

Using Principles of Health Literacy to Enhance the Informed Consent Process

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Health care today exposes consumers to a significant amount of critical information, ranging from prescription bottle labels to insurance forms and from dietary guides to procedural consents. The complexity of the information prevents a significant number of patients from fully comprehending it. Health literacy, as defined by Healthy People 2010, is

the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.^{1(p37)}

The 2003 National Assessment of Adult Literacy by the National Center for Education Statistics showed that 36% of adults have basic or below-basic health literacy.² Basic print literacy may not guarantee comprehension of presented health care-related materials, especially considering the use of health care terminology and that illness, pain, stress, and fear may alter normal abilities.

There is a critical link between health literacy, patient understanding, and patient safety. According to Osborne,

Literacy matters in health care because life-threatening or potentially harmful mistakes may happen when people cannot read or understand written information.^{3(p8)}

This link was further emphasized at a Joint Commission-sponsored conference, where Koransky identified methods of defining and ensuring informed consent.⁴ The barriers to informed consent include language-limited interpreters for some languages, cultural

issues, and lack of medical knowledge and education, which contribute to patients' inability to fully comprehend information given to them regarding their medical condition and the procedures involved.⁴ Koransky suggested solutions including using layperson's language, slowing down to allow time for the patient and family members to understand, and encouraging "repeat back." Repeat back (ie, "teach back") is the practice of asking the patients to state in their own words their understanding of what they have been told by the medical professional.

This article describes how one health system incorporated health literacy into its surgical consent document and process. The goals of the project were to

- educate the staff on health literacy concepts,
- develop an understanding that informed consent is a process,
- develop a reader-friendly consent form for surgery and procedures,

ABSTRACT

THE LANGUAGE COMMONLY used in procedural/surgical consent forms often exceeds the average reading level of US patients, and many do not read the document before signing it.

INCORPORATING READER-FRIENDLY language and formatting makes it more likely that patients will read the document, understand it, and therefore give informed consent. Adding "teach back" into the document provides a means of evaluating patient understanding.

USING READER-FRIENDLY procedural/surgical consent documents merges the objectives of both health literacy and informed consent. *AORN J* 88 (July 2008) 23-29. © AORN, Inc, 2008.

- increase the number of patients reading the consent document before signing it, and
- incorporate the use of “teach back” to evaluate patient understanding.

IMPETUS

As part of its 2003 Clinical Performance Improvement Strategic Plan, Iowa Health System incorporated health literacy as a system-wide quality initiative. Iowa Health System comprises 10 senior hospital affiliates in seven cities, a rural hospital network, and more than 300 primary care physicians. The hospital affiliate described in this article is a three-campus regional health system in a bi-state location. The Iowa Health System Health Literacy Collaborative was initiated in 2004 with overarching health literacy goals targeted toward improving interpersonal and written communication and creating a patient-centered environment.

Teams chose to improve consent documents and processes as part of their goals to improve patient understanding through the use of plain language, teach back, and reader-friendly print materials. The catalyst for choosing consent documents as one of the first major projects was the team’s concern that consent forms are complex. Fry Readability Formula⁵ analyses of representative Iowa Health System affiliate consent forms demonstrated that many were written at or above the 17th grade level. Because of this, it was uncertain whether patients understood the consent form before signing it, which made it unclear whether the consent given was informed consent.

Obtaining the patient’s informed consent is required by the Joint Commission as stated in Standards RI.2.40, “Informed consent is obtained,”⁶ and 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.”⁷ The Centers for Medicare & Medicaid Services require informed consent for hospitals in several Conditions of Participation.⁸⁻¹⁰ Revisions to

interpretive guidelines in 2007 demonstrate continued emphasis on the importance of informed consent and patient involvement with informed decisions:

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.^{11(p1)}

The Office of the General Counsel of the American Medical Association contends that the essence of informed consent is not having a patient sign a written form but is a process involving communication between a patient and physician that includes verification of a patient’s understanding and then authorization or agreement to undergo a specific medical intervention.¹² The 2005 White House Conference on Aging proceedings asserted that patients have the right to understand health care information necessary to safely care for themselves and to make choices among health care alternatives. Congruently, health care providers have a duty to provide information in simple, clear, and plain language and to evaluate whether patients have understood the information before ending the conversation.¹³

PROJECT DEVELOPMENT

Each affiliate had a health literacy team that participated in learning sessions and monthly conference calls to confer on a variety of health literacy interventions. The affiliate team cited here was multidisciplinary, including members who served in clinical education, risk management medical education, and adult learners and new readers in a local community college extension program.

Laying a foundation for understanding health literacy at the staff level was an important first step. Each affiliate team developed an education plan for staff, focusing on the Iowa Health Literacy Collaborative goals. At this affiliate, the approach to staff education included

- viewing the Institute of Medicine video *Health Literacy: A Prescription to End Confusion*,¹⁴

For more information on health literacy, visit the National Network of Libraries of Medicine web site at <http://nmlm.gov/outreach/consumer/hlthlit.html>.

- completing a computer-based learning module defining health literacy concerns and means of improving communication;
- adding material on health literacy to a learning module on patient rights for new employee orientation and annual all-staff required education; and
- designing a health literacy program and presenting the program to physicians.

Involving new readers on the teams was an important component of the Iowa Health System Collaborative. These were team members who identified themselves as having “poor or underdeveloped reading skills” and were taking steps to improve their literacy levels. A collaborative partnership between the New Readers of Iowa, as well as community adult learning programs, was instrumental in evaluating the readability of patient-education and consent materials.

DEVELOPMENT OF THE CONSENT DOCUMENT

An Institute of Medicine Committee on Health Literacy report found that the readability of informed consent documents exceeds the average reading levels of the majority of adults in the United States.¹⁵ Most adults admit to not reading consent forms for reasons including that

- the form is too long,
- the format is crowded or intimidating,
- the font size is too small, and
- unexplained medical and legal terms are used.¹⁶

An evaluation of surgical consent forms at Iowa Health System affiliates found documents that mirrored this description (Figure 1).

Beginning with the procedural/surgical consent document, an iterative process was used to develop a plain language consent. The consent was developed in collaboration with health literacy teams, risk managers, health care providers, members of the Iowa Health System Law Department, and new readers who reviewed many drafts to assist in clarifying terms and content as well as improving the design.

In accordance with the principles of reader-friendly print materials, criteria for the new form were as follows:

- limit to one page, one- or two-sided;
- simple words;
- short sentences;
- minimal medical terms;
- 12- to 14-point serif fonts;
- generous white space;
- numbering and bullets;
- clear headings;
- key use of bold text; and
- 1.5 line spacing.³

Key features of the new consent form were sections for the medical description of the procedure and for the description of the procedure in the patient’s own words, to allow an opportunity for teach back (Figure 2).

Affiliates agreed upon a near final draft consent document and a survey tool for pilot testing before the full affiliate implementation. Pilot testing was conducted in an ambulatory surgery facility on one of the affiliate’s three campuses. The education and focus for pilot testing was on informed consent as a process. The role of the nurse was emphasized in the teach-back process to evaluate patient understanding.

I, _____, hereby authorize Dr. _____ and/or such assistants as may be selected by him/her and _____ Hospital, its staff, employees or designees, to treat the condition or conditions which appear indicated by the diagnostic studies already performed.

Figure 1 • Sample section from the original consent document.

I, _____ (patient’s name) agree for Dr. _____ along with any assistants the doctor may choose, to do this surgery or procedure on me:

 Name of surgery or name of procedure in medical words including left, right or level
(Doctor or health care worker fills this out)

 of surgery or name of procedure in my own words
(What the patient or family says back to the doctor or health care worker – quote patient or family)

Figure 2 • Sample section from the new consent document.

An expected outcome of the pilot test was an increase in the number of patients who read the consent form before signing it. A secondary, and more critical, expected outcome was documenting patient knowledge regarding the anticipated procedure, thus supporting informed consent.

Initially, an affiliate hospital team member met with the vice president of medical affairs to share the objectives of the program. With administrative support, two team members met with an ophthalmologist who had expressed interest in promoting health literacy. Discussion of the proposed consent document and pilot process resulted in this physician’s agreement to pilot the new procedural/surgical consent document. Team members met with nursing staff members on the ambulatory surgery unit to introduce them to the new consent form and pilot process. Emphasis was placed on the importance and documentation of teach back and the use of the survey tool.

RESULTS

Baseline data were collected by ambulatory surgery nursing staff members using the survey tool for 41 patients, ages 26 to 80 years, who underwent varying procedures and were given the original consent form. During a subsequent seven-week period, the new consent

form was given to 35 patients ages 34 to 87 years scheduled for eye surgery (ie, Campus #1). Data were collected from these patients using the same survey process. The new consent form was then pilot tested on a second campus ambulatory surgery unit (ie, Campus #2) with a group of 53 patients ages one month to 91 years scheduled for varying procedures. Their responses were monitored through the same survey process (Table 1).

When comparing use of the original and new consent forms, significant differences were seen in nurses’ responses to the first question: “Did the patient/family read the consent?” For the original consent, 25% of patients read the form. During the pilot programs with the new consent, 77% and 91% from Campus #1 and Campus #2, respectively, read the consent. Survey comments provided by nursing staff members indicated that because of poor vision preoperatively, 57% of the patients in the first pilot group asked the nurse to read the consent form to them. Because Campus # 1 was composed of patients undergoing eye surgery, the poor vision may have played a part in the results; therefore, it is believed that the results from the Campus # 2 pilot represent a truer comparison to the original consent group (Table 2).

The second item, “Patient just asked where

**TABLE 1
Demographic Information**

	Original consent	Campus #1 pilot	Campus #2 pilot
Number of patients	41	35	53
Age range	26-80+ years	34-87 years	1 month-91 years
Gender			
Male	44%	35%	46%
Female	56%	65%	54%
Race			
Caucasian	34%	88%	85%
Hispanic	5%	6%	4%
Black	0%	6%	2%
Indian	0%	0%	2%
Not indicated	61%	0%	7%

TABLE 2
Survey Tool Questions and Answers

Patient data	Original consent		Campus #1 pilot		Campus #2 pilot	
	Yes	No	Yes	No	Yes	No
Did the patient/family read the consent?	25%	75%	77%	23%	91%	9%
Patient just asked where to sign and did not read.	66%	34%	14%	86%	10%	90%
Patient could easily describe procedure in own words.	88%	12%	89%	11%	100%	
Patient signed consent.	100%		100%		100%	
Nurse response data	Original consent		Campus #1 pilot		Campus #2 pilot	
1 Dissatisfied	Not applicable (NA)		0%		0%	
2 Less satisfied	NA		3%		0%	
3 Satisfied	NA		79%		4%	
4 Very satisfied	NA		11%		2%	
5 Most satisfied	NA		7%		94%	

to sign and did not read the consent," also showed significant differences between the original and new consent groups. Using the original consent, 66% of respondents indicated that neither the patient nor the family members tried to read the consent but asked where to sign. In the pilot cases, this percentage was reduced to 14% and 10% for Campus #1 and Campus #2, respectively.

In this survey, significantly more patients read the "reader-friendly" consent than the original complex consent. This supports the findings from the literature that most patients do not read the consent due to literacy issues with the document.¹⁶

No significant difference was found between the use of the original and new consent forms when patients were asked to describe the procedure in their own words. A response demonstrating knowledge of the procedure was given 88% of the time with the original consent compared to 89% and 100% with the new consent in the Campus #1 and #2 pilot tests, respectively.

Documentation of the patient's knowledge through the use of teach back was not an aspect of the original consent form but was added as part of the new consent form. It is important to note that this strategy indicated a need for

additional clarification in groups using both the original and the new consent forms: 12% of the patients using the original consent form and 11% of the patients in Campus #1 using the new consent form had difficulty explaining their procedure in their own words.

The majority of nursing staff members reported being satisfied with the reader-friendly consent form—79% in Campus #1 reported being "satisfied" and 94% in Campus #2 reported being "most satisfied." This was an important finding, since the addition of a teach-back strategy was expected to require more of a nurse's time and potentially create dissatisfaction. Furthermore, there was no indication that nursing time was increased through use of the new consent form, and it did provide documentation of the patient's understanding of his or her procedure, which was missing from the original process. Some patients and their families expressed appreciation for the reader-friendly format of the consent.

Data support the anticipated results, that there would be an increase in the number of patients and family members who read the reader-friendly consent compared to the original consent. Since nurse satisfaction was not measured for the original consent, the high

satisfaction rate of the new consent has no comparison.

As a last step, the document was presented to the entire medical staff in both states. Acceptance was unanimous, and the reader-friendly procedural/surgical consent form was adopted for use by this affiliate.

SPANISH VERSION

In the counties served by this affiliate, between 4.6% and 10.2% of the population is Hispanic, according to 2000 census figures.^{17,18} For this reason, the original consent form was available in Spanish.

For the Spanish consent pilot trial, one question was added to the original survey tool asking nursing staff members for their satisfaction level using the consent with an interpreter. This form was pilot tested on the same ambulatory surgery units as the English version and the project sample comprised four Spanish-speaking patients.

Three of the nurses rated the form at a 3 (ie, satisfied), and one rated it at a 5 (ie, most satisfied). Three of the patients reported having no questions; one question was referred to the surgeon. Two patients had translators from an agency; two had family members as their translators. The small sample size of this investigation is recognized as a limitation of these results; nonetheless, the Spanish version of the reader-friendly consent was implemented.

MODIFICATIONS

One issue that arose during the pilot program was the discovery of an oversight in the previous consent processes. Formerly, the Universal Protocol documentation form was on the reverse side of the original consent document. This contained the "time out" checklist. To ensure continued documentation of time out, this checklist was reattached to the new consent as a separate document.

The new consent form was intended to be used for any surgical procedure on any campus. One department, however, often performs procedures with long, descriptive names. For convenience, staff members in that nursing unit requested that the document include a checklist of procedures at the top of the page. With re-

spect to the principles of reader-friendly print materials, a checklist of multiple procedures on a single consent was considered to be a barrier to informed consent and, therefore, a safety concern. The compromise solution was to have the most frequently performed procedures preprinted, each on a separate consent document. The consent content remained uniform and maintained the opportunity to include the teach-back process. An additional line was added to accommodate lengthy medical descriptions of procedures.

IMPLICATIONS FOR NURSING

Overall, this project successfully employed a collaboration of one health care system and hospital representatives to embrace health literacy concepts by revising procedural/surgical consent documents. The resulting pilot projects have contributed to the body of evidence-based practice and to the development of best practices in the area of health literacy.

Communication between health care providers and patients can be improved by using evidence-based, health-literacy concepts. This is a fertile field for additional study. There also is a continued need to document the effect of teach back as a convincing method for verifying patient understanding. Use of the new consent documents provided nursing staff members with a clear opportunity to assess patients' comprehension of their procedures.

The new consent documents help nursing staff members confirm patient understanding by providing an easy-to-read format and by requiring the patient to articulate procedural plans through the use of teach back. Implications for nursing include the verification and documentation of patient understanding and simplification of the consent completion process with regard to time and effort.

CONCLUSION

Each step toward improving health literacy is a step toward improving patient knowledge and understanding of factors involving personal health care. This is ultimately linked to improving patient safety and honoring patient rights.

Through the use of health literacy principles, the consent document can become a tool to

encourage and evaluate informed consent. Increasing readability of the document encourages patients to read what they are signing. Most importantly, the teach-back portion provides an assessment tool for measuring patients' understanding of their procedures. Communication with medical and nursing staff is paramount in implementing a new consent document. Increasing staff member awareness of the concepts of health literacy is the starting point. — **BORN** —

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