



## Who Administers Propofol in Your Organization?

What are the necessary credentials for administering propofol (DIPRIVAN) for moderate and deep sedation? Healthcare facilities in Pennsylvania and across the country are asking this question. The American College of Gastroenterology and others contend that the safety profile of propofol is such that a gastroenterologist, registered nurse under their supervision, and other “qualified medical professionals” can safely and effectively administer the drug without specific training in the administration of general anesthesia.<sup>1</sup> However, drug manufacturers and several anesthesiology professional organizations believe this may place patients at undue risk.<sup>2-6</sup> What constitutes safe practice for this high-alert medication?

### At Issue

The use of propofol during endoscopic, radiologic, and other procedures is growing in hospitals, ambulatory surgical facilities, and physician offices across the country.<sup>7</sup> Propofol offers certain advantages over other drugs used for sedation when used by trained and credentialed practitioners because it:

- Has a rapid onset 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, resulting in less nausea and vomiting.<sup>8</sup>

However, practitioners may develop a false sense of security, allowing the perceived safety profile of propofol to influence their belief that the drug poses minimal risk. In untrained hands, propofol can be deadly. Administration to a non-ventilator-assisted patient by a practitioner who is not trained to administer drugs that cause deep sedation and general anesthesia is not safe, even if the drug is given under the supervision of a physician performing the procedure.<sup>8</sup>

Further complicating the situation is that several insurance companies have decided that propofol administration in the office setting by gastroenterologists or their assistants is acceptable and safe for some procedures.<sup>8</sup> Therefore, these insurers will no longer reimburse for anesthesiology services performed for some procedures in office settings. In the article “RNs Pushing Propofol,” Meltzer states that this unwillingness to reimburse anesthesia care for procedures in which propofol is used, such as diagnostic endo-

scopy, has increased the use of nurse-administered propofol. As a result, untrained practitioners may be caught in the middle of the debate and feel pressured to administer propofol.<sup>8</sup>

### Medication Errors

The Pennsylvania Patient Safety Reporting System (PA-PSRS) has received over 100 medical and medication error reports in which the use of propofol has been cited. Sixteen percent (16%) of these reports have been classified as Serious Events, including four patient deaths in which propofol may have played a role. Here is one example:

*A 40-year-old patient was admitted with injuries to the face and subarachnoid hemorrhaging. The patient received propofol but was not intubated. The patient was then taken to radiology for a CT scan. While in radiology, the patient became bradycardic and suffered a cardiac arrest. The patient was resuscitated but died two days later.*

Another example was reported by the Institute for Safe Medication Practices (ISMP) in November 2005. A gastroenterologist who thought propofol was “used all the time in ICU” asked a nurse to prepare “10 mL” (10 mg/mL) of propofol for a patient undergoing endoscopy.<sup>9</sup> The nurse retrieved the drug from an automated dispensing cabinet via the override function. Another nurse who was trained in the use of moderate sedation, but not deep sedation or anesthesia, assisted the gastroenterologist. She questioned the physician regarding the dose but began administering the propofol via an infusion pump. The patient experienced respiratory arrest. Fortunately, other ICU staff members were able to help with the emergency and quickly intubated and ventilated the patient.

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Another case involved a physician who thought he could safely administer propofol while performing breast augmentation.<sup>10</sup> However, he and his surgical assistant, neither of whom were able and/or qualified to monitor patients under deep sedation or anesthesia, failed to recognize the patient's rapidly deteriorating respiratory status. The patient, a young woman, died of hypoxic encephalopathy.

In another example, nurses in one particular facility have reported being asked to administer "a little more" propofol if the patient moved after the anesthesiologist left the room.<sup>8</sup> In these cases, the anesthesiologist would leave the propofol syringe attached to the IV port after placing the block and leave the nurses in the room to monitor the patient. The nurses reluctantly complied initially. Later, they brought the issue to the attention of hospital leaders, citing that they were worried about the safety of this practice.<sup>3</sup>

### Professional Society Viewpoints

There is a difference in opinion among professional societies about the necessary credentials for individuals administering propofol for sedation. In brief, the American Society of Anesthesiologists (ASA), American Association of Nurse Anesthetists, and American Association for Accreditation of Ambulatory Surgery Facilities believe that safe administration of propofol to non-ventilator-assisted patients is limited to individuals trained in the administration of general anesthesia who are not simultaneously involved in the procedure.<sup>2-4</sup> The ASA also suggests that, if this is not possible, non-anesthesia staff who administer propofol be qualified to rescue patients whose level of sedation becomes deeper than intended and who enter, if briefly, a state of general anesthesia. The ASA's "Practice Guidelines for Sedation and Analgesia by Non-anesthesiologists" is available on their website.<sup>9</sup>

In contrast, the American College of Gastroenterology, American Gastroenterological Association, American Society for Gastrointestinal Endoscopy, and Society of Gastroenterology Nurses and Associates endorse nurse-administered propofol under the direction of a physician if state regulations allow it, if the nurse is trained in the use of drugs causing deep sedation, and if the nurse is capable of rescuing patients from general anesthesia or severe respiratory depression.<sup>12,13</sup>

### Joint Commission on Accreditation of Healthcare Facilities (JCAHO) Standard

JCAHO Standard PC.13.20 requires, for the administration of moderate or deep sedation, that a sufficient number of staff, in addition to the person performing the procedure, be present to perform the procedure,

monitor and recover the patient. The person administering the sedative agent must be qualified to manage the patient at whatever level of sedation or anesthesia is achieved, either intentionally or unintentionally. While there may be a need for additional monitoring personnel for the procedure, the person administering the sedation must be qualified to monitor the patient.<sup>14</sup>

### Product Labeling

Manufacturers of propofol state in the product labeling that:<sup>5,6</sup>

- The drug should be administered only by persons trained in the administration of general anesthesia and not involved in the surgical/diagnostic procedure.
- Monitored anesthesia care (MAC) patients should be continuously monitored by persons not involved in the conduct of the surgical or diagnostic procedure; oxygen supplementation should be immediately available and provided where clinically indicated; and oxygen saturation should be monitored in all patients. Patients should be continuously monitored for early signs of hypotension, apnea, airway obstruction, and/or oxygen desaturation.

The official labeling also indicates that propofol should be administered only by persons skilled in the management of critically ill patients and trained in cardiovascular resuscitation and airway management when sedating intubated, mechanically ventilated adult patients in the ICU.

The American College of Gastroenterology has petitioned the FDA to remove the following text from the DIPRIVAN (propofol) product label: "For general anesthesia or 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."<sup>11</sup> However, the FDA has not made a final ruling on this petition, and as of March 2006 the labeling as presented above continues to be the official and approved labeling for propofol products.

### Variable Effects

Propofol dosing and titration is variable, as it is based on the patient's response and tolerance to the drug. Profound changes in respiratory status 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.<sup>8</sup>

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### No Reversal Agent

Unlike other agents used for sedation (e.g., midazolam, morphine), propofol has no reversal agent.

### State Boards

More than a dozen states specifically consider nurse-administered propofol beyond the scope of nursing practice according to their Nurse Practice Acts.<sup>8</sup> Pennsylvania does not have an official advisory opinion or declaratory statement regarding the administration of propofol by nurses.

The Pennsylvania Code stipulates that the administration of anesthesia is a proper function of a registered nurse who has successfully completed an accredited education program for nurse anesthetists and who works in cooperation with a surgeon or dentist.<sup>15</sup> The code also specifies that a registered nurse who is not a certified registered nurse anesthetist may administer intravenous conscious sedation medications during minor therapeutic and diagnostic procedures.<sup>16</sup>

### Safe Practice Strategies

Unfortunately, there is no easy answer to the question of who to allow to administer propofol in your organization. The process requires input from many parties. A good first step may be to convene a multidisciplinary team consisting of administration, nurses, pharmacists, and physicians (including representatives from anesthesia, gastroenterology, radiology, surgery, and other physicians from areas that may administer or monitor propofol) to:

- Review state regulations to ascertain which practitioners may or may not be able to administer propofol within their respective scope of practice.
- Evaluate the literature and various position statements available from professional societies such as the ASA, American Association of Nurse Anesthetists, and others. See the Resources section below for selected societies and web addresses.
- Establish policies and practice guidelines for the administration of propofol (or other agents such as thiopental, methohexital, or etomidate) to non-ventilator-assisted patients undergoing minor surgical or diagnostic procedures.
- Define qualifications of professionals who can administer propofol to non-ventilator-assisted patients during procedures.
- If nurse-administered propofol is agreed upon as

acceptable, specify the circumstances and required education and mentorship to be accomplished beforehand and competencies to be evaluated and met periodically. Keep in mind that ACLS certification alone may not be sufficient for this purpose.<sup>8</sup>

- Evaluate locations where propofol administration is appropriate, and ensure that those areas are able to follow the developed criteria for administration, including expertise and availability of equipment to intubate patients.
- Define and document the intended level of sedation that patients should receive. Ensure that all patients, even if moderate sedation is intended, are able to be monitored and rescued from deep sedation.
- Establish a continuous monitoring process and assessment criteria (e.g., vital signs, oxygen saturation, capnography) for non-ventilator-assisted patients who are receiving propofol.
- Ensure that equipment is readily accessible at the point of care to maintain a patent airway, provide oxygen, intubate, ventilate, and offer circulatory resuscitation.

### Conclusion

Propofol, an injectable emulsion, is a high-alert medication according to ISMP.<sup>17,18</sup> Based on the action and nature of the medication and the number of error reports submitted to PA-PSRS and other organizations, the safest strategy is to limit propofol use to healthcare professionals with specialized training in administering, monitoring, and treating its untoward effects. However, errors can still occur despite the presence of a trained healthcare professional. The largest number of events involving propofol received by PA-PSRS occurred in the ICU and OR—practice settings designed with constant supervision in place.

While the debate will continue over the appropriate credentials for administering and monitoring propofol, one thing is clear: whenever propofol is used for sedation/anesthesia, it should be administered only by persons who are capable of recognizing and treating any untoward effects with this largely beneficial, but potentially deadly, agent.

### Resources

American Society of Anesthesiologists  
([www.asahq.org](http://www.asahq.org))

American Association of Nurse Anesthetists  
([www.aana.com](http://www.aana.com))

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American Association for Accreditation of Ambulatory Surgery Facilities ([www.aaaasf.org](http://www.aaaasf.org))

American College of Gastroenterology ([www.acg.gi.org](http://www.acg.gi.org))

American Gastroenterological Association ([www.gastro.org](http://www.gastro.org))

American Society for Gastrointestinal Endoscopy ([www.asge.org](http://www.asge.org))

Society of Gastroenterology Nurses and Associates ([www.sgna.org](http://www.sgna.org))

### Notes

1. FDA Docket 2005P-0267. Remove from the Labeling for Propofol (Diprivan) the Warning that Propofol should be Administered Only by Persons Trained in the Administration of General Anesthesia, Rather than by Other Qualified Medical Professionals. FDA Dockets Management. [online]. [cited 2006 Feb 22]. Available from internet: <http://www.fda.gov/ohrms/dockets/dockets/05p0267/05p0267-cp00001-01-vol1.pdf>.
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An Independent Agency of the Commonwealth of Pennsylvania

The Patient Safety Authority is an independent state agency created by Act 13 of 2002, the Medical Care Availability and Reduction of Error (“Mcare”) Act. Consistent with Act 13, ECRI, as contractor for the PA-PSRS program, is issuing this newsletter to advise medical facilities of immediate changes that can be instituted to reduce serious events and incidents. For more information about the PA-PSRS program or the Patient Safety Authority, see the Authority’s website at [www.psa.state.pa.us](http://www.psa.state.pa.us).



ECRI is an independent, nonprofit health services research agency dedicated to improving the safety, efficacy and cost-effectiveness of healthcare. ECRI’s focus is healthcare technology, healthcare risk and quality management and healthcare environmental management. ECRI provides information services and technical assistance to more than 5,000 hospitals, healthcare organizations, ministries of health, government and planning agencies, and other organizations worldwide.



The Institute for Safe Medication Practices (ISMP) is an independent, nonprofit organization dedicated solely to medication error prevention and safe medication use. ISMP provides recommendations for the safe use of medications to the healthcare community including healthcare professionals, government agencies, accrediting organizations, and consumers. ISMP’s efforts are built on a non-punitive approach and systems-based solutions.