



Propofol sedation: Who should administer?

Using propofol (DIPRIVAN) to sedate patients during endoscopic and other diagnostic procedures has gained momentum in recent years in a growing number of hospitals, outpatient surgery centers, and physician offices.¹ In trained hands, propofol offers many advantages over other drugs used for sedation because it:

- has a rapid onset (about 40 seconds) and a short duration of action
- allows patients to wake up, recover, and return to baseline activities and diet sooner than some other sedation agents
- reduces the need for opioids, thus resulting in less nausea and vomiting.²

Some have been lulled into a false sense of security, believing propofol is safer than it is in untrained hands.

Trained nurses in most critical care settings often administer propofol safely to patients who are intubated and ventilated. However, some nurses and physicians have been lulled into a false sense of security, allowing the drug's good safety profile to influence their beliefs that propofol is safer than it really is. In untrained hands, propofol can be dangerous, even deadly; administration to a non-ventilated patient by a practitioner who is not trained in the use of drugs that can cause deep sedation and general anesthesia is not safe, even if the drug is given under the direct supervision of the physician performing the procedure.² After all, how closely can physicians supervise nurses and assess the effects of propofol on the patient if they are focused on the procedure itself? Not closely enough, as the following events show.

Believing that propofol was "used all the time in ICU," a gastroenterologist asked a nurse to prepare "10 mL" (10 mg/mL) of the drug for a patient

undergoing endoscopy in his room. The nurse obtained the drug from an automated dispensing cabinet via override before she transcribed the order to the patient's record. Another nurse who was trained in the use of moderate sedation, but not deep sedation or anesthesia, assisted the gastroenterologist. After questioning the physician about the dose (100 mg is a high dose), she began administering the propofol via an infusion pump. The patient suddenly experienced respiratory arrest. Fortunately, ICU staff were able to help, and the patient was quickly intubated and ventilated.

Another case involved a physician who thought he could safely administer propofol himself while performing a breast augmentation. Unfortunately, his patient, a young woman, died of hypoxic encephalopathy because neither he nor his surgical assistant (who was not qualified to monitor patients under deep sedation or anesthesia) noticed the patient's rapidly declining respiratory status.³

There are several compelling reasons why healthcare providers should be concerned about administration of propofol to unventilated patients by anyone other than anesthesia professionals.

Strict product labeling. AstraZeneca, the manufacturer of Diprivan, states in its product labeling that the drug is intended for general anesthesia or monitored anesthesia care sedation, and that the drug should be administered only by persons trained in the administration of general anesthesia who are not involved in the surgical/diagnostic procedure. For sedation of

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check it out! ✓✓✓✓

To guide policy development on nurse-administered propofol, consider the following:

✓ **Review regulations/positions.** Check with your State Board of Nursing to determine if nurse-administered propofol is deemed within the professional nurses' scope of practice. If so, explore the various position statements available on this topic from professional societies, including the:

- [American Society of Anesthesiologists \(ASA\)](#)
- [American Association of Nurse Anesthetists \(AANA\)](#)
- [American Association for Accreditation of Ambulatory Surgery Facilities \(AAAASF\)](#)
- [American College of Gastroenterology \(ACG\)](#)
- [American Gastroenterological Association \(AGA\)](#)
- [American Society for Gastrointestinal Endoscopy \(ASGE\)](#)
- [Society of Gastroenterology Nurses and Associates \(SGNA\)](#)

In brief, the ASA, AANA, and AAAASF believe that only persons trained in the administration of general anesthesia, who are not simultaneously involved in the procedures, should administer propofol to nonventilated patients. The ASA also suggests that, if this is not possible, nonanesthesia staff who administer propofol should be qualified to rescue patients whose level of sedation becomes deeper than intended, and who enter, if briefly, a state of general anesthesia. The ACG, AGA, ASGE, and SGNA endorse nurse-administered propofol under the direction of a physician if state regulations allow it, and if the nurse is trained in the use of drugs causing deep sedation and capable of rescuing patients from general anesthesia or severe respiratory depression.

✓ **Establish standard policies.** Based on patient safety, professional association position statements, and

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intubated, mechanically ventilated adult patients in the ICU, product labeling notes that the drug should be administered only by persons skilled in the management of critically ill patients and trained in cardiovascular resuscitation and airway management.

Unpredictable and profound effects.

Propofol dosing and titration is variable, based on the patient's tolerance to the drug and physical status. Profound changes can occur rapidly. A patient can go from breathing normally to a full respiratory arrest in seconds, even at low doses, without warning from typical assessment parameters.² Morbidly obese patients (those with a body mass index greater than 35 kg/m²) can take even longer to recover from propofol anesthesia.⁴

No reversal agent. Unlike other sedation agents (e.g., midazolam, morphine), there is no reversal agent for propofol. Adverse effects must be treated until the drug is metabolized.

Financial incentives. Unwillingness of insurers to reimburse anesthesia care for some procedures such as diagnostic endoscopy has increased the use of nurse-administered propofol.^{1,2} Untrained nurses may be caught in the middle of the debate and feel pressured to administer this drug.²

Legal barriers. Nurse-administered propofol falls under each state's Nurse Practice Act. Many states specifically

consider this function beyond the scope of nursing practice.²

Organizations should convene an interdisciplinary team, including chair of the anesthesia department, to establish policies and practice guidelines for the administration of propofol (or other induction agents such as thiopental or etomidate) to nonventilated patients undergoing surgery or diagnostic procedures. To best inform your team's decision about this controversial issue, consider the recommendations in **checkitout!** in the right column starting on page 1.

The debate about who should be allowed to administer propofol may continue, but one thing is clear: whenever propofol is used for sedation/anesthesia, it should be administered only by persons who are: (1) trained in the administration of drugs that cause deep sedation and general anesthesia, (2) able to intubate the patient if necessary, and (3) not involved simultaneously in the procedure itself.

References: (1) Marshall S. Pleasant dreams: office surgeries fuel demand for anesthesiologists. *Crain's New York Business*. January 10, 2005. (2) Roark J. The great debate: NAPS. Feb. 1, 2005. Available at: www.endonurse.com/articles/sedation_anesthesia/597_521feat4.html. (3) WFTS ABC Action News. Doctor still on the hook for 'accidental' surgery death. *ABC Action News Tampa-St. Petersburg*. March 18, 2004. (4) Juvn P, et al. Postoperative recovery after desflurane, propofol, or isoflurane anesthesia among morbidly obese patients: a prospective, randomized study. *Anesth Analg* 2000;91:714-9.

safetywires



A gel of an injection. A physician ordered an ultrasound for a patient in isolation. Attempting to avoid contamination of an entire tube of ultrasound gel, a technician withdrew some gel into a parenteral syringe and brought the syringe into the room. The unused portion in the unlabeled syringe was brought out of the room and left on a medication cart just outside the patient's door. Later, during a mock inspection, the unlabeled syringe, containing about 8 mL of the blue-tinted ultrasound gel, was found on top the cart. Fortunately, the unlabeled syringe did not result in an error, but it does illustrate several important points. Unlabeled syringes containing injectable, topical, or oral products should be discarded. Topical preparations should never be prepared in injectable, or even oral, syringes. A properly labeled topical syringe was really the only safe option or, in this case, a disposable, labeled cup.

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checkitout! continued

applicable state laws, determine the qualifications of professionals who can administer propofol to nonventilated patients during procedures. If nurse-administered propofol is deemed acceptable, specify the circumstances and required education and mentorship that must be accomplished beforehand, and competencies that must be evaluated and met periodically. (ACLS certification alone is not sufficient.)²

✓ **Define sedation goals.** Define the intended level of sedation when using propofol to sedate unventilated patients during procedures. However, even if moderate sedation is intended, all patients given propofol should receive care consistent with deep sedation.

✓ **Clarify location.** Clearly identify specific locations where patients may receive propofol sedation. Ensure that the location(s) supports patient monitoring and rescue, if needed, including staff with expertise to intubate patients.

✓ **Assess before sedation.** Standardize a pre-sedation patient assessment to determine suitability for nurse-administered propofol. Determine the qualifications of practitioners who can perform the assessment and make a determination to proceed with nurse-administered propofol.

✓ **Monitor patients.** Establish standard processes and measurement criteria (e.g., vital signs, oxygen saturation, ideally capnography) for continuously monitoring nonventilated patients who are receiving propofol and for a period of time after drug administration ends and the patient is awakened.

✓ **Be prepared to rescue patients.** Ensure that equipment is readily accessible at the point of care to maintain a patent airway, provide oxygen, intubate, ventilate, and offer circulatory resuscitation.

Consider all sources of latex for allergic patients

Nurses must consider all sources of latex for patients with an allergy to it. Some drug delivery catheters are coated with latex, and the rubber stoppers on some vials may contain latex. One case involved a preeclampsia patient who developed shortness of breath, bronchospasm, and chest tightness after receiving ampicillin 2 g. The drug was stopped, diphenhydramine was administered, and the patient's symptoms resolved.


Originally, this was thought to be an allergic reaction to ampicillin. However, the patient gave a history of being allergic to latex, not penicillin. The source of latex was later discovered. The nurse had prepared the ampicillin dose using the Hospira **ADD-Vantage** system, a widely used IV drug delivery system. A pharmacist discovered that, although the Hospira ADD-Vantage minibags are promi-

nently marked "latex free," the rubber stopper of the actual drug vials used with the system might contain latex.


According to Hospira, all ADD-Vantage *diluent* containers are latex-free but the vials may not be. All ADD-Vantage vials *made by Hospira*, with the exception of tobramycin and clindamycin, are latex-free. The majority of manufacturers who provide other vials to use with ADD-Vantage minibags have latex-free vials. However, in this case, the ampicillin vial used was manufactured by Sandoz and contained latex.

Surprisingly, FDA does not require products to be labeled with their latex status. Thus, in order to be sure, ask your pharmacist, who can contact the individual vial manufacturers if necessary for updated information concerning their latex-free status.

All is not as it seems...


 What medication was prescribed in this order faxed to a long-term care pharmacy?

Cardura 2mg. PO. QHS

 The physician prescribed **CARDURA** (doxazosin) 2 mg PO QHS, but the order was misinterpreted and dispensed as **COUMADIN** (warfarin) 2 mg HS. The patient received Coumadin instead of Cardura for 20 days before the error was discovered during hospitalization for uncontrolled hypertension. Fortunately, the patient did not experience bleeding episodes. Both medications are available in 1 mg, 2 mg, and 4 mg tablets, and are generally administered once daily. At first glance, these drug names may not look alike, but when handwritten, as in the order above, the similarities are much more apparent. In fact, there have been numerous reports of mix-ups between these drugs on handwritten prescriptions. Prescribers should be encouraged to include the medication's purpose on all prescriptions. Likewise, pharmacists and nurses should **verify a medication's purpose** before it is dispensed or administered, especially for a high-alert medication such as warfarin. This excellent practice habit can significantly reduce the risk of errors associated with medications that have look- and sound-alike names.

safetywires continued

Another key point: Although an ultrasound technician may play no role in actual drug administration, this event demonstrates how important it is for nurses to foster a heightened awareness among all hospital workers about how their actions could ultimately result in a patient safety issue—in this case, a medication error.

 **Strangulation risk.** A tragic case of strangulation by IV tubing was described last year in *The Lancet*, a British medical journal (Lunetta P, Laari M. Strangulation by intravenous tubes. *The Lancet* 2005;365:1542). A 10-month-old baby, hospitalized with leukemia, had been restless but was sleeping just an hour before she was found by nursing staff, pulseless, cyanotic, and apneic. IV tubing leading to a right clavicular vein was tightly wrapped twice around her neck. Resuscitation attempts failed. Legal authorities later confirmed the accidental strangulation. After similar cases in Canada in 2002 (<http://pediatrics.aappublications.org/cgi/content/full/111/6/e732>), health officials sent an advisory in December 2003 to Canadian hospitals warning staff, parents, and caregivers about risks imposed by IV tubing, oxygen tubing, and monitor leads (www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/2003/iv_tubes_2_nth-ah_e.html). The advisory recommended a careful risk assessment of young children upon admission, appropriate supervision during hospitalization, coiling of excess tubing to prevent entanglement, and use of accessories to stabilize flexible lines (e.g., hard plastic sleeves that can be placed over the tubing closest to the child to prevent it from wrapping around the child). Oral therapy or use of a saline lock should be considered as soon as possible to replace intravenous therapy. In Finland, where the latest fatality occurred, video surveillance systems are being recommended for children at risk.

Complete our survey!



Since publication of last month's front page article about promethazine, we have received many reports of severe tissue damage resulting from IV administration of this drug. Since the article has sparked renewed interest in this long-standing problem, we are asking for your help in defining the scope of the problem and prioritizing prevention strategies. Please complete the survey on page 4 and submit the findings to ISMP as directed on the survey form.

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ISMP survey on promethazine

ISMP is asking for your help in defining the scope of the problem and prioritizing strategies to avoid severe tissue damage when administering IV promethazine. Please complete the survey even if you no longer use promethazine in your facility. Submit your responses to ISMP by **Sept 29, 2006**, via the Internet (www.ismp.org/survey/Survey200608.asp) or fax (215-914-1492). Thanks for your participation!

1 The following strategies were suggested in the newsletter to reduce the risk of severe tissue damage when administering IV promethazine. Please rate the value of each recommendation and note whether your facility follows the recommendation. Select Not Applicable (NA) when necessary for recommendations that do not apply because promethazine is not administered IV in your facility, or if you do not use automated dispensing cabinets.

Recommendations	Value of recommendation 1=low value 5=high value					Does your facility follow the recommendation?			Comments
	1	2	3	4	5	Yes	No	NA	
a) Limit the concentration in stock to 25 mg/mL									
b) Limit the starting dose to 6.25 to 12.5 mg IV									
c) Dilute the drug in 10 to 20 mL of normal saline									
d) Prepare the drug in minibags containing normal saline									
e) Do not allow administration via hand or wrist veins									
f) Give the drug through a central venous site only									
g) Inject the drug through a running IV line									
h) Inject the drug through a running IV line at the port furthest from the patient's vein									
i) Administer the drug slowly over 10-15 minutes									
j) Require the person administering the drug to remain with the patient to assess the IV site during the entire injection/infusion									
k) Standing orders for promethazine IV reflect current safety requirements									
l) Patients are advised to report burning or pain									
m) An alert appears on MARs reminding staff of safety precautions									
n) An alert appears on automated dispensing cabinet screens reminding staff of safety precautions									
o) Remove promethazine from the formulary									
p) Ban IV use of promethazine									
q) Use alternative rescue antiemetics Specify: _____									

2 At your current or past facility, have there been any cases of serious tissue damage in the past 5 years that occurred after IV administration of promethazine?

Yes No Not sure

3 Do you believe FDA should withdraw approval of the IV route of administration of promethazine?

Yes No Not sure

4 Please place a checkmark in the boxes that best describe you and your facility.

Profession: Nurse Pharmacist Physician Other
 Facility: Hospital Outpatient facility Long-term care facility Other