

Time for an Informed Consent Check-Up

Informed consent in the context of an allegation of negligence.

When a patient files a malpractice lawsuit against a healthcare provider, the law requires that the patient must identify specific actions that the doctor engaged in – or failed to engage in – that resulted in harm to the patient. In a legal context, these actions are called allegations.

Failure to obtain informed consent is an allegation that falls into the category of an action the doctor failed to take on the patient’s behalf. It is an allegation that plaintiffs’ attorneys may use as an attempt to beef up the accusatory tone of a lawsuit. “You did something bad to your patient and you never attempted to help the patient or explain what happened and, oh, by the way, you never explained the possible complications that might occur and the patient would never have agreed to this treatment/procedure/drug if you had explained the risks.”

Most informed consent allegations are added in an attempt to give additional heft to the patient’s claims. In fact, many failure-to-obtain informed consent allegations can be easily disproved – but only when documentation verifies that the appropriate steps were taken by the doctor and his or her staff.

Without adequate documentation, it can be much more difficult to defend a doctor against allegations that the informed consent process never occurred or was inadequate. And such lawsuits have been associated with significant indemnity payments.

So, it is important that healthcare teams implement informed consent policies and procedures. The goal should be to ensure that patients’ records will have adequate references to: a) diagnostic and treatment discussions; b) patients education; c) responses to patients’ questions and concerns; and d) patients’ commitment to comply with the treatment plan that they have agreed to.

Any doctor looking for a way to reduce potential liability for patient dissatisfaction with outcome results should look no further than his or her practice’s informed consent policy and procedures. The following check-up can assure doctors and their teams that they are on the right track in managing this important aspect of the doctor-patient relationship. It can also identify opportunities for improvement. Remember, almost all informed consent lawsuits are preventable!

Check-up:

1. Do you have a written informed consent policy? Does it specify that patients have the right to be fully informed and engaged in decisions about their healthcare?
2. Do written procedures address:
 - a. Each doctor commits to using the practice's informed consent procedures, consistently and completely.
 - b. Each doctor acknowledges that he or she has a duty to educate and inform the patient and to answer the patient's concerns and questions – ***and that these duties cannot be delegated.***
 - c. Employees whose job descriptions and credentials allow them to assist with the informed consent process are trained about their supportive roles and allowable communication roles within the informed consent process.
 - d. Employees may not assume any portion of the informed consent process for which they are not specifically authorized.
 - e. The doctor/s regularly update patients' records to verify that patients have, indeed, been given diagnostic information, educational support, encouragement to voice their questions and concerns, and acceptable responses/answers to those questions and concerns.
3. Do educational processes include:
 - a. Documentation in the patient's record that educational exchanges have taken place between doctor and patient.
 - b. Documentation verifies the use of any pamphlets, brochures, videos, on-line informed consent systems. It should also note the dates when these materials were made available to the patient.
 - c. Archives of educational materials and their dates of use by the practice.
 - d. Opportunities for doctors to customize educational consults with patients, might include: a) sketches in the educational materials; b) or notes jotted directly into the patient's record prior to the procedure: c) additional notes that take into account the individual patient's specific health, and/or other concerns or requests.
4. Does the practice have its own informed consent forms, rather than relying on forms used by other entities, e.g., hospitals, other providers who may also be involved with patient care, etc.?
5. Does the practice have systems that help both staff and doctors to identify potential errors in the process and to address them in a timely manner?
6. Does the practice have systems that ensure the maintenance of informed consent as a permanent part of each patient's record?

Conclusion:

Remember that allegations that a doctor failed to obtain a patient's informed consent should be among the legal disputes that are easiest to prevent. By having a policy and

related procedures, doctors and their employees can increase patient understanding while at the same time reducing the likelihood that a bad outcome will lead to the accusation that, “You never told me this could happen!”

For further information or assistance in dealing with any informed consent matter, doctors insured by Medical Protective are invited to contact their regional risk management consultants. See *Risk Academy* to locate consultants by state.