Instructional Strategies to Improve Informed Consent in Healthcare Research:

Pilot Study of Interactivity and Multimedia

by

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**Abstract**

Research with human subjects requires that they be informed about the research study they are being asked to participate in and make a voluntary decision to participate. However, informed consent documents have become lengthy and complex, and participants often have difficulty understanding and remembering consent information. Many content specific interventions have been studied to improve the consent process. However, results have been inconsistent. Viewing informed consent as an instructional process, this study was designed to pilot a cognitive/perceptual approach to the informed consent process. Incorporating multimedia and interactivity into the consent process was hypothesized to improve learning of the presented content. This hypothesis was tested using an experimental design with random assignment to one of three conditions, (1) a standard, paper-based condition (control), in which the researcher explained the consent information to participants, (2) a multimedia condition in which participants viewed the consent information with very limited interactivity, and (3) an interactive multimedia condition in which participants viewed the consent information but had user control and received scripted questions with feedback. An IRB-approved informed consent document for a healthcare study was used for content, and this study was a simulation of the informed consent for that study. Ninety-five participants completed the study and responded to a knowledge assessment and a satisfaction and demographics questionnaire. Participants in the interactive multimedia condition were found to report better knowledge of the information presented than those in the control condition. Although interactive multimedia participants took longer to complete the interactive multimedia consent, they perceived that it was easier and took less time compared to those in the control condition. The study has implications for applying instructional design to improve informed consent processes and suggests the need to examine multimedia and

interactivity as separate contributing factors for education.

**Introduction**

Research with human subjects requires that specific information about the research study be provided to the participant and that the participant voluntarily consents to participate (Protection of Human Subjects, 45 C.F.R. §46.116, 2009). Often studied from a legal or ethical perspective, this informed consent process can also be viewed as a learning session. A researcher provides information about the study to the participant, and the participant uses this information to make a decision whether to participate in the study. Although federal law mandates a paper consent document, potential participants rarely read the paper documents (Behrent et al., 2011). The documents, particularly for healthcare research, have become very lengthy and complex (Baker & Taub, 1983; LoVerde, Prochanzka, & Byyny, 1989, Henry et al., 2009). Therefore, researchers or clinicians typically review all or part of the informed consent document verbally with participants (Brown, 2004).

What participants remember and understand from the informed consent process is often disappointing (Cox, Fallowfield, & Jenkins, 2006; Joffe et al., 2001). In a study among well-educated participants (including medical students), one of every five (20%) did not recall the drugs they would be exposed to or any adverse effects of the treatments; eight of ten (80%) could recall no more than 2 of 23 side effects (Fortun et al., 2008). In another study, more than two of every three patients (69%) could not identify the main side effect of the study drug (Griffin et al., 2006). For healthcare research, these issues are exacerbated  because the studies may involve higher levels of risk for potential participants, discrepancies between the goals of research and health needs of the patient-participants, and conflicting obligations for staff who are serving

multiple roles in the consent process (e.g., clinician vs. researcher; Cohn & Larson, 2007; Cox, Fallowfield, & Jenkins, 2006).

Interventions have been attempted to improve participant understanding. These interventions have focused on modifying the content of informed consent (e.g., simplifying language, reducing the length of informed consent documents) or supporting learning with activities such as decision aids and simulations (e.g., vignettes or case studies). Much research has also focused on using media to deliver consent information (Agre et al., 2003; Campbell, Goldman, Boccia, & Skinner, 2004; Dunn et al., 2002; Henry et al., 2009; Jeste et al., 2009; Karunaratne, Korenman, Thomas, Myles, & Komesaroff, 2010; Kass, et al., 2009; Strevel, Newman, Pond, MacLean, & Siu, 2007). However, much of this informed consent research has produced inconsistent results (Cohn & Larson, 2007; Dunn & Jeste, 2001; Flory & Emanuel, 2004; Jeste et al., 2008; Ryan, Prictor, McLaughlin, & Hill., 2008). Henry et al. (2009) bemoan the "relative paucity of data from methodologically rigorous and conceptually grounded studies" (p. 1), which creates a barrier to multimedia use in informed consent; Flory, Wendler, & Emmanuel (2007) argue that informed consent needs to become an evidence-based practice. The current study focused on piloting a modification of the delivery method, based on theories of multimedia learning and interactivity, for the informed consent for a medical research study, rather than modifying the content. We hypothesized that using multimedia delivery and interactive learning strategies would result in improved understanding of the information in the informed consent document.

**Background**

Although multimedia has many definitions, for this research study *multimedia* is the combination of visual and auditory delivery of information, including the use of pictures,

animations, recorded words, live words, sounds, or video (Mayer, 2009). Paivio's (1990) dual coding theory presents that people process information through two simultaneous modalities, verbal (words and symbols) and spatial (pictures and movement). Strategically and simultaneously presenting information through both modalities has been shown to enhance learning (Clark & Mayer, 2008; Mayer, 2009; Mayer & Moreno, 2003; Mousavi, Low, & Sweller, 1995). Thus, systematically adding visual images that support spoken words should assist learners to integrate and remember the presented information better (Clark & Mayer, 2008; Mayer, 2009).

Multimedia can also enhance learning when the instruction is designed based on principles of Cognitive Load Theory (Sweller, van Merriënboer, & Paas, 1998; Verhoeven, Schnotz, & Paas, 2009). Multimedia can potentially reduce extraneous load (load not related to learning the content) by using narration with text (e.g., modality effect principle) and placing words near related graphics (e.g., contiguity effect principle). In addition, multimedia can increase generative (germane) load by including structured activities that improve learning (e.g., schema acquisition). By carefully designing both content and presentation of instruction, multimedia instruction can facilitate the control of content and presentation of information, thereby maintaining optimal cognitive load (Mayer, 2009; Mayer & Moreno, 2003, 2010; Sweller, van Merriënboer, & Paas, 1998).

Distinct from multimedia, adding interactivity to informed consent can improve participant understanding by optimizing cognitive load and correcting misconceptions. Many theories of interactivity have been proposed (Downes & McMillan, 2000; Heeter, 2000; Jensen, 2008; Kiousis, 2002; McMillan, 2002, 2005). These proposals suggest a range of constructs, including direction, time, place, control, responsiveness, and perceived goals (Downes &

McMillan, 2000); duration, contiguity, usability, and gratification (Heeter, 2000); structure of technology, context, and user perception (Kiousis, 2002). Because of practical constraints for a pilot study, a simplified definition of interactivity was applied here. *Interactivity* was defined as the degree to which an individual was (1) asked to respond or use information and (2) provided with feedback on his responses (Yacci, 2000; Kiousis, 2002; Koolstra & Bos, 2009). Thus, this interactivity contrasts with passive reception of information, such as watching television.

Applying information processing and interactivity theories (Yacci, 2000), interactivity can enhance learning by making presented information more meaningful with interactions that support generative cognitive load. Meaningful learning occurs when learners build schemas by actively processing information, selecting relevant information, organizing it, and integrating it into their memory structure (Mayer, 2009). Question-response-feedback designed interactions draw attention to the target concepts, elicit memory retrieval, and reinforce or encourage reorganization and integration of these target concepts into longterm memory.

Interactivity can also enhance learner engagement by providing a sense of social presence (Yacci, 2000), encouraging perception of reduced effort (Downes & McMillan, 2000), and by attracting and maintaining learner attention (Lustria, 2007). Even the expectation of receiving feedback has been shown to improve learning behavior with learners (Vollmeyer & Rheinberg, 2005).

For this pilot, we hypothesized that multimedia and interactivity would improve participant understanding of information presented in informed consent when compared to the standard, researcher reviewed paper-document process. This hypothesis was tested in a mock study, using an IRB-approved informed consent protocol from a medical research study.

**Method**

**Participants.** Participation was open to all English-speaking students, staff, and faculty at a Midwestern state university. Ninety-five (95) individuals completed the study, with a mean age of 34 years. Participants were more likely to be female (73%), Caucasian (90%), and highly educated (graduate or professional degree 35%, some college 23%, college graduate 19%, some graduate or professional classes 16%). Most reported that they had participated previously in medical research (64%).

**Conditions and Instruments.** The study compared three informed consent processes. The information, the informed consent document for a recently completed medical study, presented in all three conditions was identical. The conditions differed only in the way that the information was presented.

*Control Condition.* In the Control Condition, researchers provided the participant with a paper copy of the informed consent document and summarized each sentence of the document for the participant, pausing after each section to ask if the participant had any questions. Researchers answered any questions that the participant asked.

*Multimedia Condition.* In the Multimedia Condition (see Figure 1), the text of the informed consent document was presented on a computer screen with relevant graphics; narration of the text was provided through the speakers. Once the presentation started, it ran automatically, moving from one screen to the next without participant input and synchronized with the narration. Participants could pause and resume the presentation and control the sound volume. The researcher was available in an outer room. Participants could pause and seek out the researcher if they had questions or wait until the presentation completed to ask the researcher questions.

***Interactive Multimedia Condition.*** The Interactive Multimedia Condition (see Figure 2) was identical to the Multimedia Condition except that (1) participants had to click on the arrow button to continue to the next screen of information, could return to prior screens to review content, and could replay the narration; and (2) the presentation included 10 multiple-choice questions, at least one per section, to test for content. These questions came after the completion of each section (e.g., Procedures, Alternative Treatments). After participants chose an answer, the program provided the participant with feedback. For correct responses, the feedback stated that the response was correct and provided reasons why. For incorrect responses, the feedback stated that the response was incorrect, provided the correct answer, and explained why the response was incorrect. Participants had to respond to the question until the correct response was given. As with the Multimedia Condition, participants could pause the presentation and seek out the researcher if they had questions, or wait until the presentation was completed to ask questions.

***Knowledge Assessment.*** The assessment consisted of 18 multiple-choice questions, based on the information presented in the informed consent, and included the key informed consent components based on federal guidelines (Protection of Human Subjects 45 CFR §46.166, 2009). These guidelines require the inclusion of the basic elements of informed consent: the purpose of the study, expected duration of participation, a description of study procedures, identification of experimental procedures, risks, benefits, alternative treatments, confidentiality, costs and compensation, the voluntary nature of the study, and contact information.

***Satisfaction and Demographic Information.*** Using a 5-point Likert scale, participants were asked to rate the perceived length of the informed consent process they completed, its

difficulty, and the importance of the information presented. These questions were included to pilot a simplified, general measure of satisfaction for the pilot study. For the demographic questionnaire, additional personal information was also requested, including age, race/ethnicity, education, gender, and income.

**Procedure.** Participants were recruited via a mass email to students, faculty, and staff; news releases to university personnel; and posted flyers. Participants received a $10 payment for their participation.

Participants were randomly assigned to one of the three conditions. For the Control Condition, researchers accompanied participants to a hospital examination room and conducted the informed consent. For the Multimedia and Interactive Multimedia Conditions, researchers accompanied participants to the examination room, started the informed consent presentation, demonstrated how to use it, and then left the room, allowing participants to complete the informed consent on their own. Participants were encouraged to contact the researcher if they had any questions during the multimedia presentation. For all conditions, participants were allowed to ask questions after completing their condition and then completed the dependent measures on a computer in the examination room.

**Results**

**Knowledge Assessment.** Knowledge assessment scores were calculated as the total number of correct responses out of the 18 questions. An analysis of variance showed that the effect of informed consent condition was significant, $F(2,92) = 5.10$, $p = .008$. Post hoc analyses using the Tukey HSD post hoc criterion for significance indicated that the average number of correct answers was significantly higher in the Interactive Multimedia Condition (M=15.9, SD=0.93, range = 14 to 17) than in the Control Condition (M=14.9, SD=1.34, range = 13 to 17),

(p < .05), although neither significantly differing from the Multimedia Condition (M=15.2, SD=1.51, range = 12 to 17).

**Satisfaction – Ratings of Length, Difficulty and Importance.** Using a 5 point Likert scale, participants rated the difficulty, length, and importance of the informed consent process. Analyses of variance revealed a significant effect for condition for difficulty ($F(2,93)=7.29$, p=.001) and length ($F(2,93)=3.53$, p=.03), but not for importance ($F(2,92)=0.17$, p=.84). Post hoc analyses (see Table 1) using the Tukey HSD post hoc criterion for significance indicated that participants in the Interactive Multimedia Condition rated the process as significantly easier (*p*=.001) and shorter in duration (*p*=.03) than those in the Control Condition, although neither significantly differing from participants in the Multimedia Condition.

**Time.** Participants were timed from the point they began the informed consent process to the point they completed it and had their questions answered, but prior to starting the knowledge assessment, and satisfaction and demographic questionnaire. The Paper-Based Condition (M=18.7 min., SD=2.32, range = 14 to 25) took significantly less time to complete (2 minutes less) than the Interactive Multimedia Condition (M=20.8, SD=5.38, range = 7 to 31); neither differed significantly from the Multimedia Condition (M=19.2, SD=1.49, range = 17 to 22).

**Discussion**

Using interactivity (i.e., question-response-feedback activities) combined with multimedia to present informed consent information resulted in participants learning the information better than participants who received the same information via the standard, paper-based approach. By applying educational principles to this authentic learning activity--an informed consent process-- participant understanding was improved. Improved understanding

provides the potential for individuals to make better informed decisions about research participation and therefore helps to protect their rights and reduce institutional risk.

Results of the multimedia without interactivity approach fell between the interactive multimedia and the paper-based approach for knowledge acquisition and ratings of length and difficulty (see Table 1). However, the multimedia without interactivity did not differ significantly from either interactive multimedia or paper-based consent processes. This suggests that interactivity and multimedia had differential and positive effects on learning. Thus, interactivity and multimedia need to be studied as separate constructs in future research to distinguish their individual and combined effects.

As mentioned, participants spent more time in the Interactive Multimedia Condition (approximately 2 minutes more than the paper-based condition), but they perceived that it took them less time and was easier than the paper-based approach. Multimedia Condition results fell again between Interactive Multimedia and Paper-Based. Thus, multimedia and interactivity separately affected not only knowledge acquisition but perceptions of length and difficulty, suggesting a more generalizable principle. Future research will need to address affective components of multimedia and interactivity in informed consent research, particularly as some medical research (e.g., oncology) may elicit high patient levels of anxiety and cognitive load.

The purpose of this study was to pilot the application of cognitive and perceptual principles to an actual learning session. Because this was a pilot study, the generalizability of the results are limited. The sample reflects limited geographic range (e.g., a Midwestern university) and is constrained in terms of education (university employees, students, and faculty), research experience and racial and ethnic diversity. Thus, findings will need to be replicated within a

more diverse sample to validate their generalizability. In addition, because the study was a mock study, a clinical setting should be used in future research.

It is also worth mentioning that the goal of the informed consent process should be to achieve 100% understanding of the content presented in the informed consent process. The assessment questions in this study were designed specifically to test the basic concepts and query for possible confusion with information presented and common misconceptions related to research studies. Although the assessment was useful to compare the participants' relative understanding of the information presented, it was not, nor was it intended to be, an indicator of any individual's understanding in an absolute sense. Given the diversity of medical research studies and the purposes, procedures, risks, benefits, and compensation plans, devising a standardized assessment is neither practical nor useful. However, some issues, such as the voluntary nature of research and issues of confidentiality bear similarity across most or all studies. Therefore, researchers on informed consent may want to develop assessment banks of questions that could be used as is or slightly modified for assessing informed consent knowledge of research issues.

The question-response-feedback model is only one interactive strategy that could be used for such purposes. Research to ascertain the individual and combined effects of interactivity and multimedia will help researchers to focus on the most effective and cost-effective approaches to improving informed consent. Other interactive strategies, such as simulations, case studies, and decision support processes could also be used, depending on costs, the complexity and severity of the research, and consequences to patient health.

Besides the question-response-feedback model, the interactivity of the participants with the delivery system was not assessed in this study. The ability of users to interact with the

interface controls in the Interactive Multimedia Condition, to navigate forward or backward, to replay narration, and to answer questions apparently either had positive effects on learning, was neutral, or had negative effects that were negligible. Since these controls are not directly related to learning the consent information, the expectation might be that they should contribute to extraneous load. On the other hand, learner control or other benefits may override this load. Similarly, the human-human interactivity inherent to the Paper-Based Condition suggests an additional load not related to content, where participants put some effort into socially acceptable responses, such as nodding and maintaining eye contact. Again, the expectation might be that this interactivity would contribute to extraneous load. Further research should explore possible differential effects of different kinds of interactivity.

A practical matter for medical research is the cost of alternative informed consent methods. Multimedia platforms, particularly ones using video and audio modes of delivery, can be expensive to develop and difficult to revise, once deployed. Improvements in informed consent must be cost effective, however. The strategies implemented in this study could be used to enhance traditional paper-based approach by adding interactive strategies and/or graphics (such as illustrations) potentially to improve understanding in a cost-effective way. Ultimately, educational researchers have a role to play in medical research to advise on strategies to improve participant understanding.

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Tables and Figures

Table 1. Satisfaction questions.

| Question Text | Condition | N | M | SD |
|---|---|---|---|---|
| 1. How do you feel about the length of this informed consent process? (Rating from 1 to 5 with 1 as "excessively short" and 5 as "excessively long") | Control | 32 | 4.03* | 0.647 |
| | Multimedia | 31 | 3.74 | 0.815 |
| | Interactive Multimedia | 31 | 3.58* | 0.564 |
| 2. How do you feel about the difficulty of this informed consent process? (Rating from 1 to 5 with 1 as "excessively easy" and 5 as "excessively difficult") | Control | 32 | 3.16* | 0.847 |
| | Multimedia | 31 | 2.77 | 0.884 |
| | Interactive Multimedia | 31 | 2.32* | 0.871 |
| 3. How do you feel about the importance of the informed consent information? (Rating from 1 to 4 with 1 as "None of it was important" and 4 as "All of it was important") | Control | 32 | 3.38 | 0.707 |
| | Multimedia | 30 | 3.27 | 0.691 |
| | Interactive Multimedia | 31 | 3.32 | 0.791 |

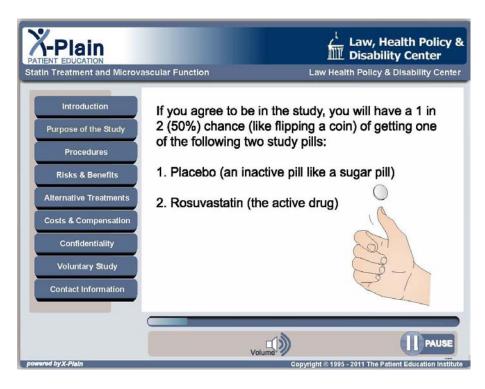* Means significantly differed between these groups, $p < .05$.

Figure 1.Example of a page in the Multimedia Condition (low interactivity).
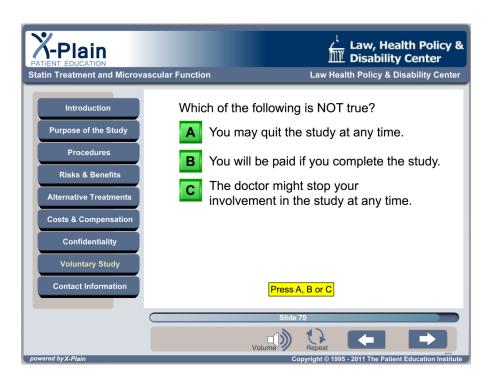
Figure 2. Example of an interactive question in the Interactive Multimedia Condition.