



# Gastrosocopy Standards and Quality Indicators for Ontario

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## Methodology

A systematic search of guidelines on esophagogastroduodenoscopy published between 2000 and 2014 was conducted using the PubMed, National Guideline Clearinghouse, and Standards and Guidelines Evidence databases. In addition, a targeted search was conducted on key professional association websites.<sup>1</sup> See Appendix 1 for the detailed search strategy, including key words. This search was supplemented in the spring of 2015 to include additional relevant guidelines published following the original search.

Standards were abstracted and grouped by type: training and maintenance of competency, quality standards and indicators. Where possible, standards were selected from the College of Physicians and Surgeons of Ontario's Out-of-Hospital Premises Inspection Program Standards, the College of Physicians and Surgeons of Ontario's Applying the Out-of-Hospital Premises Inspection Program Standards in Endoscopy/Colonoscopy Premises and Independent Health Facilities, and Ontario's Colonoscopy Quality Management Partnership<sup>2</sup> Standards (with minor modifications, if needed). In addition, the London Organisation Mondiale d'Endoscopie Digestive (OMED) Position Statement for Credentialing and Quality Assurance in Digestive Endoscopy was used as the primary source for standards training and maintenance of competency.

Two physicians conducted independent reviews of abstracted standards to identify standards for consideration.

These standards were reviewed by an expert panel consisting of experts in gastroenterology, general surgery and thoracic surgery. Additional published literature was identified to supplement areas the panel noted as being not adequately addressed by existing guidelines.

## Training, Competency and Privileges

The following standards related to training, competency and privileges are intended as ideal guidelines because they are not currently part of an organized framework.

### Definitions

**Credentials:** Documents provided after successful completion of a period of education or training as an indication of clinical competence. They include, but are not limited to, diplomas, letters from program directors and specialty certifications.

**Competency:** Competency is the minimal level of skill, knowledge and/or expertise derived through training and experience that is required to safely and proficiently perform a task or procedure without assistance or supervision.

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<sup>1</sup> American Gastroenterological Association; Canadian Association of Gastroenterology; Endoscopy Section of the Netherlands Society of Gastroenterology; Gastroenterological Society of Australia; Joint Advisory Group on GI Endoscopy (UK); Sociedad Española de Patología Digestiva; Société Française d'Endoscopie Digestive.

<sup>2</sup> The Quality Management Partnership is working closely with the colonoscopy field to implement a quality management program (QMP) that ensures consistent quality in every facility across Ontario, whether it take place in hospitals, Out-of-Hospital Premises (OHPs) or Independent Health Facilities (IHF). For more information about the QMP please see [qmpontario.ca](http://qmpontario.ca).

In addition to proficiency in the technical aspects of esophagogastroduodenoscopy (EGD), proficiency in cognitive aspects of the procedure is essential, including knowledge of appropriate contraindications and indications for EGD, application of appropriate surveillance intervals and knowledge of how to deal with findings encountered at the time of the procedure.

**Clinical privilege:** Authorization by a local institution for a physician to perform a particular procedure or clinical service. Privileges are granted by healthcare institutions, such as hospitals, and freestanding surgical or endoscopy centres or clinics.

### Training Requirements

- Be thoroughly familiar with the technical and safety features of the endoscope and accessories, and have an understanding of proper endoscope reprocessing and infection control;
- Accurately identify and interpret endoscopic findings;
- Understand the pharmacology, administration and risks of sedation/analgesia;
- Be able to perform procedures competently, including using common methods for tissue sampling and therapy, and know when these procedures are needed;
- Diagnose complications promptly and competently manage them;
- Recognize the limitations of endoscopic technology or of their own skill in the management or therapy of endoscopic findings and refer to other physicians when appropriate;
- Be able to document findings, and communicate them with patients and other healthcare providers; and
- Be able to maintain a record of key performance indicators.

The training director should provide documentation of the training the applicant has received for each procedure requested.

### Determination of Competency

Completion of a standard training program in gastroenterology, general surgery or surgical sub-specialty may suggest that the practitioner is ready for independent endoscopic practice, provided that the program included endoscopic training.

Competency for specific procedures should be determined by objective measures, wherever possible.

Competency in diagnostic procedures includes demonstrated ability to recognize and manage pathology, conduct procedure reporting to patients and referring providers, and escalate care/intervention—including involvement of sub-specialty when required, management of most complications and recognition of when help is needed. Skills required to manage complications include, at minimum, the ability to use clips, injection and electrocautery.

Competency to perform more specialized therapeutic interventions, such as stricture dilation, percutaneous endoscopic gastrostomy placement and stent placement, requires separate assessment and privileging.

### Recommended Minimum Number of Procedures for Competency

Documentation of the numbers and types of procedures performed in training is important and trainees should complete a minimum of 150 procedures while maintaining a log of completed procedures. These numbers are

intended to indicate that the trainee may have reached a stage where competency can be assessed by direct observation or other objective measures. However, numbers alone should not be used to grant privileges.

Technical proficiency implies that by the end of training, independent procedure completion (including a complete examination of the esophagus, stomach and duodenum, as well as retroflexion in the stomach) is achieved in 98 per cent of procedures performed.

### Granting Privileges

Institutions should establish specific policies for the granting of privileges.

The policies should apply uniformly to all specialties wherever EGD is performed and should be determined separately for EGD and more advanced therapeutic interventions, such as percutaneous endoscopic gastrostomy placement, stricture dilation and stent placement.

The application and credentials should be reviewed by a physician who is thoroughly familiar with the procedures in question. For small facilities, the review should involve the Regional Colorectal Screening/GI Endoscopy Lead.

Direct observation of the applicant (“proctoring”) is desirable and recommended.

Hospital policy should delineate the role of the observer, as well as specify the number of procedures to be observed and the criteria to be assessed.

### Renewal of Privileges

Endoscopists’ privileges should be subject to formal, regular, scheduled review to ensure that renewal is based on documented competence in performing specified procedures consistent with appropriate current standards.

The institution should have a policy that specifies the methods for renewal of privileges, timing (interval between renewals) and a defined approach for dealing with poor performance. Applications should include supporting evidence, including documentation of ongoing practice of the procedure and relevant continuing medical education.

As with the initial granting of privileges, the application should be reviewed by an individual who is thoroughly familiar with the procedures related to the privileges being sought.

## Facility Standards

### Equipment

Facilities should have standard equipment and policies for managing complications. Standard equipment includes, but is not limited to, thermal devices, injectors, vasoconstricting agents, and clipping devices.

All equipment used for disinfecting and reprocessing a gastroscope should be:

- Maintained and tracked with a log to ensure full equipment functionality and safety;
- Subject to compliance testing and certification where required by the Canadian Standards Association and licensed for use in Canada;
- Subject to a regular quality control program;
- Replaced when necessary to ensure it is up to date and to maintain a high standard of service; and

- Documented in a readily accessible log book.

Facilities should use automated endoscopic re-processors for all procedures.

Facilities should have appropriate re-processing capacity (i.e., appropriate ratio of re-processors to procedure volume).

Facilities should keep abreast of changes to the high-level disinfection and re-processing protocol as recommended by the manufacturer and regulatory authorities.

## Sedation

Facilities should offer sedation for appropriate procedures and have necessary infrastructure for safe sedation (i.e., recovery room and monitoring).

Physicians may elect not to offer sedation for esophagogastroduodenoscopy (EGD) or upon a patient's request if it does not compromise quality of the procedure.

Patients undergoing a low risk procedure should be aware that they may choose to undergo the procedure without sedation.

Reversal agents (naloxone and flumazenil) should be readily available and their usage should be recorded in a log, as well as in the procedure report.

## Medication

Facilities should:

- Maintain a general medication inventory record;
- Periodically inspect all medications for viability;
- Use a single dose vials whenever possible—if using multidose vials, facilities should follow Public Health Ontario's recommendations (see Appendix 2);
- Label medications in accordance with the Food and Drug Act (FDA) and the Controlled Drugs and Substances Act (CDSA) and its regulations;
- Store medications according to the manufacturer's recommendations (e.g., refrigeration if required) and in a manner suitable for security and restocking;
- Store emergency drugs in a common location—in facilities where more than one room could be used to perform procedures, a crash cart is advisable;
- Document administration of medications in the patient record; and
- Make available resources to determine appropriate drug dosages and usage.

Facilities should ensure that controlled substances are:

- Accessed by a qualified designated staff (registered nurse, registered practical nurse with medication skills, physician);
- Stored in a designated, fixed locked cabinet; and

- Accounted for in a “log of controlled substances” that specifies for each controlled substance name, quantity, date received, expiry date, loss (damaged, expired, spilled) date and quantity, and patient administration (patient name, drug name and amount removed from inventory, date and time, name of staff administering the medication).

### Special Consideration: Upper GI Bleeding

Hospitals should develop institution-specific protocols for multidisciplinary management of patients with upper GI bleeding, which should include access to an endoscopist who is proficient in endoscopic hemostasis.

Not all institutions have immediate access to these specialists, and not all patients require urgent endoscopy; thus, institution-specific protocols should be developed, updated, and be included as part of regional plan. Such protocols should be based on a multidisciplinary approach to the management of patients with acute upper GI bleeding, including early involvement of a gastroenterologist and surgeon, and a pre-specified chain of notification.

## Gastroscopy Quality Standards

### Pre-Procedure Standards

#### Indication

Esophagogastroduodenoscopies (EGDs) are performed for an appropriate, clearly documented indication, consistent with current, evidence-based guidelines (see Appendix 3).

#### Consent

For a patient to give a physician informed consent to perform an elective EGD, the patient should be advised in a timely fashion of all the relevant information about the procedure, including its risks, benefits and alternatives, if any, and be given an opportunity to ask questions that the physician should answer.

#### Pre-Procedure Assessment

The physician should:

- Assess the risks inherent in each procedure or combination of procedures to determine if the procedure(s) and setting are safe;
- Appraise each patient’s medical risk factors (particularly use of anticoagulants, diabetes, body mass index, cardiopulmonary status and presence of an intracardiac defibrillation device) and discuss the pre-procedural management plan with the patient; and
- Explain the alternatives to the patient.

#### Anticoagulation

Patients undergoing a diagnostic EGD, with or without biopsy, should not interrupt or modify their anticoagulation therapy, regardless of whether they are on warfarin or one of the novel oral anti-coagulants. Antiplatelet therapy, with either acetylsalicylic acid, clopidogrel or ticagrelor does not require interruption.

High hemorrhagic risk procedures include dilatation, variceal therapy, percutaneous endoscopic gastrostomy (PEG) placement and polypectomy. In cases where these interventions are planned, antithrombotic therapy



should be either interrupted or bridged, depending on a patient's underlying risk of a thromboembolic event. In these cases, antithrombotic management should be consistent with accepted contemporary guidelines and the facility's institutional policies/standards (see Appendix 4).

### Prophylactic Antibiotics

There is no justification for prophylactic antibiotics in patients undergoing diagnostic EGD.

The administration of prophylactic antibiotics to prevent endocarditis or infection of synthetic vascular grafts, pacemakers, defibrillators, vascular stents, filters or orthopedic prosthesis is not recommended for patients undergoing gastroscopy.

Routine administration of prophylactic antibiotics to immunocompromised patients with normal neutrophil count is not recommended; however, there is insufficient evidence to recommend for or against administration of antibiotic prophylaxis before routine endoscopic procedures in patients with severe immunosuppression.

### Special Prophylactic Antibiotic Circumstances

Prophylactic antibiotics are given before placement of a PEG or percutaneous endoscopic jejunostomy (PEJ) tube.

Prophylactic antibiotics are given on admission to patients with cirrhosis and acute upper GI bleeding.

### Use of Prokinetics

Intravenous (IV) administration of prokinetic agents (erythromycin or metoclopramide) may be considered in patients with suspected brisk upper GI bleeding.

### Timeliness

Patients should be triaged into emergent, urgent or elective procedures, according to the Canadian Association of Gastroenterology guidelines, and wait times should be monitored (see Appendix 5).

Most patients with acute upper GI bleeding should undergo (emergent) endoscopy, within 24 hours of presentation.

### Staffing Resources

The minimum registered nurse staffing pattern should consist of:

- A registered nurse in the pre-procedure area to perform patient care and assessment prior to IV sedation and anesthesia;
- One registered nurse in each procedure room to assess and monitor the patient during IV sedation and assist the healthcare team—when an anesthesia provider is administering the sedation, the registered nurse will remain to provide continuity of care and assist the healthcare team; and
- A registered nurse in the post-procedure area to perform patient care and assessment during recovery from IV sedation.

Under special circumstances, additional personnel may be required to participate in the procedure. The level of additional personnel will be dictated by the specific needs required by the procedure.

## Intra-Procedure

### Patient Monitoring

Sedated patients should be attended to for the duration of the procedure as follows:

- Oxygen saturation should be continuously monitored and documented at relevant intervals in all patients undergoing sedated and non-sedated gastroscopy;
- During conscious sedation or in the absence of sedation in healthy patients without cardiac disease, pulse should be continuously recorded and blood pressure should be regularly measured and documented; and
- Pulse, blood pressure and electrocardiography should be in continuous use during the duration of deep sedation—heart rate and blood pressure should be documented at least every five minutes.

Audible and visual alarms should not be indefinitely disabled. The variable pitch pulse tone and the low-threshold alarm of the monitors should give an audible and visual alarm. The variable pitch tone pulse oximeter should be clearly audible at all times.

### Completeness and Visualization

A diagnostic EGD should include inspection of all relevant areas spanning from the upper esophageal sphincter to the post-bulbar duodenum, including retroflexion to allow full visualization of the incisura, cardia and fundus. The procedure should also include acquisition of appropriate biopsies, as indicated, and completion of all appropriate interventions.

For a basic EGD, photo documentation of the following areas is preferable: gastroesophageal junction, duodenal intubation, cardia and fundus (via retroflexion to achieve full visualization), and relevant abnormalities.

## Intra-Procedure: Specifics

### General Statement

The following standards do not provide an exhaustive list of standards for all specific EGD indications. They are listed because they are supported by current evidence-based consensus guidelines. In addition, the standards below are based on best practices and evidence available in 2014/2015, but may evolve over time.

### Barrett's Esophagus

The following section is not intended to review endoscopy practice around Barrett's esophagus; it will simply address selected aspects of the endoscopy practice related to Barrett's esophagus.

Endoscopy screening may be considered in select patients with multiple risk factors for Barrett's esophagus and esophageal adenocarcinoma.

Barrett's esophagus should be measured (in centimetres) from the location of the gastroesophageal junction and squamocolumnar junction to the incisors, and should be documented using Prague specifications (see Appendix 6).

After a screening examination with negative findings, there should be no further endoscopic screening for Barrett's esophagus.

In patients with non-dysplastic Barrett’s esophagus who are enrolled in an EGD surveillance program, a surveillance EGD should be performed no more frequently than every three to five years, with white light endoscopy.

Surveillance for Barrett’s esophagus is performed by targeted biopsies of nodules, ulcers and other irregularities of the mucosa, as well as four-quadrant biopsies at every two centimetres of suspected Barrett’s esophagus.

### Celiac Disease

Biopsies should be taken from the second/third portion of the duodenum (at least four samples), and at least one biopsy should be taken from the duodenal bulb while the patient is on a normal (non-gluten-free) diet.

### Helicobacter Pylori (*H. pylori*)

At least two biopsies from the antrum and two biopsies from the gastric body should be taken.

### Upper GI Bleeding

#### Bleeding Ulcers

A finding of low risk endoscopic stigmata (a clean-based ulcer or a nonprotuberant pigmented dot in an ulcer bed) is not an indication for endoscopic hemostatic therapy. A finding of a clot in an ulcer bed warrants targeted irrigation in an attempt at dislodgment, with appropriate treatment of the underlying lesion. A finding of high risk endoscopic stigmata (active bleeding or a visible vessel in an ulcer bed) is an indication for immediate endoscopic hemostatic therapy.

When epinephrine injection is used to treat nonvariceal upper GI bleeding or non-bleeding visible vessels, a second treatment modality should also be used (e.g., coagulation or clipping).

Patients with peptic ulcers of the stomach or duodenum should have biopsies to assess for *H. pylori* (two in the antrum and two in the body), or have plans for subsequent testing in their endoscopy reports. In settings with a very high population prevalence of infection, empirical treatment without *H. pylori* testing of ulcer patients may be justifiable.

A negative test for *H. pylori* in an acute setting requires a repeat test outside the acute setting of bleeding.

Routine second-look endoscopy is not recommended in the management of bleeding ulcers.

The decision to perform repeat endoscopy in patients with a gastric ulcer should be individualized.

### Esophageal Varices

For the endoscopic treatment of esophageal varices, variceal ligation is the preferred modality.

## Post-Procedure Standards

### Patient Recovery

Recovery-area staff caring for recovering patients should document the care they provide in the patients’ records, which includes, but is not limited to:

- Patient identification; date and time of transfer to recovery area; and initial and routine monitoring of blood pressure, pulse, respiration, level of consciousness, pain score and general status;
- Monitoring of vital signs until patients have met requirements of discharge criteria using an objective scoring system from time of transfer to recovery area until discharge from Phase II recovery;
- Medication administered, if any, including time, dose, route, reason and effect;
- Treatments, including tests, interventions and immediate patient outcomes; and
- Discharge and follow-up.

On discharge, all patients should be given written information regarding the procedural findings, as well as plans for treatment and follow-up, including plans for pathology follow-up and resumption of medications. Patients should also be informed of worrisome symptoms to watch for and steps to be taken if symptoms develop.

A physician is responsible for writing the discharge order. However, the actual decision for discharge from the recovery area should be based on discharge criteria using an objective scoring system; the decision can be delegated to recovery-area staff.

### Procedure Report

All endoscopic procedures should be reported to provide full documentation of all necessary clinical information, extent of the procedure, relevant findings, endoscopic interventions performed, clinical impression and management plan, including medication, tests and follow-up (see Appendix 7 for report elements). The procedure report should also document the management of antithrombotic therapy, if applicable. Follow-up arrangements should identify the person responsible for booking further tests and follow-up.

In the case of bleeding ulcers, the procedure report should describe each identified ulcer, location, size and stigmata of recent bleeding based on the Forrest classification. Interventions used to control the bleeding should be clearly documented, as well as whether hemostasis was achieved.

Barrett's esophagus is documented using Prague specifications (see Appendix 6).

Extent and severity of reflux esophagitis is reported using the Los Angeles classification (see Appendix 8).

For patients being transferred to another facility, a procedural report should accompany the patient, describing, at minimum, the procedure, findings, any interventions performed and recommended management.

### Stricture Dilation

In patients undergoing dilation for peptic esophageal strictures, post procedure proton pump inhibitor therapy is recommended.

### Management and Follow-up

The endoscopist is responsible for ensuring that all pathology reports are reviewed, and that appropriate follow up is arranged and communicated to the patient and the referring physician.

It is expected that physicians will manage medical and surgical conditions within the scope of their specialty training, certification and experience. Therefore, the endoscopist should be cognizant of most upper GI conditions

and is responsible for the management of the findings, which may include therapy, appropriate and sufficient follow-up or further investigations and/or referrals.

## Quality Assurance

The use of the endoscopy global rating scale as a tool to guide quality assurance and quality improvement activities is recommended for all facilities.

## Quality Indicators

For a complete list of proposed gastroscopy quality indicators see Appendix 9.

## Documentation

Facilities should have a documented process for the storage and retrieval of endoscopic images, and ensure that each image is linked with a patient. They should also implement policies for monitoring and ensuring the timeliness and completeness of procedure reporting.

In addition, endoscopy facilities should implement and monitor the effect of pre-, intra- and post-procedure policies to ensure best practice, as well as document individual scope tracking information and protocols in case of scope contamination.

## Complications

### Reporting for Out-of-Hospital Premises (OHPs)/Independent Health Facilities (IHF)

All facilities should monitor and record in a log:

- Any facility that admits a patient for an unplanned hospitalization within 10 days of an esophagogastroduodenoscopy for any cause (including, but not limited to, uncontrolled upper GI bleeding, perforation, cardiovascular and/or respiratory compromise), whether the procedure was performed in that facility or elsewhere—if the original procedure was performed elsewhere, the need for hospitalization should also be reported back to the original facility, so that it can report the event to the college;
- Any use of reversal agents; and
- Clinically or potentially clinically relevant instrument malfunction, including endoscope, accessories or ancillary equipment (e.g., processor, monitor, lighting, computer and impaction of accessories, including therapeutic accessories, such as snares or a basket) should be reported directly to the nurse manager.

The log of adverse events and reversal agents should be reviewed monthly and quality assurance interventions planned if concerning trends are seen. The impact of interventions should be evaluated, and the results documented and used to inform new initiatives that are, in turn, monitored. A summary of the results should be sent to the Regional Colorectal Screening/GI Endoscopy Lead on a quarterly basis for OHPs, IHFs and hospitals. Results should be reviewed periodically so they can be integrated into quality assurance and quality improvement initiatives.

	Document in a log	Required reporting
<p><b>Tier 1 events are:</b></p> <ul style="list-style-type: none"> <li>• Death on the premises;</li> <li>• Death within 10 days of a procedure performed at the premises;</li> <li>• Any procedure performed on the wrong patient; and</li> <li>• Transfer of a patient from the premises directly to a hospital for care.</li> </ul>	<p>OHPs and IHFs</p> <p>Hospitals, where tier 1 events relate to the procedure being performed</p>	<p>OHPs and IHFs</p>
<p><b>Tier 2 events include, but are not limited to:</b></p> <ul style="list-style-type: none"> <li>• Unscheduled treatment of a patient in a hospital within 10 days of a procedure performed at a premises;</li> <li>• Complications, such as infection, bleeding or injury to other body structures;</li> <li>• Cardiac or respiratory problems during the patient’s stay at the facility;</li> <li>• Allergic reactions; and</li> <li>• Medication-related adverse events.</li> </ul>	<p>OHPs and IHFs</p> <p>Hospitals, where tier 2 events relate to the procedure being performed</p>	<p>OHPs and IHFs</p>

### Patient Satisfaction

The facility should regularly measure patient satisfaction and address issues that they highlight through quality improvement initiatives.

**The working group would like to thank Dr. Catharine Walsh, MD MEd PhD FRCPC, for her contribution to these standards, as well as the members of the Gastroscopy Standards and Indicators Expert Panel.**

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## Appendix 1. Search Strategy and Methodology

Source type	Name
Guideline databases	National Guideline Clearinghouse
	PubMed
	Standards and Guidelines Evidence (SAGE) Repository
Professional association websites  (selection informed by initial results generated through review of guideline databases and PubMed*)	American Gastroenterological Association
	Canadian Association of Gastroenterology
	College of Physicians and Surgeons of Ontario
	Endoscopy Section of the Netherlands Society of Gastroenterology
	Gastroenterological Society of Australia
	Joint Advisory Group on GI Endoscopy (UK)
	Ontario's Quality Management Partnership
	Sociedad Española de Patología Digestiva
	Société Française d'Endoscopie Digestive

\*Note that >5 potentially relevant guidelines from the *American Society for Gastrointestinal Endoscopy* and the *French Society of Digestive Endoscopy* were identified through the initial database search.

### KEYWORDS

Guideline databases—search terms: endosc\* or gastrosc\*

PubMed—search terms: (endosc\* and guidelines) or (gastrosc\* and guidelines)

Professional association websites—scan for terms: (guideline or standard or “quality indicator” or “quality assurance”) and (endosc\* or gastrosc\*)



## Appendix 2. Multidose Vials (Public Health Ontario, 2015)

Outbreaks associated with the use of multidose vials in both the outpatient and inpatient settings are frequent and continue to occur in Ontario. Any error in following protocols for the correct use of multidose vials can result in the transmission of bacterial and blood-borne viral pathogens. Transmission of hepatitis C, hepatitis B and HIV have been associated with the use of multidose vials.

The use of multidose vials for injectable medications and vaccines increases the risk of transmission of blood-borne pathogens and bacterial contamination of the vial and should be avoided. Patient safety should be prioritized over cost when choosing between multidose and single-use medication vials. If multidose vials are selected for use, the following recommendations must be followed each time the multidose vial is used:

- All needles are SINGLE PATIENT USE ONLY.
- All syringes are SINGLE PATIENT USE ONLY.
- NEVER re-enter a vial with a used needle OR used syringe.
- Once medication is drawn up, the needle should be IMMEDIATELY withdrawn from the vial. A needle should NEVER be left in a vial to be attached to a new syringe.
- Use a multidose vial for a single patient whenever possible and mark the vial with the patient's name.
- Mark the multidose vial with the date it was first used and ensure that it is discarded at the appropriate time.
- Adhere to aseptic technique when accessing multidose vials. Multidose vials should be accessed on a surface that is clean and where no dirty, used or potentially contaminated equipment is placed or stored. Scrub the access diaphragm of vials using friction and 70 per cent alcohol. Allow to dry before inserting a new needle and new syringe into the vial.
- Discard the multidose vial immediately if sterility is questioned or compromised or if the vial is not marked with the patient's name and original entry date.
- Review the product leaflet for recommended duration of use after entry of the multidose vial. Discard opened multidose vials according to the manufacturer's instructions or within 28 days, whichever is shorter\*.

\* Exceptions can be considered for multidose vials used for a single patient (e.g., allergy shots) if the manufacturer's instructions state that the vial can be used for longer than 28 days. All of the above steps must be followed and the vial must only be used for a single patient.

## Appendix 3. Indications and Contraindication for Esophagogastroduodenoscopy (EGD) (Adapted from American Society for Gastrointestinal Endoscopy, 2014)

### 1. EGD is generally indicated for evaluating:

- Upper abdominal symptoms that persist despite an appropriate trial of therapy
- Upper abdominal symptoms associated with other symptoms or signs suggesting serious organic disease (e.g., anorexia and weight loss) or in patients ages 45 years and older
- Dysphagia or odynophagia
- Esophageal reflux symptoms that are persistent or recurrent despite appropriate therapy
- Persistent vomiting of unknown cause
- Other diseases in which the presence of upper GI pathology might modify other planned management (e.g., patients who have a history of ulcer or GI bleeding who are scheduled for organ transplantation, long-term anticoagulation or chronic nonsteroidal anti-inflammatory drug therapy for arthritis, and those with cancer of the head and neck)
- Familial adenomatous polyposis syndromes
- For confirmation and specific histologic diagnosis of radiologically demonstrated lesions:
  - Suspected neoplastic lesion
  - Gastric or esophageal ulcer
  - Upper tract stricture or obstruction
- GI bleeding:
  - In patients with active or recent bleeding
  - For presumed chronic blood loss and for iron deficiency anemia when the clinical situation suggests an upper GI source, or when colonoscopy result is negative
- When sampling of tissue or fluid is indicated
- In patients with suspected portal hypertension to document or treat esophageal varices
- To assess acute injury after caustic ingestion
- Treatment of bleeding lesions such as ulcers, tumours, vascular abnormalities (e.g., electrocoagulation, heater probe, laser photocoagulation or injection therapy)
- Banding or sclerotherapy of varices
- Removal of foreign bodies
- Removal of selected polypoid lesions
- Placement of feeding or drainage tubes (peroral, percutaneous endoscopic gastrostomy or percutaneous endoscopic jejunostomy)
- Dilation of stenotic lesions (e.g., with transendoscopic balloon dilators or dilation systems by using guidewires)
- Management of achalasia (e.g., botulinum toxin, balloon dilation)
- Palliative treatment of stenosing neoplasms (e.g., laser, multipolar electrocoagulation, stent placement)
- Endoscopic therapy for intestinal metaplasia
- Intraoperative evaluation of anatomic reconstructions typical of modern foregut surgery (e.g., evaluation of anastomotic leak and patency, fundoplication formation, pouch configuration during bariatric surgery)
- Management of operative adverse events (e.g., dilation of anastomotic strictures, stenting of anastomotic disruption, fistula or leak in selected circumstances)

### 2. EGD is generally not indicated for evaluating:

- Symptoms that are considered functional in origin (there are exceptions where an endoscopic examination may be done once to rule out organic disease, especially if symptoms are unresponsive to therapy)
- Metastatic adenocarcinoma of unknown primary site when the results will not alter management
- Radiographic findings of:
  - Asymptomatic or uncomplicated sliding hiatal hernia
  - Uncomplicated duodenal ulcer that has responded to therapy
  - Deformed duodenal bulb when symptoms are absent or respond adequately to ulcer therapy

3. Sequential or periodic EGD may be indicated if surveillance is required for malignancy in patients with premalignant conditions (e.g., Barrett's esophagus)

4. Sequential or periodic EGD is generally not indicated for:

- Surveillance for malignancy in patients with gastric atrophy, pernicious anemia or prior gastric operations for benign disease, but if a patient is from Japan with high risk of gastric cancer, they should be scoped
- Surveillance of healed benign disease, such as esophagitis or gastric or duodenal ulcer
- Surveillance during repeated dilations of benign strictures, unless there is a change in status
- Surveillance for patients with benign fundal polyps

5. Indications for patients with gastroesophageal reflux disease (GERD)

- GERD symptoms that are persistent or progressive despite appropriate medical therapy
- Dysphagia or odynophagia
- Involuntary weight loss greater than five per cent
- Evidence of GI bleeding or anemia
- Finding a mass, stricture or ulcer on imaging studies
- Screening for Barrett's esophagus in selected patients (as clinically indicated)
- Persistent vomiting (seven to 10 days)
- Evaluation of patients before or with recurrent symptoms after endoscopic or surgical antireflux procedures
- Placement of wireless pH monitoring

## Appendix 4. Antithrombotic Management (Adapted from Spyropoulos and Douketis, 2012)

Risk category	MHV	Atrial fibrillation	VTE
High (>10%/y risk of ATE or > 10%/mo risk of VTE)	Any mechanical mitral valve	CHADS <sub>2</sub> score of 5 or 6	Recent (<3 mo) VTE
	Caged-ball or tilting disc valve in mitral/aortic position	Recent (<3 mo) stroke or TIA	Severe thrombophilia
			Deficiency of protein C, protein S or antithrombin
	Recent (<6 mo) stroke or TIA	Rheumatic valvular heart disease	Antiphospholipid antibodies
			Multiple thrombophilias
Intermediate (4%–10%/y risk of ATE or 4%–10%/mo risk of VTE)	Bileaflet AVR with major risk factors for stroke	CHADS <sub>2</sub> score of 3 or 4	VTE within past 3–12 mo
			Recurrent VTE
			Nonsevere thrombophilia
			Active cancer
Low (<4%/y risk of ATE or <2%/mo risk of VTE)	Bileaflet AVR without major risk factors for stroke	CHADS <sub>2</sub> score of 0–2 (and no prior stroke or TIA)	VTE >12 mo ago

TIA: transient ischemic attack, AVR: aortic valve replacement, ATE: arterial thromboembolism, VTE: venous thromboembolism, MHV: mechanical heart valve

For more information on CHADS<sub>2</sub> score please see the following:

Broderick JP, Bonomo JB, Kissela BM, et al. Withdrawal of antithrombotic agents and its impact on ischemic stroke occurrence. *Stroke* 2011 Sep;42:2509-14.

Gage BF, Waterman AD, Shannon W, et al. Validation of clinical classification schemes for predicating stroke: results from a national registry of atrial fibrillation. *JAMA* 2001 Jun 13; 285 (22):2864-70.

Kwok A, Faigel DO. Management of anticoagulation before and after gastrointestinal endoscopy. *Am J Gastroenterol* 2009 Dec; 104:3085-97.

## Appendix 5. Overview of Recommended Maximal Wait Times by Acuity Category (Adapted from Paterson et al., 2006)

### Within 24 hours:

- Acute gastrointestinal bleeding;
- Esophageal food bolus or foreign body obstruction;
- Clinical features of ascending cholangitis;
- Severe acute pancreatitis (endoscopic retrograde cholangiopancreatography within 72 hours if indicated);
- Severe decompensated liver disease; or
- Acute severe hepatitis.

### Within two weeks:

- High likelihood of cancer based on imaging or physical examination;
- Painless obstructive acute jaundice;
- Severe and/or rapidly progressive dysphagia or odynophagia; or
- Clinical features suggestive of active inflammatory bowel disease.

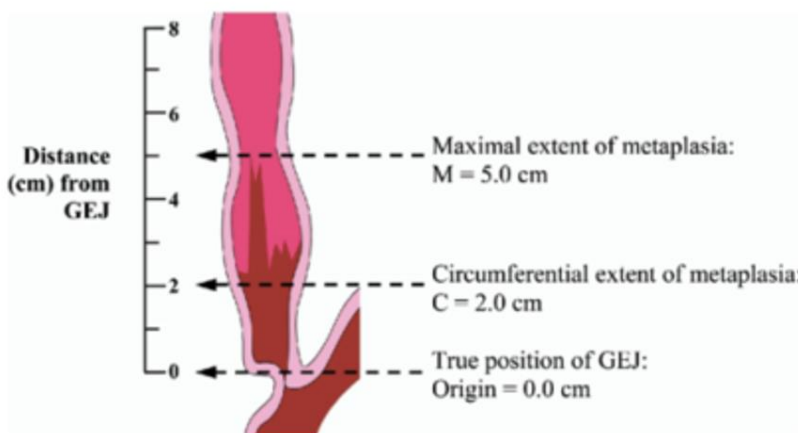
### Within two months:

- Bright red rectal bleeding;
- Documented iron deficiency anemia;
- One or more positive fecal occult blood tests;
- Chronic viral hepatitis;
- Stable dysphagia (not severe);
- Poorly controlled reflux/dyspepsia;
- Chronic constipation or chronic diarrhea;
- New onset change in bowel habit;
- Chronic unexplained abdominal pain; or
- Confirmation of a diagnosis of celiac disease (antibody test).

### Within six months:

- Chronic gastroesophageal reflux disease for screening endoscopy;
- Screening colonoscopy; or
- Persistent (more than six months) unexplained abnormal liver enzyme tests.

## Appendix 6. Barrett's Esophagus: The Prague C&M Criteria (Adapted from Sharma et al., 2006)



C: extent of circumferential metaplasia, M: maximal extent of the metaplasia (C plus a distal “tongue” of 3 cm), GEJ: gastroesophageal junction

## Appendix 7. Required Endoscopy Report Elements (Adapted from Canadian Association of Gastroenterology, 2012)

- Type of procedure
- Date and time of procedure
- Name of endoscopist, including name of trainee and supervisor
- Name(s) of assistant(s)
- Age and sex of patient
- Indication(s) for procedure (consistent with guidelines for appropriate indications)
- Comorbidities
- Management of antithrombotic therapy, if applicable
- Type and dose of sedation used, including incremental dose adjustments
- Other medication and related information (e.g., administration route, reversal agents, antispasmodics, allergies)
- Extent and completeness of examination (confirmed by independent observer and/or photodocumentation, retroflexion manoeuvres)
- Relevant findings, using relevant, standardized descriptions and validated scales
- Pertinent negatives, using relevant, standardized descriptions and validated scales
- Adverse events and resulting interventions, using relevant, standardized descriptions and validated scales
- Patient comfort, using formal descriptors and, if possible, a validated scale
- Diagnoses, using standard terminology and validated scales
- Endoscopic interventions performed, using standard terminology and descriptors
- Details of pathology specimens (number and location of biopsies; numbers, size and location of polyps)
- Details of follow-up arrangements (identify person responsible for booking further tests and follow-up)
- Appended pathology report(s), when available (requires reconciliation of endoscopy and pathology reports)
- Management recommendations, including medication, tests and follow-up
- Information provided to patient and/or family (description of findings, contact details in the event of an emergency)

## Appendix 8. The Los Angeles Classification of Esophagitis (Adapted from Lundell et al., 1999)

Grade	Description
<b>A</b>	1 (or more) mucosal break no longer than 5 mm that does not extend between the tops of 2 mucosal folds
<b>B</b>	1 (or more) mucosal break >5 mm that does not extend between the tops of 2 mucosal folds
<b>C</b>	1 (or more) mucosal break that is continuous between the tops of $\geq 2$ mucosal folds, but that involves <75% of the circumference
<b>D</b>	1 (or more) mucosal break that involves at least 75% of the esophageal circumference



## Appendix 9. Gastroscopy Quality Indicators for Ontario

Domain	Inpatient/Outpatient	Proposed Quality Indicator	
Effectiveness	Inpatients	Frequency with which, unless contraindicated, endoscopic treatment is given to ulcers with active bleeding or with nonbleeding visible vessels	
		Frequency with which achievement of primary hemostasis in cases of attempted hemostasis of upper GI bleeding lesions is documented	
		Frequency with which a second treatment modality is used (e.g., coagulation or clipping) when epinephrine injection is used to treat actively bleeding or nonbleeding visible vessels in patients with bleeding peptic ulcers	
		Frequency with which patients presenting with an acute upper GI bleed are readmitted with recurrent upper GI bleeding within six months	
	Outpatients	Frequency with which six intestinal biopsies are done in patients in whom celiac disease is suspected	
		Frequency with which endoscopic investigation for iron deficiency anemia includes biopsies for celiac disease	
		Frequency with which plans to test for <i>H. pylori</i> infection are documented for patients diagnosed with gastric or duodenal ulcers	
		Frequency with which biopsies are obtained in cases of suspected Barrett's esophagus	
		Frequency with which Barrett's esophagus is appropriately measured when present	
		Frequency with which a complete examination of the esophagus, stomach and duodenum, including retroflexion in the stomach, is conducted and documented	
	Appropriateness	Inpatient and Outpatient	Frequency with which EGD is performed on patients who have had a normal gastroscopy procedure within the past two years

<b>Safety</b>	Inpatient and Outpatient	Frequency with which reversal agents are used
		Frequency with which procedure is interrupted due to concerns over patient safety/instability (e.g., over-sedation, airways management issues)
		Frequency with which delayed adverse events leading to hospitalization, additional procedures or medical interventions occur within 10 days
<b>Timeliness</b>	Inpatients	Frequency with which patients presenting with an acute upper GI bleed receive an endoscopy within 24 hours
	Outpatients	Frequency with which patients referred for dysphagia that is non-responsive to proton pump inhibitors receive an endoscopy within two months
<b>Continuity of care</b>	Inpatient and Outpatient	Frequency with which a standardized and approved procedure report, including a plan for pathology follow-up, is completed
		Frequency with which management of antithrombotic therapy is documented in the procedure report

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