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Do I have your permission? Proper informed consent can avoid medical malpractice

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A 16-year-old patient presents to your office with an inflamed furuncle on her right thigh. The lesion requires incision, drainage and packing. After discussion with the patient and her guardian, the area is cleaned and the procedure performed. The patient is left with a scar that requires cosmetic repair. The patient's parent assumed the area would return to normal. A malpractice claim alleging medical negligence and lack of informed consent ensued.

In such a situation, legal risk likely depends on the quality of the informed consent obtained from the patient's guardian.

What constitutes informed consent?

The need for informed consent grows from the legal concept of battery and the ethical principle of autonomy. Battery is both a crime and an actionable tort for unwanted touching. Failure to engage in adequate informed consent could constitute medical malpractice as well as assault.

In simplest terms, informed consent is how patients give permission for medical evaluations and treatments. For a minor child, permission is given by a parent or guardian, except for emancipated minors and when state law grants the minor authority to consent.

To meet legal and ethical requirements, consent must be based on adequate information and understanding. Therefore, a medical provider needs to discuss with the patient the risks and benefits of the choices for specific medical evaluation and treatment, including no treatment. Remember, informed consent is not a document; it is a dialogue between the decision-maker and physician that results in the patient understanding and agreeing to the course of action.

Although not a legal prerequisite to treatment, “assent” should be sought from mature children. This includes sharing information and discussing risks, benefits and alternatives with the child.

When is consent implied?

Legal and ethical principles necessitate that everything medical providers do requires some degree of informed consent.

Obviously, health care providers do not engage in a formal written consent process for many patient interactions. The choice to present to a medical office, urgent care center or emergency department implies a certain degree of understood consent for medical care. Taking a medical history and vital signs as well as a basic physical examination also would fall into this category.

More invasive, but not surgical, evaluations, such as pelvic and rectal examinations are discussed with the patient to ensure understanding and agreement, but they rarely are memorialized with a consent document. Similarly, it would be uncommon to employ a formal consent process for routine prescriptions and minor procedures such as cryotherapy for wart removal.

More invasive procedures as well as medical therapies with significant risk are best handled with a formal consent process, including a thorough discussion and appropriate written documentation in the medical record.

How do you determine if informed consent is needed?

State law delineatesthe need for informed consent in various situations.

In general, requirements for consent are based on reasonableness. There are at least two standards for this among the states. Most commonly, consent is assessed based on the “reasonable patient standard”: What would a reasonable patient want to know about the treatment before providing consent?

In other states, consent is reviewed based on the “reasonable physician standard”: What information would a reasonable physician provide in similar circumstances?

The individual performing the procedure or prescribing the medical therapy is the best choice to engage in the consent process. An experienced provider with knowledge of the risks and benefits of the medical intervention can educate the patient and caregiver most

thoroughly. At least one state supreme court has held that consent obtained by someone other than the physician performing the procedure was invalid. Regardless of who communicates with the patient or guardian, the attending physician is responsible for the adequacy of the consent process.

In a true medical emergency where the decision-maker is unavailable or unable to consent, the law presumes consent for life- and limb-saving treatment under a reasonable patient standard (i.e.,a reasonable patient in similar circumstances would want the treatment). Nonemergent care should be deferred until it can be discussed with an appropriate decision-maker.

Importance of documentation

If an adverse outcome occurs, documentation will be an important element for defending a lawsuit. The patient or guardian will have a specific recollection of the process while, often several years later, the physician may only be able to state his or her usual custom and practice to provide certain information.

A written and signed form explaining the appropriate consent components provides clear documentation of the discussion of potential risks. Similarly, when patients or caregivers decline important recommended care, it is important to document this informed refusal (see *AAP News*article "Document 'informed refusal' just as you would informed consent," http://bit.ly/3oI0hHi).

Because informed consent requirements depends on state law, it may be helpful to consult with a lawyer practicing in your state.

Take-home points

- Informed consent is a dialogue consisting of thorough discussion of the risks, benefits and alternatives of a medical intervention to facilitate understanding and agreement by the patient.
- Necessity for and adequacy of informed consent are assessed based on reasonableness, usually from the perspective of a reasonable patient.
- The provider performing the procedure or prescribing the treatment plan is the best choice to engage in the informed consent process and to document it.

Drs. Bondi and Oken are members of the AAP Committee on Medical Liability and Risk Management.

Resources

- AAP policy statement "Informed Consent in Decision-Making in Pediatric Practice"
- AAP policy statement "Consent for Emergency Medical Services for Children and Adolescents"
- AAP clinical report "Consent by Proxy for Nonurgent Pediatric Care"
- "Informed consent: More than getting a signature" from The Joint Commission, Division of Health Care Improvement
- Additional Pediatricians and the Law columns