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CLINICAL CASE
Informed Consent: When and Why
Commentary by Erin A. Egan, MD, JD

Dr. Wood opened the door to the exam room and smiled at Mrs. Robertson who was waiting in her patient gown. "Hi, Mrs. R, I'd like to ask a favor. Del, here, is on a family medicine rotation and, if it's OK with you, he'll assist with your exam today. Is that alright with you?"

"Sure," replied Mrs. Robertson, "I'm all for medical education."

"Thank you," said Del.

"Why don't you begin by checking Mrs. Robertson's vitals," instructed Dr. Wood. After noting these results, Dr. Wood took over the physical, asking questions and sharing a few observations with Del. Dr. Wood then asked Mrs. Robertson to undo her gown and he proceeded to conduct a breast exam by raising her arm, pressing on her breast to check for lumps, and looking carefully at the nipples for signs of discharge. After examining both breasts and palpating Mrs. Robertson's liver and ovaries, Dr. Wood asked Del to step outside and send the nurse in, so he could collect a Pap smear.

After Mrs. Robertson left, Del said, "This is my first rotation, and one thing I've been wondering, Dr. Wood, is do we just do all of the standard aspects of the physical on our patients without asking? Like the breast exam, for instance. Because I'm so young and everything, I feel as though I should ask permission, but you just went right ahead. She didn't object so I guess it's OK, but is that routine? Where is the line where I have to ask or get consent? Did you ask consent to do the Pap, or is it all assumed consent?

Dr. Wood considered Del's question. "That's a really good point. Mrs. Roberston has been my patient for a while, for one thing. But still, I don't recall ever having my professors tell me specifically what are or are not the trigger events for a consent—verbal or otherwise—in a routine check-up. I can't remember a lot of articles on that, and I've been in practice for quite a while."

Commentary
What level of consent is required for a patient-physician encounter? There is no fixed answer. The threshold varies with each patient, each physician, the type of interaction, and the risks and benefits that intervention presents. That being said, there are some general rules about when to obtain consent. Our case deals with

consent in the context of an interview and examination, not the invasive procedure setting that usually sparks informed consent concerns. Nevertheless patients deserve to be told about and agree to all aspects of proposed care, regardless of whether they are undergoing a procedure or having a conversation. Often consent is tacit—a patient's presence and cooperation with the interview and the exam are taken to mean that he or she consents to the proceedings. If the patient is likely to have made assumptions about the interaction that are untrue, the physician should correct those misconceptions. A clear example of this is described in the case—a patient should be made aware that a medical student is involved in her care and should be allowed to consent to or refuse the student's participation with special attention given to sensitive aspects of the history and examination [1, 2].

The basis for the informed consent requirement is the principle of respect for personal autonomy [3]. The ethical responsibility to respect the autonomy of a person is fulfilled by telling a patient what he or she needs to know to make informed decisions about treatment options. Clinical judgment is involved here; what is the balance between too little information and too much? Legal guidance for adequacy of disclosure for informed consent can be thought of as providing either what a reasonable patient would want to know or what a reasonable physician would disclose [4]. The exact standards vary by state, but these guidelines can help physicians determine when they need to get a patient's consent and what they should disclose.

Small variations in details can change the informed consent requirement. It is probably safe to assume that a patient who comes to a cardiologist expects to have a heart exam, so the physician need not solicit "consent," but he or she should engage in the good clinical practice of telling the patient what he or she is doing throughout the examination. Imagine that our cardiologist believes that a breast exam could be relevant to making an accurate diagnosis. It is reasonable to anticipate that the patient would want to be informed of that exam and allowed to ask questions before it is performed since this may exceed the scope of what the patient expects and involves a particularly sensitive area of the body. An informal (not written) discussion explaining why the breast exam is necessary, providing information to the patient based on her concerns, and obtaining verbal assent from the patient after this explanation may be "consent" enough. Described in this way, consent sounds like a laborious practice that requires so much time that it will limit the number of patients a physician can see. Actually discussing a procedure or exam takes as much time as it took to read this. Often the need for a formal discussion doesn't come up, but is more a part of the exchange that occurs while care is provided and received.

Getting beyond Broad Consent for Treatment

At the initiation of a health care relationship the patient signs some type of broad consent to being evaluated and treated. Routine, very low-risk procedures are done under this blanket agreement. Small changes that increase risk, encroach on a particularly sensitive subject, or have the potential to have a significant effect on the life of the patient require further discussion between the physician and the patient.

Examples of procedures that require specific discussion are blood testing for HIV (versus routine blood draws); giving blood products (versus giving IV fluids); lumbar puncture (versus venipuncture). The difference between these technically similar procedures is clear: the risks are different, the personal implications are greater, or the level of training and skill needed by the clinician is greater.

Informed consent requires a discussion of risks, benefits, and alternatives with a patient who can understand and react to the information and make choices. Once a course of therapy is initiated, it may be carried out without further consent discussion, assuming that the patient doesn't ask to revisit or revoke assent [5]. Anything that changes the equation of risks, benefits, alternatives, understanding, or ability to make a choice requires returning to the consent process with the patient. If, for example, a patient does not respond well during the course of treatment, and it becomes unlikely that he or she will benefit from the agreed-upon treatment, consent must be discussed because the potential for benefit has changed. If a complication puts a patient at higher risk for further complications with continuing treatment, the patient must decide how to balance this increased risk within his or her own values.

The consent also needs additional clarification whenever an area of special sensitivity becomes involved. In discussions of intensely personal matters, patients deserve to set the parameters of the discussion. Genital exams involve an obvious area of sensitivity, and elements of sexual history are very personal. The patient's desire for privacy should be discussed and respected. If a patient has a particular concern or anxiety that the doctor is aware of, it should be addressed directly during a consent discussion. Finally, a patient has a right to know the level of skill and experience of anyone performing a procedure.

In sum, a solid understanding of the goals of informed consent can guide one's decisions about when it needs to be discussed and what level of disclosure is satisfactory. Respecting a person's right to autonomous decision making defines the boundaries of consent. Good clinical practice and an emphasis on communication as a routine part of any interaction eliminate much of the need to overthink consent in routine situations. It is respectful to introduce everyone in the room and clarify each person's role. It is sound clinical practice to explain what you are doing while you examine a patient and to state what you will need to touch or look at. As situations become more complex and interventions more invasive, the fundamental value that is to be protected is the patient's autonomy. If you are unsure about whether consent is needed, talking to a patient should be the first step. Having discussions about what respect and autonomy mean to them, even briefly, will help you decide how to tailor the care the patient receives to their individual needs and expectations.

Notes and References

1. American Medical Association. Opinion 8.087 Medical student involvement in patient care. *Code of Medical Ethics*. Chicago, IL: American Medical Association; 2008. http://www.ama-assn.org/apps/pf_new/pf_online?f_n=browse&doc=policyfiles/HnE/E-

8.087.HTM&&s_t=&st_p=&nth=1&prev_pol=policyfiles/HnE/E-7.05.HTM&nxt_pol=policyfiles/HnE/E-8.01.HTM&. Accessed June 14, 2008.
2. See the discussion in Beauchamp TL, Childress JF. *Principles of Biomedical Ethics.* 4th ed. New York, NY: Oxford University Press; 1994:438.
3. Beauchamp, 142-146.
4. Beauchamp, 147-150.
5. For an example of this principle see *Gorab v Zook*, 943 P2d 423 (Colo 1997). This is Colorado case law and not binding in all states, but it explains the legal position that consent for a treatment plan holds for the duration of that treatment plan.

Erin A. Egan, MD, JD, is an assistant professor of medicine at the University of Colorado Denver, a faculty associate with the Center for Bioethics at the University of Colorado Denver (UCD), and a visiting lecturer at the Neiswanger Institute for Bioethics and Health Policy at the Loyola University Stritch School of Medicine in Maywood, Illinois. She serves on the ethics consultation subcommittee, the ethics committee, and the organizational ethics committee at UCD, is the director of quality improvement for the Hospital Medicine Group, and the program director for the Holocaust in Contemporary Bioethics Program.

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