

# Unscheduled Procedural Sedation: A Multidisciplinary Consensus Practice Guideline



This guideline has been organized by the American College of Emergency Physicians and has been endorsed by the American Academy of Emergency Medicine, the American Board of Emergency Medicine, the American College of Cardiology, the American College of Medical Toxicology, the American College of Osteopathic Emergency Medicine, the Association of Academic Chairs of Emergency Medicine, the Emergency Medicine Residents' Association, the Emergency Nurses Association, the Society for Academic Emergency Medicine, and the Society for Pediatric Sedation

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The American College of Emergency Physicians (ACEP) organized a multidisciplinary effort to create a clinical practice guideline specific to unscheduled, time-sensitive procedural sedation, which differs in important ways from scheduled, elective procedural sedation. The purpose of this guideline is to serve as a resource for practitioners who perform unscheduled procedural sedation regardless of location or patient age. This document outlines the underlying background and rationale, and issues relating to staffing, practice, and quality improvement. [Ann Emerg Med. 2019;73:e51-e65.]

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## INTRODUCTION

The provision of sedation and analgesia to facilitate the humane performance of painful and/or anxiety-provoking procedures is now a widespread and integral practice for a variety of specialists. The safety of procedural sedation is supported by a large and robust body of literature, with serious adverse events being extremely rare. The multidisciplinary field of procedural sedation has fostered a strong safety culture following many decades of close attention to provider training, patient evaluation, physiologic monitoring, and other critical safeguards.<sup>1-41</sup>

Various specialty societies, including the American College of Emergency Physicians (ACEP), have crafted practice guidelines to outline core procedural sedation principles and to address specialty-specific needs, challenges, and patient populations. However, a limitation of existing guidelines has been their primary emphasis on issues and practices germane to scheduled, elective sedation encounters. Many patients in various clinical settings regularly require unscheduled procedural sedation on short notice to facilitate urgent or emergent procedures, for which many aspects of patient management must differ from elective procedural sedation.<sup>1-30</sup> To better address the needs of time-sensitive, unscheduled procedural sedation,

ACEP has organized a multidisciplinary effort to create a clinical practice guideline specific to unscheduled procedural sedation regardless of location or patient age.

## WHY DOES UNSCHEDULED SEDATION REQUIRE A SEPARATE GUIDELINE?

To provide patient care that is safe, effective and patient-centered, some procedures require urgent or emergent sedation and cannot be scheduled or delayed. Unique aspects of unscheduled sedation include:

- For urgent and emergent procedures, the sedation provider must manage not just the sedation encounter, but also the acute pain, anxiety, and associated circumstances of the precipitating injury or illness.
- Fasting may not be an option for time-sensitive procedures.
- Unscheduled procedures must often be performed while a patient is in a dynamic physiological state or prior to a definitive diagnosis.
- The goals and requirements for unscheduled procedural sedation can differ from elective procedural sedation, and some practices specific to the latter may unnecessarily complicate or delay preparations for the former to the detriment of patient comfort and care.

- Existing regulatory and accreditation standards focus primarily on elective procedural sedation, and extrapolation to unscheduled, time-sensitive procedures can confuse and impede patient care.

## METHODS

Given the identified need, ACEP organized the effort to produce this consensus guideline.

### Literature Search

This guideline is based on critical analysis of the existing literature. Our medical librarian performed searches of the MEDLINE and Scopus databases. We limited all searches to human studies from English-language sources published between January 1, 2000 and August 10, 2018. Key words/phrases for literature searches: sedation, unscheduled sedation, procedural sedation, conscious sedation, dissociative sedation, dissociative anesthetics, premeditation, urgent, emergent, emergency medicine, pediatric emergency medicine, ketamine, skill set, professional skills, privileging, credentialing, support personnel, equipment, supplies, patient evaluation, oral intake, adjunctive, regimen, supplemental oxygen, recovery, and variations and combinations of the key words/phrases. We screened titles and abstracts of all articles identified by the search, with full text review of reports pertinent to the guideline. We reviewed the reference lists of identified publications and consulted with content experts to identify additional reports.

### Writing Committee

ACEP commissioned a writing committee of three general emergency physicians and two pediatric emergency physicians—each of whom had extensive experience with procedural sedation practice, research and/or policy management, extensive familiarity in the related literature, and no financial conflicts of interest.

### Multidisciplinary Review

We identified specialties other than emergency medicine that also regularly administer unscheduled procedural sedation (Figure 1), and invited them to appoint a representative to critically review and provide input on serial iterations of the document. To ensure optimal perspective, we asked that these representatives be practicing members of their primary specialty with regular clinical exposure to unscheduled procedural sedation, and to be free from relevant conflicts of interest (disclosures shown in the APPENDIX).

The writing group and organizational representatives met in Dallas, TX on June 21, 2018 to debate and edit the draft. Further refinement occurred during subsequent review cycles.

## DEFINITIONS

We adopted this previously published<sup>4</sup> and cited<sup>8-10</sup> definition of 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.”<sup>4</sup>

We adopted definitions for levels of procedural sedation as shown in Figure 2, listed in increasing order of complexity and potential risk. Any administration of sedative drugs for which apnea is the desired endpoint is general anesthesia and not sedation, and is beyond the scope of this guideline.

Procedural sedation can be unscheduled or elective. We define unscheduled procedures as medical, surgical, or dental interventions that are emergent or urgent and, to optimize patient outcomes, must be performed within a short time frame unsuitable for that used to schedule elective procedures.

Examples of unscheduled procedures that can be time-sensitive (whether urgent and emergent) include, but are not limited to: cardioversion, tube thoracostomy, central venous line placement, imaging, fracture and dislocation reduction, cardiac catheterization, upper endoscopy, arthrocentesis, abscess incision and drainage, lumbar puncture, laceration repair, care of contaminated wounds, and foreign body removal.

We adopted the previously published<sup>9</sup> and cited<sup>10</sup> definition of a procedural sedation-related adverse event, as an “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.”<sup>9</sup>

We defined procedural sedation rescue as one or more interventions to correct adverse physiologic consequences from procedural sedation. Although the word “rescue” suggests an alarming situation, its interventions may occur in response to adverse events presenting either low or high risk.

## SCOPE OF GUIDELINE

This document provides guidance for practitioners of unscheduled, time-sensitive procedural sedation, as defined above. We did not seek to address scheduled

<p>Organizations that participated and endorsed the guideline</p> <ul style="list-style-type: none"> <li>• American College of Emergency Physicians</li> <li>• American Academy of Emergency Medicine</li> <li>• American Board of Emergency Medicine</li> <li>• American College of Cardiology</li> <li>• American College of Medical Toxicology</li> <li>• American College of Osteopathic Emergency Physicians</li> <li>• Association of Academic Chairs of Emergency Medicine</li> <li>• Emergency Medicine Residents' Association</li> <li>• Emergency Nurses Association</li> <li>• Society for Academic Emergency Medicine</li> <li>• Society for Pediatric Sedation</li> </ul> <p>Organizations that participated and provided input</p> <ul style="list-style-type: none"> <li>• American Academy of Pediatrics</li> <li>• American Academy of Pediatrics Section on Critical Care</li> <li>• American Academy of Pediatrics Section on Pediatric Emergency Medicine</li> <li>• American Society for Gastrointestinal Endoscopy</li> <li>• Council of Emergency Medicine Residency Directors</li> <li>• American Association of Oral and Maxillofacial Surgeons</li> <li>• Society of Critical Care Medicine</li> <li>• Society of Interventional Radiology</li> </ul> <p>Organizations that provided review comments</p> <ul style="list-style-type: none"> <li>• American Association of Nurse Anesthetists</li> </ul> <p>Eight other organizations representing general medicine, anesthesiology, dentistry, and gastroenterology were invited to participate, but either declined or did not respond.</p>
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**Figure 1.** Organizations involved in the development of this guideline

elective procedural sedation, the administration of analgesics to achieve analgesia or sedatives to achieve anxiolysis or sedation in the absence of a concurrent procedure, and minimal sedation (Figure 2) given its negligible patient risk.

We intend this guideline to be applicable to the practice of all emergency providers, and have incorporated multidisciplinary input in the belief that it will be useful to other practitioners of unscheduled procedural sedation.

## GUIDING PRINCIPLES

The principal difference between this guideline and its predecessors is the focus on the special needs and issues relating to unscheduled procedural sedation. Other guiding principles are:

### Evidence-Based Guideline Components

We sought to be parsimonious—emphasizing what is known to be important, and omitting or deemphasizing that which is not.

Responsiveness-Based Sedation State Definitions (best to guide sedation effectiveness)	Airway & Ventilatory Focus (best to assess safety)
<p><b>Minimal sedation</b> (anxiolysis)</p> <p>“A drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination might be impaired, ventilatory and cardiovascular functions are unaffected.”<sup>34</sup></p>	<p>The airway and effective spontaneous ventilation are consistently maintained.</p>
<p><b>Moderate sedation</b></p> <p>“A drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.”<sup>34</sup></p>	<p>The airway and effective spontaneous ventilation are essentially always maintained.</p>
<p><b>Dissociative sedation</b></p> <p>“A trance-like cataleptic state induced by the dissociative drug ketamine characterized by profound analgesia and amnesia, with retention of protective airway reflexes, spontaneous respirations, and cardiopulmonary stability.”<sup>2-6</sup></p>	<p>The airway may require repositioning. Effective spontaneous ventilation is essentially always maintained.*</p>
<p><b>Deep sedation</b></p> <p>“A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.”<sup>34</sup></p>	<p>The airway may require repositioning. The ventilatory pattern may be at times slowed or irregular, but effective spontaneous ventilation is usually maintained such that assisted ventilation or other interventions are typically not required.</p>
<p><b>General anesthesia</b></p> <p>“A drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.”<sup>34</sup></p>	<p>The airway and ventilatory pattern are often impaired, and patients often require assisted ventilation or other interventions.</p>
<p>*Transient respiratory depression and apnea have been reported 1 to 2 minutes after rapid IV administration, and for this reason IV ketamine is typically administered over at least 30 seconds.<sup>5</sup></p>	

**Figure 2.** Common sedation state definitions listed in increasing order of complexity and potential risk, together with their corresponding airway and ventilatory focus.

**Patient- and Family-Centered Care**

Given their importance, we have prioritized patient-centered and family-centered care more strongly than prior guidelines. The ethical imperative to diminish pain, alleviate anxiety, and optimize patient comfort during unscheduled procedures may be even greater given the added stress of the precipitating acute condition.

Time is of the essence for urgent and emergent procedures—not just to minimize physical harm from the active condition, but to minimize distress for the patient and their family. Delaying procedural sedation for reasons not supported by evidence<sup>23-31</sup> may result in extended periods of unremitting pain and anxiety with a negligible decrease in risk and must be avoided.

**All Sedation States**

To accommodate the wide range of unscheduled procedures for which sedation is required and to maximize the applicability and usefulness of this guide, we discuss all states of sedation beyond minimal sedation. (Some guidelines omit deep<sup>42</sup> or dissociative<sup>32,42</sup> sedation.) With the exception of dissociative sedation with ketamine, sedation exists as a continuum, and patients will move up and down the sedation continuum and can transition between defined sedation states during any given procedure.<sup>3,4,15,22</sup> Dissociative sedation has particular utility for urgent or emergent procedures, especially in children, non-fasting patients, and those with co-morbid conditions.<sup>5</sup>

## Multidisciplinary Field

Procedural sedation (whether elective or unscheduled) has always been administered by providers of different backgrounds working in diverse settings. This multispecialty experience fosters productive debate and innovation.

Accordingly, it is appropriate that institutional oversight of procedural sedation practice be collaborative and multidisciplinary, usually in the form of a local procedural sedation committee. A single individual may chair such a committee; however, all procedural sedation providers should have sufficient and diverse representation in this process such that sound, evidence-based procedural sedation advances receive full and appropriate consideration. When unmet procedural sedation needs are identified, the collaborative multidisciplinary leadership should assist with forming strategies for their solution.<sup>43-45</sup> Procedural sedation leadership crosses multiple specialties with the demonstrated skills and commitment to safely.<sup>14,43-46</sup>

## Ventilatory Adequacy Versus Responsiveness

When the first procedural sedation guidelines appeared in 1985,<sup>47,48</sup> pulse oximetry and capnography were unavailable in the outpatient setting, and physiologic monitoring was limited to cardiac rhythm and vital signs. Sedation levels were defined by the patient's response to verbal or tactile stimulation, with ventilatory quality descriptors secondary (Figure 2).

This responsiveness-based taxonomy is valuable for targeting procedural sedation depth to ensure patient comfort but should not be promoted as the principal metric of sedation safety. Responsiveness is itself not a clinically useful safety measure, but rather represents a crude and indirect surrogate for ventilatory adequacy.<sup>49,50</sup> Furthermore, responsiveness is an imprecise measure of procedural stress and subsequent procedural recall.<sup>51,52</sup> A consequence of this focus is that procedural sedation providers and monitors feel compelled to repeatedly stimulate their patients to re-verify their targeted sedation level—with such disturbances fundamentally counterproductive to the intended state of tranquility. An additional adverse consequence of this taxonomy is that, given the inherent subjectivity of these definitions, their incorporation into guidelines and policy has fomented semantic disputes regarding procedural sedation boundaries, eg, what is the dividing line between moderate and deep sedation, and between deep sedation and general anesthesia?<sup>44-46,49,50,53</sup>

Modern procedural sedation practice is best served by focusing on patient responsiveness when the intent is to

ensure effectiveness,<sup>54</sup> while focusing on ventilatory adequacy when the intent is to ensure safety,<sup>49,50</sup> with both assessments occurring concurrently throughout the procedural sedation encounter. Cardiovascular stability is of similarly vital concern; however clinically important hemodynamic alterations are rare in patients without serious systemic disease or acute cardiovascular compromise. If a sedated patient has a stable and effective ventilatory pattern, from a safety perspective it is functionally irrelevant whether at that moment they are responsive to voice or to pain. Such ventilatory adequacy is verified through close, continual observation of the airway and chest wall motion, supplemented with physiologic monitoring of oxygenation (pulse oximetry) and ventilation (capnography). This safety focus is compared to the traditional effectiveness focus in Figure 2.

Given continued advances in ventilatory monitoring technology and real-time computational data analysis and algorithm development, it seems highly likely that responsiveness-defined sedation levels will be replaced in many procedures with objective physiological monitoring that continually predicts the ongoing risk of serious ventilatory impairment.<sup>49,50,55</sup>

## Procedural Sedation Depth, Not Drug

A longstanding hallmark of procedural sedation guidelines is the concept of a sedation continuum, ie, that all sedatives and opioids, excluding ketamine—depending upon dose and patient response—are capable of producing any sedation depth along this scale from minimal sedation to general anesthesia. Accordingly, it is more meaningful and useful to focus clinical decisions and management upon sedation depth and ventilatory adequacy rather than the specific drug itself, recognizing that different drugs have different pharmacological properties and windows of effect and side effect. There is no evidentiary or pharmacological basis<sup>1-6,12-15,32,36-40,44-46</sup> for the designation of specific procedural sedation agents as intended or not intended for general anesthesia, or for restricting them on this basis.<sup>42</sup>

## Skill Sets, Not Specialty

A vital role for a procedural sedation guideline is to specifically outline the skill sets that render practitioners competent and suitable for procedural sedation privileges.<sup>56</sup>

Given ample evidence that modern procedural sedation is widely and safely practiced by a variety of specialists, competencies and privileges for procedural sedation should not be defined solely by specialty training. Instead, they should focus on whether the provider possesses specific procedural sedation knowledge in addition to assessment,

management, and rescue skills targeted to sedation needs, the procedure, and the individual patient (Figure 3).<sup>56</sup> Providers may acquire and demonstrate procedural sedation competency as part of the curricula of their specialty training programs. Alternatively, providers may acquire and demonstrate procedural sedation competency through additional focused training and education.<sup>56</sup> All sedation practitioners must maintain their skills over time.

**Intervention-Oriented Definitions for Adverse Events**

An important advance in the evaluation of procedural sedation adverse events for quality improvement and for research is the shift away from event and threshold-based definitions (eg, apnea for >30 s) to the more clinically relevant intervention-based orientation (eg, assisted ventilation for apnea).<sup>8,10</sup> The act of performing an intervention is typically unambiguous, and thus more likely to be reported in a standardized, reproducible fashion. Intervention-based definitions better predict clinical importance, as any event would be trivial if no intervention was performed in response to its occurrence.<sup>8,10</sup> Periodic interventions are an expected part of procedural sedation practice, and their performance does not necessarily signify a clinical error.

**Modern Procedural Sedation is Off-Label**

Current product labeling from the United States Food and Drug Administration (FDA) is incomplete and inconsistent with the extensive procedural sedation literature.<sup>46</sup> As a result, essentially all medications used in modern procedural sedation practice are off-label, while simultaneously being highly safe and effective when used by those with proper training and support.<sup>1-41</sup> Unless and until there is a comprehensive update of FDA product labeling to comply with recent decades of procedural sedation advances, such product labeling should not supersede the wealth of evidence from the procedural sedation-specific medical literature.<sup>1-7,12,13,15,31-33,35-41,45,46,51-53</sup>

**SEDATION STAFFING**

**Two-Person Sedation Team**

Safe procedural sedation requires a minimum of two trained health care practitioners at the bedside: the sedation provider who takes responsibility for oversight of the procedural sedation encounter and a sedation monitor (commonly a registered nurse or respiratory therapist) whose primary duty is continuous patient monitoring and documentation. Requisite skill sets for each role are shown in Figure 3.

At least one individual present must be skilled in vascular access.

**Procedural Sedation Provider Skill Set**

The sedation provider is a licensed health care professional with the sedation provider skill set (Figure 3). The procedural sedation provider must possess these core skills regardless of targeted sedation depth. Rescue skills are essential, given that it is not always possible to predict how an individual patient will respond. Procedural sedation providers must also possess the skills to identify a patient who is beyond the intended target depth, and to be prepared to correct any adverse physiologic consequences and return the patient to the originally intended level of sedation. Likewise, procedural sedation providers must recognize inadequate sedation and address the insufficient condition through administration of either more sedative or an alternative agent to achieve the optimal state while maintaining patient safety.

Emergency physicians have long-standing, proven procedural sedation skills and a track record as research leaders in this multidisciplinary field. The Centers for Medicare & Medicaid Services (CMS) acknowledged the special situation and training of emergency medicine: “The ED is a unique environment where patients present on an unscheduled basis with often very complex problems that may require several emergent or urgent interventions to proceed simultaneously to prevent further morbidity or mortality.”<sup>57</sup> They continue: “... emergency medicine-trained physicians have very specific skill sets to manage airways and ventilation that is necessary to provide patient rescue. Therefore, these practitioners are uniquely qualified to provide all levels of analgesia/sedation.”<sup>57</sup>

Although short courses such as Advanced Cardiac Life Support and Pediatric Advanced Life Support have educational merit, their completion does not assure appropriate sedation provider skills (Figure 3), and for some specialists—including emergency medicine and critical care—their residency or fellowship training offers a higher level of knowledge and skill acquisition than these courses and supersedes them.<sup>58</sup> ACEP is a member of the Coalition to Oppose Medical Merit Badges,<sup>59</sup> comprised of all major emergency medicine organizations. These organizations oppose credentialing or privileging based on brief, episodic courses for physicians who are already maintaining certification by the American Board of Emergency Medicine and the American Osteopathic Board of Emergency Medicine, as such maintenance of certification goes well beyond short courses designed to be taken by paramedics, nurses, and other providers.<sup>58,59</sup> For

Safe procedural sedation requires a minimum of two licensed health care practitioners in attendance: the procedural sedation provider who takes responsibility for oversight of the procedural sedation encounter, and a procedural sedation monitor whose primary duty is continuous patient monitoring and documentation. Requisite skill sets for each role are shown below.

	<b>Procedural Sedation Provider</b>	<b>Procedural Sedation Monitor</b>
<b>Cognitive skills</b>	<p>Must understand:</p> <ul style="list-style-type: none"> <li>• airway, respiratory, and cardiovascular physiology and pathophysiology</li> <li>• the function and interpretation of continuous monitoring of cardiac rhythm, pulse oximetry, and capnography</li> <li>• sedative and antagonist drug pharmacology, e.g., pharmacokinetics, pharmacodynamics, dosing, administration, contraindications, adverse event profiles</li> <li>• sedation adverse events and when intervention is appropriate</li> <li>• the principles of patient pre-sedation evaluation and factors which increase sedation risk</li> <li>• the procedure to be performed and how it might impact the sedation course or sedation risk</li> </ul>	<p>Must be familiar with:</p> <ul style="list-style-type: none"> <li>• airway, respiratory, and cardiovascular physiology and pathophysiology</li> <li>• the function and interpretation of continuous monitoring of cardiac rhythm, pulse oximetry, capnography, and blood pressure</li> <li>• the sedative drugs being used, including their dosing, administration, duration, and adverse event profiles</li> <li>• sedation adverse events and when intervention is appropriate</li> <li>• the equipment used during rescue, and where it is stored</li> </ul>
<b>Interactive monitoring skills</b>	<p>Must be able to:</p> <ul style="list-style-type: none"> <li>• monitor airway patency, identify airway obstruction, and identify and distinguish obstructive and central apnea</li> <li>• monitor ventilatory adequacy using continual observation of chest wall motion supplemented with pulse oximetry and capnography</li> <li>• monitor cardiovascular stability using physical assessment supplemented with cardiac rhythm and blood pressure monitoring</li> <li>• recognize when a patient is excessively or inadequately sedated</li> </ul>	<p>Must be able to:</p> <ul style="list-style-type: none"> <li>• monitor airway patency and identify partial or complete airway obstruction</li> <li>• monitor ventilatory adequacy using continual observation of the airway and chest wall motion supplemented with pulse oximetry and capnography</li> <li>• monitor cardiovascular stability using physical assessment supplemented with cardiac rhythm and blood pressure monitoring</li> <li>• recognize when a patient is excessively or inadequately sedated</li> </ul>
<b>Rescue skills</b>	<p>Must be able to:</p> <ul style="list-style-type: none"> <li>• relieve airway obstruction through appropriate application of head tilt, chin lift, or placement of nasal or oral airway</li> <li>• perform bag mask ventilation</li> <li>• manage a patient who is excessively sedated, with or without active intervention as appropriate</li> <li>• rapidly initiate resuscitative measures for hypoxia, apnea, laryngospasm, hypotension, bradycardia, anaphylaxis, seizure, or cardiac arrest</li> <li>• rapidly summon additional resuscitation assistance, if required</li> </ul>	<p>Must be able to:</p> <ul style="list-style-type: none"> <li>• assist the sedation provider in resuscitation</li> <li>• rapidly summon additional resuscitation assistance, if required</li> </ul>

**Figure 3.** Requisite Skill Sets for Procedural Sedation

other specialties, periodic short courses may be a helpful component of training and skills maintenance.

Airway repositioning and bag mask ventilation are the most common airway rescue interventions,<sup>11-13,36,40</sup> even for emergency physicians and critical care physicians whose core training and practice includes intubation. For procedural sedation providers who do not intubate or place laryngeal mask airways regularly, it is preferable to focus their rescue skills on airway repositioning, bag mask ventilation, and the placement of oral and nasal airways rather than to stipulate intubation or laryngeal mask airway skills.<sup>32</sup>

### **Procedural Sedation Monitor Skill Set**

The sedation monitor is a licensed health care professional (commonly a registered nurse or respiratory therapist) with the sedation monitoring skills shown in [Figure 3](#), and whose principal role is continuous monitoring and documentation. The sedation monitor can assist with minor, interruptible tasks as long as they do not materially interfere with effective procedural sedation monitoring. If suitably trained, such tasks may include sedative drug administration under the direct supervision of the sedation provider.

### **Procedural Sedation Provider Privileging and Credentialing**

Competencies for procedural sedation should be defined by the specific sedation skill set a practitioner must be able to perform, rather than by specialty training ([Figure 3](#)).<sup>56</sup> The granting of procedural sedation credentials and privileges can be comprehensive or focused.

Comprehensive procedural sedation privileges include all levels of sedation, including general anesthesia limited to emergency rapid sequence intubation and post-intubation management. Some providers will already possess comprehensive procedural sedation skills by virtue of their postgraduate training and ongoing clinical practice sufficient to support continued competence. For example, the core curricula of emergency medicine, pediatric emergency medicine, and critical care residency and fellowship programs accredited by the Accreditation Council for Graduate Medical Education and American Osteopathic Association include advanced airway management, resuscitation, critical care, vascular access, monitoring, pharmacology, pain management, and training and supervised practice in all levels of procedural sedation. Graduates of these programs are routinely credentialed for rapid sequence intubation based upon this training and should, in essentially all cases, be simultaneously credentialed to manage all levels of procedural sedation.

Focused procedural sedation privileges are appropriate when a sedation provider possesses the skill set ([Figure 3](#)), but in accordance with his or her specific practice needs chooses to implement them in a manner restricted by sedation level or drug. One physician, for example, may be fully trained for moderate but not deep or dissociative sedation. In this case his or her procedural sedation skill set may appropriately be limited to the knowledge and skills pertinent to moderate sedation, ensuring that they possess rescue skills ([Figure 3](#)) and have no intent to perform dissociative or deep sedation. Another physician, for example, may be fully trained in moderate and deep sedation, but have never used ketamine nor feel any need to ever administer this agent. In this case, his or her procedural sedation skill set may appropriately omit the knowledge and skills unique to dissociative sedation.

Department medical directors and/or hospital procedural sedation committees can specify focused procedural sedation privileges based upon an individualized evaluation of each provider's skills, experience, and competency. In some circumstances departmental training and/or proctoring can be used to confirm or expand privileges.

### **Procedural Sedation Provider Quality Improvement**

As with every other aspect of medical practice, departmental leadership and/or hospital procedural sedation committees continually monitor ongoing competencies as part of a quality improvement process (discussed later). Renewal without additional action should be expected for those who regularly provide procedural sedation, have no deficiencies identified through this quality improvement, and demonstrate no other reason to question their ongoing skills. In all other cases departmental leadership and/or the hospital procedural sedation committee will evaluate the current status of each provider's skills and competency on an individualized basis. If appropriate, privileges for specific sedation levels may be withdrawn or withheld contingent upon focused training and/or proctoring.

### **Procedural Sedation Monitor Privileging and Credentialing**

The capability for a nurse, respiratory therapist, or other health care professional to serve as a procedural sedation monitor is a privilege based upon local oversight, training, and verification of skills.

### **Procedural Sedation Roles**

When unscheduled moderate or dissociative sedation is performed, the procedural sedation provider may also be the provider performing the procedure, assuming that the

procedure can be immediately halted should an adverse event occur that requires urgent attention or resuscitation.<sup>1-6</sup>

Some procedural sedation guidelines specify that the sedation provider during deep sedation should be fully dedicated to sedation management and not involved in the procedure.<sup>32,33,42</sup> Although such a practice is optimal for both scheduled and unscheduled procedures, there is a longstanding track record of sedation providers (with standard backup from their sedation monitors) simultaneously performing brief unscheduled procedures while managing moderate, dissociative, or deep sedation. This practice has been shown to be safe, without evidence of any increased frequency of clinically important adverse events or outcomes.<sup>3,17-20,35-40</sup>

There remain circumstances in which time-sensitive deep sedation is necessary, but resources do not permit the timely availability of a third provider or the operating room without risk of physical harm based on the underlying condition and/or undue exacerbation of pain or anxiety for the patient and their family. Examples include a patient who promptly requires a tube thoracostomy, central line placement, cardioversion, or hip relocation. In these circumstances, the benefits outweigh the risks for the procedure and sedation to commence without delay, as assessed by the sedation provider—particularly when the procedure at hand can be readily interrupted. Should an adverse event require urgent attention or resuscitation, the sedation provider must be able to immediately halt the procedure and attend to the patient as appropriate. These circumstances also assume the rapid availability of additional licensed health care practitioners (eg, nurses, respiratory therapists) beyond the sedation provider and sedation monitor who can assist with rescue, as is typical in a hospital setting but may not be in a clinic or office.

### **Nurse Administration of Sedatives**

Just as qualified registered nurses routinely administer sedatives and paralytics for intubation under direct supervision of an ordering provider, they are similarly qualified and capable of administering medications for procedural sedation while under the direct supervision of the ordering provider. Some state and nursing board regulations restrict (or are locally interpreted to restrict) such administration—but without supporting evidence. Nurses with the required skills to serve as sedation monitors (Figure 3) should be permitted to administer any and all medications used for unscheduled procedural sedation while under the direct supervision of the ordering provider, with the ordering provider specifying the dosing and administration.

## **PROCEDURAL SEDATION PRACTICE**

### **Procedural Sedation Needs Assessment**

When clinical circumstances dictate the need for an unscheduled procedure, the sedation provider must first assess the specific circumstances of the situation. How urgent or emergent is the procedure? What depth of sedation will be needed to ensure patient comfort? What level of responsiveness on the sedation continuum (Figure 2) will be compatible with procedural success? What is the likely duration of the procedure? Are the key patient needs analgesia, anxiolysis, immobility, or some combination of the three? Is the patient at higher risk of adverse events based upon the pre-sedation patient evaluation (see full section below)? What level of ventilatory adequacy (Figure 2) is to be anticipated?

It may be possible that procedural sedation can be avoided, and that a high level of patient comfort can be attained through some combination of analgesics, local anesthesia, regional anesthesia, and non-pharmacological techniques (see section below). Conversely, if the patient is at high risk based upon their pre-sedation evaluation, consider the feasibility of referral for general anesthesia, while recognizing the delays required arranging an operating room, anesthesia services, and an operating surgeon or proceduralist.

The procedural sedation provider will discuss the sedation plan with the patient (and/or his or her parents or caregivers, as appropriate), including risks and benefits, using shared decision making. Appropriate consent will be obtained in accordance with local policies. This process will of necessity be abbreviated for some urgent and emergent procedures.

### **Pre-Sedation Patient Evaluation**

Sedation providers should perform the following pre-sedation evaluation, which will at times require abbreviation based upon the urgent or emergent nature of the required procedure.

The procedural sedation provider should perform a focused history and physical examination, including a review of current medications. Does the patient have substantial underlying illness? Patients who are healthy or have mild systemic disease (commonly classified as American Society of Anesthesiologists (ASA) physical status I and II respectively) are generally excellent procedural sedation candidates. Those with severe systemic disease (ASA III or greater) are at greater risk of adverse events.<sup>21,22,31</sup>

What have been the patient's prior experiences with procedural sedation or anesthesia? Have they experienced

prior adverse events? Do they have any pertinent allergies? Do they have any absolute or relative contraindications to the specific sedatives being considered?

Does the patient have any anatomic or physiologic variants that put them at greater risk of airway or ventilatory compromise, or that might complicate assisted ventilation? Examples include: airway abnormalities (eg, micrognathia, macroglossia, laryngomalacia, tonsillar hypertrophy), short neck, severe obesity, a history of obstructive sleep apnea, very young age (such as infants under 3 months), and premature birth in an infant. There is no evidence that adding the Mallampati score to this general airway evaluation has any impact on clinical outcomes, and thus it cannot be recommended.<sup>60-63</sup> This score—a graded visual assessment of the pharynx and tonsils—poorly predicts both difficult bag mask ventilation<sup>60</sup> and endotracheal intubation,<sup>60,61,64</sup> is unreliably assessed,<sup>62,65</sup> and is frequently not obtainable in younger children who are unable to comply with the exam.<sup>63</sup>

Females of childbearing age should be questioned regarding the potential for pregnancy, although in urgent or emergent situations procedural sedation will likely need to proceed regardless. There is inadequate evidence to guide specific sedative agent selection in pregnancy.

### Pre-Sedation Oral Intake

The combination of vomiting and loss of airway protective reflexes is rare during procedural sedation, and resulting aspiration is extremely rare.<sup>31</sup> To date, only nine reports of aspiration-associated deaths have been reported in the post-1984 procedural sedation literature, of which eight were during upper gastrointestinal endoscopy. None of these occurred in children or in healthy adults.<sup>66</sup> Currently, there is no evidence that non-compliance with elective fasting guidelines increases the risk of aspiration or other adverse events.<sup>23-31</sup> Any concerns regarding aspiration vastly exceed the actual risk.<sup>31,66-69</sup>

Providers of unscheduled procedural sedation should assess the timing and nature of recent oral intake. The urgency of the procedure will dictate the necessity of providing sedation without delay, regardless of fasting status. For patients with established risk factors for aspiration (eg, serious underlying illness,<sup>31,66</sup> obstructive sleep apnea,<sup>31</sup> obesity,<sup>70-73</sup> age less than 12 months,<sup>31</sup> upper endoscopy as the procedure,<sup>37,38,66,74,75</sup> or bowel obstruction),<sup>31</sup> consider the risks versus benefits of delaying procedural sedation after recent ingestion of a substantial meal. When such a delay is not feasible, consider the use of dissociative sedation, as unlike other sedatives ketamine

helps preserve protective airway reflexes,<sup>5,32</sup> and there have been no reported occurrences of aspiration (despite its association with vomiting and laryngospasm) in patients receiving this agent alone except in compromised neonates.<sup>5,66</sup>

### Sedative Regimens

Assuming that procedural sedation remains appropriate, the sedation provider will plan the sedative regimen based on the needs and considerations identified above. This must be customized to each patient, as no single sedative agent or combination of agents is ideal for every patient or procedure. A full discussion of drugs and administration strategies is beyond the scope of this guideline (examples can be found elsewhere).<sup>4-7,12,15</sup> Agents used for unscheduled procedural sedation include but are not limited to opioids, benzodiazepines, barbiturates, ketamine, propofol, dexmedetomidine, etomidate, and nitrous oxide. Strategies include single versus combined agents. Drug doses and drug concentrations should be confirmed right before administration and calculated on a mg/kg basis for children.

### Room and Supplies

Procedural sedation must be performed in an area with oxygen, suction, physiological monitoring equipment, resuscitation medications, and age- and size-appropriate equipment for airway and ventilatory rescue (eg, bag-valve mask, oral airway, nasal airway) and for intravenous access. When opioids or benzodiazepines are principal sedatives, their reversal agents should be readily available. Drugs to treat allergic reactions and recovery nausea and vomiting should be readily available.

The need for intravenous access is dependent on the medications, the dose, the route used, and risk factors for adverse events. Ketamine, for example, can be safely administered intramuscularly without need for intravenous access.<sup>5</sup> Inhaled nitrous oxide and intranasal medications can be safely administered without intravenous access.

### Non-Pharmacological and Other Adjunctive Techniques

Age-specific interventions for managing fear and pain can often reduce anxiety and distress in children and their families, and augment the procedural sedation experience.<sup>76,77</sup> The sedation provider should utilize developmentally appropriate interventions to reduce fear, anxiety and pain and, when available, enlist child life specialists specifically trained to provide this service. Immobilization devices in children should generally be

avoided and should certainly not be used in lieu of non-pharmacological interventions as described above and, when appropriate, effective pharmacologic sedation.

### Interactive Monitoring

The sedation monitor must continually observe the quality of airway patency and ventilation, as noted in their specific skill set (Figure 3). The sedation provider must similarly observe the patient in an intermittent or continual fashion as per their specific skill set (Figure 3), and continually monitor sedation status to ensure patient comfort and to avoid oversedation.

The procedural sedation team should actively verify the procedure to be performed, the patient identity, and, when appropriate and when the proceduralist has not been in constant attendance with the patient, mark the correct anatomic site for the procedure. This “time-out” (as per The Joint Commission)<sup>34</sup> should not delay care in a life-threatening situation.

### Physiologic Monitoring

The sedation monitor will observe and periodically document the output of physiologic monitors. The use of these devices has become routine during procedural sedation, although it must be acknowledged there is little or no convincing evidence that they specifically enhance clinically important outcomes beyond interactive monitoring.<sup>1-4,16</sup> But given their simplicity, theoretical basis of utility, the reassurance they provide to caregivers, and their low added expense, cardiac monitoring, blood pressure assessment, and pulse oximetry should be used routinely during procedural sedation.

Cardiac monitoring permits the immediate continuous assessment of heart rate and rhythm. Clinically important bradycardia and other arrhythmias are extremely rare during procedural sedation but can be promptly identified with cardiac monitoring.

Blood pressure should be assessed at appropriate intervals including—if possible and not unduly disturbing to the patient—before, during, and after procedural sedation, and at the earliest evidence of potential cardiovascular compromise. Clinically important hypotension is rare during procedural sedation in patients without serious systemic disease or acute cardiovascular compromise. Greater attention and more frequent blood pressure measurements should occur in patients with serious underlying illness, and in those otherwise judged at higher risk. Patients with known or possible volume depletion should be rehydrated at the earliest time that is safe and feasible—prior to sedative drug administration

whenever possible—and their blood pressure frequently monitored.

Pulse oximetry permits immediate identification of downward trends in oxygen saturation, and must be continuously monitored.

Capnography is now routine in most settings for deep sedation but is optional for moderate or dissociative sedation. Capnography provides continuous, immediate, objective verification of the quality of ventilation, and is more reliable for this purpose than pulse oximetry or interactive monitoring alone.<sup>16</sup> Capnography is simple, noninvasive, easy to interpret, provides the earliest warning of hypoventilation and apnea, and its use can reduce the risk of developing hypoxia.<sup>2,3,16,55</sup> Normal capnography can quickly and unambiguously confirm ventilatory activity. Abnormal capnography can signal clinicians to reevaluate their patients, to be prepared to provide ventilatory support and/or to administer a reversal agent, and to avoid administering additional doses of sedatives until the concern is resolved.<sup>55</sup> Capnography also permits clinicians to safely administer supplemental oxygen (discussed below).

A limitation of physiologic monitoring is that anxious or frightened children and uncooperative adults may be unable to tolerate the blood pressure cuff, pulse oximetry sensor probe, or capnography cannula prior to procedural sedation. In these circumstances procedural sedation may need to be initiated without one or more of these monitoring modalities. Once the patient is sufficiently sedated the devices may then be fitted.<sup>32</sup> At lower levels of sedation uncooperative patients may not be able to tolerate a capnography cannula, and continual capnography may not be feasible.

Given the absence of supporting evidence, the use of a precordial stethoscope<sup>32</sup> during procedural sedation is optional.

### Supplemental Oxygen

In the event of apnea, high-flow pre-oxygenation delays oxygen desaturation by up to 6 minutes in a healthy adult and 2 to 4 minutes in a healthy child with a patent airway.<sup>78</sup> Such hyperoxygenation can permit patients to safely tolerate short periods of respiratory depression or apnea without need for positive-pressure-assisted ventilation and its potential for gastric insufflation. Clinicians can instead closely monitor the patient and avoid further drug administration.<sup>79</sup> Supplemental oxygen is commonly avoided when capnography is not used, thus permitting pulse oximetry to provide warning should interactive monitoring fail to detect ventilatory compromise. When using

capnography to directly measure ventilatory status, high-flow supplemental oxygen can be administered throughout procedural sedation. In these situations, capnography can provide immediate evidence of apnea or hypopnea, and when respiratory effort has returned or is strengthening.

**Rescue**

The procedural sedation provider must be prepared to perform rescue interventions, according to their skill set (Figure 3), should the situation warrant, with efforts made to avoid positive pressure ventilation (and potential gastric insufflation) unless necessary. The procedural sedation team should recognize that ventilatory depression may occur shortly after a stimulating procedure has ceased, and the patient then becomes relaxed as the pain abates.

**Recovery**

Patients should be monitored post-sedation until they are no longer at risk for respiratory depression, their vital signs return to pre-sedation states, and they are alert and at age-appropriate baseline level of consciousness.<sup>3,4,15</sup> There is no need to establish a willingness or ability to take oral liquids. If the patient is being discharged post-recovery, appropriate written care instructions should be given to the patient and their family or caregivers.

**Documentation**

The urgency of the procedure may not permit pre-sedation charting, but post-procedure the sedation provider must document the original procedural sedation plan; patient evaluation; procedural sedation course; drugs, drug doses, and when given; and any adverse events and their interventions. The sedation monitor will separately document sedation events and serial assessments of interactive and physiologic monitoring. This documentation must be sufficient to permit quality assurance reviews (discussed next).

**QUALITY IMPROVEMENT**

Each procedural sedation provider should be accountable to an organized quality assurance and improvement program (eg, departmental, institution-wide) that monitors procedural sedation practice, tracks adverse events, ensures satisfactory documentation and compliance with this guideline or local protocols, and identifies opportunities for improvement.

An example of a standardized tool for this purpose is TROOPS (Tracking and Reporting Outcomes Of

Procedural Sedation, <http://proceduralsedation.org/troops-overview>),<sup>10</sup> which was developed through a rigorous multidisciplinary consensus process.

**THE FUTURE**

We pose key steps for future procedural sedation research and practice. First, as with this document, we believe that there should be greater collaboration between specialties in the development and oversight of optimal practice recommendations for this long-standing multidisciplinary field.<sup>9,10,14,43-46</sup>

Although the safety of procedural sedation practice by a variety of specialists is now well established, research should focus on patient-centered outcomes. How can we improve the quality of the experience for patients and their families? Can we increase satisfaction? Can we decrease the frequency and magnitude of procedural awareness? Without compromising safety or efficacy, are there ways in which the procedural sedation encounter can be accomplished more quickly or more cost-effectively?

Target-controlled infusion technology has yet to be rigorously studied in procedural sedation. Such computer-driven drug administration based upon pharmacokinetic modeling smooths out the peaks and troughs of sedative drug concentrations, and thus should diminish hypoventilation, help ensure more consistent patient comfort, and permit the sedation provider to more closely focus on the patient without the distraction of repeat bolus sedative drug administration.<sup>80</sup>

Future research should better define optimal procedural sedation strategies for patients who require time-sensitive procedural sedation despite substantial underlying illness, and for those who are pregnant.

Given the exceptionally low risk of pulmonary aspiration with procedural sedation and absent evidence of an impact from fasting, reform is appropriate for recommendations regarding pre-procedural oral intake.<sup>23-31</sup>

Regarding clinical practice, there should be a continued refocusing of sedation provider credentialing and privileging on specific pertinent skill sets as outlined in this guideline, and away from specialty training alone. Future research should better clarify the role of simulation in procedural sedation training. State-based nursing regulations should, where barriers exist, be amended to permit qualified nurses to administer any and all medications used for unscheduled procedural sedation while under the direct supervision of the ordering provider.

As noted earlier, the next few years will hopefully permit movement beyond our current responsiveness-based

cognitive framework for the sedation continuum, and shift our focus from sedation depth to sedation risk.<sup>49,50,55</sup> The application of computational tools for analysis of continuous, high-resolution monitoring data may permit ongoing, real-time estimates of risk, allowing clinicians to titrate drug administration and focus interactive monitoring based upon such risk assessments rather than upon repeated patient stimulation.<sup>49,50,55</sup>

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