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Evidence-Based Series #15-5 Version 2 REQUIRES UPDATING

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

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

An assessment conducted in January 2019 indicated that Evidence-based Series (EBS) 15-5 Version 2 REQUIRES UPDATING. It is still appropriate for this document to be available while this updating process unfolds. The PEBC has a formal and standardized process to ensure the currency of each document (PEBC Assessment & Review Protocol)

EBS 15-5 Version 2 is comprised of three sections. You can access the summary and full report here:
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Section 1:	**Recommendations**
Section 2:	**Evidentiary Base**
Section 3:	**EBS Development Methods and External Review Process**

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Evidence-Based Series #15-5 Version 2

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Guideline for Colonoscopy Quality Assurance in Ontario

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.
Version 2 2013	2006-2012	New data added to original Full Report	Updated web publication.	N.A.

Evidence-Based Series #15-5 Version 2: Section 1

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

Guideline for Colonoscopy Quality Assurance in Ontario: Guideline Recommendations

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 Table of Contents

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 ≥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 ≥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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REFERENCES

1. 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.
2. European Commission. European guidelines for quality assurance in colorectal cancer screening and diagnosis. 2010.
3. National Health Service Bowel Cancer Screening Program. Quality Assurance Guidelines for Colonoscopy. 2011.
4. Armstrong D, Enns R, Ponich T, Romagnuolo J, Springer J, Barkun AN. Canadian credentialing guidelines for endoscopic privileges: an overview. Can J Gastroenterol. 2007 Dec;21(12):797-801.
5. Rex DK, Petrini JL, Baron TH, Chak A, Cohen J, Deal SE, et al. Quality indicators for colonoscopy. Am J Gastroenterol. 2006 April;101(4):873-85.
6. Sedlack RE. Training to competency in colonoscopy: Assessing and defining competency standards. Gastrointest Endosc. 2011 August;74(2):355-66+66.e1-66.e2.
7. Spier BJ, Benson M, Pfau PR, Nelligan G, Lucey MR, Gaumnitz EA. Colonoscopy training in gastroenterology fellowships: determining competence. Gastrointest Endosc. 2010 February;71(2):319-24.
8. Faigel DO, Baron TH, Lewis B, Petersen B, Petrini J, et al. Ensuring competence in endoscopy. ASGE Press; 2006. Available from: http://www.asge.org/WorkArea/showcontent.aspx?id=3384.
9. MacKen E, Moreels T, Vannoote J, Siersema PD, Van Cutsem E. Quality assurance in colonoscopy for colorectal cancer diagnosis. Eur J Surg Oncol. 2011 January;37(1):10-5.
10. College of Physicians and Surgeons of Ontario. Expectations of physicians who have changed or plan to change their scope of practice to include endo-colonoscopy.
11. Dominitz JA, Ikenberry SO, Anderson MA, Banerjee S, Baron TH, Cash BD, et al. Renewal of and proctoring for endoscopic privileges. Gastrointest Endosc. 2008 Jan;67(1):10-6.
12. Baxter NN, Sutradhar R, Forbes SS, Paszat LF, Saskin R, Rabeneck L. Analysis of administrative data finds endoscopist quality measures associated with postcolonoscopy colorectal cancer. Gastroenterology. 2011 Jan;140(1):65-72.
13. Rabeneck L, Paszat LF, Hilsden RJ, Saskin R, Leddin D, Grunfeld E, et al. Bleeding and perforation after outpatient colonoscopy and their risk factors in usual clinical practice. Gastroenterology. 2008 December;135(6):1899-906.e1.
14. Lieberman D, Nadel M, Smith RA, Atkin W, Duggirala SB, Fletcher R, et al. Standardized colonoscopy reporting and data system: report of the Quality Assurance Task Group of the National Colorectal Cancer Roundtable. Gastrointest Endosc. 2007 May;65(6):757-66.
15. U.S. Food and Drug Administration and Centers for Disease Control and Prevention and Department of Veterans Affairs, Preventing Cross-Contamination in Endoscope Processing. 2009. Available from: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm190273.htm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=endoscope&utm_content=1.
16. College of Physicians and Surgeons of Ontario. Independent Health Facilities Clinical Practice Parameters and Facility Standards for Endoscopy. 2006.
17. College of Physicians and Surgeons of Ontario. Guide to Applying the Out-of-Hospital Standards in Endoscopy/Colonoscopy Premises. November 2011.

18. American Society of Gastrointestinal Endoscopists. Automated endoscope reprocessors. Gastrointest Endosc. 2009;69(4):771-76.
19. Beilenhoff U, Neumann CS, Rey JF, Biering H, Blum R, Cimbro M, et al. ESGE-ESGENA Guideline: cleaning and disinfection in gastrointestinal endoscopy. Endoscopy. 2008;40:939-57.
20. Aldrete JA. The post-anesthesia recovery score revisited. J Clin Anesth. 1995 Feb;7(1):89-91.
21. Armstrong D, Hollingworth R, Macintosh DG, Cabrera J, Chen Y, Daniels S, et al. Quality indicators for colonoscopy in Canada: The Canadian association of gastroenterology (cag) endoscopy quality initiative (EQI) practice audit project. Gastroenterology. 2009 May;1):A332.
22. Romagnuolo J, Enns R, Ponich T, Springer J, Armstrong D, Barkun AN. Canadian credentialing guidelines for colonoscopy. Can J Gastroenterol. 2008;22:17–22.
23. Armstrong D, Hollingworth R, Macintosh D, Chen Y, Daniels S, Gittens S, et al. Point-of-care, peer-comparator colonoscopy practice audit: The Canadian Association of Gastroenterology Quality Program--Endoscopy. Can J Gastroenterol. 2011 Jan;25(1):13-20.
24. Millan MS, Gross P, Manilich E, Church JM. Adenoma detection rate: The real indicator of quality in colonoscopy. Dis Colon Rectum. 2008 August;51(8):1217-20.
25. Sheridan TB, Fenton H, Lewin MR, Burkart AL, Iacobuzio-Donahue CA, Frankel WL, et al. Sessile serrated adenomas with low- and high-grade dysplasia and early carcinomas: An immunohistochemical study of serrated lesions “Caught in the Act”. Am J Clin Pathol. 2006 October 1, 2006;126(4):564-71.
26. Kaminski MF, Regula J, Kraszewska E, Polkowski M, Wojciechowska U, Didkowska J, et al. Quality indicators for colonoscopy and the risk of interval cancer. New Engl J Med. 2010 13 May;362(19):1795-803.
27. Denis B, Sauleau EA, Gendre I, Piette C, Bretagne JF, Perrin P. Measurement of adenoma detection and discrimination during colonoscopy in routine practice: An exploratory study. Gastrointest Endosc. 2011 December;74(6):1325-36.
28. Williams JE, Holub JL, Faigel DO. Polypectomy rate is a valid quality measure for colonoscopy: Results from a national endoscopy database. Gastrointest Endosc. 2012 March;75(3):576-82.
29. Baxter NN, Sutradhar R, Forbes S, Paszat L, Saskin R, Rabeneck L. Can quality indicators for colonoscopy be derived from administrative data? Identifying predictors of new or missed cancers after colonoscopy. Gastrointest Endosc. 2009 April;69(5):AB120.
30. Rex DK, Johnson DA, Anderson JC, Schoenfeld PS, Burke CA, Inadomi JM. American College of Gastroenterology Guidelines for Colorectal Cancer Screening 2008. Am J Gastroenterol. 2009;104(3):739-50.
31. Rostom A, Jolicoeur E. Validation of a new scale for the assessment of bowel preparation quality. Gastrointest Endosc. 2004 Apr;59(4):482-6.
32. Lai EJ, Calderwood AH, Doros G, Fix OK, Jacobson BC. The Boston bowel preparation scale: a valid and reliable instrument for colonoscopy-oriented research. Gastrointest Endosc. 2009 March;69(3 SUPPL.):620-5.
33. Armstrong D, Barkun A, Bridges R, Carter R, de Gara C, Dube C, et al. Canadian Association of Gastroenterology consensus guidelines on safety and quality indicators in endoscopy. Can J Gastroenterol. 2012 Jan;26(1):17-31.
34. Inadomi JM. In Search of Quality Colonoscopy. Gastroenterology. 2008 December;135(6):1845-7.

35. Lieberman D. A call to action - Measuring the quality of colonoscopy. New Engl J Med. 2006 14 Dec;355(24):2588-9.
36. Sawhney MS, Cury MS, Neeman N, Ngo LH, Lewis JM, Chuttani R, et al. Effect of institution-wide policy of colonoscopy withdrawal time >=7 Minutes on polyp detection. Gastroenterology. 2008 December;135(6):1892-8.
37. Yarze JC. Utility of colonoscopy withdrawal time measurement in the setting of an adequate adenoma detection rate. Gastrointest Endosc. 2011 January;73(1):189.
38. Lin OS. From good to great: Further thoughts on improving quality during routine colonoscopy. Gastrointest Endosc. 2011 March;73(3):464-6.
39. Rabeneck L, Paszat LF. Circumstances in which colonoscopy misses cancer. Frontline Gastroenterol. 2010 April 1, 2010;1(1):52-8.
40. Lakoff J, Paszat LF, Saskin R, Rabeneck L. Risk of developing proximal versus distal colorectal cancer after a negative colonoscopy: a population-based study. Clin Gastroenterol Hepatol. 2008 Oct;6(10):1117-21; quiz 064.
41. Whitlock EP, Lin JS, Liles E, Beil TL, Fu R. Screening for colorectal cancer: a targeted, updated systematic review for the U.S. Preventive Services Task Force. Ann Intern Med. 2008 Nov 4;149(9):638-58.
42. Nelson DB, McQuaid KR, Bond JH, Lieberman DA, Weiss DG, Johnston TK. Procedural success and complications of large-scale screening colonoscopy. Gastrointest Endosc. 2002 Mar;55(3):307-14.
43. Levin TR, Zhao W, Conell C, Seeff LC, Manninen DL, Shapiro JA, et al. Complications of colonoscopy in an integrated health care delivery system. Ann Intern Med. 2006 Dec 19;145(12):880-6.
44. Rutter CM, Johnson E, Miglioretti DL, Mandelson MT, Inadomi J, Buist DSM. Adverse events after screening and follow-up colonoscopy. Cancer Causes Control. 2012 February;23(2):289-96.
45. Baudet JS, Diaz-Bethencourt D, Aviles J, Aguirre-Jaime A. Minor adverse events of colonoscopy on ambulatory patients: The impact of moderate sedation. Eur J Gastroenterol Hepatol. 2009 June;21(6):656-61.
46. National Bowel Cancer Screening Program Quality Working Group. Improving Colonoscopy Services in Australia. 2009.
47. Krist AH, Jones RM, Woolf SH, Woessner SE, Merenstein D, Kerns JW, et al. Timing of repeat colonoscopy: disparity between guidelines and endoscopists' recommendation. Am J Prev Med. 2007 Dec;33(6):471-8.
48. Carey M, Sanson-Fisher R, Macrae F, Hill D, D'Este C, Paul C, et al. Improving adherence to surveillance and screening recommendations for people with colorectal cancer and their first degree relatives: a randomized controlled trial. BMC Cancer. 2012;12:62.