PROFESSION AND SOCIETY

Consent Administrator Training to Reduce Disparities in Research Participation

Elaine L. Larson, RN, PhD, FAAN, CIC1, Elizabeth Gross Cohn, RN, NP2, Dodi D. Meyer, MD3, & Bernadette Boden-Albala, PhD4

1 Alpha Zeta, Associate Dean for Research, Professor of Therapeutic and Pharmaceutical Research, School of Nursing, Professor of Epidemiology, Mailman School of Public Health, Columbia University, New York, NY
2 Assistant Professor, Adelphi University School of Nursing, Garden City, NY
3 Assistant Clinical Professor, Department of Pediatrics, College of Physicians and Surgeons, Columbia University, New York, NY
4 Assistant Professor, Department of Neurology, College of Physicians and Surgeons, Department of Sociomedical Science, Mailman School of Public Health, Columbia University, New York, NY

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Correspondence
Dr. Elaine L. Larson, School of Nursing, Professor of Epidemiology, Mailman School of Public Health, Columbia University, 630 W. 168th St., New York, NY 10032. E-mail: ELL23@columbia.edu

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Abstract

Purpose: The aims for this paper are to summarize the current state of disparities in clinical research participation, discuss regulatory and interpersonal causes for these disparities, and to suggest an approach to address this problem by standardized training for consent administrators.

Organizing Construct: A program based on the Precede-Proceed model for training consent administrators is proposed and described.

Conclusions: The current process for informed consent for research is unstandardized and inadequate, and may contribute to racial and ethnic disparities. Researchers are urged to consider a formal training program for members of their research teams who will be obtaining participants’ consent.

Clinical Relevance: An educational program for consent administrators may help to reduce disparities in research participation by improving communication between research staff and potential participants.

Annually in the United States (US), several million people sign consent forms for participating in clinical research (Centerwatch, 2007). Despite increasing regulatory scrutiny, disparities persist among various racial, ethnic, and cultural populations (Barrett, 2005; Flory & Emanuel, 2004; Sugarman et al., 2005; Verheggen & van Wijmen, 1996). These disparities exist because of a variety of factors including mistrust of the healthcare system, stereotypes on the part of researchers and potential participants, problems with access to care, and inadequate communication skills and cross-cultural education among healthcare professionals conducting research (Smedley, Stith, & Nelson, 2003).

Many interventions to improve diversity and representativeness in clinical studies have been focused on potential research participants; e.g., simplifying written consent forms or using multimedia approaches such as videos or consent educators to interact with patients. On the other hand, while there are mandated human participants’ training requirements for clinical researchers, no standard exists for preparing members of research teams to oversee the consent process. Studies to date indicate that any successful consent process must at a minimum include the use of various communication modes—written, verbal, asking participants to repeat what they understand, and so on—as well as one-on-one interaction with someone knowledgeable about the study (Cohn & Larson, 2007; Flory & Emanuel, 2004). The aims for this paper are to summarize the current state of disparities in research participation, discuss regulatory and interpersonal causes for these disparities, and to suggest a possible approach to address this problem—by standardized training for research staff members who are responsible for obtaining informed consent from potential research participants (i.e., consent administrators).
Disparities in Research Participation

Disparities in research participation particularly among non-Whites, the elderly, women, and those with lower education and socioeconomic status have been widely documented. The National Cancer Institute Clinical Trial Cooperative Group conducted a population-based analysis of participants in cancer clinical trials from 2000-2002, compared with those enrolled from 1996-1998. As compared with White patients, there were significantly lower enrollments among Blacks and Hispanics and a decline in Black enrollment since the 1990s (Murtby, Krumholz, & Gross, 2004). African Americans are disproportionately under-represented in AIDS clinical trials (Mabunda-Temple, 1998), had considerably lower response rates in a survey of 16,000 adults in four U.S. communities regarding atherosclerosis risk (Jackson et al., 1996), and have been shown to be 1.8 times more likely than are White participants to fear involvement in biomedical research (Katz et al., 2006).

In a telephone survey of women who did not respond to a recruitment mailing for the Women’s Health Initiative, Black women had more negative attitudes toward clinical trials; almost one-third agreed that scientists could not be trusted and only 28% reported that clinical research in the US was ethical (Mouton, Harris, Rovi, Solorzano, & Johnson, 1997). Nonrespondents in epidemiologic studies are more likely than others to be from lower socioeconomic and educational groups (Drivsholm et al., 2006). Such disparities among research participants are important for several reasons: generalizability of results is limited, certain groups fail to receive the benefits and opportunities associated with research participation, exclusion of certain groups distorts effect estimates, and nonparticipants often have poorer health outcomes.

Factors Associated With Disparities in Research Participation

The demographic mix of research participants is influenced at two important levels. The first is the systems-institutional level because of the geographic location and demographics of the catchment area served as well as factors that affect access to an institution (e.g., financial policies and cultural sensitivity of the providers of care). Another institutional factor is trust in the research enterprise and in institutions. Numerous investigators have confirmed that one major deterrent among under-represented groups is a lower level of trust in biomedical research enterprises (Farmer, Jackson, Camacho, & Hall, 2007; Moutsiakis & Chin, 2007; Smith et al., 2007).

In fact, in a survey of 301 African Americans in North Carolina, distrust was the strongest inverse predictor of willingness to participate in AIDS clinical trials (Sengupta et al., 2000). Among 198 adult patients from 26 clinical trials, Verheggen and colleagues found that participants’ attitudes about the consent process were influenced by their more general attitudes toward health care and research, and by their trust in the system (Verheggen, Jonkers, & Kok, 1996).

The second level on which individuals are influenced to participate in research is during clinician-patient encounters (Agre & Rapkin, 2003; Sugarman et al., 1998). The Institute of Medicine Report “Unequal Treatment” indicated three mechanisms that might result in discriminatory patterns of health care: bias against nondominant populations, greater clinical uncertainty regarding outcomes among minorities, and beliefs or stereotypes of clinicians about health or behavior of minorities (Smedley et al., 2003). For example, significant differences in diagnosis or treatment decisions were made by health professionals assessing hypothetical vignettes that were identical except for the race or gender of the patient (Abreu, 1999; Rathore et al., 2000; Weisse, Sorum, & Dominguez, 2003). These findings regarding the effect of provider attitudes on therapeutic decisions are also relevant to research participation.

Especially vulnerable in the process of consent are research participants in developing countries or those newly immigrated or not yet acculturated to U.S. norms because of issues of education, economics, and access to health care (Marshall et al., 2006). In a trial conducted with 60 advanced-cancer patients in Mexico (Verastegui, 2006), 31% of the patients were illiterate but had nevertheless signed a 14-page consent form written at the 8th grade reading level. Only 4 of 20 responding physicians (15%) recognized this population as vulnerable and although all answered that informed consent was a requirement of the hospital and clinical trial sponsor, most were not sure how the current Mexican Health Law applied rules for informed consent.

Interventions to reduce disparities in research participation must take into account beliefs and cultural differences among subpopulations. Patients from nondominant cultures who were interviewed about informed consent reported that they wanted information translated in culturally sensitive ways and wanted their families directly involved in such discussions (Oliffe, Thorne, Hislop, & Armstrong, 2007), but consent administrators are often expected to meet recruitment quotas under time pressure and may therefore fail to recognize misunderstandings or uncertainty that arise in discussions with potential participants.
Among six focus groups of Black men and women, several themes emerged regarding clinical trial design that were deterrents to participation. In addition to socioeconomic, access, and trust factors, respondents noted their extensive use of nontraditional support systems and therapies, and the need to preserve their unique cultural identity as important (Ard, Durant, Edwards, & Svetkey, 2005).

Current Consent Processes Are Inadequate

In addition to the systems problems noted above, the regulatory environment as well as cultural competence and commitment of researchers are important barriers or facilitators to an individual’s propensity to participate in clinical studies.

The Role of the Regulatory Environment and Institutional Review Boards (IRBs)

The regulatory environment may serve as a barrier or facilitator to a person’s propensity to participate in clinical studies. Ironically, despite the fact that IRBs are concerned with assuring the safety of research participants and the adequacy of the consent process, consent forms actually became more complex and less readable after review by members of 25 local IRBs (Burman et al., 2003). Investigators are generally dissatisfied with IRBs, complaining that they are overly conservative, lack expertise, uncommunicative, and that their excessively protective stance may actually trigger misconduct (Keith-Spiegel & Koocher, 2005). Further, in a single federally funded project which was reviewed by 68 U.S. IRBs, the review process varied considerably, requiring from 0 to 303 days before approval (Larson, Bratts, Zwanziger, & Stone, 2004).

Institutions which receive federal research funding are required to certify that researchers complete human subjects research training. Many institutions have developed their own training programs; others have adopted or adapted a myriad of training programs available through governmental agencies such as the National Institutes of Health, Health Resources and Services Administration, the Veteran’s Administration, The Office for Human Research Protections, or other groups such as the Collaborative Institutional Training Initiative, Thompson CenterWatch, Public Responsibility in Medicine & Research (PRIM&R), and Family Health International. Although such training has been available for years, no evidence was found that this additional training is associated with fewer disparities in participation.

The Role of Researcher-Consent Administrators

A considerable body of literature indicates that the form in which risks are communicated can significantly influence the way information is perceived and used (Godolphin, 2003; Thorne, Hislop, Kuo, & Armstrong, 2006), and clinicians and patients interpret risk information in very different ways (Mackillop & Quirt, 1997; Quiet et al., 1997). Clinicians have an important responsibility when soliciting participation in research because therapeutic misconception can readily occur (and may sometimes be passively encouraged by researchers), and the suggestion of enrollment in a study by a patient’s clinician may be construed as an endorsement (Henderson et al., 2006; Kass, Sugarman, Faden, & Schoch-Spana, 1996). Unfortunately, researchers themselves as well as patients can suffer from therapeutic misconception (Henderson et al., 2006; Joffe, Cook, Cleary, Clark, & Weeks, 2001) and may convey ambiguous messages to participants (Verheggen & van Wijmen, 1996).

The importance of community involvement in recruiting minorities and the elderly is recognized, but is often lacking (Branson, Davis, & Butler, 2007). Because clinical research is generally conducted in large, urban, academic health centers, biomedical researchers often lack personal contact with the community and the time to devote to the long-term commitment essential to nurturing such community relationships and trust. Pressures on the research team to meet recruitment goals as well as researcher and participant beliefs and stereotypes are likely to have a particularly negative effect on recruiting minorities and other under-represented groups into research protocols (Smedley et al., 2003).

Communication Gaps Are Common

Clearly, individual researchers cannot address disparities in research participation which have longstanding roots in the history of research and in geographic, sociocultural, and economic conditions. Nor will there be any quick or simple resolution. Nevertheless, individual researchers must identify strategies to assure equity and justice in their own projects, even in the context of structural and political issues. Approaches to improvement to date have been primarily to provide education for patients and research participants, and regulations as well as educational strategies for researchers. Despite such efforts, no intervention or series of actions has yet resulted in consistent, fundamental changes needed in the consent process (Cohn & Larson, 2007).

Patients have reported that conflicts arise in provider-patient interactions because of their vulnerability to both style and content of the communication, the sensitive...
nature of the communication which often involves issues of great concern to patients, and because the communication often includes both verbal and nonverbal and intended and unintended messages (Coyle & Sculco, 2003). Simon and Kodish (2005) have shown that the content and quality of the consent process is linked to the researcher’s attitudes toward the participant’s ethnicity. These communication gaps regarding research occur in the larger context of a healthcare system in which little appreciation is expressed for the relationship between how messages are delivered and how they are understood by recipients.

Hansson and colleagues (Hansson, Kihlbom, Tuvemo, Olsen, & Rodriguez, 2007) demonstrated a strong correlation between increased consultation time (up to 20 minutes) and verbal and nonverbal positive behaviors on the part of clinicians with higher ratings on components of ethical practice. In fact, according to an analysis of sentinel events reported to The Joint Commission, communication failures are the leading cause of inadvertent patient harm (Wilson-Stronks, Lee, Cordero, Kopp, & Galvez, 2008).

Clinicians may have little insight into the barriers and facilitators of communication and inadequate training in communication skills. In a 2007 survey of communication techniques for patients with low health literacy, physicians, nurses, and pharmacists (n=307) were unable to identify strategies currently recommended by health literacy experts (Schwartzberg, Cowett, VanGeest, & Wolf, 2007). Similarly, only half of family medicine residents were able to identify patients with limited literacy skills whom they had just interviewed (Rogers, Wallace, & Weiss, 2006).

Several factors beyond those related to language and cultural barriers also contribute to communication failures in the healthcare system (Leonard, Graham, & Bonacum, 2004). First, physicians, nurses, and other clinicians are taught to communicate in very different styles, often resulting in misunderstandings among themselves as well as among patients or research participants. Nurses are socialized to be broad, narrative, and descriptive in their communications (i.e., not to make diagnoses) and physicians are trained to be concise, directive, and conclusive.

Second, power differentials and hierarchies in the healthcare system inhibit people from speaking up, asking questions, or expressing an opinion. Healthcare professionals believe that quality of care is associated with being well trained and being conscious rather than with hearing what their patients have to say (Leonard et al., 2004). Hence, the consent interaction often fails to meet the communication needs of potential participants because basic principles of communication are not applied. Taken together, these factors are likely have an adverse effect on efforts to discuss research by people with varying educational, cultural, and communication backgrounds.

Because current strategies to assure an informed consent process are insufficient, a more theory-driven, conceptually sound (but not more complex) approach is essential. Hence, we propose that rather than continuing to focus interventions primarily on the patient, there is need for standardized training of consent administrators to create a fundamental intentional conceptual change (Sinatra & Pintrich, 2003) in the consent process. Despite the fact that principal investigators often delegate the responsibility of obtaining patient consent to others such as research nurses, we found no research in the literature that was focused on the preparation and effectiveness of consent administrators. Given the negative attitudes of many researchers toward IRBs and regulations associated with the research process, it is likely that consent administrators can become infused with similar attitudes. Because interaction between the potential participant and consent administrator is so crucial and represents a vital component of the social contract among participants, healthcare research staff, and individual researchers, the appropriate training of consent administrators is warranted.

Currently, most consent administrators are being oriented and trained by principal investigators, and no standardization exists. Some may be getting excellent training, but others clearly are not. Fewer than half of 41 clinical research coordinators in one survey had received additional training in clinical research or good clinical practices (Rico-Villademoros et al., 2004). Intentional conceptual change as described by Sinatra and Pintrich (2003) cannot occur without addressing mediators such as the cultural frame; social context; and moderators such as beliefs, desires, and intentions.

**Development of a Theory-Driven Approach to Improving the Consent Process**

As one approach to reducing disparities in research participation, we developed an educational program, called The Consent Administrator Research Education (CARE) Program, with conceptual underpinnings that included educational and communication principles. We selected The Precede-Proceed health-education model (Green & Kreuter, 2005) to indicate the mediators and moderators necessary for conceptual change. This model shows three factors essential for change (Figure). Predisposing factors include those related to beliefs, attitudes, and knowledge. Enabling factors are those relating to the skills necessary
to perform a function (in this case, the ability to communicate in a clear and culturally relevant way). Reinforcing factors are associated with feedback and approval (or disapproval) and support from peers and other important people (in this case, potential research participants and members of the research team).

The Precede-Proceed Model has been successfully used in medically underserved and minority populations to identify and address minority disparities in cancer prevention in East Harlem, NY (Jandorf et al., 2006). Through the use of this model, the East Harlem Partnership for Cancer Awareness brought together public and private sectors of the community in mutual respect and with a clear purpose. Others have used the model to identify barriers to the control of hypertension in African Americans (Dennison, Peer, Steyn, Levitt, & Hill, 2007). Darrow et al. (2004) reported that through the use of a program designed with the model, recognition of the prevalence of HIV disease and participation in HIV-prevention efforts had both increased significantly.

The Precede-Proceed model is a widely used framework for training healthcare professionals. For example, Linnan et al. (2005) studied professional preparation of community health care educators and found that 62% used the Precede-Proceed model as an approach to teaching and implementing community health. In addition the model has been used for evidence-based psychosocial care in oncology (Schofield, Carey, Bonevski, & Sanson-Fisher, 2006), public education in psychosis (Yeo, Berzins, & Addington, 2007), and follow-up of mammography in multicultural women (Arnsberger et al., 2006).

We also incorporated into this model some principles of communication from the consensus statement, “Essential Elements of Communication in Medical Encounters” (Makoul, 2001), which defines seven steps in clinical interactions: build a relationship, open the discussion, gather information, understand the patient’s perspective, share information, reach agreement on problems or plans, and provide closure. Although interactive communication underlies all clinical encounters (Klamen & Williams, 2006), consent administrators often focus only on the step about sharing information.

Congruent with these guidelines, Leonard et al. (2004) described several elements of critical importance to effective communication, including human factors training, standardized communication, culture change from the bottom up rather than the top down, critical event training and simulation, checklists, and briefings. The authors provided specific examples of improved patient outcomes associated with these strategies. The recent AHRQ Guide for “Accessible Health Information Technology for Populations with Limited Literacy” (Eichner & Dullabh, 2007) provided additional useful guidance for planning effective educational strategies.

Several criteria were used to develop the training program. It had to be feasible (i.e., deliverable within a few hours), reproducible, and generalizable (i.e., not dependent upon the skill of individual facilitators). It had to be available in a format that could be used in other settings and require minimal resources so that it could be implemented in many types of facilities. Our initial program included three 1-hour sessions, each of which addressed one component of the Precede-Proceed model (predisposing, enabling, and reinforcing factors). This format, although educationally sound, did not meet our criterion of feasibility because of difficulties in retaining participation across three sessions. We also consulted with the IRB administrative staff and staff at the Office of the University’s Vice President for Research to determine the amount of time the university would be willing to support in a mandated course. Based on these findings, we modified our approach and developed a 3-hour, single-session program.

Approval for the pilot test of the CARE Program was obtained from the Columbia University Medical Center Institutional Review Board. The requirement for written consent was waived by the IRB, but each participant received information describing the project. The curriculum and tools were first reviewed for inclusiveness and content validity by four experts in the IRB consent process and by five clinicians, including three physicians, a public health researcher, and a bioethicist who had expertise in communication and experience in obtaining consent. These experts were faculty members and clinicians who were experienced principal investigators and had published in areas of bioethics, therapeutic misconception, and patient consent. Then the program was pilot tested by 13 participants: 5 clinical research coordinators and research assistants, 3 physicians, 3 public health professionals, and 2 medical students. Participants were recruited
from among research staff employed by three funded research projects; 10 were experienced consent administrators, and 3 had never administered consent.

The CARE Program consisted of a 3-hour session.

- The first hour was focused on predisposing factors (beliefs, attitudes, knowledge). Trainees first described their own experiences (if any) either as a research participant or consent administrator and what they thought research participants needed to know about a study. Then they received a short presentation on the basic principles of ethical conduct of human research, including several examples of misconduct, as well as the essential key elements of the consent process.
- The second hour was focused on enabling factors and skill building. Trainees in small groups reviewed a typical consent form from an ongoing community study, evaluated its readability, edited or rewrote sections from the perspective of the participants, identified issues related to health literacy, and discussed these in the small group. Four vignettes of consent interactions were used with permission for role playing by group members, followed by discussion and feedback. These had been developed by bioethics experts from the Regulatory Knowledge Support and Ethics Resource section of the institution’s Clinical and Translational Research Award team and tested in role-playing sessions with several dozen research staff and trainees. Participants reported that the interactive vignettes were powerful in raising their awareness of issues such as coercion, therapeutic misconception, and health literacy; and in motivating them to change their own communication styles.
- The third hour was focused on reinforcing factors. Trainees participated in a simulation activity in which they observed and rated each other’s performance in conducting a consent discussion. To standardize observations, a checklist was adapted from one developed by the Compliance Oversight Group of the Columbia University Medical Center IRB that was designed to assess consent interactions for the purposes of compliance (available from ell23@columbia.edu). The original checklist included the mandatory factual components of consent such as purpose of research, voluntary nature of the research, and risks and benefits. We added other communication aspects of the consent process such as seeking feedback and confirming participant understanding. The Table shows the teaching activities-strategies used in The CARE Program to address the predisposing, enabling, and reinforcing factors in our model.

The CARE Program was feasible and participants were enthusiastic about what they had learned. Of those who completed a pretest, 72.7% (8/11) stated that potential research participants do not receive enough information but that they understand the information they are given reasonably well. By the end of the session, however, they uniformly expressed enthusiasm and surprise about how much they had learned, and in the post-test were less likely to report that research participants understand the information they receive about a research project. This program is presented as an example of a theoretically based educational program to improve the consent process, but such programs would need to be developed or adapted locally, based on available local resources, expertise, and needs. Additional testing of the program, including patient and consent administrator outcomes, is ongoing. Meanwhile we urge other clinical research colleagues to consider more standardized training of consent administrators and assess the effect of such training on outcomes such as recruitment and retention, particularly of under-represented groups, and participants’ comprehension of the research.

### Conclusions and Practical Implications

The under-representation of certain groups, particularly ethnic-racial minorities, is a persistent problem in research projects. This disparity is associated with system-level problems such as distrust and difficulties with access as well as interpersonal communication barriers at the level of participant-researcher interaction. Clearly, solutions to this pervasive problem will require changes at both system and interpersonal levels.

In this paper, a framework and sample program for training consent administrators is proposed as one necessary approach to addressing this problem. The next steps will be formal, large trials to assess the outcomes of the

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training, including effect on participant comprehension and rates of retention of minority participants. We are presenting this preliminary work here to inform other investigators about foundational materials that they can develop and test for their own educational programs for consent administrators.

Clinical Resources

- Regulations from the Office for Human Research Protection, OHRP. http://www.hhs.gov/ohrp/
- The Office for Human Research Protections OHRP. http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp

References


misconception in early phase gene transfer trials. Social Science Medicine, 62, 239–253.


