Informed Consent and Health Literacy: Workshop Summary

DETAILS

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Informed Consent and Health Literacy

Workshop Summary

Joe Alper, *Rapporteur*

Roundtable on Health Literacy

Board on Population Health and Public Health Practice

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"Knowing is not enough; we must apply.
Willing is not enough; we must do."
—Goethe

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This workshop summary has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published workshop summary as sound as possible and to ensure that the workshop summary meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the process. We wish to thank the following individuals for their review of this workshop summary:

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Although the reviewers listed above have provided many constructive comments and suggestions, they did not see the final draft of the workshop summary before its release. The review of this workshop summary was overseen by **Hugh Tilson,** University of North Carolina at Chapel Hill. Appointed by the Institute of Medicine, he was responsible for making certain that an independent examination of this workshop summary was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this workshop summary rests entirely with the rapporteur and the institution.

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The roundtable wishes to express its gratitude to the following speakers for their interesting and thoughtful presentations: Linda Aldoory, Alicia Fernandez, Sara Goldkind, Michael Paasche-Orlow, Sandra Crouse Quinn, Kenneth Saag, Yael Schenker, Rebecca Sudore, Jeremy Sugarman, and Christopher Trudeau. The roundtable also wishes to extend its appreciation to the planning committee members: Lori Hall, Laurie Myers, Michael Paasche-Orlow, Kim Parson, and Christopher Trudeau.

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Acronyms and Abbreviations

AHRQ	Agency for Healthcare Research and Quality
AMA	American Medical Association
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare & Medicaid Services
CPR	cardiopulmonary resuscitation
EDGE	Effectiveness of Discontinuing Bisphosphonates trial
FDA	U.S. Food and Drug Administration
HEW	U.S. Department of Health, Education, and Welfare
HHS	U.S. Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
IOM	Institute of Medicine
IRB	institutional review board
LVAD	left ventricular assist device
NCI	National Cancer Institute
NIH	National Institutes of Health
PCORI	Patient-Centered Outcomes Research Institute
POLST	Physician's Orders for Life-Sustaining Treatments

1

Introduction[1]

George Isham,[2] senior advisor at HealthPartners and roundtable chair, welcomed participants and provided an overview of the workshop topic. Informed consent—the process of communication between a patient or research subject and a physician or researcher that results in the explicit agreement to undergo a specific medical intervention—is an ethical concept based on the principle that all patients and research subjects should understand and agree to the potential consequences of the clinical care they receive. Regulations that govern the attainment of informed consent for treatment and research are crucial to ensuring that medical care and research are conducted in an ethical manner and with the utmost respect for individual preferences and dignity, Isham said. These regulations, however, often require—or are perceived to require—that informed consent documents and related materials contain language that is beyond the comprehension level of most patients and study participants, a fact recognized for decades (Fernandez, 2010; Herz et al., 1992; Howard and DeMets, 1981; Ingelfinger, 1972; Sharp, 2004). To explore what actions can be taken to help close the gap between what is required in the informed consent process

[1] The planning committee's role was limited to planning the workshop, and the workshop summary has been prepared by the workshop rapporteur as a factual summary of what occurred at the workshop. Statements, recommendations, and opinions expressed are those of individual presenters and participants and are not necessarily endorsed or verified by the Institute of Medicine (IOM), and they should not be construed as reflecting any group consensus.

[2] This section is based on the presentation by George Isham, senior advisor, HealthPartners, and senior fellow, HealthPartners Institute for Education and Research, and the statements are not endorsed or verified by the IOM.

and communicating it in a health-literate and meaningful manner to individuals, the Institute of Medicine's (IOM'S) Roundtable on Health Literacy convened this 1-day public workshop featuring presentations and discussions that examine the implications of health literacy for informed consent for both research involving human subjects and treatment of patients.

The Roundtable on Health Literacy brings together leaders from academia, industry, government, foundations and associations, and representatives of patient and consumer interests who work to improve health literacy. To achieve its mission, the roundtable discusses challenges facing health-literacy practice and research and identifies approaches to promote health literacy through mechanisms and partnerships in both the public and private sectors.

Examples of the topics covered in this workshop include an overview of the ethical imperative to gain informed consent from patients and research participants, a review of the current state and best practices for informed consent in research and treatment, the connection between poor informed consent processes and minority underrepresentation in research, new approaches to informed consent that reflect principles of health literacy, and the future of informed consent in the treatment and research settings.

FEDERAL POLICY ON INFORMED CONSENT

Isham explained that all 50 states have legislation that requires some level of informed consent for patients receiving medical care (Pape, 1997), and although the details of these state laws vary, they all affirm that failure to obtain informed consent renders caregivers liable for negligence or battery and constitutes medical malpractice. The current U.S. system for protecting human research subjects is heavily influenced by the Belmont Report, written in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (HEW, 1979). The current federal policy for the protection of human subjects is known as the "Common Rule" and is codified in separate regulations by 15 federal departments and agencies. The regulations of the U.S. Department of Health and Human Services (HHS), for example, are detailed in the *Code of Federal Regulations*, Title 45, Part 46 (HHS, 2009), and they spell out the basic provisions for institutional review boards (IRBs), informed consent, and assurances of compliance. According to HHS policy, the informed consent process involves three key features:

1. Disclosing to potential research subjects information needed to make an informed decision,
2. Facilitating the understanding of what has been disclosed, and

3. Promoting the voluntariness of the decision about whether to participate in the research.

HHS guidelines cover several elements of the informed consent process for research, explained Isham. First, the process should be an active one of sharing information between the investigator and the prospective subject. Second, prospective subjects should be provided with ample opportunity to ask questions and seek clarification from the investigator. Third, prospective subjects should be given the opportunity to decide freely whether to initially enroll in the research and, later, to withdraw or continue participating in the research. Fourth, the informed consent process should ensure that all critical information about a study is completely disclosed and that prospective subjects or their legally authorized representatives adequately understand the research so that they can make informed choices. Fifth, the procedures used in seeking and obtaining informed consent should be designed to communicate with the subject population in terms that every individual in that population can understand. Moreover, information about a research project must be presented in a way that enables each person to decide voluntarily whether to participate as a research subject. Thus, Isham said, the information must be conveyed in language understandable to those being asked to participate as subjects in the research.

For most research, informed consent is documented using a written document—the consent form—that provides key information regarding the research, Isham said. The consent form is intended, in part, to provide information for the potential subject's current and future reference and to document the interaction between the subject and the investigator. However, even if a signed consent form is required, it alone does not constitute an adequate consent process, explained Isham. The informed consent process is an ongoing exchange of information between the investigator and the subject and could include, for example, use of question-and-answer sessions, community meetings, and videotape presentations.

ORGANIZATION OF THE SUMMARY

The workshop (see Appendix A for the agenda) was organized by an independent planning committee in accordance with the procedures of the National Academy of Sciences. The planning committee comprised Lori Hall, Laurie Myers, Michael Paasche-Orlow, Kim Parson, and Christopher Trudeau (see Appendix B for biographical information). This publication summarizes the presentations and discussions regarding what occurred throughout the workshop, highlighting the lessons presented, practical strategies, and needs and opportunities for improving discharge instructions. Chapter 2 provides an overview of why informed consent is important

and reviews some of the best practices and new models that are influencing approaches to informed consent. Chapter 3 discusses the current state of informed consent and the relationship between informed consent and minority underrepresentation in clinical trials. Chapter 4 examines some new approaches to informed consent, and Chapter 5 looks at the future of informed consent. Chapter 6 recounts the discussion that the roundtable's members and other participants had at the end of the workshop. A paper commissioned by the roundtable on health literacy and informed consent is contained in Appendix C.

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Overview of the Key Issues Involved in Informed Consent

The workshop's first panel provided an overview of why informed consent is important and reviewed some of the best practices for obtaining informed consent. Jeremy Sugarman, the Harvey M. Meyerhoff Professor of Bioethics and Medicine and deputy director for medicine of the Berman Institute of Bioethics at Johns Hopkins University, spoke about the ethical imperative to gain informed consent from patients and research participants. Linda Aldoory, Endowed Chair and Director of the Herschel S. Horowitz Center for Health Literacy and associate professor in behavioral and community health at the University of Maryland, College Park, discussed a commissioned paper reviewing the impact of informed consent regulations on health-literate communications that she and her team wrote for the roundtable (Aldoory et al., 2014). An open discussion followed the two presentations.

INFORMED CONSENT: WHY DO WE CARE?[1]

Jeremy Sugarman
Johns Hopkins University

Though informed consent procedures for medical treatment and research evolved separately, today they use similar processes, said Jeremy

[1] This section is based on the presentation by Jeremy Sugarman, the Harvey M. Meyerhoff Professor of Bioethics and Medicine at Johns Hopkins University, and the statements are not endorsed or verified by the IOM.

Sugarman. For medical treatment, informed consent evolved largely through patient litigation. "Doctors did things to patients without their permission, and litigation resulted in a series of court cases which then led to legislation and regulation regarding the need for consent," he explained. For research, early consent practices evolved because investigators thought that it was important to inform human subjects who were normal volunteers about potential risks of participating in research. Various scandals involving human research—the Tuskegee Syphilis Study perhaps being the most infamous example—triggered more formal efforts to strengthen and codify informed consent regulations.

Treatment-associated informed consent owes its origins to a case from the turn of the 20th century that involved a patient in New York with a large abdominal mass, Sugarman said. The state of the art at that time was to palpate the mass while the patient was under anesthesia, which relaxes the abdominal and pelvic musculature, to determine whether the mass was a tumor. This exam revealed the likely presence of fibroids. Because the patient was asleep, the physicians decided to remove the fibroids, a benign tumor, along with the woman's uterus. As Sugarman explained, the patient was distressed on learning what had happened, and she sued the doctors. In a ruling issued in 1914, Justice Benjamin Cordozo, then sitting on the New York Court of Appeals, wrote, "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages. This is true except in cases of emergency where the patient is unconscious and where it is necessary to operate before consent can be obtained."

This statement began a cascade of court cases that formed the basis for informed consent relating to medical treatment, and every state has since passed laws requiring consent for medical practice. "Whenever the medical profession was not good about particular features of consent, when things were risky or scary, legislatures jumped in to provide additional rules and regulations," said Sugarman. Until recently, for example, every state had a separate consent regulation for HIV counseling and testing, and almost every state has statutes regarding consent for abortion. Several states have regulations specific to electroconvulsive therapy.

Research-related informed consent originated, Sugarman explained, when researchers realized that if they were doing research with volunteers, they needed to get consent. A famous early instance of researchers deciding consent was necessary involved Walter Reed's experiments proving that yellow fever was transmitted by mosquitoes. These experiments, conducted in 1906 in Cuba following the Spanish-American War, required that healthy volunteers be exposed to mosquitoes that had bitten someone with yellow fever. Before doing so, Reed obtained written consent in English and

Spanish and witnessed by two witnesses. "There were no rules. He just thought it was the appropriate way to go," explained Sugarman. Consent was not perfect—compensation for participating in the study was excessive and volunteers were not allowed to withdraw from the study once they gave consent—but the notion of getting consent was in place.

Sugarman then discussed a conceptual model of consent developed by Ruth Faden and Tom Beauchamp (Faden and Beauchamp, 1986) that spells out what he characterized as the two senses of informed consent: autonomous authorization and the social rules of consent. Autonomous authorization, he explained, addresses the ethical principle of respect for persons or autonomy, the right to liberty or the right to be left alone that is one of the founding principles of the nation and that is embedded in multiple court decisions. "This notion of liberty—the right to be left alone—is really central to who we are," said Sugarman. "This idea about being left alone is really critical to justifying what it means to make our own decisions and to give consent for research or in the health care setting. It is a powerful construct." Although the exact specification of this construct can differ culturally—different cultures around the world have their own sense of acceptable social distance and personal space—all cultures have notions of what it means to be respected, to be left alone, and to have the right to liberty. The social rules of consent, he explained, relate for example to consent of minors, the use of special forms, and the need for witnesses to consent.

The rules for consent can be confusing, Sugarman acknowledged, but the regulatory details are there to remind physicians and researchers to do a thorough job. "In and of themselves, [the rules] are inherently not interesting," said Sugarman. "They are there in large part to serve as a reminder to meet the ethical goal." However, he added, "the conceptual models for consent do not quite capture all of the things that happen in the informed consent process and why we ought to care." There are other considerations, for example, such as whether a patient knows something about herself or himself that can change a side-effect profile. "They may know that if any pill makes them nauseous at all, they are not going to take it," he said, or a research subject might have a moral objection to the use of a human embryonic stem cell line as a therapy for their illness. Individuals may be concerned about group harms or the distribution of benefits, and they may worry about transparency. "These are welfare considerations that go beyond our typical evidence base regarding consent," he explained.

Another important consideration he discussed involves the notion of trust. "We know that trust is central to participation in research. If we don't create a trustworthy system, we are not going to engage enough people in research," said Sugarman. "Unfortunately, consent has been the place

where all of this is taking place, and none of the federal regulations are going to capture this."

Some of these challenges associated with obtaining informed consent are related to literacy, and others are not, he said, and associating literacy concerns with those aspects that are unrelated to literacy may be a poor use of resources. "Not everything is about understanding. Part of it is about these other features," he said.

Turning to the actual process of informed consent—what needs to be done in practice to meet the ethical goals of consent—Sugarman said that informed consent is largely, though not completely, a cognitive task. "We think of it as a cognitive task, but sometimes when we are obtaining consent, people have already made a decision to participate in medical care or research. Other times you are enticing people in the process of getting consent to participate or to do something you believe is in their interest or in the interest of a researcher," he explained. Regardless, there is a large cognitive element to informed consent, which means that individuals need to have decision-making capacity or competency, and that, in turn, can be influenced by factors such as whether an individual is using a psychoactive substance and the nature of that substance. An individual on an antidepressant medication, for example, may be in a better position to make an informed decision, whereas the first-time crack cocaine user is not. The critical factor, said Sugarman, is whether a particular individual is able to take in, process, and use new information. "You have to be able to make a choice and express that choice," he said.

In some instances, said Sugarman, patients may know more or think they know more than their doctors or the person obtaining consent because of research they have done prior to the consent process. "It is not always information giving—sometimes it's information correcting," he said. The consent process is not all about intelligence, either, and he used the example of Dustin Hoffman's character in the movie *Rain Man*, who was intelligent and could take in information, but who could not make a responsible choice.

An important threshold for consent is that an individual has to be positioned to make a voluntary choice. Without decision-making capacity, he noted, a person is not positioned to make a voluntary choice. As an example, he used the situation of a person about to have surgery who is asked to sign consent forms in the preoperative waiting area. The patient already has his arms secured because he has intravenous lines connected to both arms, and a research assistant comes in and explains that the anesthesiologist, whom the patient has not yet met, is conducting a study and would like enroll the patient in that study. Sugarman noted that none of the federal regulations prohibit approaching people who are "naked, cold, scared, and about to have surgery," yet he was worried about why consent

was not done when the patient was dressed and in a more reassuring environment, one that would not have the effect of impairing voluntariness.

Once this voluntary threshold is achieved, existing federal rules are good about spelling out the type of information that the potential research participant needs to make an informed decision. That information includes details about what is going to happen; the risks, benefits, alternatives, and procedures to be followed; who to call if something goes wrong or whom to call for information about rights and interests; and confidentiality provisions. The trick, though, is to provide that information in a way that is understandable.

Sugarman noted that he and his colleagues have done some empirical work for the White House Advisory Commission on Human Radiation Experiments and found that the very terms used to describe the research process have different denotative and connotative meanings to the people involved. The word "experiment," for example, implies something risky and scary. The word "study" had the complete opposite connotation—that the physician was going to study up on the patient and his or her disease. He added that being able to describe the research process to an individual is just as important as being able to explain all of the relevant medical terms. "Is this a survey? Or is this trial a first in human study of a drug that has never been tested, and we don't know what is going to happen? Those are very different things and very nuanced differences that matter completely in peoples' understanding of what is going on. In order for informed consent to be obtained, you have got to give information in a way that is understandable," said Sugarman.

The final step in the consent process is to give the individuals the consent document for them to examine. Giving the consent document to the patient can accomplish two things. First, handing this document to the patient gives them the opportunity to read it independently or to have it read to them. Second, it allows the patient use it later and to look up all of things they might have been afraid to ask at the time of consent and to use it as a reference source. "So the documents themselves are doing things besides being the be-all and end-all in giving information," said Sugarman. He concluded his presentation with the comment that "respect for persons is manifest in the expectations of a meaningful informed consent process. We ought to care about consent."

BEST PRACTICES AND NEW MODELS OF HEALTH LITERACY FOR INFORMED CONSENT[2]

Linda Aldoory
University of Maryland

The challenge to create informed consent documents that are understandable by the average patient or potential research subject is not a new one, said Linda Aldoory, citing several papers from as early as 1972 (Ingelfinger, 1972) to as recently as 2010 (Fernandez, 2010). "The body of knowledge on informed consent and health literacy is actually quite massive," she said, noting that in much of this literature, the authors struggle to create more understandable documents for the purposes of informed consent within the constraints of federal regulations. "Federal regulations often interfere with our ability to create health-literate informed consent," added Aldoory.

However, upon conducting a systematic literature review of more than 100 studies, government reports, videos, toolkits, websites, and presentations, along with several in-depth interviews with experts in the field, Aldoory's team identified a set of best practices and lessons learned as well as gaps that can serve as a research agenda going forward. Aldoory's team also created two models of health-literate informed consent that they detailed in the commissioned paper (Aldoory et al., 2014).

The literature review spotted a number of trends in informed consent procedures and health literacy. Approaches today are more patient centered, are more likely to enable empowered and active decision making, and are increasingly emphasizing meaningful consent as opposed to or in addition to completion of an informed consent form, Aldoory said. Over the past decade in particular, researchers are using technology to streamline the informed consent process and improve understanding. As an example of how technology is being used to improve the health literacy of the informed consent process, though not necessarily as a best practice, Aldoory cited the Enroll system developed by Mytrus. This interactive electronic informed consent learning tool measures an individual's understanding of the risks and benefits of participation while delivering the necessary information to obtain informed consent.

Aldoory said that the commissioned paper summarizes 30 of the top best practices (see Appendix C for the complete list), and she described sev-

[2] This section is based on the presentation by Linda Aldoory, Endowed Chair and Director of the Herschel S. Horowitz Center for Health Literacy and associate professor in behavioral and community health at the University of Maryland, College Park, and the statements are not endorsed or verified by the IOM.

eral of them, noting in the process that these best practices are supported by findings from earlier decades. Best practices today recognize the importance of time, and she referred to the example that Sugarman gave about seeking consent earlier than the last minute before treatment is about to begin. She noted that research suggests that the longer the time that patients or participants have to consider the informed consent documents and ask questions, the better prepared they are to make a decision when they begin treatment or enrollment in a research study. In the best cases, patients or participants receive documents and information a week or two ahead of time.

Many researchers today are considering the level of risk involved in a clinical trial or therapy when they decide how much information to put into the informed consent document, Aldoory said. Instead of following the federal regulations to the letter and putting all necessary information into informed consent documents when the risk is minimal, they are looking at what information is needed by patients or participants to make an informed, meaningful decision. As an example, Aldoory cited what she characterized as a wonderful template for informed consent forms for minimal risk research developed by the Agency for Healthcare Research and Quality (AHRQ).

Aldoory explained that best practices today also view other individuals as part of the decision-making process and, in particular, consider cultural and language differences. In many cultures, it is common for people to bring their family members or other important individuals with them and to make decisions as a family or group. Accounting for this type of group decision-making process can improve the informed consent process.

Best practices check to make sure that informed consent documents are written at or below an eighth-grade reading level—research has shown repeatedly that documents are often written at more than a high school reading level, Aldoory explained—and they use teach-back and teach-to-goal techniques to increase understanding of the information in these documents. Not only do best practices involve asking patients to recite what they learned or how they are interpreting information, but they do that continually through the consent process until the patient or participant understands each piece of the informed consent procedure.

One example of a best practice in clinical research that Aldoory and her colleagues learned about during an interview brings potential participants together in groups and uses a combination of interactive PowerPoint presentations on informed consent and group discussions to increase understanding before each participant consents individually. This approach greatly reduced study dropout rates, Aldoory noted. She added that there are comprehensive toolkits, other resources, and templates for informed consent available on the Web from AHRQ, the National Cancer Institute

(NCI), the Food and Drug Administration (FDA), and various nonprofit organizations.

Multimedia and online approaches to improve informed consent in both treatment and research settings have been an area of focus over the past decade, but the findings on the effectiveness of these methods have been mixed, said Aldoory (see Figure 2-1). On the pro side, authors have found that the approaches using Internet-based interactive tools, as well as video and audio, create a more user-centered environment where the participant has more control over the situation. Researchers have also found that these approaches offer more consistency across the different individuals in the study and that they lower anxiety among participants. Multimedia and online approaches have the advantages of allowing for an audit trail and reducing staff time and costs.

There are mixed findings on the efficacy of these methods, however, and every situation is different and must take into account different factors, such as low health literacy. Aldoory said that research on low health literacy has not yet found solid evidence that alternative formats beyond verbal and written communications have been effective and that, further-

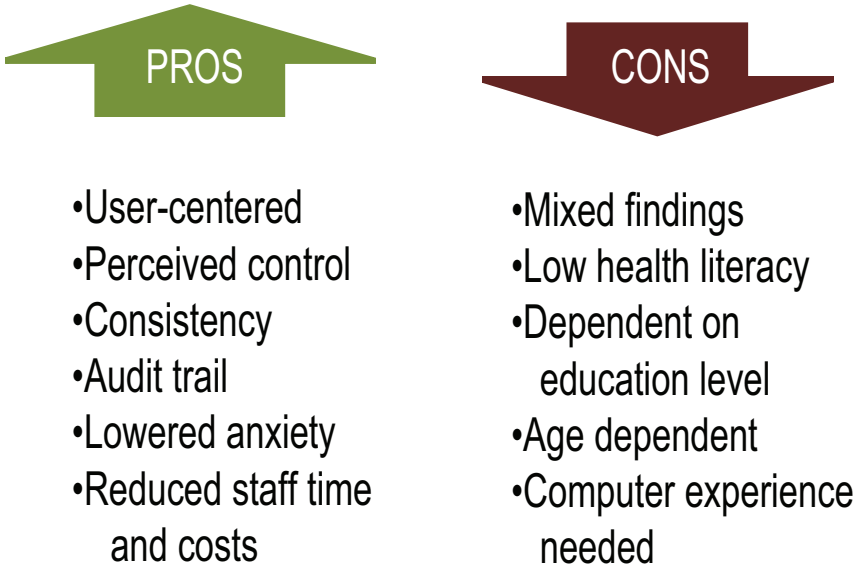


FIGURE 2-1 Pros and cons of the effectiveness of multimedia and online approaches.
SOURCE: Aldoory et al., 2014.

more, the effectiveness of these alternative formats depends on education level, age, and computer experience. "Some researchers have suggested that in the absence of consistent findings, the format to use should depend on the level of risk in the study," said Aldoory. "If it is minimal risk, you may be able to use different formats that are appropriate for the audience. If it is high risk, you may need to combine written and oral with multimedia."

Turning to the subject of the two models that she and her colleagues developed after completing their review and expert interviews, Aldoory said that she views these as prototypes that will require dialogue, revision, and empirical testing to show that they work beyond the context of their review. These two models, she explained, are based on the universal precautions approach to health literacy and a situational communication framework that is context dependent. The models also fill some of the gaps in research that they identified.

The first model, which assumes that the target participants have low health literacy, uses a roadmap to health-literate informed consent and is a step-by-step visualization of the sequential order of larger process phases to complete in order to reach patient understanding regardless of the level of health literacy (see Figure 2-2). Each step in the roadmap builds on the one before it and embeds the best practices identified during the review and interview process.

The first step, Aldoory explained, is to know the setting and risks, which includes understanding practitioner characteristics such as training of the people who are giving informed consent. The second step is staff training on both study details and informed consent. The third step is to understand the participants' cultural differences, literacy differences, ages, and technological skills and to use that understanding in the fourth step, which is to simplify written forms. Step five considers alternative formats, including multimedia and computer-based forms, and step six involves dialogue. "We have found that verbal exchange is still core to increasing understanding and informed decision making among participants and patients," said Aldoory. The seventh step involves assessing comprehension using teach-back and teach-to-goal methods, and the eighth and final step is to assess the system used to improve the entire process.

The second model is a situational risk model for communicating informed consent (see Figure 2-3). This model incorporates a more tailored approach to communicating with different audiences based on level of risk in the study and uses the AHRQ template and other templates that are based on minimal risk or high risk. As risk increases, the model adds more information in the informed consent documents, such as additional details on the right to refuse or discontinue participation and on common side effects, alternative treatments, and postsurgery plans.

In closing, Aldoory said that some of the suggestions she and her

FIGURE 2-2 A roadmap to health-literate informed consent.
NOTE: IC = informed consent.
SOURCE: Aldoory et al., 2014.

colleagues found were simple, such as spending more time meeting with participants and patients and using clear language. Others were more complicated, and as an example she cited one study that developed computer avatars that teach participants about decision making and informed consent. "What was surprising to us was that even with an accumulation of this information, there continue to be barriers to informed consent," she said. "Authors continue to talk about the restrictive federal guidelines and how challenging it is to reach meaningful informed consent." She said that her hope is that the commissioned paper and the discussions at this workshop

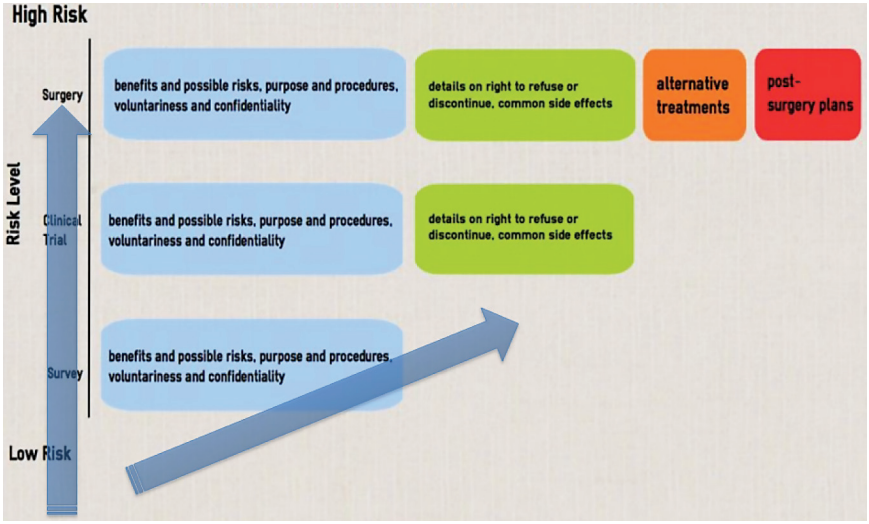


FIGURE 2-3 Situation risk model for communicating informed consent.
SOURCE: Aldoory et al., 2014.

would increase meaningful dialogue about these barriers and identify ways to improve health-literate communication during the informed consent process.

DISCUSSION

Cindy Brach, senior health policy researcher with AHRQ and a roundtable member, started the discussion by saying that she has been working on moving from the AHRQ toolkit for informed consent and authorization for minimal-risk research to a set of trainings for hospital staff or for clinical practice and that she has been getting bogged down in some of the practicalities to make this transition. Brach remarked, for example, that patients being prepared for surgery often have questions about anesthesia when talking to the surgeon during the informed consent process but that the surgeon then refers those questions to the anesthesiologist, whom the patient has yet to meet. She then asked Sugarman if he had any ideas on how this process could work better. He replied that Brach had identified a structural problem that exists in many health care organizations and that these organizations are trying to address this problem as part of the need to increase the efficiency of the health delivery system. Some health systems, such as Johns Hopkins, have created preoperative clinics at which patients can meet with an anesthesiologist in advance of surgery.

Sugarman noted that unexpected illnesses can also present a challenge. "I see patients on Tuesdays, but not all my patients get sick on Tuesdays," he said. "If they come in on a different day, there is going to be a different process. Not all of health care can be planned." He added that when structural issues act as barriers to informed consent, the goal should be to fix those problems rather than trying to correct them by changing the consent process at the end.

Ruth Parker, professor of medicine, pediatrics, and public health at Emory University School of Medicine and roundtable member, asked the panelists if they had any ideas on how to handle potential conflicts of interest in the consent process, and she cited the use of new technologies as something that could be perceived by some as a conflict of interest. Sugarman based his reply in part on the results of the Conflict of Interest Notification Study he and his colleagues conducted with funding from the National Institutes of Health (NIH) (Weinfurt et al., 2009). The issue they studied was that, although every IRB wanted investigators to disclose potential conflicts of interest as a first step, it was unclear who on a research team should disclose, when and how disclosure should occur, and what the impact of disclosure would be on the research enterprise and potential participants. The bottom line, said Sugarman, was that most people do not care about most financial interests in research in spite of the attention that is brought to this issue. "If an investigator is paid by a company to do research, if there is a per capita payment, the general public understands that money changes hands to do different kinds of research," he said. What people do care about is equity interest in research. "The fact that researchers stand to gain financially depending upon how the investigator physician interprets things matters to people." Sugarman and his colleagues have since developed template language that can be used to accurately describe certain financial interests in research. He also noted that discussions about conflict of interest are sometimes about conflict of obligation between the integrity of the research process versus the obligation to the patient and not a conflict of interest per se.

In terms of whether a particular technology would be viewed by the consumer as a conflict of interest, Sugarman said he did not know the answer of how to address conflict of interest. "That's an empirical question that needs to be asked," he said. Sugarman went on to describe that he and his colleague Philip Lavori put together the Brief Informed Consent Evaluation Protocol, which serves as a tool for measuring the quality of the informed consent process independent of the experience of a research participant (Sugarman et al., 2005). This protocol involves having the participant call a phone bank immediately after obtaining informed consent and going through a process that maps to Faden and Beauchamp's conceptual model he had discussed in his presentation. In a site-randomized clinical

trial involving some 800 patients at 30 sites, Sugarman and his colleagues tested a checklist and found that although every research coordinator involved in the study liked the idea of a checklist to improve informed consent, the data showed that a checklist did not improve the consent process and that there is room for improvement in the informed consent process of research (Lavori, 2007).

Aldoory added that research supports Sugarman's answers and that it also shows that too much information has been found to be negatively associated with participation. "If you give too much, it actually increases confusion, and it makes people not want to participate in trials and makes them more nervous," she said. "Sometimes the conflict-of-interest information comes in at a level of too much information if it is beyond what they really need to know."

In a general comment to the two panelists, Kim Parson, strategic consultant in the Corporate Consumer Experience Center of Excellence at Humana, stressed the importance of engaging actual consumers and doing human-centered design when plotting these different efforts. Parson commented that it is important to vet these different models iteratively in real time and even co-create them with consumers. Sugarman agreed that such testing is important when the risk profile of the research matters but that there are other types of research where it would not matter as much. As an example, he discussed the vaginal microbicide trials that were conducted among sex workers in Africa to test the prevention of HIV transmission. "The stakes were enormous, and we made sure that we did really careful formative research to figure out how we could communicate to people who had less than 4 or 5 years of education in a six-arm randomized trial of different gels," said Sugarman. In the end, they used a 15-page consent document that had three sentences and pictures per page, and they used two dice to explain randomization. With two or three rolls of the dice, people without education could understand randomization.

In response to a question from roundtable member Wilma Alvarado-Little, director for community engagement/outreach at the University at Albany's Center for the Elimination of Minority Health Disparities, about whether adolescents are considered to have their own culture, Aldoory said that she did not find any studies where adolescence was considered a cultural difference. "There were cultural differences in terms of older adults," Aldoory noted. She added that in terms of accommodations for the visually impaired, which Alvarado-Little also asked about, a few studies looked at visual impairment and other situations, such as patients with schizophrenia. The findings in those cases tended to show that one-to-one oral communication seems to be the best way to communicate. Oral communication, she noted, allows people to ask questions more easily and to question information that is not clear. In addition, it allows the person doing the consent

process to use nonverbal clues to judge whether the individual understands the consent process. "That really seemed to increase comprehension more than the other modalities," said Aldoory.

Robert Logan, communications research scientist at the National Library of Medicine, asked Aldoory to discuss some of the major gaps in research that she uncovered. One significant gap, Aldoory replied, was the lack of visual models of any kind that used infographics or sequential ordering to help people who might be at the beginning stages of understanding informed consent. Researchers may have years of experience with the informed consent process, whereas people involved in a clinical trial may be doing so for the first time or may not have the expertise to know what they are doing, she explained. Another gap was that there has been little work done on the role of situational factors such as risk levels and how they affect informed consent. "We found many essays and conclusions from studies that said risk level is probably a dependent factor on how much we should communicate, but we haven't found any empirical studies looking at those factors and their effects," said Aldoory.

She also reiterated her earlier statement that research on new technologies and multimedia approaches has largely generated mixed results and that more work is needed to understand why that is true. There has also been little research on low-health-literate populations, and there is a dearth of studies on developing models for informed consent in community-based research studies.

Benard Dreyer, professor of pediatrics at the New York University Langone Medical Center and a roundtable member, asked the panelists to comment on the issue of providing too much information in the treatment setting, as opposed to the research setting. As an example, he noted that in his career he has seen three children die during tonsillectomies, mostly from anesthesia reaction, and he wondered whether it was necessary to mention the risk of death from anesthesia, a real but nonetheless rare risk, when obtaining consent from patients for the tonsillectomy. "From the ethical point of view and maybe from the practical point of view, how does one make a decision to throw yourself back from the ledge of too much information?" he asked. Sugarman replied that the issue of understanding the disutility of information is a challenging one because each individual has a different tolerance or desire for ever more information. "The bottom line is the big things matter to most people. Death matters to most people, and major risks are things that need to be on the table," said Sugarman. "People have talked about the idea of drilling down into more and more information and making information available to people if they want to hear more and coming up with a bulleted list of main items, with additional information put behind them." Sugarman also said that different risks are

important to different people. A musician, for example, might be very interested in even small risks for ototoxicity or peripheral neuropathy.

Sugarman noted in this regard that informed consent documents for HIV prevention trials funded by the NIH are "ridiculously long—they are 20 or 30 pages—it can take a day for people to go through the consent document," he said, adding that individuals are getting little usable information from these documents. He and his colleagues are trying to determine how to shorten these documents, and they are running up against institutional constraints. His team is asking all of the stakeholders in the process to identify what could be successfully eliminated from the consent form and why, and then see if they can reach a consensus as to what is really needed in these forms.

Aldoory added that the research she reviewed showed the importance of giving people time to assimilate risks prior to surgery. When giving consent in the minutes before surgery, patients may have some vague idea of risk and benefit, but at that point they have little choice, which increases their fear. Another problem is that people often come into the clinic full of misinformation that they gleaned from the Internet, which leads to their giving meaning to information beyond what they are actually hearing from the health professional conducting the consent process.

George Isham, senior advisor at HealthPartners, senior fellow at the HealthPartners Institute for Education and Research, and roundtable chair, asked Aldoory whether the situational risk model applies to everybody or whether there needs to be segmentation of the audience, given that different people have different values about different outcomes. "Is there an ethical question about providing people with different levels of information?" he asked. "Is a one-size-fits-all approach equitable and yet not helpful to a lot of the people? It seems like there is a bit of tension there between different concepts in terms of what you provide the people and yet tailoring the information to what matters to people given their levels of situation and also their level of literacy." Aldoory said that her team asked themselves those very same questions. "When we wanted to come up with visual models, we wanted to find a way to incorporate both the universal precautions approach and tailored communication approach," she explained, noting that each of these two philosophies are beneficial in the situation of informed consent. She acknowledged that she does not have answers yet to Isham's questions but noted that these questions are indeed on the table for study.

Sugarman added that enormous debates in court cases have led to the development of consent processes for the clinical setting. He explained that there are three standards for adequate disclosure of information during the consent process: a professional standard, a reasonable patient standard, and a subjective standard. The professional standard concerns what the aver-

age professional would want to know in a given situation. In the case of tonsillectomies, for example, do most pediatric otolaryngologists describe the risk of death? The courts have leaned toward this standard because, as Sugarman put it, "it is easier to haul in a bunch of professionals in a court setting where there is an allegation of improper consent. That doesn't mean it is the right way to go, but it is the court doing its business."

This issue is easier to resolve in the research setting, he said. A phase I first-in-human study is a different situation from a research survey study, for example. He noted that with comparative effectiveness research that uses data that are already going to be acquired in the normal course of practicing medicine in the health care setting, there is the question of why there is even the need for consent, given that there is no incremental burden or risk to the patient. "There is a bit of push-back now against always building up consent to be the most important element," said Sugarman.

Bernard Rosof, chief executive officer of the Quality in Healthcare Advisory Group and a roundtable member, noted that the complicating impact of federal regulations on the health literacy level of the informed consent document was mentioned frequently in the commissioned paper and asked Aldoory if she could comment more on that with regard to clinical research on community health benefits. She responded that the chief complaint voiced by researchers concerns the volume of information that has to be communicated in the informed consent process. "I do not think that it is anything in terms of structural or behavioral restrictions that the researchers feel," she said. What she and her colleagues learned in studying the regulations carefully is that many things are actually optional, which is why they developed the situational-risk model. Federal regulations, she explained, state that there is basic information that needs to be conveyed—what the study is about, what the risks are, and a few other factors—but that the regulations are not as restrictive as they are made out to be. She also noted that the paper does list a few best practices that do relate to community-based work, as does the example she discussed about holding group meetings prior to obtaining individual consent

Roundtable member Winston Wong, medical director for Community Benefit and director of Disparities Improvement and Quality Initiatives at Kaiser Permanente, asked how political power factors into the conversations around informed consent, particularly with regard to safety net organizations that may be seeing significant numbers of undocumented individuals who may come in seeking care. Aldoory said that research in this area has not panned out, at least in the context of health literacy, though she noted that there is a much broader body of knowledge around issues of informed consent that do not address health literacy and that were not part of her review. However, this subject did come up in the interviews she and her team conducted, and the interviewees pointed out the importance of tak-

ing time to provide an understanding of the informed consent process long before discussing what the study was about and eventually seeking consent. She added that some interviewees commented on the difficulties they encountered with their IRBs getting approval for using informed consent processes aimed at low-literacy populations. "They became advocates of their populations, but they had to battle the IRB," said Aldoory.

Sugarman said that he was not aware of any empirical literature on political power and consent but that this highlights the critical issue of voluntariness, one of the understudied areas of the consent process. In a literature review he conducted about 15 years ago, he found that many hypotheses were addressed, and most were about understanding and disclosure, whereas only a handful were about voluntariness (Sugarman, 1999). "If we really want to get to consent, we want to think about voluntariness," said Sugarman. He did note that in certain circumstances the federal regulations do provide some leeway for waiving the need for a consent document. Roundtable member Laurie Francis, senior director of Clinical Operations and Quality at the Oregon Primary Care Association, remarked that the power differential in society can be an important influence on voluntariness and asked whether there had been any research on that issue. Aldoory replied that most of the research on health literacy and informed consent focused on the literacy end and that there was only one formalized empirical study looking at self-efficacy. Sugarman added that one way of reducing the power differential is to have people other than the doctor or nurse involved in the consent process. However, solving this problem does not get rid of literacy issues.

Brach noted that many of these issues have to do with what Sugarman called the subjective standard for informed consent, which she interpreted as relating to those pieces of information that would make a difference to each individual. Although this standard would be difficult to enforce legally, given the challenge of knowing what specific individuals need to make their decision, it is what the field should be striving for in the consent process. "There is a model out there that says what we should be telling people is what is going to be important for them to make that decision," said Brach. She also remarked that page length is not a good measure of literacy, as Sugarman's example of the 15-page form with three sentences per page illustrates. She commented, too, on the use of short and simplified forms to better guide those who are conducting the consent discussion and to ensure that they are in fact communicating all of the important information needed for meaningful informed consent.

Parker asked the two panelists to name one or two areas that are ripe for the roundtable to tackle. Aldoory nominated the use of multimedia and interactive technologies, given the mixed results obtained so far. She said she would like to see more dialogue to tease out the reason for the mixed

results that have been observed so far. Sugarman agreed with Aldoory's suggestion, saying that gathering good data on these newer approaches is humbling and noting how hard it is to develop these methods and test them. He added that developing health-literate consent documents is about more than just information giving and understanding. "Any model that reduces it prematurely to that simple question is going to fail," he said. The first step, he said, should be to make a model that reflects this complexity and then generate data before introducing recommendations. "The things that we think about in closed rooms without data can be hazardous and resource intensive," he remarked.

The final comment in this discussion came from Isham, who asked Sugarman to clarify his statement that financial conflicts of interest do not matter, given the public's concern about the costs of medical care. Sugarman reiterated that although most patients want to know about financial interests in research they do not care about most of them, but they do care about equity interests. "The question is if it is something that poses a threat to [a patient's] welfare, then it should matter," Sugarman said. "I think the dominant paradigm for conflicts of interest is that it is critical to simply disclose them during the consent process, but I think we need to come up with management strategies for conflicts of interest and research rather than rely on the consent process to solve all of the issues with it." He noted in closing the discussion that his summary paper (Weinfurt, 2009) made reference to language that IRBs and investigators can use to describe different financial interests and that he and his colleagues have used this language with thousands of people. He asked Isham to look at that paper and see whether he saw problems with that language.

3

The Current State of Informed Consent in Research and Treatment

The workshop's second panel included four speakers who together presented a picture of the challenges created by poor informed consent processes. Sara Goldkind, research and clinical bioethics consultant, discussed the impact of these processes on clinical trials and information sharing, and Yael Schenker, assistant professor of medicine at the University of Pittsburgh, spoke about one approach to developing a better informed consent process. Sandra Crouse Quinn, associate dean for academic affairs, professor of family science, and senior associate director of the Center for Health Equity at the University of Maryland, College Park, described strategies for improving the informed consent process to help increase minority participation in clinical trials, and Alicia Fernandez, professor of clinical medicine at the University of California, San Francisco, highlighted the disproportionately negative impact that poor informed consent processes have on the medical treatment that minorities receive. An open discussion followed the four presentations.

THE IMPACT OF A POOR INFORMED CONSENT PROCESS ON CLINICAL TRIALS[1]

Sara Goldkind

To start her presentation, Sara Goldkind noted that the FDA's guidance on informed consent, of which she was one of the authors, was published in draft form recently and is available for comment. Goldkind encouraged the workshop attendees to review the draft guidance and provide feedback to the FDA. She also remarked that the draft guidance document addresses some of the issues that this workshop is tackling, particularly those issues related to literacy and numeracy and how to work with research participants who are physically impaired.

To frame the rest of her presentation, Goldkind listed the conclusions she has drawn regarding how to improve the informed consent process. Any approach, she said, must be multipronged, and it must be driven by research on informed consent that produces a sound evidence base. There also needs to be more effort to educate the public and potential research participants about the informed consent process, the benefits of participating in clinical research, and the essential role that the public plays in the research endeavor, she added. In addition, the research community needs to partner more extensively and effectively with patients and disease-based foundations and advocacy groups.

In discussing the basic components of informed consent, Goldkind said that although it is important to disclose adequate information to allow for an informed decision about participating in research and to facilitate comprehension, the crux of informed consent is not just about disclosure or understanding. A good informed consent process should also provide potential participants adequate opportunity to ask questions and consider whether to participate and should ensure that agreeing to participate is completely voluntary. She also noted that many complex learning activities go on in informed consent that impact the quality and success of the consent process. "I think we need to bear that in mind as we think about how to improve informed consent, and in fact, I think we need to have empiric research on all areas of the various components of informed consent. Clearly, we have largely focused on understanding," said Goldkind.

Another factor that adds to the complexity of studying informed consent is that clinical research itself is diverse, Goldkind explained. Survey research, for example, is different from first-in-human research with a new investigational product. At the same time, study populations are also

[1] This section is based on the presentation by Sara Goldkind, research and clinical bioethics consultant, and the statements are not endorsed or verified by the IOM.

diverse, and research is needed to understand whether that diversity affects the implementation of adequate informed consent and, if so, what those effects can be. The data derived from various components of the informed consent process are also heterogeneous in terms of the setting, the timing of data collection, and the types and quality of the methodology used to study those components. As a result, there is a question of whether findings from specific studies can be generalized to other groups. "Is someone who has gone through multiple clinical trials as part of cancer therapy different from someone who is a novice to the research setting?" asked Goldkind. "I think that we ought to not only bear in mind how complex informed consent is itself, but also how complex are the data that we are acquiring about informed consent."

She noted that various practical concerns result when informed consent is conducted poorly. For example, failing to describe the nature of the research and the scientific reasons for it could potentially affect recruitment and retention. She noted that researchers need to conduct exit interviews to ascertain why participants withdraw from studies and determine if the informed consent process played a role in that decision and whether there was a disconnect between an individual's experiences in the study and what was learned through the informed consent process. It would also be useful, she said, to ask people who decline to participate in research for their reasons for doing so. "It would be really interesting to know after they have gone through an informed consent process whether that changed their minds. Did they come to the clinical context thinking they were going to be part of the research? After they went through the informed consent process, did they say 'this is not for me' and why? I think there are ways that we can get more information about recruitment and retention."

Another practical concern is that long and complex forms may inhibit reading and processing, and as an example she cited the terms-of-use agreements that almost everyone skips when installing new software or joining a new website. Certainly, said Goldkind, long and complex forms may increase resource burdens when drafting them and when reviewing them at the IRB level, which in turn could delay start-up times, particularly when multiple sites and multiple IRBs are all editing various aspects of the informed consent documents. She commented that although many people believe that federal regulations are largely to blame for long and complex informed consent documents, she agrees with the prior speakers that this is not the case. She said that these regulations have been in place and have changed little since the 1980s; what has changed is the way these regulations are being interpreted and implemented.

Goldkind reiterated Aldoory's statement that consent documents do not need to disclose everything that is in the regulations and cited the fact that of the 14 basic pieces of information listed in the regulations, only 8

are required to be disclosed, with the other 6 required only when appropriate and applicable. Moreover, the regulations do state that the informed consent process has to be in language understandable to the research participants. "In the guidance that I mentioned to you, we actually describe that low literacy and low numeracy should be taken into account when you think about what 'language understandable to the research participants' means," said Goldkind.

If long and complex informed consent forms cause confusion and misunderstanding among research participants, that might in turn affect data integrity, said Goldkind. For example, if participants are not following the protocol-driven procedures, outcome data can be negatively impacted, or if they are participating in a phase I safety study but think that they are in a treatment study, they may underreport adverse events.

Goldkind then discussed what she believes are some of the aspirational goals of informed consent. Informed consent should honor self-determination and be thought of as an expression of the principle of autonomy, she said. Informed consent should empower the potential participant to decide whether the risk/benefit ratio is acceptable to that individual and whether it remains acceptable through the research study. "You can think of informed consent as an expression of beneficence and non-malfeasance in that regard," said Goldkind. Informed consent should also aspire to convey respect for potential participants as true partners and maintain an ongoing dialogue that starts before study initiation and continues after the study ends. She said that she has heard from patients that they are interested in seeing the aggregate data from a study and learning about the conclusions drawn from their study. Maintaining a dialogue after a study is complete is a way of honoring the participants' role in the study, said Goldkind. Although not a subject for this workshop, another aspirational goal for informed consent should be to protect individuals with diminished autonomy or decreased decisional capacity, Goldkind stated.

She then discussed what she called "sublime concerns." At the top of her list was that the failure to provide contextual meaning to a research study may degrade the participant's autonomy and decision-making abilities. The goal, she said, citing an IOM report on health literacy and numeracy (IOM, 2014), is to enable participants to draw meaning from information to make the choices they need to make. Another sublime concern of hers is that informed consent handled poorly fails to engage participants as true partners and may lead to their sense of objectification or "commoditization" that can then promote distrust and anger.

There are several areas, said Goldkind, where further research is needed in order to improve the informed consent process. Studies have shown, for example, that research participants have a limited understanding of aspects of research after standard informed consent and that interventions

to improve understanding are not effective or are of limited or inconsistent effectiveness. One review of 42 trials of consent processes (Flory and Emanuel, 2004) found that person-to-person interactions, especially those involving extended discussion interventions, may be more consistently effective than approaches using multimedia, test/feedback, or enhanced forms at improving understanding.

Goldkind noted, too, that it is essential for the field to conduct evidence-based research on informed consent interventions. She acknowledged that quality data are challenging to obtain and that it is necessary to assess whether the results from disparate study populations can be generalized and to ensure that the tools used to measure understanding and participant satisfaction are valid and of high quality. Given the complexities of studying informed consent, Goldkind said the field ought to think about nesting informed consent studies within clinical research. "What I mean by that is if you are doing a cardiovascular study, can you build in an informed consent study as an ancillary study to that research so that you actually have real-world data on informed consent rather than simulating certain informed consent projects?" Goldkind explained.

Additional research is also needed to understand what participants want and need to know, she said. Goldkind cited research by Deborah Schrag, from the Dana-Farber Cancer Institute, showing that participants in clinical trials of palliative chemotherapy did not want the informed consent organized by drug but rather by regimen. They wanted to know how chemotherapy was going to affect them: Would they be able to drive? Would they have to be hospitalized? What would they be given to combat nausea? They also wanted to hear real patient voices as part of the informed consent process. Schrag and her colleagues have compiled a booklet with pictures and quotes from real patients that they are now going to test in their population. "I thought that was a really interesting way of thinking beyond the informed consent document," said Goldkind.

Along similar lines, the NCI revised its informed consent template for late-phase clinical trials based on expert input from a wide range of stakeholders, including physicians and nurses, IRB members and industry representatives, the FDA, lawyers and ethicists, and patient advocates. One of the results of the NCI's studies was that shortening and simplifying its document had little impact on satisfaction among a group of colorectal cancer survivors. The NCI also found that people who were familiar with clinical trials were more inclined to want to be part of clinical research. Goldkind said that this finding goes back to one of her earlier points that educating people regarding what clinical research is about on a larger, community-wide basis could provide a contextual framework for people to understand information given to them within the informed consent process.

With regard to going beyond the informed consent form, it is important

that the entire process educating individuals rather than simply informs them, Goldkind said. Understanding informed consent is a continuous process rather than a single event, and informed consent must reflect the diversity of research, meaning that one approach to the informed consent process may not be suitable for all types of research. It is also important, Goldkind said, to recognize the role that the larger community, such as patient advocacy groups, community-based advisory boards, and disease-specific foundations, can play in improving the informed consent process beyond improving the actual consent document. She also suggested that the field should reach out to other disciplines and co-opt successful research tools from the social-behavioral and decisional sciences, successful teaching techniques from educators, and effective communication skills.

Goldkind concluded her talk by describing the challenges of discussing information sharing in the informed consent process. It will be important, she said, to conduct research that can identify what people want to know about how data will be shared, what will be disclosed when data are pooled and shared across multiple sites, and how their biospecimens will be used. Questions that she said need answering with regard to data sharing include the following:

- What does privacy mean in today's highly matrixed and technologically sophisticated world?
- How would the public weigh protection of individual privacy against the utilitarian benefits to public health that could come from future use of linked datasets and/or biospecimens?
- How should differing national concerns and sensitivities be bridged?
- Ultimately, what is the optimal manner to present this information in an informed consent process?

She ended her comments by stating, "I want to emphasize the need for public dialogue and for education coupled with evidence-based research on informed consent."

FACILITATING INFORMED DECISION MAKING DURING THE CONSENT PROCESS: STRATEGIES FOR INCREASING MINORITY PARTICIPATION IN CLINICAL TRIALS[2]

Sandra Crouse Quinn
University of Maryland

Sandra Crouse Quinn started her presentation by asking how many of the workshop participants had ever heard somebody say, "I am going to consent the subjects." Her point in asking that question was to show the power differential that is inherent in the informed consent process and to begin the discussion of how that power differential might affect how members of racial and ethnic minorities might react in the context of the informed consent process. She also noted that, although research has been showing that racial and ethnic minorities are increasingly willing to participate in research, they still are not in fact participating. "How can we look at informed consent to help address that?" Quinn asked, adding that she particularly wanted to focus on the conversation part of the process rather than on the document.

She said that research shows that there is poor recall and understanding of information presented during the informed consent process and that there is a lack of knowledge, particularly among racial and ethnic minorities, about research and research terms. When the consent process is done well, these challenges can be overcome, and trust can be built between researcher and participant, but when done poorly, mistrust can be reinforced by the consent process.

In an effort to improve this situation, Quinn and her colleagues conducted a survey of 347 investigators, research staff, and IRB members whose racial and ethnic identity included Caucasian, African American, Latino, Asian, and Native American researchers (Butler et al., 2013). On average, these investigators had 14 years of research experience and were nearly 47 years old. They also conducted a national phone survey of adults in African American and Latino communities (see Table 3-1). They asked researchers such questions as "What methods do you use during the informed consent process?" "How do you assess understanding?" and "What generally do members of the public know about research terms and the purpose of informed consent?" They asked community members such

[2] This section is based on the presentation by Sandra Crouse Quinn, associate dean for academic affairs, professor of family science, and senior associate director of the Center for Health Equity at the University of Maryland, College Park, and the statements are not endorsed or verified by the IOM.

TABLE 3-1 Demographic Distribution of Participants in a National Phone Survey About Informed Consent

Demographics (Total n = 2,455)	Latinos (n = 1,264)	African Americans (n = 1,191)
Gender (females)	63%	68%
Age (mean and SD)	47.1 (17.4)	54.3 (16.9)
Education (college or above)	45%	56%
Marital status (married or living with a partner)	63%	50%
Employment		
• Full-time	37%	31%
• Retired	18%	35%
Health insurance	74%	82%
Income		
• <$36,000	56%	56%
• $36,000–$76,000	27%	27%
• >$76,000	18%	17%

NOTE: SD = standard deviation.
SOURCE: Quinn, 2014.

questions as "How would you like to learn about the consent process?" and "What strategies do you use to increase understanding, and what methods might be helpful for you to understand the informed consent document?"

In discussing some of the results, Quinn said that the phone surveys revealed that two-thirds of the community members understand the terms "confidentiality" and "anonymous" but that the level of understanding drops from there. When they compared the methods the researchers used to elicit the preferences of the community members, they found that some methods, such as taking home information, one-on-one discussions, having a family member or friend present, and holding multiple meetings, were closely matched. However, whereas researchers were less inclined to talk with the participants, hold group discussions, and use new methods such as video and interactive games, participants were much more likely to prefer these methods. "Community members wanted more meetings and more opportunities to talk about the consent process," said Quinn. They wanted to talk with other participants or potential participants in group discussions, and they saw videos as potentially helpful (see Figure 3-1). On the other hand, community members did not find it particularly useful to have the consent form read to them, a practice that was common among researchers. Quinn noted that many of the community members' prefer-

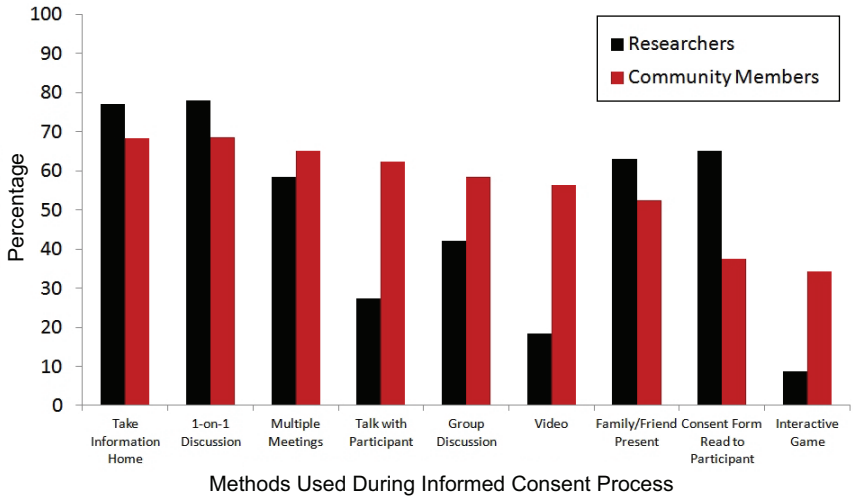


FIGURE 3-1 Comparison of researchers' methods to community member preferences. SOURCE: Quinn, 2014.

ences coincided with what the literature says are the most effective means of conveying the information needed to make an informed consent decision.

Regarding the format of the consent form and how content was delivered, 97 percent of researchers said they used plain language, a finding that Quinn called into question, given the state of most informed consent documents and the research showing that informed consent documents are written at a relatively high grade level. Fewer than 20 percent of researchers used a summary at the end of these complex documents, but a majority of the community members said that a summary would be helpful (see Figure 3-2).

In this study, Quinn and her colleagues also asked researchers how they assess understanding. Some 52 percent of the researchers asked open-ended questions of the potential participants, and nearly the same number had participants sign and initial every page, which Quinn said has never been shown to be an effective means of assessing understanding. Nearly 40 percent used teach-back methods, and about 10 percent used an independent monitor or some form of questionnaire. One disturbing finding was that 32 percent of the researchers did not assess understanding at all.

Summarizing these findings, Quinn said that what is known about informed consent is that participants may have incomplete comprehension of information delivered during the informed consent process and that there

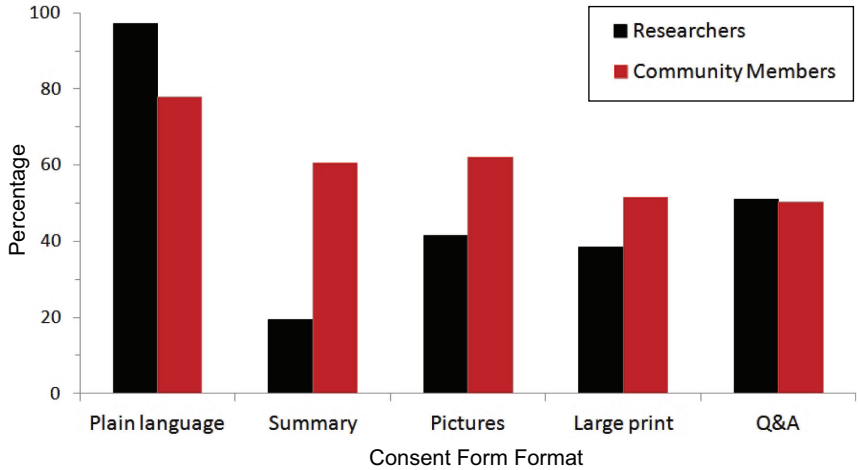


FIGURE 3-2 Comparison of formatting approaches that researchers use and community members' preferences.
SOURCE: Quinn, 2014.

are discrepancies between researchers' practices and community members' preferences in both learning about a study and in the informed consent document. She added that it is clear that researchers' assessment of participant comprehension is limited and sometimes inadequate and that there are issues with the use of plain language in the informed consent document. She then made two recommendations. First, she said, it is imperative to increase comprehension using methods that research has shown to work, such as one-on-one discussion, multiple meetings, and plain language, and then to make it a standard practice to assess understanding. Second, it is important to increase satisfaction using such methods as one-on-one discussions, multiple meetings, pictures, and summaries. "Our team firmly believes that recruitment and the informed consent process are the beginning of a relationship, and if we begin that relationship in a way that fosters trust and understanding and dialogue, we believe that will ultimately play out in a successful completion of that research subject," said Quinn. "Increasing satisfaction will help us to build that trust at the beginning."

She then described the Building Trust research initiative that she and her colleagues have been conducting and the Web-based interaction educational program that they have developed as a resource for researchers and their community partners. On the basis of the data collected, Quinn's team is creating three curricula, two of which are largely complete. One curriculum is aimed at researchers and staff, and it answers such questions as the following:

- How do you recruit?
- How do you address the history of race and distrust and research abuses?
- How do you address issues that are more complex even when we adhere to the guidelines, even when we do everything right?
- How do we think about complicated ethics?
- How do we have critical conversations in our own research teams about race and ethnicity and recruitment?
- How do we retain people, and how do we build community partnerships?

The second curriculum is for researchers and community organizations to use to explain what research is to their community members. "What we are saying is that it is time for a broader educational component about informed consent that doesn't wait until the person arrives in your clinic ready to potentially participate in the study, but really helps them to understand it," said Quinn. This curriculum aims to explain why community members should participate in research and how their participation makes a difference, particularly in the context of health disparities, she explained.

She then showed parts of the Web-based version of this second curriculum, which comprises three components: the importance of research, informed decision making, and the ways community members can be involved with researchers. Each component has video and audio materials, didactic material, questions for discussion, and resources that community members can download for later use. The informed decision-making component, for example, starts by addressing a set of myths and facts about research and informed consent (http://www.buildingtrustumd.org/unit/informed-decision-making/do-you-know). It then addresses the lessons that were learned from the past, particularly from some of the abuses that occurred and the precautions that have since been put into place to protect participants in research studies. The curriculum then answers questions about why community members should participate in research and what informed consent is, including a glossary of terms and the 10 key elements of the informed consent process and the means to identify them. The curriculum then provides a list (which can be downloaded and printed) of 10 key questions to ask a researcher before agreeing to join any study (http://www.buildingtrustumd.org/unit/informed-decision-making/knowledge-is-power). The questions are as follows:

1. What is the main purpose of the study?
2. What will I be asked to do during the study?
3. How will I benefit from participating in this study?
4. What are the possible risks?

5. How will the results be shared?
6. How will my personal information be kept confidential?
7. How long is the study going to last?
8. Are there any reimbursements or incentives offered?
9. Who is funding the study?
10. What are the credentials of the researcher and the researcher's institution?

In conclusion, Quinn said that she and her colleagues believe that a several-pronged process is essential to overcoming underrepresentation of minorities in clinical research and that the informed consent process can be one of those prongs. "There is a broader educational effort that is important, and then there are the specific components of improving informed consent when somebody comes in to talk about participation," said Quinn. "Those are critical to building trust and to creating a more educated participant."

DEVELOPING A BETTER PROCESS FOR INFORMED CONSENT[3]

Yael Schenker
University of Pittsburgh

The focus of her talk, said Yael Schenker, was to describe practical steps to improve the process of informed consent in the effort to achieve ethical goals (Schenker and Meisel, 2011), and she used a specific case to frame the discussion. This case involved "Mr. L," a 70-year-old man with end-stage heart failure who was being evaluated for a destination left ventricular assist device (LVAD). An LVAD, explained Schenker, is a complex device consisting of a pump connected to an external computer that does the work of the left ventricle of the heart pumping blood throughout the body. Surgical mortality for LVAD surgery ranges from 5 to 30 percent: it is considered a high-risk procedure. The decision to have a destination LVAD implanted is also a preference-sensitive one, meaning that it involves significant tradeoffs affecting quality and length of life. Schenker emphasized that LVADs are one of many cases where we face challenges in informed consent, and she believes that it is equally important to examine and improve the consent process for less complex and lower-risk procedures.

Schenker drew an analogy between informed consent and scaffolding. Like scaffolding, informed consent performs a basic safety function—

[3] This section is based on the presentation by Yael Schenker, assistant professor of medicine at the University of Pittsburgh, and the statements are not endorsed or verified by the IOM.

protecting patient autonomy and helping ensure that patients have the fundamental right to decide what is done to their bodies. And, like scaffolding, she said, informed consent supports the building of the cathedral; in this case, the cathedral is patient-centered health care. "Informed consent is the platform from which we work to help ensure that patients are involved in medical decisions and that these decisions reflect their values and preferences," Schenker said.

There are many documented failures of informed consent, according to Schenker, including the failure to achieve adequate patient understanding that can lead to medical errors or the receipt of preference-discordant care. Some commentators have viewed these failures as evidence that the requirements of informed consent are unrealistic or that the concept itself is somehow flawed. Schenker said she does not share this view; rather, she believes that it is possible to improve the process of informed consent, and she cited evidence to support this more optimistic view (Schenker et al., 2011). Data from a systematic review that she conducted with several colleagues demonstrate that relatively simple or straightforward interventions can improve patient comprehension in informed consent (see Figure 3-3). "I would submit that rather than abandon the cathedral, we build a better scaffolding," said Schenker. "I think that when we look carefully at key

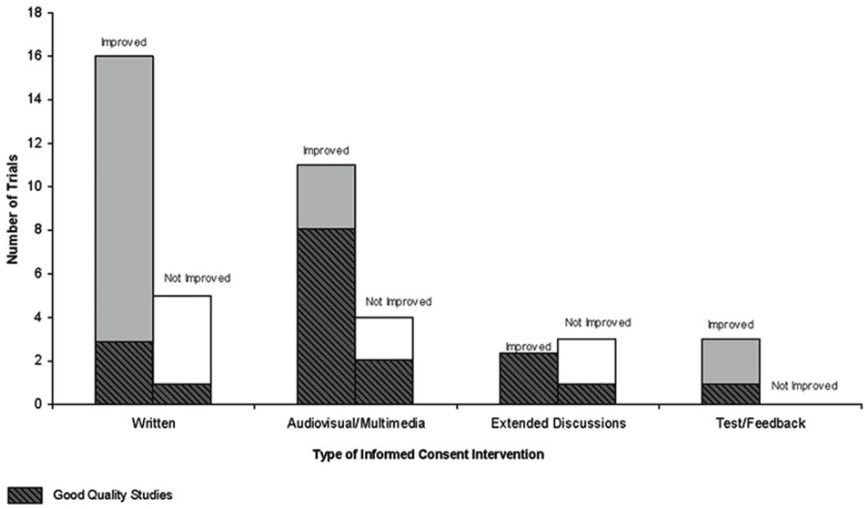


FIGURE 3-3 Review of 44 trials indicating possibility of improving patient comprehension.
SOURCE: Schenker et al., 2010.

steps of the process—the who, when, what, and how of informed consent—we find room for simple improvements."

The "who" of informed consent is the person obtaining informed consent—traditionally this is the physician performing the procedure. In the case of Mr. L, this would be the cardiothoracic surgeon. Schenker emphasized that it is important for Mr. L and the family to have the opportunity to meet with the surgeon prior to surgery and to ask questions, but she questioned whether the surgeon is the best person to conduct the consent process. The surgeon may, for example, have poor communication skills or have little time to conduct a thorough consent process that leads to meaningful consent, or simply may not enjoy talking with patients. Schenker noted that there are other important members of the clinical team involved in the consent process of a destination LVAD. For example, perhaps the LVAD nurse coordinator, Schenker said, probably knows more about these devices than anyone and has more time to spend at the patient's bedside.

As of 2013, the Center for Medicare & Medicaid Services (CMS) also requires that a palliative care physician be involved in the consent process for this procedure. "When you think about it, this makes sense because a surgeon knows a lot and thinks about the risks of surgery but may not be the best person to discuss alternatives to surgery," said Schenker, likening the situation to asking an air conditioning company representative for information about ceiling fans. Palliative care clinicians, in contrast, are trained to discuss alternatives, including the alternative of not pursuing a potentially life-prolonging intervention, to think about and compare outcomes for different options, and to elicit patient values.

Schenker noted that a team-based approach to informed consent requires clearly defined roles. She said that involving members of the team who are not involved in performing the procedure may provide more balanced information, improve patient understanding and help to ensure that informed consent is truly an informed choice that reflects patient values. "I would propose that this approach can also be more efficient if each member of the team is charged with achieving a smaller piece of the consent process at the appropriate time," she added.

Turning to the "when" of informed consent, Schenker noted that previous speakers at the workshop had addressed the problem of obtaining informed consent immediately prior to a planned procedure. Mr. L, for example, may be too sick at the point of receiving an LVAD to participate meaningfully in the consent process, meaning that a family member (or surrogate) may be required to provide consent. He may also be psychologically committed to the procedure at that point. Commentators have written that informed consent in such a situation constitutes little more than a medical Miranda warning (Meisel and Kuczewski, 1996). In contrast, there are several potential advantages to starting the consent process in advance—

the patient may not be as sick, and multiple information sessions may be possible, for example. For LVAD surgery and other high-risk procedures, starting the process in advance would give the patient more time to prepare, engage, and ask questions, making informed consent an informed choice rather than an acknowledged understanding of a treatment option that has, for all intents and purposes, already been chosen.

Timing does matter, said Schenker, and she illustrated one possible workflow for LVAD surgery (see Figure 3-4). "I think the nature of this workflow will vary depending on the urgency, complexity, and preference-sensitive nature of a procedure," she said. "When we talk about informed consent as a process, I think it is important that we allow time for this process to occur."

In discussing the "what" of informed consent, Schenker noted that the current focus of consent discussions and consent forms is on risks. She said that for a high-risk procedure such as LVAD surgery, it is appropriate to discuss these risks in detail. However, an overwhelming focus on risk has several potential downsides. One is that risks are often described in vague terms—"There is a risk of bleeding and infection," for example—that could apply to a simple blood draw as much as it does to destination LVAD. Laundry lists of risks are also overwhelming. When presented with forms written in fine print, patients will often just skim them, sign them, and hope for the best. Schenker emphasized that a focus on risks in this manner can also be impersonal. "It is not clear to what extent each risk on the laundry list will apply to you," she explained. "If the risk of surgical mortality is 30 percent, patients may hope that they will be in the 70 percent."

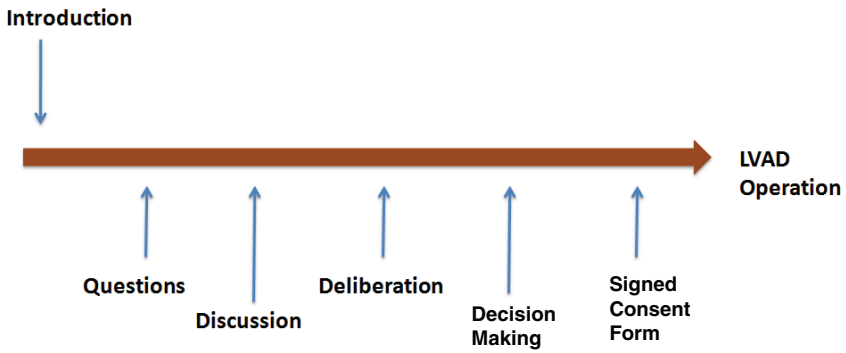


FIGURE 3-4 Possible workflow for conducting meaningful informed consent for a high-risk surgical procedure.
SOURCE: Schenker and Meisel, 2011.

Instead of focusing on risks, Schenker proposed that the focus of informed consent discussions should be on outcomes. A focus on outcomes involves thinking about the best-case scenario, the worst-case scenario, and the most likely case scenario for an individual patient (Schwarze et al., 2013). For Mr. L, the best-case scenario may be that he survives the operation and can return home and live independently for another five to seven years. The worst-case scenario may depend on Mr. L's values: it may be that he dies during the operation, or it may be that he suffers a devastating postsurgical complication, such as a stroke, that leaves him requiring 24-hour care for the rest of his life. Finally, the most likely scenario for Mr. L may be that he survives the surgery and is able to return home but is unlikely to be able to return to activities he previously enjoyed, such as sailing. Once these scenarios are compiled, it is then possible to discuss how these outcomes, and the outcomes for alternative therapies, align with the patient's goals (see Figure 3-5). "Thinking about outcomes in light of a patient's goals helps to contextualize risks and may aid patients in making more informed and personal choices," said Schenker.

Ending with the "how" of informed consent, Schenker spoke about two best communication practices: "ask-tell-ask" and "show, don't tell." Ask-tell-ask is a variation of teach-back that has been recommended for use in many types of medical conversations, including discussions with seriously ill patients near the end of life and conversations to engage patients in the self-management of chronic illness (Back et al., 2009; Bodenheimer et al., 2005). Schenker believes that "ask-tell-ask" is also a useful model for informed consent. Ask-tell-ask starts by inviting the patients to share

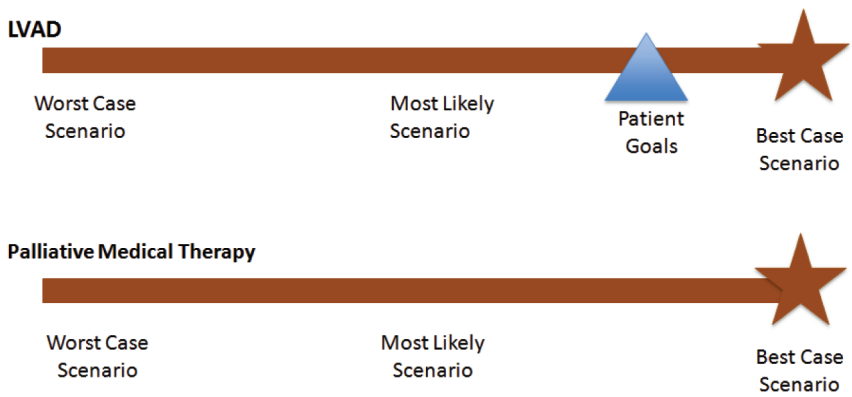


FIGURE 3-5 Aligning patient goals and outcomes.
NOTE: LVAD = left ventricular assist device.
SOURCE: Schwarze et al., 2013.

what they know about a procedure. This approach not only signals the importance of the patient's involvement but also elicits any potential misunderstandings or misconceptions at the start. The clinician can then use the time more efficiently to fill knowledge gaps and correct misconceptions. The final ask is framed *not* as a test or a challenge but rather as an opportunity to help the clinician to do a better job of explaining the next time. For example, the clinician may say something like, "I want be sure I have done a good job of explaining things today. Can you tell me what we talked about?"

The "show, don't tell" approach replaces descriptive text with pictures, videos, and demonstrations. "As I mentioned, LVADs are complex devices requiring lines of fine print to describe. Why not show a picture instead? Postsurgical care and conditions are also complicated. Why not use a video or perhaps even introduce a real patient?" asked Schenker. Evidence supports the idea that pictures or video can help patients envision both treatments and their outcomes (Volandes et al., 2009). Technology can also help engage patients in the informed consent process and connect patients with others who are contemplating or have already received a high-risk procedure, for example through online support groups.

INFORMED CONSENT AND PATIENTS WITH LIMITED ENGLISH PROFICIENCY[4]

Alicia Fernandez
University of California, San Francisco

Alicia Fernandez began this session's final presentation by noting that there are no national or multicenter data on how best to overcome language barriers in conducting the treatment-related informed consent process. She also explained that the definition of limited English proficiency comes from the U.S. census, which starts with the question of whether an individual speaks a language other than English at home and, if the answer is yes, then asks if that individual speaks English very well, well, not well, or not at all.

According to the Census Bureau's American Community Survey, some 60 million people, or 21 percent of the U.S. population, speak a language other than English at home, and of this group, 62 percent speak Spanish and under 5 percent speak Chinese, with all other languages accounting for less than 2 percent of those who speak a language other than English at home. About 24 million people speak English below the "very well"

[4] This section is based on the presentation by Alicia Fernandez, professor of clinical medicine at the University of California, San Francisco, and the statements are not endorsed or verified by the IOM.

proficiency level (see Figure 3-6), and 14 million people—11 million who speak Spanish as their primary language—fall into the "not well" or "not at all" categories, representing a population of American residents who cannot really participate in treatment conversations. Fernandez put this population in perspective by saying that it is larger than the combined populations of Guatemala, Honduras, Nicaragua, and El Salvador, and it gives the United States the world's third-largest Spanish-speaking population. She also noted that the Hispanic or Latino population in the United States has grown from 6.4 percent in 1980 to 9 percent in 1990, 12 percent in 2000, and 16.3 percent in 2010 (see Figure 3-7). Currently, more than 17 percent of the U.S. population is Hispanic or Latino, and one-quarter of these individuals do not speak English well or at all.

The challenges for achieving meaningful informed consent in the low-English-proficiency population go beyond language. Some 60 percent of this population have less than a high school education—in studies by Fernandez's group at San Francisco General Hospital, the mean education level for patients with diabetes was third grade, for example—and about 6.6 million individuals with low English proficiency fall below the poverty

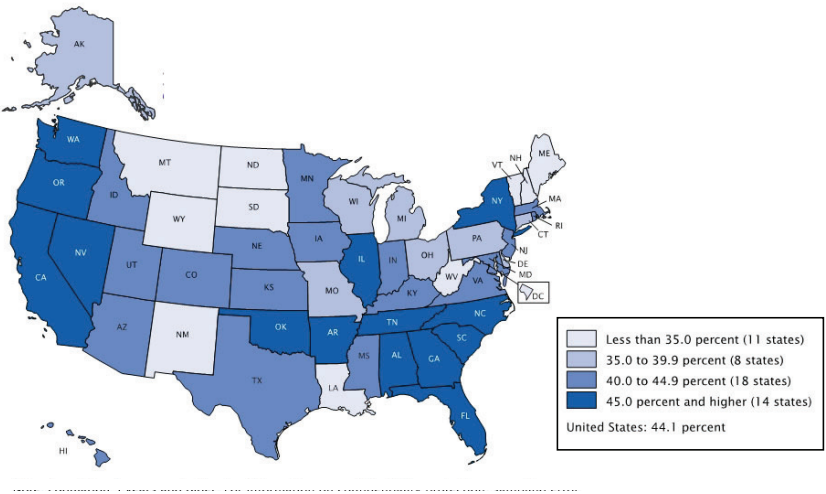


FIGURE 3-6 Percentage of the U.S. population speaking a language other than English at home who spoke English less than "very well," by state, 2007.
NOTE: Population 5 years and older. For information on confidentiality protection, sampling error, nonsampling error, and definitions, see www.census.gov/acs/www.
SOURCE: Census Bureau, 2007.

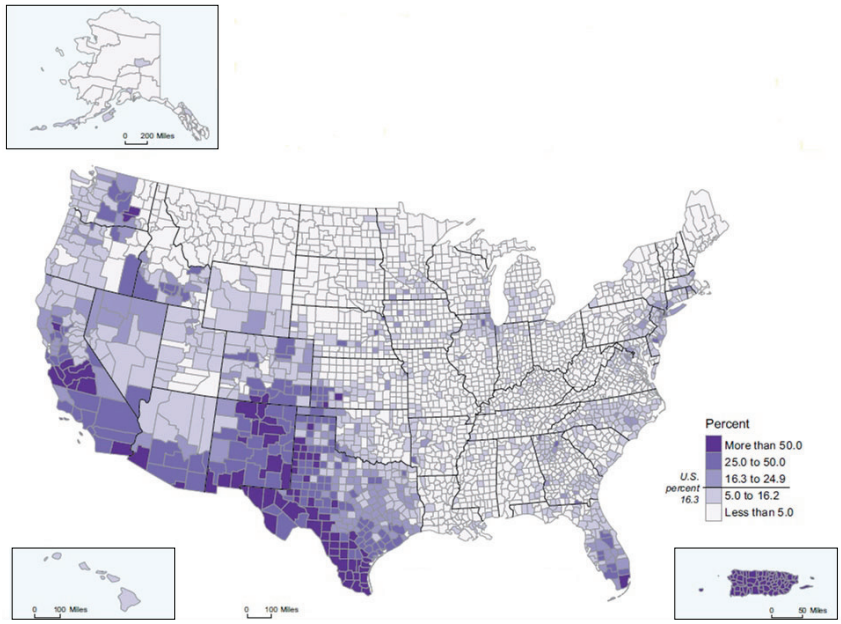


FIGURE 3-7 Hispanic or Latino population as a percentage of total population, by county, 2010.
SOURCE: Census Bureau, 2010.

line. Patients in the low-English-proficiency population are also less acculturated to U.S. health practices, including informed consent practices, and are less likely to question physicians, Fernandez said.

Fernandez listed four options for navigating language barriers: get by with limited language skills and gestures; use untrained interpreters, such as family and untrained staff; hire professional interpreters; and rely on bilingual clinicians. She noted again that there are no national data to answer the question of how the U.S. health care system is actually dealing with this challenge. "We could know, but we don't know," is how she characterized the situation. At San Francisco General, which she said has one of the country's most robust interpreter systems, she and Yael Schenker found that among Chinese- and Spanish-speaking patients with limited English proficiency who received a thoracentesis, paracentesis, or lumbar puncture, only 22 percent had signed a consent form in a language they could read, and only 28 percent had fully documented informed consent that made use of an interpreter (Schenker et al., 2007) (see Table 3-2).

Fernandez said that the biggest factors that drive underuse of skilled

TABLE 3-2 Rates of Informed Consent Documentation for Invasive Procedures in Low-English-Proficiency and English-Speaking Patients

	LEP (n = 74) %	English (n = 74) %	p-value
Procedure note documenting IC discussion, n (%)	59%	58%	0.9
Consent Form—any language, n (%)	70%	85%	0.03
Consent Form—patient's language, n (%)	22%	85%	<0.001
Fully Documented Informed Consent, n (%)	28%	53%	0.003

NOTE: IC = informed consent; LEP = low English proficiency.
SOURCE: Schenker et al., 2007.

interpreters, even at a hospital with a well-developed interpreter system, are physician culture, the perception that communication is perhaps not that important, and the time and hassle involved in getting an interpreter. San Francisco General attacked this last problem by installing a bedside system that connects automatically to the hospital's interpreter corps via phone or video conferencing, she said. Training physicians in interpreter use, combined with making it convenient, increased interpreter use by 30 percent, she noted. However, physicians at San Francisco General report using untrained interpreters frequently, largely because it is convenient and because they are not aware of the evidence on communication errors associated with using family members or untrained staff as interpreters (Diamond et al., 2009).

In contrast, said Fernandez, there is substantial evidence from audiotape studies that professional interpreters provide more accurate information than ad hoc interpreters and that the use of professional interpreters increases patient and physician satisfaction compared to when ad hoc interpreters or no interpreters are used (Karliner et al., 2007; Tschurtz et al., 2011). Nonetheless, there are issues about the use of professional interpreters that bear underscoring, she said. Currently, there is a certification and supply problem, as there are no mandatory national standards for what constitutes appropriate certification for professional interpreters. California, for example, mandates interpreter training, but many states do not. Fernandez explained that the Joint Commission suggests that hospitals have some way of knowing that their interpreters are competent, but it has not established clear standards for doing so.

The quality of interpreters varies across the country, she added, with limited national data on actual interpreter use or availability. One study conducted in Washington State, a state that Fernandez said has paid a great deal of attention to informed consent, used audio recordings in the intensive care unit to check the accuracy of information passed on by professional

interpreters (Pham et al., 2008). A blinded review of the tapes by the investigators found that for every exchange of information, there was a 55 percent chance that an alteration, such as an addition, omission, substitution, or editorialization, would occur. Of these alterations, 75 percent were judged to be of clinical significance, and 93 percent of them were likely to have a negative effect.

For example, in one case a family member asked the doctor, "What we want to know is, after his lungs get better, and when he wakes up, will his brain suffer and affect his ability to recognize people?" What the interpreter said was, "Okay, so she wants to know about the lungs when he wakes up. So about his lungs and what about after, will it not affect him?" The physician replied, "Right now, it is very interesting to us because we don't understand what the problem is in his lungs." In another example, the physician said, "I don't know. This is a very rapidly progressing cancer," whereas the interpreter said, "He doesn't know because it started gradually."

Fernandez said that interpreters themselves believe they need to do a better job. She and Schenker, along with other colleagues, surveyed interpreters regarding end-of-life discussions. Some 85 percent of them—most of whom were experienced and certified—had multiple discussions per week, but only half of the interpreters reported that those discussions usually went well. Eighty percent reported wanting additional training in end-of-life interpreting, and 81 percent thought that physicians needed more training in working with interpreters (Schenker et al., 2012). Fernandez described another study, conducted at Bellevue Hospital Center in New York City, that compared two state-of-the-art interpreter systems and language-relevant bilingual physicians who were seen in the emergency department (Gany et al., 2007). When patients were asked whether they understood the doctor's explanation of their diagnosis and their medication instructions, fewer than 40 percent of those who received those explanations via either of the interpreter systems understood key points. In contrast, close to 60 percent of those who received their instructions straight from the bilingual physician understood key points (see Table 3-3).

Multiple studies, said Fernandez, have shown that language-discordant care results in lower levels of comprehension, patient satisfaction, and trust in the physician. In a study that she and her colleagues conducted at Kaiser Permanente of Northern California, 35 percent of low-English-proficiency patients with diabetes who were treated by a physician who did not speak Spanish reported a lack of trust, compared to only 16 percent of those treated by a Spanish-speaking physician who reported a lack of trust (Schenker et al., 2010). "Trust is an essential element of any informed consent discussion, as we cannot expect our patients to become physicians and make the choices that we can help them make," said Fernandez. In addition, 20 percent of the patients who received language-discordant care

TABLE 3-3 Professional Interpreters Versus Bilingual Physicians

	Interpreter System A	Interpreter System B	Language Concordant MD
Understood MD explanation Dx	35%	39%	59%
Understood Rx instructions	33%	38%	63%

NOTE: Dx = diagnosis; MD = physician; Rx = prescription.
SOURCE: Gany et al., 2007.

reported feeling poorly treated because of the language barrier, and 40 percent thought their physician did not show respect when their doctor did not speak their language (see Table 3-4). Unfortunately, she added, "about 30 percent of all of our patients, irrespective of language, believe that we do a poor job of listening to them."

Bilingual physicians are more likely to be patient centered and elicit their patients' points of view, Fernandez said. In observational studies comparing bilingual physicians and interpreted discussions, the latter have fewer open-ended questions and less elicitation of questions or values. Data from studies that Fernandez and her colleagues conducted (Fernandez et al., 2011) show that patients with diabetes treated by language-discordant

TABLE 3-4 Suboptimal Communication Resulting from Language-Discordant Care

	English-proficient n = 8,116	LEP n = 522	P value	LEP-LC n = 210	LEP-LD n = 153	P value
Lack of trust in MD	26%	25%	0.37	16%	35%	<0.0001
Treated poorly because language	2%	12%	<0.001	9%	20%	0.001
MD not showing respect	28%	30%	0.31	29%	39%	0.04
MD not listening	33%	28%	0.02	26%	32%	0.24

NOTE: LC = language concordant; LD = language discordant; LEP = low English proficiency; MD = physician.
SOURCE: Schenker et al., 2010.

physicians are twice as likely to have poor glycemic control, though they are equally likely to take a cholesterol medication. "We think that as discussions become more complex, the role of language and direct communication takes on more importance," said Fernandez.

Regarding how to address the challenges regarding individuals with limited English proficiency, who are among the most vulnerable of all patients, Fernandez said that to start, more data are needed on the state of the problem and on what is happening nationwide. There is also a need, she said, for national standards for interpreters and the mandatory use of certified professional interpreters for high-risk treatments and procedures, including high-risk outpatient decisions, such as a decision to start chemotherapy. "I think we could set a minimal standard requiring documented use of an interpreter for hospitalized patients as once a day. Once a day, if you are sick enough to be in the hospital, you should be able to speak to a treating physician." There should also be a signature line for the interpreters on the informed consent form to enable auditing. Health care systems should also facilitate additional interpreter training as well as training for medical students and residents on the use of professional interpreters. Technology, such as video-mediated interpretation and qualified telephone interpreters, could also be better used to address language barriers.

Several years ago, San Francisco General created state-of-the-art consensus forms in five languages that prompt a physician to call an interpreter. However, a survey of physician behavior conducted 1 year after rolling out these forms found no change despite what Fernandez characterized as "our best efforts at scolding and educating the residents." Today, the situation has improved, as the most recent survey showed an increase in resident self-reporting of interpreter use for informed consent, though she cautioned that the results of an audit are pending. She believes, though, that it is possible to change physician practice patterns, albeit slowly.

In summary, said Fernandez, many patients—including those proficient in English—have trouble with complex communication. For example, a study of English-speaking patients undergoing angioplasty found that 80 percent believed erroneously that angioplasty would reduce their risk of myocardial infarction and reduce mortality (Rothberg et al., 2010). The physicians, who were also interviewed, did not share that erroneous belief. In Fernandez's opinion, "Improving care for low-English-proficiency patients and focusing on low-English-proficiency patients will help improve informed consent for all patients." Accomplishing that task, she added, requires "ongoing commitment from all levels of leadership and from all levels of participation in the health care industry." She recommended that the roundtable convene a group to focus specifically on the problems of language barriers and to do it for two reasons. "One, it is the right thing to do. People are struggling out there knowing how to best take care of these

patients ethically and legally. Second, if it is not because of these patients, then do it because I think it will improve informed consent for all patients."

DISCUSSION

George Isham started the discussion with the comment that when lawyers help their clients with estate planning, they often introduce decision making with respect to their clients' preferences at the end of life. He wondered whether there is a way to disaggregate the decision-making process by first understanding patients with respect to their values and preferences. "I wonder if we are really thinking about the relationship of these concepts and the systems approach to understanding our patients' needs and preferences and approaching them with decision-making and then using technology on the provider side to make that information available at the point of care," said Isham. He then asked Schenker if she and her colleagues were thinking about this type of approach. "Yes, definitely," she replied. "Informed consent is often the trigger that gets doctors thinking about this." She added that, in her opinion, there is time to start the consent process in advance for many kinds of procedures. In the case of destination LVAD surgery, for example, heart failure is often a chronic disease, and most of these patients have been seen in the hospital repeatedly, long before the decision is made to implant an LVAD. "We don't think about bringing some of these things up until the procedure is imminent," said Schenker. "I think the more we can incorporate these conversations earlier, the better."

Kim Parson remarked that she was surprised by Goldkind's statement that dropouts from clinical trials were not interviewed to find out why they withdrew and asked whether there were rules or regulations that would limit such conversations. Goldkind replied that she was not aware of any legal limitations and that she believed that investigators should be encouraged to conduct such interviews as part of doing good research. She also said that not doing so is a missed opportunity and forfeits the ability to collect valuable information. "You don't know whether it is because they are disgruntled with the study, whether they had adverse events that they are not reporting, or whether they feel like they didn't get the benefits out of the research that they thought they were going to be getting," said Goldkind. These data would not only help improve the consent process but also help researchers design better trials and provide better data on the efficacy and safety of the intervention being studied. She did acknowledge that it takes effort to track down trial dropouts because often they simply stop returning to the clinical setting.

Roundtable member Catina O'Leary, president and chief executive officer of Health Literacy Missouri, asked the panelists if the risk level differed between biomedical studies and community studies. "When you talk

to community members as Dr. Quinn's group has done, you see that many times those community members feel the risk of what they are doing in the moment is as significant as anything else that anybody else would do, even a surgery or other things," said O'Leary. Quinn commented that in her study of community members, she and her colleagues asked African Americans and Latinos if they would be willing to participate in a range of studies with different levels of risk. What they found was that there was a surprising willingness to participate even as the level of risk rose. The respondents were motivated, she said, by wanting to help future generations, believing that they could make a contribution somehow. She cautioned that "when we focus on risk, we need to be careful that we don't have preconceived notions about what people are willing to do, and we have to talk about benefits," said Quinn. "The benefits may be not simply benefits to the individual but benefits to the community or to broader society."

Goldkind added, citing anecdotal experiences she has had working with disease-based foundations and groups in a number of settings where risk was high, that in some cases it was clear that the people who were going to be enrolled in research were not going to be the beneficiaries of that immediate intervention. "What struck me was how very engaged the groups were and how much input there was in terms of design, the informed consent process, the language used, and the understanding of what risk levels they were willing to tolerate beyond what we actually expected they would [be willing to incur]," said Goldkind. The lesson she learned from these anecdotal experiences is that investigators should not underestimate the power of dialogue and person-to-person exchanges.

Isham then asked if that dialogue should be conducted only when there is something to offer participants in research or if it should happen in the treatment setting, too. "Should we be asking those questions beforehand so that we know how to approach our patients in the first place?" asked Isham. Quinn said that it should happen and that community review boards are a good avenue to engage in those conversations about risks and concerns before studies even get started. She noted that her team was about to submit a paper describing a conceptual model for creating and maintaining openness to research. "We think of this as a long-term relationship," said Quinn, "and if we are really smart as researchers, we would go back to these communities and [tell them] here is what we found and ask what they think the results mean."

Wilma Alvarado-Little asked Quinn if she had looked at the generational status of African American and Latino patients to see if that would lend some insight into their responses and reactions. Quinn replied that she and her colleagues are in the process of analyzing data from such a study. Regarding the idea of the medical Miranda warning, Alvarado-Little asked Schenker if patients hear that they have a right to remain silent, and

Schenker replied that informed consent discussions often convey the notion that patients should remain silent. Addressing Fernandez, Alvarado-Little asked if any steps were being taken to address inaccuracies that occur during translation, and Fernandez replied that interpretation is very difficult, particularly in end-of-life discussions because many concepts may not be known and because of nuances that might be lost during translation. She and her colleagues have been working with the California HealthCare Foundation and the California Interpreter Association to create a free online curriculum designed to help interpreters improve their end-of-life conversations. Preliminary data show that interpreters like this curriculum, that they learn from it, and that they are more open to doing palliative care because of it.

Benard Dreyer asked Fernandez if there were any data showing the comparative effectiveness of live interpreters and telephone-based interpretation, and Fernandez replied that telephone interpretation is the least effective option. Video interpretations are gaining wider use, and these are more effective, she said. Thanks to technology solutions such as Skype and tablet computers, it should be possible to make use of interpreters with skill in any language and have interpreted conversations in real time wherever the patient is. She said that the private sector needs to step up to make this type of capability broadly available, and she added that "the research is unequivocal that video or in-person are both much better than telephone interpreters."

In response to a question from Dreyer about whether there are any interventions in the clinical as opposed to the research setting that get people to take more time during the consent process, Schenker replied that it is sometimes difficult to find more time in busy clinical settings. However, she said, the timing of when the patient is engaged in the consent process should change, and we should also think about who is conducting the informed consent process. As an example, she said that a surgeon may rush from one surgery into the preoperative waiting room to start the consent process for the next. "There may be a member of the team who is much more present and able to complete pieces of that process earlier," said Schenker.

Cindy Brach continued on the theme of bringing in other members of the health care team to conduct pieces of the consent process by asking Schenker if the CMS requirement to bring in a palliative care expert prior to LVAD surgery might raise accusations of death panels. "How do we make sure all of the choices get on the table?" asked Brach. "Who are the right people to talk about those choices?" Schenker replied that, in her experience as a palliative care physician, she and her colleagues are good at taking a patient-centered approach that aims to elicit values and helps patients weigh options. She noted that she has watched the consent process

evolve to become more of a team process where each team member brings something different to the table.

Bernard Rosof voiced the opinion that an important contribution to increased understanding by research participants would be to increase understanding among the research community about excellence in informed consent. Ruth Parker responded that what she hears in the patient-centered community environment is that the focus still needs to be on helping patients and prospective participants better understand the consent process at the community level.

Parker then asked Goldkind if the same informed consent processes will work in the clinical and research settings, given that research studies are mostly about determining safety and efficacy and that informed consent in the clinical setting has more to do with personal liberty and doing no harm. Goldkind replied that she believes that there are some distinct differences between informed consent in the clinical setting and the research setting that have to do with some of the assumptions that are made about motivations behind the consent process. "When clinicians are speaking to their patients about a treatment, the idea is, 'I am trying to do something good for you. You are my center of focus,'" explained Goldkind. "As a physician who does clinical ethics, I really think it ought to be about taking the medical options and putting them within the patients' value systems, their medical needs, and their life context."

Informed consent in the research setting is more about protection that is downstream, Goldkind said. "We should never get to informed consent if we don't think as a research community, as a researcher investigator, as an IRB, that the research has the right risk/benefit ratio and that the scientific questions that are being asked are critically important," she continued. "Once that is all in place, there is still the idea that this research is protocol driven. The interventions are not necessarily for the treatment of that individual patient, but to generate scientific knowledge. That shift changes, in my mind, the parity between clinical informed consent and informed consent obtained in the research context."

Michael Villaire, chief executive officer of the Institute for Healthcare Advancement and a roundtable member, asked whether there are any anecdotes or observations regarding how much value individuals with limited English language capabilities place on the informed consent process as a concept. He noted that his health care nonprofit is signing up people for health insurance who have never had health insurance, and they are so excited to be able to receive medical care now that they do not want to be faced with choices and to digest information, which creates another barrier for the informed consent process. In fact, replied Fernandez, there are data showing that 20 to 30 percent of older patients or patients in vulnerable groups do not want a consumer model of shared decision making—they

want their doctor to decide. Fernandez herself has patients who want her to make the choices and who say they trust her to do so. "I think that is completely valid and should be respected," she said.

The situation becomes more complicated when trust is broken, however, and Fernandez referred to the fact that most of her residents do not know the story about experiments conducted in Guatemala in which people were intentionally infected with syphilis but that most of her patients—many of whom cannot read—all know that story.[5] "What happens when there is no trust or when there isn't a trusted care relationship or when the patient is sick, and the doctor asks, 'Chemotherapy or no chemotherapy?' This is very complicated and cannot be fixed by a form," she said.

Turning to the role that regulations may or may not play in complicating informed consent forms, Andrew Pleasant, senior director for health literacy and research at the Canyon Ranch Institute and a roundtable member, noted that in his work as a community researcher he interacts with multiple IRBs across the country, and they all apply the existing regulations differently. What he has heard from the presentations is that tailoring situational approaches to the process is missing and very necessary, and he wondered if the regulations should actually require tailoring according to best practices in health literacy. He then asked the panelists if they had some idea of what such regulations would look like. Goldkind responded that it is important to remember that applying regulations uniformly eliminates the ability to have the very flexibility Pleasant wants. "Regulations just can't be granular enough to cover all of the nuances of different contexts and study populations and scenarios," said Goldkind, and she cautioned that layering additional requirements on top of those already mandated will only make it harder to incorporate the type of changes that the literature or empirical studies might demonstrate would work best for a specific context.

Fernandez took the opposite view and said that there are areas where more regulation may be beneficial but that empiric data are needed to settle that question. As an example, she said that Washington State regulates what needs to be included in informed consent, but other states do not. The empiric question that needs to be answered is whether people in Washington State understand the same procedure better than someone from western Massachusetts. "I haven't seen any data, but I suspect they do," said Fernandez, but the bottom line, she noted, is that the answer is currently unknown.

Isham concluded the discussion by wondering if the process of improving informed consent should start with patients rather than with the process

[5] This research was funded by the U.S. government and conducted in Guatemala from 1946 to 1948. More information is available at http://www.hhs.gov/1946inoculationstudy/factsheet.html (accessed January 29, 2015).

itself and if those who are involved in efforts to improve informed consent should start thinking about the categories of information that patients want. "What are the questions of life or death, function, consequences of the intervention, likelihood of success, potential impact of research? Is it a worthwhile study? Is it a trivial study? Is it a big question? Is it a little question? Is it an early calibration issue or not? Do the answers to these questions make a difference to whether people want to step forward and volunteer or not?" asked Isham. Schenker agreed that the field should take such a patient-centered approach but noted that this is not always seen in the clinical setting. "I think the requirements of informed consent really grew out of a desire to involve and protect patients," said Schenker. "Unfortunately, I think, given the way the process has been operationalized for many procedures in many different clinical settings, that is not what has happened. To the extent that we can rethink our approach and extend beyond informed consent to informed choice, this would be valuable."

4

Approaches to Informed Consent

In the workshop's third session, two panelists addressed new approaches to creating a meaningful informed consent process. Rebecca Sudore, a practicing geriatrician and hospital and palliative care physician at the San Francisco VA Medical Center and associate professor at the University of California, San Francisco, discussed the important role that conversation can play in creating a meaningful informed consent process. Christopher Trudeau, associate professor at the Thomas M. Cooley Law School, spoke about how to redesign consent forms so that they are understandable and meet the requirements of federal and state regulations. An open discussion followed the two presentations.

THE IMPORTANCE OF THE INFORMED CONSENT CONVERSATION IN ADDITION TO THE FORM[1]

Rebecca Sudore
University of California, San Francisco

For Sudore, advance directives represent the ultimate informed consent. Informed medical decision making, that may have life-and-death consequences, should be occurring when patients are completing advanced

[1] This section is based on the presentation by Rebecca Sudore, a practicing geriatrician and hospital and palliative care physician at the San Francisco VA Medical Center and associate professor at the University of California, San Francisco, and the statements are not endorsed or verified by the IOM.

directives, physicians are discussing Physician's Orders for Life-Sustaining Treatments (POLST forms), and do-not-resuscitate orders. In these instances, as with informed consent under other circumstances, people are often confused by the content of the forms and the many legal terms associated with advanced directive types of forms. Often, patients or their surrogates sign forms with answers to questions regarding resuscitation, machine-assisted breathing, and other life-sustaining treatments that conflict with prior advance directive forms and the patient's true wishes.

Over the past decade, Sudore has worked with roundtable member Michael Villaire to create advanced directive forms that are easy to understand. These forms, she said, are written at a fifth-grade reading level, use pictures to help explain complicated concepts and terms, and are available in Chinese, English, Farsi, Russian, Spanish, Tagalog, and Vietnamese (see Figure 4-1). A randomized controlled trial showed that people preferred this form overwhelmingly and that it doubled 6-month completion rates (Sudore et al., 2007). Sudore and her colleagues did find, however, that uncertainty still exists regarding hypothetical scenarios that are used to portray what could happen in the future, whether those were used for informed consent or advance directives. For example, 50 percent of a diverse population of older adults who reported a life-sustaining treatment preference on the basis of a hypothetical scenario were uncertain about their decision (Sudore et al., 2010). She noted that she and other investigators have shown that uncertainty is often associated with limited literacy, lower education, minority status, and poor health status (Allen et al., 2008; Volandes et al., 2010).

One lesson to draw from these studies with regard to informed consent conversations, said Sudore, is that "just because somebody makes a choice, it does not mean that they fully understand the meaning and the ramifications of that choice." As an example, she showed a portion of a POLST form used to direct a physician regarding life-sustaining treatment (see Figure 4-2). Section A of the form asks patients if they want cardiopulmonary resuscitation (CPR) in the event that they do not have a pulse. Section B is about medical interventions and asks patients if they want (a) comfort measures only, (b) limited additional interventions including comfort care, medical treatment, antibiotics, intravenous fluids, and noninvasive positive airway pressure but not intubation, or (c) full treatment. When she asked one of her patients what it meant to check the "limited additional interventions" box, the patient's response was, "I only want to be on machines for a few days. My family knows this." This is not, however, what a physician would do, said Sudore.

Sudore's patient was not alone in being confused by these options. Unpublished pilot study data from her colleague Susan Hickman show that only 55 percent of people understand what is on a POLST form. Moreover,

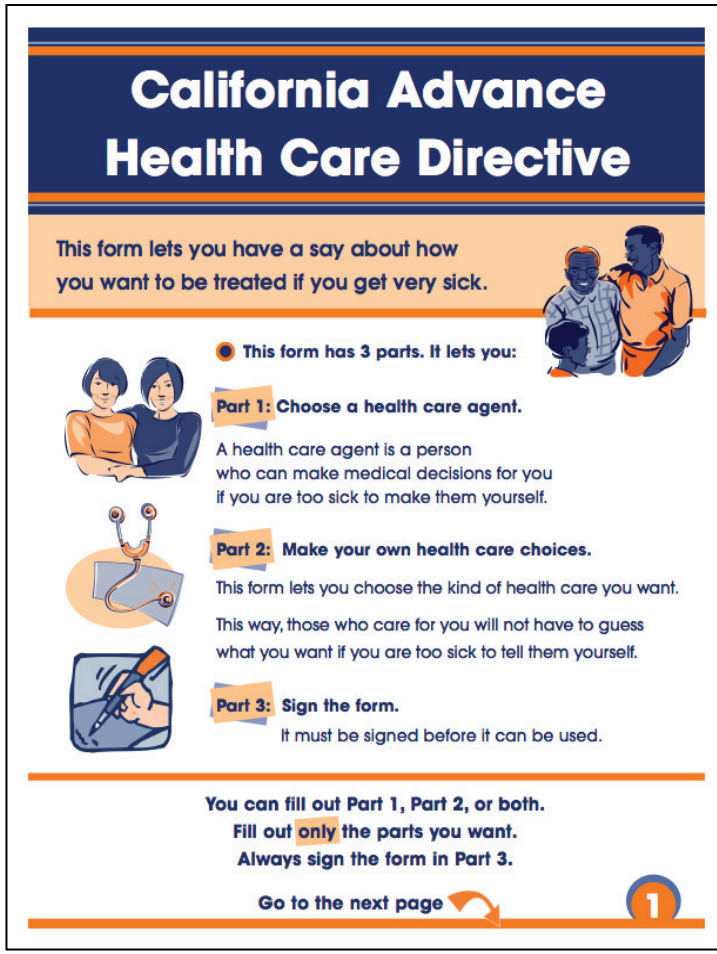
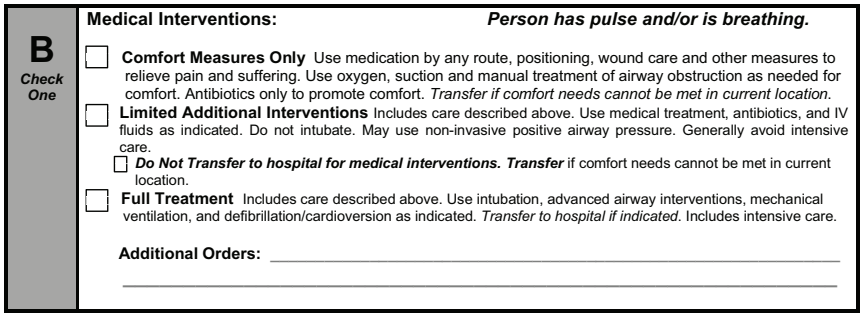


FIGURE 4-1 First page of the California's advance health care directive.
SOURCE: Institute for Healthcare Advancement, 2014.

59 percent of the time, the answers on this form are not in agreement with what the patients' actual goals when asked in the moment. Other investigators have found similarly confused patient responses to the questions on advance directive forms (Hammes et al., 2010; Heyland et al., 2013; Zhang et al., 2009). According to a study by Heyland and colleagues, 70 percent of documented end-of-life wishes in the hospital do not reflect what patients say they want for themselves at that moment in time.

However, studies that focused on discussions and not just on forms show different results, said Sudore (Detering et al., 2010; Kirchhoff et al.,



B *Check One*

Medical Interventions: ***Person has pulse and/or is breathing.***

☐ **Comfort Measures Only** Use medication by any route, positioning, wound care and other measures to relieve pain and suffering. Use oxygen, suction and manual treatment of airway obstruction as needed for comfort. Antibiotics only to promote comfort. *Transfer if comfort needs cannot be met in current location.*

☐ **Limited Additional Interventions** Includes care described above. Use medical treatment, antibiotics, and IV fluids as indicated. Do not intubate. May use non-invasive positive airway pressure. Generally avoid intensive care.

☐ ***Do Not Transfer to hospital for medical interventions. Transfer*** if comfort needs cannot be met in current location.

☐ **Full Treatment** Includes care described above. Use intubation, advanced airway interventions, mechanical ventilation, and defibrillation/cardioversion as indicated. *Transfer to hospital if indicated.* Includes intensive care.

Additional Orders: _____

_____

FIGURE 4-2 Medical intervention form offering patients three choices for care. SOURCE: Sudore, 2014.

2010). She noted that work done by a group called Respecting Choices, which works with trained facilitators to conduct in-depth conversations with patients, produced documented end-of-life wishes accurately representing patient desires approximately 90 percent of the time. These discussion-centered methods also increased patient understanding and satisfaction and helped surrogates know what patients want. These discussions also decreased cost and increased the quality of care. The lesson from these studies, said Sudore, is that discussions are needed to confirm understanding.

Sudore then spoke about the work that she and her colleagues have done to modify the consent process. The study she described was nested in a study of the advance directive trial she had already noted. It involved providing test subjects with a consent form written at the sixth-grade reading level and reading it to them verbatim in either English or Spanish. The researchers then assessed the patients' knowledge with seven true/false questions about the content of the consent form and followed that assessment with a teach-to-goal process that used repeated, targeted education until the patients achieved comprehension (Sudore et al., 2006). Through the first pass of the program, only 28 percent of the people were able to answer correctly all of the knowledge questions. Some 52 percent needed a second pass, and 20 percent needed a third pass. All of the non-native English speakers required more than one pass. "We found that as the literacy score decreased, the odds of requiring more passes increased," said Sudore (see Figure 4-3). The good news from this study was that all study participants were able to understand the information presented within three passes.

Limited health literacy is surmountable, Sudore said. She cited a study on hospitalized patients with asthma as an example (Paasche-Orlow et al., 2005). In this study, mastery of an inhaler was achieved in 100 percent of the patients after three passes through the instructions. In addition, a

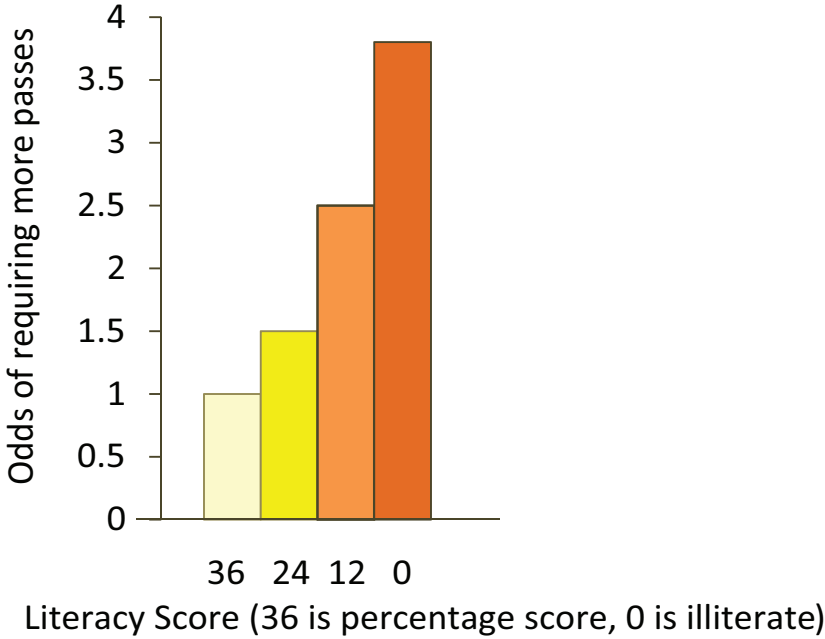


FIGURE 4-3 Results of assessment indicating that as literacy score decreased, the odds of requiring more passes increased.
SOURCE: Sudore et al., 2006.

study of surgical intensive care patients found that repeat or teach-back techniques improved informed consent comprehension from 53 percent of the patients to 70 percent, and the improvement was particularly notable with regard to understanding risks and alternatives (Fink et al., 2010). The investigators found that this repeat-back process took a mere 2.6 minutes longer than the regular informed consent process. The lessons for informed consent, said Sudore, are that an interactive teach-to-goal techniques may be necessary and that literacy and language do need to be addressed.

Sudore explained that the basic teach-back or teach-to-goal process starts with a new concept or new piece of health information and then uses an iterative process to achieve and assess understanding (see Figure 4-4). The problem with this approach, said Sudore, is that it gives patients information on risks, benefits, and alternatives before it addresses the patient's concerns. "What matters most to patients is not the treatment, but the outcome of the treatment," said Sudore. As an analogy, she said the current process is like putting the cart before the horse. "It is not intubation, CPR,

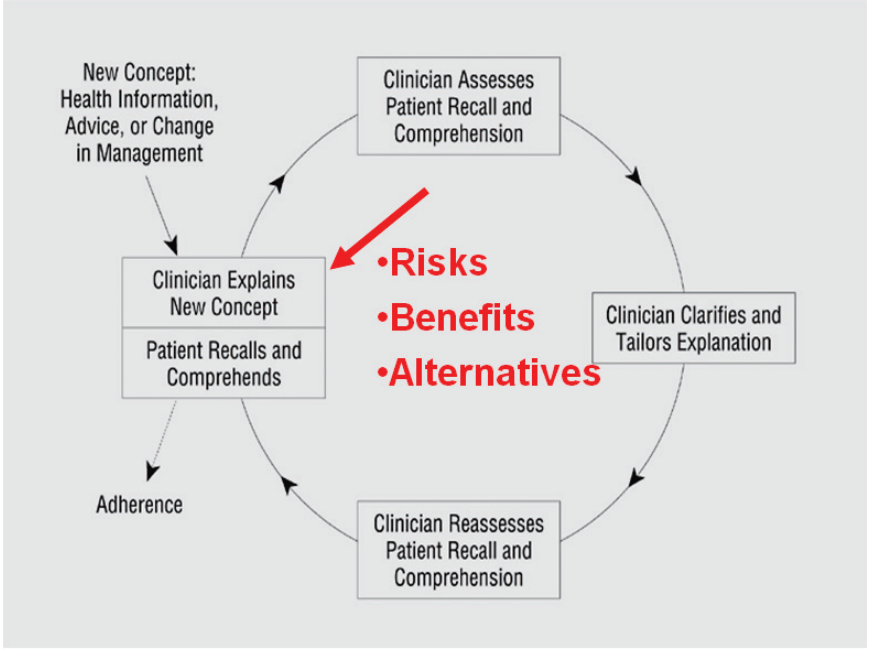


FIGURE 4-4 The teach-back or teach-to-goal process.
SOURCE: Schillinger et al., 2003.

surgery, blood transfusion, or chemotherapy, which I call the cart, but how their life will be after treatment, which I am calling the horse," she said. As one patient from a focus group said, "If I go through all of this, how weak will I be? Will I be able to get myself up out of bed and take a bath, you know, or what will happen to me?"

To make this point, Sudore presented another example from one of her surgery colleagues (Schwarze et al., 2013). As described in Schwarze and colleagues' publication, "a 77-year-old frail woman came into the emergency room with a large abdominal aneurysm. Though she had previously declined elective surgery on multiple occasions, she now agreed to have surgery, given that the main risk of not having surgery was death. After eight hours of surgery and admittance to the intensive care unit, the patient went into cardiac arrest and was brought back to the operating room to have her bleeding controlled. After another six hours of surgery and 45 units of blood stabilized her, the patient was brought back to the intensive care unit without the need for blood pressure support." Sudore said the

surgeons were happy because they believed that this was the best outcome they could expect for this frail older person. The woman's family, however, was horrified because the extra life-support treatments went against the woman's values and wishes—for years, the woman had voiced fears about the use of life support and spending her remaining life in a nursing home.

Revisiting the concept of using best-case and worst-case scenarios that Schenker had described in the previous panel session to get at this patient's values and wishes, Sudore said that a better approach than using risks, benefits, and teach-back might be to first understand what is the most important outcome to the patient and then describe all the options in terms of best-case and worst-case expected outcomes (Schwarze et al., 2013). This allows a range of options the patient can choose from that is focused on the outcome of treatment and what their life may look like after a particular treatment path. The best-case outcome for surgery in this example would be a 6- to 10-hour operation followed by 5 to 7 days of intensive care with a breathing tube and maybe dialysis, 2 to 3 weeks in the hospital, and then transition to a nursing home. After the surgery, it is unlikely that the patient would be able to return to living independently and would likely require living the rest of her life in a nursing home or with palliative care. The best-case outcome of palliative care would be that the patient would be admitted to the hospital's palliative care service, which would provide enough pain medication to stop the pain in her chest and enable the woman's family to be with her at her bedside during what would likely be another 24 to 48 hours before death. It might even be possible for the patient to go home, with hospice care providing pain relief. The lesson from this and other similar examples, said Sudore, is that "the first thing we need to do is elicit patients' values and then describe the outcome of treatment in real-life terms that the patient can understand." The use of stories can be helpful for understanding, she added.

Sudore noted that back when Terri Schiavo's story was in the news, she and her colleagues found that 92 percent of both English and Spanish speakers—including those who were illiterate and could not read in either language—were familiar with Schiavo and the media coverage of her case and that as a result, 70 percent of those people had clarified their own goals for medical care, and more than 60 percent had been motivated to discuss their wishes with their family and wanted to complete advance directive forms (Sudore, 2008). In addition to stories in the news, video images help improve understanding, increase engagement, decrease decisional conflict, and help people identify their own goals, Sudore added.

Geriatric patients have their own issues, including clinician bias that assumes that older patients have dementia. "People often automatically assume that older adults are demented, delirious, and cannot make their own decisions. Clinicians often defer to caregivers, when they haven't done

the work to find out if a patient has decision-making capacity," said Sudore. Other issues result from chronic illness and neurocognitive processing deficits, both from disease and medication, that can cause cognitive slowing. However, this does not automatically mean that these patients cannot process information. It may be necessary to speak more slowly when going over informed consent documents or discussing end-of-life issues.

In addition, 63 percent of adults over age 70 and 80 percent of people over age 85 have hearing loss, particularly with respect to high-frequency hearing that helps make consonants distinct and understandable. Unfortunately, Sudore added, speaking more loudly does not help, and often patients misinterpret information as a result (Bainbridge, 2014). Many patients also lose their hearing aids during a hospitalization, making them vulnerable to poor understanding. The use of a small portable amplification device can be a lifesaver, and Sudore recommended that everyone who works in a hospital have one. "We will go into the ICU, and people will say that this person does not understand, and they think the patient is delirious. We put a pocket talker on them and have a completely lucid conversation," she said.

She also noted that patients often lose their glasses while in the hospital, which can create communication difficulties because many patients accommodate their hearing loss by lip reading. In fact, it is important to always face patients when speaking to them, she said—often, health care providers are working on a computer while talking to their patients, making it hard for patients to both hear and see. She also recommended decreasing background noise by putting each patient's back to the wall, sitting as close as possible to the patient, and using all forms of hearing amplification, including hearing aids and portable amplification devices. Sudore recounted the story of a patient in the intensive care unit who had a tracheotomy tube and could not communicate. Having the respiratory therapist insert a Passy-Muir valve enabled the patient to speak and have a meaningful conversation about her care.

In the case of patients with dementia, teach-back may not work, but the possibility exists that it could, because even people with cognitive impairments can make informed medical decisions. When they cannot, caregivers are the alternative for consent, but caregivers do not always have high health literacy. One study found that 36 percent of paid caregivers for the elderly had low health literacy (Lindquist et al., 2011).

In summary, Sudore listed six lessons that she hoped the workshop participants would take from her presentation:

- An interactive teach-to-goal process may be necessary.
- Literacy and language need to be addressed.

- Patients' values need to be elicited first, and then the outcome of the treatment needs to be described in real-life terms.
- Visual images and stories are powerful teaching tools.
- Hearing and all forms of communication should be maximized.
- Health care providers need to be aware of age/dementia bias and caregiver literacy.

ESTABLISHING HARMONY BETWEEN THE RULES AND HEALTH LITERACY[2]

Christopher Trudeau
Thomas M. Cooley Law School

"How can we create a form that complies with the law and promotes a conversation?" asked Christopher Trudeau at the start of his presentation. That is the question he is attempting to answer in his work, specifically with regard to the design of informed consent forms for medical procedures as opposed to those for clinical trials. He noted that the former are easier than the latter because there are fewer rules and regulations at the federal level and because most state-enacted regulations are based on the common law principles that Jeremy Sugarman talked about in the workshop's first presentation.

While every state has slightly different requirements, the informed consent document must always describe the risks and alternatives, contain a description of the procedure, and provide a place for the patient to give consent to treatment; it might also contain a few other legal disclosures that depend on the state and provider's needs, Trudeau said. These are the basic limitations, but they do not mandate the specific language or words that have to be used to fulfill these regulations, though most legal counsel that Trudeau speaks with believe that the regulations do mandate specific language. "That is not true. These topics need to be covered, but the language that we use is usually not covered by law," said Trudeau. What the consent form language does have to satisfy is one of two standards: the professional customs standard, used by 23 states, and the reasonable patient standard, required by 24 states and the District of Columbia. Tennessee uses an international tort standard, and the other two states use a hybrid of the professional and patient standards. The professional customs standard refers to what the prevailing practicing physician knows in a specific locality or community. The reasonable patient standard refers to what a reasonable

[2] This section is based on the presentation by Christopher Trudeau, associate professor at the Thomas M. Cooley Law School, and the statements are not endorsed or verified by the IOM.

patient would understand, which, as Trudeau pointed out, is not the same thing as what is reasonable to a judge or lawyer.

He also noted that when laws and regulations concerning informed consent for treatment were first being promulgated at the turn of the 20th century, there was no knowledge base about health literacy. That type of information about what patients understand is only 15 to 20 years old, he explained. So how, asked Trudeau, does health literacy fit within the legal standards? "It doesn't," he said. In fact, his attempt to find cases where people have argued that a lack of health literacy and understanding should lower the standard has largely failed, being confined to three or four cases that deal with a patient not understanding a piece of information because the individual could not read.

Trudeau argued that, from an advocacy perspective, it may be necessary to threaten or pursue lawsuits to trigger changes in the consent form regulations that reflect the health literacy literature that has developed over the past two decades. If health literacy starts becoming the standard, and groups such as the IOM or the American Medical Association (AMA) start promoting that standard, it will provide lawyers who are suing over a lack of informed consent to better make the argument that standards must change. "Once we get one liable case, everybody starts to change their forms and get on board with us, which is really what we want," said Trudeau.

Acknowledging that inducing change in this manner will take time, Trudeau said that some steps can be taken now to aid patient understanding for the simple fact that the law and health literacy are not mutually exclusive, even though lawyers sometimes think they are. "Frankly, that's because most lawyers do not know what health literacy is," he said, adding that advocacy can change that misperception.

Trudeau's efforts to redesign informed consent forms has focused on colonoscopy, a nonemergency procedure for which there is time in advance to procure informed consent. He showed three forms that he found in a random search and noted that all three were written at about an 11th-grade level. That two of the forms were similar, he suggested, makes it likely that one facility found a standard form and modified it to fit its particular needs as determined by a lawyer, and all three of the forms had many problems with the writing above and beyond the grade level at which they were written. He questioned, for example, whether it was necessary to use medical terms such as "coagulation," "sedation," or "digital optical instrument" or to create ambiguity using constructs such as "and/or," by adding what seemed to be random "(s)" after some nouns but not others, or by being inconsistent in the use of the first-person singular or second person. He pointed out these flaws not just to show how unintelligible these forms could be but also to underscore that lawyers are not good at creating these

documents. "We are good at protecting our clients from liability," said Trudeau. "We are not good at document design. We are not good at thinking about the impact of language on the patients and on others."

One example that he thought was particularly egregious described what would happen during the colonoscopy if some abnormality was spotted. Instead of saying something such as "small growths can frequently be completely removed," this document said, "If an abnormality is seen or suspected, a small portion of tissue may be removed for microscopic study or the lining may be brushed and washed with a solution that can be sent for analysis of abnormal cells, cytology," none of which wording is required by law. His point in describing one flaw after another was to show that lawyers do not think about patient understanding and about drafting a clear form. They just draft a form that is going to comply with what they believe is mandated in a specific state's regulations.

The first step in creating a form that complies with the principles that have been raised at this workshop is to understand where the form fits into the consent process, given that the form is just part of the consent process, Trudeau said. In the case of a colonoscopy, the process starts when a physician recommends to someone 50 years or older that he or she needs to get a colonoscopy. Ideally, Trudeau explained, there should be a conversation at this point with some initial information and some questions from the patient, and the patient should receive some educational materials or complete a tutorial that helps the person understand the procedure, the alternatives, and the risks. The patient then prepares for the exam, goes to the appointment, and then receives the consent form. Even though it is unlikely that the patient would back out at this point, having already prepped for the procedure, there should be time for further discussion and the opportunity for teach-back before the patient signs the consent form. Trudeau noted that, although his emphasis is on redesigning the form, there is also the need to redesign most of the educational materials on colonoscopy that patients receive.

Step two in the process, he said, is to create clear content that incorporates health literacy principles while also containing the necessary language that describes the technique and outlines the risks, alternatives, and other information germane to a particular treatment that federal and state regulations mandate. Step three is to consider a design strategy that limits the document in size—two pages maximum for a colonoscopy, said Trudeau—and that provides space for office administrative needs and signature lines, including lines for witnesses in states with that requirement. Trudeau noted that no regulations specify what a consent document must look like and that the design is subject to the discretion of each organization.

With these ideas in mind, and after reviewing the dozens of consent forms that he could find and the requirements of his state, he created a

couple of versions of a consent form for colonoscopy. The first version (see Figure 4-5) is one piece of paper, front and back, and makes liberal uses of subheads that pose the common questions that patients ask, but Trudeau said that this version appears too dense and has too much information. After thinking about how to create more white space so that the form is more inviting, he created a second version (see Figure 4-6), which uses simplified explanations of the basic concepts of colonoscopy on the assumption that the patient would have already received some information from the physician who recommended that the patient undergo this procedure. This second version, he said, tested at a 7.18 grade level and noted that the words "colonoscopy" and "colonoscope" are enough to increase the grade level. He also conceded that it might be possible to replace "bowels" with "colon" or "insides."

To go along with this form, a physician could start the conversation, before handing out the form, by describing the procedure with language such as this: "This is what is going to happen. We are just going to go in the behind and look at your large bowel and see if there are any problems with your bowel such as cancer." Trudeau pointed out that he did not have to use the word "polyp." He noted, too, that in his state, only a physician, not a nurse practitioner or physician's assistant, can start the consent process. The physician could explain the colonoscope with language such as "I may use this instrument to remove any growths that I find or to remove small pieces of your bowel for testing."

Trudeau questioned whether his use of the word "risks" in a subhead was the best approach and wondered if describing the worst-case, best-case, and most likely scenarios might be more understandable by the average patient. If it was not possible to use that type of presentation on the consent form, he suggested that such information be included in education materials to accompany the consent form. He also wondered if his approach to quantifying risk was the best one—instead of stating the risk of bleeding at 1 in 100 or perforating the bowel at 1 in 1,000, the document explains that 99 people will not bleed and that one will and that 999 people will not have a hole in the bowel and that one will. "This is just a different way of conveying the same information that might have an impact on at least a wider array of people," he explained.

The second side of both forms contains the consent boxes, signature lines, and teach-back area. It will be necessary, said Trudeau, to teach physicians how to conduct a teach-back using this form. He explained that if the provider is properly trained, the form and the discussion that goes with it at this point not only will help with patient understanding but should also make the lawyers happy by providing a record of the patient's understanding in case of later litigation. In the end, said Trudeau, there are many design options that can increase readability and understandability, but they

will not by themselves do much good if the content is neglected and if the physician's intent is to simply hand out the form and get the patient to sign it. "What I want you to understand is that we can cover our legal bases and use plain language and incorporate teach-back and probably produce more legal protection for all of our providers as well," said Trudeau in closing his presentation. "Don't let lawyers tell you it can't be done. We can create this harmony."

DISCUSSION

Cindy Brach opened the discussion by asking Trudeau why lawyers are not leading the charge to simplify forms and explain terms and concepts more clearly. To her, lawyers should be most concerned about liability concerns that would go along with having patients sign forms they do not understand. "How do we get them over that hump to realize, even if their only goal is to protect against lawsuits and malpractice that this is what they should be arguing for?" asked Brach. Trudeau blamed the lack of lawyer leadership on this issue to two factors. First, he said, lawyers need to know about and understand health literacy and the impact of poorly designed and complicated forms, and, second, they need the skills to draft these forms. Lawyers, he said, have little training in literacy principles, let alone those of health literacy—if they had, he stated, the Affordable Care Act would not be 2,200 pages long, and credit card agreements would not be written at a 12th-grade level.

Law schools share at least part of the responsibility for this lack of knowledge, he added, and noted that there is a significant body of research on what judges want to see in a legal brief, and in general they want documents that are clear and understandable. Nonetheless, he said, law schools spend little time instructing students in how to draft documents that are clear and understandable despite the efforts of what he called the plain language movement. He noted that he is part of several organizations that are working to inform lawyers about literacy factors, yet despite their efforts change is occurring slowly. What could move the field along more quickly is to use the stick of litigation over forms that are not understandable, given that lawyers are trained to be more concerned with what the courts say than with what the average person says.

Andrew Pleasant first commented that moving the informed consent moment to a time prior to the colonoscopy appointment would potentially save time and money if someone says no to consent, and it would reduce the pressure of deciding on consent when the procedure is about to take place. He also supported the idea of framing the consent document and discussion around outcomes, but he wondered if physicians are resistant to discussing outcomes because they tend to be hesitant about predicting

Consent Form: Colonoscopy

(Version #1: described alternatives)

[Insert company name]
[Insert company address]
[insert phone number & website]

Patient's Name: _____

Date of Birth: _____

What is a colonoscopy?

Your medical provider will use an instrument called a colonoscope to look at the inside lining of your bowel.

Your provider will start from your rectum and look at your large bowel. This is done to see if there are any problems with your bowel, such as cancers, growths that could turn into cancer, or other medical problems.

During this process, your provider may use the instrument to remove any growths found or to remove small pieces of your bowel for testing.

Will I need drugs during the colonoscopy?

Yes. These drugs are usually very safe, but there are risks and side effects with any drugs. Your risks will depend on a number of factors, such as your weight, whether you smoke, and your past or current medical conditions.

Usually, you will receive drugs that make you feel very relaxed during the procedure. You may remember some (or very little) about what happened during the procedure.

Your medical provider will discuss these risks with you before these drugs are given.

What if I do not have the colonoscopy?

A colonoscopy helps to catch problems earlier, so they are more treatable. If you do not have one, it will be harder to diagnose your illness or screen for cancer.

Do I have other options?

Rectal exam: Your provider will examine you by hand. This is not painful, but it does not examine your colon.

Barium enema: In this test, a fluid is put in your rectum that makes your colon show up on X-ray. But if something shows up on X-ray, then your provider will suggest a follow-up colonoscopy.

Fecal blood test: This test checks your stool for blood that you can't see. Your doctor gives you a test kit and instructions to use it at home. But this test can result in false positives.

Flexible sigmoidoscopy: In this test, your provider puts a thin, flexible, hollow tube with a light on the end into your anus. This does not go up very far, so your provider cannot see problems in your upper colon.

What are the risks of having a colonoscopy?

There are risks and complications with this procedure. They include, but are not limited to, the following:

Common risks and complications:

- Mild pain or discomfort in your mid-section that can last up to 5 days.
- A weak or numb feeling in your arm due to your body positioning during the procedure.
- Nausea and vomiting.
- Dizziness or feeling faint, typically when you start to move.
- Headaches and muscle aches.

Uncommon risks and complications:

- ***1 in 100 people*** will significantly bleed from their bowel after a growth is removed. If this happens, further scoping, an operation, or a blood transfusion may be needed.

99 people will not bleed	1 person will bleed

- ***1 in 1000 people*** will get a hole (perforation) in their bowel causing the bowel's contents to leak into the abdomen. If this happens, you may need surgery to repair the hole.

999 people will not get a hole	1 person will get a hole

Rare risks and complications:

- Blood infection (called Bacteraemia), which will require antibiotics.
- Stroke.
- Severe allergic reaction (anaphylaxis) to the drugs given at the time of the colonoscopy.

What can I expect after the colonoscopy?

- You will be in recovery until the effects of the drugs wear off.
- You may not drive after the colonoscopy. You must have someone take you home.
- You might have some bloating or cramping caused by air entering the bowel during the colonoscopy. Moving around will help get rid of this.
- Your provider will tell you when you can eat or drink. Typically, you can do this right away.
- Your provider will tell you the results of the colonoscopy. You may need to come back to discuss the results.

Continues⇒

FIGURE 4-5 A colonoscopy consent form incorporating teach-back.
SOURCE: Trudeau, 2014.

Patient's Consent to Treatment *(Patients: please read and initial each statement)*	Medical Provider's Acknowledgment of Consent *(Providers: record answers in patient's own words)*
Initial	
☐ I understand what a colonscopy is, and I know it involves risks, including risks specific to me.	**What is a colonoscopy?**
☐ I have been educated about these risks, and my provider has answered my questions about these risks.	**Why are we doing this colonoscopy?**
☐ I understand that drugs will be used to help relax me and relieve pain. My provider has discussed this with me, and I understand the risks of using these drugs.	**What are some of the risks we discussed?**
☐ I understand the other treatment options available, but I have decided against those options.	**Do you have any questions about these risks?**
☐ I allow my provider (or anyone directed by my provider) to treat me. I understand that this means I may be treated by providers still in training.	**What are your other options besides a colonoscopy?**
☐ I allow my provider to remove tissue for testing and to treat any growths or cancers that can be treated with the instrument.	**What can you expect after the colonoscopy?**
☐ I allow my provider to record video or take images of my bowel if it will help determine the proper treatment.	**What other questions do you have?**
☐ I understand that there are no guarantees about the results of the colonscopy, and I realize that the procedure will not cure medical conditions.	
☐ If anything immediate and life-threatening occurs during the colonoscopy, I allow my medical provider to treat me.	

I was able to ask my provider questions about this procedure, my risks, and my other options. My questions have been answered, and I agree to receive a colonoscopy:

Sign your name here

Print your name here

Today's date

The patient and I have discussed this procedure, its risks, and its alternatives. I have answered the patient's questions, and I believe that the patient is informed and consents to the colonoscopy:

Medical provider's signature

Printed name of medical provider

Today's date

Disclaimer: This document was created for educational purposes by Chris Trudeau, a Michigan lawyer. It may not be used for medical purposes without his prior approval.

FIGURE 4-5 Continued

Consent Form: Colonoscopy

(Version #2: more white space)

[Insert company name]
[Insert company address]
[insert phone number & website]

Patient's Name: _____

Date of Birth: _____

What is a colonoscopy?

Your medical provider will use an instrument called a colonoscope to look at the inside lining of your bowel.

Your provider will start from your rectum and look at your large bowel. This is done to see if there are any problems with your bowel, such as cancers, growths that could turn into cancer, or other medical problems.

During this process, your provider may use the instrument to remove any growths found or to remove small pieces of your bowel for testing.

Will I need drugs during the procedure?

Usually, you will receive drugs that make you feel very relaxed during the procedure. You may remember some (or very little) about what happened during the procedure.

These drugs are usually very safe, but there are risks and side effects with any drugs. Your risks will depend on a number of factors, such as your weight, whether you smoke, or your past or current medical conditions.

Your medical provider will discuss these risks with you before the drugs are given.

What if I do not have the colonoscopy?

If you do not have a colonoscopy, it will be harder to diagnose your illness or screen for cancer. Colonoscopies help to catch problems early, so they are more treatable.

What are the risks of having a colonoscopy?

There are risks and complications with this procedure. They include, but are not limited to, the following:

Common risks and complications:

- Mild pain or discomfort in your mid-section that can last for 1 to 5 days.
- Weak or numb feelings in your arm due to your body positioning during the procedure.
- Nausea and vomiting.
- Dizziness or feeling faint, typically when you start to move around.
- Headaches and muscle aches.

Uncommon risks and complications:

- ***1 in 100 people*** will significantly bleed from their bowel after a growth is removed. If this happens, further scoping, an operation, or a blood transfusion may be needed.

99 people will not bleed	1 person will bleed

- ***1 in 1000 people*** will get a hole (perforation) in their bowel causing the bowel's contents to leak into the abdomen. If this happens, you may need surgery to repair the hole.

999 people will not get a hole	1 person will get a hole

Rare risks and complications:

- Blood infection (called Bacteraemia), which will require antibiotics.
- Stroke.
- Severe allergic reaction (anaphylaxis) to the drugs given at the time of the colonoscopy.

Are there other options to a colonoscopy?

Yes, there are other options to a colonoscopy. These may include fecal blood tests or radiologic-imaging tests. These tests have their own problems, risks, and benefits.

Your provider will discuss these options with you.

What can I expect after the colonoscopy?

- You will be in recovery until the effects of the drugs wear off.
- You may not drive any type of vehicle after the colonoscopy. You must have someone take you home.
- You might have some bloating or cramping pain caused by air entering the bowel during the colonoscopy. Moving around will help get rid of this.
- Your provider will tell you when you can eat or drink. Typically, you can do this right away.
- Your provider will tell you the results of the colonoscopy. You may need to come back to discuss the results.

continues⇒

FIGURE 4-6 A colonoscopy consent form incorporating teach-back and a more open design with alternatives minimized.
SOURCE: Trudeau, 2014.

Patient's Consent to Treatment

(Patients: please read and initial each statement)

Initial

- ☐ I understand what a colonscopy is, and I know it involves risks, including risks specific to me.
- ☐ I have been educated about these risks, and my provider has answered any questions I have about these risks.
- ☐ I understand that drugs will be used to help sedate me and relieve pain. My provider has discussed this with me, and I understand the risks of using these drugs.
- ☐ I understand that there are other treatment options available, but I have decided against those options.
- ☐ I allow my medical provider (or anyone directed by my provider) to treat me. I understand that this means I may be treated by providers still in training.
- ☐ I allow my medical provider to remove tissue for testing and to treat any growths or cancers that can be treated with the instrument.
- ☐ I allow my provider to record video or take images if it will assist in determining the proper treatment.
- ☐ I understand that there are no guarantees about the results of the colonscopy, and I realize that the procedure will not cure medical conditions.
- ☐ If anything immediate and life-threatening occurs during the colonoscopy, I allow my medical provider to treat me.

I was able to ask my provider questions about this procedure, my risks, and my other options. My questions have been answered, and I agree to receive a colonoscopy:

_____
Sign your name here

_____
Print your name here

_____
Today's date

Medical Provider's Acknowledgment of Consent

(Providers: record answers in patient's own words)

What is a colonoscopy?

Why are we doing this colonoscopy?

What are some of the risks we discussed?

Do you have any questions about these risks?

What are your other options besides a colonoscopy?

What can you expect after the colonoscopy?

What other questions do you have?

The patient and I have discussed this procedure, its risks, and its alternatives. I have answered the patient's questions, and I believe that the patient is informed and consents to the colonoscopy:

_____
Medical provider's signature

_____
Printed name of medical provider

_____
Today's date

FIGURE 4-6 Continued

outcomes and, in fact, are not trained to do so, given the potential liability problems that could come with predicting outcomes as opposed to merely describing procedures. Trudeau agreed with Pleasant about giving patients the consent form earlier in the process, perhaps with the education forms, but he wondered about the practicality of reforming the process in that way. Regarding Pleasant's comment about outcomes, Sudore responded that the potential for liability when discussing outcomes is higher when the physician does not know the patient who is being asked for consent and does not know what that person's desires and goal are relative to the treatment procedure in question.

Michael Villaire noted that his organization and others teach the principles of health literacy to people who create forms and who write patient education materials. "We give them all of the basics on how to use white space and plain language and graphics and limit messages and all of those principles that at least remove barriers to comprehension," he explained. "Nothing will ever guarantee comprehension, but we can at least take out as many barriers as we can see." Where the process of creating health-literate consent forms and education materials fails is often when they reach a company's attorneys, he said. "There is often a power imbalance in many organizations where the patient educator, the person writing these forms, does a great job in creating these documents. Then it goes to legal, and that's the end of it," said Villaire. He asked Trudeau if he had any ideas on how to approach the legal department and start a conversation over the balance between understandability and legal obligation.

Trudeau noted that he was preparing a 3-hour answer to that very question that he would be presenting to the FDA the day after the workshop and that he could not do justice to this question. He did reiterate his earlier statement that the problem lies in the balance of power, with the lawyers in the power position. "In reality they [lawyers] don't know what they are talking about when it comes to creating an understanding. They know what they are talking about when it comes to protecting the client," said Trudeau. Correcting that imbalance is what drove him to create simplified forms that he can use to show lawyers that their client protection goals are not incompatible with health literacy goals. It also drives him to try to recruit others in his profession to become what he calls "health literacy lawyers." "We have a lot of health lawyers in the country," said Trudeau, "people that know everything about HIPAA [Health Insurance Portability and Accountability Act] and the Affordable Care Act, but they are not necessarily the best health literacy lawyers. We need to teach those folks and that, I think, is going to pay dividends in the long run because you will get some of those folks that could be champions for you."

Villaire asked how to start the process of creating a cadre of health literacy lawyers, and Trudeau said the first step should be to provide plain

language training to lawyers in the health care field and to convey the fact that plain language can provide greater protection to their clients. At the same time, it is important to recognize that lawyers will always put client protection first because that is how they were trained, and it is why they were hired in the first place.

Referring to Sudore's anecdote about the woman whose directives were not in sync with her wishes, roundtable member Winston Wong asked if there was a way to systematically document the health literacy capacity of both the patient and family members. Is there a way, he wondered, to document that patients have spoken to their family members about their wishes and that the family members understand the implications of the patients' decisions. "Is there a role for family health literacy to be part of this solution?" he asked. Sudore replied that this issue arises all the time, such as when dealing with patients with severe dementia or when addressing advance care planning. What she does is to make sure that family members are part of the discussion and then to use teach-back with both the patient and the family. "For instance," said Sudore, "somebody will say to me, 'This is what I want, and here are the reasons.' We will talk about that, and then I will turn to a family member and say, 'Did you just hear what [somebody] said, and can you say in your own words what that means to you?'" She then documents that this conversation took place. Trudeau added that he has added places where caregivers also need to demonstrate understanding for procedures, such as signing on for insulin infusion pump therapy, and he reiterated the idea that the discussion that proceeds signing the form is just as important as getting that signature on the form. He added that educating caregivers would probably be beneficial from a legal standpoint, too.

Benard Dreyer commented that his institution forbids the use of preprinted consent forms. He asked Trudeau if there were any question-based template guides that would allow people to create a form similar to his colonoscopy form and if he had given any thought regarding how to institute those templates in medical care. Dreyer thought such templates would be useful for procedures that are not as common as colonoscopy and for which preprinted forms do not exist regardless of the institution. Trudeau said that he needed more time to think about this problem, but he did note that the question-and-answer format itself can serve as a template from which a well-trained physician could create a form. He suggested that the IOM or AMA could create templates for most procedures, and then the templates could be used to individualize forms for even rarer procedures. He added that it might not be a bad thing to force lawyers and doctors to work together to create forms for use with some rare procedures that entail a major risk.

Lindsey Robinson, president of the California Dental Association, commented on how much she values the work that Trudeau is doing and the

empirical research he provided to the roundtable. She then asked Sudore if she could expand on how the advance directive can reflect health literacy principles, given that directives are often drafted in a lawyer's office. Sudore said that advance directives can come from many places, including from nurses and doctors. She then recounted a story from her own family involving her grandmother's advance directive. Her grandmother had to be hospitalized, and when Sudore asked her father where her grandmother's advance directives were, he told her everything was okay because they were with the family lawyer. Sudore then asked her father if the doctor had a copy because the lawyer was not the one treating grandma in the hospital.

"I think a lot of times the lawyers do a good job, but not always," said Sudore. "I have met many dedicated lawyers who want peoples' voices to be heard and actually sit down and have conversations and document them, but then they [the documents] stay at the lawyer's office, or they stay in somebody's file cabinet rather than make it to the doctor's office. I would say that even with the advent of electronic medical records, if somebody could figure this one piece out—I know there are a lot of companies looking at cloud-based options and things like that—that could really help." She did mention that the American Bar Association has an app that allows individuals to upload to their phone the documents created by their lawyers.

Robinson asked Sudore to comment on a personal story involving her own mother, who was diagnosed with a terminal pulmonary disease. Robinson's mother's primary care physician would not refer her mother to hospice, even though that was her mother's and the family's desire, because this physician once had a patient who had outlived the permitted stay at hospice. Sudore said that she discharges patients from hospice care frequently and that there are studies showing that people who get palliative care live longer. "If someone graduates from hospice, it is usually not a problem," said Sudore.

George Isham also provided an anecdote about advance directives and estate planning, an exercise he recently completed. At one point, the lawyer suggested including an option that would allow two doctors to determine whether Isham would want treatment if he were otherwise incapacitated, an idea that Isham thought was the worst possible recommendation that he could imagine. "It seems that we are approaching this document with very different assumptions depending upon whether you are a lawyer or whether you are using it," said Isham, and he wondered if there might be some upstream remedies to that fundamental issue in terms of viewing the document as more than just a legal document, but rather being explicit about that in terms of training lawyers as well as doctors and other health professionals.

He also wondered if the experts in this field ought to be challenged to think more about the time dimension regarding when to start the consent

process and the information requirements associated with the progression from being well and doing advance planning to then developing a disease and having to make some of these decisions in a more immediate time frame. "It seems like there is a model or framework that needs some good intellectual work to suggest when it is appropriate to have which conversations and what kinds of issues and domains to discuss and then make some proposals about a systems approach to handling these issues," said Isham.

Sudore responded to Isham's comment by noting that too much of advance planning is focused on the end of life and that much of her work aims to bring that process upstream, to redefine the planning in advance planning. She added that advance planning should not be just about CPR and mechanical ventilation; it should also be about helping people even when they are healthy learn how to talk to their doctors, how to identify what is important to them, and how to translate those desires into the right medical care, whether that be starting a blood pressure medication or having elective knee surgery. Trudeau voiced his approval for starting the process earlier in life and said that although there could be a synergy between what Sudore does and what he does, it is probably not feasible yet to merge the two efforts. Sudore replied that she is in fact working with faculty from the University of California Hastings School of Law and that there are medical and legal partnerships forming.

Lori Hall, consultant on health education at the Lilly Corporate Center and a roundtable member, asked Trudeau if he could see informed consents coming into the realm where quality would be judged according to some metrics on plain language. Trudeau responded that judges are the ones who now do the measuring and that is why he believes that convincing one judge of the merits of a lawsuit based on low-health-literacy consent documents would have a major impact. He acknowledged that metrics might be useful but that he had not given it much thought yet.

Wilma Alvarado-Little commented on the fact that some of the forms she sees have signature lines for witness, patient, responsible party, and physician. Others have signature lines for patient legal representative and witness or for patient, witness, and physician, and she wondered if there was any significance to these different formats. She also asked if there should be a place for her to sign as an interpreter—not as a witness, which would be inappropriate—to represent that the patient was given information in a language-appropriate manner. Trudeau replied that whether these differences are significant has to do with state regulations. Some regulations require a witness signature, others require it only for certain types of treatments, but having a witness signature even when it is not required will not cause any problems. He also remarked that some countries do make provisions to have the interpreter's signature on the consent form, and he

thought that adding such a provision to consent forms would be easy to accomplish and a good idea.

Bernard Rosof told the workshop that during the discussion he looked at the website of the American College of Gastroenterology to see what it had to say on the matter of informed consent and found an entire PowerPoint presentation using many of the discussion points that had been raised at this workshop. In particular, three bullet points seemed important to him. The first was that shared decision making among patient, family, and physician is the key to obtaining legally effective informed consent regardless of what consent form is used. The second point was that, in Louisiana, an expert advisory group develops a list of material risks that is updated on a regular basis for physicians to use. The third point was that current lists and shared decision making are the primary keys to maintaining a constitutionally valid informed consent statute. Trudeau commented that Louisiana is unusual because its legal system is derived from the French system and therefore is based more on civil law rather than common law. Although the principles are similar, the list of requirements will be longer under civil law. He noted that any consent form that he would draft would include all of the risks as listed by the expert advisory group because the form has to comply with state regulations.

The final question for this panel came from Brach, who asked Sudore to clarify how she presents the best-case and worst-case scenarios to patients and to comment on whether she elicits not only a patient's preference but also their understanding of how likely the different outcomes are for their choices. Sudore replied that she and her colleagues do present patients with that information and that they do communicate to patients how likely each outcome is relative to the other. She noted that the most likely and least likely scenarios are going to differ according to each patient's health status.

5

The Future of Informed Consent

The workshop's final panel featured two presentations on how informed consent may evolve over the coming years. Kenneth Saag, the Jane Knight Lowe Professor of Medicine at the University of Alabama at Birmingham, discussed ways in which information technology could improve the informed consent process. Michael Paasche-Orlow, associate professor of medicine at Boston University School of Medicine, spoke about the need to create a culture of change that can drive improvements in the informed consent process. An open discussion followed the two presentations.

INFORMED CONSENT, CLINICAL TRIALS, AND INFORMATION TECHNOLOGY[1]

Kenneth Saag
University of Alabama at Birmingham

As an example of how information technology can improve the informed consent process, Kenneth Saag discussed how he and his colleagues are using an electronic consent platform to address the challenge of obtaining informed consent in the context of pragmatic clinical trials. Pragmatic clinical trials, he explained, measure "real-world" effectiveness

[1] This section is based on the presentation by Kenneth Saag, the Jane Knight Lowe Professor of Medicine at the University of Alabama at Birmingham, and the statements are not endorsed or verified by the IOM.

and not efficacy, using large sample sizes to produce results that are generalizable. He noted that the Patient-Centered Outcomes Research Institute (PCORI) and the NIH Research Collaboratory, among others, are investing substantial resources in developing the infrastructure to conduct pragmatic clinical trials.

Pragmatic clinical trials use less-restrictive patient eligibility criteria, broader patient populations, and simpler treatment arms than the traditional randomized controlled trials used for drug approvals, Saag explained. The goals of well-designed and executed pragmatic clinical trials are to involve community physicians and study sites that are not typically included in traditional phase III clinical trials, to create a learning health care environment, and to turn routine clinical care into a potential research encounter (Chalkidou et al., 2012). Saag said that there are many challenges to achieving those goals, however, with cost being the biggest one. As an example, Saag cited the $125 million Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT) study that showed that low-cost thiazide diuretics were as effective as more expensive antihypertensives at reducing mortality in patients with clinically advanced peripheral artery disease. Although this study was undoubtedly valuable, the nation does not have the resources to conduct many pragmatic clinical trials at this price, he said.

Improving the efficiency and effectiveness of conducting pragmatic clinical trials will require addressing several other challenges, Saag said, such as the need to efficiently collect data and conduct study procedures that include recruiting patients, measuring outcomes, and obtaining informed consent (Eapen et al., 2014; Warner et al., 2013). Meeting the complex regulatory requirements of multiple IRBs, institutions, and partners involved in large multisite studies is another real challenge, as is engaging busy practicing clinicians and clinical staff who are not charged with conducting research as part of their daily responsibilities.

Saag explained that there are also a number of challenges for using informed consent in pragmatic clinical trials. For example, there are few validated methods for soliciting effective, efficient, and ethical informed consent in the community setting at sites with limited research expertise. Few community practices, he added, have dedicated research staffs or on-site coordinators, let alone IRBs, with the know-how or certification to oversee research. In addition, optimizing study participant comprehension and satisfaction while minimizing the burden on the staff is a significant challenge to overcome, he said.

Electronic informed consent may offer one approach to addressing these challenges. Saag noted that, for researchers, electronic consent offers several potential benefits. It is a paperless process, one that reduces administrative burden yet still allows a copy to be printed for study participants

or an IRB. Electronic consent can provide the opportunity to follow study progress at multiple sites, yet allow the flexibility to alter the consent form to meet the requirements of local IRBs or translate it into other languages, and it can provide real-time monitoring of recruitment and the informed consent process. Interactions are recorded immediately into a tracking system, creating an audit trail of timed and dated information on the consent process. Saag pointed out that electronic consent can improve security and privacy protections via the ability to upload data to a remote, central site and remove it from the specific device used to collect patient information and consent.

There are potential benefits for the study participant as well, he said. Electronic consent, explained Saag, is patient centered because it allows participants to review the consent with the family, particularly if the study allows for online or at-home enrollment. Electronic consent can also include audiovisual aids, other educational information, dictionaries, and translational capabilities aimed at increasing comprehension, and it can include real-time knowledge assessment to determine whether a participant truly understands the consent materials.

There are challenges to using electronic consent, however, said Saag. Start-up expenses are high, given the cost of building the initial infrastructure needed to manage online documents, validate electronic consent, and even verify the identity of the participants in direct-to-patient studies. There are also compliance challenges regarding electronic data and data security as required by Title 21, Part 11 of the *Code of Federal Regulations*, which imposes certain requirements on an entity when it chooses to maintain FDA-required records and signatures in electronic form. Electronic consent can also present challenges for participants, given that not everyone is familiar or comfortable with new electronic technologies and that electronic consent can make it more difficult to have consent discussions with investigators. Participants might also have confidentiality concerns in terms of who will have access to the consent documentation and the answers given to screening questions. Saag said that he and his colleagues have tried to make their electronic consent application as simple as using an ATM machine.

Citing a study that Sara Goldkind mentioned during the workshop's second session (Flory and Emanuel, 2004), Saag said that a systematic review of 12 trials using multimedia as a means of improving comprehension in the consent process found that only 3 of the studies showed significant improvement in participant understanding. The authors of that study concluded that having a study team member or a neutral educator spend more time with the patient was the best way of improving research participants' understanding. However, noted Saag, having a study team member or a neutral educator spend more time with the patient is not going to be practical for studies involving thousands of patients at hundreds of sites.

"We can't add more personnel to the equation," said Saag. "We need to figure out how to do it cheaper and more efficiently in addition to maintaining adequate understanding and comprehension."

To illustrate how he and his colleagues are addressing these challenges, Saag discussed the Effectiveness of Discontinuing Bisphosphonates (EDGE) trial, a pragmatic study of 9,500 subjects at about 300 study sites to look at the effect of either continuing or discontinuing alendronate therapy for osteoporosis. The study was designed to answer the question of how long patients should stay on this drug, given reports of rare but severe adverse side effects. Participants are screened, asked for consent, and randomized using a tablet application. The study design adheres to the principles of pragmatic clinical trials: minimal inclusion and exclusion criteria; limited patient responsibilities and minimal commitment of time for providers; same-day single-visit enrollment; and dynamic randomization performed centrally on the day of that visit. Saag noted that the EDGE team is networking with primary care physicians to create a practice-based research network. Another innovation in this study, he said, is that it links to data that are collected more passively, such as Medicare and insurance data and electronic health records, as a means of trying to lower the cost of conducting such a study.

Saag talked about the results of a pilot study designed to test the feasibility of using tablets for enrollment and consent and to develop some of the tools needed for the EDGE study. The pilot found that 80 percent of the 160 women 65 years or older who were asked to participate in the study agreed to complete the osteoporosis screening questions in 10 different family physician offices (Mudano et al., 2013). In general, the women who completed the screening questions preferred the tablet over an interactive voice response system (see Table 5-1), and they were able to use the tablet without too much difficulty and without significantly burdening the staff or interrupting workflow. Saag inferred that, compared to the voice interactive response system, the tablet was judged easier to use and understand and was less time-consuming. Users of the tablet were more likely to express an interest in participating in future trials, and they reported that they would not mind spending extra time in their physician's office to enroll in a study, Saag said.

A second pilot study, using the Mytrus electronic consent platform, compared pen-and-paper consent with electronic consent and was conducted as a mock trial in order to more closely model how potential participants would behave in a real trial. Saag noted that the reason for not conducting this pilot study as part of a bigger study was that investigators did not want to use an unproven technology in their trials. He also explained that the hypothesis for this pilot, which was conducted at nine primary care sites, was that clinics and patients would prefer the tablet

TABLE 5-1 Patient Satisfaction and Feasibility Survey Comparing a Tablet with an Interactive Voice Response System

	iPAD (n = 93 pts.)			IVRS (n = 67 pts.)		
	Strongly agree or disagree	Neither agree nor disagree	Strongly disagree or disagree	Strongly agree or disagree	Neither agree nor disagree	Strongly disagree or disagree
The iPAD/phone was easy to use	78 (85.7%)	4 (4.4%)	13 (9.9%)	58 (86.6%)	2 (3.0%)	7 (10.4%)
The questions were easy to see/hear	88 (96.7%)	1 (1.1%)	2 (2.2%)	61 (91.0%)	3 (4.5%)	3 (4.5%)
The questions were easy to answer	90 (97.8%)	1 (1.1%)	1 (1.1%)	64 (95.5%)	0 (0%)	3 (4.5%)
The process did not take too long	84 (91.3%)	1 (1.1%)	7 (7.6%)	61 (91.0%)	3 (4.5%)	3 (4.5%)
If eligible, I would be interested in participating in osteoporosis drug trial	32 (35.2%)	22 (24.2%)	37 (40.7%)	13 (20.3%)	18 (28.1%)	33 (51.6%)
I would not mind spending extra time at my doctor visit to enroll in the study	37 (41.1%)	17 (18.9%)	17 (18.9%)	17 (26.6%)	20 (31.3%)	27 (42.2%)

NOTE: IVRS = interactive voice response system.
SOURCE: Mudano et al., 2013.

over pen-and-paper consent, leading to improved efficiencies and a more effective consent process. All told, 41 participants were screened, and 31 were enrolled in the pilot.

As Linda Aldoory explained in her earlier presentation at the workshop, the Mytrus system has been vetted by more than 30 IRBs in the United States and abroad, and the FDA has encouraged its use in clinical trials. Saag noted that the consent form is embedded in the tablet application. Participants can scroll back and forth through the consent form to see different parts of it as they complete the consent process. The platform also allows participants to click on terms they do not understand and get additional illustrated explanations, and it includes quiz questions to ensure that the participants understand key concepts of the study and the consent process.

The Mytrus application also collects some preliminary demographic data and links individuals to their Medicare data. After the participant has signed the consent document electronically, the tablet application also verifies inclusion criteria and randomizes participants dynamically via links to the Web. Saag acknowledged that although this system has been approved by many IRBs, there is still some controversy associated with it, the reasons for which he did not discuss in his presentation.

Although the pilot involved a small number of participants, Saag said that the data suggest that participants trended toward being more interested in using the tablet than in using pen and paper and that their comprehension was better using the tablet. The study design also allowed Saag and his team to compare what providers thought about the tablet compared to pen and paper, and there was some indication that the tablet was better received among providers.

Saag also reviewed a prospective randomized study that Mytrus conducted comparing both participant and researcher satisfaction using its interactive tablet application or an IRB-approved pen-and-paper consent form (Rowbotham et al., 2013). The results of this study showed that overall satisfaction and overall enjoyment slightly favored the tablet presentation among both participants and researchers and that combining an introductory video, standard consent language, and an interactive quiz on a tablet-based system improves comprehension of research study procedures and risks. Saag noted that the tablet consent process took longer than pen and paper.

Summarizing what he thinks about the use of electronic consent based on the results of these pilot studies and his reading of the literature, Saag said that informed consent barriers are a particular concern when considering the growing national interest in pragmatic clinical trials. Platforms do exist that use multimedia information technology to facilitate the informed consent process. Preliminary data suggest similar to better effectiveness

and satisfaction, with adequate efficiency, compared to traditional pen-and-paper consent. He cautioned, though, that regulatory and economic barriers may delay the widespread implementation of electronic consent technology. Regarding the policy implications of electronic consent, Saag said that there are a number of questions that need answering. What, for example, are the best study types for electronic consent? Would it be simpler studies, pragmatic trials, direct-to-patient trials, or more complicated studies? What are the best patient populations for using electronic consent? Is it those that have lower literacy or who are not native English speakers and who might find illustrations helpful? Would children, who tend to like playing games, benefit from electronic consent forms? Saag noted that there has been some research to suggest that mentally ill patients may do better with multimedia consents.

When it comes to researchers, his focus has been on community-based physicians who may lack sufficient staff and expertise or the infrastructure to support the consent process associated with clinical trials. "If we can link this to the electronic health record and make this part of the learning health care environment, I think we will have gone a long way," said Saag.

INITIATING A CULTURE CHANGE AROUND INFORMED CONSENT[2]

Michael Paasche-Orlow
Boston University School of Medicine

Michael Paasche-Orlow began the workshop's final presentation by stating that he believes people should be angrier about the current state of informed consent. Paasche-Orlow used terms such as "travesty," "sham," and "a shame" to characterize the current state of informed consent. In his mind, risk managers do not care enough about informed consent, appear to be stymied by their own aversion to change, and fear using new models for informed consent that are available. He said that providers and researchers do not care enough because informed consent is not their priority, and patients do not care enough because they have become acculturated to checking off consent concepts everywhere they go. It is hard to change these attitudes in the health context. "It's actually much more work to learn all the things we want them to learn," said Paasche-Orlow.

He then addressed what he sees as the goals of the consent process. Liability protection seems to be the number one goal these days, he said, but

[2] This section is based on the presentation by Michael Paasche-Orlow, associate professor of medicine at Boston University School of Medicine, and the statements are not endorsed or verified by the IOM.

informed consent should have the goals of serving an ethical duty, empowering patients, and strengthening trust between patient and physician or study participant and researcher. A health-literacy analysis can further all of these goals, he said, but it will take a major cultural change to bring health-literacy concerns front and center, and the field should not wait for regulatory change or the evolution of jurisprudential norms to make that happen. He also noted that these concerns are tied heavily into social justice, given how low the rate of health literacy is in the U.S. population (see Figure 5-1), particularly among those individuals with less than a high school education (see Figure 5-2) and among members of ethnic and racial minorities (see Figure 5-3).

Paasche-Orlow then described research that he conducted 11 years ago that looked at the readability of informed consent forms compared to the standards set by the organizations that created them (Paasche-Orlow et al., 2003). He and his colleagues extracted relevant data from 114 of 123 medical school websites. Of these, 61 (54 percent) had a grade level standard in the 5th- to 10th-grade levels, and 47 (41 percent) had descriptive guidelines such as "in simple lay language." The mean Flesch-Kincade grade level across all of the templates was 10.6, but in schools with a specified grade-level standard, only 5 of 61 (8 percent) met their own specific standards

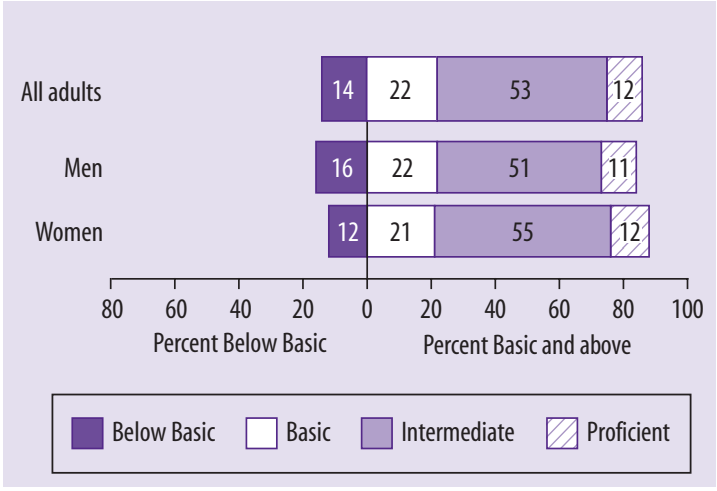


FIGURE 5-1 Percentage of U.S. adults in each health-literacy level.
SOURCE: National Center for Education Statistics, 2003.

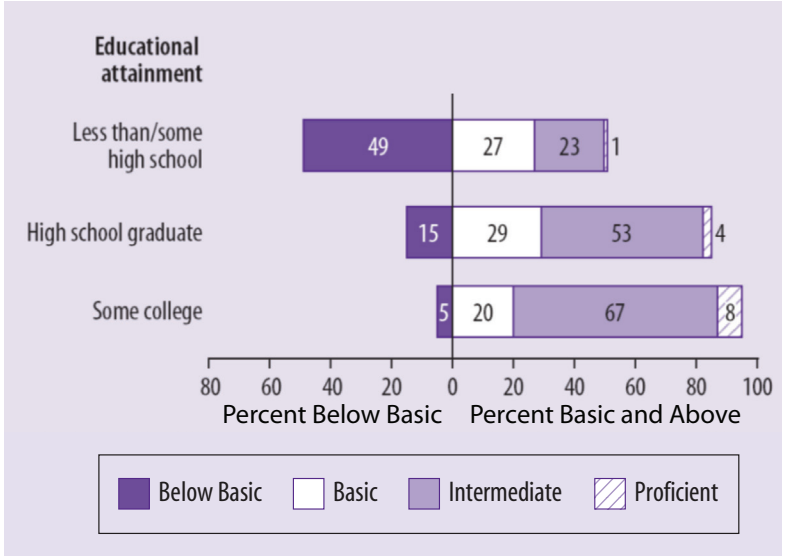


FIGURE 5-2 Percentage of U.S. adults in each health-literacy level by highest educational attainment.
SOURCE: National Center for Education Statistics, 2003.

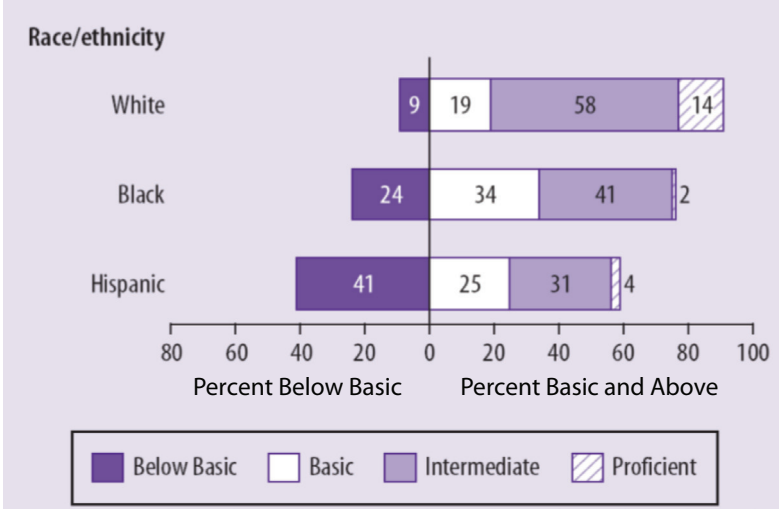


FIGURE 5-3 Percentage of U.S. adults in each health-literacy level by race/ethnicity.
SOURCE: National Center for Education Statistics, 2003.

(see Figure 5-4). On average, the consent forms from those institutions tested at nearly three grade levels higher than the stated standard. Paasche-Orlow called this difference the "hypocrisy index." When he repeated this exercise a decade later, he found that the hypocrisy index improved slightly, but that it was still unacceptable (Paasche-Orlow et al., 2013). Ten years after his initial study, the mean Flesch-Kincade grade level across all of the templates had dropped to 9.8, and 12 percent now met their own standard, with the average template scoring a little over two grade levels higher than the standard (see Figure 5-5). However, this improvement is only evident because he had examined HIPAA language separately, as this language had not been in place at the time of the initial study.

In fact, inclusion of the HIPAA-mandated text only made matters worse. Including HIPAA-mandated language increased the mean Flesch-Kincaid grade level to 11.6, and only 8 percent of institutions were able to meet their own standards, with the average template scoring over four grade levels above the standard. "This sends a very, very bad message to all

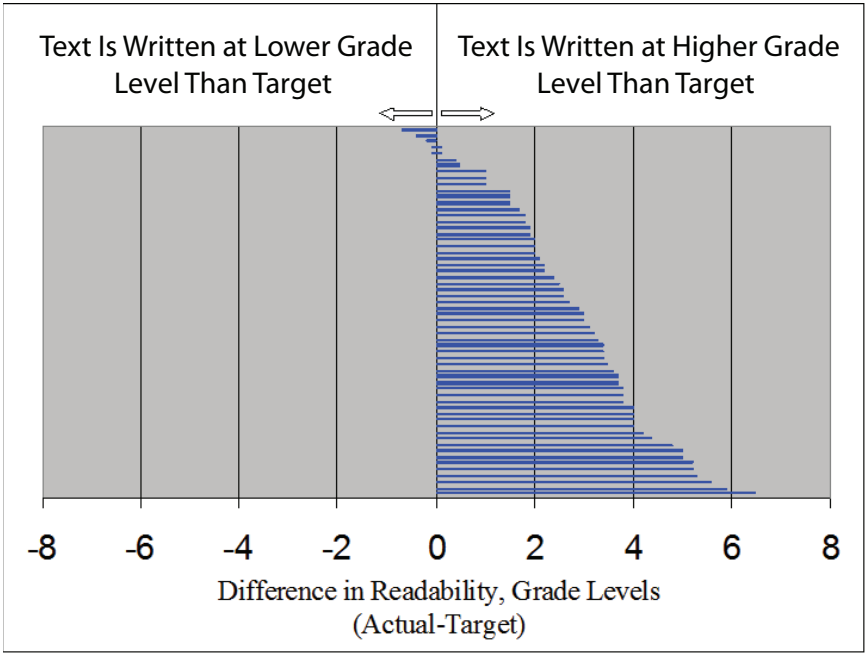


FIGURE 5-4 Actual versus target readability scores for the 61 institutions with stated standards in 2003.
SOURCE: Paasche-Orlow et al., 2003.

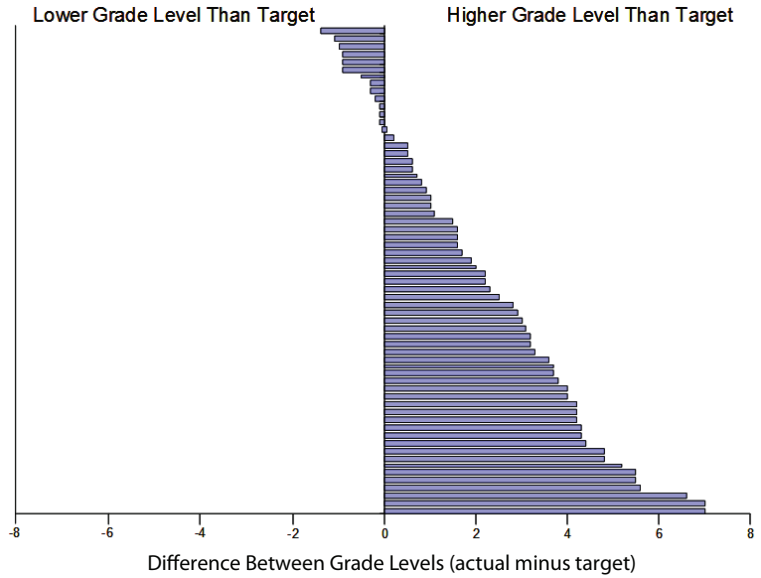


FIGURE 5-5 Actual versus target readability scores for the 64 institutions with stated standards in 2013.
SOURCE: Paasche-Orlow et al., 2013.

of the investigators and all of the clinicians out there. We are telling them to do a better job, but the templates from the organizations themselves are deplorable," said Paasche-Orlow.

Reiterating what other speakers had said regarding informed consent being a process, not just a form, Paasche-Orlow said that it would nonetheless be cynical not to do a better job of acting on research that shows that simplifying and shortening informed consent forms improves understanding. In fact, he said, the forms can be useful because patients and participants can take them home and learn from them, and the forms can inspire questions and further discussion with clinicians and researchers. They can even inspire staff to do better. In the end, though, readability will only be part of the answer, given that some concepts, such as randomization or conflict of interest, will still be confusing to patients and participants. He also reinforced the message that others at the workshop had delivered, which is that it is impossible to know what people do and do not understand unless there is a mechanism to test for understanding. "Without checking, without confirming comprehension, you just won't know what people understand or don't understand," said Paasche-Orlow.

What is needed, he said, is a massive cultural shift—not a subtle one—that has to occur at the organizational level, at the practitioner and investigator level, and at the patient level. This shift, he said, requires moving from persuasion to pedagogy. He said that when he listens to audiotapes of the consent process, the basic thing that he hears is persuasion. "The clinicians, the investigators are trying to persuade someone to do something," said Paasche-Orlow. Shifting to a model based on pedagogy will flip the default situation from one in which the patient or participant has to step forward and ask for more information to one that embraces a positive ethical duty to ensure and document substantive comprehension.

"When an investigator or research assistant or a clinician says, 'So do you have any more questions?' I would say that is not an honest play for an interaction to learn about questions," said Paasche-Orlow. The reason it is not an honest attempt to judge a patient's comprehension, he explained, is that the medical profession has taught the general public that its time is not as important as a doctor's time. "We have acculturated people to say be quiet," explained Paasche-Orlow. Referring to Yael Schenker's likening the current process to the Miranda warning, Paasche-Orlow said that the situation is worse than one in which the patient or participant has the right to remain silent. "You sign this form, and we are going to imply to you that you can't sue us," he said. "Once you sign this form, it is some kind of weird act that you sign this form and give away your rights. Actually, it is not supposed to give away your rights, but that is how people understand it. They think this is some kind of a contract where they have lost rights by signing the form."

Paasche-Orlow said the deck is so stacked against the patient or participant that, in fact, they do not even read the consent document in many cases. Studies that he and his colleagues have conducted using gaze tracking show that even when given the time to read the consent document, patients and participants are not really reading it.

One question that intrigues him is how organizational leaders, clinicians, and research staff learn about the consent process. Many research assistants report that they do not get any training at all, so part of the move toward pedagogy will require that everyone involved in the consent process receive adequate training and supervision and that institutions implement quality control metrics to ensure that staffs are properly trained. Paasche-Orlow recommended that there be a national survey of training, supervision, and documentation approaches in order to compile best practices that could be relevant to the informed consent process. He also recommended that the nation should establish a model training program for investigators, clinicians, organizational leaders, and patients. He noted that successful large organizations outside of health care devote significant resources to training, monitoring, quality control, and feedback, and that it is time for

health care organizations to follow suit to improve and support informed consent.

Paasche-Orlow cautioned that "we do have to be humble about these things," given that people have tried to develop interventions in this area, but many have not succeeded. Part of what will need to be done is to test different models on the basis of pedagogy. His group, for example, has been thinking about this problem in terms of general adult education and looks at the person doing the consent process as an educator. Taking that perspective leads to an examination of the materials that are available to educate the patient or participant. Today, for example, there is no teaching version of consent forms, so Paasche-Orlow recommended that institutions create a teacher's version that embeds all of the things that you want them to do—this is a common pedagogic practice that educators use outside of health care—and then see if they actually take all of those actions. "If you want to have a result, you should check it," said Paasche-Orlow.

Part of the idea of confirming comprehension, he explained, is that it can shift the goals of the people involved in the consent process. The goal today for the most part is to get people into the system, whether it be for surgery or other procedures or as study participants. Making a cultural change that turns research assistants or nurses or surgeons into educators gives them a different job and a different goal. He noted, as had earlier speakers, that the physician may not be the best person to conduct the consent process. In fact, in his experience, physicians are the least likely participants in the consent process to change their behavior.

Taking this approach will create opportunities for monitoring and providing feedback on what works and what does not. It can, however, decrease patient and participant satisfaction because it often increases the time to complete the consent process, said Paasche-Orlow. Again, a culture change is needed to create an environment that alters the public's perception of why the consent process is important and why patients should truly understand the information they receive during that process. He noted that patients often believe that their physician, whom they trust, would not put them in the placebo arm of a trial, because they misunderstand the research process.

A shift has to happen at the organizational level, too, one that emboldens leadership to support creating interventions that will address current structural problems. One problem that must be addressed, which other speakers referred to, is the Hobson's choice that surgery patients often face. He explained that a Hobson's choice is an ethical scenario in which neither choice is good. In the case of the patient being prepared for surgery, the Hobson's choice is either sign the consent form with no real comprehension, or there will not be surgery.

Part of the solution, said Paasche-Orlow, is advocacy. Time is money in

these organizations, and solving this problem requires an ongoing program of training, supervision, and evaluation that will be implemented only if patients and prospective study participants advocate for health systems spending the necessary money to create those programs. On the practitioner side, he said, there is an overt culture that needs to be developed to override the hidden culture that exists in the medical profession. "Every single time the attending says to the lowest person on the team, 'Go consent that person,' it is a very, very strong hidden message that 'I don't care about this,'" said Paasche-Orlow. Recognizing and understanding this hidden culture is necessary to eliminate it from the culture of the organization.

He also said that the professional standard for judging when to do consent is inadequate. In his opinion, a patient is asked for consent based more on professional traditions than on the actual level of risk, but Paasche-Orlow said that what is risky is in the eye of the beholder. "Why is it that you consent for every little punch biopsy of a mole, but you don't consent for incredibly toxic pills that the doctor gives you?" he asked. The answer, in his view, is that there is some kind of convention about surgical procedures versus pills. "We have all kinds of biologics that are incredibly dangerous, but no consent is happening," he said.

Instead of this tradition-based, professional standard, the decision on what needs consent should be based on what a reasonable patient would want to know. For a relatively dangerous drug, patients should truly understand the possible side effects and the risks involved in taking the drug or stopping therapy at some point in the future. "The professional standard has not been a good guide of where this should be done," said Paasche-Orlow. In his opinion, research in health literacy has revealed the risk that the professional standard can lead to racial or cultural bias. Simply giving patients time to read a form is not enough, he said in closing. The cultural agenda for physicians has to become one that promotes shared decision making, and there needs to be an advocacy agenda to promote such a culture. He also summarized his recommendation as follows:

- Shorten the forms.
- Simplify the forms.
- Require documentation of comprehension.
- Conduct a national survey of training, supervision, and documentation approaches.
- Establish model training programs for health system leaders, clinicians, investigators, patients, and families.

DISCUSSION

Cindy Brach started the discussion by recounting the results of an AHRQ project demonstrating the Health Literacy Universal Precautions Toolkit (DeWalt et al., 2010). This demonstration project attempted to use tablets to help overcome literacy barriers, but of the 10 practices selected to participate in this project, half ended up using paper and pencil because of several problems, including slow Internet connections, their patients' preferences, troubleshooting challenges, and others. "I just want to point out that I don't think we are quite there yet for those kinds of solutions," said Brach. With that in mind, she questioned whether Paasche-Orlow's recommendation to conduct a national survey of best practices was in fact doable today. She then asked him for any ideas he might have on what documentation of confirmed understanding would look like and how it would function as one of the levers to achieve cultural change in an organization. Paasche-Orlow first responded that he likes the Brief Informed Consent Evaluation Protocol (BICEP), which was developed by Jeremy Sugarman and his colleagues and is administered by a third party via telephone interview immediately following consent (Sugarman et al., 2005). He then explained that at the end of the toolkit, there is a form for evaluating comprehension in the context of research that would provide a document that people could examine and then discuss with the staff.

Saag remarked that it is important not to discount the potential for technology to improve the informed consent process just because some physicians are reluctant to overcome the challenges inherent in switching from pen and paper to tablets. For example, Saag said, "I would argue that one size fits none. Maybe tablets are not at all what we need to use, and then again, it may not be that you need Wi-Fi and that maybe a WAN [Wide Area Network] signal is sufficient. Maybe people are going to be doing more of this at home. Maybe they are going to be using the kiosk in the waiting room. These are all things that are very rapidly changing, and I think we should think more about what the technology can bring and less about the hardware." He then recounted a recent experience in which he and his collaborators were going to use storytelling via a Web-based application, and the grant review committee said that there also had to be a DVD available for those who did not use the Web. His team did spend the money and time developing the DVD, but in the end, nobody used it—everyone went to the Web. "When we try to dumb down the technology, we are always a step behind," said Saag. He also referred to recent polling numbers showing that use of the Web continues to grow, even among older Americans. Paasche-Orlow noted that even his homeless patients have phones, many of them smartphones.

Laurie Francis commented that she believes there is a way to go to get to a place where patient priorities and preferences drive all conversations, and she agrees with the Hobson's choice analogy that Paasche-Orlow noted. "That idea of shared decision making isn't about us taking time for the patient to get on board with our decisions but, in fact, is bidirectional. I would love for us to confirm understanding and use teach-back," she said. Paasche-Orlow responded by saying that he had just finished 1 month on the wards and heard clinicians complaining frequently that they spend more time with the computer than they do with the patients, a sentiment for which he has little compassion. He then commented that he believes that values clarification and bidirectional agenda setting is potentially time saving. He also thinks that insurers should get involved by stating that meeting patients' agendas matters to them. Paasche-Orlow did acknowledge that perhaps agenda setting might need to happen in a more complicated way, perhaps by first meeting with another staff member to determine that agenda. He noted that there have been studies looking at that type of activity.

Andrew Pleasant commented that it may be useful to look at the social sciences for a model of how to change culture, given that social sciences researchers approach people from very different perspectives. He noted that some of the missing best practices in a clinical context may already be available from the social sciences.

Ruth Parker thanked Paasche-Orlow for his recommendations and wondered if there might be another item on that list, that is, to better understand what the public wants and needs to know about various health care–related topics, whether that topic be what various drugs do or what some surgical procedure entails. Similarly, she thought it might be useful to know what pharmaceutical companies, for example, have learned from their own safety and efficacy studies about what patients need to know. Paasche-Orlow agreed that the lack of understanding about what patients want to know is a serious problem. He noted some work that he has done in which he asked various clinicians about what they thought a patient would need to know about various medications, and the agreement among them was "horrendous." He also said that what patients know today about their medications largely comes from direct-to-consumer advertising, and he has had patients come in asking if they can please have a particular side effect that was mentioned in an advertisement. He then recounted work that he and his collaborators have done to identify the critical information that patients need for more than 1,000 drugs. They also prepared a set of additional questions, with the corresponding answers, that patients who want more information might ask. Despite the researchers' spending thousands of hours preparing that supplementary information, patients never

used it. However, when he asked patients if they need that information in the system, they said they did.

Saag said he believes that part of the problem is that, because of the driving force of risk aversion, "we are busy [getting the consent] for things that aren't important, both in clinical care and in research studies, and so we are not doing a good job when it really matters." He suggested that what is needed is a public relations campaign to get out the word that getting medical care is dangerous and that there is a benefit to being part of a learning health care system. "There is a public good in doing that, and there is an ethical framework for promoting that," said Saag. Focusing on what is important and getting rid of the superfluous content in consent forms would improve things dramatically, he added.

Benard Dreyer applauded Paasche-Orlow for his anger at the current state of the field and commented that the powers that be are all happy with how the system works today and that getting them to change, in his experience, is nearly impossible. He also recounted his experience with an effort to train all of his institution's pediatricians to use teach-back with regard to asthma treatments. During the study, all of the pediatricians used teach-back, and they did it effectively, said Dreyer, but when the research project stopped, the pediatricians stopped using teach-back immediately. He asked Paasche-Orlow if he had any ideas on how to sustain good practices in the face of this type of behavior. Paasche-Orlow replied this is not a set-it-and-forget-it activity, like roasting a turkey. "This is one of those kinds of things that require supervision and feedback," he said. Various studies and his experience support that need. He did note that some health care professionals, particularly pharmacists, are easier to train and to persuade them to continue in these kinds of activities. He also said that this is a broader cultural issue. "For whatever reason, medical schools somehow communicate one way or the other that patient education and empowerment is somebody else's job," said Paasche-Orlow. Both he and Dreyer characterized their efforts at training doctors to be Sisyphean in that regard.

As for how to change culture at the level above the physicians, Paasche-Orlow said that culture change takes leadership and gumption. One approach might be to find lawyers who can be compatriots in this effort and to get insurers more involved in setting an agenda. "There is a lot of power in that room that hasn't been tapped for this agenda," he said. Saag agreed with these ideas but worried about placing yet another burden on primary care physicians, who already have too much to do. "We have to come up with a solution that doesn't involve adding more responsibilities to primary care providers," said Saag, who suggested that pharmacists, nurse educators, and others could take on the added responsibility of agenda setting and better understanding patient desires and needs.

Robert Logan asked Paasche-Orlow if the pedagogically oriented paradigm that he advocates is more about decision making or about empowering those who have the least influence in the consent process, namely, patients and caregivers. Paasche-Orlow replied that he would like it to be about empowerment and that shared decision making can be empowering for people. One of reasons that he worries about the subjective standard is that people often judge what others need to know on the basis of what they look like or how big a vocabulary they have. "You can see that people who are more educated are given more information by their clinicians," he said.

Kim Parson reiterated the idea that one size does not fit all regarding what technologies are appropriate to use in a given setting. Each person, she said, has his or her own style of learning and is in his or her own space in terms of health needs at a particular moment in time. She also stressed the importance of discussion and of the finding that most people, regardless of literacy level, are unable to recall or understand the information presented to them during an informed consent process. George Isham then said that his impression is that many of the people attending the workshop are too close to this issue and are not seeing the forest for the trees. "I think one of the things that I have gotten from today is the fact that informed consent is really part of a larger patient education/patient decision-making framework. I don't have, at the end of this day, a sense that we have a good logic model that encompasses all those things," said Isham. He also wondered what Paasche-Orlow's recommendations would look like if the field took a bigger view of this issue in terms of the kinds of things that could be done. "We need the smart people who are in this room to come to a working session where we would have white boards and stickies and get people working on processes and take advantage of their knowledge in a different kind of way to understand the issues and try to create solutions," said Isham. He then added that he believes that problem lies with clinicians and institutional leaders who have created a culture that does not respect patient desires to the extent that it should.

Saag responded with the observation that what was missing from this workshop was the view of patients, particularly patients from different educational backgrounds and greater diversity in terms of ethnic and racial backgrounds and language skills. "That is the perspective that we need to bring in, particularly in the area of patient-centeredness," said Saag. Paasche-Orlow remarked that he has seen too many projects on organizational change fail because of poor management or commitment or lack of resources. What is needed, he said, is for an organization to embrace an entire campaign, complete with marketing and infrastructure, for cultural change. He also noted that this change will take generations to complete.

6

Reflections on the Workshop

Cindy Brach started this session by recounting what she heard regarding the tools that are available to create a new culture in health care organizations. Her list started with medical and continuing education, IRB education in the case of research, and legislation and regulations, including those that state which standard applies and that mandate access to language-appropriate documents or translators. Malpractice suits and the threat they hold are also a potential tool, and she asked Christopher Trudeau if he would provide a list of the most salient cases in that area after the workshop's conclusion. She thinks that efforts to empower patients to demand change and to support leadership that drives change should also become part of the toolkit for culture change. Brach asked if there are other things that leadership cares about that can be a driver for change, such as patient-centered care or shared decision making. She also commented on the need to "hardwire" these change agents through sustained attention and the role that better consent forms, communication tools, supervision, and documental and other structural processes can play as levers in that regard.

Kim Parson commented that what she heard was that the current system for informed consent is not effective for any person, no matter the health-literacy level. She noted that there have been many attempts at making processes and documents more patient friendly, that these efforts should be applauded, and that the lessons learned from those efforts should be applied going forward. The unintended complexity that results from the intended protections put in place by state departments of insurance and through multiple regulations from federal agencies has a disproportionate impact on patients, caregivers, and providers, she said. Parson thought that

the day's discussions were a good starting point for further exploration of the impact of rules and regulations on organizations' abilities to act in a health-literate manner. Parson also heard that the opportunity exists to compile best practices for informed consent that are built on the concepts of simplicity, human-centered design principles, and, above all, partnerships with patients and participants. "By co-creating with patients who have experienced the informed consent process and with people who are potential participants in the process, we will discover their needs and how they want those needs to be met. The results will be a more knowledgeable, willing, and engaged end user while we are achieving the goals of those seeking consent," said Parson. George Isham added the comment that the next step may be for the roundtable to convene a conversation around determining needs and wants and design principles.

Lori Hall commented that she is often inspired by sources outside of health care and noted a book called *A Whole New Mind* by Daniel Pink. In this book, Pink talks about how in this age of information overload, although it is possible to create efficiencies and streamline processes, the power of empathy should not be overlooked. With that in mind, she noted that nothing replaces the power of human engagement to induce change. Patient engagement, she said, is required to build the trust needed to educate and empower patients so that true shared decision making can take place.

After thanking Paasche-Orlow for his list of recommendations and several of the speakers for emphasizing the need to add cultural and linguistic pieces to the informed consent process, Wilma Alvarado-Little noted the importance of tone of voice when interpreting for visually impaired patients. She also noted that it is important to remember that the deaf and hard-of-hearing community is full of people who do not speak English as their native language or who are not literate. Simply handing them a consent document will not be sufficient to obtain meaningful informed consent, she said.

Another thing to keep in mind, said Alvarado-Little, is that a patient's caretaker, regardless of education, may not have the foresight to ask certain questions, particularly when the caretaker has an emotional connection to the patient. She stressed the need to educate health care providers on the proper use of an interpreter in the consent process. Alvarado-Little said that if she, in her role as an interpreter, misspeaks with the consent form in front of her, she can be subpoenaed just like anybody else. She also said that from a community research perspective, IRBs in academia need to have some insight about what resonates with the community.

Alvarado-Little also provided comments from Lindsay Robinson, who had to leave the workshop prior to this discussion. Robinson noted that dentistry was not represented in these discussions, in part because dentists

are not asked to engage in informed consent even though they should be for many procedures. The perception exists that the level of risk associated with dental procedures is low and that there is less litigation in dentistry compared to medicine. There is also an inherent conflict of interest, she said, because most of the services are provided by dentists who are in a private business, and they are the ones making the decisions.

Robert Logan mentioned that some law schools have programs in mediation that train attorneys to think of a standard or goal that is higher than meeting the needs of one particular client or adversary. He wondered if there is a vital role for mediation in establishing better cooperation and collegiality among the stakeholders involved in the informed consent process. He added that he does not think of the legal profession as part of the problem but a potential part of the solution. "I think we are not talking to the right lawyers today," said Logan, suggesting that those who are concerned about informed consent should speak with experts in mediation who can look at informed consent not as a means of protecting a hospital from litigation but as a tool that can serve a broader social purpose. Isham said that he supported this idea because working through judges, while effective, will take too long to achieve the necessary change.

Logan also thought it would be useful to outline in a paper all of the individual, cultural, clinical, ethical, social, public health, and community harm that stems from dense language or excessive complexity in consent in other clinical forms, an idea that Isham said that he supports. Logan noted that there is currently no good way of outlining those issues to people so that anybody who is interested in those things will see immediately how they are involved in a process that causes enormous harm. "Can't we find people who can better outline the range of that harm and, from a very ethical perspective across the range, demonstrate what that is?" Logan asked.

Catina O'Leary commented that the discussions at the workshop were rather narrow in their focus on what is informed consent and why it matters, whereas the paper that the roundtable commissioned also highlighted the fact that not much is known about health literacy and informed consent in community-based research. While acknowledging that it is important to talk about risks involved in participating in clinical trials in a hospital setting, she said that the risks of doing informed consent poorly in the community setting is that it can destroy the trust of researchers and health care providers throughout a community. She stressed the importance of having conversations on who gets to decide who gets to have the conversation, what shared decision making is, and who gets to lead that conversation in shared decision making.

Bernard Rosof supported O'Leary's emphasis on community research and said that there is a notable lack of guidelines and toolkits for health-literate informed consent in community-based research, particularly given

the increasing emphasis that is being put on community-based research as a means of improving population health and defining healthy living. "If we talk about shared decision making, particularly between the family and the participant or the patient, I think the community is the area where that needs emphasis more than anything else in the hospital environment," said Rosof.

Benard Dreyer focused his initial comments on the role of language in informed consent and said that the field is nowhere near where it should be in terms of providing appropriate interpretation of any kind to the large and growing population of people in this country who have limited English proficiency. He said that raising awareness of the challenges in achieving health literacy in this group of less-than-proficient English speakers is an important task, given how little progress has been made in this area despite its obviousness. He then commented on the important role that partnerships with patients and families can play in creating a better informed consent process. Building these partnerships will require empowering patients and families and educating them on the importance of asking questions during the informed consent process.

Regarding complexity, Dreyer said he was impressed with the tension between the obvious need to create simpler and more understandable forms and the need to convey specific information to patients or study participants. "When you start adding all of those things up, it ends up, even if it is in clear language, being pretty complex," said Dreyer. He encouraged the roundtable to think further about how to address this tension.

Winston Wong said that for him, informed consent comes down to two conflicting dynamics—protection and empowerment. Taken from an institutional point of view, there is protection of the organization, the individual, and the provider, and empowerment to be able to do the right kind of thing ostensibly for the benefit of the patient, explained Wong. That same dynamic is also apparent with regard to patient and family, that is, protecting patients from insult and injury, but also empowering them to make the right kinds of decisions for themselves and their families. "It seems that there is a very thin line between what constitutes protections and empowerment," said Wong. "To that extent, I think that having the patient voice be the definitive voice with regard to looking at how the balance between protection and empowerment is achieved is a really important point."

Dreyer also noted that the field needs to consider the role that numeracy plays in conveying risk and to integrate what has been learned about numeracy into the informed consent process. The field also needs to develop a better understanding about the role of culture in influencing health beliefs and how to accommodate that in the informed consent process.

Isham remarked that the field needs to use data systematically to understand the needs of patients, both in the aggregate and individually, a point

with which Rosof agreed. Rosof then noted that improving informed consent is not really about patient education but rather is about a culture change for researchers, IRBs, clinicians, and other members of the health care team. Wong suggested that the argument for change could be made from the perspective of health equity and health disparities. Another possibility, said Wong, would be to capture the kind of suffering that is occurring because of poor informed consent processes.

In his comments, Gem Daus, public health analyst for the Health Resources and Services Administration, underscored the importance of language in informed consent and the fact that translation does not equal comprehension. "Translating is not the end of the intervention," said Daus. "It is really just the beginning." He encouraged the roundtable to continue discussing the role of language in informed consent and, more broadly, health literacy. He also noted that his agency is quite interested in primary care, primary care physicians, and the system of primary care. From this perspective he commented that it is not just the primary care physician's responsibility to educate patients and ensure comprehension, but it is also that of other members of the care team who interact with the patient along the care continuum. He pointed out that community health centers, which are by law consumer focused and required to have consumers on their boards, could be an important venue for accomplishing many of the tasks that were raised at the workshop in terms of building partnerships and changing expectations among members of the community. He also noted that by increasing health care plan enrollment, the Affordable Care Act has created opportunities to reach a larger proportion of the American public as well as created the challenge of obtaining consent from more of them. His final comment was that he supported the use of infographics and pictures to enhance comprehension throughout the consent process.

Steven Rush, director of the Health Literacy Innovations Program at UnitedHealth Group, said that he heard several concepts repeated several times during the workshop. The first was that informed consent needs to move from an ethos of persuasion to one of pedagogy and that the focus has to shift to that of consumers and their values. He commended Trudeau and others for stressing the importance of plain language and its potential role as an agent of change. The third concept was that one size does not fit all for informed consent and for shared decision making.

Michael Villaire's takeaway from the workshop was that informed consent needs to get back to its original intended function, which was to protect the patient. From that perspective, it is essential to ask patients what they want and use that as a baseline for how much information and complexity to build into the consent process. He liked the emphasis that the workshop speakers placed on putting the patient at the center of the informed consent process. To him, "patient centered" means using all of

the arsenal, all of the terminology, and all of the facets of how health care providers look at patients in terms of language and culture and how much they are activated by and are interested in the informed consent process. A patient-centered process also means that patients will be given the time that they need to understand all of the important concepts and terms in a consent document. Villaire asked the question, "Who does the informed consent process serve?" and his answer was that it should be serving the patient. "We need to communicate on their turf, not on ours," said Villaire.

Andrew Pleasant pointed out that it is easy to criticize the informed consent form and process from a perspective that is different from what the process and form were initially designed to do. It would be lovely, he said, if informed consent were designed to protect patients, but as Jeremy Sugarman noted, it was designed to protect institutions and professionals from lawsuits. "To change the culture, I believe we need to be direct and up front that we are not asking for tweaks to the process, we are asking for a very different process with a very different desired outcome," said Pleasant. "Anything else, and people who have the power to make those changes will sort of nod their head and say how nice for you and walk away as they have done for some time because their priorities are not our priorities."

He supported the need for more work in the area of informed consent in community-based research and noted that he would not be surprised that when that research is conducted, it will identify best practices that can guide all aspects of the informed consent process. Pleasant also reiterated the importance of language interpretation and pointed out that there are existing laws regarding interpretation that are not being enforced. Having made that point, he said that he is convinced that enough is known to push regulations forward beyond where they are now to change the process. "Whether that happens in the guidance aspect, the regulations, or in the actual writing of a law or the issuing of an executive order is something that a group should explore and figure out," said Pleasant. He also said that there is enough evidence on health literacy, shared decision making, and how to create informed decisions among patients in health care contexts to move that bar forward now. "More research is always nice, but not at the expense of actual action," he said.

One thing that he did not hear over the course of the day, he said, was including a group process in the informed consent process, something that can save time and money in that one person's question becomes the group's question. Although the whole consent process cannot be performed solely in a group format, it can be an important contributor to the process. He also commented that the field does a good job at getting information to people but not so much at getting people to a place where they comprehend that information in the context of their lives and getting them to act on that information. "That is something that most informed consent processes

absolutely don't do, helping patients communicate their understanding to their friends and families around them to create a platform for behavior change," said Pleasant. "As a result, we really don't achieve a true informed consent because we haven't included those processes of health literacy in the overall effort. I think we can and should."

Laurie Francis said that the field is getting better at nesting health literacy in the context of human-to-human interactions, and so she applauded the panelists for making that connection repeatedly throughout the day. She also noted that the field has much to learn from the way that the palliative care and mental health communities involve patients in shared decision making. She made the point that "until we understand what the person with whom we are engaging wants and needs in their lives and how our conversation fits with that, I think we have missed the boat."

Francis also said that testing should extend not only to patient comprehension but also to health care provider comprehension. "Test us on if we understand the priorities of the people we are sitting across from and how this informed consent fits within their priorities," said Francis. "I really think we would move the world with that test." She finished her comments by stating that "we are a lot of smart people in the room, but we are not as smart as we think. I think that to really change our mental model, we actually need different thinkers at the table. Bringing ourselves together over and over to try and tweak a system we are pretty comfortable in probably won't create the disruptive innovation we need in this world to try to engage people in the way that they can make behavior changes."

Parson seconded that idea and suggested that the nation needs to have a shared conversation about informed consent. Parson also said that there is a need for a primer on informed consent that would answer basic questions about informed consent: What is it? How do I administer it? Why is it important for me? Why is it important for my family and my community? Such a primer could serve as the basis for having a shared national conversation. She noted that one of the beauties of working on this topic and striving to improve informed consent is that it encourages everyone participating to care. "I applaud those who are engaged in caring and the opportunity to be part of a conversation with others working to roll the Sisyphean ball," said Parson.

Christopher Trudeau said that he liked the idea of taking a systems approach to informed consent and getting the right stakeholders to sit down and hash out a system that could create informed consent for those rare occasions when there will not be any type of preprinted form. He said he believes that it is possible to create a system for categorizing informed consent according to the setting or risk levels, for example. Isham seconded this idea and wondered if something like the Institute for Healthcare

Improvement's Improvement Map[1] would enable a group of stakeholders to figure out what informed consent is really about, who it is serving, what the desired outcomes are, and what each stakeholder needs to get from the process.

The last comments came from Alicia Fernandez, who reminded attendees that even simple changes can be slow in coming. As an example, she pointed out that the science of hand washing is more than 100 years old. Yet when she was a medical student in the Bronx at the height of the HIV epidemic, hand washing was not yet common in the wards. Today, everyone washes their hands, but it took a great many actions, including education and leadership, to change the culture to one in which nobody now thinks twice about washing their hands when they come into the wards. In her mind, we are facing a much more difficult task than making hand washing standard procedure because there are entrenched interests that are happy with the system as it now exists. She encouraged continuing efforts to shine a light on informed consent and health literacy, stating that doing so will bring others to the table. "If you say informed consent matters and we need to look at literacy and language and all of the issues that were raised here today, perhaps the [American Association of Medical Colleges] will consider it a core competence in communication that medical students should learn to do informed consent and that that should be a measurable core competence for every medical student," said Fernandez.

Isham thanked the roundtable and planning committee members, speakers, and participants for an interesting and informative day and adjourned the workshop.

[1] According to the Institute for Healthcare Improvement's website, "The Improvement Map is a free, interactive, Web-based tool designed to bring together the best knowledge available on the key process improvements that lead to exceptional patient care." See http://www.ihi.org/Engage/Initiatives/Improvemaphospitals/Pages/default.aspx (accessed December 10, 2014).

References

Aldoory, L., K. E. B. Ryan, and A. M. Rouhani. 2014. *Best practices and new models of health literacy for informed consent: Review of the impact of informed consent regulations on health-literate communications*. Washington, DC: National Academy of Sciences. http://www.iom.edu/Activities/PublicHealth/HealthLiteracy/~/media/Files/Activity%20Files/PublicHealth/HealthLiteracy/Commissioned-Papers/Informed_Consent_HealthLit.pdf (accessed August 26, 2014).

Allen, R. S., J. Y. Allen, M. M. Hilgeman, and J. DeCoster. 2008. End-of-life decision-making, decisional conflict, and enhanced information: Race effects. *Journal of the American Geriatric Society* 56(10):1904–1909.

Back, A., R. Arnold, and J. Tulsky. 2009. *Mastering communication with seriously ill patients*. New York: Cambridge University Press.

Bainbridge, K. E., and M. I. Wallhagen. 2014. Hearing loss in an aging American population: Extent, impact, and management. *Annual Review of Public Health* 35:139–152.

Bodenheimer, T., K. MacGregor, and C. Sharifi. 2005. *Helping patients manage their chronic conditions*. Oakland: California HealthCare Foundation.

Butler, J. 3rd, S. C. Quinn, C. S. Fryer, M. A. Garza, K. H. Kim, and S. B. Thomas. 2013. Characterizing researchers by strategies used for retaining minority participants: Results of a national survey. *Contemporary Clinical Trials* 36(1):61–67.

Chalkidou, K., S. Tunis, D. Whicher, R. Fowler, and M. Zwarenstein. 2012. The role for pragmatic randomized controlled trials (pRCTs) in comparative effectiveness research. *Clinical Trials* 9(4):436–446.

Detering, K. M., A. D. Hancock, M. C. Reade, and W. Silvester. 2010. The impact of advance care planning on end of life care in elderly patients: Randomised controlled trial. *British Medical Journal* 340:c1345.

DeWalt, D. A., L. F. Callahan, V. H. Hawk, K. A. Broucksou, A. Hink, R. Rudd, and C. Brach. 2010. *Health literacy universal precautions toolkit*. Prepared by the North Carolina Network Consortium, the Cecil G. Sheps Center for Health Services Research, the University of North Carolina at Chapel Hill, under Contract No. HHSA290200710014. AHRQ Publication No. 10-0046-EF. Rockville, MD: Agency for Healthcare Research and Quality. http://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/literacy-toolkit/healthliteracytoolkit.pdf (accessed September 4, 2014).

Diamond, L. C., Y. Schenker, L. Curry, E. H. Bradley, and A. Fernandez. 2009. Getting by: Underuse of interpreters by resident physicians. *Journal of General Internal Medicine* 24(2):256–262.

Eapen, Z. J., M. S. Lauer, and R. J. Temple. 2014. The imperative of overcoming barriers to the conduct of large, simple trials. *Journal of the American Medical Association* 311(4):1397–1398.

Faden, R. R., and T. L. Beauchamp. 1986. *A history and theory of informed consent*. New York: Oxford University Press.

Fernandez, A. 2010. Improving the quality of informed consent: It is not all about the risks. *Annals of Internal Medicine* 153(5):342–343.

Fernandez, A., D. Schillinger, E. M. Warton, N. Adler, H. H. Moffet, Y. Schenker, M. V. Salgado, A. Ahmed, and A. J. Karter. 2011. Language barriers, physician-patient language concordance, and glycemic control among insured Latinos with diabetes: The Diabetes Study of Northern California (DISTANCE). *Journal of General Internal Medicine* 26(2):170–176.

Fink, A. S., A. V. Prochazka, W. G. Henderson, D. Bartenfeld, C. Nyirenda, A. Webb, D. H. Berger, K. Itani, T. Whitehill, J. Edwards, M. Wilson, C. Karsonovich, and P. Parmelee. 2010. Enhancement of surgical informed consent by addition of repeat back: A multicenter, randomized controlled clinical trial. *Annals of Surgery* 252(1):27–36.

Flory, J., and E. Emanuel. 2004. Interventions to improve research participants' understanding in informed consent for research: A systematic review. *Journal of the American Medical Association* 292(13):1593–1601.

Gany, F., J. Leng, E. Shapiro, D. Abramson, I. Motola, D. C. Shield, and J. Changrani. 2007. Patient satisfaction with different interpreting methods: A randomized controlled trial. *Journal of General Internal Medicine* 22(S2):312–318.

Hammes, B. J., B. L. Rooney, and J. D. Gundrum. 2010. A comparative, retrospective, observational study of the prevalence, availability, and specificity of advance care plans in a county that implemented an advance care planning microsystem. *Journal of the American Geriatric Society* 58(7):1249–1255.

Herz, D. A., J. E. Looman, and S. K. Lewis. 1992. Informed consent: Is it a myth? *Neurosurgery* 30(3):453–458.

HEW (Department of Health, Education, and Welfare). 1979. Ethical principles and guidelines for the protection of human subjects of research. *Federal Register* 44(76):23191–23197.

Heyland, D. K., D. Barwich, D. Pichora, P. Dodek, F. Lamontagne, J. J. You, C. Tayler, P. Porterfield, T. Sinuff, and J. Simon. 2013. Failure to engage hospitalized elderly patients and their families in advance care planning. *JAMA Internal Medicine* 173(9):778–787.

HHS (U.S. Department of Health and Human Services). 2009. Protection of human subjects. *Code of Federal Regulations*, Title 45, Part 46. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html (accessed August 26, 2014).

Howard, J. M., and D. DeMets. (1981). How informed is informed consent? The BHAT experience. *Controlled Clinical Trials* 2(4):287–303.

Ingelfinger, F. J. (1972). Informed (but uneducated) consent. *New England Journal of Medicine* 287(9):465–466.

Institute for Healthcare Advancement. 2014. *California advance health care directive*. http://www.iha4health.org/our-services/advance-directive (accessed September 2, 2014).

IOM (Institute of Medicine). 2014. *Health literacy and numeracy: Workshop summary.* Washington, DC: The National Academies Press.

Karliner, L. S., E. A. Jacobs, A. H. Chen, and S. Mutha. 2007. Do professional interpreters improve clinical care for patients with limited English proficiency? A systematic review of the literature. *Health Services Research* 42(2):727–754.

Kirchhoff, K. T., B. J. Hammes, K. A. Kehl, L. A. Briggs, and R. L. Brown. 2010. Effect of a disease-specific planning intervention on surrogate understanding of patient goals for future medical treatment. *Journal of the American Geriatric Society* 58(7):1233–1240.

Lavori, P. W., T. J. Wilt, and J. Sugarman. 2007. Quality assurance questionnaire for professionals fails to improve the quality of informed consent. *Clinical Trials* 4(6):638–649.

Lindquist, L. A., N. Jain, K. Tam. G. J. Martin, and D. W. Baker. 2011. Inadequate health literacy among paid caregivers of seniors. *Journal of General Internal Medicine* 26(5): 474–479.

Meisel, A., and M. Kuczewski. 1996. Legal and ethical myths about informed consent. *Archives of Internal Medicine* 156(22):2521–2526.

Mudano, A. S., L. C. Gary, A. L. Oliviera, M. Melton, N. C. Wright, J. R. Curtis, E. Delzell, T. M. Harrington, M. L. Kilgore, C. E. Lewis, J. A. Singh, A. H. Warriner, W. D. Pace, and K. G. Saag. 2013. *Patient Preference and Adherence* 2013(7):517–523.

National Center for Education Statistics. 2003. *National assessment of health literacy.* http://nces.ed.gov/naal/kf_demographics.asp (accessed September 3, 2014).

Paasche-Orlow, M. K., H. A. Taylor, and F. L. Brancati. 2003. Readability standards for informed-consent forms as compared with actual readability. *New England Journal of Medicine* 348(8):721–726.

Paasche-Orlow, M. K., K. A. Riekert, A. Bilderback, A. Chanmugam, P. Hill, C. S. Rand, F. L. Brancati, and J. A. Krishnan. 2005. Tailored education may reduce health literacy disparities in asthma self-management. *American Journal of Respiratory and Critical Care Medicine* 172(8):980–986.

Paasche-Orlow, M. K., F. L. Brancati, H. A. Taylor, S. Jain, A. Pandit, and M. S. Wolf. 2013. Readability of consent form templates: A second look. *IRB* 35(4):12–19.

Pape, T. 1997. Legal and ethical considerations of informed consent. *AORN Journal* 65(6): 1122–1127.

Pham, K., J. D. Thornton, R. A. Engelberg, J. C. Jackson, and J. R. Curtis. 2008. Alterations during medical interpretation of ICU family conferences that interfere with or enhance communication. *Chest* 134(1):109–116.

Quinn, S.C. 2014. *Informed consent and minority underrepresentation in clinical trials.* Presentation at the Institute of Medicine Workshop on Health Literacy and Informed Consent, Washington, DC, July 28.

Rothberg, M. B., S. K. Sivalingam, J. Ashraf, P. Visintainer, J. Joelson, R. Kleppel, N. Vallurupalli, and M. J. Schweiger. 2010. Patients' and cardiologists' perceptions of the benefits of percutaneous coronary intervention for stable coronary disease. *Annals of Internal Medicine* 153(5):307–313.

Rowbotham, M. C., J. Astin, K. Greene, and S. R. Cummings. 2013. Interactive informed consent: Randomized comparison with paper consents. *PLoS ONE* 8(3):e58603.

Schenker, Y., and A. Meisel. 2011. Informed consent in clinical care. *Journal of the American Medical Association* 305(11):1130–1131.

Schenker, Y., F. Wang, S. J. Selig, R. Ng, and A. Fernandez. 2007. The impact of language barriers on documentation of informed consent at a hospital with on-site interpreter services. *Journal of General Internal Medicine* 22(S2):294–299.

Schenker, Y., A. J. Karter, D. Schillinger, E. M. Warton, N. E. Adler, H. H. Moffet, A. T. Ahmed, and A. Fernandez. 2010. The impact of limited English proficiency and physician language concordance on reports of clinical interactions among patients with diabetes: The DISTANCE study. *Patient Education and Counseling* 81(2):222–228.

Schenker, Y., A. Fernandez, R. Sudore, and D. Schillinger. 2011. Interventions to improve patient comprehension in informed consent for medical and surgical procedures: A systematic review. *Medical Decision Making* 31(1):151–173.

Schenker, Y., A. Fernandez. K. Kerr, D. O'Riordan, and S. Z. Pantilat. 2012. Interpretation for discussions about end-of-life issues: Results from a National Survey of Health Care Interpreters. *Journal of Palliative Medicine* 15(9):1019–1026.

Schillinger, D., J. Piette, K. Grumbach, F. Wang, C. Wilson, C. Daher, K. Leong-Grotz, C. Castro, and A. B. Bindman. 2003. Closing the loop: Physician communication with diabetic patients who have low health literacy. *JAMA Internal Medicine* 163(1):83–90.

Schwarze, M. L., J. M. Kehler, and T. C. Campbell. 2013. Navigating high risk procedures with more than just a street map. *Journal of Palliative Medicine* 16(10):1169–1171.

Sharp, S. M. 2004. Consent documents for oncology trials: Does anybody read these things? *American Journal of Clinical Oncology* 27(6):570–575.

Strunkel, L., M. Benson, L. McLellan, N. Sinaii, G. Bedarida, E. Emanuel, and C. Grady. 2010. Comprehension and informed consent: Assessing the effect of a short consent form. *IRB* 32(4):1–9.

Sudore, R. L., C. S. Landefeld, B. A. Williams, D. E. Barnes, K. Lindquist, and D. Schillinger. 2006. *Journal of General Internal Medicine* 21(8):867–873.

Sudore, R. L., C. S. Landefeld, D. E. Barnes, K. Lindquist, B. A. Williams, R. Brody, and D. Schillinger. 2007. An advance directive redesigned to meet the literacy level of most adults: A randomized trial. *Patient Education and Counseling* 69(1–3):165–195.

Sudore, R. L., C. S. Landefeld, S. Z. Pantilat, K. M. Noyes, and D. Schillinger. 2008. Reach and impact of a mass media event among vulnerable patients: The Terri Schiavo story. *Journal of General Internal Medicine* 23(11):1854–1857.

Sudore, R. L., D. Schillinger, S. J. Knight, and T. R. Fried. 2010. Uncertainty about advance care planning treatment preferences among diverse older adults. *Journal of Health Communication* 15(Suppl 2):159–171.

Sugarman, J., D. C. McCrory, D. Powell, A. Krasny, B. Adams, E. Ball, and C. Cassell. 1999. Empirical research on informed consent: An annotated bibliography. *The Hastings Center Report* 29(1):S1–S42.

Sugarman, J., P. W. Lavori, M. Boeger, C. Cain, R. Edson, V. Morrison, and S. S. Yeh. 2005. Evaluating the quality of informed consent. *Clinical Trials* 2(1):34–41.

Trudeau, C. 2014. *Establishing harmony between the rules and health literacy.* Presentation at the Institute of Medicine Workshop on Health Literacy and Informed Consent, Washington, DC, July 28.

Tschurtz, B. A., R. G. Koss, N. J. Kupka, and S. C. Williams. 2011. Language services in hospitals: Discordance in availability and staff use. *Journal of Healthcare Management* 56(6):403–417.

Volandes, A. E., M. K. Paasche-Orlow, M. J. Barry, M. R. Gillick, K. L. Minaker, Y. Chang, E. F. Cook, E. D. Abbo, A. El-Jawahri, and S. L. Mitchell. 2009. Video decision support tool for advance care planning in dementia: Randomized controlled trial. *British Medical Journal* 338:b2159.

Volandes, A. E., M. J. Barry, Y. Chang, and M. K. Paasche-Orlow. 2010. Improving decision making at the end of life with video images. *Medical Decision Making* 30(1):29–34.

Warner, E. T., R. E. Glasgow, K. M. Emmons, G. G. Bennett, S. Askew, B. Rosner, and G. A. Colditz. 2013. Recruitment and retention of participants in a pragmatic randomized intervention trial at three community health clinics: Results and lessons learned. *BMC Public Health* 13:192.

Weinfurt, K. P., M. A. Hall, N. M. King, J. Y. Friedman, K. S. Schulman, and J. Sugarman. 2009. Disclosure of financial relationships to participants in clinical research. *New England Journal of Medicine* 361(9):916–921.

Zhang, B., A. A. Wright, H. A. Huskamp, M. E. Nilsson, M. L. Maciejewski, C. E. Earle, S. D. Block, P. K. Maciejewski, and H. G. Prigerson. 2009. Health care costs in the last week of life: Associations with end-of-life conversations. *JAMA Internal Medicine* 169(5):480–488.

Appendix A

Workshop Agenda

Informed Consent and Health Literacy: A Workshop

Keck Center Building, Room 100
Washington, DC
July 28, 2014

OPEN SESSION

8:30–8:45	Welcome, Workshop Overview, Introduction of First Speakers *George Isham, Roundtable Chair*
8:45–10:00	Overview
8:45–9:05	Informed Consent: Why Do We Care? *Jeremy Sugarman* *Johns Hopkins University*
9:05–9:25	Best Practices and New Models of Health Literacy for Informed Consent: Review of the Impact of Informed Consent Regulations on Health-Literate Communications (presentation of commissioned paper) *Linda Aldoory* *University of Maryland*
9:25–10:00	Discussion
10:00–10:15	**BREAK**

10:15–11:45 The Current State of Informed Consent in Research and Treatment

10:15–10:20 Introductions

10:20–10:40 Impact of Poor Informed Consent Process on Clinical Trials (including information sharing)
Sara Goldkind

10:40–11:00 Informed Consent and Minority Underrepresentation in Clinical Trials
Sandra Crouse Quinn
University of Maryland

11:00–11:20 Developing a Better Process for Informed Consent
Yael Schenker
University of Pittsburgh

11:20–11:40 Disproportionate Impact of Poor Informed Consent Process on Minorities
Alicia Fernandez
University of California, San Francisco

11:40–12:15 Discussion

12:15–1:15 LUNCH

1:15–2:30 Approaches to Informed Consent

1:15–1:20 Introductions

1:20–1:40 Importance of Conversation/Discussion as Well as the Form
Rebecca Sudore
University of California, San Francisco

1:40–2:10 Establishing Harmony Between the Rules and Health Literacy
Christopher Trudeau
Thomas M. Cooley Law School

2:10–2:45 Discussion

2:45–3:00	**BREAK**
3:00–4:15	The Future of Informed Consent
3:00–3:05	Introductions
3:05–3:25	Informed Consent Using Information Technology *Kenneth Saag* *University of Alabama at Birmingham*
3:25–3:45	Initiating a Culture Change Around Informed Consent *Michael Paasche-Orlow* *Boston University School of Medicine*
3:45–4:15	Discussion
4:15–5:00	Reflections on the Day (Roundtable members are each asked to identify one key point from the day's presentations.)
5:00–5:15	Participant Discussion
5:15	**ADJOURN**

Appendix B

Biographical Sketches of Workshop Speakers and Planning Committee Members[1]

Linda Aldoory, Ph.D., is Endowed Chair and Director of the Herschel S. Horowitz Center for Health Literacy and associate professor in behavioral and community health at the School of Public Health, University of Maryland, College Park. The center was created to advance the science of health literacy and to evaluate communication tools and messages used by government, media, and health care settings. Dr. Aldoory's research focuses on the role of health communication in improving health literacy. She is part of the recent Health Enterprise Zone grant awarded to Prince George's County, Maryland, and she received a grant from Atlantic General Hospital to develop a health literacy curriculum for Worcester County Public Schools in Maryland. Through her research, she has faced informed consent challenges with study participants who do not speak English, who have limited formal education, and who have low health literacy. Dr. Aldoory has designed culturally competent and simple messages to use during informed consent procedures. She has also completed several interview-based studies and has used expert panels for government reports. Her research is published in the top journals in her field, such as the *Journal of Health Communication* and *Health Communication*. Dr. Aldoory has worked in health communication for more than 20 years, specializing in campaigns and media messages for women of color and adolescents. She has consulted for the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the U.S. Department of Agriculture regarding health media and campaigns in food safety,

[1] Names appear in alphabetical order.

injury prevention, and teen health. Before joining the School of Public Health in 2011, Dr. Aldoory was associate professor in communication at the University of Maryland for 13 years. She also formerly worked for the Bronx Perinatal Consortium, a maternal child health organization in the Bronx, New York, and for the American Psychiatric Association in Washington, DC, in public affairs.

Alicia Fernandez, M.D., is a professor of clinical medicine at the University of California, San Francisco, and an attending physician in the General Medical Clinic and the medical wards at San Francisco General Hospital. Her research primarily focuses on health and health care disparities, and she is particularly interested in vulnerable populations, Latino health, immigrant health, and language barriers. In addition to her research and clinical practice at San Francisco General Hospital, she does a great deal of mentoring for students, residents, fellows, and faculty. She has received several honors and awards, including the Arnold P. Gold Professorship for Humanism in Medicine. She has served as an adviser to the Robert Wood Johnson Foundation, The California Endowment, the National Quality Forum, the Commonwealth Fund, the American Medical Association, the American Board of Internal Medicine, and other organizations on projects focused on health care disparities, Latino health, and limited English proficiency populations. She was a standing member of the Agency for Healthcare Research and Quality's (AHRQ's) Health Care Quality and Effectiveness study section (2006–2010) and is currently a member of National Institutes of Health's (NIH's) Health Services Organization and Delivery study section.

Sara Goldkind, M.D., M.A., is a bioethics consultant in research and clinical settings. Recently she left the FDA, where she served as the senior bioethicist for more than 10 years. In that position, she addressed ethical issues arising in cutting-edge research, such as informed consent processes; rare diseases; pregnant women; children; consent-impaired individuals; and emergency care. In addition, she is an active member of the Walter Reed National Military Medical Center's clinical ethics committee. Dr. Goldkind is a board-certified internist, having completed her internship and residency at Boston City Hospital and her M.D. from the University of Maryland School of Medicine. She was on the faculty at the University of South Florida School of Medicine, Department of Internal Medicine. She obtained an M.A. in religious studies with a concentration in comparative religious ethics and completed a fellowship in clinical ethics from the University of South Florida.

Lori Hall, R.N., is a health education consultant with Eli Lilly and Company and has nearly 30 years of health care experience, including direct

patient care and work in the diagnostics and pharmaceutical industries. Throughout her career, her focus has been in the areas of training and leadership development, adult learning, and coaching.

Lilly's Health Education Department develops and delivers nonbranded, nonpromotional, patient-focused education materials aligned with health literacy principles in the areas where Lilly has presence and expertise. Ms. Hall played an integral role in Lilly's entry in the Eleventh Annual Institute for Healthcare Advancement Health Literacy Awards, "Feel Your Best: Patient Education Brochures," which was selected as the winner in the Published Materials category, thus giving national recognition to the company's commitment to health literacy principles.

Ms. Hall is also spearheading an effort to raise corporate awareness on how better health communications help to improve patient adherence and, therefore, achieve better health outcomes. Through her work with a grassroots initiative of Lilly advocates from other major patient "touch points," health literacy pilot programs are being conducted in the areas of clinical trial management and informed consent, medical call centers, medical education grants, global patient safety, and consumer marketing. Each of these pilot programs aligns with the overall vision to help engage, educate, and empower patients to be more active in their own health care. Ms. Hall has a bachelor of science degree in nursing from Purdue University.

Laurie Myers, M.B.A., leads the health literacy strategy for Merck in the United States. In this role, she focuses on the integration of health literacy across the organization, including patient labeling, data transparency for clinical trials, and patient education. She represents Merck as part of the Walgreens/Northwestern/Alliance of Chicago partnership, measuring the impact of the Universal Medication Schedule on patient adherence and health. In May 2011, she led a breakout session at the Institute for Healthcare Advancement's Health Literacy conference regarding integrating health literacy into a large organization. Ms. Myers joined Merck in 1999 after receiving her M.B.A. in health care management from the Wharton School at the University of Pennsylvania and her B.A. in psychology from Yale University.

Michael Paasche-Orlow, M.D., M.A., M.P.H., is associate professor of medicine, Boston University School of Medicine. Dr. Paasche-Orlow is a general internist and a nationally recognized expert in the field of health literacy. Dr. Paasche-Orlow is currently a coinvestigator with five funded grants that examine health literacy, including two intervention studies evaluating simplified information technologies for behavior change among minority patients with a range of health literacy levels. Dr. Paasche-Orlow's work has brought attention to the role that health literacy plays in racial

and ethnic disparities, self-care for patients with chronic diseases, end-of life decision making, and the ethics of research with human subjects. Dr. Paasche-Orlow is the associate program director for the Boston University School of Medicine's General Internal Medicine Academic Post-Doctoral Fellowship Program and the associate section chief for research for the Section of General Internal Medicine in the Boston University School of Medicine's Department of Medicine.

Kim Parson joined Humana's Innovation Center in 2006 as part of the team that developed SmartSummary and SmartSummaryRx, the health care industry's first comprehensive and personal consumer-focused health benefits budgeting, planning, and reporting statements. These statements are a tool consumers can use to communicate with doctors and pharmacists about health care services they receive and medications they take. SmartSummary helps consumers understand plan benefits and better manage their costs. Proactive consumer messaging is designed to change consumer behavior and to improve clinical outcomes.

In her current role in the corporate Consumer Experience Center of Excellence, Ms. Parson is part of a collaborative effort to define the desired Humana consumer experience. She explores external partnership opportunities for joint consumer learning and identifies innovative technologies that improve processes, leading to transformed consumer experiences. Her team facilitates business area identification of the current consumer experience utilizing experience design processes based on human-centered design methodology. Ms. Parson designs and leads ideation workshops and futuring sessions using experiential learning to stimulate innovative thinking.

Her previous work to identify the holistic provider experience with Humana led to the identification of the financial impact of health literacy on consumers and payers, prompting Humana to create a team focused on health literacy efforts internally and externally. In her time at Humana, Ms. Parson also led the Provider Interface department, which is responsible for helping providers and Humana reduce administrative costs by increasing provider self-service.

During Ms. Parson's earlier career as a journalist with the Tribune Company, Knight Ridder, and Gannett, she led staffs at the *Orlando Sentinel* and the *Lexington Herald-Leader* that received numerous writing and design awards. A Society of News Design award winner herself, Ms. Parson served as a judge in the society's 28th international design competition. She earned bachelor's degrees in journalism and English and has done graduate studies in communications management at Western Kentucky University.

Sandra Crouse Quinn, Ph.D., is the associate dean for academic affairs, professor in the Department of Family Science, and senior associate direc-

tor of the Center for Health Equity at the School of Public Health, University of Maryland, College Park. She is the principal investigator (PI) (with S. Thomas) on a Center of Excellence on Race, Ethnicity and Health Disparities Research, funded by the National Institute for Minority Health and Health Disparities, NIH. Within that center, she is also the PI of a 4-year study, "Uncovering and Addressing Cultural Beliefs Behind Vaccine Racial Disparities." In addition, Dr. Quinn is currently the PI on a study titled "Investigating Factors Associated with Participation of Racial and Ethnic Minority Populations in FDA Regulated Research," funded by the FDA through the Maryland Center for Regulatory Science and Innovation.

Until the grant's completion in 2012, Dr. Quinn was the PI (with S. Thomas) on "Building Trust Between Minorities and Researchers: A Bioethics Research Infrastructure Initiative" (NIH Grand Opportunity grant) funded by the National Institute for Minority Health and Health Disparities and the Office of the Director, NIH. She was the co-PI on a 5-year Research Center of Excellence on Minority Health Disparities funded by the National Institute for Minority Health and Health Disparities, NIH. From 2008 to 2010, she was also the co-PI on a 5-year, CDC-funded Preparedness and Emergency Response Research Center, Public Health Adaptive Systems Studies (PHASYS) project, which focuses on public health systems' capacities to respond to disasters and emergencies. In the PHASYS Center, her specific focus was on risk communication and vulnerable populations. From 2009 to 2010, Dr. Quinn was the PI on a CDC-funded national study of public attitudes toward H1N1. From 2002 to 2005, she was the PI on a CDC-funded study on communication between postal workers and public health professionals during the 2001 anthrax attack. Finally, she was the site PI on a subcontract for the Mid-Atlantic Public Health Training Center, funded by the U.S. Health Resources and Services Administration (prime grantee: Johns Hopkins Bloomberg School of Public Health).

Her research interests include engagement of minority and marginalized communities in research; vaccine acceptance, attitudes, and communication; and risk communication in emergencies, disasters, and pandemics with a specific focus on minority populations and disparities. In recent years, Dr. Quinn has served as guest editor for several journals, including a 2013 theme issue on ethical issues on inclusion of minority populations in research in the *American Journal of Public Health*; a 2008 theme issue on emergency risk communication and pandemic influenza for the journal *Health Promotion Practice*; and a 2006 theme issue on health disparities in *Health Education and Behavior*. She has presented internationally on her research in Israel, Japan, the Netherlands, Portugal, South Africa, Thailand, and the United Kingdom. She co-led the development of an interactive educational website, www.buildingtrustumd.org, which focuses

on enabling minorities to become informed decision makers about participation in research.

Dr. Quinn was a 2006–2007 fellow in the Hedwig van Ameringen Executive Leadership in Academic Medicine Program for Women. She was also a Fulbright Senior Specialist at the Universidade de Fortaleza in Brazil in 2010.

Kenneth G. Saag, M.D., is the Jane Knight Lowe Professor of Medicine, Division of Clinical Immunology and Rheumatology, at the University of Alabama at Birmingham (UAB) in Birmingham, Alabama. Dr. Saag's primary research interests are in the epidemiology of osteoporosis and gout, methods to translate evidence into practice, and the design of large pragmatic trials in rheumatic disease. He is the founding director of AHRQ's Deep South Center for Education and Research on Therapeutics, established in May 1999. He is also director of the AHRQ-supported UAB T32 in Health Services Research and UAB K12 in Patient-Centered Outcomes Research, the UAB Center of Research Translation in Gout and Hyperuricemia, and codirector of the Multidisciplinary Clinical Research Center. He has received support from the National Institute of Arthritis and Musculoskeletal and Skin Diseases as a K24 recipient, allowing him to mentor more than 35 students, fellows, and junior faculty. He has published more than 220 peer-reviewed manuscripts and has also written more than 100 other materials, including reviews, editorials, books, and book chapters. Recently he published the first edition of the clinical handbook *Diagnosis and Management of Osteoporosis*.

Dr. Saag is on the American College of Rheumatology (ACR) Board of Directors, has been a leader in the development of the 2008 and 2011 ACR Recommendations on the Treatment of Rheumatoid Arthritis, and is a member of the ACR Council on Healthcare Economics. He received the ACR Rheumatology Research Foundation Excellence in Investigative Mentoring Award in 2013. He also serves as vice president on the Board of Trustees of the National Osteoporosis Foundation, is on the Board of Directors of the Gout and Uric Acid Society, and is a member of the National Committee for Quality Assurance Expert Panel, Osteoporosis Advisory Workgroup.

Yael Schenker, M.D., M.A.S., received her undergraduate degree in literature from Harvard University. She completed all of her medical training at the University of California, San Francisco, before joining the faculty of the University of Pittsburgh in 2010. She is currently an assistant professor in the Division of General Internal Medicine, Section of Palliative Care and Medical Ethics, and holds a secondary appointment in the Clinical and Translational Science Institute. She is also an affiliate faculty member in

the Center for Bioethics and Health Law, a member of the Biobehavioral Oncology Program at the University of Pittsburgh Cancer Center, and an associate faculty member of Clinical Research Modeling of Acute Illness in the Department of Critical Care Medicine. Dr. Schenker's research focuses on the integration of palliative care services in oncology, surrogate decision making, informed consent, and medical advertising. She has received funding from the National Palliative Care Research Center, the University of Pittsburgh Clinical Research Scholars program, and the National Cancer Institute. Dr. Schenker is also a practicing primary care physician and conducts palliative care consults at the University of Pittsburgh Medical Center.

Rebecca Sudore, M.D., is a geriatrician and a hospice and palliative care physician at the San Francisco VA Medical Center and an associate professor at the University of California, San Francisco. Dr. Sudore is a former K23 and VA Career Development Award recipient and VA–Robert Wood Johnson Physician Faculty Scholar. She has also been awarded a VA IIR and R01 through the NIH and a Patient-Centered Outcomes Research Institute (PCORI) grant to conduct research on improving advance care planning and medical decision making for diverse, vulnerable older adults with limited health literacy. She has designed and tested an informed consent process for patients with limited literacy and an advance directive that is both literacy and culturally appropriate. Her current research program is focused on creating and testing culturally and literacy appropriate tools to help patients engage in advance care planning. She developed a new paradigm of advance care planning that focuses on preparing diverse, older adults to communicate their evolving wishes over time and to make real-time, complex medical decisions over the course of chronic and advanced illness. She recently launched the PREPARE website (www.prepareforyourcare.org), which walks patients and their families through a step-by-step process to prepare for communication and medical decision making. The goal of this work is to better enable patients to engage in the advance care planning process and to make informed medical decisions at the end of life.

Jeremy Sugarman, M.D., M.P.H., M.A., is the Harvey M. Meyerhoff Professor of Bioethics and Medicine, professor of medicine, professor of health policy and management, and deputy director for medicine at the Berman Institute of Bioethics at Johns Hopkins University. He is an internationally recognized leader in the field of biomedical ethics with particular expertise in the application of empirical methods and evidence-based standards for the evaluation and analysis of bioethical issues. His contributions to both medical ethics and policy include his work on the ethics of informed consent, umbilical cord blood banking, stem cell research, international HIV prevention research, global health, and research oversight.

Dr. Sugarman is the author of more than 200 articles, reviews, and book chapters. He has also edited or coedited four books (*Beyond Consent: Seeking Justice in Research*; *Ethics of Research with Human Subjects: Selected Policies and Resources*; *Ethics in Primary Care*; and *Methods in Medical Ethics*). Dr. Sugarman is a contributing editor for *IRB* and is on the editorial boards of several academic journals.

Dr. Sugarman consults and speaks internationally on a range of issues related to bioethics. He has served as senior policy and research analyst for the White House Advisory Committee on Human Radiation Experiments, as consultant to the National Bioethics Advisory Commission, and as senior advisor to the Presidential Commission for the Study of Bioethical Issues. He also served on the Maryland Stem Cell Research Commission.

He was the founding director of the Trent Center for Bioethics, Humanities and History of Medicine at Duke University, where he was also a professor of medicine and philosophy. He is a faculty affiliate of the Kennedy Institute of Ethics at Georgetown University and an Academic Icon of the University of Malaya.

Dr. Sugarman currently serves on the Scientific and Research Advisory Board for the Canadian Blood Service, the Ethics and Public Policy Committee of the International Society for Stem Cell Research, and the Board of Directors of PRIM&R (Public Responsibility in Medicine and Research). He is cochair of the Johns Hopkins Institutional Stem Cell Research Oversight Committee. In addition, he is chair of the Ethics Working Group of the HIV Prevention Trials Network and is the ethics officer for the Resuscitation Outcomes Consortium.

Dr. Sugarman has been elected as a member of the American Society of Clinical Investigation, the Association of American Physicians, and the Institute of Medicine. He is a fellow of the American Association for the Advancement of Science, the American College of Physicians, and the Hastings Center.

Christopher Trudeau, J.D., is an associate professor at Thomas M. Cooley Law School. He teaches all forms of legal research, analysis, and writing, but he particularly enjoys teaching legal drafting. Professor Trudeau is a zealous advocate for plain language. He has focused much of his recent research on combating archaic, traditional language in law, health care, government, and business.

He recently published novel empirical research on the public's preference for plain language—"The Public Speaks: An Empirical Study of Legal Communication"—in volume 14 of *The Scribes Journal of Legal Writing* (2012). Professor Trudeau received a grant from Lexis/Nexis to conduct this research, the first U.S. study of its kind.

In addition to his research on plain language, Professor Trudeau is active in the Legal Writing Institute, Scribes (the American Society for Writers on Legal Subjects), and Clarity International (an international plain language organization). He has presented at numerous conferences for these organizations, and he has spoken on health literacy for the Institute of Healthcare Advancement, the FDA, and other health care organizations.

Appendix C

Best Practices and New Models of Health Literacy for Informed Consent: Review of the Impact of Informed Consent Regulations on Health-Literate Communications

Linda Aldoory, Ph.D., Endowed Director and Chair
Herschel S. Horowitz Center for Health Literacy
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Contents

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We would like to thank Luz Mahecha, graduate student in the Department of Behavioral and Community Health at the University of Maryland, College Park, who worked long hours collecting research articles, government reports, and other literature for this paper. Her organizing and data entry skills were the cornerstone of this project, which was based on the hundreds of resources Mahecha found, read, and sorted for the databases.

INTRODUCTION AND EXECUTIVE SUMMARY

> "Informed (But Uneducated) Consent" (Ingelfinger [editorial], *New England Journal of Medicine*, 1972)
>
> "How Informed Is Informed Consent?" (Howard and DeMets, *Controlled Clinical Trials*, 1981)
>
> "Informed Consent: Is It a Myth?" (Herz, Looman, and Lewis, *Neurosurgery,* 1992)
>
> "Consent Documents for Oncology Trials: Does Anybody Read These Things?" (Sharp, *American Journal of Clinical Oncology*, 2004)
>
> "Improving the Quality of Informed Consent: It Is Not All about the Risks" (Fernandez [editorial], *Annals of Internal Medicine*, 2010)

For decades, authors have debated and tested the value of informed consent for people considering clinical trials and preparing for surgery or diagnostic procedures. The body of knowledge has become massive and includes randomized control trials, essays, websites, and computerized presentations. Across much of this literature, authors have struggled with creating better communication for informed consent within the constraints of federal regulations that interfere with the use of plain language and other health-literate practices. Individuals with limited health literacy are less likely to understand terminology, risks, and benefits as described in traditional informed consent documents (Donovan-Kicken et al., 2012). In

fact, studies have shown that most people, regardless of literacy level, are unable to recall or understand the information presented to them during an informed consent process (Cordasco, 2013). As a result, individuals are more likely to give uninformed consent, to refuse beneficial medical treatments, and to prematurely drop out of clinical trials (Davis et al., 2002). Studies have examined how to improve the format and content of informed consent documents to address low health literacy and improve patient understanding while abiding by requirements for information mandated by the U.S. Department of Health and Human Services (HHS).

There is an abundance of helpful advice already published to address health literacy in informed consent; what can a commissioned paper for the Institute of Medicine possibly add? First, we find support across the most recent research and expertise for a set of best practices and lessons learned. Second, we identify significant gaps in the recent literature to create a future research agenda. Finally, we share two visual models we developed to help explain health-literate informed consent.

We collected, filtered, and analyzed more than 120 research studies, government reports, videos, toolkits, and presentations and then interviewed eight experts in informed consent. This report summarizes themes found in the literature review and lessons learned from interviewees and then lists best practice suggestions. In summary, the research emphasized written communication and recommended reducing complex and confusing wording of documents. A combination of written, verbal, and some multimedia formats was generally more effective in adhering to federal requirements while gaining participant understanding. In emergency settings and with low literacy, greater comprehension resulted from verbal exchanges with someone to ask questions and take as much time as needed. Relying on multimedia formats and computerized interactivity showed promise among certain populations, such as highly educated and younger participants. Helpful toolkits have been produced that offer a universal precautions approach to simplifying informed consent documents while adhering to federal mandates. These toolkits include templates for health-literate forms and are described in this paper and listed in the bibliography. In other research, however, the level of risk in a study emerged as an important situational factor in deciding how comprehensive and complex the informed consent procedures might need to be.

As in the United States, international research is testing standardization of formats and messages for low literate audiences and studying the role of technology in improving patient understanding. These complexities across different countries, cultures, medical institutions, and research practices have fostered hundreds of studies. The European Union and countries outside the European Union currently espouse different guidelines and cultural norms that influence informed consent, making it challenging to find

standardized best practices. According to Matiasek and Wynia (2008), "In countries where autonomy and shared decision making are less prevalent models of care, clinicians might rarely solicit patient . . . opinions, and patients might have experienced few opportunities to make choices about the care they receive" (p. 135). They add that in some countries where lawsuits are not pervasive, researchers may not present patients with a standard list of potential risks. The varied nature of international regulations and cultural norms makes it impossible to suggest global, health-literate improvements. Nevertheless, certain patterns of behaviors can be normalized, such as valuing the informed consent process, empowering the participants to make decisions on their behalf, and simplifying written documents to be at a lower grade level. For this paper, however, given the specificity of the U.S. regulations as well as national norms for medical and scientific procedures, we analyzed only U.S.-based communication practices.

After winnowing down the literature found and synthesizing best practices with expert input from interviewees, we identified gaps in the recent body of knowledge. The gaps were significant and pointed to five key areas of health literacy and communication. First, there were few models that described and visualized the sequential steps required for health-literate informed consent and when to do what to improve comprehension and decision making. Second, limited work has been done on the role and impact of situational yet critical factors, such as risk and literacy levels, on informed consent communication and content. Third, empirical research is lacking to confirm the benefits of new technology and multimedia formats on informed consent. The findings are mixed as to the effect of interactive communication modules. Fourth, little research has focused on low-health-literate populations and health literacy disparities in informed consent outcomes. Finally, there is a dearth of research on communicating informed consent in community-based research. A couple of interviewees expressed frustration over the lack of guidelines and toolkits for health-literate community-based work.

Once research gaps were identified, we conceptualized two models explaining the current status of health-literate informed consent. One model is a step-by-step path for what to do and when to do it. A second model is a situational assessment of what content to use in informed consent depending on contextual factors, such as risk level. The two models are described in more detail in the Discussion and Conclusion section of this paper and are shown in Appendixes C-A and C-B.

The implications of this paper are threefold. First, the accounting of recent research and expert perspectives updates as well as confirms some unifying best practices and principles for health-literate informed consent. Second, by reviewing recent literature, gaps in the body of knowledge from the last decade became visible, and we were able to develop a future

research agenda to help close these gaps. Finally, we developed two prototype models for use in future testing and debate over what makes health-literate informed consent that is framed within federal regulations.

Methods for Data Collection

Two procedures were conducted to gather data relevant for the paper: a literature review and interviews with individuals experienced with alternative approaches for informed consent. Each procedure is described here, with findings from each separated and summarized in later sections.

Phase 1: Literature Review

Phase 1 was a systematic collection and review of research, government reports, and Web-based information focused on informed consent and health literacy. The following search engines were used: Medline, HealthSource, and PubMed databases, plus Communication and Mass Media Complete, ERIC, PsycInfo, and Academic Search Premiere from EPSCO. We generated a list of inclusion and exclusion criteria for the search. Below are listed the criteria used to guide the collection of information:

- Study populations: Included were all adults over age 18 from all races, ethnicities, sexes, and other culturally defined groups.
- Time period: Literature published or presented since 2004 (including 2004). The most recent literature was our priority in order to home in quickly on the role of health literacy in informed consent and on best practices for health-literate informed consent.
- Location of study site: Limited to the United States and its territories. There is federal specificity to informed consent guidelines and procedures, along with cultural norms and societal values governing informed consent expectations. Lidz (2006) stated that informed consent is framed in ways that honor a central value in the United States, that of individual autonomy. With respect to U.S.-bound federal regulations and best practices within those regulations, the review of literature was limited to this country.
- Publication language: English language only.
- Search term: The term *health literacy* was searched so that health literacy would be included as an aim, as a mediator, or as a moderating factor in the literature collected. Although there were a few articles specifically centering on health literacy as a main variable (e.g., Donovan-Kicken et al., 2012; Hammil et al., 2011; Lorenzen et al., 2008; Miller et al., 2011), several articles were related to health literacy and were included in the collection. These other

articles focused on readability of forms, literacy level of participants, comprehension factors among participants, and research on media and communication modalities.

We originally collected more than 120 published research articles, book chapters, government reports, nongovernmental white papers, and other documents. Hundreds of resources discuss implications and evaluations of informed consent for various medical conditions and procedures, but we filtered this literature to include those specifically pertinent to a paper on health literacy and informed consent. The pertinent literature fell into a wide variety of types of documents. In addition to the scholarly journal articles and government reports, the search also turned up the following:

- Toolkits were found online that were specifically focused on how informed consent can be conducted to address low-health-literate populations of patients. These were primarily found on websites of teaching hospitals, nonprofit organizations, and federal and state agencies. For example, Temple University's health system, Temple Health, hosts a comprehensive toolkit on informed consent and health literacy; it is available at http://www.templehealth.org/ICTOOLKIT/html/ictoolkitpage1.html.
- There are presentations and supplemental materials for trainings in health literacy and informed consent for patients undergoing surgery or medical treatments. These were typically produced by medical schools, nonprofit organizations, and federal agencies. For example, the Dartmouth Medical School has a training presentation that is accessible online titled *Effective Patient Communication: Informed Consent*. It is available at http://www.slideshare.net/pickerins/informed-consent-final-with-video-link.
- Videos of presentations and lectures exist that are focused on health literacy and informed consent. In particular, the Institute of Medicine's workshops and presentations on informed consent and health literacy in clinical trials can be found online at http://www.youtube.com/watch?v=S36nnF9sVLk.
- Paid online and technological vendor services are also available. Companies have created online and electronic informed consent procedures, some originally geared for pharmaceutical controlled trials but now broadened to offer lessons on improving communication for patient decision making. iMedConsent, for example, is a Web-based application for conducting informed consent online. Mytrus (2014) offers a product called Enroll, another Web-based informed consent and patient enrollment system for clinical trials. It is available at https://www.mytrus.com/en.

We reviewed all of these to ensure that we highlighted a fair range of best practices and alternative informed consent forms and procedures. As the literature was being reviewed, first by one reviewer, and then by two others for verification to include in the analysis, the redundancy in topics and best practices became apparent; we quickly reached a saturation point of new best practices.

Phase 2: Expert Interviews

Phase 2 involved interviews with experts who could speak about best practices and specific case examples of health-literate informed consent approaches. Originally, we invited 10 individuals to be interviewed, but two prospective participants were unable to schedule an interview in the time frame allotted. The eight participants included an institutional review board (IRB) chair, scholars known for their work on informed consent, and researchers who have created alternative health-literate informed consent processes. The original list of invited experts was derived from two sources: (1) the literature collected where experts were cited frequently and offered best practices; and (2) experiences by authors with researchers and other professionals who successfully used alternative informed consent processes. After this purposive and convenience sampling, we used snowball sampling to obtain other names of prospective interviewees; some of the interviewees were recommended by other interviewees. Interviews lasted between 20 minutes to 1 hour; some were in person at the interviewees' worksite, and others were done by phone if the interviewees were not within a short traveling distance. The interviews were audio recorded in order to capture details to be reviewed later, and notes were taken during the interview sessions.

An interview guide was developed with open-ended questions that asked about health literacy and informed consent. Questions addressed perceptions about informed consent, applicability of federal guidelines, challenges experienced with the process and forms, and examples and resources that would be helpful in increasing the health literacy of the informed consent process. See Appendix C-D for the interview guide.

Interview notes were combined and coded for common responses across topics. The topics analyzed and relevant for this paper were as follows:

- Perceptions of applicability of federal guidelines,
- Challenges faced in completing informed consent,
- Lessons learned about informed consent, and
- Suggestions for best practices and helpful resources to improve informed consent among low-health-literate participants.

Once the process of analyzing interviews and coding by topic was completed, an independent reviewer read through the interview notes and codes to verify similar analyses and links between codes and topics. Once the codes were verified, a summary by topic was drafted and included in this paper.

A SUMMARY OF FEDERAL GUIDELINES

The main sources for guidelines on informed consent were the HHS (45 CFR 46.116), and the FDA (21 CFR 50.25). The HHS informed consent guidelines source is Section 46.116, "General Requirements for Informed Consent," found in Part 46, "Protection of Human Subjects," of the *Code of Federal Regulations* (HHS, 2009) (see Appendix C-E). The regulations explain that the informed consent process comprises three elements: (1) disseminating information to inform the individual, (2) ensuring that decisions are voluntary, and (3) facilitating comprehension of the information conveyed to the individual (HHS, 2009). The FDA informed consent guidelines are found in 21 CFR Section 50.25, "Elements of Informed Consent" of Part 50, "Protection of Human Subjects" (FDA, 2014).

Requirements state that the informed consent process must include information on the fact that a study involves research, and it must explain the purpose of the study, provide explanations of procedures, and describe which of them are experimental. In addition, the information must outline benefits and possible risks, list confidentiality measures, and provide a name of a contact for information. A statement should be included that explains that the FDA may access certain documents. The informed consent process must convey voluntariness of the participant and include an explanation about having the right to refuse or discontinue participation at any time (FDA, 2014). When applicable, informed consent must also describe alternative treatments that might benefit the individual, whether compensation or special accommodations will be made in case of related injury, and contact information for whom to reach.

The regulations cite optional information when necessary. Informed consent should include possible future risks to an unborn baby in the case of pregnancy, costs that may appear as a result of participation in a clinical trial, and the promise that if study findings influence desire to participate in research, these findings will be shared with participants (FDA, 2014).

There are exceptions to the informed consent requirements, outlined in Section 50.23 of the FDA guidelines. Exceptions can include life-threatening emergency situations, lack of time to receive consent from a legal representative, and circumstances in which there is no alternative treatment or method to address a life-threatening situation.

Consent from participants does not have to be in a written format.

Consent can be received verbally as well. In addition, short forms are allowed in the informed consent process as long as the process includes the required elements.

The FDA guidelines include suggestions for constructing consent materials for low health literacy. One main recommendation is to ensure that the reading level for documents does not exceed the eighth-grade level. Other recommendations involve word choice, pronoun usage, and terminology. For example, the FDA recommends writing consent documents that mirror oral conversations between the investigator and the participant. Thus the use of the pronouns *you*, *I*, and *we* is encouraged. The following explains the reason for this pronoun usage:

> This second person writing style also helps to communicate that there is a choice to be made by the prospective subject. Use of first person may be interpreted as presumption of subject consent, meaning the subject has no choice. Also, the tone of the first person "I understand" style seems to misplace emphasis on legal statements rather than on explanatory wording enhancing the subject's comprehension. (FDA, 2014)

The federal government offers several resources for constructing readable consent documents and for improving the informed consent process while incorporating the federal guidelines. In addition to HHS recommendations for word usage and grade level of documents, the National Institutes of Health (NIH) has prepared a compendium of resource links and toolkits addressing different stages in the informed consent process (NIH, 2007). Also, the Agency for Healthcare Research and Quality (AHRQ) has developed a toolkit to facilitate the process of obtaining informed consent in minimal risk settings (AHRQ, 2009). According to AHRQ, the toolkit "is consistent with the regulations for obtaining and documenting informed consent for participation in minimal risk research and authorization for use of protected health information as required under HIPAA" (2009, p. 1). Included in the toolkit is a recommended process for improving informed consent, a checklist for covering all the information with participants, and sample consent forms. Appendix C-F has a copy of AHRQ's Sample Informed Consent Form.

FINDINGS FROM THE LITERATURE REVIEW

The body of literature on informed consent and health literacy mainly fell within two domains or major areas for informed consent. First, 57 percent of the published studies and reports examined patient-based informed consent for surgery, medical treatments, and diagnostic screenings. Second, 36 percent of the literature tested informed consent within the setting of

clinical trials, particularly for pharmaceutical trials. A handful of studies and reports, about 7 percent of the total, addressed community-based research or IRB processes in general or were systematic reviews of research (Albala et al., 2010; Wee et al., 2009). One recent article studied advanced directives (Sudore et al., 2006). More than half of the collected articles were published since 2010. When analyzing this literature for communication challenges, impact on patient understanding, and best practices, the findings are not distinguishable by domain of informed consent. In other words, with few exceptions informed consent for clinical research, medical treatment, and diagnostics offer similar best practices for health-literate communication. This is likely due to similar attempts at adhering to the same federal guidelines for protection of human subjects. The summary below is thus organized by best practices for health literacy before, during, and after enacting informed consent procedures. First, however, we define the terms "informed consent" and "health literacy" and describe the overall trend across the literature.

Informed Consent Defined

About one-quarter of the documents offered a formal definition of informed consent, which was constructed out of either the legal context or the provider-patient relationship. For example, Marco (2008) stated, "The doctrine of informed consent is a fundamental principle of the U.S. legal system, introduced by case law in 1957. . . . Informed consent and refusal of treatment are recognized as significant legal and ethical rights of patients" (p. 269). Matiasek and Wynia (2008) defined informed consent as the "willing and uncoerced acceptance of a medical intervention by a patient after adequate disclosure . . . of the nature of the intervention, its risk and benefits, as well as of alternatives with their risks and benefits" (p. 127). Informed consent is viewed as valid in clinical trials if a participant understands the following: study purpose, study protocol, risks, benefits to self, benefit to others, freedom to withdraw, alternatives, duration of study, voluntariness, confidentiality, and whom to contact (Tait et al., 2005). Hammil et al. (2011) summarized successful informed consent as including five principles: voluntarism, capacity, disclosure, understanding, and decision making. In the communication discipline, informed consent has been characterized as "a complex exchange of information between professionals and patients that occurs through both interpersonal and mediated communication," where the process is only meaningful "to the extent that communication is complete, transparent, and effective" (Donovan-Kicken et al., 2012).

Health Literacy Defined

In most cases, the literature did not define health literacy. However, a few articles that had health literacy as a central factor defined it by referring to the definition of the Institute of Medicine and *Healthy People 2020*: the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions (Hammil et al., 2011; Lorenzen et al., 2008).

Overall Trend Across the Literature

Overall, the literature reflected the following trends in health sciences research and health care practice in this country: (1) in medical and surgical procedures, more patient-centered approaches for informed consent; (2) in clinical trials, increasingly empowered and active decision making for participants; and (3) across domains for informed consent, increased use of technology to streamline the informed consent process and improve patient understanding. As authors have shown, traditional consent forms have been intended primarily for the providers' legal protection, so the forms are swathed in complex medical and legal terminology and often written above the eighth-grade reading level (Brink, 2012; Lidz, 2006; Lorenzen et al., 2008; Matiasek and Wynia, 2008; Paasche-Orlow et al., 2003). Informed consent literature over the last four decades has consistently been testing and improving forms and content to increase patient comprehension of clinical trials and medical procedures; however, authors today emphasize technological advances that might enhance patient control and active decision making, Much of the recent research frames the desired outcome of the informed consent process as *meaningful* consent and not just informed consent of a medical procedure or clinical trial (Goske and Bulas, 2009; Lidz, 2006; Matiasek and Wynia, 2008; Sugarman and Paasche-Orlow, 2006). Brink (2012), for example, developed a framework for "a patient-centric approach to the consent process" (p. 36) that included patient knowledge, patient values and preferences, and patients' everyday lives. Some of the literature focused on the context, format, and structure of informed consent, and other research tested effects of verbal, written, and multimedia messages on patient understanding. Findings for best practices were pulled together, and each best practice is summarized below; within each best practice, we included information on the challenges to developing this practice and the effects on patient understanding. The best practices are organized in sequential order: before, during, and after informed consent takes place.

Before: Preparation for Informed Consent

Know Your Setting

Researchers have suggested that the setting for informed consent has influenced participant comprehension and satisfaction (Fink et al., 2010; Schenker et al., 2011; Wee et al., 2009). Health-literate informed consent resulted in patients feeling more comfortable and created an environment that allowed for more dialogue with providers (Miller et al., 2011).

Providing participants with sufficient time for interpreting and completing informed consent forms can help increase satisfaction as well as comprehension and compliance (Fink et al., 2010; Griffin et al., 2006; Lorenzen et al., 2008). Having more time not only encourages questions but also allows time for the patient and patient's family to understand the information being given and allows time for "repeat back" (Lorenzen et al., 2008). Schenker and Meisel (2011) stated that completing forms before arriving for a procedure or appointment might keep participants from feeling rushed or pressured to sign the informed consent forms without expressing their questions or concerns. The authors wrote, "If patients are expected to engage in informed consent as a meaningful process of shared decision making, they must be given time for contemplation before having to decide" (p. 1131). Hammil et al. (2011) and others further argued that there should be a short time span between the informed consent process and the actual procedure being done (Fink et al., 2010; NQF, 2005b). Fink et al. (2010) posited that "comprehension was maximized when the informed consent discussion was undertaken for 15 to 30 minutes."

Know the Risks

Studies on the informed consent process illustrated the primary need for practitioners and investigators to know the study's protocol and the weight of its risks and benefits in order to convey the risk level to participants (NQF, 2005a). The result of having the staff or others conduct informed consent without this knowledge may lead to an informed consent process with a greater burden of time and effort than the study itself. Sometimes attempts at standardizing informed consent produce this imbalance. Sugarman and Paasche-Orlow (2006) claimed in an editorial, "While the methods of standardizing informed consent and ensuring comprehension . . . are important, it is unclear whether such 'big guns' should be used for minimal risk research" (p. 898). These authors suggested that the time to do an in-depth and comprehensive procedure for informed consent is when the research in question "poses clear psychosocial, economic, or physical risk to participants" (p. 898). Similarly, authors of a systematic review of

research on weight loss surgery suggested providing realistic risk estimates that consider patient characteristics and health provider characteristics, such as experience, that may affect level of risk (Wee et al., 2009). Volker (2005) suggested that level of risk should influence the type of format used to communicate informed consent. In his pilot study of a high-risk research context, interactive video on mobile tablets increased patient knowledge and compliance.

Goske and Bulas (2009) presented a model of informed decision making that they claimed uses individual risk estimates and provides participants with a context of everyday relevancy. The approach suggests using several different formats and examples that coincide with different participants' preferences and backgrounds. These authors have claimed that different health problems and medical treatments contextualize the informed consent materials and should guide how the materials are formatted and written.

Know Your Staff and Their Level of Expertise

The literature revealed several aspects of the complexities of informed consent that mandate the need for well-trained staff. In particular, in clinical trials and medical procedures with high risk, authors recommend specially trained communicators (Fernandez, 2010). Lorenzen et al. (2008) recommended training staff on the importance of the informed consent process and on health-literate approaches to informed consent. Authors outlined four steps for staff:

- 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,
- Updating staff education annually, and
- Designing a health literacy program for physicians.

Other authors have suggested that the person who conducts the consent procedures be different from the researcher responsible for the study outcomes (Sugarman and Paasche-Orlow, 2006). These authors argue that the researcher has a stake in the successful enrollment and retention of participants in the study, and thus, in order to ensure a focus on health literacy and participant comprehension regardless of the outcome goals of the study, the roles should be separated.

Know Your Participants

Some authors studied the importance of understanding cultural and other differences that may influence how participants comprehend informed consent (Fink et al., 2010; Wee et al., 2009). Studies have shown that, depending on cultural and social norms as well as prior experiences with the health care field, participants may misconstrue the rationale behind informed consent or assume that other family members should be part of their decision making (Matiasek and Wynia, 2008). One of the simpler recommendations offered for handling cultural and language differences among participants was to translate informed consent forms into languages prevalent in the targeted participant communities (Matiasek and Wynia, 2008). However, as Matiasek and Wynia (2008) argued, "even with translated forms, patients will need opportunities to discuss the information on the forms and ask questions" (p. 135). Some participants may assume they can invite a friend or family member to accompany him or her to the informed consent discussion, and researchers have found this tactic to increase comfort level and interpretation of risks (Hammil et al., 2011).

Disparities in Health Literacy

Some of the literature addressed disparities in health literacy that certain vulnerable populations have that leads to more problems with informed consent. Groups that have been given greater attention in research have been non-English speakers, Spanish speakers, African Americans, and those with low levels of formal education (Brice et al., 2008; Clark et al., 2011; Cordasco, 2013; Cortes et al., 2010; Fink et al., 2010; Griffin et al., 2006). Fink et al. (2010) found that patients' race, education, and age predicted the level of comprehension in medical consent, whereas gender, literacy, and marital status did not influence comprehension level. Another study found that individuals with a high school reading level were over four times more likely to comprehend information given than individuals with a third-grade reading level or lower (Kripalani et al., 2008). A review of the literature from 1966 to 2011 found very limited research on how to improve informed consent for low-literacy populations. Only six research studies met authors' criteria, and evidence showed that teach-back and other verbal interactions were the most effective type of communication for less literate participants. Authors concluded that difficulty and risk differences across studies might have served as a confounder in their evaluation (Tamariz et al., 2013).

Nonnative speakers of the English language have significant difficulty understanding informed consent in this country (George et al., 2013; Schenker et al., 2007; Sudore et al., 2006). Cordasco (2013) reviewed

research that cited significant differences between patients with limited English proficiency and native English speakers. Creating a comfortable environment that invites the former group to express their questions and concerns is of particular importance because they often fail to share their low level of literacy and may be embarrassed to ask questions throughout the process (Sudore et al., 2006; Wee et al., 2009).

Within the limited literature on health literacy disparities, suggestions were made to improve informed consent. Some authors suggested that the teach-to-goal method be used to help reduce disparity (Sudore et al., 2006). Other practices, such as the use of multimedia, animation, and visual images, were found to be beneficial tools for increasing knowledge of the study, meaningful dialogue, and number of questions (Brice et al., 2008; Cortes et al., 2010; George et al., 2013). Some researchers found that an additional class, such as one on endoscopy in this particular case, increased comprehension in non-English speakers and individuals with a low educational background (Clark et al., 2011; Siao et al., 2014). Siao et al. (2014) indicated that the multilingual class increased patients' recall of facts about the screening and the understanding that they could refuse the procedure. Prearranging verbal translations of information also addressed gaps for non-English speakers (Brice et al., 2008). Schenker et al. (2007) posited that "for patients who do not speak English, additional time and effort may be required to find a consent form in the patient's primary language, obtain the services of an interpreter, and ensure adequate understanding." Other studies mentioned putting the informed consent form in the language of participants (Cortes et al., 2010; Matiasek and Wynia, 2008; NQF, 2005a). An article that focused on Spanish speakers with low health literacy in clinical trials demonstrated the importance of additional training for researchers to increase their ability to effectively interact with this group to ensure that particular information needs are met (Cortes et al., 2010). Fink et al. (2010) found that additional time for the consent process can improve comprehension of low-literacy populations.

During: Communication and Informed Consent Documents

The majority of studies compared the effects of the type of format—written, verbal, multimedia, or combination—on participant comprehension and satisfaction. In summary, findings show mixed results (McCarthy et al., 2012). One of the more significant trends found in the literature of the last decade is the exploration of alternative technologies for informed consent (Brink, 2006, 2012). As Brink (2012) argued, for clinical trials "the informed consent process has yet to make significant use of electronic technologies after initial recruitment, remaining firmly focused on a paper consent document" (p. 36). However, researchers are experimenting with

multimedia presentations to impart study information and with digital and online systems to conduct informed consent. For much of the work, verbal formats were more favored for low-literacy audiences, and multimedia programs sometimes improved patient comprehension, especially about the knowledge and risks of the study (Schenker et al., 2011). However, Marco (2008) found that written was as good as verbal if simplistic and graphical, and Tait et al. (2005) found that written documents that complied with federal guidelines for readability and processability improved participant comprehension. Flory and Emanuel (2004) found little effect from multimedia formats. Authors have claimed that the differences in findings could be the result of the type of informed consent being addressed, such as surgical versus community-based survey research, where personal risks are low (Schenker et al., 2011).

Written Communication

The literature is consistent in citing problems with the written format and messaging used in consent forms and other documents related to the informed consent process. Authors have indicated that common problems across clinical trials, medical treatment, and community research studies vetted through IRBs include consent forms that are too long, have complex terminology, and have high reading levels (Albala et al., 2010; Brink, 2012; Donovan-Kicken et al., 2012; Lorenzen et al., 2008). These problems are ongoing despite several attempts at improvement by individual researchers and health care systems (Albala et al., 2010; Schenker et al., 2011). In fact, Albala and colleagues (2012) found that the length of consent forms increased over time, from 1978 to 2002.

The literature includes several studies comparing the effects of different content length, readability, and visual cues to be used during informed consent to increase the likelihood of comprehension among low-literacy audiences. The length of the informed consent form has been found to be negatively associated with comprehension and retention (Denzen et al., 2012; Sharp, 2004). Sharp (2004) found that consent forms longer than 1,000 words are unlikely to be read. Others recommended using bulleted lists as opposed to long sentences and dividing text into subheadings (AHRQ, 2009; Denzen et al., 2012). Another study found that prioritizing the most important pieces of informed consent at the start and end of a slide-show presentation improved retention of vital information (Carr et al., 2012). Denzen et al. (2012) suggested five key elements in developing easy-to-read informed consent forms: organization, layout, typography, plain language, and avoiding the use of stylized initial letters or all capitals. Other studies recommended including a brief introductory summary that explains

what it means to participate in a research study and why the informed consent process is important in research (Cortes et al., 2010; Marco, 2008).

Although less a main goal of the research published in the last few years, readability assessments remain part of the literature on consent documents, as is how to improve consent documents for persons with low health literacy (Cordasco, 2013; Denzen et al., 2012; Fernandez, 2010; Lorenzen et al., 2008). The consensus in the literature is to adhere to the federal guideline of forms written at the eighth-grade reading level or lower (Denzen et al., 2012). Some research found better results with forms lowered to the sixth-grade reading level (Donovan-Kicken et al., 2013; Hammil et al., 2011; Windle, 2008).

In summary, authors found that reducing the reading level, simplifying terminology, and shortening the length of forms increased the number of patients reading the consent forms and their ability to describe procedures in their own words (Cordasco, 2013; Lorenzen et al., 2008). Although there was no difference in the number of patients signing consent forms, Lorenzen et al. (2008) found that comprehension and active, meaningful consent increased significantly with simpler, easier-to-read forms.

Verbal Communication

Most of the literature focuses on written communication because informed consent documents are the primary means by which individuals are reaching their decisions to participate in trials, medical treatments, and screenings. Also, according to some authors, the research in health literacy has focused on print, with limited work conducted on oral literacy (McCarthy et al., 2012). Yet, patients often rely on spoken communication with providers and researchers to vet questions, comments, or other verbal feedback (McCarthy et al., 2012). The Oral Literacy Demand framework was suggested in the McCarthy et al. (2012) study as a useful guide to improving the verbal portion of informed consent among low-health-literate participants. The framework includes three factors: technical term use, general language complexity (such as grade level or passive voice), and structural dialogue characteristics, such as pacing, density, and interactivity. Researchers found that the Oral Literacy Demand metrics were useful in analyzing verbal communication for informed consent and that resident physicians' discussions with patients were characterized by their verbal dominance and complex terminology.

Other tactics for verbal communication include speaking slowly and using plain language (Dawson, 2006). Also, some scholars suggest repeating information, particularly problematic gaps for the individual, until full comprehension is reached (Sudore et al., 2006; Wee et al., 2009). In this test of the teaching-to-goal process, investigators repeated the informed

consent information along with participants until the participant correctly answered questions about the study (Sudore et al., 2006). Verbal interactions facilitate trust and improve comprehension (Miller et al., 2011; Tait et al., 2005). One study, however, found that verbal interactions in addition to a slide show and a readable format showed little improvement in comprehension (Carr et al., 2012).

Multimedia Formats for Informed Consent

Multimedia techniques have been found to have some mixed results, depending on literacy level, health problem being addressed, and type of medium. In several studies, video and computer formats have been shown to improve understanding and decision making among low-literacy participants and have resulted in perceived control by other participants (Brink, 2006, 2012; Campbell et al., 2004; Cowan et al., 2007; Harmell et al., 2012; Rossi et al., 2005; Wanzer et al., 2010). Research indicated that the use of electronic programs promoted consistency, provided an audit trail and documentation, improved recruitment rates, decreased patient anxiety, and improved comprehension (Brink, 2012; Harmell et al., 2012).

Harmell and colleagues (2012) found that among patients with schizophrenia, Web-based consent documents increased comprehension and satisfaction with a clinical trial. Brink (2012) argued that the availability of electronic media makes it worthy of testing for better informed consent, because the media combines sound, still pictures, video, and text. Brink's (2012) article includes a chart outlining the advantages and disadvantages of using computers, telephones, televisions, or stand-alone kiosks in the informed consent process. Schenker and Meisel (2011) encouraged the use of interactive technology to keep costs down and "reduce variation in the quality of informed consent across institutions."

Bickmore and colleagues (2009) tested the use of a computerized avatar for information delivery and found that the animated computer agent was more successful in getting participants to understand and sign consent forms than a human agent. Participants with limited literacy, however, did poorly on comprehension across treatment conditions. According to Bickmore and colleagues (2009), "The low comprehension scores for participants with inadequate health literacy indicate that much work remains to make the computer agent effective for this population" (p. 319).

Although findings are relatively promising on the use of multimedia (Bickmore et al., 2009; Brink, 2012; George et al., 2013; Harmell et al., 2012), some sources discouraged a radical move away from print and face-to-face formats (Flory, 2004; Synnot et al., 2014). For example, research has shown that patients in the emergency department, who may have less cognitive ability to understand informed consent in general, may

have corresponding trouble with multimedia formats (Cowan et al., 2007). Campbell and colleagues (2004) found that video and computer formats did not consistently result in improvements in comprehension over simplified print materials. Other studies found that video-enhanced consent materials made little difference in patient understanding compared to print forms (Flory and Emanuel, 2004; Sonne et al., 2013). Sonne and colleagues (2013) found that more-educated participants preferred the video to print, and the video version was lengthier than the print version. Although Harmell and colleagues (2012) supported the use of multimedia, they considered that low-literate patients might have relatively low computer experience, and therefore computer-generated resources might not prove to be beneficial. In addition, the Web-based approach was lengthier than the traditional written informed consent form. Other researchers similarly questioned large impacts of multimedia resources on informed consent (Clark et al., 2011; Synnot et al., 2014). Some of the fears of using multimedia are that it would replace verbal discussion and provide more detail than patients want regarding their illness (Hall et al., 2012; Matiasek and Wynia, 2008; Rossi el al., 2005).

Some researchers have suggested that, in the absence of solid evidence, which format to use should depend on the aspects of the risk, the setting, and the staff (Schenker et al., 2011; Volker, 2005). Schenker and colleagues (2011) argued that teach-back procedures and simplified written consent forms may be easy ways to improve understanding without significant alterations in time and staff skill.

Online Systems

For online or digital systems that supplant on-site procedures, research has indicated some promising results. Hall and colleagues (2012) found that iMedConsent, an online informed consent process, increased patient comprehension of procedure-specific risks and benefits. It also increased participant engagement in the decision-making process. However, the system provided more information than desired by patients. Other paid interactive computer programs, such as Enroll by Mytrus, provide information that attempts to be tailored to the individuals' specific cultural background and literacy needs (Mytrus, 2014). On its website, the company defines the product's role in informed consent:

> While clinical research has been significantly impacted by technology such as electronic data capture systems, clinical trial management systems, and other automation tools that make the clinical trial process more efficient, a gap has emerged as the informed consent step has remained a highly inefficient paper process that leaves many patients feeling more confused

than informed and many sponsors feeling left in the dark as to what is happening at trial sites.

Researchers such as Saag and his colleagues (Mudano et al., 2013) are studying Enroll for its impact on effective patient screening and informed consent regarding orthopedic treatment.

Supplementary Visual Aids

Images, decision aids, and charts are recommended for further explaining information (AHRQ, 2009; Cordasco, 2013). Several scholarly works suggest adding structural or supplementary resources as part of the informed consent process for low-literate patients.

Decision aids are designed to help people make choices by having a personalized and specific focus on options and outcomes of the treatment or trial (Cordasco, 2013). Decision aids and educational handouts have been found to improve participant comprehension. These materials have been described as helping to convey key information in treatment while also helping patients explore their own preferences among treatment options (Fernandez, 2010). Fernandez (2010) commented, "Routine use of decision aids can certainly be no worse than our current makeshift attempts to convey [informed consent] complexities" (p. 343). Cordasco (2013) described touch-screen technology used to provide information on probabilities of risks from medicine options, which showed greater knowledge gain than traditional print format. One article used stickers or labels with information such as potential risks to hand out to each patient or participant to ensure that important points are covered and that terms are legible and easy to read (Wright, 2006).

After: Assessing Comprehension

A few studies focused on the effect of federal regulations and IRB requirements on participant understanding as it relates to informed consent. This literature also suggested how best to assess participant comprehension during the informed consent process (AHRQ, 2009; Cortes et al. 2010; Fernandez, 2010; Tamariz et al., 2013). Some authors have argued that comprehension is often measured only by how much is recalled about the specific goals and protocol of the one study or treatment option. This limited assessment may be reflecting confusion as to how to address federal mandates on ethical content of informed consent and how to assess comprehension of these ethics (Lidz, 2006; Sugarman and Paasche-Orlow, 2006). Sugarman and Paasche-Orlow (2006) stated that it is the "central ethical requirements" that should be tested for understanding. They claimed that

researchers should measure whether "all potential participants . . . understand that participation is voluntary and that they can leave the research at any time. In addition, for research conducted in health care settings, potential participants need to understand that their decision will not affect their regular medical care" (p. 898).

Role of Self-Efficacy in Comprehension

Donovan-Kicken and colleagues (2012) tested the effects of self-efficacy on the relationship between health literacy and patient confusion and comprehension of informed consent forms. They found that lower health literacy predicted lower self-efficacy, which predicted feeling less well informed and less prepared, being more confused about treatment procedures and risks, and wanting more information about the risks.

Use of Questioning

Studies examined different tactics to questioning participants as a measure of comprehension. If a participant demonstrates repeating or parroting of the information, it is important to question further and perhaps suggest that the participant explain ideas in his or her own words to ensure full comprehension (AHRQ, 2009; Brach et al., 2012; Cordasco, 2013). For example, one article used open-ended questions to encourage participants to feel comfortable enough to respond that they did not know the answer (Sudore et al., 2006).

The most effective procedures for evaluating comprehension is not necessarily the most efficient, and some authors suggested that instead of creating new assessments, researchers should adapt procedures already created. Sugarman and Paasche-Orlow (2006) recommended the Brief Informed Consent Evaluation Protocol (BICEP). This short questionnaire developed by Sugarman and colleagues is administered via telephone interview immediately following consent (Sugarman et al., 2005). The BICEP focuses less on study facts and more on the rights and voluntariness of the participant involvement.

Teach-Back

Close to one-third of the sources evaluated or recommended the teach-back method. The teach-back method consists of asking participants to repeat back information conveyed to them to ensure full comprehension before they agree to the treatment or participation in the trial and sign the informed consent form (AHRQ, 2009; Hammil et al., 2011). Teach-back has been shown to improve comprehension and can possibly result in

hospital savings by decreasing last-minute surgery cancellations (Kripalani et al., 2008; Lorenzen et al., 2008; Miller et al., 2011; NQF, 2005a). While time consuming compared to traditional methods, the teach-back method is promoted as an alternative to other methods of ensuring comprehension, such as written questions and answers (AHRQ, 2009; Cordasco, 2013; Joint Commission, 2007).

Teach-to-Goal

In addition to using the teach-back method, some sources suggested the teach-to-goal strategy, or repeating information until there is full understanding. This method consists of continuing the educational exchange of the informed consent process until the patient or participant is able to successfully demonstrate comprehension (Kripalani et al., 2008; Sugarman and Paasche-Orlow, 2006; Wee et al., 2009). On the basis of the gaps of understanding when applying the teach-back approach, the researcher can focus on specific elements of the informed consent that address the individual's particular information needs (Fink et al., 2010). Sudore and colleagues (2006) tested the process of teaching-to-goal by having participants answer questions regarding seven aspects of a study after reading out loud simplified informed consent documents. The participants repeated the reading and questions until they answered most questions correctly. Authors described this process as a way to improve informed consent without a significant increase in effort and time on the part of the investigators.

FINDINGS FROM EXPERT INTERVIEWS

Interviewees were selected from various professional backgrounds and had experience with clinical trials, medical procedures, community-based research, and IRBs. These individuals were asked to share their perspectives on different aspects of informed consent procedures, documents, and work with institutions and the federal government. The discussions mainly centered on three aspects: federal regulations, challenges to improving informed consent processes in the context of these regulations, and lessons learned about communicating informed consent. Each of these topics is summarized below.

Perspectives on Federal Regulations

Most of the interviewees perceived federal regulations as too often leading to challenges that complicate the informed consent process. One critique was that the regulations often result in language and words used in an informed consent process that are too technical and confusing. A couple

of interviewees who work with community-based organizations found that the federal regulations are even more complicated for local research. They thought the guidelines naturally created clinically based language and did not offer translations adapted for other types of studies, such as public health interventions. In general, interviewees agreed that they have difficulty balancing patient comprehension needs with fulfilling ethical desires along with regulatory requirements.

Another common perception was the lack of uniformity across regulations and down to local levels, as interviewees found that regulations seemed to differ across counties and states and between different federal agencies. One interviewee said that global regulations and individual country requirements do not offer enough details on how to provide information for participants. Further exacerbating the lack of uniformity were the diverse interpretations by interviewees about what needed to be included in informed consent forms. This situation caused confusion about what alterations and additions could be performed to the informed consent documents and overall process that would be permissible by the federal agencies that were funding research.

Some of the interviewees discussed working with IRBs and IRB interpretations of the federal guidelines. Some interviewers described the burdensome process of getting approval for improvements and simplified documents they hoped to use in their studies. In addition, regulations can be misinterpreted and result in unnecessary roadblocks and personal limits to creativity and progress. However, despite challenges posed, interviewees viewed the regulations as necessary because they do bring attention to the importance of informed consent, and without them the process would receive less care and awareness by researchers and health practitioners.

Perceived Challenges

The main challenge discussed by interviewees was working with the federal regulations in a way that translated guidelines into readable and understandable messages for research participants. Just as time-consuming and difficult, however, was working with home institutions and IRBs in accepting changes to standardized forms and procedures. Requirements and forms have not been adapted for community-based research, so translating the forms can be challenging for some interviewees. One interviewee was frustrated because of the perception that there are no overarching models on how best to communicate informed consent. Although there were many studies on effective methods, the interviewee claimed, there is no "defined gold standard" for communicating about informed consent in clinical trials.

A poor organizational culture surrounding the informed consent process creates a lack of value placed on the process and increases challenges

specific to health-vulnerable participants. One interviewee described a scientific environment that seems disempowering and lacking the intent of having an honest and genuine informed consent process. An interviewee shared that medical training helps maintain traditional assumptions about informed consent. One norm is the practice of using an individual of lower academic seniority to carry out the informed consent procedures, giving other staff the impression that the process lacks importance and value.

A challenge related to cultural awareness and working with diverse populations is that a profound history of mistrust is often overlooked and ignored when working with certain community members. Because of negative past experiences that may include broken promises made by health professionals, participants might feel increased anxiety, mistrust, and confusion when signing the informed consent form. It is important to note that marginalized communities are more likely to feel anxiety and mistrust.

Lessons Learned

Value the Process

Research organizations need a culture that values truly informed decision making. "A dismissive attitude," as one interviewee described it, is detrimental to increasing the commitment of participants. The staff member with the lowest seniority should not always be the one to carry out the informed consent process. This may send an incorrect message to other staff members that informed consent is not important. In addition, staff members may be hesitant to document failures, so it is beneficial to create an environment that views failures as learning opportunities. One interviewee recommended the Clinical Trials Transformation Initiative as an example of organizational commitment and value placed on the informed consent process. One interviewee described the paradigm shift needed as one from "persuasion" to "pedagogy."

Commit to Supervision and Accountability

Researchers and practitioners should supervise and monitor staff throughout the informed consent process and address possible improvements that need to be made afterward to improve future informed consent procedures. They also need to assume that they are responsible for ensuring that the participant asks questions throughout the process and has full comprehension of information. Being accountable means that the researcher or practitioner is responsible if the staff is not well trained and sensitive to participants' health literacy needs. Training the staff on how to address

possible challenges that may occur and how to prioritize information for participants is required.

Encourage the Interactive Exchange of Information

One way to avoid uninformed refusal is by encouraging and addressing questions and ensuring comprehension. Information delivery is an important consideration, but just as important is opening up dialogue, allowing participants time to cognitively process and ask questions, taking time to respond, and using teach-back strategies. One interviewee relies on verbal explanations to supplement the forms and allots double the time expected to complete the process. Another interviewee described how the staff members at her office have participants read forms out loud as part of the exchange and then discuss each section point by point to get questions rather than waiting until the end to ask for questions. One interviewee said, "I notice body language getting more relaxed" after explaining what will be done with the information collected.

Be Aware That Multimedia and Technology May Offer Benefits to Certain Populations

The outcomes from using multimedia techniques are mixed, bu there are benefits for certain audiences. One interviewee recounted the successful use of a computerized avatar in imparting informed consent information to a low-literacy population. Another interviewee described the use of an electronic presentation along with video and verbal interactions with participants. A third uses electronic consent forms. The lesson learned here is to consider and test alternative approaches for informed consent when thinking of the best way to increase the chances of comprehension by the target population.

Continuously Evaluate Success and Allow for Feedback

Details of every study should be documented to permit analysis of failures. One interviewee shared a third-party evaluation system, where the participants phone a reviewer who asks comprehension questions after the informed consent process. Another interviewee video records each process for proper documentation and evaluation. Also, interviewees view teach-back and teach-to-goal approaches as very valuable in ensuring comprehension of consent forms.

Ensure Both Patient-Centered and Patient-Driven Communication

Before beginning the informed consent process, it is important to know your audience and incorporate their language and level of comprehension into the process. Patients should be asked for feedback on what they already know at the start of the informed consent process to help tailor information that can efficiently address needs and gaps in understanding. One interviewee explained that using "common language" understood by participants is critical to increasing trust and comfort among participants. Another interviewee recommended using AHRQ's Toolkit on Informed Consent (AHRQ, 2009) and the National Cancer Institute's new informed consent template (http://ctep.cancer.gov/protocolDevelopment/templates_applications.htm) as resources that help focus informed consent on the participant's information needs (NCI, 2013). NCI's recommendations include a "lay" title for the study in addition to the official title, a description of risks from the participant's perspective, and a list of potential side effects using a table format in the section of the form dealing with risks.

SUMMARY OF TOP 30 BEST PRACTICES

In synthesizing the literature with the interview findings, a set of best practices emerged. Many of these were redundant in both the literature and the interview findings, and some were unique to an interviewee's experience with an IRB or with a new format piloted for informed consent communication. The best practices are organized in similar fashion as the literature summary earlier: practices important in preparing for informed consent, practices important for communicating during informed consent, and practices relevant for evaluating when informed consent is completed.

Preparing

1. Create a culture that places a high value on the informed consent process. Creating a culture that values truly, informed consent leads to better patient-centered practices and communication.
2. Know well the risks of the procedures and outcomes. The level of risk may influence the amount and type of information provided during informed consent procedures. Different medical treatments might change how information is formatted and written and how much information is provided.
3. Know how the setting of the project or study may affect participant comfort and comprehension of informed consent materials. Find out what type of room, what type of writing space, and what type

of noises might be part of the environment where informed consent is being requested.

4. Train staff on the new informed consent process. Include how to address possible challenges that may occur, how to encourage participant questions, and how to prioritize information shared with the participant.
5. Assign a staff person to conduct informed consent who is not the principal investigator but who has a decision-making role in the project. This may be challenging because, on one hand, having the principal investigator conduct informed consent procedures reflects the important value of this stage to participants. On the other hand, in clinical trials the principal investigator has a stake in recruitment, and separating this role offers unbiased communication during informed consent.
6. Supervise and be accountable. Address possible improvements and changes that need to be made to facilitate progress.
7. Allot enough time for participants to interpret and understand the content of forms. Some advise maximizing time allotment to 30 minutes.
8. Weigh the benefits of using multimedia and new technology against population characteristics. Consider age, education, health literacy, the health problem being addressed, cultural values, and health beliefs to judge whether to alternate formats for informed consent information. Video and computer formats have been found to be more effective with higher education levels.
9. Translate all documents into the primary language used by participants.
10. Measure the reading level of documents to ensure a less than eighth-grade reading level. Use one of several well-tested grade-level reading assessments, such as the Flesch-Kincaid readability test.
11. Borrow from toolkits that offer easy-to-use templates for forms. Look at AHRQ's toolkit or NCI's templates for assistance.
12. Invite friends and family of the participant. Some participants feel more comfortable if they have someone with them when they complete the informed consent process.
13. Think creatively for non-English speakers and people with low health literacy. Create an additional class, use an electronic presentation, add time to the meetings, and incorporate other tactics to ensure comprehension.

Communicating

14. Emphasize the voluntary role of the participant. One commonly misunderstood area of informed consent has been that participants do not understand that they do not have to participate and can withdraw at any time.
15. Judge what information or content is not necessary and more likely to overwhelm the participant. There may be some optional content for the particular study and its level of risk. For example, explaining confidentiality of data and personal risks are necessary to include, but it may not be necessary to include how study findings may affect one's desire to participate in subsequent studies.
16. Rely on verbal exchange for supporting and reminding participants about most the important information, risks, voluntarism, and confidentiality.
17. Encourage participants to ask questions.
18. Use the "common language" used by participants as well as plain language.
19. Never assume that language translation equals comprehension. Even with translated materials, participants will need someone available to ask questions and talk about the forms.
20. Speak slowly.
21. Repeat information in different ways until participants understand.
22. Prioritize the most important pieces of the informed consent information at the start and end of the process.
23. Write with little to no technical jargon.
24. Format documents using large type and white space.
25. Use supplemental decision aids and other visuals, which can be in a video, on a computer, or in an infographic format.

Evaluating

26. Document the process. Take notes or video- or audiorecord details of the process in order to outline failures that must be addressed.
27. Assess comprehension before beginning informed consent procedures. Ask participants for feedback on what they already know at the start of the process to tailor information that can efficiently address needs and gaps in understanding.
28. Use teach-back strategies to assess comprehension during and after procedures.
29. Use a variety of open-ended questions to ask participants to clarify what they learned.

30. Try the teach-to-goal approach to ensure comprehension. Have participants "tested" on aspects of the study and, equally important, on aspects of voluntarism and confidentiality.

DISCUSSION AND CONCLUSION

The literature review and interviews completed for this paper focused on the past 10 years of research and expertise in informed consent to assess best practices for health-literate communications. This recent body of knowledge supported findings from earlier decades that recommended tactics for simplifying written documents, clarifying verbal exchanges, and spending time ensuring patient understanding of study risks. These tactics were simple ways to address federal regulations for protection of human subjects while also attempting to increase chances of patient understanding. The current trends show that multimedia formats and computerized exchanges might ameliorate constraints to health-literate communications caused by federal mandates. However, the findings are still inconclusive on the effect of these alternative formats on low-health-literate populations. Some of the research espoused relatively simple solutions to communicating within the context of burdensome federal requirements: spend more time and meet one-on-one with participants while also using simplified and clear language. These types of best practices help to engage participants in active decision making during informed consent procedures because they reflect value and respect for participants while also implementing effective communication tactics. Interviewees and authors of various editorials and studies have argued for a move away from "persuasion" to get participants to consent and toward "pedagogy" and individualized empowerment for informed consent.

However, what we found surprising was that, even with the accumulation of evidence and examples of best practices for communication, there continue to be barriers with regard to health literacy during informed consent used in clinical trials, medical treatments, and diagnostic screenings. More than 40 years of research have highlighted ways to simplify documents and increase participant comprehension, and yet authors identified highly complex terminology, high-school-and-above reading levels, and lengthy forms. This research illustrates the ongoing challenges of abiding by federal regulations, which seem to continue to interfere with communicating effectively for informed consent. We outline below a future research agenda that addresses this and other gaps in the current literature. We then describe two prototype models that are infographic representations of what we found in the literature and interviews about health-literate informed consent.

Future Research Agenda

While the list of best practices suggests a relatively straightforward track from improved communication to increased patient comprehension, the landscape for health-literate informed consent actually conveyed a complex set of challenges and considerations (Goske and Bulas, 2009; Lidz, 2006). On the one hand, it was apparent that simplified forms needed to be used during informed consent, verbal interactions remained important for participant comprehension, and step-by-step procedures needed to be enacted to ensure participant autonomy and voluntariness. It was also evident that the level of risk, setting characteristics, and participant factors might be used to construct clear and comprehensible informed consent procedures. On the other hand, there were gaps in the current literature about health literacy and its effects on informed consent, which led us to suggest a research agenda for the future. The key areas where gaps were found are listed below, along with suggested future research.

1. Few models were found that described and visualized the sequential steps required for effective informed consent and when to do what to improve comprehension and decision making. Whereas many simpler, easy-to-understand forms or procedures were available, few comprehensive models or process maps were found to help standardize an improved, health-literate system for informed decision making. Future research should develop and test process models for how to systematically incorporate health literacy before, during, and after informed consent procedures.
2. Limited work has been done on the role and effect of situational yet critical factors, such as risk and literacy levels, on informed consent procedures and content. Many authors encouraged standardized approaches to improving participant comprehension of clinical trials or medical treatments, though several authors argued for a tailored communications approach that allowed for flexibility depending on participant factors and setting factors. However, few empirical studies were found that tested the factors that may affect knowledge, motives, self-efficacy, and decision making. Future research should tease out such factors as risk level and health literacy level to test effects on comprehension and decision making.
3. Empirical research is lacking to confirm the benefits of new technology on informed consent. The findings are mixed as to the effect of multimedia and computerized interactive modules and seem to point to the role of situational factors. In particular, authors highlighted differences by health literacy levels of participants and

setting characteristics such as type of treatment option and whether the situation was an emergency. This area of research is growing, and additional randomized controlled trials would help confirm findings for certain populations compared to others.

4. Little research has focused on low-health-literate populations and health literacy disparities in informed consent outcomes. Although education level, reading level, and socioeconomic status have been markers for low-health-literate populations, few studies measured health literacy in their study to assess specifically how health literacy moderates or mediates the relationship between communications and informed decision making. Findings that have included health literacy as a variable have shown mixed results as to the benefit of multimedia and verbal communications. Future studies should assess health literacy in participants to measure its impact on different informed consent contexts and outcomes.
5. There is a dearth of research regarding health literacy and informed consent for community-based research. Yet, in social work and public health, as well as other fields, community-based studies testing population health and preventive health interventions are widespread. A couple of interviewees expressed frustration over the lack of guidelines and toolkits for health-literate informed consent in community-based research. Future studies in community-based research should look to replicate the work done on informed consent in clinical trials and medical treatments. While teasing out lessons learned, there should be efforts to create an independent agenda for informed consent research and practice. One of the priorities might be the concern over trust, which seems to have eroded over time and affects informed consent successes. The Institute of Medicine might consider hosting a workshop focused on informed consent and health literacy in the community setting.
6. No research study was found that compared informed consent and communicating benefits and risks in the contexts of medical treatment, diagnostic screening, and clinical trials with the type of informed consent process appropriate for each participant. This seems particularly important when assessing informed consent for low-health-literate populations. For example, from a surgical consent perspective, Hammil et al. (2011) pointed out that patients who are embarking on especially complex procedures, such as surgery, and who have low health literacy have an even more difficult time understanding forms. Research indicates that structural and supplementary resources may assist patients in understanding the informed consent process better. In particular, using decision aids, such as booklets, video, interactive computer programs, and

charts, may make the informed consent process less intimidating (Goske and Bulas, 2009). Less invasive, low-risk procedures may not require the same structural or supplementary resources (Sugarman and Paasche-Orlow, 2006). These differences require future research to assess if categorizing communication best practices by domain for informed consent is a worthy endeavor.

Visual Models for Health-Literate Informed Consent

In addition to summarizing best practices and noting research gaps for future studies, we have attempted to extend the identified practices and research into working models of health-literate informed consent. We developed two infographics, which were based on health literacy best practices and inspired by gaps found in the information gathered. Each model is framed within the philosophies grounding health literacy that we found to be interwoven in the literature and interviews about informed consent.

One philosophy is the "universal precautions" approach to health literacy (DeWalt et al., 2010). This approach was created to help design health-literate communications for everyone regardless of their level of health literacy. According to the Health Literacy Universal Precautions Toolkit, "Providers don't always know which patients have limited health literacy" and should therefore consider systems or practices "to promote better understanding for all patients, not just those you think need extra assistance" (DeWalt et al., 2010, p. 2). In the area of informed consent, a universal precautions approach suggests that information be geared to the lowest health literacy levels, and a universal procedure of clear, meaningful, and simple messages would be implemented. Any one individual, regardless of education level or cultural background, would understand the process and make an informed decision to consent. The models we developed took the numerous best practices and recommendations framed within this philosophy and visualized a standardized, step-by-step approach to completing health-literate informed consent.

The other model reflects somewhat of a universal precautions approach but also a second philosophy of a situational communication framework. This philosophy is derived from the "tailored communication" and cultural sensitivity lines of research, which suggest that certain factors and characteristics within the situation guide messages and format. Although it is important to standardize certain content and patient comprehension of ethical mandates, the model we developed depends on level of risk, setting, and context.

The two infographics should be viewed as prototypes for what we hope will be well-developed models following future research. The models' power is in explaining the need to develop a systematic path for health-

literate procedures and in situating risk for purposes of communicating the federal guidelines for content and informed consent.

Roadmap to Health-Literate Informed Consent

Appendix C-A presents the "Roadmap to Health Literate Informed Consent," an eight-step visualization of the sequential order of larger process phases to complete in order to reach patient understanding regardless of the level of health literacy among target participants. This model takes a universal precautions approach to standardizing practices for informed consent. A similar approach was found within AHRQ's toolkit for informed consent in minimal-risk research. AHRQ's steps included creating a research culture that promotes health-literate informed consent, staff training, knowing the physical environment where informed consent procedures will take place, and communicating to promote comprehension (AHRQ, 2009). Although other toolkits and resources illustrate steps to increasing the effectiveness of informed consent, we found no infographic to assist in visualizing the steps before, during, and *after* informed consent.

Each of the eight steps builds on the one before and embeds best practices that were found in the research and among the expertise for informed consent to low-literacy audiences. The first five steps are in preparation of enacting informed consent procedures; the last three occur during them and can help in evaluating success afterward.

1. The first step is to *know your setting and the risks*. The setting includes study details as well as risks to participants and practitioner characteristics that might influence setting and study, such as experience and length of time for study.
2. After knowing all the details of the setting, *train staff* not just in the study protocol but in health-literate informed consent procedures. To assist with changing the culture that constrains health-literate procedures, the staff can also be part of the construction of health-literate forms.
3. After the staff are trained in new informed consent techniques, the third step is to get to *know your participants*. Although individual levels of health literacy are not always possible to measure, there are several factors to understanding your population: what might be average health literacy levels and formal education, and how cultural norms and beliefs about medicine and health might influence the participants' reaction to informed consent procedures.
4. Once an analysis of your population is complete, the next step is to prepare written forms on the basis of the population, the setting characteristics, and, in particular, the risk level of the study.

This step, *simplify written forms*, is implemented when the toolkits available online as well as other best practices can be employed.

5. Once forms are adjusted according to best practices for less health-literate audiences, the fifth step is to *consider alternate formats*. Video, computer presentations, computerized avatars, online interactivity, and other alternative media can be used as supplements to the main documents, as decision aids, or as a substitution for main print documents. The research on understanding population characteristics assists practitioners with this decision, although the findings on multimedia and computerized support are still inconclusive.
6. The sixth step is *dialogue*, which represents the verbal interactions that should occur during informed consent procedures.
7. The seventh step addresses a very important task, to *assess comprehension*. At this point, the research consistently points to the value of teach-back and teach-to-goal approaches in evaluating and confirming comprehension before moving forward.
8. Finally, the last step is to *improve your process*, that is, document and evaluate the system. The purpose of this step is to evaluate not the comprehension of a participant, but the success of the overall system put in place for health-literate informed consent. Having the staff document successes and discuss failures allows for transparency of the values and goals in place for what is really the intent of the informed consent process.

Situational Risk Model of Communicating Informed Consent

Appendix C-B presents the "Situation Risk Model for Communicating Informed Consent." This visual model incorporates a "tailored" approach to communicating with different audiences on the basis of the level of risk in the study. The motivation behind the situational risk framework is derived from some of the literature and interviews. The level of risk indicates the differing amount and type of content to share with participants, thus simplifying notions of informed consent for many projects. At the lowest level of study risk, such as with surveys or community public health interventions, the content of informed consent forms must include benefits, procedures, and information on voluntariness and confidentiality. At this level of risk, the AHRQ informed consent template is helpful (see Appendix C-F for an example of this template). At a medium level of risk, where many clinical trials fall, not every detail of information is necessary, and in fact, some research supported the fact that too much information lessens comprehension for some participants. Yet, at this level additional information is necessary about common side effects, for example. At the top of

the rating is the highest risk, such as life-saving surgeries and some clinical trials. Here, it is necessary to take the time to communicate all information for participants to make informed decision making. This model is not appropriate when individuals face emergency medical situations or are incapable of making decisions. However, this may be a template to enable practitioners to consider variable factors that affect how much information is necessary. The model provided here is what we hope will be the beginning of research on the different factors that influence how health-literate informed consent can be shaped.

Conclusion

The commissioned work that the Institute of Medicine requested combined literature from the last decade and expert voices to examine the effects of informed consent regulations on health-literate communication. We did encounter limitations in the search, interviewing, and analyzing of resources, however. First, although the parameters for the literature search helped us complete a worthy paper within the assigned time frame, it also limited our ability to conduct a systematic, comprehensive literature search outside the United States and outside of the past decade. Although we feel confident that we amassed a thorough amount of literature, we did not collect all the published and online resources available to help communicate about informed consent. Second, many individuals were out of the office or working on June deadlines for grants, so we did not obtain 10 interviews as originally planned, and we relied on convenient and snowball sampling for interviewees. The interviewees who participated offered insightful and creative expertise on informed consent and health literacy, but the paper might have been richer if more voices had been included with those that were summarized here.

Even with the limitations, we found the relationship between health literacy and participant understanding of informed consent to be a strong one, with research supporting the links between plain language, clear communication, and informed consent. However, communicating for informed consent is complex. Participant characteristics, practitioner skills, and study risks interact to challenge practitioners to think about alternative formats effective for their populations. The most promising avenue of research seems to be with the use of computerized and online interactive communications, although findings are mixed. However, the mixed findings may reflect the need to understand participants better: their health literacy, cultural values, and beliefs about medicine. This ambiguity suggests future research opportunities, as do the gaps in research on situational factors, community-based informed consent, and testable communication models.

We hope this paper sparks dialogue on these and other topics in order to foster research on health literacy and informed consent.

REFERENCES

AHRQ (Agency for Healthcare Research and Quality). 2009, September. *The AHRQ informed consent and authorization toolkit for minimal risk research*. Rockville, MD: Agency for Healthcare Research and Quality. http://www.ahrq.gov/funding/policies/informedconsent/index.html (accessed June 1, 2014).

Albala, I., M. Doyle, and P. Appelbaum. 2010. The evolution of consent forms for research: A quarter century of changes. *IRB: Ethics and Human Research* 32:7–11.

Bickmore, T., L. Pfeifer, and M. K. Paasche-Orlow. 2009. Using computer agents to explain medical documents to patients with low health literacy. *Patient Education and Counseling* 75:315–320.

Brach, C., D. Keller, L. M. Hernandez, C. Baur, R. Parker, B. Dreyer, P. Schyve, A. J. Lemerise, and D. Schillinger. 2012. *Ten attributes of health literate health care organizations*. Discussion paper, Institute of Medicine. http://iom.edu/Global/Perspectives/2012/HealthLitAttributes.aspx (accessed May 28, 2014).

Brice, J., D. Travers, C. Cowden, M. Young, A. Sanhueza, and Y. Dunston. 2008. Health literacy among Spanish-speaking patients in the emergency department. *Journal of National Medical Association* 100:1326–1332.

Brink, S. G. 2006. Making informed consent work for all. *Journal of Clinical Research Best Practices* 2(12):1–5.

———. 2012, April. Toward a patient-centric e-consent process. *Monitor: Publication of the Association of Clinical Research Professionals* 35–39.

Campbell, F. A., B. D. Goldman, M. L. Boccia, and M. Skinner. 2004. The effect of format modifications and reading comprehension on recall of informed consent information by low-income parents: A comparison of print, video, and computer-based presentations. *Patient Education and Counseling* 53:205–216.

Carr, K., H. Fields, M. Beck, E. Kang, A. Kiyak, C. Pawlak, and A. Firestone. 2012. Impact of verbal explanation and modified consent materials on orthodontic informed consent. *American Journal of Orthodontics and Dentofacial Orthopedics* 141:174–186.

Clark, S., A. Mangram, D. Ernest, R. Lebron, and L. Peralta. 2011. The informed consent: A study of the efficacy of informed consent and the associated role of language barriers. *Journal of Surgical Education* 68(2):143–147.

Cordasco, K. M. 2013. Obtaining informed consent from patients: Brief update review. In *Making health care safer II: An updated critical analysis of the evidence for patient safety practices*. Evidence Reports/Technology Assessments, No. 211. Rockville, MD: Agency for Healthcare Research and Quality. Pp. 461–471.

Cortes, D., M. Drainoni, L. Henault, and M. Paasche-Orlow. 2010. How to achieve informed consent for research from Spanish-speaking individuals with low literacy: A qualitative report. *Journal of Health Communication* 15:172–182.

Cowan, E. A., Y. Calderon, P. Gennis, R. Macklin, C. Ortiz, and S. P. Wall. 2007. Spanish and English video-assisted informed consent for intravenous contrast administration in the emergency department: A randomized controlled trial. *Annals of Emergency Medicine* 49(2):221–230.

Davis, T. C., M. V. Williams, E. Marin, R. M. Parker, and J. Glass. 2002. Health literacy and cancer communication. *CA Cancer Journal* 52:134–149.

Dawson, C. 2006. *The intersection between health literacy and informed consent*. Presentation to the Roundtable on Health Literacy, September 14, 2006. www.iom.edu/~/media/Files/Activity%20Files/PublicHealth/HealthLiteracy/05DaltonOverviewofInformedConsent.ashx (accessed May 28, 2014).

Denzen, E., M. Burton Santibáñez, H. Moore, A. Foley, I. Gersten, C. Gurgol, N. Majhail, R. Spellecy, M. Horowitz, and E. Murphy. 2012. Easy-to-read informed consent forms for hematopoietic cell transplantation clinical trials. *Biology of Blood Marrow Transplant* 18:183–189.

DeWalt, D. A., L. F. Callahan, V. H. Hawk, K. A. Broucksou, A. Hink, R. Rudd, and C. Brach. 2010. *Health literacy universal precautions toolkit*. AHRQ Publication No. 10-0046-EF. Rockville, MD: Agency for Healthcare Research and Quality.

Donovan-Kicken, E., M. Mackert, T. Guinn, A. Tollison, B. Breckinridge, and S. Pont. 2012. Health literacy, self-efficacy, and patients' assessment of medical disclosure and consent documentation. *Health Communication* 27:581–590.

Donovan-Kicken, E., M. Mackert, T. Guinn, A. Tollison, and B. Breckinridge. 2013. Sources of patient uncertainty when reviewing medical disclosure and consent documentation. *Patient Education and Counseling* 90:254–260.

FDA (Food and Drug Administration). 2014. *A guide to informed consent*. http://www.fda.gov/regulatoryinformation/guidances/ucm126431.htm (accessed July 1, 2014).

Fernandez, A. 2010. Improving the quality of informed consent: It is not all about the risks. Editorial. *Annals of Internal Medicine* 153:342–343.

Fink, A. S., A. V. Prochazka, W. G. Henderson, D. Bartenfeld, C. Nyirenda, A. Webb, D. H. Berger, K. Itani, T. Whitehill, J. Edwards, M. Wilson, C. Karsonovich, and P. Parmelee. 2010. Predictors of comprehension during surgical informed consent. *Journal of American College of Surgeons* 210:919–926.

Flory, J., and E. Emanuel. 2004. Interventions to improve research participants' understanding in informed consent for research: A systematic review. *Journal of the American Medical Association* 292:1593–1601.

George, S., E. Moran, N. Duran, and R. A. Jenders. 2013. Using animation as an information tool to advance health research literacy among minority participants. *AMIA Annual Symposium Proceedings Archive* 475–484.

Goske, M. J., and D. Bulas. 2009. Improving health literacy: Informed decision-making rather than informed consent for CT scans in children. *Pediatric Radiology* 29:901–903.

Griffin, J. M., J. K. Struve, D. Collins, A. Liu, D. Nelson, and H. Bloomfield, H. 2006. Long-term clinical trials: How much information do participants retain from the informed consent process. *Contemporary Clinical Trial* 27:441–448.

Hall, D., B. H. Hanusa, G. E. Switzer, M. J. Fine, and R. M. Arnold. 2012. The impact of iMedConsent on patient decision-making regarding cholecystectomy and inguinal herniorrhaphy. *Journal of Surgical Research* 175:227–233.

Hammil, S., D. L. Helitzer, and R. G. Rogers. 2011. Health literacy and surgical informed consent. *Female Patient* 36:51–54.

Harmell, A. L., B. W. Palmer, and D. W. Jeste. 2012. Preliminary study of a web-based tool for enhancing the informed consent process in schizophrenia research. *Schizophrenia Research* 141(2–3):247–250.

Herz, D. A., J. E. Looman, and S. K. Lewis. 1992. Informed consent: Is it a myth? *Neurosurgery* 30(3):453–458.

HHS (U.S. Department of Health and Human Services). 2009. Protection of human subjects. *Code of Federal Regulations*, Title 45, Part 46. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html (accessed June 1, 2014).

Howard, J. M., and D. DeMets. 1981. How informed is informed consent? The BHAT experience. *Controlled Clinical Trials* 2(4):287–303.

Ingelfinger, F. J. 1972. Informed (but uneducated) consent. Editorial. *New England Journal of Medicine* 287:465–466.

Joint Commission. 2007. "*What did the doctor say?" Improving health literacy to protect patient safety.* Oakbrook Terrace, IL: Joint Commission.

Kripalani, S., R. Bengtzen, L. E. Henderson, and T. A. Jacobson. 2008. Clinical research in low- literacy populations: Using teach-back to assess comprehension of informed consent and privacy information. *IRB: Ethics and Human Research* 30:13–19.

Lidz, C. W. 2006. The therapeutic misconception and our models of competency and informed consent. *Behavioral Sciences and the Law* 24:535–546.

Lorenzen, B., C. E. Melby, and B. Earles. 2008. Using principles of health literacy to enhance the informed consent process. *AORN Journal* 88:23–29.

Marco, C. 2008. Impact of detailed informed consent on research subjects' participation: A prospective, randomized trial. *Journal of Emergency Medicine* 34:269–275.

Matiasek, J., and M. Wynia. 2008. Reconceptualizing the informed consent process at eight innovative hospitals. *Joint Commission Journal on Quality and Patient Safety* 34(3): 127–137.

McCarthy, D. M., K. A. Leone, D. H. Salzman, J. A. Vozenilek, and K. A. Cameron. 2012. Language use in the informed consent discussion for emergency procedures. *Teaching and Learning in Medicine* 24(4):315–320.

Miller, M. J., M. A. Abrams, B. Earles, K. Phillips, and E. M. McCleeary. 2011. Improving patient-provider communication for patients having surgery: Patient perceptions of a revised health literacy-based consent process. *Journal of Patient Safety* 7:30–38.

Mudano, A. S., L. C. Gary, A. L. Oliveira, M. Melton, N. C. Wright, J. R. Curtis, E. Delzell, et al. 2013. Using tablet computers compared to interactive voice response to improve subject recruitment in osteoporosis pragmatic clinical trials: Feasibility, satisfaction, and sample size. *Patient Preference and Adherence* 13:517–523.

Mytrus. 2014. *Reinvent consent with Enroll.* https://www.mytrus.com/en/products-services/enroll (accessed June 20, 2014).

NCI (National Cancer Institute). 2013, May 12. *NCI consent form template for adult cancer trials.* http://ctep.cancer.gov/protocolDevelopment/templates_applications.htm (accessed June 3, 2014).

NIH (National Institutes of Health). 2007. *Annotated compendium of NIH resources on informed consent.* Bethesda, MD: National Institutes of Health. http://osp.od.nih.gov/sites/default/files/resources/AnnotatedCompendiumofNIHResourcesonInformedConsent-28Nov2007.pdf (accessed June 28, 2014).

NQF (National Quality Forum). 2005a. *Implementing a national voluntary consensus standard for informed consent: A user's guide for healthcare professionals.* Washington, DC: National Quality Forum.

———. 2005b. *Improving patient safety through informed consent for patients with limited health literacy.* Washington, DC: National Quality Forum.

Paasche-Orlow, M. K., H. A. Taylor, and F. I. Brancati. 2003. Readability standards for informed-consent forms as compared with actual readability. *New England Journal of Medicine* 348:721–726.

Rossi, M. J., D. Guttmann, M. J. MacLennan, and J. H. Lubowitz. 2005. Video informed consent improves knee arthroscopy patient comprehension. *Arthroscopy* 21(6):739–743.

Schenker, Y., and A. Meisel. 2011. Informed consent in clinical care: Practical considerations in the effort to achieve ethical goals. *Journal of the American Medical Association* 305:1130–1131.

Schenker, Y., F. Wang, S. Seliq, R. Ng, and A. Fernandez. 2007. The impact of language barriers on documentation of informed consent at a hospital with on-site interpreter. *Journal of General Internal Medicine* 22:294–299.

Schenker, Y., A. Fernandez, R. Sudore, and D. Schillinger. 2011. Interventions to improve patient comprehension in informed consent for medical and surgical procedures: A systematic review. *Medical Decision Making* 31:151–173.

Sharp, S. M. 2004. Consent documents for oncology trials: Does anybody read these things? *American Journal of Clinical Oncology* 27(6):570–575.

Siao, D., J. L. Sewell, and L. W. Day. 2014. Assessment of delivery methods used in the informed consent process at a safety-net hospital. *Gastrointestinal Endoscopy* 80:61–68.

Sonne, S. C., J. O. Andrews, S. M. Gentilin, S. Oppenheimer, J. Obeid, K. Brady, S. Wolf, R. Davis, and K. Magruder. 2013. Development and pilot testing of a video-assisted informed consent process. *Contemporary Clinical Trial* 36:25–31.

Sudore, R. L., S. Landefeld, B. Williams, D. Barnes, K. Lindquist, and D. Schillinger. 2006. Use of a modified informed eConsent process among vulnerable patients: A descriptive study. *Journal of General Internal Medicine* 21:867–873.

Sugarman, J., and M. Paasche-Orlow. 2006. Confirming comprehension of informed consent as a protection of human subjects. Editorial. *Journal of General Internal Medicine* 21:898–899.

Sugarman, J., P. W. Lavori, M. Boeger, C. Cain, R. Edson, V. Morrison, and S. S. Yeh. 2005. Evaluating the quality of informed consent. *Clinical Trials* 2:34–41.

Synnot, A., R. Ryan, M. Prictor, D. Fetherstonhaughm, and B. Parker. 2014. Audio-visual presentation of information for informed consent for participation in clinical trials. *Cochrane Database of Systematic Reviews* 5.

Tait, A. R., T. Voepel-Lewis, S. Malviya, and S. J. Philipson. 2005. Improving the readability and processability of a pediatric informed consent document. *Archives of Pediatric and Adolescent Medicine* 159:347–352.

Tamariz, L., A. Palacio, M. Robert, and E. N. Marcus. 2013. Improving the informed consent process for research subjects with low literacy: A systematic review. *Journal of General Internal Medicine* 28(1):121–126.

Volker, M. 2005. The informed consent process: Future directions. *Applied Clinical Trials Supplement* 22–26.

Wanzer, M. B., A. M. Wojtaszczyk, J. Schimert, L. Missert, L. Baker, R. Baker, and B. Dunkle. 2010. Enhancing the "informed" in informed consent: A pilot test of a multimedia presentation. *Health Communication* 25:365–374.

Wee, C. C., J. S. Pratt, R. Fanelli, P. Q. Samour, L. S. Trainor, and M. K. Paasche-Orlow. 2009. Best practice updates for informed consent and patient education in weight loss surgery. *Obesity* 17:885–888.

Windle, P. E. 2008. Understanding informed consent: Significant and valuable information *Journal of PeriAnesthesia Nursing* 23(6):430–433.

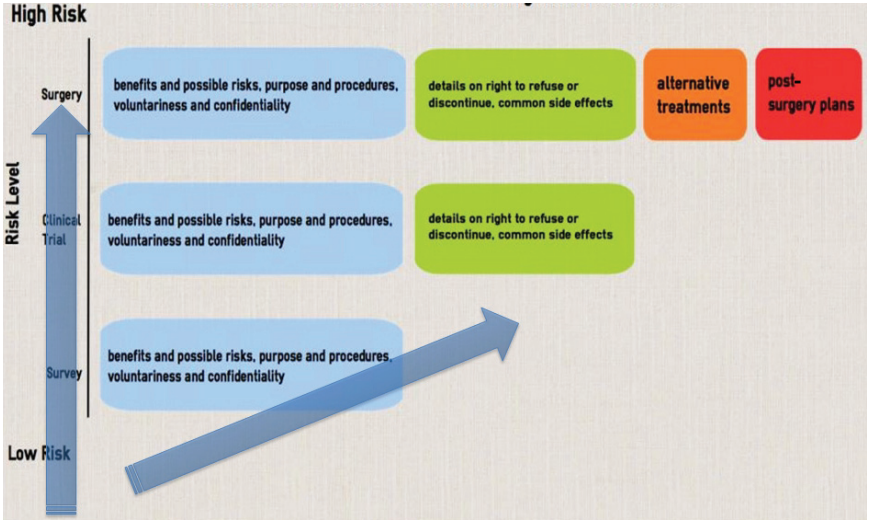
Wright, J. 2006. *Best practice: Informed consent that sticks*. Podcast of CRICO of the Harvard Medical Institutions. https://www.rmf.harvard.edu/Clinician-Resources/Article/2006/Best-Practice-Informed-Consent-that-Sticks (accessed June 24, 2014).

APPENDIX C-A

A Roadmap to Health-Literate Informed Consent

APPENDIX C-B

Situation Risk Model for Communicating Informed Consent



APPENDIX C-C

Bibliography of Useful Resources

AAMC (Association of American Medical Colleges). 2007, August. *Universal use of short and readable informed consent documents: How do we get there? Summary of strategic planning meeting, May 30, 2007*. Washington, DC: Association of American Medical Colleges.

AHRQ (Agency for Healthcare Research and Quality). 2009, September. *The AHRQ informed consent and authorization toolkit for minimal risk research*. Rockville, MD: Agency for Healthcare Research and Quality. http://www.ahrq.gov/funding/policies/informedconsent/index.html (accessed June 1, 2014).

Albala, I., M. Doyle, and P. Appelbaum. 2010. The evolution of consent forms for research: A quarter century of changes. *IRB: Ethics and Human Research* 32:7–11.

American Academy of Ophthalmology. 2011, December. *Practice guidelines for informed consent*. San Francisco: American Academy of Ophthalmology. http://one.aao.org/patient-safety-statement/informed-consent-guidelines-2 (accessed June 24, 2014).

American Cancer Society. *Informed consent*. http://www.cancer.org/acs/groups/cid/documents/webcontent/003014-pdf.pdf (accessed May 20, 2014).

Aoki, N., M. Sakai, T. Nakayama, S. Fukuhara, S. Ohta, N. Kikuchi, M. Oishi, T. Kiuchi, K. Nozaki, and N. Hashimoto. 2007. u-SHARE: Web-based decision support/risk communication tool for healthcare consumers with unruptured intracranial aneurysms. *Studies in Health Technology and Informatics* 129(2):1012–1016.

AUGS (American Urogynecologic Society). 2013. *Transvaginal mesh informed consent toolkit*. Washington, DC: American Urogynecologic Society. http://www.augs.org/p/cm/ld/fid=174 (accessed June 20, 2014).

Bickmore, T., L. Pfeifer, and M. K. Paasche-Orlow. 2009. Using computer agents to explain medical documents to patients with low health literacy. *Patient Education and Counseling* 75:315–320.

Brice, J., D. Travers, C. Cowden, M. Young, A. Sanhueza, and Y. Dunston. 2008. Health literacy among Spanish-speaking patients in the emergency department. *Journal of National Medical Association* 100:1326–1332.

Brink, S. G. 2006. Making informed consent work for all. *Journal of Clinical Research Best Practices* 2(12):1–5.

———. 2012, April. Toward a patient-centric e-consent process. *Monitor: Publication of the Association of Clinical Research Professionals* 35–39.

Campbell, F. A., B. D. Goldman, M. L. Boccia, and M. Skinner. 2004. The effect of format modifications and reading comprehension on recall of informed consent information by low-income parents: A comparison of print, video, and computer-based presentations. *Patient Education and Counseling* 53:205–216.

Caramenico, A. 2010, November 12. Technology helping patients to understand informed consent. *FierceHealthcare*. http://www.fiercehealthcare.com/story/technology-helping-patients-understand-informed-consent/2010-11-12 (accessed June 1, 2014).

Carr, K., H. Fields, M. Beck, E. Kang, A. Kiyak, C. Pawlak, and A. Firestone. 2012. Impact of verbal explanation and modified consent materials on orthodontic informed consent. *American Journal of Orthodontics and Dentofacial Orthopedics* 141:174–186.

CISCRP (Center for Information and Study on Clinical Research Participation). 2013. *Report on the informed consent process*. https://www.ciscrp.org/wp-content/uploads/2014/01/2013-CISCRP-Study-the-Informed-Consent-Process.pdf (accessed June 26, 2014).

Clark, S., A. Mangram, D. Ernest, R. Lebron, and L. Peralta. 2011. The informed consent: A study of the efficacy of informed consent and the associated role of language barriers. *Journal of Surgical Education* 68(2):143–147.

Cordasco, K. M. 2013, March. Obtaining informed consent from patients: Brief update review. In *Making health care safer II: An updated critical analysis of the evidence for patient safety practices*. Evidence Reports/Technology Assessments, No. 211. Rockville, MD: Agency for Healthcare Research and Quality. Pp. 461–471.

Cortes, D., M. Drainoni, L. Henault, and M. Paasche-Orlow. 2010. How to achieve informed consent for research from Spanish-speaking individuals with low literacy: A qualitative report. *Journal of Health Communication* 15:172–182.

Cowan, E. A., Y. Calderon, P. Gennis, R. Macklin, C. Ortiz, and S. P. Wall. 2007. Spanish and English video-assisted informed consent for intravenous contrast administration in the emergency department: A randomized controlled trial. *Annals of Emergency Medicine* 49(2):221–230.

Dartmouth Medical School. 2014. *Effective patient communication: Informed consent*. Online presentation. http://www.slideshare.net/pickerins/informed-consent-final-with-video-link (accessed June 24, 2014).

De Bord, J. 2014. *Ethics in medicine: University of Washington School of Medicine*. https://depts.washington.edu/bioethx/topics/consent.html (accessed May 20, 2014).

Denzen, E., M. Burton Santibáñez, H. Moore, A. Foley, I. Gersten, C. Gurgol, N. Majhail, R. Spellecy, M. Horowitz, and E. Murphy. 2012. Easy-to-read informed consent forms for hematopoietic cell transplantation clinical trials. *Biology of Blood Marrow Transplant* 18:183–189.

DeWalt, D. A., L. F. Callahan, V. H. Hawk, K. A. Broucksou, A. Hink, R. Rudd, and C. Brach. 2010, April. *Health literacy universal precautions toolkit*. Prepared by the North Carolina Network Consortium, the Cecil G. Sheps Center for Health Services Research, the University of North Carolina at Chapel Hill, under Contract No. HHSA290200710014. AHRQ Publication No. 10-0046-EF. Rockville, MD: Agency for Healthcare Research and Quality.

Donovan-Kicken, E., M. Mackert, T. Guinn, A. Tollison, B. Breckinridge, and S. Pont. 2012. Health literacy, self-efficacy, and patients' assessment of medical disclosure and consent documentation. *Health Communication* 27:581–590.

Donovan-Kicken, E., M. Mackert, T. Guinn, A. Tollison, and B. Breckinridge. 2013. Sources of patient uncertainty when reviewing medical disclosure and consent documentation. *Patient Education and Counseling* 90:254–260.

Drotar, D., V. Miller, V. Willard, K. Anthony, and E. Kodish. 2004. Correlates of parental participation during informed consent for randomized clinical trials in the treatment of childhood leukemia. *Journal of Ethics and Behavior* 14:1–15.

FDA (Food and Drug Administration). 2014, June 25. *A guide to informed consent*. http://www.fda.gov/regulatoryinformation/guidances/ucm126431.htm (accessed June 1, 2014).

Fernandez, A. 2010. Improving the quality of informed consent: It is not all about the risks. Editorial. *Annals of Internal Medicine* 153:342–343.

Fink, A. S., A. V. Prochazka, W. G. Henderson, D. Bartenfeld, C. Nyirenda, A. Webb, D. H. Berger, K. Itani, T. Whitehill, J. Edwards, M. Wilson, C. Karsonovich, and P. Parmelee. 2010. Predictors of comprehension during surgical informed consent. *Journal of American College of Surgeons* 210:919–926.

Florida Department of Health. 2011. *Improving informed consent*. Human Research Protections Program. http://flpublichealthethics.net/index.php/eng/researchers/improving_informed_consent (accessed May 26, 2014).

Flory, J., and E. Emanuel. 2004. Interventions to improve research participants' understanding in informed consent for research: A systematic review. *Journal of the American Medical Association* 292:1593–1601.

George, S., E. Moran, N. Duran, and R. A. Jenders. 2013. Using animation as an information tool to advance health research literacy among minority participants. *AMIA Annual Symposium Proceedings Archive* 475–484.

Goldfarb, E., J. A. Fromson, T. Gorrindo, and R. J. Birnbaum. 2012. Enhancing informed consent best practices: Gaining patient, family and provider perspectives using reverse simulation. *Journal of Medical Ethics* 38:546–551.

Goske, M. J., and D. Bulas. 2009. Improving health literacy: Informed decision-making rather than informed consent for CT scans in children. *Pediatric Radiology* 29:901–903.

Greenley, R. N., D. Drotar, S. J. Zyzanski, and E. Kodish. 2006. Stability of parental understanding of random assignment in childhood leukemia trials: An empirical examination of informed consent. *Journal of Clinical Oncology* 24:891–897.

Griffin, J. M., J. K. Struve, D. Collins, A. Liu, D. Nelson, and H. Bloomfield. 2006. Long term clinical trials: How much information do participants retain from the informed consent process. *Contemporary Clinical Trial* 27:441–448.

Hall, D., B. H. Hanusa, G. E. Switzer, M. J. Fine, and R. M. Arnold. 2012. The impact of iMedConsent on patient decision-making regarding cholecystectomy and inguinal herniorrhaphy. *Journal of Surgical Research* 175:227–233.

Hammil, S., D. L. Helitzer, and R. G. Rogers. 2011. Health literacy and surgical informed consent. *Female Patient* 36:51–54.

Harmell, A. L., B. W. Palmer, and D. W. Jeste. 2012. Preliminary study of a web-based tool for enhancing the informed consent process in schizophrenia research. *Schizophrenia Research* 141(2–3):247–250.

HHS (U.S. Department of Health and Human Services). 2009. Protection of human subjects. *Code of Federal Regulations*, Title 45, Part 46. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html (accessed April 1, 2014).

Joint Commission. 2007. "*What did the doctor say?" Improving health literacy to protect patient safety.* Oakbrook Terrace, IL: Joint Commission.

Kneipp, S., B. Lutz, and D. Means. 2009. Reasons for enrollment, the informed consent process, and trust among low-income women participating in a community based participatory research study. *Public Health Nursing* 26:362–369.

Kripalani, S., R. Bengtzen, L. E. Henderson, and T. A. Jacobson. 2008. Clinical research in low-literacy populations: Using teach-back to assess comprehension of informed consent and privacy information. *IRB: Ethics and Human Research* 30:13–19.

Lidz, C. W. 2006. The therapeutic misconception and our models of competency and informed consent. *Behavioral Sciences and the Law* 24:535–546.

Lorenzen, B., C. E. Melby, and B. Earles. 2008 Using principles of health literacy to enhance the informed consent process. *AORN Journal* 88:23–29.

Marco, C. 2008. Impact of detailed informed consent on research subjects' participation: A prospective, randomized trial. *Journal of Emergency Medicine* 34:269–275.

Matiasek, J., and M. Wynia. 2008, March. Reconceptualizing the informed consent process at eight innovative hospitals. *Joint Commission Journal on Quality and Patient Safety* 34(3):127–137.

McCarthy, D. M., K. A. Leone, D. H. Salzman, J. A. Vozenilek, and K. A. Cameron. 2012. Language use in the informed consent discussion for emergency procedures. *Teaching and Learning in Medicine* 24(4):315–320.

Medline Plus. 2012, February 26. *Informed consent, adults.* http://www.nlm.nih.gov/medlineplus/ency/patientinstructions/000445.htm (accessed May 20, 2014).

Meisel, A., and M. Kuczewski. 1996. Legal and ethical myths about informed consent. *Journal of the American Medical Association* 156:2521–2526.

Miller, M. J., M. A. Abrams, B. Earles, K. Phillips, and E. M. McCleary. 2011. Improving patient-provider communication for patients having surgery: Patient perceptions of a revised health literacy-based consent process. *Journal of Patient Safety* 7:30–38.

Minnesota Health Literacy Partnership. 2007, October. *Statewide informed consent process*. http://healthliteracymn.org/downloads/Informed-Consent-white-paper.pdf (accessed May 28, 2014).

Mudano, A. S., L. C. Gary, A. L. Oliveira, M. Melton, N. C. Wright, J. R. Curtis, E. Delzell et al. 2013. Using tablet computers compared to interactive voice response to improve subject recruitment in osteoporosis pragmatic clinical trials: Feasibility, satisfaction, and sample size. *Patient Preference and Adherence* 13:517–523.

Mytrus. 2014. *Reinvent consent with Enroll*. https://www.mytrus.com/en/products-services/enroll (accessed June 20, 2014).

National Center for Ethics in Healthcare. 2006. *Informed consent: Do's and don'ts for best practice from the National Center for Ethics in Health Care*. http://www.ethics.va.gov/docs/infocus/InFocus_20060801_Informed_Consent_Dos_and_Donts.pdf (accessed June 24, 2014).

NCI (National Cancer Institute). 2013, May 12. *NCI consent form template for adult cancer trials*. http://ctep.cancer.gov/protocolDevelopment/templates_applications.htm (accessed June 3, 2014).

NIH (National Institutes of Health). 2007, November 28. *Annotated compendium of NIH resources on informed consent*. Prepared by the Clinical Research Policy Analysis and Coordination Program, Office of Biotechnology Activities. Bethesda, MD: National Institutes of Health. http://osp.od.nih.gov/sites/default/files/resources/AnnotatedCompendiumofNIHResourcesonInformedConsent-28Nov2007.pdf (accessed June 28, 2014).

NQF (National Quality Forum). 2005a. *Implementing a national voluntary consensus standard for informed consent: A user's guide for healthcare professionals*. Washington, DC: National Quality Forum.

———. 2005b. *Improving patient safety through informed consent for patients with limited health literacy*. Washington, DC: National Quality Forum.

O'Reilly, K. 2007. Hospitals look to improve informed consent. *AMEDNews.com*. http://www.amednews.com/article/20071119/profession/311199969/7 (accessed June 26, 2014).

Ormond, K. E., S. Banuvar, A. Daly, M. Iris, J. Minogue, and S. Elias. 2009. Information preferences of high literacy pregnant women regarding informed consent models for genetic carrier screening. *Patient Education and Counseling* 75:244–250.

Paasche-Orlow, M. K. 2005. The challenges of informed consent for low-literate populations. In *Understanding health literacy: Implications for medicine and public health*, edited by J. G. Schwartzberg, J. B. VanGeest, and C. C. Wang. Chicago: AMA Press. Pp. 119–140.

Paasche-Orlow, M. K., H. A. Taylor, and F. I. BrancatiI. 2003. Readability standards for informed-consent forms as compared with actual readability. *New England Journal of Medicine* 348:721–726.

Ramsey, C. 2008, October 30. *Looking at CBPR through the lens of the IRB*. PowerPoint presentation at the University of South Dakota. http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=S&ved=OCEIQFjAE&url=http%3A%2F%2Fwww.usd.edu%2Fresearch%2Fresearch-and-sponsored-programs%2Fupload%2FLooking-at-CBPR-Through-the-Lens-of-the-IRB.ppt&ei=PHesU96yI87FsASMwoCICA&usg=AFQjCNG7HMHZ8OPADS-2iWadWb3qpu93HQ&bvm=bv.69837884,d.cWc (accessed June 26, 2014).

Ridpath, J. R., S. M. Green, and C. J. Wiese. 2007. *PRISM readability toolkit*, 3rd ed. Seattle, WA: Group Health Research Institute.

Rosenberg, R. 2011, February 11. Technology companies adapt interactive video concepts for clinical trial informed consent. *CenterWatch News Online*. http://www.centerwatch.com/news-online/article/1036-sthash.k8VzsCEZ.8ob88k3l.dpbs (accessed June 20, 2014).

Rossi, M. J., D. Guttmann, M. J. MacLennan, and J. H. Lubowitz. 2005. Video informed consent improves knee arthroscopy patient comprehension. *Arthroscopy* 21(6):739–743.

Schenker, Y., and A. Meisel. 2011. Informed consent in clinical care: Practical considerations in the effort to achieve ethical goals. *Journal of the American Medical Association* 305:1130–1131.

Schenker, Y., F. Wang, S. Seliq, R. Ng, and A. Fernandez. 2007. The impact of language barriers on documentation of informed consent at a hospital with on-site interpreter. *Journal of General Internal Medicine* 22:294–299.

Schenker, Y., A. Fernandez, R. Sudore, and D. Schillinger. 2011. Interventions to improve patient comprehension in informed consent for medical and surgical procedures: A systematic review. *Medical Decision Making* 31:151–173.

Sharp, M. 2004. Consent documents for oncology trials: Does anybody read these things? *American Journal of Clinical Oncology* 27(6):570–575.

Siao, D., J. L. Sewell, and L. W. Day. 2014. Assessment of delivery methods used in the informed consent process at a safety-net hospital. *Gastrointestinal Endoscopy* 80:61–68.

Silverman, H., J. Luce, P. Lanken, A. Morris, A. Harabin, C. Oldmixon, B. Thompson, and G. Bernard. 2005. Recommendations for informed consent forms for critical care clinical trials. *Critical Care Medicine* 33:867–882.

Sonne, S. C., J. O. Andrews, S. M. Gentilin, S. Oppenheimer, J. Obeid, K. Brady, S. Wolf, R. Davis, and K. Magruder. 2013. Development and pilot testing of a video-assisted informed consent process. *Contemporary Clinical Trial* 36:25–31.

Strauss, R., S. Sengupta, S. Quinn, J. Goeppinger, C. Spaulding, S. Kegeles, and G. Millett. 2001. The role of community advisory boards: Involving communities in the informed consent process. *American Journal of Public Health* 91:1938–1943.

Sudore, R. L., S. Landefeld, B. Williams, D. Barnes, K. Lindquist, and D. Schillinger. 2006. Use of a modified informed consent process among vulnerable patients: A descriptive study. *Journal of General Internal Medicine* 21:867–873.

Sugarman, J., and M. Paasche-Orlow. 2006. Confirming comprehension of informed consent as a protection of human subjects. Editorial. *Journal of General Internal Medicine* 21:898–899.

Sugarman, J., P. W. Lavori, M. Boeger, C. Cain, R. Edson, V. Morrison, and S. S. Yeh. 2005. Evaluating the quality of informed consent. *Clinical Trials* 2:34–41.

Sugarman, J., A. Corneli, D. Donnell, T. Liu, S. Rose, D. Celentano, B. Jackson, A. Aramrattana, L. Wri, Y. Shao, F. Liping, R. Baoling, B. Dye, and D. Metzger. 2011. Are there adverse consequences of quizzing during informed consent for HIV research? *Journal of Medical Ethics* 37:693–697.

Synnot, A., R. Ryan, M. Prictor, D. Fetherstonhaughm, and B. Parker. 2014. Audio-visual presentation of information for informed consent for participation in clinical trials. *Cochrane Database of Systematic Reviews* Issue 5.

Systemedicus, Inc. 2013. *Electronic informed consent: Types and technologies*. http://www.systemedicus.com/?p=476 (accessed June 26, 2014).

Tait, A. R., T. Voepel-Lewis, S. Malviya, and S. J. Philipson. 2005. Improving the readability and processability of a pediatric informed consent document. *Archives of Pediatric and Adolescent Medicine* 159:347–352.

Tamariz, L., A. Palacio, M. Robert, and E. N. Marcus. 2013. Improving the informed consent process for research subjects with low literacy: A systematic review. *Journal of General Internal Medicine* 28(1):121–126.

Temple University Health System. 2009, April 1. *A practical guide to informed consent*. http://www.templehealth.org/ICTOOLKIT/html/ictoolkitpage1.html (accessed May 19, 2014).

Volker, M. 2005, February. The informed consent process: Future directions. *Applied Clinical Trials Supplement* 22–26.

Wagner, R. A. 2014, June 23. What is informed consent? *emedicine health*. http://www.emedicinehealth.com/informed_consent/article_em.htm (accessed May 28, 2014).

Wanzer, M. B., A. M. Wojtaszczyk, J. Schimert, L. Missert, S. Baker, R. Baker, and B. Dunkle. 2010. Enhancing the "informed" in informed consent: A pilot test of a multimedia presentation. *Health Communication* 25:365–374.

Wee, C. C., J. S. Pratt, R. Fanelli, P. Q. Samour, L. S. Trainor, and M. K. Paasche-Orlow. 2009. Best practice updates for informed consent and patient education in weight loss surgery. *Obesity* 17:885–888.

Wiles, R., G. Crow, V. Charles, and S. Heath. 2007. Informed consent and the research process: Following rules or striking balances? *Sociological Research Online* 12(2):1–2.

Windle, P. E. 2008. Understanding informed consent: Significant and valuable information *Journal of PeriAnesthesia Nursing* 23(6):430–433.

Wirshing, D. A., M. J. Sergi, and J. Mintz. 2005. A videotape intervention to enhance the informed consent process for medical and psychiatric treatment research. *American Journal of Psychiatry* 162:186–188.

Wright, J. 2006. *Best practice: Informed consent that sticks*. Podcast of CRICO of the Harvard Medical Institutions. https://www.rmf.harvard.edu/Clinician-Resources/Article/2006/Best-Practice-Informed-Consent-that-Sticks (accessed April 24, 2014).

Wu, H., R. Nishimi, C. Page-Lopez, and K. Kizer. 2005. *Improving patient safety through informed consent for patients with limited health literacy.* http://www.qualityforum.org/Publications/2005/09/Improving_Patient_Safety_Through_Informed_Consent_for_Patients_with_Limited_Health_Literacy.aspx (accessed May 19, 2014).

Zite, N. B., and L. S. Wallace. 2011. Use of a low-literacy informed consent form to improve women's understanding of tubal sterilization: A randomized controlled trial. *Obstetrics and Gynecology* 117(5):1160–1166.

APPENDIX C-D

Interview Guide

The purpose of today's interview is to talk about informed consent and your opinions about how to make the process better for people. We are interviewing a lot of people, and there are no right or wrong answers to these questions. Your responses are not part of a research project, but instead part of expert feedback from people experienced with informed consent. We are completing a paper for the Institute of Medicine and wish to get people's feedback, along with the literature in the field that we are gathering. I am recording this just so I can listen and get details later.

1. To get started, I wanted to ask you what first comes to your mind when you think of "informed consent"?
   1A. What are the main types of informed consent you see or work with?
2. There are regulatory entities and requirements, from the FDA and Health and Human Services, for example, that guide informed consent. How have these guidelines affected your experiences and work with informed consent?
   2A. How do you think government regulations affect how people understand the informed consent process?
3. What are the main barriers or challenges you have experienced or seen with informed consent today?
4. We are looking for examples or case studies of effective and perhaps new ways of communicating the informed consent process to people. Do you have examples in your work of clear and understandable communications used to help the informed consent process?
   4A. Are there materials you can suggest; verbal cues; other examples? Have you heard of or use the teach-back method?
5. Some people talk about cultural competence in informed consent. What have you experienced with cultural competence in the informed consent process?
6. Do you have examples of communication practices that should be *avoided* in informed consent because they have not worked?
7. What would be your recommended resources for more information about informed consent: any published articles, websites, or reports that you would refer us to?

Those are all of the questions; thank you!

APPENDIX C-E

Code of Federal Regulations, Part 46, Protection of Human Subjects, Basic HHS Policy for Protection of Human Research Subjects, Sections on Informed Consent

§ 46.116 General requirements for informed consent.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth

above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§ 46.117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by § 46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by § 46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

APPENDIX C-F

AHRQ Sample Informed Consent Form from Toolkit (first two pages of sample)

Consent Form*

Study Title

We are asking you to be in a research study.

You do not have to be in the study.

If you say yes, you can quit the study at any time.

Please take as much time as you need to make your choice.

Your medical care will not change in any way if you say no.

Why sign this document?

To be in this study, sign this document.

Why are you doing this research study?

We want to learn more about how to help people who have [insert condition]. This study will help us learn more about [insert specifics]. We are asking people like you who have [insert condition] to help us.

What happens if I say yes, I want to be in the study?

If you say yes, we will:

- Ask about [describe survey items, e.g., your health, what you eat, and if you exercise, smoke, or drink alcohol, and what medicines you take].
- Give you a form with questions for you to answer.
- Read the questions out loud and fill out the form with you, if you want.

* This form is designed for minimal risk, noninterventional

There are no right or wrong answers to these questions. You can skip any question you do not want to answer.

How long will the study take?

The study will take about [insert time] of your time.

What happens if I say no, I do not want to be in the study?

No one will treat you differently. You will not be penalized. [**Note to researcher:** For studies with prospect of benefit add: While you would not get the benefit of being in this study, you will not lose any other benefits.] [**Note to researcher:** For studies with no prospect of benefit add: You will not lose any benefits.] The care you get from your doctor will not change.

What happens if I say yes, but change my mind later?

You can stop being in the study at any time. You will not be penalized. [**Note to researcher:** For studies with prospect of benefit add: While you would not get the benefit of being in this study, you will not lose any other benefits.] [**Note to researcher:**For studies with no prospect of benefit add: You will not lose any benefits.]The care you get from your doctor will not change.

Who will see my answers?

The only people allowed to see your answers will be the people who work on the study and people who make sure we run our study the right way. [**Note to researcher:** If there is a study sponsor that will have access to the data, name sponsor here.]

Your survey answers, health information, and a copy of this document will be locked in our files. We will not put your answers into your medical record.