Insurers heat up propofol controversy

Insurance companies are stirring the controversy already boiling between anesthesia and gastrointestinal endoscopy providers over safe administration of propofol (Diprivan) for routine endoscopies.

WellPoint, Inc, the nation’s largest health insurer, announced in December it will no longer pay for anesthesia providers during routine endoscopies. Aetna Inc’s policy is under review, but observers expect the company also to restrict anesthesia services for routine colonoscopies. The Wall Street Journal (Dec 27, 2005) reported that Noridian Administrative Services, an administrator of Medicare benefits in 14 states, restricts reimbursement for anesthesia services during routine colonoscopies.

Who will give propofol?

Who will administer propofol if services of anesthesia providers are not covered? The majority of anesthesiologists and certified registered nurse anesthetists (CRNAs) believe propofol is safest in the hands of trained anesthesia providers. But a growing number of GI physicians are pushing for nurse-administered propofol sedation (NAPS).

“The evidence is overwhelming that nonanesthesiologists can deliver propofol safely,” says Douglas Rex, MD, director of endoscopy at Indiana University Hospital (IU), Indianapolis, and former president of the American College of Gastroenterology (ACG). He is lead author of a Gastroenterology report (November 2005;129:1384-1391) that documented safe use of NAPS for 37,743 patients.

“Considering the evidence, it’s becoming more difficult to understand the resistance of the anesthesia community,” Dr Rex told OR Manager.

Gastroenterologists and anesthesia providers do agree propofol can be tricky to administer. According to the ACG, propofol is inherently risky because it is a cardiovascular and respiratory depressant. Propofol is short-acting and may require frequent reinforcing doses, causing greater peak levels of sedation. Also, propofol has no reversal drug, so an overdose must be treated with ventilatory and sometimes cardiovascular support.

The American Society of Anesthesiologists (ASA) says propofol’s rapid action and high potency also can make it difficult to reach the intended level of sedation. Propofol can induce an unintended state of general anesthesia within as little as 30 seconds of a single intravenous dose. Also, patients differ widely in their reactions to a standard dose, with a 20-fold variation in the rate of their metabolism.

Patients like propofol

Yet propofol is preferred by many patients, GI physicians, and nurses. A survey of ACG members showed the percentage of GI physicians who use the drug is doubling every 2 years, reaching 25% in 2004.

According to the ACG, propofol has several advantages over alternative sedative agents (benzodiazepines and narcotics) for endoscopic procedures. Propofol induces sedation more rapidly than a midazolam (Versed)-meperidine (Demerol) combination or a midazolam-fentanyl combination. Propofol results in faster recovery and better post-procedure functioning.

“Patients love it because they’re more alert and interactive and not nauseated post-procedure, unlike with other sedatives,” says Helen Rolf, RN, BSN, nurse manager at Green Spring Station Endoscopy in Lutherville, Md. “Patients tell me they would pay
What do states say about NAPS?

Source: Deborah Krohn, RN, JD. All state boards of nursing were polled for updates in January 2006; not all had responded. Some board positions are confusing or unclear. Contact boards directly for position statements.

Notes:
Arizona: RNs may administer anesthetic agents as long as not administered to provide anesthesia.
Oklahoma: Recent change to say RNs who are not CRNAs shall not administer drugs with manufacturers’ general warning saying the drug should be administered by persons experienced in use of general anesthesia not involved in conduct of the procedure. www.ok.gov/nursing/
Oregon: Draft nonconsensus statement under review by board would say NAPS is within RN scope of practice under direction of licensed independent practitioner in accord with specific guidelines. www.oregon.gov/OSBN/
Washington State: Addresses procedural sedation; does not specifically address NAPS.

for the drug and CRNA out of their own pocket if necessary.”

So will the endoscopy center. Rolf says that if insurance carriers and Medicare deny coverage for the services of CRNAs who contract with the center to administer and monitor propofol, her endoscopy center will hire them as employees.

“It definitely will be detrimental to our revenue,” she says, “but our physicians are not interested in going back to conscious sedation. Once you go with propofol, you don’t go back.”

Deborah Krohn, RN, JD, an endoscopy nurse at Johns Hopkins and an attorney in private practice in Towson, Md, has had several colonoscopies, including one performed with CRNA-administered propofol.

“I thought propofol was fabulous,” Krohn says. “In terms of physical comfort, it was tough to distinguish between propofol and Versed and fentanyl, but I was definitely more clearheaded afterward with propofol.

Yet Krohn is not a NAPS advocate.

“I have profound respect for the integrity of patients’ airways, and I think propofol compromises those,” she says. “Nurses who are not CRNA-trained are not pre-
pared to adequately handle airway complications. I do not think we serve patients well to have nurses with 2 weeks of training do the job of nurse anesthetists who have had years of focused training and clinical experience.”

**Data on safety**

Dr Rex and many, but not all, of his GI colleagues disagree. He cites data showing more than 200,000 patients have received propofol safely by nonanesthesiologists.

In March 2004 the ACG, the American Gastroenterological Association, and the American Society of Gastrointestinal Endoscopy issued a joint statement supporting use of propofol by adequately trained nonanesthesiologists and declaring that routine assistance of an anesthesiologist/anesthetist for average-risk patients undergoing standard upper and lower endoscopic procedures is not warranted.

WellPoint, Inc, spokesperson Laura Stallman says the company’s new clinical guideline for anesthesia services for routine GI procedures was based largely on this joint recommendation.

“For the majority of Americans, moderate sedation is effective and well tolerated,” Stallman says. “Our clinical guideline does support use of medications such as propofol during a colonoscopy when their use is medically appropriate, for example, in the case of a patient who is considered high risk, an elderly adult, or a patient who previously did not tolerate the sedatives used most frequently during a routine colonoscopy.”

If anesthesia services are not covered or are unavailable in areas with anesthesiologist and CRNA shortages, and GI physicians want to use propofol, 2 questions emerge for endoscopy nurses in the ambulatory setting: What will be required of them, and what is their liability?

**NAPS training for nurses**

Jo Harbaugh, RN, BS, CGRN, past president of the Society of Gastroenterology Nurses and Associates, says she is concerned about NAPS because rescuing patients from deep sedation using advanced airway management techniques has not been the customary practice of nurses in freestanding GI centers and office settings. Also, anesthesiologists and CRNAs are not always available on site.

“NAPS could change the landscape of ambulatory nursing,” Harbaugh says. “Right now, the vast majority of ASC nurses do not have the skills to independently manage a patient going into deep sedation or general anesthesia. Certainly most can learn, but some will not be comfortable with anesthesia monitoring or patient rescue.”

Harbaugh also is concerned that NAPS nurses will not maintain their advanced airway management and rescue skills because the skills may be used infrequently.

“Advanced airway management is not something you want to use often,” she says. “However, if you don’t use it, you lose your skills. I believe a 6-month refresher course for NAPS would be essential.”

Harbaugh would also like to see a universal training and certification NAPS protocol that would ensure nurses in all settings receive the same training and follow the same safety protocols.

“Teaching hospitals always have anesthesia and backup immediately available, but that is not the case in GI ASCs and physician offices,” she says. “We have to ensure everyone is practicing the same standard of care.”

**Roadblock to NAPS**

A roadblock to NAPS is the propofol package insert, which 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 (italics added) and not involved in the surgical or diagnostic procedure.”

For the anesthesia community, “persons trained in the administration of general anesthesia” translates to anesthesiologists, CRNAs, or anesthesia assistants, says Jeffrey Apfelbaum, MD, ASA first vice president.

“The principal concern of ASA members is the safety of our patients,” he says.
“The safety concerns that led the FDA (Food and Drug Administration) to support
this warning are still valid, and the warning should remain in place. Propofol is a
potent anesthetic that typically produces varying and often unpredictable levels of
sedation, sometimes unintentionally progressing to general anesthesia with signifi-
cant respiratory and hemodynamic compromise.”

GI society petitions FDA

In June, the ACG petitioned the FDA to change AstraZeneca’s package insert for
propofol by removing the warning so other qualified medical professionals can
deliver the sedative. The petition cites numerous studies and reports it says demon-
strate the safety of NAPS, argues that the current label imposes unnecessary restric-
tions on gastroenterologists, and asserts that its removal will reduce costs by elimi-
nating the need for anesthesiologists or nurse anesthetists in routine endoscopic pro-
cedures.

The ASA countered the ACG petition with these arguments:
• Removing the warning label will compromise patient safety because nurses or
other staff not trained and experienced in the administration of general anesthe-
sia may not be able to restore breathing or normal cardiac activity in time “to pre-
vent a catastrophe.”
• The ACG petition does not provide legal grounds to make the warning change
but “is simply a summary of numerous published scientific articles designed to
support an economic objective.”
• Removing the warning label would encourage its use in nonregulated settings,
such as doctor’s offices, or in isolated settings where there is no anesthesia back-
up. Many of the GI reports cited in the FDA petition take place in controlled envi-
rions with anesthesia support readily available.

At press time, the FDA was still reviewing the petition and comments, says
spokesperson Karen Mahoney. In general, FDA reviews clinical data and other infor-
mation to determine if a label revision is needed and works with the drug manu-
ufacturer to establish appropriate language.

The majority of comments submitted to the FDA have opposed the ACG’s posi-
tion, including comments from members of Congress, says Valerie Bomberger,
AstraZeneca spokesperson.

Nurses’ liability

Twenty-three state nursing practice acts expressly restrict propofol sedation to
those trained to administer general anesthesia. Several boards are reviewing their
positions (page 33).

Krohn says nurses who deliver propofol are in a vulnerable position. First, they
could be sued for malpractice for delivering the drug off label contrary to the manu-
ufacturer’s warning and in opposition to the well-publicized position of anesthesia
providers. Second, they could be at risk for discipline by their state boards of nursing
if NAPS is considered beyond the scope of practice for RNs.

NAPS in practice

Despite the off-label liability risk, NAPS has been practiced in the outpatient
endoscopy unit at IU Medical Center for 5 years. Attorneys for Clarian Health,
owner of the medical center, reviewed the Indiana Nurse Practice Act and found it
vague on the issue.

Dr Rex consulted with IU’s anesthesiology department to develop the GI unit’s
protocol for NAPS. The first physicians and nurses to practice NAPS attended train-
ing led by John Walker, MD, at Gastroenterology Associates in Medford, Ore.

Five GI nurses at IU were chosen to be trained in NAPS. Other GI nurses who
want to deliver propofol must first administer nonpropofol sedatives for 6 months,
receive didactic instruction on propofol sedation, and perform a minimum of 15
NAPS cases with a preceptor.

“The experienced nurses and physicians choose the nurses who deliver propofol
carefully,” says Lea Rae Herron-Rice, BSN, RN, CGRN, administrative director of GI
services. “Many of them are interested in professional growth and value autonomy.”
IU has a clinical ladder for staff nurses with levels of associate, partner, and senior partner. Nurses who deliver propofol must be at the partner level.

Herron-Rice says the IU anesthesiologists have been so impressed with the endoscopy NAPS training that Clarian Health requires the GI nurses to train staff from any unit that delivers propofol by bolus.

“I think our nurses are courageous to not believe what is written in some package insert,” says Dr Rex. “If nobody has the courage to do the things they feel are right, we’re never going to make any progress.”

Looking at options
Dr Rex notes several potential solutions to the propofol dilemma, including:
• Following the multiple-agent protocol developed by Lawrence Cohen, MD, associate clinical professor of medicine/gastroenterology at Mount Sinai Hospital in New York City. Dr Cohen uses low-dose propofol plus low-dose midazolam and narcotic. This combination maintains patients in moderate sedation with the fast-acting benefits of propofol but without the grogginess or amnesic effects of midazolam and narcotics. Dr Rex uses this protocol almost exclusively for routine upper GI procedures.
• Working with drug companies to develop other sedation options. MGI Pharma is beginning phase III trials of Aquavan Injection, which the company hopes will combine the best qualities of propofol and midazolam—rapid onset and rapid recovery—and may not require monitored anesthesia care. Aquavan could be on the market within 2 years.
• Performing controlled NAPS safety studies and developing a NAPS training protocol with anesthesia colleagues.

“We need to acknowledge the safety concerns of our anesthesia colleagues and engage them in helping us find ways to deliver propofol in a way that meets their standards for safety, keeps healthy the practice of endoscopy, and controls health care costs,” Dr Rex says.

Leslie Flowers is a freelance writer in Indianapolis.

Resources on NAPS

American Society of Anesthesiologists/American Association of Nurse Anesthetists
Statements on safe use of propofol

Tri-society statement on sedation during endoscopic procedures
American College of Gastroenterology (ACG), American Gastroenterological Association, and American Society for Gastrointestinal Endoscopy
www.acg.gi.org/physicians/nataffairs/trisociety.asp

Citizen petition to FDA
ACG petition to change propofol package insert
www.fda.gov/ohrms/dockets/dockets/05p0267/05p-0267-cp00001-01-vol1.pdf

ASA response to citizen petition
ASA response to FDA on changing propofol package insert
www.asahq.org/news/ASAresponse.htm

AGE/Society of Gastroenterology Nurses and Associates
Role of GI registered nurses in the management of patients undergoing sedated procedures.
www.sgna.org/resources/statements/jointstatement.cfm

Institute for Safe Medication Practices
Propofol sedation: Who should administer?
www.ismp.org/Newsletters/acute care/articles/20051103.asp