American Society of Anesthesiologists®

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January 15, 2012

Terry Moore
Vice President of Health Policy
Abt Associates
55 Wheeler Street
Cambridge, MA 02138-1168

Re: Proposed CMS Measure to Provide Appropriate Monitoring to Patients Using Opioids via Patient Controlled Analgesia (PCA) – 3040

Dear Ms. Moore:

The American Society of Anesthesiologists (ASA) commends CMS for their efforts to improve safety of patients receiving opioids via Patient Controlled Analgesia (PCA) and agrees with CMS that appropriate monitoring may provide improved outcomes. ASA has reviewed in detail the information and measure justification that Abt Associates, the measure's steward, provided so that we could better understand the rationale behind this proposed EHR hospital quality measure.

Although ASA is listed among the "clinical expert stakeholders," we would like to make clear that ASA received no official correspondence formally designating our organization or any of our members as stakeholders. Nevertheless, as the recognized leader in perioperative patient safety, ASA supports CMS' concern that respiratory depression with opioids via an IV PCA device has an important impact on health care quality. Associated adverse events such as preventable death or other morbidities, including hypoxic brain injury, increased level of care, and prolonged hospital stay not only cause patient harm and family distress but also markedly increase the cost of care.

ASA agrees with CMS objectives for quality measures as those that are "effective, safe, efficient, patient-centered, equitable and timely." ASA does not agree that the current quality measure, as proposed, will effectively reduce or eliminate respiratory depression following opioid use, and, thus it will not meet those stated goals. ASA believes that the 1) method of opioid administration, 2) risk adjustment and 3) frequency and type of monitoring are not adequately addressed in this proposed electronic health record process measure.

The ASA Closed Claims database (1990-2009) has demonstrated that postoperative respiratory depression (RD) from opioids remains a significant cause of high-severity injuries for patients, often resulting in death or brain damage. (Lee LA, Stephens LS, Caplan RC et al: Postoperative Respiratory Depression: A Closed Claims Analysis, Anesthesiology 2012; A305). One quarter of the acute pain claims involved postoperative RD. Different modes of pain control were used in over half of the claims. PCA (42%) and epidural infusions (42%) were the most commonly used

modalities of pain control. These finding suggest that a **majority** of severe RD episodes do not involve PCA.

Factors associated with higher incidence of respiratory depression were more than one physician prescribing opioid or sedation medications and using multiple non-opioid sedation medications and opioids. While these data tracked postoperative use of opioids, and the proposed measure addresses hospital-wide use of IV PCA, the data makes a compelling case that IV PCA is only one part of the problem.

When properly used, existing research suggests that IV PCA may be safer than alternative methods of potent opioid delivery. Limiting the measure to IV PCA fails to recognize the many additional factors that put patients at risk for opioid-induced respiratory depression. While not a function of the IV PCA per se, poor communication between prescribing physician, nurses and other members of the healthcare team also foster opioid-induced respiratory depression. Opioids, sedatives, sleep aids and other medications have a synergistic depressant effect on respiratory drive, an often-unrecognized contributor to morbidity and mortality. This measure does not include important patient-specific risk factors for increased susceptibility to opioid-related respiratory complications. Patient and drug related factors along with drug delivery modalities all contribute to RD, so the most appropriate method for delivering the opioid and monitoring for respiratory depression must consider these various elements.

Risk stratification is possible based on known contributors to opioid-related respiratory complications. These include obstructive sleep apnea, obesity, opioid naivety, advanced age, concomitant administration of other sedative medications, or a combination thereof. Severe pain treated only with systemic opioids may also be a risk factor, especially if the pain is intermittent in nature, such as surgical pain that varies with activity. Additionally, many hospitalized patients receive supplemental oxygen. A decrease in oxygen saturation is a very late sign of RD in those receiving supplemental oxygen; thus supplemental oxygen can mask impending respiratory depression, especially if one primarily depends on pulse oximetry monitoring for detection. In addition, we know of no evidence that <u>intermittent</u> monitoring of any of the CMS proposed parameters (respiratory rate, sedation score, oxygen saturation) reduces the risk of significant opioid-related RD complications, although we do believe that some monitoring is better than none.

As noted in the measure justification, ASA guidelines (Anesthesiology 2009; 110:218-230) and those of other specialty organizations support the need for regular and frequent monitoring of patients receiving respiratory depressant medications. Patients at increased risk for such events often display periodic airway obstruction and hypoxemia, which can easily go undetected with only intermittent monitoring. Under the circumstances of infrequent and intermittent monitoring, the first manifestation of RD is typically a very rapid clinical deterioration leading to serious sequelae, such as death or other severe organ injury secondary to severe hypoxemia. For those patients prospectively identified as being at increased risk, more intensive monitoring, such as continuous physiologic monitoring, may aid in early detection and rescue. Additionally, high-risk patients may benefit from increased use of non-opioid analgesic modalities and minimal use of sedative medications known to contribute to RD.

Minimizing risk of opioid-related respiratory complications requires patient-centered care, including an individualized analgesic regimen and monitoring plan based on the

pharmacokinetics and pharmacodynamics of the drug, the modality for delivery, and patient specific risk factors.

Regarding the specific monitoring parameters assessed, respiratory rate is an unreliable indicator of ventilatory depression in patients with pain, and a severely low respiratory rate is a late sign of impending respiratory arrest. Furthermore, oximetry is useful for detecting an adverse event only when it is used continuously, when there is an alarm reliably detectable to those providing care, and when an individual trained to manage RD is always available to respond to the alarm. Decreased oxygen saturation is a late sign of severe respiratory compromise. Assessing this on an every 2½ hour basis, as has been proposed, will be, at best, marginally effective in identifying and promoting rescue of patients from RD.

While we understand CMS' desire to leverage the capabilities of electronic health records to create incentives for improved care and to prospectively and objectively monitor performance, the proposed measure falls short in several areas. As described, the monitoring interval and the specific monitoring proposed are insufficient to achieve the desired goals. With significant revisions addressing our stated concerns, the EHR measure may become useful in monitoring hospital performance; however, this approach does not go far enough.

The ASA believes that the best approach to addressing in-hospital opioid-related RD is to develop a risk-adjusted evidence-based outcome measure that also measures timely rescue from RD. To reduce morbidity and mortality from RD, both early recognition and effective rescue go hand-in-hand. A number of primary and secondary endpoints have been used in clinical trials as indicators of significant medication-related adverse respiratory events, including physiologic values (PaCO2, PaO2, oxygen saturation), clinical criteria (respiratory rate, sedation score), and interventions (administration of naloxone/opioid reversal, positive-pressure ventilation, activation of rescue/"code blue" team, unintended intubation, ICU transfer) (Taenzer AH, Pyske JB, McGrath SP, Blike GT: Impact of pulse oximetry surveillance on rescue events and intensive care unit transfers: A before-and-after-concurrence study. Anesthesiology 2010; 112: 282-7; Dahan A, Aarts L, Smith T: Incidence, reversal and prevention of opioid-induced respiratory depression. Anesthesiology 2010; 112: 226-238) .These factors would likely prove helpful in crafting an effective outcome measure.

In the event CMS determines that developing such an outcome measure is not feasible, the ASA is willing to help craft a process measure that incorporates continuous monitoring and risk-stratified management. We do recognize the barriers to the successful development of a process measure for RD, but believe, absent an appropriate outcome measure, such a process measure would prove much more effective than what has been proposed by the agency to address this problem.

In summary, ASA cannot support this measure as written. ASA strongly encourage CMS to develop an alternative measure based on available evidence that addresses the use of potent opioids for all delivery modalities, not just IV PCA. ASA proposes that CMS endorse:

1. an outcome measure based on significant opioid-related respiratory complications and/or interventions made to manage the effects of respiratory depression, or

2. an evidence-based and/or expert opinion-based process measure if a suitable outcome measure cannot be devised.

Appropriate processes to consider include continuous physiologic monitoring and risk stratification. Pulse oximetry and capnography can be used to detect adverse respiratory events, although ASA recognizes limitations in the practical application of such continuous monitoring in all settings. ASA welcomes the opportunity to discuss the proposed measure and our comments, as well as to assist CMS in developing a better measure to promote safe use of opioids in all patients.

Sincerely,

John Zerwas M.D.
President, American Society of Anesthesiologists