Developing an Informed Consent Process With Patient Understanding in Mind

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As part of its 2003 Clinical Performance Improvement Strategic Plan, Iowa Health System incorporated health literacy as a cross-cutting, system-wide quality initiative. With 10 senior hospital affiliates in 7 cities, a 14 rural hospital network, and 430 primary care physicians, Iowa Health System provides health care for a third of Iowans. Health literacy teams have been established at hospital affiliates, outpatient clinics, and home health agencies using the Model for Improvement, learning sessions, conference calls, training workshops, and electronic communication to test and implement a variety of health literacy interventions. Iowa Health System’s overarching health literacy goals are targeted toward improving interpersonal and written communication and creating a patient-centered care environment that welcomes questions and encourages dialogue.

Teams chose to improve consent documents and processes as part of their goals to improve patient understanding through plain language, teach back, and reader-friendly print materials. This was predicated on the increasing prominence of health literacy as a health care quality and safety priority; on case law involving communication of risks where claims have involved a lack of informed consent; and on concern that consent forms are written in language that patients cannot understand. Below we describe our rationale, experience, and lessons learned.

Building the Case

Health Literacy as a Quality and Safety Priority

Recognizing and communicating that a diverse set of leading health care organizations identify improving patient understanding during the informed consent process as an important quality and patient safety strategy helps garner support among physicians, staff, and organizational leaders.

The National Quality Forum (NQF) published Safe Practices for Better Healthcare in 2003. Updated in 2006, the report presents evidence-based practices that should be used universally to reduce the risk of harm in the health care setting. Safe Practice 2 (originally Safe Practice 10) states: “Ask each patient or legal surrogate to ‘teach back’ in his or her own words key information about the proposed treatments or procedures for which he or she is being asked to provide informed consent.” Additional guidance is provided about teach back; reading level and language for consent documents; engaging in a dialogue about the procedure for which consent is being sought; and use of qualified medical interpreters or readers to assist those with limited English proficiency or health literacy, or visual or hearing impairments. Safe Practice 2 is relevant to practitioners in multiple clinical areas and to patient-centered care, especially for those who are particularly vulnerable to medical errors associated with communication barriers, including low health literacy.

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The Safe Practices are included in the Hospital Quality and Safety Survey of the Leap Frog Group, an organization working to mobilize employer health care purchasing power to achieve breakthrough improvement in safety, quality, and affordability.6

The Joint Commission and Centers for Medicare and Medicaid Services promulgate standards and regulations related to informed consent. The Joint Commission standards address informed consent as stated in Standard RL.2.40—“Informed consent is obtained,” and Standard PC.6.30—“The patient receives education and training specific to the patient’s abilities as appropriate to the care, treatment, and services provided by the hospital.” There are Centers for Medicare and Medicaid Services requirements related to informed consent for hospitals in several Conditions of Participation (CoP) (Patients’ Rights CoP at 42 CFR 482.13(b)(2); Medical Records CoP at 482.24(c)(2)(v); Surgical Services CoP at 482.51(b)(2)). Revisions to interpretive guidelines in 2007 demonstrate continued emphasis on the importance of informed consent and patient involvement with informed decisions:

The right to make informed decisions means that the patient or patient’s representative is given the information needed in order to make ‘informed’ decisions regarding his/her care…The patient or the patient’s representative should receive adequate information, provided in a manner that the patient or the patient’s representative can understand, to assure that the patient can effectively exercise the right to make informed decisions. (Interpretive Guidelines §482.13(b)(2))

The American Medical Association (AMA) states, “Informed consent is more than simply getting a patient to sign a written consent form. It is a process of communication between a patient and physician that results in the patient’s authorization or agreement to undergo a specific medical intervention.”7 In Health Literacy and Patient Safety: Help Patients Understand, Reducing the Risk by Designing a Safer, Shame-Free Health Care Environment,8 the AMA states:

Patient understanding is the first patient right and without such understanding there are limitations on the ability to exercise all other rights customarily credited or formally contracted to patients. This right is not one that physicians confer, but one they assist patients in exercising freely. It is neither just nor fair to expect a patient to make appropriate health decisions and safely manage his or her care without first understanding the information needed to do so.

This is underscored in the 2005 White House Conference on Aging proceedings:

“Patients have the right to understand healthcare information that is necessary for them to safely care for themselves, and to choose among available alternatives. Healthcare providers have a duty to provide information in simple, clear, and plain language and to check that patients have understood the information before ending the conversation.”9

Case Law

National case law addresses the way risk is communicated and recognizes that claims have involved lack of informed consent. Informed consent is a process, not merely the signing of a document. Consent documents, in conjunction with provider documentation, are used as evidence that informed consent was given. Studies have shown that 18% to 45% of patients are unable to recall the major risks of their surgery; 44% do not know the exact nature of their operation; and 60% to 69% do not read or understand the information contained in a hospital consent form.10 Legally, a signed consent form is not proof of informed consent. If the patient does not understand, the form is meaningless.

Readability

In Health Literacy: A Prescription to End Confusion, the Institute of Medicine of the National Academies found that the readability levels of informed consent documents for research and clinical practice exceed the documented reading levels of the majority of adults in the United States, and that this has important ethical and legal implications that have not been fully explored.1 Readability analyses from representative Iowa Health System senior hospital affiliate consent forms demonstrated that many were written at or above 17th grade level.

The Iowa Health System Experience

In 2004, the trends described above led Iowa Health System to embark on its work to create a reader-friendly written consent document to prompt action on the informed consent process using teach back. Beginning with the Consent for Surgery/Procedure document, an iterative process was used to develop a plain language consent that improved readability and patients’ understanding, ability to make informed choices, and satisfaction. The revised document was also intended to help providers ensure that patients understand their procedures and have the ability to ask questions as needed while not adding complexity to the perioperative care environment. The consent was developed in collaboration with Iowa Health System health literacy teams, risk managers, health care providers, the Iowa Health System Law Department, and adult learners who reviewed multiple drafts, clarifying terms, content, and design. A cardinal feature of the consent is a space for description of the procedure not only in medical terms, but also in the patient’s own words—a form of teach back. Plain language characteristics of the new consent include: simple words; short sentences; short paragraphs; minimal medical terms; clear headings, bullets, and numbering; generous white space; 12-14 point serif fonts; key uses of bold text; and 1.5 line spacing. The final document has a seventh to eighth grade reading level calculated manually using the Fry formula and electronically using Readability Calculations software.11

When team members had agreed on a near-final draft, an evaluation tool was developed for pilot testing at a single hospital. Data were collected using the original consent form followed by the new consent form on patient demographics
and procedure type; time to complete the document; whether the consent was actually read; who read it (eg, patient, family, and/or nurse to patient/family); ease of patients in recounting the name of the surgery in their own words (teach back); questions asked by patients or their families during the consent discussion; and patient/family and nurse satisfaction with the process and new consent form.

Results were positive for all types of patients and procedures. Patients and staff reported high satisfaction with the reader-friendly form and process. Nurses did not find that asking for teach back (description of the procedure in the patients’ own words) during the consent process was awkward; all respondents moderately/highly valued this use of teach back. Nurses also reported it was much easier to clearly evaluate patients’ knowledge about their surgery, and patients’ comfort level in asking questions was enhanced by the “permission” wording on the form. Patients/families reported appreciation of the easier-to-read format and being asked to state in their own words the description of their surgery. Increases in time, interruptions, or extra calls to physicians for clarifications or answers to questions that arose when patients actually read and understood the consent document have not been reported.

Following communication with key departments, senior administration, physicians, and thought/opinion leaders, the first pilot hospital adopted the new consent document for all surgical procedures. Three hospitals followed, and a fifth hospital recently initiated pilot testing. Testing is repeated at each hospital, somewhat more rapidly, to build will, acquire local data, and problem solve at the local level. Each affiliate is asked to chronicle their experience so others can learn from their work. As support for the new consent increases, widespread implementation at other affiliate hospitals occasionally has to be tempered as pilot testing, communication, and staff and provider education are conducted.

Additional health literacy-related consent work continues. The new Surgery/Procedure consent has been translated into Spanish with additional pilot testing. English and Spanish versions of a Blood/Transfusion consent have been developed and are being pilot tested by the hospitals. Work has begun on a Consent for Procedure by Non-Physician Providers.

**Lessons Learned and Keys to Success**

Building support among physicians, staff, and senior leaders requires underscoring the increasing focus on health literacy by professional, payer, accrediting, and regulatory organizations; health literacy’s relationship to risk management; and evidence demonstrating the impact of low health literacy and its integral role in the informed consent process.

Documenting the processes of testing and adopting new forms, conducting pilot tests, communicating proactively with affected leaders, departments, and committees, and continuously learning from others’ experience build will, provide local data to support the effort, and help navigate potential roadblocks. It is important to involve all those with roles in the consent process, organizational change, and quality of care. It is equally and vitally important to include patients and adult learners. Patient input and feedback helped structure the ultimate content and layout of the new consent and provided an effective counterpoint to arguments against simplification.

All providers must be educated about the difference between the informed consent process and the consent form. Signing the consent form alone is not sufficient to meet legal requirements for informed consent. It is the role of the provider to discuss, through a process of shared decision making, the recommended surgery, procedure, treatment plan, anesthesia, or other service. Physicians then need to be sure patients understand what is being recommended, its risks and benefits, other options and their risks and benefits, and risks and benefits of no treatment before patients make a decision.

Providers and staff also should be educated about the need to use simpler language and teach back. Building capacity on use of teach back should be part of improving the informed consent process because asking patients to describe or repeat back in their own words what they understood they have been told is our way to make sure they really understand. If gaps or misunderstandings are heard, further teaching can be done. Ultimately and ideally, teach back will be interwoven throughout the entire informed consent discussion, even if additional assistance (eg, trained interpreters) must be provided to help patients understand.

Other health care organizations are also working to improve the consent process. Their efforts include standardized education using employee orientation and ongoing educational and peer reinforcement and requiring documentation of teach back on the consent form or in the health care record prior to the procedure.

As additional Iowa Health System affiliates adopt the reader-friendly consent, continuing emphasis will center on moving beyond use of the new form toward incorporating teach back to check for and ensure understanding and documenting these discussions during everyday interactions with patients and families. In the context of patient-centered care, consent is a shared decision-making process between the patient and their provider, not an event or a signature on a form. True informed consent is a core component of quality health care.

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REFERENCES