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Effectiveness of Multimedia Aids to Enhance Comprehension of Research Consent Information: *A Systematic Review*

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A longstanding concern among researchers and others involved in human subjects protection is whether individuals fully comprehend the information conveyed to them during the consent process for research.[1] This concern has heightened as consent forms continue to increase in length and complexity, despite calls for shortening them and using understandable lay language.[2] Researchers have also been encouraged to use interactive computer programs, video, and other multimedia tools to complement printed consent documents.[3] Yet it remains unclear whether multimedia tools are effective in enhancing comprehension of consent information. Literature reviews of reports of multimedia studies published through 2007 reveal that the studies have mixed or indeterminate findings about the effectiveness of multimedia tools to enhance comprehension of research consent materials.[4]

In this report, we provide an up-to-date comprehensive and critical review of empirical studies on the effectiveness of multimedia tools as a means to enhance comprehension of information conveyed during the consent process for research. As we have previously argued,[5] there is no logical reason to expect multimedia tools to be universally superior to standard consent materials. Thus, the other intended contribution of this review is to consider the extent to which multimedia consent tools have been grounded in a specific conceptual model or theory regarding the conditions under which these tools might reasonably be expected to effectively aid the consent process.

Literature Review Methods

The term multimedia specifically refers to integration of two or more forms or channels of information, such as auditory (voice and other sound), visual (still and motion pictures, animation, graphs), and/or text.[6] However, as computer presentation is often intermixed with multimedia methods, our use of the term multimedia includes computer-based consent procedures. The literature search through May 8, 2012, was conducted with the PubMed and PsycINFO Cambridge Scientific Abstracts (CSA) Illumina databases. PubMed search terms were "(informed consent OR consent forms) AND (computer-assisted

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instruction OR audiovisual aids OR computerized OR multimedia OR video)." The PsycINFO CSA database search phrase was "(de=computer mediated communication OR de=audiovisual communications media OR de=computer applications OR de=technology OR de=computers OR de=human computer interaction OR de=videotapes OR de=videotape instruction) AND de=informed consent." For both databases, the search was further limited to English-language journal articles tagged as involving human subjects. No restrictions were placed in terms of year of publication.

To be included in this review, studies had to 1) be an empirical report of original data published in a peer-reviewed English-language journal; 2) focus on effectiveness of multimedia tools to enhance individuals' comprehension in the research consent process; and 3) evaluate the utility of multimedia consent compared to routine or other control consent conditions. We excluded reports focused on comprehension of a single methodological component of research (e.g., placebo control[7]); those focused solely on outcomes other than comprehension, such as satisfaction or agreement to enroll in a study; and those focused on multimedia decision aides for clinical, not research, purposes.[8]

Applying the above search criteria yielded 761 records (712 in the PubMed database, and 49 in the PsycINFO CSA database); after identifying and removing 15 duplicate records (those appearing in both databases), there were 746 unique records. Through review of the titles, abstract, and—where necessary—full text, we identified 16 reports from the electronic database search meeting the above stated inclusion/exclusion criteria.[9] In addition, through cross-references from other articles, we identified four additional reports that had not been identified with the above electronic search, yielding a total of 20 reports for this review.[10] The 20 reports were published between December 1988 and January 2012. Details of the 20 studies are summarized in Appendix I.

We carefully read each of the 20 reports and recorded information on the setting, sample, type of protocol, comparison group, conceptual model, or theory guiding the intervention design and implementation (if any), details of the multimedia consent, and the key findings, including whether the multimedia consent was more effective than the comparison condition (yes, partial, or no). To further standardize and structure the review, we also evaluated each included report using a modified version of the Scale to Assess Scientific Quality of Investigations (mSASQI) that had been developed and employed in a prior review of multimedia aides to educate patients and aid treatment decisions.[11] As modified for use in the present review, the mSASQI consisted of 15 items, each referring to a specific aspect of study design, methods, analyses, or interpretation, and each rated by the first (BWP) and second (NML) authors as 0 (absent or inadequate) or 1 (present and adequate), such that the mSASQI total score had a potential range of 0 to 15. Although BWP and NML completed their mSASQI ratings independently, they met after rating five of the articles[12] to identify any discrepancies or ambiguities in scoring rules and then independently scored the remaining reports (Intraclass Correlation Coefficient for mSASQI total score = 0.921). BWP and NML then discussed any discrepancies; their final consensus scores were applied for subsequent analyses.

Given the small number of reports using overlapping interventions or outcome measures, the primary focus of the review was on qualitative rather than meta-analytic or other quantitative review of the empirical literature. However, as a tentative exploration of the degree to which effectiveness findings may have differed by overall methodological quality of the empirical reports, we used the trichotomized effectiveness findings (coded as: "Yes" = 1, "Partial" = 0, "No" = -1) and calculated the bivariate correlation between this trichotomized variable to mSASQI total score using Spearman's rho. Significance was defined as $p < .05$ (two-tailed).

Characteristics of Studies Reviewed

■ ***Populations Sampled.*** The two most commonly sampled populations were people with cancer[13] and people with schizophrenia or other psychoses.[14] However, a variety of other patient populations were also studied, including people who had abused drugs[15] or who suffered from depression,[16] borderline personality disorder,[17] Alzheimer disease or mild cognitive impairment,[18] diabetes,[19] duodenal ulcers,[20] or other unspecified medical conditions.[21] One additional study focused on enhancing consent for perinatal research with pregnant women.[22] Several of the studies also included nonpatient samples, either as the primary study sample with which to test the effects of multimedia consent[23] or as a basis for comparing the results from the patient group.[24]

■ ***Type of Multimedia Aid or Platform.*** The most common multimedia intervention was videotape, studied either alone,[25] or in comparison to a computer-based intervention.[26] Three studies used DVDs,[27] two used bulleted text on a computerized PowerPoint presentation,[28] and two used bulleted text via PowerPoint plus supplementary embedded videos.[29] Six studies used other forms of computer presentation with text only[30] or with embedded video and graphics.[31]

■ ***Effectiveness of Multimedia Consent Aids.*** Ten of the 20

reports (50%) found multimedia-aided consent was associated with significantly better understanding (either overall comprehension or understanding of key informational components) of disclosed information than was achieved without multimedia aids.[32] Six additional studies (30%) reported partial benefits of multimedia consent—i.e., the multimedia-aided consent was more effective than the control consent for at least one study subgroup, at initial or follow-up assessment, or in other subanalyses.[33] Only four studies (20%) reported negative results—i.e., no significant differences between multimedia and comparison consent procedures.[34]

■ *Overall Quality.* The mSASQI quality ratings across the 20 reports are summarized in Table 1. The mean mSASQI total score ranged from 8 to 15 (mean = 11.0 [SD = 1.6]). There was no significant correlation between the mSASQI total score and overall outcome (trichotomized in terms of the demonstrated superior effectiveness of the multimedia consent over the comparison condition: "yes" = +1, "partial" = 0, "no" = -1) rs = -0.121, p = 0.611.

Common Critical Limitations of Studies Reviewed

■ *Use of Conceptual Models or Theory.* Of the 20 reports included in this review, only three[35] described a conceptual model or theoretical rationale guiding development and/or implementation of multimedia tools to enhance comprehension. The computer-based tool devised by Campbell et al.[36] and the DVD-based consent tool from our research group[37] were each partially guided by what are known as the multiple representation and contiguity principles of multimedia theory. Prevailing models of human information processing posit separate channels for initial storage and manipulation of verbal versus visual-spatial information.[38] According to the multiple representation and contiguity principles, learning is facilitated when information is provided simultaneously through both the auditory and visual-spatial channels.[39] There were other considerations given in each of these two studies (Campbell et al. focused specifically on modifications to reduce the influence of literacy levels; we considered additional multimedia learning principles). The third conceptually guided study was not focused on multimedia learning principles per se, but rather the goal of the investigators was to use animated computer presentations to duplicate the nonverbal behaviors (such as hand gestures) that would be exhibited by an expert explaining consent material to a potential research participant.[40]

The present review indicates that multimedia consent tools often have at least partial benefits in terms of improved comprehension in the consent process.

Some of the other published reports (including two from our research group) cited findings from prior studies about enhancing the consent process in the clinical or research settings as a basis for one or more components of their multimedia tools (i.e., use of bulleted text), but no specific theory or model was specified as to why or under what conditions the enhancement components should be expected to facilitate comprehension.[41] The multimedia aids described in some of the other reports were developed or refined in response to suggestions or feedback from clinicians or clinician researchers,[42] bioethicists,[43] participants,[44] or a mixture of representatives from these relevant stakeholder groups,[45] but there were no clear indications that such input was obtained from experts in multimedia learning.

■ *Exploratory Versus Hypotheses-Driven Analyses.* Four of the 20 reports explicitly stated one or more a priori hypotheses about the effects of multimedia consent on comprehension.[46] The implicit/unstated hypothesis in the other 16 reports was presumably that the multimedia-enhanced consent process would lead to superior participant comprehension relative to that achieved with the routine or other nonmultimedia comparison consent procedure, but the expected outcomes in the presence of multiple analyses could not generally be inferred as representing implicit a priori hypotheses.

■ *Other Key Methodological Issues.* Only four reports clearly described use of independent interviewers blind to consent condition.[47] Several other studies employed self-administered questionnaires.[48] (With self-administered questionnaires there is less opportunity to ask follow-up questions for clarification.) In the remaining studies, either the interviewer was not kept blind to consent condition, or the description in the methods section of the associated report was not sufficiently detailed to discern whether the interviewer was kept blind to consent condition.[49]

Discussion

We identified 20 empirical reports testing the effectiveness of multimedia aids relative to routine or other comparison conditions in fostering comprehension of information disclosed in the research consent process. The studies varied widely in terms of the populations targeted, the form and content of multimedia interventions, the nature of measures employed to assess comprehension, and their overall conceptual and methodological nature. Based on the reviewed findings, it appears that multimedia consent tools can be effective aids to the consent process under

some circumstances and/or with some study populations, but the effectiveness is not uniform across all study populations, contexts, or types of multimedia interventions. The three most common methodological limitations were 1) the lack of specification of a theory or model guiding the structure, design, content, and/or implementation of the multimedia consent tool (provided in only three of 20 [15%] reports[50]); 2) the lack of specific a priori hypotheses (provided in only four of 20 [20%] reports[51]); and 3) the lack of a structured, interview-based assessment of comprehension by an interviewer blind to consent condition (provided in only four of 20 [20%] studies[52]).

Due to the diversity of methods and populations in the existing literature, it is difficult to identify clear trends that would indicate the degree to which the various factors influenced the key outcomes. Although the existing studies represent an excellent foundation, there is clearly a need for a "second generation" of conceptually grounded empirical research on multimedia-aided consent. This second generation of studies will be critical to identifying which types of multimedia tools are useful in which specific contexts and for which specific population of research participants.

A potential objection to our call for more theory-grounded research is that positive findings within the reviewed studies did not appear to depend on whether a study was driven by hypothesis, firmly grounded in theory, or even associated with overall methodological quality as indexed by the mSASQI ratings. However, the role of a conceptual model or theory in science is not to guarantee positive results, but rather to enable investigators to approach experimental manipulation and plan follow-up studies in an organized manner to reduce ambiguity when interpreting and comparing positive or negative results.[53] Theory-grounded research informs not only what does and does not work, but also gives insight into why an intervention is or is not effective, which then helps guide further refinements or application to the consent process for new studies.[54]

Information-processing models from cognitive psychology, as well as multimedia learning theory from educational psychology, provide a useful framework from which to develop reasoned, specific, and falsifiable a priori hypotheses for future development in studies of multimedia aids for consent, as well as for understanding many of the results in the existing empirical literature.[55] The working memory system is thought to be a core component of information acquisition (learning) and use, short-term storage, and manipulation of information required in decision-making and problem solving.[56] It includes separate auditory and visual channels for representing new information.[57] Two of the reviewed studies made reference to a component of multimedia learning theory that suggests learning is facilitated by simultaneous presentation of information to the auditory and visual channels.[58] But information-processing models also predict that under some conditions, simultaneous audio and visual presentation may hinder, not facilitate, learning.[59] For example, if a participant is simultaneously presented with important but distinct (nonredundant) information in the auditory and visual channels, this can create what has been called a "split-attention effect," which can interfere with learning and comprehension.[60] As discussed below, the key concept in understanding such differential effects is that of "cognitive load."[61]

A firmly established and critical aspect of the auditory and visual-spatial components of working memory is that they have limited capacity (resources) in the number of units (or "chunks") that can be simultaneously held and processed.[62] The concept of "cognitive load," essentially referring to how much of the limited working memory resources are taken up by a cognitive task, is key to developing theory-grounded predictions about the types and conditions under which specific forms of multimedia presentation should facilitate comprehension of consent-relevant information.[63] Graphic presentation is more effective than text when the figures or images reduce the need to rely on limited working memory resources. Empirical data outside the context of studies of the research consent process have shown that graphic presentation fosters more efficient comprehension than text or speech when the images permit the recipient to simultaneously see or grasp key relationships among components.[64] A very basic example is that it is easier to communicate and comprehend the relative positions of the 50 states in the United States when they are presented as a map than it is through words or text alone. In contrast, there is no reason to expect that a video of an investigator describing a study would be any more effective than if the same information were provided in person. Indeed, a video might be less effective than an in-person presentation because the former delivers a more passive experience, and it is harder when using video presentations to adapt the rate of information to the processing needs of individual recipients.

As we noted previously,[65] there is also no reason to expect that presenting text on a computer screen, in itself, would facilitate more efficient processing of information than when presenting it as printed text. However, with hypertext, computers have the potential for presenting adjunctive information in a way that facilitates keeping the standard text relatively succinct, while making the additional information readily available to those partici-

Table 1.
Results from Modified Scale to Assess Scientific Quality of Investigations

	Proportion of Reports Meeting Criterion
Was the key dependent variable operationalized via standardized scale or other appropriately established method?	100.0%
Were the conclusions justified by the data/findings?	100.0%
Was (were) the sampled population(s) appropriate to the study aims/hypotheses (e.g., patient groups justified, presence or absence of nonpatient comparison group appropriate to study aims)?	90.0%
Were the inclusion and exclusion criteria clearly described and appropriate?	90.0%
Were effects of enhanced consent tested relative to an appropriate control condition (e.g., routine consent rather than another experimental condition)?	90.0%
Was the consent strategy tested in an ecologically valid context (e.g., either actual research consent, or, if simulated, functionally equivalent)?	90.0%
Were statistical analyses appropriate to aims/hypotheses?	90.0%
Were the key limitations of the study appropriately addressed in discussion/conclusions?	90.0%
Are there any concerns about power (sample size)?	85.0%
Was assignment to experimental conditions done with appropriate randomized assignment method?	85.0%
Were demographic or other confounds between compared groups appropriately addressed via analyses and/or interpretation?	85.0%
Was risk of type I and/or type II errors appropriately addressed?	65.0%
Was one or more falsifiable a priori hypotheses specified/tested?	20.0%
Were ratings of key dependent variable(s) done by blinded interviewers?	20.0%
Were the design and implementation of the enhanced consent appropriately grounded in a specified theory or model?	15.0%

Note: Items presented in order of decreasing frequency; modified from the Scale to Assess Scientific Quality of Investigations (mSASQI).

pants for whom it may apply.[66] One of the studies included in the present review did employ hypertext presented on a computer screen so that the information could be organized under menus and submenus.[67] No significant benefits of such presentation were found relative to when information was presented in a fixed serial format (via audiotape accompanied by a printed consent form). However, printed consent forms can also be scanned and read in nonserial order. From an information-processing perspective, the best use of hypertext may be to link it to supplemental material so that the essential material remains uncluttered. Computers also foster a relatively seamless and efficient integration of text with audio/video components, and potentially allow for a more interactive consent process, which can lead to better attention to and retention of information.

Similar considerations of the demands on limited working memory resources also explain the value and potential limits of bulleted text as a consent aid. Specifically, bullet points may facilitate comprehension because the relevant information is made salient, reducing the need to search through and process nonessential details to identify the relevant components. Three of the four studies employing PowerPoint—which typically presents text as bullet points—reported positive effects.[68] In the fourth study there were no differences between the PowerPoint and the comparison condition. However, the latter was an enhanced consent procedure, albeit without multimedia, designed to make critical information more salient.[69] Given the ubiquity of PowerPoint and similar computer slideshow software programs—as well as the ease and low cost of producing such presentations—it seems such methods could be commonly and readily incorporated into standard consent procedures with little added cost or burden. On the other hand, such tools may be best employed as an adjunct to printed consent forms, as there is a balance between providing too much and too little detail. Supporting text can provide contextual information activating relevant prior knowledge

or conceptual schema in the reader's working memory, which, as discussed further below, also facilitates efficient information processing.[70]

Even when including a visual presentation is clearly preferable, however, the information-processing demands of specific types of information may affect which form of visual presentation is the most effective. There is strong evidence from studies of medical decision-making that comprehension of risk and benefit probabilities is facilitated when they are communicated graphically rather than through spoken or printed words alone,[71] but the type of graphic presentation is also important. A number of studies of hypothetical health care decisions indicate that understanding of risk ratios and other probabilistic information may be better achieved with icon arrays (pictographs) than with bar graphs.[72] Pictographs appear to be superior in such contexts because they foster processing key information about the relationship between the numerator and denominator that people otherwise tend to process in suboptimal form (a.k.a., "denominator neglect").[73] A limitation of the reports we reviewed is that they did not generally provide sufficient detail to discern what specific forms of graphics (e.g., bar graphs, pictograms, and/or icon arrays) may have been employed.

Another consideration in incorporating multimedia tools into the consent process is what specifically to communicate. Fifteen of the 20 reviewed studies employed multimedia tools to convey protocol-specific information—i.e., as an alternative way of communicating the information that would appear in a protocol-specific printed consent form. However, in five of the studies, the multimedia presentation was used as a primer to teach potential participants about research concepts, such as randomized assignment, placebo control, the distinction between early and later phase trials, and/or about the consent process itself.[74] Four of the latter five studies found positive effects for the multimedia tool.[75] In the fifth study—in which subjects were given general information about HIV vaccine trials via video or an informational pamphlet—baseline knowledge increased in both conditions, and the videotape group had better retention after one month.[76] None of these studies specified a theoretical rationale for this intervention, but such findings make conceptual sense in relation to limited working memory/processing resources, particularly from the perspective of schema theories.[77] "Schemas" (or schemata) are conceived of as mental structures or organized bundles of knowledge and expectations about specific types of objects or situations; these schemas guide and foster efficient information processing and response. In the context of research consent, having relevant knowledge and expectations about research concepts, methods, and terms, and about the consent process itself, should enable individuals to more rapidly discriminate essential versus nonessential information and reduce the need to use limited working memory resources for active processing. The increased efficiency should foster better comprehension and retention of the information.

Beyond the lack of theoretical grounding and a priori hypotheses, another difficulty in comparing outcomes across studies is the lack of a standard method for assessing the effectiveness of multimedia consent tools. Three studies[78] used the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR),[79] but by far the most common outcome measure was self-administered questionnaires idiosyncratically developed for each specific enhanced consent study.[80] The remaining studies used other semistructured interviews[81] or a questionnaire read aloud by the research staff.[82] One study employed qualitative interviewing (which was consistent with the primary goals of that study but less ideal for drawing definitive conclusions about the effectiveness of multimedia tools).[83] Common evaluation approaches would facilitate comparing observed effect sizes across independent studies.

One caveat should also be noted in regard to our quality ratings. The focus of the present review was on the effectiveness of multimedia consent tools in enhancing participant comprehension and, as reflected in the specific mSASQI item content (see Table 1), our assessments of methodology emphasized criteria deemed relevant to that particular focus. But many of the reviewed studies had multiple aims, and the methods of some studies may have been selected for the investigators' other, perhaps more primary, aims. Thus, our ratings of quality should be read solely in the context of the goals of this review, rather than as a statement about the merits of individual studies in their own right.

What still stands out from the present review is that at least partial benefits in terms of improved comprehension were seen from multimedia presentation in 16 of 20 reviewed studies. Thus, it appears multimedia consent tools often have at least partial utility in the consent process. This conclusion contrasts with that from a 2004 review by Flory and Emanuel,[84] in which they noted that multimedia tools "often failed to improve research participants' understanding," and with the conclusion of the 2007 review by Ryan et al.,[85] who stated that "the value of audio-visual interventions for people considering participating in clinical trials remains unclear." And yet, we agree with the spirit of the conclusions from both the prior reviews that further conceptually grounded and methodologically rigorous research is needed to definitively identify the conditions under

which multimedia has sufficient added value to warrant the production costs and burden. As described above, an information processing perspective, including the concept of "cognitive load," offers a clear framework in which to ground this future work and make substantive progress in the design and evaluation of multimedia aids for the consent process. In the interim, and as noted above, use of bulleted summaries presented via PowerPoint or similar slideshow programs, along with corrective feedback, appears to be at least one low-cost, minimal-burden method that is readily available to enhance the consent process. There also seems to be clear value in not only teaching subjects about protocol specifics, but—in at least some cases—in priming that discussion with a brief discussion about clinical research concepts.

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26. See ref. 9, Campbell et al. 2004; see ref. 10, Agre and Rapkin 2003.

27. See ref. 9, Hutchison et al. 2007, Strevel et al. 2007, Jeste et al 2009.

28. See ref. 9, Dunn et al. 2002; see ref. 10, Moser et al. 2006.

29. See ref. 9, Mittal et al. 2007, O'Lonergan and Foster-Harwood 2011.

30. See ref. 10, Llewellyn-Thomas et al. 1995, Agre and Rapkin 2003.

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Appendix I.
Research on Multimedia or Computer Aids for the Research Consent Process

Authors	*Setting or sample (and type of protocol – real vs. simulated)*	*Comparison*	*Theory, model, or rationale for design of enhancement*	*Multimedia consent results in better comprehension?*	*Quality (mSASQI)*	*Comments*
Norris and Phillips (1990)[1]	Duodenal ulcer patients (N = 200) (Real protocol)	Routine consent vs. routine consent + informational videotape	Video intervention atheoretical (although there was allusion to multimedia principles in the discussion as an explanation of the results)	Yes	Total score = 8	100% of those in videotape condition correctly answered ≥8 of 10 posttest questions vs. 30% of those in the routine condition
Dunn et al. (2002)[2]	Older patients with psychosis (n = 100); NC subjects (n = 19) (real protocol)	Routine consent vs. PowerPoint-aided consent (both conditions received corrected feedback)	Enhanced consent based on review of empirical literature, but no specific theory or model	Yes	Total score = 12	PowerPoint led to better understanding than routine consent; Corrected feedback also aided understanding
Wirshing et al. (2005)[3]	Schizophrenia (n = 83); medical patients (n unstated); undergraduate students (n unstated) (real, but not protocol-specific)	Instructional videotape vs. control videotape	Atheoretical intervention	Yes	Total score = 11	Instructional videotape resulted in improved understanding
Moser et al. (2006)[4]	Schizophrenia (n = 30) and NC subjects (n = 30) (simulated protocol)	Routine text-based consent followed by PowerPoint presentation	Enhanced consent based on review of empirical literature, but no specific theory or model was specified	Yes	Total score = 11	PowerPoint improved understanding and eliminated group differences in appreciation and reasoning
Hutchison et al. (2007)[5]	173 oncology patients (real clinical trials)	Consultation + audiovisual presentation about oncology clinical trials (customized to tumor type but not protocol-specific) versus consultation alone (refusal/ acceptance of enrollment was primary outcome; effects on comprehension tested only as a secondary outcome)	The audiovisual materials were prepared through a thorough multicomponent development process, described in a companion paper,[6] but it remained unclear from information in the report if this included grounding in a particular conceptual model or theory of multimedia learning	Yes	Total score = 12	More improvement of understanding about clinical trials in audiovisual presentation arm than in routine consultation arm

Authors	*Setting or sample (and type of protocol – real vs. simulated)*	*Comparison*	*Theory, model, or rationale for design of enhancement*	*Multimedia consent results in better comprehension?*	*Quality (mSASQI)*	*Comments*
Strevel et al. (2007)[7]	Oncology patients qualifying for participation in phase I clinical trials (N = 49) (real, but not protocol-specific)	Instructional DVD (general information on phase I trials) versus placebo DVD (describing accomplishments of the researchers and cancer institute)	The content of the DVD was "based upon knowledge deficits described in the literature in the phase I population; script content was reviewed and modified by medical oncologists involved in drug development"	Yes	Total score = 11	Relative to the placebo DVD, those receiving educational DVD were less likely to believe phase I drugs have proven efficacy against cancers in humans or that the goal of phase I clinical trials is to establish effectiveness, and they were more likely to know that the study drug had not been thoroughly tested in humans
Hultgren et al. (2009)[8]	Undergraduate college students (N = 41) consenting for a study employing transcranial direct current stimulation (tDCS) (simulated protocol)	Standard text consent form (read by subjects over the Internet) versus standard text consent form (over Internet) plus a five-minute video (presented over Internet)	Principles guiding the development and implementation of the video were not described	Yes	Total score = 8	Relative to those receiving text consent alone, those receiving the video plus text had significantly higher scores on a post-consent test of the nature and risks associated with tDCS and participant rights
Kass et al. (2009)[9]	Oncology patients (N = 130) (real, but not protocol specific)	Computerized multimedia program vs. text-based pamphlet	Atheoretical intervention; on the other hand, modification was based on feedback from relevant stakeholder representatives	Yes	Total score = 11	Computer condition led to better understanding than pamphlet in regard to most key informational components
Karunaratne et al. (2010)[10]	Diabetes patients (N = 30) (simulated protocol)	Computerized multimedia program vs. printed consent form	Atheoretical intervention; although the computer presentation was described in detail, the principles guiding its development were not specified	Yes	Total score = 12	Average percentage correct answers significantly higher in computer consent than the paper-based consent
O'Lonergan and Forster-Harwood (2011)[11]	170 parent-adolescent dyads (N = 340) (consent/assent for a simulated study of general pediatric research)	PowerPoint with video hyperlinks versus printed consent form	The materials were pretested and then refined in accord with responses from an independent sample of parent-child dyads, but no theory or model was presented.	Yes	Total score = 12	Multimedia led to better overall comprehension than routine consent

Authors	*Setting or sample (and type of protocol – real vs. simulated)*	*Comparison*	*Theory, model, or rationale for design of enhancement*	*Multimedia consent results in better comprehension?*	*Quality (mSASQI)*	*Comments*
Fureman et al. (1997)[12]	Intravenous drug users (N = 186) (real, but not protocol-specific)	Pamphlet vs. pamphlet plus videotape of a discussion presented in the format of "a TV talk show"	Informational videotape developed with input from community advisory board and clinical researchers. No theoretical or empirical rationale was given for choice of this format. However, as the focus was not only on comprehension but also trust and willingness to participate, one might expect such a format to be useful in those two domains based on participant modeling/social learning theory (see Bandura[13]).	Partial	Total score = 11	Baseline knowledge increased in both conditions; videotape group had better one-month retention
Weston et al. (1997)[14]	Pregnant women (N = 90) (simulated)	Text-based consent vs. text-based consent plus video	No explicit rationale or theory stated	Partial	Total score = 11	No difference observed initially posttest; however, video group had greater retention over two to four weeks
Agre and Rapkin (2003)[15]	Oncology patients (n = 204); family/ friends (n = 109); nonpatients (n = 128) (real protocol)	Printed text-based (standard consent or booklet) vs. multimedia (computer-assisted instructional program or video)	The only rationale provided was that some previous studies of clinical or research consent had shown "success" with videotape, computer, and booklet format consent materials	Partial	Total score = 11	Comparison of group means were not significant; however, relative to those receiving text-based consent, participants receiving multimedia consent were more likely to be in the tail clusters (excellent understanding or poorest understanding groups) and less likely to be in the intermediate understanding clusters. There was no clear interaction between consent type and participant (patient, family, or nonpatient) type. However, participants with lower education did worse with the multimedia/computer tools than with standard consent.

Authors	*Setting or sample (and type of protocol – real vs. simulated)*	*Comparison*	*Theory, model, or rationale for design of enhancement*	*Multimedia consent results in better comprehension?*	*Quality (mSASQI)*	*Comments*
Bickmore et al. (2009)[16]	Community sample, ages 28–91 (N = 29) (simulated)	Computerized agent versus explanation by human versus self-study	The enhanced consent tool in this study was developed in reference to theory and prior data on the use of "animated agents" to duplicate the communication benefits of face-to-face interaction, particularly for persons with low health literacy, together with considerations of limitations in sole reliance on face-to-face disclosure with the actual clinician or researcher	Partial	Total score = 9	Significant main effects of consent condition on comprehension. However, health literacy may have moderated effectiveness comprehension scores for computer and human presentation significantly better than self-study among the 16 participants with "adequate" health literacy. No significant comprehension effects of condition observed among n = 13 with "inadequate health\ literacy," while sub-group sample sizes were unclear.
Jeste et al. (2009)[17]	Middle-aged or older patients with schizophrenia (n = 128); NC subjects (n = 20) (simulated protocol)	DVD versus routine consent procedure	Development and implementation of the DVD consent aid was guided by several key principles from multimedia learning theory, including the multiple representation, contiguity, coherence, personalization, signaling, and interactivity principles (Mayer[18])	Partial	Total score = 15	Among patients (but not NCs), DVD-aided consent resulted in better understanding and greater likelihood of being categorized as "capable to consent" than those in the routine consent condition (as categorized with several previously established criteria)
McGraw et al. (2012)[19]	Oncology biobank (N = 43) (real protocol)	Video versus printed consent form	Video was modified based on feedback from a small pilot study; no multimedia theory or model specified	Partial	Total score = 10	Descriptive only (no inferential statistics presented); consisted of coded transcripts of qualitative interview with a series of content queries: "What would you tell a friend if you were explaining ___?" (purpose, risks, benefits, etc.). Specific purpose of biobank appeared less salient in printed consent condition, but there were no notable differences in salience of study risks among the two groups. Results regarding salience of procedures were equivocal.

Authors	*Setting or sample (and type of protocol – real vs. simulated)*	*Comparison*	*Theory, model, or rationale for design of enhancement*	*Multimedia consent results in better comprehension?*	*Quality (mSASQI)*	*Comments*
Benson et al. (1988)[20]	Different consent methods were examined sequentially within each of four psychiatric studies (1) antidepressant clinical drug trial (n = 24); (2) schizophrenia clinical drug trial (n = 24);(3) social skills training for schizophrenia (n = 20); (4) borderline personality clinical drug trial (n = 20) (real protocols)	Four different disclosure techniques utilized sequentially within each of the four studies: (a) routine "usual care" consent, (b) routine + instructional video, (c) assisted disclosure with "improved" video (designed in light of results from the first two conditions), (d) neutral educator provided information to prospective participants	Video intervention was atheoretical (modified in response to input from bioethics experts, but nature of theoretical or empirical basis of those modifications was not specified)	No	Total score = 10	The enhanced consent (particularly the improved video and neutral educator) methods tended to result in slightly better comprehension than routine consent, but the differences were not statistically significant, and the effect sizes were small and varied by patient characteristics. Notably, subjects' comprehension mean scores were abysmal under all four conditions, ranging from 15 of 30 points in routine consent (50%) to 20 of 30 points (67%) with the neutral educators (each of whom was an author of the paper and expert on bioethics and consent issues)
Llewellyn-Thomas et al. (1995)[21]	Oncology patients (N = 100) (simulated protocol)	Audiotape + printed consent form vs. text presented on a computer organized by menus and submenus	Largely atheoretical; there was no explanation of how the text-tree on the computer fosters comprehension relative to a printed consent form, which itself can be scanned and revisited in nonsequential order	No	Total score = 11	Presentation format did not affect levels of understanding
Campbell et al. (2004)[22]	Parents of children in Head Start program (N = 233) (simulated protocol – not relevant study)	Standard print, enhanced print, video, or computer presentation	The enhanced consent in this study was guided by prior surveys that indicated high rates of illiteracy among adults, combined with dual processing and multimedia principles	No	Total score = 13	No effects of disclosure format observed. It is noted that research staff were instructed not to answer participant's questions. The investigators speculated that "it may be easier for attention to wander when one is passively watching a video. In support of this possibility, we found that, for poorer readers, the enhanced print version and the laptop computer version, both of which required the

Authors	Setting or sample (and type of protocol – real vs. simulated)	Comparison	Theory, model, or rationale for design of enhancement	Multimedia consent results in better comprehension?	Quality (mSASQI)	Comments
						active involvement of the participant, led to more information being recalled than was true for either the original written form or the video" (p. 213).
Mittal et al. (2007)[23]	Patients with: Alzheimer disease (n = 19) mild cognitive impairment (n = 13) (simulated protocol)	PowerPoint slideshow presentation (SSP) versus enhanced written consent procedure (EWCP)	The design and implementation intervention was largely based on prior empirical reports in other populations, although there was reference to multimedia learning in support of one hypothesis	No	Total score = 12	Corrective feedback improved understanding in both conditions, but no effects of SSP versus EWCP

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