

# Endoscopic Sedation With Propofol: Legal Risks and Risk Management

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## ABSTRACT

Clinical data suggest propofol-mediated sedation can be safely administered by trained registered nurse/endoscopy teams, with advantages reported to include patient comfort, physician preference, and office efficiency. Clinicians often assume that favorable epidemiologic data will afford legal protection. However, the structure of medical epidemiology and malpractice law are different. A legal analysis will involve application of the tort of negligence. Factors to consider would include statutory restrictions (Nurse Practice Act), regulatory restrictions (Food and Drug Administration [FDA] label warnings), differing expert witness interpretations of the standard of care, and questions of informed consent. Further, practice efficiency and patient safety may be weighted differently in a public health analysis versus a courtroom setting. Exploring the difference between medical epidemiology and legal risk will allow physicians interested in physician-directed/nurse-assisted propofol sedation programs to understand potential risks associated with propofol programs and incorporate risk-management strategies. Although a growing body of epidemiological data in the gastroenterology literature supports the safety of propofol use in appropriately trained, experienced endoscopy teams, no court case has yet pitted the opposing parties in the nurse-administered propofol sedation (NAPS) debate, and the legal risks in the event of a serious untoward outcome are unknown.

A separate issue involves anesthesiologist-administered propofol sedation for routine endoscopic procedures with cost impact and possible billing concerns: refusal of coverage for average risk procedures, accusation of duplicate billing, and potential reevaluation of procedural reimbursement.

## INTRODUCTION

There is increasing clinical data suggesting that propofol-mediated sedation can be safely administered by trained registered nurse/endoscopy teams.<sup>1</sup> The use of propofol has been felt to offer advantages that include patient comfort, physician preference,<sup>2,4</sup> and office efficiency.<sup>5</sup> For instance, no deaths were reported in the use of nurse-administered propofol sedation (NAPS) in 80,000 patients, with endoscopic literature citing mortality rates of 1 in 3 to 1 in 11,000; however, the former study was recent and evaluated highly selected centers.<sup>6</sup> Concern about colon perforation when the endoscopist does not receive feedback of pain from the patient has been expressed but debated.<sup>4,8</sup> Recovery room time dropped from 70 minutes to 18 minutes.<sup>2,3</sup> To achieve quality outcomes, training programs are suggested. A program for endoscopy nurses took from 2 weeks to 3 months.<sup>1</sup>

Medical progress is often made by the introduction of new ideas, tested and proven with epidemiologic data, followed by widespread acceptance. Many gastroenterologists would conclude that NAPS has successfully completed that path. Indeed, a

recent convincing article on use of physician-directed endoscopic propofol<sup>1</sup> was accompanied by a favorable editorial, which declared, "Nurse-assisted Propofol Sedation: The Jury Is In!"<sup>6</sup> Although the intriguing choice of words in this NAPS-favorable editorial was a legal metaphor, "The jury is in!," the authors are highly respected physicians using a medical analysis. A strictly legal point of view is less comforting: the lawsuit has yet to occur, the case has not been presented, and the jury has neither gone out nor returned a verdict.

From a medical practice point of view, the studies of NAPS may be reassuring and convincing. However, not all physicians have been convinced, and the literature documents concerns about possible deep sedation without reversal agent and the importance of safety over efficiency.<sup>7</sup> From a medical innovation point of view, considerable and careful scientific efforts have been made to understand the role of NAPS and to advance the practice of endoscopic sedation. However, from a strictly legal point of view, little hard data are available, and the legal questions remain unanswered.<sup>8</sup> These questions will be explored.

## MALPRACTICE LAW PRIMER

### Risk Management

Risk management programs attempt to understand the actual risk by an analysis of malpractice data and use that analysis to develop awareness of specific risk in specific treatment encounters. Thus, the goal of risk management programs is to develop preventive measures to reduce both patient injury and malpractice risk.

### Tort of Negligence

A tort may be defined as a civil wrong for which a remedy may be obtained. The most common form of a malpractice action against a physician takes the form of the tort of negligence, a "civil wrong." The plaintiff's attorney must prove 4 elements: 1) that the physician has an obligation (duty) of care for that individual, 2) the duty was violated (breach) by practice below the applicable standard of care, 3) that substandard practice caused the harm asserted (proximate cause), and 4) that the plaintiff suffers compensable damages (harm). Expert witness testimony, often relying on clinical guidelines, establishes the standard of care. Informed consent requires disclosure of risk, benefit, and alternatives to the patient. This transfers the risk of a nonperfect sedation from the endoscopist to the patient, who assumes the risk with the decision to proceed despite the knowledge of sedation and procedural risks.

Not every possible risk must be disclosed, *only those a reasonable patient would wish to know in order to make an appropriate decision* (Canterbury v Spence).<sup>10</sup> These have been termed "material risks" and are specific to each procedure and patient situation. Vicarious liability makes physicians potentially liable for the actions of others for whom they have supervisory responsibility.

## LEGAL ISSUES

### Imaginary Lawsuit After Propofol Complication: Plaintiff Assertions/Defense Responses

If a patient is injured during endoscopic sedation with propofol, a lawsuit could ensue alleging failure to meet the standard of care and failure of appropriate informed consent (an independent cause of action, which the defendant could win even if defendant physician was found to have met standard of care). Of course, if complications of NAPS sedation are as rare as recent studies suggest, there will be few lawsuits, and the legal issues here may be unimportant.

#### 1. Standard of Care Problems

The Food and Drug Administration (FDA) medication label warning that “for general anesthesia or monitored anesthesia care (MAC) sedation [propofol] 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> would be highlighted by plaintiff attorney, with a suggestion that gastroenterologists do not have general anesthesia skills, nor sufficient ability, to rescue patients from deep sedation.<sup>7</sup> The defense will assert that trained endoscopists do possess sufficient skills, that current noncontroversial endoscopic sedative agents may also achieve deep sedation risks, and that studies show conventional sedation may have higher complication rates than NAPS.<sup>12,13</sup>

Expert witnesses would offer very different views of the safety of propofol. The plaintiff attorney could line up anesthesiologists and try to characterize anesthesia as the specialty more expert in all matters of sedation. JACHO standards may help in that regard. The plaintiff attorney would note the many states that do not allow nurse-administered propofol<sup>14</sup> and highlight propofol guidelines by anesthesiology societies, such as the AANA–ASA Joint Statement Regarding Propofol Administration, April 2004.<sup>15</sup> The plaintiff attorney may even get respected gastroenterologists to say current sedation is sufficient and propofol is dangerous. The current pro-NAPS studies would likely be criticized as inadequate. A lot of attention would be paid to deep versus moderate (conscious) sedation. The defense attorney could effectively use the local anesthesiologist who helped establish the program to counter “outside” anesthesiology opinion, have gastroenterologists highlight the numerous studies showing little propofol risk, have pharmacy experts emphasize the short half-life of propofol, and could emphasize studies showing patient and physician preference for propofol. The defense could also demonstrate the risks of narcotic/sedative combination regimens and assert that anesthesia opinion may be more turf battle than science. ASGE guidelines and/or ACG/ASGE/SGNA society position statements<sup>16,17</sup> may be used to support new standards of care most relevant to endoscopic sedation. Use of recommended training protocols<sup>4,18</sup> will reflect careful adoption of new techniques. Awareness of developing sedation improvements in medications, medication delivery, and monitoring systems may reflect well on standard of care challenges. The effect of sophisticated epidemiologic data on an average jury may depend more on how convincing and credentialed is the expert than on the quality of the data itself.

#### 2. Statutory Problems

Some state statutes forbid nurses to administer propofol under

the state’s Nurse Practice Act. Clinical evidence does not trump state law. Further, even in states allowing NAPS, plaintiff attorneys may try to discredit the program by noting prohibition of NAPS in other states. Defense attorneys may assert that those other statutes do not reflect current clinical understanding and research. Experts will support each position.

#### 3. Informed Consent Problems

The plaintiff attorney will certainly assert that a reasonable patient would wish to know of an FDA warning and any controversy over the use of this drug versus other available alternatives, and that anesthesiologists have expressed serious concerns about NAPS. They will assert that risks up to and including death should have been mentioned. The defense will assert that the risks are similar to (or safer than) current standard sedation and that whatever consent process is currently considered acceptable for standard endoscopy should be acceptable for NAPS. A major question is whether NAPS, or gastroenterologist-directed propofol, is a special situation; does this require a different consent discussion than standard endoscopic sedation? On one hand, one generally wouldn’t do drug-specific consent and change the consent process based on whether one used fentanyl versus demerol as the narcotic agent, or added glucagon. On the other hand, the plaintiff would argue that propofol has a different FDA label, state the nursing restrictions in some states, and state anesthesiology opposition for some uses. A reasonable patient wishes to know bottom-line safety issues. The defense would respond that a large and growing body of clinical data and experience suggests NAPS sedation is as safe and favorably comparable to standard endoscopic conscious sedation. Discussion of labels and medical politics is superfluous and confusing. Recall that informed consent is an independent cause of legal action: even if the plaintiff loses on the standard of care argument (i.e., you are not found to have practiced substandard care), they can win the entire lawsuit on the informed consent argument (i.e., had I known these risks, I never would have agreed to NAPS). There is no endoscopic sedation trial verdict to show a jury’s opinion.

#### 4. Cost Savings, Self-interest

The plaintiff may present efficiency data and assert that propofol is all about money; that NAPS puts lives at risk to add an extra procedure or two in the ASC daily schedule and enrich the physician. The defense may assert its all about patient comfort and benefit; that even sophisticated patients (e.g., doctors) choose propofol in a NAPS setting. Also, that there is a public health benefit to medical efficiency (need more ability to do colonoscopy screening by fewer gastroenterologists), but that is never at the expense of safety. Further, the defense may argue that it is anesthesia self-interest that forms the basis of opposition to the clinical evidence of NAPS safety.

## OTHER ISSUES

A separate concern involves anesthesiologist-administered sedation for routine endoscopic procedures. The cost of endoscopy in areas with significant use of anesthesiologist-delivered routine endoscopic sedation has risen substantially.<sup>19</sup> This has raised the possibility of reevaluation and lower reimbursement for procedures since sedation is being billed separately, or an eventual interpretation of that practice as inappropriate “double billing,” a potential fraud.<sup>8,20,21</sup> A large insurer recently suspended cover-

age for anesthesiology services in routine endoscopic procedures.<sup>25</sup>

Vicarious liability may apply for mistakes made by your hired personnel. Even the mistakes of contracted anesthesia personnel may involve the gastroenterologist in a lawsuit.

## RISK MANAGEMENT STRATEGIES

Epidemiologic studies and expert gastroenterologic opinion suggest there is much promise in the use of NAPS. Opposition to NAPS creates additional legal burden over that of standard endoscopic sedation. There are potential risk management strategies to reduce this risk.

From a gastroenterology society perspective, there is potential, and interest, in helping move NAPS to safer legal ground. Development and strengthening of evidence-based society guidelines and position statements, carefully crafted by members both involved and uninvolved in NAPS, will both add credibility and help assure that a safe programmatic approach to NAPS within an acceptable standard of care for gastrointestinal endoscopy. Involving anesthesia societies, or if they are unwilling, perhaps noninterested specialty societies or regulatory groups to review the data and programs could be useful. Joint guidelines will seem even more credible if a courtroom turf battle were to occur.

Change in the FDA warning label, or an acceptance that the meaning is not a requirement for anesthesiologist-level training (the current NAPS gastroenterologic view), would be helpful.

Any new medication or sedation device/monitoring system that can be demonstrated to further promote sedation safety may make prior concerns seem less relevant.<sup>22,23</sup>

From an individual's perspective, careful program development is key. Having a local anesthesiologist involved in your program development, and documenting that involvement, will be helpful to future challenge by outside anesthesiology experts.

An initial training program, based on published models,<sup>4,23</sup> and use of regular quality assessment can be more easily presented as within standard of care.

Understand your states Nurse Practice Act restrictions (if any) or any other statutory or regulatory local committee regulations.<sup>24</sup>

It is not clear if special informed consent materials (written or video) that present NAPS positively, but inform the patient about its controversial aspects and leave the physician to briefly answer questions as needed, could address the current informed consent questions.

## SUMMARY

Propofol-mediated sedation may offer advantages to patient and physician. However, controversy and differing opinion regarding its safe use by nonanesthesiologists raises the concern about malpractice risk. Clinicians often assume that favorable epidemiologic data will translate into/afford legal protection, but the structure of medical epidemiology and malpractice law are different. Factors considered in this malpractice analysis included statutory restrictions (Nurse Practice Act), regulatory restrictions (FDA label warnings), differing expert witness interpretations of the standard of care, questions of informed consent, the interpretation of practice efficiency and patient safety, and the difference between public health analysis versus courtroom setting.

The potential risks associated with propofol programs and risk management preventive strategies were reviewed.

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