Research, Relevant History and References

Clinical Practice Statement:

Propofol and Other Sedating Agents Can Be Safely Used by Emergency Physicians without an Anesthesiologist Present (2/17/2012)

Research and Relevant History:

A 2008 peer-reviewed report by the Canadian Agency for Drug Technologies in Health[6] cited 97 references, including over 40 peer-reviewed manuscripts regarding propofol in some aspect. All but five of these were published by American scientific journals. The report presented a systematic review of studies that compared emergency department sedation provided with short acting drugs such as propofol, ketamine, etomidate, or ketamine plus propofol ("ketofol"), versus one another, and more importantly, versus conventional opioid plus benzodiazepine sedation. This report concluded that from a Canadian perspective, propofol is the superior pharmaceutical agent for procedural sedations, and that its increased use should be encouraged in Canadian EDs. An anesthesiologist co-authored this peer-reviewed report. Its conclusions are further detailed in Appendix 2. The 12/11/09 CMS document[2] failed to consider this 2008 report, but the 1/14/11 CMS revised bulletin considered this data, after EM organizations' appeals to CMS to revise the 12/11/09 bulletin. Appeals came from representatives of AAEM, the American College of Emergency Physicians (ACEP), and the Emergency Nurses Association (ENA)[7]. By employing the AAEM Clinical Practice Advisory Statement Literature Search/Grading Process Proposal-Final Revision Version 3.0, November, 2011, it is clear that nothing has appeared in the peer-reviewed literature to contradict the findings of the Canadian panel[6]. Newer references exist attesting to the safety and cost-effectiveness of propofol[8].

The American Society of Anesthesiologists (ASA), jointly with American Academy of Nurse Anesthetists (AANA), wrote a position statement in 2004 stating that they alone should be credentialed to utilize propofol. Not only this 2004 statement, but also the 2009 revision, failed to reflect the available emergency medicine literature on the topic[9]. (The 2004 statement reflected anesthesiologists' appropriate concerns that arose from adverse patient events involving gastroenterologists, who lacked airway training, and perpetrated predictable adverse events.) The 2009 ASA-AANA joint position statement completely omitted reference to the extensive scientific literature from our specialty between 2002 and 2007 regarding propofol.

Discussion:

The revised CMS directive of 1/14/11[1] explicitly recognized that while a hospital's anesthesia services must be organized under the supervision of an anesthesiologist, emergency medicine specialty colleges' Clinical Practice Guidelines, such as those issued in 2011 by ACEP[10], constitute a valid resource to assist hospitals in development of policies and procedures regarding the use of propofol. Further, on 1/14/11, CMS explicitly stated that EPs possess not only the rescue capacity for airway issues that may ensue during sedation with propofol, but also that EPs possess the ability to use propofol and other short-acting anesthetic agents for general anesthesia during procedures such as rapid sequence endotracheal intubation. CMS also deemed as irrelevant the fact that no "reversal" agents exist for propofol[1].

References:

1. Center for Medicare and Medicaid Services. Revised hospital anesthesia services interpretive guidelines-State operations manual (SOM) Appendix A. Department of Health and Human Services, Baltimore MD; January 14, 2011
2. Center for Medicare and Medicaid Services. Revised hospital anesthesia services interpretive guidelines-State operations manual (SOM) Appendix A. Department of Health and Human Services, Baltimore MD; December 11, 2009
3. American College of Emergency Physicians. Clinical policy: Procedural sedation and analgesia in the emergency department. *Ann Emerg Med*. 2005;45:177-196.
4. Accreditation Council for Graduate Medical Education: Emergency medicine and pediatric emergency medicine program requirements. Available at: http://www.acgme.org/acWebsite/RRC_110/110_prIndex.asp accessed 12/21/2011
5. American Osteopathic Association: Basic standards for residency training in emergency medicine. Available at: http://www.osteopathic.org/inside-aoa/accreditation/postdoctoral-training-approval/postdoctoral-training-standards/Pages/default.aspx, accessed 12/21/2011
6. Bond K, Fassbender K, Karkhaneh M, et al: Short-Acting Agents for Procedural Sedation and Analgesia in Canadian Emergency Departments: A Review of Clinical Outcomes and Economic Evaluation. [Technology report number 109]. Canadian Agency for Drugs and Technologies in Health, Ottawa, ON, Canada; as amended April, 2008; initially disseminated March, 2008.
7. Gardner AF, Blumstein H, Gurney D. Appeal letter [re: Revised Hospital Anesthesia Services Interpretive Guidelines Ref. S&C 10-09 (revised 2/5/10) 42. CFR.482.52] to Thomas Hamilton, Director, Survey and Certification Group, Centers for Medicare and Medicaid Services, Baltimore, MD (sent on behalf of the American College of Emergency Physicians, the American Academy of Emergency Medicine, and the Emergency Nurses Association by the Presidents of these three organizations). March 22, 2010.
8. Hohl CM, Nosyk B, Sadatsafavi M, Anis AH. A cost-effectiveness analysis of propofol versus midazolam for procedural sedation in the emergency department. *Acad Emerg Med*. 2008;15:32-9.
9. AANA-ASA Joint Statement Regarding Propofol Administration (April 14, 2004, amended October 21, 2009). Available at: www.asahq.org/.../For%20Members/documents/Standards%20Guidelines%20Stmts/Safe%20Use%20of%20Propofol.ashx Accessed 12/21/2011
10. O'Connor RE, Sama A, Burton JH, et al. Procedural sedation and analgesia in the emergency department: Recommendations for physician credentialing, privileging, and practice. *Ann Emerg Med*. 2011; 58:365-70.

Appendix 1:
A regulatory bulletin from CMS in 2009 supported the assertions of the anesthesia community that emergency physicians are not qualified to utilize propofol[2]. That 2009 CMS bulletin neither utilized nor recognized the term "procedural sedation". The service which emergency physicians know as "procedural sedation" occasionally involves "deep sedation", as defined by CMS[1,2]. "Deep" sedation, which carries the risk of hypoventilation, was reserved only for anesthesiologists, nurse anesthetists, and similarly trained clinicians. Therefore, it for a time, it appeared that emergency physicians might be barred from use of propofol.

However, the 2009 CMS document[2] did not provide any acknowledgement that emergency physicians possess the rescue capacity to temporize transient hypoventilation that sometimes accompanies procedural sedation. This CMS document also did not note that traditional procedural sedation agents (such as narcotics or benzodiazepines) also can cause "deep" sedation, which is typically longer lasting than "deep" sedation occurring due to propofol.

Together, the American Academy of Emergency Medicine (AAEM), the American College of Emergency Physicians (ACEP), and the Emergency Nurses Association (ENA) appealed to CMS[7]. CMS regulators then met with representatives of the emergency medicine community.

Ten months later, in January, 2011, CMS issued its updated regulatory bulletin[1] This document gave emergency physicians all they requested, and more, by specifically noting that emergency physicians possess not only the rescue capacity for airway issues that may ensue during sedation, but also that even general anesthesia, when employed appropriately, reasonably falls within the purview of emergency physicians.

CMS, in its revised regulatory bulletin of January 14, 2011,[1] has clarified that it is definitely permissible to permit emergency physicians to employ the use of propofol, even in the absence of an anesthesiologist. In its "Attachment 2", the document specifically mentioned the ACEP Clinical Policy regarding procedural sedation[10] as an example of a recognized and valid Clinical Policy issued by "…a national organization that has appropriate expertise…". Further, the document of January 14, 2011 contained this exact wording (in "Question 4"):

Q4: Why is there a particular mention in the IG on the emergency department's (ED's) sedation policies?*
A4: The ED is a unique environment where patients present on an unscheduled basis with often very complex problems that may require several emergent or urgent interventions to proceed simultaneously to prevent further morbidity and mortality. In addition, emergency medicine-trained physicians have very specific skill sets to manage airways and ventilation that is necessary to provide patient rescue. Therefore, these practitioners are uniquely qualified to provide all levels of analgesia/sedation and anesthesia (moderate to deep to general)."

*IG = Interpretative Guideline

Appendix 2:
The three primary conclusions of a multidisciplinary group of Canadian authors, which included not only representatives of the emergency medicine community, but also an economist and representation from anesthesia, were as follows[6]:

- ***Clear differences exist between short-acting and traditional agents.*** *Short-acting agents are at least as effective as other regimens in terms of procedural success and clearly more effective in terms of reduced procedure time. With the exception of etomidate, short acting agents were associated with no additional risk of minor adverse events (AEs) (and some may argue fewer risks of AEs)*
- ***Short –acting agents are associated with reduced costs.*** *Propofol, etomidate, ketamine, and ketofol yield cost savings per procedure of $(Canadian, 2008)335.70, $301.76, $244.41, and $243.47 respectively, compared with standard therapy. Etomidate generates the greatest savings from a time and labour costing perspective, but savings associated with propofol are greater because the differences in costs from hospitalization more than offset the differences in labour costs.*
- ***Opportunities for optimal usage exist.*** *A survey of Canadian EDs revealed traditional agents are still in common usage. Opportunities may exist for the use of these agents by clinicians with less experience (e.g. rural physicians and nonphysician extenders, such as nurse practitioners and paramedics), given enough guidance or training.*

Thus, the Canadian Technology Report went out of its way to not only encourage increased use of propofol by emergency physicians, but also by appropriately trained "physician extenders" such as Physicians' Assistants, whether or not they are provided continuous supervision by an emergency physician.