SUMMARY
Canadian Association of Gastroenterology

Consensus Guidelines on Safety and Quality Indicators in Endoscopy


Introduction

In the last decade, the Canadian Association of Gastroenterology (CAG) has undertaken important initiatives to improve access to timely, high-quality 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 in the provision 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 esophageogastroduodenoscopy (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 in the provision of endoscopy services (do it, possibly do it, don't do it). The CAG Consensus on Safety and Quality Indicators in Endoscopy was a natural extension of these programs.

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.
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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.
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5. Endoscopy facilities should implement and monitor the effect of pre-procedure policies that ensure best practice.
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Pre-procedure guidelines that should be implemented

- Antibiotic prophylaxis guidelines for prevention of 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. aspirin, clopidogrel, ticlopidine, glycoprotein IIb/IIIa receptor inhibitors) increase the risks of procedural bleeding and, hence, the CAG Consensus recommends pre-procedure assessment of the bleeding risks associated with antithrombotic therapy and the procedure and the thrombotic risk of stopping therapy.
- Surveillance guidelines: e.g. Barrett’s esophagus, ulcerative colitis
- Diabetes mellitus management guidelines
- Anesthetic / sedation risk guidelines
- Allergy or drug sensitivity guidelines
- Procedural pause

Full disclosure for informed consent: Required elements for review

- Indication for the procedure
- Nature of the procedure
- Need for preparation
- Benefits and risks of preparation
- Alternative preparations
- Patient’s 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 infection
- Risks of infection, 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 nitrous relaxation, music, electro-acupuncture and nitrous oxide

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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%

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- Surveillance schedules (e.g. Barrett’s esophagus, ulcerative colitis).
- Diabetes mellitus management guidelines.
- Antibiotic prophylaxis guidelines for prevention of endocarditis.
- Antiplatelet agent guidelines on management of antithrombotic agents for endoscopic procedures.
- Pre-procedure guidelines that should be implemented.
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%

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%

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%

Quality Assurance
10. Endoscopy facilities should maintain a comprehensive quality assurance 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%

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)

Policies for discharge of patients that should be implemented
• Standard criteria (e.g. Aintree 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

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)

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
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Indicator Definitions
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
3. Appropriateness of procedure
4. Completeness of procedure
5. Withdrawal time
6. Adenoma detection rate

7. Polyp detection rate
8. Appropriateness of endoscopic intervention
9. Appropriateness of antibiotic prophylaxis management
10. Appropriateness of biopsy
11. Quality of patient experience
12. Sedation dosage
13. Appropriateness of antibiotic prophylaxis management
14. Appropriateness of antithrombotic management
15. Appropriateness of antibiotic prophylaxis management
16. Completion of endoscopy reporting
17. Interval cancer incidence
18. Number of procedures performed annually

A marker for maintenance of competence
6. Endoscopy facilities should implement and monitor the effect of intra-procedural policies that ensure best practice.

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   • Verified, objective photo or video documentation of caudal 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)
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   • Dual observation during examination (endoscopist and nurse)

   Policies for discharge of patients that should be implemented

   • Standard criteria (e.g. Ankle Brachial Index) 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

   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)

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Indicators

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Policies for discharge of patients that should be implemented

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   • Instructions for follow-up (why, when, where and with whom)
**14. Endoscopy facilities should provide high-quality training, education, competency and privileges.**

**Agreement was 80% or greater for all safety indicators.**

**Indicators of Safety Compromise in Endoscopic Service.**

- **Table 2.**
  - Upper or lower gastrointestinal origin: e.g. post-polypectomy or post-biopsy
  - Hypotension: <90/50 mmHg or fall of ≥20% from baseline
  - Impaction of instrument
  - Allergic reactions
  - Severe persistent abdominal pain
  - Gastrointestinal bleeding within 14 days of the procedure
  - Unplanned hospitalization within 14 days of the procedure
  - Unplanned contact with health care provider within 14 days of the procedure
  - Hypotension: <90/50 mmHg or fall of ≥20% from baseline
  - Symptomatic hypoglycemia or hyperglycemia; symptomatic disturbance of fluid and/or electrolyte status
  - Fever: >38°C for any cause – with assessment of causal relationship
  - Any cause – with assessment of causal relationship
  - Absence of documentation
  - Any cause – with assessment of causal relationship
  - Malignant neoplasia
  - Any cause – with assessment of causal relationship
  - Admission or transfer to an emergency department
  - Any cause – with assessment of causal relationship
  - Adverse reaction to a medication
  - Any cause – with assessment of causal relationship
  - Failure to achieve an end point

**Endoscopy Reporting Standards.**

- **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, 94%
  - 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 (e.g. 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 local and safety features of the endoscope and accessories and an understanding of proper endoscope reprocessing and infection control
  - Ability to accurately identify and interpret endoscopic findings
  - Understanding of pharmacology, administration and risks of sedation/analgia
  - Ability to perform procedures competently, including common methods for tissue sampling and therapy
  - Ability to identify and manage complications promptly and competently
  - Ability to recognize limitations of endoscopic technology and of their own skill in management or referral 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
14. Endoscopy facilities should provide high-quality education programs or opportunities for all staff.

Strength of recommendation: Do it, 86%

Level of agreement with recommendation: 100%

Evidence grade: Low/very low

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%

Evidence grade: Low/very low
Table 3. Required Endoscopy Report Elements. Agreement was 91% or greater for all quality indicators.

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%

Report field

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.

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For more information on CAG’s quality programs please visit:
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Canadian Association of Gastroenterology
Consensus Guidelines
on Safety and Quality Indicators in Endoscopy

SUMMARY