

Effect of the Centers for Medicare & Medicaid Services Policy About Deep Sedation on Use of Propofol

Douglas K. Rex, MD

On 11 December 2009, the Centers for Medicare & Medicaid Services issued a policy stating that deep sedation can only be administered by an anesthesiologist, a certified registered nurse anesthetist, or a trained medical doctor or a doctor of osteopathy not involved in the performance of a medical procedure. Propofol is a popular sedation agent that is usually administered by anesthesia specialists in a service termed *monitored anesthesia care* (MAC). Monitored anesthesia care adds substantial new fees to procedural sedation. However, available evidence shows that propofol can be used safely by nonanesthesiologists for procedural sedation. The American

Society of Anesthesiologists considers that propofol implies deep sedation and should only be administered by anesthesia specialists. The Centers for Medicare & Medicaid Services policy on deep sedation can be viewed as supporting an ongoing conversion to MAC to deliver propofol for procedural sedation. However, the absence of an evidence base supporting a need for MAC to deliver propofol, combined with its high cost, suggests that alternatives to MAC to deliver propofol deserve fair and balanced evaluation.

Ann Intern Med. 2011;154:622-626.

For author affiliation, see end of text.

www.annals.org

Sedation for many procedures done by internists has traditionally been administered by the proceduralist or a registered nurse under their supervision. According to the CPT (Current Procedural Terminology) committee of the American Medical Association, the professional fee for many procedures done by internists and internal medicine subspecialists, including central venous catheter placements, gastrointestinal endoscopy, bronchoscopy, and nonsurgical cardiac procedures, includes payment for administration of sedation (1). Opioids and benzodiazepines have been commonly used for procedural sedation, but in recent years, many proceduralists have developed a preference for propofol-based sedation. Propofol is popular because of its rapid onset and offset of action and because patients are alert and feel well shortly after the procedure. In gastrointestinal endoscopy, propofol-based sedation had increased to 26% of total U.S. volume by 2006 (2), and a recent study projected that it will be used in 53% of endoscopy cases by 2015 (3).

Propofol is often equated with “deep sedation,” although it can be titrated to moderate sedation when combined with low doses of opioids and benzodiazepines (4, 5). The package insert for propofol states that it should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical or diagnostic procedure. Primarily for this reason, propofol for procedural sedation is commonly administered by an anesthesiologist or a certified registered nurse anesthetist; this service is called *monitored anesthesia care* (MAC).

Despite the package insert warning, propofol has commonly been administered by emergency department physicians for short procedures (6). Also, more than 30 reports have described the safe use of propofol by gastrointestinal endoscopists, often working with specially trained registered nurses (7), a practice termed *endoscopist-directed propofol administration*.

The administration of propofol by nonanesthesiologists remains controversial. Anesthetist groups are concerned that propofol can induce general anesthesia and apnea very rapidly, that propofol does not have a reversal agent, and that nonanesthesiologists lack sufficient airway expertise to rescue patients who receive propofol. Anesthetist groups typically cite the package insert to support their position (8). Nonanesthesiologists who use propofol counter that the drug is safe if used according to the principles that underlie safe procedural sedation with any agent—that is, slow titration to the desired level of sedation and awareness of individual variability in pharmacologic response. They contend that the very short duration of action of propofol means that a reversal agent is not needed because any episodes of apnea that occur are short and easily managed if the drug dosage is titrated carefully. Nonanesthesiologists cite the published evidence to support their position (6, 7).

SEDATION LEVELS AND THE HISTORY OF DEEP SEDATION

The American Society of Anesthesiologists (ASA) endorsed the concept of a continuum of sedation in 1999 as a statement of its House of Delegates (9). According to the ASA Web site, “Statements represent the opinions, beliefs, and best medical judgments of the House of Delegates. As such, they are not necessarily subjected to the same level of formal scientific review as ASA Standards or Guidelines.” However, this continuum of sedation was subsequently presented in a guideline for sedation by nonanesthesiologists in 2002 (9). Four levels of sedation, termed *minimal sedation*, *moderate sedation* (replacing the previous term *conscious sedation*), *deep sedation*, and *general anesthesia*, were described. The guideline did not preclude nonanesthesiologists from administering deep sedation but stated that practitioners targeting specific levels of sedation should be able to rescue patients from the next deepest

level of sedation. Recommendations for patient monitoring were made for each level of sedation. Furthermore, it was recommended that patients given propofol should be treated as if deep sedation were the target.

In 2006, the ASA House of Delegates issued a brief statement on the ASA Web site, without supporting references, indicating that nonanesthesiologists should not target deep sedation (10). Subsequently, the ASA issued a model set of policies and procedures for the use of anesthesia in hospitals in which the ASA encouraged hospitals to adopt the content of the 2006 House of Delegates statement in granting deep sedation privileges (11).

COST IMPLICATIONS OF CURRENT TRENDS

Every procedure that uses MAC generates an additional fee. According to 1 source, the Centers for Medicare & Medicaid Services (CMS) pays an average of \$155 to an anesthesia specialist for performing MAC for endoscopy using CPT code 00810, but private insurers pay an average reimbursement of \$437 for CPT code 00810 (12). A nationwide conversion to MAC for procedural sedation could result in as much as \$5 billion per year in new U.S. health care costs for gastrointestinal endoscopy procedures alone (12).

Endoscopist-directed propofol results in no additional charges for sedation because it is covered under the professional fee for performance of the procedure. Lack of financial incentives for endoscopist-directed propofol and the medical and legal risks associated with the package insert for propofol combined to limit the growth of endoscopist-directed propofol. Anecdotally, MAC may be attractive to anesthesia professionals because it is relatively easy to do; it is lucrative; and if it is established as the sole professional service provided by the anesthetist, it may not involve on-call duty. Monitored anesthesia care can also be a source of income for proceduralists. If MAC is used in office or ambulatory surgery practice, there is no need to hire a registered nurse to monitor and assist with sedation (13). Many proceduralists now hire anesthesia specialists, pay them either a salary or a set fee for each procedure, and bill insurers for the anesthesia services (14). The difference in revenue from the anesthesia services and what is paid to the anesthesia specialist then becomes an income stream to the proceduralists.

EVIDENCE BASE FOR THE SAFETY OF ENDOSCOPIST-DIRECTED PROPOFOL AND MAC

In 2009, a consortium of 28 centers in 10 countries that prospectively collected safety data on endoscopist-directed propofol described the results of 646 080 cases of endoscopist-directed propofol administration, including 422 424 previously unpublished cases (7). That study is substantially larger than all reports on traditional sedation with opioids and benzodiazepines by endoscopists (15).

Four deaths occurred (1 per 161 520 cases), each after an upper-endoscopic procedure. The patients were 2 men with advanced pancreatic cancer, 1 with alcoholic cardiomyopathy, and 1 with severe mental retardation. In a “back-of-the-envelope” analysis, the authors estimated that use of anesthesia specialists for all cases, assuming the anesthesiologists could have prevented all 4 deaths, would cost at least \$5.3 million per life-year saved.

Randomized trials comparing endoscopist-directed propofol with traditional sedation with opioids and benzodiazepines found that endoscopist-directed propofol administration results in faster time to onset of sedation, faster recovery, and similar or better patient satisfaction (5, 16, 17). Randomized trials (4) and observational studies (5) have also shown that endoscopist-directed propofol administration can be titrated to moderate sedation if propofol is given with small doses of opioids and benzodiazepines rather than used as a single agent. When endoscopist-directed propofol is administered in this regimen, it is referred to as *balanced propofol sedation* and is favored by some practitioners of endoscopist-directed propofol administration. However, most of the safety experience with endoscopist-directed propofol administration is with propofol given as a single agent with a target of deep sedation (7).

A recent retrospective review of 324 737 patients who were sedated by endoscopists in the Clinical Outcomes Research Initiative of the American Society of Gastrointestinal Endoscopy, using opioids and benzodiazepines, reported a rate of 8 cardiopulmonary deaths per 100 000 patients (15). In prospective series, endoscopists using opioids and benzodiazepines produce deep sedation in more than one half of patients (18), and deep sedation occurs more often than with the balanced propofol sedation form of endoscopist-directed propofol administration (5).

Although the volume of procedures done with MAC far exceeds that of endoscopist-directed propofol, there is only 1 report on the safety of MAC. In 799 cases of propofol administered by certified registered nurse anesthetists for endoscopic retrograde cholangiopancreatography, there were no major complications (19). Monitored anesthesia care done by anesthesiologists has been associated with deaths and malpractice claims (20), including endoscopic procedures (20), but an incidence rate for serious complications cannot be determined.

Endoscopist-directed propofol has been endorsed as safe and cost-effective by the American Gastroenterological Association, the American College of Gastroenterology, the American Society for Gastrointestinal Endoscopy, the American Association for the Study of Liver Diseases, the Canadian Association of Gastroenterology, the European Society of Anesthesiology, the European Society of Gastrointestinal Endoscopy, the European Society of Gastroenterology and Endoscopy Nurses and Associates, the European Board of Anesthesiology, and the German Society of Intensive Care Medicine and Anesthesiology (21–

25). All of these groups agree that special training is needed for endoscopists to use propofol without assistance from anesthesia specialists, and several have made specific recommendations about what that training should include (21–26).

THE CMS POLICY

On 11 December 2009, the CMS issued publication 100-07 (27) as a clarification statement of an interpretive guideline. As such, no public comment period was required. The key provision was that only a trained medical doctor or a doctor of osteopathy not involved in the performance of a procedure could administer deep sedation or general anesthesia for procedural sedation, similar to the 2006 ASA House of Delegates position about who can administer deep sedation. The example given of such a procedure was a patient requiring propofol for colonoscopy. For unclear reasons, the policy applied to hospitals but was never issued for ambulatory surgery centers, which logically would have fewer airway experts available to rescue patients who were inadvertently oversedated.

The impetus for issuance of the policy remains unclear. Three days after the policy was issued, the American Association of Nurse Anesthetists took credit for it, indicating that it was the result of years of advocacy (28).

An interpretive guideline from the CMS is a regulation, and hospitals choosing not to follow it may be subject to citation during the accreditation review process. The implications for procedural sedation in hospital departments using propofol without anesthesiologists were substantial. In my endoscopy unit, we had experience with more than 35 000 cases of endoscopist-directed propofol administration, with an outstanding safety record. According to hospital officials, 27 departments in my hospital system were using propofol without anesthesia specialists, including the bronchoscopy suite, cardiac laboratories, and the emergency departments. After a brief continuance of the practice while appeals were made, we were instructed to discontinue endoscopist-directed propofol administration. According to the hospital lawyers, the hospital cannot endorse one standard of care for Medicare and Medicaid patients and another for private patients, so the prohibition of endoscopist-directed propofol administration applied to all patients. We returned to opioids and benzodiazepines for sedation, but in the first months we had a 20% decrease in patient-satisfaction scores because returning patients who had previously been sedated with propofol rendered their objections. Under pressure to restore patient satisfaction, we invited our anesthesia group into the unit to administer propofol. When they were unable to meet the needs of the unit because of staffing shortages, we brought in a private group of anesthesiologists.

The gastrointestinal and emergency physician professional societies voiced objections about the policy to the CMS. In response to arguments that propofol has been targeted to moderate sedation (4, 5), the CMS cited the U.S. Food and Drug Administration (FDA) package insert.

In January 2011, the CMS issued a revised appendix about publication 100-07 (29). The new policy relieves emergency physicians from the restrictions, stating in an accompanying list of frequently asked questions that “these practitioners are uniquely qualified to provide all levels of analgesia [or] sedation and anesthesia.” The new policy also removes mention of propofol, apparently acknowledging that specific agents may be titrated to variable levels of sedation. Hospitals are instructed to “establish policies and procedures, based on nationally recognized guidelines.” The revised CMS guideline says,

We encourage hospitals to address whether the sedation typically provided in . . . procedure rooms involves anesthesia or analgesia. In establishing such policies, the hospital is expected to take into account the characteristics of the patients served, the skill set of the clinical staff in providing services, as well as the characteristics of the sedation medications used in the various clinical settings.

In the frequently asked questions section, the CMS cites several national guidelines, including the joint gastrointestinal society endorsement of endoscopist-directed propofol. This could seem to represent a reversal of the 2009 CMS guideline with regard to nonanesthesiologist administration of propofol. However, there is ambiguity because the 2011 CMS guideline continues to state that “Deep sedation [or] analgesia is included in monitored anesthesia care”—that is, deep sedation can only be administered by a medical doctor or a doctor of osteopathy not involved in the performance of the procedure. This creates a problem for hospitals that might want to allow nonanesthesiologists to use propofol because the ASA considers that propofol implies deep sedation and that propofol should only be given by anesthesiologists (8).

The new guideline does create an opening for proceduralists to use propofol titrated to moderate sedation, provided that their hospitals will create policies that run counter to the ASA positions about propofol. The evidence used by the CMS to exclude nonanesthesiologists from administering deep sedation is uncertain. The only reference cited in both the 2009 and the 2011 CMS guideline is the 2002 ASA guideline (9), and that guideline did not exclude nonanesthesiologists from using deep sedation or propofol. As previously noted, the ASA House of Delegates decreed in a 2006 statement (10) that nonanesthesiologists should not administer deep sedation. This statement was issued even though it ran counter to all published evidence (see Rex and colleagues [7] for publications before and after

2006). In essence, the CMS transformed a statement by the ASA House of Delegates into a federal regulation.

FDA POLICIES RELEVANT TO PROCEDURAL SEDATION WITH PROPOFOL

Recent decisions by the FDA suggest general resistance to any change in the approach to administration of propofol. For example, an advisory panel of the FDA voted 6 to 3 (with 1 abstention) in favor of nonanesthesiologist administration of the new agent fospropofol, which is a pro-drug of propofol, but the final decision by the FDA was for use only by anesthesiologists. A randomized, controlled trial of 1000 patients who were sedated by endoscopists for endoscopy or colonoscopy using either traditional sedation or the Sedasys System (Ethicon Endo-Surgery, Cincinnati, Ohio), which administers a bolus of fentanyl followed by a propofol infusion, indicated that use of the device resulted in less apnea and oxygen desaturation than with opioids and benzodiazepines (30). The FDA advisory panel voted 8 to 2 for approval of the device, but the FDA declined to approve it. The FDA did not accept the American College of Gastroenterology's 2005 petition to change the restrictive labeling of propofol, although the FDA decision was not rendered until 2010.

CONCLUSION

Procedural sedation with propofol is likely to continue to expand, given the popularity of the agent with both patients and proceduralists. If MAC is the model for this growth in propofol sedation, the cost implications are substantial. New medical procedures and services are typically subjected to cost analysis, and available data suggest that MAC, particularly for routine procedures in healthy patients, is not cost-effective. However, substantial incentives for both anesthesia specialists and proceduralists who hire anesthesia specialists are likely to stimulate more growth in MAC. This trend is counter to recent calls for value-based medical practice and consistent with the widely recognized separation between health care expenditures and outcomes in the United States.

The CMS policy on deep sedation and the need to modify it substantially 1 year later suggest that the CMS did not acquire balanced advice about procedural sedation. Given the ASA's positions on deep sedation and propofol and the widespread growth in propofol use, both the initial CMS policy and the revised version can be viewed as supporting the expansion of MAC. However, there is no evidence base establishing a need to convert to MAC to provide propofol for either moderate or deep sedation. It is not clear that the CMS reviewed published evidence or conducted cost analyses in developing the policies. Even if the CMS is not required to conduct these reviews and analyses in order to clarify an interpretive guideline, they should not be excused from doing an evidence-based and

transparent analysis when a policy affects billions of dollars in expenditures.

Procedural sedation and its associated costs are important issues to internists and internal medicine subspecialists. Propofol is an excellent agent for procedural sedation, but is it worth it if its use requires MAC? Given the high costs of MAC, alternatives to MAC for administration of propofol deserve fair and balanced evaluations.

From Indiana University Hospital, Indianapolis, Indiana.

Potential Conflicts of Interest: None disclosed. Forms can be viewed at www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M10-2863.

Requests for Single Reprints: Douglas K. Rex, MD, Indiana University Hospital, #4100, 550 North University Boulevard, Indianapolis, IN 46202; e-mail, drex@iupui.edu.

Author contributions are available at www.annals.org.

References

1. American Medical Association. CPT Standard Edition 2010. Appendix G. Chicago: American Med Assoc; 2010:416-7.
2. Cohen LB, Wechsler JS, Gaetano JN, Benson AA, Miller KM, Durkalski V, et al. Endoscopic sedation in the United States: results from a nationwide survey. *Am J Gastroenterol*. 2006;101:967-74. [PMID: 16573781]
3. Inadomi JM, Gunnarsson CL, Rizzo JA, Fang H. Projected increased growth rate of anesthesia professional-delivered sedation for colonoscopy and EGD in the United States: 2009 to 2015. *Gastrointest Endosc*. 2010;72:580-6. [PMID: 20630511]
4. VanNatta ME, Rex DK. Propofol alone titrated to deep sedation versus propofol in combination with opioids and/or benzodiazepines and titrated to moderate sedation for colonoscopy. *Am J Gastroenterol*. 2006;101:2209-17. [PMID: 17032185]
5. Cohen LB, Hightower CD, Wood DA, Miller KM, Aisenberg J. Moderate level sedation during endoscopy: a prospective study using low-dose propofol, meperidine/fentanyl, and midazolam. *Gastrointest Endosc*. 2004;59:795-803. [PMID: 15173791]
6. Symington L, Thakore S. A review of the use of propofol for procedural sedation in the emergency department. *Emerg Med J*. 2006;23:89-93. [PMID: 16439733]
7. Rex DK, Deenadayalu VP, Eid E, Imperiale TF, Walker JA, Sandhu K, et al. Endoscopist-directed administration of propofol: a worldwide safety experience. *Gastroenterology*. 2009;137:1229-37. [PMID: 19549528]
8. American Society of Anesthesiologists. Statement on safe use of propofol. Accessed at www.asahq.org/For-Members/Clinical-Information/-/media/For%20Members/documents/Standards%20Guidelines%20Stmts/Safe%20Use%20of%20Propofol.aspx on 28 March 2011.
9. American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists. Practice guidelines for sedation and analgesia by non-anesthesiologists. *Anesthesiology*. 2002;96:1004-17. [PMID: 11964611]
10. American Society of Anesthesiologists. Statement on granting privileges to non-anesthesiologist practitioners for personally administering deep sedation or supervising deep sedation by individuals who are not anesthesia professionals. Accessed at www.asahq.org/publicationsAndServices/-/media/For Members/documents/Standards Guidelines Stmts/Granting Privileges to NonAnesthesiologist Practitioners for Personally Administering Deep Sedation.aspx on 17 February 2011.
11. American Society of Anesthesiologists. Policies and procedures governing anesthesia privileging in hospitals. Accessed at www.asahq.org on 21 March 2011.
12. Brill JV. Endoscopic sedation: legislative update and implications for reimbursement. *Gastrointest Endosc Clin N Am*. 2008;18:665-78, viii. [PMID: 18922406]
13. Jain R, Ikenberry SO, Anderson MA, Appalaneni V, Ben-Menachem T,

Decker GA, et al; ASGE Standards of Practice Committee. Minimum staffing requirements for the performance of GI endoscopy. *Gastrointest Endosc*. 2010; 72:469-70. [PMID: 20579993]

14. Kaye JM. Five ways your ASC can profit from anesthesia services. *SurgiStrategies*. 2005. Accessed at www.surgistrategies.com/articles/2005/05/five-ways-your-asc-can-profit-from-anesthesia-ser.aspx# on 21 March 2011.

15. Sharma VK, Nguyen CC, Crowell MD, Lieberman DA, de Garmo P, Fleischer DE. A national study of cardiopulmonary unplanned events after GI endoscopy. *Gastrointest Endosc*. 2007;66:27-34. [PMID: 17591470]

16. Sipe BW, Rex DK, Latinovich D, Overley C, Kinser K, Bratcher L, et al. Propofol versus midazolam/meperidine for outpatient colonoscopy: administration by nurses supervised by endoscopists. *Gastrointest Endosc*. 2002;55:815-25. [PMID: 12024134]

17. Ulmer BJ, Hansen JJ, Overley CA, Symms MR, Chadalawada V, Liangpunsakul S, et al. Propofol versus midazolam/fentanyl for outpatient colonoscopy: administration by nurses supervised by endoscopists. *Clin Gastroenterol Hepatol*. 2003;1:425-32. [PMID: 15017641]

18. Patel S, Vargo JJ, Khandwala F, Lopez R, Trolli P, Dumot JA, et al. Deep sedation occurs frequently during elective endoscopy with meperidine and midazolam. *Am J Gastroenterol*. 2005;100:2689-95. [PMID: 16393221]

19. Coté GA, Hovis RM, Ansstas MA, Waldbaum L, Azar RR, Early DS, et al. Incidence of sedation-related complications with propofol use during advanced endoscopic procedures. *Clin Gastroenterol Hepatol*. 2010;8:137-42. [PMID: 19607937]

20. Bhananker SM, Posner KL, Cheney FW, Caplan RA, Lee LA, Domino KB. Injury and liability associated with monitored anesthesia care: a closed claims analysis. *Anesthesiology*. 2006;104:228-34. [PMID: 16436839]

21. Vargo JJ, Cohen LB, Rex DK, Kwo PY; American Association for the Study of Liver Diseases. Position statement: nonanesthesiologist administration of propofol for GI endoscopy. *Gastroenterology*. 2009;137:2161-7. [PMID: 19961989]

22. Dumonceau JM, Riphaus A, Aparicio JR, Beilenhoff U, Knappe JT, Ortman M, et al; NAAP Task Force Members. European Society of Gastrointestinal Endoscopy, European Society of Gastroenterology and Endoscopy Nurses

and Associates, and the European Society of Anaesthesiology Guideline: non-anesthesiologist administration of propofol for GI endoscopy. *Endoscopy*. 2010; 42:960-74. [PMID: 21072716]

23. Knappe JT, Adriaensen H, van Aken H, Blunnie WP, Carlsson C, Dupont M, et al; Board of Anaesthesiology of the European Union of Medical Specialists. Guidelines for sedation and/or analgesia by non-anaesthesiology doctors. *Eur J Anaesthesiol*. 2007;24:563-7. [PMID: 17568472]

24. Byrne MF, Chiba N, Singh H, Sadowski DC; Clinical Affairs Committee of the Canadian Association of Gastroenterology. Propofol use for sedation during endoscopy in adults: a Canadian Association of Gastroenterology position statement. *Can J Gastroenterol*. 2008;22:457-9. [PMID: 18478130]

25. Riphaus A, Wehrmann T, Weber B, Arnold J, Beilenhoff U, Bitter H, et al. S3 guideline: sedation for gastrointestinal endoscopy 2008. *Endoscopy*. 2009;41: 787-815.

26. Training Committee; American Society for Gastrointestinal Endoscopy. Training guideline for use of propofol in gastrointestinal endoscopy. *Gastrointest Endosc*. 2004;60:167-72. [PMID: 15278039]

27. Centers for Medicare & Medicaid Services (CMS). Clarifications of the Interpretive Guidelines for the Anesthesia Services Condition of Participation, and Revised Hospital Anesthesia Services Interpretive Guidelines—State Operations Manual (SOM) Appendix A, S&C-10-09-Hospital. CMS publication no. 100-07.

28. American Association of Nurse Anesthetists Federal Government Affairs. CMS replaces anesthesia interpretive guidelines for hospitals. AANA Federal Government Affairs Hotline, Number 2009-30a—Week of Monday, 14 December 2009. Accessed at www.aana.com on 21 March 2011.

29. Centers for Medicare & Medicaid Services (CMS). State Operations Provider Certification. Revised Appendix A, Interpretive Guidelines for Hospitals. CMS publication no. 100-07.

30. Pambianco DJ, Vargo JJ, Pruitt RE, Hardi R, Martin JF. Computer-assisted personalized sedation for upper endoscopy and colonoscopy: a comparative, multicenter randomized study. *Gastrointest Endosc*. 2011;73:765-72. [PMID: 21168841]

CME CREDIT

Readers can get CME credit for the following: 1) questions from the ACP's Medical Knowledge Self-Assessment Program (MKSAAP) related to In the Clinic articles that are published in the first issue of every month, and 2) designated articles in each issue. To access CME questions, click on the CME option under an article's title on the table of contents at www.annals.org. Subscribers may take the tests free of charge. For a nominal fee, nonsubscribers can purchase tokens electronically that enable them to take the CME quizzes.

Reviewers who provide timely, high-quality reviews also may get CME credit.

Author Contributions: Drafting of the article: D.K. Rex.
Final approval of the article: D.K. Rex.