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Improving informed consent: Stakeholder views

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Abstract

Purpose—Innovation will be required to improve the informed consent process in research. We aimed to obtain input from key stakeholders—research participants and those responsible for obtaining informed consent—to inform potential development of a multimedia informed consent "app."

Methods—This descriptive study used a mixed-methods approach. Five 90-minute focus groups were conducted with volunteer samples of former research participants and researchers/research staff responsible for obtaining informed consent. Participants also completed a brief survey that measured background information and knowledge and attitudes regarding research and the use of technology. Established qualitative methods were used to conduct the focus groups and data analysis.

Results—We conducted five focus groups with 41 total participants: three groups with former research participants (total $n = 22$), and two groups with researchers and research coordinators (total $n = 19$). Overall, individuals who had previously participated in research had positive views regarding their experiences. However, further discussion elicited that the informed consent process often did not meet its intended objectives. Findings from both groups are presented according to three primary themes: content of consent forms, experience of the informed consent process, and the potential of technology to improve the informed consent process. A fourth theme, need for lay input on informed consent, emerged from the researcher groups.

Conclusions—Our findings add to previous research that suggests that the use of interactive technology has the potential to improve the process of informed consent. However, our focus-group findings provide additional insight that technology cannot replace the human connection that is central to the informed consent process. More research that incorporates the views of key

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Author contributions

Drs. Anderson and Matthews were responsible for the conception and design of the study. All authors contributed to data collection and analysis. Dr. Anderson was responsible for the first draft of the article, and Dr. Matthews and Ms. Newman contributed substantively to all revisions. All authors have read and approved the final version.

Conflicts of interest

None.

Ethical approval

This study was approved by the institutional review board at the University of Illinois at Chicago.

stakeholders is needed to ensure that multimedia consent processes do not repeat the mistakes of paper-based consent forms.

Keywords

informed consent; focus groups; stakeholder engagement; technology

The informed consent process demonstrates respect for the prospective research participant's ethical and legal right to self-determination (National Commission 1979). Thus, ensuring voluntary informed consent is an ethical and legal responsibility of all researchers. Nevertheless, much research shows that the consent process for research participation often does not meet the intended ideals of informed, voluntary participation. Available data suggest that only about half (54%) of all research participants adequately understand the goals of a given research proposal, and even fewer understand concepts associated with randomization, risks, voluntary participation, or the ability to withdraw participation (Nishimura et al. 2013). Evidence also indicates that for certain groups, such as patients with low literacy (Tamariz et al. 2012) or low-income patients (Ittenbach et al. 2015), comprehension may be even worse. Additional research on ways to improve informed consent is warranted as researchers seek to appropriately engage and assist diverse populations in the complex decision making associated with research participation.

In addition to concerns about the demonstrated lack of understanding by those who do agree to participate in research, there is the added problem of trials that fail to recruit adequate numbers of participants or that fail to recruit adequately diverse and representative samples (Halpern et al. 2002). Concerns about inducement notwithstanding, low enrollment rates can be framed as a failure of the informed consent process. Importantly, research suggests that genuine, substantive concerns about risks and burdens or lack of alignment of personal values with study aims are not often cited as reasons for refusal (Stevens and Ahmedzai 2004). Research suggests that individuals may decline research participation due to a lack of understanding about a specific trial's purpose or procedures such as randomization (Gillies and Entwistle 2012). Or, they may decline participation because of misunderstanding or mistrust of research in general (Byrne et al. 2014). As Sugarman succinctly stated in a recent article in *Academic Medicine*, "Current approaches [to informed consent] … might be inappropriately hindering research without actually offering protection" (2016, 456).

Previous research on informed consent has focused heavily on the paper-based consent form, rather than the whole process of informed consent. To this end, much of the research on improving informed consent has tested basic modifications to informed consent documents, such as decreasing length, lowering reading levels, and enhancing formatting. These interventions have shown at best only modest improvements in understanding (Flory and Emanuel 2004; Kass et al. 2014; Nishimura et al. 2013; Sand et al. 2008).

Research on "electronic" or multimedia informed consent (e.g., audio, video) suggests that such approaches are acceptable to participants (Henry et al. 2009) and may indeed be superior to paper-based consent forms in improving short-term outcomes such as participant understanding of research objectives, risks, and benefits (Kass et al. 2009; Madathil et al. 2012; Rowbotham et al. 2013). Indeed, a multimedia consent process can utilize multiple

means of information delivery that appeal to different learning styles and preferences (Mayer 2009), a great advantage over paper-based forms. Technology can also be used to track which pieces of information participants actually spend time viewing and to assess and improve understanding without making individuals feel like they are being "tested." Perhaps most importantly, the potential of multimedia delivery formats to improve comprehension can ultimately improve the quality of the discussion between the potential participant and the research team member; studies of informed consent have found that interventions that are able to promote this dialogue are most promising (Brehaut et al. 2008; Brehaut et al. 2010; Brown et al. 2011; Kass et al. 2014; Hallinan et al. 2016). However, despite great interest on the part of researchers and funders, there is currently insufficient evidence to support wide adoption of any particular multimedia informed consent approach (Agre and Rapkin 2003; Nishimura et al. 2013; Synnot et al. 2014).

Additional gaps in understanding pose challenges to the widespread adoption of multimedia consent tools. For example, will older individuals, or individuals with limited education and/or low incomes, be comfortable using a computer, tablet (e.g., iPad), or smartphone? How might interactive, multimedia materials support research staff recruitment and informed consent efforts? How can we avoid "importing" the problems of paper-based consent forms? We recognized that as a first step toward development of an interactive, multimedia informed consent process, we needed to talk to key stakeholders.

Many studies of informed consent have assessed participants' comprehension and recall of information presented during the informed consent process, but few efforts to improve informed consent have included input from previous or potential research participants to inform the development of intervention tools or strategies (Mahnke et al. 2013). This may explain their limited success (Dresser 2017). (It should be noted that formative research on informed consent is common in developing countries, where requiring a signature on a written consent form would be confusing or culturally unacceptable.) Research on specific aspects of multimedia consent, such as the acceptability of a touchscreen interface, has included college students (Madathil et al. 2011) and rural community members (Mahnke et al. 2014), but is not generalizable to an older, urban, more socioeconomically diverse patient population. Further, research on the perspectives of those responsible for obtaining informed consent is surprisingly limited.

Exploring the experience of informed consent from the perspectives of multiple stakeholders can provide insight into potential informed consent innovations that extend beyond simply reducing the length or wordsmithing forms. To this end, we conducted focus groups with a diverse sample of patients from underrepresented minority groups (primarily African American) with prior research experience, as well as researchers and research staff. Information gathered will guide development of a multimedia informed consent process for future testing.

Methods

Focus groups with former research participants and researchers/research staff responsible for obtaining informed consent were conducted during June–October 2015. Approval was received from the University of Illinois at Chicago Institutional Review Board (IRB).

Recruitment

Patient groups—We sought to recruit patients over 18 years of age who had prior experience participating in a research study as an adult. Flyers posted at University of Illinois at Chicago outpatient clinics directed interested individuals to contact project staff. Callers were screened to verify past research participation. In order to be eligible, an individual had to have participated in or have been invited to participate in a research study (i.e., they had to have gone through the informed consent process but could have either agreed to or refused participation). They could have participated in any phase of a clinical trial for medications, devices, diagnostic tools/methods, or other modalities (e.g., behavioral interventions) for the prevention, treatment, or diagnosis of disease or for relieving symptoms of a disease. We did not restrict participation based on any particular diseases or disorders, location, or how long ago participation had been. To confirm previous research experience, we asked a few simple questions (e.g., What was the study about? Do you remember being asked to sign a written consent form?).

Researcher groups—Researchers/research staff members were recruited exclusively from the University of Illinois at Chicago campus. To be eligible for focus-group participation, individuals must have had experience either writing consent forms or obtaining informed consent in at least one health-related research study. We did not otherwise restrict participation based on experience, roles or responsibilities, formal training, or research setting (e.g., inpatient, outpatient, community).

Development of focus-group guides

Based on the research literature on informed consent, discussion guide questions aimed to (1) identify barriers to understanding in the informed consent process; (2) determine elements that are essential to truly informed consent; and (3) gather feedback on the potential of technology (e.g., video, audio, and interactive activities delivered via a computer, tablet, or smartphone) to overcome identified barriers. Advisory groups consisting of patient and professional (researchers and IRB/human research protections) stakeholder partners provided input on focus group guides.

Quantitative survey data

Prior to the start of each focus group, we administered a paper-based survey that collected demographics and information regarding participants' experiences with and views of participating in, reviewing, or conducting research. Patients were administered the four-item short version of the Researcher Trust Scale (RTS) (Hall et al. 2006); a seven-item modified version of the Research Attitude Questionnaire (RAQ) (Rubright et al. 2011); and a five-item modified version of the Satisfaction with Decisions in Health Care scale (SDHC) (Holmes-

Rovner et al. 1996). We also asked patients about their experience with and views on technology, to get a sense of the comfort levels of our institution's patient population.

Implementation

All focus groups took place in a conference room at the University of Illinois at Chicago. Focus groups were led by one of the investigators, either EEA or AKM, both of whom are experienced moderators, and were observed by the other and an additional staff member (SBN). Sessions were digitally audio recorded and professionally transcribed verbatim. Observers took notes to provide context and clarification regarding participants' statements.

Focus-group sessions lasted 2 hours, with approximately 90 minutes devoted to the primary discussion. During the first 15 minutes, the moderator obtained informed consent, reviewed ground rules for the focus groups, explained the recording procedures, and addressed questions. Then participants completed questionnaires prior to starting the focus-group discussion. Participants in the patient focus groups each received a $30 gift card. Participants in the researcher groups were not compensated. Breakfast or lunch was served at all groups.

Data analysis

Focus-group transcripts were coded in MS Word. Coding consisted of an iterative multistep process using a content analysis approach (Forman and Damschroeder 2008). Content analysis is an approach widely accepted in health research that aims to understand a phenomenon or experience, not making generalizations based on statistical inference (Morgan 1993).

The two investigators (EEA and AKM) began the coding process by generating open codes based on an initial reading of transcripts. Investigators reviewed transcripts separately and then compared notes to identify key themes and look for both overlap and disagreement. Themes were confirmed by the third author, who observed all focus groups. During initial analysis, stakeholder advisory groups provided input on interpretation of key themes. Then data were reorganized into code reports, listing all text to which each particular code is applied. Data were reassembled to promote coherent interpretation, identify patterns, test preliminary conclusions, and place findings within an analytic framework (Sandelowski 1995). Conclusions were verified by going back to the data that supported (or refuted) conclusions.

While our sample size is too small to support rigorous statistical analysis or comparisons among groups, survey data were analyzed using IBM SPSS Statistics 23 in order to characterize our sample (e.g., frequencies, means, standard deviations).

Results

We conducted five focus groups with 41 total participants: three groups with former research participants (total $n = 22$), and two groups with researchers and research coordinators (total $n = 19$). Data from each set of groups are presented separately.

Former research participants

Table 1 displays the demographic characteristics of the patient sample. Former research participants (n = 22) were primarily female (77%), middle-aged (only two participants were under age 40 years; eight were over age 60 years), and African American (86%). Groups were mixed in terms of education level, with six (27%) having less than a high school education and five (23%) having a bachelor's or master's degree. These demographics reflect the University of Illinois at Chicago patient population. Participants provided information about the most recent research study in which they had participated. Mental and emotional health, diabetes, and respiratory/cardiovascular health were most frequently mentioned. Most participants had been in a research study fairly recently. For 14, participation had ended within the last year, and only one reported that participation was more than 10 years ago.

Overall, individuals who had previously participated in research had positive views regarding their experiences. Participants' mean score on the RTS was 14.18 (out of 20, SD ±3.57). Participants' mean score on the RAQ was 27.86 (out of 35, SD ±3.94). Regarding satisfaction with their decision to participate in the most recent study, participants' mean score on the SDHC was 20.47 (out of 25, SD ±4.9).

However, discussion elicited that the informed consent process often did not meet its intended objectives. Findings are presented according to three primary themes: content of consent forms, experience of the informed consent process, and potential of technology. Each primary theme includes several subthemes (see Table 2).

Content of consent forms—In discussing the content of consent forms, four subthemes arose. These included information overload; need for clarity regarding study purpose; study tasks as a primary focus; and need for clarity regarding risks.

Information overload: Not surprisingly, former research participants noted that consent forms are extremely long, contain confusing medical and legal jargon, and focus on things that, to them, do not seem important. Long consent forms were viewed as burdensome. As one participant said, "I think it's too much. Then you try to process all this information so quick. You know what I'm saying? You ain't got time to breathe."

Need for clarity regarding study purpose: Federal guidelines (45 CFR 46) cite study purpose as a required element of informed consent. However, former research participants stated that they had difficulty understanding the study objectives as described in informed consent documents. One participant even said, "The particular study that I was in, I couldn't tell you what it was for if my life depended on it." When asked about the research in which they had taken part, they tended to describe what they did in the study (e.g., specific tasks and activities) rather than the purpose of the study (e.g., the research question). Another participant said, "I'm not 100 percent sure what the study was about on paper. I know that I had to participate and give permission and stuff like that."

Study tasks as a primary focus: The fact that they did not understand a study's purpose did not seem to be a major concern for former research participants. They were most interested

in knowing *what* they would need to do (e.g., number of visits, how long visits would last, what they would do at the visits). In the words of one participant, "I would like to know *how* am I supposed to participate."

Need for clarity regarding risks: Information about risks was cited as an important influence on the decision to participate. Some participants questioned why consent forms focused so heavily on voluntariness and privacy, as they were more concerned about risks related to medications or procedures. Those who had participated in multiple studies understood that assurances regarding privacy and voluntariness were required in all research studies, but they felt that that these should be presented separately from study-specific information such as risks and tasks.

The experience of the informed consent process—In discussing the experience of the informed consent process, three subthemes arose: importance of personal interaction; feeling rushed and pressured; and feeling disrespected and used.

Importance of personal interaction: Former research participants discussed the importance of personal interaction during recruitment and informed consent. The attitudes and behavior of frontline personnel are critical for building trust. Personal attention from study staff is key to participants' comfort. Said one participant: "I think people who are running these studies, they have to be a people person and nice personality to make [participants] feel comfortable, and do a lot of explaining. You can comprehend what they're saying. That's important to me on whether I even want to participate." Trust in the research, the research team, and the institution gets established—or not—during the initial recruitment encounter:

> [When I] call the number, it depends on how that person acts. That is what gonna determine if I'm gonna be in the study or not. If I call these people and you acting all like "Excuse me, ma'am, sorry, what did you say you were doing," or the questions they ask and their attitudes over the phone, I'll be like "Uh-huh, no, baby, I'm cool, uh-huh." Because if you acting like that [to] me on the phone, how you act [in person] … I be like "You know what, I'm fine, click." No.

Feeling rushed and pressured: Former research participants noted feeling rushed during the informed consent process. At times they felt forced into signing, even when they had not yet read the entire consent form or had an opportunity to ask questions. The following statements illustrate these feelings:

> They just hand you the paper, have you sit there and read it, and then make you sign it.

> [The person telling you about the study says], "This is basically saying this. This is basically saying that." That makes you feel … obligated to sign it cuz they gonna say this stuff real quick to you, like all right. That makes you uncomfortable, and it makes you feel obligated.

> With the consent forms … they'll just be "I need your signature." They'll put the X. "I need your signature there and there and there." I'm like okay, all right, and I'm signing cuz you wanna hurry up and get the process going.

Some participants discussed instances when they signed a consent form because they felt pressure but then did not return for follow-up visits.

Feeling disrespected and used: Former research participants know that they have a responsibility to ask questions about anything they do not understand. They know that they should not sign if they do not understand. However, asking questions can be intimidating, especially if the researcher does not make them feel comfortable to do so. Participants discussed that researcher attitude or behavior sometimes kept them from asking questions about things they did not understand. For example, one participant said:

> When you see something on the informed consent that you don't understand and you tell the person, "I really don't understand this," and the way, the tone they give you the answer in. Oh, that makes me feel—I'm gonna tell you just straight up—make me feel … dumb. "Why didn't you know that?" They make you feel like that. It's the way they give you the answer. Feel like I'm so dumb … I shouldn't have never asked her … They be one step from saying, "How can you ask me what that means?" That's the way I feel.

Feeling rushed and disrespected can make research participants feel used. Focus-group participants were aware of past exploitation of research participants. The Tuskegee Syphilis Study came up spontaneously in one group, and concerns about being used as "guinea pigs" were mentioned in two groups.

Potential of technology—The attitudes of former research participants toward technology were mixed but encouraging. Fifty percent of participants owned an iPad or other computer tablet, but five of the 22 stated they were not comfortable using a tablet. Table 3 displays participants' comfort using different types of technology.

In discussing potential ways technology might improve the informed consent process, six subthemes arose: show, not just tell; decrease pressure; encourage asking questions; promote patient engagement; provide opportunities to learn about technology; and do not replace the personal touch.

Show, not just tell: Discussion arose spontaneously about the potential of pictures and videos to show prospective participants what participation would actually be like:

> Pictures they say are worth 1,000 words, so videos and PowerPoints with words under them are even better than just listening, and reading, and trying to figure out. Most of the time, videos are much better at explaining whatever the person is trying to tell you … and maybe even what your part of the study is.

Decrease pressure: When we raised the issue of learning about a study on a computer or tablet, participants thought that technology might ease some of the pressure they felt from researchers to sign quickly before they understand. Said one participant:

> It's a little more privacy cuz you not sitting there, signing something flipping the page and flipping the page, and there's not no person breathing over your neck, or are you through with that page, okay, give me that one … You got a little more privacy. You may wanna go over in the corner and just they can say, "Here's the tablet. You sit over there."

Having the opportunity to review information using interactive technology could give potential participants more time to learn about a research opportunity and decide on their own.

Encourage asking questions: Participants thought that interactive multimedia consent could let them ask questions or get more information in a "less intimidating" way. Said one participant, "If I have questions I could answer myself by clicking [on a hyperlink with more information or a definition], without feeling dumb." To this, another participant responded, "You ain't got to be like looking around, scared, be like no, I ain't gonna even ask that, cuz I supposed to know that one."

Promote patient engagement: Particularly striking were former research participants' comments about ways in which an interactive, technology-assisted informed consent process could be more engaging and patient-centered. Said one participant, "[An interactive, technology-assisted informed consent process] allows the patient to have more control and gain an understanding of what they're putting themselves into." Said another:

> Interactive video allows you to be a participant. You're actively looking for information. You're actively retrieving information. You're getting it verbally and visually, but by you being a participant, the person who's actively searching through the data that's being provided for you, it sticks better.

Provide opportunities to learn about technology: Despite the relatively high levels of comfort with technology (see Table 3), some participants expressed a general dislike of "computers." Interestingly, during this discussion, others tried to convince them that they needed to "get on board" with technology. Said one participant, "You don't have to be an [expert], but you're gonna have to learn the basics. This is the way the world is changing." Another participant responded, "That's true. There are too many free computer literacy classes. You can go to the library. Whatever. You can learn. We're gonna have to get on board. There is no excuse for age. Age has nothing to do with it." Said another, "You're going to get left behind if you don't." During this conversation, other participants noted that using technology during the informed consent process might present an opportunity for individuals unfamiliar with tablet computers to learn more about them. Said one participant:

> It would be very educational. It would also be like an ice-breaker. She [referring to another participant] may not know how to work with a tablet, and I may be sitting there like okay, this is how we gonna—this is how you do it. She's learning something in that process of her doing her consent.

Do not replace the personal touch: Some participants were quite positive about their previous interactions with research staff. These individuals, who tended to be a bit older,

were wary about replacing a person with a computer. They liked the one-on-one interaction and reacted positively to the idea that the informed consent process could include both a person and a computer. Said one participant, “I feel that if somebody went over it with me it would give me more confidence. There’s nothing like a real person.” Another participant responded, “I was gonna say the same thing. That’s all they do is phones and computers. There ain’t no human contact anymore.”

Researchers

Two researcher focus groups included a total of 19 participants. We did not specifically ask about titles and roles but rather focused on responsibilities specifically related to informed consent. However, conversation elucidated that participants were principal investigators; research field staff whose responsibilities primarily included recruitment, obtaining informed consent, and data collection; and research coordinators with responsibilities for project management and training/supervising other research staff. In reporting findings, we refer to participants of these focus groups collectively as “researchers.” Researchers were very experienced and had worked in a variety of inpatient, outpatient, and community settings on studies related to diabetes, heart disease, asthma, kidney disease, and breast cancer, among other conditions. They had also worked with a wide range of patient populations, including children, adults with cognitive impairments, and adults with limited education and/or low literacy. See Table 4 for researcher demographics.

We surveyed researchers regarding training they had received in human subjects protections and informed consent and asked what else they would like to see as the focus of future training efforts. Most researchers stated that they completed required CITI training (https://www.citiprogram.org), and many had participated in a variety of other training activities, such as online courses, discussions with the principal investigator (PI) and research staff, supervised practice, and/or “on the job” training. However, only about one-third specifically mentioned that informed consent was included in their formal training activities.

Researchers’ suggestions for informed consent training reflected those concerns they identified when discussing the content of consent forms. They would like to learn more about how to help participants feel more comfortable and better understand what they are agreeing to do, including the “big picture” as well as the fine print. They seek training on how to provide clarity regarding some of the perceived contradictions and address therapeutic misconceptions, especially for those participants with low literacy.

Findings from focus-group discussions are presented according to four major themes, the first three of which parallel those from the research participant groups: content of consent forms, experience of the informed consent process, potential of technology, and need for more lay input on informed consent (see Table 1).

Content of consent forms—In discussing the content of consent forms, five major subthemes emerged: information overload; therapeutic misconception; need for clarity regarding study purpose, research environment, and big picture; contradictions; and alarm. Several of these are similar to subthemes that arose in research participant groups.

Information overload: Overwhelmingly, researchers believed that participants simply do not read long consent forms, regardless of efforts to encourage and support this. The length of most consent forms—even those that seem short by comparison—is "intimidating" to participants. In addition to creating cognitive overload, the long forms are "unfriendly." Put succinctly by one researcher: "It's so complex. People get really frustrated, and then don't even bother with it." Another expanded on this comment:

> They are not paying attention. Some people that have participated in previous studies, they know that there is a lot of this blah-blah-blah, so they automatically just go off. You can see there are other people, when we are going through it, they are not understanding … [A]lthough we are reading it and trying to read it with them, they are not focusing.

Researchers also felt that "legalese" (e.g., Health Insurance Portability and Accountability Act [HIPAA] language, explanations of privacy risks and protections, statements assuring voluntariness) should be separate from the "meat and potatoes," which they considered to be the study requirements and risks. Researchers discussed that most people primarily want to know what they will need to do. This can be complicated if there are a lot of research visits and assessments. Researchers emphasized that key information should not be buried:

> In my experience, a lot of my subjects really care about—the meat and potatoes … what they really wanna know about is "What is it that you need me to do?" … They wanna know what to expect, not necessarily because they're gonna drop out of the study if it looks like it's gonna be too invasive.

Therapeutic misconception—Researchers find it difficult to explain to participants that research is not clinical care and that they might not benefit from participating. They discussed that long consent forms contribute to the therapeutic misconception, that is, the mistaken belief that the primary goal of research is individual care or cure rather than knowledge that will benefit future patients. Said one researcher:

> I find that people aren't reading [consent forms] very carefully. Cuz you hand them this thing, or you give them pages. Then we have to go through—they're signing up for something cuz they're like, "Yes, I'd like depression treatment," but they didn't actually read about what's involved in the depression treatment cuz they saw this thing or ignored it or stopped halfway … I want them to get the main points. It seems like sometimes they don't because of all of that.

Due to information overload, the message that research may not provide direct benefit to participants gets lost. One researcher noted:

> One really key thing is that people understand that what we're doing's not gonna help them individually. I think that's part of that, being fair. It gets diluted out with so many other things that I think they lose sight of that. You still have people who think it's gonna help them …after reading this long thing.

Need for clarity regarding study purpose, research environment, and big picture: Researchers commented that the purpose of a study is often challenging to explain, especially if the study is observational or if revealing the study's hypothesis might bias

participants' responses. Researchers also noted that consent forms lack good descriptions of the research environment. Participants ask what the experience will be or "look" like. Researchers suggested having a concise summary of the "big picture" before getting into the details could help participants better contextualize—and therefore better understand—specific information. Said one researcher:

> I find the more time you put into that process and showing them the big picture … allows them, when they do come in to do the informed consent, they have this general concept. Now maybe they can focus on the particulars a little more … it goes a lot more smoothly when they've had a better description of the overall study prior to coming in and doing the actual informed consent.

Contradictions: Researchers discussed pieces of information in the consent form that they see as "contradictory." Promises regarding extensive efforts to protect privacy and confidentiality are usually followed by required consent form template language listing groups and individuals that may have access to participant data. However, the specific circumstances that would lead these groups (e.g., sponsors, the IRB) to see the data are not explained. As one researcher stated, "When [the consent form] starts talking about the blood analysis, when people start to say this could be shared with this person, this could be shared with that person. You keep talking about confidentiality and privacy, but then, after a while, it's shared with everybody."

Other perceived contradictions are related to voluntariness. Language in the consent form emphasizes that participation is voluntary, but sections on withdrawal often say that data cannot be withdrawn once collected. The risks section often says that participants can refuse any question they do not want to answer, but PIs ask research staff to contact participants when responses are missing. Said one research staff member:

> [PIs] are like, "No, no, they're not allowed to skip that question in the 100 items on your surveys because we can't have missing data. Go track them down. Go call them. Call them six times. No missing data." Those are important attitudes, but there's also this sense of, people need to be able to make some decisions about what they're willing to do or not do, and we need to approach it from that perspective. Not that we give up on the reliability of our data, but that people do have some—discretion.

Alarm: Researchers mentioned that overemphasis on certain things in the consent form, such as strong statements about privacy or the risks of getting upset from survey questions, can raise unnecessary alarm and do not, in their view, truly protect participants. In the words of one researcher:

> I don't know if we need to do this, but we include stuff about data safety … We detail the server that the data's gonna be saved on, and it's like, "Why do I need to know this?" Actually, by bringing it up makes them more concerned that, "Okay, why are you telling me this?" Cuz then they're like, "I don't care." That's the overall attitude for that.

Experience of the informed consent process—In discussing the experience of the informed consent process, three major subthemes emerged: difficulty standardizing the process; those responsible for informed consent also have problems with comprehension; and dual roles.

Difficulty standardizing the process: Researchers discussed that in training, they learned that informed consent is a process, not just a form. However, they note that IRB review emphasizes standardization of written materials—the consent form, as well as scripts for recruitment, verbal consent, or follow-up phone calls. Researchers viewed IRBs' demands for scripts as contradicting the ideal of informed consent as a meaningful conversation driven by participants' questions. For researchers, standardization does not reflect reality:

> The informed consent process is very much designed to be laid out and be the same from subject to subject. I think we've all realized that each individual subject has their own needs, and being flexible with your conversation, whether it's having more of a lighter conversation to get people to open up or take their defenses down or describing something through images, I think it's certainly more individualized than the actual process is laid out and designed to be, which is a little contradictive.

In response, another participant said that the idea of informed consent as a process "is a paradox because … everything is supposed to be the exact same thing for each—according to the IRB."

Those responsible for informed consent also have problems with comprehension: Some researchers candidly admitted to obtaining informed consent when they themselves did not completely understand everything in the consent form. Said one researcher:

> I myself don't understand the—I can't understand what exactly they are saying. I have to read it several times to figure out, what are they saying here? I don't know how they can understand, but the IRB says, no. In fact, they told me, "You have to put this in this way." Fine. I will do it, but it's very confusing.

Dual roles: Researchers recognize tensions as they recruit participants and obtain informed consent. Said one, "If we're gonna be honest, we have a somewhat contradictory—well, we have a conflict of interest. Let's put it that way. Because I have to be somewhat of a salesperson." Researchers feel it is an important part of their job to make potential participants comfortable while also explaining the study. They may even view themselves as advocates for potential participants. But they also acknowledge that they have "a job to do," that is, to meet enrollment goals. The analogy of "sales" came up several times:

> I find that I have so much influence over how a person understands their involvement in the study, regardless of how the consent form is drafted up … my responsibility is to my PI, and what she wants me to do is stay on schedule. By staying on schedule, I have to be a salesperson. I have to recruit people and sign people up, at the rates that she prefers.

For subordinate research staff, PI support is crucial:

> There's that interesting disparity between my goal [to support voluntary choice], and then my PI's goal, and how much she's actually interested in me being 100 percent ethical … I think a lot of that could be reduced by she and I maybe having regular conversations about what my process is like, what am I encountering.

Potential of technology—In discussing the potential of technology, three major subthemes emerged: possibilities; challenges and needs; and concerns about IRB barriers.

Possibilities: Researchers thought multimedia tools could be used to make informed consent more "engaging." In describing her experience using tablet computers in a research intervention, one researcher noted that "Patients who were feeling rushed … felt a lot more comfortable with holding an iPad … I just noticed that they were engaging with technology in a really easy and simple way, compared to people who were feeling really overburdened by all the paperwork that I had for them."

Researchers also saw potential for technology to ensure that potential participants take in the most important information about a study. Said one researcher:

> We can highlight the summaries and that information that we see as very important to make sure that they're reading cuz then it would be visible, but the rest of that information could be there. Cuz there's definitely some people who are interested and want to check each one of those things, and so it would be available, but perhaps not tripping them up in seeing the overview. Something like that.

Researchers also suggested that technology could support assessment of participant understanding.

> To test their knowledge a little bit about—because I guess, from a researcher point of view, when I say I'm giving informed consent, I use talk back, or I have them try to give me an explanation of what's happening, but I'm never 100 percent sure they really understand, I guess, like I feel confident enough. If they are not clear, then we can go through things again.

Challenges and needs: Concerns about limited time and resources loomed large in discussions of multimedia informed consent. Researchers stressed that technology needs to be flexible to accommodate unanticipated changes to the research protocol. Most importantly, technology needs to support the individuals responsible for obtaining informed consent in being efficient and effective.

Concerns about IRB barriers: Researchers expressed skepticism that an IRB would approve an "alternative" consent process. When discussion turned to technology and multimedia informed consent, one of the first comments was: "How do you present that to IRB? How do you present an iPad presentation as a part of consent? Because any conversation that we have with potential subjects, we have to submit that to IRB." Researchers view IRBs as anti-innovation; for example, when one researcher mentioned having been part of a study that used a consent form that included pictures, another expressed surprise that the IRB would allow that. Said another researcher, "All I can say is

who wants to be the first person to try to go before the IRB? Cuz that is the real problem." Concerns about getting through the IRB submission and approval process seemed to limit the imaginations of researchers regarding solutions to the problems with informed consent.

Need for more lay input on informed consent—A specific example provided by a researcher highlights how researchers and IRBs might not always get it right—and the simple potential of supplementing words with visuals. In a particular study, the IRB had suggested that the amount of blood be described using a number of teaspoons. This researcher soon discovered that many people did not know how big a teaspoon is and were surprised at how much blood was being drawn. She found it to be more effective to show potential participants the actual vials that would be used. In discussing stories like this one, researchers stressed the need to get lay/patient input to improve informed consent. This is a common practice in intervention development that they thought should be applied to informed consent. Said one researcher:

> Because [consent forms are] so antiquated, [IRBs] need to just redo the process and get other people's input, not just in the research communities and the medical doctors or the PhDs. They gotta go out and get other information cuz it seems as if the processes in which they use are so antiquated. It's like there was some point. Oh, this is the language for the federal regs. Okay, so nothing can ever change?

Discussion

Given what is known from prior research about the shortcomings of participant understanding of the informed consent process (Rowbotham et al. 2013), much of what was reported by our focus-group participants is not surprising. However, our study is unique in three ways: (1) We assess the views of a diverse group of African American participants with prior different experiences participating in research (rather than hypothetical participants, participant advocates, or individuals who had all participated in the same study); (2) we triangulate the views of these former participants with those of researchers with significant experience obtaining informed consent; and (3) we explore the views of both sets of stakeholders on the potential of technology to improve the informed consent process.

As in our study, other research has found (Cortes et al. 2010)—and indeed there seems to be consensus (Lorell et al. 2015)—that the leading problem regarding informed consent is the length and amount of information included in informed consent documents. However, much of this information is critical. Consent forms could be made shorter, but ultimately, a solely text-based delivery system has significant limitations. Our participants noted, as in other studies, that they often felt rushed during the informed consent process (Hallinan et al. 2016; Cortes et al. 2010). Multimedia formats have numerous benefits for presenting information in more user-friendly ways; they allow individuals to absorb information at their own pace through their own preferred means of delivery (Shneerson et al. 2013). Even if the amount of information is the same, multimedia formats may minimize the experience of information overload.

As in previous studies (Wade et al. 2009; Loh et al. 2002), research staff members in our study acknowledged that they have significant influence over what information is presented/emphasized to participants, regardless of what is written. True to the spirit of informed consent as a process, multimedia information delivery formats can ensure consistency in what information is presented while also offering a personalized experience. Multimedia formats also have the advantage of being able to provide a sense of what the experience of participation will look or feel like—something that is important to prospective participants' decision making—without adding more text to an already lengthy document.

Ultimately, those interventions found to best improve research participant comprehension and recall are those that improve the quality of the discussion with the researcher or research staff member (Brown et al. 2011; Kass et al. 2014; Hallinan et al. 2016). It is therefore important to envision a multimedia tool as replacing the consent form, but not the entire process of informed consent; human interaction is the core of informed consent. Despite expressed preference, especially from older participants, for the "human touch," we were not surprised to hear that participants sometimes felt pressure from researchers, nor that they felt uncomfortable asking questions about things they did not understand. However, we had not previously considered the potential of a multimedia informed consent process to eliminate some of that pressure and intimidation, as our participants suggested. Participants may be less intimidated to seek additional information or ask specific information questions if they can do so without feeling that they are admitting ignorance to the researcher. By leaving factual clarification and assessment of understanding to the impersonal multimedia tool, more meaningful discussion between a potential participant and a researcher can ensue. Once they have a solid foundation of information, gleaned from an interactive, multimedia tool, discussion with the researcher can focus on supporting the participant in making a decision that is right for the participant.

Other studies have found that multimedia informed consent processes are acceptable to potential research participants (Shneerson et al. 2013; Henry et al. 2009), and this is true of our sample of older underrepresented minorities. Interestingly, some of our participants suggested that using a computer or tablet for informed consent could provide the indirect benefit of familiarizing potential participants with technology. This is worth keeping in mind when weighing the potential costs and benefits of a multimedia consent process.

Both stakeholder groups raised issues regarding participant understanding of key research information, such as study purpose or randomization to placebo. Given the general population's lack of familiarity with research concepts, this problem may not be solved through a short-term informed consent process, no matter how good the explanation. Other issues were identified by focus-group participants that may not be easily addressed through the informed consent process, including the fact that assurances of voluntariness, no matter how strong or how often repeated, are met with some skepticism.

Limitations

This study has several limitations. Given our small, nonrandom samples, findings are not generalizable to the larger population of research participants or researchers. However, we aimed to collect preliminary data to inform more robust formative and developmental work

on informed consent with the patient population being invited to participate in studies at our academic medical center, and to test strategies for eliciting stakeholder views on the informed consent process. Additionally, triangulation of information sources during formative research increases the appropriateness, relevance, and breadth of information obtained.

Research directions

Some research on multimedia informed consent has employed cognitive interviewing methods (Henry et al. 2009), but more basic research is needed to elicit input from experienced and potential research participants in the development of multimedia informed consent tools, not simply assessing their reactions to interventions developed by well-meaning researchers who are unfortunately constrained by the status quo—and, as we have heard, perhaps by concerns about IRB resistance to innovation. Others have noted barriers to changing the informed consent process, despite the overwhelming evidence that significant improvements are needed (Hallinan et al. 2016). Skepticism about whether IRBs are amenable to alternatives to written consent forms may explain the general lack of innovation regarding informed consent practices. This is worth further exploration.

Research reports of multimedia interventions provide limited details regarding key features and use inconsistent terminology. This makes it difficult to determine which features of a multimedia informed consent intervention are responsible for improved participant understanding or satisfaction. Future research must be designed to better detect the effects of specific elements and to determine how preferences and effectiveness varies by different subgroups. Future research should also assess outcome measures beyond participant comprehension and recall, such as satisfaction with one's decision to participate (or not), overall satisfaction with the experience of participation (e.g., were expectations met?), and completion of study requirements. Key moderators, such as improvement in the quality of the discussion with a research staff member, will also be important to measure.

Policy implications

Comments from researchers and research participants in our study suggest that core elements of informed consent required by the U.S. federal regulations are not adequately communicated nor understood. But participants' comments also suggest rethinking what elements should be included or highlighted. We heard from former research participants that some of the information that makes the consent form so long does not really inform their decision about participation. Perhaps the biggest shortcoming of the final revisions to the Common Rule (https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/pdf/2017-01058.pdf) is that the Office of Human Research Protections (OHRP) failed to seek the input of a diverse sample of experienced research participants. Future efforts to develop more specific guidance and template language should certainly do so.

Conclusion

Informed consent continues to be a challenge for researchers. The informed consent process is not just about reading comprehension or simply relaying information. It is also about

engendering trust among potential research participants. Therefore, informed consent cannot be approached solely in terms of understanding and recall of the consent form. Participant confusion can lead to dissatisfaction with the informed consent process. This dissatisfaction can in turn negatively affect recruitment, retention, and the experience of participation.

Our findings from a sample of underrepresented minority patients who have previously participated in research add to findings from other studies that suggest that the use of interactive technology has the potential to improve informed consent. Our focus-group findings provide additional insight that technology cannot replace the human connection that is central to the informed consent process. More research that incorporates the views of key stakeholders is needed to ensure that multimedia consent processes do not repeat the mistakes of paper-based consent forms.

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Table 1

Former research participants: Demographics ($n = 22$).

	n	%
Sex		
Female	17	77.3
Male	5	22.7
Age (years)		
26–40	2	9.1
41–60	12	54.5
Over 60	8	36.4
Race		
Black or African-American	19	86.4
American Indian or Alaskan Native	1	4.5
White or Caucasian	1	4.5
Other	1	4.5
Ethnicity		
Hispanic or Latino	2	9.1
Not Hispanic or Latino	20	90.9
Highest level of education completed		
Less than high school diploma	6	27.3
High school or GED	3	13.6
Technical college/trade school diploma	1	4.5
Some college	7	31.8
Four-year college degree/bachelor's	2	9.1
Master's degree	3	13.6
Focus of most recent study		
Mental/emotional health	7	31.8
Diabetes	4	18.2
Respiratory/cardiovascular health	3	13.6
Health behavior (e.g., smoking)	3	13.6
Cancer	1	4.5
Other/don't remember	4	18.2
Year most recent study ended		
2014–2015	14	63.6
2012–2013	6	27.3
2008	1	4.5
<2005	1	4.5

Table 2

Summary of focus-group themes from patients and researchers.

Patients' Subthemes	Themes	Researchers' Subthemes
• **Information overload** *	**Content of consent forms**	• **Information overload**
• **Need for clarity regarding study purpose**		• Therapeutic misconception
• Study tasks as primary focus		• **Need for clarity regarding study purpose**, environment, and "big picture"
		• Contradictions
		• Alarm
• Importance of personal interaction	**Experience of the informed consent process**	• Difficulty standardizing the process
• Feeling rushed and pressured		• Those responsible for IC do not always understand the study purpose
• Feeling disrespected and used		• Dual roles
• Show, not just tell	**Potential of technology**	• Possibilities
• Decrease pressure		• Challenges and needs
• Encourage asking questions		• Concerns about IRB barriers
• Promote patient engagement		
• Provide opportunities to learn about technology		
• Do not replace personal touch		
		Need for more lay input on informed consent **

* Bold indicates areas of overlap.

** Research groups only; no subthemes.

Table 3

Former research participants' comfort levels with using electronic devices ($n = 22$).

	Very comfortable		Somewhat comfortable		Not at all comfortable	
	n	**%**	***n***	**%**	***n***	**%**
Personal computer	13	59.1	5	22.7	4	18.2
Tablet computer	13	59.1	4	18.2	5	22.7
Smartphone *	11	50.1	4	18.2	3	13.6
Searching the Internet	16	72.7	4	18.2	2	9.1

* Four missing responses.

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Table 4

Researchers: Demographics (n = 19).

	n	%
Sex		
Female	14	73.7
Male	5	26.3
Age (years)		
26–40	8	42.1
41–60	7	36.8
Over 60	4	21.1
Race		
Black or African-American	5	26.3
White or Caucasian	13	68.4
Other	1	5.3
Ethnicity		
Hispanic or Latino	4	21.1
Not Hispanic or Latino	15	78.9
Highest level of education completed		
Technical college/trade school diploma	1	5.3
Four-year college degree/bachelor's	3	15.8
Master's degree	6	31.6
Doctoral degree or professional degree	9	37.4
Number of years working in research		
More than 1 year but less than 3 years	1	5.3
More than 3 years but less than 5 years	1	5.3
More than 5 years but less than 10 years	4	21.1
10 years or more	13	68.4
Number of studies responsible for writing consent forms		
1	4	21.1
2–3	2	10.5
4–5	2	10.5
6 or more studies	9	47.4
Other	2	10.5
Number of studies responsible for obtaining informed consent		
1	1	5.3
2–3	6	31.6
4–5	4	21.8
6 or more studies	8	42.1