



# Procedural Sedation & Analgesia in the ED

## An Issue Brief for ENA Members

### **ISSUE**

In recent years, conflicting opinions from medical and nursing specialties have surrounded the administration of procedural sedation and analgesia in the emergency department. The pivotal question being “can medications administered for the purposes of moderate or deep sedation and analgesia be administered safely by individuals, such as emergency nurses, who have not been trained in administration of general anesthesia?”

### **ENA POSITION**

The Emergency Nurses Association believes that facilitating interventional procedures and minimizing patient suffering are essential steps to proactively addressing pain and anxiety being experienced by the ED patient. ENA asserts that the administration of medications for the purposes of procedural sedation and analgesia is within the scope of practice of the institutionally-credentialed registered nurse working in the ED. ENA also contends that this practice must be supervised by an emergency physician or other appropriately trained and credentialed specialist capable of emergency airway management.

ENA firmly believes that professional scope of practice should be based on scientific evidence and consensus-based clinical guidelines. Efforts to restrict the use of specific medications are impractical and not in the best interests of patient care and, in fact, could significantly delay care and prolong patient suffering.

The Emergency Nurses Association encourages institutions to adopt policies that ensure proper education and credentialing of nurses, continuous patient monitoring by qualified nurses who have no other responsibilities that would compromise the nurse’s ability to adequately monitor the patient during or after the procedure, and the guaranteed availability of resuscitation equipment at the patient’s bedside. In addition, ENA and the American College of Emergency Physicians (ACEP) jointly support the delivery of medications used for procedural sedation and analgesia by credentialed emergency nurses working under the direct supervision of an emergency physician. These agents include but are not limited to etomidate, propofol, ketamine, fentanyl, and midazolam.

### **RATIONALE AND BACKGROUND INFORMATION**

The ED is a unique environment where a variety of patients with emergent and urgent conditions are managed. Many of these conditions result in significant pain and are associated with varying degrees of anxiety making the management of sedation and analgesia an important component of comprehensive emergency medical care for patients of all ages. Procedural sedation is defined by ACEP as “a technique of administering sedatives or dissociative agents with or without analgesics to induce a state that allows the patient to tolerate an unpleasant procedure while maintaining cardiorespiratory function.”

The American Society of Anesthesiologists (ASA) has identified four levels of sedation and analgesia:

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- Minimal sedation: A medication-induced state during which cognitive function and coordination may be impaired, but cardiovascular and ventilatory functions remain unaffected.
- Moderate sedation/analgesia (formerly called “conscious sedation”): A medication-induced depression of consciousness during which patients can respond purposefully to verbal commands and independently maintain a continuous airway. Cardiovascular function is usually maintained and spontaneous ventilation is adequate.
- Deep sedation/analgesia: A medication-induced depression of consciousness during which patients cannot be easily awakened, but can respond purposefully after repeated or painful stimulation. Cardiovascular function is usually maintained, but spontaneous ventilation may not be adequate and airway patency may require assistance.
- General anesthesia: A medication-induced loss of consciousness during which patients cannot be aroused, even with painful stimulation. Cardiovascular function may be impaired, spontaneous ventilation is frequently inadequate, and assistance is usually required to maintain airway patency.

### **COMPETENCY STANDARDS**

As noted in the **ACEP Clinical Policy on Procedural Sedation and Analgesia in the Emergency Department**, proper administration of sedative medications is a continuum and it is often difficult to predict how an individual will respond to a specific sedative agent. As a consequence, practitioners should possess the skills required to rescue a patient one level greater than the intended level of sedation. Should deep sedation be required to perform a procedure, the practitioner is expected to be competent in skills involving cardiovascular support and airway management as in general anesthesia. These competencies are now considered core skills for all board-certified emergency physicians.

ANA has identified nursing competencies related to procedural sedation and recommends that registered nurses who administer and monitor procedural sedation and analgesia be able to:

- ▶ Identify and differentiate the various levels of sedation.
- ▶ Demonstrate the acquired knowledge of anatomy, physiology, pharmacology, cardiac dysrhythmia recognition, and complications related to procedural sedation and analgesia.
- ▶ Demonstrate competence in pre-procedural, procedural, and post-procedural nursing care from the initial patient evaluation to patient discharge.
- ▶ Anticipate, recognize, and address potential complications during the process.
- ▶ Understand the medical/legal aspects of procedural sedation and analgesia.

And finally, JCAHO has further strengthened the standards and competencies in relation to procedural sedation by requiring hospitals to assure that qualified individuals are trained in professional standards and techniques to manage patients in the case of a potentially harmful event. Sufficient numbers of qualified staff should be present to evaluate the patient, help with the procedures, provide the sedation, monitor, and recover the patient.

Individuals administering moderate or deep sedation should be qualified and have the appropriate credentials to manage patients at whatever level of sedation is achieved, either intentionally or unintentionally. In addition, appropriate equipment to resuscitate patients as needed must be available.

## **THE CONTROVERSY**

Not all relevant nursing and medical organizations are in total agreement with ENA and ACEP regarding procedural sedation practice. ASA and the American Association of Nurse Anesthetists (AANA) identify optimal practice as the administration of sedation and analgesia medications by anesthesia professionals but note that this is not always possible.

Both organizations have identified practice guidelines for administration of medications used for sedation during procedures. ASA has delineated two different sets of practice guidelines regarding the privileges of non-anesthesiologist practitioners involved in the administration of moderate and deep sedation. ASA noted in a policy statement dated October 18, 2006, that because of the significant risk to patients who receive deep sedation and who may enter a state of general anesthesia, privileges to administer deep sedation should be granted only to practitioners who are qualified to administer general anesthesia or to appropriately supervised anesthesia professionals.

Additional statements related to specific medications used for sedation also have been issued. In a joint statement issued in 2004, ASA and AANA stated that when propofol is used for sedation, it should be administered only by persons trained in administration of general anesthesia, who are not simultaneously involved in these surgical or diagnostic procedures. They note that similar concerns apply when other intravenous induction agents are used for sedation such as etomidate, methohexital, and thiopental.

In addition, the manufacturer of diprivan (propofol) added a warning to its product insert stating that for general anesthesia or monitored anesthesia care sedation, diprivan injectable emulsion should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure.

The ED is not the only environment being affected by this issue. The American College of Gastroenterology petitioned the FDA in June of 2005 to remove from the labeling for propofol (diprivan) the warning that propofol should be administered only by persons trained in the administration of general anesthesia, rather than by other qualified medical professionals. The FDA has not yet responded to this petition.

## **FOCUS ON PATIENT SAFETY AND EVIDENCE-BASED PRACTICE**

The National Center for Education Statistics (NCES) is the primary federal entity for collecting, analyzing, and reporting data related to education in the United States. The NCES defines competency as “the combination of skills, abilities, and knowledge needed to perform a specific task.” Competencies are not restricted by professional license and in many cases several professions may hold competency for an intervention such as intubation or ACLS response. Competency-based educational programs embedded within an institutional credentialing process will help ensure the safe administration of medications, the ongoing assessment of patients, and the interventions necessary to maintain a safe environment for patients undergoing painful procedures.

The selection of any agent prescribed and administered by licensed practitioners in an emergency care environment must be based on a patient’s individual needs. Formulating policy around language contained in a product insert rather than evidenced-based practice and competencies is unwise. Labeling may change but a licensing board’s intent to protect patients from inadvertent error should remain secure by creating regulatory goals that support competency-based education. Professional nursing organizations and health care facilities can further support patient safety by developing credentialing standards, prerequisites, and criteria for nurses commensurate with current and accepted standards of practice in a manner that will meet the goals established by professional licensing boards.

Evidence provided by a broad range of studies demonstrates medications classified as anesthetics have been safely used for purposes other than anesthesia. While serious side effects may occur, they are no more common than those associated with other medications and may be appropriately managed by a multidisciplinary team including an appropriately qualified registered nurse. Restricting RNs from administering a certain classification of sedating medication creates a structure that is overly restrictive and difficult for nurses and health care facilities to understand and apply. It may result in delay of care, increased pain for the patient, and inefficient use of the skills of a CRNA or anesthesiologist. It also creates situations in which non-nurses, such as emergency medical services personnel, are legally authorized to administer medications that registered nurses are not. ENA encourages state boards of nursing to support regulatory policies that are evidence based with a focus on competency standards commensurate with nursing interventions.

## **KEY QUESTIONS AND ANSWERS**

### **What is the difference between moderate and deep sedation?**

When in a state of moderate sedation, patients can respond purposefully to verbal command, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway and patients can breathe on their own. In deep sedation, patients cannot be easily aroused but respond purposefully to repeated or painful stimulation. Their airway may be impaired and patients may require assistance to maintain a patent airway and ventilation. In both states, cardiovascular function is usually maintained.

### **Why has propofol been singled out from other medications?**

Propofol's popularity is due to several characteristics that render it superior to other sedatives in terms of side effects and duration. Its high lipid solubility results in a very fast onset of action (30–60 seconds) the plasma half life ( $t_{1/2}$  distribution) is very short with 1.3–4.1 minutes (compared with 30 minutes for midazolam.) This results in a rapid decline of propofol concentrations to levels below those required for hypnosis, and permits a rapid awakening and shorter recovery times even after prolonged administration. Some critics argue that the drug is dangerous because it lacks a reversal agent; however, in order to maintain its effect, boluses of propofol must be administered every three to 10 minutes or its hypnotic effects wear off.

Most categories of medications represent the potential for severe harm (including death) to patients. Unexpected and untoward patient outcomes have occurred in the administration of every drug that is currently listed in the American Heart Association's formulary for Advanced Cardiac Life Support. A common drug utilized in the resuscitation scenarios is vecuronium bromide, a paralytic agent arguably far more dangerous to patients than most anesthetics in the hands of an untrained person. As the patient's central nervous system becomes unresponsive to voluntary command, a patient can't even signal his caregiver that he/she is suffering serious respiratory compromise yet the manufacturer's insert simply reads: **“THIS DRUG SHOULD BE ADMINISTERED BY ADEQUATELY TRAINED INDIVIDUALS FAMILIAR WITH ITS ACTIONS, CHARACTERISTICS, AND HAZARDS.”**

### **What is the greatest concern during the administration of procedural sedation and analgesia?**

Airway, airway, airway. Respiratory depression and loss of a patent airway may occur should the patient progress to a level of sedation deeper than intended. Careful preparation and administration have been shown to prevent harmful sequelae.

### **What is the incidence of negative outcomes related to propofol administration in the ED?**

The incidence of negative patient events related to propofol administration as well as other common procedural sedation and analgesia agents has been relatively low. In a prospective observational study performed in the ED, propofol induced procedural sedation was reported to have the lowest rate of respiratory depression when compared with methohexital, fentanyl/midazolam, and etomidate. No significant complications were noted.

In Pennsylvania, the Patient Safety Authority developed the Pennsylvania Patient Safety Reporting System (PA-PSRS), a secure, web-based system that permits healthcare facilities to submit reports of what Act 13 of 2002 defines as "serious events" and "incidents." Statewide mandatory reporting through PA-PSRS went into effect on June 28, 2004. More than 460 healthcare facilities are subject to Act 13 reporting requirements.

To date, more than 425,000 reports have been submitted through PA-PSRS. Ninety-six percent of these reports are incidents or "near-misses." Based on those reports, the Authority issues quarterly and supplementary Patient Safety Advisories to advise hospitals and other healthcare facilities about steps they can take to reduce and prevent patient harm. Incidents involving propofol classified as "serious" comprise only 0.0023% of PA-PSRS's total database of nearly half a million reports

### **What does the research state?**

There is a growing body of literature supporting the safe use of a large variety of agents for procedural sedation and analgesia in the ED. Ketamine, midazolam, fentanyl, propofol, and etomidate are just a few of these agents in common usage. A detailed review of the literature can be found in the **ACEP Clinical Policy: Procedural Sedation and Analgesia in the Emergency Department**.

### **What are the competency guidelines for emergency nurses administering procedural sedation and analgesia?**

Health care organizations should have educational and credentialing mechanisms in place that include a process for evaluating and documenting the registered nurses' knowledge, skills, and abilities related to management of patients receiving procedural sedation and analgesia. Evaluation and documentation of competency should occur on a periodic basis according to institutional policy.

Recommended competencies as outlined by AANA for the registered nurse administering sedative and analgesic drugs under the direct supervision of an emergency physician are to:

1. Demonstrate the acquired knowledge of anatomy, physiology, pharmacology, cardiac arrhythmia recognition and complications related to sedation and analgesia sedation and medications.
2. Assess the total patient care requirements before and during the administration of sedation and analgesia, including the recovery phase.
3. Understand the principles of oxygen delivery, transport and uptake, respiratory physiology, as well as understand and use oxygen delivery devices.
4. Recognize potential complications of sedation and analgesia sedation for each type of agent being administered.
5. Possesses the competency to assess, diagnose, and intervene in the event of complications and institute appropriate interventions in compliance with orders or institutional protocols.

6. Demonstrate competency, through ACLS or pediatric life support, in airway management and resuscitation appropriate to the age of the patient.

**What assessment and monitoring are required to provide procedural sedation in the ED?**

Recommended assessment and monitoring of the patient's physiological parameters during sedation may include but are not limited to: level of consciousness and physiological changes observed, blood pressure, respiratory rate, oxygen saturation by pulse oximetry, electrocardiographic monitoring, and capnometry.

The registered nurse who monitors the patients should have no other duties to perform during the sedation and recovery process that would compromise the nurse's ability to adequately monitor the patient. Monitoring should continue post-procedure until the patient returns to his or her baseline level of function and is ready for discharge.

**What equipment and supplies are required to provide procedural sedation and analgesia?**

Oxygen, suction, reversal agents, and advanced life support medication and equipment should be available when procedural sedation and analgesia is provided. Generally, IV access will be required as it is the route of medication administration. There may be situations however, dependent upon medications used as well as their dosages and route, that IV access is not necessary. Ketamine, for example, has been shown to exhibit a wide safety margin with preservation of protective airway reflexes and no cardiovascular suppression, and is often administered intramuscularly.

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