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Review

How to implement adverse events as a quality indicator in gastrointestinal endoscopy

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Quality improvement through the registration of endoscopy-related adverse events (AEs) has been recognized by major international endoscopy societies as an important quality indicator. The theory behind this is easier to approve than its implementation in daily practice. The results of many valuable attempts have been published in the literature, mainly highlighting the diverse hurdles trying to capture events related to endoscopy and the sedation used for endoscopic procedures. The current review discusses the difficulties encountered attempting to register AEs and incidents related to endoscopic procedures. Government-driven and financed health-care databases with automated coupling of specific data seem the only efficient way to implement endoscopy-related AEs and outcomes on a prospective and complete basis. This will not only allow continuous confidential feedback to endoscopists in relation to the pooled national benchmark data, but also follow-up in time through data-driven credentialing aiming to progressively optimize these benchmark data.

Key words: adverse event, endoscopy, incident, registration

INTRODUCTION

OVER THE PAST few years, major national and international endoscopy societies have developed or endorsed standardized quality improvement measures for endoscopy in general and for specific endoscopic procedures in particular.[1,2] These measures aim to improve the technical quality of the different endoscopic procedures as well as the safety and clinical outcomes for the patients. To define general and specific quality indicators in endoscopy is one thing; however, the numbers tell the tale. To measure and to implement these indicators in daily clinical practice is more of a challenge.

Let us take the well-known example of adenoma detection rate (ADR) in screening colonoscopy. This is generally considered a straightforward and frequently used quality indicator for colonoscopy in daily clinical practice.[3] However, when looking in detail at the American Society for Gastrointestinal Endoscopy/American College of Gastroenterology (ASGE/ACG) guidelines and the European Society of Gastrointestinal Endoscopy/United European Gastroenterology (ESGE/UEG) guidelines, it is not clear what a screening colonoscopy exactly defines.[4] Does it imply only patients aged 50 years and older with an average risk (ASGE/ACG)?[5] Or should all diagnostic colonoscopies performed in patients aged 50 years and older with symptoms such as abdominal pain, change in bowel habit, and positive fecal occult blood test be included, with the exception of emergency colonoscopy, colonoscopy with a specific therapeutic indication, and follow-up colonoscopy to evaluate disease activity in patients with inflammatory bowel disease (ESGE/UEG)?[6] What should be the target ADR in screening colonoscopy and in diagnostic colonoscopy with positive fecal occult blood test (ESGE/UEG)?[6] Should there be a difference in target ADR between male and female patients (ASGE/ACG)?[5] What about the number of adenomas per colonoscopy?[3,7] How do we effectively calculate the ADR because it depends on the colonoscopy report and the pathology report, the latter only available days later? This requires automatically linked endoscopy and pathology databases, if it is to be used in daily clinical practice with implementation of routine endoscopist audit and feedback to improve ADR if necessary.[3,7–10] In many countries, ADR measurement relies on local or even individual initiatives with manual linking of endoscopy and pathology data.[11,12] This is in contrast with national databases providing ADR for each endoscopist on a continuous base.[13] This example illustrates the difficulties of a seemingly easy-to-implement quality indicator such as ADR in daily clinical practice.[2,4,14]

Another even more challenging-to-implement quality indicator is the adverse event (AE) rate related to

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Table 1 Aspects of adverse events (AEs) related to endoscopy to be registered

Definitions	AE type	AE severity	AE timing	Attribution
Adverse event Incident Negative outcome Sequela	Regular AEs • Bleeding • Perforation Specific AEs • Pancreatitis • Postpolypectomy syndrome • Infection transmission • Unlimited . . . Anesthesia-related AEs • Cardiovascular • Pulmonary Anticoagulant-related AEs • Bleeding • Thromboembolic	Minor vs. serious AEs AGREE classification I to V (Table 2)	Preprocedure Intraprocedure Postprocedure • Immediate (<24–48 h) • Late (<14 days) • Delayed (>14 days) • Early (in hospital) • Late (after discharge)	Unlikely Possible Probable Definite

AGREE, adverse events in gastrointestinal endoscopy.

gastrointestinal endoscopy.[15,16] In contrast to ADR, which is a quality indicator for colonoscopy, AE registration is a quality indicator common to all gastrointestinal endoscopy procedures.[17] Although it might seem fairly simple to register endoscopy-related AEs, the current review will highlight the many hurdles encountered when trying to do so.

DEFINITION OF AE

THERE IS A wide range of reported incidences of endoscopy-related AEs, mainly because of a lack of consensus on definitions. When defining endoscopy-related AEs, different aspects need to be considered (Table 1). The type of AE (e.g., perforation, bleeding, cardiorespiratory insufficiency), the AE severity (i.e., minor vs. serious), the timing of the AE (i.e., preprocedure vs. intraprocedure vs. early postprocedure vs. late postprocedure) all need to be taken into account in the AE registry. It starts with the correct definition, which is based on the ASGE lexicon of endoscopy-related AEs.[18] AEs are to be differentiated from incidents, negative outcomes, and sequelae.

The lexicon states that an AE is defined as "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/anaesthesia), or subsequent medical consultation," whereas an incident is "an unplanned event that does not interfere with completion of the planned procedure or change in the plan of care (i.e., does not obey to the stated criteria for AE)."[18] For major events, such as cardiac arrest during an endoscopic procedure, there is no difficulty in understanding that it cannot be considered an incident, but the matter becomes more complex when dealing with minor events or events that can be managed endoscopically during the actual procedure. For example, a drop in arterial blood pressure during the procedure, needing reversal or a vasoconstrictor agent without preventing the completion of the procedure and without sequela on the plan of care, should be considered an incident when referring to the definitions given previously, but in fact it appears in the ASGE AE lexicon list.[18] Bleeding or a perforation that is easily clipped during an endoscopic submucosal dissection procedure, without impacting the outcome or hospitalization duration, will be considered an incident by one but an AE by the other. This differentiation remains vague and is still not standardized in current endoscopic research protocols, increasing the risk of variance in reported AE incidence.[18–21] AEs should also be distinguished from a negative outcome, defined as a failed but yet uncomplicated procedure (i.e., inability to cannulate the papilla during endoscopic retrograde cholangiopancreatography [ERCP]), and from sequela, which is an expected effect resulting from a successful procedure (i.e., esophageal ulcer after variceal band ligation).[22]

Because the currently used definition of AE goes back to the ASGE lexicon of endoscopy-related AEs, there will always be the discussion about what to consider as an AE or an incident for events in the subset range between these two definitions.[18] To avoid further inconsistencies, the ASGE lexicon needs to be fine-tuned and updated based on newly arisen AEs with recently emerged endoscopic procedures.

AE SEVERITY

ADVERSE EVENTS ARE not only characterized by their type, but also by severity, and different grading

systems are used.[18] Overall, AEs are classified into categories of severity ranging from no AE, mild AE, moderate AE, severe AE, and lethal AE. Here, the difficulty lies again within the definition of mild, moderate, and severe. The classification proposed by the ASGE lexicon is based on the need for and the duration of an unforeseen hospitalization after the endoscopic procedure, and on the need for intervention endoscopically, radiologically, or surgically.[18] This classification is open to interpretation, too difficult to use in daily practice and therefore often reduced to minor vs. serious AE (Table 1).[23,24] A more practical ready-to-use method to stratify the severity of AEs is the Clavien-Dindo classification of surgical complications.[25] In this classification, AEs are graded from I to V. Grade I corresponds with incidents, grade II corresponds with AEs needing pharmacological treatment or blood transfusion, grade IIIa requires surgical, radiological, or endoscopic intervention not under general anesthesia, whereas in grade IIIb therapeutic intervention is performed under general anesthesia, grade IVa requires hospitalization in the intensive care unit because of single organ dysfunction, grade IVb because of multiple organ dysfunction, and grade V corresponds to death related to the surgery.[25] This clinically useful classification of surgery-related AEs is widely accepted and even adopted in endoscopic clinical trials.[24,26] It was therefore recently adapted and improved for endoscopy under the name of the adverse events in gastrointestinal endoscopy (AGREE) classification of endoscopy-related AEs (Table 2).[27] The use of a surgical classification for endoscopy-related AEs should not be surprising because therapeutic endoscopy is progressively evolving onto the surgical terrain. This may explain why the Clavien-Dindo classification seems more practical to use than the ASGE lexicon to stratify severity of endoscopy-related AEs.[28,29] In addition, the AGREE classification showed a higher interobserver agreement than the ASGE lexicon to stratify endoscopy-related AEs.[30]

Despite the improved usability of the AGREE classification over the ASGE lexicon of endoscopy-related AE severity, the timing of the AE is not captured in the classification. To define whether the event is attributable to the endoscopic procedure is an important aspect of AE registration.

AE TIMING

AS FOR AE severity, timing of AEs faces different classifications, especially to define postprocedure AE timing (Table 1). This again does not allow standardization and comparison of outcomes of clinical trials. Moreover, the later the AE occurs after the endoscopic procedure, the more difficult the attribution to the actual procedure. For example, the relation of 30-day mortality after placement of a percutaneous endoscopic gastrostomy in patients with serious underlying comorbidity, is not always clearly attributable to either the endoscopic procedure or to the progression of the underlying clinical condition.[31]

According to the ASGE lexicon, AEs can occur preprocedure, intraprocedure (from entering the preparation area through leaving the endoscopy room), postprocedure (up to 14 days), and late (any time after 14 days).[18] For delayed events, the number of days after the procedure should be documented. Recording intraprocedure AEs seems straightforward. However, intraprocedure AEs are prone to interpretation. Let us take bleeding occurring during an endoscopic resection procedure. According to the

Table 2 Adverse events in gastrointestinal endoscopy (AGREE) classification of endoscopy-related adverse events (AEs) according to severity[27]

Grading	Definition
No AE	• A telephone contact with the general practitioner, outpatient clinic, or endoscopy service without any intervention or • Extended observation of the patient after the procedure, <3 h, without any intervention
Grade I	AEs with any deviation of the standard postprocedural course, without the need for pharmacologic treatment or endoscopic, radiologic, or surgical interventions. • Presentation at the emergency department, without any intervention or • Hospital admission (<24 h), without any intervention or • Allowed therapeutic regimens are drugs as antiemetics, antipyretics, analgesics, and electrolytes or • Allowed diagnostic tests: radiology and laboratory tests
Grade II	• AEs requiring pharmacologic treatment with drugs other than those allowed for grade I AEs (e.g., antibiotics, antithrombotics) or • Blood or blood product transfusions or • Hospital admission for more than 24 h
Grade III	AEs requiring endoscopic, radiologic, or surgical intervention
Grade IIIa	• Endoscopic or radiologic intervention
Grade IIIb	• Surgical intervention
Grade IV	AEs requiring intensive care unit/critical care unit admission
Grade IVa	• Single-organ dysfunction (including dialysis)
Grade IVb	• Multiorgan dysfunction
Grade V	Death of the patient

ASGE lexicon, bleeding is defined as an AE in case of hematemesis and/or melena or hemoglobin drop of >2 g.[18] Following this AE definition, bleeding will rarely be documented as an intraprocedure AE, leading to systematic underreporting of intraprocedure bleeding in mucosal resection and submucosal dissection studies. Therefore, other and more realistic definitions of intraprocedure bleeding AEs are suggested in clinical trials: any immediate bleeding episode during the procedure requiring any form of endoscopic hemostasis or oozing for more than 60 s, or simply active bleeding during endoscopic submucosal dissection.[19,32] These definitions correspond better to intraprocedure bleeding in daily clinical endoscopy practice, although they still leave room for personal interpretation to consider the bleeding as an AE or an incident.

Postprocedure AE registration usually divides the timing into immediately after the endoscopic procedure (within 24–48 h), late (up to 14 days), and delayed (up to 28–30 days or longer).[18] For practical reasons, the postprocedure period may also be divided into early (during recovery after the procedure) and late (after the patient is discharged from the recovery room), especially when dealing with an outpatient setting.[33] In the ESGE colonoscopy quality guideline, AE timing is divided into immediate AE, 7-day readmission rate, and 30-day mortality rate.[6] In fact, postprocedure AE timing may vary according to the author's choice, depending on the endoscopic procedure and the type of AE under study. How to track and reliably register late AEs will be discussed later. However, the longer the delay, the more difficult the AE is to recognize and the greater the chance that the event is not causally connected.[16,18] In case of delayed bleeding or perforation, the relation with the endoscopic procedure is usually clear. However, the attribution of other delayed AEs can be more challenging. This is particularly true for sedation- and anesthesiology-related events or for mortality in patients with serious underlying comorbidities.[31,34] Therefore, a judgment about attribution is added to the registration of AEs and is divided into levels of certainty ranging from definite, probable, possible, to unlikely.[18] A similar attribution scale is used when studying endoscopes used for therapeutic procedures, when the AE can be related to the used endoscope or to the therapeutic procedure.[23]

TYPE OF AE ACCORDING TO ENDOSCOPIC PROCEDURE

BLEEDING AND PERFORATION are ubiquitously occurring endoscopy-related AEs, whatever the gastrointestinal segment or the endoscopic procedure. It is obvious that the risk of bleeding and perforation is higher in therapeutic endoscopic procedures as compared to diagnostic endoscopy.[6,35] More specific AEs occur in relation to the type of endoscopic procedure and to the intubated gastrointestinal site. Retained food during upper gastrointestinal endoscopy is a risk factor for aspiration pneumonia.[36–38] Acute pancreatitis is a known AE after ERCP but also after endoscopic ultrasound-guided radiofrequency ablation of pancreatic lesions and even after antegrade device-assisted enteroscopy.[37–41] Splenic injury is a rare AE related to a difficult colonoscopy.[42] Postpolypectomy coagulation syndrome with localized peritonitis is related to endoscopic resection techniques in the colon using coagulation, and even coagulation-induced gas explosion with colonic perforation has been described after incomplete bowel preparation.[43,44] These are just some examples of specific AEs related to the type of endoscopic procedure or to the gastrointestinal segment. Many more exist, and the list of rare or extremely rare AEs is long. Moreover, previously unknown AEs arise with the development of new endoscopic techniques.[45,46]

A particular AE that gained a lot of attention recently is infection transmission from one patient to another through endoscopic procedures, especially related to the use of duodenoscopes and linear echo-endoscopes. Although this problem has been known for many years, and attributed to the defective disinfection process of these endoscopes, this AE is very difficult to capture because of its delayed aspect and the challenging traceability of endoscopes contaminated with multidrug-resistant microorganisms.[47,48] Apart from the regular and specific AEs induced by endoscopic interventions, there is a group of AEs related to whether to use sedation and anesthesia during endoscopy and to the interruption or not of anticoagulant and antiaggregant medication (Table 1). These AEs are characterized by cardiovascular, pulmonary, and thromboembolic events as well as bleeding.[18,49,50] They should not be forgotten when tracking endoscopy-related AEs and incidents. Anesthesia-related events during an endoscopic procedure are to be looked for in anesthesiology reports.

WHY TO TRACK AE

FORMAL REVIEW OF each endoscopy-related AE is highly recommended to provide insight in the sequence of events leading to the AE, the treatment of the AE, and the patient outcome.[35] Regular morbidity and mortality reviews of all endoscopic procedures should be discussed within the endoscopy team as part of an effort to audit performance and to learn from own and others' AEs.[35] Multidisciplinary staff meetings with other involved disciplines such as surgery, radiology, and intensive care unit might also be of benefit.

These audits are meant to improve the standard of endoscopic care on a personal level for the endoscopist, but also on the level of the endoscopy team and to adapt and improve multidisciplinary in-hospital pathways to deal with endoscopy-related AEs. Data-driven credentialling improves the safety of endoscopic procedures and thus patient outcomes. The final aim is dual: to reduce the risk and to optimize the treatment of future AEs. Another quality indicator related to AE registration is inclusion in the informed consent document to be discussed with the patient before the endoscopic procedure. In this context, only the most common and most severe AEs should be mentioned including their estimated frequency because the exhaustive list of possible endoscopy-related AEs is too long.[51] Endoscopy-related AEs only represent a minority of the malpractice claims against gastroenterologists.[52]

HOW TO TRACK AE

AS MENTIONED EARLIER, AE registration is an important part of the quality improvement process endorsed by international endoscopy societies.[17,53] However, as straightforward as it seems, correct and complete tracking of endoscopy-related AEs and incidents is very challenging.[16] Reasons for not registering are diverse, ranging from resistance to changing common practices, over misconceptions of regulation (punishment of underperforming endoscopists), to the practical difficulties of systematically measuring endoscopic performance measures.[2] The many challenges are discussed in the current review.

Endoscopy units and their staff members should be convinced about the usefulness and need of the measurement of endoscopy-related AEs and incidents as an incentive to continuously improve endoscopy performance and patient care through ongoing training of all personnel.[2] The ESGE safety checklist aims to improve efficacy and safety of endoscopic procedures, but is not designed to track AEs.[54] The use of a (digital) template document including all aspects of endoscopic AEs to be recorded (Table 1) helps to improve awareness and registration of AEs in daily practice.[16,55] Intraprocedure AEs are easily captured, whereas intraprocedural incidents, both endoscopy- and anesthesia-related, are much less recorded.[16] The differential characteristics of AEs and incidents are not always well-defined, as previously explained. Moreover, it is the endoscopist's responsibility to record any intraprocedural AE or incident, even when it is anesthesia-related, and to document it in the endoscopy report. Voluntary self-reporting of AEs by endoscopists has been unreliable, capturing only half of the AEs, despite specific training and awareness campaigns.[16] Attempts to improve the registration of AEs have been studied. Repetitive staff meetings help to increase awareness of the registration within the department and the hospital.[16,55] Patient questionnaires, either on paper or app-based, to capture postprocedure AEs rely on patient collaboration and willingness to respond to the questions and to (digitally) send back the document. The return of these questionnaires is usually far from complete, and patients tend to experience symptoms from any underlying condition as possibly related to the recently undergone endoscopic procedure.[16,55,56] These patient questionnaires have a reliability issue. Therefore, systematic postprocedure patient contact by phone calls have been proposed, as a method to capture postprocedure AEs in a more complete and trustworthy manner. Contacting patients by phone turned out to be optimal at 7 days postprocedure.[57] Although effective, this method is very resource intensive without any financial compensation.[58] Retrospective review of the medical files of all patients who underwent endoscopy by an independent external auditor was also shown very effective, but too labor intensive to be implemented in daily clinical practice.[16,59] Continuous prospective registration of AEs may be more efficient, provided rigorous follow-up of all patients by the respective endoscopists up to 30 days postprocedure.[55] This monitoring system also needs external audits in order to maintain quality and completeness. The overall weakness of these different registry methods is identical to the voluntary self-reporting system: they depend on the endoscopists' willingness to collaborate, to complete the registration forms immediately after the endoscopic procedure, and to follow-up the patients to capture any postprocedure event. This extra effort requires motivation and additional time, usually free of charge. External audits are mandatory to keep track of missing data, to provide personalized feedback to the participating endoscopists to keep them informed and motivated. This is why this mode of action only results in small-scale initiatives of local endoscopy units for a limited time duration.[16,55–57,59] National surveys to monitor quality in endoscopy led by scientific societies are characterized by poor response numbers and by unrepresentative data collection of only the best performers.[60–63]

More efficient methods are eagerly needed to reliably capture endoscopy-related AEs (and incidents) in a continuous and complete way. Automated national databases containing all medical records of all civilians seem the only way to succeed to effectively capture endoscopy-related AEs and incidents correctly. Standardized terminology allows correct data extraction and coupling, generating a national pooled benchmark registry of AEs. This requires a government-driven and financed approach and should

comply with the general data protection regulation.[64] It will allow short-term confidential feedback to the care providers on an individual and at the hospital level, as well as long-term comparative data on the national level.[13,65] Despite the valuable voluntary local initiatives, nationwide prospective registration of endoscopic procedures and outcomes seems the only reliable solution, as already successfully implemented in some countries.[65–69]

CONCLUSIONS

QUALITY IMPROVEMENT THROUGH the registration of endoscopy-related AEs has been recognized by major international endoscopy societies as an important quality indicator. The theory behind it is easier to approve than its implementation in daily practice. The following aspects need to be taken into account when registering AEs: the type of AE, the severity, the timing, and the attribution. In addition, the treatment and clinical outcome of endoscopy-related AEs are important to capture. AEs, morbidity, and mortality data related to endoscopic procedures should be subject to regular multidisciplinary review to provide feedback to the care providers and to improve clinical pathways dealing with AEs on the hospital level. The final aim is dual: reduction of the risk of AEs and optimization of the treatment of AEs to improve patient care.

Despite the many local initiatives, government-driven and financed health-care databases with automated coupling of specific data seem the only efficient way to implement endoscopy-related AEs and outcomes on a prospective and complete basis. This will not only allow continuous confidential feedback to endoscopists in relation to the pooled national benchmark data, but also follow-up in time through data-driven credentialing aiming to progressively optimize these benchmark data.

CONFLICT OF INTEREST

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