Indicators of safety compromise in gastrointestinal endoscopy

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INTRODUCTION: The importance of quality indicators has become increasingly recognized in gastrointestinal endoscopy. Patient safety requires the identification and monitoring of occurrences associated with harm or the potential for harm. The identification of relevant indicators of safety compromise is, therefore, a critical element that is key to the effective implementation of endoscopy quality improvement programs.

OBJECTIVE: To identify key indicators of safety compromise in gastrointestinal endoscopy.

METHODS: The Canadian Association of Gastroenterology Safety and Quality Indicators in Endoscopy Consensus Group was formed to address issues of quality in endoscopy. A subcommittee was formed to identify key safety indicators. A systematic literature review was undertaken, and articles pertinent to safety in endoscopy were identified and reviewed. All complications and measures used to document safety were recorded. From this, a preliminary list of 16 indicators was compiled and presented to the 35-person consensus group during a three-day meeting. A revised list of 20 items was subsequently put to the consensus group for vote for inclusion on the final list of safety indicators. Items were retained only if the consensus group highly agreed on their importance.

RESULTS: A total of 19 indicators of safety compromise were retained and grouped into the three following categories: medication-related – the need for CPR, use of reversal agents, hypoxia, hypotension, hypertension, sedation doses in patients older than 70 years of age, allergic reactions and laryngospasm/bronchospasm; procedure-related early – perforation, immediate postpolypectomy bleeding, need for hospital admission or transfer to emergency department from the gastroenterology unit, instrument impaction, severe persistent abdominal pain requiring evaluation proven to not be perforation; and procedure-related delayed – death within 30 days of procedure, 14-day unplanned hospitalization, 14-day unplanned contact with a health provider, gastrointestinal bleeding within 14 days of procedure, infection or symptomatic metabolic complications.

CONCLUSIONS: The 19 indicators of safety compromise in endoscopy, identified by a rigorous, evidence-based consensus process, provide clear outcomes to be recorded by all facilities as part of their continuing quality improvement programs.

Key Words: *Digestive system; Endoscopy; Health care; Quality assurance; Surgical complications; Safety*

Les indicateurs d'atteinte à la sécurité en cas d'endoscopie gastro-intestinale

INTRODUCTION : On convient de plus en plus de l'importance des indicateurs de qualité en endoscopie gastro-intestinale. Pour assurer la sécurité des patients, il faut déterminer et surveiller les occurrences associées aux dommages et au potentiel de dommages. Il est donc essentiel de déterminer les indicateurs pertinents d'atteinte à la sécurité pour la mise en œuvre efficace de programmes d'amélioration de la qualité des endoscopies.

OBJECTIF : Déterminer les principaux indicateurs d'atteinte à la sécurité en cas d'endoscopie gastro-intestinale.

MÉTHODOLOGIE : Le groupe consensuel d'indicateurs de la sécurité et de la qualité en endoscopie de l'Association canadienne de gastroentérologie a été formé pour se pencher sur la question de la qualité en endoscopie. Un sous-comité en est issu pour déterminer les indicateurs de sécurité. Il a entrepris une analyse systématique des publications et repéré et analysé les articles pertinents pour la sécurité en endoscopie. Il a consigné toutes les complications et les mesures utilisées pour attester la sécurité. Il en a tiré une liste préliminaire de 16 indicateurs qu'il a compilés et présentés au groupe consensuel de 35 personnesdans le cadre d'une réunion de trois jours. Une liste révisée de 20 points a ensuite été proposée au groupe consensuel qui devait voter pour établir les éléments inclus dans la liste définitive d'indicateurs de sécurité. Les points ont ensuite été retenus seulement si le groupe consensuel convenait grandement de leur importance.

RÉSULTATS : Au total, 19 indicateurs d'atteinte à la sécurité ont été retenus et regroupés dans les trois catégories suivantes : liées à des médicaments – la nécessité d'une RCR, l'utilisation d'agents d'inversion, l'hypoxie, l'hypotension, l'hypertension, les doses de sédation chez les patients de plus 70 ans, les réactions allergiques et le laryngospasme ou le bronchospasme; rapides liées à l'intervention – perforation, hémorragie immédiate après une polypectomie, besoin d'une hospitalisation ou d'un transfert de l'unité de gastroentérologie à l'urgence, enclavement d'instruments, douleur abdominale persistante grave qui exige une évaluation démontrant l'absence de perforation; et tardives liée à l'intervention – décès dans les 30 jours suivant l'intervention, hospitalisation non planifiée au bout de 14 jours, contact non planifié avec un professionnel de la santé au bout de 14 jours, hémorragie gastro-intestinale dans les 14 jours suivant l'intervention, infection ou complications métaboliques symptomatiques.

CONCLUSIONS : Les 19 indicateurs d'atteinte à la sécurité en endoscopie, déterminés par un processus consensuel rigoureux et probant, fournissent des résultats clairs que tous les établissements peuvent consigner dans le cadre de leurs programmes continus d'amélioration de la qualité.

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Gastrointestinal (GI) endoscopy has become increasingly common and important for the diagnosis and treatment of many GI disorders. The central role of colonoscopy in colon cancer screening programs, both in hospital and stand-alone ambulatory facilities, has resulted in a significant increase in the number of procedures performed (1). Most Canadian hospitals provide some level of endoscopy services and stand-alone out-of-hospital facilities have become more common in many regions of Canada.

As a consequence of the growth of GI endoscopy, there is significant variation in service provision, such as choice of medications for sedation, depth of sedation provided, and the training and background of the providers (2). A study from the United Kingdom (UK) (3) demonstrated significant variations in the quality of endoscopy services in different regions. For example, cecal intubation rates ranged from 74.5% at district general hospitals to 89.7% at private hospitals. This recognition prompted a nationwide program to improve and standardize endoscopy services, which has been successful in reducing wait times for endoscopy, improving patient satisfaction with endoscopy services and improving parameters such as colonoscopy completion rates (4,5).

The importance of quality in endoscopy is increasingly recognized worldwide, and efforts are underway in various countries, such as Canada, Australia, the United States and the Netherlands, to adopt nationwide programs for quality improvement (6). The Canadian Association of Gastroenterology (CAG), therefore, formed a committee to systematically review different aspects of endoscopy and quality, with a view to stimulating improvement. This group held a consensus conference in June 2010 and generated a broad range of recommendations, which if adopted, could lead to significant changes in how endoscopy services are provided (7). The present article focuses specifically on the patient safety indicators that were developed. These indicators are applicable to esophagogastroduodenoscopy (EGD), colonoscopy and sigmoidoscopy, but are not intended to encompass advanced endoscopic procedures such as endoscopic retrograde cholangiopancreatography (ERCP) or advanced interventions such as endoscopic mucosal resection.

METHODS

The CAG Safety and Quality Indicators in Endoscopy Consensus Group was led by a steering committee of nine people, and had a total membership of 35 individuals with knowledge on matters related to the provision of endoscopy services, including gastroenterologists, surgeons, gastroenterology nurses, health policy experts and a lawyer. In addition, nine subcommittees were struck to address specific issues in greater detail, including a four-person group that was tasked with reviewing the literature surrounding safety in GI endoscopy and recommending key indicators of safety that all endoscopy units should record and track. The methodology behind the consensus group process has been described elsewhere (7). The present article will focus specifically on the identification and endorsement of safety indicators.

Literature search

The steering committee performed a systematic search of PubMed from 1990 using the following search terms: "diagnostic errors/adverse events", "diagnostic errors/standards safety", "adverse events", "complications", "mortality", "colonoscopy", "quality of health care", "quality control", "colorectal neoplasms", "rectal neoplasms", "adenomatous polyps", "colonic polyps", "intestinal polyps", "digestive system neoplasms" and "diagnosis". Additional searches using the same search terms were used to identify relevant abstracts from the American Gastroenterology Association Digestive Disease Week 2007, 2008 and 2009, and United European Gastroenterology Week 2007 and 2008.

A total of 2475 citations were identified and assigned in batches to pairs of assessors who identified relevant articles for retention. All conflicts were resolved by consensus. After two rounds of review, 817 articles were retained and made available to the entire consensus group on a web portal. The subcommittee on safety searched this database of articles to identify articles that specifically dealt with safety issues. The references from those articles were reviewed to identify other important articles, and additional electronic searches of PubMed were performed as necessary. The subcommittee used the articles to determine the range of safety compromise indicators that could be considered for collection for systematic monitoring as part of a quality improvement program.

Consensus conference and voting

The entire 35-person committee met for a three-day consensus conference in June 2010. During this meeting, the safety compromise indicators identified by the safety subcommittee were presented and thoroughly discussed during a plenary session. Following discussion, the initial list of indicators was revised, after which the entire group voted on each safety compromise indicator with respect to its importance and whether it should be recommended as a measurable indicator by all endoscopy facilities. This voting process occurred via a web portal over a one-week period in September 2010. Respondents were asked to indicate their level of agreement with each item being an indicator of safety in endoscopy using a 6-point Likert scale (disagree strongly, disagree moderately, disagree slightly, agree slightly, agree moderately, agree strongly). Items were retained only if at least 80% of the consensus group agreed that they were appropriate for inclusion as safety indicators (a vote of either agree slightly, agree moderately or agree strongly). The voting results determined the final selection of safety compromise indicators.

RESULTS

Literature search and consensus

A report from an American Society of Gastrointestinal Endoscopy (ASGE) workshop was the only article identified that dealt with the broad issue of how endoscopic adverse events (AEs) should be identified and defined (8). This article was instrumental in determining how AEs were considered and classified. The committee adopted the definition of an AE proposed by the authors: "An event that prevents completion of the planned procedure and/or results in admission to hospital, prolongation of existing hospital stay, another procedure (needing sedation/anesthesia) or subsequent medical consultation". This was in distinction to an 'incident,' which is a minor occurrence that does not affect care. The authors suggested that attribution of AEs to the endoscopic procedure should be determined and that a classification of severity should be recorded. It was also recommended that endoscopy units record risk factors for AEs, such as patient age and the degree of procedural difficulty. These points are summarized in Table 1.

The above definition of an endoscopic AE falls within Accreditations Canada's more general definition of an AE, as an "unexpected and undesirable incident directly associated with the care or services provided to the client" (9). Sentinel events are a subset of AEs that "lead to death or major and enduring loss of function for a recipient of healthcare services". Thus, not all AEs are considered to be sentinel events; furthermore, not all reportable incidents are considered to be AEs. A near miss is an "event or situation that could have resulted in an accident, injury or illness to a client but did not, either by chance or through timely intervention". Based on these definitions, Accreditation Canada notes that a reporting system for AEs, sentinel events and near misses may be part of a larger incident reporting system, the aim being to learn from these incidents and prevent recurrences (9).

All other articles were observational studies that measured the rates of various AEs of interest to those authors or case reports of uncommon AEs. The majority of articles addressed AEs following colonoscopy (10-33). Articles that described complications from EGD (34-38) and sigmoidoscopy (39-41) were also identified.

The safety subcommittee identified 16 indicators of safety compromise from the literature review, which were grouped into three categories: medication-related, procedure-related early, and procedure-related delayed (Table 2). At the consensus conference, there was general agreement about the importance of each of these items.

TABLE 1
Factors to consider when developing an adverse event reporting system

Definitions
Adverse event: An event that prevents completion of the planned procedure and/or results in admission to hospital, prolongation of existing hospital stay, another procedure (needing sedation/anesthesia) or subsequent medical consultation
Incident: An unplanned event that does not interfere with completion of the planned procedure or change the plan of care
Attribution
Definite
Probable
Possible
Unlikely
Severity
Mild (eg, procedure aborted, unplanned hospital admission ≤3 nights)
Moderate (eg, unplanned anesthesia, unplanned hospital admission 4–10 nights)
Severe (eg, unplanned hospital admission >10 nights, ICU admission >1 night)
Fatal

ICU Intensive care unit. Data from reference 8

TABLE 2
Initial list of safety compromise indicators in gastrointestinal endoscopy

Safety compromise indicator
Medication related
Need for cardiopulmonary resuscitation
Unplanned use of reversal agents
Allergy
Laryngospasm/bronchospasm
Hypoxia (oxygen saturation <85%)
Hypotension (blood pressure <90/50 mmHg or <20% of baseline)
Hypertension (blood pressure >190/130 mmHg or >20% of baseline)
Procedure-related early
Perforation
Immediate postpolypectomy bleeding
Impaction of instrument
Malfunction of instrument
Procedure-related delayed
Delayed postpolypectomy bleeding
Unplanned 14-day hospitalization
Infection (including transmission of viruses)
30-day mortality
Bowel preparation-related complications

The group discussion about 'unplanned use of reversal agents' identified several issues that necessitated revision of this indicator. From the literature review, it was evident that reversal agents are used in some facilities to hasten patient recovery and discharge; such an intervention would be planned and would not necessarily indicate a sedation-related AE (2). However, the group considered that this practice was rare and, furthermore, that it was potentially unsafe. Consequently, this indicator was modified to address any 'use of reversal agents,' regardless of whether it was planned. An additional indicator – 'sedation dosages in patients older than 70 years' – was created to reflect the increased risk in this important subgroup (26).

After discussion of 'bowel preparation-related complications,' the group believed it was appropriate to include bowel preparation-related AEs as part of a broader category of general metabolic complications. This indicator was revised to reflect this: 'Symptomatic metabolic complications (symptomatic hypo/hyperglycemia, symptomatic electrolyte disturbance)'.

TABLE 3
Results of vote by the consensus group on each indicator of safety compromise

Indicator	Agreement, %
Medication related	
Need for cardiopulmonary resuscitation	97.2
Use of reversal agents	88.6
Hypoxia (oxygen saturation <85%)	88.6
Hypotension (BP <90/50 mmHg or ≤20% of baseline)	88.6
Hypertension (BP >190/130 mmHg or ≥20% of baseline)	80.0
Sedation doses in patients older than 70 years	82.8
Allergic reactions	80.0
Laryngospasm/bronchospasm	80.0
Procedure-related early	
Perforation	100.0
Immediate postpolypectomy bleeding	94.3
Need for admission or transfer to the emergency department from the gastroenterology unit for any reason other than underlying GI condition	94.3
Impaction of instrument	94.3
Severe persistent abdominal pain requiring further evaluation and proven not to be perforation	91.4
Procedure-related delayed	
Death within 30 days of procedure	94.3
Unplanned hospitalization occurring within 14 days of the procedure	94.3
Unplanned contact with health provider occurring within 14 days of the procedure	91.4
Gastrointestinal bleeding occurring within 14 days of the procedure	88.6
Infection – including acute and chronic infections	88.6
Symptomatic metabolic complication (hypo or hyperglycemia, electrolyte disturbance)	80.0
Malfunction of instrument	77.1

BP Blood pressure; GI Gastrointestinal

After review of the initial 16 indicators, three additional indicators: 'unplanned physician contact or visit within 14 days'; 'severe persistent abdominal pain requiring further evaluation and not proven as perforation'; and 'need for admission or transfer to the emergency department (ED) from the GI unit for any reason other than underlying GI condition', were developed to ensure that postprocedure abdominal pain be recorded specifically (42) and to ensure that any unplanned physician contact be captured.

After the main consensus conference, 20 safety compromise indicators, revised to reflect group consensus, were presented via the web portal, enabling all participants to vote on the importance of each indicator and on their agreement with the need for each indicator to be recorded by all endoscopy facilities (Table 3). Consensus (at least 80% of the group agreed with the statement) was achieved for all safety compromise indicators except 'malfunction of instrument'. Each safety compromise indicator is discussed in detail below.

SAFETY COMPROMISE INDICATORS

Medication-related

Need for cardiopulmonary resuscitation: The need to initiate cardiopulmonary resuscitation (CPR), either to treat ventilatory or circulatory impairment, is a serious AE (8). The best available data indicate that it occurs infrequently, at a rate of 6.3 per 100,000 endoscopic procedures (20).

Use of reversal agents; sedation dosages in patients older than 70 years of age: Reversal agents, such as flumazenil and naloxone, are used to antagonize the sedative effects of benzodiazepines and opiates,

respectively. Their use is indicative of excess patient sedation and, therefore, constitutes an AE (20). A national study of cardiopulmonary events following GI endoscopy in the United States found reversal agents were required in 490 per 100,000 endoscopic procedures (20). An observational study of GI endoscopy services in 21 European centres found reversal agents were used in 7.7% of procedures, although in the majority of cases, its planned use was to hasten patient recovery (2). The consensus group agreed that the planned use of these agents to expedite patient recovery is not consistent with best practice, and is not advised due to the possibility of rebound sedation as the effect of the antagonist drug wanes with the patient no longer under observation.

Elderly patients are at greater risk for oversedation and sedation-related AEs. A prospective cohort study showed that patient age >70 years is a significant risk factor for prolonged recovery after GI endoscopy (25). A study of cardiopulmonary events in the United States found increasing patient age to be an independent risk factor, with patients >60 years of age almost twice as likely to experience an AE (20). Comorbidity, as measured by the American Society of Anesthesia (ASA) classification, was also a predictor of unplanned events (20).

A study of 1818 deaths in the United Kingdom within 30 days of GI endoscopy found associations between higher sedation doses and the need to administer flumazenil, and between flumazenil administration and patient death (26). The investigators also noted that for the same dose of midazolam (5 mg), flumazenil was more often required for patients >70 years of age (up to 8% of cases) compared with younger patients (<3% of cases) (26).

Based on these data, the consensus group agreed that the use of reversal agents should be included as an indicator of safety compromise. The group also agreed that sedation doses in the elderly (patients >70 years of age) should be specifically monitored. The optimal sedation dose in this patient population is not known, but through measurement and comparison with other units, an endoscopy unit will be able to monitor how their practice compares with other units, which may enable discrepant practices to be identified, reviewed and improved.

Hypoxia

Hypoxia during GI endoscopy may be mild and transient, or severe and prolonged. There is no universally recognized threshold or definition for hypoxia in GI endoscopy. The consensus group elected to use the definition of hypoxia proposed by the ASGE of oxygen saturation <85% (8). It is recognized that some units may choose to use a higher threshold, such as 90%.

An American study of 327,737 procedures at 81 centres (20) provides the most up to date and comprehensive data regarding cardiopulmonary events. In that study, transient hypoxia occurred at a rate of 240 per 100,000 EGDs and 230 per 100,000 colonoscopies. Transient hypoxia occurred most frequently during ERCP (700 per 100,000 cases). In contrast, prolonged hypoxia was uncommon, occurring at a rate of 21 per 100,000 EGDs and 7.8 per 100,000 colonoscopies. The specific definitions of both 'transient' and 'prolonged' hypoxia were not stated.

The risk of clinical sequelae due to hypoxia is not clear (43). Moreover, the effects of mild and transient hypoxia are believed to be minimal (8). However, it has been shown that intraprocedure hypoxia is associated with a greater risk of postprocedural events and prolonged recovery time (25).

Most instances of hypoxia during GI endoscopy will be considered 'incidents' (unplanned events that do not interfere with completion of the procedure or change the plan of care) rather than AEs. Endoscopy units may or may not decide to record episodes of hypoxia that are classified as incidents. However, Cotton et al (8) suggested that incidents be recorded by endoscopy facilities as part of comprehensive quality improvement to determine whether incidents predict subsequent AEs (8); the consensus group agreed with that position.

Hypotension; hypertension

Minor changes in blood pressure may be noted during endoscopy, but require no intervention. However, marked changes in blood pressure may prevent completion of the procedure, require clinical management and have clinical consequences. The optimal threshold or definition of both hypotension and hypertension in the setting of GI endoscopy is not clear. The group elected to use the definition proposed by the ASGE – hypotension <90/50 mmHg or down 20% from baseline; hypertension >190/130 mmHg or up 20% from baseline (8).

A large American study of cardiopulmonary events during GI endoscopy (20) found that hypotension was fairly common, occurring at a rate of 150 per 100,000 EGDs and 480 per 100,000 colonoscopies. Hypertension occurred in 22 and 21 of 100,000 EGDs and colonoscopies, respectively. Hypertension occurred more frequently during ERCP – at a rate of 116 per 100,000 cases. The clinical consequences of these events were not reported.

The consensus group agreed that hypotension and hypertension should be included in the list of safety indicators (with a stronger level of agreement for hypotension). However, it was recognized that most events would be classified as incidents rather than AEs. It was agreed that recording instances of hypotension and hypertension would serve as a general indicator of quality that might enable analysis to determine whether such cases were associated with significant AEs subsequently.

Allergic reactions; laryngospasm/bronchospasm

The United States study of cardiopulmonary events (20) found that respiratory distress occurred during EGD at a rate of 48 per 100,000, and during colonoscopy at a rate of 13 per 100,000 procedures. Wheezing and tracheal compression were rare, occurring in no more than three cases per 100,000 (20). However, it was noted by the ASGE that when such events (including allergic reactions, laryngospasm and bronchospasm) occur as the result of drug administration for the purpose of GI endoscopy, they must be recorded as AEs (8). This principle may be extended to other adverse drug reactions, such as disinhibition caused by benzodiazepines.

Procedure-related early

Perforation: Perforation of the GI tract is perhaps the most significant endoscopic complication. Although the majority of studies investigated the perforation rate for colonoscopy (10-17,19,22-24), articles regarding perforation during EGD (34,35) and sigmoidoscopy (39) were also identified. The key findings are summarized in Table 4.

The rate of perforation during colonoscopy varied among studies, and was as high as one in 769 cases (3). A recent meta-analysis of 17 studies and 274,265 colonoscopies (13) reported an overall perforation rate of 0.035% (95% CI 0.019% to 0.05%) (one in 2857). The perforation rate for therapeutic colonoscopy was 0.066% (95% CI 0.025% to 0.108%) (one in 1515), compared with a rate of 0.017% (95% CI 0.007% to 0.027%) (one in 5882) for diagnostic colonoscopy. The article noted a trend toward lower perforation rates in more recent studies, suggesting improving safety over time (13). This might reflect improvements in training, technique and endoscopic equipment.

A systematic review of articles published between 2000 and 2008 identified 15 studies comprising 491,311 colonoscopies (14). The overall perforation rate was 0.07% (one in 1428), with the perforation rate for therapeutic colonoscopy at 0.1% (one in 1000).

Certain patient- and procedure-related risk factors for perforation were noted in many studies, and included polypectomy (11,13-15), older age (11,14,16), sex (both male [11] and female [14]), comorbidity (14,16), diverticulosis (14), obstruction as an indication for colonoscopy (14,16), invasive procedures other than polypectomy (eg, submucosal injection, foreign body removal) (16) and having the procedure performed by a low-volume endoscopist (endoscopist performing fewer than 200 to 300 colonoscopies annually) (10,11).

A Canadian study examined 13,792 EGDs and found no perforations for diagnostic procedures, but a perforation rate of 0.15% (one in 667) for therapeutic procedures (34). Similarly, in a study of 10,236 EGDs performed in pediatric patients (35), no perforations were identified. Studies performed several decades ago, when the medical profession first adopted EGD as a diagnostic tool, reported perforation rates as high as 0.11% (one in 909) (44) and 0.03% (one in 3333) (38).

Perforation as a result of flexible sigmoidoscopy occurs rarely. A review published in 1996 (40) reported a rate of one per 10,000 sigmoidoscopies. A more recent study (41) found only two cases of perforation in 49,501 sigmoidoscopies, indicating a perforation rate of approximately one in 25,000. Levin et al (39) examined the complications of sigmoidoscopy when used exclusively for cancer screening, and identified two perforations out of 109,534 sigmoidoscopies.

Immediate postpolypectomy bleeding

Bleeding after polypectomy may not occur for days, or it may occur immediately during the procedure. Most studies have focused on delayed bleeding (10-12) because most cases of immediate postpolypectomy bleeding are controlled at the time of the procedure and do not affect its completion. It is not clear whether immediate postpolypectomy bleeding that is controlled endoscopically is of clinical consequence. Some authors have suggested that even cases in which immediate hemostasis was achieved might represent important events and may be risk factors for subsequent adverse bleeding events (8).

A prospective, multicentre, observational study identified 5152 polypectomy patients who had a total of 9336 polyps ≥5 mm in size removed endoscopically (18). Immediate postpolypectomy bleeding (persisting at least 30 s) occurred in 2.6% of all patients, but only 0.4% of all polypectomy patients experienced immediate bleeding that required endoscopic therapy. Risk factors independently associated with immediate bleeding were the following: age ≥65 years; cardiovascular or renal disease; anticoagulant use; polyp >1 cm in size; pedunculated polyps; poor bowel preparation; use of cutting current for polypectomy; and inadvertently cutting the polyp without applying electrocautery. The authors also noted an increased risk of delayed bleeding in patients who experienced immediate postpolypectomy bleeding (18).

Therefore, although most immediate postpolypectomy bleeding is mild or controlled at the time of endoscopy, it does represent a significant event, may be a risk factor for subsequent bleeding and should be recorded.

Need for admission/transfer to the ED

Some patients are transferred to the ED for further management after completion of the endoscopic procedure. The group believed that if this was part of the ongoing management of the patient's underlying GI illness (eg, hospital admission for severe Crohn's disease, assessment by surgical service for colon cancer), it should not be recorded as an AE. However, all other instances of transfer to the ED should be recorded as an AE. Such instances may overlap with other AEs (eg, allergic reaction, need for CPR, etc) but will serve as another method to ensure important events are identified.

Impaction of instrument

Impaction of an instrument may occur during GI endoscopy, most commonly a snare during polypectomy (16,22,45). The results of the literature review did not allow for an estimate of the incidence of instrument impaction, but it appears rare. However, it is clearly an important event when it occurs and may necessitate surgical therapy (16).

Severe, persistent abdominal pain proven not to be perforation, but requiring further evaluation

Abdominal pain is common following colonoscopy. In one randomized trial using insufflation with room air (42), 45% and 31% of patients had abdominal pain at 1 h and 6 h postcolonoscopy, respectively. Abdominal pain usually resolves; however, for some patients, it persists to the point that medical attention is required (12,23). The source of pain may be identified as perforation, but if not, the pain is often attributed to gaseous tension caused by air insufflation (42). Other patients with persistent postcolonoscopy pain experience postpolypectomy syndrome (serosal irritation and localized peritonitis due to transmural effects of electrocautery) (12). Such patients usually require hospitalization and management with antibiotics and, if necessary, surgical intervention.

TABLE 4
Summary of complications of colonoscopy, flexible sigmoidoscopy and esophagoduodenoscopy (EGD)

Procedure (reference), year	n	Perforation	Hemorrhage	Procedure-related mortality
Colonoscopy (12), 2010	21,375	0.019 (1 in 5344)	0.16 (1 in 629)	0
Colonoscopy (13), 2009	274,265	0.035 (1 in 2857)	–	–
Colonoscopy (14), 2009	491,311	0.07 (1 in 1428)	–	–
Colonoscopy (15), 2009	277,434	0.082 (1 in 1219)	–	–
Colonoscopy (10), 2009	24,509	0.12 (1 in 847)	0.086 (1 in 1162)	–
Colonoscopy (11), 2008	97,091	0.085 (1 in 1176)	0.164 (1 in 610)	0.0074 (1 in 13,513)
Colonoscopy (16), 2006	16,318	0.09 (1 in 1111)	0.5 (1 in 208)	0.006 (1 in 16,318)
Colonoscopy (3), 2004	9223	0.13 (1 in 769)	0.065 (1 in 1537)	0.065 (1 in 1537)
Colonoscopy (23), 2002	3196	0	0.22 (1 in 455)	–
Sigmoidoscopy (14), 2009	109,614	0.04 (1 in 2382)	–	–
Sigmoidoscopy (39), 2002	109,534	0.0018 (1 in 54,767)	0.0082 (1 in 12,170)	0
Sigmoidoscopy (41), 2000	49,501	0.004 (1 in 24,750)	–	0
EGD (35), 2007	10,236	0	0.27 (1 in 366)	0
EGD (34), 2004	13,792	0.06 (1 in 1724)	–	0

Data presented as % unless otherwise indicated

The consensus group agreed that pain after an endoscopic procedure requiring medical evaluation or referral to the ED was a significant AE and should be included as an indicator of safety compromise. Abdominal pain that resolves without the need for medical attention need not be included.

Malfunction of instrument

During any endoscopic procedure, there is potential for instrument malfunction that could prevent completion of the procedure or compromise patient safety. For example, a broken wire could impair colonoscope manoeuverability and increase the risk of perforation if the procedure were to continue. The ASGE group recommended that endoscopy units record instances of instrument malfunction (8). There was very little literature regarding this issue otherwise. When this item was put to the group for vote, the level of agreement did not meet the prespecified level of 80%. Consequently, this item was not retained as one of the recommended safety compromise indicators, although it may be one that some endoscopy units choose to track nevertheless.

Procedure-related delays

Death within 30 days of procedure: Mortality following GI endoscopy is rare but clearly is the most important AE that can occur. A 30-day period following the procedure has been recommended by most authors to ensure capture of events that are delayed, although some have suggested that a 14-day time period was adequate (8). If an AE occurs that leads to death more than 30 days after the endoscopic procedure, than that death should still be recorded.

Many deaths that occur following GI endoscopy are not related to the procedure itself but due to the underlying illness for which the procedure was performed or due to another comorbidity. Therefore, it is critical that each endoscopy unit review each death to determine causation. For example, an American interventional radiology data reporting system, the Heath and Inventory Information for Quality, classifies deaths as related or unrelated to the procedure (8). The National Institutes of Health uses a 4-point scale in which attribution is considered to be definite, probable, possible or unlikely (8). Recording all deaths and then judging attribution is more complicated than only recording deaths that appear to be procedure-related. However, it ensures that unexpected deaths due to endoscopy are identified.

The mortality rate of GI endoscopy appears to be low. In one study of 21,375 outpatient colonoscopies (12), there were three deaths within 33 days; however, none appeared attributable to the procedure. A study from California of 16,318 colonoscopies (16) found only one death attributable to colonoscopy. A larger Canadian study of 67,362 outpatient colonoscopies identified 51 deaths that occurred within 30 days. However, chart review determined that three deaths were probably and two more were possibly colonoscopy-related, yielding a death rate of 0.074 per 1000 (one in 13,513 cases) (11). In a study of colonoscopy in the UK, Bowles et al (3) found a higher mortality rate of one in 1537 cases (3). In that study, it was noted that only 17% of endoscopists had received supervised training, prompting changes in endoscopy training and service delivery, with subsequent improvement in outcomes (4).

The mortality rate for EGD and sigmoidoscopy is lower than that for colonoscopies, such that most studies report a mortality rate of 0% (34,39,41).

Unplanned hospitalization occurring within 14 days of procedure; unplanned health provider contact occurring within 14 days of procedure

Most studies of the complications of GI endoscopy record the hospitalization rate within 14 to 30 days of the procedure. The ASGE workshop group recommended a period of 14 days, given that events later than this are not very likely to be causally related to the procedure (8).

Although perforation and bleeding are the most common complications of GI endoscopy, many other AEs may occur as a consequence of the procedure resulting in the need for hospitalization. Examples of AEs that may occur following colonoscopy include, but are not limited to, angina or myocardial infarction (3,9,21,22), cerebrovascular accident (3,23), cardiac dysrhythmia (23), pneumonia (3,10), thrombophlebitis (23), splenic rupture (29), postpolypectomy syndrome (10,16), diverticulitis (10,16), diabetic ketoacidosis (16), acute renal failure (10) and pulmonary embolism (22).

The consensus group agreed with the inclusion of 14-day unplanned hospitalization as a safety indicator. This item should capture all serious AEs. It was recognized that AEs could occur while preparing for the endoscopic procedure. Examples include renal failure due to bowel preparation or a thrombotic event due to discontinuation of an antiplatelet agent. Such AEs should still be recorded and attributed to the endoscopic procedure.

As outlined above, there are many possible, but uncommon, AEs that may occur after GI endoscopy. Not all require hospitalization (eg, phlebitis at intravenous site), but most require assessment by a health care provider. To ensure that such events are identified in a monitoring system, the group agreed that any unplanned contact with a health care provider (either an in-person visit or communication by another means such as telephone or e-mail) be included as an indicator of safety.

Gastrointestinal bleeding occurring within 14 days of procedure

Bleeding is the most frequent serious AE following colonoscopy and is almost always a result of polypectomy (46). Bleeding may also occur following EGD (35). Although some cases are immediate, most are delayed and require the patient to seek medical attention.

Almost all studies demonstrate that postpolypectomy bleeding is a more common occurrence than perforation. Rabeneck et al (11) found a rate of 1.64 per 1000 colonoscopies in a large population-based study of several Canadian provinces. Other studies have shown similar rates of 2 per 1000 (23), 3.2 per 1000 (16) and 6.4 per 1000 (10). Although most cases can be successfully managed conservatively or endoscopically, postpolypectomy bleeding is considered to be an important AE.

Infection – including acute and chronic infections

Colonoscopy has been implicated in the transmission of both bacterial (47) and viral (48) infections. Although the actual risk is not known, it appears to be very low (49). Moreover, it is believed that adherence to best practices for endoscope reprocessing can essentially eliminate the risk of infectious transmission by endoscopes, whereas deviation from accepted practices may increase the risk (49).

The consensus group believed that infectious transmission by endoscopy was an important safety compromise indicator that should be tracked by units. It was recognized that some infections (such as *Clostridium difficile* colitis) would be easier to identify as being endoscopy related, whereas other infections that might have a delayed presentation and diagnosis (such as hepatitis C) could be more difficult to identify. Not withstanding these challenges, it was believed that units must be vigilant in seeking endoscopy-related infectious complications.

Symptomatic metabolic complications

Colonoscopy requires patients to take a laxative preparation to cleanse the colon before the procedure. There is considerable evidence of associated metabolic derangements such as hypokalemia, hyponatremia, hypocalcemia and renal impairment (27,28). Phosphate-containing preparations have been associated with acute phosphate nephropathy and, as a result, their use is now limited (50). Also, the act of preparing for a colonoscopy may interfere with the control of underlying health problems, most notably, diabetes mellitus (16).

There was insufficient evidence in the literature to recommend that all patients be screened for metabolic abnormalities at the time of endoscopic procedures. However, the consensus group beleived that symptomatic metabolic disturbances constituted important AEs. Many of these events (such as hyperglycemia or dehydration) will be identified in the endoscopy unit at the time of the procedure. However, other events may not become apparent until after the procedure, when patients visit health providers or the local ED.

DISCUSSION

The importance of quality improvement in the provision of GI endoscopy services has been well documented in various countries, such as the UK, and has become increasingly recognized elsewhere, including Canada (3,6). The association of quality measures with important outcomes such as complications and long-term incidence of cancer further highlights their importance (51). This is well recognized for interval colon cancer following colonoscopy (52), and is also true for other events such as post-EGD esophageal and gastric cancer. In one study, 10% of all upper GI malignancies were missed during endoscopy, equivalent to one missed cancer per 536 procedures (53). A key aspect of this process is the recognition of the various AEs that may occur as a result of endoscopy and the importance of individual endoscopy units recording these. It is only through a systematic approach that endoscopy facilities may confidently identify problems and take the necessary actions to improve outcomes.

The purpose of the present project was to reach consensus on the key safety compromise indicators that all endoscopy units should record. We identified 19 indicators based on our literature review and consensus process for which there was strong support. The consensus group followed the same process to identify quality indicators in GI endoscopy, and those results will be published elsewhere.

The next step is to encourage/mandate endoscopy units to prospectively collect information on these indicators as a basis for improving the overall quality of endoscopy service delivery. It is recognized that

TABLE 5
Strategies endoscopy units may use to identify individual safety compromise indicators

Indicator	Patient reports adverse event	Follow-up by staff	Review of hospitalization	Chart review for causation	Prospective data entry
Cardiopulmonary resuscitation				X	X
Reversal agents					X
Hypoxia					X
Hypotension/hypertension					X
Sedation doses					X
Allergy	X	X	X	X	X
Laryngospasm			X	X	X
Perforation	X	X	X	X	X
Immediate bleeding					X
Hospitalization/health care	X	X	X	X	X
Admission/emergency department			X	X	X
Impaction					X
Abdominal pain	X	X	X	X	X
Death		X	X	X	X
Gastrointestinal bleeding	X	X	X	X	X
Infection	X	X	X	X	X
Metabolic	X	X	X	X	X

recording many of these indicators will prove to be challenging. There is no literature regarding which mechanisms are optimal for recording different events. However, it is apparent from the literature review that many different methods may be used. Examples include the following: providing patients with contact information for an individual to whom they can report AEs (23,54); telephone call follow-up by endoscopy unit staff at specified times postprocedure to identify AEs (12,23); prospective entry of all procedure-related data, including AEs, into a database (20,35); tracking hospital admissions within 30 days of the procedure through review of administrative databases (10,11,16,39); and chart review of admissions following the procedure to extract details and determine causation (16,34). This list is not all encompassing, and facilities may already have developed locally applicable solutions. Table 5 summarizes strategies that may be most relevant to each safety indicator. The choice of methods will likely depend on the resources available at each endoscopy unit.

We used best practices to develop these indicators, including an explicit, reproducible search strategy, seeking broad input from a national and international panel of experts with a broad range of expertise, and a sophisticated voting process. We believe that it is unlikely that important safety indicators were missed. However, the list of safety indicators is expected to evolve over time, with items being added, omitted, and modified to reflect current evidence and best practice. The voting results (Table 3) may be useful to units by helping to prioritize items to record.

SUMMARY

We endeavoured to follow a process that was systematic, comprehensive and transparent to identify the important indicators of safety compromise in GI endoscopy, drawing on both the published literature and the experience of a group of health professionals that are involved in various aspects of GI endoscopy. We recommend that every endoscopy unit record and monitor these indicators to ensure best practice and the provision of high-quality care.

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REFERENCES

1. Rex DK, Johnson DA, Anderson JC, Schoenfeld PS, Burke CA, Inadomi JM. American College of Gastroenterology guidelines for colorectal cancer screening 2009. Am J Gastroenterol 2009;104:739-50.
2. Froehlich F, Harris JK, Wietlisbach V, Burnand B, Vader JP, Gonvers JJ. Current sedation and monitoring practice for colonoscopy: An international observational study (EPAGE). Endoscopy 2006;38:461-9.
3. Bowles CJA, Leicester R. Romaya C, Swarbrick E, Williams CB, Epstein O. A prospective study of colonoscopy practice in the UK today: Are we adequately prepared for national colorectal cancer screening tomorrow? Gut 2004;53:277-83.
4. Joint Advisory Group on Gastrointestinal Endoscopy (JAG). The Global Rating Scale. <www.grs.nhs.uk/> (November 18, 2011).
5. Palmer KR. Complications of gastrointestinal endoscopy. Gut 2007;56:456-7.
6. Rabeneck L, Rumble RB, Axler J, et al. Cancer Care Ontario colonoscopy standards: Standards and evidentiary base. Can J Gastroenterol 2007;21(Suppl D):5D-24D.
7. Armstrong D, Barkun A, Bridges R, et al. Canadian Association of Gastroenterology consensus guidelines on safety and quality indicators in endoscopy. Can J Gastroenterol 2012;26:17-31.
8. Cotton PB, Eisen GM, Aabakken L, et al. A lexicon for endoscopic adverse events: Report of an ASGE workshop. Gastrointest Endosc 2010;71:446-54.
9. Accreditation Canada Required Organizational Practices, September 2011. <www.accreditation.ca> (November 18, 2011).
10. Singh H, Penfold RB, DeCoster C, et al. Colonoscopy and its complications across a Canadian regional health authority. Gastrointest Endosc 2009;69:665-71.
11. Rabeneck L, Paszat LF, Hilsden RJ, et al. Bleeding and perforation after outpatient colonoscopy and their risk factors in usual clinical practice. Gastroenterology 2008;135:1899-906.
12. Ko CW, Riffle S, Michaels L, et al. Serious complications within 30 days of screening and surveillance colonoscopy are uncommon. Clin Gastroenterol Hepatol 2010;8:166-73.
13. Abbas Fehmi SM, Choksi N, Saini SD, Elta GH, Schoenfeld PS. Risk of perforation during colonoscopy: A systematic review and meta-analysis. Gastroenterology 2009;136(Suppl 1):210.
14. Panteris V, Haringsma J, Kuipers EJ. Colonoscopy perforation rate, mechanisms, and outcome: From diagnostic to therapeutic colonoscopy. Endoscopy 2009;41:941-51.
15. Arora G, Mannalithara A, Singh G, Gerson LB, Triadafilopoulos G. Risk of perforation from a colonoscopy in adults: A large population-based study. Gastrointest Endosc 2009;69:654-64.

16. Levin TR, Zhao W, Conell C, et al. Complications of colonoscopy in an integrated health care delivery system. Ann Intern Med 2006;145:880-6.
17. Consolo P, Luigiano C, Strangio D, et al. Efficacy, risk factors and complications of endoscopic polypectomy: Ten year experience at a single center. World J Gastroenterol 2008;14:2364-9.
18. Kim HS, Kim TI, Kim WH, et al. Risk factors for immediate postpolypectomy bleeding of the colon: A multicenter study. Am J Gastroenterol 2006;101:1333-41.
19. Luning TH, Keemers-Gels ME, Barendregt WB, Tan AC, Rosman C. Colonoscopic perforations: A review of 30,366 patients. Surg Endosc 2007;21:994-7.
20. Sharma VK, Nguyen CC, Crowell MD, Lieberman DA, de Garmo P, Fleischer DE. A national study of cardiopulmonary unplanned events after GI endoscopy. Gastrointest Endosc 2007;66:27-34.
21. Bilotta JJ, Floyd JL, Wade JD. Arterial oxygen desaturation during ambulatory colonoscopy: Predictability, incidence, and clinical significance. Gastrointest Endosc 1990;36(Suppl 3):S5-8.
22. Robinson MHE, Hardcastle JD, Moss SM, et al. The risk of screening: Data from the Nottingham randomized controlled trial of faecal occult blood screening for colorectal cancer. Gut 1999;45:588-92.
23. Nelson DB, McQuaid KR, Bond JH, Lieberman DA, Weiss DG, Johnston TK. Procedural success and complications of large-scale screening colonoscopy. Gastrointest Endosc 2002;55:307-14.
24. Imai N, Takeda K, Kuzuya T, et al. High incidence of colonic perforation during colonoscopy in hemodialysis patients with end-stage renal disease. Clin Gastroenterol Hepatol 2010;8:55-59.
25. Lugay M, Otto G, Kong M, Mason DJ, Wilets I. Recovery time and safe discharge of endoscopy patients after conscious sedation. Gastroenterol Nurs 1996;19:194-200.
26. Lord D, Bell G, Gray A, Quine A, et al. (2006). Sedation for gastrointestinal endoscopic procedures in the elderly: getting safer but still not nearly safe enough. NCEPOD, 1-14. <www.bsg.org.uk/clinical-guidance/endoscopy/sedation-for-gastrointestinal-endoscopic-procedures-in-the-elderly-getting-safer-but-still-not-nearly-safe-enough.html> (Accessed on March 10, 2011).
27. Russman S, Lamerato L, Marfatia A, et al. Risk of impaired renal function after colonoscopy: A cohort study in patients receiving either oral sodium phosphate or polyethylene glycol. Am J Gastroenterol 2007;102:2655-63.
28. Hookey LC, Depew WT, Vanner S. The safety profile of oral sodium phosphate for colonic cleansing before colonoscopy in adults. Gastrointest Endosc 2002;56:895-902.
29. Jaboury I. Splenic rupture after colonoscopy. Intern Med J 2004;34:652-3.
30. de Graaf P, Slagt C, de Graaf JL, Loffeld RJ. Fatal aspiration of polyethylene glycol solution. Neth J Med 2006;64:196-8.
31. Holm C, Christensen M, Rasmussen V, Schulze S, Rosenberg J. Hypoxaemia and myocardial ischaemia during colonoscopy. Scand J Gastroenterol 1998;33:769-72.
32. Cappell MS. Safety and efficacy of colonoscopy after myocardial infarction: An analysis of 100 study patients and 100 control patients at two tertiary cardiac referral hospitals. Gastrointest Endosc 2004;60:901-9.
33. Davidson ET, Levine M, Meyerowitz R. Ventricular fibrillation during colonoscopy: Case report and review of the literature. Am J Gastroenterol 1985;80:690-3.
34. Misra T, Lalor E, Fedorak RN. Endoscopic perforation rates at a Canadian university teaching hospital. Can J Gastroenterol 2004;18:221-7.
35. Thakkar K, El-Serag HB, Mattek N, Gilger MA. Complications of pediatric EGD: A 4-year experience in PEDS-CORI. Gastrointest Endosc 2007;65:213-21.
36. Rudolph SJ, Landsverk BK, Freeman ML. Endotracheal intubation for airway protection during endoscopy for severe upper GI hemorrhage. Gastrointest Endosc 2003;57:58-61.
37. Lai PJ, Chen FC, Ho ST, Cherng CH, Liu ST, Hsu CH. Unexpected pulmonary aspiration during endoscopy under intravenous anesthesia. Acta Anesthesiol Taiwan 2010;48:94-8.
38. Mandelstam P, Sugawa C, Silvas SE, Silvis SE, Nebel OT, Rogers BH. Complications associated with esophagogastroduodenoscopy and esophageal dilation. Gastrointest Endosc 1976;23:16-9.
39. Levin TR, Conell C, Shapiro JA, Chazan SG, Nadel MR, Selby JV. Complications of screening flexible sigmoidoscopy. Gastroenterology 2002;123:1786-92.
40. Waye JD, Kahn O, Auerbach ME. Complications of colonoscopy and flexible sigmoidoscopy. Gastrointest Clin N Am 1996;6:343-77.
41. Anderson ML, Pasha TM, Leighton JA. Endoscopic perforation of the colon: Lessons from a 10-year study. Am J Gastroenterol 2000;95:3418-22.
42. Sumanac K, Zealley I, Fox BM, et al. Minimizing postcolonoscopy abdominal pain by using CO_2 insufflation: A prospective, randomized, double blind, controlled trial evaluating a new commercially available CO_2 delivery system. Gastrointest Endosc 2002;56:190-4.
43. Ehrenfeld JM, Funk LM, Van Schalkwyk J, Merry AF, Sandberg WS, Gawande A. The incidence of hypoxemia during surgery: Evidence from two institutions. Can J Anesth 2010;57:888-97.
44. Schiller KFCR, Cotton PB, Salmon PR. The hazards of digestive fibre-endoscopy: A survey of British experience. Gut 1972;13:1027.
45. Nivatvongs S. Complications in colonoscopic polypectomy: Lessons to learn from an experience with 1576 polyps. Am Surg 1988;54:61-3.
46. Van Gossum A, Cozzoli A, Adler M, Taton G, Cremer M. Colonoscopic snare polypectomy: Analysis of 1485 resections comparing two types of current. Gastrointest Endosc 1992;38:472-5.
47. Dwyer DM, Klein EG, Istre GR, Robinson MG, Neumann DA, McCoy GA. *Salmonella Newport* infections transmitted by fiberoptic colonoscopy. Gastrointest Endosc 1987;33:84-7.
48. Bronowicki J-P, Venard V, Botte C, et al. Patient-to-patient transmission of hepatitis C virus during colonoscopy. N Engl J Med 1997;337:237-40.
49. Leung JW. Working party report: Care of endoscopes. J Gastroenterol Hepatol 2000;15:G73-7.
50. Gonlusen G, Akgun H, Ertan A, Olivero J, Truong LD. Renal failure and nephrocalcinosis associated with oral sodium phosphate bowel cleansing. Arch Pathol Lab Med 2006;130:101-6.
51. Kaminski MF, Regula J, Kraszewska E, et al. Quality indicators for colonoscopy and the risk of interval cancer. N Engl J Med 2010;362:1795-803.
52. 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;140:65-72.
53. Lassen A, Hallas J, Schaffalitzky De Muckadell OB. The risk of missed gastroesophageal cancer diagnoses in users and nonusers of antisecretory medication. Gastroenterology 2005;129:1179-86.
54. Bair D, Pham J, Seaton MB, Arya N, Pryce M, Seaton TL. The quality of screening colonoscopy in an office-based endoscopy clinic. Can J Gastroenterol 2009;23:41-7.