
Decision-Making Issues for Randomized Clinical Trial Participation Among Hispanics

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Introduction and Purpose

Despite large numbers of eligible patients, accrual into randomized cancer clinical trials (RCTs) remains low.¹ Little is understood about reasons for low RCT accrual of ethnic minorities. Hispanic participation in RCTs is far below their representation in the general population.^{2,3} When comparing Hispanic and non-Hispanic cancer incidence and mortality, Hispanics carry a higher burden due to cervix, stomach, and liver cancer, and the death rates for easily detectable cancers (eg, breast) are decreasing more slowly for Hispanics than for non-Hispanics.^{4,5} Without an ethnically and culturally representative sample in RCTs, the generalization of findings becomes questionable for minority cancer patients.⁶ To date, we have insufficient information from the patient perspective about what is needed to make an informed decision about enrollment in cancer RCTs.⁷⁻⁹ It is therefore critical that local cancer providers realize the diverse needs of our community. The purpose of this project was to better understand RCT decision-making issues among Hispanics.

Design and Methods

Development of Focus Group Questions

This present report is a pilot study using a qualitative focus group design. A multi-ethnic, multi-lingual project team devised group questions according to the methods of Morgan and Kreuger.¹⁰ Each 90-minute session began with an icebreaker, followed by questions to ascertain participants' knowledge of cancer RCTs. These preliminary questions were followed by a description of the purpose and process of RCTs pre-

sented by the facilitator. The primary focus group questions were designed to explore the interpersonal and informational wants participants might have in regards to decisions about participation in RCTs. The questions were developed by the group in English, then translated into Spanish and revised by the Spanish-speaking nurse/community liaison facilitator. Questions covered topics of treatment decisions, the role of others in treatment decision making, and the role of the healthcare provider. (The focus group guide is available upon request to the authors.)

Recruitment and Procedure

Various recruitment methods were used. Advertisements were posted at community agencies, community centers, and health clinics, and announcements were made at churches and broadcasted on local Hispanic radio and television stations. Potential participants phoned the Hispanic project coordinator who explained the study. Group meetings were held at a community center, and participants were assigned based on their history of cancer. The rationale for separate groups based on history of cancer was to allow the cancer survivors to base their discussion on their actual treatment experiences. Facilitators followed a parallel protocol but encouraged participants with no history of cancer to base their discussion on imagining they were diagnosed with cancer. Efforts were also made to group participants according to their level of education. Participants received a \$40 gift certificate upon completion of their group meetings.

Method of Analysis

Descriptive statistics were used for demographic characteristics. Narrative analysis and grounded theory were used to identify themes from transcripts.^{11,12}

Results

Sample

A total of 25 Hispanic participants volunteered. The Table lists the sample characteristics of the participants. All 25 participants preferred that the focus groups be conducted in Spanish. There were four groups, ranging in size from five to eight participants.

Knowledge and Themes

Findings on participants' knowledge of RCTs are presented below followed by decision-making themes. Analyses of both cancer patient and non-patient group transcripts led to the emergence of four com-

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Submitted April 8, 2003; accepted August 14, 2003.

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This work was made possible through the funding of a National Cancer Institute Cancer Center Support Grant (P30 CA42014).

Age:	M = 44.1 (SD = 12.3)
Sex:	
Female	20
Male	5
Marital status:	
Married	17
Divorced/separated	5
Widowed/single	3
Education (highest level completed):	
Less than high school	6
High school	4
Some college/college	12
Graduate	3
Employment:	
Employed (full or part-time)	12
Not employed	13
History of cancer:**	
Personal history	11
No personal history	14

* Country of origin: Mexico (n = 12), El Salvador (n = 1), and South American countries (Peru n = 4, Venezuela n = 4, Colombia n = 2, Argentina n = 1, and Ecuador n = 1).

** Of the participants with a positive history for cancer, 28% (n = 7) had been diagnosed with breast cancer and the rest had been diagnosed with various other cancers (eg, lymphoma, throat, pancreas). Of participants with no previous cancer diagnosis, 32% (n = 8) had a family member who had been diagnosed with cancer.

mon decision-making themes: provider-patient relationship, communication needs, informational and support needs, and discrimination barriers.

Knowledge of Randomized Clinical Trials

Knowledge about RCTs was higher and more accurate among the more highly educated Hispanic participants. Many associated RCTs with “aggressive treatment” for “aggressive cancer” and a “desperate” last effort for survival. Across all groups, participants perceived the act of volunteering for RCTs as altruistic. One participant offered this comment: “I really think that this is very good, because we can help other people, once the time comes. No one is exempt from getting this and so maybe this will help others be better prepared.”

Provider-Patient Relationship

Developing a personal, respectful relationship with their doctor was perceived as essential by the participants in making treatment decisions. Many questioned whether doctors in the United States valued personal relationships with patients. Nearly all of the Hispanic participants valued the doctors’ interaction style, and those with higher levels of education expressed a need to trust in the physicians’ competency level.

Provider-Patient Communication

Participants stated that they wanted to share their cancer experiences and related thoughts and emotions in a narrative fashion and that this was a necessary part of their decision-making process. They noted, however, that physicians provided little time for them to open up: “[Doctors] are too specific. They go right to the point.” The participants expressed a desire to communicate in ways that embrace *both* emotions and medical concerns and wanted physicians to acknowledge and reassure them about both their emotional and medical concerns. Despite language barriers, speaking directly to the physician was also important to them.

Informational and Support Needs

Differences for informational needs surfaced among the Hispanic participants. For many of them, comprehensive information from doctors was viewed as essential to make decisions about RCT enrollment. Some individuals with lower levels of education expressed a wish to be more knowledgeable about RCTs but were resigned to being dependent on doctor recommendations: “When we make a decision, we are not well informed and basically we just do what the doctor is recommending.”

A unified theme that emerged was the integral role family plays in decision making: “I think the support of my family, the support of my spouse, right? It’s when you will need the most for people to be around you. I think that is most important thing to help you go on.” In addition to the opinions and support of family and doctor recommendations, many participants related that their decision would involve their faith. For example, one participant stated that “the most important thing is to have faith in God, to feel good spiritually.”

Discrimination

Many participants believed they were discriminated against because doctors assumed they were of low social economic status due to (1) English not being their native language, (2) assumptions about no insurance, and (3) citizenship status being unknown to the provider. One woman undergoing treatment for breast cancer shared her thoughts about a doctor: “I noticed that maybe he [the doctor] was thinking at some point ‘this Hispanic lady must be an illegal alien’ or ‘maybe she isn’t even going to pay for this.’ I guess he was probably hoping that I would leave soon.” Another woman said, “Financially, it’s like they are treating you differently because they look at you as not having money.” Participants also believed that

doctors hold stereotypic views of them as patients: "Some doctors think that we are hypochondriacs and that we make things up."

Conclusions and Implications

The purpose of this study was to identify issues among Hispanics related to decisions to enroll in cancer RCTs. The emergence of themes was not linked specifically to RCTs but resided in the general context of provider-patient relationships. Four broad themes about RCT participation emerged across focus groups regardless of participants' cancer history status. It is not surprising that the basic tenets of respect, coupled with the desire to be perceived as unique, were expressed. Participants indicated that these basic tenets are likely to be achieved if they can share their cancer narratives. Unfortunately, participants believed that doctors treat patients differently based on assumptions of the patient's ability to pay for treatment and that doctors discriminate based on ethnic stereotypes.

The role of family was noted as integral to treatment decision making ("familialism"), and many noted the role of faith. Emotions were described by the participants as a normative aspect of medical communication and a desire for providers to acknowledge both their medical and emotional concerns. Finally, they noted a desire to speak directly with physicians, and physician recommendations were highly valued.

There are study limitations related to the representativeness of our sample. For example, the participants were mostly women (80%) and relatively well educated (60% had some college or higher degree). Despite consistent themes for participants with and without a personal history of cancer, generalizability may be limited based on the imagined needs of participants who had no personal history of cancer. However, these individuals derived meaningful discussions about RCT issues related to family members' experiences with cancer and from their own personal experiences with the healthcare system and providers. Even with the aforementioned study limitations, our findings elucidate some keys to physician tailoring of RCT communication while cautioning about making stereotypic generalizations.¹³ These keys are likely to emerge in values expressed within patient narratives (eg, mention of faith, family, emotional concerns) and guide physicians in areas for responsive communication.¹⁴ For example, when meeting with Hispanics, providers may want to acknowledge and reassure patients about their medical and emotional concerns. Our findings suggest that a family conference to discuss treatment options

would be optimal for Hispanics. The participants' reliance on physician recommendation for decision making indicates the importance of physician-prompted discussion of RCTs with patients and their family. More communication research with special populations is necessary to achieve equitable participation in RCTs, thus allowing minorities the opportunity to receive optimal patient care while contributing to the generalizability of research findings.^{15,16}

We gratefully acknowledge the hard work and advice of Maritza Arce-Laretta, Sara Salisbury, Linda Krebs, three anonymous reviewers, and most of all, the participants.

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