

# Informed Consent and Consent Forms

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Informed consent is not often a significant part of a malpractice claim. To prevail on this issue, a jury or arbitrator must be convinced that the claimant would not have agreed to undergo the procedure if the possibility of occurrence of the complication that ultimately occurred, no matter how rare, had been disclosed. However, failure to obtain informed consent can be the basis for a successful claim when the care was otherwise within the standard of care.

## A Finger Mass

For example, a surgeon met with a patient with a painful mass on the dorsum of her left ring finger that the surgeon thought was most likely a fibroma. In the operating suite after the patient was sedated, prepped and draped, the surgeon again inspected the planned surgical site on the dorsum of the patient's left ring finger. He found a similar mass on the palmar aspect of the same digit. Both masses were similar in character, fibrous, firm, and round, although the palmar mass was not yet as large. The doctor thought that the patient would be appreciative if the palmar mass was also removed at that time, avoiding a second operation, because palmar masses can be painful during activities involving gripping. The surgeon removed both masses without incident.

When the surgeon later discussed with the patient what had happened, she appeared grateful

that the surgeon had noticed and removed the other mass. However, she was not; later on, he was quite surprised to hear that the patient sought a second opinion. Shortly thereafter, the surgeon was notified of the patient's claim alleging absence of informed consent for removing the palmar mass.

Frequently, there is confusion about whether signed consent forms constitute informed consent. This article explains the differences and the relationship between informed consent and consent forms.

## Informed Consent

Informed consent is a process of communication between patient and physician. The physician gives the patient enough information so that the patient can make an informed decision on whether to go forward with the proposed procedure, test, or examination; the patient makes an informed decision about whether or not to proceed.

*Cobbs v Grant*<sup>1</sup> 8 Cal.3d 229 (1972) made obtaining informed consent a nondelegable duty of the surgeon or other health care professional performing a procedure. Other people can give the patient some information, but the surgeon or the person performing the procedure must participate in the process of providing informed consent.

Before *Cobbs v Grant*, a physician in California was required only to disclose risks according to the custom of physicians practicing

in the community.<sup>2-5</sup> The court determined that this allowed the physician to arrogate the decision of what to disclose to the physician alone. The court found that "unlimited discretion in the physician is irreconcilable with the basic right of the patient to make the ultimate informed decision regarding the course of treatment to which he knowledgeable consents to be subjected." Rather, the court said, "... the decision whether or not to undertake treatment is vested in the party most directly affected: the patient." The physician has a duty to make certain that "the patient possesses adequate information to enable an intelligent choice."<sup>1</sup>

## Consent Form

A completed consent form is not the same as informed consent, and consent forms do not effectively obviate the need for a documented discussion in the medical record of the risks and benefits of the proposed treatment. Consent forms are one type of evidence that informed consent has been obtained. A better type of evidence that informed consent has been obtained is documentation in the patient's medical record of a discussion between the physician and patient.<sup>1</sup>

Consent forms are required by regulators, are easy for staff members to find, and it is easy to confirm that they have been completed. A note written by the physician documenting that the

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informed-consent process has been completed and that the patient's informed consent has been obtained is more difficult for staff members to find and to verify before a medical procedure has been performed. However, such a note has at least equal and usually greater evidentiary effect than does a completed consent form.<sup>1</sup>

Anytime a physician does anything to a patient, informed consent must be obtained. The crucial issue is whether and how it is to be documented in the particular case. For example, every time a physician examines a patient, the patient must consent. For a physical examination, the patient's allowing the examination without objection is sufficient evidence of consent.<sup>1</sup> The same applies to injections, the drawing of blood, most imaging studies, electrocardiograms, and many other

examinations. When there is a major invasive procedure, however, the consent process is formally documented.<sup>1</sup> Ideally, documentation is provided by both a consent form and a note in the patient's medical record written or dictated by the physician, describing the manner in which informed consent was obtained.

### **A Continuum**

There is a continuum between these two poles. In the past, we have tried to define where on the continuum formality must begin. Not surprisingly, this beginning point is inconsistent and arbitrary between medical offices and medical centers and even between different departments in the same medical center and between the same department in different medical centers. For example, lumbar puncture may require consent forms in pediatrics but not in internal medicine in the same medical center, just as consent forms may be required in some

medical and pediatric departments but not in others.

What we are left with regarding when more formal consent is required is judgment as to the risk of the particular procedure. The general interpretation of the law is that patients must be warned of insignificant risks, if frequent, and of significant risks, even if uncommon. However, very rare and unusual risks need not be mentioned.<sup>1</sup> ❖

### **Acknowledgment**

*Katharine O'Moore-Klopf of KOK Edit provided editorial assistance.*

### **References**

1. Cobbs v Grant 8 Cal.3d 229. 1972.
2. Carmichael v Reitz 17 Cal.App.3d 958, 976. 1971.
3. Dunlap v Marine 242 Cal.App.2d 162. 1966.
4. Tangora v Matanky 231 Cal.App.2d 468. 1964.
5. Berkey v Anderson 1 Cal.App.3d 790. 1969.

## **Survival**

Protecting our ethical heritage is not an abstract, pious counsel of perfection. It is the key to our profession's survival.

— Frederick Lowy, b 1933, Canadian medical educator and former President and Vice-Chancellor of Concordia University in Montreal, Quebec