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## The Use of Diprivan (Propofol) in GI Procedures

Part 1 in a 3-part series

Diprivan (generic name, Propofol) sparked public interest following the June 2009 sudden death of pop star Michael Jackson, who, as widely reported, died of cardiac arrest following the administration of a combination of Propofol and two other benzodiazepines at his home by his personal physician for the treatment of insomnia. Clearly, this is not an appropriate indication or setting for the drug. Propofol is used most commonly to start or maintain anesthesia or sedation during certain surgeries or invasive procedures in a monitored setting.

Considered by the FDA to be intended for general anesthesia or Monitored Anesthesia Care (MAC) sedation, Propofol's black box warning on the product labeling states that the drug should be administered "only by persons trained in the administration of general anesthesia and not involved in the performance of the surgical/diagnostic procedure."

### Controversy

Research reveals that there is a decade-long history of controversy surrounding the use of Propofol in GI endoscopy; not because of disagreement within the medical community as to the drug's efficacy for this purpose, but rather to differing viewpoints between gastroenterologists and anesthesiologists over who should administer Propofol and under what conditions.

Gastroenterologists favor the use of Propofol as a fast-acting, non-analgesic sedative with amnesic effects when administered at sub-hypnotic doses for endoscopy, targeted to produce *moderate sedation*. It allows patients to wake up, recover, and return to baseline activities and diet sooner than some other sedation agents; and because it reduces the need for opioids, its use results in less post-procedure nausea and vomiting. They contend that non-anesthesiologists<sup>1</sup> can safely administer the sedation, either alone or in combination with a small dose of narcotic, a benzodiazepine, or both.

Anesthesiologists argue that the benefits of using Propofol are outweighed by the risks associated with its administration by non-anesthesiologists. Cited as the reason for this concern is the unpredictable and profound effects of the drug, in that dosing and titration are variable based on a patient's tolerance to the drug, which can lead to profound and rapidly occurring changes from moderate sedation to deep sedation and even general anesthesia. Furthermore, patients can go from breathing normally to full respiratory arrest in seconds, even at low doses, without warning from typical assessment parameters. Unlike other sedation agents, there is no reversal agent, which means that adverse effects have to be treated and monitored until the drug is metabolized. Anesthesiologists therefore assert that the administration of Propofol should be handled as MAC, or deep sedation – the purview of which remains under the domain of anesthesiologists.

### Warning label debate

The strife began in 2005 when the American College of Gastroenterology (ACG) requested that Propofol's warning label be removed, stating that the warning was neither warranted nor appropriate. The petition cited several dozen publications in support of their claim that gastroenterologists and supervised nurses can safely administer Propofol without training in general anesthesia administration; however, this was met by strong opposition from the American Society of Anesthesiologist (ASA), citing lack of adequate studies to support the ACG's position.

The FDA also did not find the ACG's argument compelling enough, concluding that the warning label is appropriate in light of the risks associated with the sedative. They based their decision on three factors:

1. their belief that, while some colonoscopies can be performed with moderate sedation, most patients require deep sedation, at least transitionally, during the course of an endoscopic examination,<sup>2</sup> which would make administration by a non-anesthesiologist outside of their scope of practice
2. the risk that a deeply sedated patient may slip into general anesthesia due to the drug's narrow therapeutic window

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3. that practitioners administering Propofol need to be appropriately trained in the management and rescue of patients at all levels of anesthesia.

The FDA also notes that the warning is consistent with the findings and policies of The Joint Commission, the American Association for Accreditation of Ambulatory Surgery Facilities, the Accreditation Association for Ambulatory Health Care, Inc., and the American Society of Anesthesiologists. Per their standards, individuals administering moderate or deep sedation and anesthesia must be qualified and have the appropriate credentials to manage patients at whatever level of sedation or anesthesia is achieved, either intentionally or unintentionally. Accordingly, 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. A sufficient number of qualified personnel (in addition to the licensed independent practitioner performing the procedure) must be present during the procedure to provide moderate or deep sedation.

We want to know – who administers Propofol in your facility? Send us an [email](#) – we'll discuss the feedback we receive in an upcoming article.

**Stay tuned for Part II where we discuss how CMS responded and the various overlapping and conflicting guidelines that have been released.**

<sup>1</sup> Most often nurses, under the direction and supervision of a gastroenterologist performing the procedure, or by a loading dose administered by gastroenterologist with titration and monitoring by nurses, under the direction and supervision of the gastroenterologist performing the procedure; referred to hereafter as "gastroenterologist-directed" Propofol ["GD-P"].

<sup>2</sup> Despite the FDA's conclusions, gastroenterologists have held firm in their contention that a satisfactory endoscopic experience can be had without producing deep sedation or anesthesia.