



Evidence-Based Series #15-5 Version 2

A Quality Initiative of the
Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO)

Guideline for Colonoscopy Quality Assurance in Ontario

*J. Tinmouth, E. Kennedy, D. Baron, M. Burke, S. Feinberg, M. Gould, N. Baxter, N. Lewis,
and the Colonoscopy Quality Assurance Guideline Expert Panel*

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Section 1:	Recommendations
Section 2:	Evidentiary Base
Section 3:	EBS Development Methods and External Review Process

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Guideline Report History

GUIDELINE VERSION	SYSTEMATIC REVIEW		PUBLICATIONS	NOTES and KEY CHANGES
	Search Dates	Data		
Original 2007	1966-July 2006	Full Report	Peer review publication. Web publication.	N.A.
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Guideline Recommendations

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A. INTRODUCTION

Guideline Objective

The objective of this guideline is to provide the basis for a quality assurance program for all colonoscopy procedures done in the province of Ontario, including those conducted as part of the fecal occult blood test (FOBT)-based colorectal cancer (CRC) screening program. This guideline is intended to provide recommendations that are based on an up-to-date systematic review of the evidence on the following three key aspects of colonoscopy: training and maintenance of competency for physician endoscopists, institutional quality assurance parameters, and performance indicators for colonoscopy. Clinical practice recommendations for how to perform colonoscopy or recommendations designed to improve the skill level of individual endoscopists are beyond the scope of this guideline. This Evidence-Based Series (EBS) provides an update to the 2007 PEBC document *EBS #15-5 Colonoscopy Standards* (1).

These recommendations are based on the best evidence currently available and are not intended to constitute absolute requirements for individual endoscopists. The recommended targets can be monitored and used to provide feedback to individuals in order to improve performance on quality indicators when necessary, and to monitor performance at the system level to improve the overall quality of colonoscopy in Ontario. A quality improvement program should document its requirements, monitor performance using established quality indicators, and then institute changes that will lead to demonstrated improvements upon reassessment.

Recommendations Development

The recommendations contained in this guideline are based on evidence from a systematic review of the primary literature and an environmental scan of existing guidance documents. The guideline development group used this evidentiary base, combined with consensus opinion, to develop recommendations. Further details related to the methodology for developing the evidentiary base can be found in Section 2 of this Evidence-Based Series (EBS).

Recommendations from the previous version of this guideline (1) were used as a starting point and were updated where new evidence justified a modification. The following criteria were used by the guideline development group as a guide to ensure consistency and transparency when specifying target thresholds or values:

1. Evidence that the target is linked to an established important outcome (e.g., adenoma detection rate, PCCRC).
2. Evidence that the target is applicable in the Ontario context.
3. Taking into account the quality of evidence, targets were identified with a preference for values that were in the middle of the range found the literature, in order to set reasonably attainable targets for Ontario.

Some indicators are dependent on the underlying risk profile of the population. For example, adenoma detection rate is expected to be higher than average in populations that have been referred for colonoscopy after a positive fecal occult blood test (FOBT) or fecal immunochemical test (FIT), or in those with a family history or other risk factors such as previous polyps.

Quality Indicators and Auditable Outcomes

Quality and safety indicators (p.13) for which there were sufficient evidence to recommend a specific target are called *quality indicators*. Important quality indicators are labelled *auditable outcomes* where there was insufficient evidence to recommend a specific target, but there was working group agreement that the indicator should be monitored for quality assurance purposes. These labels are consistent with those used in other guidance documents (2,3). As data accumulates, it may be possible to establish targets for these auditable indicators or to make necessary adjustments to targets that are already specified.

B. RESEARCH QUESTIONS

1. *Physician endoscopist training and maintenance of competency*

- What primary training is required for physicians performing colonoscopy?
- What are the requirements for maintenance of competency for physicians performing colonoscopy?

2. *Institutional quality assurance parameters*

What, if any, are acceptable quality assurance parameters for:

- Patient assessment prior to the procedure;
- Infection control, including colonoscope washing procedures and the use of high-powered washers;
- Monitoring during and after the administration of conscious sedation;
- Resuscitation capability;
- Acceptable endoscope quality.

3. *Colonoscopy quality indicators and auditable outcomes*

What, if any, are appropriate targets for the following indicators of quality colonoscopy?

- Adenoma detection rate (ADR);
- Polypectomy rate (PR);
- Cecal intubation rate (CIR);
- Colonoscope withdrawal time;
- Bowel preparation;
- Postcolonoscopy colorectal cancer (PCCRC);
- Bleeding rate after polypectomy;
- Perforation rates.

C. TARGET POPULATION

This guideline is intended to provide guidance on quality colonoscopy for adult patients undergoing this procedure in Ontario.

D. INTENDED USERS

This guideline is intended for clinicians involved in the delivery of colonoscopy to patients in Ontario and for policy makers and program planners involved in quality assurance at Cancer Care Ontario and in hospitals and clinics. Colonoscopy may be performed for a variety of indications, specifically: follow-up to a positive fecal occult blood test, screening

for those who have a family history of colorectal cancer in a first-degree relative, investigation for symptomatic patients, surveillance of those with a history of adenomatous or serrated polyps, inflammatory bowel disease or CRC, and other screening (e.g., average-risk screening).

E. RECOMMENDATIONS AND KEY EVIDENCE

I. TRAINING AND MAINTENANCE OF COMPETENCY

1. Primary training

Recommendations

- To be considered for credentialing, gastroenterologists must complete a formal two-year subspecialty training program, with the option of a third year of subspecialty training, before entering full-time practice.
- Prior to being qualified, other physicians, including surgical residents, must acquire the necessary specific knowledge and technical training in colonoscopy over a period of at least six months.

Key Evidence

The guideline development group endorses the recommendations of the Canadian Association of Gastroenterology regarding the requirements for credentialing.

2. Attainment of competency

Recommendations

- To be considered competent colonoscopists, trainees should achieve an average independent cecal intubation rate (CIR) of at least 85% for all colonoscopies and are expected to have performed at least 300 colonoscopies during training. The independent CIR should be measured on a subset of colonoscopies performed at the end of training. If 300 colonoscopies are performed during training, it is anticipated that at least 50 polypectomies would have been performed.
- In addition to proficiency in the technical aspects of colonoscopy, proficiency in cognitive aspects of the procedure is essential, including knowledge of appropriate contraindications and indications for colonoscopy, application of appropriate screening and surveillance intervals (4), histologic classification of polyps and their significance, and knowledge of how to deal with findings encountered at the time of colonoscopy.

Key Evidence

Most sources located in the review state that competent colonoscopists should be able to intubate the cecum in $\geq 90\%$ of all cases (5). The consensus of the guideline development group was that a slightly lower threshold of at least 85% for new endoscopists was realistic at the completion of training, with the justification that the higher threshold stated in the next *Recommendation* would apply as endoscopists continue in independent practice.

In determining a threshold for volumes required to attain competency, the working group assessed the relationship between volumes and cecal intubation rate. In the full-text studies found in the literature, estimates ranged from 275 colonoscopies to achieve an average CIR of 85%, and 400 colonoscopies to achieve an average CIR of 90% among 41 GI fellows (6), to 500 colonoscopies needed for all fellows in a three-year training program to achieve reliable independent completion rates of at least 90% (7). The guideline development

group chose the moderate value of 300 as a minimum volume to achieve competency because of the variability of the evidence and because lower thresholds defined in the past have, in practice, been shown to be inadequate for most trainees to achieve competence (8). It is preferable to use an objective criterion of technical competence, such as the cecal intubation rate, rather than volume when granting privileges to physicians for endoscopic procedures (8).

The statement that trainees will remove polyps in at least 50 patients is based on the target of 300 procedures during training. However, it is the opinion of the guideline development group that performing this volume should provide newly trained colonoscopists with sufficient experience with the basic therapeutic techniques in colonoscopy. A similar threshold has been used in other guidelines as a consensus-based recommendation (9).

Qualifying statement:

- Completing recommended training period and meeting volume minimums does not ensure competence in colonoscopy; the achievement of the minimum rate of cecal intubation stated in the *Recommendation* above is still required as well as proficiency in the cognitive aspects of colonoscopy.

3. Granting, maintenance and renewal of privileges

Recommendations

- Each institution or facility should develop and maintain guidelines for granting and renewing privileges.
- A physician who is requesting privileges to perform colonoscopy after having been away from practice for three or more years, or who has practised endo-colonoscopy for less than the equivalent of six months in the previous five years should undergo an individualized educational process prior to the granting of privileges (10). Detailed training requirements are provided in the College of Physicians and Surgeons of Ontario document, *Expectations of physicians who have changed or plan to change their scope of practice to include endo-colonoscopy* (10).
- Endoscopists should perform a minimum of 200 colonoscopies per year with a desired minimum cecal intubation rate for outpatient colonoscopies of 95% in patients with adequate bowel preparation and no obstructive lesions.

Key Evidence

There is good evidence that proficiency in endoscopic procedures is dependent upon continued practice and performance of adequate numbers of procedures, although the evidence for precise volume thresholds is controversial (11). One study of volumes and postcolonoscopy colorectal cancer (PCCRC) diagnosed within six to 36 months of colonoscopy did not find a significant relationship (12). Another study found that endoscopists in the lowest volume quintile (median 63 procedures annually) had three-fold higher odds of bleeding or perforation within 30 days of outpatient colonoscopy (OR, 2.96; 95%CI, 1.57%-5.61%) than the highest volume quintile (median, 417 procedures annually) (13). The consensus of the guideline development group was that the newer evidence was not significant or consistent enough to warrant a change from the recommendation of 200 colonoscopies per year stated in the previous version of this guideline (1).

II. INSTITUTIONAL RECOMMENDATIONS

1. Patient assessment

Recommendations

All patients should receive a pre-procedure assessment, and any questions that the patient may have should be answered at that time. It is advisable to conduct the pre-assessment several days before the procedure if it is the patient's first encounter with the endoscopist, in order to allow sufficient time for safety concerns to be addressed or medication such as warfarin to be withdrawn (2), and to ensure that the patient has sufficient understanding of the bowel preparation process. If a preprocedure assessment with the endoscopist is not available, patient education regarding the issues listed below must be provided in written form and the associated care provider or endoscopy unit staff must be available to answer patient questions. In addition, the referring physician must provide data on medications, allergies and medical conditions listed below to the endoscopist.

Pre-procedure patient history and assessment should include:

- Instructions for anti-platelet agents/blood thinners, to be individualized to patient risk level.
- Instructions for glucose management in diabetics.

Pre-procedure assessment should also include gathering of information regarding:

- Indication for colonoscopy.
- A list of current medications and drug allergies.
- American Society of Anesthesiologists classification of patient status and other information that may influence type and level of sedation.
- Cardiac and respiratory disorders, including ischemic heart disease, hypertension, sleep apnea, and chronic obstructive pulmonary disease. Cardio-respiratory function should be reviewed on the day of the colonoscopy.
- Any other significant medical problems, including previous abdominal surgery.

Informed consent:

- Should be obtained prior to the administration of sedation.
- Should be documented on the chart.

All patients must receive follow-up care, including:

- Reports to the referring and family physician that include the following: type of procedure, date of procedure, sedation received, anatomical extent of colonoscope insertion, colonoscopic findings, histopathology report regarding any tissue that was removed, and recommendations regarding the need for and timing of follow-up colonoscopy as required. Where possible, instructions for arranging follow-up colonoscopy should be provided.
- A follow-up appointment with the physician who performed the colonoscopy, if indicated.

The recommendations for pre-procedure assessment are the consensus of the working group, based on the previous version of this guideline, and guidance documents published by the European Commission (2) and the Quality Assurance Task Group of the National Colorectal Cancer Roundtable in US (14).

2. Infection control

Recommendations

Administrative aspects:

- Establishment of a comprehensive Quality Assurance and Safety Program and procedures for monitoring adherence to the program, including standard operating procedures for preparing endoscopes and quality assurance procedures for reprocessing endoscopes and their accessories.
- Training and retraining of the staff involved with endoscope care and maintenance a clear chain of accountability for endoscope processing procedures.

Technical aspects (15):

- Adherence to the endoscope manufacturer's operating manual and instructions for use.

The Expert Panel endorses the standards detailed by the College of Physicians and Surgeons of Ontario (CPSO) concerning infection control (16). These standards are summarized below:

- Gastrointestinal endoscopes come into contact with mucous membranes and are considered semi-critical items. The minimum standard of practice for reprocessing is high-level disinfection.
- Accessories (e.g., reusable biopsy forceps) that penetrate mucosal barriers are classified as critical items and must be sterilized between each patient use.
- It is essential that endoscopes are cleaned to remove organic material before disinfection or sterilization.
- Accessories labeled as either single use or disposable should not be reprocessed.
- Endoscopes have been implicated in the transmission of disease when appropriate cleaning or disinfection procedures were not employed, therefore proper cleaning techniques should be used.
- In contrast to the CPSO standards, the Expert Panel recommends that automated endoscope reprocessing (AER), disinfection, and sterilization processes, and not manual processes, to be used to protect patients, personnel and equipment.
- Universal precautions must be observed in each facility in order to prevent contact with blood or other potentially infectious materials. All blood or other potentially infectious material should 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- or water-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 or sterilant contact. Gowns should be changed between patient procedures.

Further guidance from the CPSO, published in 2010, is endorsed (17):

- In endoscopy/colonoscopy units, functionally separate areas are required for reprocessing, scope cabinet and dirty areas.

Key Evidence

The recommendations for the administrative and technical aspects of infection control are the consensus of the working group, based on recommendations from the United States Food and Drug Administration (15) and the previous PEBC guideline (1).

The remainder of the recommendations, except for the recommendation for AER, are based on guidance provided by the CPSO (16,17).

The recommendation for automatic endoscope reprocessing was the consensus of the guideline development group that developed the previous version of this guideline. Since that time, national consensus standards have been released by the American Society for Gastrointestinal Endoscopy (ASGE) that state: “[Automated Endoscope Reprocessors (AERs)] can enhance efficiency and reliability of high-level disinfection by replacing some manual reprocessing steps...Use of an AER may also reduce exposure of personnel to chemical germicides” (18). Likewise, European Society of Gastrointestinal Endoscopy - European Society of Gastroenterology standards call for the use of automatic “washer-disinfectors” for a number of reasons, including reliable, standardized and validated reprocessing cycles, reduction in the contact of staff and the environment with chemicals, and less risk of damage to scopes (19).

3. Use of sedation

Recommendation

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.

Key Evidence

The Expert Panel endorses the sedation recommendations contained in the previous version of this guideline (1).

4. Monitoring during and after the administration of conscious sedation

Recommendations

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.
- 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 upon patient response, assessment may need to be more frequent. These data should be recorded at the endoscopy unit level, using a system chosen by the unit.
- Modern electronic monitoring equipment may facilitate assessment but cannot replace RNs or RPNs with appropriate certification or special training in sedation and endoscopy.
- 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.

- The endoscopy unit should have a formal process to document sedation and patient comfort using a system of the unit's choice. The unit should audit its individual physicians' use of sedation.

Key Evidence

The Expert Panel endorses the sedation recommendations contained in the previous version of this guideline (1).

5. Monitoring during recovery

Recommendations

- A list of criteria such as the Aldrete score (respiration, oxygen saturation, consciousness, circulation and activity levels) (20) should be used to determine readiness for discharge (21). Readiness for discharge should be documented in the chart.
- Prior to discharge, pre-procedure teaching regarding driving, including the time period for not driving agreed to during the informed consent process, equipment operation, and making decisions requiring judgment should be reinforced. The teaching provided should be in written form and given to the patient prior to discharge.
- As the amnesia period that follows the administration of sedation is variable, written instructions should be given to the patient, including the procedures to follow if an emergency arises.

Key Evidence

Recommendations regarding monitoring during resuscitation are the consensus of the working group, based on the previous version of this guideline (1).

6. Resuscitation capacity

Recommendation

- A general plan for resuscitation, including the identification of properly trained personnel should be in place with:
 - At least one physician certified and current in Advanced Cardiac Life Support on-site and available within five minutes.
 - At least one additional person currently certified in Basic Cardiac Life Support in the endoscopy unit or in the room during the procedure (16).
- Resuscitation equipment should be available including defibrillator, endotracheal tubes, airways, laryngoscope, oxygen sources with positive-pressure capabilities, emergency drugs and oxygen tanks.

Key Evidence

Recommendations regarding resuscitation capacity are the consensus of the working group, based on the previous version of this guideline (1).

7. Endoscope quality

Recommendations

- All colonoscopies should be performed using a video colonoscope that can be maintained within manufacturers' specifications.

- The equipment should have the capacity to create photographic records, either paper or digital.

Key Evidence

This recommendation is the consensus of the working group.

III. COLONOSCOPY QUALITY INDICATORS AND AUDITABLE OUTCOMES

Recommendations where there is sufficient evidence to endorse a specific target in this section are called *quality indicators*. These include:

- CIR;
- Bleeding rate after polypectomy;
- Perforation rate.

Some indicators had insufficient evidence to recommend a specific target; however, the working group agreed that they should be monitored as important components of a quality assurance program. These are labelled *auditable outcomes* and include:

- ADR;
- PR;
- Bowel preparation;
- PCCRC;
- Interval between colonoscopies.

These labels are consistent with those used in other guidance documents (2,3).

1. Cecal intubation rate (CIR)

Cecal intubation is defined as passage of the scope beyond the ileocecal valve into the cecal pole or terminal ileum (3). Lower CIR or completion rate has been significantly associated with greater risk of a post-colonoscopy colorectal cancer in a study using a large administrative database in Ontario (12). CIR targets can be unadjusted or reported after adjustment for factors such as indication, poor bowel preparation, strictures, previous colonic surgery (i.e., right hemicolectomy) or severe colitis. Adjusted targets are set higher than unadjusted rates.

Recommendation

Quality Indicator

A cecal intubation rate of 95% is desirable in patients with adequate bowel preparation and no obstructive lesions.

Key Evidence

- The above 95% adjusted rate is considered consistent with the 90% unadjusted rate recommended in the UK in a FOBT-based screening program (3).
- An 85%-90% unadjusted rate for all colonoscopies is recommended by CAG (22) as a reasonable expectation for “competent colonoscopists.”
- Evidence that this expectation may be reasonable in the Canadian context comes from a point-of-care audit, which found that 94.9% of patients had a complete colonoscopy based on self-reported data from 5% of practicing Canadian endoscopists (23).

Qualifying statement

- Written documentation of colonoscopy completion is required, along with photographic evidence.
- Where data on bowel preparation and colonoscopy findings are not available, use of an unadjusted rate of 90% is reasonable to audit performance.

2. Adenoma detection rate (ADR)

Although CIR is the most commonly used quality indicator for colonoscopy, ADR, defined as the proportion of patients that have at least one adenoma identified and removed during colonoscopy, is a more specific and direct indicator of the quality of colonoscopy (24), because adenomas are known cancer precursors. ADR has also been associated with important clinical outcomes such as interval cancers. Expected ADR is influenced by the underlying characteristics of the population, including age, sex and a family history of a first-degree relative with colorectal cancer before age 60. ADR can also vary depending on quality of bowel preparation, and the experience level of the endoscopist. Recently, sessile serrated polyps, which are distinct from adenomas, have been recognized as important cancer precursors (25). To date, there is no consensus that they should be measured as a part of the ADR.

Recommendation

Auditable outcome

An ADR target level is not specified for this indicator; however, it should be tracked and monitored for the following patient subgroups as a key component of the quality assurance program:

- Patients undergoing primary screening with colonoscopy;
- Patients who have a positive FOBT or FIT;
- Patients with a family history of CRC.

Key Evidence

Kaminski (2010) found ADR to be a reliable independent predictor of the risk of interval colorectal cancer (26). ADRs found in the literature are highly variable, with rates of any adenoma or cancer ranging from 14.9-37.5 (2,5). The wide variation reported likely reflects important differences in the populations studied. As such, these studies are not readily generalizable to the Ontario context. Therefore, the working group determined that there was insufficient evidence to make a specific target recommendation at this time for this indicator. As auditing of this indicator in the Ontario population continues and reporting improves, it is advised that future study be undertaken to determine an appropriate target.

Qualifying statement

- Endoscopists should monitor their individual ADR.

4. Polypectomy rate

Polypectomy rate (PR) is defined as the proportion of patients who have at least one polyp identified and removed during colonoscopy. The previous version of this guideline did not assess PR as a quality assurance indicator. Since that time, research has been published on the use of PR as a proxy for adenoma detection rate. This indicator has the advantage that information on the presence or absence of polyps is available at the time of colonoscopy,

unlike adenoma detection, which requires pathologic confirmation, and that it is captured in health administrative data.

Recommendation

Auditable outcome

A PR target level is not specified; however, the rate should be tracked and monitored for the following patient subgroups as a key component of the quality assurance program:

- Patients undergoing primary screening with colonoscopy;
- Patients who have a positive FOBT or FIT;
- Patients with a family history of CRC.

Key Evidence

As this indicator was not used in the previous PEBC guideline, the working group assessed evidence to determine its relationship to previously established quality indicators such as ADR and PCCRC:

- A study found a correlation between ADR and PR of $r=0.88$ (95%CI, 0.78%-0.94%) in an average-risk asymptomatic population with FOBT positive test results (27).
- Endoscopists' PRs yielded similar assessments of quality as their ADRs ($r=.91$, $p<.0001$ in men and $r=.91$, $p<.0001$ in women) in an average-risk screening setting (28). Endoscopists who achieved a PR of 40% in men and 30% in women almost always achieved an ADR of 25% and 15%, respectively, and also found more advanced lesions.
- Baxter et al (29) found that the median PR for endoscopists over a 2-year period was 17.7% (range, 0.0%-72.5%). Patients undergoing colonoscopy performed by an endoscopist with a PR $\geq 25\%$ were less likely to develop a proximal PCCRC (diagnosed 7 to 36 months after the procedure) than if colonoscopy was performed by an endoscopist with a 10% PR (OR, 0.61; 95%CI, 0.42%-0.89%). PR was not associated with the diagnosis of a distal PCCRC.

Based on these studies, the working group concluded that PDR is a valid proxy for ADR and may be a useful quality assurance indicator where ADR is not readily available. However, as rates in the literature are highly variable, it is not possible to specify a target for this indicator at this time. As auditing of this indicator in the Ontario population continues and reporting improves, it may be possible to determine an appropriate target in the future.

5. Bowel preparation

Proper bowel preparation is important because it is associated with higher colonoscopy completion rates and ADRs (1). Split dosing (i.e., dosing at least half of the preparation on the day of the colonoscopy) has been established as superior to dosing all the preparation the day before the test (2), because it enhances the effectiveness of commercial preparations (30).

Recommendation

Auditable outcome

Endoscopists should strive for adequate bowel preparation, and quality of bowel preparation should be recorded and monitored using a standardized scale of the endoscopy unit's choice. Users of the scale should be trained on the use of the scale to ensure it is consistently applied.

Key Evidence

Several guidelines [(14) and BSG] recommend that the percentage of colonoscopies where the bowel preparation was adequate to detect polyps larger than 5 mm should be measured, and inadequate preparation should occur in no more than 10% of colonoscopies (14). As auditing continues, it may be possible to determine an appropriate target for this indicator in the Ontario population in the future.

Qualifying Statements

- In order to improve the effectiveness of bowel preparation, where possible, split dosing of the bowel preparation is preferred.
- A standardized tool such as the Ottawa Bowel Preparation Scale (OBPS) (31) or the Boston Bowel Preparation Scale (32) may be used to assess bowel preparation quality (33). An OBPS score of less than 5 can be used as a cut-off (23).

6. Withdrawal time

Withdrawal time has been proposed as a proxy quality assurance measure to ensure that endoscopists are taking adequate time to withdraw the endoscope and examine the colon for adenomas.

Recommendation

It is not necessary to achieve a specific withdrawal time target or to audit this indicator for quality assurance purposes.

Key evidence and rationale

The previous PEBC guideline found insufficient evidence to set a target for withdrawal time, although it was listed as a performance measure. The consensus of the current guideline development group is that withdrawal time as an indicator does not necessarily reflect the true characteristics of high-quality endoscopy (34), and that longer procedure time does not necessarily mean higher quality; the endoscopist must be able to recognize important pathologic features and have the technical skills to ensure appropriate management (35); therefore, the working group has chosen to focus on other indicators of endoscopic skill. This opinion is supported by a study that did not find a relationship between withdrawal time and adenoma detection rate (36). Capturing withdrawal time is less important in a setting where other quality indicators that we have recommended for monitoring, including ADR, CIR and complications, can be monitored (37). It is also possible that a focus on withdrawal time would have a negative impact on productivity and efficiency for negligible gain (38).

7. Post-colonoscopy colorectal cancer (PCCRC)

This indicator captures the occurrence of new or missed CRC diagnosed after colonoscopy. It is often defined as the proportion of persons with CRC who underwent a colonoscopy within six to 36 months prior to the diagnosis of CRC (those with a colonoscopy within 6 months of diagnosis are considered to be detected cancers) (12). The reason for a PCCRC is often unknown, and possible reasons include missed lesions, incomplete removal of adenomas, and new rapidly growing lesions (35). The associated time period in which the PCCRC is diagnosed following the colonoscopy can be specified (e.g., 1 year, 3 years, 5 years) (39). Among those with CRC who had colonoscopy, the rates of PCCRC ranged from approximately 5% (39) to 9% (12). PCCRC can also be defined as the rate of CRC in a cohort of

individuals followed prospectively from the time of colonoscopy until CRC diagnosis. A Canadian study found that 14 years after negative complete colonoscopy, the overall incidence of CRC was 1.3% in an Ontario population (40).

Recommendation

Auditable outcome

A target level is not specified for this indicator; however, it should be tracked and monitored as a key component of the quality assurance program.

Key Evidence

It is the consensus of the working group that this indicator be added to the list of important quality indicators and monitored at the province-wide level.

Qualifying statement:

- Incidence of PCCRC should be tracked at the facility or at system-wide level, because estimates at the endoscopist level are unstable due to the low incidence of PCCRC.

8. Bleeding rate after polypectomy

Bleeding is the most common complication of polypectomy and can occur during or after the procedure (3).

Recommendation

Quality indicator

Overall rates of clinically significant (leading to hospital admission) post-polypectomy bleeding should be no more than 1 per 100 colonoscopies.

Key Evidence

In the opinion of the working group, bleeding in the absence of polypectomy is not considered a clinically significant event, thus only studies that included patients who had undergone polypectomy during colonoscopy were included in the evidence base for this indicator. Three of 12 studies in the USPSTF meta-analysis met this criterion (41), with rates ranging from 0.40% (42) to 0.48% (43). Our systematic review found bleeding after polypectomy rates of 0.50% in the 30 days after the procedure in a screening population (44), and 0.94% while in the endoscopy unit for a higher risk population (45).

9. Perforation rate

Perforation is an uncommon adverse events that that can occur during or shortly after colonoscopy (5). Rates in patients being screened are expected to be lower because these patients are generally healthy and tend not to have colonic conditions that are associated with perforation.

Recommendation

Quality indicator

Overall colonoscopy perforation rates should be less than 1 per 1000.

Key Evidence

- Other guidelines have suggested an overall quality threshold of <1 per 1000 for perforations caused by colonoscopy (2,22,46).
- A systematic review was conducted by the US Preventive Services Task Force for their clinical practice guideline on screening for colorectal cancer. In a meta-analysis of 13 studies, it was noted that perforations occurred in asymptomatic populations in 0.56 per 1000 procedures. The majority of perforations were in colonoscopies with polypectomies (although the percentage with polypectomy was only reported in three studies) (41).
- Eight studies located in our review, which included diagnostic and therapeutic colonoscopies, also found that rates were generally lower than 1 per 1000. For example, using administrative data from Canadian provinces, Rabeneck et al found an outpatient perforation rate in usual clinical practice within 30 days of colonoscopy of 0.85 per 1000 (13).

Qualifying statement

- Colonic conditions that are known to affect the risk of perforation include pseudo-obstruction, ischemia, severe colitis, radiation-induced changes, stricture formation, bulky colorectal cancers, more severe forms of diverticular disease, and chronic corticosteroid therapy (5).
- As perforation is a rare event, perforation rates should be tracked at the facility and/or system-wide level. Measurements at the individual endoscopist level are likely to be unstable.

10. Interval between colonoscopies

Although this indicator was not included in the previous PEBC guideline, it has been adopted as an audible outcome for this version of the guidance document. This indicator addresses the importance of adhering to appropriate evidence-based intervals between colonoscopies, in order to balance the potential for harm from the rare adverse events associated with colonoscopy, and the benefits of CRC prevention and early detection.

Recommendation

Auditable outcome

The rate of adherence to locally recommended screening intervals should be monitored at the individual endoscopist level.

Key evidence

There is evidence that many physicians perform examinations at shorter intervals than are recommended, which consumes colonoscopy resources, increases health care costs, and exposes patients to unnecessary risk (47). As well, recommended intervals for surveillance for individuals with a family history are often not adhered to, resulting in longer intervals or no follow-up (48). The addition of this indicator and the recommendation to monitor adherence to appropriate intervals between colonoscopies are the opinion of the guideline development group, in keeping with other recent colonoscopy quality assurance guidelines (2,14).

Qualifying statement:

- The PEBC is currently developing a separate guidance document to be released in 2014 that will provide recommendations on appropriate colonoscopy intervals for individuals at various risk levels.

RELATED GUIDELINES

- Cancer Care Ontario's Colonoscopy Standards Expert Panel: Rabeneck L, Rumble RB, Axler J, Smith A, Armstrong D, Vinden C, et al. Cancer Care Ontario Colonoscopy Standards. Toronto (ON): Cancer Care Ontario; 2007 Oct 7. Program in Evidence-based Care Evidence-Based Series No. 15-5.
- Rabeneck L, Rumble RB, Thompson F, Mills M, Oleschuk C, Whibley AH, et al. Fecal immunochemical tests compared with guaiac fecal occult blood tests for population-based colorectal cancer screening. Toronto (ON): Cancer Care Ontario; 2011 Nov 8. Program in Evidence-based Care Evidence-Based Series No. 15-8.
- A PEBC guideline is in progress entitled *Colorectal Cancer Screening Clinical Practice Guideline* with an anticipated publication date in 2014.

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Updating

All PEBC documents are maintained and updated as described in the PEBC Document Assessment and Review Protocol.

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Evidence-Based Series #15-5 Version 2: Section 2

A Quality Initiative of the Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO)

Guideline for Colonoscopy Quality Assurance in Ontario: Evidentiary Base

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RESEARCH QUESTIONS

1. Physician endoscopist training and maintenance of competency

- What primary training is required for physicians performing colonoscopy?
- What are the requirements for maintenance of competency for physicians performing colonoscopy?

2. Institutional quality assurance parameters

What are acceptable quality assurance parameters for:

- Patient assessment prior to the procedure;
- Infection control, including washing procedures and high-powered washers;
- Monitoring during and after the administration of conscious sedation;
- Resuscitation capability;
- Acceptable endoscope quality?

3. Colonoscopy quality indicators and auditable outcomes

What are appropriate targets for the following indicators of quality colonoscopy?

- Adenoma detection rate;
- Polypectomy rate;
- Cecal intubation rate;
- Colonoscope withdrawal time;
- Bowel preparation;
- Postcolonoscopy colorectal cancer (PCCRC);
- Bleeding rate after polypectomy;
- Perforation rates.

INTRODUCTION

Colorectal is the most common cancer disease site after lung and prostate for men, and after lung and breast for women, with an estimated 4500 new cases of colorectal cancer

(CRC) in men and 3600 in women in Ontario in 2011. CRC accounts for 12% of cancer deaths in Ontario (1).

The risk of developing colon cancer increases with age and is more common in males than in females (2). Several lifestyle variables are also related to the development of colorectal cancer, including a convincing increased risk with the consumption of red or processed meat and sugary drinks, and obesity (3). Following guidelines for healthy eating and physical activity can reduce an individual's risk of developing colorectal cancer (4).

Colonoscopy is the examination of the large bowel and the distal part of the small bowel with a flexible tube called an endoscope. It can provide a visual diagnosis and allows the endoscopist to biopsy suspected cancers and/or to remove potential precancerous lesions. Colonoscopy plays an important role in CRC screening (either as a follow-up examination to a positive FOBT or as a primary screening tool). Therefore, it is important to optimize the quality of colonoscopy in Ontario. Colonoscopy is considered a relatively safe procedure; however, there is some risk of adverse events such as perforation or bleeding (2). A major downside of colonoscopy is the thorough bowel preparation that is required prior to the procedure (5).

Quality in colonoscopy has become a topic of interest over the past several years, as accumulating data suggest that there is substantial variability in the quality, and by extension, the clinical effectiveness of colonoscopy (6). Several organizations and groups have created quality assurance guidelines, including the Program in Evidence-Based Care (PEBC) and Cancer Care Ontario, which created *Colonoscopy Standards* (7) in 2007 to support a proposed organized CRC screening program, which was implemented in 2008. That document addressed endoscopist training and credentialing, quality indicators and targets, and institutional characteristics that contribute to quality in colonoscopy. This document provides an update to the 2007 *Colonoscopy Standards* (7).

In the previous version of this guideline, the Expert Panel believed that there was insufficient data upon which to make recommendations regarding colonoscopy-related bleeding rates, colonoscope withdrawal time, adenoma detection rate, and cancer miss rates. This update has not found a marked improvement in the quality of the evidence base for these indicators; however, there is now a greater volume of literature, and new guidance has been published by the European Commission (8), the Bowel Cancer Screening Program in the UK (9), and the Canadian Association of Gastroenterology (10). There have also been new studies published on minimum thresholds for development of competency.

Some new indicators have been added since 2007, including polypectomy rate, post-colonoscopy colorectal cancer, and adherence to recommended screening intervals. The working group also determined that withdrawal time was not an indicator that needed to be tracked or audited for this version of the guideline. Due to the publication of new evidence, it was possible to specify a target for bleeding rate after polypectomy in this version of the guideline.

This guidance document is intended to support quality improvement for colonoscopies for all indications, including follow-up to a positive fecal occult blood test, screening for those who have a family history of colorectal cancer in a first-degree relative, investigation for symptomatic patients, surveillance of those with a history of adenomatous polyps or CRC, and other screening (e.g., average risk screening). The objective of this guideline is to form the basis of a quality assurance program for all colonoscopies regardless of indication in order to improve quality and consistency of colonoscopy in the province, and ultimately to reduce the incidence of CRC.

METHODS

The evidence-based series (EBS) guidelines developed by the CCO PEBC use the methods of the Practice Guidelines Development Cycle (11). For this project, the core methodology used to develop the evidentiary base was the systematic review. Evidence was selected and reviewed by a PEBC methodologist and all other members of the Colonoscopy Guideline Working Group (Appendix 1). The indicators of interest were chosen by the working group based on the previous version of the guideline (7), with a limited number of additional indicators added based on the opinion of working group members.

The systematic review is a convenient and up-to-date source of the best-available evidence on quality assurance in colonoscopy. The body of evidence in this review is comprised of observational studies and a review of recommendations published by other guideline developers. These sources form the basis of the recommendations developed by the working group and published in Section 1 of this EBS. The systematic review and companion recommendations are intended to promote evidence-based practice in Ontario, Canada.

The PEBC is supported by the Ontario Ministry of Health and Long-Term Care (MOHLTC). All work produced by the PEBC is editorially independent of the MOHLTC.

Literature Search Strategy

Web sites of international guideline developers, Canadian provincial and national cancer agencies, and CancerViewCanada (www.cancerguidelines.ca) were searched for existing evidence-based practice guidelines or reports published after the final search date of the previous PEBC guideline (July 2006) to May 2012 (for a complete list of databases and associations see Appendix 2).

The electronic databases MEDLINE and EMBASE were searched for relevant articles from the completion date of the search for the previous PEBC guideline in July 2006 to May 2012. The search strategy was based on the previous guideline, with some modifications to allow for the expanded scope. For the full literature search, please see Appendix 3. Reference lists of papers and review articles were scanned for additional citations. The Cochrane Library was searched for topic-specific reviews from 2006 to 2012.

The articles located in the search of electronic databases were eligible for inclusion if they met the following criteria:

- Published full reports and abstract reports of randomized controlled trials or observational studies where any of the items of interest related to the research questions were reported for patients who underwent colonoscopy;
- Reports including physician endoscopists.

The following articles were excluded:

1. Letters and editorials.
2. Abstract reports of non-randomized comparative or non-comparative studies.
3. Papers published in a language other than English, because of lack of funds for translation.
4. Studies that were limited to assessment of special populations, e.g., high-risk populations.
5. Studies that assessed flexible sigmoidoscopy or colonoscopy in non-cancer-related disease.
6. Studies in which the results for colonoscopy could not be separated from the results for flexible sigmoidoscopy.

Data extraction and quality assessment of included studies

Quality assessment for quality assurance guidelines was conducted using the Appraisal of Guidelines for Research and Evaluation 2 (AGREE 2) instrument (12), a validated tool to assess the quality and reporting of practice guidelines.

For individual studies, key characteristics, including study location, design, data sources, years of data collection and follow-up, study purpose, colonoscopy indication, and the intervention and comparison under study, were extracted. Outcomes of interest including all quality indicators listed in the research questions were extracted. Where possible, indirect indicators of colonoscopy quality, such as cecal intubation rate or procedure volume, were linked to direct indicators of quality such as adenoma detection rate. ADR and PR vary with the population undergoing the procedures; therefore, studies where the indication for colonoscopy and variables such as the age and sex of the population were not reported were excluded from the analysis for these indicators.

Determination of study quality was based on an assessment of factors such as study design, publication type, and relevance to the Ontario population. Data extraction was verified by a project research assistant. All authors reviewed and discussed a draft of the evidence summary. Strengths and weaknesses were evaluated with the aim of characterizing the quality of the evidence base as a whole, without the use of a scoring system or cut-offs, according to the policy of the PEBC.

RESULTS

Search for Existing Guidelines

Several guidelines were found in the targeted search of known guideline developers and professional organizations. Three documents were located that focussed on quality assurance in colonoscopy as the primary topic, which overlapped significantly in scope with the purpose and research questions of this review (8-10). These documents, from Europe (8), Canada (10) and the United Kingdom (9), were assessed with AGREE II (Appendix 4), and are briefly described below (13). They are also summarized in Appendix 5 and in relevant sections below, along with other guidelines that did not include quality assurance in colonoscopy as the primary topic but did contain information relevant to our research questions.

European Commission (EC) (8)

The EC has issued guidelines for quality assurance in colorectal cancer screening and diagnosis for European Union (EU) member states, based on a systematic review of the evidence on colorectal cancer screening and diagnosis from 2000 to 2008 (8). Because of its high-quality methods and thorough description of the process for developing recommendations, this guideline was given the maximum score on the AGREE II Rigour of Development domain and scored highly on other domains.

Chapter 5, *Quality Assurance in Endoscopy in Colorectal Cancer Screening and Diagnosis* provides quality assurance parameters that are relevant to the objectives of this guideline. Quality indicators, for which there is sufficient evidence to recommend a standard, are provided for quality, safety, and patient feedback. As well, auditable outcomes, which should be monitored, but for which there is no evidence base, are provided. In addition, this guideline states that there should be guidelines in place for components of the procedure such as sedation and colon preparation, policies and supportive processes for other necessary components such as consent, and patient information and selection and assessment of equipment.

Canadian Association of Gastroenterology (CAG) (10)

The CAG has created consensus guidelines on safety and quality indicators in endoscopy (10). The methodology for the CAG guidelines appeared rigorous and systematic, thus it rated highly on the AGREE II tool, although the full search strategy was not provided. The guidelines were based on literature obtained through a systematic review from 1990 to 2009, as well as an adaptation of the UK's Global Rating Scale, a tool developed from the patient's perspective to improve quality in endoscopy service delivery, based on indicators developed by the British Society of Gastroenterology. A formal consensus process was used to gauge stakeholder agreement with the resulting 24 statements.

CAG has also produced credentialing guidance, which is consensus based due to a lack of high-quality data that can be used to underpin credentialing standards for endoscopy (14).

National Health Service (NHS) Bowel Cancer Screening Program (BCSP) (UK) (9)

The authors acknowledge that there is no clear evidence to support national standards in some areas of colonoscopy; however, key performance indicators for monitoring have been identified based on consensus opinion and are outlined in this document. The BCSP uses fecal occult blood tests (FOBTs) as a primary screen before colonoscopy. Therefore, their indicator targets are for a population that has had a positive screening result on FOBT. Not enough information was provided to determine whether or not a systematic review was conducted for this guideline; however, it did provide a comprehensive list of targets and key evidence underpinning each, where available. Lack of evidence of a systematic review led to a lower score on the AGREE II Rigour of Development domain.

Search for Existing Systematic Reviews

The United States Preventive Services Task Force (USPSTF) (15) released a guideline for CRC screening in 2008, which included a meta-analysis of studies of complications of colonoscopy, including bleeding rates and perforation rates. This systematic review is described in greater detail in the section below that discusses safety indicators in colonoscopy.

Search for Primary Studies

Twenty-two full-text articles were identified in the searches of Medline and Embase that contained comparisons of the outcomes of interest for the performance targets for colonoscopy (see Appendix 6 for the literature search flow diagram). Most were retrospective in design, and there was a lack of consistency between studies regarding comparison groups and outcome measures; therefore, on this basis, the quality of the evidence base as a whole was rated as lower quality. These studies are described in greater detail in the sections below.

1. Training and Maintenance of Competency for Physician Endoscopists

Existing Guidance

Achievement of competency in colonoscopy

In Canada, credentialing individuals for colonoscopy is the responsibility of the endoscopists' local institution or facility (14). To be considered for credentialing, gastroenterologists must complete a formal two-year subspecialty training program, with the option of a third year of subspecialty training before entering full-time practice. Surgical residents usually acquire their endoscopy training in the context of a two-month attachment to a gastroenterology training program. Prior to being qualified, other physicians must acquire

the necessary specific knowledge and technical training in endoscopy over a period of at least six to 12 months (14).

Often, achievement of competency in performing endoscopy is tied to a specific number of completed colonoscopies. For example, the American Society for Gastrointestinal Endoscopy (ASGE) and American College of Gastroenterology (ACG) set a minimum threshold for assessment of technical competency of 140 supervised colonoscopies, and the Gastroenterological Society of Australia (GSA) requires 100 training colonoscopies completed without assistance required. As well, ASGE and GSA recommend at least 30 supervised, unassisted snare polypectomies as a threshold for competence as the minimum experience required for proficiency in removal of large polyps and, in particular, sessile ones from high-risk locations. Although these thresholds are defined, in practice they have been shown to be inadequate for most trainees to achieve competence. Rather, objective criteria of technical competency, such as the cecal intubation rate, should be used as criteria when granting privileges to physicians for endoscopic procedures (16). Thus, CAG recommends that competent colonoscopists achieve a cecal intubation rate of 85%-90% for all colonoscopies and 95% for screening colonoscopies in healthy adults.

Training is typically conducted through a preceptor who is a recognized authority, and assessments should occur at various levels of training (17). In addition to proficiency in the technical aspects of colonoscopy, proficiency in cognitive aspects of the procedure is essential, including knowledge of appropriate indications and contraindications for colonoscopy, and application of appropriate screening and surveillance intervals.

In Australia, certification of training in colonoscopy is dependent on an assessment of the cecal intubation rate in intact colons after the completion of minimum training volumes (18). According to the American Society for Gastrointestinal Endoscopy (ASGE), when minimum training volumes have been completed, competency is assessed by the training program director, and direct observation of the applicant performing endoscopic procedures by an impartial credentialed endoscopist is preferred. According to the US Joint Commission on the Accreditation of Healthcare Organizations, credentialing is the first step in the process that leads to privileging (19).

The Joint Advisory Group on Endoscopy (JAG) in the UK has a two-step process for certification. For provisional certification, trainees must have high scores on direct observation of procedural skills and, for full certification, high scores on direct observation of polypectomy skills, low complication rates and sedation rates below mean recommended dosage. A minimum number of completed procedures (200 for provisional and 300 for full certification) are recommended in order to gain experience with all common pathology and unusual anatomy.

Maintenance of competence in colonoscopy

The College of Physicians and Surgeons of Ontario outlines expectations for those who have changed or plan to change their scope of practice to include colonoscopy (20). Essentially, these physicians and surgeons are responsible for undergoing an individualized training, supervision and assessment process in order to be qualified. The features of an acceptable minimum training program include:

- Training must be completed within two years of commencement of the program;
- More than one supervisor should be involved in the training;
- A MINIMUM of 100 upper endoscopies performed under HIGH-level supervision (learner is NOT the Most Responsible Physician - MRP);
- A MINIMUM of 200 colonoscopies under HIGH supervision;
- A CPSO-interim assessment (including chart review and observation of technique) following completion of the above requirements in order to allow for progress to

practice under MODERATE supervision (learner is the MRP, but scopes are ALWAYS performed with a supervisor IMMEDIATELY available);

- A MINIMUM of 100 upper endoscopies under MODERATE supervision;
- A MINIMUM of 100 colonoscopies under MODERATE supervision;
- During the period of MODERATE supervision, the learner will keep track of all indicators as outlined in SECTION II;
- A final CPSO assessment (including chart review and observation of technique) for review by the Quality Assurance Committee for consideration of approval of the change of scope of practice.

According to the ASGE, there is good evidence that proficiency in endoscopic procedures is dependent upon continued practice and performance of adequate numbers of procedures. Annual colonoscopy volume of fewer than 100 procedures is associated with a cecal intubation rate of less than 90%. Although the evidence for precise volume thresholds is lacking (19), the ASGE recommends that each institution develop and maintain guidelines for granting and renewing privileges, including annual threshold numbers. A physician who is requesting privileges to perform colonoscopy after having been away from practice for a period of time (e.g., 5 years) would be treated in a similar manner as a newly trained physician who is seeking initial privileges, and would undergo proctoring prior to the granting of privileges (19).

Other recommendations found in various guidance documents for maintenance of competence:

- The JAG recommends that endoscopists perform at least 300 endoscopies per year;
- European Commission (EC) recommends that each endoscopist participating in a colorectal cancer screening program should perform at least 300 procedures per year to ensure sufficient sample size to assess competence. A higher volume is desirable;
- A single study by Ontario investigators also recommends performance of at least 300 colonoscopies per year, based on the EC recommendation (21);
- The NHS' Bowel Cancer Screening Programme in the UK recommends performance of more than 150 screening colonoscopies (defined as those following a positive FOBT) in addition to non-screening colonoscopies per year in order to maintain competence;
- The Australian National Bowel Cancer Screening Program recommends 250 colonoscopy procedures per proceduralist every 5 years.

The previous PEBC guideline recommended the performance of 200 colonoscopies per year as a threshold for maintenance of competence. Seventy-six percent of endoscopists performed more than 200 colonoscopies per fiscal year in Ontario in 2008-2010 (22), although the cecal intubation rate in this group did meet recommended guidelines (95% or greater).

Primary studies

Study Characteristics (Table 1)

The systematic review identified three studies that assessed the number of procedures that needed to be performed by surgical or GI trainees during a formal period of training in order to achieve competency in endoscopy. Two of these studies were carried out in the USA, and one was conducted in Korea. One study was a retrospective analysis, and the others were prospective. Most studies included all patients that would normally undergo colonoscopy under routine circumstances. They used a variety of measures to determine competency in endoscopy, such as threshold values for CIR, PR and WT. No primary studies were found that assessed competency among practicing, non-trainee endoscopists.

Table 1. Characteristics of studies related to training and competency.

Study Year (ref)	Location	Study design	Trainees	Data collection	Purpose	Reason for colonoscopy	Follow-up	No. of procedures	Outcomes
Lee et al 2008 (23)	Korea	P	24 first-yr GI fellows	Jun 2006 - Jan 2007	Identify measures of competence, determine adequate level of training	Screening and diagnostic;	None	4351	CIR, PR
Sedlack 2011 (24)	Minnesota, USA	P	41 GI fellows	Jul 2007 - Jun 2010	Define average learning curves and minimum standards for colonoscopy	Routine outpatient procedures, excluded: therapeutic or complex procedures	None	4103	CIR, no. of procedures required to achieve competency
Spier et al 2010 (25)	Wisconsin, USA	R	21 surgical residents after 2-mth endoscopy rotation	Survey completed shortly after endoscopy rotations in Jul 2004-Jun 2007	Assess no. of colonoscopies performed and CIR for surgical residents during 2-mth rotation and their perceptions of training	NS	None	80±35/resident	CIR, PR, perceptions of training, and competency after endoscopy rotation

P = prospective, R = retrospective, GI = gastroenterology, NS = not stated, No. = number, CIR = cecal intubation rate, PR = polypectomy rate, yr = year, mth = month

Study outcomes (Table 2)

As mentioned, it has been suggested that a trainee log at least 140 colonoscopies to establish a minimal level of competence, but findings have shown that is unlikely that a trainee with this level of experience will be able to perform colonoscopy in accordance with benchmarks for quality (16). One study found that first-year GI fellows reached a CIR of 94% after 200 colonoscopy and 98% after 250 (23). Another study found that it takes an average of 275 procedures to achieve competence in colonoscopy using scores on the Mayo Colonoscopy Skills Assessment Tool, cecal intubation rates of 85%, and intubation times of less than 16 minutes as minimal competency criteria (24). Research by Spier et al suggests that 500 colonoscopies are likely required to ensure reliable independent completion rates ($\geq 90\%$). In this study, all fellows achieved a reliable independent completion rate of 90% after 500 colonoscopies, whereas no fellow reached 90% after 140 colonoscopies (25).

Table 2. Study outcomes, training and competency.

Study Year (ref)	Trainees	Indication	No. of procedures	CIR (%)	ADR (%)	PR (%)	WT (no polypectomy) (min)	Notes
Lee et al 2008 (23)	24 first-yr GI fellows	screening signs and symptoms, family hx, surveillance, other	4,351	CIR in <20min: 72 after 50 procedures 83 after 100 91 after 150 94 after 200 98 after 250 99 above 250	NR	21.8	NR	
Sedlack 2011 (24)	41 GI fellows	routine procedures	4,103	51 after 50 procedures 76 after 150 85 after 275 90 after 400	NR	NR	NR	On average, 275 procedures recommended to achieve competency
Spier et al 2010 (25)	21 surgical residents after 2-mth endoscopy rotation	NS	80±35 colonoscopies each (range 40-160)	Mean: 47 (range 9-78)	NR	NR	NR	

Yr = year, mth = month, hx = history, GI = gastroenterology, NS = not stated, No. = number, CIR = cecal intubation rate, min = minute, NR = not reported, PR = polypectomy rate, WT = withdrawal time

2. Institutional guidelines

The previous version of this guideline endorsed several recommendations from the College of Physicians and Surgeons of Ontario (CPSO)'s guidance document for Independent Health Facilities (26), which included recommendations for monitoring and resuscitation during sedation, and infection control. For this version, several new guidelines and reports were found that informed institution-level recommendations (Table 3), including newer guidance from the CPSO. Relevant recommendations from these documents are outlined below. No single primary studies related to institutional standards were found in the search of electronic databases.

Table 3. Guidance documents that addressed aspects of institutional standards for performance of colonoscopy.

Reference	Title	Brief description
ASGE 2009	Automated endoscope reprocessors (AERs)	Technology status evaluation report on AERs.
Beilenhoff 2008 (27)	ESGE-ESGENA Guideline: cleaning and disinfection in gastrointestinal endoscopy	Guidance from the European Society of Gastroenterology and the European Society of Gastroenterology and Endoscopy Nurses and Associates on cleaning and disinfection in gastrointestinal endoscopy.
Cancer Council Australia (28)	Clinical Practice Guideline for Surveillance Colonoscopy	Guidance for surveillance colonoscopy in adenoma follow-up, following curative resection of colorectal cancer, and for cancer surveillance in inflammatory bowel disease.
CAG (10)	Canadian Association of Gastroenterology consensus guidelines on safety and quality indicators in endoscopy	Guidance states that quality and safety standards should also address endoscope reprocessing, conscious sedation, monitoring protocols and resuscitation equipment. Reporting systems and databases are also recommended to facilitate quality improvement.
CPSO (no publication date provided) (29)	Expectations of physicians who have changed or plan to change their scope of practice to include endo-colonoscopy	Outlines the CPSO's expectations for change in scope of practice. Outlines a system of performance management that focuses on competence rather than paper credentials.
CPSO (30)	Out-of-Hospital Premises (OHP) Standards	Outlines standards for the provision of medical care/procedures in Ontario out-of-hospital premises.
CPSO 2011 (20)	Guide to Applying the Out-of-Hospital Standards in Endoscopy/Colonoscopy Premises	Based on the OHP core standards, this document outlines standards for out-of hospital premises where colonoscopy is performed in Ontario, with the goal of helping practitioners plan for and participate in their inspection-assessments.
European Commission (2010)	European guidelines for quality assurance in colorectal cancer	Standards are provided for quality, safety, and patient feedback before and during

(8)	screening and diagnosis.	the procedure.
The Quality Assurance Task Group of the National Colorectal Cancer Roundtable (31)	Standardized colonoscopy reporting and data system: report of the Quality Assurance Task Group of the National Colorectal Cancer Roundtable	
US FDA (32)	Preventing Cross-Contamination in Endoscope Processing	Communication that outlines the risks to patients if flexible endoscopes and their accessories are not processed properly, and recommends steps to reduce these risks.

Pre-procedure assessment

Items to consider in a pre-procedure assessment include patient demographics and history, including previous GI procedures. Certain elements of patient history may require precautions before a colonoscopy is performed, and any treatment decisions based on history should be documented. The Quality Assurance Task Group of the National Colorectal Cancer Roundtable (31) recommends documenting the following prior to the procedure:

- informed consent that conveys risks of the procedure and of false negatives;
- management plan for anticoagulation;
- management plan for patients with implantable defibrillators and pacemakers.

For meaningful analysis of prevalence rates, age and sex should also be collected.

An Australian guideline for surveillance colonoscopy (28) also includes bowel preparation in the pre-procedure assessment, using the following quality indicators:

- 100 per cent of patients receive bowel preparation education;
- 100 per cent documentation of the type and quality of bowel preparation;
- <10 percent of patients require a repeat colonoscopy examination due to poor bowel preparation.

European Commission guidance (8) also addresses the pre-procedure assessment, and recommends the collection of the following variables because they can be associated with more adverse events, longer duration, and incomplete examinations:

- Use of anticoagulants e.g., warfarin;
- Anatomy (female sex);
- Age of patient;
- Prior abdominal surgery;
- BMI;
- Diverticular disease;
- ASA PS (American Society of Anesthesiologists classification of Patient Status) and information that may influence type and level of sedation (for those procedures where sedation may be used);
- Presence of risk factors for endocarditis.

Infection control

If endoscopes and accessories are not properly processed, patients can be exposed to contaminants from prior patients, potentially spreading pathogens and causing illness. In the previous version of this guideline, the CPSO (26) standards regarding infection control were cited, and endorsed by the Expert Panel. The following infection control precautions remain relevant:

- Gastrointestinal endoscopes come into contact with mucous membranes and are considered semi-critical items. The minimum standard of practice for reprocessing is high-level disinfection.
- Accessories (e.g., re-usable biopsy forceps) that penetrate mucosal barriers are classified as critical items and must be sterilized between each patient use. Accessories labeled 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 clean equipment manually prior to any manual or automatic disinfection or sterilization process.

Newer CPSO guidance requires functionally separate areas for reprocessing, scope cabinet and dirty areas in endoscopy/colonoscopy premises (20).

Quality of sedation

Most patients in the North American setting are sedated during colonoscopy, although there is a risk of adverse events, especially in patients with pre-existing conditions (2).

Moderate (conscious) sedation allows patients to purposefully respond to verbal commands, and no interventions are needed to maintain a patent airway or spontaneous ventilation; therefore, sedation should be targeted to “moderate” for most patients (33).

The previous version of this guideline included a review of various sedation regimens and recommended that all patients be offered sedation unless contraindicated, and maintained that patients need to be aware that they have the right to refuse sedation. This version of the guideline endorses these recommendations, and did not review the primary literature on specific regimens, but focused rather on sedation quality indicators.

A reference cited in the previous PEBC document stated that a pre-procedure history and examination for risk factors should be recorded, including American Society of Anesthesiologists (ASA) classes, as the risk of cardiopulmonary complications is increased in patients with higher ASA scores. That guidance document recommends a continuous quality-improvement target of 100% for identification of ASA class and appropriate action (34).

Faigel et al (35) lists quality indicators related specifically to sedation:

- obtaining informed consent;
- specifically addressing the most common complications;
- a directed pre-procedure history and directed physical examination before the use of moderate or deep sedation;
- documented risk assessment before sedation;
- specified sedation plan with level of sedation specified before the procedure as minimal, moderate, deep or general anesthesia.

The National Bowel Cancer Screening Program Quality Working Group in Australia provides specific targets for adverse events associated with sedation (2):

- Respiratory depression or airway obstruction requiring unplanned intervention in less than 1 in 100 patients;
- Hypoxia defined as pulse oximetry more than 10 percentage points lower than awake pre-procedural baseline for greater than 60 seconds; consecutively during or after the procedure in less than 1 in 100 patients;
- Hypotension requiring drug or fluid therapy in less than 1 in 100 patients;
- Cardiac arrhythmia requiring intervention in less than 1 in 1000 patients;
- Pulmonary aspiration of gastric contents in less than 1 in 1000 patients;
- The use of reversal agents in less than 1 in 100 patients;
- Patient complaint about sedation in less than 1 in 100 patients;

- Abnormal discomfort or pain in less than 1 in 100 patients;
- Procedure-related death within 30 days in less than 1 in 10,000 patients.

Monitoring during and after the administration of conscious sedation

Monitoring during and after sedation was addressed by several documents that were reviewed for the previous version of this guideline, including the Canadian Society of Gastroenterology Nurses and Associates (CSGNA), CPSO, and ASGE. The updated search found CAG, and Australian guidelines that addressed this topic.

The CAG guideline calls for regular monitoring of sedation level, with implementation of an evidence-based sedation protocol, as well as regular monitoring of blood pressure, pulse, oxygen saturation, etc., during the procedure. Australian guidance notes that there is controversy around appropriate monitoring of sedation; however, appropriate monitoring of vital signs is advised (28).

Resuscitation capability

The EC guidance recommends that there should be properly maintained resuscitation equipment in the endoscopy room and recovery area (8). CAG does not provide any guidance on resuscitation capability, other than to say that it is necessary (10).

Endoscope quality

There were no studies found that specifically addressed endoscope quality; however, some guidance from the FDA was located regarding maintenance of endoscopes, including administrative and technical aspects (32):

- Establishment of a comprehensive Quality Assurance and Safety Program and procedures for monitoring adherence to the program, including standard operating procedures for preparing endoscopes and quality assurance procedures for reprocessing endoscopes and their accessories;
- Training and retraining staff involved with endoscope care and maintenance and establish a chain of accountability for endoscope processing procedures;
- Adherence to the endoscope manufacturer's operating manual and instructions for use.

Guidance has also been published that supports the use of automatic endoscope reprocessors (27,36).

3. Indicators of Performance Quality

The following section contains the results of the search for guidelines and electronic databases for studies that included agreed-upon measures of quality colonoscopy, including:

- Adenoma detection rate (ADR);
- Polypectomy rate (PR);
- Cecal intubation rate (CIR);
- Colonoscopy withdrawal time;
- Quality of bowel preparation.

Existing Guidelines (Table 4)

In addition to the previous PEBC guidance on this topic (7), five guidelines were located in the environmental scan that addressed the quality measures of interest and had been published after the previous PEBC search strategy had been completed (2,8,9,14,31). Most guidance located in the environmental scan provided recommendations for cecal intubation rate, which is often considered the primary indicator of quality (8). CIRs were in

the range of 90% to 95%, depending on the indication and whether the rate was adjusted for factors such as poor bowel preparation or structural abnormalities. In the UK, there is one standard (90%), which refers to unadjusted rates (37). The CAG credentialing guidelines indicate the acceptability of a somewhat lower range of CIR for all colonoscopies of 85% to 90% as acceptable.

ADRs in screening populations of >25% for men and >15% for women were recommended by the ASGE/ACG (31) and endorsed by CAG (14) and the national screening program in Australia (2); however, these thresholds are only valid for US endoscopists performing screening colonoscopies, and do not apply in countries with different CRC rates or ADRs, or where FOBT is used as a primary screening test (38). A recommended withdrawal time of at least 6 to 7 minutes was consistent among guidelines (2,9,14,31). No guidelines were found that included a recommendation for polypectomy rate.

Table 4. Quality recommendations found in the review of existing guidelines.

Organization Year (ref)	CIR; screening	CIR; symptomatic	ADR	PR	WT (without polypectomy or biopsy)
PEBC 2007 (7)	95% provided adequate prep and no structural abnormalities	No rec	No recommendation	No rec	No recommendation
ASGE/ACG 2007 (31)	95%	90%	Screening pts aged >50 years: 25% men 15% women	No rec	≥6 min
CAG 2008 (14)	95%	85-90%	Screening in healthy asymptomatic pts >50 years: 25% men 15% women	No rec	>7 min
European Commission 2010 (8)	>90% acceptable, >95% desirable		No recommendation	No rec	No WT given, but recommended as an outcome to be monitored
National Bowel Cancer Screening Program UK 2011 (9)	90% with no adjustment for poor bowel preparation or structural lesions.		≥35% in context of an FOBT-based screening program	No rec	≥ 6 min
National Bowel Cancer Screening Program Australia 2009 (2)	95%	90%	>20% in patients aged >50 for initial colonoscopy	No rec	≥ 6 min
PEBC = Program in Evidence-Based Care, ASGE/ACG = American Society for Gastrointestinal Endoscopy/American College of Gastroenterologists, pts = patients, CIR = cecal intubation rate, ADR = adenoma detection rate, PR = polypectomy rate, WT = withdrawal time, FOBT = fecal occult blood test, no rec = no recommendation, min = minutes					

Literature Search Results

Study Characteristics (Table 5)

Thirteen studies (38-50) met the inclusion criteria of the systematic review for studies that reported quality indicators. Only one of these studies took place in Canada (39), and the rest were conducted in the USA (40,41,44-50), the UK, elsewhere in Europe (38,42), Korea, and Taiwan (43). There was a mix of prospective (39-41,43,45,46,50) and retrospective studies, and data collection occurred at several different levels, from individual endoscopists, to hospital level, to the level of a national screening program. There were several indications reported for colonoscopy, including signs and symptoms, screening (as primary or secondary screen), family history, or surveillance, and the population of interest differed by study. The number of procedures ranged from 522 (43) to almost 24,000 (46). In some studies, single outcomes of interest, such as ADR (48) or PR (43) were reported, and in the rest of the studies, more than one outcome was reported. The studies that evaluated the correlation of multiple indicators on the same population were considered to be of higher quality and more informative for development of quality indicators. Due to the heterogeneity of comparison and outcome groups, it was not possible to pool outcomes across studies.

Table 5. Characteristics of studies reporting quality indicators CIR, ADR, PR, and WT.

Study	Location	Design	Data source	Data collection	Purpose	Reason for colonoscopy; exclusions	Follow-up	No. of procedures	Outcomes
Armstrong 2011 (39)	Canada	P	Data uploaded by individual endoscopists at 19 centres	Feb 2008-Jun 2009	Point of care audit	Abnormality, screening or surveillance	No	1279 pts	CIR, WT, PR
Barclay 2008 (40)	USA	P	Community-based practice	Jan 2003 -Mar 2004 compared to Apr 2005-Apr 2006	Assess implementation of time-dependent, segmental withdrawal protocol	No previous colonoscopy; Excluded: hx of CRC, FOBT+	No	2325 pts	ADR by WT
Denis 2011 (38)	France	R	Database of an FOBT-based CRC screening program	2002-2009	Determine the most appropriate quality indicator and threshold for neoplasia yield in FOBT CRC screening programs	FOBT+ average risk; Excluded: family hx	No	5852	ADR, PR
Gellad 2010 (41)	USA	P	Interview at enrollment and procedural data collected in central study database	Feb 1994-Jan 1997	Evaluate relationship between WT and advanced neoplasia at 5 years	Veterans; Excluded: lower GI, disease, symptoms, exam within previous 10yrs	4.8yrs	3121	WT and later missed adenomas
Goncalves 2011 (42)	Portugal	R	Tertiary hospital	2005-2009	Measure performance in a single department	First time screening	No	1545	CIR, bowel prep

Study	Location	Design	Data source	Data collection	Purpose	Reason for colonoscopy; exclusions	Follow-up	No. of procedures	Outcomes
Hsieh 2009 (43)	Taiwan	P	Patients of a single endoscopist in one hospital	Jul 2006-Dec 2007	Investigate effect of increasing endoscope withdrawal time to 6 mins on PR of one endoscopist	Asymptomatic; Excluded: hx of abdominal surgery, incomplete, poor prep	No	532	PR
Lee 2011 (50)	USA	R and P	5 academic tertiary care medical centres	NS	Determine importance of withdrawal technique in differentiating among endoscopists with varying ADRs	Not part of a screening program	No	752	ADR, WT, withdrawal technique
Millan 2008 (44)	USA	R	Departmental colonoscopy database	1998-2004	Examine range of adenoma detection rates and contributing factors	Asymptomatic, hx of rectal bleeding, surveillance	No	16,335	CIR, ADR, procedure time, CRC
Overholt 2010 (45)	USA	P	Data collected for routine clinical activity quality assurance	Spring/summer 2007	Evaluate the impact of colonoscopy WT on detection of polyps	Any indication	No	15,955 pts	WT (impact on polyps found)
Sawhney 2008 (46)	USA	P	Medical center GI Division	Feb 2006-Jun 2007	Determine if implementation of colonoscopy WT of 7+ min is associated with greater polyp detection	NS	No	23,910	PR by compliance with 7-min WT

Study	Location	Design	Data source	Data collection	Purpose	Reason for colonoscopy; exclusions	Follow-up	No. of procedures	Outcomes
Simmons 2006 (47)	USA	R	Procedure data from an institutional computerized database located at an outpatient endoscopy unit	Jan 2003-Dec 2003	Derive evidence-based minimum acceptable withdrawal times	“routine” cases; Excluded: complex cases, incomplete examinations, suboptimal bowel prep, prior colonic resection, trainee involvement	No	10,955	Polyp yield by size by various WTs
Williams 2011 (49)	USA	R	Endoscopic database at Health and Science University and Veterans Affairs Medical Center	2007-2008	Compare endoscopists’ PRs and ADRs and to determine benchmark PRs	Average risk screening; Excluded: hx of inflammatory bowel disease, polyposis syndrome	No	2706	ADR, PR
Williams 2012 (48)	USA	R	Community and academic endoscopy units in the United States	2005-2006	Validate the connection between PR and ADR	Average risk screening; Excluded: incomplete examinations	No	14,341	ADR

No. = number, R = retrospective, P = prospective, yr(s) = year(s), min = minutes, pts = patients, GI = gastrointestinal, NS = not stated, PR = polypectomy rate, CIR = cecal intubation rate, ADR = adenoma detection rate, WT = withdrawal time, CRC = colorectal cancer, hx = history, FOBT = fecal occult blood test

Study Outcomes (Table 6)

Cecal intubation rate (CIR) (Table 6)

CIR is the most commonly used indicator of colonoscopy quality. It is defined as the passage of the instrument tip proximal to the ileocecal valve so that the entire cecal caput is visible (2). A CIR of 90% for symptomatic patients and 95% for patients having a screening colonoscopy are commonly cited benchmarks (37). These rates allow for some adjustment for poor bowel preparation, stricture or severe colitis. The previous PEBC guideline was in agreement with the 95% recommendation for screening colonoscopy, but did not provide a target for those attending for investigation of symptoms. Despite its common use as a quality indicator, recent evidence for the relationship between CIR and incidence of CRC has been mixed: for example, one study found no significant relationship in a population that underwent colonoscopy as a primary screening test (51), while a study of administrative data in Ontario including screening and other colonoscopies did find a significant relationship (52).

The primary studies located in the literature found CIRs ranging from 91% in the context of first-time screening in a tertiary hospital in Portugal (42) to 99% in the setting of a community-based practice that was implementing a new withdrawal protocol in order to improve colonoscopy quality (40).

Most sources agree that it is important for each endoscopist to provide photodocumentation of the ileocecal valve and appendiceal orifice to document completion (53). The CAG guideline states that because photodocumentation of cecal intubation is often unavailable, ideally, visualization of landmarks should be documented in writing for every procedure (14).

Adenoma detection rate (ADR) (Table 6)

Adenomas are benign tumours of glandular origin, which may progress over time to malignant adenocarcinoma; therefore, it is important to detect and eliminate adenomas during colonoscopy. ADR is considered a robust quality indicator with a significant relationship to incidence of CRC (51); however, its use is often limited because pathologic analysis is required to determine whether or not polyps are adenomatous, and this reporting is not available at the time of colonoscopy (54). As mentioned above, prevalence rates of at least one adenoma in colonoscopy screening studies have been consistently over 25% in men and 15% in women more than 50 years old (55); however, these studies were not always representative of the general population and may not be generalizable to populations where colonoscopy is not the primary screening test. The EC's systematic review found that rates for the detection of any adenoma or cancer detection ranged in the literature from 14.9% to 37.5% (8).

In the previous PEBC guideline, eight studies were identified with ADRs that were extremely variable, ranging from 12% to 62%; thus it was determined that a target for ADR could not be specified. This update found an additional seven studies that reported ADRs ranging from 11% for endoscopists with lower scores on withdrawal technique (50) to approximately 35% in several studies (38,40,43,50). Where studies reported rates for males and females separately, the latter had ADRs that were approximately 10% lower (48,49).

Polypectomy rate (PR) (Table 6)

Polypectomy rate, defined as the detection and removal of at least one polyp during colonoscopy, was not included as a quality indicator in the last version of this guideline. Since that time, this indicator has been explored as potentially useful, because unlike ADR, it can be measured at the time of colonoscopy.

This systematic review found several studies that address the relationship between ADR and PR. One study found a correlation between ADR and PR of $r=0.88$ (95% CI, 0.78%-0.94%) in an average-risk asymptomatic population with FOBT-positive test results (38). In another study (48), endoscopists' polypectomy rates yielded similar assessments of quality as their adenoma detection rates, with a correlation between endoscopists' PRs and ADRs of $r=.91$, $p<0.0001$ (48). This finding led the researchers to propose a benchmark polypectomy rate of 40% in men and 30% in women, because endoscopists who reached these rates almost always reached the ASGE-recommended ADR benchmarks of 25% and 15%, respectively, and found more advanced lesions (36).

Baxter et al (56) found that median polypectomy rate for endoscopists over a 2-year period was 17.7% (range: 0.0%-72.5%). Patients undergoing colonoscopy performed by an endoscopist with a polypectomy rate $\geq 30\%$ were less likely to develop a proximal PCCRC than if colonoscopy was performed by an endoscopist with a 10% polypectomy rate (OR, 0.61; 95% CI, 0.42%-0.89%). Polypectomy rate was not associated with diagnosis of a distal PCCRC.

In a point-of-care audit, the mean percentage of colonoscopies performed by each endoscopist involving one or more polypectomies was 37.0% (median, 34.0%), although 10% of endoscopists reported polypectomy in 13.3% or fewer of their colonoscopies (39).

Withdrawal time (WT) (Table 6)

Some sources have recommended the monitoring of WT, as it has been positively associated with adenoma detection (40), and it can be used as a proxy quality indicator for ADR when the latter indicator cannot be measured reliably. WT is less useful when other more-robust measures of quality are available such as CIR or ADR (57). WT during colonoscopy when polyps are removed can vary greatly; therefore, monitoring at the endoscopist level should only include patients for whom polypectomy is not required. The previous guideline did not make a recommendation on average colonoscopy withdrawal time, citing insufficient evidence.

Eleven studies were located that reported WT among fully trained endoscopists ranging from 4.2 (+/-1.1) min (43) to around 10 minutes (50). In the former study, the group that averaged 4.2 minutes had a significantly lower rate of polyp detection compared to a group with an average WT of 5.7 (+/-1.6) minutes (55.4% vs. 42.4%, $p=0.004$). Another individual study corroborated the positive relationship between WT and adenoma detection rate (50). One study found that endoscopists with low ADRs may attain a WT of ≥ 6 minutes without demonstrating high-quality withdrawal technique, although this study had several limitations (50). One author proposed inspection time, defined as the period of time that the endoscopist is actively engaged in examining the colonic mucosa for polyps, not including time spent for cleaning or suctioning or during collisions with the bowel wall, rather than withdrawal time, as a better indicator (50).

Table 6. Study outcomes, CIR, ADR, PR, and WT.

Study Year (ref)	Age (yr)	% male	Indication	No. of procedures	CIR (%)	ADR (%)	PR (%)	WT (no polypectomy) (min)	Notes
Armstrong 2011 (39)	18+		Investigation screening surveillance	1279	Mean: 94.9 Med: 97.5		Mean: 37.0 Med: 34.0	Med: 6.3	
Barclay 2008 (40)	Mean: BL: 60.3 PI: 59.4	51 49	screening	2053 2325	99 99	23.5 34.7		Mean: 6.3 9.8	
Denis 2011 (38) (Haut-Rhin data)	Mean: 62.8	53.6	FOBT+ family history	5852		Mean: 35.6 Med: 35.5	Mean: 44.3 Med: 45.2		
Gellad 2010 (41)	Mean: 62.7 Range: 50-75	95.6	Screening (veterans)	3121				13.2	No association found between WT at baseline colonoscopy and neoplasia on colonoscopy within 5.5yrs
Goncalves 2011 (42)	Mean: 60.4	38	First-time screening	1545	91		33 (men: 44 vs. women: 25, p=0.0001)		
Hsieh 2009 (43)	Mean: B: 51.8 A:53.6	B: 36.1 A: 42.1	Asymptomatic routine	532		B: 23.7 A: 33.9	B: 42.4 A: 55.4	B: 4.2 A: 5.7	Single endoscopist, also included improvement in

Study Year (ref)	Age (yr)	% male	Indication	No. of procedures	CIR (%)	ADR (%)	PR (%)	WT (no polypectomy) (min)	Notes
									withdrawal technique
Lee 2011 (50)	Low ADR group: 61 moderate: 59 High: 60	72.6 69.6 52.7	Average risk screening	752		11.8 34.1 49.0		6.3 10.2 8.2 (p=0.29)	Withdrawal technique rather than withdrawal time found to be a predictor of ADR.
Millan 2008 (44)	NS	NS	Asymptomatic screening hx of rectal bleeding surveillance	16,335	96.5	21		With the exception of an outlier, WT and ADR correlation = 0.975 (P=0.0016)	CIR fairly uniform, but ADR varied widely among endoscopists.
Overholt 2010 (45)	59.9, SD 12.8)	45.5	Screening symptoms surveillance	15,955 pts					Endoscopists with mean WT ≥ 6 were 1.8 times more likely to detect 1 or more polyps and had a significantly higher rate (p<0.0001) of polyp detection compared to endoscopists with mean WT < 6 min
Sawhney 2008 (46)	Mean: 56.8	46	Screening surveillance symptoms						When compliance with a 7-min withdrawal time for nontherapeutic colonoscopies improved from 65% to 100% of 42 endoscopists at a single centre, there was no increase in polyp detection ratio (p=0.45)
Simmons 2006 (47)	Mean: 62.5	54.4	Routine out-patient	10,955					Median PR of 42.7% corresponded to a withdrawal time of 6.7 min, with a correlation between overall PR and mean endoscopist WT of 0.76, p<0.0001.

Study Year (ref)	Age (yr)	% male	Indication	No. of procedures	CIR (%)	ADR (%)	PR (%)	WT (no polypecto my) (min)	Notes
Williams 2011 (49)	50+ Mean: 59.6	71	Average risk screening	2706		men: 29.5 women:12.7	men: 43.5 women: 25.8		Suggest a PR of 40% for men and 30% for women corresponds to ADRs of 25% and 15%
Williams 2012 (48)	50+, Mean: males: 60.7 females: 61.2	49.0	Average risk screening	14,341		male: ADR: 35.4, PR: ≥40 female: ADR: 25.7 PR: ≥30 Correlation between PR and ADR males = 0.91, p=0.0001; females =0.91, p=0.0001			

No. = number, CIR = cecal intubation rate, WT = withdrawal time, PR = polypectomy rate, ADR = adenoma detection rate, hx = history, FOBT = fecal occult blood test, yrs = years, BL = baseline, PI = post-intervention, med = median, B = before, A = after, NS = not stated

Quality of bowel preparation

The previous PEBC guideline established that proper bowel preparation is essential to quality colonoscopy, because poor preparation can result in a significantly lower polyp detection rate. Guidelines suggest that percentage of colonoscopies with bowel preparation adequate to detect polyps larger than 5 mm should be measured, and inadequate preparation should occur in no more than 10% of colonoscopies (31,53). Canadian guidelines (10) recommend that a standardized tool, such as the Ottawa Bowel Preparation Scale (OBPS) (58) or the Boston Bowel Preparation scale (59), should be used to assess bowel preparation quality (10).

In a point-of-care practice audit of 1279 patients over 16 months seen by 62 endoscopists at 19 Canadian centres, bowel preparation was excellent in 75.6% of cases, using an OBPS score of less than 5 as a cut-off (39).

While clinical practice, including methods of bowel preparation, were not the subject of this review, quality assurance guidelines found in the review stated that split dosing (i.e., dosing at least half of the preparation on the day of the colonoscopy) has been established as superior to dosing all the preparation the day before the test (5,8).

Postcolonoscopy Colorectal Cancer (PCCRC)

Study characteristics (Table 7)

Three studies were found that assessed the incidence of PCCRC, i.e., new or missed colorectal cancer after colonoscopy (51,52,60). Two of the studies included Ontario data (52,60), while the other was conducted in Poland (51). Data sources included administrative data from Ontario databases (52,60) and data collected as part of the national CRC screening program in Poland (51). Two studies excluded higher-risk individuals (52,60). All studies investigated the incidence of CRC in populations that had previously undergone colonoscopy, and some tried to link this indicator with other more established indicators such as CIR (51,52).

Table 7. Study characteristics, PCCRC.

Study Year (ref)	Location	Design	Data source	Data collection	Purpose	Reason for colonoscopy; exclusions	Follow-up	# of procedures	Outcomes
Baxter 2011 (52)	Canada	R	OCR, OHIP, CIHR Discharge Abstract Database, Registered Persons Database, Ontario Physicians Human Resources Data Centre	CRC diagnosis between 2000-2005	Determine if performance-based quality indicators could be identified at the endoscopist level using admin data; validity of these indicators for predicting PCCRC	Excluded: <20 years, previous dx of CRC, outside direct billing area, Crohn's, ulcerative colitis, incomplete exam, previous colon resection	36 mon	14,064 pts with CRC	PR, CIR, PCCRC
Bressler 2007 (60)	Canada	R	CIHI, Registered Persons Database, Ontario Cancer Registry	New CRC from Apr 1997-Mar 2002	Evaluate the frequency of and risk factors for new and missed CRC by colonoscopy in a population-based study	Excluded: ulcerative colitis, Crohn's, <20 at dx, had previous flex sig	36 mon	12,487	PCCRC
Kaminski 2010 (51)	Poland	R	National CRC Screening Program for Poland	Oct 2000-2004	Assess association between quality indicators and risk of interval cancer	National colonoscopy-based screening program; Excluded: poor prep	188,788 person-yr	45,026	PCCRC by ADR, CIR

R = retrospective, OCR = Ontario Cancer Registry, OHIP = Ontario Health Insurance Plan, CIHR = Canadian Institutes of Health Research, CIHI = Canadian Institute for Health Information, CRC = colorectal cancer, PCCRC = postcolonoscopyCRC, dx = diagnosis, flex sig = flexible sigmoidoscopy, yr = year, mon = month, pts = patients, PR = polypectomy rate, CIR = cecal intubation rate, ADR = adenoma detection rate

Study outcomes (Table 8)

Among those who have cancer and who undergo colonoscopy, cancer is missed approximately 4%-6% of the time, with higher miss rates for right-sided (proximal) cancers (14). A study conducted in Ontario found that among those diagnosed with CRC, rates of PCCRC were 3.4% after 3 years overall, although the rate of new or missed right-sided CRC was 5.9% (60). A more recent study conducted in Ontario found that of 9% of patients diagnosed with CRC were considered a PCCRC (new or missed cancer diagnosis 7 to 36 months after colonoscopy), which is a higher proportion than reported in previous studies (52). In this study, patients with proximal CRC were more likely to have a PCCRC than were patients with distal CRC (12.4% vs. 6.8%, $p < 0.0001$). The authors attribute the higher rate potentially to differing methodology, time period or study population.

Kaminski et al (51) looked at cancer incidence in the interval between initial screening colonoscopy and subsequent surveillance colonoscopy in the context of a national bowel cancer screening program that uses colonoscopy as the primary screening test. Interval cancer was found to have a significant relationship to ADR, with a hazard ratio of 12.50 (95% CI, 1.51%-103.43%) for an ADR of 15.0%-19.9% compared to an ADR of at least 20%. This study did not find a significant association with CIR and PCCRC. This may have been because this study took place in a younger cohort (40-66 years of age); reaching the cecum is less of a factor for younger populations because they are at lower risk for proximal cancers.

Table 8. Study outcomes, PCCRC.

Study Year (ref)	Age (yr)	% male	Colonoscopies included in PCCRC	# of pts	PCCRC
Baxter 2011 (52)	Pts with CRC med: 68 pts with PCCRC med: 71	CRC: 56.6 PCCRC: 52.7	Complete 7-36 mths before CRC diagnosis	CRC: 34,312 Complete colonoscopy within 36 mths of CRC diagnosis: 14,064 PCCRC: 1260	<ul style="list-style-type: none"> 9% of those who had a colonoscopy within 36 mths of CRC diagnosis were considered to have a new or missed cancer (PCCRC). CIR of 85%+ vs. <80%, and PR of 25% vs. <10% both associated with significantly reduced chance of PCCRC
Bressler 2007 (60)	Mean: 67.7	56	Most recent 6-36 mths before CRC diagnosis	CRC: 12,487 PCCRC: 430 after 2 years	430 of 12,487 patients diagnosed with CRC had undergone a colonoscopy within the previous 2 yrs (excluding the 6 mths prior to diagnosis) = 2.4% After 3 y: 3.4% After 5 y: 4.6%
Kaminski 2010 (51)	50-66 (and 40-49 at increased risk)	35.7	Primary screening	45,026	<ul style="list-style-type: none"> HR for interval cancer* by ADRs: <11.0%: 10.94 (95%CI, 1.37%-87.01%) 11.0-14.9: 10.75 (95%CI, 1.36%-85.06%) 15.0-19.9%: 12.50 (95%CI, 1.51%-103.43%), 20.0%+ (ref group) p = 0.02 for all comparisons NS relationship between CIR and interval cancer (p=0.50)

Pts = patients, yr = years, mths = months, CRC = colorectal cancer, PCCRC = postcolonoscopyCRC, CIR = cecal intubation rate, PR = polypectomy rate, HR = hazard ratio, NS = non-significant
*Interval cancer defined as CRC diagnosis between screening colonoscopy and scheduled time of surveillance colonoscopy

Bleeding after Polypectomy and Perforation Rates

Existing guidelines (Table 9)

The previous PEBC guideline concluded that there was insufficient evidence to make a recommendation regarding colonoscopy bleeding rate. The working group for this guideline considered that bleeding post-polypectomy was most relevant, and looked for existing guidance on recommended thresholds for post-polypectomy bleeding. Two guidelines were found that recommend a rate of less than 1% after polypectomy (2,9).

The previous PEBC guideline endorsed the US Multi-Society Task Force on Colorectal Cancer's continuous quality-improvement target for perforations of less than 1 per 1000 overall, and less than 1 per 2000 for screening colonoscopies (34). New guidance published since that time includes targets from CAG of <1 in 500 in all patients and <1 in 1000 in screening patients (14), and the UK (9) and Australian guidance (2) both suggest a quality threshold of <1 per 1000 for perforations caused by colonoscopy. The EU review found that perforation rates were 2% with and 0.06% without removal of polyps (8).

Table 9. Safety cut-off found in the review of guidance documents.

	Bleeding rate	Perforation rate
PEBC 2007 (55)	Insufficient data to make a recommendation	Screening: ≤1/2000 Overall: ≤1/1000
CAG (14)	Overall risk for post-polypectomy bleeding should be less than 1%; however, bleeding risk increases with size of polyp and may exceed 10% for polyps larger than 2 cm, particularly in the proximal colon.	<1/500 all patients, <1/1000 screening
European Commission (8)	From literature review: major post-excision haemorrhage in range of 0.2%–2.7%, depending on size of lesion	2% with and 0.06% without excision
National Bowel Cancer Screening Program UK 2011 (9)	<1% post-polypectomy	<1/1000
National Bowel Cancer Screening Program Australia 2009 (2)	<1% post-polypectomy	< 1/1000

PEBC = Program in Evidence-Based Care, CAG = Canadian Association of Gastroenterology

Literature Search Results - Indicators of Colonoscopy Safety

Study characteristics (Table 10)

A systematic review (15) and eight other articles (39,61-67), including a review article (64), and one additional abstract contained outcomes of interest related to the safety of colonoscopy. Two studies reported rates of bleeding after polypectomy (62,66), and in addition, data on this indicator were extracted from three additional studies (68-70) that were part of the United States Preventive Services Task Force's systematic review (15). Bleeding in the absence of polypectomy was not considered an important event; therefore, bleeding rates were only extracted from studies that reported this indicator after polypectomy. Six primary studies (39,61,63,65-67) and the two reviews reported perforation rates (15,64). Two of these studies took place in Canada (39,65), and the rest were conducted in the USA (15,61,66), Europe (62,67), and Israel (63). There was mix of prospective (39,62,67) and retrospective studies (61,63,65,66). As in the studies of colonoscopy quality indicators, a variety of data sources was used, from physician self-reports

(39,63) to large health-information databases (39,71). Indications for colonoscopy varied considerably from one study to the next, and included screening, signs and symptoms, family history, and surveillance. The number of procedures ranged from 1126 (62) to over 1 million procedures from a Medicaid database (61). Due to the heterogeneity of comparison and outcome groups, it was not possible to pool outcomes across studies.

Table 10. Study characteristics, indicators of colonoscopy safety.

Study Year (ref)	Location	Design	Data source	Data collection	Purpose	Reason for colonoscopy; exclusions	Follow-up	# of procedures	Outcomes
Armstrong 2011 (39)	Canada	P	data uploaded by individual endoscopists at 19 Canadian centres	Feb 2008- Jun 2009	Point-of-care audit	Abnormality, screening or surveillance	No	1279 pts	BR, PFR
Arora 2009 (61)	USA	R	Medicaid database fee-for-services claims	Jan 1995 - Jun 2005	Assess risk of perforation and associated factors	Screening, diagnostic or therapeutic	7 d	1,350,157	PFR
Baudet 2009 (62)	Spain	P	5 randomly selected patients/day in clinic	Jan 2005- Dec 2006	Determine minor adverse event rates in outpatient colonoscopy	Signs, symptoms, family hx, polyp control; Excluded: abdominal resection, pregnant, high anaesthesia risk	30 d	1126	BR
Crispin 2009 (67)	Germany	P	Compulsory health insurance members	2006	Estimate incidence of acute complications; identify risk factors	Screening, signs and symptoms, adenoma surveillance, cancer aftercare	No	236,087	BR, PFR
Niv 2011 (63)	Israel	R	Physician self-reports to Health Institutes covered by Israeli insurance company	Jan 2000- Dec 2006	Analyze complications of colonoscopy	Most procedures performed for dx reasons	No	252,064	BR, PFR
Panteris 2009 (64)	NR	Review	Articles in MEDLINE (15 studies included to determine overall	2000-2008	Characterize incidence of perforation and related factors	Screening and other (high-risk included)	NR	491,311	PFR

Study Year (ref)	Location	Design	Data source	Data collection	Purpose	Reason for colonoscopy; exclusions	Follow-up	# of procedures	Outcomes
			perforation rate)						
Rabeneck 2008 (65)	Canada	R	Canadian Institute for Health Information Discharge Abstract Database	Apr 2002-Mar 2003	Determine rates of bleeding, perforation and death associated with outpatient colonoscopy and associated factors	Approximate screening cohort; Excluded: dx of CRC in prior 5 yrs	30 d	97,091	BR, PFR
Rutter 2012 (66)	USA	R	Washington Health Care System	1994-2009	Detailed analysis of risk for usual screening and follow-up colonoscopies	Screening and follow-up after other screening test in prior 6 mon	30d	43,456	BR, PFR
Whitlock 2008 (15)	USA	SR	Articles located through MEDLINE, Cochrane Library, expert suggestions, bibliographic reviews	Current to Jan 2008	Consider community performance of screening endoscopy, including harms	Screening	NR	Perforation:173,391 (13 studies) Bleeding with polypectomy: 31,921 (3 studies) Overall bleeding: 55,461 (12 studies)	BR, PFR

P = prospective, pts = patients, BR = bleeding rate, PFR = perforation rate, R = retrospective, d = days, hx = history, dx = diagnostic, NR = not reported, yrs = years, mon = months, SR = systematic review

Study Outcomes (Table 11)

Bleeding rates after polypectomy (Table 11)

Two studies reported a rate of bleeding after polypectomy of less than 1% (62,66). The study with the higher rate included patients who underwent colonoscopy for reasons other than screening, including signs and symptoms, family history and polyp control (0.94%) (62). In a screening population, the post-polypectomy bleeding rate was 0.50% or 1 in 200 (66). The USPSTF meta-analysis of 12 studies found that major bleeding from colonoscopy occurred in 12 per 10,000 procedures in asymptomatic patients (15); however, this analysis included studies that did not report whether or not polypectomy had been performed. The rates ranged from 0.40% (69) to 0.48% (68) for three studies from this analysis that did report bleeding only for patients who had polyps removed.

Perforation rates (Table 11)

Nine studies located in our review found perforation rates that were generally lower than 1 per 1000. The USPSTF meta-analysis of 13 studies found that perforations occurred at a rate of 0.56 per 1,000 in asymptomatic populations (15).

Table 11. Study outcomes, indicators of colonoscopy safety.

Study	Age (yrs)	% male	Indication	No. of procedures	BR (%) after polypectomy	PFR (%)
Armstrong 2011 (39)	18+	NR	Investigation screening surveillance	1,279	NR by polypectomy	0.078
Arora 2009 (61)	18+; Mean 64.2	36.6	Screening Signs and symptoms	277,434	NR	0.082
Baudet 2009 (62)	50.6	45.5	Signs and symptoms family history polyp control	1,126	During stay in endoscopy unit: 0.94	NR
Crispin 2009 (67)	Med: 61	43.3	Screening signs and symptoms surveillance cancer aftercare	236,087	NR by polypectomy	0.03
Niv 2011 (63)	Mean: 69.9	47	Pts experiencing adverse events: symptoms screening anemia	252,064	NR by polypectomy	0.035
Panteris 2009 (64)	NS	NS	Screening other	491,311	NR	0.07
Rabeneck 2008 (65)	50-75	45	Screening	97,091	NR by polypectomy	Hospitalized within 30 days of procedure: 0.085
Rutter	40-85	49	Screening	43,515 screening	Up to 30 days after	30 days after

Study	Age (yrs)	% male	Indication	No. of procedures	BR (%) after polypectomy	PFR (%)
2012 (66)			follow-up	procedures	procedure: 0.50	procedure: 0.07
Whitlock 2008 (15)	NR	NR	NR	<u>Perforation:</u> 173,391 (13 studies) <u>Bleeding with polypectomy:</u> Nelson 2002 (69) : 3,196 Levin 2006 (68): 16,318 Rathgaber 2006 (70): 12,407 <u>Overall bleeding:</u> 55,461 (12 studies)	Bleeding with polypectomy: Nelson: GI bleeding with hospitalization: 0.40 Levin: 0.48 (includes postbiopsy) Rathgaber: 0.46 Overall "major" BR: .0.12	0.056 (13 study meta-analysis)

CIR = cecal intubation rate, ADR = adenoma detection rate, BR = bleeding rate, PFR = perforation rate, WT = withdrawal time, CRC = colorectal cancer, NR = not reported, yrs = years

DISCUSSION

Over the past decade, quality assurance has become an important topic in endoscopy due to an increased focus on quality in medicine as a whole (72), and studies showing that there can be considerable variation in colonoscopy quality among endoscopists (6). Given the critical role played by colonoscopy in CRC screening (73) (either as a follow-up examination to a positive screening test or as a primary screening tool), it is important to optimize the number of high-quality colonoscopies that are completed in Ontario. Cancer Care Ontario's PEBC originally defined elements that could improve the quality of colonoscopy in the 2007 document *Colonoscopy Standards* (74). At this time, a working group has convened to reassess the state of the evidence base for the chosen indicators, and to ensure the currency of our recommendations, quality indicators and auditable outcomes. This guideline is intended to provide the basis for a quality assurance framework for colonoscopy, regardless of indication, that could incorporate future developments in the province, such as the potential adoption of immunochemical-based fecal occult blood tests.

The working group used three criteria for defining quality indicator targets: evidence that the target is being linked to an important outcome; applicability in the Ontario context; and a preference for moderate targets. When setting moderate targets, working group discussions took into account the potential adverse outcomes or harms that could result from recommendations. For example, when setting a recommended cecal intubation rate, the group considered the potential harms, such as perforation or patient discomfort, associated with an endoscopist attempting to complete a difficult colonoscopy in order to achieve the overall recommended target.

New evidence published since 2007, as well as an expanded scope to include colonoscopies for a greater number of indications, has led to some changes to indicator targets. Also, the current working group has determined through consensus that some new indicators should be included, such as post-colonoscopy colorectal cancer. Various indicators for which there is insufficient evidence in the opinion of the working group to set targets, such as ADR, are still important to monitor. These indicators are labelled auditable outcomes, and in some cases, it is recommended that individual endoscopists should be aware of their

numbers. For the sections on training and competence and institutional guidance, some new guidelines addressing these topics have been published since 2007, and have resulted in modifications to the recommendations according to the consensus of the working group.

Where it has been stated that an indicator be measured at the individual endoscopist level, such as cecal intubation rate, it is important to emphasize that this should be considered guidance for best practice and quality improvement, rather than a standard that must be strictly adhered to without consideration for context. Furthermore, events that rarely occur, and thus are highly variable at the individual endoscopist level, such as perforation rate, should only be measured or monitored at a system-wide level.

The overall goal of this guidance is to raise the level of quality and reduce the variability of performance among endoscopists in Ontario, thereby increasing the effectiveness of colonoscopy and reducing CRC incidence at the population level. A limitation of this document is that we do not provide guidance on how to improve performance of endoscopists or institutions that do not meet targets. Using the data from indicators outlined in this guideline to realize system-wide improvements is a challenge because research has shown that feedback alone does not necessarily improve ADRs among low-performing endoscopists, meaning that additional intensive training may be required in some circumstances (75). Forthcoming colonoscopy-related clinical practice guidance from the PEBC will also help to support the colonoscopy quality agenda in Ontario.

CONCLUSIONS

In conclusion, this guidance document will form the basis for a quality assurance system for colonoscopy in Ontario. It is hoped that this will contribute to consistently higher quality colonoscopy in Ontario, and ultimately lead to a reduction in CRC incidence. This document will be assessed for currency on a yearly basis and updated if necessary to ensure that the evidence base reflects the most recent developments in the field of colonoscopy quality assurance.

CONFLICT OF INTEREST

The conflict of interest details will be completed after the external review process has been completed.

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Appendix 1. Members of the Guideline Development Group

Colonoscopy Quality Assurance Guideline Working Group

- **Dr. Jill Tinmouth**, Chair, Gastroenterologist, Sunnybrook Health Sciences Centre, Toronto, Ontario
- **Dr. David Baron**, Gastroenterologist, North York General Hospital, Toronto, Ontario
- **Dr. Nancy Baxter**, Colorectal Surgeon, St. Michael's Hospital, Toronto, Ontario
- **Mae Burke**, Registered Nurse, St. Michael's Hospital, Toronto, Ontario
- **Dr. Stan Feinberg**, Gastroenterologist, North York General Hospital, Toronto, Ontario
- **Dr. Michael Gould**, Gastroenterologist, Etobicoke, Ontario
- **Erin Kennedy**, Research Coordinator, Program in Evidence-Based Care, McMaster University/Cancer Care Ontario, Hamilton, Ontario
- **Dr. Nancy Lewis**, Senior Analyst (Policy), Prevention and Cancer Control, Cancer Care Ontario, Toronto, Ontario

Colonoscopy Quality Assurance Guideline Expert Panel

- **Dr. David Armstrong**, Gastroenterologist, McMaster University, Division of Gastroenterology, Hamilton, Ontario
- **Dr. Catherine Dube**, Gastroenterologist, University of Calgary, Health Science Centre, Calgary, Alberta
- **Dr. Robert Enns**, Gastroenterologist, St. Paul's Hospital, Vancouver, British Columbia
- **Dr. James Gregor**, Gastroenterologist, London Health Sciences Centre, Victoria Hospital, London, Ontario
- **Dr. Robert Hilsden**, Gastroenterologist, University of Calgary, Gastrointestinal Research Group, Calgary, Alberta
- **Dr. Lawrence Hookey**, Gastroenterologist, Hotel Dieu Hospital, Kingston, Ontario
- **Dr. Hugh Kendall**, General Surgeon, Durham Endosurgery Centre, Ajax, Ontario
- **Dr. Desmond Leddin**, Gastroenterologist, QEII Health Sciences Centre, Halifax, Nova Scotia
- **Dr. Donald MacIntosh**, Gastroenterologist, QEII Health Sciences Centre, Halifax, Nova Scotia
- **Dr. Iain Murray**, Gastroenterologist, Markham, Ontario
- **Dr. Linda Rabeneck**, Vice-President, Prevention and Cancer Control, Cancer Care Ontario, Toronto, Ontario
- **Dr. Harminder Singh**, Gastroenterologist, University of Manitoba, Winnipeg, Manitoba

Colonoscopy Quality Assurance Guideline Targeted Peer Reviewers

- **Dr. Ron Bridges**, Gastroenterologist, University of Calgary, Calgary, Alberta
- **Dr. Daniel Sadowski**, Gastroenterologist, Royal Alexandra Hospital, Edmonton, Alberta
- **Dr. Roland Valori**, Gastroenterologist, Gloucestershire Royal Hospital, Gloucester, Gloucestershire, United Kingdom

Appendix 2. Sources included in the search for existing guidelines.

Databases

Inventory of Cancer Guidelines (SAGE):

<http://www.cancerguidelines.ca/Guidelines/inventory/index.php>

National Guideline Clearing House: <http://www.guideline.gov/>

CMAJ Infobase: http://www.cma.ca/index.php/cj_id/54316/la_id/1.htm

International Guideline Developers:

National Institute for Clinical and Health Excellence

Scottish Intercollegiate Guidelines Network (UK)

American Society for Clinical Oncology (US)

National Comprehensive Cancer Network (US) -(consensus-based)

National Health and Medical Research Council (Aus)

New Zealand Guidelines Group

GI and general surgery associations:

Canadian Task Force on Preventive Health Care

College of Physicians and Surgeons of Ontario

Canadian Association of Gastroenterology

National Committee on Colorectal Cancer Screening

American Academy of Family Physicians

Society of American Gastrointestinal Endoscopic Surgeons

American Society for Gastrointestinal Endoscopy

American Society of Colon and Rectal Surgeons

Joint Advisory Group on Gastrointestinal Endoscopy

Canadian Society of Gastroenterology Nurses and Associates

Joint Commission on the Accreditation of Healthcare Organizations (US)

American Medical Association

Other:

National Quality Forum

American Medical Association Physician Consortium for Quality Improvement

American Gastroenterologic Association

American College of Gastroenterology

Health Care Facilities Accreditation Program (CA)

The VA Hospital system

Society of Gastrointestinal Endoscopic Surgery

United States Food and Drug Administration

Appendix 3. Search terms used in the search of electronic databases.

1. colonoscopy.ti.
2. quality.ti.
3. standards.ti.
4. adverse events.ti.
5. (bleeding or hemorrhage or sedation or training or assessment).ti.
6. bowel preparation.ti.
7. cancer miss rate*.mp.
8. adenoma detection rate*.mp.
9. perforation.ti.
10. withdrawal time.ti.
11. infection control.ti.
12. resuscitation.ti.
13. c?ecal intubation rate.ti.
14. performance measures.ti.
15. competency.ti.
16. polyp detection rate.mp.
17. endoscopy quality.mp.
18. washing.mp. [mp=ti, ab, sh, hw, tn, ot, dm, mf, dv, kw, nm, ps, rs, an, ui]
19. split prep.mp. [mp=ti, ab, sh, hw, tn, ot, dm, mf, dv, kw, nm, ps, rs, an, ui]
20. 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19
21. 1 and 20
22. limit 21 to english language
23. limit 22 to yr="2006 -Current"
24. children.ti.
25. 23 not 24
26. remove duplicates from 25

Appendix 4. AGREE-2 assessment of Quality Assurance Guidelines from other jurisdictions (Ratings are on a scale from 1 (strongly disagree) to 7 (agree)).

Domain	Question	EC	CAG	NHS BCSP
Scope and Purpose	1. The overall objective(s) of the guideline is (are) specifically described	7	7	7
	2. The health question(s) covered by the guideline is (are) specifically described.	7	7	7
	3. The populations (patients, public, etc.) to whom the guideline is meant to apply is specifically described.	7	7	7
	Total	21/21=100%	21/21=100%	21/21=100%
Stakeholder Involvement	1. The views and preferences of the target population (patients, public, etc.) have been sought.	4	7	1
	2. The target users of the guideline are clearly defined.	7	7	7
	Total	11/14=79%	14/14=100%	8/14=57%
Rigour of Development	1. Systematic methods were used to search for evidence	7	7	1
	2. The criteria for selecting the evidence are clearly described.	7	7	1
	3. The strengths and limitations of the body of evidence are clearly described.	7	7	4
	4. The methods for formulating the recommendations are clearly described.	7	7	2
	6. The health benefits, side effects and risks have been considered in formulating the recommendations.	7	7	6
	7. There is an explicit link between the recommendations and the supporting evidence.	7	7	7
	8. The guideline has been externally reviewed by experts prior to its publication.	7	5	1
	9. A procedure for updating the guideline is provided.		1	1
	Total	49/49=100%	48/56=86%	23/56=41%
Clarity of Presentation	1. The recommendations are specific and unambiguous.	7	7	7
	2. The different options for management of the condition or health issue are clearly presented.	7	7	3

	3. Key recommendations are easily identifiable.	7	7	7
	Total	21/21=100%	21/21=100%	17/21=81%
Applicability	1. The guideline describes facilitators and barriers to its application.	7	1	4
	2. The guideline provides advice and/or tools on how the recommendations can be put into practice.	7	3	7
	3. The potential resource implications of applying the recommendations have been considered.	5	2	1
	4. The guideline presents monitoring and/or auditing criteria.	7	7	7
	Total	26/28=93%	13/28=46%	19/28=68%
Editorial Independence	1. The views of the funding body have not influenced the content of the guideline.	7	2	4
	2. Competing interests of guideline development group members have been recorded and addressed.	7	7	1
	Total	14/14=100%	9/14=64%	5/14 = 36%

EC = European Commission, CAG = Canadian Association of Gastroenterology, NHS BCSP = National Health Service (UK) Bowel Cancer Screening Program

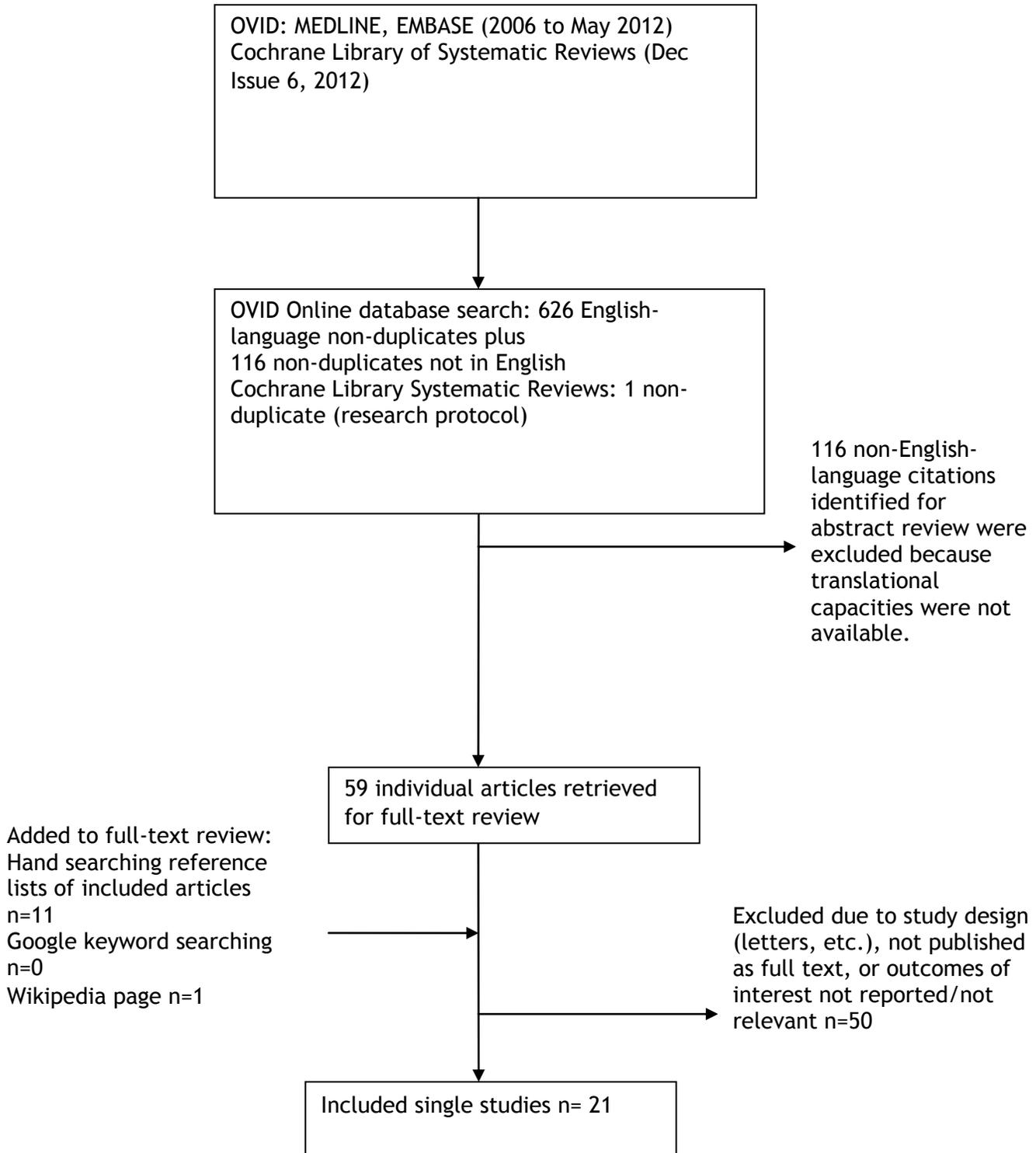
Appendix 5. Guidance located in the targeted search.

Reference	Title	Brief description
Armstrong (2012) (10)	Canadian Association of Gastroenterology consensus guidelines on safety and quality indicators in endoscopy (2012)	Twenty-three recommendation statements related to ethics, facility standards and policies, quality assurance, training, education, competency and privileges, endoscopy reporting standards, and patient perceptions.
Romagnuolo (2008) (14)	Canadian Credentialing Guidelines in Colonoscopy	Consensus based summary of basic requirements for credentialing in colonoscopy in Canada.
European Commission (2010) (8)	European guidelines for quality assurance in colorectal cancer screening and diagnosis.	Standards are provided for quality, safety, and patient feedback before and during the procedure.
Faigel, American Society for Gastrointestinal Endoscopy (2007) (16)	Ensuring Competence in Endoscopy	A guide to competence and privileging for gastrointestinal endoscopy for hospitals, credentialing organizations, insurers, and healthcare providers.
Conjoint Committee* (no date) (18)	Conjoint Committee for the Recognition of Training in Gastrointestinal Endoscopy. Information for Registrants	Training requirements for certification in endoscopy, including colonoscopy.
Dominitz (2008) (19)	Renewal of and proctoring for endoscopic privileges (ASGE 2008)	
Lieberman (2007) (31)	Standardized colonoscopy reporting and data system: report of the Quality Assurance Task Group of the National Colorectal Cancer Roundtable	An outline for a standardized colonoscopy reporting and data system. To develop this document, the Quality Assurance Task Group of the National Colorectal Cancer Roundtable used the quality indicators recommended by the Multi-Society Task Force on Colorectal Cancer (55). Includes some quality cut-offs that have appeared previously in the literature. Continuous quality improvement targets are provided for: pre-endoscopy examination: patient demographics and history (n=3), assessment of patient risk and comorbidity (n=1), procedure indications (n=5), procedure: technical indications (n=5), colonoscopic findings (n=2), assessment of procedure results (see pathology), interventions/unplanned events (n=3), follow-up plan (n=1), pathology (n=1).
National Bowel Cancer Screening Program Quality Working Group (2009) (2)	Improving Colonoscopy Services in Australia	Proposes policy development in four streams: 1. The colonoscopy procedure, 2. Colonoscopy facilities and equipment, 3. Documentation and reported, and 4. Skills, training, certification and credentialing. Standards are provided for the pre-

		procedure phase (assessment of patient indications and risk, patient consent, quality of bowel preparation), the procedure phase (proficiency of proceduralist, and minimization of complications).
Society of Gastrointestinal and Endoscopic Surgeons (US) (2010) (76)	Granting of Privileges for Gastrointestinal Endoscopy	Another consensus-based guideline notes that improving the overall impact of screening colonoscopy requires a programmatic approach that addresses quality issues at several levels. The recommended quality indicators include: <ul style="list-style-type: none"> ○ Cecal intubation rates ○ Withdrawal time ○ Adenoma detection rates ○ Appropriate intervals between endoscopic studies based on family and personal history and number and histological type of polyps on last colonoscopy ○ Minor and major complication rates ○ Pre-procedure medical evaluation ○ Appropriate prep instructions.
National Health Service Bowel Cancer Screening Program (2011)	Quality Assurance Guidelines for Colonoscopy	Quality assurance guidance including quality indicators, standards and auditable outcomes for minimum volumes, bowel preparation, acceptance of colonoscopy and attendance, consent, sedation, CIR, neoplasia detection, withdrawal time, polyp recovery and harms including perforation, bleeding and other adverse events.
Valori (2007) (53)	Joint Advisory Group on GI Endoscopy - British Society of Gastroenterology (BSG) Quality and Safety Indicators for Endoscopy:	The BSG Endoscopy Committee developed indicators, which underpin the respective indicators of the GRS. Specifically quality indicators are provided for colonoscopy and flexible sigmoidoscopy, but guideline may be superseded by the NHS Quality Assurance Guidelines for Colonoscopy.
Whitlock (2008) (15)	Screening for colorectal cancer: a targeted, updated systematic review for the U.S. Preventive Services Task Force	Clinical practice guideline with relevant information and meta-analysis on complication rates.

*Royal Australasian College of Surgeons, Gastroenterological Society of Australia, The Royal Australian College of Physicians and Surgeons

Appendix 6. Literature search results flow diagram.



**A Quality Initiative of the
Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO)**

**Guideline for Colonoscopy Quality Assurance in Ontario:
EBS Development Methods and External Review Process**

*J. Tinmouth, E. Kennedy, D. Baron, M. Burke, S. Feinberg, M. Gould, N. Baxter, N. Lewis,
and the Colonoscopy Quality Assurance Guideline Expert Panel*

**Original Report Date: October 9, 2007
Current Report Date: September 9, 2013**

THE PROGRAM IN EVIDENCE-BASED CARE

The Program in Evidence-based Care (PEBC) is an initiative of the Ontario provincial cancer system, Cancer Care Ontario (CCO). The PEBC mandate is to improve the lives of Ontarians affected by cancer through the development, dissemination, and evaluation of evidence-based products designed to facilitate clinical, planning, and policy decisions about cancer care.

The PEBC supports a network of disease-specific panels, termed Disease Site Groups (DSGs), as well as other groups or panels called together for a specific topic, all mandated to develop the PEBC products. These panels are comprised of clinicians, other health care providers and decision makers, methodologists, and community representatives from across the province.

The PEBC produces evidence-based and evidence-informed guidelines, known as Evidence-Based Series (EBS) reports, using the methods of the Practice Guidelines Development Cycle (1,2). The EBS report consists of an evidentiary base (typically a systematic review), an interpretation of and consensus agreement on that evidence by our Groups or Panels, the resulting recommendations, and an external review by Ontario clinicians and other stakeholders in the province for whom the topic is relevant. The PEBC has a formal standardized process to ensure the currency of each document, through the periodic review and evaluation of the scientific literature and, where appropriate, the integration of that literature with the original guideline information.

This EBS is comprised of the following sections:

- *Section 1: Guideline Recommendations.* Contains the clinical recommendations derived from a systematic review of the clinical and scientific literature and its interpretation by the Group or Panel involved and a formalized external review in Ontario by review participants.
- *Section 2: Evidentiary Base.* Presents the comprehensive evidentiary/systematic review of the clinical and scientific research on the topic and the conclusions reached by the Group or Panel.
- *Section 3: Development Methods, Recommendations Development, and External Review Process.* Summarizes the EBS development process, the recommendations

development process and the results of the formal external review of the draft version of the EBS.

DEVELOPMENT OF THIS EVIDENCE-BASED SERIES

Development and Internal Review

This EBS was developed by the Colonoscopy Quality Assurance Guideline Working Group of the CCO PEBC. The series is a convenient and up-to-date source of the best available evidence on quality assurance for colonoscopy in Ontario developed through review of the evidentiary base, evidence synthesis, and input from external review participants in Ontario.

Report Approval Panel Review and Approval

Prior to the submission of this EBS draft report for External Review, the report was reviewed and approved by the PEBC Report Approval Panel (RAP), a panel that includes oncologists and whose members have clinical and methodological expertise. Key issues raised by the RAP are outline below, along with working group responses:

1. More explanation was requested regarding why the threshold for training of a minimum of 300 colonoscopies was chosen; an RAP reviewer thought that this threshold was high, given the lack of evidence for this indicator.
 - *More explanation was added to the key evidence, including a statement that minimum volumes cited in the past had been shown to be inadequate to define competence. We also stressed that determination of the attainment of competency should be measured with objective criteria such as CIR, rather than being based solely on training volumes completed.*
2. Include how auditable outcomes or other data could or should be used. Will these data be collected prospectively in Ontario to assess patterns of practice? More explanation would strengthen the document.
 - *The following sentence was added to clarify the goals of a quality improvement program: "A quality improvement program should document the requirement then monitor the perceived critical elements and lastly, institute changes that will lead to demonstrated improvements upon reassessment." The working group acknowledged in discussions that quality assurance has become increasingly important in colonoscopy. This document provides a list of indicators that can be used to underpin a quality assurance program in Ontario. Further direction on how these indicators should be used was considered by the working group to be beyond the scope of this guideline.*
3. Include a chart with QI and AO indicators listed at beginning of these sections for clarity.
 - *A list was added at the beginning of this section to address this suggestion.*
4. Be clear that this document does not address all colonoscopies - just cancer-related indications.
 - *As all colonoscopies in Ontario will eventually fall under the same reporting and quality assurance program, this document is meant to apply to all colonoscopies in Ontario including cancer and non-cancer-related cases.*
5. An RAP member asked why there were not more surgeons, a Director of an endoscopy unit, and a GI or surgical trainee involved.
 - *The document will be sent to these professionals as part of the Professional Consultation component of External Review. Their comments will be reviewed and incorporated into the final document.*
6. An RAP reviewer asked about classification of studies as quality indicator studies.

- *The working group did not specifically designate studies as quality indicator studies. Studies eligible for inclusion were those that contained the outcomes of interest and met the criteria outlined in the methods section. The designation of quality indicators was a label used to describe recommendations for which the working group agreed that a target level could be specified.*
7. What is the value of sedation? (question from quality of sedation section).
- *The value of the sedation indicator was not assessed for this version of the guidelines, as indicators for this version were adopted from the previous version of the guideline.*

Expert Panel Review and Approval of the Draft Guideline

The Expert Panel comprised 11 members of CCO's Colonoscopy Expert Panel (Appendix 1). Not including relatively minor formatting or wording changes, their substantive comments are outlined below, along with the working group's responses.

Consistency/definitions of terms

1. Check for consistent use of the terms screening and surveillance;
2. Define clinically significant bleeding.
 - *These terms were checked and defined as post-polypectomy bleeding leading to hospital admission.*

Using a range of values for recommendations

1. Use actual values rather than ranges in recommendations. This would apply to the recommendation that trainees achieve a CIR of 85%-90% (it should just state 85% as the requirement), and the recommendation that experience be gained over a period of at least 6 to 12 months.
 - *This recommendation was modified to read "at least 85%." The time period for gaining experience was also modified.*

Context for the recommendations:

1. Include details on how these recommendations can be included as part of a comprehensive quality assurance program, details on how the data collected for these indicators will be used and a mechanism for addressing non-compliance with CIR.
 - *As stated above under response to RAP feedback, this document provides a list of indicators that can be used to underpin a quality assurance program in Ontario. Further direction on how these indicators should be used was considered by the working group to be beyond the scope of this guideline.*

Suggested additions:

1. All patients receiving IV access have continuous IV access, preferably through a flexible plastic cannula.
 - *This is a clinical practice recommendation; therefore, it was considered outside of the scope of the guideline.*
2. Specific scales for measuring level of consciousness and degree of discomfort.
 - *The suggestion for specific scales for measuring these indicators was not adopted; however, the recommendation was made for individual endoscopy units to monitor these indicators using a system of their choice.*
3. Time period for no driving after procedure.
 - *A specific, consistent time period for avoiding driving after colonoscopy was not evaluated as part of the systematic review for this project; therefore, a specific*

time period was outside of the scope of these recommendations. In response to this comment, that working group added that each endoscopy unit should reinforce its specific recommendations for driving, as agreed to by the patient during the consent process.

4. Include a target for the ADR.
 - *The working group extensively discussed the potential inclusion of a target for the ADR and concluded that the evidence is not consistent enough to determine an appropriate target for Ontario at this time. As data for this indicator accumulates, it may be possible in the future to specify a target.*
5. Removal of the ADR as a quality indicator should be accompanied by a discussion of withdrawal technique.
 - *The working group acknowledges the contribution of withdrawal technique to overall colonoscopy quality; however, a discussion of colonoscopy technique is a clinical practice topic that is beyond the scope of this guideline.*
6. Retain withdrawal time as an at least auditable measure.
 - *The working group extensively discussed the inclusion of withdrawal time as an auditable measure or quality indicator. Although a link with other indicators has been found, the working group believed that this indicator was susceptible to manipulation, and also not a true measure of withdrawal technique, which in the opinion of the group, was the more important determinant of colonoscopy quality. Therefore, the group chose not to include withdrawal time as an indicator to be measured in this version of the guideline.*
7. Add monitoring of patient comfort/satisfaction under quality indicators.
 - *The working group considered this suggestion and decided to add a statement in the institutional recommendations section that sedation and comfort should be documented at the endoscopy unit level using a system of the unit's choice. At this time, the working group chooses not to add these indicators to the list of quality indicators to be monitored at the population level.*
8. A reference to discharging by self or with accompaniment.
 - *The working group discussed the inclusion of a reference to discharging with accompaniment, and concluded that because it is not always possible for a patient to have accompaniment, e.g., by a family member, that this would not be included in the recommendations.*

Suggested modifications:

1. A >90% threshold for attainment of competency for new endoscopists, 85% is too low.
 - *The working group agreed that an 85% CIR threshold would be acceptable for new endoscopists, provided that the higher CIR specified in the following recommendations was adhered to as endoscopists continued into independent practice.*
2. Adjusted CIRs are open to bias and are meaningless...Unadjusted or intention-to-treat CIRs are much more likely to be “real.” Suggest using unadjusted CIR.
 - *The recommendation for an adjusted CIR was agreed upon after extensive working group discussions. The working group agrees that adjusted CIRs are more difficult to capture, although this may become easier in the future. The guideline notes that an adjusted rate of 95% is considered to be consistent with an unadjusted CIR of 90%.*
3. Section on institutional recommendations is lacking in detail. It would be preferable to reference the CPSO document on out-of-hospital requirements in its entirety.

- *The working group recognizes important of the CPSO standards for out-of-hospital premises, but did not agree that a reference to these standards would be adequate, because these PEBC guidelines are meant to address colonoscopies that are performed both within and outside of hospital premises.*
5. Delete “where possible” from requirement for photographic evidence.
 - *This qualifier has been deleted.*
 6. It is not clear why duration of training for non-GIs of 6 to 12 months is considered to be adequate. Suggest keeping this uniform for all physicians - minimum of 2 years and qualifying statement about surgical trainees.
 - *The statement that training could take place in as little as 6 months was meant to apply to surgical trainees, who would continue to gain subsequent longitudinal experience throughout their surgical training; therefore, the related qualifying statement was removed and surgical residents were added to main recommendation.*

External Review by Ontario Clinicians and Other Experts

The PEBC external review process is two-pronged and includes a targeted peer review that is intended to obtain direct feedback on the draft report from a small number of specified content experts and a professional consultation that is intended to facilitate dissemination of the final guidance report to Ontario practitioners.

Following approval of the document at Internal Review, the Expert Panel circulated the draft document with recommendations modified as noted under Internal Review, above, to external review participants for review and feedback.

Methods

Targeted Peer Review: During the guideline development process, five targeted peer reviewers considered to be clinical and/or methodological experts on the topic were identified by the Working Group. Several weeks prior to completion of the draft report, the nominees were contacted by email and asked to serve as reviewers. Three reviewers agreed, and the draft report and a questionnaire were sent via email for their review. The questionnaire consisted of items evaluating the methods, results, and interpretive summary used to inform the draft recommendations and whether the draft recommendations should be approved as a guideline. Written comments were invited. The questionnaire and draft document were sent out on March 14, 2013. Follow-up reminders were sent at two weeks (email) and at four weeks (telephone call). The Working Group reviewed the results of the survey.

Professional Consultation: Feedback was obtained through a brief online survey of health care professionals who are the intended users of the guideline. All physicians with interests in gastric (stomach) or gastrointestinal cancers in the PEBC database were contacted by email to inform them of the survey. Participants were from Ontario, Manitoba and Quebec. Participants were asked to rate the overall quality of the guideline (Section 1) and whether they would use and/or recommend it. Written comments were invited. Participants were contacted by email and directed to the survey website where they were provided with access to the survey, the guideline recommendations (Section 1) and the evidentiary base (Section 2). The notification email was sent on March 18, 2013. The consultation period ended on April 29, 2013. The Working Group reviewed the results of the survey.

Results

Targeted Peer Review: Three responses were received from three reviewers. Key results of the feedback survey are summarized in Table 1.

Table 1. Responses to nine items on the targeted peer reviewer questionnaire.

Question	Reviewer Ratings (N=3)				
	Lowest Quality (1)	(2)	(3)	(4)	Highest Quality (5)
1. Rate the guideline development methods.	0	0	0	3	0
2. Rate the guideline presentation.	0	0	1	1	1
3. Rate the guideline recommendations.	0	1	0	2	0
4. Rate the completeness of reporting.	0	0	0	3	0
5. Does this document provide sufficient information to inform your decisions? If not, what areas are missing?	0	0	1	2	0
6. Rate the overall quality of the guideline report.	0	0	1	2	0
	Strongly Disagree (1)	(2)	Neutral (3)	(4)	Strongly Agree (5)
7. I would make use of this guideline in my professional decisions.	0	1	1	1	0
8. I would recommend this guideline for use in practice.	0	0	1	2	0

9. What are the barriers or enablers to the implementation of this guideline report?

Some of the targeted peer reviewers believed this guideline would be difficult to implement without incentives for physicians to participate in a quality assurance program. They felt that this guideline needs professional endorsement from both medical and surgical stakeholders and that appropriate information technology systems are needed to evaluate and audit the guideline. Also, training for physicians needs to be available, especially when targets are not being met.

Table 2. Summary of written comments by targeted peer reviewers and modifications/actions taken.

Summary of Written Comments	Modifications/Actions/Comments
1. Some of the guideline recommendations seem to be more focused on what is easier/more convenient for the physician or unit, rather than what is best for the patient. Examples of this include the differential training standards for GI and Surgery (completion of training should be competency based at a specific standard in all cases), the lack of a recommendation for adenoma detection rate target at the physician level and the decision not to make a recommendation about scope withdrawal time as a quality measure. There was an opportunity for the guideline to take a greater leadership role in setting standards in these	The Working Group wanted to emphasize that attainment of competency is paramount. Therefore, the Working Group added that completing the recommended training period does not ensure competence in colonoscopy. The Working Group believed that the training periods, volumes, etc. are intended as guides for what is, on average, required to attain the competency. Differences between general surgeons and GIs reflect the realities in the two training programs and are in line with Canadian Association of Gastroenterology recommendations.

areas, recognizing that future evidence may result in changes to the recommendations.	
2. The process did not consider a growing body of evidence on the assessment of patient comfort during the procedure and did not consider the role of the use of patient and staff satisfaction surveys to inform recommendations and standards related to patient care. There is evidence that these are important considerations in setting and managing quality measures related to patient care.	Although the Working Group did not include patient discomfort as a specific outcome in their systematic review, they did take this into consideration when developing other recommendations (e.g., sedation).
3. The literature review and training recommendations focus solely on cecal intubation rates. It should be noted that getting to the cecum in a high proportion of cases is only half of quality colonoscopy. Trainees should develop an appreciation for quality indicators in the withdrawal phase of the colonoscopy during their training period.	The Working Group did discuss proficiency in the cognitive aspects of colonoscopy and polypectomy and, in response to this comment, also added in the qualifying statement that proficiency in the cognitive aspects of colonoscopy is required in order to attain competence.
4. The evidence that sedation actually improves adenoma detection rate is unconvincing. Whether the patient receives or does not receive sedation is probably not a true quality indicator. Should a quality indicator not focus on modifiable outcomes such as safe sedation practice? Some examples: measurement of the rate of significant O2 desaturations, requirements for airway support, rate of use of reversal agents? As well, the document makes no provision for the assessment of patient comfort during the procedure.	The recommendation is that all patients be offered sedation, as sedation does improve patient-related outcomes. There is no claim that sedation improves ADR in the document. The Working Group felt that it was important to endorse a framework for safe sedation practices (hence, guidelines around monitoring) but that it was out of scope (as this was an update of earlier guideline) to set specific indicators (such as rate of desaturations, etc.) for sedation. Also, the assessment of patient discomfort is endorsed.
5. There is a rather weak recommendation on page 10 that ‘Documentation of sedation and patient comfort should be done at the level of the endoscopy unit, using a system of the unit’s choice.’ This recommendation comes under the heading ‘institutional recommendations’ whereas it is clearly a reflection of an individual’s practice and performance. Thus sedation and comfort should be auditable outcomes for individual colonoscopists.	The Working Group believed that it was important to measure the sedation and comfort level. It was believed to be most feasible to measure sedation and patient comfort at the endoscopy unit level but that these units were responsible for auditing their physicians. The Working Group modified the recommendation to “The endoscopy unit should have a formal process to document sedation and patient comfort using a system of the unit’s choice. The unit should audit its individual physicians’ use of sedation.”
6. “Endoscopists should monitor their individual ADRs.” While this is current dogma, it is not practical for an individual physician to arduously link pathology and endoscopy databases. Perhaps the statement should indicate that it is the responsibility of the endoscopy unit or CRC screening program to monitor the ADRs of their individual scoping physicians.	The Working Group clarified the key evidence section in response to this comment to “The wide variation reported likely reflects important differences in the populations studied. As such, these studies are not readily generalizable to the Ontario context. Therefore, the working group determined that there was insufficient evidence to make a specific target recommendation at this time for this indicator. As auditing of this indicator in the Ontario population continues and reporting improves, it is advised that

	future study be undertaken to determine an appropriate target.”
7. The auditable outcome statement is vague. What is meant by adequate bowel preparation? The recommendation should also specify who is doing the rating and at what point in the procedure (before or after adequate washing). Whose responsibility is poor bowel prep? Is it the endoscopist, the endoscopy unit, or the colon cancer-screening program?	The Working Group modified the recommendation to “Endoscopists should strive for adequate bowel preparation, and quality of bowel preparation should be recorded and monitored using a standardized scale of the endoscopy unit’s choice. Users of the scale should be trained on the use of the scale to ensure it is consistently applied.”
8. Whose responsibility is it to carry out the arduous and time-consuming work of tracking post-colonoscopy colorectal cancer? To whom should the results be reported and who is responsible to act upon the results of this outcome?	The recommendations indicate that this is to be monitored at the provincial level or facility level. The intent of this statement is to ensure that it is not tracked at the individual physician level.
9. It is unclear why simply setting a rate of expected post-polypectomy bleeding of less than 1 per 100 colonoscopies is useful. Quality indicators should be actionable. A more useful quality indicator would be to indicate the expectation that a review of each case of significant bleeding will be carried out to determine if reversible factors were present in the case: example inadequate reversal of anticoagulation, inadequate reversal of antiplatelet agents, inadequate hemostatic techniques during the polypectomy itself (e.g., adrenaline injection, use of ligatures).	The Working Group believed the proposal to review every case is not currently feasible in Ontario. Using this target would allow identification of outliers who warrant more in-depth review.
10. It is unclear why setting an expected rate is useful. Every colonoscopy perforation event should be reviewed to determine if reversible factors were present.	The Working Group believed that there is no mechanism to review each event centrally and as patients may be admitted to another hospital, neither the endoscopic unit nor the physician may be aware of the complication; therefore, individual cases cannot be reviewed systematically. The Working Group modified this recommendation to “As perforation is a rare event, perforation rates should be tracked at the facility and/or system-wide level. Estimates at the individual endoscopist level are likely to be unstable.”
11. It is uncertain who will monitor the individual endoscopist’s recommendations for screening intervals. In fact, is the issuing of screening intervals really the purview of the colonoscopist? At the time of completing the operative report, the pathology is often not available. Should the colon cancer-screening program more accurately do recommendations for follow-up?	The colon cancer-screening program does not have histology data, only the endoscopist does. Therefore, at present, screening interval recommendations must be the purview of the endoscopist.
12. I strongly recommend including another measure of surveillance quality and that is pathology found at the next examination, particularly advanced adenoma and cancer. Of course this may be covered in the PCCRC rate indicator but surveillance cohorts offer unified case mix and early creation of a standard.	The Working Group believed the intention of the interval indicator was to monitor colonoscopy overuse. Rates of advanced adenoma/cancer at next colonoscopy addresses the quality of the index colonoscopy and are arguably addressed by the PCCRC indicator.

13. On pages 30/31, the Korean study showed high cecal intubation rates after relatively few cases. It is generally accepted that the Oriental colon is different from the Caucasian colon. Thus, this study is not applicable to the Ontario context (a key criterion of the guideline).	The Working Group believed it was appropriate to include this article in the evidence base and to consider it in the evidence review. However, the recommendation is clearly not solely driven by this study (the target was set at 300 colonoscopes per year).
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Professional Consultation: Twenty-one responses were received. Key results of the feedback survey are summarized in Table 3.

Table 3. Responses to four items on the professional consultation survey.

General Questions: Overall Guideline Assessment	Number (%)				
	Lowest Quality (1)	(2)	(3)	(4)	Highest Quality (5)
1. Rate the overall quality of the guideline report.	0	0	1 (5%)	13 (62%)	7 (33%)
	Strongly Disagree (1)	(2)	(3)	(4)	Strongly Agree (5)
2. I would make use of this guideline in my professional decisions.	0	0	4 (19%)	9 (43%)	8 (38%)
3. I would recommend this guideline for use in practice.	0	0	3 (14%)	9 (43%)	9 (43%)

4. **What are the barriers or enablers to the implementation of this guideline report?**
 The professional consultants had the same concerns as the targeted peer reviewers. They also believed that smaller hospitals or remote locations may have difficulty in maintaining target numbers. Also, the recommendations for pathology reporting may be difficult to enforce and monitor. As well, there may be lack of anesthesiologists, RPNs, or respiratory technologists to implement these guidelines.

Table 4. Summary of written comments by professional consultants and modifications/actions taken.

<i>Summary of Written Comments</i>	<i>Modifications/Actions/Comments</i>
1. We use a modified surgical checklist for all endoscopies. This should be included in guidelines.	The Working Group did not include a modified surgical checklist because of the lack of data on the use of surgical checklists on patient outcomes for endoscopic procedures.
2. Section 1, pg 8: Reports to family physician (Suggest to reword: to referring physician and family physician. also add a statement similar to: ..."and recommendations regarding the need for follow-up colonoscopy, the time interval and who is responsible to arrange this, if indicated".	The Working Group added 'referring and' family physician as well as "Where possible, instructions for arranging follow-up colonoscopy should be provided." They did not add who would be responsible because it might be too prescriptive. It is not the responsibility of the endoscopist to decide who will arrange follow-up.
3. Not everyone has automated endoscope reprocessing	The Working Group changed the wording by separating the recommendation to use

<p>(AER) and it's not clear that manual disinfection, if done correctly, is not adequate. We have seen sites using AER's that have inadequate cleaning technique. So it's not the AER as so much as the proper cleaning and disinfection process.</p>	<p>AERs from the recommendation for proper cleaning technique. Like any other cleaning method, appropriate use of AERs is recommended to achieve proper cleaning. However, AERs are recommended for reasons other than proper cleaning: for the safety of patients, personnel and equipment.</p>
<p>4. There needs to be stronger language with regards to the generation of colonoscope that is appropriate. There is evidence that recent-generation colonoscopes have higher ADR. Some video scopes are 25 years old. CCO should use explicit language regarding the age of colonoscope or actual model numbers.</p>	<p>The Working Group modified the recommendation to "All colonoscopies should be performed using a video colonoscope that can be maintained within manufacturers' specifications."</p>
<p>5. I didn't quite understand why bleeding in the absence of polypectomy, but with colonoscopy, is not considered clinically significant.</p>	<p>The Working Group chose this approach, as polypectomy is most common cause of bleeding. The quoted rate is based on evidence reporting the rate of bleeding in the setting of polypectomy.</p>

Conclusion

This EBS report reflects the integration of feedback obtained through the external review process with final approval given by the Expert Panel and the Report Approval Panel of the PEBC. Updates of the report will be conducted in accordance with the PEBC Document Assessment and Review Protocol.

Conflict of Interest

In accordance with the PEBC Conflict of Interest (COI) Policy, the guideline authors, the Expert Panel members, and internal and external reviewers were asked to disclose potential conflicts of interest.

For the Working Group members, Dr. M. Gould is the medical director, consultant and partner of the Vaughan Endoscopy Clinic. He also does clinical research for the Toronto Digestive Disease Association and is the clinical lead for the ColonCancerCheck Program at Cancer Care Ontario.

For the Expert Panel, four members declared they had no conflicts of interest, and eight declared conflicts. Dr. I. Murray worked in an out-of-hospital endoscopy clinic and is the owner of a relevant business called the Intestinal Health Institute, which is an out-of hospital endoscopy clinic. Dr. D. Armstrong also owns a relevant business called the David Armstrong Medicine Professional Corporation and his professional earnings accrue to his corporation. He also states that it is possible that a significant change in quality requirements or in recommendations regarding the location of service delivery might reduce or increase his access to colonoscopy, thereby affecting his income. He is also the lead author on quality and safety guidelines for endoscopy (3). Dr. R. Enns is on an advisory board for Olympus and Cook. Dr. L. Hookey has received equipment from Olympus. Dr. C. Dube has received a grant from 2007 to 2011 from the Canadian Association of Gastroenterology and Olympus. She has published articles on the object of this guideline (4,5). Dr. D. Leddin has also published an article on this topic (6). Dr. H. Kendall owns the Durham Endosurgery Clinic that is worth more than \$10,000. He has been involved in the creation of the CPSO OHP standard document. Dr. R. Hilsden was a member of the Canadian Association of Gastroenterology consensus working group on colonoscopy quality.

For the External Reviewers, three members declared they had conflicts of interest. Dr. R. Bridges stated he was the medical lead for the development and implementation of the Forzani and MacPhail Colon Cancer Screening Centre in Calgary. The details of the quality assurance program have been previously published (7). Dr. D. Sadowski wrote a position paper on colonoscopy quality indicators for Alberta Health in 2012. He also worked for the Alberta Colorectal Screening Program as the quality lead. Dr. R. Valori is the co-director of a limited liability partnership registered in the United Kingdom. It is a consultancy that provides strategic and operational advice and training to endoscopy and other medical devices, within and outside the United Kingdom.

The COI declared above did not disqualify any individuals from performing their designated role in the development of this guideline, in accordance with the PEBC COI Policy. To obtain a copy of the policy, please contact the PEBC office by email at ccopgi@mcmaster.ca.

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