Chapter 39. Obtaining Informed Consent From Patients: Brief Update Review

Kristina M. Cordasco, M.D., M.P.H., M.S.H.S.

Introduction

In health care, informed consent refers to the process whereby the patient and the health care practitioner engage in a dialogue about a proposed medical treatment’s nature, consequences, harms, benefits, risks, and alternatives.\(^1\) Informed consent is a fundamental principle of health care.

The process of informed consent can be considered a patient safety issue from several perspectives. At the extreme, performing a procedure on a patient without his or her consent has been considered by the courts to be a form of battery.\(^2\) Informed consent may also be indirectly related to patient safety in that, when done well, it opens a dialogue between the patient and provider so that the patient can ask questions, knows what to expect during and after procedure, and can at least theoretically help to avert medical errors.\(^3\)

In general, studies have shown improved patient outcomes with effective physician-patient communication and increased patient empowerment.\(^4,5\) Patient education has also been associated with preventing medical errors.\(^6\)

A review on this topic conducted in 2001 found few studies linking informed consent with health outcomes and few studies on the impact of procedures used to obtain informed consent on the quality of consent obtained; studies suggested that the value of informed consent might be modestly enhanced by augmenting standard patient provider discussions with additional learning and retention aids and that the process of consent can be modestly enhanced by using structured interviews and asking patients to recall and restate the key elements of the discussion.

This update review focuses on what we have learned about the informed consent process and the effectiveness of interventions that have been implemented to try to improve it. We conducted a search of the health care and health services literature for the time interval 2001 to present and reviewed all studies relevant to informed consent in the clinical setting.

What Is Informed Consent?

The document a patient signs to verify that he has engaged in a dialog with a health care practitioner about a proposed medical treatment is commonly referred to as an “informed consent.” However, it is the dialog itself that constitutes the actual informed consent process.\(^3\) Informed consent is used in both clinical and research settings; this review focuses primarily on informed consent in the clinical setting.

Although no evidence currently links informed consent with improved adherence to medication or other self-care procedures, to prevention of medical errors, or to improved overall health outcomes, some evidence links increased patient-physician communication with more realistic expectations, increased patient satisfaction, and fewer medical malpractice claims.\(^7-9\)
How Has Informed Consent Been Implemented?

A complete informed consent process consists of seven elements: (1) Discussing the patient’s role in the decision-making process; (2) Describing the clinical issue and suggested treatment; (3) Discussing alternatives to the suggested treatment (including the option of no treatment); (4) Discussing risks and benefits of the suggested treatment (and comparing them to the risks and benefits of alternatives); (5) Discussing related uncertainties; (6) Assessing the patient’s understanding of the information provided; and (7) Eliciting the patient’s preference (and thereby consent).10 Not every detail needs to be discussed, but all details needed for a “reasonable person” to make a decision must be provided.11 Therefore, all risks of serious complications, even if they occur very rarely, need to be discussed. Less serious risks need to be discussed if they occur more commonly.11 This process of informed consent may occur within one encounter, or across multiple encounters.12

Although informed consent is often used prior to invasive procedures, designated radiologic examinations, and other high-risk medical treatments (e.g., chemotherapy), the process of informed consent, or informed decision-making, is applicable to all medical care decisions where one or more alternatives exist (including the alternative of no treatment or procedure).13 Recently, there has also been increased attention to the importance of informed consent in screening procedures and genetic testing.14,15 As such, the informed consent process has considerable overlap with the principles of “shared decisionmaking.”13

What Have We Learned About Informed Consent?

Most Informed Consent Procedures Are Incomplete

Various studies have examined the completeness of informed consent procedures in various settings and scenarios. In an examination of the informed decisionmaking process in 1057 audio-recorded outpatient encounters in the offices of primary care physicians and surgeons, regarding mostly low-risk decisions, only 9% were deemed to contain all the elements of complete informed decision-making.16 The most common element missing was an explicit assessment of patient understanding. However, risks and benefits, and their associated uncertainties were also commonly not included in the discussions. Among 141 discussions regarding orthopedic surgical interventions, in no case were all elements fully discussed.17 Ninety-two percent had some mention of the nature of the decision, 62% listed alternatives, 59% discussed pros and cons, 14% discussed the patient’s role in the decisionmaking, and 12% of the time the patient’s understanding was assessed. In an analysis of informed decision-making for 145 patients considering high-risk elective major vascular surgery, audio-recorded discussions across multiple visits for each patient contained all informed consent elements in 45% of the cases.18 In 23% of the cases, the surgeon failed to discuss one or more of the “basic” elements of consent: clarifying the patient’s role in the decision-making; explaining the clinical condition; or eliciting the patient’s preferences for treatment.

Reading Level of Informed Consent Documents Is Often Too High

A number of studies have examined the reading level of informed consent documents and their utility for people with limited English proficiency. In a survey of informed consent forms for iodinated contrast material from 160 academic and private United States (U.S.) hospitals, average reading level exceeded 12th grade and only 5% had an 8th grade reading level or below.19 Similarly, in a survey of surgery and other procedure informed consent forms from 616
U.S. hospitals, the mean reading level was 12.6 years and only 7% of the forms had an 8th grade reading level or below. Regarding the content of informed consent documents, a separate survey of a random sample of consent forms from 157 U.S. hospitals showed significant variability in content and 74% omitted the nature of the procedure, risks, benefits, or alternatives. Perhaps related to the readability of these documents, studies have shown patients often do not read the consent forms provided to them and, in one study, patients who reported reading the consent forms given to them were no better informed than those who did not.

Patients with limited English proficiency (LEP) are at particularly high risk for receiving inadequate informed consent. In a study of 30 Latina women who were offered amniocentesis at 8 prenatal clinics without trained interpreters, the informed consent process contained all, or nearly all, of the essential informed consent elements for 9% of the LEP compared with 68% of the non-LEP women. When charts of 74 LEP Spanish and Chinese-speaking patients were compared with those of 74 English-speakers, all of whom underwent thoracentesis, paracentesis, or lumbar puncture at a teaching hospital where trained interpreters in Spanish and Chinese were available, 28% of LEP patients had informed consent documented compared with 53% of English speakers.

Most Patients Are Unable To Recall—or Don’t Understand—Content of Informed Consent Documents

Multiple studies have shown that most patients are unable to recall or do not understand most of the information that is presented to them in the informed consent process. Post-operative interviews with patients 1 to 8 weeks after they underwent head and neck surgery revealed that, on average, they could recall 48% of the main three or four complications (depending on the surgery) they were counseled about pre-operatively. Interviews with 17 surrogates who provided consent for surgery in pediatric patients, showed that 2 to 4 weeks after the surgery, only three (18%) could recall any specifics of the procedure. Interviews 3 hours after consent in 100 patients scheduled for transurethral prostatectomy revealed that less than 50% of the patients could accurately recall the risks of potential complications. Sixty five percent of 104 patients consented for neurosurgery could remember no more than two of six major risks associated with their surgery 2 hours after informed consent was obtained. Among 633 patients who were offered coronary artery bypass grafting (CABG) or percutaneous coronary interventions (PCI), there was very low concordance between what physicians reported telling the patients about expected symptom benefits and what the patients reported as their expectations, and there was no correlation between what physicians and patients expected regarding potential mortality benefit (with patients believing there would be a survival benefit even when physicians reported telling them there was not).

Lower levels of education are consistently associated with being less likely to recall information in the informed consent process. Among 54 patients who underwent head and neck surgery, 72% of those having a university education recalled more than 50% of the complications, compared with 36% of those without a university education (p=0.04). In another study of 200 patients with cancer, those who had completed high school had 35% higher scores on tests asking them to recall, within 1 day of undergoing informed consent, written and oral information provided to them in the informed consent process (p<0.001).

Older age is also associated with being less likely to recall informed consent information. Among 265 patients undergoing intrathoracic, intraperitoneal, and vascular surgery procedures, patients over 60 years of age had less knowledge about their planned procedure immediately
Limited health literacy is also likely associated with less comprehension of informed consent. Health literacy is the “capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.” In the 2003 National Assessment of Adult Literacy (NAAL) 36% of Americans had basic or below basic health-related literacy. Older age, lower educational attainment, and being African-American or Latino are all associated with lower health literacy levels. In a study of men using a CD-ROM shared decisionmaking tool about prostate cancer treatment options, lower levels of health literacy were associated with lower prostate cancer knowledge after using the tool (Pearson correlation =0.65, p<0.001). In a study of consent documents for a research study on chemotherapy agents, patients reading at or below an 8th grade level had, on average, 28 percentage point lower comprehension scores compared with participants with higher reading levels, even when the consent form was modified to a 7th grade reading level. Similarly, in another study of a research consent form, modified to a 6th grade reading level, patients with lower literacy were significantly less likely to respond correctly to comprehension questions asked after a first reading of the consent form, adjusting for other sociodemographic factors.

Studies have also shown that minority race or ethnicity may be an independent risk factor for having lower levels of comprehension in the informed consent process. Among 396 patients being consented for surgery, African-American patients scored an adjusted average 9 percentage points lower than white patients in a comprehension test administered immediately after the consent process. This association was independent of education, age, and health literacy score. In the study of a research consent form cited above, in addition to those with lower health literacy, patients who were Black or Asian/Pacific Islander were also less likely, when adjusting for other factors, to respond correctly to comprehension questions.

Other factors associated with lower informed consent recall are lower intelligence levels and having cognitive dysfunction. Patients with cognitive dysfunction are particularly vulnerable in the informed consent process. Cognitive dysfunction may be a long-term state (e.g., dementia) or transient (e.g., after a medical procedure.) In one study of 302 acutely-ill medical inpatients, 48% were estimated to have cognitive dysfunction such that they potentially lacked capacity to give informed consent. However, not all patients with cognitive dysfunction lack informed consent capacity: A structured assessment must be done to determine competence. If a patient does not have capacity and his or her cognitive dysfunction is not expected to improve (or a decision needs to be made prior to it improving), a surrogate decisionmaker must be established, except in an emergency situation where the physician can determine the choice a “reasonable person” would make.

What Methods Have Been Used To Improve Informed Consent?

Multiple potential methods have been proposed for improving the informed consent process. These methods include simplifying informed consent forms; providing supplemental written
materials; using decision aids; using video educational tools; using interactive computer-based educational tools; having structured discussions; and using “repeat back” methods.

**Simplifying Informed Consent Forms May Improve Satisfaction, if Not Comprehension**

Although the effects of simplifying informed consent forms in clinical settings have not been studied, some studies have assessed simplified forms for consenting participants for research, with mixed results. In a randomized-controlled study comparing a standard pharmaceutical industry consent form to a simplified form, participants who read the modified form had a 23% higher score on a 13-item multiple choice test about the study details \( (p<0.001) \).\(^{40}\) In another randomized-control trial of 456 parents, comprehension was compared between parents receiving a standard research consent form, written at an 11th grade level, and those who received a consent form modified to be at an eighth grade reading level.\(^{41}\) Those who received the simplified consent form demonstrated a 13% better overall understanding of the study \( (p<0.001) \), as well as better specific understandings of the study protocol \( (33\%, \ p<0.001) \), duration \( (178\%, \ p<0.001) \) and direct benefits \( (7\%, \ p<0.001) \). There was a non-significant trend to better understanding of the risks. These differences were seen across parents with high and low reading abilities. Eighty-one percent of the parents reported preferring the simpler form. In a third randomized trial that simulated research recruitment of 233 low-income children, there was no difference ascertained in comprehension between parents receiving standard and simpler forms; however, among the 124 parents with reading comprehension scores at or below 8th grade, those who received the simpler form had nearly-significant higher comprehension scores \( (p=0.06) \).\(^{42}\) In contrast to these findings, in a controlled (but not randomized) study comparing a chemotherapy research consent form written at a 7th grade reading level to a standard one, comprehension levels were similar for both forms, even among participants with reading levels of 8th grade or less. However, literacy patients stated preference for receiving the simpler form.\(^{34}\) Another trial of a chemotherapy consent form simplified to the 8th grade level, with 44 institutions randomized to using the simplified or standard consent form, also showed no difference in knowledge, but patients at the institutions using the simplified form had 9% higher patient satisfaction scores \( (p=0.004) \).\(^{43}\)

**Providing Supplemental Written Materials Improves Recall and Comprehension**

Multiple randomized controlled trials have demonstrated that that providing patients with supplemental written materials, in simplified language, results in higher patient recall of informed consent information. In a study of 192 patients who underwent intraperitoneal, intrathoracic or vascular surgery at a large teaching hospital, “information cards” which explained in a simplified manner the procedure and what the patient could expect during and after the surgery were given to half of the patients by random assignment. Both groups had the same level of knowledge 1 hour after signing the consent form but those who received the information cards had better information recall on the day of hospital discharge \( (p=0.04) \).\(^{23}\) Among 125 patients who underwent thyroidectomy or parotidectomy at an academic tertiary center, those who were randomly assigned to receive a pamphlet with illustrations and written information about the procedure were able to recall 50% of the risks compared with the control group recalling 30% of the risks \( (p<0.001) \).\(^{44}\) In another randomized-controlled study of 126 patients who underwent total hip arthroplasty, a 1.5 page written information sheet in simplified
language with an illustration, given to patients at the pre-operative visit, resulted in patients having 25% higher knowledge scores on admission for the procedure (p=0.004) compared with patients who received a structured verbal discussion. Finally, in a randomized-controlled trial of information leaflets describing risks and benefits, sent by mail 2 weeks prior to surgery to patients scheduled for elective orthopedic procedures, the group receiving the leaflets had a median comprehension score 30 percentage points higher than those who did not (p<0.001).

Decision Aids Improve Knowledge and Participation in Shared Decisionmaking

Decision aids are tools specifically designed to help patients make choices by having a “detailed, specific, and personalized focus on options and outcomes.” For example, one randomized-controlled study examined the effect of a touch-screen decision aid that provided detailed information, including outcome probabilities, to the patient based on the information the patient entered regarding his or her age and diagnosis. Patients had the option of getting more detailed information, if desired, on pharmacologic and alternative medicine options. When this decision aid was tested against an educational booklet, those who used the decision aid had an adjusted six percentage point increase in knowledge compared with those who did not (p=0.05). Another example, which is not technology-dependent, is an illustrated pamphlet decision-aid for informed consent in prostate cancer screening which, in a randomized-controlled trial, increased knowledge by 6% (p<0.01). A 2009 Cochrane review of 55 studies on the efficacy of decision-aids for screening or treatment decisions found that, overall, they improve knowledge scores by an average of 15 percentage points, improve patients’ participation in decisionmaking, result in lower “decisional conflict,” and increase accuracy of risk perceptions.

Video Educational Tools Also Improve Knowledge

Randomized-controlled trials of video educational tools (that are not also decision aids) have also shown positive results. A randomized-controlled trial of an informational video for women considering laparoscopic tubal ligation showed that women who watched the video, in addition to standard consent procedures, demonstrated 56% higher knowledge scores than women who were engaged in standard consent procedures alone (p<0.001). And, in a randomized-controlled trial of an informational video on colonoscopy, those who watched the video in addition to having a physician discussion had 19% higher knowledge scores than patients who had the physician discussion alone (p<0.01). In a randomized-controlled trial of patients scheduled for intravenous contrast for computed tomography, English and Spanish-speaking patients were exposed to a low-literacy video in their preferred language. Participants who watched the video displayed, in comparison to controls, 20 percentage point higher knowledge (95% CI 13-28%) and 10 percentage point higher satisfaction scores. This result was consistent for both Spanish and English speakers and Spanish and English speakers in the intervention group had similar post-consent knowledge scores while Spanish speakers in the control group had significantly lower post-consent knowledge scores than English-speaking controls.

Interactive Computer-Based Educational Tools Show Mixed Results

Limited studies of computer-based educational tools (that are not also decision aids) have shown mixed results. In a randomized-controlled trial of a computer program that augments practitioner-patient discussions with graphical content and illustrations, when used in patients considering cardiology or endoscopy procedures, resulted in 43% higher patient knowledge
scores (p=0.006) as well as 34% higher satisfaction scores (p<0.001). A randomized-controlled trial of an interactive computer program about colonoscopy indications, risks, and benefits, tailored to an 8th-grade reading level, showed 16% higher knowledge scores among patients who received the intervention. However, in a randomized-controlled trial of 101 patients consenting to chemotherapy, recall of treatment information showed no difference in knowledge between patients who received an interactive CD-ROM detailing treatment information and those who received standard written information. In another randomized controlled trial of 44 patients receiving standard genetic counseling versus education by an interactive computer program as part of an informed consent process prior to cystic fibrosis carrier-status testing, both groups had similar increases in knowledge.

**Structured Informed Consent Discussions Need Further Testing**

Structured discussions for informed consent are those in which the practitioner engaging the patient uses a written guide to structure the conversation. Two studies, limited by using non-randomized designs, have examined structured discussions for informed consent. In a study of patients considering cardiac catheterization, patients exposed to a half-hour structured informed consent discussion had 29% higher knowledge scores compared with controls (p<0.001). In another study of patients being consented for head and neck surgery, the group of patients for which the provider used a structured interview guide were told about 65% more complications. However, in a study that did use a randomized design, and is mentioned above in the section on “supplemental written materials,” structured verbal discussion compared with a 1.5 page simplified and illustrated information sheet showed that patients had lower knowledge scores with the structured discussion compared with the information sheet (p=0.004).

**“Repeat Back” Methods May Be Effective but Time Consuming**

The “repeat back” method, also known as “teach back,” is an interactive communication strategy in which the patient is asked to explain, in his or her own words, what has been told to the patient. Then, as needed, the practitioner clarifies or tailors the explanation, serially reassessing and re-explaining until the patient demonstrates recall and comprehension. In a randomized-controlled study of 575 patients undergoing elective surgery, a computer prompted and guided the practitioner in conducting the repeat-back procedure during the informed consent discussion. Information comprehension, tested immediately, showed that patients receiving “repeat back” comprehended 71% of the information while the control group comprehended 68% of the information (p=0.03). Discussions using “repeat back” took, on average, 2.6 minutes longer. In a randomized-controlled trail of 20 patients who underwent repair of their anterior cruciate ligament, 100% of patients whose discussions used “repeat back,” compared with 33% of patients in the control group, were able to correctly answer a 3-item questionnaire about the risks and benefits 1 month later (p=0.03).

**Conclusions and Comment**

Informed consent is a process in which patients and health care practitioners dialogue about a proposed medical treatment’s nature, consequences, harms, benefits, risks, and alternatives. Although more evidence is needed on the potential specific association between informed consent and patient safety, studies have shown that improved communication between practitioners and patients leads to improved patient outcomes, less medical errors, and lower rates of malpractice claims. Adequacy of the informed consent process has been more firmly
linked to patient satisfaction. Despite its importance, multiple studies have demonstrated that, in practice, the informed consent process is often incomplete and patient recall and comprehension of the discussion is usually low. Patients who are older, less educated, LEP, are of minority race, or have cognitive dysfunction or low intelligence levels are particularly vulnerable in the informed consent process.

Multiple methods have been proposed for improving the informed consent process. Studies have shown that, in general, providing patients with simplified supplemental written materials, using decision-aids, using video educational tools, and using the “repeat back method” improves informed consent patient recall and comprehension. Studies using interactive computer programs have had mixed results and further research is needed in this area. Studies using structured informed consent discussion have also been limited. Studies of simplifying the informed consent documents that have been done for research-related forms have shown mixed results on patient recall and comprehension, but generally improve satisfaction; studies examining this effect among informed consent documents in nonresearch clinical settings are lacking. A summary table is located below (Table 1).

Table 1. Chapter 39. Summary table

<table>
<thead>
<tr>
<th>Scope of the Problem Targeted by the PSP (Frequency/Severity)</th>
<th>Strength of Evidence for Effectiveness of the PSPs</th>
<th>Evidence or Potential for Harmful Unintended Consequences</th>
<th>Estimate of Cost</th>
<th>Implementation Issues: How Much do We Know?/How Hard Is it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common/Moderate</td>
<td>Moderate</td>
<td>Negligible</td>
<td>Low</td>
<td>Moderate/Not difficult</td>
</tr>
</tbody>
</table>

References

1. California Appellate Court, decided on Oct 22, 1957. Salgo v Leland Stanford Jr University Board of Trustees. ;
   v.16276809.
5. Stewart MA. Effective physician-patient communication and health outcomes: a review. CMAJ. 1995;152(9):1423-33.7728691.


