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The Use of Diprivan (Propofol) in GI Procedures

Part 2 in a 3-part series

In the first part, which you can read here, we discussed the background of the issue relating to Propofol and who should administer it – gastroenterologists (non-anesthesiologists) or strictly anesthesiologists. The warning label debate, involving the ACG and the ASA, took an interesting turn when the FDA got involved and spoke out in support of keeping the label. Per their standards, individuals administering moderate or deep sedation and anesthesia must have the appropriate credentials to manage patients at whatever level of sedation or anesthesia is achieved. They assert that those practitioners must be qualified to rescue patients from general anesthesia and be competent to manage an unstable cardiovascular system as well as a compromised airway and inadequate oxygenation and ventilation and that a sufficient number of qualified personnel must be present during the procedure to provide moderate or deep sedation.

CMS responds

Seemingly, this is what prompted the Centers for Medicare & Medicaid Services (CMS), in their Condition of Participation (42 CFR 482.52(a)) to limit the administration of deep sedation to “qualified anesthesia professionals” in Medicare settings (i.e. hospitals and Medicare-approved ambulatory centers). CMS further requires that any professional who administers and monitors deep sedation must be dedicated to that task only. Therefore, the non-anesthesiologist sedation practitioner who administers and monitors deep sedation must be different from the individual performing the diagnostic or therapeutic procedure.

Who should administer?

A task force comprised of one representative each from the four gastroenterology/hepatology societies convened in 2008 for the purpose of generating an evidence-based analysis of published literature, consisting of outcomes of 29 studies and more than 460,000 cases, most of which involved nurse-administered Propofol sedation. In 2009, information was updated to include an additional 200,000 cases – the outcome being the release of a four-society position statement reiterating their position, as supported by what they believe to be “overwhelming evidence” of the safety and efficacy of GD-P (a loading dose administered by gastroenterologist with titration and monitoring by nurses, under the direction and supervision of the gastroenterologist performing the procedure.)

Regardless of the evidence-based recommendations set forth by gastroenterologists in the four- society statement, the CMS appears to support a different view. Concurrent with the publication of the four-society statement, the CMS sent revised hospital anesthesia interpretive guidelines to state survey agency directors clarifying the agency’s stance on who should be allowed to deliver Propofol: the essence of which is that Propofol administration for deep sedation should only be performed or directed by an anesthesiologist. The CMS guidelines apply only to Medicare patients and Medicare settings. It does not, however, apply yet to physician offices or to non-Medicare patients –this could have a tremendous ripple effect, as other payors often follow the lead of CMS.

Following the December 2009 release of the updated interpretive guidelines for hospital anesthesia services, medical societies and organizations called for clarifications regarding the distinction between analgesia and anesthesia, suggesting that some of the examples cited in the guidelines didn’t fall clearly on one side or the other of the anesthesia/analgesia spectrum. Following complaints that the CMS policy was unworkable, the CMS released revised guidelines on January 24, 2011.

Conflicting, contradicting and overlapping guidelines

Hospitals are now directed to rely on “nationally recognized” guidelines to decide where various drugs fall within the anesthesia continuum and develop their own internal policies concerning what is anesthesia versus analgesia; which leaves open the option of using different guidelines in different clinical departments within one facility. CMS acknowledges that nationally recognized guidelines may not always fully agree with each other. For example, a hospital could use the American College of Emergency Physicians (ACEP) guidelines in their ED and follow those of the 4-specialty gastroenterology organizations position for their GI lab. The revisions also provide greater flexibility regarding pre and post-anesthesia evaluations while other problematic references were dropped entirely.

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The guidelines retain the six broad categories of anesthesia and analgesia, but acknowledge that this spectrum of described levels of sedation for a particular medication may vary on the basis of such factors as dosage, route and timing of administration. Thus, it's possible for the same drug to be used for general anesthesia in the operating room and for sedation in the emergency department or procedure room, as is the case with Propofol. The CMS stressed that "for some medications there is no bright line that distinguishes when their pharmacological properties bring about physiologic transition from the analgesic to the anesthetic effects".

Under the current guidelines, hospital policies should address whether specific clinical situations involve anesthesia versus analgesia, and specify the qualifications for each category of practitioner who administers analgesia and their supervision requirements.

In Part III, we address the current state of affairs surrounding the administration of Propofol and conclude with ways to minimize risk for GD-P.