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**Informed Consent in Mexican American Family Cancer Caregivers:
Strategies to Promote Diverse Community Research**

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Abstract

Racial and ethnic populations, such as Mexican Americans (MA), experience poor access to care, limited English proficiency (LEP) and low literacy issues which influence timely receipt of quality health care and increased societal costs of cancer care. Greater research focus must occur to implement culturally sensitive interventions to help meet these groups' needs and rights for care and address health care disparities that negatively influence overall community health. Receipt of informed consent provides the ethical and legal foundation for participant involvement in research to identify culturally sensitive interventions. However, receipt and maintenance of such consent presents challenges to research teams when the participants possess LEP, low literacy levels, and hold cultural values influencing research participation. The research team examined the cancer caregiving experience among MA females and engaged in various strategies to respond to these challenges. This article describes those challenges and strategies to provide informed consent to meet both legal and ethical standards for research with a vulnerable population group. Findings may guide other researchers who value an informed consent process based on honesty, trust, and respect for ethnic group representatives that inform needed research with ethnically diverse communities.

Keywords: Mexican American females; literacy; limited English proficiency; women's health; health care disparities; community research

Informed Consent in Mexican American Family Cancer Caregivers: Strategies to Promote Diverse Community Research

Racial and ethnic population individuals experience higher rates of cancer than the general U.S. population¹ based on poor access to care, limited English proficiency (LEP) and low literacy issues.^{2,3} Such factors influence timely receipt of quality health care that increases the overall costs of U.S. cancer care.^{4,5} Hispanics, the largest and fastest growing population in the U.S.,^{6,7} often experience low access and quality of care for a family member with cancer due to various sociocultural factors, including LEP and literacy.^{3,8}

Approximately 40% of Hispanics speak little or no English.⁶ This LEP, along with low literacy skills, prevent many Hispanics from making appropriate decisions about their health.² They practice less health self-management, preventative care, and have the least access to care of all ethnic groups. These factors support late stage diagnosis of cancer and poorer health outcomes for Hispanics than Non-Hispanic Whites.^{4,5} These outcomes among Hispanics, the majority of which are Mexican Americans (MAs),⁹ contribute to health care outcome differences among various ethnic groups and failure to meet Healthy People 2010's¹⁰ goal to eliminate health care disparities among ethnic population communities by 2010. With expected high growth rates of Hispanic and MA populations,⁶ greater research focus must occur to understand the content and process of effective and culturally sensitive interventions. These interventions will help address these groups' needs and rights for care¹¹ and health care disparities in MA and other ethnic groups that negatively influence overall community health.

The National Institutes of Health (NIH) mandates inclusion of ethnic minorities in research funded by that governmental entity.¹² However, several authors note that ethnic minorities have more negative feelings about research participation than do non-Hispanic Whites.^{13,14} Recruitment can challenge researchers working with ethnic minorities due to a legacy of minority group mistreatment by researchers.¹⁵ This has led to a perceived reluctance of ethnic minorities to participate in research studies.^{16,17} Thus, there is an urgent need to address factors that focus on racial and ethnic group participation in research, and in particular research focused on disease prevention, due to its influence on group and community health.¹¹ Factors identified as barriers to racial and ethnic group participation appear in Table 1.

One factor that may influence ethnic minority participation in research is the informed consent process. Receipt of informed consent provides the ethical and legal foundation for participant involvement in research and mandates an interactive process between participant and researcher throughout a study.¹⁸ Receipt and maintenance of such consent, however, presents various challenges to research teams when the participants possess LEP, low literacy levels or cultural values and beliefs that may prevent full understanding and comprehension of research involvement.² This article describes those challenges

and researcher responses to insure informed consent in a vulnerable population group of female MA cancer caregivers in a NIH-NINR funded study. This work may also guide other researchers who value an informed consent process based on honesty, trust, and respect for ethnic group representatives who can inform needed research with ethnically diverse communities.

Background and Significance

Meaning of Informed Consent

National Institutes of Health (NIH) describes informed consent for a clinical trial or study as much more than an individual reading and signing a piece of paper. Rather, informed consent involves two essential parts: a document and a process. The informed consent *document* provides, at a minimum, a summary of a study purpose, treatment procedures and schedule, potential risks and benefits, alternatives to participation and an offer for the participant to ask questions and withdraw any time from the research.¹⁸ The document facilitates conversations between the potential participant and the research team and initiates the informed consent process. The informed consent *process* provides ongoing explanations that help the research participant make educated decisions to begin or continue participation in a study. To ensure participant full understanding of the meaning of participation, participants must have the opportunity to ask questions or express concerns before, during, and even after a study (NIH). This research with MA women centered on addressing ethical principles of research with human subjects (see Table 2) and NIH criteria for informed consent (see Table 3) consistent with minimizing barriers identified in Table 1.

Informed Consent with a Vulnerable Group: MA Caregivers

Mexican Americans require a culturally appropriate process of informed consent. Members of this group are vulnerable to coercion because of poverty, lack of insurance, low health literacy, LEP and employment status.¹⁹⁻²² Perceived coercion may also result from cultural and language differences between MAs and health care providers that influence effective communication undermine trust between both groups, influence MA individual research participation, and affect MA individual health outcomes.^{5,23,24} This study included some recent undocumented immigrants who lacked health insurance but received care in the clinic data collection site. To minimize perceived coercion, researchers emphasized in the informed consent document and process that audiotaped study data would be held confidential and anonymous and a family member would receive care despite a MA caregiver's unwillingness to participate in the study.

Implementation of the Informed Consent Process

The researchers closely adhered to ethical principles supporting the informed consent process and also the three elements (information, comprehension, and voluntariness) of that process¹⁸ (see Tables 2, 3). Institutional Review Boards at the investigators' employment setting and the clinical data collection agency also approved the study prior to participant recruitment and data collection. Attention to ethical principles (see Table 2) and the study recruitment protocol supported a sample of 34 self-identified MA females who provided care to a family member with cancer receiving care in a public outpatient oncology clinic in the southwestern U.S. All recruited caregivers provided data through initial interviews and later completion of quantitative instruments in a mixed methods study.²⁵⁻²⁷

Information

The information phase of the informed consent process occurs initially in the study recruitment process but continues throughout the study to meet the "standard of reasonable volunteer" (see Table 3). Serious consideration must occur on recruitment activities because they have enormous impact on the quality of the sample and, thus, resulting data quality in research studies.¹⁶ Various authors suggest that word of mouth, face-to-face recruitment, and use of existing community resources are powerful recruitment strategies.^{16,28} These approaches help mitigate negative perceptions of the research process by ethnically diverse groups and add valuable information to inform needed health care for those groups.¹⁶ The researchers found these approaches successful in gaining willing and enthusiastic MA caregivers who told their stories of caregiving due to their desire to improve future care of other MA caregivers.

Based on the literature, the researchers identified possible cultural barriers to recruiting MA caregivers even with providing information during the informed consent process. These barriers included reluctance of some MA women to participate in the study related to caregiver pride, a desire to not acknowledge their caregiver needs, and perhaps a belief that it is inappropriate to talk about an obligatory role (family caregiver) despite its burden. Other barriers to participation might include women's preference to appear aware of support services for self or family member, even though literature supports they do not seek formal assistance for caregiving.²⁹ These women may also fear potential discovery of undocumented status,^{11,30} lack support from family or spouse (cultural value of "machismo"),^{20,31} and experience difficulty in speaking about cancer to a stranger.^{32,33} Additionally, some women due to poor health, weak social network, low socioeconomic status, or significant functional impairment of the ill family member might refuse to participate and remain unconvinced of the study's benefit.^{11,34}

Although the researchers recruited a sufficient number of caregivers to meet study aims, they carefully considered clinic environmental factors influencing caregiver perceptions that might affect their willingness to participate during information dissemination. Researchers had a close working relationship with

clinic staff, and they introduced the study to caregivers during a family member's care. This introduction helped decrease possible caregiver distrust of the research team because caregivers had a positive relationship with clinic staff and staff had a relationship with the members of the research team (see Table 1). Staff received updates about the study throughout its implementation and provided quality information to caregivers interested in participation. Knowing that many MAs tend to defer medical decisions, including research participation, to their families,³⁵ the research team patiently informed caregivers about the study during clinic visits, called them on the phone if they provided their number, and provided flyers they could share with family members to support study credibility. Large colorful posters with pictures of MA women appeared throughout the clinic to give caregivers sufficient information to choose to participate in the study based on their cultural values and decision-making skills.³⁰

The project focus was to gain a sample that would provide information to support intervention ideas that would lead to a better life for MA cancer patients and caregivers. The research team honored ethical principles of beneficence, respect for persons, and justice by implementing consistent recruitment and study implementation strategies. These addressed MA cultural values and beliefs of caregivers and minimized any possible harm to those meeting study inclusion criteria. The research team did not collect information on caregiver legal status nor include U.S. citizenship as an inclusion criterion. As recommended to improve recruitment outcomes,¹⁶ each woman received assurance that personal information would be held in confidence, separated from data collection tools, and all would be coded to protect her individual identity. Careful consideration also occurred with use of language in recruitment materials. For example, a MA cancer nurse study consultant told the research team that the word "investigators" in the consent form, brochures, posters, and research team nametags could be interpreted by potential participants as meaning police investigations, rather than roles associated with academic research. The consultant noted that caregivers might be afraid to participate based on a fear of discovery of undocumented status and possible deportation back to Mexico. To avoid this caregiver perception affecting recruitment, the research team avoided the use of the term "investigators" in all the study documents and oral communications with the women.

Based on the recommendations of several authors,^{20,36,37} researchers employed research assistants (RAs) who matched the ethnicity of the MA sample and reflected bicultural and bilingual status (English and Spanish) as members of the research team. These trained RAs adhered to previous ethical principles of the study protocol, provided invaluable help in study recruitment and data collection, and addressed the "standard of reasonable volunteer" for a MA study³⁸ (see Table 3). RAs read all recruitment materials and informed consent documents to caregivers and socialized with them to earn their trust before study participation. RAs also encouraged questions from individual caregivers and their families before gaining caregiver signature on consent documents.

To meet the “standard of reasonable volunteer” (see Table 3) as part of the information component of informed consent process, researchers adhered to the consent document developed by the employing institution IRB and approved by the involved clinical agency IRB. Components of the consent, aimed at a 5th grade reading level, included study purpose, participant time requirement, and information on withdrawing from or refusing to participate in the study and the lack of participant penalty for doing so. The consent document also included a description of how to contact investigators, statements providing the opportunity to ask questions and describing study risks and benefits, and the need to contact the caregiver for the second interview. The consent document also contained places for the signatures of the participant, the person obtaining the consent, and the principal investigator (PI).

Competency

Various approaches occurred to address caregiver understanding of study involvement despite sociocultural and other factors blocking such understanding (see Table 3). While low literacy levels of potential participants in MA studies pose a barrier to cross-cultural research,^{11,20} this study recruited caregivers regardless of literacy level. However, participants had to reflect the ability to speak either English or Spanish to participate in the study.

To meet the challenge of low literacy that would affect comprehension as part of informed consent, the research team selected or created study data collection tools to reflect a 5th-6th grade reading level or below. Translation of study instruments into the Spanish language addressed expected LEP of the sample. Careful attention to also insure contextual congruence between English and Spanish language consent forms and data collection tools for the study occurred through pre-study pilot testing and refinement of language of tools by two clinical experts of MA heritage who served as cultural consultants to the study.^{27,39} During the study and to respond to possible low caregiver literacy, RAs read all informed consent forms and quantitative and data collection tools to participants in their preferred language and recorded their responses. Laminated forms of each document allowed caregivers to read forms as RAs read them. These strategies responded to various barriers to ethnic group research identified in Table 1.

Many MA women have a more relaxed attitude toward time and a present time orientation. Thus, the research team used recruitment time during clinic visits to sit with caregivers and establish an interpersonal relationship with them during clinic visits with their family member. This honored the cultural value of *simpatico* and built a research team member-caregiver connection before a caregiver agreed to speak about her more personal life.^{16,20,29} With establishment of a relationship, the RA or member of the research team could present study information meeting caregiver needs (see Table 3), and utilize family member or clinic staff to interpret caregiver role in the study if deemed necessary. RAs were also available to contact participants by phone or letter between the two study

interviews and answer questions or respond to concerns about the study. Overall, an apparent partnership between RA and caregiver during the duration of the study supported retention of all caregivers who began the study.²⁵

To assess participant comprehension of her role in the study, various questions appeared at the end of the informed consent document before the caregiver signed it. As recommended by Titus & Keane,⁴⁰ RAs sought caregiver response to the following: tell me in your own words what this study is about; tell me what you think you will do in this study; tell me what would happen to you if you choose to not be in this study; what benefits do you expect to get from being in this research; what risks might you have by being in the study; and, what questions do you have? If a caregiver did not appear to fully understand her roles and rights in the study, the RA and a research investigator carefully orally reviewed the informed consent document with the caregiver or sought help from clinic staff or caregiver's family. With evidence of caregiver understanding, the RA then gained the caregiver's signature on the document.

Voluntariness

Federal regulations do not specify the length of time or place to obtain study participant informed consent. However, to allow participant autonomous and informed decision-making for study participation, time and place are critical.⁴¹ Caregivers needed time to talk to family members to gain their acceptance of study involvement and allow full understanding of such involvement without feeling coerced into participation. Although a clinic staff person told the caregiver about the study and referred her to a RA for further discussion, clear communication from staff and research team members indicated that it was the caregiver's choice to participate. Once a caregiver agreed to participate, written informed consent occurred in a private and quiet room in the clinic before data collection. Later data collection occurred in a setting preferred by the caregiver to decrease possible power relationships between the RA and participant that might influence data collection or perceptions of coercion to participate.⁴² A copy of the consent document given to the participant before data collection permitted contact with the research team between interviews and contained information that caregiver study participation was voluntary. RA phone contact with the participant before the second interview allowed caregivers to express concerns or ask questions about the study. It also provided an opportunity for the RA to assess if the caregiver and the person cared for continued to meet study criteria.

Discussion

Although this study addressed effective ways to gain MA cancer caregiver trust and engagement to give informed consent in a mixed-methods study, further work must occur to meet the same goal for more complex research, including clinical trials. Although some studies¹¹ suggest that ethnic minority recruitment for treatment trials may be more successful than that for prevention-focused studies,

additional studies must identify factors affecting low participation of ethnic populations in cancer studies.^{16,43} Such participation remains essential to obtaining needed sample sizes and quantity and quality of studies to understand factors essential for development of culturally relevant and evidence-based interventions. These interventions will support the ethical principle of justice (“to each an equal share”) by delivering a model of care that meets ethnic population needs much like the current model which many believe focuses predominately on White population needs.² Increased numbers of ethnic population participants in quality studies will improve with researcher implementation of a legal and ethical process of informed consent – providing sufficient information to gain participant interest in study participation; insuring participant comprehension about one’s study role; and, assuring each participant freely chooses to contribute to the study. Increased ethnic population participation in a variety of studies holds promise for addressing health care disparities in diseases, including cancer, found in MAs and other diverse population groups and for reaching goals identified in Healthy People 2010.¹⁰

Although not present in this study on MA cancer caregivers, community-based participatory models support an active partnership of community members, data collection setting personnel, and academic researchers to increase recruitment and retention of diverse populations in research studies. Community members, representing the intended sample, can offer insight into the structure, process, and evaluation of studies so they successfully meet outcomes to improve a community’s health.⁴⁴ These members’ rich knowledge of cultural values and behaviors can help identify potential study sampling, optimal data collection sites and processes, and ways to return study findings to benefit the community and support sustainable future clinical-academic partnerships. Community members’ intimate knowledge of health literacy and LEP of potential study participants can also structure the informed consent document/process, data collection tools, and communication methods used for recruitment and by involved study stakeholders. Community persons, as equal members of the research team, will also redefine the concept of “expert.” Their expertise will help the entire research team in bridging the culture of community model with that of the more academic research model.

Health literacy and LEP issues directly affect recruitment and retention of ethnic minorities, and research studies must address effective ways to respond to these issues.^{45,46} Health literacy, (the ability to speak, read, or write to understand at the level needed to interact effectively in the health care system),¹⁹ remains limited among many Americans, including many Hispanics and MAs.^{2,21,47} Those persons lack comprehension to provide informed consent, affecting their participation in research studies focused on disease that more often affects those with LEP (cardiovascular and communicable disease).^{3,48,49} In one study in Mexico, few participants understood that signing an informed consent document for a study was to protect their rights as a participant. Instead participants

believed that signing would give them free health care, or would free the doctor of liability related to a patient's care.⁵⁰ Fifty seven percent of the low literacy sample (31% were illiterate and 83% lived in poverty) noted they read the informed consent document only once and decided to be in the study in less than one hour's time. Most (86%) believed that they should be in the study because the doctor asked them to be. Of the 35 persons in the sample, 33 persons sought information from a family member to decide whether to participate in the study.⁵⁰

There is need for studies on audiovisual and innovative ways to meet the elements of informed consent (see Table 3) for people of diverse cultures and with variant developmental levels.⁴⁴ In at least one study, an audiotape version of a research consent in English and Spanish allowed a sample with LEP to perceive greater understanding of their study role than those who completed a written consent in their language of choice.²² Management of literacy and LEP issues in both written and oral ways in this study supported a sample size of 34 MA caregivers who willingly signed informed consent documents at a 5-6th grade reading level and maintained involvement in the study for two interviews needed for data collection.

Limited health literacy and LEP minimize the efficiency of the U.S. health care system and, thus, add cost to the overall functioning of this system. Both factors affect the quality and safety of patient care, leading to increased malpractice concerns among many health care providers.^{51,52} Although U. S. law and Joint Commission require that health care agencies provide competent translators to persons with LEP to insure their understanding of health care situations,^{45,53} services to do so are often lacking.⁵⁴ Use of such translators, as part of research teams, could meet legal and ethical criteria for informed consent. Active involvement of translators could provide information and support understanding of potential study participants who might choose study involvement.⁵⁰

Conclusion

Planning and implementation of strategies to overcome LEP barriers, literacy issues, and address cultural beliefs and values in ethnic minority research are essential for successful receipt of participant informed consent and retention in research studies. Successful studies with diverse groups, including MA cancer caregivers, focus on insuring adherence to ethical principles involving human subjects and elements of informed consent. These principles and elements support close working relationships with agency staff in recruitment settings, strong research team collaboration, and involvement of cultural experts who provide direction for effective engagement with the desired diverse sample. Researchers should be aware that the informed consent is a procedure needed to establish a respectful and ethical relation between researchers and participants. Culturally competent informed consent for diverse population with LEP and literacy levels is possible.^{22,55} However, there is no simple answer to the inevitable question of 'how valid is the informed consent for these patients?' But

it is clear, with research team planning and assessment throughout the research study, quality data generation can occur. This data can provide insight into ethnic minority perspectives and societal need to improve the health of diverse communities.

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Table 1

Identified Barriers to Health Research Participation by Ethnic Groups¹¹

- Lack of cultural sensitivity in communication materials and approaches
- Lack of encouragement by community leaders for study participation
- Lack of awareness of benefits of study participation
- Concerns about signing informed consent document
- Fears of governmental response with study participation (e.g., undocumented persons)
- Lack of time and energy related to more pressing survival priorities
- Cultural and religious beliefs
- Literacy issues related to low levels of education, particularly about health
- Fatalism – belief that study participation will not change disease trajectory
- Relationship between institution where research conducted and community sought for sample
- Lack of bilingual and bicultural research team staff for study design, recruitment, and implementation
- Lack of linking research issue to community needs or desires for study

Table 2

Ethical Principles of Research Involving Human Subjects¹⁸

Respect for Persons

- Persons receive treatment as autonomous individuals capable of making personal decisions and bearing consequences of those decisions
- Persons with diminished autonomy must receive protection from others; extension of protection relates to risk of harm and likelihood of benefit to those persons

Beneficence

- Persons receive treatment in a manner to maximize their well-being
- Researcher/provider of care has an obligation to “do no harm” and maximize predicted benefits and minimize predicted harms to persons

Justice

- Persons who are equals ought to be treated equitably
- Persons ought to have a share related to individual need, effort, merit, and societal contribution

Table 3

*Three Elements of Informed Consent Supportive of Ethical Principle of Respect for Persons*¹⁸

Information

- A person receives sufficient information to make a decision (disclosure is clear)
- “Standard of reasonable volunteer” guides extent and nature of information needed for an individual to consent

Comprehension

- Information is presented in an organized and appropriate fashion or pace to allow potential participant time to ask questions to understand role and rights in study before provision of consent
- Information type and amount relate to potential participant intelligence, maturity, language, cultural values/beliefs, and psychosocial status
- To meet participant’s best interest, may mean seeking permission and help of others to protect and insure understanding of participant

Voluntariness

- Potential participant signs consent form without perceptions of overt or covert coercion or undue influence
- Potential participant does not receive excessive or inappropriate rewards to gain study involvement