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

Commissioned Paper for the Institute of Medicine

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INTRODUCTION AND EXECUTIVE SUMMARY

"Informed (but Uneducated) Consent" (Editorial by Ingelfinger, in New England Journal of Medicine, 1972)

"How Informed Is Informed Consent?" (Howard and DeMets, in Controlled Clinical Trials, 1981)

"Informed Consent: Is It a Myth?" (Herz, Looman, and Lewis, in Neurosurgery, 1992)

"Consent Documents for Oncology Trials: Does Anybody Read These Things?" (Sharp, in American Journal of Clinical Oncology, 2004).

"Improving the Quality of Informed Consent: It Is Not All About the Risks" (Editorial by Fernandez, in 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, Mackert, Guinn, Tollison, Breckinridge, & Pont, 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, Williams, Marin, Parker, & Glass, 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 over 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, 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 EU 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. However, 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 section of this paper and are shown in Appendix A and B.

The implications of this paper are three fold. 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 a future research agenda was developed 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 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 priority in order to hone 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 within 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 mediator, or as moderating factor in the literature collected. While there were a few articles specifically centering on health literacy as a main variable (e.g., Donovan-Kicken et al., 2012; Hammil, Helitzer, & Rogers, 2011; Lorenzen, Melby, & Earles, 2008; Miller, Abrams, Earles, Phillips, & McCleeary, 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.

Over 120 published research articles, book chapters, government reports, nongovernmental white papers, and other documents were originally collected. While hundreds of resources discuss implications and evaluations of informed consent for various medical conditions and procedures, 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 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 that 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, snowball sampling was used to obtain other names of prospective interviewees; some of the interviewees were recommended by other interviewees. Interviews lasted between 20 minutes to an hour; some were in person at the interviewees' work site, and others were done by phone if the interviewee was not within a short travelling 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 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

- 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.
SUMMARY OF FEDERAL GUIDELINES

The main source for guidelines on informed consent was the HHS (45 CFR 46.116), and the U.S. Food and Drug Administration (FDA) (21 CFR 50.25). HHS informed consent guidelines 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 E). The regulations explain that the informed consent process is comprised of 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, the purpose of the study, explanations of procedures, and which of them are experimental. In addition, the information must outline benefits and possible risks, confidentiality measures, and whom to 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 from 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 written format. Consent can be received verbally as well. Additionally, 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 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 conversation between the investigator and the participant. This would encourage use of the pronouns you, I, and we. The following is the explanation 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, 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 F has a copy of the AHRQ's Sample Informed Consent Form.
FINDINGS FROM 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, Doyle, & Appelbaum, 2010; Wee, Pratt, Fanelli, Samour, & Paasche-Orlow, 2009). One very recent article studied advanced directives (Sudore, Landefeld, Williams, Barnes, Lindquist, & Schillinger, 2014). Over 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.

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). Matiasék 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, Voepel-Lewis, Malviya, & Philipson, 2005). Hammil et al. (2001) summarized successful informed consent as including five principles: voluntarism, capacity, disclosure, understanding, and decision making (Hammil et al., 2011). 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, Helitzer, & Rogers, 2011; Lorenzen et al., 2008).

**Overall Trend Across Literature**

Overall, the literature reflected 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, increasing empowered and active decision making for participants; and (3) across domains for informed consent, increased use of technology to streamline 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; Matias et & Wynia, 2008; Lidz, 2006; Lorenzen et al., 2008; Paasche-Orlow, Taylor, & Brancati, 2003). Informed consent literature over the last 4 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, & Bulas, 2009; Lidz, 2006; Matias & Wynia, 2008; Sugarman & 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, while 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, Prochazka, Henderson, Bartenfeld, Nyirenda, Webb et al., 2010; Schenker, Fernandez, Sudore, & Schillinger, 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, Struve, Collins, Liu, Nelson, & Bloomfield, 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 (2001) stated that completing forms before arriving for a procedure or appointment might avoid participants from feeling rushed or pressured to sign the informed consent forms without expressing their questions or concerns. 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 staff or others conduct informed consent without this knowledge may lead to an informed consent process with a greater time and effort burden 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.
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 from 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 their model of informed decision making, which 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,

An annual all-staff required education, and

Designing a health literacy program for physicians.

Other authors have suggested that the person who conducts the consent procedures be different than the researcher responsible for the study outcomes (Sugarman & Paasche-Orlow, 2006). 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 outcome goals of study, the roles should be separated (Sugarman, & Paasche-Orlow, 2006).

**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 misconstrue the rationale behind informed consent or assume other family members should be part of their decision making (Matiasek & 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 & 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, Travers, Cowden, Young, Sanhueza, & Dunston, 2008; Cordasco, 2013; Clark, Mangram, Dunn, Lebron, & Peralta, 2011; Fink et al., 2010; Cortes, Drainoni, Henault, & Paasche-Orlow, 2010; Griffin et al., 2006). Fink et al. (2010) found that patients' race, education, and age predicted level of comprehension in medical consent, while 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, Bengtzen, Henderson, & Jacobson, 2008). A review of 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 low literate participants. Authors conclude that difficulty and risk differences across studies might have served as a confounder in their evaluation (Tamariz, Palacio, Robert, & Marcus, 2013).

Non-native speakers of the English language have significant difficulty understanding informed consent in this country (George, Moran, Duran, & Jenders, 2013; Schenker, Wang, Seliq, Ng, & Fernandez, 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 this group to express their questions and concerns is of particular importance as 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.,
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 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 low educational background (Clark et al., 2011; Siao, Sewell, & Day, 2014). Siao et al. (2014) indicated that the multilingual class increased patients' recall of facts about the screening and 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; NQF, 2005a; Matiasek & Wynia, 2008). 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 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 literature populations.

**During: Communication and Informed Consent Documents**

The majority of studies compared effects of 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 digital and online systems to conduct informed consent. For much of the work, verbal formats were more favored for low literate audiences, and multimedia programs sometimes improved patient comprehension, especially about knowledge and risks of 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 due to 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, complex terminology, and high reading levels (Albala et al., 2012; 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 et al. found that 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 likelihood of comprehension among low literate audiences. 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, Fields, Beck, Kang, Kiyak, Pawlak 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 avoidances, such as 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).

While less a main goal of the research published in the last few years, readability assessments remain part of the literature on consent documents, as well as how to improve consent documents for persons with low health literacy (Cordasco, 2013; Denzen, Santibanez, Moore, Foley, Gersten, Gurgol 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 (David et al., 2014; 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 reading level, simplifying terminology, and
shortening length of forms increased patients reading the consent forms and their ability to describe procedures in their own words (Cordasco, 2013; Lorenzen et al., 2008). While there was no difference in 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 basing 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, Leone, Salzman, Vozenilek, & Cameron, 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 (IOM, 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
Verbal interactions facilitate trust in addition to improving comprehension (Miller et al., 2001; 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 literate participants and have resulted in perceived control by other participants (Brink, 2006, 2012; Campbell, Goldman, Boccia, & Skinner, 2004; Cowan et al., 2007; Harmell, Palmer, & Jeste, 2012; Rossi, Guttmann, MacLennan, & Lubowitz, 2005; Wanzer, Wojtaszczyk, Schimert, Missert, Baker, Baker 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 et al. (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 make it worthy of testing for better informed consent, as the media combines sound, still pictures, video, and text. Brink’s (2012) article includes a chart outlining the advantages and disadvantages of using computer, telephone, televisions, or standalone 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, Pfeifer, and Paasche-Orlow (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. "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, 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 for 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, Calderon, Gennis, Macklin, Ortiz, & Wall, 2007). Campbell et al. (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 & Emanuel, 2004; Sonne, Andrews, Gentilin, Oppenheimer, Obeid, Brady et al., 2013). Sonne et al. (2013) found that more educated participants preferred the video to print, and the video version was lengthier than the print version. While Harmell et al. (2012), supported 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 (Matiascek & Wynia, 2008; Hall et all, 2011; Rossi el al., 2005).

Some researchers have suggested that in the absence of solid evidence, which format to
use should depend on aspects of the risk, the setting, and the staff (Volker, 2005; Schenker et al., 2011). Schenker et al. (2010) 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 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 (Hall, Hanusa, Switzer, Fine, & Arnold, 2012). 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 often comprehension is 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 & 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 et al., (2002) 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 explains 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 do 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, Lavori, Boeger, Cain, Edson, Morrison 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 a third of the sources evaluated or recommended the teach-back method. The teach-back method consists of asking the participant to repeat back information conveyed to him or her to ensure full comprehension before he or she agrees to the treatment or participation in the trial and signs 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; The 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 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 & Paasche-Orlow, 2006; Wee et al., 2009). Based on 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 et al. (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 working 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 felt 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, 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 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 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, which makes translating the forms 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. While 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 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 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. Due to 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 true informed decision making. "A dismissive attitude," as one interviewee described it, is detrimental to increasing commitment of participants. It should not always be a staff member with the lowest seniority to carry out the informed consent process. This may send an incorrect message to other staff that informed consent is not important. In addition, staff 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.* 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. Assume it is the researcher's or provider's responsibility to ensure 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 staff is not well trained and sensitive to participant health literacy needs. Training staff on how to address possible challenges that may occur and how to prioritize information for participants is required.

*Interactive exchange of information is more successful.* 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 relied on verbal explanations to supplement the forms, and allots double the time expected to complete the process. Another interviewee described how they 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.

*Multimedia and technology may offer benefits to certain populations.* While the outcomes from using multimedia techniques are mixed, there are benefits for certain audiences. One interviewee recounted the successful use of a computerized avatar in imparting informed consent information to a low literate 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 chances of comprehension by the target population.

*Continuously evaluate success and allow for feedback.* Document details of each study in order to analyze failures that should be addressed in the future. 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.

*Not just patient-centered, but patient-driven communication.* Before beginning the informed consent process, know your audience and incorporate their language and level of comprehension into the process before beginning. Ask patients 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, risks described from a participant's perspective, and potential side effects listed 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, while 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 for during informed consent, and practices relevant for when informed consent is completed.

Preparing

1. Create a culture that places high value on the informed consent process. Creating a culture that values true, 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 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 different than the principal
investigator but who has a decision-making role in the project. This may be challenging, as 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 content of forms. Some advise maximizing time allotment to 30 minutes.

8. Weigh 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 were more effective with higher education levels.

9. Translate all documents into the primary language used by participants.

10. Measure reading level of documents to ensure 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. 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 understands.

22. Prioritize the most important pieces of 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 with white space.

25. Use supplemental decision aids and other visuals, which can be in video, on a computer,
or in infographic format.

**Evaluating**

26. Document the process. Take notes, or video or audio record 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 importantly, on aspects of voluntarism and confidentiality.
DISCUSSION AND CONCLUSION

The literature review and interviews completed for this paper focused on the last 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 it reflects value and respect for them while also implementing effective communication tactics. Interviewees, editorials, and some 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 continues to be barriers with health literacy during informed consent used in clinical trials, medical treatments, and diagnostic screenings. Over 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 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 & Bulas, 2009; Lidz, 2006). On one hand, it was apparent that simplified forms need 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 has also been revealed that level of risk, setting characteristics and participant factors might be used to construct clear and comprehensible informed consent procedures. However, there were gaps in 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. While 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. While on one hand many authors encouraged standardized approaches to improving participant comprehension of clinical trials or medical treatments, 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 the factors such 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. While 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 replicating 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 between the contexts of medical treatment, diagnostic screening, and clinical trials, and 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 embarking on especially complex procedures, like 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 & Bulas, 2009). Less invasive, low-risk procedures may not require the same structural or supplementary resources (Sugarman & 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 in 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, Callahan, Hawk, Broucksou, Hink, Rudd & Brach, 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. While 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 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 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. Their 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). While other toolkits and resources illustrate steps to increasing effectiveness of informed consent, we found no infographic to assist in visualizing the steps before, during, and after informed consent.

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

1. The first step is to *know the setting and the risks*. 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, staff can also be part of the construction of health literate forms.

3. After staff are trained in new informed consent techniques, the third step is to get to know your participants. While individual levels of health literacy are not always possible to measure, there are several factors to understanding your populations: what might be average health literacy levels, formal education, and how cultural norms and beliefs about medicine and health might influence their reaction to informed consent procedures.

4. Once an analysis of your population is complete the next step is to prepare written forms based on the population, the setting characteristics, and in particular, the risk level of the study. This step, simplify written forms, is when the toolkits available online as well as other best practices can be employed.

5. Once forms are adjusted according to best practices for low 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 either as supplementary to the main documents, as decision aids, or in substitution of main print documents. The research on understanding population characteristics assists practitioners with this decision, albeit 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 the important task, to assess comprehension. At this point, the
research consistently points to the value of teach-back and teach-to-goal approaches to evaluating comprehension and confirm comprehension before moving forward.

8. Finally, the last step is to document and evaluate. This is to evaluate not the comprehension of a participant, but the success of the overall system put in place for health literate informed consent. Documenting successes and discussing failures among staff 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 B presents "The Situational Risk Model of Communicating Informed Consent." This visual model incorporates a "tailored" approach to communicating with different audiences based on 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 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 risk, the AHRQ informed consent template is helpful (see Appendix F as 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 in
emergency medical situations or when individuals are incapable of making decisions. However, this may be a template for practitioners to consider variable factors that affect how much information is necessary. The model provided here is what we hope to be the beginning of research on the different factors that influence how health literate informed consent can be.

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. But this was not without limitations in the search, interviewing, and analyzing of resources. First, while parameters for the literature search helped us complete a worthy paper within the assigned timeframe, it also limited our ability to conduct a systematic, comprehensive literature search outside the United States and outside of the past decade. While we feel confident that we amassed a saturated point 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 were added to 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, albeit 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 suggests future research opportunities, as does 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.
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APPENDIX A

Roadmap to health literate informed consent

1. Know your Setting/Risks
   - Study procedures
   - Length of time for study

2. Train Staff
   - Educate on IC

3. Know your Participants
   - Health literacy level
   - Cultural norms
   - Gender

4. Simplify Written Forms
   - Plain language
   - Best practices

5. Consider Alternate Formats
   - Multi-media
   - Video
   - PowerPoint
   - Computer agent

6. Dialogue
   - Verbal exchange of information

7. Improve your Process
   - Document and evaluate system

8. Assess Comprehension
   - Teach-back
   - Teach-to-goal
APPENDIX C

Bibliography of Useful Resources


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APPENDIX 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 lots 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 that 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 a 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, 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?

That is all of the questions, thank you!
APPENDIX 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 F
AHRQ Sample Informed Consent Form from Toolkit
First two pages of sample

Sample Informed Consent Form*

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 research only.
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.