Caplan, RA: Informed Consent: Patterns of Liability from the ASA Closed Claims Project. *ASA Newsletter* 64(6):7-9, 2000.

Full Text

Informed consent is considered a basic feature of preanesthesia evaluation. Little is known, however, about the impact of informed consent on anesthesia liability. The database of the ASA Closed Claims Project offers an opportunity to explore this issue.

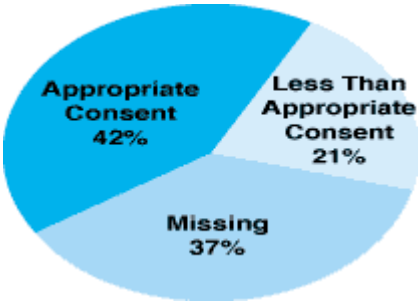
The Closed Claims Project is an in-depth study of claims against anesthesiologists based upon data collected from the files of 35 professional liability insurance carriers in the United States.[1] The project is conducted under the auspices of the ASA Committee on Professional Liability. Since the inception of the project in 1985, more than 4,400 claims have been collected.

Basic Features

Examination of the database reveals two basic features of informed consent. First, informed consent is rarely a liability issue, and second, when the quality of informed consent can be assessed in the claim file, it is usually considered appropriate.

Informed consent was a liability issue in 45 of 4,459 claims, or just 1 percent in the overall database. In the remaining 4,414 claims (99 percent), informed consent was not a liability issue. Reviewers were able to make a determination of the appropriateness of informed consent in 2,772 of 4,414 database claims (63 percent). Information about appropriateness of informed consent was not available in 1,642 claims (37 percent). Judgments about appropriateness of informed consent were based upon the reviewer's assessment of what a reasonable and prudent practitioner would do under the same or similar circumstances at the time of the event.

As shown in Figure 1, informed consent was considered appropriate in 42 percent of database claims, less than appropriate in 21 percent of claims and not assessable due to missing data in 37 percent of claims.



Appropriate Consent

When informed consent was considered *appropriate*, issues related to consent itself were rarely a factor in litigation. Reviewers considered informed consent to be appropriate in 1,881 claims. Within this group of 1,881 claims, informed consent was cited as a factor in litigation in 22 cases, or 1 percent. Two specific patterns of liability were identifiable.

The first pattern involved five claims in which a specific patient request was ignored by the anesthesiologist. For example, two patients requested that no resident be involved in anesthesia care, but the request was not honored. Postoperative complications developed in both cases. Although the complications were not convincingly related to anesthesia care, both patients sued and received sizable payments ($300,000 and $400,000). These cases serve as a reminder that failure to honor a request can provide an important stimulus for litigation.

The second pattern involved five cases in which the patient was not informed of a specific complication or there was an unexpected change in the conduct of anesthesia or surgery. For example, one patient alleged that she had not been informed of the risk of pneumothorax during intercostal block, even though this risk was documented by the anesthesiologist and corroborated by a nurse. This claim resulted in a payment of $26,000. In another case, general anesthesia was abandoned when unanticipated difficulty was encountered during intubation; the procedure was conducted uneventfully using local anesthesia and

sedation. In the postoperative period, the patient experienced emotional difficulty attributed to the unexpected change in anesthesia care. Settlement resulted in a payment of $7,500. These cases underscore the importance of explicitly mentioning and documenting a range of risks and educating the patient about the unpredictable course of perioperative events and the possibility that alternative approaches may be required.

Less-Than-Appropriate Consent

Even when informed consent is *less than appropriate*, consent itself seemed to play a relatively minor role in litigation. In the group of 929 claims in which informed consent was less than appropriate, consent was a factor in litigation in only 16 cases, or 2 percent. Two specific patterns of liability were identifiable.

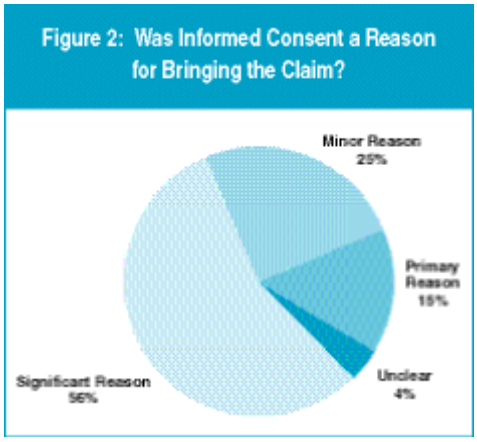
The first pattern involved six claims in which there was *no* evidence that informed consent was obtained or documented. One of these cases was dismissed. The other five cases were associated with payments ranging from $12,500 (for temporary back pain, neck pain and diplopia following an epidural for labor analgesia) to $1 million (for brain damage following cardiac arrest in a young, healthy patient receiving lumbar epidural anesthesia for arthroscopy).

The second pattern involved four cases in which the patient did not receive an adequate explanation of potential complications. All of these cases resulted in payments ranging from $6,500 to $1.5 million. Of note, two cases in this group involved failure to use an interpreter for patients with limited ability to understand English.

Liability Profile

Physicians often ask if informed consent plays an important or independent role either in the pursuit or outcome of malpractice suits.

From the standpoint of pursuit, Figure 2 shows that informed consent was identified as a significant reason but not the only reason for bringing a suit in 56 percent of the 45 claims in which consent was identified as a liability issue. In 25 percent of these claims, consent was a *minor* factor. In only 15 percent of claims was consent identified as the *primary* reason for pursuing a suit. It should be noted that claims with less than appropriate consent were also associated with overall, less-than-appropriate anesthesia care. Claims with appropriate informed consent were associated with appropriate anesthesia care.



From the standpoint of outcome, in eight of the 22 claims (36 percent) in which informed consent was appropriate, documentation of consent was identified as a significant factor in the successful defense of the anesthesiologist. One of these claims involved a patient who experienced pain while undergoing cesarean delivery with lumbar epidural anesthesia. The patient refused general anesthesia, and the infant was delivered using local infiltration. In the postoperative period, the patient developed post-traumatic stress syndrome and sought $6 million in damages. The anesthesiologist's thorough and explicit documentation of consent played an important role in obtaining a defense verdict from the jury. The database also contained one claim in which written documentation of consent contributed to the successful defense of the anesthesiologist, even though there were other features of the case that involved substandard care.

Another type of outcome that can be considered is the liability profile. Although the number of cases involving informed consent is small, the liability profile demonstrates some interesting relationships. As shown in Table 1, the profile for claims involving inadequate consent was less favorable than that of claims characterized by appropriate informed consent. Specifically, claims involving inadequate consent were associated with a higher proportion of severe injury, a higher rate of payment and a higher range of payments. A closer look at payment data revealed another interesting difference [Table 2]: Among the

claims with appropriate informed consent, there were no payments more than $500,000. In contrast, payments of $1 million or more were obtained in three of the claims associated with inadequate consent. It is important to bear in mind that precise relationships between informed consent and liability cannot be specified. This limitation arises from the subjective nature of reviewer assessment, the presence of missing data and the retrospective nature of data analysis.

Table 1: Liability of Profile Cases with Informed Consent as a Litigation Issue

	Informed Consent	
	Appropriate (n = 22)	Less than Appropriate (n = 16)
Death, brain damage or permanent injury	4 (18 %)	5 (31 %)
Payment to plaintiff	11 (69 %)	6 (27 %)
Range of Payments*	$7,500 - $400,000	$6,500 - $1,800,000

*Note: Claims with no payment or missing payment data were excluded.

Table 2: Distribution of Payments in Claims with Consent as a Litigation Issue

	Informed Consent	
Payments	Appropriate (n = 22)	Less than Appropriate (n = 16)
<50,000	4 (18 %)	7 (44 %)
$51,000 - $100,000	0	0
$101,000 - $500,000	2(9%)	1 (6%)
$501,000 - $1,000,000	0	0
>$1,000,000	0	3 (19%)

*Note: Claims with no payment or missing payment were excluded. Percentages may not sum to 100 percent due to rounding

Overall, these data suggest that inadequate consent is rarely the key reason for the bringing of a claim, but it can be a contributing factor. The data also suggest that the documentation of adequate informed consent can make a meaningful contribution to the defense of a claim.

Summary

In the current database of the ASA Closed Claims Project, informed consent plays a relatively minor role in anesthesia liability. Overall, informed consent was identified as a litigation issue in only 45 of 4,459 claims, or 1 percent of the overall database. These data suggest that informed consent is most often a "secondary" issue that has the potential to add to liability by increasing the likelihood of a claim, the magnitude of the associated demand or the frequency of payment.

From the perspective of risk management, these claims illustrate the importance of honoring specific requests, emphasizing that anesthesia involves a range of risks and educating the patient about unexpected events and alternate approaches to care.

Reference

1. Cheney FW, Posner K, Caplan RA, Ward RJ. Standard of care an anesthesia liability. *JAMA*. 1998; 261 (11):1599-1603.

Suggested Reading

Braddock CH, Edward KA, Hasenberg NM, et al. Informed decision making in outpatient practice: Time to get back to basics. *JAMA*. 1999; 282(24):2313-2320.

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