LEGAL BRIEFS

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Awareness

Key words: Awareness, informed consent, standard of care.

While attending the 2005 Assembly of States, 2 events occurred that made me feel it was time to address the legal aspects of anesthesia awareness. During one of the sessions on patient safety, I heard a very interesting conversation concerning awareness involving a hospital that had purchased monitors but was not using them. In addition, the American Association of Nurse Anesthetists (AANA) Board of Directors adopted a formal position statement that amplified its present awareness policy by adopting 5 practices on awareness that should be included in any policy concerning awareness.

The AANA has been a leader on the issue of anesthesia awareness. In 2000, the Council for Public Interest in Anesthesia presented its annual award to Jeanette Liska, PhD, the president and founder of A.W.A.R.E., a nonprofit foundation dedicated to public education and support for research in the area of awareness during anesthesia. Dr Liska must have been touched to receive recognition from a professional society in the very field she hoped to educate. Five years later, Dr Liska's receipt of the Council's award is still prominently featured on A.W.A.R.E.'s website (http://www.aware4life.com/about.html). Dr. Liska's book, *Silenced Screams – Surviving Anesthetic Awareness During Surgery: A True-life Account*, was published in 2002 by a subsidiary of the AANA as a means to publicize the problem and to focus attention of anesthesia providers on awareness. In 2004, the AANA worked with the Joint Committee on Accreditation of Healthcare Organizations (JCAHO) and the American Society of Anesthesiologists on the topic, resulting in JCAHO's issuance of a Sentinel Event Alert. In April 2005, the AANA issued its first formal statement on awareness, suggesting that policies be adopted at an institutional level and providing a model policy that raised the relevant issues to be addressed. At its meeting in November 2005, the AANA Board of Directors adopted a more specific policy on awareness developed by the Ad Hoc Task Force on Awareness with input from the Practice Committee.

The policy is well worth reading in its entirety, and it urges institutions to adopt policies on awareness that include the following essential practices:*

- During preanesthesia assessment, the risk of awareness should be assessed, and those risks should be discussed during informed consent.
- Proper function of all anesthesia equipment should be verified in order to ensure delivery of anesthetic agents to the patient.
- If appropriate, the anesthesia care plan should include pharmacologic agents, anesthesia techniques, and patient monitoring techniques considered beneficial in reducing the incidence of unintended awareness.
- Brain function monitoring, if available, should be considered, particularly in situations where the risk of intraoperative awareness is increased.
- Patients should be appropriately assessed to identify possible occurrence of unintended awareness. Any such cases should be promptly managed to minimize the potential for psychological injury.

Kiljian v Grimes

How have the courts treated awareness? Unfortunately, while there undoubtedly have been cases involving awareness at the trial court level, so far as I can tell, only 1 case involving awareness has been decided at an appellate court level where decisions are available to the public. In *Kiljian v Grimes* (2003 WL 22455969 (Cal. App 2 Dist., unpublished), the concerns about awareness were disposed of procedurally rather than substantively. The plaintiff had claimed that she experienced surgical awareness during a gallbladder operation in March 2001 and had suffered extreme pain and suffering. She brought suit against the anesthesiologist and the hospital, alleging that the anesthesiologist had negligently provided medical treatment. She also claimed that by failing to advise her of the

*** Position Statement 2.12, Unintended Awareness Under General Anesthesia, approved by the AANA Board of Directors, November 10, 2005.)**

risks of awareness, the anesthesiologist had failed to inform her of the risks of general anesthesia and had not properly obtained her informed consent for the operation. The plaintiff had not offered expert testimony, and the trial court had dismissed the case.

There are at least 2 ways in which the issue of awareness could come up in court. First, as illustrated by the *Grimes* case, a patient could claim that the failure to explain awareness when obtaining informed consent negates the consent. Where valid consent has not been obtained, an injury, including the damage caused by an incident of awareness, could result in liability of the anesthesia provider. Dr Grimes, the anesthesiologist, had attempted to excuse his failure to discuss awareness by arguing that awareness occurred so rarely that it did not need to be disclosed. The plaintiff had not presented expert testimony as to whether awareness had to be disclosed, and the trial court had dismissed the suit. On appeal, the trial court's decision was upheld.

We have often noted that anesthesia is a profession, an area that the courts have determined requires special education, skills, and knowledge that ordinarily, courts and juries lack. The hallmark of a profession, from a legal standpoint, is that the profession sets its own standard of care and when the judicial system needs to know what that standard is, or how it applies to specific circumstances, it obtains expert testimony from members of the profession regarding the standard of care. Informed consent had its origin in the legal concept of "assault and battery." A battery is any physical contact without consent with another person. By its very nature, every surgery, absent consent, is a battery. Since practitioners all had to obtain consent before operating, issues of how consent was to be handled, what was to be disclosed, and what did not have to be disclosed were, in general, left to the professional judgment of the practitioner. Informed consent became another professional obligation, the satisfaction of which could be judged against the professional standard. For many years, the standard for disclosure of informed consent was set by the profession. Leaving the standard for disclosure entirely in the hands of practitioners had its drawbacks, and exceptions developed. There is an important exception to the ability of the profession to set the standard of disclosure and that exception is that risks of death, serious injury, or significant complications that would be material to a patient's decision must be disclosed regardless of the custom in the profession.

In the *Grimes* case, the plaintiff had failed to offer expert testimony as to whether awareness was one of the risks to be disclosed to obtain a valid informed consent. The anesthesiologist and the hospital presented expert declarations that the incidence of surgical awareness was so rare that it need not be disclosed to, or discussed with, a patient in order to conform to the standard of care for informed consent. The plaintiff acknowledged that she had not presented expert evidence, but she argued that awareness was an area where the law does not require expert testimony. She asserted that awareness was so significant a complication and was so material to a patient's decision that it had to be disclosed, regardless of the custom in the profession. Apparently, the plaintiff's claims went beyond the argument that awareness was so significant and material that it had to be disclosed. She also claimed she was never advised of the specific risks of death or serious injury. This claim lacked credibility because she had signed 2 consent forms in which she acknowledged that "all operations and procedures involve risks of complications, injury, or death." The trial court granted summary motion because the plaintiff had failed to present expert testimony that the disclosure of the risk of surgical awareness in informed consent was required by the standard of care. Judgment was entered for the anesthesiologist, and the hospital and the patient appealed to the California Appellate Court. The appellate court not only dismissed the appeal but also awarded costs to the anesthesiologist, a signal that it thought the plaintiff's appeal was without merit. The opinion in the *Grimes* case is "unpublished." This means it is not to be relied on as authority in the California courts. Even if it had been published, I doubt that it could it be relied on.

As the *Grimes* case shows when the court refused to decide the issue without expert testimony, what has to be disclosed to obtain informed consent is normally a professional judgment made by anesthesia providers and not the legal profession. Nonetheless, I think I can observe that, in general, what the profession has decided to disclose is based on a calculation incorporating 2 things: the frequency with which something occurs and the seriousness if it does occur. The greater the frequency and the greater the seriousness, the more likely the profession is to require disclosure. For example, death as an anesthesia risk is very small. The generally accepted frequency is 1 in 250,000. Yet, it is routinely disclosed as an anesthesia risk because it has a high measure of seriousness. If a broken tooth occurred with the same frequency, I doubt that anyone would bother disclosing it.

How would awareness fit in the calculation? In the view of some

anesthesia personnel, awareness is merely one more creation of a media already too focused on the negative side of anesthesia. There does seem to be a lot of media attention. As stated in *Silenced Screams*, Dr Liska has appeared on the Oprah Winfrey show, Dateline, The Leeza Show, Inside Edition, Extra, Tom Snyder Show, 20/20, and ABC, CBS, and NBC National News. She also has been featured in popular national print media, such as *People, Time, US News* and *World Report, Allure,* and *Redbook*. Some anesthesia personnel have viewed the media's interest as "overkill" or attempts to sell awareness monitors. In fact, the media attention is evidence of the public's view of the seriousness of awareness. For layman, the prospect of being aware during anesthesia and unable to communicate or move is as frightening as anything that can be imagined. An awareness strategy of waiting for the "hype" to blow over does not appear to be a sound strategy. Patients view awareness as very serious.

What about frequency? In the *Grimes* case, expert testimony said awareness arose so rarely as not to require disclosure. Awareness, as an anesthesia issue, dates back at least to 1993 when Jeannette Liska (then "Tracy") organized A.W.A.R.E. to bring attention to the issue. There had already been a fair amount of media attention when Dr Liska received the Council for Public Interest in Anesthesia award in 2000. I do not know what anesthesia personnel believed the frequency of awareness was in 2001 and 2003 when the *Grimes* case arose and was decided. However, in October 2004, JCAHO, after conferring with the AANA and the ASA, issued a Sentinel Event Alert on awareness and indicated that the frequency of anesthesia awareness had been found to range between 0.1% and 0.2%. The AANA has agreed with the estimate, but warned that there were no precise figures available. In October 2005, the ASA issued its own alert using the same figures as JCAHO. The ASA's alert also stated "[u]nintended Awareness under general anesthesia is rare.…" I have my doubts as to whether something that occurs at least once or twice in every thousand cases can be considered "rare." But, then, the issue is not what I think and, despite the fact that anesthesia personnel are professionals and set their own standard of care, the issue may not even be what anesthesia personnel think.

When deciding whether the risk of awareness is so "rare" that it need not be disclosed in informed consent, you must consider the context in which the question will arise. For 999 or 998 patients out of 1,000 the issue probably will not come up at all. But for 1 or 2 cases out of 1,000, the patient has gone through every surgical patient's nightmare, and a jury of layman, not CRNAs and not anesthesiologists, has to decide if the horror experienced by this plaintiff (and more than 25,000 other patients in the United States each year) is so rare as to justify its deletion from the informed consent process. Whether or not a court could be convinced in 2001 that awareness occurred too rarely to justify disclosure, I would strongly suggest that disclosure of the risk of awareness must now be a part of every anesthesia informed consent process. This conclusion is also found in the AANA's recent policy statement on Unintended Awareness Under General Anesthesia.

Are monitors necessary?

The other way in which awareness can affect the practice of anesthesia is even more complicated. What acts should anesthesia personnel follow when administering anesthesia to avoid awareness? Are monitors necessary? Rarely have I seen the anesthesia community so lacking in consensus as I do about the need for monitors to prevent awareness. JCAHO introduced the topic and then concluded:

> These devices may have a role in preventing and detecting anesthesia awareness in patients with the highest risk, thereby ameliorating the impact of anesthesia awareness. A body of evidence has not yet accumulated to definitely define the role of these devices in detecting and preventing anesthesia awareness; the Joint Commission expects additional studies on the subjects to emerge.

The AANA in considerations issued in April 2005 suggested only that:

> Anesthesia practitioners will consider utilizing a consciousness monitor, particularly in all clinical situations that place a patient at increased risk for intraoperative awareness..., mask the patient's ability to show physiologic (blood pressure, heart rate) or somatic (movement) responses to inadequate anesthesia...or utilize a primary intravenous anesthetic technique.

The AANA also pointed out that not all devices being sold as consciousness monitors have been studied for their effectiveness in reducing the incidence of anesthesia awareness. The ASA's recent, October 2005, announcement stated that "the decision to use a brain function monitor should be made on a case-by-case basis by the individual practitioner for selected patients." At the same time, the ASA House of delegates passed a recommendation that "ASA study funding further research into the usefulness of brain function monitoring technology in minimizing the risk of intraoperative Awareness."

Obviously, all of the major standard setters in this area suggest no more than that individual practitioners or institutions *consider* the use of monitoring devices. To some extent, this has reflected the absence of reliable studies that these monitors do, in fact, reduce the incidence of awareness. While the maker of one monitor has pointed to a study that it claims shows an 80% reduc-

tion in awareness, standard setters seem intent on collecting additional data after further studies before recommending monitoring.

Washington Hospital Center v Washington

So, while the profession makes up its mind, what is the individual practitioner to do? First, if awareness is the dreaded nightmare of patients undergoing anesthesia, then, practitioners should consider the *Washington* case. In *Washington Hospital Center v Washington* (579 A. 2d 177, DC Ct of App, 1990), the plaintiff sued a hospital for failing to use end-tidal CO_2 monitors to diagnose a misplaced tracheal tube. The hospital's defense was that, in 1987, the time of the operation, end-tidal CO_2 monitors were not the standard of care and the hospital's failure to provide them was not malpractice. Now, in fact, end-tidal CO_2 monitors were not the standard of care in 1987. Pulse oximeters were just coming into use, and it would be several more years before end-tidal CO_2 monitors would come into widespread use. But this was a jury case, and the jury could only react to the evidence presented. The experts testified that the University of Southern California Medical Center had been using the devices since 1985, 2 publications said the devices were available in other hospitals, and in August 1986, the *Journal of the American Medical Association* called the monitors "an emerging standard of care." The other factors that the appellate court relied on to uphold the jury verdict were that the defendant hospital's own expert (selected from a major medical center to bolster his credibility as an expert) had testified on cross examination that his hospital used end-tidal CO_2 monitors in 1987. His testimony that end-tidal CO_2 monitors were *not* the standard of care in 1987 was apparently outweighed by his institution's actual practice. However, the most damaging evidence of all was that the chairman of the anesthesia department of the defendant, Washington Hospital Center, had placed an order for end-tidal CO_2 monitors to "meet the standard of care," but they were not yet installed when the plaintiff had her operation.

When I have previously discussed the *Washington* case, I have pointed out that its meaning for healthcare practitioners is large. Even though standards are set by the profession, identifying the standard once it is set by the profession is a job for a jury that draws its conclusions from the often conflicting evidence presented to it and makes its decisions as best it can. The jury's conclusion based on the evidence becomes the law of the case. It is not submitted to the profession for its concurrence.

Conclusion

What does this suggest about awareness? Well, not necessarily that everyone has to go out and buy monitors. (It does suggest that if you own monitors, you probably ought to be using them, especially for high risk awareness cases.)

Awareness has now reached a level where we know that it is there; we know that it happens but there is, as yet, no "magic bullet," no remedy that the profession believes will guaranty that it can be prevented or that it can be accurately identified and, therefore, eliminated. Briefly, my advice would be to first become informed. The AANA's policies are a good place to start. The JCAHO Sentinel Event Alert also would be helpful. Both AANA and JCAHO recommend that institutions develop policies on awareness. The AANA's "Considerations for Policy Development," adopted in April 2005, should be required reading. Inclusion of the essential practices identified in Position Statement 2.12 – Unintended Awareness Under General Anesthesia is a welcome addition.

Remember the *Washington* case! Make decisions as to what to do with one eye on your potential liability. When writing your policy on awareness, assume one of your patients has had an episode of awareness and you are explaining to a jury why the actions you took were appropriate and why you thought these actions were going to eliminate awareness. I do not think you want to tell a jury that you made no effort to avoid awareness because you thought it was media hyperbole.

Make sure your institution's policy addresses the issues raised by the AANA in April 2005 and incorporates the essential practices adopted by the AANA Board of Directors in November 2005. You still have to make up your own mind about the need to use a monitoring device. But decide one way or the other. What you do not want to do is to buy the devices (a sign you thought they were a good idea) and then not use them. If you have them and decide they are not helpful then either get rid of them or use them in situations where they are helpful. Just remember how difficult it was in the *Washington* case to prove that something was not the standard of care, especially if it later becomes accepted as the standard of care. But most important of all, your policy and your actions must be consistent. Nothing gets the attention of a jury faster than policies that are supposed to protect patients that are not followed.