PPM ANESTHESIA MALPRACTICE INSURANCE

ANESTHESIA & the LAW

A RISK MANAGEMENT NEWSLETTER

PREFERRED PHYSICIANS MEDICAL RISK RETENTION GROUP, INC.

ISSUE 16

Informed Consent: The Verdict Is In

Steven R. Sanford, J.D.

While the anesthesiology community continues to debate the importance and manner in which informed consent is documented, from a liability standpoint, the verdict is in: Anesthesiologists should implement an anesthesia-specific written informed consent.

From the vantage point of handling almost 3,000 litigation files during the last 20 years, our perspective as a malpractice insurance carrier is more than theoretical. Firsthand litigation experience underscores the need for a more considered approach to anesthesia informed consent. Continuing to debate the merits of adopting an anesthesia-specific consent form promotes the status quo and contributes to the specialty's lack of progress in implementing this important risk management strategy.

At the outset, it is worth noting that no amount of documentation will provide an absolute shield to litigation. Effectively engaging patients in their own health care through the informed consent process, however, may be one of the most practical steps in reducing the likelihood of litigation.[1] In addition, to the extent litigation occurs, implementation of an appropriate informed consent will substantially reduce the effectiveness of one tactical weapon in plaintiff attorneys' litigation arsenal.

The importance of informed consent in litigation is typically understated by the available statistical data. According to the ASA's Closed Claims Study, allegations of improper informed consent created a liability issue in a mere one percent of cases reviewed.[2] Our own litigation statistics demonstrate that informed consent was the central theory of recovery in only eight of 2,422 closed files.[3] These statistics fail to reflect, however, the importance that informed consent plays as a litigation strategy or as a factor in the evaluation and resolution of anesthesia malpractice litigation. In a significant number of cases, the adequacy of informed consent is included as an additional allegation, identified as a concern by defense counsel or criticized by an expert witness, and thereby influences the evaluation, defense and resolution of anesthesia malpractice litigation.[4]

Rather than focus on the rarity of true informed consent litigation, we should acknowledge that informed consent is an issue routinely included in anesthesia malpractice litigation.

Plaintiff attorneys handling medical malpractice litigation are highly organized and coordinated. As a group, plaintiff attorneys share information and collectively develop litigation strategies. The routine inclusion of informed consent allegations should, at the very least, suggest a perceived weakness in the practice of anesthesia that plaintiff attorneys believe can be exploited in the litigation environment. Lack of informed consent, while not the primary theory of recovery, is nonetheless an important strategic allegation.

Plaintiff attorneys utilize informed consent issues as a tactic to undermine a jury's confidence in the quality of the anesthesia care provided, eroding the jury's confidence in the skill, training and professionalism of the anesthesia providers. Typically plaintiff attorneys will use a poorly documented informed consent to suggest the anesthesiologist was less than thoughtful in the development of the anesthesia plan, failed to appreciate significant risks or was paternalistic and unwilling to engage the patient in a meaningful discussion regarding the selection of an appropriate anesthetic. The plaintiff attorney also may use an absence of detail to challenge the anesthesiologist's professionalism and compassion by suggesting that the anesthesiologist was more concerned with making money or in keeping to the surgery schedule. Plaintiff attorneys routinely use these lines of questioning to appeal to an individual juror's own dissatisfaction with the health care system, exploiting the perception that physicians are overscheduled and disengaged from their patients.

Shifting the jury's focus to informed consent is an all-too-common and successful method of influencing the jury's perception on the more complex and challenging medical issues presented by the litigation. To the extent that the plaintiff's attorney is able to shift the focus, the attorney defending the anesthesiologist will then be required to use valuable trial time to rehabilitate the anesthesiologist with respect to informed consent. A thoughtful, well-documented informed consent removes this tactic from the plaintiff's arsenal and allows the defense to focus its effort on defending the key medical issues.

With this litigation strategy in mind, let us review the alternative approaches that anesthesiologists typically utilize to document informed consent.

Notes

While still utilized by a number of anesthesia practices, reliance on handwritten notes to document informed consent lacks sufficient detail to assist in the defense of most malpractice litigation. The absence of detail requires both parties to the litigation to rely on distant recollections of the informed consent discussion. Statutes of limitation in most jurisdictions allow litigation to be filed up to two years after treatment, even longer in certain situations. Credibility can be severely strained when an anesthesiologist testifies to having a detailed recollection of the informed consent discussion. The alternative is to rely on the anesthesiologist's usual custom and practice to convey what is typically discussed in terms of the risk. Neither approach is very persuasive, and the jury is more likely to consider an alternative version of events offered by the injured patient.

Hospital or Surgical Consent

Other anesthesia practices continue to rely on hospital or surgical consent forms. In our review, such forms are generally so generic that they provide little legal protection. In managing the length of such documents, facilities typically edit any detailed discussion of anesthesia risks. In crafting a comprehensive informed consent, one can anticipate that the hospital's first order of business is to adequately address its own liability concerns. Anesthesia issues are frequently reduced to a couple of sentences that provide no more protection than a cursory handwritten note.

Anesthesia Consent Form

An anesthesia-specific consent form provides the best methodology for documenting the informed consent discussion. Format and content may vary depending on the anesthesia practice, but in general, our litigation experience suggests a one-page[5] document that identifies all the significant risks of anesthesia and provides some specific information regarding the available anesthetic choices. Informed consent documents that permit the anesthesiologist to direct the patient's attention to a particular anesthetic technique can help to overcome arguments that the patient had insufficient time to review the entire document. Adopting a standardized anesthesia-specific informed consent provides the most effective evidence that each anesthesiologist within a practice has provided the necessary level of informed consent.

Once an anesthesia-specific consent form is implemented, anesthesiologists should be encouraged to circle or highlight specific risks that may be present. Notations reflecting efforts to tailor the informed consent discussion to a specific patient create powerful evidence of engaging the patient in a meaningful discussion that supports, rather than distracts from, the defense of the underlying medical issues.

References:

1. Levinson W. Physician-patient communication: The relationship with malpractice claims among primary care physicians and surgeons. *JAMA*. 1997; 277(7):553-559.
2. Caplan RA. Informed consent: Patterns of liability from the ASA Closed Claims Project. *ASA Newsl*. 2000; 64(6):7-9.
3. Preferred Physicians Medical's review of closed litigation files identified 6 cases where "informed consent" was the primary allegation and two additional cases involving allegations of "battery" related to a failure to obtain an appropriate consent.
4. Preferred Physicians Medical conducted a preliminary review of approximately 325 closed files based on a reference to "informed consent" in the analysis fields. Further study of the role of informed consent in the evaluation and outcome of these and other files was not possible prior to the deadline for this article.

5. One-page informed consents are generally less susceptible to arguments that an average patient was unable to comprehend the document or given insufficient time. In addition, multi-page documents increase the likelihood that signatures will be overlooked or that the signature page will become separated or lost, or doubt cast on whether the patient reviewed all pages of the consent.

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Defense Verdict: New York Jury Finds in Favor of Pain Management Specialist

Preferred Physicians Medical (PPM), industry-leading provider of anesthesia malpractice insurance, successfully defended litigation filed against a New York policyholder.

The patient, a 43-year-old female, presented to her neurosurgeon complaining of pain and numbness of her right foot and ankle following a motor vehicle accident. Her neurosurgeon diagnosed the patient as suffering from RSD (Reflex Sympathetic Dystrophy) and referred the patient to a PPM pain management specialist who administered several lumbar blocks over the next two months, which provided the patient with temporary pain relief. In consultation with the patient, the PPM pain management specialist recommended and performed a radio-frequency rhizotomy.

In her lawsuit, the patient alleged the rhizotomy caused the RSD to spread throughout her body, eventually leading to severe back pain along with pain and numbness in her right thigh. Additionally, the patient claimed her RSD eventually spread up to her right pelvis and thereafter to her left leg and left arm. According to the patient, PPM's pain management specialist was negligent in the performance of the rhizotomy procedure and failed to provide appropriate follow-up treatment. The patient further alleged that PPM's pain management specialist had not adequately informed her of the risks and alternatives to the procedure.

A demand for settlement of $1.7 million was made to PPM prior to trial. During the course of the trial, this demand was eventually lowered to $900,000. PPM's pain management specialist, in consultation with PPM and defense counsel, refused to consent.

Plaintiff's expert witnesses were identified as anesthesiologists Alexander Weingarten, MD and Charles Argoff, MD. Dr. Weingarten, a pain management specialist, testified the radio-frequency procedure was contraindicated because the patient had experienced "seizure-like" episodes following four of the lumbar sympathetic blocks. Dr. Weingarten claimed these episodes indicated an unusually sensitive sympathetic nervous system, which increased the likelihood of negative consequences from the rhizotomy. Dr. Weingarten also testified that five to ten percent of RSD patients experience a spread of their RSD following rhizotomy. On cross-examination, Dr. Weingarten was unable to furnish any source for these percentages and conceded that he was providing an estimate. Lastly, Dr. Weingarten insisted that given the potential complications it was imperative to offer alternatives to the performance of the rhizotomy, including a Bier block or intravenous Lidocaine.

Dr. Argoff, initially identified by the patient's attorney as one of their experts, indicated on the eve of trial that he did not wish to testify on the patient's behalf. Nevertheless, the patient's attorney subpoenaed Dr. Argoff and forced him to appear. During his testimony, Dr. Argoff acknowledged that RSD patients are difficult to manage, and even under the best medical care there is no assurance that the patient's condition will improve and may even worsen.

PPM's expert witnesses included both a neurologist and an anesthesiologist specializing in pain management. PPM's neurology expert testified that the patient's shaking episodes did not constitute "seizure-like" activity and that such shaking may have reflected a sensitivity to the narcotic, patient anxiety or shivering. PPM's pain management expert testified that in his practice patients often experience shaking after receiving lumbar blocks, but that such a finding is irrelevant in determining whether or not to perform a radio-frequency rhizotomy. As for the issue of informing the patient of alternatives to the rhizotomy, PPM's pain management expert testified that the only viable alternative to radio-frequency rhizotomy in this case was to implant a spinal cord stimulator. According to the expert, in presenting this alternative, the patient would need to be informed that implanting a stimulator carried a higher risk of complication than the rhizotomy.

Although rarely the central theory of an anesthesia or pain management case, informed consent can become a major focus of the jury's deliberation as it was in this case. Under New York law, in order for the jury to find a lack of informed consent, the jury must conclude that the physician did not disclose, in sufficient detail, the risks and alternatives of the procedure. Additionally, the jury must find that a "reasonably prudent person" in the patient's position would have declined to undergo the procedure had the risks and alternatives been properly disclosed. Lastly, the jury must determine whether the failure to disclose the risks and alternatives contributed to the injury suffered.

After about four hours of deliberation, the jury returned a unanimous defense verdict in favor of PPM's pain management specialist. The jury found in favor of PPM's pain management specialist both with respect to the claims of negligence in performing the rhizotomy and in failing to provide appropriate follow-up care. With respect to the issue of informed consent, the jury concluded that PPM's pain management specialist did not provide informed consent as required by law. The jury, however, went on to conclude that a reasonably prudent person would have still undergone the procedure had sufficient informed consent been given, and accordingly the patient was not entitled to recover damages.

After the verdict, PPM filed a motion to recover costs from the plaintiff.

Joyce Rogak of the Rogak & Gibbons law firm in East Meadow, NY, served as defense counsel. Wade Willard, Senior Claims Attorney, managed the claim file on behalf of PPM. ❖

Visit PPM's New Website

In conjunction with our upcoming 20th anniversary, PPM is launching its new updated company website, www.ppmrrg.com. In addition to providing an overview of PPM's operations, the revised website will provide PPM policyholders with up-to-the-minute news, an events schedule and access to our risk management newsletter, *Anesthesia & the Law*.

We are also in the process of creating a secure area on our website for the exclusive use of our policyholders. In this restricted area, policyholders will have access to an archive of *Anesthesia & the Law*, discussion papers referencing "hot topics" in anesthesia and other timely risk management materials. ❖

Implementing an Effective Anesthesia Consent Form

Over the years, PPM has reviewed hundreds of anesthesia consent forms and while one-size rarely fits all, our litigation experience provides important guidance on the elements of an effective anesthesia consent form. A detailed discussion of these elements is available in the online edition of this newsletter available at www.ppmrrg.com.

An effective informed consent process requires more than merely asking a patient to sign a consent form. Informed consent is a process that contemplates engaging the patient in a discussion about his/her own medical treatment and accurately documenting this conversation in the medical record. A standardized anesthesia consent form provides an excellent starting point for meeting both goals; providing both a template for the informed consent discussion and serving as documentation.

While any standardized informed consent form should be tailored to reflect the group's specific practice environment, for the majority of hospital-based practices, PPM endorses the use of a standardized anesthesia consent form similar to the model form included in this newsletter.[1] In PPM's experience this single page document effectively meets each of the typical litigation arguments PPM encounters in defending anesthesia litigation.

References:

1. The anesthesia consent form included in this newsletter is one of many similar versions submitted to PPM over the years by its policyholders. PPM routinely reviews and modifies these model documents to reflect the most current trends in anesthesia losses. ❖

Consent For Anesthesia Services

I, _____, have been scheduled for _____ surgery. I understand that anesthesia services are needed so that my doctor can perform the operation or procedure.

It has been explained to me that all forms of anesthesia involve some risks and no guarantees or promises can be made concerning the results of my procedure or treatment. **ALTHOUGH RARE, SEVERE UNEXPECTED COMPLICATIONS CAN OCCUR WITH EACH TYPE OF ANESTHESIA, INCLUDING THE POSSIBILITY OF INFECTION, BLEEDING, DRUG REACTIONS, BLOOD CLOTS, LOSS OF SENSATION, LOSS OF VISION, LOSS OF LIMB FUNCTION, PARALYSIS, STROKE, BRAIN DAMAGE, HEART ATTACK OR DEATH.** I understand that these risks apply to **ALL** forms of anesthesia and that additional or specific risks have been identified below as they may apply to a specific type of anesthesia. I understand that the type(s) of anesthesia service checked below will be used for my procedure and that the anesthetic technique to be used is determined by many factors including my physical condition, the type of procedure my doctor is to do, his or her preference, as well as my own desire. It has been explained to me that sometimes an anesthesia technique that involves the use of local anesthetics, with or without sedation, may not succeed completely and therefore another technique may have to be used including general anesthesia.

☐ General Anesthesia	Expected Result	Total unconscious state, possible placement of a tube into the windpipe.
	Technique	Drug injected into the bloodstream, breathed into the lungs, or by other routes.
	Risks (include but not limited to)	Mouth or throat pain, hoarseness, injury to mouth or teeth, awareness under anesthesia, injury to blood vessels, vomiting, aspiration, pneumonia.
☐ Spinal or Epidural Analgesia/ Anesthesia ☐ With sedation ☐ Without sedation	Expected Result	Temporary decreased or loss of feeling and/or movement to lower part of the body.
	Technique	Drug injected through a needle/Catheter placed either directly into the fluid of the spinal canal or immediately outside the spinal canal.
	Risks (include but not limited to)	Headache, backache, buzzing in the ears, convulsions, infection, persistent weakness, numbness, residual pain, injury to blood vessels, "total spinal."
☐ Major/Minor Nerve Block ☐ With sedation ☐ Without sedation	Expected Result	Temporary loss of feeling and/or movement of a specific limb or area.
	Technique	Drug injected near nerves providing loss of sensation to the area of the operation.
	Risks (include but not limited to)	Infection, convulsions, weakness, persistent numbness, residual pain requiring additional anesthesia, injury to blood vessels, failed block.
☐ Intravenous Regional Anesthesia ☐ With sedation ☐ Without sedation	Expected Result	Temporary loss of feeling and/or movement of a limb.
	Technique	Drug injected into veins of arm or leg while using a tourniquet.
	Risks (include but not limited to)	Infection, convulsions, persistent numbness, residual pain, injury to blood vessels.
☐ Monitored Anesthesia Care (with sedation)	Expected Result	Reduced anxiety and pain, partial or total amnesia.
	Technique	Drug injected into the bloodstream, breathed into the lungs, or by other routes, producing a semi-conscious state.
	Risks (include but not limited to)	An unconscious state, depressed breathing, injury to blood vessels.
☐ Monitored Anesthesia Care (without sedation)	Expected Result	Measurement of vital signs, availability of anesthesia provider for further intervention.
	Technique	None.
	Risks (include but not limited to)	Increased awareness, anxiety and/or discomfort.

I consent to the anesthesia service checked above and authorize that it be administered by ANESTHESIA GROUP, INC. through an anesthesia care team, including Certified Registered Nurse Anesthetists under the supervision of an Anesthesiologist, all of whom are credentialed to provide anesthesia services at this health facility. I also consent to an alternative type of anesthesia, if necessary, as deemed appropriate by the anesthesia care team.

I understand the importance of providing my health care providers with a complete medical history, including the need to disclose any medications that I am taking, both prescription and over the counter. I also understand that my use of herbal remedies, alcohol or any type of illegal drug may give rise to serious complications and must also be disclosed. I further understand that I should also disclose any complications that arose from past anesthetics.

I acknowledge that I have read this form or had it read to me, that I understand the risks, alternatives and expected results of the anesthesia service and that I had ample time to ask questions and to consider my decisions.

_____ _____

Patient's Signature *Date and Time*

_____ _____ _____

Anesthesia Care Team's Signature *Substitute's Signature* *Relationship to Patient*

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In This Issue

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Thanks for reading,

Steven Sanford, 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.