PPM ANESTHESIA & the LAW
A RISK MANAGEMENT NEWSLETTER

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ISSUE 32

Drug-Induced Respiratory Depression in the Postoperative Period

Preferred Physicians Medical (PPM), industry-leading provider of medical professional liability insurance for anesthesia practices, participated in a June 8, 2011 workshop organized by the Anesthesia Patient Safety Foundation (APSF) to address drug-induced respiratory depression in the postoperative period.

Steve Sanford, PPM's President and COO, provided conference attendees with medical liability data suggesting drug-induced respiratory depression remains a significant patient safety concern. In his remarks to the workshop attendees, Mr. Sanford suggested malpractice litigation is an additional perspective for helping to define the scope of this patient safety issue.

PPM, in its role as a medical professional liability insurance carrier providing coverage exclusively to anesthesiologists and their practices, has an anesthesia database of over 10,000 adverse outcomes, including 3,250 claim and litigation files (2,876 closed and 374 open). Mr. Sanford noted that litigation and loss data by its nature tends to understate the incidence of adverse medical outcomes. Litigation focuses on extreme outcomes; those resulting in significant compensable harm. With respect to drug-induced respiratory depression, non-catastrophic outcomes and close calls, including cases where the patient is rescued without injury are unlikely to result in a claim or litigation.

After reviewing its anesthesia database, PPM identified 96 claim and litigation files involving postoperative respiratory depression or arrest. Almost all the reported cases involved primary allegations of brain damage or death. According to the data, Chart 1, approximately 3% of all anesthesia losses arise from postoperative respiratory arrest. The financial impact of this litigation accounts for approximately 5% of all anesthesia losses, including both indemnity payments to injured parties and legal costs associated with defending the litigation. According to Sanford, the 96 claim and litigation files involving postoperative brain damage or death resulted in total indemnity payments of $15.5 million and additional defense costs of $7.5 million.

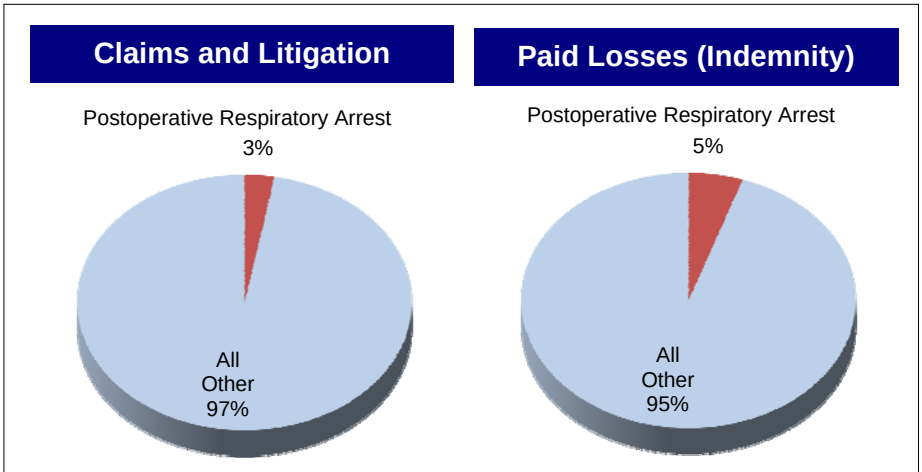
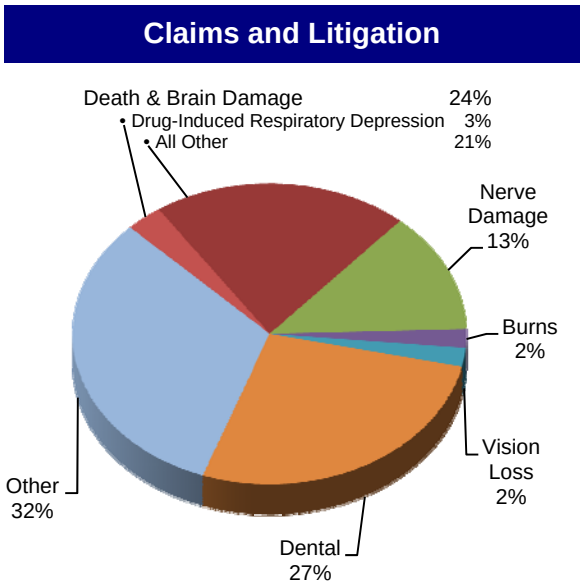


Chart 1

Mr. Sanford contrasted this data with other loss categories in order to provide attendees with additional context. Similar to other anesthesia claims resulting in catastrophic injury (brain damage and death) a relatively small percentage (24%) of all anesthesia claims and litigation result in a disproportionate share of all anesthesia losses (42%). In contrast, dental injuries (the most common anesthesia claim) account for 27% of all anesthesia claims or litigation filed; however, dental claims and litigation result in less than 1% of all anesthesia losses. Other recent patient safety initiatives, including postoperative vision loss (POVL) and intra-operative fire (burns),

accounted for both fewer injuries and lower anesthesia losses. Chart 2 reflects the inclusion of drug-induced respiratory arrest resulting in brain damage or death in the broader category of brain damage and death arising from any cause.



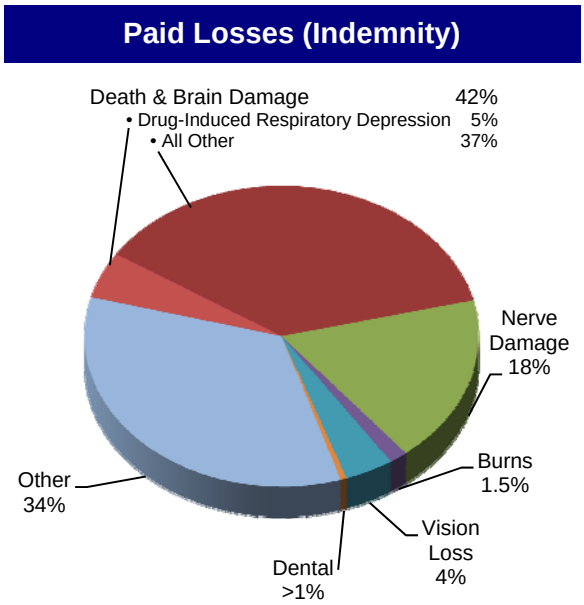


Chart 2

A smaller subset of the above data identified 35 cases specifically focused on allegations of drug-induced respiratory arrest resulting in brain damage or death. Patients formally diagnosed or suspected of having obstructive sleep apnea (OSA) were identified in 11 of the 35 cases. In each of these 11 cases, inadequate monitoring was identified by an expert witness or reviewer as contributing to the adverse outcome.

During his presentation, Mr. Sanford noted several significant limitations in the data presented. First, PPM's loss data as an anesthesia-only insurance provider is limited to loss and defense costs incurred by the anesthesia providers. Mr. Sanford noted anesthesia providers are frequently not named in cases involving drug-induced respiratory depression as these cases typically arise after the anesthesia care has concluded. In cases that include anesthesia providers, many cases are dismissed early in the litigation or the anesthesia provider is eventually exonerated by jury verdict. Litigation arising from drug-induced respiratory arrest more typically focuses on floor nurses responsible for monitoring the patient, the hospital that employs the nurses and establishes monitoring protocols, and surgeons who more typically prescribe postoperative PCA or narcotics. For this reason, Mr. Sanford suggested loss data from multi-specialty insurance companies - those that insure the hospital, surgeon, nursing staff and anesthesia providers - may provide a more complete picture of the incidence of drug-induced respiratory depression and the loss costs associated with these adverse outcomes.

Despite its limitations, Mr. Sanford concluded PPM's loss data supported the view that drug-induced respiratory depression was a serious patient safety concern requiring the development of strategies to identify and monitor patients at risk during the postoperative period. ❖

APSF Conference Highlights

By Steve Sanford, JD

Twenty-one presenters, including patient advocates, physicians, nurses, medical researchers, medical device manufacturers and the insurance industry, provided workshop attendees with a wide range of perspectives on the issue of drug-induced respiratory depression. While the focus of the workshop centered on in-patient care, several presenters noted similar concerns existed in the out-patient setting.

Presentation by family members impacted by adverse medical outcomes underscored the importance of addressing drug-induced respiratory arrest. Helen Haskell, Melinda Loflin and Laura Batz-Townsend each provided emotionally powerful stories.

Several speakers attempted to quantify the scope of this patient safety issue, but most conceded accurate measures were difficult. Close calls and successful rescues were likely to be underreported. At least one conference participant, Dr. Lorri A. Lee from the University of Washington, suggested tracking the doses of Naloxone administered to patients on the nursing floor might provide a reliable indicator of the incidence of over-sedation.

Dr. Lawrence A. Lynn, Executive Director of The Sleep and Breathing Institute in Columbus, OH, discussed three very different pathophysiologic patterns of unexpected hospital death. According to Dr. Lynn these differences make early detection and prevention difficult to achieve by any single monitoring device or strategy. Dr. Lynn suggested that any effective monitoring strategy would require physicians and nurses to learn and understand the underlying patterns leading to respiratory arrest and death.

Several presenters observed the use of supplemental oxygen can mask and delay the timely diagnosis of respiratory depression. Capnography or other monitoring modalities that measure the adequacy of ventilation and airflow are indicated when supplemental oxygen is utilized.

Dr. Frances F. Chung discussed the increasing role of OSA and the importance of identifying patients at increased risk of drug-induced respiratory depression. Other presenters noted the complexity of attempting to accurately identify patients at risk. By the conclusion of the conference, the majority of attendees eventually agreed electronic monitoring and oxygenation should be available and considered for all patients receiving opioids for acute pain management.

Presenters, including Nurse Chris Pasero and Dr. J. Paul Curry, discussed the challenges of implementing new strategies, including alarm fatigue, desensitization and the staffing requirements that any recommendations may require.

Device manufacturers welcomed the direction provided by workshop attendees and responded to one attendee's suggestion that innovation with respect to monitoring devices was slow to emerge. One product developer attending the workshop, Dr. Lloyd Olsen, suggested that future PCA pumps may be designed to monitor the patient's condition and deliver a dose of Naloxone in the event respiratory depression was detected. ❖

Defending Drug-Induced Respiratory Depression Litigation

As reflected by PPM's loss data and the following case summaries, PPM has successfully defended the majority of lawsuits involving allegations of drug-induced respiratory depression in the postoperative period by either obtaining defense verdicts or entering into reasonable settlements on behalf of its policyholders.

Case #1

- A 31 year-old female presented for repair of an anterior cruciate ligament under general anesthesia. The procedure was uneventful and the patient was placed on a PCA morphine pump for postoperative pain relief. The pump was set at a 4 hour lock out to limit the maximum dose to 20mg. The PPM insured anesthesiologist wrote the orders for the PCA, including an order to call anesthesia if there were any problems. The surgeon also left postoperative pain orders to give extra-strength Vicodin ES regularly every four hours.

  That night the patient complained of inadequate pain relief. The nurse increased the dosage of the PCA pump per the PPM insured anesthesiologist's order. The patient continued to complain of pain so a call was placed to the anesthesiologist's partner who was on call that evening. The nurse later testified the on-call anesthesiologist approved an immediate bolus of morphine with additional boluses thereafter, but ordered a hold on the oral Vicodin ES until the surgeon could see the patient.

The PPM insured anesthesiologist's partner did not come to the hospital to see the patient and no notes were recorded. No additional calls were placed by the nurses and no other physicians were involved in the patient's care. Pain relief was achieved and no other problems were noted on that night shift.

Another nurse came on shift the following morning. This nurse later testified she did a full assessment of the patient who was alert, well oriented, cooperative and interactive. The patient continued to complain of pain during the day so nursing continued to give additional boluses of morphine. The patient only ate approximately 20% of her breakfast and no lunch, but this information was not passed along to any physician. Additionally, records did not indicate any significant fluid volume administered during that time period.

At approximately 1:45 p.m., the patient was still in pain so the nurse on duty called the surgeon in the operating room. She advised him of the patient's pain and the amount of the bolus therapy, but did not tell him the on-call anesthesiologist had stopped the Vicodin pending the surgeon seeing the patient. The nurse did not ask the surgeon to see the patient, nor did she tell him she was about to administer Phenergan in response to complaints of nausea. She instead asked the surgeon if he still wanted the Vicodin ES given. According to the nurse, the surgeon became irritated his orders were not being followed and ordered her to immediately give Vicodin ES.

The nurse also made a note that the surgeon told her anesthesia was with him and concurred with resuming the Vicodin ES. In less than an hour with no food, the patient received a bolus of morphine, two Vicodin ES tablets and Phenergan. Approximately an hour later, the patient's blood pressure was 76/48, although this was not immediately reported to the shift nurse. The patient was found by a friend who alerted the nursing staff the patient was in respiratory distress. When nursing arrived, the patient's respiration rate was 12 breaths per minute with severely labored breathing. The shift nurse called the PPM insured anesthesiologist while others administered Narcan. The patient sustained full respiratory arrest and a code was called. The patient was resuscitated and intubated within seven minutes. However she arrested again and remained comatose until she died five days later.

The patient's parents (the patient was single with no children) sued the surgeon, hospital and the PPM insured anesthesiologist's practice group and the on-call anesthesiologist (who was also a PPM insured). Plaintiffs sued the PPM insured anesthesiologist's practice group under the theory of vicarious liability based on the employer/employee relationship. The on-call anesthesiologist was subsequently dismissed from this lawsuit and the case proceeded against the surgeon, hospital and the PPM insured anesthesiologist's practice group.

The allegations against all defendants were failing to communicate and monitor the administration and timing of opioids causing narcotic overdose, postoperative respiratory arrest and death.

The defense anesthesiology expert was critical of the nurses' lack of knowledge regarding opioid dosages and failure to adequately monitor the patient. The defense expert was also critical of the surgeon's actions. In his opinion, the surgeon's written order for Vicodin ES directing the nurses to administer Vicodin ES regularly in addition to the PCA pump orders was below the standard of care.

Plaintiffs' nursing expert was critical of the nurses for their poor communication with the surgeon and failure to properly monitor the patient. Specifically, she was critical that when the nurse contacted the surgeon due to the patient's continued complaints of pain, she did not tell him how much morphine had been administered or advise him that the on-call anesthesiologist had directed the nurse to hold the Vicodin ES until the surgeon could see the patient. Plaintiffs' nursing expert also criticized the delay in advising the other nursing staff and physicians of the patient's abnormal vital signs prior to the code.

Plaintiffs' anesthesiology expert was critical of the PPM insured anesthesiologist for failing to check the patient personally or reviewing her chart to determine what other narcotics or medications she was receiving.

Prior to trial, the hospital and surgeon settled for confidential amounts. The PPM insured anesthesiologist's practice group consented to a settlement of $75,000.

Case #2

- A 35 year-old female with history of severe depression, suicide attempts and multiple psychiatric medications (some of which were suspended during her pregnancy) presented for a scheduled c-section. The procedure was performed at 9:55 a.m. and a healthy infant was born without complications. The PPM insured anesthesiologist chose continuous lumbar epidural analgesia with Fentanyl and Marcaine 3ccs per hour for postoperative pain management.

  The patient did well in PACU and was eventually transferred to the floor. The PPM insured anesthesiologist saw the patient at 4:30 p.m. She noted the patient was doing well and was comfortable with her continuous lumbar epidural. The PPM insured anesthesiologist ordered pulse oximetry monitoring for 24 hours. She also ordered that the on-call anesthesiologist was to be notified of any respiratory rate less than 10 breaths per minute, O2 SATs of less than 90%, evidence of airway obstruction, patient drowsiness, inadequate pain relief, numbness or weakness in lower extremities, administration of Narcan and Ambu bag resuscitation, if necessary.

  At approximately 10:30 p.m., the OB/GYN ordered the administration of Stelazine, Ativan, Wellbutrin and Tegretol. The PPM insured anesthesiologist was unaware the OB/GYN ordered the administration of these psychotropic medications.

  The records indicated the patient was visited by nursing staff at 11:15 p.m. and was alert and oriented. At 11:50 p.m. the patient was found in her room in full arrest and a code was called. She was resuscitated and transferred to ICU. The patient was intubated and placed on a ventilator. The patient never regained consciousness or purposeful movement. The family ultimately decided to end supportive care and the patient expired.

  The patient's husband and three minor children sued the PPM insured anesthesiologist, the OB/GYN and the hospital. The allegations against the PPM insured anesthesiologist included: inadequate history and physical to recognize and treat the patient's probable obstructive sleep apnea and dyspnea; administering an epidural with Fentanyl in a manner and amount that was contraindicated for this patient; failing to order and ensure appropriate monitoring following transfer to the floor; and failing to communicate with the OB/GYN and the nursing staff regarding the use of Fentanyl and subsequent administration of psychotropic medications.

  Through discovery, evidence was obtained that the nursing staff failed to follow the PPM insured anesthesiologist's orders. Specifically, the nursing staff failed to: utilize pulse oximetry; inform the PPM insured anesthesiologist supplemental oxygen had to be administered to improve the patient's oxygen saturation; inform the PPM insured anesthesiologist of the patient's wheezing; and, resuscitate the patient using Narcan and an Ambu bag.

  Prior to trial, plaintiffs' last settlement demand was $10 million. The hospital offered $2.5 million, which was rejected by plaintiffs. The PPM insured anesthesiologist and OB/GYN did not consent to settlement and the case proceeded to trial.

  During trial, the hospital settled for $6 million. The trial proceeded against the PPM insured anesthesiologist and OB/GYN. Following a two week trial, the jury returned a defense verdict in favor of the PPM insured anesthesiologist and awarded plaintiffs more than $16 million against the OB/GYN. Post trial, plaintiffs settled with the OB/GYN within his insurance policy limits. ❖

Essential Monitoring Strategies to Detect Clinically Significant Drug-Induced Respiratory Depression in the Postoperative Period

APSF Conference Conclusions and Recommendations (reprinted with APSF permission)
Prepared by Robert K. Stoelting MD and Frank J. Overdyk, MD
Conference Co-Moderators

APSF believes clinically significant drug-induced respiratory depression (oxygenation and/or ventilation) in the postoperative period remains a serious patient safety risk that continues to be associated with significant morbidity and mortality since it was first addressed by APSF in 2006. With this background, APSF sponsored its second one-day conference on this topic bringing together 136 stakeholders from diverse backgrounds (physicians, nurses, industry representatives, family representatives, pharmacists, hospital administrators, insurers, regulators) to address the following question: ***Essential Monitoring Strategies to Detect Clinically Significant Drug-Induced Respiratory Depression: Why and How?***

The attendees were asked to approach this topic from the perspective of three questions:

1. Should electronic monitoring be utilized to facilitate detection of drug-induced postoperative respiratory depression?
2. If Yes to electronic monitoring, who should be monitored (inclusive or selective) and what monitors/technology should be utilized?
3. If No to electronic monitoring, why?

The program consisted of oral presentations from subject matter experts followed by small group breakout sessions, general audience comments, and discussion and written responses to questions created to stratify opinions on specific aspects of the conference topic.

APSF believes the following **Conclusions and Recommendations** reflect the majority opinions (consensus) of the 136 attendees. In some instances, the Conclusions and Recommendations are expanded by **Observations**.

*These **Conclusions and Recommendations** are *intended to facilitate detection of clinically significant drug-induced respiratory depression in non-ambulatory adult patients receiving parenteral opioids for management of acute postoperative pain while being cared for in a healthcare facility*.

APSF Conclusions and Recommendations*

1. Future technology developments may improve the ability to more effectively utilize continuous electronic monitoring of oxygenation and ventilation in the postoperative period. **However, maintaining the status quo while awaiting newer technology is not acceptable.**
2. Intermittent “spot checks” of oxygenation (pulse oximetry) and ventilation (nursing assessment) are not adequate for reliably recognizing clinically significant evolving drug-induced respiratory depression in the postoperative period.
3. Continuous electronic monitoring of oxygenation and ventilation should be available and considered for all patients and would reduce the likelihood of unrecognized clinically significant opioid-induced depression of ventilation in the postoperative period.
4. Continuous electronic monitoring should complement and not replace traditional intermittent nursing assessment and vigilance.
5. All patients should have oxygenation monitored by continuous pulse oximetry (see Observation 1).
6. Capnography or other monitoring modalities that measure the adequacy of ventilation and airflow are indicated when supplemental oxygen is needed to maintain acceptable oxygen saturations.
7. Although careful pre-operative screening for conditions that may be associated with an increased risk of postoperative respiratory insufficiency (obstructive sleep apnea, obesity, chronic opioid therapy) is

recommended and may be part of a graduated continuous monitoring adoption plan, applying electronic monitoring selectively based upon perceived increased risk is likely to miss respiratory depression in patients without risk factors (see Observation 2).

8. Monitoring continuous oxygenation and ventilation from a central location (telemetry or comparable technologies) is desirable. This information needs to be reliably transmitted to the healthcare professional caring for the patient at the bedside.
9. Structured assessment of the level of sedation/consciousness is a critical component of the nurse's routine postoperative patient assessment for detecting respiratory depression.
10. Nurse and physician education is critical to ensure an (1) understanding of the physiology and pharmacology of drug-induced respiratory depression, (2) the potential obscuring impact of patient arousal on respiratory depression during clinical assessment and (3) the interference of supplemental oxygen administration on detection of progressive hypoventilation when pulse oximetry is the only continuous electronic monitor.
11. Continuous electronic monitoring systems should integrate multiple physiologic parameters to identify clinically significant changes earlier and more reliably.
12. Threshold-based alarm limits on individual physiologic parameters may result in the caregiver failing to recognize early signs of progressive hypoventilation by either being too sensitive (excess false alarms) or insufficiently sensitive.
13. Impediments to continuous electronic monitoring of oxygenation and ventilation in the postoperative period are multi-faceted. Among attendees categorizing their responses to the written questions as *Caregivers or Corporate*, the two greatest impediments were (1) initial investment cost in instituting existing technology and (2) failure of caregivers to recognize (inadequate education) the true risk of drug-induced respiratory depression.

APSF Observations

1. APSF is aware of hospital systems that have adopted continuous capnography in combination with pulse oximetry, or in lieu of pulse oximetry.
2. APSF acknowledges that, due to limited healthcare resources, implementation of these conclusions and recommendations may be part of a graduated continuous electronic monitoring adoption plan. However, institution of these conclusions and recommendations must not be delayed while awaiting newer technology.
3. APSF advocates increased public and private investment in research to develop monitors with high reliability and ease of use.
4. APSF strongly encourages research and continuous quality improvement (CQI) to evaluate the impact and cost effectiveness of these **Conclusions and Recommendations**.
5. APSF believes that multi-modal analgesia techniques need to be used more often to decrease the use of opioids alone for postoperative pain management.

APSF Disclaimer Statement

Recommendations developed and promulgated by APSF are intended to assist professionals who are responsible for making health care decisions. APSF's mission is to assure that no patient is harmed by anesthesia care. Thus, our recommendations focus on minimizing the risk to individual patients for rare adverse events rather than necessarily on practices that balance all aspects of population health quality and cost. APSF does not intend for these recommendations to be standards, guidelines, practice parameters or clinical requirements nor does application of these recommendations guarantee any specific outcome. Furthermore, these recommendations may be adopted, modified or rejected according to clinical needs and restraints. APSF recognizes that these recommendations are subject to revision as warranted by the evolution of medical knowledge, technology, and practice. ❖

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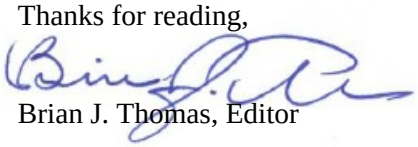

Brian J. Thomas, Editor

Note: The purpose of this newsletter is to provide information to policyholders and defense counsel regarding professional liability issues. Risk management analysis is offered for general guidance and is not intended to establish a standard of care or to provide legal advice.