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Development and pilot testing of a video-assisted informed consent process ☆

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ABSTRACT

The informed consent process for research has come under scrutiny, as consent documents are increasingly long and difficult to understand. Innovations are needed to improve comprehension in order to make the consent process truly informed. We report on the development and pilot testing of video clips that could be used during the consent process to better explain research procedures to potential participants. Based on input from researchers and community partners, 15 videos of common research procedures/concepts were produced. The utility of the videos was then tested by embedding them in mock-informed consent documents that were presented via an online electronic consent system designed for delivery via iPad. Three mock consents were developed, each containing five videos. All participants ($n = 61$) read both a paper version and the video-assisted iPad version of the same mock consent and were randomized to which format they reviewed first. Participants were given a competency quiz that posed specific questions about the information in the consent after reviewing the first consent document to which they were exposed. Most participants (78.7%) preferred the video-assisted format compared to paper (12.9%). Nearly all (96.7%) reported that the videos improved their understanding of the procedures described in the consent document; however, the comprehension of material did not significantly differ by consent format. Results suggest videos may be helpful in providing participants with information about study procedures in a way that is easy to understand. Additional testing of video consents for complex protocols and with subjects of lower literacy is warranted.

1. Introduction

Informed consent is the cornerstone to ethical research on human subjects. However, the increasing emphasis on regulatory procedures, combined with more complex and highly technical research procedures, has resulted in lengthier informed consent documents that are often highly technical and difficult to understand. Given these concerns and the ubiquity of alternative communication modalities, it is logical to consider innovative methods of communicating information in the informed consent process. For some research protocols, short videos may better communicate difficult procedures and concepts, be less intimidating, and help potential participants to focus on important aspects of the research.

Informed consent documents are more often oriented to regulatory requirements than participant comprehension. The traditional informed consent process involves providing potential research participants with written material that requires reading and does not take into account other styles of learning, such as visual, auditory, or experiential learning. As consent forms increase in length, there is a decrease in the likelihood that they will be read and adequately comprehended [1]. Even

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when documents are prepared at appropriate reading levels, it is often difficult for potential participants to comprehend and retain the most important details [1,2]. Furthermore, those who are older and more infirm demonstrate lower levels of understanding of research procedures [3]. These issues could jeopardize the process of obtaining consent to participate in research that is truly informed.

There have been a number of studies on multimedia interventions to improve a potential participant's understanding of a clinical trial, but results have been mixed [4–8]. Jimison and colleagues [9] developed a multimedia consent tool after receiving input from key stakeholders, including prior research participants, researchers, and institutional review board members. The tool itself included a structured modular approach that contained standard consent language and allowed investigators to add in research specific information. The key components included general information about clinical trials, printable listing of available resources, interviews with previous study participants, self-test, and trial-specific information. This prototype was favorably reviewed by research participant stakeholders; however, researchers and IRB members had concerns about methods for reviewing the system for potential biases in presentation. The utility of tools in which investigators would need to do a great deal of set up is unclear. Several other studies have found that oral and videotaped presentations of consent content may help patients comprehend consent information [10–12]; however, video remains an underutilized tool in the informed consent process. This may be due, in part, to the types of videos being used. Many studies have merely repackaged the information found in a consent document into a verbal presentation (either audio or a video of a person talking) [13]. Having additional videos of actual procedures may add to a participant's understanding of what he/she will be asked to do during a clinical trial.

The purpose of this study was to develop short video clips of common research procedures and concepts and to test their acceptability and effect on comprehension within a mock informed consent process.

2. Methods

This study was conducted in several phases. The Medical University of South Carolina (MUSC) Institutional Review Board (IRB) approved all aspects of the study, including focus groups conducted with community members and medical researchers, review of video content by a community advisory panel, and the video consent pilot.

2.1. Development of video consents

2.1.1. Video production

In preparation for video production, the research team developed a list of possible research procedures and concepts. From this list, MUSC researchers and community members were asked to rank and prioritize which procedures/concepts may best be communicated by video format. Video scripts for the selected procedures/concepts were developed by an outside production company and were reviewed and approved by the research team. The production company developed scripts and produced the videos under contract with MUSC using grant funding. Final draft versions of the videos were reviewed in six focus groups comprised of community members and then edited by the production company based on feedback. Fifteen high quality videos were produced that described either research procedures or research concepts using visual images with voice over. Additional on-screen instructional text was provided to highlight and summarize important information about the procedure or the concept being viewed. There were no subtitles used in the videos in order to allow for voice over to be re-recorded in additional languages as necessary. The 15 videos were produced over a 6-month time period (from script development to final penultimate version). Each video cost approximately $3,000 to produce.

Developed videos fell into two general categories: specific procedures and research concepts. Procedural videos included: magnetic resonance imaging (MRI), BodPod, intravenous (IV) infusion, echocardiogram, transcranial direct current stimulation (tDCS), transcranial magnetic stimulation (TMS), biopsy, CT scan, ultrasound, and DEXA scan. Conceptual videos included genetic research, gene therapy, data de-identification and coding, randomization, and biorepository. Each video clip was approximately 60 to 120 s long, depending on content, with an average length of 102.7 s. It is important to note that the developed videos focused on what could be expected during a given procedure and did not address risks of the procedures.

2.1.2. Electronic consent platform

The South Carolina Clinical and Translational Research Institute's bioinformatics team, part of MUSC's Clinical and Translational Science Award, developed a platform for the electronic informed consent based on a Research Permissions Management System (RPMS). The RPMS was developed and piloted at MUSC in collaboration with Health Sciences South Carolina with funding from the National Library of Medicine. Specifically, the videos were programmed using HTML5 and incorporated into electronic consent forms as hyperlinks. Metrics on video usage were collected to assess usability. Research electronic data capture (REDCap) [14], a web-based database system, was used for participant registration. The video-assisted consent (VAC) system pulled registration information using the REDCap application program interface to display the appropriate consent material.

The integrated VAC platform allowed the written words of the consent to be emulated on the iPad and videos to be incorporated. Fig. 1 shows an example of an iPad screen that participants saw when reviewing the video-assisted consent. Participants clicked the yellow bar to view the video and could navigate between pages/screens using the forward and back buttons.

2.1.3. Development of mock consents

Once the videos were completed, the research team devised three mock consent documents that contained elements described in the videos. The three consents contained five videos each, using fourteen of the fifteen videos (although a gene therapy video was developed, it was not used; the randomization video was used in two of the mock consents). Resulting mock consent materials were presented at a 10th to 11th grade reading level (see Table 1).