the program across the province, CCO will be responsible for quality assurance in the delivery of colonoscopies.

The present report describes the findings and recommendations of CCO's Colonoscopy Standards Expert Panel (Appendix A), which was convened in March 2006 by the Program in Evidence-Based Care. The recommendations will form the basis of the quality assurance program for colonoscopy delivered in support of Ontario's CRC screening program.

BACKGROUND

CRC is the third most commonly diagnosed cancer in men, following prostate and lung cancer, and in women, following breast and lung cancer (1). CRC is the second leading cause of cancer mortality in men, following lung cancer, and the third in women, following lung and breast cancer (1).

The primary treatment for CRC is surgery, which offers the best hope for long-term survival. However, offering surgery with curative intent depends on the cancer being detected at a resectable stage (10). For that reason, there is great interest in the early detection of CRC through screening.

Individuals with a positive FOBT or FS are advised to undergo colonoscopy, an examination of the rectum and entire colon using a colonoscope, a flexible fibre optic instrument. The tip of the colonoscope is equipped with a miniature video camera and a light that provide the endoscopist with a high-resolution image of the bowel wall. The endoscopist can insufflate the colon with air and irrigate or suction the colon, perform biopsies, and snare and remove polyps. Colonoscopy requires complete bowel preparation to empty the colon of its contents. Although most patients are sedated for the procedure, colonoscopy can be performed as either an inpatient or an outpatient procedure. Colonoscopy is associated with a risk of complications such as bowel perforation and bleeding. FS is an examination of the rectum and lower colon using a flexible fibre optic instrument.

The purpose of the present report is to evaluate the existing evidence concerning the following three key aspects of colonoscopy: physician endoscopist standards, institutional standards and performance standards for the procedure.

Physician endoscopist standards

- What is the training required for physicians performing colonoscopy?

Institutional standards

What is needed for:

- Patient assessment before the procedure?
- Infection control?
- Monitoring during and after the administration of conscious sedation?
- Resuscitation capability?

Performance standards

What is/are acceptable:

- Colonoscopy-related perforation and bleeding rates?
- Cecal intubation rates?
- Average colonoscope withdrawal time?
- Adenoma detection rates?
- CRC miss rates?
- Use of sedation?
- Bowel preparation?

To address these questions related to colonoscopy practice, a systematic literature review and a comprehensive Internet search were undertaken.

METHODS

Literature search strategy

The MEDLINE and EMBASE databases, the Cochrane Library database of Systematic Reviews, and the Database of Abstracts of Reviews of Effects were systematically searched in March and June/July 2006 for evidence. Relevant papers were also solicited from the Expert Panel members. The searches were done in the following two stages; first, the initial MEDLINE and EMBASE searches in March 2006, and then, five additional searches in June/July 2006 to gather additional information. The literature searches were completed as follows:

Search date	Topic and/or database	Search terms used
March 6, 2006	MEDLINE	Colonoscopy, adverse events, standards
March 15, 2006	EMBASE	Colonoscopy, practice guidelines, randomized controlled trial
June 8, 2006	Assessment MEDLINE only	Colonoscopy, risk assessment, needs assessment, process assessment (health care)
June 8, 2006	Bleeding MEDLINE only	Colonoscopy, adverse events, bleeding, hemorrhage
June 8, 2006	Bowel preparation MEDLINE only	Colonoscopy, bowel preparation
June 8, 2006	Sedation MEDLINE only	Colonoscopy, propofol, hypnotics and sedatives, conscious sedation, midazolam
July 14, 2006	Cancer miss rates MEDLINE only	Colonoscopy, cancer miss rates, missed cancer rates

Inclusion criteria

Eligible sources of information included:

1. Published full reports and abstract reports where any of the items of interest were reported for patients who underwent colonoscopy;
2. Randomized controlled trials (RCTs), retrospective study designs, prospective case series, educational interventions, mixed designs and other relevant designs;
3. Reports including physician endoscopists; and
4. Reports published in English.

Exclusion criteria
Ineligible sources of information included reports in which the results for colonoscopy could not be separated from the results for FS.

Internet search strategy
An Internet search was conducted to capture the relevant unindexed literature that would not be found in the formal literature review. The intent was to obtain both governmental and nongovernmental publications, policy statements, bulletins, health technology assessments and similar documents. In addition, members of the Expert Panel were polled regarding unindexed publications about which they might be aware. The Internet search strategy was to review the first 50 hits, and if no compelling sources were flagged in the 10 hits before 50, the search would be considered complete. If relevant sources continued to be found, the search would continue until a series of 10 nonuseful hits had been reviewed.

Inclusion criteria
Eligible sources of information included any report as described above that provided information on the aspects of colonoscopy practice described above.

RESULTS

Literature search
Eighty-five of the total 641 MEDLINE hits were determined to be relevant, through a review of the title and abstract, and were ordered for full publication review. Forty-one of the total 301 EMBASE hits were determined to be relevant, through a similar review, and after removing the five duplicates already identified in the MEDLINE search, the remaining 36 were ordered for full publication review. The June/July 2006 supplemental search resulted in an additional 36 articles being ordered. The search details include:

Date	Topic and database	Database searched up to	Hits	Ordered for full article review, n
March 6, 2006	Initial search MEDLINE	February 2006 (week 4)	641	85
March 15, 2006	Initial search EMBASE	2006 (week 10)	301	36
June 8, 2006	Assessment MEDLINE only	May 2006 (week 5)	6	0
June 8, 2006	Bleeding MEDLINE only	May 2006 (week 5)	26	4
June 8, 2006	Bowel preparation MEDLINE only	May 2006 (week 5)	107	15
June 8, 2006	Sedation MEDLINE only	May 2006 (week 5)	84	14
July 14, 2006	Cancer miss rates MEDLINE only	July 2006 (week 1)	3	3

In summary, a total of 1168 articles were found in the literature search, and the 157 considered possibly relevant were ordered for full publication review. Of these 157 articles, 49 met the full inclusion criteria and were retained (11-59). Additionally, two of the coauthors forwarded six articles (Regula et al [60], Levin et al [1], Rex et al [62,63], Bressler et al [64] and Barkun et al [65]), that were not found in the literature review. No relevant articles were found in the Cochrane Library Database of Systematic Reviews search. However, a protocol of an ongoing review that might be relevant was listed and, when made publicly available, will be included in a future update of this standards document (66).

A total of five papers (11-15) were obtained that included data on who could perform colonoscopy and the type of training required. No studies were obtained that provided data on patient assessment, infection control, monitoring during and after administration of conscious sedation, or resuscitation capability. However, the following data were provided in specific papers: perforation rate – eight papers (12,17-21,60,61), bleeding – nine papers (12,13,18,22-25,60,61), cecal intubation rates – 14 papers (11-15,17,18,26-31,60), average colonoscope withdrawal times – five papers (18,30,32-34), adenoma detection – eight papers (11,15,32,35,39,40,60,62), CRC miss rates – seven papers (15,35,36,38,41,63,64), the use of sedation – 12 papers (42-53) and bowel preparation – 15 papers (11,13,17,18,28-30,32,37,54-59).

Internet search results
An Internet search, using the Google search engine (www.google.ca), was performed on March 20 and 21, 2006, using the terms "colonoscopy guideline". A title review of the first 50 results yielded 10 sources that were deemed relevant; these were obtained for full review. Eight of these met the inclusion criteria and were retained (67-74).

These eight sources (detailed below) informed such topics as what training is required to perform the procedure (67-70); institutional standards (69,70); monitoring during the use of conscious and deep sedation, as well as monitoring during resuscitation and recovery (71,72); perforation rates (73,74); cecal intubation rates (69,70,73,74); average colonoscopy withdrawal times (73,74); and adenoma detection rates (74). The report by the College of Physicians and Surgeons of Ontario (CPSO) (70) included standards that covered all endoscopy facilities, not just colonoscopy facilities.

Reference	Source
67	Statement on colonoscopy privileging: American Academy of Family Physicians.
68	Principles of privileging and credentialing for endoscopy and colonoscopy. Joint statements by the American Society for Gastrointestinal Endoscopy, the Society of American Endoscopic Surgeons, and the American Society of Colorectal Surgeons; American Society for Gastrointestinal Endoscopy.
69	Guidelines for the training, appraisal and assessment of trainees in gastrointestinal endoscopy. Joint Advisory Group on Gastrointestinal Endoscopy, representing the Royal College of Physicians of the United Kingdom (UK), the Royal Colleges of Surgeons of the UK, the Royal College of Radiologists, and the Royal College of General Practitioners.
70	Independent Health Facilities, Clinical Practice Parameters and Facility Standards: Endoscopy. The College of Physicians and Surgeons of Ontario.
71	Guidelines for the care of the patient receiving conscious sedation. Canadian Society of Gastroenterology Nurses and Associates.

Continued on next page

Reference	Source – continued
72	Guidelines for conscious sedation and monitoring during gastrointestinal endoscopy. American Society for Gastrointestinal Endoscopy.
73	Quality indicators for colonoscopy. ASGE/ACG Taskforce on Quality in Endoscopy. American Society for Gastrointestinal Endoscopy.
74	Quality in technical performance of colonoscopy and the continuous quality improvement process for colonoscopy: Recommendations of the US Multi-Society Task Force on Colorectal Cancer. Rex et al on behalf of the US Multi-Society Task Force on Colorectal Cancer.

PHYSICIAN ENDOSCOPIST STANDARDS

Training required to perform colonoscopy – Literature search results

A total of five papers were obtained that included data on the type of training involved in developing skill in colonoscopy (11-15). Three of the reports were retrospective chart reviews (11,12,14), and two were prospective case series (13,15). A summary of the findings appears in Table 1.

The findings were that intensive, supervised training programs are integral to acquiring colonoscopy skills. There is evidence that physician endoscopists who do not receive this type of training take much longer to acquire skills and raise them to an accepted level of competence (14). However, the evidence shows that, after proper training, family physicians and surgeons perform at the same level of skill as gastroenterologists (11-13). One study suggested that, in clinicians competent in FS, 50 supervised colonoscopies is the minimum number needed to ensure safety (11), while another concluded that there is no detectable threshold where competence can be assured (13).

Training required to perform colonoscopy – Internet search results

Four sources were obtained that provided data on the training required (67-70) (details provided below). Two sources stated that hospital governing boards should determine who can perform colonoscopies at their institutions (67,68). The American Society for Gastrointestinal Endoscopy (ASGE) guidelines (United States [US]) (68) recommend that adequate clinician training may consist of training and experience outside formal residency programs, following completion of an accredited program in general surgery, pediatric surgery, colorectal surgery or gastroenterology. The Joint Advisory Group (JAG) in the United Kingdom (UK) (69) recommends that trainees have received prior training in basic endoscopy skills, eg, upper gastrointestinal endoscopy or FS. The CPSO (70) recommends that physicians performing colonoscopy with polypectomy either be certified with the Royal College of Physicians and Surgeons of Canada or be family physicians with acceptable certification (or equivalent certification from a country other than Canada [CAN]). They should also have completed a residency program providing structured experience, with competency determined either by an instructor or the training program, or have equivalent postgraduate training and also have privileges at an accredited Ontario hospital to perform this procedure.

American Academy of Family Physicians (US) (67)

- Hospital governing boards must determine who should be granted colonoscopy privileges at their institutions with input from the medical staff.
- Adequate clinician training may consist of documented education in an Accreditation Council for Graduate Medical Education-approved residency program on colonoscopy, continuing medical education courses that provide didactic and procedural training, and/or preceptored experience focused on colonoscopy.
- Past research has indicated that family physicians who perform colonoscopy compare favourably with specialists when outcome measures (eg, cecal intubation rates) are the determinants of competency.

ASGE (US) (68)

- Hospitals should be responsible for the credentialing structure and process.
- Adequate clinician training may consist of training and experience outside a formal residency program after completion of an Accreditation Council for Graduate Medical Education-accredited general surgery, pediatric surgery, colorectal surgery, gastroenterology or equivalent training program.
- Proctoring of applicants for privileges in gastrointestinal endoscopy by a qualified, unbiased staff endoscopist may be desirable when competency for a given procedure cannot be adequately verified by any submitted materials.
- Hospitals should have monitoring procedures in place for the ongoing renewal of privileges.
- Participation in continuing medical education related to endoscopy should be required as part of the renewal of endoscopic privileges.
- Renewal of privileges should require an appropriate level of continuing clinical activity, satisfactory performance as assessed by the monitoring mechanism, and continuing medical education related to gastrointestinal endoscopy.

JAG on gastrointestinal endoscopy (UK) (69)

Diagnostic

- Trainees in colonoscopy should have acquired basic endoscopic skills, usually by prior training in upper gastrointestinal endoscopy or FS.
- For trainees in coloproctology, attendance at a UK-JAG-compliant basic skills or FS course to learn the basics of safe endoscopy would be an acceptable starting point.
- Trainees need to understand the techniques of patient preparation, the mechanics of the procedure and its indications, limitations and complications.
- Trainees should be able to perform 100 procedures within the course of a year, and will be considered to have achieved an acceptable level of expertise when the cecum is reached when possible.

Therapeutic

- Trainees should be competent in the techniques of hot biopsy, polypectomy and treatment of colonic bleeding.

TABLE 1
Colonoscopy training, method of post-training assessment and results

Study	Method of training	Method of post-training assessment	Results
Pierzchajlo et al (11) (1997) Design: Retrospective chart review Unit of analysis: 751 colonoscopies Setting: Two hospitals One physician performed procedures	• Medical school and family practice residency (no formal training in gastrointestinal endoscopy). • Attended a didactic, model-based colonoscopy course. • Preceptored for 80 colonoscopies by general surgeons and family physicians for a two-year period.	Cecal intubation was the sole criterion for assessment.	Cecal intubation rate: 91.5%*
Wexner et al (12) (1998) Design: Retrospective chart review Unit of analysis: 2069 procedures Setting: Two hospitals Four surgeons performed procedures	• No discussion of colonoscopy-specific training was given.	Assessment was made by measuring: cecal intubation rate; average procedure time; serious complication rates (bleeding, perforations)	Cecal intubation rate†: 96.5%; average procedure time: <30 min; serious complication rates: 0.24%; bleeding: 0.10% (n=2); perforations: 0.14% (n=3)
Wexner et al (13) (2001) Design: Prospective case series Unit of analysis: 13,580 colonoscopies Setting: Not specified 207 surgeons performed procedures	• No discussion of colonoscopy-specific training was given.	Assessment was made by measuring: cecal intubation rate; time to completion; intraprocedural complication rates; (arrhythmia, bradycardia, hypotension, hypoxia); postprocedural complication rates for diagnostic colonoscopy (bleeding, perforations)	Cecal intubation rate: 92%; average time to completion: 22.7 min (range 1 min to 170 min); complication rates: 0.2%‡; bleeding: 0%; perforations: 0.02%
Kirby (14) (2004) Design: Retrospective chart review Unit of analysis: 616 procedures Setting: Single hospital One physician performed procedures	• Training of general practitioner consisted of 30 supervised colonoscopies over 2.5 years during general surgery training.	Assessment was made by measuring: cecal intubation rate. Complications examined: bleeding, perforation, hypotension	Cecal intubation rate: 60% to 70% (90% in last three years of study)§. Complications: 0%
Edwards and Norris (15) (2004) Design: Prospective case series Unit of analysis: 200 colonoscopies Setting: Single hospital Four family physicians performed procedures	• No discussion of colonoscopy-specific training was given.	Assessment was made by measuring: cecal intubation rate; time to reach cecum; procedure time; complications examined¶	Cecal intubation rate: 96.5%: (range 91% to 100%); average time to reach cecum: 15.9 min (range 6.5 min to 23.8 min); average procedure time: 34.4 min; complications: 2% (no bleeding or perforations)

**The authors conclude that family physicians can acquire colonoscopic skills, including polypectomy, after completing family practice residency training. No training effect was observed over the 751 procedures; however, complication rates were higher in the first 120 procedures. The authors suggest that for physicians competent in flexible sigmoidoscopy, 50 supervised colonoscopies is a reasonable number to assure competency and safety; †The authors suggest that it is not the specialty of the surgeon or physician that predicts the safety, efficacy and outcome of colonoscopy but the amount of training and experience; ‡Surgeons can safely and effectively perform colonoscopy. The authors suggest that these data imply a threshold level to ensure safe colonoscopy does not exist; §The authors suggest that a partially trained individual working alone takes longer to develop competence (eg, to achieve 80% to 90% cecal intubation rates, 300 colonoscopies were required); ¶Use of reversal agents with sedation, cardiorespiratory problems with sedation, bowel perforation, hospital admission, emergency department visits and bleeding requiring transfusion*

- Trainees should be familiar with balloon dilation of strictures and techniques to stop bleeding and treat angiodysplastic lesions.
- Some trainees may wish to gain a higher degree of training in more advanced techniques, including dye spraying, tattooing, endoscopic mucosal resection, tumour debulking and stenting.

Training

- To facilitate the above standards, courses should be offered to trainees for basic skills in colonoscopy (JAG-compliant) and a more advanced course (also JAG-compliant).

The CPSO recommendations for independent health facilities (CAN) (70)

Physicians

- Physicians performing endoscopic procedures:
  - Should have certification with the Royal College of Physicians and Surgeons of Canada or are family

physicians with acceptable certification or have equivalent certification from a country other than Canada; and

- Must be licensed by the CPSO.

- To perform colonoscopy with polypectomy, credentials and qualifications specific to this procedure must be met and are defined as the following:
  - Completion of a residency program providing structured experience with level of competency documented by either an instructor or the training program;
  - Equivalent postgraduate training incorporating structured experience with competency documented by the instructor or preceptor or training program; and
  - Currently held privileges to perform the procedure in an accredited hospital in Ontario.

For physicians using conscious sedation

- Physicians using conscious sedation should have an appropriate level of training in this field, acquired either during the training period, or separately in a structured experience, with the level of competency assessed by the instructor or preceptor.

Nurses using conscious sedation

- These nurses must have training in the pharmacology of agents commonly used during sedation/analgesia including: knowledge of opioids and benzodiazepines, dosages, titration, possible side effects, use of reversal agents, potentiation of sedative-induced respiratory depression by concomitantly administered opioids, knowledge of time intervals between doses of sedatives or analgesics resulting in cumulative overdose, familiarity of pharmacological antagonists for sedatives or analgesics, knowledge of complications associated with opioids and benzodiazepines, and the ability to recognize associated complications and be trained to perform basic life support skills (cardiopulmonary resuscitation, bag-valve-mask, ventilation); and
- All nurses administering sedation and analgesia must be trained in the following: basic cardiopulmonary resuscitation, airway management and intravenous (IV) fluid administration.

INSTITUTIONAL STANDARDS

Literature search results

No articles were obtained that provided any data on institutional standards.

Internet search results

Three papers obtained in the Internet search (70-72) provided information on institutional standards (see details below). The CPSO document (70) did not recommend a minimum number of procedures but did provide extensive information covering the use of conscious and unconscious sedation, the role of nurses, and the monitoring and resuscitation capability that must be present by facility type (either a Type I, II or III), as well as information on infection control. The Canadian Society of Gastroenterology Nurses and Associates document (71) provided information on monitoring during conscious sedation, as well as on resuscitation. The ASGE document (72) provided information on monitoring during conscious and deep sedation, as well as monitoring and procedures during resuscitation.

ASGE (US) (72)

When conscious or deep sedation is used

- Patients undergoing procedures with conscious or deep sedation must have continuous monitoring before, during and after sedative administration.
- Standard monitoring includes recording heart rate, blood pressure, respiratory rate and oxygen saturation.
- Modern electronic monitoring equipment may facilitate assessment but cannot replace well-trained assistants.
- Continuous electrocardiogram monitoring is reasonable in high-risk patients. This subgroup of high-risk patients would include those who have a history of cardiac or pulmonary disease, the elderly, and those patients for whom a prolonged procedure is expected.

Monitoring during resuscitation

- Following the procedure, patients are to be monitored for adverse events from either the procedure or the sedation.
- The duration of monitoring depends on the perceived risk to the patient.
- Patients may be discharged from the endoscopy unit once vital signs are stable and an appropriate level of consciousness has been achieved.
- A competent companion must accompany the patient from the recovery area.
- Because the amnesia period that follows the administration of sedation is variable, written instructions should be given to the patient to take with him or her, including the procedures to follow if an emergency arises.

The CPSO (CAN) (70)

- Along with the endoscopist, several other disciplines may be required (as needed), including anesthesiologists, registered nurses and endoscope reprocessing technicians. Adequately trained nurses may perform the tasks generally assumed by the endoscope reprocessing technician.

When conscious sedation is used

- At least one physician certified and current in Advanced Cardiac Life Support or trained in general anesthesia should be on-site and available within 5 min.
- At least one Independent Health Facility person currently certified in Basic Cardiac Life Support must be present on-site during the procedure.

When deep sedation is used

- A physician qualified to administer general anesthesia should be present.
- Assistance with the procedure is recommended for the following situations:
  - If there is an increased risk of complications due to severe medical comorbidity;
  - If there is an anticipated intolerance to standard sedatives, particularly if propofol is considered; or
  - If there is an increased risk for airway obstruction due to variant anatomy.

Note: If the physician performing the procedure does not have hospital admitting privileges, emergency transfer agreements with a nearby hospital must be prearranged.

Nurses assisting with endoscopy procedures

- Nurses assisting with endoscopy procedures must have current registration with the College of Nurses of Ontario.
- In addition to this, nurses should also have completed an electrocardiogram interpretation course and a health assessment course, and have training in electrocautery application and x-ray safety (as given by the Healing Arts Radiation Protection Act).

For the institutional standards, the CPSO has delineated Type I, II and III facilities. Only the main points are listed below; for more complete listings, please refer to the original document.

Type I endoscopy facility: Topical/local anesthesia only

- Proper environment for endoscopic procedures.
- Medications for anaphylactic reactions.
- Defibrillator and emergency resuscitation equipment.

Type II endoscopy facility: Topical anesthesia with sedation

- Proper environment for endoscopic procedures.
- Patient monitoring equipment, including blood pressure apparatus, electrocardiogram and oximeter. This equipment must be tested on the day of and before endoscopy.
- Resuscitation equipment present, including defibrillator, endotracheal tubes, airways, laryngoscope, oxygen sources with positive pressure capabilities, emergency drugs and oxygen tanks.
- Access to a hospital for the transfer of emergency cases.
- An emergency power source.

Type III endoscopy facility: General or regional anesthesia

- All of the above plus a Fellow of the Royal College of Physicians of Canada anesthesiologist present for all general and spinal anesthesia.

Infection control

- Gastrointestinal endoscopes come into contact with mucous membranes and are considered semicritical items. The minimum standard of practice for reprocessing is high-level disinfection.
- Accessories (eg, reusable biopsy forceps) that penetrate mucosal barriers are classified as critical items and must be sterilized between each patient use. Accessories labelled as either single-use or disposable should not be reprocessed.
- Endoscopes have been implicated in the transmission of disease when appropriate cleaning, disinfection or sterilization procedures were not employed. Of particular significance is the need to thoroughly manually clean equipment before any manual or automatic disinfection or sterilization process.

Safety of personnel

Consistent practice must be maintained to prevent the spread of disease and to protect staff from the dangers of chemicals used in the cleaning and high-level disinfection of endoscopes. Practices that should be followed include:

- All personnel performing or assisting with endoscopic procedures must follow universal precautions and wear appropriate equipment to protect themselves from fluid and body substances including but not limited to gowns, gloves, goggles and masks.
- Irritation can be minimized with covered containers and by using disinfectants in a well-ventilated area.
- Eye protection and moisture-resistant masks or face shields should be worn to prevent contact with splashes during the cleaning procedure and disinfection/sterilization process.
- Moisture-resistant gowns should be worn to prevent contamination of personnel due to splashes of blood or other body fluids or injury due to chemical disinfectant/sterilant contact. Gowns should be changed between patient procedures or when visibly soiled.
- Protective apparel should not be worn outside the procedure room and cleaning room.
- Nonsterile gloves must be worn for handling and cleaning dirty equipment, as well as for any potential contact with blood or body fluids. Gloves are recommended when handling disinfectant solutions to prevent caustic effects.
- All needles and sharps are to be appropriately disposed of in puncture-resistant containers at their point of use. Do not recap needles.
- Fingernails should be kept short to prevent puncturing of gloves. Jewellery should not be worn on the hands because it harbours micro-organisms, hinders hand washing and may puncture gloves.
- Meticulous hand washing with an appropriate anti-microbial solution must be done between patient contact, after glove removal, and when entering or leaving the endoscopy area. If hands or other skin surfaces are contaminated with blood or body fluids, wash immediately.
- All personnel performing or assisting with endoscopic procedures and personnel responsible for reprocessing the equipment must be knowledgeable about the infectious

TABLE 2
Colonoscopy-related perforation rates

Study	Study design	Clinician specialty*	Patients/procedures (n)	Perforation rate, n (%)
Wexner et al (12); Setting: Two hospitals	Retrospective	Surgeons (n=4)	2069 colonoscopies	3 (0.14)
Minoli et al (17); Setting: Four endoscopy units	Prospective	Gastroenterologists	603 colonoscopies	2 (0.33)
Nelson et al (18); Setting: 13 VA Medical Centers	Prospective	Gastroenterologists	3196 screening colonoscopies	0 (0)
Gatto et al (19); Setting: Random sampling of 5% of United States Medicare claims (patients aged 65 years or older)	Retrospective	Not specified	39,286 colonoscopies	77 (0.19)
Cobb et al (20); Setting: A single teaching hospital (Carolinas Medical Center)	Prospective	Total	43,609 colonoscopies	14 (0.03)
		General surgeons	1243 colonoscopies	1 (0.08)
		Gastroenterologists	42,366 colonoscopies	13 (0.031)
Misra et al (21); Setting: A single teaching hospital (University of Alberta Hospital)	Retrospective	Gastroenterologists	7425 colonoscopies	10 (0.13)
Regula J et al (60); Setting: A national screening program in Poland (6 to 40 sites at study end)	Prospective	Not specified	50,148 colonoscopies	51 (0.10)
Levin et al (61); Setting: Kaiser Permanente of Northern California health care system	Retrospective	Endoscopists	16,318 colonoscopies	15 (0.092)

**Unless shown, the number of persons performing the procedure was not reported in the paper. VA Veterans affairs*

and chemical hazards associated with these procedures and equipment, including the relevant Workplace Hazardous Material Information System Guidelines.

Universal precautions

- According to the concept of 'universal precautions', all human blood and certain human body fluids are treated as if known to be infectious for HIV, hepatitis B virus and other bloodborne pathogens.
- Universal precautions must be observed in each facility to prevent contact with blood or other potentially infectious materials. All blood or other potentially infectious material will be considered infectious, regardless of the perceived status of the source individual.

Canadian Society of Gastroenterology Nurses and Associates (CAN) (71)

When conscious sedation is used

- Minimal monitoring of all patients, including blood pressure, pulse, respiration, level of consciousness, temperature and dryness of skin, and pain tolerance at the initiation, during and at the completion of the procedure, is recommended.
- Depending on patient response, assessment may need to be more frequent.

Monitoring during resuscitation

- Minimal monitoring during resuscitation should include the following:
  - Monitor oxygen saturation level and heart rate as determined by continuous pulse oximetry.
  - Assess blood pressure, heart rate, respiratory rate depth and effort, and level of consciousness on admission to recovery area, after 15 min, until stable and at discharge. Postprocedure oximetry must be performed until the patient's respiratory status is stable or returned to preprocedure state.
  - Assess and document unexpected events and postprocedure complications as related to sedation and take interventions as required.
  - Assist and accompany patient to the bathroom, assessing the presence of orthostatic hypotension.
  - Assess gait before discharge.
  - Remove IV access before discharge, assess site and document.
- Reinforce preprocedure teaching regarding driving, equipment operation, and making decisions requiring judgment. The teaching provided should be in written form and a copy given to the patient before discharge.

PERFORMANCE STANDARDS

Perforation rates – Literature search results

Eight reports (12,17-21,60,61) that provided data on perforation rates encompassed screening, diagnostic and therapeutic procedures in different patient populations. Four of the studies were retrospective designs (12,19,21,61) and four were prospective designs (17,18,20,60). The reported perforation rates ranged from a low of 0% (18) to a high of 0.33% (17). The highest rate (0.33%) was obtained in a series of patients undergoing therapeutic procedures (Table 2).

An additional study by Garbay et al (16) not included in Table 2 was a retrospective survey covering the years 1981 to 1993 that reported on the complications associated with colonoscopy requiring surgery. The investigators found that perforations represented up to 93% of all complications that resulted in surgical interventions. In this study, which included 183 perforations, the diagnosis of perforation was immediate in 75 patients (42%) and delayed in 100 (58%), and delays ranged from 1 h to 42 days postprocedure. In the group of patients with delayed presentation of perforations, the observed mortality rate

TABLE 3
Colonoscopy-related bleeding rates

Study	Study design	Clinician specialty*	Patients/ procedures, n	Bleeding rate n (%); Incidence rate/1000	Bleeding requiring laparotomy (%)
Gibbs et al (22)	Retrospective	Colorectal surgeons, gastroenterologists	6365 polypectomies†	13 (0.20); 2/1000	Not reported
Wexner et al (12)	Retrospective	Surgeons (n=4)	2069 patients	2 (0.10); 1/1000	Not reported
Zubarik et al (23)	Telephone survey	Colorectal surgeons, gastroenterologists	1196 patients	22 (1.8); 18/1000	Not reported
Dafnis et al (24)	Retrospective	Surgeons, gastroenterologists, radiologists	6066 colonoscopies, 4304 patients	12 (0.20); 2/1000	n=2 (<0.03%) 0.3/1000
Wexner et al (13)	Prospective	Surgeons	13,580 colonoscopies	10 (0.074); 0.7/1000	Not reported
Ker et al (25)	Retrospective	Single surgeon	5120 patients	6 (0.11); 1/1000	Not reported
Nelson et al (18)	Prospective	Gastroenterologists	3196 screening colonoscopies	Major bleed‡: 7 (0.22); 2.2/1000 Minor bleed§: 6 (0.18); 1.8/1000 Overall: 13 (0.41); 4/1000	Not reported
Regula et al (60)	Prospective	Not specified	50,148 participants	13 (0.025); 0.25/1000	Not reported
Levin et al (61)	Retrospective	Endoscopists	16,318 patients	53 (0.32); 3/1000	Not reported

**Unless shown, the number of persons performing the procedure was not reported in the paper; †Bleeding rate for colonoscopy not reported; ‡Gastrointestinal bleeding with hospitalization; §Gastrointestinal bleeding without hospitalization*

was 12%. In 77 patients where perforation was detected 12 h postprocedure or sooner, the observed mortality rate was 0%.

Two of the eight studies in Table 2 provided data on the risk factors associated with perforations (19,21). Gatto et al (19) detected associations between perforations and the following risk factors: age 75 years or greater (in this study, those 75 years of age or older had four times the risk of perforation compared with patients aged 65 to 69 years), increasing comorbidity, the presence of diverticulosis and the presence of colonic obstruction. Misra et al (21) reported associations between perforation and diverticulosis, previous abdominal surgery and poor bowel preparation.

Perforation rates – Internet search results
Two articles were obtained (73,74) that provided data on perforation rates (see details below).

ASGE (US) (73)
Perforation rates less than or equal to one in 500 (0.2%) overall or less than one in 1000 (0.1%) in screening patients are acceptable.

The US Multi-Society Task Force on Colorectal Cancer (US) (74)
Incidence rates for perforation overall should be less than one per 1000 (less than 0.1%), and for screening examinations, less than one per 2000 (less than 0.05%).

Bleeding rates – Literature search results
Nine studies (12,13,18,22-25,60,61) reported data on bleeding, and one of these studies reported the number of patients experiencing bleeding who required laparotomy (24). The incidence rates provided by the studies ranged from a low of 0.25 in 1000 (60) to a high of 18 in 1000 (23) (Table 3).

Bleeding rates – Internet search results
No articles were obtained through the Internet search that provided data on bleeding rates.

Cecal intubation rates – Literature search results
A total of 14 studies (11-15,17,18,26-31,60) obtained through the search provided data on cecal intubation rates. Ten of these studies were prospective (11,13,15,17,18,26-28,30,60), and four were retrospective (12,14,29,31). The reported cecal intubation rates ranged from a low of 76% (14) to a high of 99.2% (27). The weighted mean was 91.9% (authors' calculation). Removing the outlier data from the Kirby study (14) resulted in a weighted mean of 92% (Table 4).

Cecal intubation rates – Internet search results
Four articles (69,70,73,74) obtained in the Internet search provided data on cecal intubation rates (see details below). Three of the articles recommended that cecal intubation rates should exceed 90% for all cases (69,73,74), two articles recommended cecal intubation rates exceed 95% of all screening cases (73,74), and one article recommended cecal intubation rates exceed 95% in asymptomatic cases, both screening and surveillance (70).

JAG on gastrointestinal endoscopy (UK) (69)
Cecal intubation rates should exceed 90% in patients without stricturing or marked fecal contamination.

The CPSO recommendations for independent health facilities (CAN) (70)
For colon cancer screening and surveillance, cecal intubation rates should approach 95% of otherwise asymptomatic patients.

TABLE 4
Colonoscopy cecal intubation rates

Study	Study design	Clinician specialty*	Patients/ procedures, n	Cecal intubation rate (%)
Pierzchajlo et al (11); Setting: Two hospitals	Prospective	Family physician (n=1)	751 colonoscopies	91.5
Wexner et al (12); Setting: Two hospitals	Retrospective	Surgeons (n=4)	2069 colonoscopies	96.5
Wexner et al (13); Setting: Two hospitals	Prospective	Gastroenterologists (n=207)	13,580 colonoscopies	92.0
Kirby (14); Setting: Single hospital	Retrospective	Surgeon (n=1)	616 colonoscopies	76.0†
Edwards and Norris (15); Setting: Single hospital	Prospective	Family physicians (n=4)	200 colonoscopies	96.5
Minoli et al (17); Setting: Four endoscopy units	Prospective	Gastroenterologists	486 colonoscopies	91.1
Nelson et al (18); Setting: 13 VA Medical Centers	Prospective	Gastroenterologists	3196 screening colonoscopies	97.2
Chak et al (26); Setting: Single teaching hospital	Prospective	Gastroenterologists (n=17)	496 colonoscopies	94.3
Rex (27); Setting: Single teaching hospital	Prospective	Gastroenterologist (n=1)	358 patients	99.2
Fasoli et al (28); Setting: Multicentre (25 sites)	Prospective	Gastroenterologist teams (n=1), Surgeon teams (n=18), Mixed teams (n=21)	1406 colonoscopies	84.1
Ball et al (29); Setting: Single teaching hospital	Retrospective	Gastroenterologists, surgeons	1166 colonoscopies	88.1
Denis et al (30); Setting: Single hospital	Prospective	Gastroenterologists (n=5)	500 colonoscopies	92.0
Harewood (31); Setting: Single teaching hospital	Retrospective	Endoscopists (n=45)	17,100 colonoscopies	93.9
Regula et al (60); Setting: A national screening program in Poland (6 to 40 sites at study end)	Prospective	Not specified	50,148 colonoscopies	91.1

**Unless shown, the number of persons performing the procedure was not reported in the paper; †Unweighted 12-year mean. VA Veterans affairs*

TABLE 5
Average colonoscope withdrawal times

Study	Study design	Clinician specialty*	Patients/ procedures, n	Average withdrawal time (min)
Nelson et al (18); Setting: 13 VA Medical Centers	Prospective	Gastroenterologists	3196 screening colonoscopies	20.1†
Denis et al (30); Setting: Single hospital	Prospective	Gastroenterologists (n=5)	500 colonoscopies	<6
Froelich et al (32); Setting: Multicentre (21 centres in 11 countries)	Prospective	Not reported	4535 patients	10.1
Barclay et al (33); Setting: Single institution	Prospective	Gastroenterologists (n=12)	2053 patients	6.3 with no polyps; 10.3 with polyps
Simmons et al (34); Setting: Single institution	Retrospective	Endoscopists (various, unspecified) (n=43)	10,955 colonoscopies	6.3

**Unless shown, the number of persons performing the procedure was not reported in the paper; †Including polypectomy time. VA Veterans affairs*

ASGE (US) (73)

The cecum should be intubated in 90% or greater of all cases and in 95% or greater of all screening cases.

The US Multi-Society Task Force on Colorectal Cancer (US) (74)

Cecal intubation rates in all cases (90% or greater) and in screening cases (95% or greater), with cecal intubation verified with photographic evidence that a visual landmark has been reached.

Average colonoscope withdrawal times – Literature search results

Five of the obtained studies reported data on average colonoscope withdrawal times (18,30,32-34). Four were prospective case series (18,30,32,33), and one was a retrospective chart review (34). When calculating the average withdrawal time at 20.1 min, one study included patients who had polyps removed (18). For the four studies that did not include polyp removal time, the reported average withdrawal times ranged from less than 6 min (30) to a high of 10.1 min (32). The weighted mean withdrawal time for the three prospective studies that did not include polyp removal time (30,32,33) was 10.8 min. When the retrospective study (34) was included, the weighted mean was 7.2 min (Table 5). Additionally, the study by Simmons et al (34) examined the relationship between withdrawal times and the rate of polyp detection and found that, as withdrawal times increased, polyp detection rates also increased ($P<0.0001$), but this relationship was weaker for larger polyps, which are easier to detect. The authors of that study recommended a minimum withdrawal time of 7 min, which corresponds to a polyp detection rate above the median level of performance.

TABLE 6
Adenoma detection rates

Study	Study Design	Clinician specialty*	Patients/procedures, n	Adenoma detection rate (%)
Froehlich et al (32)	Prospective	Not specified	5832 patients	Low cleansing quality: 23.8; OR=1.00 Intermediate cleansing quality: 32.8; OR=1.73 (intermediate versus low), (P<0.001) High cleansing quality: 29.4; OR=1.46 (high versus low), (P<0.007)
Edwards and Norris (15)	Prospective	Family physicians (n=4)	200 colonoscopies	22.5
Gorard and McIntyre (35)	Retrospective	Endoscopists (n=8)	915 colonoscopies	25.0
Wan et al (39)	Prospective	Not specified	2196 patients	62.1
Hunt et al (40)	Prospective	Not specified	193 patients	12.0
Rex et al (62)	Prospective	Attending staff physicians, all with more than 500 past procedures (n=26)	183 patients who received two consecutive colonoscopies	Adenomas missed: 27% (≤5 mm) 13% (6 mm to 9 mm) 6% (≥10 mm) Overall: 24%
Pierzchajlo et al (11)	Retrospective	Family physician (n=1)	555 patients (751 colonoscopies)	17.8
Regula et al (60)	Prospective	Not specified	50,148 participants	13.4

**Unless shown, the number of persons performing the procedure was not reported in the paper*

Average colonoscope withdrawal times – Internet search results
Two articles obtained in the Internet search reported on average withdrawal times (73,74) (see details below). Both the sources stated that withdrawal times should be at least 6 min (73,74), and one stated mean withdrawal times should be between 6 min and 10 min (74).

ASGE (US) (73)
Average withdrawal times should be 6 min or longer in colonoscopies with normal results performed in patients with intact colons.

The US Multi-Society Task Force on Colorectal Cancer (US) (74)
Mean examination times (withdrawal phase) should average at least 6 min to 10 min.

Adenoma detection rates – Literature search results
Eight studies were obtained that reported on adenoma detection rates (11,15,32,35,39,40,60,62). The characteristics of the study populations varied across the reports. Six of these studies were prospective (15,32,39,40,60,62), and two were retrospective in design (11,35). In these studies, the adenoma detection rates ranged from a low of 12% (40) to a high of 62% (39). A weighted mean could not be calculated because some studies did not report the necessary data. One study (62) of same day back-to-back colonoscopies reported an overall miss rate for adenomas of 24%, and the risk of a missed adenoma increased with decrease in polyp size.

The study by Froehlich et al (32) found a positive relationship between the quality of bowel cleansing and the adenoma detection rates, with intermediate-quality and high-quality cleansings being associated with superior adenoma detection rates compared with low-quality cleansings (Table 6).

Adenoma detection rates – Internet search results
One article was obtained that reported on adenoma detection rates (74), with the target being greater than 25% in men older than 50 years and greater than 15% in women older than 50 years in persons undergoing first-time colonoscopies (see details below).

The US Multi-Society Task Force on Colorectal Cancer (US) (74)
Adenoma prevalence rates detected during colonoscopy in persons undergoing first-time examinations, with the goal being 25% or greater in men older than 50 years and 15% or greater in women older than 50 years.

Cancer miss rates – Literature search results
Seven studies were obtained that reported on cancer miss rates (15,35,36,38,41,63,64) (Table 7). One of these was a prospective design (15); the rest were retrospective designs (35,36,38,41,63,64). In these studies, the reported cancer miss rates ranged from a low of 0% (38) to a high of 5.9% (36).

Cancer miss rates – Internet search results
No articles were obtained that reported cancer miss rates.

Use of sedation – Literature search results
Twelve studies were obtained that reported on the use of sedation in colonoscopy (42-53). Ten of these were RCTs (42-51) and two were prospective studies (52,53) (Table 8). A variety of sedatives were tested in these studies, including midazolam (42-47,49,50), diazepam (42), meperidine (44,45,47,49,53), propofol (45-48,50-52), alfentanil (45,52), remifentanil (48), fentanyl (50,53) and promethazine (53) (see Appendix B for the regimens used).

Several sedation regimens showed greater efficacy compared with other regimens in these trials. Midazolam was more efficacious than diazepam (42) or placebo (43). Propofol was more efficacious than midazolam with meperidine (47), remifentanil (48), and midazolam with fentanyl (50). Midazolam with meperidine showed greater efficacy than midazolam alone (49). Two RCTs showed a significant benefit

TABLE 7
Cancer miss rates

Study	Study design	Clinician specialty*	Patients/ procedures, n	Cancer miss rate, n (%)
Bressler et al (64)	Retrospective	Gastroenterologists, surgeons, internal medicine, family practice and others	12,487 patients	430 (3.4)
Bressler et al (41)	Retrospective	Gastroenterologists, surgeons, internal medicine, family practice and others	2654 patients	105 (4)
Edwards and Norris (15)	Prospective	Family physicians (n=4)	200 colonoscopies	5 (2.5)
Gorard and McIntyre (35)	Retrospective	Endoscopists (n=8)	915 colonoscopies	36 (3.9)
Leaper et al (36)	Retrospective	Colonoscopists	286 patients	17 (5.9)
Shehadeh et al (38)	Retrospective	Gastroenterology fellows under supervision of gastroenterologist or attending physicians (n=10)	232 patients	0 (0)
Rex et al (63)	Retrospective	Gastroenterologists and nongastroenterologists	941 patients	47 (5)

**Unless shown, the number of persons performing the procedure was not reported in the paper*

for patient-controlled sedation regimens over either continuous infusion or nurse-administered sedation (for patient satisfaction) (45) or over nurse-administered sedation alone (for better patient cooperation with the procedure, higher endoscopist satisfaction rates and higher patient satisfaction) (46). Another study did not detect a difference between patient-administered and nurse-administered sedation (51).

Use of sedation – Internet search results
No sources obtained in the Internet search reported on the use of sedation.

Bowel preparation – Literature search results
A position paper was obtained that was based on a literature review of bowel preparation conducted by the Canadian Association of Gastroenterology (65) that mainly assessed RCTs evaluating the efficacy and tolerability of four commonly used preparations: polyethylene glycol, sodium phosphate, magnesium citrate, and sodium picosulphate, citric acid and magnesium oxide-containing preparations. In that review, 43 RCTs were evaluated. The authors concluded that all four preparations provided effective bowel cleansing in the majority of patients, with varying tolerability, and stated that effective bowel preparations are critical to high-quality colonoscopy and to successful screening programs. In addition, Barkun et al (65) concluded that large volume preparations can be poorly tolerated and that adequate hydration was important in minimizing side effects, especially in those who received sodium phosphate solutions, and probably also sodium picosulphate, citric acid and magnesium oxide-containing preparations.

Rather than conduct a repeat evaluation of the efficacy and tolerability of different bowel preparations, the focus in the present document is on studies that evaluate the relationship between adequacy of bowel preparation, cecal intubation and adenoma detection. Fifteen studies were obtained that reported on bowel preparation (11,13,17,18,28-30,32,37,54-59). Five of these were retrospective designs (11,29,55,58,59) and 10 were prospective designs (13,17,18,28,30,32,37,54,56,57) (Table 9).

Three of these studies (11,18,32) reported on the relationship between bowel preparation and cecal intubation rates. Excellent preparation was associated with higher cecal intubation rates.

Nine studies (13,17,28-30,54-57) reported on the percentage failure to reach the cecum due to poor bowel preparation, with values ranging from a low of 0.7% (57) to a high of 11.4% (17). One study (37) reported on the inverse relationship between aborted procedures and poor bowel preparation.

A retrospective study by Harewood et al (59) was obtained reporting on 93,004 colonoscopies. The authors found that after adjusting for age and sex, adequate bowel preparation (compared with inadequate preparation) was associated with greater colonic lesion detection (odds ratio [OR], 1.21; 95% CI 1.16 to 1.25; P<0.05), and adequate preparation was also associated with superior detection rates for small lesions (polyp 9 mm or less) compared with large lesions (mass lesion, polyp greater than 9 mm) (OR 1.23; 95% CI 1.19 to 1.28).

Bowel preparation – Internet search results
No sources obtained in the Internet search reported on bowel preparation.

RECOMMENDATIONS

1. Target audience
These recommendations apply to all physicians and institutions performing colonoscopy in support of Ontario's FOBT-based CRC screening program.

2. Physician endoscopist standards
Based on the consensus of opinion by members of the Expert Panel, informed by the evidentiary base, the following recommendations are made as standards for physician endoscopists:

- Physicians wishing to perform colonoscopy in the Ontario CRC screening program can be categorized into different groups, with respect to the training, credentials and experience expected of them, before they can perform colonoscopy or continue to perform the procedure in support of the Ontario CRC screening program.

  A. Recently qualified gastroenterology/general surgical specialists: These are physicians who have just completed, within the past two years, an appropriate specialty/subspecialty residency program that provides them with formal training in endoscopy, colonoscopy and associated interventional techniques. These physicians can be presumed to be proficient for a period of two years provided that they:

  - continue to practice, defined by no fewer than 200 colonoscopies annually;

TABLE 8
Efficacy of sedation for colonoscopy

Study	Regimen	Patients, n	Results
Randomized controlled trials			
Macken et al (42)	Midazolam	51	Patient tolerance scores were similar among the treatment groups, but midazolam induced significantly more amnesia, resulting in significantly lower pain recall scores 14 days postprocedure
	Diazepam	50	
	Diazepam	49	
	Midazolam	47	
Ristikankare et al (43)	Midazolam	58	Patients in the midazolam group reported the examination significantly less difficult than the placebo group (P<0.05), but no difference was detected between the midazolam group and no treatment
	Placebo*	61	
	No treatment	61	
Morrow et al (44)	Meperidine + midazolam†	49	Patient mean tolerance scores were similar. Bolus injection and infusional delivery achieved similar outcomes
	Meperidine + midazolam‡	52	
Külling et al (45)	Propofol + alfentanil†§	150 total patients	There were no differences between the groups for pain scores. However, patient-controlled analgesia and sedation yielded a higher degree of patient satisfaction than continuous infusion of propofol + alfentanil or nurse-administered midazolam + meperidine
	Propofol + alfentanil¶	(number in each	
	IV midazolam + meperidine	arm unspecified)	
Ng et al (46)	IV midazolam	44	Patient-controlled sedation was associated with better patient cooperation (good versus minimal; P=0.008) and higher endoscopist satisfaction rates (very good versus good; P=0.001). More patients in the patient-controlled sedation group were satisfied with their overall level of comfort (86% versus 61%; P<0.001)
	Propofol§	44	
Sipe et al (47)	Propofol	40	Patients receiving propofol reported greater overall mean satisfaction scores
	Midazolam + meperidine	40	
Moerman et al (48)	Propofol	20	Patient satisfaction scores were higher in the propofol group
	Remifentanil	20	
Radaelli et al (49)	Midazolam + placebo	125	Adding meperidine to midazolam improved patient tolerance and decreased pain during colonoscopy. Significantly more patients in the midazolam alone group reported moderate or severe pain (28% versus 9%; P<0.001), poor or unbearable tolerance (18% versus 6%; P<0.01), and unwillingness to undergo future colonoscopy 14% versus 5%; P<0.05)
	Midazolam + meperidine	128	
Ulmer et al (50)	Propofol	50	The propofol group scored higher in time to sedation, depth of sedation, full recovery postprocedure and time to discharge. No difference in patient satisfaction scores were detected between the two groups (9.3 versus 9.4; P>0.05)
	Midazolam + fentanyl	50	
Heuss et al (51)	Propofol§	36	No difference in patient satisfaction with patient-controlled sedation compared with nurse-administered sedation with propofol (1.6 versus 1.1; P>0.5) using a VAS scale
	Propofol**	38	
Other prospective studies			
Lee et al (52)	Propofol + alfentanil§	500	Patient-controlled sedation with propofol + alfentanil is safe, feasible and acceptable to patients
Speroni et al (53)	Midazolam + meperidine	19	Compared with the other sedations examined, a larger proportion (P<0.05) of patients receiving midazolam + fentanyl reported 'no' or 'slight pain' during the procedure.
	Midazolam + meperidine + promethazine	2	
	Midazolam + fentanyl	70	
	Midazolam + fentanyl + either promethazine or meperidine	9	

**Intravenous (IV) saline; †Bolus administration; ‡Infusional administration; §Patient administered; ¶Continuous infusion; **Nurse administered. VAS Visual analogue scale*

- maintain in good standing with their hospital/college (CPSO); and
- have no identified practice problems.

B. Practicing gastroenterologists/general surgeons who maintain a regular colonoscopy service: These are physicians who have received formal or, in some cases, informal training and have maintained their competence in colonoscopy as defined by ongoing endoscopic practice for at least three of the previous five years. These physicians will have full colonoscopy privileges locally, granted by their hospital. These physicians can be presumed to be proficient for a period of two years provided that they:

- continue to practice, defined by no fewer than 200 colonoscopies annually;
- maintain in good standing with their hospital/college (CPSO); and
- have no identified practice problems.

C. Physicians who offer colonoscopy services, other than practicing gastroenterologists/general surgeons included in groups A and B. This group may include family

TABLE 9
Bowel preparation for colonoscopy

Study	Study design	Clinician specialty*	Patients/ procedures, n	Results
Pierzchajlo et al (11)	Retrospective chart review	Family physician (n=1)	555 patients (751 colonoscopies)	Adequacy of preparation (cecal intubation rate, %): Excellent (94.6); Fair (87.8); Poor (45) Overall, P<0.0001
Minoli et al (17)	Prospective	Gastroenterologists	603 colonoscopies	There was no attempt made to reach the cecum in 11.4% (69 of 117) of procedures due to poor bowel preparation
Kim et al (54)	Prospective	Endoscopist (n=1)	909 colonoscopies	Poor bowel preparation was the most common cause of incomplete insertion (1.7%)
Wexner et al (13)	Prospective	Gastroenterologists (n=207)	13,580 colonoscopies	Poor bowel preparation resulted in 10.2% (111 of 1085) of procedures being incomplete.
Fasoli et al (28)	Prospective	Gastroenterologist teams (n=1) Surgeon teams (n=18) Mixed teams (n=21)	1406 colonoscopies	Poor bowel preparation resulted in 5.7% (67 of 1184) of procedures being incomplete
Mitchell et al (55)	Retrospective	Gastroenterology consultants (n=4) and trainees	2216 colonoscopies	Poor bowel preparation resulted in 6.5% (144 of 2216) of procedures being incomplete
Nelson et al (18)	Prospective	Gastroenterologists	3196 screening colonoscopies	Adequacy of preparation (cecal intubation rate, %): Good (97.8); Fair (97.2); Poor (80.7) Overall, P=0.001
Rex et al (37)	Prospective	Experienced attending physicians and fellows	400 colonoscopies	Aborted examination rates due to poor bowel preparation varied from 20% to 12.5% between public and private hospitals (P=0.04)
Ball et al (29)	Retrospective	Gastroenterologists, surgeons	1166 colonoscopies	Poor bowel preparation resulted in 2.6% (31 of 1166) of procedures being incomplete
Denis et al (30)	Prospective	Gastroenterologists (n=5)	500 colonoscopies	Poor bowel preparation resulted in 2% (10 of 500) of procedures being incomplete
Varma et al (56)	Prospective	Consultants, specialists and fellows	202 colonoscopies	Poor bowel preparation resulted in 2.9% (6 of 202) of procedures being incomplete
Bernstein et al (57)	Prospective	Attending colonoscopists and gastroenterology fellows (n=16)	587 patients	Poor bowel preparation resulted in 0.7% (4 of 587) of procedures being incomplete
Froehlich et al (32)	Prospective	Not reported	6004 patients (5832 evaluable for preparation)	Quality of preparation (cecal intubation rate, %): High (90.4); intermediate (90.1); low (71.1) Overall P<0.001
Aslinia et al (58)	Retrospective	Gastroenterologists (n=10)	5477 colonoscopies	Inadequate bowel preparation accounted for 30.5% of all incomplete procedures

**Unless shown, the number of persons performing the procedure was not reported in the paper*

physicians: These are physicians who have not completed a formal colonoscopy training program and/or perform fewer than 200 colonoscopies annually and/or have had a substantial gap in the provision of an ongoing colonoscopy service over time. These physicians may or may not have full colonoscopy privileges locally, granted by their hospital. These physicians cannot be presumed to be proficient in colonoscopy. To be deemed proficient, they:

- will have to complete a formal training; and
- need to submit evidence of appropriate training and credentialing.

D. Physicians who currently do not offer endoscopic services and who have not completed a formal training program: These are physicians who wish to take up colonoscopy practice for the first time and who do not currently have full colonoscopy privileges locally, granted by their hospital. To be deemed proficient, they:

- will have to complete a Royal College of Physicians and Surgeons of Canada-accredited training; and

- will have to submit evidence of appropriate training and credentialing.

- Credentialing and documentation required before granting privileges will vary across physicians represented in the four groups above.
- Physicians performing colonoscopy should have certification with the Royal College of Physicians and Surgeons of Canada and/or the Canadian College of Family Physicians.
- To maintain appropriate standards for colonoscopy in the Ontario CRC screening program, it will be necessary to have:
  - initial credentialing standards; and
  - participation in a routine auditing process by the hospital.
- The evidence clearly shows that intensive, supervised training programs are integral to acquiring colonoscopy skills. The published evidence concerning the minimum number of colonoscopies needed to achieve or maintain competency is mixed. Therefore, while the number of colonoscopies needed to achieve or maintain competence may be less than 200 annually, until further evidence emerges, it is reasonable to set 200 colonoscopies annually as the standard. During the fiscal year 2005/06, physicians who performed at least 200 colonoscopies provided more than 94% of colonoscopies in Ontario (75).

3. Institutional standards

Based on consensus of opinion by members of the Expert Panel, informed by the evidentiary base, the following recommendations are made as standards for institutions.

Patient assessment

- All patients should receive a preprocedure assessment, where information regarding the following items is obtained:
  - informed patient consent;
  - history of gastrointestinal bleeding;
  - history of cardiac and respiratory disorders, including ischemic heart disease, hypertension and chronic obstructive pulmonary disease;
  - history of coagulation disorders, such as hemophilia;
  - history of communicable disease, such as hepatitis C, HIV or tuberculosis;
  - list of current medications, including anticoagulants (such as warfarin), acetylsalicylic acid and clopidogrel (Plavix, sanofi-aventis Canada Inc);
  - list of drug allergies;
  - indication whether there is a family history of CRC; and
  - list of operations, especially abdominal and gynecological surgery.
- All patients must receive follow-up care, which must include:
  - reports to the family physician that include the following: type of procedure, date of procedure, sedation received, depth of colonoscope insertion, colonoscopic findings, histopathology report regarding any tissue that was removed, and recommendation regarding the need for follow-up colonoscopy and the time intervals, as required; and
  - a follow-up appointment with the physician who performed the colonoscopy, if indicated.

Infection control

- The Expert Panel endorses the standards detailed by the CPSO concerning infection control (70). The CPSO standards and Expert Panel modifications are summarized below:
  - Gastrointestinal endoscopes come into contact with mucous membranes and are considered semicritical items. The minimum standard of practice for reprocessing is high-level disinfection.
  - Accessories (eg, reusable biopsy forceps) that penetrate mucosal barriers are classified as critical items and must be sterilized between each patient use. Accessories labelled as either single use or disposable should not be reprocessed.
  - Endoscopes have been implicated in the transmission of disease when appropriate cleaning, disinfection or sterilization procedures were not employed. In contrast to the CPSO standards, the Expert Panel strongly recommends that automated machine cleaning, disinfection and sterilization processes be used following manual cleaning of the equipment to protect both patients and personnel.
  - Universal precautions must be observed in each facility to prevent contact with blood or other potentially infectious materials. All blood or other potentially infectious material will be considered infectious, regardless of the perceived status of the source individual. All personnel performing or assisting with endoscopic procedures should follow universal precautions and wear appropriate equipment to protect themselves from fluid and body substances.
  - Eye protection should be worn to prevent contact with splashes during the cleaning procedure and disinfection/sterilization process.
  - Moisture-resistant gowns should be worn to prevent contamination of personnel due to splashes of blood or other body fluids or injury due to chemical disinfectant/sterilant contact. Gowns should be changed between patient procedures.

Monitoring during and after administration of conscious sedation

- The Expert Panel endorses the standards detailed by the ASGE and the Canadian Society of Gastroenterology

Nurses and Associates regarding sedation. These standards are summarized below, with slight modifications by the Panel.

When conscious or deep sedation is used

- Patients undergoing procedures with conscious or deep sedation must have continuous monitoring before, during and after sedative administration.
- Minimal monitoring of all patients, including blood pressure, pulse, respiration, level of consciousness and degree of discomfort at the initiation, during and at the completion of the procedure, is recommended.
- Depending on patient response, assessment may need to be more frequent.
- Modern electronic monitoring equipment may facilitate assessment but cannot replace well-trained assistants.
- Continuous electrocardiogram monitoring is reasonable in high-risk patients. This subgroup of high-risk patients would include those who have a history of cardiac or pulmonary disease, elderly patients, and those patients for whom a prolonged procedure is expected.

Monitoring during resuscitation

- Minimal monitoring during resuscitation should include the following:
  - Monitor oxygen saturation level and heart rate as determined by continuous pulse oximetry;
  - Assess blood pressure, heart rate, respiratory rate depth and effort, and level of consciousness on admission to recovery area, after 15 min, until stable and at discharge. Postprocedure oximetry must be performed until the patient's respiratory status is stable or returned to preprocedure state;
  - Assess and document unexpected events and postprocedure complications as related to sedation and interventions taken as required;
  - Assist and accompany patient to the bathroom and assess for the presence of orthostatic hypotension;
  - Assess gait before discharge;
  - Remove IV access before discharge, assess site and document findings;
  - Reinforce preprocedure teaching regarding driving, equipment operation and making decisions requiring judgment. The teaching provided should be in written form and a copy given to the patient before discharge;
  - A competent companion must accompany the patient from the recovery area; and
  - Because the amnesia period that follows the administration of sedation is variable, written instructions should be given to the patient to take with him or her, including the procedures to follow if an emergency arises.

Resuscitation capability

- The Expert Panel endorses the standards detailed by the CPSO regarding resuscitation capability. These standards are summarized below. There are no modifications by the Panel.

When conscious sedation is used

- At least one physician certified and current in Advanced Cardiac Life Support or trained in general anesthesia should be on-site and available within 5 min;
- At least one independent health facility personnel currently certified in Basic Cardiac Life Support must be present on-site during the procedure; and
- Resuscitation equipment to be present includes defibrillator, endotracheal tubes, airways, laryngoscope, oxygen sources with positive pressure capabilities, emergency drugs and oxygen tanks.

4. Performance standards

Perforation rates

- The Expert Panel endorses the standards detailed in the US Multi-Society Task Force on Colorectal Cancer regarding perforation rates, as summarized below:
  - Screening colonoscopy perforation rates no higher than one in 2000; and
  - Overall colonoscopy perforation rates no higher than one in 1000.

Cecal intubation rates

- All colonoscopies should be performed using a video colonoscope.
- The equipment used to perform colonoscopies should have the capacity to create photographic records.
- The cecal intubation rate should be greater than 95% for screening colonoscopy provided bowel preparation is adequate and no structural abnormalities exist.

Use of sedation

- There is evidence that adequate sedation contributes to better patient outcomes in terms of greater patient cooperation, less patient memory of discomfort, reduction in reported pain and increase in patient tolerance of the procedure. All patients should be offered sedation unless the endoscopist judges this to be contraindicated. Patients need to be aware that they have the right to refuse sedation if they so desire.

Bowel preparation

- There is evidence that proper bowel preparation is associated with better cecal intubation rates and better adenoma detection rates. Appropriate bowel preparation is therefore recommended.

Pathology

- Tools and infrastructure are required to support the systematic collection of data associated with the

colonoscopic and pathological findings. These include, but are not limited to:

- development and implementation of synoptic reports using uniform criteria and nomenclature; and
- appropriate information technology/information management infrastructure to collect these data and to enable integration with other relevant CCO initiatives.

Other performance measures

- There are currently insufficient data on which to make definitive recommendations regarding colonoscopy-related bleeding rates requiring hospital admission, colonoscope withdrawal time, adenoma detection rates and cancer miss rates. Therefore, it is recommended that the Ontario CRC Screening Program develop a system to report on these measures.

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For information about the PEBC and the most current version of all reports, please visit the Cancer Care Ontario Web site at www.cancercare.on.ca/ or contact the PEBC office at: telephone 905-525-9140 ext 22055, fax 905-522-7681.

APPENDIX A
Cancer Care Ontario's Colonoscopy Standards Expert Panel

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APPENDIX B
Sedation regimens

Study	Regimens
Randomized controlled trials	
Macken et al (42)	Midazolam 5.3±1.1 mg IV (2 min) versus diazepam 11.2±2.3 mg IV (2 min)
	Diazepam 11.2±2.3 mg IV (2 min) + flumazenil 0.2 mg IV
	Midazolam 5.3±1.1 mg IV (2 min) + flumazenil 0.2 mg IV
Ristikankare et al (43)	Midazolam* 0.0 5mg/kg† IV (age 20–40 years), 0.04 mg/kg‡ IV (age 41–60 years), 0.03 mg/kg§ IV (age 61–75 years)
	Placebo (IV saline) 0.05 mg/kg† IV (age 20–40 years), 0.04 mg/kg‡ IV (age 41–60 years), 0.03 mg/kg§ IV (age 61–75 years)
	No treatment
Morrow et al (44)	Bolus meperidine + midazolam (dosing nomogram)¶
	Infusion meperidine 25 mg initially, then 25 mg + midazolam 1 mg initially, then 1 mg (3 min)
	Infusion meperidine 25 mg initially, then 12.5 mg + midazolam 1 mg initially, then 0.5 mg (3 min)
Külling et al (45)	Bolus propofol 10 mg/mL + alfentanil (patient-administered) 0.5 mg/mL, bolus dose of 0.5 mL (4.8 mg propofol and 12 µg alfentanil) with a zero lockout interval
	Continuous infusion propofol 10 mg/mL + alfentanil 0.5 mg/mL rate of 0.005 mL/min × kg
	IV midazolam 0.035 mg/kg + meperidine 0.35 mg/kg with alternating boluses of midazolam 0.015 mg/kg or meperidine 0.35 mg/kg given as needed
Ng et al (46)	IV midazolam 0.05 mg/kg, 1 min before procedure (1 mg increments as required)
	Patient-controlled propofol 0.3 mg/kg with a zero lockout interval
Sipe et al (47)	Propofol 40 mg followed by titration with 10 mg to 20 mg**
	Midazolam 0.5 mg or 1 mg boluses + meperidine 12.5 mg or 25 mg boluses

Continued on next page

APPENDIX B – CONTINUED
Sedation regimens

Study	Regimens
Moerman et al (48)	Propofol 1 mg/kg, followed by 10 mg/kg/h (additional dose of 0.5 mg/kg when lightening of anesthesia was observed)
	Remifentanil 0.5 µg/kg, followed by 0.2 µg/kg/min (30 s) (supplemental doses of 0.25 µg/kg if needed)
Radaelli et al (49)	Midazolam 5 mg IV + placebo
	Midazolam 5mg IV + meperidine 50 mg iv
Ulmer et al (50)	Propofol 40 mg** IV followed by titration with 10 mg to 20 mg boluses
	Midazolam 0.5 mg to 1.0 mg + fentanyl 12.5 µg or 25 µg IV
Heuss et al (51)	Patient-controlled propofol – initial dose of 20 mg, followed by 10 mg over 1 min as needed
	Nurse-administered propofol – 20 mg IV initially followed by titration in steps of 10 mg to 20 mg IV
Other prospective trials	
Lee et al (52)	Prospective case-series: Patient-controlled propofol (200 mg in 20 mL) 4.8 mg + alfentanil (0.5 mg in 1 mL) 12 µg
Speroni et al (53)	Midazolam BMI <27 kg/m^2 4.2 mg, BMI>27 kg/m^2 3.5 mg†† ; BMI <27 kg/m^2 4 mg, BMI >27 kg/m^2 3.8 mg‡‡; + meperidine BMI <27 kg/m^2 100 mg, BMI >27 kg/m^2 87.5mg†† and BMI <27 kg/m^2 69.2 mg, BMI>27 90 mg
	Midazolam 4.5 mg + meperidine 100 mg + promethazine 12.5 mg
	Midazolam BMI<27 kg/m^2 2.9 mg, BMI>27 kg/m^2 3.4 mg†† and BMI <27 kg/m^2 3.5 mg, BMI >27 kg/m^2 3.6 mg‡‡ + Fentanyl BMI <27 kg/m^2 154.5 mg, BMI >27 kg/m^2 179.2mg†† and BMI <27 kg/m^2 175 mg, BMI >27 kg/m^2 167.6 mg**
	Midazolam BMI <27 kg/m^2 5.3 mg, BMI >27 kg/m^2 5.3 mg†† and BMI >27 kg/m^2 5 mg‡‡ + Fentanyl BMI <27 kg/m^2 200 µg, BMI >27 kg/m^2 150 µg†† and BMI >27 kg/m^2 100 µg‡‡ + either promethazine BMI <27 kg/m^2 18.8 mg, BMI >27 kg/m^2 18.8 mg†† and BMI >27 kg/m^2 16.7 mg‡‡ or meperidine BMI <27 kg/m^2 50 mg, BMI >27 kg/m^2 50 mg††

** A supplemental dose of 1.0 mg midazolam was delivered if the cecum was not reached within 30 min after introduction of the endoscope. After the procedure, patients received a dose of 0.1 mg flumazenil for each mg of midazolam administered for reversal of sedation; †But no more than 5.0 mg; ‡but no more than 3.5 mg; §But no more than 2.0 mg; ¶Meperidine: 50 mg (<60 kg, age 18 to 65 years; and 61 kg to 75 kg age 36 to 65 years; and 76 kg to 90 kg, age 51 to 65 years and >90 kg females age 51 to 65 years), 62.5 mg (61 kg to 75k g age 18 to 35 years and 76 kg to 90 kg age 36 to 50 years and >90 kg females age 36 to 50 years, males age 51 to 65 years), 75 mg (76 kg to 90 kg age 18 to 35 years and >90 kg males 18 to 50 years, females 18 to 35 years) Midazolam: 2 mg (<60 kg age 18 to 65 years and 61 kg to 75 kg age 36 to 65 years and 76 kg to 90 kg age 51 to 65 years and >90 kg females age 51 to 65 years), 2.5 mg (61 kg to 75 kg males age 18 to 35 years and 76 kg to 90 kg age 36 to 50 years and >90 kg males age 51 to 65 years and >90 kg females age 36 to 50 years), 3 mg (76 kg to 90 kg age 18 to 35 years and >90 kg males age 18 to 35 years and >90 kg females age 18 to 35 years); **Initial bolus reduced to 20 mg to 30 mg for elderly adults or smaller patients; ††Patients experiencing no pain to slight pain; ‡‡Patients experiencing moderate pain to severe pain. BMI Body mass index; IV Intravenous*

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