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Clarity and Appeal of a Multimedia Informed Consent Tool for Biobanking

Biobanks are a promising means for advancing biomedical knowledge in the twenty-first century. Also known as biorepositories, biobanks collect and store a range of biospecimens that are then available for later analysis in numerous types of studies. Although there are many kinds of biobanks, each with different purposes, those with the most powerful ramifications for human subjects protection share two common features: 1) they are repositories of human biospecimens (e.g., blood, urine, buccal cells, or leftover tissue from biopsies or surgeries) that lend themselves to a wide range of molecular analysis, including genomic and proteomic analysis; and 2) they can include clinical, behavioral, and lifestyle information about the contributors gathered through medical record review and/or surveys.[1]

Biobank research is fundamentally different from clinical trials and other research studies, thus presenting its own unique set of challenges for human subjects protection.[2] Biobanks are a research resource, which means that participants' biospecimens—as well as their medical records, information, and genetic research results—will be shared with many researchers, some of whom may not be affiliated with the biobank's institution. Widespread sharing of personal health information and genetic research data raises concerns about information privacy. The types of studies for which data and specimens might be used raise another set of concerns.[3] When biobanks use a "tiered consent approach," they give participants more control over the use of their biospecimens and data by allowing them to opt in or out of a particular type of research, such as genetic research.[4] On the other hand, a broad consent approach means that individuals give consent for researchers to use their biospecimens and associated data for future, unspecified studies, thus foregoing control over how researchers use their specimens and data.[5] Of particular concern is whether individuals understand that broad consent means they cannot limit the use of their biospecimens and personal information to only selected research. Broad consent may therefore result in participants' specimens and data being used for studies that they object to on cultural, religious, or other grounds. An additional challenge is that genetic studies—particularly whole-genome studies—may uncover genetic information that has clinical meaning for research participants. Depending on the nature of the genetic analyses, the study design, and the clinical relevance of a particular genetic finding, researchers may or may not share this information with study participants. This raises issues regarding participants' understanding of the return of genetic research results and the concepts of risks and benefits in the biobank context.

Although little is known about how individuals understand consent information for participation in biobank research, the handful of studies that have been conducted suggest that individuals recruited to participate may not understand the information conveyed to them in the way researchers intend. Thus, their consent may not be truly informed.[6] Given the unique challenges associated with biobank research, it is important to explore strategies for conveying information in the consent process. An alternative to the traditional approach of a written consent document is to use multimedia tools—for example, video presentation of the consent information that can be paired with written consent documents and/or staff member support to answer questions. Such tools offer a strategy to convey consent information to prospective research participants in a manner that may enhance participants' ability to pay attention to critical information and understand the information conveyed.[7] Although a large number of

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Table 1.
Cognitive Debriefing Interview

General reactions	To begin, it would be helpful to hear your thoughts, in general, about the multimedia tool/written consent form. What did you think about the multimedia tool/written consent form? • Was there anything that you particularly liked or did not like about the multimedia tool? What and why? (asked in video group only) • If you were thinking about joining the biobank study, what questions, if any, would you want to ask at this point? • How clear was the information presented on the multimedia tool/written consent form? • Were there any sections you found that were more difficult to understand than other sections? Which and why? • Were there any sections you wanted to see/had to read more than once? Which? Why?
What is the study?	To begin, imagine that you are explaining the registry study to a friend. What would you say to explain the biobank study?
Purpose	What would you tell a friend if you were explaining what information is being collected in the biobank and how the researchers will use the information? • (probe) What do the researchers want to learn from the biobank?
Participant's role	What will be asked of someone who agrees to join the biobank study? • (probe) What will be done with your biologic specimen (your blood or tissue)?
Risks	What about the risks for someone who joins the biobank? What would you tell a friend about the risks?
Benefits	Again, thinking about what you would tell a friend, if you were explaining this study, what would you tell a friend about the benefits of joining the biobank?
Confidentiality	How will the privacy of someone who joins the biobank be protected?
Voluntary participation	What, if anything, might happen to someone if he or she decides not to join the biobank? • (probe) Do you think there might be any consequences for someone who declines to join the biobank? • (probe) What effect, if any, would there be on the health care of someone who decides not to join the biobank?
Withdrawing	What about leaving or withdrawing from the biobank? What would you explain to a friend about that?

studies reveal the potential of multimedia, particularly video, to enhance understanding of informed consent information, the bulk of that work has focused on consent to treatment, not to research.[8] Of the studies that do focus on research, most look at consent to participate in clinical trials, not biobank research.[9]

In this paper we report on the results of a formative evaluation study of a multimedia informed consent tool developed for a biobank. Formative evaluations are used to gather information to guide the development of a program.[10] We used this approach to identify areas of the multimedia consent tool that needed modification to improve the clarity and appeal of the tool. We compared the cognitive interview responses of individuals who viewed a beta version of the multimedia tool to the interview responses of those who read a written consent form. We also report on the changes made to the beta version of the multimedia tool based on the outcome of the formative study.

Study Methods

■ ***Setting and Intervention.*** In partnership with the North Carolina Cancer Hospital (NCCH), the Lineberger Comprehensive Cancer Center at the University of North Carolina (UNC) is creating a biobank, the UNC Health Registry/Cancer Survivorship Cohort.

The goal of the biobank is to collect personal health information and biospecimens from about 10,000 adult patients of the NCCH. The biospecimens collected for the biobank include a blood sample or buccal cells, as well as any tissues remaining from biopsies or surgery. Health and other personal information such as lifestyle, quality-of-life indicators, and general demographic data will be obtained from medical records and a participant questionnaire. Data collection associated with the biobank will be ongoing for an undefined period of time and will include annual follow-up surveys and medical record reviews. Prospective participants are told that they are providing broad consent for future unspecified research and that studies with their biospecimens could include genetic research. They are also told that researchers from other institutions may have access to their biospecimens and associated health information for their studies.

In addition to a written consent form and a HIPAA authorization form for disclosure of identifiable health information for research purposes, UNC researchers included in the consent process a multimedia tool—in this case, a video—to convey the information provided in the written consent document. Before producing the beta version of the multimedia tool, we conducted interviews with six African American and six non-Hispanic white English-speaking individuals to assess the clarity and acceptability of the content covered in the video script. We then modified the script based on these findings and filmed the beta version of this tool. It consisted of a series of dramatic vignettes and documentary-style video (20 minutes in length), using narration and captions.

■ ***Study Design.*** For the formative evaluation, we used cognitive interviews to elicit information about the salience of topics covered in both the multimedia tool and the written consent document. In this way, we were able to identify topics that were potentially confusing and required clarification, as well as assess the appeal and usability of the multimedia tool. Cognitive interviewing is a methodology to assess the extent to which text is understood as intended.[11] Techniques include asking a respondent to paraphrase a segment of text or "think aloud" when responding to a question. Although typically used to pretest survey questionnaires and improve the questions' wording, this methodology[12] can be applied to other contexts that require assessing the clarity and interpretation of text, such as in the development of educational materials.[13]

We invited patients visiting clinicians at the NCCH clinics to participate in the study, as well as individuals from the general UNC community who were notified about the study through an e-mail blast. Recruitment was designed to ensure a sample equally divided by three racial/ethnic/linguistic groups: English-speaking non-Hispanic whites, English-speaking African Americans, and Spanish-speaking Hispanics. In addition, we made an effort to recruit both men and women in each ethnic group, as well as individuals with a range of educational backgrounds (at least one individual in each group with a high school/GED degree or less).

To enable a limited comparison of the salience of the content covered in the multimedia consent tool to that covered in the written consent document, participants were randomly assigned to one of two study groups (multimedia group or written group). Since the focus of this study was to learn what participants thought about the clarity and appeal of a multimedia consent tool, we used weighted randomization to assign a larger proportion of participants to the multimedia group. Statistical tests were not used when comparing the multimedia and written groups because inferences from this convenience sample to a larger population are not appropriate. However, the randomization within the sample facilitates comparison of the two groups.

■ ***Data Collection and Measures.*** Interviews were conducted individually in a private setting. With the interviewer present, each participant viewed the multimedia consent tool or read the written consent document. Immediately following these activities, the cognitive interviews were conducted, beginning with open-ended questions about general reactions to the multimedia tool for those in the multimedia group (Table 1). This was followed by debriefing questions designed to elicit descriptions of the program content in the respondents' own words. All materials were translated into Spanish and translated back into English by a professional translator. The interviews were audiotaped and transcribed. Atlas.ti was used to facilitate coding and analysis.

■ ***Content Analysis.*** The purpose of the content analysis of the transcripts was to answer three analytic questions: 1) What were viewers' perceptions about the appeal and utility of the multimedia tool? 2) What information regarding key domains of informed consent covered in both the multimedia tool and written consent document was salient to the participants, and how did this differ between the two study groups? and

Table 2.
Sociodemographic Characteristics of Study Sample

	African American *% (n)* *35.0% (15)*	*Hispanic/Latino (Spanish-speaking)* *% (n)* *35.0% (15)*	*Non-Hispanic, white* *% (n)* *30.0% (13)*
Treatment	Multimedia: 66.6% (10) Written: 33.3% (5)	Multimedia: 80.0% (12) Written: 20.0% (3)	Multimedia: 84.6% (11) Written: 15.4% (2)
Gender	Male: 20.0% (3) Female: 80.0% (12)	Male: 47.0% (7) Female: 53.0% (8)	Male: 46.0% (6) Female: 54.0% (7)
Age (Mean)	36.4	38.0	40.7
Education level[1]	1: 6.7% (1) 2: 6.7% (1) 3: 53.3% (8) 4: 33.3% (5)	1: 0.0% (0) 2: 20.0% (3) 3: 33.0% (5) 4: 47.0% (7)	1: 0.0% (0) 2: 23.0% (3) 3: 46.0% (6) 4: 31.0% (4)

[1] 1 = some high school or less; 2 = high school/general equivalency diploma; 3 = some college, or vocational, technical, or bachelor's degree; 4 = postgraduate degree.

3) What topics covered in the multimedia tool were confusing to viewers?

To address the first analytic question, coding proceeded in two steps. First, coders read through each transcript, reviewing it line by line to identify text relevant to the following seven domains of informed consent: the purpose of the biobank, what would be expected of a participant who enrolls in the biobank (the participant's role), the risks and benefits of participation, protection of confidentiality, voluntariness of participation, withdrawing from the biobank, and compensation for research-related injury. Second, the coders catalogued verbatim quotes from the transcripts for each domain that arose in response to general questions about the multimedia or written consent tool, and also as specific responses to the interview question asked about each domain: "What would you tell a friend if you were explaining _____?" These quotations were grouped into topic areas relevant to each domain as outlined on Table 3. To assess the impact of viewing or reading the informed consent tools, we examined the salience of the content covered for each consent domain by tracking a respondent's spontaneous mention of a topic over the course of the cognitive interview.

To identify content covered in the multimedia tool that was confusing to the viewers, the coders categorized each respondent's statements into one of three types: as suggesting understanding, misunderstanding, or partial understanding of a topic. Evidence of *misunderstanding* was defined as paraphrasing the content in a way that was inconsistent with the intended meaning, as a stated lack of understanding, or as a request for clarification of everything covered on the topic. A *partial understanding* was defined as a statement or query about the domain that suggested partial confusion or lack of clarity. *Understanding* was defined as paraphrasing the content in a way that was consistent with the intended meaning of the content of the consent tools. For this analysis, we counted misunderstanding and partial understanding together, taking both as evidence of confusion about a topic.

To address the third analytic goal regarding appeal and utility of the tools, the coders reviewed the transcripts to identify relevant text. This text was coded and grouped into categories that included recommended changes to the format and presentation of information. Three coders independently coded the data. Differences across coding were reconciled in discussion.

Study Results

■ ***Participants.*** Forty-three individuals participated in the study. The study was based on a sample stratified by ethnic group (African American, Spanish-speaking Hispanic American, and non-Hispanic white) and

Table 3.
Spontaneous Mention of Informed Consent Topics

TOPICS COVERED IN THE STUDY TOOLS[1]		# participants who mentioned topic spontaneously	
		Multimedia group (N = 32) % (n)	*Written group (N = 11) % (n)*
Purpose	Collect biosamples for research	100 (32)	100 (11)
	Study causes of diseases	84 (27)	73 (8)
	Collect health record information	63 (20)	55 (6)
	Understand how genes and personal health are related to causes of disease	53 (17)	36 (4)
	Gather personal and lifestyle data	44 (14)	18 (2)
	Enroll people who are healthy and sick	16 (5)	9 (1)
Participant's role	Give small sample blood from a blood draw	94 (30)	91 (10)
	Give a buccal sample through a mouth rinse	94 (30)	64 (7)
	Permit medical record abstraction	59 (19)	55 (6)
	Complete lifestyle surveys annually	56 (18)	9 (1)
	Allow researchers future contact for recruitment into other studies	50 (16)	64 (7)
	Allow researchers to collect samples from tissue leftover from biopsies or surgeries	47 (15)	64 (7)
Risks	Might experience pain, bruising, fainting, or infection from blood draw	81 (26)	73 (8)
	Potential for breach of privacy/confidentiality	31 (10)	36 (4)
	Might experience cheek irritation from mouth rinse	25 (8)	9 (1)
	Might feel uncomfortable when completing survey	3 (1)	0 (0)
Benefits	Findings from studies using biobank can benefit future generations	88 (28)	91 (10)
	Altruism; findings can make a difference in health of community	72 (23)	91 (10)
	No personal benefit from participation in biobank	53 (17)	64 (7)
	No compensation	34 (11)	45 (5)
Confidentiality	Names replaced with a number	84 (27)	100 (11)
	Only a small number of staff have access to biobank data	81 (26)	73 (8)
	Have a certificate of confidentiality from NIH	66 (21)	45 (5)
	The data are password protected	47 (15)	45 (5)
	Access to data for future studies must be approved by IRB	41 (13)	18 (2)
	Files are stored in locked cabinets	38 (12)	36 (4)
	Individual participants will not be identified in any report or publication	0 (0)	0 (0)
Voluntariness	You can refuse to participate	97 (31)	100 (11)
	You can stop participation at anytime	91 (29)	100 (11)
	Participation in biobank does not impact current and future health care	84 (27)	73 (8)
	Can so say no to future studies if asked	19 (6)	9 (1)
Compensation	Medical expenses from possible injury are not covered for injury	19 (6)	27 (3)

[1] Topics are ordered within each domain according to the rates of spontaneous mention by the multimedia group in descending order.

educational level. The sample matched the recruitment goals with respect to race and ethnicity and was evenly distributed across the three racial ethnic groups (Table 2). However, more African Americans (33.3%) and fewer non-Hispanic whites (15.4%) comprised the group assigned to read the written consent form. We also met the recruitment goals of having both men and women in each group, as well as at least one individual who did not complete high school. Overall, there were more females in the study; the gender difference was most notable among the African American group, with smaller gender differences among the Spanish-speaking Hispanic and non-Hispanic white groups. The average age was similar across the three ethnic groups (African American, 36.4 years; Hispanic/Latino, 38.0 years; and non-Hispanic white, 40.7 years); the age range for the entire sample was 18–68 years.

■ ***General Reactions to the Multimedia Tool.*** Twenty-two of the 32 participants who viewed the multimedia tool said they thought it was a useful source of information and felt they would be prepared to make an informed choice about enrolling after viewing the program. Some of these participants commented that the multimedia tool gave them good information with which to formulate questions and increased their comfort with asking questions in general. However, ten felt the tool alone would not be adequate. These respondents said they wanted an additional source of information—someone who could answer questions or a written consent document to read.

The most common criticism of the multimedia tool was its length. Eighteen of the 32 participants commented that the program became "tedious," particularly the second half of the program, which covered information about the institutional review board (IRB) review process and the HIPAA authorization. For some, there was too much detailed information, too many different images, and some of the information and video scenes felt repetitive.

In response to participants' comments about the multimedia tool, the UNC researchers made several substantial changes. They decided against having a standalone multimedia program that would cover information conveyed in the written consent document and HIPAA authorization form. Instead they created a consent process combining the multimedia tool with a written consent document and HIPAA authorization form. In addition, a member of the study team was available during the consent process to answer questions. The researchers also shortened the program (from 20 to 13 minutes) but included an optional section of "frequently asked questions."

■ ***Salience of Information Covered in the Informed Consent Tools.*** Table 3 presents the seven domains of informed consent that both the multimedia and written informed consent tools covered and the topics corresponding to each domain. For the multimedia and the written study groups, the proportion of respondents who spontaneously mentioned each topic during the course of the cognitive interview is presented.

When describing the purpose of the biobank, all respondents in both study groups spontaneously mentioned the collection of biospecimens; a smaller proportion of the respondents focused on the collection of other forms of data. Compared to those in the multimedia group, participants in the group that read the written consent form mentioned less frequently that the purpose of the biobank was to understand how genes and personal health are related to causes of disease and that the biobank would gather personal and lifestyle data. Finally, only a small proportion of participants in both study groups recalled that both healthy and sick individuals would be invited to enroll in the biobank.

In talking about what would be expected of a biobank participant, almost all participants said that they would be asked to provide a blood sample, and over half noted they would be giving permission for the review of their medical records. A greater proportion of participants in the multimedia group compared to those in the written group noted that buccal samples would be collected using a mouth rinse and that a lifestyle survey would be conducted. Yet a greater proportion of those in the written group mentioned the collection of tissue samples left over from biopsies or surgeries. With regard to the indefinite period of time during which they might be contacted for future studies, a greater proportion of participants in the written group referred to this aspect of the biobank compared to those in the multimedia group.

There were no notable differences between study groups in the apparent salience regarding the risks of participation. The risks the majority of respondents in both groups (21 in total) described were those associated with physical injury from the blood draw and/or the mouth rinse. In contrast, a third of respondents (14) mentioned the risk of breach of confidentiality associated with participation in the biobank. It is notable that

Table 4.
Multimedia Group: Confusing Content and Recommended Changes

Confusion or recommended changes to content	*% confused*[1] *or who recommend change (n)*	*Illustrative quotation*
Unclear about period of time over which I will be contacted for future studies or my samples stored	28 (9)	And then I remember there was something somebody said about indefinitely and I was, like, that is kind of a very big word. Indefinitely. Exactly what do you mean because indefinitely means indefinitely so I think that could be concerning to some people so. Another asked: How long? It said something about years, but does that just mean two or ten or 20, until you die? What does that mean?
Unclear about certificate of confidentiality from NIH	25 (8)	I got a little confused about how the privacy stuff would work. First, they started talking about protecting your privacy and there was something about, well, it doesn't really protect you if the federal government wants to know something. That was kind of confusing, the extent to the confidentiality.
Unclear about who would have access to data and how privacy would be protected when outside researchers access data	9 (3)	. . . maybe a little more emphasis on who exactly has access to your personal information . . . I guess right now there's a little doubt in my mind as to who they said (laughs) would see that information. Because the research groups that are trying to get approved by the IRB, they don't see the information, do they?
Concerns about who and how many people will have access to biobank data	6 (2)	I think I would like to know more about how many people we are talking about are going to have access. Three researchers or just one? I am not worried about the information that is coded, what I am worried about is the information that has the name on it like the information about health . . . if it is coded, it doesn't matter who looks at it, nobody will know.
Want more information about tissue samples (buccal sample through a mouth rinse and blood draw)	6 (2)	However, my only concern was I'm not sure what the cheek cell thing is. It might be helpful to explain to people who don't have any medical background what it involves before they are actually asked to take it, because I know that, I know I've been in the medical field a long time, and I still hadn't heard of the blood cheek thing. All I know is swabbing, and it looks like he was drinking something.
Although no personal benefit from participation, emphasize that enrollment in biobank is a contribution to others	6 (2)	Unfortunately, most people are usually looking for the direct benefit even though some things have a general benefit, that is why I think it is important to really highlight the indirect benefits. For example, I participate in the study, but they are going to tell me you are not going to benefit financially but you will help others.

[1] "Confused" participants constitute both those whose comments suggested that they misunderstood the topic and those who had partial understanding of the topic.

three of these 14 individuals expressed specific concerns about the impact on a participant's immigration status if confidentiality was breached.

Overall, a greater proportion of respondents in both study groups spontaneously mentioned benefits of participating in biobank research, rather than the potential risks. The majority of respondents in both groups cited the benefits of knowledge for future generations (88% of the multimedia group and 91% of the written group) and altruism. In contrast, a smaller proportion of respondents mentioned the lack of any personal benefit. Respondent comments about protect-

ing privacy and data confidentiality emphasized the use of study identification numbers in place of names and restricting access to databases. The only notable difference between study groups was the spontaneous mention of the IRB or steering committee to approve access to data by researchers; 41% of the multimedia group mentioned this compared to 18% (two out of 11) of respondents in the written group. Topics related to the voluntary nature of participation were described by the majority of participants in both study groups with one exception: 19% of respondents in the multimedia group and 9% in the written group mentioned that they could refuse to participate in future studies conducted through the biobank if invited. Finally, 19% of participants in the multimedia group mentioned that compensation for medical expenses arising from a study-related injury would not be provided, compared to a slightly larger proportion (27%) of those in the written group who mentioned this topic.

■ ***Findings to Clarify and Improve the Appeal of the Multimedia Tool.*** The cognitive interviews with the multimedia group revealed program topics that confused viewers and elicited recommendations from study participants to improve the clarity of the program. The UNC researchers used these findings to revise the program after reviewing them with the UNC IRB. Table 4 is a summary of these topics with illustrative quotations. In the majority of instances when respondents were confused, the respondent had at least a partial understanding of the topic; there were very few instances in which any respondents misunderstood the topic entirely.

Two topics confused the greatest number of participants. Twenty-eight percent of the participants in the multimedia group said they were confused about the length of time of data collection and what was meant by an "indefinite" period of time. To address this concern, the UNC researchers substituted "over the course of many years" for "indefinite." Twenty-five percent of the participants in the multimedia group made statements indicating they were confused about the purpose of the certificate of confidentiality. Some were confused about how it was related to the IRB, whereas others were confused about the role of the federal government and what information about them would be available to government officials. Based on the cognitive interview comments regarding the certificate of confidentiality, the researchers thought this information was too abstract to communicate clearly in a video segment. To address this confusion, the researchers removed the segment from the multimedia program and left it in the written consent document where it could be addressed through personal interaction with study staff.

The UNC researchers did not make changes in response to every comment. For example, two participants noted that the information about the benefits of participation should emphasize more pointedly that although there are no direct personal benefits to participation, enrolling in a biobank may help improve the health of others. The UNC researchers did not change any text in response to these comments. They felt that sufficient emphasis was already provided, given that 88% and 91% of both study groups understood the benefits to future generations, and that an increased emphasis on this topic might be an undue inducement to participate in biobank research.

Discussion

The purpose of this formative evaluation study was to assess the clarity and appeal of a multimedia consent tool for biobank research in order to identify and inform specific improvements in conveying consent information to prospective biobank participants. In general, participants who viewed the multimedia tool found it to be an appealing and useful format.

Responses from the cognitive interviews offer insights into prospective participants' views about written and multimedia informed consent tools, as well as about the salience of the information in those tools. Respondents in both the multimedia and written study groups placed a greater emphasis on the benefits of participation compared to the risks, suggesting that they might focus more on benefits than on risks when making a decision about enrollment. Although not a surprising finding given that individual risks associated with participation in a biobank are minimal, these responses suggest the importance of describing the forms of data collection and the potential risks associated with each in a way that would enable a prospective participant to appropriately weigh the greatest risks against the benefits.[14]

The cognitive interviews revealed that some respondents appeared to place greater emphasis on the collection of physical data (biospecimens) and on physical risks. This was shown by the relative frequency with which these topics were mentioned compared to the other risks concerning personal health information and breach of confidentiality. Respondents in both study

groups mentioned risks of injury associated with the blood draws and mouth rinse more frequently than risk of breach of confidentiality. This is noteworthy, since there is some empirical evidence that people have concerns about the confidentiality of medical record and genetic research data in the context of biobanks.[15] It is possible that the concept of physical risk may have greater impact for most people in general because all individuals have real-life experiences with physical injury, making it easier to imagine than the types of harms that might result from unauthorized access to their genetic information, especially since breach of confidentiality in research is rare.[16]

While half or more of participants noted that they might be contacted for future studies, less than one-fifth mentioned that they could refuse to participate in these studies. This raises some concerns about how well they understood the voluntary nature of future involvement and emphasizes the need to describe this clearly, particularly when using a process to give broad consent, regardless of format.

Observed differences in prominent topics among the group who used the multimedia tool as compared to the group who read the written consent form might be explained by differences in the manner of presentation of information in the two tools. For example, it is possible that a larger proportion of participants in the multimedia group spontaneously mentioned genetic studies and use of personal data compared to their counterparts in the written group because the visual images used in the multimedia tool made a stronger impression on participants than did the text in the written consent form. Second, the nature of the narrative style used in the multimedia tool wove together content corresponding to multiple sections of the written document over the course of the program, repeating some topics.

That only a small number of topics in the multimedia tool required clarification suggests that the tool can be useful to help prospective participants understand biobank research. However, while a multimedia tool may be an important supplement to written consent documents, it probably should not replace written documents or the opportunity to ask questions of someone associated with the study. This point is consistent with conclusions drawn by Flory and Emanuel[17] based on their systematic review of multimedia interventions to improve understanding of informed consent for clinical trials, and with those of Henry et al.,[18] based on a small qualitative study of participant preferences for consent aids. It may be that a multifaceted process best accommodates diverse learning styles by employing auditory, visual, and written forms of presentation.

Several limitations and strengths of this study should be noted. First, although individuals in our study resemble potential biobank candidates, sample size restricts our ability to generalize study findings to other populations. However, as a qualitative study, statistical testing was not the goal of the study. Despite the small numbers in the study groups, an important strength of this study is the use of random assignment to study group to ensure lack of bias. In addition, this study is one of only a few published studies that made an effort to enroll a diverse group of respondents drawn from a range of educational, linguistic, and ethnic groups.

We cannot ascertain the reasons why respondents mentioned some topics with greater or lesser frequency than others. It is possible that some topics were not mentioned because the tools differed in clarity or emphasis. Furthermore, salience can vary across topics, and many factors besides the content of the consent tool—such as culturally defined attitudes or values and learning styles—can influence salience or interpretation of meaning.[19] Another possible explanation for different rates of mentioning topics may be differences in the interviewers' ability to ask follow-up questions over the course of the interview. We made every effort to prevent problems in this area. We carefully trained the interviewers in the study protocol, and we emphasized use of probes—for example, asking, "Is there anything else?" to elicit a comprehensive list from each participant.

Conclusion

Findings reported in the literature to date about the effectiveness of multimedia consent aids to enhance informed consent have been equivocal.[20] Moreover, prior studies suffered from a number of methodological limitations including small, unrepresentative samples with limited or poorly described socioeconomic and cultural diversity, a failure to use randomized trial design or validated measures, and lack of blinding.[21] In addition, it is difficult to assess the relative quality of the multimedia tools compared across studies with regard to their clarity. Finally, none of these studies examined understanding of consent for biobank participation. Given the uncertainty of knowledge about the efficacy of multimedia tools in general and the lack of information about the efficacy of the consent process

for biobank research, we see the need for a rigorous randomized trial to determine the value of multimedia tools for the consent process.

The results of this formative evaluation suggest that cognitive interviewing may help ensure that the information covered in any informed consent tool, written or multimedia, is clear and relevant to prospective study or biobank participants, as suggested by Willis.[22] Seeking and incorporating input from potential participants through cognitive interviewing is commonly used when developing survey instruments and is recommended when developing patient education materials.[23] Commentators concerned with informed consent note the importance of seeking input from prospective participants to create a process that "more fully honors the concept of respect for persons."[24] Indeed, Willis[25] suggests that cognitive interviewing might be embedded directly in the consent process itself to ascertain if a prospective participant understands the content and to correct misperceptions. However, reports of the application of cognitive interviewing in relation to the informed consent process for biobanking are limited in number and scope. Beskow and Dean[26] report on a cognitive interviewing study of informed consent for biobanking, but their focus is primarily on prospective participants' opinions about the information covered in the consent document.

The UNC multimedia tool has been successfully implemented in a fast-paced clinical setting, and its assessment is ongoing. Researchers continually gather feedback from both biobank staff and participants involved in the consent process to better understand how to make it more effective and efficient. The feedback suggests that the current multimedia tool may need several minor modifications to remove redundancies and improve the clarity of the information. Future multimedia tool development and evaluation should consider additional factors that may impact clarity, appeal, and understanding. These factors should include the sequence of information presented, individuals' ability to attend to and retain information at different points in the presentation (early vs. late), and fatigue during the consent process. These factors may be particularly important for individuals who are ill or elderly, especially when a consent process covers complex and abstract information.

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