



**CLINICAL JURISPRUDENCE COLUMN**

# Informed consent: The more you know, the more you and your patient are protected

**⬇️** A dubious case of informed consent illustrates the essentials of an ever-changing process

**Steven R. Smith, JD, and Joseph S. Sanfilippo, MD, MBA**

**CASE** Surgeon accused of performing tubal ligation without consent

A patient was scheduled for an elective cesarean delivery to be performed by her ObGyn (Dr. Surgeon) at the nearby medical center. The patient was asked to sign an electronic signature pad in her ObGyn's office, which transposed her signature onto an electronic form that she could not see at the time. She signed it. The consent was not printed out in the office but was added to

her electronic medical record, and a copy was sent to her via email. Among other things, the consent included, "[Name] hereby agrees that all appropriate medical and surgical procedures as determined by the physicians and others in this hospital are in my best interest. No further consent is required to any of the treatment in this hospital."

In the hospital, Dr. Surgeon spoke preoperatively with the patient about cesarean delivery, the various risks and benefits, and the possibility and risks of an alternative trial of labor. Dr. Surgeon noted the conversation in the patient's chart.

A nurse brought a standard hard copy "Zee Hospital Surgical Consent Form" to the patient. In a relevant part it provided, "I hereby consent to the surgical procedure Dr. Surgeon has discussed with me: \_\_\_\_\_" (the blank was filled in with "cesarean delivery"). The form continued: "He/She has explained the risks and benefits. I also authorize Dr. Surgeon, and such assistants as he/she may select, to perform this procedure. In his/her medical judgment, if additional procedures are appropriate, I hereby consent to their performance, in addition to the procedures listed in this form." The patient signed the form.

While Dr. Surgeon was scrubbing for the delivery, the patient's husband (also a surgeon at the hospital; Dr. Husband), stopped

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In this quarterly column, these medical and legal experts and educators present a case-based discussion and provide clear teaching points and takeaways for your practice.



Mr. Smith is Professor of Law and Dean Emeritus at California Western School of Law, San Diego, California.



Dr. Sanfilippo is Professor, Department of Obstetrics, Gynecology, and Reproductive Sciences, University of Pittsburgh, and Director, Reproductive Endocrinology and Infertility, at Magee-Womens Hospital, Pittsburgh, Pennsylvania. He also serves on the OBG MANAGEMENT Board of Editors.

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by, thanked Dr. Surgeon, and said, “Oh, by the way, my wife would like you to do a tubal ligation as well—she really wants it for health reasons. Her chronic hypertension skyrocketed during this pregnancy, and we don’t want any more children.”

“She didn’t mention that a little earlier while I was talking with her,” replied Dr. Surgeon, “but I can see how it would have slipped her mind.”

Dr. Surgeon performed the cesarean delivery and tubal ligation. All went well, with a healthy baby and mother. Several months later, the patient and Dr. Husband separated and sought divorce.

The patient, surprised by the cost of the hospital bill (Dr. Surgeon did not bill for his surgical services as a professional courtesy), was astonished to see a charge related to tubal ligation. Knowing how common billing mistakes were at Zee Hospital, she called to have the bill corrected. The clerk informed her that her medical record showed that a tubal ligation had been performed and that the bill was correct.

The patient sued Dr. Surgeon, Zee Hospital, and her (now former) husband, Dr. Husband, both for the cesarean delivery and the tubal ligation. Her claims are primarily based on the lack of informed consent.

### WHAT'S THE VERDICT?

The patient likely has a strong case regarding the tubal ligation claim, but a weak case related to the cesarean delivery claim.

### Ethical and medical considerations

Although this case seems too strange for fiction, the basic facts are taken from events that did occur at a major institution. The puzzling features of this case are meant to be a cautionary tale: it is easy in the rush with the pressure of clinical practice to view informed consent as a bothersome technical detail. Yet as the following discussion suggests, adhering closely to the tenets of informed consent protects not only the fundamental interests of the patient but also the physicians and medical institutions.

### Informed consent serves as protective communication

Informed consent at its core is a “process of communication” that involves you as the health care provider and the patient. It provides authority for an activity based upon an understanding of what that activity entails.<sup>1,2</sup> Aspects of informed consent, from the physician–patient perspective, include the following:

- disclosure
- comprehension
- voluntary choice
- authorization.

In one other sense, informed consent is based on a fiduciary relationship between the ObGyn and patient.<sup>3</sup> Overall, the process consists of an educational communication by the physician to the patient. Ideally, providers perceive the process from an ethical point of view that has been formalized by cases and statutes.<sup>4</sup>

Informed consent protects one of the most basic values of medicine and society: autonomy. From the perspective of moral philosophers, the principle of autonomy establishes the moral right to choose and follow one’s own plan for life and action.<sup>5,6</sup> For ObGyns, the patient’s autonomy and her ability to participate in the medical decision-making process is of paramount importance. Informed consent is also a reflection of trust inherent to the physician–patient relationship.<sup>4</sup>

Informed consent is too often viewed as a mere legal formality. In truth, it melds legal and ethical values and concerns. The President’s Commission reflected this, noting that informed consent is rooted in “the fundamental recognition that adults are entitled to accept or reject health care intervention(s) on the basis of their own personal values and in furtherance of their own personal goals.”<sup>7</sup>

The historic perspective of informed consent dates back to Egyptian, Greek, and Roman eras. Dhar and Dhar suggest that the concept of “physicians’ love for humanity—philantropia” dates back to Plato and is complemented by the term “philotechnia” (love of medicine), all of which have evolved into



The process of informed consent protects an important basic value of medicine and society: the patient’s autonomy

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today's use of the terms "risks, benefits, and alternatives."<sup>8</sup>

We emphasize that informed consent is much more than a legal concept. It has strong clinical roots because it provides an opportunity for physicians to improve communication with their patients. Informed consent is not a form; it is a process to be taken seriously.

### Legal principles of informed consent

The famous New York case of *Mary Schloendorff v. Society of New York Hospital*, in 1914, heralded a principle that remains central in American law. Justice Benjamin Cardozo, writing for the majority, held that, "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages."<sup>9</sup> The surgeon in the *Schloendorff*

case had undertaken a gynecologic procedure—removal of a fibroid tumor—without patient consent. (In that case the hospital rather than the physician was sued, but the principle clearly applied to the physician.)

Over the last century, the American law of informed consent has developed in a number of ways.<sup>10</sup> Lack of informed consent is now almost always considered a form of negligence rather than an intentional tort of battery. The details of the legal requirements vary from state to state as a result of statutory changes and court decisions. But in one way or another, to be "informed," consent generally must include 4 things:

1. a description of the procedure or intervention that is proposed
2. the risks and benefits of the proposal—the focus here is generally on the risks of the treatment
3. alternatives, if there are any (eg. pharmacologic vs surgical treatment)
4. the consequences of not undertaking the

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**FAST TRACK**

**The surgeon must take ultimate responsibility for the informed consent process**

proposed treatment (eg, the refusal to have a Papanicolaou smear).

A fifth point might be added—the offer to answer any questions or provide additional information.

These 4 or 5 basic items and the expanded list are efforts to simply describe the information that a reasonable person would need in order to make a decision that represents the patient's values, personality, and preferences. (Informed consent is in some ways an ongoing process—since a patient may withdraw his/her consent.)

**Exceptions to the informed consent requirement**

Before turning to the facts in the hypothetical case, it is worth noting that there are 2 common exceptions to the informed consent requirement. The first is an emergency exception. When someone requires immediate attention and the patient is not conscious or capable of consent (nor is a “next of kin” available), treatment may proceed.

The second is therapeutic exception. Its designation is narrow, and it is risky to rely on it except in extreme circumstances. But when the very process of informing the patient of all the risks of a proposed treatment would create significant additional risks for the patient, the consent process may be modified. For example, for an extremely suggestible patient, describing certain risks might, in a psychosomatic way, cause the risk to be realized. In such cases, the record must be clearly documented. It is generally best to discuss the matter with a family member or other surrogate decision maker.

**What went wrong with consent in this case?**

Our case illustrates a number of problems that occur when informed consent is not properly completed.

**The electronic signature** on the broadly stated consent form the patient initially signed in the office was nearly useless. She did not know what she was signing, did not have any chance to read it before signing, and

was provided no help with any of the information factors of informed consent.

**The surgical consent form** is among the most interesting elements of this case. The form itself was seriously flawed because it contained no real evidence that the patient received information about the risks and alternatives. If the form is all there was, it would be a problem. But the conversation that Dr. Surgeon documented with the patient seemed to provide the basic elements of informed consent, including discussion of risks and benefits.

**Oral informed consent** is recognized in most states. To his credit, Dr. Surgeon appropriately recorded the conversation in the record. The risk of oral informed consent not backed up by text signature is that, if a dispute arises about the consent, it is difficult to prove details of what was said. (There was, of course, no such dispute about the cesarean delivery as it turned out in this case.)

**Technological add-ons to consent: Pros and cons**

Video and computer software are increasingly becoming an integral part of the informed consent process, and may improve comprehension by patients.<sup>11</sup> Electronic consent may be helpful in proving what the patient was told during the consent process. A difficulty can result from overreliance on the electronic aspect and forgetting the human part of the informed consent equation. The health care team often can be productive parts of the informed consent process, but the surgeon must take ultimate responsibility for the informed consent.<sup>12</sup>

**Was there informed consent for the tubal ligation?**

The major problem in this case, of course, was the tubal ligation. It does not take much of an understanding of the legal niceties of informed consent to know that there was no real consent to this procedure. Dr. Husband did not have authority to consent, and his comment to Dr. Surgeon did not qualify as consent.

The hospital consent form may appear

to provide some legal protection (“In his medical judgment, if additional procedures are appropriate, I hereby consent to doing those...”). Such language was once common in informed consent forms, but it offered little real consent except for trivial incidental processes (removal of an appendix) or where there was a real medical necessity for doing an expanded procedure (removal of a previously unknown cancerous growth).

Thus, Dr. Surgeon performed the sterilization without consent and may well be liable for that part of the surgery even though it did not turn out badly in a medical sense. If not for the tubal ligation, the damages would probably have been trivial. The real loss here is not a medical injury; it is the loss of reproductive capacity.

**Protecting reproductive capacity.** Modern law has been especially sensitive to protecting decisions regarding reproductive capacity. Therefore, the absence of clear consent to permanent sterilization is legally problematic. Dr. Surgeon may claim that he reasonably believed that the husband could give surrogate consent and it was too late to check with the patient herself. This situation does not fit well with the emergency exception, and it appears from the facts that Dr. Surgeon acted without informed consent to the sterilization.

### Was it negligence or battery?

**Dr. Surgeon.** The most likely basis for liability for Dr. Surgeon is negligence. There is some argument that the tort of battery is a possibility because there was no consent at all for the sterilization. The claim would be that it was not the “information” that was lacking; it was the consent itself. The fact that Dr. Surgeon did not charge for his services would not absolve him of liability.

**Dr. Husband.** The potential liability of Dr. Husband is complicated by questions of whether he was acting in the capacity of a physician (which would likely involve the question of whether his malpractice insurance would be available), the degree to which he was acting in good faith, and facts we do not have in this case. If Dr. Husband

gave consent (and thereby “caused”) the sterilization knowing that his wife did not want to have it or because of animus toward her (they were about to be separated and divorced, after all), there is the possibility of liability. (In some states a form of interspousal liability might complicate some of these claims—but that is a topic for another day.) He essentially took action for the purpose of wrongly causing the sterilization—which may be a battery (an intentional offensive or harmful touching). The legal rules around battery allow punitive damages as well as compensatory damages. In addition, many malpractice insurance policies provide limited coverage for intentional torts. To complicate matters further, it is not clear that Dr. Husband’s actions were related to his practice of medicine in any event (although Dr. Surgeon might claim that Dr. Husband’s expressed concern about his wife’s hypertension was enough to create a malpractice issue if Dr. Surgeon did not perform the verbally requested tubal ligation).

If, as we have speculated, Dr. Husband’s actions were motivated by improper personal considerations at the expense of a patient, he may also face medical board complaints from the patient. It is plausible that a state law makes it a criminal offense to wrongfully (or fraudulently) consent to medical treatment, particularly if related to reproductive capacity.

**The hospital** may face liability on several grounds, depending in part on the relationships between the hospital, Dr. Surgeon, and Dr. Husband. If Dr. Surgeon is an employee or agent of the hospital, he would be liable for his negligence. Even if Dr. Surgeon is technically an independent contractor, the failure of the hospital to offer more oversight concerning the surgical procedures in its facilities could give rise to a claim of negligence.

As to Dr. Husband, many of the same considerations are present. In addition, even if he is an agent of the hospital, the hospital may claim that his actions (especially if motivated by personal considerations) were a “lark of his own” and not in the course of his employment by the hospital.



**Even though the surgery did not turn out badly, the surgeon is liable because he did not have the patient’s consent to perform that procedure**

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### The clinical opportunity of informed consent

More than a technical legal doctrine, informed consent provides ObGyns an important opportunity for better communications with patients, and is a chance to create reasonable expectations and a more therapeutic relationship that involves the patient in care and decision making. It is likely that engaging the patient in good informed consent processes can set the stage for improved outcomes.

Interactive dialogue with the patient is one advised approach.<sup>10</sup> This undertaking in part reflects that, as patients have more ready access to information in the digital age, they are positioned to play a more active role in health care decision making.

The benefits of informed consent are likely to be greatest if you view the process not as a technical legal requirement but as an excellent opportunity to engage the patient in her own care and treatment. Planning, intervention, and evaluation of care options as well as education regarding the medical problem at hand are integral to the informed consent process. And, of course, the right to consent is a "basic patient right" that in a sense guarantees that he/she has the right to make informed decisions regarding one's care.<sup>6</sup>

### Special considerations

Informed consent most often is associated with but not limited to surgical procedures (often performed with the use of surgical instruments and/or devices). It applies to diagnostic interventions as well as treatment. The

more invasive or risky an intervention, the more important it is that the information is thorough.<sup>14,15</sup>

Pharmaceuticals have informed consent issues. The theory has been that pharmaceutical companies inform physicians of the risks and instructions for the use of pharmaceuticals and the physicians inform the patients. Indeed, traditionally pharmaceutical companies have gained immunity for "failure to warn" patients because the physicians were the "learned intermediaries" providing information to the public. Patient package inserts and pharmacists have taken over the informational role, but informed consent does apply to pharmaceuticals.

It is also worth noting that informed consent in any formal research study or the trial of new techniques, compounds, or devices requires a special process of approval by an institutional review board.

### Set the stage for best outcomes

The main objective of informed consent is promoting the autonomy of your patient. That requires that she understand the risks, benefits, and alternatives associated with the procedure and the risks associated with a refusal of treatment. Done properly, this can result in your patient gaining confidence and trust in you as her provider.

Informed consent is a process that reflects our interactions with our patients. It is part of the broader commitment by the medical profession to "first do no harm."



**Informed consent provides you with an important opportunity to improve communication with patients**

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