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Improving the Informed Consent Process

When informed consent is a piece of paper, it fulfills a legal obligation. When it's a process, it improves quality of care.

It has been nearly 100 years since Justice Benjamin Cardozo outlined the principle of informed consent in the New York Supreme Court case of *Schloendorff v. Society of New York Hospital*. The term "informed consent" was coined in a medical malpractice case in 1957. But, while the concept and definition of informed consent has long been established, the actual process has a long way to go.

Most people readily agree that patients should be actively involved in their own healthcare and decisions about treatment – or, as Judge Cardozo put it, that "Every human being of adult years and sound mind has a right to determine what shall be done with his own body." In addition to being the right thing to do in terms of patient rights, properly executed informed consent has the potential to increase patient safety, enhance patient-physician communication, decrease risk of malpractice claims, and even reduce healthcare costs.

But informed consent can be difficult to accomplish in practice, especially in the high pressure, fast-paced environment of a hospital. In this setting, patients are less likely to speak up and more likely to just sign the form without reading it or asking questions. Healthcare professionals also have less time to get to know the patient and pick up on cultural clues or problems with literacy.

"It's a disadvantage to patients and to health systems that the informed consent process does not in any way fulfill its potential," says John Spertus, MD, Director, Health Outcomes Research at Mid America Heart Institute in Kansas City, MO. Spertus cites one study of surgical patients in which 69 percent of patients admitted they hadn't read the forms they signed. In another study, 44 percent of patients could not describe the procedure they had and 27 percent could not even name the organ that had been operated on.

Fueled by a variety of forces – including new requirements from the Centers for Medicaid and Medicare Services (CMS) and Joint Commission (JC) – many hospitals and healthcare organizations across the country are putting increased emphasis on improving the informed consent process. Some of the goals of this process are:

- **Improved Health Outcomes:** The Institute of Medicine points out that the quality of communication between provider and patient often correlates with the quality of care rendered. Informed consent is part of the ongoing dialogue between patient and provider.

- **Increased Patient Safety:** Joint Commission's Speak Up initiative emphasizes that patient's role in his or her own safety in the hospital. If a patient understands what is supposed to happen during the procedure, he or she is more likely to speak up and point out something that seems amiss.

- **Reduced Liability Exposure:** Breakdowns in communication are at the root of many malpractice claims. Improving the quality of communication during the informed consent process can go a long way to reducing liability exposure. "When patients aren't informed and feel that things were kind of 'done to them' without them knowing, the patients don't feel an ownership of that decision-making process," explains Spertus. "If something goes wrong they're likely to blame the doctors and the institutions and that leads to malpractice suits." Hospitals are often named in these cases.

Sue Dill Calloway, RN, JD, a medical-legal consultant based in Columbus, OH, points out that a properly documented informed consent can often stop a claim before it's filed. "It's difficult to find a lawyer who will take a case when informed consent is in place," she says.

And, of course, the hospital has an obligation to adhere to accreditation guidelines and other regulations in regard to informed consent. "Failure to do so implies a breakdown in the standards of care, which is a liability issue," adds Elaine Ziemba, Managing Director of the Risk Management Department at Stanford University Medical Center.

Spertus sums it up this way: "If you think about what the Institute of Medicine is challenging us to do in terms of healthcare – to be more evidence-based, safer, more patient-centered, more cost-effective. We're accomplishing all of those [by improving the informed consent process.]"

Can one piece of paper do all that?

Of course not. But an organized effort on the part of a hospital and its medical staff can.

So what can hospitals do to improve the process in their hospitals?

Make sure you know the requirements of your state and accrediting organizations, in addition to CMS.

According to Joint Commission (JC) requirements, "Informed consent is not merely a signed document. It is a process that considers patient needs and preferences, compliance with law and regulation, and patient education."

CMS requirements clearly give hospitals a role in that process: "Hospitals must utilize an informed consent process that assures patients or their representatives are given the information and disclosures needed to make an informed decision about whether to consent to a procedure, intervention, or type of care that requires consent." Furthermore, documentation of this process should be in that patient's file prior to the procedure (except in case of emergencies).

All 50 states have their own laws pertaining to informed consent. In addition, there are federal guidelines. Joint Commission and other accrediting organizations add another layer of requirements, which may be different for different departments of the same hospital or medical center.

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Develop policies and procedures that meet regulations and clearly state which staff should be involved in the informed consent process.

Once upon a time, hospitals could make a case that informed consent was the physicians' responsibility only. The new CMS and JC requirements clearly put that in the past.

"Everybody has a piece of this," says Ziemba. "Not all staff members have the legal duty, but we all have an opportunity to help the patient understand."

The moment before surgery is probably not the best time to start this process, Calloway points out: "Don't wait until the patient is in the OR to do the first check." Pre-admission testing is a good opportunity to make sure the patient understands the procedure and that the signed form is in the works. Calloway recommends that the hospital offer multiple ways for the form to get from the physicians' office into the patient's hospital chart – email, fax, hand-delivered, etc.

Ziemba recommends that constant reminders and checks and balances be built into the process: When the patient checks in for a procedure, registration clerk confirms the condition and procedure. Nurse checks for understanding, and then witnesses the patient's signature. The medical records clerk confirms that the form is properly signed and witnessed before enters it into the record. A before surgery checklist offers another opportunity to ensure that informed consent has been properly executed.

Calloway reminds hospitals that they must maintain list of all consent-required procedures the hospital has credentialed and privileged medical staff to perform. When a medical staff member gets a request for a procedure that's not on the list, the list needs to be updated.

Support medical staff in their efforts.

While hospitals may not directly control the patient-physician interaction, there's quite a bit that can be done to make the informed consent process easier on physicians.

One of the first things hospitals can do is take a look at the consent forms that are available to medical staff. Many hospitals keep pre-printed forms at the ready, but often these are standard-issue for all procedures, not customized to the procedure or the patient's needs and preferences.

"Most consent forms are written in a legalese which is not read by patients," says Dr. Spertus. "They're very vague and uninformative, and they really don't support shared decision making."

At Mid America Heart Institute, Spertus and his team rewrote the informed consent forms to explicitly explain common cardiac procedures (such as angiogram, angioplasty, stent placement etc) at an 8th grade reading level with supporting illustrations. ("You had to have graduated from college to understand the old forms," Spertus says.) They also added individualized risk estimates based on information about the patient and statistics from the American Heart Association and the American College of Cardiology. When the patient signs this form, it shows very clearly that he or she has received a clear explanation of the procedure, and its risks, benefits and alternatives.

At Stanford, medical staff now can give patients access to a web-based program with interactive patient education about the procedure. The physician gives the patient an access code, and the patient signs on from a home computer or a computer in the clinic. The program documents the patient's interaction with the program. If the patient shows up for the procedure without using the program, the hospital can offer alternative learning materials, such as a verbal explanation or printed patient education brochures.

Calloway says that the ideal tool would not only offer patient education about the specific procedure, but would also automatically generate an informed

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consent form that meets the requirements of the appropriate state and accrediting organizations. That way the physician, patient and hospital get what they need from the process.

Make sure medical and hospital staff have training in methods to improve patient-provider communications.

Another way to support staff is to provide communication training and tools. To healthcare providers, the hospital is a familiar environment, and the procedures that they perform each day are second nature. Not so for the patient.

"In an unfamiliar environment, patients can get tense and stressed," Ziemba says. "Communication can help patients feel calmer." Ziemba likens the experience to being on an airplane going through turbulence. "Passengers feel better when the pilot talks to them and explains what's happening."

Methods advocated by the Joint Commission – such as teach back, open-ended questions – can help the clinicians get to know their patients better and build trust, which have been linked to higher patient satisfaction as well as better health outcomes.

"At Stanford, we work on many aspects of communication between staff and patient," says Ziemba, pointing out that "communication breakdowns are the number one problem in patient safety and patient satisfaction."

These training sessions should also focus on cultural considerations for the populations likely to be served by the hospital. This includes not only people from other countries, but also elderly patients, people with disabilities, and other situations that can make communication and understanding difficult.

Essential Elements of Informed Consent Process

Informed consent is both an ethical and a legal requirement. According to the American Medical Association, the physician (not a delegate or representative) should convey to the patient the following information:

- Diagnosis
- Nature and purpose of proposed treatment or procedure
- Risks and benefits of proposed treatment or procedure
- Alternatives and their risks and benefits
- Risk and benefits of not receiving treatments or procedures

Physicians should document the informed consent process in the patient's record. This not only protects the physician in case of a malpractice claim, but also serves as evidence that the physician and hospital are following policies and procedures recommended and/or required by CMS and Joint Commission.

The informed consent form is just one part of that documentation. The form itself should contain the following information:

- Name and signature of patient or legal representative
- Name of hospital
- Name of procedure
- Name of practitioners performing the procedure
- Risks and Benefits
- Alternative procedures and treatments and their risks
- Date and Time
- Statement that procedure was explained to patient/guardian
- Signature of witness
- Name and signature of person who explain the procedure

"It's an important process not just because of CMS but because it's really important to have that level of communication with the patient," Ziemba says.

Patients have come to expect this communication and shared decisionmaking. According to a study published in the Journal of Hospital Medicine in 2008, 85 percent of hospitalized patients wanted to participate in decisions made about their care even when the risk of the procedure was minimal. That number increased to 95 percent for high-risk procedures.

"Any of us would want to know, to be able to ask questions and to become involved in our care," says Ziemba.

And that's what true informed consent is all about.

Resources:

Joint Commission, New and Revised Hospital EPs to Improve Patient-Provider Communication, January 2010

Joint Commission, What Did the Doctor Say? Improving Health Literacy, 2007

Joint Commission, Speak Up Initiative, 2002-2010

The Joint Commission 2009 Requirements Related to the Provision of Culturally Competent Patient-Centered Care, Ambulatory Health Care Accreditation Program (AHC), 2009

CMS, State Operations Manual Appendix A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals, rev. 6-5-09, A-0466 informed consent

CMS Memo on Informed Consent, April 2007

Temple Health, *A Practical Guide to Informed Consent,* 2007

HealthLeaders Media, Informed Consent: It's Not Just a Form, It's a Process, Jeffrey Driver, June 24, 2008

Health IT, Informed consent key, Fay Rozovsky, President of Rozovsky Group, February 02, 2009

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