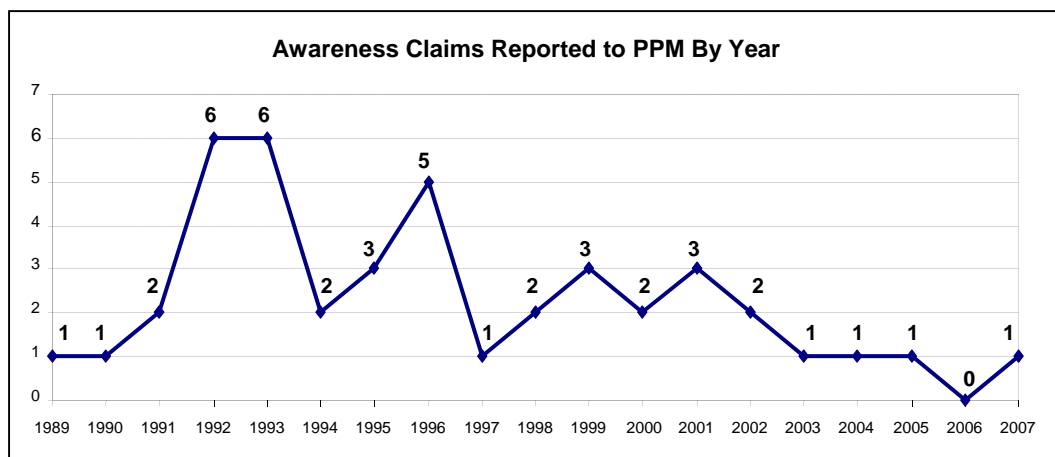
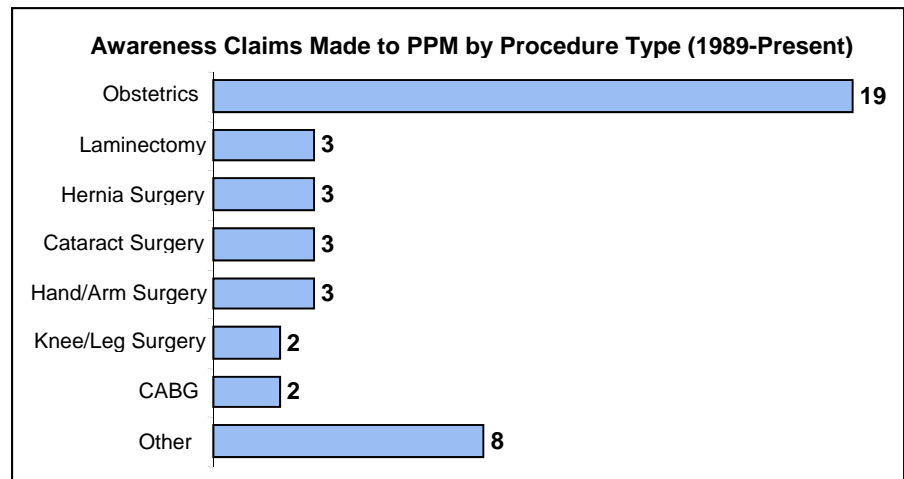


Awareness: How Often Does It Really Happen?

Intraoperative awareness occurs when a patient becomes conscious during a procedure performed under general anesthesia and subsequently has recall of these events.¹ The incidence of awareness has been estimated to be approximately 1 to 2 per 1,000 surgeries² to over 30,000 cases every year in the United States.³ However, other recent reports show the incidence of awareness may be as low as 1 in 14,000 surgeries.⁴ PPM's claim data suggest the incidence of actual awareness may be even lower.

Since 1989, only 43 adverse outcomes reported to PPM involving allegations of awareness have resulted in claims or litigation. In addition, only 14 of the 43 adverse outcomes involved claims in which intraoperative awareness was reported following a procedure during which general anesthesia was administered. The majority of the awareness claims reported to PPM involved obstetric procedures with spinal and/or epidural analgesia.



The charts illustrate the awareness claims reported to PPM based on the procedure type and the total number per year since 1989.

Defending Awareness Cases in the Courtroom

While the number of “true” awareness (intraoperative awareness following general anesthesia) claims reported to PPM has been very low, these claims are challenging to defend and can result in significant settlements based on the serious psychological sequelae that can occur, including post traumatic stress disorder (PTSD). The case summaries below highlight the difficulty defending “true” awareness claims:

- A 40 year-old female underwent a laminectomy with general anesthesia. Postoperatively the patient complained she experienced awareness including feeling pain and hearing sounds during the procedure. An investigation and statements from an attending certified registered nurse anesthetist confirmed the

Forane vaporizer was empty and the patient was bucking during the procedure. In her lawsuit, the patient alleged she suffered from PTSD and produced psychiatric records to support her PTSD claim. This lawsuit was settled on behalf of the PPM policyholder for \$400,000.

- A 56 year-old female, ASA IV, presented for cardiac artery bypass graft (CABG) with general anesthesia. The PPM policyholder intentionally administered a “light” anesthetic because of the patient’s history of myocardial infarction and the planned procedure. Postoperatively, the patient complained of awareness including feeling pain, anxiety and hearing sounds. In her lawsuit, the patient alleged she suffered a hypertensive stroke that was caused by her severe anxiety and PTSD. This lawsuit was settled on behalf of the PPM policyholder for \$750,000.

However, most awareness claims defended by PPM have been resolved without payment or settled for relatively nominal amounts. According to Randy Obert, PPM Claims Attorney, “Plaintiff attorneys typically don’t file awareness lawsuits because the damages are mostly subjective and difficult to prove.” Indemnity payments (settlements and verdicts) only occurred in 11 of the 43 awareness claims defended by PPM. The average indemnity payment for those 11 awareness claims was \$34,555. To date, PPM has tried 2 awareness cases to jury verdict with the following results:

- A 38 year-old female underwent a cesarean section due to pregnancy complications which included pre-eclampsia, gestational diabetes, fetal macrosomia and morbid obesity. A labor epidural was administered as the PPM policyholder decided that general anesthesia was not indicated due to plaintiff’s morbid obesity and increased risk for airway difficulties. During the procedure the patient complained of inadequate anesthesia. Fentanyl, Ketamine and Versed were administered to help ease the patient’s reported pain. The patient filed litigation alleging she suffered from PTSD and major depressive disorder caused by awareness during the procedure. Plaintiff’s demand prior to trial was \$1,000,000. This case was tried to a jury which returned a defense verdict.
- A 34 year-old female presented for cesarean section with epidural analgesia. The patient complained during the procedure that she could feel the incision and pain. The decision was made to complete the delivery as converting to a general anesthetic could have potentially compromised the infant. The plaintiff claimed pain and suffering and emotional damages. Plaintiff demanded \$1,000,000 prior to trial. This case was tried to a jury which returned a verdict in favor of plaintiff for \$80,000.

Brain Function Monitors

Given the attention directed at the issue of awareness, many anesthesiologists have turned to or explored utilizing brain function monitors. However, a recent independent study conducted by Washington University casts doubt on the effectiveness of Bispectral Index (BIS) monitors.⁵ The study compared two groups of patients deemed “high risk” for waking during surgery. Each group consisted of 1,000 patients; one group was provided with BIS monitors, the other group with end-tidal anesthetic gas (ETAG) monitors. Results of the study showed that two people from each group reported awareness. Of the four who reported awareness, one from each group showed no indication of awareness according to the monitors. Dr. Michael Avidan, lead researcher for the study, said that in two of those awareness cases, one with each monitoring system, the monitors indicated no anesthesia issues or problems. In the other two cases, the monitors indicated some type of problem.

This study reinforces the anecdotal information PPM has received from our policyholders over the last several years. BIS monitors should not be viewed as a panacea, but as an optional tool that physicians may use to address awareness concerns. Most PPM policyholders indicate they continue to rely primarily on clinical techniques (e.g., checking for clinical signs such as purposeful or reflex movement) and conventional monitoring systems (e.g., electrocardiogram, blood pressure, heart rate, end-tidal anesthetic analyzer and capnography) to monitor the depth of anesthesia and minimize the occurrence of awareness.

ASA Task Force Concludes Brain Function Monitors are not Standard of Care

According to the ASA Task Force on Intraoperative Awareness, the general clinical applicability of brain function monitors in the prevention of intraoperative awareness has not been established. Further, there is insufficient evidence to justify a standard, guideline or absolute requirement that these devices be used to reduce the occurrence of intraoperative awareness in high-risk patients or any other group of patients undergoing general

anesthesia. The ASA Task Force has recommended that the decision to use a brain function monitor be made on a case-by-case basis by the individual practitioner for selected patients.¹

References:

1. Practice Advisory for Intraoperative Awareness and Brain Function Monitoring: A Report by the American Society of Anesthesiologists Task Force on Intraoperative Awareness. *Anesthesiology*. 2006;104(4): 847-864.
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3. *Awake*, The Movie. For a review of the movie *Awake* visit the News & Events section of PPM's website at ppmrrg.com.
4. Intraoperative Awareness in a Regional Medical System: A Review of 3 Years' Data. *Anesthesiology*. 2007;106(2): 269-274.
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Risk Management Analysis

Brain Function Monitors

In the event of an adverse outcome involving awareness when a BIS monitor was available but not used, PPM's policyholders will have to be able to clearly articulate the reason for not using a BIS monitor. Given the increasing presence of BIS and other brain function monitors in operating rooms across the country, PPM recommends that policyholders consider adopting an anesthesia protocol that broadly outlines when a BIS or other brain function monitor should be utilized. For example, a BIS monitor will be utilized with patients reporting a history of awareness or recall; a BIS monitor should be utilized in cases where the anesthetic is kept purposefully light (e.g., certain cardiac procedures); and a BIS monitor may be used in any other case in which the policyholder's clinical judgment indicates the use of a BIS monitor may provide additional useful information. The benefit of such a protocol is to get everyone in the anesthesia group on the same page with respect to those areas where the group consensus is that the BIS monitor should be used. In cases where there is a greater likelihood of awareness or recall (e.g., light anesthesia or history of such complaints) it will be more difficult to defend a decision not to use the BIS monitor if it is available.

Preventing Awareness Claims

PPM recommends that policyholders include the risk of awareness on their anesthesia consent forms. Patients at increased risk of awareness based on personal history and/or planned procedure should be identified during the pre-anesthesia evaluation. Patients reporting awareness should be addressed directly and frankly. "In several cases, patients who have filed awareness claims have expressed anger that their complaints of awareness were not taken seriously," according to Shelley Strome, PPM Senior Claims Specialist. PPM policyholders are encouraged to acknowledge that, albeit very rare, awareness does occur. Patients should also be offered a referral for counseling or psychological support. PPM recommends further that the PPM policyholder send the patient a letter acknowledging the reported awareness, describing the anesthetic that was administered and advising the patient to provide a copy of the letter to any future anesthesia providers. PPM's in-house attorneys are prepared to assist PPM policyholders in drafting appropriate letters to send to patients who have reported awareness. Finally, policyholders should also report any complaints of awareness to PPM.

Visit PPMRRG.com

PPM's updated website provides PPM policyholders with up-to-the-minute news, an events schedule and access to our risk management newsletter, *Anesthesia & the Law*. There is also a secure area on the website for the exclusive use of our policyholders. In this restricted area, policyholders have access to an archive of *Anesthesia & the Law*, recommended forms and protocols, discussion papers referencing "hot topics" in anesthesia and other timely risk management materials. PPM policyholders should visit the MyPPMrrg area of the website to obtain their personal password. ❖

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ANESTHESIA & the
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ISSUE 20

In This Issue

Intraoperative awareness continues to be a topic addressed in many published articles and sensationalized by the media and Hollywood. The incidence of awareness continues to be debated in recent literature and media reports and has been further fueled by manufacturers of brain function monitors. However, a retrospective review of PPM's claim data suggests the actual incidence of intraoperative awareness may be much lower than reported. In this issue, we examine the types of awareness cases reported to PPM and the efficacy of brain function monitors in reducing or preventing intraoperative awareness. Finally, we offer some risk management advice on how to address the issue of intraoperative anesthesia awareness preoperatively and in the event a patient reports this serious, but rare, adverse outcome.

Thanks for reading,

A handwritten signature in blue ink, appearing to read 'Brian J. Thomas', is written over a horizontal line.

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.

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