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Recruitment and Retention of Under-represented Groups with Health Disparities Into Clinical Trials: A Formative Approach

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Abstract

Background—We evaluated the perceived success of recruitment and retention protocols for Native Hawaiian/Pacific Islander/Filipino populations. These three groups were found to have a significantly higher incidence of health disparities than the general population. Training applications of selected vignettes were also generated.

Methods—Focus groups and questionnaires were used to achieve the objective: Identification of themes related to facilitators and deterrents to participation in clinical trials in these populations. This mixed methods approach evaluated promotional materials preferred. Responses to animated videos and vignettes with actors regarding clinical research participation were analyzed. Participants included adults of Hawaiian/Pacific Islander or Filipino ethnicity. Analysis included grounded theory methods, such as constant comparative techniques.

Results—The results revealed that attention to the following categories is essential: culturally sensitive knowledge, attitudes, and beliefs related to individuals, families and communities.

Discussion—These themes are recommended as the structure for future interventions to improve participation and retention within these groups.

Keywords

Recruitment; Retention; Clinical Research; Disadvantaged Groups

INTRODUCTION

Successful recruitment and retention strategies are crucial to the success of longitudinal studies, particularly those designed to represent large, national samples such as the National Children's Study (NCS). Prior to the past three decades, recruitment and retention efforts in research studies were rarely evaluated. However, recent studies have engaged communities in efforts to strengthen recruitment and retention. Vignettes have been used, particularly in

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social science research, since the 1950's. Technological advancements have contributed opportunities to translate complex recruitment and retention procedures and protocols of a study into short video vignettes for public review and response. Once developed, vignettes are often complemented with short survey questions to capture audience attitudes, perceptions, beliefs, and norms on a variety of issues. The purpose of this investigation was to generate an understanding of which strategies are most effective in developing materials to target difficult to reach populations, such as Native Hawaiians, Asians and Filipinos.

The following strategies were used to generate the theoretical underpinnings for the vignettes and videos. They evolved from a comprehensive review of the literature (1). Visuals assist participants to understand the action recommended. The following concepts directed the development of these materials:

- The behavior desired was stated clearly in a way that is easy to understand
- The number of messages were limited
- The focus was on behaviors rather than facts
- Videos were used to help visualize instructions
- Videos were less than 8 minutes in duration
- A low reading level and graphics were incorporated
- Objectives were limited to what the reader needed to learn and do.

Headings in advertisements were made clear using bullets, instead of paragraphs, and ample white space was incorporated. Sentences were short and active voice employed; pictures and examples were used to illustrate important points.(2)

Communication can be improved by addressing cultural beliefs and values. However, in populations that are culturally diverse, this is not possible, as "one size may not fit all". Graphics, pictures, and examples were used that attempted to reflect the audience. Materials attempted to incorporate members of the population served in developing strategies and materials.(3)

AIMS

1. Qualitatively assess the linguistic and cultural appropriateness and acceptability of the animated videos among public populations of Native Hawaiian and Pacific Islanders, Asians and Filipinos using focus groups (mothers, fathers, families, men and women).
2. Establish a foundation on which to refine animated and traditional videos that may enhance health literacy among multi-cultural populations with limited research literacy.

METHODS

We used focus groups to evaluate existing recruitment materials and procedures. We also identified resources that are needed in order to effectively recruit participants and generate

materials and strategies that could be used to successfully recruit difficult-to-reach populations, such as: mothers, fathers (living in or out of the home) and family members of Native Hawaiian, Pacific Islanders and Filipinos. Focus groups and key informant interviews were used to assess the acceptability of the videos (animations and vignettes) with these three ethnic groups.

Given the focus of expertise on video vignette development, the University of Louisville created the first draft of each vignette and produced the video versions of each. Scripts were written and shared, critiqued and rewritten by members of the Recruitment and Retention (RR) network of the NCS. In 2011, monthly conference calls and emails were exchanged to create ten different scripts for the vignettes. A request for proposals was advertised for a video production company to provide all technical services and locations and to recruit appropriate actors for all roles in all the vignettes. Once selected, the producer cast all roles with the assistance of local NSC staff. Shooting was scheduled to maximize the use of actors, some of whom were cast multiple times in the same or completely different roles. A single location depicting either the inside or the outside of a family home sufficed for all vignettes. All seventeen vignettes fit on a single DVD and copies were distributed to all Recruitment and Retention study sites. We used vignettes #2 and #5.

Seven versions of the recruitment and retention encounters were finalized. From these, study sites picked from two to six for their own local use in their focus groups based on the time allotted.

A short summary of each vignette produced and distributed throughout the RR follows below:

Vignette #2: Procedure of Focus and Potential Problem Solving

Initial information via community engagement efforts at an enumerated household visit.

Description of vignette—A recruiter comes to the door of an enumerated household, introduces herself, and explains the purpose of her visit. She asks if the residents have heard about NCS and the woman responds that she has. The recruiter listens to the woman and clarifies how she could get involved.

Vignette #5: Procedure of Focus and Potential Problem Solving

Engagement approach.

Description of vignette—The recruiter attempts to enroll a skeptical woman by being open to answering a barrage of questions and delivering the responses in a sympathetic and convincing way.

Additionally, another animated video describing the clinical research process was evaluated and used.

FOCUS GROUP PROCEDURES

Sample

A series of 12 focus group sessions with samples of 8–10 individuals who represented Native Hawaiian, Pacific Islander and Filipino populations were conducted. University of Hawaii Institutional Review Board approval was obtained. Sessions took place at a time and location convenient for the participants.

These groups included male members of couples who were thinking of becoming pregnant, women, mothers, fathers (living in or out of the home), family members and Hawaiian Aunties (a “culturally adopted” relative in Hawaii, related or unrelated by blood, who provides support and education for an individual or group) were of Native Hawaiian and Pacific Islander, or Filipino ancestry. Most had high school educations; the remainder, except for one, had some college. Ages ranged from 10 to 59. The average age was 38. The groups were composed of about 33% men and 66% females. Nearly all lived at home or with family. About 50% were married. Incomes ranged from \$0 to \$5,000 per month, with the average falling in the \$1,501 to \$2,000 per month range. Occupations varied significantly, from psychologist to medical aide; only 2 were unemployed. Nearly all did not own a computer, have internet access, or own a car, and only one had participated in health research.

Methods

A moderator’s guide was developed to script the entire session. Each focus group session included the following activities: 1) group review of the introductory NCS promotional film as background material; 2) group rating of printed images used for RR; 3) group review of selected vignettes for reaction; and 4) collection of basic demographics.

Specific responses requested from participants regarding the vignettes’ thematic areas were as follows: 1) the positive and negative characteristics of the recruiter’s specific words and/or behaviors; 2) the positive and negative characteristics of the interactions and exchanges between the recruiter and the eligible participant; 3) overall positive and negative comments about the vignette and sequence of activities; 4) elements that were perceived missing from the vignette; and 5) summative remarks about NCS. Focus groups were audio taped and transcribed for later analysis.

Analysis

After transcription was complete, participant responses to each of the vignettes used across the network were compiled. The five areas for discussion that were described in the moderator’s guide were used to organize the participant responses across all the sites that used each version of a vignette.

Constant comparative analysis was used to identify themes, and excel spread sheets were used to analyze the responses to the material evaluations. Those generated included community, family, self, knowledge, attitudes, beliefs and structural themes.

Introductory Video—*(These videos are available through the National Children's Study-NCS)*

Appropriate ethnic models are essential. Participants stated that this video was not seen as “Hawaii Friendly” because few persons looked like persons in the Hawaii environment. The pregnant model used was not realistic, and not enough information was provided by the model to the group to identify with her. Some felt the approach was intrusive and not respectful, as personal questions are now asked initially in this community. Few of the respondents liked the Agency's Deputy Director. Most believed more benefits needed to be identified upfront and the benefits described in the video about the National Children's Study were unclear, in comparison to the perceived intrusive nature of the investigation.

Data shows that regardless of race/ethnicity and gender, minority participants perceived lack of information about research as a barrier across all groups to research participation.(2) The acceptability of the animated videos was also compared with traditional videos describing Native Hawaiians/Other Pacific Islanders, and Filipinos in Hawaii.

National Children's Study Vignettes—*(Videos of Vignettes are available through the National Children's Study-NCS)*

The analysis revealed themes as both facilitators and barriers. Knowledge, attitudes and beliefs were revealed in relationship to the community, family and self.

Clearly, materials used to recruit that facilitated enrollment were large images, bold color, large fonts and diversity in people shown in the materials; all were preferred by the majority. “Busy” images (i.e., many people present in the image) were seen as barriers. Use of local pictures were confirmed to promote participation. Most advertisements did not contain images that were seen as culturally appropriate to Hawaii.

THEMES GENERATED, RESPONSES AND RECOMMENDATIONS

Community

Participants suggested that recruiters should be positive and not make the process appear “daunting”. Perhaps recruiters should smile, break messages into small pieces, talk story, make appointments, wear proper identification, and have referrals when possible. In the 2 vignettes viewed, the respondents felt that the benefits were “not made clear to them”. They indicated that some benefit needed to be documented to encourage participation in such a long-term investigation. They also felt that “the purpose was not made clear”. Most suggested that concern regarding scams was seen as a barrier, because the culture has been taken advantage of in the past. They suggested that the NCS representative should have a badge or visible official ID. They also felt that a campaign should occur that describes such “credentials to the community”.

Family

In both the Hawaiian/Pacific Island and Filipino communities, responses included “family will have a significant impact on decisions to participate”. Thus, family should be included

in any recruitment effort. Interestingly, more than one group felt that “families with compromised children would be more likely to participate”.

Self

In the area of knowledge, “clarity of purpose” was cited as of paramount importance. In addition, door-to-door contact was identified consistently as a barrier. Attitudes reflecting “respect for privacy and a need for a culturally-similar appearance of the interviewer” were described as facilitators. Confidentiality and privacy were cited as important values. The recruiter should look like other community members. Beliefs proposed that would facilitate participation included “use of an introductory letter”. Information about how the data would be collected is essential. Use of “sales” approaches were cited as barriers. “Openness, smiling and allowing participants to ask questions” was deemed very important by all focus groups.

Beliefs

Themes related to beliefs revealed the recruiter should be “polite and explain their approach in a respectful manner”. Information should be “limited and time commitments clearly stated. A handout would be useful”. Many respondents revealed they thought better-educated persons were more likely to participate. “Beliefs” incentives revealed a need for them to be clearly articulated. These cultural groups saw door-to-door recruitment as a barrier and felt that recruitment should occur through churches, community centers, businesses, hospitals and doctors’ offices. Any reference to blood samples must be clearly stated. The recruiter was seen as answering the questions and explaining the study effectively. They felt the “words the recruiter used were to-the-point”. However, the setting “did not seem realistic” to some. Most believed the recruiter “should have made an appointment”.

Respondents stated the vignette did not seem real. It “was a little acted” and “disjointed, it should be less forceful and highlight the benefits, privacy and confidentiality”. Other statements were: “Going to homes is intrusive” and that incentives and benefits should include “scholarships, saving bonds and progress reports”. Respondents believed the exact descriptions of how the information would be used should be provided “upfront”. Attitudes included a need to know “how the study would impact the life of the participant”. Respect for people’s need to control their time should be appreciated. Additional comments included: “The 1st video made me feel solicited, and the 2nd video made me feel like a lab rat; credentials “are important”; “people don’t answer the door if they don’t know who it is”; house to house recruitment “is not effective”; recruiters should be “confident and comforting”; “believability and trust” must be established; a timeline would be useful; “respect is the most important value”; it is important to “pass on knowledge to next generation”; “clarity in presentation is important”; “an ID is essential”; confidentiality needs to be “reinforced and preliminary information is essential”(i.e., a pamphlet); communicators “should speak slowly”; in the Hawaiian culture “Aunties will have a great influence”; “Native Hawaiian culture is more compassion and more love”; Hawaiian culture “just opens its arms to anybody”; to be called “an Aunt or Uncle in the Hawaiian culture is out of respect”; “they see from outside”; Hawaiian culture is “about giving without expecting

anything back”; and, if you “can convince the Aunties, then the Aunty can influence the family”, because “they are an extension of you”.

DISCUSSION

Limited health literacy affects people of all ages, races, incomes, and education levels, but the impact of limited health literacy disproportionately affects lower socioeconomic and minority groups. It affects people’s ability to search for and use health information, adopt healthy behaviors, and act on important public health alerts. Limited health literacy is also associated with negative health outcomes and higher costs.

This investigation reinforces seven goals that will improve health literacy and suggests strategies for achieving them:

1. Develop and disseminate health and safety information that is accurate, accessible and actionable.
2. Promote changes in the health care system that improve health information, communication, informed decision making, and access to health services
3. Incorporate accurate, standards-based, and developmentally-appropriate health and science information and curricula in child care and education through the university level.
4. Support and expand local efforts to provide adult education, English language instruction, and culturally and linguistically appropriate health information services in the community.
5. Build partnerships, develop guidance, and change policies.
6. Increase basic research and the development, implementation, and evaluation of practices and interventions to improve health literacy.
7. Increase the dissemination and use of evidence-based health literacy practices and interventions.(4)

Many of the strategies highlight actions that particular organizations or professions can take to further these goals. It will take everyone working together in a linked and coordinated manner to improve access to accurate and actionable health information and usable health services. By focusing on health literacy issues and working together, we can improve the accessibility, quality, safety of health care and also reduce costs.

Between enumeration and face-to-face encounters, there should be minimally invasive communications with potential enrollees, or the relationship may suffer rejection or a short-lived commitment from lack of trust. Respondents stated: “I’ll probably be more interested if I know more details, if you put the full details in the ad, then when you come to my house, let me know all the details, if you can’t let me know all the details, and what you’re really here for then no, I’m not interested. I want details. What are you here for?”

What would you like me to do or say? You know, like that.” Incorporating blood work discussions must receive considerable attention. The blood work, particularly from the

children later in the study, is perceived as a significant risk and barrier. Recruiter characteristics are very important. Tone, appearance, approach with recruitment, retention, and individuals can hinder recruitment and retention.

IMPLICATIONS OF THIS STUDY

Reactions related to the recruiter, the interaction approach, communications about the study, and retention can be considered and incorporated into protocols for the current alternative recruitment sites (where applicable) and in the future main study protocol. The video vignettes had both strengths and weaknesses based on respondent reactions.

LIMITATIONS

Sample sizes were limited. Future work will be needed that incorporates the recruiting methods proposed using larger samples of more diverse participants.

CONCLUSION

All of the vignettes created for this study have potential in that they can serve as stimulus material in training interviewers who are relatively inexperienced with face-to-face recruiting. All are too compact to stand alone as demonstrative of a recruiting encounter and none are ideal examples of what to do or what not to do. Their power is to soften the fear of rejection in gaining access and seeking cooperation from potential enrollees. Trainers should endeavor to select appropriate themes and outcomes to meet the needs of their specific training sessions and improve the health and quality of life of millions of people in the United States.⁽⁵⁾ There were no identifiable differences in knowledge, attitudes or beliefs dependent on ethnicity, except for the information related to Aunties/Uncles and Hawaiian values. Native Hawaiians, Pacific Islanders and Filipinos are all communal cultures and the individual is not placed in importance ahead of the family. This was consistent through all Native Hawaiian, Pacific Islander, and Filipino groups. This was also consistent across all of the NCS groups. In the future, we will develop tool kits and will be submitting for funding to implement additional phases of this investigation.

Scientific knowledge may be advanced by accepting new and novel methods which address the shared barrier of lack of information about clinical research among low research literacy multicultural populations.

The video/vignettes enhance literacy about health research for multicultural populations, since data shows that regardless of race/ethnicity and gender, minority participants perceived that lack of information about research was a barrier across all groups to research participation.

Researchers must quantitatively compare the pre-intervention proportion of populations with health disparities in clinical investigations with post-intervention levels, to determine if the enrollment of these populations has increased when using interventions such as these video vignettes. Hopefully, this will enhance the population's participation and potentially positive health outcomes.

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