Endoscopic Sedation
Medicolegal Considerations

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KEYWORDS

• Informed consent • Endoscopy • Medicolegal risk • Malpractice

KEY POINTS

- Informed consent for endoscopy should include discussion of the risks, benefits, and alternatives in sedation, thus including informed consent for sedation.
- The endoscopist should be aware of the possibility that a patient whose sedation is not felt to be sufficient from the patient's perspective may withdraw consent for the procedure.
- The endoscopist should keep up to date regarding the standards of care for monitoring sedation, and for choosing anesthesiologist/anesthetist sedation for appropriate patients.

MALPRACTICE LAW REVIEW

Consider a brief review of malpractice concepts to guide our understanding of the legal aspects of sedation.[1]

Risk Management

Risk management programs attempt to understand actual risk by an analysis of malpractice data, and use that analysis to develop awareness of specific risks 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 malpractice action against a physician typically takes form in 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) that the duty was violated (breach) by practice below the applicable standard of care, (3) that substandard practice caused the harm asserted (causation), and (4) that the plaintiff suffers cognizable and compensable harm (damages).

Disclaimer: These are general thoughts presented for their educational value, and are NOT intended to represent specific legal advice. That would require independent legal counsel.

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Standard of Care

Guidelines

Establishing that the provider has violated the standard of care is often the most critical element of the lawsuit. Expert witness testimony is usually required to explain the current standard of care and how the provider has practiced below it. However, expert witnesses are not needed under the so-called common knowledge[2] or obvious occurrence[3] exception, wherein the wrong committed is within the realm of a layperson's comprehension (eg, a sponge retained in the abdomen at surgery or amputation of the wrong limb). In addition, expert witnesses are unnecessary under a similar but technically separate doctrine called *res ipsa loquitur* (the thing speaks for itself), a legal term applying to a narrow category of malpractice cases in which the jury may infer negligence from the mere fact of an accident's occurrence.[4] Whereas some jurisdictions openly disfavor application of *res ipsa loquitur* in medical malpractice cases,[5] other jurisdictions apply it in common knowledge/obvious occurrence cases.[6] Furthermore, with increasing frequency, respected national guidelines have become a key element used to establish the standard of care. Nonetheless, although a court will regard such guidelines as relevant evidence, it typically will not allow them, standing alone, to establish the standard of care for any given situation.[7]

Informed Consent

Because informed consent requires a communication between provider and patient, and because studies of malpractice risk note that better communication reduces malpractice risk, the process of informed consent can actually be a provider's tool to reduce malpractice risk. Further, the process of disclosing the inherent risks of a procedure essentially asks the patient to accept that risk as part of the performance of the procedure. 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. The risk shift does not apply to substandard care, but would apply to many of the known complications of procedures and sedation that may occur even with appropriate technical performance of the procedure.

The patient must be competent to understand the information disclosed. There must be no duress. Material risks should be disclosed. The standard in most jurisdictions is a patient-based standard, not physician-based standard. That means we are obligated to inform based on what a reasonable patient would want to hear (as interpreted/decided by a jury), rather than what a reasonable physician believes should be disclosed.

Material risks

Not every possible risk must be disclosed, only those a reasonable patient would wish to know in make an appropriate, intelligent decision whether or not to submit to surgery or treatment.[8] These have been termed "material risks," and are specific to each procedure and patient situation. There are guiding principles that can be used to help determine what an average patient (and average jury!) would find significant. The 4 elements of risk the physician needs to consider include (1) the nature of the risk, (2) the magnitude of the risk (seriousness), (3) the probability that the risk may occur, and (4) the imminence of the risk.

Vicarious Liability

Vicarious liability is a legal concept that extends liability for a wrongdoing beyond the original wrongdoer to persons who have not committed a wrong, but on whose behalf the wrongdoers acted. The primary practical importance of this concept is that it provides the plaintiff with additional financially responsible defendants who likely