Consensus-Based Recommendations for Standardizing Terminology and Reporting Adverse Events for Emergency Department Procedural Sedation and Analgesia in Children

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Children commonly require sedation and analgesia for procedures in the emergency department. Establishing accurate adverse event and complications rates from the available literature has been difficult because of the difficulty in aggregating results from previous studies that have used varied terminology to describe the same adverse events and outcomes. Further, serious adverse events occur infrequently, necessitating the study of large numbers of children to assess safety. These limitations prevent the establishment of a sufficiently large database on which evidence-based practice guidelines may be based. We assembled a panel of pediatric sedation researchers and experts to develop consensus-based recommendations for standardizing procedural sedation and analgesia terminology and reporting of adverse events. Our goal was to create a uniform reporting mechanism for future studies to facilitate the aggregation and comparison of results. [Ann Emerg Med. 2009;53:426-435.]

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INTRODUCTION AND IMPORTANCE

A large number of children receive procedural sedation and analgesia for diagnostic and therapeutic procedures in emergency departments (EDs) each year. Although it is critical to establish evidence-based practice in procedural sedation, efforts have been limited by an inability to aggregate results from existing studies. Practice is varied and results are reported inconsistently because investigators do not have a standardized set of definitions and reporting guidelines to follow.[1-11]

Using the same definitions to describe sedation practices, interventions, adverse events and time intervals is an important first step to facilitate comparisons between studies and the aggregation of data from multiple studies.[12-15] Well-defined adverse events reported in studies of sufficiently large patient populations will permit improved assessment of procedural sedation risk and patient outcomes.

Goals and Objectives

Following the International Liaison Committee on Resuscitation Task Force on Cardiac Arrest and Cardiopulmonary Resuscitation Outcomes that developed uniform definitions and reporting templates in the "Utstein

style" to standardize research reporting of cardiac arrest,[16] we created standardized definitions for sedation-related terms, adverse events, and time intervals. We also propose consensus-based recommendations for uniform adverse event reporting based on review of the existing pediatric sedation literature.

It is our intention that the definitions and reporting framework presented here be adopted by sedation researchers and used in future procedural sedation investigations.

MATERIALS AND METHODS

In July 2007, we assembled a panel of experts in procedural sedation and analgesia from 2 national collaborative pediatric emergency medicine research networks to establish consensus on uniform terms, definitions, and reporting for pediatric ED procedural sedation and analgesia. The panel chairs (M.B. and M.G.R.) approached the leadership of Pediatric Emergency Research Canada (PERC) and the Pediatric Emergency Care Applied Research Network (PECARN) for recommendations within their membership for researchers who had a particular expertise in emergency medicine, procedural sedation and analgesia, or patient safety. The panel chairs selected a representative group, composed of 6 pediatric emergency physicians and 2 pediatric anesthesiologists. PERC and PECARN were equally represented. These 2 national collaborative research networks represent institutions that care for approximately 1.3 million children annually in 34 EDs.

A reference list was generated from a MEDLINE search (1950 to week 1 July 2007), using the search strategy (sedation OR anesthesia OR analgesia) AND (emergency department OR pediatrics) AND (adverse event OR adverse outcome). We identified all articles from emergency medicine or anesthesia that contained information on sedation-related adverse outcomes, searched the bibliographies of all identified articles, and queried the expert panel for additional relevant articles. A draft list of sedation terms, adverse events, and definitions of these items found in the reference list articles was compiled and circulated to panel members. Consensus was reached on which events should be routinely reported in future pediatric ED sedation studies.

We used electronic communication, teleconferencing, and one face-to-face meeting to review the literature, discuss terminology, and reach consensus on definitions and recommendations for uniform reporting of adverse events. All members participated in discussions on each topic, and consensus was reached through debate and dialogue that was not time limited. Some terms and concepts, including laryngospasm, depth of sedation, and determining the optimal format for the definitions of adverse events, were more difficult to ratify. Disagreement between panel members was resolved through repeated discussion (teleconference and face-to-face meeting) until unanimous group consensus was reached. During a meeting at Mont Tremblant, Quebec, on January 28, 2008, the panel rediscussed all terms and ratified their definitions. When the existing literature was deemed insufficient to come to a consensus agreement on definition, recommendations for data collection pertinent to a given term were made and direction for future study required to develop definitive definitions was provided.

Determining the optimal measure to define adverse events was the greatest challenge of this project, resulting in one of the most difficult decision points for the panel. The pros and cons of including a discrete threshold and duration of an event (eg, an oximeter reading of less than 90% for 30 seconds or longer for oxygen desaturation) or interventions performed in response to the event in the definitions were discussed at length. Although using the traditional structure of a prespecified threshold and duration to describe adverse events is the most obvious and, ostensibly, objective approach, the panel believed that this method may yield inaccurate and unreliable results. Using a single numeric value to identify patients who have experienced an adverse event has several important limitations: a single threshold may *miss* clinically significant events (eg, a child with a precipitous oxygen desaturation requiring airway maneuvers, who does not meet the absolute number threshold required to be considered an adverse event), is prone to mechanical artifact, leading to detection of clinically insignificant events (eg, oximeter reads 88% but resolves spontaneously before the clinician intervenes), and is not uniformly applicable (eg, may not be meaningful at higher altitudes). Further, and perhaps most significantly, the duration of an event is particularly difficult to assess in a clinical setting where precise measurement of time intervals is inaccurate and somewhat arbitrary when left to the clinician's best estimation.

Intervention-based definitions were chosen because the panel believes this framework will yield the greatest possibility of uniform data collection for clinically important events. Definitions using this approach require specific clinical criteria to be present *and* for one or more interventions to be performed with the intention of treating or managing the event. The presence or absence of an intervention performed in response to a clinical event is a reproducible measure and reflects the clinician's interpretation of the significance of the event in the clinical context. The panel does recognize that interventions *performed* reflect the provider's clinical judgment and experience and may not necessarily be absolutely *required*. However, by including the number and type of interventions performed, as well as the documentation of objective characteristics (eg, lowest reliable oxygen saturation observed), researchers will be able to determine the severity and significance of each event.

The panel considered several hypothetical scenarios of adverse events, and all would have had 1 or more intervention(s) performed. An intervention could have been as simple as airway repositioning. We contend that researchers are not concerned with events that are extremely short lived (seconds) or resolve spontaneously (error in equipment reading or are an expected physiologic effect) and thus are of questionable clinical significance. Documenting interventions performed yields reproducible measures that will lead to more standardized and accurate data collection. Although this approach is not

instinctive, it is our belief that it will allow sedation researchers to collect a robust data set of clinically important adverse events with a range of severity defined by the number and type of interventions performed while minimizing the recording of events whose significance is difficult to interpret.

Our intent was to create a comprehensive core data set of adverse events to be reported. Researchers may choose to study a subset of terms applicable to their chosen study hypothesis. Similarly, for their specific research needs they may add to this data set as they desire.

The content of this article has been endorsed by the research networks of PERC and PECARN.

SEDATION TERMINOLOGY

Procedural Sedation and Analgesia

Definition. Procedural sedation and analgesia, commonly referred to as "sedation," is the use of anxiolytic, sedative, analgesic, or dissociative drugs to attenuate pain, anxiety, and motion to facilitate the performance of a necessary diagnostic or therapeutic procedure, provide an appropriate degree of amnesia or decreased awareness, and ensure patient safety.[17,18]

Commentary. "Conscious sedation" is a misleading and outdated term that should no longer be used in research or clinical practice.[19] The use of analgesic drugs alone is not considered sedation.

Presedation Assessment

Definition. A focused history and physical examination to determine factors that may influence the selection of the sedation technique and affect the safety of the sedation.[20] This evaluation includes ascertainment of current or past patient health issues, the indications for sedation, previous patient experience with sedation or anesthesia, and the presence of airway or other conditions that may affect the efficacy of the sedation or the incidence of side effects, adverse events, or complications.

Rationale. Patients exhibit variable responses to sedative and analgesic drugs. The presedation assessment guides the selection of the sedation technique. Drug dose requirements, depth of sedation, and frequency of adverse events may be influenced by a variety of patient factors such as age, coexisting illness or injury, pharmacogenetic factors, and psychological or anatomic variability. Documentation of relevant factors gleaned during the presedation assessment and correlation with adverse events may lead to improved recognition of specific risk factors for sedation-related adverse events. Future procedural sedation and analgesia research will progress by identifying risk factors for adverse events and by evaluating strategies to minimize sedation-related adverse events. We recommend that future research include a statement that this assessment was performed and that relevant patient or situational risk factors and potentially confounding variables were assessed in the context of the specific research question.

Presedation State

Definition. The patient's behavioral state immediately before sedation. A child's behavior can be characterized as calm (eg, not crying), agitated but responds to comforting (eg, briefly stops crying), or agitated and does not respond to comforting (eg, continuous crying).

Rationale. A child's behavioral state before sedation may affect the dose of sedative required, unpleasant recall of the procedure, or unpleasant recovery reactions.[5,21,22] Presedation agitation has been described by several authors, but no definitions or validated measures exist. Two studies have collected data on this entity: one using a visual analog scale[22] to rate the degree of agitation and the other using an ordinal scale.[23] Because of limitations in using a single visual analog scale measurement to compare groups of individuals,[24] and in the absence of a validated measure, we suggest using a simple ordinal scale to describe the patient's behavior. We recommend that investigators describe in the methods section how a child's behavioral state was assessed and any interventions that were performed to affect this state.

Depth of Sedation

Definition. Depth of sedation has been qualitatively defined and described as a continuum, progressing from mild through moderate to deep sedation and potentially to general anesthesia.[25-29] Identifying depth of sedation is important because it is believed that the risk of adverse events increases as patients become more deeply sedated. The correlation between depth of sedation and risk of adverse events is altered with ketamine because of its unique dissociative properties.[20,30-32]

Rationale. Depth of sedation should be part of the patient assessment and reported in research to help understand the efficacy and safety of the sedation technique. Scales commonly used to assess depth of sedation were developed to determine a patient's state of recovery or have not been validated in the ED setting.[33-36] Because of these limitations, we are unable to endorse a specific tool or definition for this term. Further research is needed to objectively define the stages on the continuum and to create or validate a tool for use in the ED setting. It is important for investigators to state in the methods section how depth of sedation is quantified.

Efficacy of Sedation

Definition. The creation of conditions necessary to safely facilitate the completion of a procedure through attenuation of pain, anxiety and movement with amnesia or decreased awareness.[11,17,18] All of the following criteria must be present for a sedation to be considered efficacious:[37]

a) The patient does not have unpleasant recall of the procedure.
b) The patient did not experience sedation-related adverse events resulting in
abandonment of the procedure *or*
a permanent complication (Section VIII) *or*
an unplanned admission to the hospital or prolonged ED observation

c) The patient did not actively resist or require physical restraint for completion of the procedure. The need for minimal redirection of movements should not be considered as active resistance or physical restraint.

Commentary. Presence of any of the above criteria is considered a sedation failure.

Rationale. Previous researchers have described sedation failure as the inability to complete a procedure because of patient anxiety, pain, or distress.[9] We have expanded this definition to include the patient's perception of efficacy (lack of unpleasant recall of the procedure) and have added a measure of safety in delivering the sedation. We are unable to endorse a specific measure of patient distress because there are no validated tools that are easily applicable in this setting. Further research is needed to objectively define and quantify this term in the ED setting. It is important for investigators to state in the methods section how efficacy of sedation is quantified.

Readiness for Discharge

Definition. The time at which a patient emerges from the effects of sedation to a level of consciousness that reflects satisfactory physiologic recovery (ability to achieve a satisfactory state of wakefulness and maintain a patent airway without respiratory depression and return to baseline motor function and vital signs) *and* demonstrates adequate pain control.

Rationale. Readiness for discharge is an important outcome measure in sedation research because it defines clinical recovery from the pharmacologic effects of sedation. Reporting time to physiologic recovery will allow researchers to identify trends and quantify recovery times for sedation agents. We recommend that investigators document the time to physiologic recovery in addition to the time of actual ED discharge because many factors unrelated to a patient's recovery from sedation such as the availability of diagnostic imaging, consultants, ED staff, and ED patient census influence the time a patient is actually discharged from the ED. Many consensus-based criteria exist to confirm a patient's readiness for discharge; however, none have been objectively studied or validated. Further research is needed to objectively define and quantify this term in the ED setting. We recommend that investigators document in the methods section criteria used to define readiness for discharge.

SEDATION INTERVALS

The time of sedation may be broken into 4 distinct intervals or phases: presedation, sedation, ED recovery, and postdischarge. Definitions, as well as subphases, are listed and defined in the Figure. It has been postulated that patients' risk for certain adverse events varies with their phase of sedation. Further study of adverse events and severity by sedation interval is warranted. We recommend that investigators record the times a patient begins and ends all phases and subphases.

ADVERSE EVENT TERMINOLOGY

Accurate reporting of adverse events, the circumstances surrounding these events, and the interventions that result from their occurrence are of vital importance in the identification of the risk factors for and causes of adverse events associated with procedural sedation. The panel has recommended reporting all sedation events that result in an intervention or a change in disposition from the ED. All clinically relevant events, from minor (eg, mild desaturation requiring a jaw thrust) to more serious (eg, clinically apparent pulmonary aspiration), will be captured with this method. Only transient or minor physiologic effects that have no clinical consequence (eg, minor changes in the pulse rate, respiratory rate, and blood pressure caused by many sedation drugs) will not be detected with this framework. These events do not require a change in the sedation plan and were deemed not to contribute to the understanding of the risk factors for and causes of adverse events associated with procedural sedation.

The adverse events listed below fall into several categories: respiratory (oxygenation or ventilation-associated and clinically apparent pulmonary aspiration), vomiting, cardiovascular (bradycardia and hypotension), excitatory movements (myoclonus, muscle rigidity, and generalized seizure), adverse behavioral reactions (paradoxic response to sedation and unpleasant recovery reaction), and permanent complications (neurologic injury and death).

Patients may experience more than one category of adverse events, as well as more than one type of adverse event within a given category. All events should be reported separately, even when occurring in the same category (eg, apnea associated with oxygen desaturation should be reported as 2 separate events). We provide definitions for adverse events (below), sedation intervals (Figure), and a template for adverse event data collection for sedation research (Appendix E1, available online at http://www.annemergmed.com).

OXYGENATION

1.1 Oxygen Desaturation

Definition. Oxygen desaturation *and* one or more interventions are performed with the intention of improving the oxygen saturation.[3,38-40] The interventions include the following:

a) Vigorous tactile stimulation
b) Airway repositioning—chin lift, jaw thrust, neck extension, midline repositioning
c) Suctioning
d) Supplemental or increased oxygen delivery
e) Oral or nasal airway placement
f) Application of positive pressure or ventilation with bag mask
g) Tracheal intubation

Rationale. Definitions for oxygen desaturation use a combination of threshold and duration of desaturation to describe the event (eg, oxygen saturation $<90\%$ for ≥ 30 seconds).[41-43] We chose an intervention-driven definition because a prespecified threshold may miss some cases of important desaturation. For example, a child who has been preoxygenated to 100% may experience a precipitous decrease

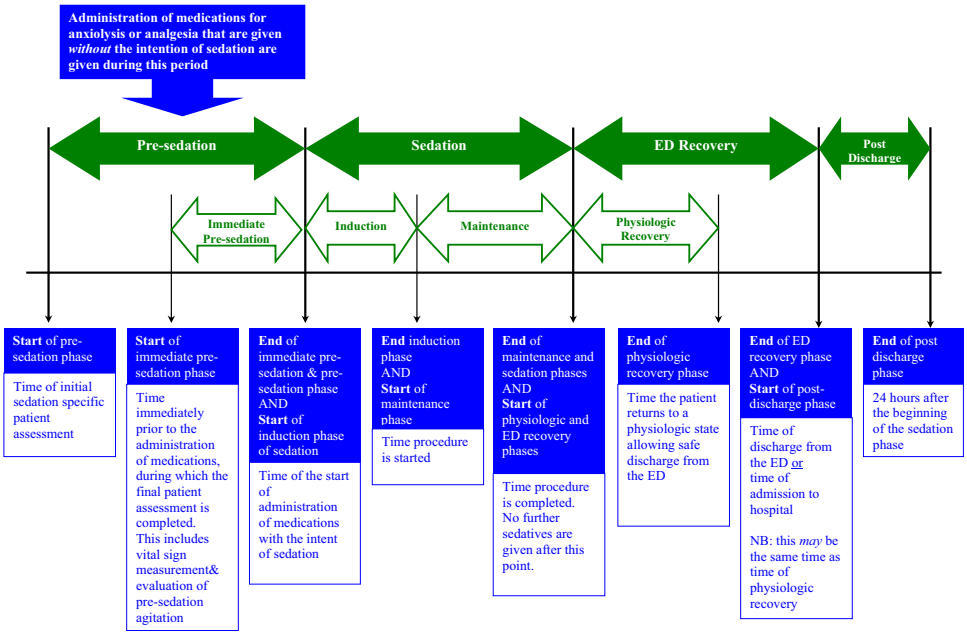

Figure. Sedation time intervals.

in saturation to 90% that is managed by the administration of supplemental oxygen and maneuvers to reposition the airway. This event is clinically relevant yet would be missed if a threshold alone were used to define oxygen desaturation. Further, duration of desaturation is difficult to accurately assess. All clinically significant cases will be captured in the proposed intervention-driven definition. Researchers will be able to distinguish the severity of desaturation with the documentation of lowest oxygen saturation, use of preoxygenation, and the number and type of interventions performed.

VENTILATION

2.1 Apnea: Central

Definition. Cessation or pause of ventilatory effort *and* one or more interventions are performed with the intention of stimulating or assisting ventilation. The interventions include the following:

a) Vigorous tactile stimulation
b) Application of bag mask *with* assisted ventilation
c) Tracheal intubation
d) Administration of reversal agents (opioid or benzodiazepine antagonists)

Rationale. Definitions for apnea describe the event as a loss of respiratory effort for a specified duration (eg, no respiratory effort for 30 seconds).[2,44-48] We chose an intervention-driven definition because accurate measurement of apnea duration is difficult. Researchers will be able to verify whether patients met the definition of central apnea by documenting the criteria used for recognition of the event and will be able to assess severity by the number and type of interventions performed.

2.2 Apnea: Obstructive

2.2.1 Partial Upper Airway Obstruction

Definition. Incomplete obstruction to air exchange manifested by the presence of one or more of the following:

a) Stridor
b) Snoring
c) Chest wall and suprasternal retractions AND rapid resolution with one or more of the following interventions to treat the partial airway obstruction:[9,49,50]

a) Airway repositioning
b) Suctioning
c) Oral or nasal airway placement
d) Application of positive pressure with bag mask but *without* assisted ventilation

Rationale. Most existing studies include partial airway obstruction in a general category of respiratory adverse events.[5,7,41] We believe it is important to distinguish partial from complete airway obstruction because the interventions, treatments, and outcomes may be quite different. We chose a definition according to specific criteria and the requirement for either an airway maneuver or the application of positive pressure with a bag mask apparatus continuous positive airway pressure in an attempt to alleviate the obstruction.[9,49] Airway obstruction that does *not* rapidly and easily respond to these simple interventions does not meet the requirements for partial airway obstruction and must be reclassified.

2.2.2 Complete Upper Airway Obstruction

Definition. Ventilatory effort with no air exchange* *and* one or more of the following interventions are performed with the intention of relieving complete airway obstruction:

a) Airway repositioning
b) Suctioning
c) Oral or nasal airway placement
d) Application of positive pressure with bag mask +/− assisted ventilation
e) Tracheal intubation
f) Administration of additional sedation agents
g) Administration of neuromuscular blockade agents

*No air exchange is manifested by the absence of upper airway (eg, stridor or snoring) and breath sounds on auscultation and the loss of CO_2waveform, when capnography is used.

2.3 Laryngospasm

Definition. Partial or complete upper airway obstruction, *with* oxygen desaturation caused by involuntary and sustained closure of the vocal cords *and* is *not* relieved by routine airway repositioning maneuvers, suctioning, or insertion of a nasal or oral airway.[51,52]

Note. A characteristic stridulous noise can be heard with partial laryngospasm but will be absent in complete laryngospasm

Rationale. Although laryngospasm is a subset of airway obstruction, it warrants separate data collection because of its association with commonly used sedation drugs and high likelihood for treatment with aggressive airway interventions. Laryngospasm is the sudden pathologic adduction of the vocal cords with partial or complete closure of the glottic opening and may be intermittent or sustained, brief or prolonged.[51-53] Emergency physicians do not routinely visualize the airway when administering procedural sedation; therefore, laryngospasm in the ED setting is a clinical diagnosis. Laryngospasm has been reported in association with ED sedation, and these cases likely represent a spectrum of severity because several cases improved without intervention.[1,5,8,10,31,40,54,55] Differentiating partial airway obstruction caused by decreased muscle tone or soft tissue obstruction from incomplete laryngospasm is difficult. However, partial airway obstruction relieved by simple airway repositioning or placement of an oral or nasal airway should not be considered laryngospasm.[52]

Only sustained partial or complete closure of the cords associated with oxygen desaturation, not responsive to airway maneuvers, representing an acute life-threatening airway obstruction should be considered true laryngospasm.[51-53] The severity of the event will be further described by documenting interventions performed (eg, bag-valve-mask ventilation, administration of a muscle relaxant) in response to the laryngospasm.

CLINICALLY APPARENT PULMONARY ASPIRATION

Definition. Suspicion* *or* confirmation† of oropharyngeal or gastric contents in the trachea during the sedation or physiologic recovery phase *and* the appearance of respiratory signs and symptoms that were not present before the sedation.[56,57] The new signs and symptoms must present before the end of the ED recovery phase (Figure).

(i) Physical signs
Cough
Crackles/rales
Decreased breath sounds
Tachypnea
Wheeze
Rhonchi
Respiratory distress

(ii) Oxygen requirement
Decrease in oxygen saturation from baseline, requiring supplemental oxygen

(iii) Chest radiograph findings
Focal infiltrate, consolidation or atelectasis

**Suspicion* of contents in the trachea is established if, during the sedation phase or before physiologic recovery in the ED recovery phase, (1) a patient vomits or retches (without visible gastric contents) *or* (2) there is evidence of gastric contents in the material suctioned from the oropharynx *or* (3) there is an onset of coughing with oxygen desaturation.

†*Confirmation* of contents in the trachea is established when there is direct visualization of oropharyngeal or gastric contents in the trachea on laryngoscopy.

The patient must develop one or more signs or symptoms in any of the following 3 categories:

Rationale. Definitions of clinically apparent pulmonary aspiration require *confirmation* of gastric secretions or particulate matter in the tracheobronchial tree by laryngoscopy or flexible bronchoscopy.[58,59] Emergency physicians do not routinely perform laryngoscopy in association with procedural sedation; therefore, a proviso was made for those cases in which the presence of gastric contents in the tracheobronchial tree is suspected but has not been confirmed. Suspicion of aspiration is clearly defined and is an event that leads a physician to believe that a patient may be at risk for aspiration because of the timing of the regurgitation/vomiting in relation to a patient's state of arousal. Confirmation is achieved when new respiratory signs and symptoms develop before the end of the ED recovery phase. Documentation of the factors contributing to the diagnosis of aspiration, clinical manifestations, and treatments will allow researchers to gain a better understanding of this rare entity in ED procedural sedation.

RETCHING/VOMITING

Definition. The motor reflex response characteristic of retching with or without the expulsion of gastric contents through the mouth or nose that occurs during sedation, ED recovery or postdischarge phases of sedation (Figure).

If the timing and extent of vomiting present a suspicion or confirmation of clinically apparent pulmonary aspiration, this adverse event must also be documented (Section III).

Rationale. Retching and vomiting are unpleasant for children and their families, may increase the risk of aspiration, may increase the length of the ED stay, and are more commonly associated with certain sedative drugs. For these reasons, retching or vomiting during the sedation, ED recovery, or postdischarge phase is important and should be reported. Documenting the administration of an antiemetic as prophylaxis or treatment is also important.

CARDIOVASCULAR EVENTS

5.1 Bradycardia

Definition. Pulse rate decreasing 2 standard deviations below normal for age as described by the American Heart Association (AHA) in the Pediatric Advanced Life Support (PALS) Provider Manual[60] during the sedation or physiologic recovery phase (Figure) *and* one or more interventions are performed with the intention of improving pulse rate and cardiac output. The interventions include the following:

a) Suctioning
b) Vigorous tactile stimulation
c) Airway repositioning
d) Supplemental oxygen
e) Application of bag mask *with* assisted ventilation
f) Tracheal intubation
g) Chest compressions
h) Administration of medications

Bradycardia may be an expected adverse effect of some drugs and is a normal finding in certain populations (eg, athletes, those with eating disorders, those taking certain medications). Bradycardia is considered an adverse event only if an intervention is performed in an attempt to improve the pulse rate and cardiac output.

Rationale. The AHA offers the most accepted definition for bradycardia in pediatrics and is taught during PALS. Although some studies use a percentage change in pulse rate from baseline, this is a difficult calculation to make and may lead to inaccurate reporting. An intervention-driven definition based on AHA criteria will capture all significant events of bradycardia and exclude those with a normal resting pulse rate that decreases below the AHA thresholds but is not clinically significant.

5.2 Hypotension

Definition. Systolic blood pressure less than the fifth percentile for age, as defined by the AHA in PALS[61] during the sedation or ED recovery phase (Figure) *and* one or more intervention is performed with the intention of improving the blood pressure. These interventions include administration of:

a) IV Fluid
b) Medications
c) Chest compressions

Hypotension may be an expected adverse effect of some drugs used for sedation. Hypotension is considered an adverse event only if an intervention is performed to improve the blood pressure.

Rationale. The AHA offers the most accepted definition for hypotension in pediatrics and is taught during PALS. Although some studies use a percentage change in blood pressure, this is a difficult calculation to make and may lead to inaccurate reporting. An intervention-driven definition based on AHA criteria will capture all clinically significant episodes of hypotension.

EXCITATORY MOVEMENTS

6.1 Myoclonus

Definition. Involuntary, brief contraction of some muscle fibers, of a whole muscle, or of different muscles of one group, leading to movements of the corresponding body parts, usually not longer than 1/10 of a second (100 milliseconds)[62] *and* interferes with the procedure, requiring an intervention or administration of medications. Hiccupping is a form of myoclonus.

6.2 Muscle Rigidity

Definition. Involuntary muscle stiffening in extension that can be associated with shaking *and* interferes with the procedure, requiring an intervention or administration of medications.

6.3 Generalized Motor Seizure

Definition. Temporary abnormal neural electrophysiologic phenomenon that manifests as involuntary contractions or series of contractions of the voluntary muscles. The contractions can be sustained (tonic) or repeated (tonic-clonic).[63]

Commentary. An extreme form of muscle rigidity with shaking can resemble seizure activity; therefore, confirming a true seizure would require the use of electroencephalography.

Rationale. Although it is thought that the likelihood of a true seizure is low during procedural sedation and analgesia because of anticonvulsant properties of many sedation drugs, some excitatory movements can resemble tonic-clonic seizures. Rigidity with shaking cannot be distinguished from true seizure activity without concurrent electroencephalography monitoring, which is impractical during sedation in the ED. Further, it is known that some excitatory movements are more commonly associated with certain sedation drugs (eg, myoclonus with etomidate). These side effects are considered adverse events when they prolong or interrupt the procedure or require additional medications to treat the movements.

ADVERSE BEHAVIORAL REACTIONS

7.1 Paradoxic Response to Sedation

Definition. Unanticipated restlessness or agitation in response to the administration of sedation drugs occurring during the sedation phase *and* results in the unplanned administration of reversal agents or alternative sedation drug(s),

or results in a delay in the completion or discontinuation of the procedure.[64]

Rationale. Paradoxic reactions to sedation drugs have been reported and often result in an alteration or discontinuation of the sedation plan. These events are important and should be reported in research.

7.2 Unpleasant Recovery Reactions

Definition. Abnormal patient affect or behaviors during the ED recovery phase[11,22,54,55,65] (Figure) that requires additional treatment and a change or delay in patient discharge from the ED. The behaviors include one or more of the following[54,66]:

a) Crying—Inconsolable
b) Agitation—Restless, continuous activity
c) Delirium—State of severe confusion
d) Dysphoria—Inappropriate mood of sadness
e) Nightmares—Unpleasant dreams
f) Hallucinations—Responds to sensory phenomena (ie, seeing, hearing, or feeling) that are not physically present.

Rationale. Many terms have been used to describe this event. We have chosen to restrict this definition to unpleasant reactions that result in an unexpected intervention. Documentation of a patient's recall of the event will be important to determine the clinical significance of these events.

PERMANENT COMPLICATIONS

8.1 Permanent Neurologic Injury

Definition. A neurologic deficit that was not present before sedation and does not resolve.

Commentary. This definition requires follow-up to confirm that the deficit was not transient.

8.2 Death

The irreversible cessation of cerebral function, spontaneous function of the respiratory system, and spontaneous function of the circulatory system.[67]

OTHER

Any effect of sedation not specifically mentioned above that results in an unexpected intervention should be described and documented.

DISCUSSION

In this article, our consensus panel proposes a framework of definitions and recommendations for reporting sedation terminology, time intervals, and adverse events for procedural sedation research. It is our goal that through this standardization, future sedation studies will generate data that may be readily compared and aggregated. It is our further intention that this work facilitate study of the large populations of patients required to allow for definitive clinical care guidelines to be devised that will ensure the safety of ED procedural sedation and analgesia in children.

Although we believe that uniform reporting of adverse events will improve pediatric procedural sedation research, this approach must be interpreted in light of several important limitations. First, the proposed definitions represent a consensus opinion. Every effort was made to develop evidence-based definitions; however, this was often not possible because of the paucity of existing information. Second, our intervention-based approach to definitions is not commonly used in current sedation research. Although we believe this method will yield a more objective, uniform data set, the deviation from the traditionally used "threshold and duration" approach may initially be met with resistance from sedation researchers. It is our desire that Appendix E1 (available online at http://www.annemergmed.com) will provide researchers with a reporting template that will ease the transition to intervention-based definitions in sedation research. Third, the definitions and data collection template have not been piloted. According to the Utstein experience, with incorporation into general use, we expect that some adaptations to the reporting framework will be needed in the future. The panel is committed to following this forward and making modifications as needed. Finally, as reflected by the experience of the panel, the focus of our recommendations was on children undergoing procedural sedation and analgesia in the ED; however, the same principles could be applied to patients of all ages and to other sedation settings outside of the operating room.

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Appendix E1. Recommended documentation for sedation research.

A. SEDATION DOCUMENTATION

1. Pre-Sedation Behavioral State

Definition: The patient's behavioral state immediately prior to sedation.

1. Indicate the state that best describes the child's behavior immediately prior to the administration of the sedation drugs:
   ☐ Calm (eg, not crying)
   ☐ Agitated but responds to comforting (eg, briefly stops crying)
   ☐ Agitated and does not respond to comforting (eg, continuous crying)

2. Efficacy of Sedation

Definition: A successful sedation creates conditions necessary to safely facilitate completion of a procedure through attenuation of pain, anxiety and movement with amnesia or decreased awareness. Patient must fulfill all criteria for a sedation to be considered successful.

1. Sedation was efficacious ☐ YES ☐ NO
   If YES, indicate which of the following criteria were met during the sedation
   ☐ The patient does not have unpleasant recall of the procedure
   ☐ The patient did not experience a sedation-related adverse event, resulting in the abandonment of the procedure
   ☐ The patient did not experience a permanent complication
   ☐ The patient did not have an unplanned admission to hospital or prolonged ED observation
   ☐ The patient did not actively resist or require physical restraint for completion of the procedure

B. ADVERSE OUTCOME DOCUMENTATION

1. Oxygenation

1.1 Oxygen Desaturation ☐ YES ☐ NO

Definition: Oxygen desaturation AND one or more intervention(s) are performed with the intention of improving the saturation

1. Baseline oxygen saturation on room air prior to PSA _____%
2. Oxygen delivered at start of Sedation phase ☐ NO ☐ YES
   If YES, Method of oxygen delivery: ☐ nasal canula ☐ blow-by ☐ face mask ☐ face mask + non-rebreather
   Flow rate delivered: _____litres/minute
3. Indicate the interventions performed in response to the oxygen desaturation *(indicate ALL that apply)*
   ☐ Vigorous tactile stimulation
   ☐ Airway repositioning
   ☐ Suctioning
   ☐ Supplementing/increasing oxygen
   ☐ Oral or nasal airway placement
   ☐ Application of positive pressure +/- ventilation with bag mask
   ☐ Tracheal Intubation
   ☐ Other _____
4. Lowest reliable oxygen saturation measured during the sedation _____%

2. Ventilation

2.1 Apnea: central ☐ YES ☐ NO

Definition: Cessation or pause of ventilatory effort AND one or more intervention(s) are performed with the intention of stimulating or assisting ventilation.

1. Indicate the criteria used for recognition *(indicate ALL that apply)*
   ☐ Visual confirmation of cessation/pause of ventilation
   ☐ Cyanosis
   ☐ Oxygen desaturation
   ☐ Loss of CO_2 waveform
   ☐ Other _____
2. Indicate the interventions performed in response to the apnea (*indicate ALL that apply)*
   ☐ Vigorous tactile stimulation
   ☐ Administration of reversal agents
   ☐ Other _____
   ☐ Application of bag mask *with* assisted ventilation
   ☐ Tracheal intubation

2.2 Apnea: Obstructive

2.2.1 Partial Upper Airway Obstruction ☐ YES ☐ NO

Definition: Manifested by stridor, snoring OR chest wall and suprasternal retractions AND one or more intervention(s) are performed with the intention of relieving the partial airway obstruction.

1. Indicate the criteria used for recognition *(indicate ALL that apply)*
   ☐ Stridor
   ☐ Snoring
   ☐ Chest wall or suprasternal retractions
   ☐ Oxygen desaturation
   ☐ Other _____

2. Indicate the interventions performed in response to the partial obstruction (*indicate ALL that apply)*
   - ☐ Airway repositioning
   - ☐ Suctioning
   - ☐ Oral or nasal airway placement
   - ☐ Application of positive pressure with bag mask but *without* assisted ventilation
   - ☐ Other _____

2.2.2 Apnea: Complete Upper Airway Obstruction ☐ YES ☐ NO

Definition (general terms): Ventilatory effort with NO air exchange manifested by absence of upper airway (e.g. stridor or snoring) and breath sounds on auscultation *and* a loss of CO_2 waveform if capnography is used AND the obstruction is relieved by one or more intervention(s) performed with the intention of relieving the complete airway obstruction.

1. Indicate the criteria used for recognition *(indicate ALL that apply)*
   - ☐ Ventilatory effort with NO air exchange
   - ☐ Loss of CO_2 waveform (if capnography used)
   - ☐ Oxygen desaturation
   - ☐ Other _____

2. Indicate the interventions performed in response to the complete obstruction (*indicate ALL that apply)*
   - ☐ Airway repositioning
   - ☐ Suctioning
   - ☐ Oral or nasal airway placement
   - ☐ Administration of additional sedation agents
   - ☐ Application of positive pressure +/- ventilation with bag mask
   - ☐ Tracheal intubation
   - ☐ Administration of neuromuscular blockade agents
   - ☐ Other _____

2.3 Apnea: Laryngospasm ☐ YES ☐ NO

Definition: Partial or complete upper airway obstruction, *with* oxygen desaturation due to involuntary and sustained closure of the vocal cords AND is NOT relieved by routine airway repositioning maneuvers, suctioning or insertion of a nasal or oral airway

1. Indicate the criteria used for recognition *(indicate ALL that apply)*
   - ☐ Ventilatory effort with NO air exchange
   - ☐ Loss of CO_2 waveform (if capnography used)
   - ☐ Oxygen desaturation
   - ☐ Partial airway obstruction not relieved with airway maneuvers
   - ☐ Other _____

2. Indicate the interventions performed in response to the laryngospasm (*indicate ALL that apply)*
   - ☐ Administration of additional sedation agents
   - ☐ Application of positive pressure +/- ventilation with bag mask
   - ☐ Tracheal intubation
   - ☐ Administration of neuromuscular blockade agents
   - ☐ Other _____

3. Clinically Apparent Pulmonary Aspiration ☐ YES ☐ NO

Definition: Suspicion OR confirmation of oropharyngeal or gastric contents in the trachea during the Sedation or Physiologic Recovery phase AND the appearance of respiratory signs and symptoms that were not present prior to the sedation. The new signs and symptoms must present before the end of the ED Recovery phase.
The patient must develop one or more sign or symptom in any of the following three categories:
(i) Physical Signs: cough, crackles/rales, decreased breath sounds, tachypnea, wheezing, rhonchi OR respiratory distress
(ii) Oxygen Requirement: decrease in oxygen saturation from baseline requiring supplemental oxygen
(iii) Chest X-Ray Findings: focal infiltrate, consolidation or atelectasis

1. Indicate if there was physical evidence of regurgitation ☐ NO ☐ YES
   If YES, was this confirmed by direct visualization of gastric contents in the trachea by laryngoscopy? ☐ NO ☐ YES

2. Indicate ALL signs and symptoms present (*these MUST NOT have been present prior to the sedation)*
   - ☐ Cough
   - ☐ Crackles/rales
   - ☐ Decreased breath sounds
   - ☐ Tachypnea
   - ☐ Wheeze
   - ☐ Rhonchi
   - ☐ Respiratory distress
   - ☐ Need for supplemental oxygen
   - ☐ CXR changes
   - ☐ Other _____

3. Indicate the response to the signs and symptoms of aspiration *(indicate ALL that apply):*
   - ☐ No active intervention
   - ☐ Supplemental oxygen
   - ☐ Other _____
   - ☐ Administration of medications
   - ☐ Application of positive pressure +/- ventilation with bag mask
   - ☐ Extended observation or admission to hospital

4. Indicate the medications, if any, that were administered: *(indicate ALL that apply)*
   - ☐ No medications administered
   - ☐ Albuterol or salbutamol
   - ☐ Antibiotics
   - ☐ Steroids
   - ☐ Other _____

4. Retching/Vomiting

Definition: The motor reflex response characteristic of retching with or without the expulsion of gastric contents through the mouth or nose that occurs during Sedation, ED Recovery or Post-Discharge phases of sedation

1. Indicate whether the patient retched during sedation
   ☐ YES ☐ NO
   If YES, indicate when the retching occurred *(indicate ALL periods of occurrence)*
   ☐ Sedation – Induction ☐ ED Recovery
   ☐ Sedation – Maintenance ☐ Post-Discharge
2. Indicated whether the patient vomited during sedation
   ☐ YES ☐ NO
   If YES, indicate when the vomiting occurred *(indicate ALL periods of occurrence)*
   ☐ Sedation – Induction ☐ ED Recovery
   ☐ Sedation – Maintenance ☐ Post-Discharge
   a. If YES, indicate the number of times the patient vomited (Consider as a *single* episode if there is <2min between vomits) _____
3. Indicate whether the patient received an anti-emetic ☐ NO ☐ YES
   If YES, indicate the reason for administration ☐ as prophylaxis ☐ in response to vomiting
   Indicate which anti-emetic was administered _____

5. Cardiovascular Events

5.1. Bradycardia ☐ YES ☐ NO

Definition: Heart rate less than 2 standard deviations below normal for age as described by the AHA in the PALS provider manual during the Sedation or Physiologic Recovery phase AND one or more intervention(s) are performed with the intention of improving the heart rate and cardiac output.

1. Indicate when the bradycardia occurred: ☐ Sedation – Induction ☐ Sedation – Maintenance ☐ ED Recovery – Physiologic
2. Indicate the interventions performed in response to the bradycardia (*indicate ALL that apply)*
   ☐ Suctioning ☐ Application of bag mask *with* assisted ventilation
   ☐ Vigorous tactile stimulation ☐ Tracheal intubation
   ☐ Airway repositioning ☐ Chest compressions
   ☐ Supplemental oxygen ☐ Administration of medications
   ☐ Other _____
3. Indicate if medications were administered: ☐ NO ☐ YES
   If YES, indicate what was administered ☐ Atropine ☐ Epinephrine ☐ Reversal agents ☐ Other_____
4. Indicate if the bradycardia was isolated or associated with other events:
   ☐ Isolated ☐ With oxygen desaturation ☐ With hypotension ☐ Other _____
5. Indicate the lowest heart rate attained: _____ beats/min

5.2. Hypotension ☐ YES ☐ NO

Definition: Systolic blood pressure less than the 5th percentile for age as defined by the AHA in PALS during the Sedation or Physiologic Recovery phase AND one or more intervention(s) are performed with the intention of improving the blood pressure.

1. Indicate when the hypotension occurred: ☐ Sedation (Induction) ☐ Sedation (Maintenance) ☐ ED Recovery (Physiologic)
2. Indicate the interventions performed in response to the hypotension (*indicate ALL that apply)*
   ☐ IV fluid administration ☐ Administration of medications
   ☐ Chest compressions ☐ Other _____
3. Indicate if medications were administered: ☐ NO ☐ YES
   If YES, indicate what was administered ☐ Epinephrine ☐ Dopamine ☐ Reversal agents ☐ Other _____
4. Indicate the cause that best fits with the cause of the hypotension:
   ☐ Drug effect ☐ Unknown
   ☐ Co-morbid condition (blood loss, sepsis) ☐ Other _____
5. Indicate the lowest blood pressure attained: _____ / ____ mmHg

6. Excitatory Movements ☐ **YES** ☐ **NO**

6.1 Myoclonus, Definition: Involuntary, brief contraction of some muscle fibers, of a whole muscle, or of different muscles of one group, leading to movements of the corresponding body parts, usually not longer than $1/10^{th}$ of a second (100 milliseconds) AND interferes with the procedure, requiring an intervention or administration of medications. Hiccupping is a form of myoclonus.

6.2 Muscle rigidity, Definition: Involuntary muscle stiffening in extension that can be associated with shaking AND interferes with the procedure, requiring an intervention or administration of medications.

6.3 Generalized motor seizure, Definition: Temporary abnormal neural electro-physiologic phenomenon that manifests as involuntary contractions or series of contractions of the voluntary muscles. The contractions can be sustained (tonic) or repeated (tonic-clonic).

1. Indicate which excitatory movement occurred: ☐ Myoclonus ☐ Muscle rigidity ☐ Generalized motor seizure
2. Indicate if the excitatory movement interfered with the completion of the procedure or required treatment
   ☐ Procedure was delayed, interrupted or not completed
   ☐ Administration of medications
   ☐ Benzodiazepine
   ☐ Other _____

7.1. Paradoxical Response to Sedation ☐ **YES** ☐ **NO**

Definition: Unanticipated restlessness or agitation in response to the administration of sedation drugs occurring during the Sedation phase AND results in the unplanned administration of reversal agents or alternative sedation drugs, a delay in the completion of the procedure or discontinuation of the procedure.

1. Indicate the impact of the paradoxical reaction:
   ☐ Administration of reversal agents
   ☐ Administration of sedation drug(s) (*please specify)* _____
   ☐ Procedure performed but with physical restraint
   ☐ Delay in completion of the procedure
   ☐ Discontinuation of the procedure

7.2. Unpleasant Recovery Reactions ☐ **YES** ☐ **NO**

Definition: Abnormal patient affect or behaviors during the ED Recovery phase that requires additional treatment and a change or delay in patient discharge from the ED. The behaviors include one or more of the following

1. Indicate criteria used for recognition of the unpleasant recovery reaction:
   ☐ Crying – inconsolable
   ☐ Agitation – restless, continuous activity
   ☐ Delirium – state of severe confusion, altered mental status
   ☐ Hallucinations – responds to sensory (i.e. seeing, hearing or feeling) phenomena that are not physically present
   ☐ Dysphoria – mood of restlessness, depression, and anxiety
   ☐ Nightmares – unpleasant dreams
2. Indicate whether the patient had an unpleasant recall of the procedure
   ☐ NO ☐ YES ☐ Not questioned ☐ Too young to ascertain
3. Indicate the interventions performed in response to the unpleasant recovery reaction (*indicate ALL that apply)*
   ☐ Physical restraint
   ☐ Administration of medications
   ☐ Other _____
   ☐ Allocation of additional personnel to care for patient
   ☐ Delayed discharge from the ED

8. Permanent Complications ☐ **YES** ☐ **NO**

8.1 Permanent Neurological Injury Definition: A neurologic deficit that was not present prior to sedation and does not resolve.

8.2 Death Definition: The irreversible cessation of cerebral function and spontaneous function of the respiratory and circulatory systems.

1. Indicate which permanent complication occurred:
   ☐ Permanent neurological injury ☐ Death

9. Other

Any effect of sedation not specifically mentioned that results in an unexpected intervention should be described and documented