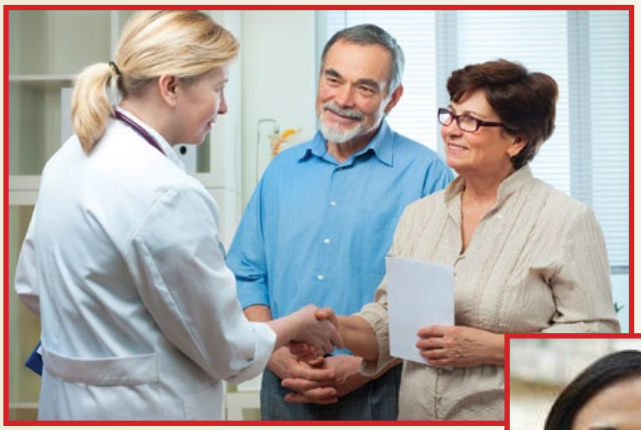
Canadian Association of Gastroenterology Consensus Guidelines on Safety and Quality Indicators in Endoscopy

SUMMARY



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For the full consensus guidelines please see Can J Gastroenterol 2012;26(1):17-31.

Introduction

In the last decade, the Canadian Association of Gastroenterology (CAG) has undertaken important initiatives to improve access to timely, high-quality digestive health care for Canadians. CAG was one of the first national specialty societies in Canada to define wait time benchmarks, monitor wait times and evaluate human resources.

Human resource constraints and limited capacity in the face of increasing demands have highlighted the need for safe, high-quality, patient-centred health care delivery to make best use of these limited resources. Endoscopy is central to the effective management of many digestive problems; however, despite increased procedural volumes, with 1.6 million endoscopies performed annually in Canada, demand still exceeds supply. The CAG has, therefore, developed a number of programs to promote quality in endoscopy. The Quality Program – Endoscopy (QP-E) provides a means of assessing and, ultimately, improving the delivery of patient-centred endoscopic services in Canada. The related Quality Endoscopy Recognition Program recognizes endoscopy units that have demonstrated a commitment to quality by participation in the QP-E. The CAG Consensus on Safety and Quality Indicators in Endoscopy was a natural extension of these programs.

Background and Methods

The primary aim of the consensus was to identify processes and indicators relevant to the provision of high-quality endoscopy services and to achieve consensus on broadly-applicable standards and key indicators that will support continuing quality improvement for endoscopy services across many jurisdictions. Guideline development addressed only the most commonly-performed endoscopic procedures of esophagogastroduodenoscopy (EGD) and colonoscopy. However, the principal issues addressed in this process are also applicable to more specialized endoscopic procedures.

A multidisciplinary group of 35 voting participants developed recommendation statements and performance indicators. Systematic literature searches generated 50 initial statements that were revised iteratively following a modified Delphi approach, using a web-based evaluation and voting tool. Statement development and evidence evaluation followed the AGREE and GRADE guidelines. At the consensus conference, participants voted anonymously; first on whether the statement should be implemented (strength of recommendation: do it/possibly do it/don't do it), and then on their level of agreement (disagree strongly/disagree moderately/disagree slightly/agree slightly/agree moderately/agree strongly). Subsequent, web-based voting evaluated recommendations for specific, individual quality indicators, safety indicators and mandatory endoscopy reporting fields. Consensus was defined, a priori, as agreement by 80% (agree slightly/agree moderately/agree strongly) of participants.

Recommendations

Ethics

1. For a patient to give a physician informed consent to perform an elective endoscopic procedure, the patient must be advised, in a timely fashion, of all relevant information about the procedure, its risks, benefits, and alternatives, if any, and be given an opportunity to ask questions that the physician must answer.
   Evidence grade: Low/very low
   Strength of recommendation: Do it, 91%
   Level of agreement with recommendation: 100%

Facility standards and policies

2. Endoscopy facilities should meet or exceed defined operating standards, in all domains, consistent with accreditation by the appropriate national or regional standards.
   Evidence grade: Low/very low
   Strength of recommendation: Do it, 91%
   Level of agreement with recommendation: 97%

3. Endoscopic procedures are performed for an appropriate, clearly documented indication, consistent with current, evidence-based guidelines.
   Evidence grade: Low/very low
   Strength of recommendation: Do it, 97%
   Level of agreement with recommendation: 97%

4. Endoscopy facilities should have the technical and personnel resources required by national and/or regional standards to complete all planned procedures safely and effectively.
   Evidence grade: Low/very low
   Strength of recommendation: Do it, 91%
   Level of agreement with recommendation: 100%

5. Endoscopy facilities should implement and monitor the effect of pre-procedure policies that ensure best practice.
   Evidence grade: Low/very low
   Strength of recommendation: Do it, 97%
   Level of agreement with recommendation: 97%

Full disclosure for informed consent: Required elements for review

- Indication for the procedure
- Nature of the procedure
- Need for preparation
  - Risks and benefits of preparation
  - Alternative preparations
- Patients' concerns about discomfort and pain
- Benefits and limitations of the procedure
  - Full disclosure of risks
    - Procedure-specific risks (e.g. bleeding, perforation, need for surgery or stoma to manage complications)
    - Risks of missed lesions
    - Risks of sedation, if administered
- Alternatives to the procedure
  - Option of no investigations or treatment
  - Potential alternative therapies including risks and benefits
- Sedation options
  - Risks, benefits and adverse events of all options
    - No sedation
    - Conscious sedation and deep sedation/general anesthesia
    - Alternatives including hypnotic relaxation, music, electro-acupuncture and nitrous oxide

Pre-procedure guidelines that should be implemented

- Antibiotic prophylaxis guidelines for prevention of infective endocarditis: e.g. American Heart Association and British Society of Gastroenterology guidelines.
- Antithrombotic agent guidelines on management of antithrombotic agents for endoscopic procedures; e.g. American Society for Gastrointestinal Endoscopy guidelines state that anticoagulant agents (e.g. warfarin, unfractionated heparin, low molecular-weight heparin) and antiplatelet agents (e.g. acetylsalicylic acid, clopidogrel, ticlopidine, glycoprotein IIb/IIIa receptor inhibitors) increase the risks of procedure-related bleeding. Pre-procedural assessment should encompass the benefits, risks and urgency of the procedure, the bleeding risks associated with antithrombotic therapy and the procedure and the thromboembolic risk of stopping therapy.
- Surveillance schedules (e.g. Barrett's esophagus, ulcerative colitis)
- Diabetes mellitus management guidelines
- Anesthetic / sedation risk guidelines
- Allergy or drug sensitivity guidelines
- Procedural pause

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6. Endoscopy facilities should implement and monitor the effect of intra-procedural policies that ensure best practice.
   Evidence grade: Low/very low
   Strength of recommendation: Do it, 94%
   Level of agreement with recommendation: 97%

Intra-procedural policies that should be implemented

- Verified, objective photo or video documentation of cecal intubation
- Regular monitoring of sedation level (e.g. implementation of an evidence-based sedation protocol)
- Regular monitoring of relevant physiological parameters (blood pressure, pulse, oxygen saturation, etc.)
- Routine evaluation of bowel preparation (i.e. a standardized tool such as the Ottawa bowel preparation scale or the Boston bowel preparation scale)
- Documentation of withdrawal time during colonoscopy – a minimum of 8 minutes is ideal (withdrawal time is correlated with a thorough examination)
- Regular monitoring of patient comfort
- Dual observation during examination (endoscopist and nurse)

7. The endoscopy facility should implement and monitor the effects of policies for the discharge of patients that ensure best practice.
   Evidence grade: Very low
   Strength of recommendation: Do it, 97%
   Level of agreement with recommendation: 100%

Policies for discharge of patients that should be implemented

- Standard criteria (e.g. Aldrete score) to determine readiness for discharge
- Result of discharge tool entered on the patient's record
- Regular monitoring of patient satisfaction with discharge process
- Standards for 24-hour activity restrictions for patients who receive sedation

8. Endoscopy facilities should ensure that there is a policy in place to notify patients of the need, and appropriate interval, for follow-up.
   Evidence grade: Low/very low
   Strength of recommendation: Do it, 76%
   Level of agreement with recommendation: 90%

9. All patients, on discharge, are given written information regarding the procedural findings, plans for treatment and follow-up, worrisome symptoms to watch for, and steps to be taken.
   Evidence grade: Very low
   Strength of recommendation: Do it, 97%
   Level of agreement with recommendation: 100%

Discharge Report – key elements

- Description of key findings, interventions, complications and sedation
- Description of symptoms of potential complications
- Instructions on actions to be taken if symptoms of complications arise
- Contact details in the event that complications arise
- Instructions on resumption of anticoagulants
- Instructions for follow up (why, when, where and with whom)

Quality Assurance

10. Endoscopy facilities should maintain a comprehensive quality improvement program incorporating formal, regular, scheduled review of performance reports.
    Evidence grade: Low/very low
    Strength of recommendation: Do it, 85%
    Level of agreement with recommendation: 94%

11. Endoscopy facilities should appoint a review committee to monitor and report back to management on adherence to and implementation of quality standards.
    Evidence grade: Low/very low
    Strength of recommendation: Do it, 79%
    Level of agreement with recommendation: 97%

12. Endoscopy facilities should systematically and regularly review current indicators of quality for all endoscopic procedures and implement appropriate responses.
    Evidence grade: Low/very low
    Strength of recommendation: Do it, 88%
    Level of agreement with recommendation: 97%

Table 1.
Indicators of Quality in Endoscopic Service.
Agreement was 82%
or greater for all quality indicators.

13. Endoscopy facilities should systematically and regularly review current indicators of safety for all endoscopic procedures and implement appropriate responses.
    Evidence grade: Low/very low
    Strength of recommendation: Do it, 91%
    Level of agreement with recommendation: 100%

Indicator Comment
Indicator related to entire endoscopy facility
1. Participation in a recognized quality assurance program
Indicators related to the technical performance of the procedure and appropriateness
2. Completion of procedure Documented inspection of duodenum, cecum or terminal ileum
3. Appropriateness of procedure Performed for an appropriate indication
4. Completeness of procedure Inspection of all relevant areas, acquisition of appropriate biopsies and completion of all appropriate interventions
5. Withdrawal time As a minimum, rapid withdrawal precludes complete inspection; especially for colonoscopy
6. Adenoma detection rate Requires reconciliation of pathology and endoscopy reports
7. Polyp detection rate A surrogate marker for a careful examination
8. Appropriateness of endoscopic intervention Interventions are performed, or eschewed, appropriately according to the indication and findings
9. Completion of endoscopic intervention Interventions are performed to completion (e.g. polypectomy)
10. Appropriateness of biopsy Biopsies are performed, or eschewed, appropriately according to the indication and findings
Patient-centred indicators of quality
11. Quality of patient experience There is a formal assessment of the patient's experience, preferably using a standard tool
12. Sedation dosage Systematic overuse or underuse of sedation is identified; usage is correlated with outcome
Indicators relevant to quality of preparation before procedure
13. Quality of bowel preparation Assessed formally, using a validated tool or, at a minimum, a standard scale (e.g. poor, fair, good)
14. Appropriateness of antithrombotic management Consistent with accepted guidelines
15. Appropriateness of antibiotic prophylaxis management Consistent with accepted guidelines
Indicator relevant to quality of communication regarding results
16. Completion of endoscopy reporting Procedure results report should be complete, with all relevant information included, and should be available immediately
Indicator of procedural quality relevant, predominantly, to colonoscopy screening and surveillance programs
17. Interval cancer incidence Requires reconciliation of endoscopy report and health records
Indicator of technical competence related, predominantly, to the endoscopist
18. Number of procedures performed annually A marker for maintenance of competence

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Training, Education, Competency and Privileges

14. Endoscopy facilities should provide high-quality education programs or opportunities for all staff.
    Evidence grade: Very low
    Strength of recommendation: Do it, 86%
    Level of agreement with recommendation: 100%

15. All endoscopy facility personnel in training should be supervised and their performance monitored regularly until they have achieved competency to perform specified routine and/or emergency procedures according to appropriate current standards.
    Evidence grade: Low/very low
    Strength of recommendation: Do it, 97%
    Level of agreement with recommendation: 100%

Table 2.
Indicators of Safety Compromise in Endoscopic Service.
Agreement was 80% or greater for all safety indicators apart from Instrument Malfunction (77%).

Indicator Comment
Indicators of increased risk of complications
1. Use of reversal agents An indication of inappropriate sedation practice
2. Sedation doses in patients older than 70 years Evaluation of sedation use in susceptible patients who have greater risk of co-morbidities
Indicators related to an increased risk of immediate complications
3. Need for cardiopulmonary resuscitation For any cause – with assessment of causal relationship
4. Allergic reactions For documented or undocumented allergens
5. Laryngospasm or bronchospasm For any cause – with assessment of causal relationship
6. Hypoxia (oxygen saturation < 85%) For any cause – with assessment of causal relationship
7. Hypotension: <90/50 mmHg or fall of ≥20% from baseline For any cause – with assessment of causal relationship
8. Hypertension: >190/130 mmHg or rise of ≥20% from baseline For any cause – with assessment of causal relationship
9. Symptomatic metabolic complications Symptomatic hypoglycemia or hyperglycemia; symptomatic disturbance of fluid and/or electrolyte status
10. Perforation Occurring during or after procedure
11. Immediate post-polypectomy bleeding This may have been treated successfully during the procedure or it may be persistent and/or requiring transfusion
12. Severe persistent abdominal pain Requiring further evaluation but not proven as perforation
13. Impaction of instrument Includes therapeutic accessories, e.g. snare or basket
14. Instrument malfunction Includes endoscope, accessories or ancillary equipment (e.g. processor, monitor, lighting, computer, etc.)
15. Admission or transfer to an emergency department Includes transfer from the endoscopy unit for any reason other than the underlying gastrointestinal condition
Indicators related to an increased risk of late complications
16. Infection Including acute (e.g. *Clostridium difficile*, abscess, endocarditis) and chronic (e.g. hepatitis C) infections; presentation may be early or delayed
17. Gastrointestinal bleeding within 14 days of the procedure Upper or lower gastrointestinal origin: e.g. post-polypectomy or post-biopsy
18. Unplanned hospitalization within 14 days of the procedure For any cause – with assessment of causal relationship
19. Unplanned contact with health care provider within 14 days of the procedure For any reason – e.g. for abdominal pain or infection – with assessment of causal relationship
20. Death within 30 days For any reason – with assessment of causal relationship and evaluation of mortality attributable to the underlying gastrointestinal condition

16. All endoscopy facility personnel engaged, directly or indirectly, in endoscopy service delivery should be trained and certified as having competency to perform specified routine and/or emergency procedures according to appropriate current standards.
    Evidence grade: Low/very low
    Strength of recommendation: Do it, 97%
    Level of agreement with recommendation: 97%

17. Endoscopists should regularly review their endoscopic practice and outcome data with the aim of continuous professional development.
    Evidence grade: Low, very low
    Strength of recommendation: Do it, 94%
    Level of agreement with recommendation: 97%

18. Endoscopists should be granted privileges to perform specified procedures based on a formal evaluation of their competence consistent with appropriate current standards.
    Evidence grade: Low/very low
    Strength of recommendation: Do it, 100%
    Level of agreement with recommendation: 100%

19. Endoscopists' privileges should be subject to formal, regular, scheduled review to ensure that renewal is based on documented competence to perform specified procedures consistent with appropriate current standards.
    Evidence grade: Low/very low
    Strength of recommendation: Do it, 94%
    Level of agreement with recommendation: 97%

Endoscopy Reporting Standards

20. Endoscopic procedures should be reported in a standardized electronic format, including mandatory reporting fields, to provide full documentation of all necessary clinical and quality measures.
    Evidence grade: Low/very low
    Strength of recommendation: Do it, 82%
    Level of agreement with recommendation: 97%

Competencies required by end of training (World Gastroenterology Organisation/World Endoscopy Organization)

- Successful completion of a recognized medical or surgical training program
- Ability to integrate endoscopy into clinical management plan (be this medical, surgical or referral for specialty services)
- Understanding of indications, contraindications and risks related to procedures
- Ability to clearly describe to the patient, in layman's terms, details of the procedure including attendant risks, and thus, to obtain informed consent
- Sound knowledge of endoscopic anatomy
- Familiarity with the technical and safety features of the endoscope and accessories and an understanding of proper endoscope reprocessing and infection control
- Ability to accurate identify and interpret endoscopic findings
- Understanding of pharmacology, administration and risks of sedation/analgesia
- Ability to perform procedures competently, including common methods for tissue sampling and therapy
- Ability to diagnose and manage complications promptly and competently
- Ability to recognize limitations of endoscopic technology and of their own skill in management or therapy of endoscopic findings
- Ability to document findings and communicate them with patients and other health care providers
- Ability to maintain a record of key performance indicators

Grading systems appropriate for electronic reporting forms

- Patient status: American Society of Anesthesiologists physical status classification system, Mallampati score
- Boston bowel preparation scale or Ottawa bowel preparation scale
- Reflux esophagitis severity: Los Angeles classification
- Barrett's esophagus diagnosis and extent: Prague C & M criteria
- Crohn's disease – SES-CD activity score
- Ulcerative colitis disease activity: Mayo score
- Bleeding lesions – Forrest classification
- Esophageal varices – grade size
- Readiness for discharge: Aldrete score

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21. Endoscopy facilities should implement policies to monitor and ensure the timeliness and completeness of procedure reporting.
    Evidence grade: Low/very low
    Strength of recommendation: Do it, 100%
    Level of agreement with recommendation: 100%

Patient Perceptions

22. Endoscopy facilities should ensure that the services they provide are patient-centred.
    Evidence grade: Moderate to very low
    Strength of recommendation: Do it, 85%
    Level of agreement with recommendation: 100%

23. Endoscopy facilities should systematically and at least annually solicit patient feedback, report the results to the service and to the institution's quality committee, and implement effective measures to address patients' concerns.
    Evidence grade: Very low
    Strength of recommendation: Do it, 94%
    Level of agreement with recommendation: 100%

Table 3.
Required Endoscopy Report Elements.
Agreement was 91% or greater for all quality indicators.

Report field Comment
1. Type of procedure EGD, colonoscopy, etc.
2. Date and time of procedure
3. Name of endoscopist Including trainee and supervisor
4. Name(s) of assistant(s) Endoscopy nurse, respiratory technician, etc.
5. Age and sex of patient
6. Indication(s) for procedure Consistent with guidelines for appropriate indications
7. Co-morbidities Assessed using American Society of Anesthesiologists physical status classification system, Mallampati score, etc.
8. Type of bowel preparation Including timing and adherence to prescribed regimen
9. Type and dose of sedation used Including incremental dose adjustment
10. Other medication and related information Administration route, reversal agents, antispasmodics, allergies, etc.
11. Extent and completeness of examination Confirmed by independent observer and/or photodocumentation; withdrawal time (colonoscopy) and retroflexion manoeuvres
12. Quality of bowel preparation Assessed formally, using a validated tool or standard scale
13. Relevant findings Using relevant, standardized descriptions and validated scales
14. Pertinent negatives Using relevant, standardized descriptions and validated scales
15. Adverse events and resulting interventions Using relevant, standardized descriptions and validated scales
16. Patient comfort Using formal descriptors and, if possible, a validated scale
17. Diagnoses Using standard terminology and validated scales
18. Endoscopic interventions performed Using standard terminology and descriptors
19. Details of pathology specimens Number and location of biopsies; number, size and location of polyps
20. Details of follow up arrangements Identify person responsible for booking further tests and follow-up
21. Appended pathology report(s), when available Requires reconciliation of endoscopy and pathology reports
22. Management recommendations Including medication, tests and follow up
23. Information provided to patient and/or family Description of findings; contact details in the event of an emergency

Conclusions

Gastrointestinal endoscopy is a complex diagnostic and therapeutic undertaking that demands a high level of skill and knowledge on the part of the operator. However, high-quality endoscopy requires more than a skilled operator; the delivery of high-quality endoscopy services, in a cost-effective manner consistent with the broader needs of a health care system, requires a formal quality improvement framework that addresses all aspects of endoscopy service delivery from the patient's initial contact with a health care provider (e.g. the identification of family history of colon cancer in an asymptomatic individual) through to documentation of long-term outcomes (e.g. freedom from colon cancer over decades). Recognition of the patient as the focus of the endoscopy process provides a structure for integrating the efforts of the many, diverse disciplines whose contribution is needed to ensure a high-quality service.

The consensus process and meeting were organized by the CAG and supported, in part, by the:

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For more information on CAG's quality programs please visit:
http://www.cag-acg.org/special-projects/quality-in-gastroenterology
or email QP-E@cag-acg.org

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The Canadian Association of Gastroenterology is dedicated to research, professional education, and patient care in all areas of digestive health and disease, in support of the economic and social health of all Canadians.

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