

Adverse event reporting tool to standardize the reporting and tracking of adverse events during procedural sedation: a consensus document from the World SIVA International Sedation Task Force

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Editor's key points

- Sedation techniques vary and adverse events (AEs) are relatively rare.
- Absence of standardized definitions and terminology for sedation-AEs, impedes monitoring and comparison of outcomes.
- An International Sedation Task Force has addressed these problems.
- An event-reporting tool for sedation related AEs is presented for widespread adoption.

Summary. Currently, there are no established definitions or terminology for sedation-related adverse events (AEs). With clear terminology and definitions, sedation events may be accurately identified and tracked, providing a benchmark for defining the occurrence of AEs, ranging from minimal to severe. This terminology could apply to sedation performed in any location and by any provider. We present a consensus document from the International Sedation Task Force (ISTF) of the World Society of Intravenous Anaesthesia (World SIVA). The ISTF is composed of adult and paediatric sedation practitioners from multiple disciplines throughout the world.

Keywords: adults; outcome; paediatrics; safety; sedation

Procedural sedation and analgesia is administered worldwide by a diverse group of practitioners to patients of all ages in a variety of clinical settings both inside and outside the operating theatre. Patient harm was not rare before the implementation of critical safeguards, including training, monitoring, and quality assurance.^{1–13} Fortunately, serious sedation-related adverse events (AEs) such as permanent neurological deficit or death are now rare.^{2 3 14}

AEs that may occur during procedural sedation are varied and include respiratory depression, manifest by oxygen desaturation or apnoea, and haemodynamic fluctuations.^{2 3 14} Although these occurrences signal the risk of impending patient deterioration, actual injury is usually averted by either spontaneous resolution of the event or by intervention of the sedation care provider. These events are at times referred to as 'near misses' or 'close calls', but in fact, rarely pose any serious danger (permanent neurological injury or mortality) when managed by a skilled practitioner in an appropriate setting.^{1–3 14 15} The risk of cardiopulmonary depression is always present because sedatives, hypnotics, and analgesics depress the central nervous system in a dose-related way. Although these sedation-related AEs rarely result in significant morbidity, reduction in the frequency and severity of AEs is widely regarded as a surrogate marker for improving safety. They are typically the primary outcome measure in

sedation research trials. Institutions with quality assurance or improvement programmes typically monitor such AEs to gauge their quality and delivery of care.

Unfortunately, there is immense variability worldwide in how sedation-related AEs are reported and tracked. Specific definitions for AEs vary substantially from setting to setting, are often imprecise, and exhibit inconsistent thresholds for events that are meant to be of clinical importance. For example, definitions of oxygen desaturation vary from ranges of 80% to 95% over periods of time that span a single instant to a requisite duration of up to 60 s. Dissimilar nomenclature thwarts the reliable comparison of research or quality assurance data between settings, and thus impairs our ability to identify areas of strength and weakness. Inconsistent definitions may result in over- or under-reporting of AEs.

Objectives

The World SIVA International Sedation Task Force (ISTF) comprises 26 physicians from 10 specialities and 11 countries, with a clinical expertise, research commitment to the sedation of adults and children, or both. The countries represented by members of the ISTF include Australia, Brazil, China, Finland, Germany, Israel, Italy, Japan, South Africa,

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the UK, and USA. The ISTF has convened to reach a consensus between sedation experts representing a wide variety of specialities all over the world. Agreement on standardized definitions and terminology for sedation-related AEs between specialities is a first step toward identifying the frequency and severity of these events. Our intent is to incorporate the sedation-related AE taxonomy into an AE Sedation Outcome Tool that is clinically relevant to all specialities and providers, is applicable to sedation provided in any location (from the intensive care unit to the emergency department), is internationally applicable, and is as objective and reproducible as possible.

We foresee this standardized nomenclature and AE Sedation Outcome Tool as having the potential to be applied in the following ways:

- (i) incorporation by individuals and institutions into their local policy and quality improvement to evaluate the safety and efficacy of facilities where sedation procedures are performed;
- (ii) worldwide utilization in areas without organized sedation systems, including the developing world;
- (iii) sharing and comparison of data, facilitating the identification of sedation practices with the safest and most efficacious outcomes;
- (iv) allowing comparison of sedation studies and subsequent systematic reviews and meta-analyses;
- (v) incorporation and adoption of the World SIVA AE Sedation Outcome Tool as an open access web-based template (www.InternationalSedationTaskForce.com) in which the sedation care provider can document and track his individual and institutional sedation outcomes while simultaneously contributing to a worldwide data collection of sedation outcomes through this website; this effort is designed to promote standardized and safe sedation care worldwide;
- (vi) facilitation of sedation-related didactics, training, and simulation as a foundation for developing standardized approaches to training and (re)credentialing;
- (vii) helping to build an objective hierarchical structure that predicts ongoing risk of serious AEs;¹⁶
- (viii) contribution towards an awareness among practitioners of the importance and relevance of sedation-related AEs.

Methods

The 26 members of the World SIVA ISTF represent the specialities of anaesthesia, emergency medicine, paediatrics, critical care, hospital medicine, dentistry, and gastroenterology from 11 countries. This group represents sedation providers across the specialities and continents, including those caring for both adults and children. Members were nominated by World SIVA leadership based on their demonstrated

dedication and competence in research, clinical experience in the field of procedural sedation, or both.

The Task Force engaged in a detailed exchange of ideas via e-mail and during a group meeting held in San Francisco, CA, on September 12, 2010. We carefully reviewed existing descriptions and definitions of sedation-related AEs. Preliminary consensus definitions were drafted and subsequently revised.

General definitions

Procedural sedation

The use of anxiolytic, sedative, hypnotic, analgesic, and/or dissociative medication(s) to attenuate anxiety, pain, and/or motion. These agents are administered in order to facilitate amnesia or decreased awareness and/or patient comfort and safety during a diagnostic or therapeutic procedure.^{2 3 17}

Adverse event

The task force considered several reference definitions when considering how best to define AEs.

The Institute of Medicine (IOM) states that: 'An adverse event is an injury resulting from a medical intervention, or in other words, it is not due to the underlying condition of the patient'.¹⁸ The Task Force regarded this definition as insufficient in the context of procedural sedation because the requirement of actual patient injury would restrict its use to rare sentinel events and eliminate the more common warning signs of potential patient deterioration. Additionally, we did not want to exclude AEs largely attributable to the underlying condition of the patient.

The World Health Organization (WHO) defines an adverse reaction as: 'A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function'.¹⁵ The Task Force regarded this definition as not sufficiently comprehensive to reflect the administration of medications for which 'normal' dosing has not been clearly established, medications which are being used off-label, events which occur at doses lower than 'normally' used, events which may not be considered noxious, and occurrences of inadvertent overdose.

The European Medicines Agency (EMA) has modified the definition of AEs with input from the WHO Collaborative Centre in order to recognize the pre-approval and development period before the implementation of clinical investigations. An AE (or adverse experience) is 'Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment'.^{19 20}

According to the United States Food and Drug Administration (FDA), 'An adverse event is any undesirable experience associated with the use of a medical product in a

patient'.²¹ The Task Force regarded this definition as too broad and non-specific for describing sedation-related AEs.

After consideration of the above, the Task Force incorporated elements of the IOM, WHO, EMA, and FDA definitions of AEs into a definition that is specific to sedation-related occurrences: 'Unexpected and undesirable response(s) to medication(s) and medical intervention used to facilitate procedural sedation and analgesia that threaten or cause patient injury or discomfort'.

AE definitions: thresholds vs interventions

The most critical decision point for the Task Force was whether to devise definitions based upon events and thresholds, or to instead endorse a novel but controversial intervention-oriented philosophy.¹⁷ The first approach is currently in widespread use for both hospital quality assurance and sedation research. Examples of such 'events and thresholds' are: apnoea for >30 s, oxygen desaturation <90% persisting for 30 s or more, end-tidal CO₂ change of >10 mm Hg, and systolic arterial pressure <90 mm Hg or below the 5th normal percentile for age in children.

Events and thresholds

The primary disadvantage to the 'event and threshold' approach is that clinicians rarely agree on optimal thresholds—hence the unacceptable diversity of definitions currently in use. A second challenge is subjectivity or errors in implementation. Apnoea, for example, might logically be defined as the absence of respiratory effort for >30 s. However, when respiratory cessation actually occurs, the complete focus of the sedationist is patient monitoring and rescue (if needed), with little or no effort devoted to accurately timing the length of the event. Later estimation by the practitioner is unlikely to be consistently reliable. Furthermore, a prompt intervention will preclude the identification of apnoea, as the requisite 30 s time span was not met and then by this definition, apnoea then did not occur.

A final disadvantage to events and thresholds is that they often do not correlate with clinical importance or critical adverse outcomes. Defining hypoxia as an oxygen saturation at any time of <90% may seem logical on first glance, but would unfairly classify as an AE a deeply sedated, closely monitored patient breathing room air whose oxygen saturation slowly and transiently reaches 89% before slowly normalizing without intervention. Conversely, consider a patient breathing room air who exhibits short periods of breath-holding which is accompanied by oxygen desaturation to 90%. A rapid intervention with positive pressure ventilation and oxygen during these periods is able to reverse the situation in <30 s. Because of the quick intervention, neither apnoea nor desaturation is identified. An additional challenge is how to apply such a definition to patients with diminished baseline oxygen saturations (e.g. congenital cardiac conditions, cystic fibrosis, chronic obstructive pulmonary disease). Finally, such a definition cannot be

applied in resource-limited world regions lacking access to pulse oximetry.

Intervention orientation

Given these limitations to events and thresholds, the recent Quebec Guidelines for sedation research used the novel approach of defining AEs based primarily upon interventions performed on their behalf.¹⁷ For example, they defined oxygen desaturation not using any specific numerical threshold, but rather as 'oxygen desaturation *and* one or more interventions (are) performed with the intention of improving the oxygen saturation'. Qualifying interventions could be major (e.g. intubation, assisted ventilation) or minor (e.g. verbal command to breathe, tactile stimulation, airway repositioning, starting or increasing supplemental oxygen).

The driving impetus behind intervention-based definitions is that they better predict clinical importance and are more easily identifiable. AEs that are brief or resolve spontaneously are likely less significant and foreboding of patient injury than those in which the sedation care provider feels compelled to act.¹⁷ A second strength of this orientation is that the act of performing an intervention is more objective and unambiguous, and thus more likely to be recorded in a standardized, reproducible fashion than something less concrete such as the estimated duration of apnoea.

An intervention-based approach is not without disadvantages and limitations. First, not all interventions should be weighted equally. For example, if a patient experiences a slow decrease in oxygen saturation (the trend is downwards) from 99% to 97% and the sedation care provider elects to add supplemental oxygen as a non-urgent precaution, this must be coded as an oxygen desaturation AE using the intervention-based definition discussed earlier. A second and more disturbing downside to intervention-based definitions is that clinicians' thresholds for intervention are not always the same and a baseline level of sedation proficiency must be assumed. What if serious oxygen desaturation or apnoea occurs and the clinician simply fails to intervene? No set of AE definitions can effectively compensate for a lack of suitable training, experience, and judgement. Will the intervention-based approach tempt sedation care providers to refrain from a rescue action in order to avoid coding an AE? Although initial rescue may be delayed, it must be assumed that a serious event will lead to a critical, identifiable outcome should there be no intervention.

Task Force amalgamation

The intervention-based approach was widely favoured by the Task Force and was judged ideal for sedation research. However, its disadvantages for our purposes were that, as currently described, it does not stratify AEs by clinical importance to facilitate outcome stratification and quality assurance.¹⁷ Furthermore, it might not as readily translate to non-hospital or international settings with limited training resources, experience, or both. An additional limitation is that we felt that our tool needed to explicitly recognize

catastrophic outcomes, for example, permanent neurological deficit and death. Finally, given our focus on quality assurance, we judged it optimal for such a tool to include the more serious underlying factors that precipitated or materially contributed to the occurrence.

After carefully weighing the issues, the Task Force elected to present an amalgamated taxonomy founded upon the intervention-based paradigm, but also including event and threshold-based descriptors of the most serious AEs and outcomes. The addition of these items as a failsafe should enable the tool to consistently identify 100% of clinically important occurrences by all practitioners in all settings.

Tool organization

The tool devised by the Task Force is configured as a check box form suitable for use on a web page or paper document, or as part of an electronic medical record (Fig. 1). It characterizes each AE across three domains: description, intervention, and outcome. This tool is meant to be as objective as possible. To this end, it does not require that a depth of sedation be assigned, as it was the opinion of the Task Force that the current markers for depth of sedation require subjective interpretation of patient response to verbal, tactile, and painful stimulation.^{22–25} This tool is a five-step process that requires the identification and description of the AE, the intervention performed, the outcome, and the overall severity of the AE. The specific features within each domain define the severity or clinical importance of the AE: sentinel, moderate, minor, or minimal. It is expected that severity levels will often differ between the domains for a given AE; however, the most serious severity level of the three is the one ultimately assigned by the tool.

Sentinel AEs

Sentinel AEs are the most serious and represent those critical enough to pose a real or major imminent risk of patient injury. Once recognized, they warrant immediate and aggressive rescue interventions. Once clinically concluded, they warrant immediate reporting within sedation care systems, and the highest level of peer scrutiny for continuous quality improvement.

The Joint Commission term ‘Sentinel’ was chosen because its meaning is already well known within most North American healthcare systems and recognized by many worldwide.⁴ As defined by the Commission, ‘A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase “or the risk thereof” includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called “sentinel” because they signal the need for immediate investigation and response’.⁴

As shown in Figure 1, sentinel AEs are defined as any one or more of the following conditions described below.

Description of AE

Oxygen desaturation, severe or prolonged (defined as any oxygen saturation <75% or an oxygen saturation <90% for >60 s), apnoea, prolonged (defined as cessation of respirations for >60 s); cardiovascular collapse/shock (defined as clinical evidence of inadequate perfusion); or cardiac arrest (defined as an absent pulse).

Interventions performed with the intent of treating the AE

Chest compressions, tracheal intubation, or the administration of neuromuscular blockers (e.g. succinylcholine), vaso-pressors including epinephrine, or atropine (with the intent to treat bradycardia rather than hypersalivation).

Outcome of AE

Permanent neurological deficit, pulmonary aspiration syndrome (defined as known or suspected inhalation of foreign material such as gastric contents into the respiratory tract associated with new or worsening respiratory signs), or death.^{26 27}

Moderate AEs

Moderate AEs are those that, while not sentinel, are serious enough to endanger the patient if not promptly managed. Once clinically concluded, moderate AEs warrant timely reporting within sedation care systems and periodic peer scrutiny for continuous quality improvement.

As shown in Figure 1, moderate AEs are defined as any one or more of the following conditions described below.

Description

AEs are labelled moderate only if they are associated with a moderate intervention or outcome, that is, there are no specific descriptions that alone define a moderate AE.

Interventions performed with the intent of treating the AE

Administration of bag valve mask (i.e. positive pressure) ventilation or continuous positive airway pressure, insertion of laryngeal mask airway or oral/nasal airway, or the administration of sedative reversal agents (i.e. naloxone, flumazenil), rapid (rate of administration as quickly as possible) i.v. fluids, or i.v. anticonvulsants.

Outcome of AE

Unplanned hospitalization or escalation of care (e.g. transfer from ward to intensive care or prolonged hospitalization).

Minor AEs

Minor AEs are those encountered periodically in most sedation settings that pose little threat or danger of permanent harm to the patient, given appropriate sedation care provider skills and monitoring. A highly organized and established sedation care system providing a high volume of sedations might choose to record them on monitoring records and

World SIVA adverse sedation event reporting tool

World SIVA adverse sedation event recording tool configured for a web page or paper form. Completion of this tool requires execution of all five steps. Responses to each step will often occupy different columns.

Step 1: Was there one or more adverse events associated with this sedation encounter?

- No, this form is now complete.
- Yes, fill out remainder of form below.

Step 2: Please DESCRIBE the adverse events(s). Check all that apply.

| <i>Minimal risk descriptors</i> | <i>Minor risk descriptors</i> | <i>Sentinel risk descriptors</i> | |
|-----------------------------------------------------------------------|--------------------------------------------------------------|----------------------------------------------------------------------------------------------------|--------------------------------------------|
| <input type="radio"/> Vomiting / Retching | <input type="radio"/> Oxygen desaturation (75–90%) for <60 s | <input type="radio"/> Oxygen desaturation, severe (<75% at any time) or prolonged (<90% for >60 s) | <input type="radio"/> Other, specify below |
| <input type="radio"/> Subclinical respiratory depression ^a | <input type="radio"/> Apnoea, not prolonged | <input type="radio"/> Apnoea, prolonged (>60 s) | |
| <input type="radio"/> Muscle rigidity, myoclonus | <input type="radio"/> Airway obstruction | | |
| <input type="radio"/> Hypersalivation | <input type="radio"/> Failed sedation ^e | | |
| <input type="radio"/> Paradoxical response ^b | <input type="radio"/> Allergic reaction without anaphylaxis | <input type="radio"/> Cardiovascular collapse/shock ^g | |
| <input type="radio"/> Recovery agitation ^c | <input type="radio"/> Bradycardia ^f | <input type="radio"/> Cardiac arrest/absent pulse | |
| <input type="radio"/> Prolonged recovery ^d | <input type="radio"/> Tachycardia ^f | | |
| | <input type="radio"/> Hypotension ^f | | |
| | <input type="radio"/> Hypertension ^f | | |
| | <input type="radio"/> Seizure | | |

Step 3: Please note the INTERVENTIONS performed to treat the adverse events(s). Check all that apply.

| <i>Minimal risk</i> | <i>Minor risk</i> | <i>Moderate risk</i> | <i>Sentinel intervention</i> | |
|-------------------------------------------------|-------------------------------------------------------------|-----------------------------------------------------------|---------------------------------------------------------------------|--------------------------------------------|
| <input type="radio"/> No intervention performed | <input type="radio"/> Airway repositioning | <input type="radio"/> Bag valve mask-assisted ventilation | <input type="radio"/> Chest compressions | <input type="radio"/> Other, specify below |
| Administration of: | <input type="radio"/> Tactile stimulation | <input type="radio"/> Laryngeal mask airway | <input type="radio"/> Tracheal intubation or the administration of: | |
| <input type="radio"/> Additional sedative(s) | <input type="radio"/> Supplemental oxygen, new or increased | <input type="radio"/> Oral/nasal airway | <input type="radio"/> Neuromuscular block | |
| <input type="radio"/> Antiemetic | <input type="radio"/> Antisialagogue | <input type="radio"/> CPAP | <input type="radio"/> Pressor / epinephrine | |
| <input type="radio"/> Antihistamine | | or the administration of: | <input type="radio"/> Atropine to treat bradycardia | |
| | | <input type="radio"/> Reversal agents | | |
| | | <input type="radio"/> Rapid i.v. fluids | | |
| | | <input type="radio"/> Anticonvulsant i.v. | | |

Step 4: Please note the OUTCOME of the adverse events(s). Check all that apply.

| <i>Minimal risk outcome</i> | <i>Moderate risk outcome</i> | <i>Sentinel outcome</i> | |
|------------------------------------------|------------------------------------------------------------------------------------|------------------------------------------------------------------|--------------------------------------------|
| <input type="radio"/> No adverse outcome | <input type="radio"/> Unplanned hospitalisation or escalation of care ^h | <input type="radio"/> Death | <input type="radio"/> Other, specify below |
| | | <input type="radio"/> Permanent neurological deficit | |
| | | <input type="radio"/> Pulmonary aspiration syndrome ⁱ | |

Step 5: Assign a SEVERITY rating to the adverse event(s) associated with this sedation encounter.

- If there are any options checked in the Sentinel columns above, then this is a Sentinel^l adverse event.
- If the most serious option(s) checked above are Moderate risk, then this is a Moderate^k risk adverse event.
- If the most serious option(s) checked above are Minor risk, then this is a Minor^l risk adverse event.
- If the most serious option(s) checked above are Minimal risk, then this is a Minimal^m risk adverse event.

Additional details (including 'other' entries):

Footnotes:

- a. "Subclinical respiratory depression" is defined as capnographic abnormalities suggesting respiratory depression that do not manifest clinically.
- b. "Paradoxical response" is defined as unanticipated restlessness or agitation in response to sedatives.
- c. "Recovery agitation" is defined as abnormal patient affect or behaviors during the recovery phase that can include crying, agitation, delirium, dysphoria, hallucinations, or nightmares.
- d. "Prolonged recovery" is defined as failure to return to baseline clinical status within 2 hours.
- e. "Failed sedation" is defined as inability to attain suitable conditions to humanely perform the procedure.
- f. Alteration in vital signs (bradycardia, tachycardia, hypotension, hypertension) is defined as a change of >25% from baseline.
- g. "Cardiovascular collapse/shock" is defined as clinical evidence of inadequate perfusion.
- h. Examples of "escalation of care" include transfer from ward to intensive care, and prolonged hospitalisation.
- i. "Pulmonary aspiration syndrome" is defined as known or suspected inhalation of foreign material such as gastric contents into the respiratory tract associated with new or worsening respiratory signs.
- j. "Sentinel^l" adverse events are those critical enough to represent real or serious imminent risk of serious and major patient injury. Once recognized, they warrant immediate and aggressive rescue interventions. Once clinically concluded, they warrant immediate reporting within sedation care systems, and the highest level of peer scrutiny for continuous quality improvement.
- k. "Moderate" adverse events are those that, while not sentinel, are serious enough to quickly endanger the patient if not promptly managed. Once clinically concluded, they warrant timely reporting within sedation care systems, and periodic peer scrutiny for continuous quality improvement.
- l. "Minor" adverse events are those encountered periodically in most sedation settings, and that pose little threat given appropriate sedationist skills and monitoring.
- m. "Minimal" adverse events are those that alone present no danger of permanent harm to the patient.

Fig 1 World SIVA adverse sedation event-reporting tool.

not routinely track them for continuous quality improvement. However, it is prudent for settings with more limited experience, resources, or both to track these events to best monitor the care provided.

As shown in Figure 1, minor AEs are defined as any one or more of the following conditions described below.

Description of AE

Oxygen desaturation (75–90% for <60 s), airway obstruction, failed sedation (defined as inability to attain suitable conditions to humanely perform the procedure), allergic reaction without cardiovascular collapse, alteration in vital signs (bradycardia, tachycardia, hypotension, hypertension) at >25% from baseline, or seizure.

Interventions performed with the intent of treating the AE

Airway repositioning, tactile stimulation, airway suctioning, the addition of supplemental oxygen (or increase if already in place), or the administration of an antisialogogue.

Outcome

These AEs are not associated with injury or permanent outcome.

Minimal AEs

Minimal AEs are those that alone present no danger of permanent harm to the patient. They should be routinely noted on monitoring records but may or may not be tracked for continuous quality improvement based on local concerns and resources.

As shown in Figure 1, minimal AEs are defined as any one or more of the following conditions described below.

Description of AE

Vomiting/retching, subclinical respiratory depression (defined as capnographic abnormalities suggesting respiratory depression that do not manifest clinically), muscle rigidity or myoclonus, hypersalivation, paradoxical response to sedation (defined as unanticipated restlessness or agitation in response to sedatives), recovery agitation (defined as abnormal patient affect or behaviours during the recovery phase that can include crying, agitation, delirium, dysphoria, hallucinations, or nightmares), or prolonged recovery (defined as failure to return to baseline clinical status within 2 h).

Interventions performed with the intent of treating the AE

Administration of additional sedatives (with the purpose of treating an AE such as paradoxical response to sedation), antiemetics, or antihistamines.

Outcome of AE

These AEs are not associated with injury or permanent outcome.

Incorporation of standardized AEs into an AE sedation tool outcome

We advocate adoption of the tool shown in the figure by sedation and training systems worldwide to document and track AEs, when they occur, after each sedation encounter. This could be in the form of a paper document, a computerized page from an electronic medical record, or an Internet-based web log (www.InternationalSedationTaskForce.com).

The tool that we present is unique, in that it is not intended to track every sedation encounter, but rather just those that result in an AE. By minimizing the data collection for the majority of sedations, we hope that this tool will enhance the cooperation and participation of sedation care providers worldwide and serve the ultimate goal of facilitating accurate data capture.

This use of four progressive categories of clinical importance permits the tool to be used by all sedation providers and to be adapted to any setting. A highly organized and established sedation care system providing a high volume of sedations, for example, might appropriately only need to track the top two acuity levels of AEs. In other settings with less experience, resources, or both, it may be appropriate to track most or all acuity levels to best monitor the care provided. Although the definitions of AEs and the assigned acuity may be the subject of debate among providers, this consensus document, if followed, could lay the foundation of collecting and presenting outcome-related data using standardized definitions. These definitions, collected with accompanying patient characteristics and other sedation-related details (sedation agent, dosage, type of procedure, ASA score, etc.), will provide important first steps at aggregating data from a variety of specialists worldwide. If adopted, this data collection tool will provide the foundation for evaluating sedation practice and patient outcome across the specialities and continents. Researchers could readily choose certain acuity levels (or groupings thereof) to represent composite endpoints for comparing sedation regimens or protocols.

Implications

The practice of sedation encompasses multiple specialities, varied clinical settings, and patients of all ages. The ability to evaluate, present, and compare sedation outcomes has been hampered by the lack of consistent definitions and terminology for AEs. These definitions can differ between institutions, individuals, and speciality societies. Without uniform definitions, it is impossible to evaluate and compare sedation-related outcomes. We present a reconfigured approach to the identification of AEs—an approach primarily based upon the need for interventions that unarguably represent an action intended to resolve, relieve, or reverse a sedation-related outcome.

The incorporation of these standardized definitions into a World SIVA AE Sedation Outcome Tool (www.AESedationReporting.com, www.InternationalSedationTaskForce.com, www.WorldSIVA.org) is intended to present a means for the

simple, quick, and easy documentation of the standardized AEs. It may be used as supplementary documentation either for every sedation encounter or just those with an AE. Implementation of this tool could be accomplished through completion of a paper form, incorporation into an electronic medical record, or as an open access, free of charge, web-based tool which can store each user's data, be downloaded onto individual or group servers, and enable shared collection of all users.

The adoption of standardized definitions and nomenclature has become a worldwide effort across the specialties and disciplines. The WHO has pioneered the adoption of standardized definitions and processes for medical conditions, biological assays, treatment outcomes, and even surgical checklists.^{28–35} The adoption of surgical checklists, for example, has improved the outcome of patients at those facilities that have adopted the checklist and process.^{28 32 34 35} Currently, there are no standardized definitions for sedation-related outcomes. Completion of this tool with concomitant collection of patient characteristics and sedation-related specifics will allow the collection and aggregation of sedation-related outcomes in a wide range of settings. The Adverse Events Sedation Reporting tool could, if adopted, provide a means to standardize the definitions of sedation-related AEs and provide a benchmark to evaluating sedation practice and outcome.

Declaration of interest

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