

Knowledge, Awareness, and Interest in Cancer Clinical Trials among Rural Latinos Following Brief Education by Promotores de Salud

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Received date: June 16, 2015; Accepted date: July 9, 2015; Published date: July 17, 2015

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Abstract

Background: Promotores have been widely used for health promotion in underserved Latino communities and are increasingly being partnered with throughout the country to enhance health care access when there are cultural and economic barriers to care. A community network approach using Promotores de Salud may be a useful strategy for increasing overall knowledge and participation of Latinos in clinical trials.

Objective: To assess knowledge, attitudes, and interest related to participating in cancer clinical trials among rural Latinos following receipt of a brief community-based cancer research educational session delivered by previously trained *promotores de salud*.

Methods: Trained *promotores de salud* conducted 10-15 minute one-to-one educational sessions with Latinos. Participants completed a pre-post assessment on knowledge, attitudes and interest in participating in clinical trials.

Results: Over a period of two months, five trained *promotores* recruited and delivered a single educational session with 228 Latinos. At baseline, 68% of participants had heard about clinical trials, but only 5% had participated in one. Compared to baseline, after training, participants increased significantly their positive views of clinical trials, trust in medical researchers, and belief in general safety of clinical research ($p < 0.001$). Interest in participating in cancer clinical trials increased from 68% to 79% ($p < 0.001$). Providing bio-specimens for research purposes ($p < 0.001$) also increased significantly.

Conclusion: Use of *Promotores de Salud* to conduct community-based clinical trials education is a promising approach to promote widespread community participation in cancer clinical trials available to ethnic and racial underserved populations.

Keywords: *Promotores de Salud*; Promotores training; cancer clinical trials; Latinos; immigrants; Community Advisory Board

Introduction

Despite an increase in research on the factors influencing accrual of racial and ethnic minorities into cancer clinical trials [1,2], participation of Latinos remains minimal [3,4]. Among Latinos, barriers such as limited knowledge about cancer clinical trials, lack of trust in entities leading trials, and an inability to include family members in the decision-making process at the time of clinical trials recruitment remain unaddressed [5,6]. Furthermore, language barriers, poverty, immigration status, and geographical segregation further aggravate disparities in clinical trial engagement [7,8]. Rural communities, in fact, have the lowest level of accrual into clinical trials, possibly because of distance from metropolitan areas and limited access to specialty physicians such as oncologists [9]. Low clinical trial participation rates among Latinos limits understanding of ethnic, racial, and cultural differences in screening, diagnosis and treatment and could dramatically affect the effectiveness of treatments for this understudied group [10,11].

Notable interventions to overcome these barriers to clinical trial participation have emerged. Vicini et al. (2011) recently described a successful Community Clinical Oncology Program called Minority Outreach Program (MOP), which resulted in a 10-fold increase in annual minority patient clinical trial accruals. MOP included the development of a network of community-based organizations and a bilingual educational program to jointly promote knowledge about clinical trials. These approaches and their results suggest that the creation of a culturally sensitive environment in which to promote clinical trials participation may facilitate the recruitment of multi-ethnic populations [12]. Another successful program, "Redes En Acción," has established a cohort of Hispanic leaders and researchers to support community awareness studies around cancer clinical trials. By engaging the community in cancer research and education, this program has increased trials accrual and led to new programs for addressing cancer disparities [13].

Researchers and policymakers have increasingly acknowledged the role of community health workers to address clinical trials recruitment and retention challenges. The National Coalition of Hispanic Health and Human Services Organizations has described a critical need for the development and evaluation of infrastructure to meet the health

needs of Latino communities, focusing on community-based services and sustainable efforts to reach the underserved [14,15]. Community-based participatory research (CBPR) builds on the unique strengths and resources of communities to promote co-learning and capacity building, sharing and dissemination of data and knowledge, and the building of long-term commitments [16,17]. CBPR approaches offer great promise for addressing disparities in clinical trials participation because they can engage untapped community resources and strengths, such as social networks, to enhance the involvement of communities in the cancer clinical trials enterprise [18].

Among Latinos, community networks extend beyond family to include neighbors and friends who serve complementary roles as sources of support, advice, and role modeling [16,19]. Novel branches to Latino social networks might also include community leaders, friends or kinship (compadre or comadre) who can become credible sources of health information and/or community health workers (CHW)/*Promotores de Salud*. These CHWs can be trained to deliver information and services and deployed to increase knowledge and interest in cancer clinical trials among their Latino communities. Additionally, CHWs can enhance community member trust in the medical system and clinical trials by providing new information about different treatment choices, screening modalities, and resources for clinical trials [20]. According to a systematic review of randomized controlled trials that utilized CBPR approaches, most trials reached adequate rates of recruitment and retention, focused on ethnic underserved populations, and generally achieved good participant outcomes [21]. An interesting approach to recruit diverse populations is described by Greiner et al. in five cancer screening and prevention trials carried out in three National Cancer Institute funded Community Networks Program Centres. Community participation in the creation of a study, planning of a study design, and follow-up education and explanation of results to participants were key components that led to enhanced recruitment. The community-based approaches emphasize that studies involving community and academic partners can improve the recruitment of underrepresented populations [22].

To address critical disparities in rates of participation in cancer clinical trials in rural Latino communities of Kansas, we applied a CBPR approach to test a *promotores de salud*-delivered intervention designed to increase knowledge, awareness, and interest in cancer clinical trials among rural dwelling Latinos. Empowering community health workers as educators and advocates within their own communities was hypothesized to be a crucial pathway to increase minority participation in cancer clinical trials. The results of this study were intended to increase our understanding of the roles that CHWs can assume in rural communities where access to cancer information resources are scarce.

Methods

Procedures

Recruitment and training of promotores: The present study was implemented in rural communities in Southwest Kansas. The population of Seward County, where this study took place, is 57% Latino. In-migration of Latinos seeking jobs in the meatpacking and feedlot industries within the county has dramatically changed the local demographics over the last 20 years. Twenty-two trained *promotores de salud* who completed all training in cancer and cancer clinical trials themselves on a preceding study by Cupertino et al. (2015) were

invited to become involved in the recruitment, education, and pre-post-testing activities of this study. Four women and one man agreed that they had the time and interest to participate.

Promotores were trained by bilingual research study staff to deliver community-based educational sessions in the previous study. Training took place over three separate sessions in a faith-based facility. Using an interactive training format, sessions covered the National Cancer Institute's (NCI) "Cancer 101" curriculum modules on cancer clinical trials [23]. This curriculum is available in Spanish and all training occurred in Spanish [24]. *Promotores* had the opportunity to role play delivery of the educational sessions and collection of participants' pre and post education assessments that they themselves had learned in the previous study. They went out to community and disseminated the information that they acquired. *Promotores* completed an additional two-hour refresher session 6 months later.

Promotores were equipped with a program intervention folder containing educational materials from the training session, a PowerPoint presentation printout with key points and visual aids, a checklist to track the session, and participant tracking logs. Additionally, trained *promotores* received individual packets to be shared with each research participant. Participant materials included a written informed consent form specific to this research study, pre and post assessments, National Institutes of Health and NCI brochures on cancer and cancer clinical trials, and a journal for each participant to track the material covered, time spent training, and space for taking notes regarding the sessions [25]. *Promotores* were not reimbursed based on the number of community members targeted or the number of trainings and assessments completed, but instead on full participation in training, ongoing education and assessment activities, and maintaining updated records.

Promotor-led educational sessions with community members: *Promotores* identified and recruited Latinos at regional community events. *Promotores* obtained written consent using a low-literacy Spanish-language consent form after reading the form aloud to participants. *Promotores* delivered a single educational intervention in Spanish in a 15-20-minute encounter at a place that was convenient for participants. The research team provided ongoing supervision of *Promotores* and was available monthly for tracking meetings to support and troubleshoot with the *promotores*.

Participants completed a pre assessment prior to and post assessment immediately after the education session from *promotores*. All assessments were completed in Spanish and required approximately 10 minutes to complete. *Promotores* were available in case participants had questions and read questions to participants, as needed.

Based on feedback from our larger group of *promotores* and Community Advisory Board, we developed a reimbursement plan to provide compensation for participant time and travel/childcare costs. Participants each received a \$10 gift card for the training session.

Measures

Pre-intervention socio-demographic measures included participants' age, gender, ethnic background, country of origin, education level, medical insurance status, most frequented medical care facility, Spanish and English language usage, marital status, employment status, household number, weekly income, and residency postal code. The pre- and post-assessments contained the following three types of measures: 1) attitudes about medical research and

clinical trials, 2) exposure to and knowledge about cancer clinical trials, which included open-ended questions to assess knowledge of clinical trials, and 3) willingness to participate in cancer clinical trials.

Descriptive variables: Behavioural Risk Factor Surveillance System (BRFSS) survey items were used to assess demographic and health care access questions in both English and Spanish [26].

Attitudes about cancer clinical Trials: To assess attitudes towards clinical trials, we used the Research Attitudes Questionnaire (RAQ) [27]. We used 11 multiple choice questions such as “I have a positive attitude towards research in general” with 3-level response options of “totally agree/agree,” “neutral,” and “disagree/totally disagree.”

Exposure to and knowledge of cancer clinical trials: To assess knowledge of clinical trials, we used two multiple choice questions: “Have you heard about clinical trials?” with a “yes” or “no” response option, and “Where have you heard something about clinical trials?” Response options were “radio,” “poster,” “my doctor,” “Kansas University Medical Center (KUMC),” “Ventanilla de Salud Program,” “Promotores de Salud,” and “Other.” In addition, we used one open-ended question: “What have you heard about cancer clinical trials?” This allowed for learning more details about participants’ familiarity with cancer clinical trials.

Willingness and interest related to participation in cancer clinical trials. We relied on the work of Wallington et al. (2011) to measure awareness about clinical trials and willingness to participate [28]. We developed multiple choice questions based on this work. For example, one question was “If there was a cancer clinical trial study available in your area and you qualified, would you be interested in participating?” The response options were “yes,” “no,” and “don’t know.” Additional items assessed interest in providing bio specimens for clinical trials.

Data Analysis

Descriptive demographic data were analysed using PASW Statistics 18.0 software to report frequencies and proportions. Pre-post changes in participants’ attitudes and willingness to participate were evaluated using Wilcoxon signed-ranked tests. Knowledge of and interest in participating in cancer clinical trials were assessed using McNemar’s t-tests.

Results

Over a two-month period, five trained promotores de salud each identified between 20-60 participants within their social network and delivered educational sessions to 228 participants. The average number of participants that each promotor recruited was 45. Of the 228 Latino participants who completed the educational session, half were younger than age 40 (50.4%), approximately two-thirds were females (62.3%), most were born in Mexico (73.7%), and over half had less than a high school graduate level of education (57.7%) (Table 1). Ninety-seven percentage of the participants self-identified as Latino and only 3% stated being Chicano or Mexican American. Roughly half of our participants had no health insurance (46.1%) and lived in a household with 5 or more persons (52.2%) (Table 1). Overall, participants reported low levels of acculturation to the United States; the majority reported speaking, reading, and thinking only in Spanish (62.2%), and only 37% reported speaking English well or very well.

Age (years)	50.4 (115)
17-39	38.6 (88)
40-64	7.0 (16)
≥ 65	3.9 (9)
Unknown	
Female	62.3 (142)
Hispanic/Latino	96.9 (217)
Country of Birth	
United States	18.9 (43)
Mexico	73.7 (168)
Other	7.4 (17)
Education Status	
Less than high school graduate	57.4 (131)
High school graduate or GED	21.5 (49)
Some post high school education	16.7 (38)
College graduate or more	3.1 (7)
Don't Know/Decline to state	1.3(3)
Health insurance	
Private	35.1 (80)
Public only	15.8 (36)
None	46.0 (105)
Don't Know/Decline to state	3.1 (7)
Employment status	
Employed	59.7 (136)
Household number	
1 or 2	15.8 (36)
3 or 4	32.0 (73)
5 or more	52.2 (119)
Weekly Household Income	
Less than \$300 dollars	17.1 (39)
\$300-\$500	41.7 (95)
\$501 or more	24.5 (56)
Overall Self-Rated English Proficiency	
Very well/Well	36.8 (84)

Table 1: Demographics, socio-economic and health access characteristics among participants (n=228).

At baseline, approximately half of participants “agreed/strongly agreed” to having a positive attitude about research in general.

Characteristic	%(n)
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Approximately 70% held altruistic attitudes about volunteering in research to help others, felt that society should invest more resources in clinical research, and believed research finds cures for major diseases (Table 2). Simultaneously, about one-third of participants agreed that medical research needs to be closely regulated to prevent harm to research participants and that a great deal of emphasis on research is likely to harm volunteers.

In terms of knowledge and awareness of clinical trials at baseline, about 70% of participants had previously heard about clinical trials (Table 3), but only 5% had participated in a clinical trial. However, when asked to define the term, approximately half of the participants who had heard about clinical trials (45.2%) could not provide a clear definition for “clinical trials” and simply indicated “nothing” or left the question blank. Interestingly, at baseline, we identified high interest regarding participation in clinical trials with 68% reporting willingness to participate in cancer clinical research, 74% willing to provide saliva samples, 68% predisposed to provide blood samples, and 53% in favor of providing tissue samples for cancer clinical trials. Prior to receiving an explanation of the meaning of randomization, at baseline, 35% of participants indicated that they would be willing to participate in a treatment chosen at random (Table 3).

Pre-post intervention changes in attitudes toward cancer clinical trials were significant and positive for all attitudes except for two items dealing with the protection of human subjects in research, specifically, the belief that medical research needs to be closely regulated to protect

participants and the idea that much emphasis on medical research is likely to harm participants. After training, participants significantly increased their positive views of clinical trials, trust in medical researchers, responsibility to help others by participating in medical research, belief in the general safety of clinical research (all with p values <0.001), belief that society should devote more resources to research, and that research will find cures to diseases during their lifetime (all with p values <0.01). Also, post-intervention, participants were more likely to disagree with negative statements about clinical research that it does more harm than good (p <0.01) and that researchers are mainly motivated by personal gain (p <0.001).

Pre-post changes in the knowledge item regarding whether they had ever heard of cancer clinical trials increased from 68% to 92% (p value <0.001). Importantly, the post-test results showed that 56% correctly defined clinical trials as “research opportunities to cure, a “prevent,” “detect cancer,” and “ways to find new treatments for cancer.”

Compared to baseline (Table 3), the percentage indicating interest in participating in cancer clinical trials increased from 68% to 79% (p<.001) pre- to post-intervention. Other increases in interest fell along the following lines: provide saliva samples rose from 74% to 84%, blood samples from 68% to 78%, and tissue samples from 53% to 63% (all p values <0.001). Furthermore, significant increases were observed in the proportion that indicated willingness to participate in a therapeutic study comparing treatments (53% to 69%; p>.001) and a randomized therapeutic study (35% to 53%; p>.001).

	Pre-Assessment	Post-Assessment	P-value
	% (n)	% (n)	
I have a positive attitude towards cancer clinical trials.			
Agree/Strongly agree	57.0 (130)	78.1(178)	<0.001
Neutral	33.3 (76)	13.2 (30)	
Strongly Disagree/Disagree	9.7 (22)	6.6 (15)	
No Response	0.0 (0)	2.2 (5)	
Medical researchers are mainly motivated by personal gain.			
Agree/Strongly Agree	27.2 (62)	21.9 (50)	<0.001
Neutral	39.0 (89)	20.6 (47)	
Strongly Disagree/Disagree	32.5 (74)	55.3 (126)	
No Response	1.3 (3)	2.2 (5)	
Medical researchers can be trusted to protect the interests of people who take part in their studies.			
Agree/Strongly Agree	61.4 (140)	77.2 (176)	<0.001
Neutral	26.3 (60)	14.0 (32)	
Strongly Disagree/Disagree	11.8 (27)	7.0 (16)	
No Response	0.4 (1)	1.8 (4)	
We all have some responsibility to help others by volunteering for medical research.			
Agree/Strongly Agree	73.3 (167)	82.0 (187)	<0.001
Neutral	17.5 (40)	10.5 (24)	

Strongly Disagree/Disagree	8.3 (19)	5.3 (12)	
No Response	0.8 (2)	2.2 (5)	
Modern science does more harm than good.			
Agree/Strongly Agree	14.9 (34)	14.0 (32)	<0.01
Neutral	30.3 (69)	15.8 (36)	
Strongly Disagree/Disagree	53.9 (123)	67.5 (154)	
No Response	0.8 (2)	2.6 (6)	
Society needs to devote more resources to medical research			
Agree/Strongly Agree	68.9 (157)	79.4 (181)	<0.01
Neutral	20.6 (47)	11.4 (26)	
Strongly Disagree/Disagree	9.2 (21)	6.1 (14)	
No Response	1.3 (3)	3.1 (7)	
Medical research needs to be closely regulated in order to prevent harm to research participants			
Agree/Strongly Agree	69.7 (159)	71.5 (163)	0.83
Neutral	22.8 (52)	18.4 (42)	
Strongly Disagree/Disagree	7.0 (16)	7.0 (16)	
No response	0.4 (1)	3.1 (7)	
Participating in medical research is generally safe			
Agree/Strongly Agree	42.1 (96)	63.2 (144)	<0.001
Neutral	43.4 (99)	26.8 (61)	
Strongly Disagree/Disagree	14.0 (32)	7.9 (18)	
No Response	0.4 (1)	2.2 (5)	
If I volunteer for medical research, I know my personal information will be kept private and confidential			
Agree/Strongly Agree	78.9 (180)	83.3 (190)	<0.05
Neutral	17.5 (40)	11.4 (26)	
Strongly Disagree/Disagree	3.5 (8)	3.9 (9)	
No response	0.0 (0)	1.3 (3)	
A lot of emphasis on medical research and scientific progress is likely to harm research volunteers			
Agree/Strongly Agree	27.6 (63)	32.0 (73)	0.78
Neutral	36.4 (83)	28.1 (64)	
Strongly Disagree/Disagree	36.0 (82)	38.6 (88)	
No Response	0.0 (0)	1.3 (3)	
Medical research will find cures for many major diseases during my lifetime			
Agree/Strongly Agree	77.2 (176)	84.2 (192)	<0.01
Neutral	16.7 (38)	11.4 (26)	
Strongly Disagree/Disagree	6.1 (14)	3.1 (7)	

No Response	0.0 (0)	1.3 (3)	
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Table 2: Pre-post Intervention attitudes about cancer clinical trials among participants (n=228).

	Pre-Assessment	Post-Assessment	P-value
	% (n)	% (n)	
Have you ever heard of cancer clinical research studies?			
Yes			
No	68.4 (156)	89.9 (205)	
Don't Know	29.0 (66)	7.5 (17)	<0.001
No Response	2.6 (6)	0.88 (2)	
	0.0 (0)	1.8 (4)	
Would you be interested in participating in a cancer clinical research studies?			
Yes			
No	68.0 (155)	77.2 (176)	
Don't Know	13.6 (31)	13.6 (31)	<0.001
No Response	18.0 (41)	7.0 (16)	
	0.4 (1)	2.2 (5)	
Would you take part in a study comparing different treatments?			
Yes			
No	52.6 (120)	67.1 (153)	
Don't Know	23.2 (53)	16.7 (38)	<0.001
No Response	23.6 (54)	14.0 (32)	
	0.4 (1)	2.2 (5)	
Would you participate in a study where treatment was chosen at random?			
Yes			
No	34.6 (79)	51.3 (117)	
Don't Know	37.7 (86)	28.1 (64)	<0.001
No Response	27.2 (62)	18.4 (42)	
	0.4 (1)	2.2 (5)	
Would you participate in a study where you were asked to give a sample of saliva?			
Yes			
Maybe	73.2 (167)	82.9 (189)	
No	8.3 (19)	N/A	
Don't Know	9.6 (22)	10.1 (23)	<0.001
No Response	8.3 (19)	5.3 (12)	
	0.4 (1)	1.8 (4)	

Would you participate in a study where you were asked to give a sample of blood (one small tube)?			
Yes			
Maybe			
No	68.0 (155)	76.3 (174)	
Don't Know	8.3 (19)	N/A	
No Response	13.6 (31)	13.6 (31)	<0.001
	9.6 (22)	7.9 (18)	
	0.4 (1)	2.2 (5)	
Would you participate in a study where you were asked to give a sample of tissue?			
Yes			
Maybe	53.1 (121)	61.4 (140)	
No	10.1 (23)	N/A	
Don't Know	24.1 (55)	25.4 (58)	<0.001
No Response	12.3 (28)	11.0 (25)	
	0.4 (1)	2.2 (5)	

Table 3: Knowledge and Willingness to participate in Cancer Clinical Trials among Participants (n=228).

Discussion

This study employed a community-based participatory model to teach *promotores* to conduct community-based education regarding cancer clinical trials. The study assessed whether, among rural Latinos, a brief, in-person educational intervention was sufficient to increase positive attitudes toward clinical trial research and the willingness of community members to participate in such research, including randomized cancer therapeutic trials and those requiring donation of bio-specimens. Our study found that a brief, educational intervention delivered in community settings by *promotores* was sufficient to produce significant improvements in positive attitudes toward research, willingness to participate in therapeutic and randomized trials, and willingness to donate bio-specimens.

Our cancer clinical trials training for *promotores de salud* offered them the knowledge and skills to recruit and disseminate cancer and cancer clinical trials information to more than 200 people in rural communities. Overall, *promotores* were able to positively impact the community with increased knowledge of clinical trials. This community-based study capitalized on *promotores'* social networks to reach rural participants in areas characterized by a dearth of cancer information resources. Results from the first phase of this study also indicate that the *promotores* had a positive attitude and willingness to participate, which translated into more motivated recruiters educating those reached for one-on-one sessions [24].

Promotores have established efficacy for health promotion in underserved Latino communities [29-32] and are increasingly being engaged with throughout the country to enhance health care when there are cultural and economic barriers to care. This study reinforces this literature and provides evidence that community health workers have the propensity to bridge the gap between cancer centres conducting clinical trials and underserved rural Latinos who may not

know about these trials. The intent of the creation of the National Cancer Institute Community Oncology Program (NCOPR) in 2013 was to bring state-of-the-art cancer research studies to individuals in their communities [33]. However, outreach to minority communities will need to occur to ensure equitable access to this research and associated benefits. CHWs could work with the NCOPR sites and to ensure that underserved communities are aware and informed regarding existing trials in their area. Furthermore, the Affordable Care Act is generating changes in the health care delivery system that encourage active roles for CHWs in state Medicaid programs, e.g., support for receipt of preventive care or self-management of chronic illness [34]. Such CHWs could be trained to link patients and community members to available trials in their area.

Lack of prior studies on clinical trial participation among rural Latinos required heavy community engagement for both development and deployment of the intervention. This research improved community knowledge by empowering *promotores de salud* and by training these individuals to facilitate dissemination of clinical trials information among the rural Latino community in southwest Kansas. Logistical difficulties in reaching underserved Latinos in rural areas were overcome largely due to a well-defined sense of community found in rural localities and towns. These are resources that have been overlooked to a great extent by clinical researchers.

In conclusion, we learned that the ability to influence a broader community is greatly enhanced by setting a strong foundation in networking and training of community leaders. Such a foundation increases the potential for widespread dissemination of cancer clinical trials information. As we increase the number of trials available to ethnic and racial underserved populations in rural areas, trained *promotores* can be advocates to engage the community at large. A community-based community network approach using *promotores de salud* and community-based participatory research methods can help

bridge gaps and overcome barriers to bringing scientific discovery to underserved rural communities. Results are particularly important as *promotores* are increasingly integrated into patient-centred medical homes and other health promotion efforts to deliver more patient-centred care.

Study Limitations

This study had several limitations, first of which was its single group design and lack of randomization and a control group. However, we are aware of no other concurrent community initiatives that might have affected secular changes in attitudes about clinical research. Our study provides intriguing results supporting the effectiveness of community-based *promotor* programs in effecting positive changes in hard-to-reach, underserved communities, especially in areas where time and travel are constant challenges due to geographic dispersion. In our study, these challenges were significant and required additional resources to reach persons in rural areas, such as transportation, constant emails, and repeated phone calls. Another limitation was potential selection bias due to *promotores* only recruiting within their own social network, allowing for a narrower illustration of the community. Further research should be performed to compare results of urban vs. rural communities. It would be important to understand how knowledge, awareness, and interest change based on geography following the same cancer clinical trials training.

Acknowledgements

This research was supported by National Cancer Institute grant no. 1U54CA154253 to Redes en Acción: the National Latino Cancer Research Network and grant no. 1U54CA 153511 to the Kansas Community Cancer Health Disparities Network. We appreciate the efforts of community members, our community partners and *Promotores de Salud* in southwest Kansas, Ms. Dora Ponce, Ms. Rudy Alfaro, Ms. Lucina Perez and Ms. Carmen Castillo.

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