Section H. Role of the Patient

Chapter 48. Procedures For Obtaining Informed Consent

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Background

The process of obtaining informed consent, whether a written document or an oral communication is one means of ensuring that patients understand the risks and benefits of a treatment or medical intervention. Rooted in medical ethics and codified as a legal principle, it is based on the assertion that a competent individual has the right to determine what will or will not be done to him or her.[1] The American Medical Association (AMA) Code of Medical Ethics establishes informed consent as an ethical obligation of physicians.[2] In addition to being an ethical obligation of physicians, legislation in all 50 states requires that patients be informed of all important aspects of a treatment and/or procedures, although the details of these laws and statutes differ greatly.[2] Failure to obtain adequate informed consent renders a physician liable for negligence or battery[3] and constitutes medical malpractice.

To date, studies of informed consent have not investigated outcomes related to the adequacy of the communication, insofar as this may impact patient safety.[4,5] Physician-patient communication styles have been linked to lower rates of malpractice claims.[6] Nonetheless, as noted by Levinson, malpractice claims do not reflect the actual rate of negligence. While some have hypothesized that better informed consent could improve the patient-physician relationship, establish trust, increase patient compliance, and provide information that could reduce medical error, this has not been shown.[7,8] In the absence of a direct link between adequate informed consent and the reduction of medical error, the "patient safety outcome" reviewed in this chapter is the patient's provision of adequate informed consent.

Practice Description

Informed consent is a process through which a physician informs a patient about the risks and benefits of a proposed therapy and allows the patient to decide whether the therapy will be undertaken.[9] It may be received in one sitting, or over a period of time,[7] either orally or in writing or a combination of the two. Informed consent procedures have been instituted in both research and clinical medicine. In the former case, Federal regulations establish strict guidelines for informed consent that are monitored by a special board at each institution (Institutional Review Board). In addition, risks and adverse events that occur while research is in progress are followed closely and reported. As such informed consent in the research setting differs greatly from informed consent in the clinical setting.[10]

In clinical practice, formal efforts, such as the signing of a consent form, (presumably preceded by adequate exchange of information), are only undertaken in some circumstances, notably prior to major invasive procedures such as radiologic procedures and surgery. Less well appreciated is that all medical care, including pharmacy prescriptions or laboratory tests, requires informal informed consent, except when the patient is incompetent to make a decision or relinquishes the right to provide it.[3] Studies suggest that in practice only minimal formal efforts are made to obtain informed consent for routine interventions.[11, 12]

Legislation governing the requirements of, and conditions under which, consent must be obtained varies greatly from State to State. General guidelines, such as those proposed by the AMA require patients to be informed of the nature of their condition and the proposed procedure, the purpose of the procedure, the risks and benefits of the proposed treatments, the probability of the anticipated risks and benefits, alternatives to the treatment and the associated risks and benefits, and the risks and benefits of not receiving the treatment or procedure.[2,3,13]

As discussed below, procedures to obtain informed consent may not adequately promote the patient's comprehension of the information provided, rendering the consent not truly "informed." Interventions that may prove beneficial in improving and ensuring the patient's understanding include redrafting of consent forms to reduce complexity, providing written materials to accompany oral conversations, using multimedia or other techniques to improve comprehension, and asking patients to recap discussions about the procedure.

Prevalence and Severity of Target Safety Problem

Procedures to obtain consent must ensure that the patient understands his or her condition, as well as the risk and benefits of treatment, and its alternatives. It has been estimated that less than half of the US population understands commonly used medical terms.[14,15] This "health literacy" problem may impact the ability of the patient to understand any attempts to obtain information. In addition to lack of comprehension, procedures to obtain informed consent may be incomplete.

Several studies have noted the various insufficiencies in procedures to obtain informed consent. Three studies examined the completeness of physician-patient conversations in obtaining informed consent. Braddock et al[12] focused on outpatient discussions. Recognizing that some procedures may require more discussion than others, they created a three-tiered evaluation procedure, in which the completeness of patient-physician discussion differ according to the complexity of the decision being discussed. Basic decisions, such as laboratory tests, require the least in-depth discussion, covering only the patient's role, the clinical nature of the decision, and exploration of patient preferences. Intermediate decisions, such as changes in medication, require a moderate depth of discussion, incorporating the Tier 1 subjects, and adding a discussion of alternative treatments, the risks and benefits of the alternatives, and an assessment of the patients understanding. Complex decisions such as surgery require a discussion of the uncertainties associated with the decision, in addition to all of the aforementioned steps. Analyzing audiotaped conversations between 1057 patients and 59 primary-care physicians and 65 surgeons, Braddock et al found that 17.2% of basic decisions contained all required components, while none of the intermediate decisions and only one of the complex decisions contained all of the required components. Applying only the Tier 1 basic consent standards, 20.5% of basic decisions, 21.9% of intermediate decisions, and 38.2% of complex decisions met all the criteria.

In a study of informed consents of surrogates for pediatric patients undergoing surgery, coders examined audiotaped conversations with surrogates, as well as structured interview and questionnaire data regarding the conversations. They noted that patients' recall of the conversations with physicians often omitted key components, such as the risks and benefits of the procedures.[16]

Bottrell et al[13] examined the completeness of 540 consent forms from 157 hospitals nationwide. Of these, 26.4% included all four of the basic elements (risks, benefits, alternatives, and other important aspects of the procedure). Eighty-seven percent noted the general possibility of risk, but less than half provided specific information. Alternatives were noted in 56.9% of the

forms, and benefits appeared in 37%, though most of these were general references rather than specific information. Although 74% of consent forms were deemed incomplete, it is unknown whether physician-patient discussions that preceded the signing of the consent form included the missing information.

A study by Mark et al[9] found that 82.4% of 102 participants reported that they understood everything that their physicians had described about a procedure and indicated that all of their questions had been answered. Eighteen patients had remaining unanswered questions. Half of this group requested more time to speak with their physicians, while the other 9 felt that their questions were not important.

In a study by Lavelle-Jones,[17] 69% of patients admitted that they did not read a consent form before signing it. In addition, approximately half of the patients awaiting treatment were unhappy with the amount of information they received, with 21% stating that most of the information they obtained about their surgical treatment was obtained outside of the hospital.

Consent forms have been targeted for their lack of readability. Patients with limited reading ability are at increased risk for medical errors, due to problems reading medication bottles, appointment slips, self-care instructions, and health education brochures.[18] These patients may also have trouble reading materials intended to aid in obtaining informed consent. According to the National Adult Literacy Survey of 1993, approximately 40-44 million Americans were functionally illiterate, defined as the inability to complete basic reading tasks required to function as a member of society.[19] In addition, even in educated adults, the highest grade-level completed may not reflect actual reading comprehension level. A study of 100 adult cancer patients found that most read at a mean grade-level equivalent of between 10th and 11th grade. The authors suggest that forms and educational materials be written at a grade-level three levels below the highest level of education completed by a patient.[20]

Several studies have examined the readability of procedure consent forms. Two studies examined consent forms for radiologic procedures using computer generated “readability” scores. Consent forms for use with iodinated contrast media found that 12.35 years of education were required to read consent forms.[21] A similar study of general radiologic procedure consent forms found that they required a mean of 15 years of education. Only 16% of forms could be understood by patients with a high-school education.[11] Another Hopper et al study[22] found that general hospital consent forms were written at a grade level of 12.6. Just over half could be understood by a patient with a high school education, less than a third by patients with a 10th grade reading level, and just over 5% by patients with an 8th grade reading level.

Opportunities for Impact

While informed consent is a well-established practice, it often fails to meet its stated purpose. Several methods of improving the procedures of obtaining informed consent have been proposed, including improving the readability of consent forms,[22] asking patients for recall to establish understanding,[3,23] adding additional stimuli, such as multimedia presentations[24] and providing written information.[17]

Lavelle-Jones[17] found that elderly patients (over 60 years of age) had poorer recall than younger patients. In addition, patients with internal locus of control—those who believed their health was in their own control—were better informed than those with an external locus of control. Patients with above average IQ exhibited better recall. These findings could indicate “at-risk” groups that interventions may target.

One author argues that an important opportunity for impact is to change the model of implementing informed consent from a single event approach to a process approach.[7] Currently

obtaining informed consent often revolves around the signing of the consent form. Although this approach clearly delineates the responsibility of health care providers, provides documentation of the consent, and fits easily into the current provider structure, it often results in patients failing to actually comprehend the information and reinforces physicians' conception that the consent ritual is futile. In contrast, a process model involves the physician providing information over time, establishing a better patient-physician relationship and better comprehension of medical care. As of yet there is no data to support these suppositions.

Since the definition of adequate informed consent is debatable, the number of individuals currently not receiving interventions to obtain adequate informed consent is likely to be quite high, but is not known.

Study Design, Outcomes and Effectiveness of Various Approaches

Improving Readability of Consent Forms and Education Materials

In order to ensure that patients understand the procedure to which they are consenting, it is important that all materials be presented in a comprehensible manner. Consent forms are written with relatively complex sentence structure and vocabulary, making it difficult for the average adult to interpret the information. In addition, providing consent forms in the primary language of patients may improve consent procedures. However, we located no studies examining the effectiveness of such practices.

Structured Discussions

Informed consent is often obtained during informal discussion between physicians or nurses and patients, and (as discussed above), these discussions frequently do not cover all of the relevant information.[12] Two studies examined the use of a structured interview format in providing information to patients. Solomon et al[25] studied 36 patients receiving cardiac catheterization for the first time at a Veterans hospital. Patients were randomized into two groups (Level 1 design). Both groups were briefed by a cardiologist regarding the procedure (standard care). In addition, the experimental group received a 30-minute structured teaching session with a nurse to discuss all aspects of the procedure, including the purposes, techniques, sensations, risks and benefits. Patients in the experimental group also received an illustrated guide to cardiovascular procedures and an educational pamphlet. All subjects were tested using a 13-item questionnaire covering the information that should have been imparted during informed consent procedures (Level 3 outcome). The intervention group scored significantly better than the control group (11.5 vs. 8.9).

In a later study, Dawes et al[26] studied 190 hospitalized patients undergoing ENT surgery. Patients were assigned to one of 4 groups. Groups 1 and 2 were assigned at different times (Level 2 design), while groups 3 and 4 were randomly assigned (Level 1 design). Group 1 had no consent interview until after assessment at the conclusion of the study. Group 2 engaged in an informal interview with a physician (reflecting current practice), during which the number of complications discussed was recorded. Group 3 engaged in a structured interview with a physician, covering the purpose and technique of the procedure, complications, sensations, alternatives, and benefits (a checklist was used as a guide). The final group, Group 4, engaged in the same structured interview, except that the patient was provided with a copy of the checklist and allowed to take it with them after the interview. Patient anxiety was assessed following consent using a visual analog scale, then reassessed at an interview, given 4 hours later. At the later interview, patients were asked to recount orally the operation name, describe what would be

done, list complications, and state whether they understood the information given to them (Level 3 outcome). All but Group 1 (control group) patients showed a drop to normal anxiety after informed consent. Group 2 (informal discussion) remembered proportionately more complications mentioned in the informal interview, although fewer complication were covered. Groups 3 and 4 recalled more total complications than Group 2. There was no differences between Groups 3 and 4 (structured interviews).

Asking for Recall

A simple method of determining whether a patient understands information regarding a procedure is to ask the patient to recount what he or she has been told.[3] Two studies examined this intervention, using a randomized controlled trial design (Level 1 design). In the first study, informed consent was solicited from 50 patients undergoing percutaneous lung biopsy.[23] Twenty-seven patients in the control group were offered the standard procedure for obtaining informed consent: approximately 30 minutes prior to the procedure, the physician described the procedure in detail, including its risks and benefits. Four complications were specifically described, along with their relative risks. Patients were asked to sign a standard consent form. Twenty-three patients received the same procedure, but in addition, they were asked to describe all 4 potential complications. The procedure was repeated until all patients in the intervention group could recount all of the complications. This modified procedure usually took less than 5 minutes extra compared with the traditional approach. Patients were interviewed 2 hours after the procedure was completed. Patients in the modified consent group had better recall (Level 2 outcome) than patients in the control group (56% vs. 14% with high recall (recalling 3-4 out of 4 risks), and 13% vs. 44% with low recall (recalling 0-1 out of 4 risks)).

A second study examined verbalization in 20 patients undergoing anterior cruciate ligament (ACL) reconstruction.[27] Patients were randomly assigned to 2 groups. Both groups received the standard education for ACL reconstruction, which included the use of a 3-D model of the knee, discussion with a physician about the procedure, and obtaining informed consent. The experimental group (8 subjects) also were asked to repeat back the risks of the procedure until they could accurately recall all risks discussed. One-month later, recall regarding the information received was tested using a 3-item questionnaire (Level 2 outcome). All 8 in the experimental group answered all questions correctly, while only four out of the 12 in the control group answered all questions correctly ($p=0.03$).

Use of Visual or Auditory Learning Aids

Adding additional stimuli may increase the ability of the patient to understand information being conveyed or increase retention of that information. For instance, use of visual diagrams may make a procedure easier to understand. Multi-media may also promote better comprehension. Three studies have examined the addition of visual stimuli for informed consent. One study of patients undergoing back surgery examined the impact of a diagnosis-specific videodisk program on patient outcomes.[24] Patients (n=393) who were candidates for elective back surgery (primarily for herniated disc and spinal stenosis) were randomized to two education groups (Level 1 design). The control group received a written booklet regarding the surgical and non-surgical treatments for herniated disc and spinal stenosis, a description of expected outcomes, and a short self-test on the booklet information. Patients in the experimental group also received the booklet, but in addition viewed a videodisk program. The program allowed a patient to enter their diagnosis and age and receive customized information on the alternative treatments, discussion of the diagnoses (and the ambiguities of diagnosis), and interviews from

patients that had been treated surgically and non-surgically. At the end the patient was provided with a printout of outcome probabilities. Patients in the experimental group were slightly more likely to report that they had all the information they wanted (Level 3 outcome). Rates of patients consenting to surgery for herniated disk (32% vs. 47%) and other diagnoses (5.4% vs. 14.0%) were lower in the videodisk group.

Hopper et al[28] also tested an interactive video program, although the tested program was computer based. One-hundred and sixty outpatients referred for IV contrast media studies were stratified by age, sex, and previous exposure to contrast media, then randomized to receive either a written consent form, or an interactive computer-based video (Level 1 design). Subjects in the control group received a consent form designed to be read at an eighth grade reading level. Subjects in the experimental group viewed a video in which a physician used identical words as the consent form to inform subjects about the procedure and risks. Subjects then had an option of hearing more about the risks. If subjects chose not to hear additional information, they were provided with printouts of the risks (with the minimal information already given). Otherwise subjects were provided with printouts certifying that they had completed the program. All subjects were tested using a 7-item questionnaire regarding the procedure and risks (Level 2 outcome). Patients that viewed the video responded correctly more often than the control group when asked about general aspects of the procedure. Female patients in the video group also responded correctly more often to questions about risks, although this finding did not hold for male patients. The video did take approximately 1.6 minutes of additional time to complete, and there was no difference in patients desire for additional knowledge between the groups (Level 3 outcome).

One final study did not use an interactive video, but tested whether providing information via video was superior to providing information via an informal discussion with the physician (standard practice).[29] Two-hundred and twenty four subjects referred for colonoscopy were stratified into previous or no previous colonoscopy, then randomized into 3 groups (Level 1 design). The control group had a structured discussion with a physician, in which the physician covered the same information covered in the video according to a checklist. The video-only group watched a 5-minute videotape, in which a physician described the procedure, and its risk and benefits. The third group (video and discussion), watched the video and then engaged in a structured discussion with a physician. All patients were tested using a 13-item questionnaire (Level 2 outcome). Both video groups gave more correct responses than the discussion-only group, although they did not differ from each other. In addition, patient anxiety levels were measured using the State-Trait Anxiety Inventory (Level 3 outcome). There were no differences among the 3 groups.

Providing Written information to Patients

Providing written information to patients regarding their diagnoses, proposed treatments, and other information given during informed consent discussion allows the patient to refer back to such information, and possibly increases comprehension. One early study compared the then-common practice, informal interview between patient and doctor, with provision of a written consent form.[30] Eighty patients, referred for a first excretory urography, were randomly assigned to 2 groups (Level 1 design). The control group received standard care, the informal interview. The experimental group received the same interview along with a detailed written consent form to read and sign. Patient clinical reactions and side effects were monitored (Level 1 outcome). One to 3 days after the procedures, patients retrospectively rated discomfort, fear or apprehension, and understanding of the procedure (Level 3 outcome). Patients also completed an

8-item knowledge examination covering the information on the consent form (Level 2 outcome), or in the informal interview. Experimental subjects scored significantly better ($p=<0.01$) than control subjects for the knowledge exam (scoring 73% vs. 48%), but did not differ in their discomfort, perception of the procedure, or anxiety.

Some investigators have proposed that patients should receive written consent forms days before receiving a procedure. Neptune et al[31] studied 160 subjects referred for a contrast media radiology exam. The patients were stratified by age, sex, and previous exposure to constrast media, and then were randomized within the strata into 2 groups (Level 1 design). The control group received a simple consent form (designed such that it could be read with an eighth grade education), 15-60 minutes before the procedure, consistent with standard care. Patients in the experimental group received the same consent form 24-72 hours before the procedure, and were called one day in advance to remind them to read the form. Subjects' knowledge concerning their procedures was tested using a 7-item questionnaire (Level 2 outcome). Overall, there were no significant differences between the two groups on either a knowledge or satisfaction score.

In a British study,[17] 265 patients undergoing intrathoracic, intraperitoneal, or vascular procedures, were assigned to one of 2 consent groups (Level 2 design). The control group was provided with an oral explanation of their disease and the proposed procedures. Members in the experimental group were provided with the same information, and also provided with an "operation card" detailing the same information. Patients were given 30 minutes to review the cards before signing the consent form. Patients were interviewed for recall (Level 2 outcome) immediately after consent (1 hour), the day of discharge, 4-6 weeks post-discharge, and at 6 months post-discharge. Control and experimental groups did not differ, except on the day of discharge ($p<0.0001$). The only significant factor in predicting recall was the age of the patient, as older patients had poorer recall than younger patients, even when controlling for psychological factors. Written information did not appear to aid in recall for older patients at any time point.

Two other studies provided written information to patients, although this was combined with structured teaching programs. These studies are reviewed under "Structured Discussions" above.[25, 26]

Comment

While much has been written regarding informed consent and the ethical obligations of providers to obtain proper informed consent, serious shortcomings have been reported. However, very little literature has examined the impact of different procedures for obtaining informed consent on the quality of the consent obtained. The weight of the literature suggests that the value of informed consent can be modestly enhanced by augmenting standard provider-patient discussions with additional learning and retention aids (written or videodisk materials). Moreover, the process of consent can be mildly improved by using structured interviews and by asking patients to recall and re-state key elements of the discussion. In addition to the ethical imperative of informed consent, it may be that informed patients are less likely to experience medical errors by acting as another layer of protection (as when a patient is able to inform providers about his or her correct medications or the correct surgical procedure he or she is to undergo). More research is needed to establish the best practices to improve informed consent, and to test the impact of such practices on patient safety.

References

1. Edwards SJ, Lilford RJ, Thornton J, et al. Informed consent for clinical trials: in search of the "best" method. *Soc Sci Med.* 1998;47:1825-40.
2. American Medical Association. Informed consent. American Medical Association. April 11, 2001.
3. Pape T. Legal and ethical considerations of informed consent. *AORN J.* 1997;65:1122-7.
4. Stewart MA. Effective physician-patient communication and health outcomes: a review. *CMAJ.* 1995;152:1423-33.
5. Greenfield S, Kaplan S, Ware JE, Jr. Expanding patient involvement in care. Effects on patient outcomes. *Ann Intern Med.* 1985;102:520-8.
6. Levinson W, Roter DL, Mullooly JP, et al. Physician-patient communication. The relationship with malpractice claims among primary care physicians and surgeons.
7. Lidz CW, Appelbaum PS, Meisel A. Two models of implementing informed consent. *Arch Intern Med.* 1988;148:1385-9.
8. Kuyper AR. Patient counseling detects prescription errors. *Hosp Pharm.* 1993;28:1180-1, 1184-9.
9. Mark JS, Spiro H. Informed consent for colonoscopy. A prospective study. *Arch Intern Med.* 1990;150:777-80.
10. Code of Federal Regulations. Title 45: Public Welfare. .Revised June 18, 1991.Effective August 19, 1991.
11. Hopper KD, TenHave TR, Hartzel J. Informed consent forms for clinical and research imaging procedures: how much do patients understand? *AJR Am J Roentgenol.* 1995;164:493-6.
12. Braddock CH, 3rd, Edwards KA, Hasenberg NM, et al. Informed decision making in outpatient practice: time to get back to basics. *JAMA.* 1999;282:2313-20.
13. Bottrell MM, Alpert H, Fischbach RL, et al. Hospital informed consent for procedure forms: facilitating quality patient-physician interaction. *Arch Surg.* 2000;135:26-33.
14. Boyle CM. Difference between patients' and doctors' interpretation of some common medical terms. *Br Med J.* 1970;1:286-9.
15. Cole R. The understanding of medical terminology used in printed health education materials. *Health Educ J.* 1979;38:111-21.
16. Lashley M, Talley W, Lands LC, et al. Informed proxy consent: communication between pediatric surgeons and surrogates about surgery. *Pediatrics.* 2000;105:591-7.
17. Lavelle-Jones C, Byrne DJ, Rice P, et al. Factors affecting quality of informed consent. *BMJ.* 1993;306:885-90.
18. Baker DW, Parker RM, Williams MV, et al. Health literacy and the risk of hospital admission. *J Gen Intern Med.* 1998;13:791-8.
19. Kirsch I, Jungblut A, Jenkins L, et al. Adult literacy in America: a first look at the results of the national adult literacy survey. Washington, DC: National Center for Education, US Department of Education; 1993.
20. Jubelirer SJ, Linton JC, Magnetti SM. Reading versus comprehension: implications for patient education and consent in an outpatient oncology clinic. *J Cancer Educ.* 1994;9:26-9.
21. Hopper KD, Lambe HA, Shirk SJ. Readability of informed consent forms for use with iodinated contrast media. *Radiology.* 1993;187:279-83.

22. Hopper KD, TenHave TR, Tully DA, et al. The readability of currently used surgical/procedure consent forms in the United States. *Surgery.* 1998;123:496-503.
23. White CS, Mason AC, Feehan M, et al. Informed consent for percutaneous lung biopsy: comparison of two consent protocols based on patient recall after the procedure. *AJR Am J Roentgenol.* 1995;165:1139-42.
24. Deyo RA, Cherkin DC, Weinstein J, et al. Involving patients in clinical decisions: impact of an interactive video program on use of back surgery. *Med Care.* 2000;38:959-69.
25. Solomon J, Schwegman-Melton K. Structured teaching and patient understanding of informed consent. *Crit Care Nurse.* 1987;7:74-9.
26. Dawes PJ, O'Keefe L, Adcock S. Informed consent: the assessment of two structured interview approaches compared to the current approach. *J Laryngol Otol.* 1992; 106:420-4.
27. Wadey V, Frank C. The effectiveness of patient verbalization on informed consent. *Can J Surg.* 1997;40:124-8.
28. Hopper KD, Zajdel M, Hulse SF, et al. Interactive method of informing patients of the risks of intravenous contrast media. *Radiology.* 1994;192:67-71.
29. Agre P, Kurtz RC, Krauss BJ. A randomized trial using videotape to present consent information for colonoscopy. *Gastrointest Endosc.* 1994;40:271-6.
30. Winfield AC, Ford CV, James AE, et al. Response of patients to informed consent for excretory urography. *Urol Radiol.* 1986;8:35-9.
31. Neptune SM, Hopper KD, Houts PS, et al. Take-home informed consent for intravenous contrast media: do patients learn more? *Invest Radiol.* 1996;31:109-13.