SPECIAL ARTICLE

A lexicon for endoscopic adverse events: report of an ASGE workshop

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Patients and practitioners expect that their endoscopy procedures will go smoothly and according to plan. There are several reasons why they may be disappointed. The procedure may fail technically (eg, incomplete colonoscopy, failed biliary cannulation). It may seem to be successful technically but turn out to be clinically unhelpful (eg, a diagnosis missed, an unsuccessful treatment), or there may be an early relapse (eg, stent dysfunction). In addition, some patients and relatives may be disappointed by a lack of courtesy and poor communication, even when everything otherwise works well.

The most feared negative outcome is when something ''goes wrong'' and the patient experiences a ''complication.'' This term has unfortunate medicolegal connotations and is perhaps better avoided. Describing these deviations from the plan as ''unplanned events'' fits nicely with the principles of informed consent, but the term adverse events (AEs) is in common parlance.

AEs can occur before the endoscope is introduced (eg, a reaction to prophylactic antibiotics or the bowel cleansing preparation), during the procedure (eg, hypoxia), immediately afterward (eg, pain caused by perforation), a few hours later (eg, pancreatitis after ERCP), or can be delayed for several days or weeks (eg, aspiration pneumonia, delayed bleeding). Some events (eg, viral transmission) may be so far delayed that the connection is difficult to make or is missed completely.

There is substantial literature describing individual AEs and many large collected series.[1-11] What is lacking is a standardized nomenclature and agreed-on definitions for AEs. For example, what is meant by hypoxia or bleeding or infection? At what level do they become significant enough to be counted? Another major issue is how to classify and report delayed events, which may or may not be attributable to the procedure.

This lack of standardization has many consequences.[12] It hampers the comparison of data from different research and quality improvement studies. It makes individual studies suspect because practitioners may not be consistent in their own perceptions and definitions. Furthermore, it makes it impossible to compare endoscopic outcomes with those from other disciplines such as surgery. The need for standardized nomenclature has come into closer focus recently with the increasing use of electronic report writers, which demand a lexicon.

In pursuing quality outcomes, it would also be helpful to document the factors that may increase the risk of endoscopic procedures. Many of these risk factors are known,[11] but there is no consensus on a data set with which to describe them and no link to those used in other disciplines.

The American Society for Gastrointestinal Endoscopy (ASGE) has played a leadership role in enhancing the quality of endoscopic practice and has made numerous recommendations about the metrics of quality and how

Abbreviations: AE, adverse event; ASA, American Society of Anesthesiologists; ASGE, American Society for Gastrointestinal Endoscopy; CNS, central nervous system; CTCAE, Common Terminology Criteria for Adverse Events; HI-IQ, Health & Inventory Information for Quality; MST, minimum standard terminology; NIH, National Institutes of Health; NSQIP, National Surgical Quality Improvement Program; ODD, outcome, disability, death; OMED, World Organisation of Digestive Endoscopy; SNOMED CT, Systematized Nomenclature of Medicine–Clinical Terminology.

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to apply them.[13-15] However, it had not addressed the details of AE documentation. For this reason, the ASGE Quality Task Force convened a workshop in September 2008 to explore the current situation and to make recommendations. Invitations were issued to representatives from ASGE, the American College of Gastroenterology, and the Society for American Endoscoping Surgeons and also to those familiar with related lexicons, such as National Surgical Quality Improvement Program (NSQIP) (Surgery), Health & Inventory Information for Quality (HI-IQ) (Radiology), National Institutes of Health (NIH), Common Terminology Criteria for Adverse Events (National Cancer Institute), SNOMED CT (Systematized Nomenclature of Medicine–Clinical Terms), and the Minimum Standard Terminology (MST).

GOALS OF THE WORKSHOP

The overall goal of the workshop was to make recommendations about the data points and menus for AEs and for risk factors that should be incorporated into endoscopy reporting systems. To do so, the group was charged to do the following:

- Provide clear definitions for AEs.
- Define levels of severity, including the minimum threshold at which an AE should be documented and thus be counted and reported.
- Consider how to deal with delayed events, in particular, the issues of timing and attribution.
- Be consistent across the spectrum of endoscopy procedures.
- Review the main risk factors for AEs and recommend a minimum list of data points.
- Be mindful of the lexicons already proposed or in use in current endoscopy report writers and in other disciplines.

WHAT SYSTEMS ARE NOW IN USE FOR DOCUMENTING AEs OF INTERVENTIONS?

Several authors have attempted to address these issues over the years. Cotton[16] and Fleischer[17] made general suggestions for thresholds, attribution, and severity of AEs, but these were not sufficiently specific. However, recommendations from a subsequent consensus workshop on ERCP complications have been used in many studies and publications.[18] Fleischer et al[19] proposed the outcome, disability, death (ODD) scoring system, for all endoscopic procedures, based on detailed documentation of 3 negative factors, ie, outcomes, disability, and death. This was thoughtful and comprehensive, but proved to be too cumbersome for routine use, and it was not adopted.

All current proprietary endoscopy reporting systems and the Clinical Outcomes Research Initiative database research project, supported by the ASGE, have menus for reporting immediate AEs, but the terms have not been defined precisely and there is little guidance about how to describe and capture severity. Most allow late entry of delayed events, but do not define an appropriate time period or the information that is to be collected.

The NSQIP was initiated in the Veterans Affairs system more than 20 years ago, but was later embraced by the American College of Surgeons.[20] It is now a well-established system by which large U.S. medical centers (mainly academic) can track their postoperative 30-day occurrences (in general and vascular surgery) and benchmark themselves against other institutions. It is comprehensive, with 135 data points per case and with detailed descriptions of all possible events, but it is labor-intensive and expensive. For these reasons, the system is used in less than 5% of U.S. hospitals.

The HI-IQ data set[21] was developed by the U.S. Society for Interventional Radiology. It provides menus for reporting AEs, but does not define all of them. The system has not been used widely, and there is no central organization to provide comparative data (benchmarking).

The NIH criteria for AEs occurring in research studies are published in the Code of Federal Regulations.[22] Common Terminology Criteria for Adverse Events (CTCAE) is the official reporting language for AEs recommended by the National Cancer Institute.[23] It provides exhaustive lists of all possible AEs that may occur during cancer trials.

SNOMED CT was initially developed for use in pathology, but has now become the official international medical language.[24] It is extremely comprehensive, but the structure is currently relatively unhelpful in this specific context.

The MST is an attempt to standardize endoscopy terminology. It originated in Europe but is now the property of OMED (World Organisation of Digestive Endoscopy). The recent third version includes a basic structure for AE terminology.[25]

How each of these systems deals with the key points at issue is discussed in the relevant sections.

WHAT DEFINES AN AE? THRESHOLDS FOR REPORTING AND SEVERITY GRADING

Some things that happen during procedures are relatively trivial (eg, brief hypoxia, bleeding at polypectomy that is self-limited or easily treated endoscopically). Patients are unaware of such events, which do not prevent the completion of the planned procedure and have no sequelae. These incidents should be documented so that quality improvement processes can be applied and to assess whether they predict subsequent AEs. However, they are not significant enough clinically to be called AEs and thus counted in complication statistics.

The same issue applies to some events that occur after the patient leaves the recovery area. Minor phlebitis

sometimes occurs at intravenous line sites, and most people feel bloated after prolonged procedures.

A key question therefore is where to place the threshold; that is, at what level of severity, inconvenience, or disturbance does an incident become an AE?

Once the threshold has been reached, there must be criteria that distinguish relatively minor events (eg, 1 extra unplanned day of hospitalization for pancreatitis after ERCP or brief aspiration pneumonia) from those that are more severe or life threatening (eg, esophageal perforation). Several severity grading systems have been recommended, based on the extent of the impact on the patient (ie, how much the expected plan of care is changed, additional needed interventions) and on the final outcome.

The workshop reviewed how the available systems approach these issues.

The ERCP consensus conference[18] and more generic publications from the same source[11,26] attempted to define a threshold by stating that ''a complication is an unplanned event, related to the procedure, that requires the patient to be admitted to hospital, or to stay in hospital longer than expected, or to undergo other unplanned interventions.'' By this definition, we did not count in our AE statistics and publications any deviation that occurred during a procedure but that was not obvious to the patient afterward (eg, transient bleeding) or one that can be treated on an outpatient basis (eg, localized thrombophlebitis at an infusion site). These minor unwanted events were called incidents. Later, a softer threshold criterion was suggested (ie, the need for face-to-face medical consultation and management, but not necessarily hospital admission).

Four grades of severity were recommended based mainly on the need for hospitalization (with other criteria for specific events such as bleeding): Mild, events requiring hospitalization of 1 to 3 days; moderate, 4 to 9 days in hospital; severe, more than 10 days in hospital or needing surgery or intensive care; fatal, death attributable to the procedure.

NSQIP documents few intraprocedure events (ie, cardiac arrest, myocardial infarction, unplanned intubation, and other).[20] Postoperative occurrences include issues with wounds, respiration, urinary tract, central nervous system (CNS), cardiac, bleeding, deep venous thrombosis/thrombophlebitis, and sepsis, but the threshold for each is high. Thus, bleeding means more than 4 units in the first 72 hours and a CNS event means cerebrovascular accident or coma longer than 24 hours. There are no equivalents of the incidents described and no severity grades other than death, which is counted if within 30 days of any cause or after 30 days if attributable and the patient had remained in acute care.

HI-IQ distinguishes 2 minor and 4 major levels of severity.[21] Minor AEs are those that need no therapy and have no sequelae (A) or have minor therapy or consequence, including overnight admission (B). Major events include those that require major therapy or hospitalization (24-48 hours) (C); major therapy, need unplanned increase in level of care, or hospitalization >48 hours (D); or result in permanent adverse sequelae (E) and death (F).

Level A (and maybe most B) events are equivalent to incidents. The system has other event categories.

O is ''not a complication, AE not worth tracking (eg, patient had some pain during procedure).'' T is ''a technical failure, not a complication/AE.'' X describes ''a technical, laboratory, or anatomical event, where there are no (immediate) sequelae, but that has the potential for future harm to the patient'' (eg, foreign body left in the patient).

The NIH criteria separate AEs and serious AEs.[22] AEs are defined as ''any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporarily associated with use of a medical treatment or procedure regardless of whether it is considered related.'' A serious AE is ''an AE that results in death, life-threatening adverse experience, inpatient hospitalization, or prolongation of existing hospitalization (excluding the planned overnight stay post-procedure), persistent or significant disability/incapacity, congenital birth defect, or cancer or any other experience that suggests a significant hazard, contraindication, side effect, or precaution that may require medical or surgical intervention to prevent one of the outcomes listed above or an event occurring in a gene therapy study or an event that changes the risk benefit/ratio of the study.'' This definition covers a range of outcomes from 1 night of hospitalization to death. It is noted that severity is not the same as serious. Thus, a severe headache may not be medically serious.

CTCAE version 3.0 is the National Cancer Institute system for cancer trials.[23] It mirrors the NIH definitions previously listed and adds a 5-point severity grading scale with specific definitions for all possible AEs: 1 = mild AE (did not require treatment); 2 = moderate AE (did not require treatment); 3 = severe AE (inability to carry on normal activities), required professional medical attention); 4 = life-threatening or permanently disabling AE; 5 = fatal AE.

Thus, grades 1 and 2 probably correspond to incidents.

MST 3.0 recommends the term ''incidents'' and 4 levels of severity for AEs (ie, mild, moderate, severe, and fatal).[25] These categories are defined by whether the procedure could be completed (or was aborted); the length of any needed hospitalization; the need for endoscopic, radiologic, or surgical treatment; and whether there was permanent disability or death.

Thus, some classifications (eg, HI-IQ, CTCAE) count as mild AEs those that the ERCP conference and MST prefer to call incidents.

DELAYED EVENTS: TIMING AND ATTRIBUTION

Dealing with delayed events is particularly challenging, both in collecting the data and interpreting them.[11,12]

Studies have shown that many more AEs are found when patients are contacted at 30 days.[9,27-29] However, the longer the delay is, the greater the chance that the event is not causally connected. This is especially true after the simplest endoscopic procedures and when other procedures have occurred in the intervening period.

The simplest answer to this problem would be to mirror the traditional surgical standard, which is to count all occurrences within 30 days, without any discussion about attribution. This convention was developed when many if not most (open) operations resulted in a 2-week hospital stay and prolonged recovery. It would seem to be an onerous standard for endoscopy. We are disinclined to count a cardiac event that occurred 29 days after a simple diagnostic endoscopy in an elderly patient with known heart disease, especially if the patient had undergone multiple other medical (or surgical) interventions in the interim. However, attribution would seem reasonable if the same event had occurred only a few days later, especially if aspirin or anticoagulants had been discontinued or if the patient had experienced transient hypotension or hypoxia during the procedure. These difficulties could be minimized by reducing the time period (eg, to 14 days) or to allow subjectivity in attribution or both.

The NIH and National Cancer Institute systems are sympathetic to allowing judgment about attribution, stating clearly that investigators should evaluate ''AE causality…and make an independent determination as to whether the AE was thought to be related to any study-related activity.'' They offer a choice of 4 possible relationships (ie, definite, probable, possible, and unlikely).

HI-IQ also counts all 30-day events, but classifies deaths as related or unrelated. For other events, judgment in attribution is allowed.

MST 3.0 currently allows classification of postprocedure events into those that are ''probably, possibly, or unlikely related,'' but does not define a time period. NSQIP has a Y modifier to indicate an event that is ''not related.''

It has been suggested that it would be helpful to distinguish between direct and indirect events.[11] When considering AEs, most endoscopists think first about the obviously related direct events (such as bleeding and perforation) that occur in organs that are being traversed or treated. However, there are also many indirect events that occur outside the digestive tract, most of which are cardiopulmonary and related to sedation/anesthesia. These indirect events are more likely to occur after the patient leaves the procedure unit, are more often overlooked and underreported, and are often not causally related. It has thus been argued that direct events (such as postpolypectomy bleeding) should be counted whenever they occur, even after 30 days, but that it might be legitimate to have a shorter time period for the indirect events, such as 3 days.[11] However, this concept adds complexity to data collection and is unnecessary if attribution is permitted.

The National Gastroenterology Quality Improvement in Endoscopy Pilot for Colonoscopy is currently using a 2-week window (I.M. Pike, personal communication), whereas the ERCP Quality Network uses 1 week.[30]

KEEPING TRACK OF DELAYED EVENTS

Recording AEs that occur after patients leave the procedure unit is a challenge. This is true particularly for referral centers whose patients often come from long distances (and it is these centers that most often publish their data). Some countries have integrated medical information systems that allow all patient encounters to be tracked, so that it is possible to link admissions to recent procedures, and thereby to produce reliable data on the more serious delayed events.[31] In the United States, outside the Veterans Affairs system, the only routine practical way to obtain these data (if they are not seen in follow-up clinics) is to contact the patient directly. Many practices call their patients on the day after procedures, but this will not capture most delayed events. For that purpose, a later call at 1 or 2 weeks or 30 days (or whatever counting period is chosen) will be needed. However, these calls are time-consuming, not completely reliable, and are rarely done. The fact that most people have cell phones nowadays does make contact easier. Some units give patients questionnaires when they leave to return by mail at a set time, and call those who do not comply (usually the majority). Perhaps computer-generated ''robocalls'' or automatic e-mails will be useful in the future.

Regarding documentation of delayed events, reporting systems should make it possible not only to document delayed events, but also to state when they are known *not* to have occurred (ie, confirmed by phone call or clinic follow-up).

Late AEs

Another issue is how to characterize later delayed events that clearly relate to procedures, such as an esophageal stricture caused by Barrett's ablation and a late infection that can be traced to the endoscope. Endoscopically placed foreign bodies, such as stents, pose other questions. It could be argued that the procedure is still ongoing while a stent is in situ. If so, cholangitis caused by biliary stent blockage (or dysphagia caused by esophageal stent blockage) might be counted even when it occurs after many months. Simple stent failure is not really an AE, but it should perhaps be included if the consequence of failure requires more than simple stent manipulation or exchange on an outpatient basis (eg, if percutaneous drainage is needed for a liver abscess, surgery for a migrated stent).

A related issue that has been highlighted in research studies (M.L. Freeman, personal communication, 2009) is whether and how to attribute AEs that occur during

or after other procedures necessitated by a failed or incomplete (or complicated) endoscopy. Examples include hemobilia caused by percutaneous transhepatic cholangiography necessitated by a failed ERCP and a bad surgical outcome of débridement of pancreatic necrosis caused by ERCP. It seems logical to include such events, but there are other situations that are less clear cut, eg, a bad surgical outcome after failed hemostasis in an acute bleeder.

Risk factors for AEs

It is self-evident that some procedures carry greater risk than others, either because of their complexity (eg, endoscopic treatment of esophageal cancer, pseudocyst drainage) or because of patient factors (eg, cardiopulmonary status, coagulopathy). We need ways to document these issues. It is also known that the risk may be somewhat dependent on the expertise of the endoscopist.[11,32,33] Data on experience should be included in benchmarking exercises, but not in routine reporting systems.

Degree of difficulty scales. ERCP procedures have been divided into 3 categories of complexity, which correlate somewhat with the risks involved.[34] In general, the most complex (level 3) procedures are performed mainly at referral centers. In reporting complication rates, it will be important to know the level of complexity of the procedures being included. Thus, members of the workshop recommended and initiated development of analogous scales for the other common procedures (eg, upper endoscopy, colonoscopy, EUS).

Comorbidities. Recognizing and documenting risk factors is important in being able to inform patients of their specific risk profiles and to compare different case series appropriately. No one has yet proposed a comprehensive data set of patient risk factors for endoscopic application. The relevant literature was reviewed comprehensively for this workshop.[35] Established systems for measuring the burden of comorbidities in general or specific situations such as Charlson et al,[36] APACHE,[37] and POSSUM[38] are not directly relevant to the endoscopy context. NSQIP has a preoperative risk assessment sheet with 45 items ranging from pulmonary problems to sepsis to bleeding disorders, all of which are defined very precisely, but were developed to predict surgery-specific risks, some of which (eg, wound infection) do not apply to endoscopy. From a practical standpoint, the most important items are cardiopulmonary compromise, bleeding disorders, allergies, sepsis, and severe immunocompromise. Most units mandate documentation of allergies and both the American Society of Anesthesiologists (ASA)[39] and Mallampati et al[40] scores. The latter purports to predict difficulties in intubation (if needed), but it has not been validated. The ASA score is a widely used crude measure of ''fitness for anesthesia'' that does correlate well with adverse cardiopulmonary events[41] and is incorporated into most reporting systems.

RECOMMENDATIONS: PROPOSED DATA SETS AND DEFINITIONS

Definitions and severity criteria should be generic across the different endoscopic procedures, although certain events will occur only after some of them (eg, pancreatitis after ERCP). We make a distinction between incidents and AEs.

AEs

Definition. An AE is 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.

Timing. Events can occur pre-procedure, intra-procedure (from entering the preparation area through leaving the endoscopy room), post-procedure (up to 14 days), and late (any time after 14 days). For delayed events, the number of days after the procedure should be documented.

Attribution. Definite, probable, possible, unlikely.

The data set for AEs and additional qualifiers is shown in Table 1. Severity is graded by the degree of consequent disturbance to the patient and any changes in the plan of care, as shown in Table 2. AEs should be followed until their conclusion to assess severity and should include the outcome of any new procedures required to treat them. Thus, death after débridement surgery of post-ERCP pancreatitis would be attributable to the ERCP. However, this should not apply to AEs occurring after second procedures done solely because of the technical failure of the initial endoscopy (ie, without any AE prompting failure or abortion of the procedure).

Incidents

Incidents are unplanned events that do not interfere with completion of the planned procedure or change the plan of care, (ie, do not fulfill the stated criteria for AEs). Examples include bleeding that stops spontaneously or with endoscopic therapy and transient hypoxia that resolves with or without reversal agents, supplemental oxygen, or bagging. These incidents should be recorded for the purposes of quality improvement and perhaps to see which incidents may predict later AEs. Incidents may occur during the procedure or in the immediate recovery period (ie, while patients are still under supervision).

Event tracking

Attempts should be made to contact patients at about 14 days after procedures to determine whether any AEs have occurred and whether they are attributable. Report generators should allow these data to be included as an addendum to the endoscopy report, including the

TABLE 1. Adverse event* documentation

Category	Event	Definition	Qualifiers
Cardiovascular	Hypotension	<90/50 or down 20%	
	Hypertension	>190/130 or up 20%	
	Dysrhythmia		Specify
	Arrest		
	Myocardial infarction		
	Cerebrovascular event		Specify
Pulmonary	Hypoxia	O_2 < 85%	
	Hypopnea		
	Laryngospasm		
	Bronchospasm		
	Pneumonia		
	Pneumonitis		
Thromboembolic	Deep venous thrombosis		
	Pulmonary embolus		
Instrumental	Perforation	Evidence of air or luminal contents outside the GI tract	Organ, site instrument
	Penetration	Visual or radiographic evidence of unintended penetration beyond the mucosa or duct, without perforation	Organ, site, instrument
	Impaction	Unable to remove instrument or device	Site, instrument
	Malfunction		Specify site, instrument
Bleeding		Hematemesis and/or melena or hemoglobin drop >2 g	Units
Infection	Cholangitis	>38C >24 hours with cholestasis	
	Pancreatic infection	>38C >24 h with collection	
	Fever?cause	>38C >24 h without obvious source	
	Transmission		Organism
Drug reaction	Allergy		Agent, reaction
Pain	Abdominal	Not caused by pancreatitis or perforation	
	Nonabdominal		Site
Pancreatitis		Typical pain with amylase/lipase >3 times normal	
Integument		Damage to skin, eyes, bones, muscles	Specify
Other			Specify

(*continued on next page*)

TABLE 1 (*continued*)

Category	Event	Definition	Qualifiers
Qualifiers for all events			
Timing	Preprocedure, intra, post (<14 days), late; day of onset for postprocedure events		
Attribution	Definite, probable, possible, unlikely		
Severity	See Table 2		

*An adverse event is one that prevents completion of the planned procedure (does not include failure of completion because of technical failure or interference by poor preparation or disturbed anatomy or disease or surgery) and/or results in hospital admission, prolongation of existing hospital stay, another procedure (needing sedation/anesthesia), or subsequent medical consultation.

TABLE 2. Severity grading system

	Severity grade			
Consequence	**Mild**	**Moderate**	**Severe**	**Fatal**
Procedure aborted (or not started) because of an adverse event	x			
Postprocedure medical consultation	x			
Unplanned anesthesia/ventilation support, ie endotracheal intubation during conscious sedation		x		
Temporary ventilation support by bagging or nasal airway during conscious sedation, and endotracheal intubation during a modified anesthesia care procedure are not adverse events				
Unplanned hospital admission or prolongation of hospital stay for ≤3 nights	x			
Unplanned admission or prolongation for 4-10 nights		x		
Unplanned admission or prolongation for >10 nights			x	
ICU admission for 1 night		x		
ICU admission >1 night			x	
Transfusion		x		
Repeat endoscopy for an adverse event		x		
Interventional radiology for an adverse event		x		
Interventional treatment for integument injuries		x		
Surgery for an adverse event			x	
Permanent disability (specify)			x	
Death				x

ICU, Intensive care unit.

statement that there were definitely no AEs, when this had been confirmed by patient contact.

Reporting statistics

When reporting complication rates, only definite and probably attributable events occurring within 14 days should be included. Rare AEs that occur after 14 days and are clearly attributable can be recorded as a separate category. Examples include a proven nosocomial infection or stent migration causing a new clinical problem, not just failure of the original treatment goal.

Risk factor documentation

Further study is needed to develop and validate a comprehensive and precise data set for recording patient risk

factors relevant to the outcomes of endoscopy. In the meantime, we recommend recording standard demographics, ASA score, and the presence of sepsis, uncorrected coagulopathy, and severe immunocompromise, as well as any other major comorbidity (eg, cardiopulmonary challenge).

CONCLUSIONS AND NEXT STEPS

This lexicon is published so that it can be tested and improved. We recommend its incorporation in endoscopy studies and reporting systems. In addition, we propose a large prospective collaborative study to evaluate the results of its use in practice and to correct any deficiencies. A variety of centers with different spectra of practice should institute these definitions and rules, and contact their patients after 21 days. This will show which delayed events occur, when (and whether any appear between 2 and 3 weeks), and how the attribution rules function.

Documentation of the complexity of the procedures and any incidents will demonstrate whether they predict subsequent AEs. A parallel attempt should be made to document relevant comorbidities to help to develop a concise risk factor data set to incorporate into future reporting systems.

Despite authoritative input from colleagues in surgery and radiology, we have so far failed to recommend definitions for AEs and risk factors that can be applied across all interventional disciplines. That remains a worthy goal for the future.

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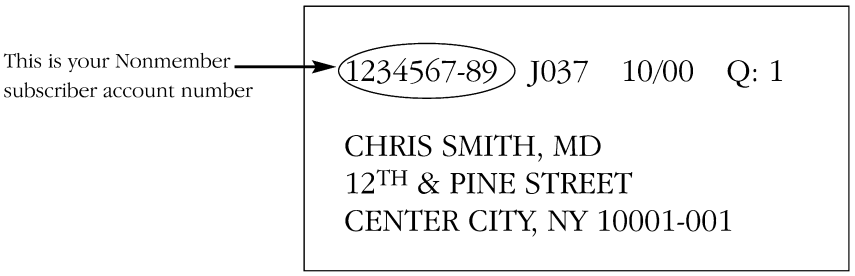

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