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Communicating Risks and Benefits in Informed Consent for Research: A Qualitative Study

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Abstract

Multiple studies have documented major limitations in the informed consent process for the recruitment of clinical research participants. One challenging aspect of this process is successful communication of risks and benefits to potential research participants. This study explored the opinions and attitudes of informed consent experts about conveying risks and benefits to inform the development of a survey about the perspectives of research nurses who are responsible for obtaining informed consent for clinical trials. The major themes identified were strategies for risks and benefits communication, ensuring comprehension, and preparation for the role of the consent administrator. From the experts' perspective, inadequate education and training of the research staff responsible for informed consent process contribute to deficiencies in the informed consent process and risks and benefits communication. Inconsistencies in experts' opinions and critique of certain widely used communication practices require further consideration and additional research.

Keywords

risks and benefits, research, clinical, informed consent, interviews, semistructured

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Introduction

The informed consent process for clinical research requires good communication of study risks and benefits by the consent administrator so that potential research participants can decide whether or not to participate (Council for International Organizations of Medical Sciences [CIOMS], 2016; International Conference on Harmonisation [ICH], 1996; U.S. Department of Health and Human Services [HSS] & U.S. Food and Drug Administration, 2016; World Medical Association [WMA], 2013). Robust communication of risks and benefits is a key feature of an effective informed consent process. Research professionals, including research nurses, who seek informed consent are expected to convey information in a clear and unambiguous way, adapting "the presentation of the information to the subject's capacities" (National Commission, 1979, Part C, para. 8) and ensuring its comprehension (Federal Register, 2017). In recent years, several approaches have been suggested to facilitate communication of informed consent information. Guidelines were proposed for the simplification of the language of informed consent forms (National Cancer Institute [NCI], 2013; Paasche-Orlow, Taylor, & Brancati, 2003; HSS & Agency for Healthcare Research and Quality, 2009). Methods for conveying numerical probabilities of risk were developed and tested showing improvement in research participants' understanding of risk information (Cabeeza, Ramisetty, Thompson, & Khan, 2005; Fagerlin, Zikmund-Fisher, & Ubel, 2011; Ulph, Townsend, & Glazebrook, 2009). The Agency for Healthcare Research and Quality (AHRQ), an agency in the HSS, published general recommendations on how to enhance the informed consent process (HSS & AHRQ, 2009). For example, the AHRQ informed consent toolkit suggests methods for improving the informed consent process, such as reading the informed consent form with participants, asking them to repeat study information in their own words, using open-ended questions to assess comprehension of the main consent messages, and encouraging the potential research participant to ask questions.

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Despite these requirements and recommendations, many research participants still feel inadequately informed about study risks, discomforts, and/or benefits (Koh, Goh, Yu, Cho, & Yang, 2012; Montalvo & Larson, 2014) nor has there been routine evaluation of participant comprehension (Brown, Butow, Butt, Moore, & Tattersall, 2004). Ineffective communication of risks and benefits information jeopardizes obtaining ethically appropriate consent which compromises reaching an informed decision about joining the research study. Although there are published recommended strategies to enhance the informed consent communication process, particularly for risks and benefits communication, there is a paucity of research focused on how and whether these strategies are being used in the field when recruiting individuals for clinical trials (Ferguson, 2003; Sabik et al., 2005). There are even fewer studies that provide this information with respect to research nurses who frequently obtain informed consent for clinical studies. A survey of attitudes, practices, and preparedness of those tasked with obtaining informed consent could provide information to address this.

Study Aim and Questions

The aim of this qualitative study was to explore the perspectives of key stakeholder experts in informed consent provision, representing clinicians, regulators, researchers, and patients advocates, about conveying risks and benefits messages to potential research participants during the informed consent process. The findings will shed light on the current challenges in the informed consent process and provide greater understanding and suggest solutions to improve risks and benefits communication. Outcomes from this study will also be used to develop and design a survey of research nurses' attitudes and practices regarding risks and benefits communication while obtaining informed consent for a clinical trial. We interviewed experts in clinical research informed consent to answer the following research questions.

Research Question 1: What are the opinions and attitudes of experts about current informed consent process practices in relation to communication of risks and benefits information to potential research participants?
Research Question 2: What are the attitudes and experiences of experts about the training of informed consent administrators in relation to communication of risks and benefits information to potential research participants?

Method

Study Design

A qualitative descriptive study design based on semistructured, open-ended individual in-depth interviews was used to complement literature review findings for the development of a future survey. The qualitative descriptive method is an effective method for obtaining informants' direct answers in relation to practical issues and for instrument development (Sandelowski, 2000; Sullivan-Bolyai, Bova, & Harper, 2005). The design focused on "the what" and "the how" from experts' perspectives and provided near-data detailed descriptions of their opinions and experiences related to communication practices used in the informed consent process and to training of professionals responsible for obtaining informed consent for research (Neergaard, Olesen, Andersen, & Sondergaard, 2009; Sandelowski, 2000). Personal interviews allowed access to interviewees across the United States, in a place and a time that was convenient for them. Several key questions were used in a semistructured interview format, providing a common framework for all interview encounters and defining areas to be explored in the studied topic (McIntosh & Morse, 2015).

To capture a diversity of perspectives, a nonprobabilistic, purposeful maximum variation sampling technique was used to select key informants for the study sample (Creswell, 2007). The inclusion criteria were demonstrated informed consent expertise and written consent to be audio-recorded during the interview. Expertise was defined as any combination of the following: (a) publications in peer-reviewed literature, current research activity in clinical area, presentations in national and international scientific conferences or (b) currently serving on an Institutional Review Board (IRB) committee.

The lead investigator (L.N.) identified and recruited potential interviewees, verified their eligibility, and conducted and analyzed the interviews. The 17 key informants were identified from professionals presenting at conferences on the topic of human subjects' protection (e.g., Public Responsibility in Medicine & Research conference) and from authors of peer-reviewed publications on the studied topic. All of the experts invited to participate in the study agreed to be interviewed. Recruitment of informants stopped once data saturation was achieved. Saturation occurred when interviewing additional informants did not add new information and the ideas provided by the informants were repeated in a number of cases (Richards & Morse, 2007).

Data Collection and Analysis

Interview procedure. The interviews were carried out in English from October to December 2013. They were held at a pre-arranged day and time in a private place at the convenience of the informant. Most interviews were conducted in person; however, when face to face interviews were not possible, telephonic interviews were conducted. The interviews took on average 65 minutes (range: 40–150 minutes). All interviews were audio-recorded and transcribed verbatim. In addition, memos were completed immediately after each interview. The memos supplemented interview data by documenting the date, time, and location, along with notes of the ideas and new insights related to the responses and interview

Table 1. Exemplars of Interview Questions.

No.	Example Questions
1	From your experience and/or knowledge, how is information about risks and benefits of research communicated to potential research participants?
2	What do you think is the best way for members of the research team who seek informed consent to convey information about risks and benefits?
3	How would you define/describe effective communication about risks and benefits of research participation to potential participant?
4	What don't you like about the current process of communication of risks and benefits?
5	How can confirmation of the understanding of risks and benefits be done effectively?
6	How do you think a practitioner should be prepared to adequately discuss risks and benefits of research with potential participant?

procedure. Informants were not compensated for their participation but each was offered a copy of the final report of the study.

Ethical considerations. Written consent was obtained by the investigator before each interview. After the potential informant read the informed consent document, the investigator reviewed it with them, and asked if they had any questions. Once satisfied that all concerns had been discussed, they were asked to sign the consent form and then provided a copy. Phone interviewees signed the consent form electronically. The study protocol and the informed consent form were reviewed and approved by the Northeastern University IRB.

Interview protocol. The interview protocol included several predefined open-ended questions (see Table 1). The literature review and three pilot interviews, conducted by the lead investigator, were used to develop the study's qualitative codebook. New in vivo codes and categories were added as they emerged through the process of close analysis of the transcripts (Saldaña, 2016).

The interview protocol was used as a conceptual guide across the topic domains generated for this study. During the interview, the lead investigator personalized the question order, adding various questions and probes depending on the responses and applying insights gained from previous informant interviews. The questions were designed to assist informants to consider the issues in a critical manner. For example, they were encouraged to describe which communication practices work better than others and to reflect on whether the current required training in informed consent adequately addresses the risks and benefits communication process.

At the conclusion of the interview, informants were invited to complete a short form, answering several background questions, such as basic demographics (age, gender), primary profession, length of clinical research experience, practice setting, and perceived proficiency pertaining to clinical research conduct and protection of human subjects.

Qualitative analysis. All verbatim transcriptions from the structured interviews underwent thematic analysis using Qualitative Data Analysis Miner v.4 software (Provalis Research, 2011). The software application assisted with efficient data storage and coding procedures (Creswell, 2009).

The interviews were coded prospectively. This iterative approach helped to further develop and modify the coding system and determine when saturation was reached. Notes reflecting on the process and documenting ideas about the evolving themes were made during the process. These records were later integrated into the final report of the study (Creswell, 2009; Miles, Huberman, & Saldaña, 2014).

The transcripts were coded both deductively and inductively, using a "hybrid coding" analytic approach (Saldaña, 2016, p. 75). Several predetermined categories, informed by the study aim and literature review, guided the initial coding process and facilitated the organization of the materials by increasing its efficiency (Guest, MacQueen, & Namey, 2012; Miller & Crabtree, 1994). Some of the predefined categories in this study were actual communication strategies of risks and benefits information, and preparation and training of consent administrators. Additional codes were added to the analysis as the interviews proceeded.

The coding was done in several iterative steps. Initially, the entire transcript was read to obtain an overall sense of the data. In an attempt to describe and interpret the data, the text was summarized with codes, providing a code report. After the initial coding of long texts of verbatim data, expressions with similar meaning along with an immediate part of the context and reference (informant's identifying code) were compiled together into categories through classifying and integrating coded units of the data (Saldaña, 2016). Doing constant inter- and intra-categorical comparison increased sensitivity to new categories that emerged from the data.

The final results were classified as a thematic survey, similar to Sandelowski and Barroso's (2007) typology of qualitative findings. This typology addresses the "degree of researcher transformation of data" (2007, p. 140). The transformation of the data represents the actual intellectual work that is done to impart a "latent pattern" in the data. The qualitative categories were further analyzed to identify repetitions and possible relations or patterns in the data, which were compiled into the overarching themes. The results of the qualitative analysis were also used to formulate statements and response alternatives for a survey on perceptions and experiences of research nurses regarding the communication of risks and benefits. Conclusions from this analysis were documented in the final descriptive summary, presenting themes and main points from the code report with verbatim

quotations from the informants to exemplify the discussed point.

Data Rigor and Credibility

Rigor of the data was achieved through several features in the study design (Lincoln & Guba, 1985). The verbatim transcription from audio-recordings accurately captured the words of the informants ensuring data trustworthiness. Only one person, the lead investigator, collected and transcribed all of the data. The investigator's involvement in the project from the conception stage made her the most knowledgeable person about what data could best address the study aims. She was trained in qualitative research methods, including interview data collection and analytic techniques, and she received additional training by an experienced qualitative researcher in personal interviewing as a data collection method. Another expert in qualitative research methods was consulted across all aspects of the study to ensure adherence to the study design and support dependability of the data.

Coding was conducted in a systematic manner, and any changes in codes and code definitions, their justifications and causes, and all other analytic decisions were documented, contributing to the transparency in the interpretive process.

During text analysis, reliability checks were conducted. The coding process was performed twice, each time starting with the raw data and then comparing and documenting the findings. Constant comparison of the data with the code definitions assured stability of the code meaning. An expert in qualitative research methods reviewed and examined the qualitative codebook and coding application to the data to assure clarity and stability. Credibility of the final conclusions was verified by returning to the interview text to evaluate related explanations, making certain that the findings were anchored in sound evidence.

Results

Characteristics of Participants

The study sample (n = 17) was mostly female (n = 14, 82%) with a mean age of 54 years (range: 28–70 years). The majority (59%) were nurses (n = 6, 35%) or physicians (n = 4, 24%); others were clinical psychologists (n = 2), research assistants (n = 2), a lawyer-ethicist, a health educator, and an IRB administrator. All informants were based in the United States. The mean length of primary professional experience was 26 years, with 18 years of experience on average related to conducting clinical research. Seventy-five percent of all informants had prior experience in research informed consent; all but one had trained others to obtain consent. Most informants were currently employed by academic institutions (n = 15, 88%), one worked for the federal government, and one for a nonprofit organization. The informants represented a number of overlapping clinical research–related roles, such as principal investigator, data collector, regulation or IRB member, and research nurse. Thirteen individuals were interviewed in-person, and the other four interviews were conducted by telephone.

Table 2. Descriptive Coding Scheme Developed to Classify Informants' Utterances.

No.	Theme	Subtheme
1	Risks and benefits communication: process and strategies	a. The informed consent form and its delivery b. Conveying probability of the risks and benefits c. Using presentation means and supplemental materials d. Reading aloud e. Summarizing and highlighting information f. "Take it home" procedure
2	Assuring comprehension of the risks and benefits information	a. Importance of ensuring understanding b. Current and recommended practices
3	Consent administrators—preparation for the role	a. Controversial assumptions b. Informed consent training requirements c. Local training initiatives d. Envisioning training in informed consent

Findings From a Thematic Analysis

Three themes and several subthemes were derived from the key informant interviewees as described in the following paragraphs and in Table 2.

Theme 1—Risks and Benefits Communication: Process and Strategies

The informed consent form and its delivery. Informants noted that in general, the research community is making efforts to improve the effectiveness of the consent process. However, some informants felt that the current consenting process is not as effective as it should be. "I don't think we do a better job explaining consent" (P8). Another stated, "I think it's clear [that] what we are doing now doesn't work and doing more of what we do now is not likely to work any better" (P4).

Some informants believed that improvement has mainly resulted from simplifying consent forms, for example, by using plain language and an appropriate level for potential participant language. Others noted that improving the consent process is about more than creating consent forms in simple sentences. Many expressed concern that current major efforts to improve the informed consent process are limited to changes in consent forms. "We can tweak these

consent forms to death, but I don't really know if we know how to explain [risks and benefits] that well" (P17). The preoccupation with the consent form wording might mask a more problematic, but less controllable or enforceable components of the consent encounter. This refers to the process of delivery of the consent information to the potential research participant, the ways and words used by professionals to actually explain risks and benefits.

> So, I would say like this—the consent forms themselves it would be cynical not to make them better, but that's not enough. Even the very simple document and easy to understand, and easy to use, easy to read is meaningless if the process doesn't support it. So, really it has to be connected with a process that make sense and supports the goals of having substantively informed people choosing to be in [research] projects. (P16)

Additional concerns were raised specifically about the process of communication of risk information. Some informants shared experiences of describing and explaining risks in simpler terms:

> It's hard to figure out how to do this [to simplify risks related information]. (P8)

> Legal department is not going to allow you to simplify those sections [concerning risks and benefits] . . . at least you should be able to simplify the purpose of the study and the procedures. Those areas that are more under the control of the investigator. (P12)

Informants expressed their concerns over professionals failing to present the information in a meaningful manner to potential participants. They also noted the lack of a generally accepted or standard procedure of delivering this information during the informed consent encounter.

> You know, we have really lousy, lousy ways of explaining it [risks] and people don't understand anything. (P17)

> Somehow, we do have trouble of sort of putting risks in an appropriate category for the patient. Like these are important risks, these are not very likely to happen, these are not important, there is some risk we don't know; there is always risk you don't know. (P5)

Conveying probability of risks and benefits. Informants' opinions differed on the best ways to convey the probability of experiencing positive or negative effects of participating in the research. They ranged from a focus on numbers to a focus on verbal descriptors.

Some informants believed that it is important to provide research participants with precise numbers, such as percentages. They argued that, in this evidence-based era, there is an expectation to "give [research participants] some objective data rather than being subjective" (P15) and "[we should] encourage [investigators] to break [risks] out by likelihood, and list the things" (P9). Another informant stated that she would make sure to "put all the numbers that are available both for the benefits and the risks" (P7). Another informant found it difficult to talk about possible harm when its chance of occurring is not known.

One informant suggested numerical information should be included in the supplemental materials only and provided to people who are interested in this type of data. This informant explained that "some mechanism [is needed] for giving basic information, essential information for all subjects . . . and then for those who want more, those who want the statistics and who want some other details, provide them with that" (P6).

Others felt that when using numbers, a verbal description should always be provided to " . . . somehow define what those [numbers] mean" (P10). Also, they noted that there is a need for guidelines that identify effective communication techniques for the appropriate disclosure of numerical data. "There are some people that do better when you describe things in non-numerical terms" (P2).

Several informants did not support the use of numbers during the consent encounter. They believed that numbers were not that helpful or understandable. They also argued that the number itself does not say anything to the individual about his or her personal risk and is not necessary in the consent discussion. Some informants suggested that only verbal expressions should be used to describe and explain chances of all the potential harms and discomforts of the study.

> When [research participants] see . . . statistics, the percentages, they skip that paragraph . . . they don't read [numbers]. (P1)

> Because people are innumerate, as they say . . . people can't assess risk . . . "You gonna feel weak, and you probably will have tingling in your fingers" . . . 25%? 10%? Who cares? . . . [research] subjects are not scientists . . . and they shouldn't be treated like scientists. If I said to you—"You know, I've been doing this research for 10 years and I'd never heard of anyone dying, that's how rare it is," as opposed to saying "It's a .001% risk of dying," which means nothing to anybody. (P13)

Using presentation means and educational materials. Most informants noted the importance of presentation methods and supplemental materials to enhance risks and benefits comprehension and to assist with potential research participant's decision making, such as tables or pictographs, and additional educational materials, such as brochures. Adapting the presentation of risks and benefits information to the individual's capacity by combining different explanatory strategies would possibly improve its comprehension. "You want to show it, say it and have people read it—three different ways of doing it" (P17).

The majority of the experts viewed presentation methods as a relatively new "up-and-coming technique in getting

informed consent," mentioning that some institutions are "starting to encourage people to [use] charts . . . [and other] visual aids instead of just wording" (P12). However, few of the informants had used graphics themselves. Their impression was that this type of communication aid is rarely used by others in the research field to support the risks and benefits communication and the informed consent process.

Some informants assumed that this practice is probably limited due to the lack of valid and approved materials. One informant noted that the rare use of educational aids is "mostly because who is going to develop those supplemental materials, you know whose responsibility is it to develop them; and will our IRB [Institutional Review Board] allow it?" (P13). Another informant noted that any additional materials would only add another layer of complexity to the consent process and would not be as helpful as people expect. "I am not sure a pictograph can work because of the amount of information in the informed consent" (P15).

One of the informants suggested developing a kit with graphics and pictorial explanations. This kit for supporting reading comprehension of the information and assisting with the decision about research participation has to be IRB approved for use along with the consent form. After the consent discussion, potential participants may be given a copy of the kit along with the consent form.

Reading aloud. A commonly used informed consent communication strategy is reading aloud the consent information for the potential research participant. This is performed in addition to providing the written consent form. One informant suggested that this strategy should be used in all instances because "we just assume that [research participants] won't read [the consent form]" (P7). Other informants preferred to give participants a choice.

> If I'm not certain about a person's reading level, I'll ask them how they like to get their information. Do they like to read it themselves? Do they like to someone to read to them? (P3)

> Do they feel like they're a slow reader or a fast reader? So, I put it in such a way . . . and I say, because I'm happy to read it to you, and I always say that. And many patients that can't read will always say, please read it to me. They won't say they can't read, but they'll say, read it to me. (P14)

Some informants described drawbacks to the read-aloud approach. They witnessed consent encounters where potential research participants became a passive listener. The professionals read the entire form verbatim and did not stop to allow any comments or clarifying questions.

> I have seen many people who simply read the consent form to the subject. They just read it through. Twenty pages they read it through. With very little additional explanation. At the end, they say: "Do you have any questions?" And of course, the person says "No" because they have no idea what they just heard, and then say "Okay, then, sign right here." (P4)

Summarizing and highlighting information. Several informants discussed another common practice that involves giving an oral summary of the risks and benefits sections. This summary is expected to provide major points and describe the main effects that the research participant might experience while omitting details that might not be seem relevant to the participant. This approach is thought to be more meaningful. "They [participants] benefit from it more if you summarize each section; the most relevant and should be the instrumental information that they make their decision on" (P11).

Informants elaborated on what information should be highlighted for the person who is considering research participation. In their opinion, only risks and benefits that are most likely to happen or which are severe should be included in the summary.

> The most serious things or what is the most likely things should be highlighted . . . encourage people [consent administrators] to break them [risks] out by likelihood, and list the things . . . really try to focus the attention either on that which is most serious or that which is most likely. (P10)

> There has to be some judgment on what the risks that are significant enough . . . some judgment in developing those informed consent forms about which risk to focus on. (P15)

"Take it home" procedure. There were varying opinions and attitudes about the "take it home" procedure. This procedure usually involves providing research participants with the consent form for "reading and re-reading and putting it under the pillow . . . and asking [the opinions of] friends and physicians" (P2) to assist with decision about study participation. Potential participants are given a copy of the consent form before or after the consent meeting, which they get in-person, via email, or by regular mail. Some informants argued in support of this commonly used approach. Research professionals who use this procedure believe that it provides individuals with more time to "read each and every word" and to "mark [the consent form] up and write all of their questions" (P9) and then "talk over the phone" or "come back again . . . if they have any questions" (P16).

An informant who trained consent administrators shared concerns that research staff are not motivated to consider participants' questions. One of her trainees said she "was relieved" when a potential participant "came back with no questions, because it's easier." This informant interpreted the trainee's words as follows: "So, the idea is—let's hope you have no questions because if you're gonna have a lot of questions it's gonna take me more time" (P17).

Several informants argued against the "take it home" approach. According to their experience, it does not serve the consent process well and people could not be trusted to really

read the information provided in the form. One informant felt strongly that this "infamous" procedure "should not be used at all" (P17). Another skeptic stated,

> Both the investigator and the doctors are busy and they will not do homework on research participants. But the consent process is trying to introduce homework for the subject . . . and we are assuming and hoping that the subjects will do this. (P4)

One informant questioned the effectiveness of this procedure because she does not "feel comfortable giving [participants] the [consent] form" (P9) believing that only a professional can convey the consent information properly. Most informants believe that people will not read the consent form at home. It is better to assume that nobody reads it and whoever asks for consent should always explain everything to all potential participants. Another said "[Participants] won't read [the consent form]" at home "because it goes on and on forever, and [the participants] don't care" (P13). The complexity of the consent form was also reported as a potential problem.

> A lot of people use the take-it-home method, which I think is a really poor way of assessing people's questions . . . because basically [the consent form is] an overwhelming document that I don't think many people will understand anyway. (P17)

He argued that the consent administrator has to go over the consent document details with the person, regardless of the use of the "take it home" strategy.

Theme 2—Assuring Comprehension of the Risks and Benefits Information

Importance of ensuring understanding. The prevalent impression by the informants was that individuals usually fail to fully appreciate the risks and benefits when they provide consent. There is no confidence that an ordinary person could deal with all the extensive and often times complex information. One of the informants confessed, "I assume that a large number of times when I use statistics, it falls on deaf ears, and nobody understands" (P9). Others expressed discomfort with the process of assessing comprehension.

> I have never specifically asked a patient "When I say 40%, can you tell me what that means to you?" I have not done that. I think I feel that it could be taken as a sign that I'm disrespectful. (P2)

Despite the above comments, the informants unanimously agreed that people should participate in research only when they are substantively informed about the study and have a good understanding of risks and benefits. For many, the level of understanding indicated the level of the effectiveness of the consent discussion. Also, informants noted the importance of the usefulness and relevance of the conveyed information for the potential participant and his or her situation. They suggested the need to evaluate "how comfortable [the participants] felt . . . if they felt able to use it [the information] in making their decision . . . So, you can ask them, from their perspective, if it was helpful to them" (P15).

An assessment of the risks and benefits comprehension is a critical component of ethical principles and regulatory requirements for clinical research conduct. Therefore, informants believed that the consent administrator must "be able to engage the potential participant in understanding about the study" (P14). However, they also believed that consent administrators "are not so good at making sure that the potential participant really understands" (P5). A favorable outcome of this evaluation process is " . . . ideally, the person getting informed consent should be able to say at the end of [the assessment]—this person understands this study as fully as one can expect someone to understand" (P2). One informant suggested that people should not be expected to remember "all of the detailed information [which] may not be that relevant" but to focus on "demonstration that they understand the gist of it, the main points" (P15). There is a lack of consensus across informants on the range and depth of the information we should expect people to understand.

According to several informants, evaluating comprehension of the risks and benefits is not routinely done, often depending on the specific situation. Some informants said they would do the checking, for example, when the conversation is not flowing. One informant explained that she assesses understanding "if I am struggling" (P9). One said,

> if you're skilled with communication, you need to have tools [to assess comprehension], and so if everything is going swimmingly, I don't need to use them, but in situations where I'm not so sure, then I need to use them. (P16)

Current and recommended practices. Based on the informants' experiences, there are two common ways of assessing comprehension of the consent form used in the field. One of these practices includes posing evaluation questions after completion of the entire consent discussion, such as "Do you understand what I said?" (P1) or "Do you have any questions about this?" Both questions were clearly perceived as "not helpful" (P17). One informant criticized the second question explaining that the problem sometimes is "that [the participant] doesn't even know what questions to ask. Because you say, 'Do you have any questions?' and he doesn't even understand what you just said. So, how does he know what questions to ask?" (P17).

A second common practice refers to some implicit or intuitive ways of judging participant's comprehension status, such as "just guessing by their questions that they understood" or "assessing them . . . from their nods of understanding" (P1). In this connection, one informant commented, "the way that comprehension is assessed basically is the 'gut' of the researcher saying—well, I think [the participant]

understood" (P17). Another informant, who felt very confident in her intuitive capacities, explained,

> I'm a very intuitive person, I try to read the body language and eye contact . . . but those aren't very objective measures, I totally understand that there are flaws in those methods, but personally I usually rely on things like that. (P15)

Some informants described additional ways to ensure risks and benefits comprehension, such as by asking specific study-related questions. In some instances, these questions are asked at the initiative of the investigators. In other cases, the questions are part of the formal requirements of the institution where the research is conducted. Two informants felt it was important to them to ask the following questions: "What are three things that I told you should watch out for in terms of risk? What are three things that are most important?" (P17) "What is the worst side effect that you could get?" (P14). Another informant shared a different approach. She said that for "one of our complicated studies" they developed and administered a study-specific multiple-choice 20-item questionnaire to potential participants.

> After we went over the consent . . . I could assess how much they understood . . . if they missed any of questions . . . we would focus on that question and we'd explain it before we had them sign the consent form.

From this informant's point of view, the questionnaire not only was "incredibly helpful" in ensuring comprehension but also "doubled the length of the informed consent discussion" (P10).

The most commonly recommended strategy to ensure and improve risks and benefits understanding was by using a teach-back. As one informant stated, "we know it's the best thing" (P3). This is a strategy where potential research participants are asked to relay the information they have been provided in their own words and then a professional "[tries] to assess their comprehension by what they're then saying back to you." Teach-back was reported as useful for several reasons: "It tells what the [participant] himself is thinking and you have the opportunity to correct anything that wasn't correctly communicated" (P5).

Despite the positive features of the method, it is not routinely used. Some informants noted that they are "not sure that [teach-back] happens" (P1) and "certainly not on a daily basis in a research" (P3). One informant noted that even though the topic of teach-back is sometimes "mentioned in lectures" (P8) about consent, people are not trained to apply this method and develop appropriate skills.

To choose the appropriate timing for a teach-back, one informant suggested considering the complexity of the study protocol in the following way: "If it's a simple study with very low risk, I'd probably do the teach-back at the very end of the whole discussion. If it's a complicated study, I'd stop at the end of each section and do the teach-back" (P12). Another informant supported this chunk-and-check communication strategy, regardless of the complexity of the delivered information.

Theme 3—Consent Administrators: Preparation for the Role

Controversial assumptions. Several informants noted that normally, investigators believe that informed consents for their study will be obtained appropriately, though they did not seek evidence to confirm this expectation. Also, investigators expect that professionals who were delegated the responsibility to obtain informed consent, "know how to do it," (P4) are "able to engage the potential participant in understanding about the study," (P2) and are "able to judge the level of comprehension of the person," even though "there's no way that . . . [these professionals were] tested about [their] proficiency in how to do it" (P13). Some informants were certain that the issue of the consent information process is never brought up by the investigators in preparing their research team for the informed consent procedure.

> So, in many studies where consent is being obtained by the project coordinator, or the research assistant, depending on the nature of the study, or co-investigators, who may be physicians, not a PI [principal investigator] him or herself, how consent is obtained is often not discussed at all. (P4)

> There is no explicit discussion of how to do [the disclosure of risks and benefits]. I think it's just ignored . . . That question is just ignored. (P13)

Some of the informants criticized assumptions concerning the consent process made by the IRBs and other officials at the institution where the research study takes place. Institutions assume that the investigators they have hired have the skills needed for appropriate informed consent. Another informant noted that there is no systematic supervision on the way the consent procedure is actually performed, which creates a dangerous situation where the lack of monitoring over the consent process leads to "people starting to cut corners, and it erodes the [consent] process" (P2).

Informed consent training requirements. One of the major disappointments shared by the informants was insufficient training opportunities to support the development of skills of the research staff, including investigators themselves. "There actually is no training for physicians or research staff about how to do [informed consent] and in fact, the way that they do it is pretty crappy" (P17). Another informant explained that informed consent "is learned by doing, there is no learning process in any official way" (P4).

Informants mentioned that there are general requirements across the United States, which include taking "basic training on research ethics" to be on a research team that involves human participants. The two most common training requirements are

completed online and directed by the governmental agencies such as National Institutes of Health (NIH) and by the Collaborative Institutional Training Initiative (CITI) program. The main issue about these programs is that they do not "provide skills" (P5). The NIH and CITI basic training programs only provide "a basic kind of understanding of certain [consent] elements, but it's not sufficient . . . to help develop skills" (P3). Another informant commented that "if it was like—'This is what you need to do in informed consent and this is how you best do it'—then it would be useful" (P7). Concerning training in risk communication, one informant stated, "I don't think anybody has any training in risk communication. That's true whether you are clinician, researcher, whatever. Nobody has training in risk communication . . . We simply don't know how" (P5).

Local training initiatives. Informants described other initiatives, such as employer-based training courses and workshops in informed consent in which they took an active part in the developmental and operational stages. In some cases, attendance for these training programs was mandatory for individuals who want to work on research teams in their institution.

One informant shared that training at her workplace used "role modeling and . . . videos . . . [of a] consent process that [research staff] observe and then [are] asked to rate the quality of the process" (P8). Another informant said that she was a part of a group that developed a training module in IC for research coordinators in their facility. They developed a 40-minute didactic section describing the regulatory aspects and gave tips on how to lead an effective informed consent process. They also created several informed consent scenarios accessible online. Although there was positive feedback about the training, the training did not become mandatory. She also did not have "a good feeling for how many people take advantage of that [course]" (P11). Another informant described her academic research facility's hour-long monthly workshop on obtaining informed consent. At the beginning, it was a short lecture. Over time the workshop became more skills based. Workshop participants were required to bring their consent forms to obtain feedback from peers. This approach was viewed as useful by many participants.

Training in informed consent for a specific study protocol is not standardized. "There are no standards for that, it's really . . . the investigator's personal way of how they train individuals to do [the consent procedure]" (P3). Another informant investigator's explanation helped to illustrate the previous point. She said that on her team, it is the duty of her project director to coordinate training for the research staff. In this training, she described,

> we first explain the study really well, and then . . . we do mock consents. So, we show them what it would sound like to be consented and then we ask them to do that back . . . That's my standard, as an investigator. (P14)

Envisioning training in informed consent. Informants believed that every professional who is going to seek consent for research must undergo hands-on training in the informed consent process. "If your role in the study would be to do informed consent, to be listed on that study with that task . . . you have [to have these] additional educational requirements" (P16). Another informant noted, "the training [in informed consent] really needs to be very much integrated into institutions that are consenting individuals at an ongoing basis" (P10). The informant also recommended integration in terms of "any time you have a research project, there'll be an opportunity to continue with training staff." Another informant reinforced the need for the development of "actual skills related to informed consent and communication . . . skills development should require some simulation and feedback, where you actually practice and get feedback to people about how you're communicating" (P16). Standard training should be provided by "someone who does it well" and who can document "[the research staff] expertise in doing [consent]" (P17). Informed consent training should include guidance on

> how do you compare and contrast standard treatment with clinical research, how do you explain risks and benefits, how do you explain the rights of the patient, and how do you assess comprehension. All those things need to be tested. (P7)

Discussion

This study's findings from in-depth interviews with 17 key informants add to the current literature on the informed consent process in a number of ways. The essential contribution of this study is to provide an up-to-date review of experts' opinions about the actual use of various communication strategies during the research informed consent encounter, providing an empirical basis for the development of a quantitative instrument to study the use of various communication techniques, a topic that has not been covered extensively in the literature. The findings of the present study also add to the body of academic literature that focuses on better ways to make the informed consent process more effective (Lentz, Kennett, Perlmutter, & Forrest, 2016; Lorell, Mikita, Anderson, Hallinan, & Forrest, 2015), by documenting the strengths and areas of improvement needed from the perspective of diverse group of experts in the informed consent process. In addition, findings from experts' interviews allowed us to expand on related issues for discussion about informed consent, such as consideration of the relative importance of currently used communication strategies, the extent of their use, and their perceived effectiveness in the process of gaining ethical, meaningful informed consent for research participation. Our study also presents opinions about current training opportunities for research staff to perform this complex task.

The interviews revealed that there is an awareness among the consent administrators about several recommended practices. These practices include reading the information out loud to potential research participant, employing the "take it home" procedure, and conveying numerical information accompanied by an explanation of what these expressions mean. Both our informants and the literature evaluate each of these and find fault with many. In an international survey of research participants' experiences, the research staff read the informed consent form to participants in nearly a third of the consent meetings (The Center for Information and Study on Clinical Research Participation [CISCRP], 2013). Yet, as also noted in other related literature (Sugarman & Paasche-Orlow, 2006), the informants in our study criticized this practice, and specifically the way in which the "reading aloud" practice is commonly implemented. They question the necessity and overall effectiveness of this strategy in increasing the comprehension of the prospective participant. In past studies and in our study, findings provide more evidence of the need to re-examine the use of this method.

Criticism in our study by the majority of informants of the "take it home" procedure, used to encourage discussion of possible participation in a study with family and health care providers, is supported by other studies (Bickmore, Pfeifer, & Paasche-Orlow, 2009; Kass, Taylor, Ali, Hallez, & Chaisson, 2015; Lentz et al., 2016). In addition, results from the Kass et al. (2015) study demonstrate that many of surveyed clinical trial participants did not show the consent form to others (129/144; 90%) and they did not read the consent form on their own (33/144; 23%), and 40% of 2,223 respondents from a large international survey of clinical trial participants did not read the consent form by themselves (CISCRP, 2013). Bickmore et al. (2009) found that providing as much time as necessary for potential participants to read and try to understand the consent form by themselves was ineffective strategy for those with low literacy levels. It was also a statistically significantly inferior strategy compared with consent explanations that were provided by a human research assistant or computerized agent to potential research participants with adequate health literacy. All the above suggest that research staff should not rely on research participants reading the form and reviewing it with others as an effective means to facilitate participant's comprehension of the informed consent form. As emphasized by the informants in this study, provider–participant interaction during the informed consent encounter is critical. The findings here underscore the importance of the frequently recommended practice for improving the informed consent process through more extensive consent discussion as found in other studies (see, for example, Flory & Emanuel, 2004; Nishimura et al., 2013), and which is also found to be effective for research participants with low health literacy levels (Tamariz, Palacio, Robert, & Marcus, 2012). In addition, other researchers suggested that the informed consent process should not be just a discussion but should involve an educational interactive discussion about all the required informed consent elements with explanations adjusted by the provider to a person's individual needs and health literacy level (Meade, 1999; Sugarman & Paasche-Orlow, 2006). The informants in this study concur with these findings.

There is one area in which the informants in this study diverged from the rest of the literature. A recently published systematic literature review found that simplified or enhanced consent forms appeared to increase potential research participant understanding of the study-related information (Nishimura et al., 2013) and was reported as a frequently supported strategy for a "single actionable change" by the majority of participants in a diverse panel of stakeholders (Lorell et al., 2015, p. 693). Interestingly, expert informants in our study had different opinions. They unanimously argued that based on their experience, solely making the forms better cannot improve the consent process; instead, an improved process should be aimed at assisting potential research participants in making informed decisions. Our findings are consistent with another methodologically robust study performed under real conditions of recruitment into multiple types of biomedical trials (Paris et al., 2015). Paris's study findings indicated that enhanced informed consent forms did not add any statistically significant advantage to the level of participants' understanding. As suggested by expert informants in our study, the real challenge probably does not lie in the consent form simplification or enhancement, which usually is done through revising text styling, layout, and editing language to improve readability. What really matters is the information providing procedures used in the informed consent process. The real challenge, according to the informants' opinions in our study, is to find the right way and right words to explain study details in a simple, clear, and meaningful way for the individual research participant, in which specific risks and benefits communication skills are important.

Concerning the process of delivering risks and benefits information, all of the informants underscored the need for encouraging the use of educational aids and graphics to facilitate understanding of this information in addition to verbal explanations. Current literature demonstrates inconsistency in research findings. Some studies support the use of supplements and graphical aids as facilitators of comprehension (Drake et al., 2016; Hawley et al., 2008), while others indicated that the use of graphics did not lead to a better understanding of risks and benefits by potential research participants (Tait, Voepel-Lewis, Brennan-Martinez, McGonegal, & Levine, 2012; Tait, Voepel-Lewis, Zikmund-Fisher, & Fagerlin, 2010). Further investigation is required to determine what presentation methods are useful for delivering different types of risk and benefits information and which ones could possibly become a standard method for more effective communication of this information in the research setting.

One of the main concerns expressed by the informants is insufficient comprehension of risks and benefits by many potential research participants. Our findings are consistent with the results of other studies that show that an assessment of comprehension of the consent information is not carried out routinely (Montalvo & Larson, 2014). The informants in this study pointed to "teach-back" as the most effective method, which is supported by research evidence for evaluating comprehension during the informed consent encounter (Isles, 2013; Tamariz et al., 2012), but unfortunately it is not routinely used in practice. Alarmingly, only 44% of the surveyed 114 IRB chairs reported that they observed the teach-back method in research proposals without either requirement or monitoring of this practice, and less than 15% of the chairs reported that they would consider a teach-back method for a future use (Kane & Gallo, 2017). The most common way to assess potential participant's comprehension, as indicated by informants, is by asking at the end of the consent meeting "Do you understand what I said?" This kind of question, however, was referred as to the "worst question you can ask during the consent process" by Michaels (2011), reflecting an ineffective approach in practice to informed consent assessment. This ineffective practice continues despite increasing emphasis on the value and the importance of potential research participant's understanding as indicated by ethical research guidelines (Federal Register, 2017) and in light of frequently raised concerns on the issue by stakeholders (Fink et al., 2010; Kane & Gallo, 2017; Sanchini, Reni, Calori, Riva, & Reichlin, 2014).

The informants also commented that the current mandatory training for researchers and research staff on human subjects' protection, such as those run by NIH and CITI, are not intended to provide practical tools and skills necessary for conducting an adequate informed consent process (Larson, Cohn, Meyer, & Boden-Albala, 2009). In addition, employer-based training programs that focused on the informed consent procedure are often isolated to a specific institution or single research team. These programs are mostly not mandatory and do not specifically consider the uniqueness and complexity of conveying risks and benefits and their related uncertainties. The informants in this study also emphasized that research professionals involved in the informed consent process are insufficiently prepared for carrying out their related duties. A number of studies and experts support the need for adequate hands-on training in the informed consent process and communication skills of the research staff required to ensure properly conducted consent discussion when specific information, such as the risks and benefits of a research study, are conveyed in an accurate, ethical, and personalized manner to potential research participants (Hallinan, Forrest, Uhlenbrauck, Young, & McKinney, 2016; Lentz et al., 2016).

There are potential limitations of this study related to its methodology that might restrict the transferability of its findings. The study results are rooted in the opinions and attitudes of the diversity of professionals who hold different roles and positions that surround clinical research. However, we were not able to discern salient interprofessional variations in perceptions probably because of the limited number of informants belonging to each professional category. In addition, even though the informant's origin included 10 states and numerous academic institutions, the voices of professionals employed in private research industry and from additional states would enrich the findings.

The expert informants' opinions are indicative of some of the contributing factors that can lead to a poor quality of the informed consent process and communication of the risks and benefits in particular, and as noted in findings from other related studies on informed consent. Due to these concerns about our sample and ability to understand salient interprofessional variations, the prevalence and validity of our findings need to be further examined by eliciting responses from a larger sample of professionals involved in the informed consent process. Future studies need to determine whether the issues identified are broadly comparable with those faced by the consent administrators in the field. Our next step in this research is to use these findings to help develop a quantitative survey. This survey will focus on attitudes, training received and desired, and practices related to risks and benefits communication strategies.

Conclusion

Qualitative interviews with expert key informants succeeded in generating an important discussion about communication strategies used in the informed consent process with the emphasis on communicating risks and benefits to potential research participants. Inconsistencies in opinions, attitudes, and critique with respect to certain widely used communication practices should be cause for concern necessitating further consideration and research. This qualitative study was essential for the development of a survey about research nurses' experiences with the informed consent process that we will use in a subsequent study. We expect that research to identify possible variations in surveyed research nurses' attitudes, preparedness, and practices related to risks and benefits communication which will lead to recommendations directed at strengthening the informed consent process and the related role of research nurses.

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