Two decades ago, “conscious sedation” was the oxymoronic netherworld between brutane and general anesthesia. As abscesses and conditions requiring painful procedures are now more common (in part due to USA300, a new strain of methicillin-resistant Staphylococcus aureus that causes abscesses to produce more pus, thus requiring incision and drainage), the field of procedural sedation has evolved. Concurrently, awareness of the effects of untreated pain have led to statements from the American Academy of Pediatrics recommending pain management “even for venipuncture.”¹ Many of the lessons studied in the pediatric emergency department can be applied to painful procedures in the primary care office.

Although a host of modalities from nitrous oxide to propofol are now available to a hospital-based sedation team, regulations surrounding procedural sedation in primary care make outpatient options more murky. This article reviews the recent advances, requirements, and research in procedural pain management and sedation in the outpatient primary care setting.

HISTORY
In 1992, the American Academy of Pediatrics (AAP) published guidelines for “conscious and deep” sedation in primary care make outpatient options more murky. This article reviews the recent advances, requirements, and research in procedural pain management and sedation in the outpatient primary care setting. The American Academy of Pediatrics (AAP) introduced the nomenclature of “procedural sedation and analgesia” (PSA),³,⁴ supporting the idea that a combination of sedatives and analgesics was appropriate to administer during painful procedures. ACEP also acknowledged that medications were to be given in doses “not intended to depress cardiopulmonary function” but left open the implication that they might.³,⁴ After conducting a study of the root causes of death and other adverse outcomes in outpatient procedural sedation, the AAP issued procedural sedation guidelines in 2006 that focused more on

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Amy L. Baxter, MD, FAAP, FACEP, is Director of Emergency Research, Pediatric Emergency Medicine Associates, Children’s Healthcare of Atlanta Scottish Rite.

Address correspondence to: Amy L. Baxter, MD, FAAP, FACEP, Pediatric Emergency Medicine Associates, Children’s Healthcare of Atlanta Scottish Rite, 1001 Johnson Ferry Road NE, Atlanta, GA 30342; email: Amy_Baxter@PEMA-LLC.com.

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preparation, rescue, and discharge criteria for intended levels of sedation.\textsuperscript{4}

**SEDATION DEFINED**

Currently, the literature defines four levels of sedation, with safety measures protective of patients who descend into a deeper level than intended.

**Minimal Sedation/Anxiolysis**

At this level of sedation, patients respond normally to verbal commands, although their cognitive function and coordination may be impaired. Analogous to mild intoxication, their cardiopulmonary function should not be affected. Although hospitals are free to define standards for this level of sedation, typically this refers to a single dose of a sedative or opioid, or nitrous oxide when used alone. Pre-examination of patients includes baseline vital signs, mental status, allergies, current medication history, and general medical history; however, NPO (nil per os) time is not required documentation. Intravenous (IV) administration is not required for this level of sedation.

**Moderate Sedation**

At this level, a patient should respond to verbal or light tactile stimulation, as would a person sleeping lightly. No intervention is required to maintain an airway, and breathing should be sufficient for adequate oxygenation and ventilation. Hospital policies vary widely, as this level of “light sleep” will typically occur when doses of analgesics and sedatives are combined.

As this situation adds risks associated with additive medication peaks, the AAP recommends that a licensed practitioner capable of bag-valve-mask resuscitation be immediately available. In addition, moderate sedation requires an additional caregiver to monitor and help with the procedure, and an emergency cart and back-up plan in place. Continuous oxygen saturation monitoring and functioning suctioning equipment at the bedside are required, and equipment to start an IV is recommended.\textsuperscript{4}

**Deep Sedation**

Deep sedation occurs when a patient only responds purposefully following repeated or painful stimulation. A clinical analogy would be a “passed out” state, in which the ability to maintain ventilatory function may be impaired. At this level, a licensed independent practitioner capable of advanced pediatric life support is required to be “immediately available”, should the need arise to rescue a patient from the state of general anesthesia.\textsuperscript{4}

An additional person whose only responsibility is to monitor the patient is recommended by the guidelines; suction, IV, continuous oxygen, and electrocardiogram (ECG) monitoring are required. In addition, a defibrillator should be available. At this level of sedation, an informed consent from the patient/guardian, and a physical exam and a medical history that includes an American Society of Anesthesiology (ASA) level and focused airway exam are required. Only ASA levels I and II should be considered to be candidates.\textsuperscript{4}

**General Anesthesia**

General anesthesia is the level of sedation where a patient cannot be aroused, even with repeated or painful stimulation. Independent ventilatory function is often, but not always, impaired.

**DISTRESS**

Central to successful procedural sedation is addressing each facet of pediatric distress: pain, attention, and fear (see Figure 1). When managed properly, it may even be possible to avoid sedation.

**Pain Management**

For a laceration, the most studied and effective topical analgesic is a mixture
of lidocaine, tetracaine, and adrenaline (epinephrine), also known as LET or LAT. It is optimally applied by lightly packing cotton soaked in the solution into the wound. When placed on an open facial wound, data have shown LET to be 73% to 90% effective at preventing the need for injected lidocaine. The same data showed that as only 45% of extremities were adequately anesthetized with topical LET alone, injecting lidocaine may still be needed.

One recipe for compounding LET is lidocaine 20% 100 mL (20 g lidocaine powder/100 mL NS); racemic epinephrine 2.25% 50 mL; tetracaine 2% 125 mL; Na metabisulfite 315.4 mg; 225 mL sterile H2O. This mixture can be stored in refrigeration for up to 5 months. When LET is not available, a eutectic mixture of local anesthetics (EMLA) has been found moderately effective. When lidocaine injection is needed, warming, buffering, and injecting from within the wound all make for a more comfortable experience.

**Gate Control**

Another class of interventions for local pain control during injection of lidocaine or removal of soft tissue foreign bodies, is “gate control.” By over-stimulating the A-beta vibration nerves or the C-fiber cold nerves, sharp pain can be blocked or reduced. Cold spray (vapocoolant, ethyl chloride) has been found effective for children over the age of 12 years. Although a vibrating, cold medical device (the Buzzy; MMJ Labs) that stimulates both A-beta and C fibers has been shown to reduce IV pain in children, simply scratching the same dermatoine, or applying an ice pack proximally to the procedure, may achieve the same effect.

Research on local pain management for abscess drainage is scant. As EMLA can descend up to 0.5 cm when left in place up to 4 hours, this may at least dull the pain of an injected lidocaine ring block. Using gate control stimulation simultaneously will help with lidocaine injection or when only a small needle aspiration is anticipated. For larger abscesses, adjunct sedation or at least a combination of a nonsteroidal anti-inflammatory drug (NSAID) and opioid analgesia is likely necessary. One clinical pearl is to use Glad Press-N-Seal (Glad Company) rather than Tegaderm (3M) to occlude larger areas. The Press-N-Seal pulls off painlessly, in contrast to the tightly adhering medical occlusive dressing.

**ACTIVE AND PASSIVE DISTRACTION**

During hospital procedures, child life specialists provide “directed distraction” to lower anxiety. When a child has an entertaining task, pain is less noticed and procedures are reported to be less painful. In one study of IV blood draws, pain was reduced 40% and fear by 60% simply by having parents ask seek-and-find questions from a set of Distraction cards (MMJ Labs, LLC). Although the literature supports both active distraction (blowing bubbles, playing video games) and passive distraction (watching television) for IV access, in more painful procedures such as shots or lumbar punctures, passive distraction may be inadequate. One exception is self-selected music. Although ambient interventions such as music or asking parents of toddlers to sing are ineffective for shots, older children, choosing their own music has provided significant reduction in distress. Cognitive distraction, such as asking a patient to perform arithmetic, is not effective.

To optimize the effects of distraction, let pediatric patients know that their job is to play with something while the procedure is being done, and ideally let them choose an activity. If they become distressed, redirecting them to their “job” can work better than trying to introduce a distraction after the wails have commenced. Today’s smart phones and tablet applications can also provide ideal active distraction.

Even without props, posters placed on the ceiling or even the ceiling tiles themselves may provide opportunities for directive counting and finding. In the largest randomized controlled trial of distraction for laceration repair, Sinha et al found distraction to be effective for all children by parent-report, although self-report only differed for older children. In contrast, a smaller study by Gur-sky et al found that extensive preparation and active distraction was extremely effective, even in a younger cohort.

**FEAR MANAGEMENT**

The differences between the trials by Sinha et al and Gursky et al highlight the importance of the final component of distress, which is fear. Lack of knowledge of what to expect, lack of control over the procedure, and physical vulnerability all contribute to a sense of fear.

**Reduced Sense of Vulnerability**

Gursky et al used a 15-minute protocol that included modeling the procedure to the patient on dolls and allowing the patient to feel the suture material. Although this extensive level of preparation may be excessive for many primary care settings, explaining the procedure while a topical anesthetic is placed on the child may mitigate fear even without anxiolytic medications.

Newer techniques to decrease feelings of vulnerability and fear include using minimal restraint, whereby the patient’s arms are placed in a pillow case instead of having the child in a papoose. The child is then placed on an incline rather than lain flat against the gurney or table. This restrains the child’s arms while still allowing sufficient mobility so that the child feels less vulnerable.

**Tactile Fear Reduction Techniques**

To further reduce the anxiety caused by lying supine, one can suggest the
use of “comfort positioning,” in which a parent can sit next to a child or sit on the table with the child in his or her lap. Placing an arm around the child’s shoulder, the parent can tuck one of the child’s arms behind the parent’s back, using a shoulder to gently restrain the child’s other arm. This approach significantly reduced distress when used for IV placement.21

Fear can be reduced by the practitioner moving slowly in the preparation process, alerting the child prior to each touch (“Now you’re going to feel some wetness,” “Now you might feel a little push,”) and letting a child experience sensations prior to feeling them near the laceration. As the cleaning phase is often the most distressing, warming the irrigant, letting the child feel the temperature of it on his or her hand immediately prior, and dripping the first few drops slowly can set the child’s expectations and avoid the delay of having to calm a child mid-procedure.

Verbal Fear Reduction Techniques

Language also has a powerful effect on fear. Humor, direction, nonprocedural distraction, and talk decrease distress, whereas, perhaps counterintuitively, empathy and reassurance (“I know, honey, it’s okay”) increase distress in children.22,23

Avoid words such as “shot,” “needle,” “hurt,” or “sting,” and replace them with softer words such as “medicine,” “poke,” “bother,” “tight squeeze,” or “push.”

PROCEDURAL SEDATION

When a clinician judges that maximal preparation will not be adequate, midazolam is by far the most studied anxiolytic for outpatient procedures.24,25 Oral doses of 0.5 mg/kg to 1 mg/kg with a max of 15 mg result in mild sedation within 15 to 30 minutes. Alternately, 0.3 mg/kg to 0.4 mg/kg of the IV formulations given intransnasally provide effective sedation in 5 to 15 minutes.26 Using a mucosal atomizer device (MAD, Wolf-Tory, both approximately $1 per device) provides more regular uptake to mucosal surfaces. As the pH of the IV formulation is very acidic, pretreatment with lidocaine 10 mg/puff in the nares,25 or an oral drop of cherry syrup post-administration may make the administration more tolerated. Recently Klein et al 27 described 0.5 mg/kg aerosolized buccal administration of the IV formulation to be better tolerated with similar sedative efficacy.

Paradoxical Reactions

Paradoxical reactions are a concern with midazolam, and occur anywhere from 1.4% of the time with IV administration at 0.1 mg/kg to as high as 6% with oral administration.28 At an average of 14 minutes after sedation in the IV group, tachycardia, inconsolability, and tachypnea were noted, with complete resolution with administration of flumazanil.29 Although flumazenil can be administered intranasally, it has only been described in case reports. Agitation tends to wear off at approximately the duration of sedation, or a bit longer. The duration of sedation from oral midazolam is between 20 and 40 minutes. Intranasal had an average duration of sedation of 23.1 minutes.

Addition of Analgesics

When complete local anesthesia is not possible, as for an abscess or foreign body removal, opioid analgesia adds the benefit of mild sedation as a side effect. Oxycodone is typically dosed at 0.2 mg/kg to 0.3 mg/kg and has peak plasma effects in 1 hour. Hydrocodone comes in a 2.5 mg/5 cc formulation dosed at 0.2 cc/kg formulation or 1 teaspoon per 10 kg of body weight. Its peak takes a bit longer — between 60 and 90 minutes. The delayed peaks of action need to be considered during outpatient opioid use, particularly for discharge safety and if an additive sedating medication is considered.

One rapidly acting and dissipating option now used commonly in pediatric emergency departments is intranasal fentanyl. When dosed at 1-2 mcg/kg up to 200 mcg, fentanyl offers rapid pain relief and mild euphoria within 10 minutes, with resolution of most of the effects by 30 minutes after administration. Again, a mucosal atomizer device helps assure even absorption, but unlike midazolam the IV formulation does not burn. Oral fentanyl in combination with midazolam led to increased vomiting without significant improvements in procedural success, so it is not recommended.30 Intranasal fentanyl and midazolam have not been studied, but a relevant work for preoperative relief indicates the combination may work.31 Ibuprofen has been shown to be more effective for initial management of pediatric fractures than acetaminophen with codeine.32 Administering both ibuprofen and midazolam, or ibuprofen and an opioid, would stay within the realm of minimal sedation/anxiolysis. Because a small study found ibuprofen alone was not significantly different than oxycodone or a combination of oxycodone and ibuprofen, the clinical effect of using both may be small.33,34

In a series by Luhmann et al,35 nitrous oxide in combination with an opioid caused moderate sedation (and even deep sedation in 20% of patients). Compared with midazolam, nitrous oxide has a superior onset for minor procedures and faster recovery.35 Because of the risk to the developing fetus, however, the scavenging systems required may be too great a burden for most outpatient practices.

Post-Sedation

After sedation, a child should be observed until both the expected peak of the medicine has passed and the child is back to the pre-sedation level of consciousness. Following moderate or deep sedation, the recommendation is to have a second adult accompany the child in...
the car home in order to attend the child exclusively rather than while also driving. A 24-hour contact number for these patients is also recommended.

When billing for sedation, moderate sedation should be documented in an initial 30-minute block then subsequent 15-minute increments. As of 2006, sedation’s Current Procedural Technology (CPT) code for a procedure you are completing yourself is 99143 for a patient under 5 years and 99144 for patients 5 years or older.

CONCLUSION
Sedation in primary care is a mix of art, preparation, and temperament-based interventions. When all aspects of non-pharmacologic and sedative medication align, the result is a faster procedure, a satisfied parent, and a less-stressed staff. It is well worth the effort.

REFERENCES