Procedural Sedation and Analgesia in the Emergency Department: Recommendations for Physician Credentialing, Privileging and Practice

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INTRODUCTION

Procedural sedation refers to the technique of administering sedatives or dissociative agents with or without analgesics to induce an altered state of consciousness that allows the patient to tolerate unpleasant procedures while preserving cardiorespiratory function.[1] Procedural sedation and analgesia is a core competency in emergency medicine and a daily part of emergency department (ED) practice.[2-4] As noted by the United States *Centers for Medicare and Medicaid Services* (CMS): "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." The CMS guidelines also state that "…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 and anesthesia (moderate to deep to general)."[5]

Emergency medicine residency and pediatric emergency medicine fellowship core curricula include all of the requisite procedural sedation skills, eg, advanced airway management, resuscitation, critical care, monitoring, sedation pharmacology, pain management.[2-4] Emergency physicians have a well-established track record of safe sedation, and are important research and thought leaders in this multidisciplinary field.

The *American College of Emergency Physicians* (ACEP) is an authoritative body that has established guidelines for the use of sedation, analgesia, and anesthesia by emergency physicians.[1] CMS guidelines support the use of the ACEP guideline: "A hospital could use multiple guidelines, for example, ACEP for sedation in the ED and American Society of Anesthesiologists (ASA) for anesthesia/sedation in surgical services, etc."[5] ACEP convened this task force in 2011 to provide this update to guide hospital policy for the administration of analgesia, sedation, and anesthesia by emergency physicians.

HOSPITAL SEDATION LEADERSHIP

The *Joint Commission* and CMS each require that hospitals maintain central leadership over the sedation practices of their various specialists and departments.[6,7] Accordingly, many institutions have a hospital-wide sedation committee that oversees each individual department's sedation practices.

Given that procedural sedation is a multidisciplinary field, ACEP strongly supports the principle that institutional oversight is best provided by a committee structure in which all of those providingsedation services have representation. This format best facilitates open inter-specialty dialog on optimal sedation practice, collaboration, and innovation.[8] Inter-specialty collaborative institutional sedation authority is necessary to ensure that sedation practices are in accordance with specialty-specific national standards, and that sedation privileges are granted to all appropriate specialties, such as emergency medicine.[8,9] ACEP further believes that the statement in the CMS Guidelines specifying that "the anesthesia services must be under the direction of one individual who is a qualified doctor of medicine (MD) or doctor of osteopathy (DO)" may be counterproductive to their stated intent of developing "anesthesia policies and procedures in collaboration with several other hospital disciplines; especially since the CMS guideline FAQs explicitly raise the possibility that "policies and procedures that define the various uses of analgesia and anesthesia ..(may be).. too narrow (or broad) or based on the opinions of .. (only)…one individual."[5]

SCOPE AND DEFINITIONS

This policy encompasses all items classified as "anesthesia services" by CMS,[7] including analgesia, local anesthesia, regional anesthesia, sedation, and anesthesia.

Analgesia: The full or partial relief of painful perception without affecting consciousness, whether by parenteral, topical, oral mucous membrane, or other routes. In the ED analgesia is commonly achieved with opioids (eg, morphine, hydromorphone, and fentanyl), acetaminophen, and/or non-steroidal anti-inflammatory agents (eg, ibuprofen, ketorolac).

Local anesthesia: The localized injection or topical application of anesthetic agents to render specific portions of the skin insensitive to pain without affecting consciousness. In the ED local anesthesia is commonly achieved with injected lidocaine or bupivacaine, administered to facilitate dermal procedures such as laceration repair and abscess incision and drainage.

Regional anesthesia: The use of anesthetic agents to render specific regions of the anatomy insensitive to pain without affecting consciousness. In the ED regional anesthesia is commonly achieved with lidocaine or bupivacaine. It is administered to facilitate procedures such as fracture reduction and laceration repair, with examples being blocks of digital, facial, and forearm nerves.

Sedation and anesthesia overview: Nondissociative sedation exists as a continuum, and the *Joint Commission* has defined its series of progressive levels as minimal sedation, moderate sedation, deep sedation, and general anesthesia.[6] Dissociative sedation is considered separately due to its unique features and incompatibility with *The Joint Commission's* hierarchy of sedation definitions.[1,10,11] Emergency physicians are trained and qualified to rescue a patient from a deeper level of sedation than intended, and return the patient to the originally intended level of sedation.

To follow are definitions for sedation states listed in increasing order of complexity and potential risk.[10]

Minimal sedation (anxiolysis): "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."[6] In the ED minimal sedation is commonly administered to facilitate minor procedures, and to achieve anxiolysis prior to initiating a greater level of sedation.

Moderate sedation (formerly conscious sedation): "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."[6]

In the ED moderate sedation is commonly achieved with a benzodiazepine or nitrous oxide usually in conjunction with an opioid such as fentanyl. It is administered to facilitate moderately painful procedures (eg, shoulder reduction, abscess incision and drainage) in cooperative patients, and minor procedures (eg, laceration repair, lumbar puncture) in less cooperative patients.

Dissociative sedation: "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."[1,10,11]

In the ED ketamine, is commonly administered to facilitate moderate to severely painful procedures (eg, fracture and dislocation reduction, abscess incision and drainage) and for procedures requiring immobilization in uncooperative patients (eg, laceration repair in children).

Deep sedation: "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."[6]

In the ED deep sedation is commonly achieved with pharmacologic agents such as propofol, etomidate, or a benzodiazepine to facilitate non-painful procedures requiring immobilization in less cooperative patients, eg, magnetic resonance imaging in children. For painful procedures (eg, fracture and dislocation reduction, cardioversion), these sedatives are used in conjunction with an opioid such as fentanyl or with the dissociative agent ketamine.

General anesthesia: "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."[6]

In the ED general anesthesia is commonly used for multiple indications: 1) to facilitate rapid sequence intubation, typically using etomidate or propofol in conjunction with a paralytic agent; 2) for post-intubation sedation/anesthesia, typically using a propofol infusion or repeated doses of a benzodiazepine; and 3) to humanely facilitate critical care procedures in already-intubated patients, typically using propofol, fentanyl, and/or a benzodiazepine during tube thoracostomy, central line placement, cardioversion, intracranial pressure monitoring, critically urgent imaging requiring an immobile patient, etc. Emergency physicians are also skilled in managing cases involving the inadvertent progression to deeper than intended levels of sedation, using their rescue skills to return the patient to the originally intended level of sedation.

The United States *Food and Drug Administration* (FDA) approved product labeling for some sedatives (including propofol) recommends that they "be administered only by persons trained in the administration of general anesthesia".[12] The FDA has clarified that this definition extends to specialists other than just anesthesiologists and registered nurse anesthetists.[12] The extent of emergency medicine training in general anesthesia, while focused on ED applications, is amply sufficient to comply with the FDA terminology in the context of using these drugs for the indications described above.

Rescue Capacity.[5] The level of sedation is a continuum, and it is not always possible to predict how an individual patient will respond. Hospitals must ensure that procedures are in place to rescue patients whose level of sedation becomes deeper than initially intended. "Rescue" from a deeper level of sedation requires an intervention by a practitioner skilled in airway management and resuscitation to correct adverse physiologic consequences of the deeper-than-intended level of sedation and return the patient to the originally intended level of sedation.

EVIDENTIARY BASIS

The literature supporting the safety and efficacy of ED procedural sedation and analgesia is robust, and includes large series in both adults and children using moderate, dissociative, and deep sedation.[13-16] There is no evidence to suggest that emergency physician directed sedation is less safe or of lower quality than that delivered by any other specialist, and very large clinical studies support the safety equivalence to that administered by anesthesiologists.

Recently, a multicenter study examined the rate of major complications (defined as aspiration, death, cardiac arrest, unplanned hospital admission or level-of-care increase, or emergency anesthesia consultation) for 131,751 cases of in-hospital pediatric sedation.[17] Major complication rates and 95% confidence intervals per 10 000 sedations were as follows: anesthesiologists, 7.6 (4.6–12.8); emergency medicine, 7.8 (5.5–11.2); intensivist, 9.6 (7.3–12.6); pediatrician, 12.4 (6.9–20.4); and other, 10.2 (5.1–18.3). There was no statistical difference ($P > .05$) among provider's complication rates before or after adjustment for potential confounding variables. Even though procedural sedation performed outside the operating room is unlikely to yield serious adverse outcomes, the sedation team should be prepared to manage major complications.

Emergency physicians are important research leaders in sedation.[13-25] and have contributed methodological guidelines for sedation research,[26] sedation clinical practice guidelines,[11,18,27] and high-profile articles regarding the state of the art and future of sedation.[10,28,29]

EMERGENCY MEDICINE SERVICE PROCEDURAL SEDATION, ANALGESIA, AND ANESTHESIA PRIVILEGES AND CREDENTIALING

ACEP makes the following recommendations for emergency medicine credentialing and privileging for procedural sedation, analgesia, and anesthesia. It is important to understand the distinction between

credentialing and privileging in order to properly understand the role of the department head and hospital administration in overseeing procedural sedation in the ED.

Credentialing is the process of reviewing a health professional's credentials, training, experience, or demonstrated ability, practice history and medical certification or license to determine if clinical privileges to practice in a particular place are to be granted. The chief of the emergency medicine service at each institution shall be responsible for establishing criteria for credentialing, and recommending emergency physicians for sedation privileges by the institution.[30]

Privileging is defined as permission granted by a hospital or other health care institution to a physician or other provider to render specific diagnostic or therapeutic services. Such privileging will apply to all physicians or mid-level providers working under the emergency medicine service, and will apply to the ED and any other locations in which these practitioners oversee sedation under the auspices of the emergency medicine service (eg, sedation services, procedure rooms, radiology). Privileging for each practitioner is tailored to their skill and may include all sedation levels, or may be restricted to certain levels. Privileging for each practitioner may include all patient ages, or may be specifically restricted to children or adults.[31]

Emergency medicine graduates. Graduates of emergency medicine residency and fellowship programs accredited by the *Accreditation Council for Graduate Medical Education* (ACGME) or *American Osteopathic Association* are qualified for all forms of analgesia and all levels of sedation in all ages; as such training is part of their program core curricula and accreditation requirements.[2-4]

Other practitioners. ED practitioners without emergency medicine residency or pediatric emergency medicine fellowship training may include practice-track emergency physicians, physician assistants, and nurse practitioners. Some EDs also employ physicians of other specialties for lower acuity areas, such as family physicians or pediatricians. The emergency medicine chief will be responsible for recommending individual practitioners for privileges using analgesia, specifying sedation levels, and patient age ranges based upon an individualized evaluation of each such practitioner's skills, experience, and competency. At the discretion of the emergency medicine chief, departmental training and/or proctoring will be used to recommend expanded privileges for additional sedation levels or additional patient age categories (adult or pediatric).

Sedation training. As above, practitioners may undergo sedation training using department-specific or third party training modules including simulation with a focus on the unique ED environment. Any such training should conclude with satisfactory demonstration of competency.

Proctoring. As above, practitioners may undergo proctoring by observing and then performing sedation under the immediate supervision of a credentialed emergency physician designated by the ED chief, or by training or skill maintenance using simulation techniques. Similar proctoring may be required for airway management skills. The ED chief will determine the details of proctoring including type and number of cases needed to demonstrate competency, as attested by the proctoring physician.

Short courses. Certificates of short course completion in various core content areas of emergency medicine (eg, *first aid courses, CPR courses, sedation courses, or airway management courses*) may serve as evidence of focused review; however, certification in emergency medicine by the *American Board of Emergency Medicine, American Osteopathic Board of Emergency Medicine,* or certification in pediatric emergency medicine by the *American Board of Pediatrics* and the *American Board of Emergency Medicine* supersedes the need for practitioners to complete short courses.[32]

Re-evaluation of competency. At pre-determined intervals, the ED chief will re-evaluate the sedation privileges granted for each practitioner. Renewal without additional action should be expected for those who regularly provide sedation, have no deficiencies identified through ongoing quality assurance, and demonstrate no other reason to question their ongoing skills. In all other cases the ED chief will evaluate the current status of each practitioner'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.

Practitioner administering sedation: Sedation may be used by a physician with appropriate credentials and privileges. Actual drug administration may be delegated to a registered nurse or other

qualified staff with established competency for sedative administration under direct- contemporaneous physician supervision. The supervising physician is required to have been credentialed by Emergency Medicine leadership, and granted hospital privileges, to administer sedation.

Emergency nursing. Emergency nursing is vital to the success of any ED sedation program. The chief of emergency medicine should have ongoing collaboration with nursing leadership to develop policy and practice guidelines regarding nursing roles in sedation and the ability of nurses to administer sedatives. The capability of qualified ED nurses to administer propofol, ketamine, and other sedatives under the direct supervision of a privileged emergency physician is strongly supported by ACEP.

EMERGENCY MEDICINE SEDATION PRACTICE

ACEP makes the following recommendations for sedation practice under the auspices of an emergency medicine service.

Pre-sedation evaluation. The emergency physician chooses when sedation is appropriate based on the pain and distress typical for the procedure and the patient's anxiety, cooperativeness, age, and health. Competing needs for physician attention throughout the ED should be taken into account before making the decision to use sedation. The emergency physician will discuss the plan to administer sedation with the patient and other team members, and appropriate consent will be obtained (either verbal or written is acceptable).

A pre-procedural history and physical exam, as documented in the ED record, should reflect a focused evaluation of the airway, cardiovascular status, pulmonary status, allergies, and history of prior adverse reactions to sedatives or anesthetics. High risk patients should be approached with extra care and additional resources or personnel may be considered. There will be occasions when patients without immediate threat to life or limb may be referred to the operating room by emergency medicine for procedural management.

Aspiration risk should be assessed by balancing patient risk factors, the timing and nature of recent oral intake, and the urgency of the procedure.[27] Lack of fasting is not a contraindication for administering procedural sedation and analgesia, but should be considered in choosing the timing and target level of sedation.[27] The combination of vomiting and loss of airway protective reflexes is an extremely rare occurrence during procedural sedation, and aspiration is unlikely.[27] The sedation team should collectively verify the procedure to be performed and confirm patient identity, correct site in case of a surgical procedure, patient consent, and team member roles prior to each case. This "time-out" is a requirement of the Joint Commission and part of the standard universal protocol. A time out is to be documented in all sedation cases in the ED, with the only exceptions being if the "time-out" would be deleterious to patient care or if the physician has been in constant attendance with the patient. If the same patient has two or more procedures, a "time out" needs to take place before starting each procedure or if the person performing the procedure changes.

Procedural sedative agents. There is no single sedative agent, or combination of agents that can be recommended for every patient or procedure. The selection of the specific pharmacologic agents should be tailored to each patient by the emergency physician and should not be otherwise restricted. Agents used for ED procedural sedation include but are not limited to opioids, benzodiazepines, barbiturates, ketamine, propofol, remifentanil, dexmedetomidine, etomidate, chloral hydrate, nitrous oxide, and other agents.

Adjunctive techniques. Distraction and visual imagery should be used as needed to reduce patients' fear, discomfort, and anxiety. Although physical immobilization may be needed to prevent inadvertent movements, pharmacologic and non-pharmacologic techniques should be used to reduce pain- and fear-related movements whenever possible.

Interactive monitoring. Moderate or dissociative sedation requires one practitioner (typically an ED nurse) to monitor the patient and another (typically an emergency physician) to perform the procedure.

Deep sedation may be accomplished with the emergency physician monitoring the patient and a separate practitioner performing the procedure, or by the same emergency physician both administering

sedation and performing the procedure. Given that ED procedures are typically brief and can be readily interrupted, there will be occurrences when the benefits outweigh the risks for performing deep sedation using a single emergency physician and an ED nurse. In these circumstances, the emergency physician will initiate effective sedation and, once stable sedation is established, the physician will perform the procedure while the nurse monitors the patient. The caveat is that the supervising practitioner performing sedation may also perform the procedure only if the procedure is of such a nature that it can be immediately halted should the patient suffer an adverse reaction that requires urgent attention or resuscitaiton.[10,11,28]

Mechanical monitoring. Vital signs should be measured at appropriate intervals, including at a minimum before, during, and after sedation. Emergency physicians will assess the patient on an ongoing basis during the procedure to ensure that appropriate levels of sedation, analgesia, and anxiolysis have been achieved. Continuous pulse oximetry should be routine during moderate, dissociative, or deep sedation. Continuous capnography is not mandatory, but is increasingly being recommended for deep sedation. This technology provides the earliest possible warning of hypoventilation and can reduce hypoxia.[22,33]

Other equipment and supplies. Sedation should be performed in an area with oxygen, suction, medications, and equipment for advanced airway management. When opioids or benzodiazepines are used, their reversal agents should be available.

Intravenous access. The need for intravenous access is dependent on the medications, the dose, and the route used. Ketamine, for example, can be safely administered intramuscularly without need for intravenous access.[11]

Supplemental oxygen. ED sedation is widely practiced both with and without supplemental oxygen, and such use is left to emergency physician discretion.[21,34]

Recovery. Patients should be monitored until they are no longer at risk for respiratory depression, their vital signs are stable, and they are alert and at age-appropriate baseline level of consciousness.[10,28] The ED record should reflect how well the patient tolerated the procedure, the patient's condition post-procedure, and when transfer or discharge took place.

QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT

Sedation services policies and procedures should "undergo periodic re-evaluation that includes analysis of adverse events, medication errors and other quality or safety indicators related not only to anesthesia, but also to the administration of medications in clinical applications that the hospital has determined involve analgesia rather than anesthesia."[5]

Each emergency medicine service should participate in a departmental and/or institution-wide multidisciplinary quality assurance program which monitors procedural sedation and analgesia practice, tracks adverse events, ensures satisfactory documentation and compliance with protocols, and identifies opportunities for improvement. At a minimum, adverse event indicators for review should include aspiration, clinically important change in vital signs (that require a clinical intervention for correction beyond the use of intravenous fluids), unplanned endotracheal intubation, the use of reversal agents, unplanned emergent anesthesia consultation, cardiac arrest, and death.

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