

## Propofol By Non-Anesthetists: 2009 Update

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The use of propofol when administered by surgeons and nurses who are not anesthesia professionals is a hotly debated subject. Some of the issues involved are surely financial, but our challenge is to assess how and whether this can be done safely. In order to make sense out of the claims and counterclaims, we will begin with definitions of sedation and then how to care for patients that will receive different levels of sedation.

The definitions of sedation and anesthesia appear in the ASA's **Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia** {<http://www.asahq.org/publicationsAndServices/standards/20.pdf> , 2004}. This document defines four levels of increasing depth of sedation and anesthesia using 4 categories of criteria: Responsiveness; Ability to maintain airway; Spontaneous ventilation; Cardiovascular function. The core definitions are the level of patient responsiveness:

1. Minimal sedation (anxiolysis) {Italics by BKP}
  - “A drug-induced state during which patients *respond normally to verbal commands*.”
2. Moderate sedation/analgesia (formerly known as “conscious sedation”):
  - “A drug-induced *depression of consciousness* during which patients *respond purposefully\*\** to verbal commands, either alone or accompanied by light tactile stimulation.
3. Deep sedation/analgesia:
  - “A drug-induced depression of consciousness during which *patients cannot be easily aroused* but *respond purposefully\*\** following *repeated or painful stimulation*.”
4. General Anesthesia:
  - “A drug-induced loss of consciousness during which patients are *not arousable, even by painful stimulation*.”

\*\*Note: Reflex withdrawal from a painful stimulus is **not** considered a purposeful response.

General Anesthesia has an additional, specific definition: “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.” {**Position on Monitored Anesthesia Care**, <http://www.ASAhq.org/publicationsAndServices/standards/23.pdf>}

Anesthesiologists possess specific expertise in the pharmacology, physiology, and clinical management of patients receiving sedation and analgesia. For this reason, they are frequently called upon to participate in the development of institutional policies and procedures for sedation and analgesia for diagnostic and therapeutic procedures. To assist in this process, the American Society of Anesthesiologists has developed **Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists** {Introduction,

<http://www.ASAhq.org/publicationsAndServices/sedation1017.pdf>}. These guidelines specifically exclude Minimal Sedation (Anxiolysis). They do address multiple aspects of safe patient care:

- Patient evaluation including history and physical examination;
- Preprocedure preparation- counseling; fasting;
- Monitoring-consciousness, ventilation, oxygenation, hemodynamics;
- Recording of monitored parameters;
- Personnel dedicated to patient monitoring and safety;
- Education and training of personnel;
- Appropriately-sized emergency equipment;
- Supplemental O2 if hypoxemia anticipated or develops;
- Multiple sedative/analgesic drugs increase all effects;
- Titrate drugs to achieve the desired effect;
- Propofol & methohexital require care for deep sedation;
- Intravenous access;
- Reversal agents available;
- Recovery care and discharge;
- Patients with special problems.

There is large experience with levels of moderate sedation, formerly known as ‘conscious sedation’, being provided safely by nonanesthesiologists. However, increasingly, procedures are being done with drugs that can produce deep sedation and even general anesthesia, such as propofol. In the **Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists**, we find the recommendation that patients receiving propofol need to receive care consistent with deep sedation. The document highlights some differences when deep level of sedation is given. One difference relates to the individual who is monitoring the patient. For moderate sedation there needs to be a designated individual, other than the practitioner performing the procedure, who is present to monitor the patient throughout procedure; this individual may assist the operator with minor, interruptible tasks once the patient's level of sedation/analgesia and vital signs have stabilized. However, if deep sedation is provided, the monitor should have no other responsibilities. Also, for moderate sedation, it is recommended that an individual with advanced life support skills be immediately available (within 5 minutes), but be within the procedure room for deep sedation.

In response to the increasing use of propofol as a preferred sedation agent by nonanesthesiologists, ASA has developed the **Statement on Safe Use of Propofol** (<http://www.ASAhq.org/publicationsAndServices/standards/37.pdf>), Similar concerns apply when other intravenous induction agents are used for sedation, such as thiopental, methohexital or etomidate. This Statement addresses the education, training and skills needed by the physician who is responsible for the sedation and the education training and skills needed by the practitioner who monitors the patient. This document also addresses the potential for reaching unintended deeper levels of sedation/anesthesia than planned, and how to rescue patients who do go deeper:

“Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Due to the potential for rapid, profound changes in sedative/anesthetic depth and the lack of antagonist medications, agents such as propofol require special attention. Even if moderate sedation is intended, patients receiving propofol should receive care consistent with that required for **deep sedation**.

... (N)on-anesthesia personnel who administer propofol should be qualified to **rescue\*** patients whose level of sedation becomes deeper than initially intended and who enter, if briefly, a state

of general anesthesia.

**\*Rescue** of a patient from a deeper level of sedation than intended is an intervention by a practitioner proficient in airway management and advanced life support. The qualified practitioner corrects adverse physiologic consequences of the deeper-than-intended level of sedation (such as hypoventilation, hypoxia and hypotension) and returns the patient to the originally intended level. It is not appropriate to continue the procedure at an unintended level of sedation.

In 2006, ASA adopted the “**Statement on Granting Privileges for Administration of Moderate Sedation to Practitioners Who Are Not Anesthesia Professionals**” (emphasis added), <http://www.ASAhq.org/publicationsAndServices/standards/40.pdf>. This document addresses the education and training, licensure, practice pattern and performance improvement both for the nonanesthesiologist sedation practitioner and the supervised sedation professional. ASA also adopted the “**Statement on Granting Privileges to Nonanesthesiologist Practitioners for Personally Administering Deep Sedation Or Supervising Deep Sedation By Individuals Who Are Not Anesthesia Professionals**” (emphasis added), <http://www.ASAhq.org/publicationsAndServices/standards/39.pdf>. This document states that “Because of the significant risk that patients who receive deep sedation 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.”

Although sedation is often offered as ‘safer than general anesthesia’, this may not be altogether correct. In 1984, Natof conducted a survey in 40 freestanding ambulatory surgery centers, encompassing 87,492 patients. He reported that the highest incidence of complications occurred in patients who received local with sedation, 1 in 106, compared to 1:120 with general anesthesia. Patients who had local anesthesia alone had a lower incidence, 1:268. {Natof HE. FASA Special study I. Alexandria, VA 1986, Federated Ambulatory Surgery Association}

Data from the ASA Closed Claims database show that ‘Inadequate oxygenation/ ventilation’ was more common in MAC claims (15%) than with GA (7%) and RA claims (5%,  $p < 0.05$ ). There was no difference in the severity of injury (proportion of claims for death or brain damage), nor was there a difference in the proportion of claims for substandard anesthetic care (37%), payments (54%), or the amount payment (median \$99,500) {Bhananker SM et al. Anesthesiology 2006; 104: 228-34}.

Fospropofol [Lusedra®] may not be the answer either. It is a water-soluble prodrug of propofol, and onset and duration are slower than the active drug. Fospropofol’s sedative and respiratory depressant effects may be difficult to titrate.

The Gastroenterology literature can give us a window into the safety of sedation by non-anesthesiologists. They have championed “NAPS” (Nurse-Administered Propofol Sedation) which is a 2-week training program, now done nurse-to-nurse. {Walker JA. Am J Gastroent 2003; 98: 1744-50}. In one series of 9152 primarily ASA 1 & 2 patients, most complications occurred in 1836 upper GI endoscopies. Three patients had ‘prolonged apnea’ with ‘hypoxemia’: 2 were given mask ventilation and one recovered spontaneously after 30 sec. Three

patients had laryngospasm, and 7 had colonic perforations (3 due to ‘forceful sigmoid disruption’). Another series of 2000 patients excluded ASA 3, aspiration risk and difficult airway patients. {Rex DK et al. Am J Gastroent 2002; 97: 1159-63}. In this series, 11 desaturated <90% despite 4L/m O<sub>2</sub> and were treated with increased O<sub>2</sub>; 4 desaturated <85%, were ‘assumed apneic’ and treated with mask ventilation. These authors note that experience did not prevent apnea: 2 of the 4 desaturations <85%, occurred in the first thousand patients, and 2 in the second. 2/2000 sedations were converted intentionally to general anesthesia due to restlessness. Even more illuminating as to the depth of sedation actually achieved was the observation that patients were “often unable to assist with position changes” during colonoscopy.

Emergency Medicine physicians are another group promoting their practice of deep sedation. Here the series are smaller.

	<u>#Adults</u>	<u>Dose</u>	<u>Adverse Events</u>
Swanson	4	0.14 mg/kg/min	none
Swanson	20	0.21 mg/kg/min	2 apnea; 1 assisted ventilation (AV)
Miner	21	not stated	4 respiratory depression (RD), 1 hypoxia. No AV.
Miner	54	not stated	22 RD, 5 hypoxia, 5 AV
Miner	51	1mg/kg+ 0.5mg/kg prn	28 RD ,5 hypoxia, 2AV
Coll-Vinent	9	1.5 mg/kg	4 hypoxia, 2 apnea

{Green SM, Krauss B Ann Emerg Med 2003; 42:792-7}

Only the patients in Coll-Vinent series were NPO. Other practitioners such as dentists are also considering giving deep sedation in their practice {Yagiela JA J Dent Educ 2001; 65:1348-56}.

Currently, the package insert for propofol (Diprivan®) contains a Warning that states:

“For general anesthesia or monitored anesthesia care (MAC) 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.”

Fospropofol [Lusedra®] will have the same warning.

The American College of Gastroenterologists has petitioned the FDA to remove this statement from the label, which would eliminate all three requirements addressed there. The comment period ended December 2005, and no FDA action was taken.

What else do we need to know? We need studies comparing safety before and after introduction of other propofol use, as well as safety data from anesthesiology. With this information, and with ASA documents as guidance, we will need to make ongoing assessments concerning the safety of propofol use by non-anesthesiologists.