CLINICAL JURISPRUDENCE COLUMN

Could thorough documentation have changed the outcome of this trial?

What details need to be included in office-visit records, written consent form, operative report, and postoperative notes?

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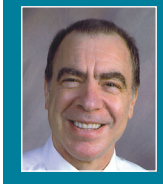
CASE* Did the gynecologist have the right to *not* remove the ovaries?

A 36-year-old woman (G3 P3003) presented to her gynecologist with dysmenorrhea and abnormal uterine bleeding. She reported a family history of ovarian cancer for two generations. She was evaluated and underwent physical examination and preoperative ultrasound examination of pelvic organs. All findings were unremarkable. The gynecologist prescribed oral contraceptives (OCs). After an initial excellent response, the patient reported a reoccurrence of pelvic pain and abnormal bleeding 6 years later. The gynecologist suggested options including operative hysteroscopy, dilatation and curettage (D&C), endometrial ablation, off-label use of an intrauterine contraceptive system, or hysterectomy performed via a minimally invasive, vaginal, or abdominal approach. The patient opted for hysteroscopy, D&C, and endometrial ablation and operative laparoscopy. The patient received a diagnosis of stage I endometriosis, which was treated with fulguration.

Two years later, she reported menorrhagia and pelvic pain. The gynecologist suggested trying an OC again, and the patient was given a prescription for a low-dose estrogen/desogestrel combination pill. The patient then changed her mind within 72 hours, never took the OC, and contacted her gynecologist to schedule surgery with him. Upon a return visit to the office, the patient and gynecologist decided to proceed with laparoscopic-assisted vaginal hysterectomy (LAVH) with bilateral salpingo-oophorectomy (BSO). The written consent included laparoscopic hysterectomy with removal of ovary or ovaries and bilateral fallopian tubes, with a possibility of abdominal hysterectomy.

The gynecologist met with the patient preoperatively to update the history, which was unchanged from her prior office visit. In the operating room, "time out" occurred and was

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.



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*The facts of the actual case have been modified for this discussion.

documented appropriately—concerns were to be provided to the gynecologist; none were noted.

Intraoperatively, the ovaries were normal in appearance and no endometriosis was noted. The gynecologist proceeded with LAVH and, because the ovaries were normal, did not remove them or the fallopian tubes.

The patient sued the gynecologist on the grounds that, because the originally planned BSO was not performed, she was fearful of developing ovarian cancer in the future.

Preoperative documentation was "sketchy" at best and did not reflect the preoperative discussion and options presented to the patient. There was no documentation of anyone accompanying the patient at the preoperative office visit.

The case went to trial.

WHAT'S THE VERDICT?

Final verdict was for the patient

The jury awarded damages to the patient based on the absence of adequate consent and failure to perform what was preoperatively agreed to in the consent form.

FAST TRACK

A signature alone typically does not constitute informed consent

Legal takeaways from this case

This is an unusual case. Absent something else, it is unusual for there to be liability for *not* doing a procedure, where the procedure seemed medically unnecessary based on observations during surgery and where language of the signed written consent form created ambiguity about the plan for the removal of the ovaries. Here the patient alleged that her consent was not "informed." Although informed consent claims are fairly common in malpractice litigation, they are generally appended to an underlying count (or counts) of negligent care; it is uncommon for there to be recovery of damages based solely on the absence of informed consent.

A signed consent form may not be sufficient. In general, a patient's signature on a consent form alone is not sufficient evidence of informed consent. Whether the patient was truly informed will be judged by the circumstances during which the patient's consent was obtained.

State laws vary on the specifics of informed consent. Many states have specific statutes or regulations dealing with informed consent. The "informed" part of informed consent generally requires that the patient be informed of:

- the nature of the procedure proposed
- the risks and benefits of the procedure
- the alternative forms of treatment
- the consequences of not undertaking the proposed procedure or an alternative.

In this case, the lawsuit alleges damages based on the fear of future ovarian cancer. It is likely that the patient offered credible testimony that she decided to proceed with surgery specifically because of her fear of ovarian cancer. The patient may have offered testimony about her specific request for her ovaries to be removed because of this fear, or she may have offered testimony about her belief or understanding that the ovaries were going to be removed based on her preoperative discussion with the gynecologist.

Written consent must reflect the actual preoperative discussion

The written consent stated: "hysterectomy with removal of ovary or ovaries," creating some ambiguity regarding whether the gynecologist had latitude in deciding whether or not to remove the ovaries. However, certain "facts" in this case scenario support the claim that the written consent form was meant to have reflected a decision and agreement between the doctor and patient that the ovaries were to be removed, including:

- the patient had a significant family history of ovarian cancer, making the fear of future ovarian cancer reasonable
- the patient opted out of a conservative treatment plan within 3 days and asked instead to schedule major surgery.

The gynecologist may have testified that the preoperative discussion included only the possibility of removing the ovaries, to be determined based upon what was observed in the course of the surgery. However, in the case description, we are told that the "preoperative documentation was 'sketchy' at best." The jury

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Litigation prevention rule #1: Thorough documentation

Vital elements to document

Preoperative office-visit records

- who is in attendance
- detailed patient history
- preoperative examination
  - test results
- discussion of possible alternatives to surgery
  - what alternatives were discussed
  - patient's reaction to each alternative
- discussion of procedural options
  - what options were offered
  - patient's reaction to each option
- decision made

Written consent form

- objective of surgery
- reasonably detailed notation of specific discussion with patient, noting special concerns or circumstances

Operative report

- preoperative examination
- preoperative (day of surgery) discussion notes
- intraoperative findings
  - describe unusual or unexpected findings (distorted anatomy, dense adhesions, etc.)
- physician's decision-making process
  - include rationale for any variance* from your usual practice, methodology, etc. or from the surgical plan as set in your preoperative note
- procedures undertaken
- surgical outcome
  - in OR
  - postoperative examination prior to discharge
  - discharge instructions

Postoperative office-visit records

- who is in attendance
- physical examination
- discussion of operative outcome
- discussion of postoperative processes
- recommended follow-up
- whether and when to restart any medications

*In the event of an adverse outcome, your actions will be judged on whether you were acting reasonably and using your best judgment. Your documentation needs to explain in detail what you did and why you did it that way. If what you did was a "variance," explain why.

may have concluded that the gynecologist did not know the wishes of the patient in the event that the ovaries appeared normal during the surgery.

We also know that when the patient returned to the gynecologist's office after requesting surgery, a "discussion occurred to 'proceed with LAVH with BSO.'" If this precise language was noted in the patient's chart, the jury may have concluded that the gynecologist ignored the patient's wishes!

A claim that the patient was adequately informed prior to treatment can be difficult to address if the informed consent process has not been adequately documented. Often in litigation the decisive question is not whether the right thing was done but whether that can be demonstrated. This case emphasizes the need for good documentation reflecting the specific discussions with the patient.

Clinical takeaways

The importance of a good rapport with patients as well as clear discussion of clinical findings, test results, and options for treatment remains paramount. This includes documentation of discussions, recording of who is present during the discussion (including witnesses), as well as the patient's response to various treatment offerings.

The informed consent process from the clinician's perspective should reflect discussion of risks, benefits, alternatives, sequelae of complications, and an appropriate risk of refusal. It is most important to pay attention to detail, and record that detail which will reflect your effort to be thorough. Make sure that the surgical consent form includes the operating physician's name, the name(s) of the assisting physician(s), and no blank spaces.

Open communication plus complete documentation are key

A well-designed history form—without blanks but with documentation of the physical examination and reflection of the impression and plan—can serve to avert litigation. Ideally, the operative report will reflect not only what was done but also the intraoperative decision-making process on the part of the gynecologist. Documentation of the physician's thoroughness with intraoperative assessment may well avoid acceptance of a case by a patient's attorney. Most importantly, transparent postoperative discussions with the patient and family detailing what occurred and the intraoperative decision-making process may convince the patient and family that the clinician has nothing to hide and has the patient's best interest in mind.