Trends in Anaesthesia and Critical Care 4 (2014) 141–146

Contents lists available at ScienceDirect

Trends in Anaesthesia and Critical Care

journal homepage: www.elsevier.com/locate/tacc

REVIEW

# Sedation in children outside the operating room: The rules of the road

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*Keywords:*
Pediatric
Anesthesia
Sedation
Remote

SUMMARY

Children undergoing tests and treatments often require sedation, frequently in environments remote from the operating room. This article reviews national guidelines focusing on the safe provision of anesthesia for children remote from the operating room, demonstrating the evolution in care and increasing complexity faced by anesthesia and sedation providers. The weaknesses in the current literature about this topic are also discussed with different approaches to assessing efficacy of sedation/anesthesia explored, focusing on the use of pooled data from multiple institutions, the human factors aspects of sedation and simulation based training.



## 1. Introduction

Children undergoing tests and treatments often require sedation, frequently in environments remote from the operating room. A wide variety of practitioners from different subspecialties may be involved in the provision of sedation and, as such, guidelines from many different organizations exist. This article will review logical methods for assuring safe and effective sedation in children. We will consider several of the guidelines that have been produced and the published literature around the general topic of sedation for children.

## 2. The guidelines/rules

We begin with several of the most important guidelines for providers of pediatric sedation. In the USA, the Centers for Medicare and Medicaid Services (CMS) has issued clear directives on the nature of the responsibilities that Anesthesia Departments have in assuring safe sedation in a facility[1]:

1. They define types of sedation/anesthesia services as ranging from minimal sedation to general anesthesia.
2. All services along this continuum must be organized under a single Anesthesia Service which must be directed by a qualified physician. (Logically the Chair of Anesthesiology – but not required to be an anesthesiologist). Standards of care must be consistent across all areas where the sedation or anesthesia is delivered.
3. Hospitals must ensure that procedures are in place to rescue patients whose level of sedation becomes deeper than initially intended.
4. The anesthesia service is responsible for developing policies and procedures governing the provision of all categories of anesthesia services – including the category of practitioner who is permitted to provide anesthesia services that are not subject to the anesthesia administration requirements.
5. The administration of anesthesia must be by a qualified anesthesiologist, a doctor of medicine or osteopathy, dentist, oral surgeon, CRNA, or anesthesia assistant. This requirement does not apply to local anesthesia, minimal or moderate sedation.
6. Medical staff bylaws must include criteria for determining the anesthesia service privileges to be granted to an individual practitioner.
7. Delivery of anesthesia services must be consistent with recognized standards for anesthesia care including patient consent, infection control, safety practices, reporting requirements, documentation, and equipment requirements.

In the United Kingdom, the Royal College of Anesthetists produces guidance on the provision of services for anesthetic care in the non-theatre environment[2] and the National Institute for Clinical Excellence (NICE) published Clinical Guideline 112 'Sedation in Children and young people' in 2010.[3] A summary of their recommendations include:

1. Thorough pre-sedation assessments by appropriately trained healthcare providers, focusing on medical history, medications being taken, physical status (including airway evaluation) and developmental/psychological status.

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http://dx.doi.org/10.1016/j.tacc.2014.06.003
2210-8440/

2. Specialist advice should be sought before delivering sedation if there is concern about the airway or breathing, if the patient is assessed as an ASA 3 or higher grade and/or the patient is a neonate/infant (i.e. any child under 1 year of age).
3. Ensure that a healthcare professional and assistant, both trained in delivering sedation to children, who have access to resuscitation and monitoring equipment are present during sedation.
4. The choice of sedation techniques takes into account the procedure, target level of sedation, side effects of the medication used and any contraindications or patient/carer preference.
5. Anyone delivering sedation should have knowledge and understanding of the pharmacology of the medication used and the effects on underlying patient physiology. They should also demonstrate competence in the clinical assessment of children, interpretation and response to procedural monitoring and the management of potential complications of sedation, up to and including pediatric life support.

The above are examples of generic guidelines for the provision of sedation and anesthesia in a remote (non-operating room) environment.

A more specific outline of safe sedation practice in children comes from the American Academy of Pediatrics (AAP) guidelines written by Cote and the AAP Committee on Drugs. There have been several iterations of these guidelines and, just as the technology has evolved, so have the AAP sedation guidelines. This first monitoring guideline was written in collaboration with the American Academy of Pediatric Dentistry (AAPD) and the American Society of Anesthesiologists (ASA).[4] It emphasized concepts that had been well established as promoting safety in the field of anesthesiology. This document addressed the need for informed consent, appropriate fasting intervals, regular charting of vital signs, the availability of age and size appropriate equipment, the use of physiologic monitoring, the need for basic life support skills, and proper recovery/discharge procedures. As had been accepted in anesthesia care, the concept of an independent observer whose only responsibility was to monitor the patient was introduced for deeply sedated pediatric patients. These guidelines also addressed the equipment needs for sedation, as well as basic information on the various drug interactions that can impact the safety of sedation. The original guidelines defined three terms for depth of sedation: conscious sedation, deep sedation, and general anesthesia. These terms became ingrained in the lexicon of sedation provision for children and subsequent iterations of these guidelines have sought to refine and improve these categories.

In 1992, the Committee on Drugs of the AAP (primary author Dr. Coté) revised the 1985 guideline.[5] The statement was careful to point out how a patient could readily progress from a given level of sedation to another without warning. It also emphasized the fact that the practitioner should be prepared to increase vigilance and the level of monitoring if a deeper level of sedation is attained. Pulse oximetry was widely available and was recommended for all patients undergoing sedation.

Another amendment to this guideline was produced in 2002.[6,7] Perhaps most importantly, this time the use of the term "conscious sedation" (and its inherent contradiction in terms) was eliminated in favor of "moderate sedation". The guidelines now unified the terminology used for levels of sedation as "minimal sedation", "moderate sedation", "deep sedation" and "anesthesia". This terminology is still accepted by the AAP, AAPD, ASA, and The Joint Commission.[8] The authors also clarified the fact that these guidelines apply to any location where children are sedated – in or out of the hospital (including dental offices and similar free standing locations).

The most recent version of the guideline was published in 2006.[7] In terms of the depth of sedation, this iteration states that any child under age 6 must be assumed to be deeply sedated. Given the increased use of potent sedation agents such as propofol and dexmedetomidine, the guidelines require that the sophistication of the monitoring and the skills of the sedation provider must match this level of sedation. It moved us closer to using the term "procedural sedation" to encompass the entire spectrum of the level of sedation in the pediatric population. By doing this, it unified the approach so that all patients receiving any type of sedative agent for procedures should undergo the same evaluation, preparation, monitoring, and recovery regarding the agent or agents used. It advises that all providers must have advanced airway management skills so as to be able to rescue the child from unintended deep sedation or general anesthesia where native airway reflexes and tone may be lost. The routine use of capnography was "encouraged" as this technology had become widely available and had proven beneficial in the anesthesia operating room environment. Finally the guideline stressed the importance of recent advances in human simulation for training sedation providers and the collection of quality improvement data.

Any rules of the road for safe sedation should start with these principles. Specific questions such as which providers should administer potent sedatives (*e.g.* propofol) should be entertained only after basic monitoring, personnel, and equipment issues have been addressed.

### 2.1. The nature of pediatric sedation literature

The reports that are routinely published rarely help us to understand the safety and effectiveness of pediatric sedation. They are usually small (50-300 patients) and retrospective, or at best prospective and observational studies. Negative studies are not usually published and the studies that are published tend to be procedure specific and from a single institution. Sedation studies almost invariably end with a version of the sentence "we found that sedation technique X is safe for procedure Y". Unfortunately the limited scope and patient numbers minimize our ability to generalize results.

By the very nature of the procedures that are performed in children, the level of sedation described and required to prevent movement or reaction to external stimulus is almost always deep sedation or anesthesia. The ASA definition of deep sedation is 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."[9]

The ASA also states that:

> "If the patient loses consciousness and the ability to respond purposefully, the anesthesia care is a general anesthetic, irrespective of whether airway instrumentation is required."

And:

> "….reflex withdrawal from a painful stimulus is NOT considered a purposeful response."[9]

Because there is such a narrow line between deep sedation and anesthesia, it is often difficult to differentiate between the two in the literature. For example, a recent paper looking at the induction