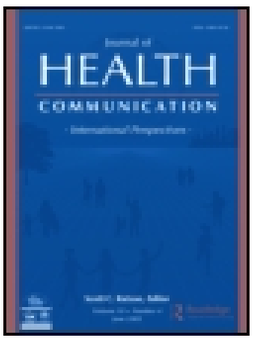

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Clinical Trial and Research Study Recruiters' Verbal Communication Behaviors

SUSAN E. MORGAN [1], ASHTON MOUTON[2], AURORA OCCA[3], and JONELL POTTER[4]

[1]*School of Communication, University of Miami, Coral Gables, Florida, USA*
[2]*Brian Lamb School of Communication, Purdue University, West Lafayette, Indiana, USA*
[3]*School of Communication, University of Miami, Coral Gables, Florida, USA*
[4]*Miller School of Medicine, University of Miami, Coral Gables, Florida, USA*

The lack of accrual to research studies and clinical trials is a persistent problem with serious consequences: Advances in medical science depend on the participation of large numbers of people, including members of minority and underserved populations. The current study examines a critical determinant of accrual: the approach of patients by professional recruiters who request participation in research studies and clinical trials. Findings indicate that recruiters use a number of verbal strategies in the communication process, including translating study information (such as simplifying, using examples, and substituting specific difficult or problematic words), using linguistic reframing or metaphors, balancing discussions of research participation risks with benefits, and encouraging potential participants to ask questions. The identification of these verbal strategies can form the basis of new communication protocols that will help medical and nonmedical professionals communicate more clearly and effectively with patients and other potential participants about research studies and clinical trials, which should lead to increased accrual in the future.

Although researchers agree on the critical need for clinical trials and research studies in order to generate new knowledge on the most effective protocols and treatments for a wide variety of diseases and conditions (Bell & Balneaves, 2014; Friedman et al., 2014; Haddad, Chan, & Vermorken, 2015; Jenkins et al., 2013), clinical trial research is often compromised because of a low rate of accrual, even for studies deemed to be high priority (Albrecht et al., 2008; Haddad et al., 2015). The need for participation by members of minority and underserved populations is particularly acute (Kim, Tanner, Friedman, Foster, & Bergeron, 2015; Spiker & Weinberg, 2009; Tanner, Kim, Friedman, Foster, & Bergeron, 2015). In fact, at least 39% of Phase III oncology trials are closed because of lack of accrual (Dilts, Cheng, & Crites, 2010). It is sad that clinical trials are offered to qualified patients in only 20% of interactions with physicians; when a trial *is* offered, 75% of patients consent (Eggly et al., 2008). Even an analysis of hundreds of thousands of conversations between patients and Cancer Information Service specialists revealed that information about clinical trials was offered in fewer than 10% of calls, with such information being offered 40% less often to African Americans and 30% less often to Hispanics than to Whites (Byrne, Kornfeld, Vanderpool, & Belanger, 2012). Without the participation of underrepresented and minority populations, the true efficacy of new protocols and treatments is uncertain (Heller et al., 2014). Furthermore, the offer of clinical trials and research studies to underrepresented populations is intertwined with social justice concerns; such studies often represent the best care available in the form of cutting-edge treatments, technologies, and protocols (Cohen, Underwood, & Gottlieb, 2000).

There are many reasons why the majority of clinical trials fail to accrue adequate numbers of participants, particularly from underserved populations; these have been synthesized in the clinical trial accrual model (see Figure 1; Morgan & Mouton, 2015). Although there are many reasons for low accrual rates (which can be generally divided into patient factors, physician factors, and systems-based factors), the recruitment process itself relies on the ability of recruiters to effectively present information about trials/studies. It is interesting that the bulk of the recruitment process is done not by physicians but rather by paraprofessionals such as research study coordinators, study nurses, and professional study recruiters who have no professional background in either research or medicine but who are trained to discuss specific studies with potential participants (Fedor, Cola, & Pierre, 2006). However, there is virtually no published literature on how these professionals communicate with patients and members of the public about the prospect of joining a trial or study. Information about communication practices in the course of the recruitment process could eventually lead to the development of interventions for medical and nonmedical professionals that can (a) improve communication with patients and other potential study participants and (b) eventually improve accrual rates (particularly for underrepresented populations) to clinical trials and research studies. In this study, we examine the role of specific verbal communication factors in the process of recruitment to trials and other studies.

Address correspondence to Susan E. Morgan, School of Communication, University of Florida, 5100 Brunson Drive, Coral Gables, FL 33146, USA. E-mail: semorgan@miami.edu

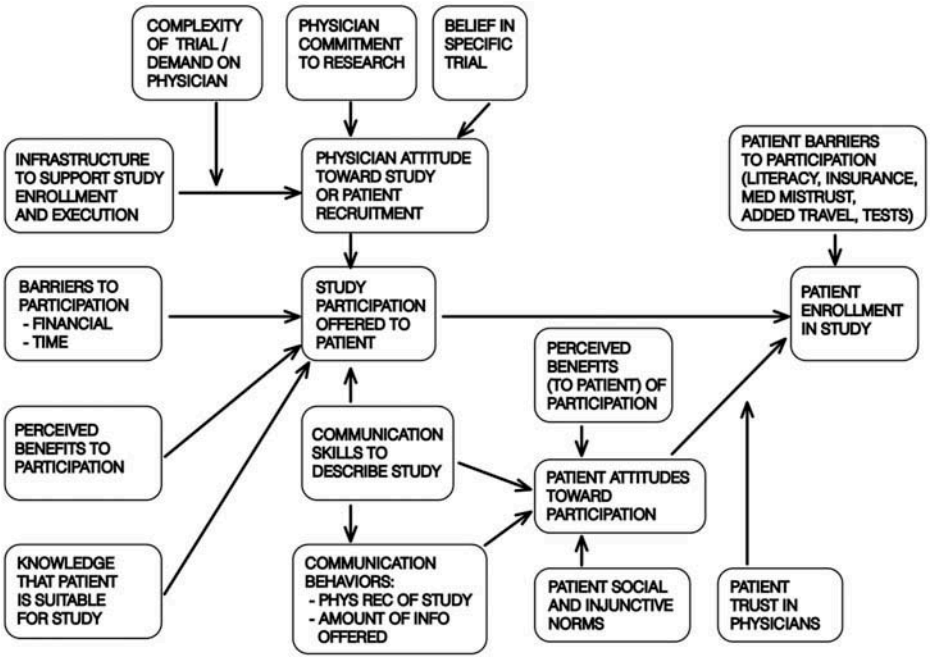

Fig. 1. Model of clinical trial accrual. MED MISTRUST = mistrust in the medical system; PHYS REC = physician recommendation.

Communicating About Clinical Trials: The Role of Verbal Communication

Relatively little attention has been paid to the impact of communication factors on the rate of accrual to clinical trials in spite of calls for research in this area by the National Cancer Institute (Denicoff, 2013). The literature that is available on the role of verbal communication largely focuses on the role of physicians. Indeed, there is no more powerful influence on a patient's decision to join a trial than a physician's recommendation, whether perceived or real. Siminoff and Fetting (1991) reported that 80% of patients accept a physician's treatment recommendation, with two factors being most influential: the amount and specificity of the information about the treatment and the strength of the physician's recommendation. Of course, there are many ways to present information, and yet there is little systematic guidance on exactly which elements might make verbal communication more effective.

Most of the limited literature on the role of verbal communication in the clinical trial recruitment process focuses on the amount and type of information that is provided to potential participants. There seems to be a very reasonable concern about information overload (Stevens & Ahmedzai, 2004), although some researchers believe that patients want more information than their physicians expect (Fallowfield, 2001). However, the problem may not be the quantity of information but its quality. Stevens and Ahmedzai (2004) charged that physicians often provide an unhelpful amount of highly technical information while simultaneously conveying other information that is grossly oversimplified. A better strategy is to use plain language in the course of an unrushed explanation of a trial (Eggly et al., 2008; McSweeney, Pettey, Fischer, & Spellman, 2009; Siminoff & Step, 2005). Clear communication appears to be most likely among communicators who understand the trial well, are comfortable explaining a trial, and are able to answer questions clearly (Albrecht, Blanchard, Ruckdeschel, Coovert, & Strongbow, 1999; McSweeney et al., 2009; Siminoff, Colabianchi, Saunders Sturm, & Ravdin, 2000; Siminoff, Colabianchi, Saunders Sturm, & Shen, 2000; Siminoff & Fetting, 1991). Such practices are particularly important when communicating about trials and research studies with individuals with limited health literacy (McSweeney et al., 2009). In addition, empirical studies of the communication of health care professionals who are more successful in clinical trial recruitment indicate that support should be provided for managing adverse effects, that randomization procedures should be clearly described (Albrecht et al., 1999), and that information about study participation benefits as well as risks should be discussed (Albrecht et al., 1999; McComas et al., 2010). However, the literature provides little additional guidance or insight on specific verbal communication strategies that support the process of clinical trial and research study recruitment.

The following research question guides our study:

Research Question 1: What verbal behaviors do recruiters use when communicating with potential participants?

Methods

Sites and Recruitment Procedures

Clinical trial and research study recruiters in Indianapolis, Indiana, and Miami, Florida, were selected as the target population for this study. The two sites are similar in that they are

metropolitan areas with significant populations of underserved patients. However, Miami has fewer non-Hispanic Whites (about 12% of the population in Miami compared to approximately 62% in Indianapolis, according to the U. S. Census Bureau (2010), and there is a greater proportion of Hispanics in Miami than Indianapolis (about 70% vs. 9%, respectively). However, Indianapolis has a higher population of Blacks/African Americans than Miami (approximately 28% vs. 19%, respectively).

Following approval from institutional review boards (IRBs) at each location, recruitment of focus group participants was done via administrators who managed groups of recruiters. The managers or administrators of groups of recruiters forwarded an e-mail describing the study, eligibility criteria, and incentives for participation. All participants were given lunch or snacks as well as $60 in exchange for their participation. After completing the consent form and a brief demographics form, participants were asked about their perceptions of the ways in which a variety of factors, including verbal communication, impact the process of study recruitment. Based on participants' responses, follow-up questions were asked. Focus groups lasted between 1.5 and 2 hours. Each focus group was video recorded (with an audio backup) to aid the transcription process.

Participants

A total of 63 recruiters participated in our 11 focus groups. Of the 11 focus groups, three were conducted in Indianapolis with recruiters working in the ResNet system, a practice-based research network that is affiliated with Indiana University School of Medicine (see Kho, Zafar, & Tierney, 2007, for more details), whereas the remaining eight were conducted with recruiters working across the University of Miami as well as the University of Miami Health and Jackson Memorial Health hospital systems. All focus group participants recruited (or had recruited) patients or potential research study participants who represented minority or underserved populations living in a diverse metropolitan area. The recruiting environment varied widely, encompassing in-person recruitment in clinical environments, telephone recruitment, and community-based or in-home recruiting efforts.

The size of the focus groups ranged from three to nine, with an average of six recruiters per group. Participants in the focus groups were required to have study recruitment as a part of their formal job duties and to have recruited at least 35 patients/participants in the past year. Recruiters were predominantly female (92%) and ranged in age from 20 to 63 (M = 37.8). Most were Latina/o (53.3%), followed by Caucasian, non-Hispanic (28.3%) and Black/African American (18.3%). Participants were highly educated, with the majority indicating that they had a graduate degree (66.7%) The remaining reported having some graduate education (10.4%) or having a college degree (18.8%) or some college (4.1%). Years of experience with research study recruitment ranged from 6 months to 24 years, with a mean of 7.48 years. All names of participants have been changed to preserve anonymity.

Data Analysis

Transcripts were uploaded into NVivo 10.0 for coding and analysis. Coding proceeded using a constant comparative method, as described by Corbin and Strauss (2008). Categories were not orthogonal; a single utterance might be an example of multiple coding categories. The final coding categories that emerged that were relevant to the present study included various aspects of verbal communication behavior. The codes with the greatest number of entries (in terms of both number of focus groups mentioning and number of participants discussing) are presented here.

Results

In this section, we refer to both patients and participants. For the purposes of this study, *patients* are individuals who are receiving medical treatment at the point where they are being asked to join a study or a clinical trial. *Participants* is an umbrella term that can encompass both patients and individuals who are not receiving medical treatment but are being asked to join a research study or clinical trial as a healthy volunteer. For example, a recruiter might ask a resident of a low-income community to participate in an observational study; similarly, a participant might be associated in some way with a person who has been affected by a disease or condition (e.g., the caregiver of a person with cancer). Alternatively, healthy participants are also routinely involved in clinical trials to test new therapeutic treatments.

Research Question 1 asked about the ways in which recruiters use verbal behaviors to communicate with potential participants. The most frequently mentioned verbal behaviors included translating information to enhance patient comprehension, using linguistic framing or metaphors, encouraging potential participants to ask questions about the study, and balancing discussions of study risks with the benefits of participation.

Translating Study Information (11 Focus Groups, 31 References, 33 Recruiters Mentioning)

By far the most common verbal communication behavior recruiters used to enhance patient willingness to participate in a clinical trial or research study was the translation of information about prospective studies. This behavior included a constellation of activities that included simplification of language, the use of examples to illustrate concepts, and substitutions of specific words for more difficult concepts.

Simplification of Language

Every focus group highlighted the need to translate the details of a study into simpler language and to try to adopt a conversational style. Although study investigators are routinely exhorted to write consent forms in a way that patients can readily comprehend, this is a challenge that is not often met. Randi stated:

> I pretend like I'm trying to explain it to my 5-year-old.... Honestly when I started out ... I would practice on my kids. I mean you have to get it down to like sixth [grade]. Trying to get a consent form that's 20–30 pages long in oncology down to a sixth-grade reading level is next to impossible.

Janine concurred, saying that she uses "lay language" and explains studies as though she were "speaking to a friend."

Recruiters are often frustrated by principal investigators (PIs) who do not translate medical and scientific language into words and phrases that are more commonly used by members of the population they seek to enroll in their studies. Although not limited to language embedded into the consent form, most recruiters focused on these particular challenges in the communication process. Kelli added:

> If there's a [difficult] word then I'll kind of insert verbal parentheticals so, just to kind of explain it and try to present it in a way that isn't like "You probably don't know what this means" but [instead] "*So*, blah blah blah." … When we did the X registry … the consent for that was pretty hefty and not written in an especially easy reading level, and so I think I did a lot of going over key points and then saying "So this means …"

Use of Examples to Illustrate Concepts

Not all difficult concepts can be easily translated into more basic language, so recruiters sometimes used examples instead. As Alli said:

> I think a lot of people don't really know, when you say "medical legal issues," they don't really know what that is, so I try to give examples … You know like, "Has your child's doctor talked to you about issues you might have had with housing or not having a safe place to live?" or something like that, so they know what I'm talking about.

Similarly, recruiters reported giving specific examples of what would happen as part of the study, breaking down the study protocol into smaller steps that would make the prospect of participating in a study less intimidating.

Substitutions of Specific Words

Recruiters reported that there were certain words that were sometimes problematic for members of the populations in which they recruited. These included the words *research, study, trial*, and *randomization*. For example, some recruiters replaced the word *trial* with the word *test*. Similarly, *research* can be problematic. Ruby said the following:

> I don't say the word "research"; I say "study." I don't use the word "research" 'cause that seems like, I know in the African American community, you have that stigma that all researchers are bad, so I don't even use that word. I just say "study." "We're doing a study on blah blah blah, are you interested?"

However, another recruiter, Dana, reported that the word *study* was potentially problematic in the Haitian community:

> We kind of I think, [speaking to Mara] you can agree or disagree with me on this. [Speaking to group] when you're dealing with the Hispanic and Haitian populations you kind of have to phrase it a little bit differently sometimes. You can't just say oh this is a research study because then someone is like, well study? And then they think am I in school. You say study, you think school.… Well, okay, this is what research is, it's similar, I mean it's a program but it's research because we're trying to get *information* from the community because we want to learn how to better help the community.

Thus, it is clear that language choices must be made carefully based on a thorough knowledge of the culture of potential participants. Similarly, it should be said that *research* does not always have a negative connotation, particularly when participation in research is accompanied by monetary incentives and when past participation (or the participation of family members or friends) has been associated with a positive experience.

Randomization is another concept that is often difficult for patients to understand, but there is little consensus among recruiters about the most effective term to substitute. Although many recruiters use a coin flip or lottery analogy, others tell potential participants that "the computer decides." Doris said, "I always say it goes into our 'randomizer.' You know, a 'randomizer' like some sort of gobbledy-gook box."

However, some recruiters reported less success with telling patients that computers will decide their treatment. Cristina said the following:

> In many cities you have to treat them like people, you say "computer," that's too cold, they wanna feel like somebody, like PI or physician, you are involved in their health and you are helping them. You say "computer," it's too cold.

One alternative for the gambling metaphors of the lottery and coin flip is describing study participation as a valuable opportunity. Nora explained:

> I offer it as an opportunity, so I say, "You are eligible for this research opportunity" so it's not like, "We would like you to participate in this research study" because why they would care what I want them to do? But offering that as an opportunity, I found it really, really helpful because it's their choice, they can feel themselves special, having this opportunity.

Thus, although recruiters agreed that it is important to substitute difficult words or those with problematic associations, there are no systematic translations that can be made. This process has to be adapted to each population and each participant as appropriate.

Using Linguistic Reframing and Metaphors (9 Focus Groups, 50 References, 29 Recruiters Mentioning)

There are many ways in which recruiters used language to try to encourage participation in research studies and clinical trials. Most focus groups mentioned that depending on the type of trial, participation can be framed in ways that appeal to patients' altruistic natures (benefit to society), or their desire to help family members who might be afflicted with a particular condition, or their own search for the most effective treatment (benefit to self). Euphrates said:

> I tell them, I like to give them benefits that has happened from doing treatment, [like] a drug trial, you know. Like [one] guy … [I was] showing him his medications, [I told him] you know, someone had to … take these for a trial or what have you. Letting them see the bigger picture of it all, you know, that you're not just taking these medications just because; somebody had to test them for you to make sure that they were healthy … Someone had to do it. So I give them that perspective of it.

Recruiters often seek ways to frame foreign or potentially frightening concepts in terms that are more familiar or acceptable. Genevieve reported successfully using this type of strategy when explaining drug treatments and medical testing:

> For me, . . . the person who designed the study actually did a really good job of saying things like, this drug has been approved by the [Food and Drug Administration] and things like that, like it's already used for this purpose. So it's like less scary that they're taking new drugs, like this is not experimental; this drug is safe. Or, like there's a blood draw. "This is the same amount of blood they would take if you were getting a blood draw at the doctor's office." "This blood pressure cuff is being inflated to the same level if you were getting your blood pressure checked." It just kind of those things, like recognizing things that they're familiar with already . . . Just kind of making it less scary because it's kind of like, you've already experienced this before; it's okay.

Similarly, Lillian reported that using an analogy to explain a potentially scary test can be an effective communication strategy:

> Like [Fronovo], they get a Dexiscan, that's like a bone density thing that's used for osteoporotic patients. Any of those words aren't going to land. So you have . . . to kind of give the gist of what it does without comparing it to something that they're not gonna know unless you know they've had it.. . . I'm like yeah, it's kind of like a quick x-ray just to see how thick your bones are, just to see how well they're made, things like that.

Some recruiters reframed the consent form to make clear to patients that they were not signing a contract but something more akin to a form designed for patient protection. Marta said:

> I always try to explain that this is not a contract because they get afraid, "I'm going to sign this and I need to be—" No, this is not a contract, this is *information*. You need to sign to prove that we provide you with this information. Always I use this because they get panic about this . . . You know, by law, we need to have a copy, by law, we need to prove you got all the information, that we are trying to protect the patient, this is why.

Similarly, the IRB was sometimes framed as the "research police" that enforced federal laws designed to protect research participants. Lillian said:

> It's that one more layer of protection, that not only do we offer protection, but it is a federal law, and once people hear that, they loosen up a little bit. So being able, for us to know the background of things, when we're talking through things, to be sure to point out how they're protected. That really makes people a lot more comfortable.

Euphrates added, "IRB's protecting you, you know, making sure that we follow the laws that are required for research.. . . You want to break it down so that they understand what they're getting into, how they're protected, that's how I do it."

Clearly, recruiters are attuned to issues of mistrust of the medical and research systems among many potential participants and attempt to assuage concerns through reframing of research processes.

Encouraging Potential Participants to Ask Questions About the Study (8 Focus Groups, 25 References, 22 Recruiters Mentioning)

Recruiters reported that inviting potential participants to ask questions not only encouraged people to thoroughly understand the risks and benefits of a study but allowed people to feel more comfortable with the prospect of joining a study. Inviting questions from potential participants appears to be a way that recruiters signal to potential participants that they are not trying to conceal anything about the study. Lillian said:

> [With] suspicious patients, if you get that feeling when you're reading people, I emphasize contact numbers for questions, and you can contact them anytime. And say it's totally voluntary, and just how free they are, and just show them the consent where those words are to prove that I'm telling you this and it's here, so there are all kinds of escape routes, if they want it, if they need it.

Not all recruiters are permitted to answer questions about a study, unfortunately. In these cases, recruiters tell potential participants that they have to contact the PI or their physician for further information. This situation appears to be less likely to be an issue when the organization (or PI) employing recruiters engages in extensive training for recruiters on the details of each individual study.

Balancing Discussion of Potential Risks With Benefits (8 Focus Groups, 8 References, 9 Recruiters Mentioning)

Although IRBs require extensive disclosure of all conceivable risks associated with trial or study participation, consent forms are not required to rigorously detail all possible benefits of participation. This imbalance puts recruiters (and arguably potential participants as well as society as a whole) at a disadvantage, which recruiters sometimes find frustrating. Yolanda explained:

> Sometimes we tell [the PIs] that the ICF [informed consent form] looks like those prescription drug inserts that have a long list of all the possible symptoms that may occur. Many of them are really rare. It's hard not to get scared by those risks. They can be ready and willing to be in the study and then they see all the risks and they think they're so many risks, "I don't know if this is a good idea!" Then, you have to explain the more realistic view . . . I try to tell them that they need to list every possible risk on that ICF even if it's very rare . . . so that's why it looks like there are so many risks.

Cora concurred with a complaint about the lack of balance in the presentations of risks and benefits:

> Well, you know, IRB says you can say this, but in a conversation other things come up. Obviously I give them what's written there. Sometimes it doesn't say the incentives.. . . Sometimes it just gives [only] all the bad news about the study.

Recruiters also point out to participants when they will receive expensive medical services and extra medical attention from top doctors, who keep "a closer eye on them." When a limited incentive does not compensate for a potential

loss in wages because of the time required for participation, some recruiters emphasize the value of the medical tests and the coverage of regular medical visits. When studies do not offer incentives or if participants would not benefit directly from participation, recruiters have to adopt other strategies, including explaining researchers' (presumably altruistic) motivations for conducting the study, explaining the benefits that society as a whole will experience as a result of increased knowledge about a disease or condition when better medications or treatment protocols are developed, and emphasizing the fact that participants' own descendants may benefit if a disease is inheritable.

Clearly recruiters use a wide range of verbal strategies to enhance comprehension of research study and clinical trial information. Central to this set of strategies is the desire to find a common ground with potential participants, to "meet them where they're at." One recruiter memorably described this process as being "like a chameleon."

Discussion and Conclusion

It is clear from recruiters' focus group discussions that verbal communication is critically important to the process of clinical trial and research study recruitment. Verbal behaviors that support the recruitment process include translating study information through simplification, word substitution, and use of clear examples; reframing unfamiliar concepts like consent forms or research itself in terms that are more familiar to potential participants; encouraging questions; and balancing the discussion of risks with the benefits of participation. A number of the specific verbal strategies used by recruiters strikingly mirror compliance-gaining strategies used by organ procurement coordinators (Anker & Feeley, 2011a, 2011b), including the provision of clearly explained information, the framing of participation as a rare opportunity, an emphasis on benefits to both self and other, and the articulated need for people to participate for the benefit of society as a whole, although the use of these strategies appears to be rather less overt among research study recruiters than among organ procurement coordinators.

In particular, it is worth noting that gambling metaphors may be problematic for patients who already face an uncertain future with a frightening diagnosis. Thus, referring to a clinical trial as a "lottery" or a "flip of a coin" may be fine for certain studies (such as observational studies or studies of new treatments for otherwise untreatable cancers), but this may not be a helpful linguistic frame for new treatments or protocols for serious diseases for which established treatments exist (see Krieger, 2014, and Krieger, Parrott, & Nussbaum, 2011, for further explication of this issue). Although hope is a positive form of uncertainty and a powerful motivator for action, this is likely to be true only for patients with diseases that have no cure or for which a new approach would be a welcome alternative to existing treatments that are not well tolerated. In other words, when a clinical trial or research study is framed in a way that introduces unwanted uncertainty, potential participants may be more likely to reject the opportunity to join that study.

Much of what recruiters disclosed about how they communicate with patients and potential participants was embedded in a larger discussion about the consenting process. Recruiters agree that consent forms are often very difficult for participants to understand, even while they recognize the critical protection this process affords. The difficulty recruiters face is a function not only of the interaction of patient health literacy levels and the reading level of consent forms but of the sheer length and complexity of the forms. Eligible and willing potential participants frequently glaze over, leaving recruiters with a dilemma. Research ethics and the nature of their professional position requires them to continue their explanations of a study even if potential participants want to simply sign the form.

The actual effectiveness of the recruiters who participated in these focus groups, however, has not been established. Therefore, we can report only on the themes that emerged from the discussions of a wide variety of recruiters in two major U.S. cities who have considerable experience recruiting participants from minority and underserved populations. Subsequent research may want to try to identify recruiters who are rock stars and attempt to identify what communication behaviors make them particularly effective, using a positive deviance approach (Pascale, Sternin, & Sternin, 2010). Given the substantial size and diversity of our qualitative sample, however, we would be quite surprised if there was not a large degree of overlap in the factors that are identified.

Other limitations of this study are endemic to much qualitative research. The recruiters represented in this study are not representative of research recruiters as a whole. In addition, specific communication behaviors may be more effective with a more homogeneous population, not only in terms of racial or ethnic backgrounds but in terms of disease type or stage. It is worth acknowledging that the use of specific verbal communication behaviors varies significantly depending on the culture, social class, and education level of participants. These variations are certainly worthy of much attention in future research, particularly on recruitment practices for underserved and minority patient populations.

Future research that seeks to improve clinical trial accrual should focus on the development of a set of communication best practices, especially in the area of recruitment among minority and underserved populations. In addition to verbal communication behaviors, best practices will necessarily include nonverbal communication (see Morgan, Mouton, Occa, & Potter, in press). Moreover, improvements in recruiters' communication with potential participants may need to begin with PIs' communication with recruiters, as PIs typically construct consent forms and create the scripts that recruiters must work with. A cooperative and collaborative relationship between these two important agents in the recruitment may be a necessary first step to increasing accrual.

Of course, there are many reasons why clinical trials and research studies fail to accrue sufficient numbers of participants; communication is only one piece of this puzzle. The current study was designed to identify behaviors and strategies used with hard-to-reach, minority, and underserved

populations with the hope that what works with groups of people who are more difficult to recruit will be even more effective with those who are easier to reach or who experience fewer barriers to research study participation. By identifying the types of communication behaviors that experienced clinical trial and research study recruiters use when talking with patients and potential participants, we hope to identify communication best practices that can be shared with medical and nonmedical professionals who regularly interact with patients and other potential participants. By improving communication around the prospect of study participation, we hope to increase accrual to important studies, thus improving both knowledge and the quality of available treatment protocols for a wide variety of diseases and conditions. We believe that this study constitutes an advancement toward this long-term goal.

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ORCID

Susan E. Morgan http://orcid.org/0000-0001-7610-4496

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