VIEWPOINT

Digital Multimedia
A New Approach for Informed Consent?

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The bioethical principle of respect for persons requires that individuals participating in research studies are provided with sufficient information to allow them to make autonomous and informed decisions. In general, the process of informed consent requires that investigators disclose pertinent information regarding procedures to be performed, risks, and benefits, etc, in a manner that participants can understand. In most cases, this information is reinforced by having the study participant or parent/guardian read a consent document, which is then signed to authorize participation.

Despite the ethical and legal imperatives of this process, concern exists that many study participants and parents do not fully understand the information provided and as such may not be truly informed. The reasons for this are multifactorial but often result from incomplete disclosure and/or poorly formatted and excessively long consent forms written above the recommended grade reading levels. However, rather than becoming simpler, the complexity and length of the traditional consent form appear to be increasing, particularly with consent forms designed for sponsored clinical trials.[1]

In an attempt to address some of these concerns, the Office for Human Research Protections (OHRP) recently issued an advanced notice of proposed rulemaking that included limiting the length of consent documents, inclusion of prescribed content, prescribing how information should be presented, reducing institutional boilerplate consent forms, and standardizing the consent template.[2] In light of this advanced notice, it may be time for investigators, institutional review boards, and regulatory agencies to reevaluate the mounting evidence that supports the use of innovative strategies to enhance participants' understanding of research information.[3]

Although the consent form represents only one aspect of the informed consent process, it continues to serve as a primary vehicle for disclosure of research information. However, in an attempt to meet regulatory and legal requirements, many boilerplate consent forms appear to do so at the expense of participants' comprehension. As Waisel[4] suggests, "focusing on the legal requirements suffocates the primary goal of the consent process to satisfy the decision makers' needs." Excessively long consent forms containing complex information in a one-size-fits-all format can be intimidating to many participants, particularly for those enrolled in randomized clinical trials or who have low education or poor literacy and numeracy abilities. Indeed, evidence suggests that approximately half of participants do not read the consent document carefully.[5]

Given the concerns regarding the inability of many research participants to comprehend information using traditional consent forms, consideration of other modes of information delivery may be warranted. One approach that has shown promise in the delivery of health information is the use of digital multimedia. With the expanding societal use of computers and the universal trend toward medical informatics and electronic medical records, it may be that digital multimedia could offer unique opportunities for improving the approach to the informed consent process.

Although the same concerns regarding the amount of information, readability, and formatting apply regardless of the mode of message delivery, digital multimedia offer several important advantages over traditional paper consent forms. First, computer-based multimedia can promote active participation in learning through interaction, whereas information acquisition using paper consent forms is typically passive. It has been estimated, for example, that individuals remember approximately 10% of what they read, 20% of what they hear, 30% if they visualize in addition to hearing, 50% if they observe someone doing something along with an explanation, and 90% if they perform the task themselves.[6] Thus, whereas paper consent forms can only be read, digital multimedia have the potential to enhance understanding by utilizing all of these approaches (ie, read, hear, watch, and do).

A second potential advantage of digital multimedia over paper media is to leverage the so-called pictorial superiority effect. This concept is best characterized by the phrase "a picture is worth a thousand words," which, despite the cliché, is a concept firmly grounded in science. Pictorial superiority effect explains that individuals remember concrete items more readily when presented as pictures rather than words and that pictures drive conceptual processing, require less cognitive effort, and aid retention.[7] The visual salience provided by the pictorial superiority effect is particularly effective when using graphical media to present risks and benefits and for participants with poor literacy/numeracy and for explaining complicated decisions in which shared decision making is important.[8]

Third, digital media are able to incorporate interactive in-line exercises that can establish "real-time" understanding of information at the time decisions are made. This function can be enhanced by using corrective feedback that alerts the participant and investigator to an incorrect answer and provides the correct response. Results from these exercises could be downloaded via computer with the e-signed consent form directly into the patients' electronic medical records. Several studies support corrective feedback;

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Festinger et al[9] showed that participants randomized to receive corrected feedback following disclosure of study information had greater long-term retention compared with those who received no feedback.

Fourth, digital multimedia have the potential to "tailor" information to the individual participants' learning styles and information preferences. Computer tailoring has been shown to be effective in helping individuals understand and modify health behaviors by providing information that is personally relevant. For example, participants who require additional clarifying information can do so by simply clicking on a hyperlink. Options for risk-benefit presentations, eg, graph vs text based on personal preferences and understanding, can also be accommodated. Thus, both the amount of information and message delivery can be tailored to an individual participant's information needs.

Evidence supporting the effectiveness and acceptance of digital multimedia for research and health care consent is increasing. Studies reveal that computer-based educational interventions for chronic conditions such as asthma, diabetes, and arthritis elicit a greater sense of control and empowerment, improve understanding of the conditions, and are preferred by patients.[10] Video informed consent has also been shown to improve patient comprehension of various surgical procedures and increases the likelihood of clinical trial participation. Use of multimedia to help parents and children understand clinical trials has also been demonstrated. However, even though this technology has been shown to improve participant understanding, an investigator's discussion with a participant remains the cornerstone of "informed" consent.

Despite the promise of digital multimedia, potential disadvantages exist, including cost, threats to confidentiality, and access. However, these issues are likely to diminish as technology and access advance. Creation of digital libraries from which investigators can download content and design their own study-specific documents is possible and would mitigate future costs.

Given the ongoing concerns regarding the inability of research participants to understand information using conventional consent forms and the recent OHRP-proposed rulemaking changes to the informed consent process, new and innovative approaches to the provision of research information are warranted. Continued reliance on traditional boilerplate consent forms that serve to meet regulatory requirements but inhibit comprehension is no longer acceptable. Regulatory agencies, institutional review boards, and investigators should consider and implement innovative evidence-based strategies to ensure that respect for persons through improved understanding remains central to the tenet of informed consent for both research and patient care.

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