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## Improving Awareness of Cancer Clinical Trials Among Hispanic Patients and Families: Audience Segmentation Decisions for a Media Intervention

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### Abstract

Clinical trials hold great promise for cancer treatment; yet, Hispanic cancer patients have low rates of clinical trial participation. Lack of awareness and knowledge of clinical trials and language barriers may account for low participation rates. Patient education through audiovisual materials can improve knowledge of and attitudes toward clinical trials among Hispanic populations. In this study, 36 Hispanic cancer patients/survivors and caregivers in Florida and Puerto Rico participated in focus groups to aid in developing a Spanish-language DVD and booklet intervention designed to increase knowledge about clinical trials. Focus group results showed (a) low levels of knowledge about clinical trials, (b) uncertainty about why a physician would expect a patient to make a choice about treatment, and (c) desire for family participation in decision making. Respondents expressed various preferences for aspects of the DVD such as showing extended family in the DVD and physician explanations about key terms. On the basis of these preferences, the authors developed a creative brief for a DVD. The content of the DVD was reviewed by Hispanic community leaders and key stakeholders. A final DVD was created, in Spanish, using Hispanic patients and physicians, which contained the information deemed important from the

focus groups and stakeholder interviews. The DVD is complete with companion booklet and currently undergoing a randomized control trial.

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Clinical trials hold great promise for cancer treatment and cures; yet, cancer patients—minorities in particular—have low rates of clinical trial participation (Sateren et al., 2002). Several pilot studies have shown this difference may at least in part be explained by a lack of awareness and knowledge about clinical trials among cancer patients (Brown, Fouad, Basen-Engquist, & Tortolero-Luna, 2000; Cox & McGarry, 2003; Verheggen, Nieman, & Jonkers, 1998).

Recent research indicates that racial and ethnic minority populations have been shown to have additional and unique barriers to cancer care services and clinical trials. Knowledge and language barriers are particularly prevalent among Hispanic populations with limited or no English proficiency (American Cancer Society, XXXX; O'Brien et al., 2003; Williams & Flora, 1995). With approximately 45.5 million Hispanics living in the United States, the largest and fastest growing minority group in the United States (Ramirez & de la Cruz, 1997; U.S. Census Bureau, 2000, 2008), there is increased need to develop targeted linguistically and culturally appropriate outreach and educational materials. Improvements in cancer treatment and risk-reduction strategies are inherent upon involving minorities in research, including behavioral research and clinical trials (O'Brien et al., 2003).

Recent research has focused on patient education as a way to increase knowledge of the research process and promote positive attitudes toward clinical trials (Aaronson et al., 1996; Ellis, Butow, & Tattersall, 2002). Some studies have documented that educational information has been successful in increasing accrual to clinical trials across various cancer sites (Albrecht et al., 2003a, 2003b; Eng, Taylor, Verhoef, Ernst, & Donnelly, 2005; Melisko et al., 2005; E. Mills et al., 2006; N. Mills et al., 2003; Quinn et al., 2007). These educational interventions include group educational sessions, individual education sessions, educational booklets, and audiovisual materials (Borrayo, 2004; Cull et al., 1998; Ellis et al., 2002; Hutchison & Campbell, 2002; Hutchison, Cowan, McMahon, & Paul, 2007; Strevel, Newman, Pond, MacLean, & Siu, 2007; Thomas, Daly, Perryman, & Stockton, 2000; Weston, Hannah, & Downes, 1997). Of these, audiovisual materials offer advantages to Hispanic populations in that they have been shown to have high acceptability (Albrecht et al., 2003a), easy dissemination, appeal to low-literacy populations (Albrecht et al., 2003a), and can also be viewed with family (Albrecht et al., 2003a, 2003b; Williams & Flora, 1995).

In addition, studies indicate that health education materials, particularly those with a focus on promoting behavior change, are more successful when “transcreated” and available to the target population in their native language (Bender, Harbour, Thorp, & Morris, 2001; Quinn, Hauser, Bell-Ellison, Rodriguez, & Frias, 2006; Solomon et al., 2005). In transcreated materials, the text is not merely translated into another language; it is reconstructed to meet the health literacy and informational needs of the target audience in a manner that is culturally appropriate. In addition, transcreation involves the infusion of acceptable cultural images, sounds, words, and dialects (Quinn et al., 2006).

Social marketing has been successfully used with a variety of populations to influence knowledge, attitudes, and behaviors for chronic health conditions (Kreuter & Wray, 2003; Quinn et al., 2006; Redding, Rossi, Rossi, Velicer, & Prochaska, 2003). As in commercial marketing, the primary focus is on learning about the consumers' wants and needs. For cancer patients facing uncertainty about different treatment options, there are considerable unmet knowledge and informational needs. The lack of awareness and misperceptions about clinical trials resulting from this information gap can influence decisions not to give consideration to clinical trials as a cancer treatment option. Some theoretical models suggest that emotions felt by the patients and their caregivers while making the decision about a treatment option can combine with outcome expectations and other cost-benefit assessments to lead patients to a decision avoidance mode thus negating options (Miles, Voorwinden, Chapman, & Wardle, 2008). Combining insights gained by applying the constructs identified in psychological theoretical models with social marketing techniques provides an opportunity to identify and address unique barriers related to cancer clinical trials.

Audience segmentation is a key aspect of social marketing, with a focus on the delivery of specific information to a given audience based on the characteristics, preferences and needs of the subjects involved (Rodgers, Chen, Duffy, & Fleming, 2007). Segmenting consists of dividing a large population into smaller manageable groups on the basis of similar demographics, levels of knowledge, or psychographics that may link groups of people together (e.g., previous experience, confidence; Myers, 1996; Urban, 2003). Identification of a segment's media usage and preference is proven to save time and money while reaching the maximum amount of consumers in a health-related setting (Rodgers et al., 2007). For example, in a study of low-income high school students currently living in South Africa, significant differences were found between students of African American origin and students of Indian origin in regard to their respective knowledge about HIV/AIDS and what they felt were sources for accurate advice about HIV. African American students considered nurses to be a credible source, whereas Indian students considered their friends to be credible sources, indicating that spokesperson decisions that are effective with one population may be less effective with another population (Yun, Govender, & Mody, 2001).

The present study aimed to develop a media product to prepare Hispanic cancer patients for decision making about clinical trials using audience segmentation within a social marketing approach.

## Method

### Design and Setting

The target audience for this project was Hispanic cancer patients and caregivers living in Tampa, Florida whose language of preference was Spanish, and cancer survivors and caregivers living on the island of Puerto Rico. This initial audience was selected based on a partnership between Moffitt Cancer Center and the Ponce School of Medicine in Ponce, Puerto Rico. This partnership aims to improve the research skills, cultural competency, and administration of clinical trials between the two institutions. This study was built on the institution's prior work, with English-speaking cancer patients, that was aimed at developing an educational intervention that addressed specific informational needs about clinical trials

identified by this audience. On the basis of literature reviews showing that Hispanic cancer patients have low rates of participation on clinical trials, a preliminary logic model (Lara et al., 2001; Murthy, Krumholz, & Gross, 2004) was developed (see Appendix A). The ultimate goal of this work was to design an intervention that would meet the specific needs of Spanish language preferring cancer patients to enable them to make informed decisions about any clinical trials that may be offered to them in the future. Additional goals included addressing the lack of information and misperceptions, understanding the specific barriers to clinical trial participation among this population and factors that influence the behavior. To achieve the formative research goals, researchers conducted four focus groups, each containing 8–10 participants ( $n = 36$ ). Participants were Hispanic cancer patients/survivors and their caregivers. Two of the focus groups were held at Moffitt Cancer Center in Tampa, Florida, and the other two were held at the Ponce School of Medicine in Ponce, Puerto Rico. The focus groups were conducted in Spanish using a semi-structured focus group guide (see Appendix B). Participants were also shown a compilation of two previously developed educational DVDs focused on clinical trials for Spanish-speaking cancer patients: (a) “Los Estudios Clínicos de Cáncer” by the Center for Information and Study on Clinical Research Participation and (b) El Estudio Clínico ¿Le Conviene o No Participar?” by the Dana-Farber Cancer Institute.

Participants were asked to reflect on the messages, preferences, perceptions, design, and tone of the DVDs. The focus group discussions took place in a private room and were approximately 90 minutes in length. The discussions were guided by a moderator and an assistant moderator previously trained by the investigators. All procedures were approved by the institutional review boards of the University of South Florida and the Ponce School of Medicine.

Focus groups were audiorecorded, and verbatim transcripts were created. The transcripts were systematically coded, using a content analysis and crystallized immersion approach, whereby the researchers reviewed all the transcripts and culled out those aspects most relevant to the objectives (Patton, 2002; e.g., the coding of the text identified common themes relating to preferences for tone, content, and messages for the creation of a DVD on clinical trials for Spanish-speaking patients) and these results were used as a guide to develop a creative brief.

### Participant Recruitment

Candidates for the focus groups included Hispanic cancer patients and their caregivers who reside around Tampa, Florida, or Ponce, Puerto Rico. Eligibility criteria for patients were to (a) be older than 18 years of age; (b) have no documented or observable psychiatric or neurological disorders that would interfere with study participation (e.g., dementia, psychosis); (c) be capable of speaking and reading standard Spanish; (d) have a primary diagnosis of cancer; (e) have completed at least one visit with an oncologist. Eligibility for caregivers was to (a) be older than 18 years of age, (b) have no documented or observable psychiatric or neurological disorders that would interfere with study participation (e.g., dementia, psychosis), (c) be capable of speaking and reading standard Spanish, (d) report

providing care on a regular basis to an individual being treated for cancer in the Tampa Bay area or in Puerto Rico.

Hispanic cancer patients and caregivers in Tampa were recruited through flyers posted throughout Moffitt Cancer Center and at Hispanic community events. Patients and caregivers in Puerto Rico were also recruited through flyers posted at community health related events at the Ponce School of Medicine and local radio programs. Individuals who met the eligibility requirements called a 1–800 number to register for the study. All eligible individuals who gave informed consent were assigned to a focus group. After the discussion, participants were compensated with a US\$25 gift card in recognition of their time.

## Analysis

The focus group discussions were audiorecorded, transcribed, and translated into English by a certified translator. The transcripts were analyzed using qualitative coding. Through content analysis, key themes were organized related to the identified barriers. Basic descriptive data related to demographic and clinical characteristics were summarized using descriptive statistics such as frequencies and distributions (SPSS, version 17.0).

## Results

Table 1 shows sociodemographic characteristics of participants in this study. The majority of participants were above the age of 50 and self identified as Puerto Rican. Of the participants, 75% were female, and 25% were male. Approximately half of the participants were caregivers, and the other half were cancer patients. Breast cancer was the most common type of cancer reported overall by the participants (27.8%). Tampa focus group participants reported an equal number of breast cancer and pelvic/stomach cancer diagnoses, while none of the Puerto Rico participants reported having pelvic/stomach cancer. More than 70% of the participants were diagnosed with cancer between 2005 and 2010.

A summary of the results are provided along with representational quotes from the respondents. There were few differences in responses between the participants living on the island of Puerto Rico and the participants living on the mainland United States. In response to the question, “What comes to mind when you hear the word *clinical trial*?” the majority of participants across all groups did not have an understanding of what clinical trials are, and this was true even among respondents who had participated in a clinical trial. One respondent indicated, “I was in a clinical trial, but I do not really know what it means; I could not explain it to anyone.” The term *clinical trial* (*estudio clínico*, in Spanish) was misunderstood across all groups. For example, the use of the term *clínico* led participants to believe it was a test or procedure conducted at a clinic to diagnose a patient (e.g., PET scan, MRI). One participant said, “During my treatment I had to have several scans, I think in some ways this is like a clinical trial because they were a test which took place in the clinic.” When the moderator explained what a clinical trial was, using additional terms such as *ensayo*, which translates to “test” or “trial,” it became apparent that it was the concept of a clinical trial that respondents did not understand, not necessarily the term. One participant confessed, “I did not know that such a thing happened in medicine. They are testing the drugs on the patients who have cancer? I thought all this testing was done in animals?” The

majority of participants stated that one barrier for them to consider participating in a clinical trial was the lack information targeted to Hispanics in Spanish. Further, respondents recalled the available translated information provided to them on clinical trials when they were a newly diagnosed patient was too scientific for them to understand. One respondent stated, “Oh, my God. I needed help to understand those words in those brochures I was given. I saw words like apoptosis and neoplasm. Still, to this day, I do not understand that.” Another commonly reported barrier to participation was fear, with specific concerns regarding new treatments, unknown drugs, and side effects. In addition, many had worries about the expenses they would be required to cover when participating in a clinical trial. Most participants were not aware of how studies are funded. Most participants agreed that making decisions with the family and doctor was an integral part of cultural decision making. Another important theme that emerged was the expectation that the doctor would make all health care decisions. For example, some participants mentioned that if a clinical trial were relevant for them, their doctor would tell them to participate.

In addition to investigating the knowledge, awareness, and attitudes regarding clinical trial participation, we sampled participant’s perceptions and thoughts on current clinical trial media. This phase of the research yielded highly useful information regarding the creative aspects for the creation of the video and channels for future dissemination. For example, most patients indicated that they would prefer to receive the video during their regular doctor’s appointment and be allowed to take it home to discuss with their family. Participants wanted the video to include a diversity of actors (e.g., various Hispanic looks and diverse accents). The majority of the participants were confused about the clinical trial phases described in the compilation videos they viewed. One participant asked, “Does every patient go through all the phases of the trial 1, 2, 3, 4, or is it the drug that goes through the phases?” All participants thought the current videos were perceived as “respectful,” and this was very important to them. “For me and my family, we appreciate when there is respect for us as a person, especially when you talk about health. I show this same respect to people who come to my business and I expect the same.” Participants noted they liked the imagery they saw in the videos related to spirituality, such as the scenes of a family praying together and the images of a dove. Participants all viewed the people in the videos as trustworthy, except for the one video in which the audio was dubbed into Spanish. The Spanish audio dubbing was regarded as distracting. Participants saw the benefit of having both doctors and cancer patients as spokespeople for the videos. The majority felt strongly that personal stories should be included in the video such as having real patients describe their experiences with getting a cancer diagnosis and the need to participate in treatment decision making:

God forgive me I could think of nothing but the word cancer when I heard my diagnosis. I could not stop to think about anything else, but with a little time, this gets better. It’s important for patients to know that we all go through this and we must take time to adjust to the diagnosis and then we can think about what is the best treatment.

Further, respondents wanted to see more images of what happens to a person in treatment and patients in their home environment, but fewer images of labs and microscopes.

I prefer to see the patients getting the clinical trial treatment—I want to see what that really is.

It would ease people's minds if they could see that a patient gets his treatment and then goes home to his family. They do not have to sleep at the hospital.

The formative research phase generated rich data for the development of the video. Several prevailing concepts from the formative research data were instrumental for refining the preliminary logic model (see Appendix C for the revised, working logic model). First, it was clear that most participants had little understanding about clinical trials. Thus, researchers decided to present clear, concise information about clinical trials to an audience with low levels of knowledge and focus on building knowledge. In our previous work with English speaking cancer patients we identified a number of myths and misperceptions about clinical trials, such as the belief that trials were only for patients who failed standard treatment or that trials were for those who had rare types of cancer, or that the offer of a trial meant the physician had no hope for the patients (Quinn et al., 2007; Wells et al., in press). These concerns were not expressed in the Spanish audience, thus, there was no need to address myths and misperceptions about clinical trials in, the final video. Another important finding was the need to increase efficacy about treatment decision making. Thus, researchers decided that the areas of behavioral focus of the intervention should be (a) encouraging patients to talk to their health care providers about clinical trials, (b) encouraging patients to ask their health care providers questions regarding clinical trials, and (c) supporting patient's ability to make treatment decisions with their family. Also, findings from the formative research indicated it would be necessary to include information about funding sources for clinical trial and/or costs related to participating in a clinical trial. On the basis of study results, the researchers decided that product placement should be at the time of the first appointment with the medical oncologist. To meet participants' desires for diversity, the study team carefully chose patients and physicians for the video with variant Hispanic ethnic backgrounds and accents. Because of the confusion caused by the information presented to participants related to the phases in a clinical trial and randomization patterns, this information was not included in the current video. Researchers decided that the tone of the video should be respectful and include subtle elements of spirituality (e.g., a woman holding a Bible). The spokespeople chosen for the video were physicians in a hospital environment and Hispanic cancer patients in a home environment. The concept of family involvement was also captured by scenes with family interaction.

### **Estudios Clínicos: Considere Todas Sus Opciones**

A final DVD with a 12-page accompanying booklet was created, in Spanish, using Hispanic patients and physicians, which contained the information deemed important from the focus groups (see Appendix B for the focus group guide). The process of development included revising the logic model (see Appendix C for the revised logic model) and preparing a creative brief on the basis of the focus group data. The outline for the content of the DVD and accompanying booklet was reviewed by Hispanic community leaders and key stakeholders. The 8-minute DVD and 12-page booklet were professionally produced through an iterative process of revisions (see Appendix D for the DVD description). A randomized

control trial is underway to explore the feasibility and effectiveness of the multimedia intervention developed by our team.

## Discussion

The present project found no differences in responses between the focus groups conducted in Puerto Rico and those conducted in Tampa, Florida. To our knowledge, there are no qualitative studies comparing health care delivery preferences among Hispanics living on the island of Puerto Rico and Hispanics living on the mainland United States. Consistent with our findings, low levels of knowledge and awareness about clinical trials among Hispanics has been frequently reported in previous studies (Ellington, Wahab, Sahami Martin, Field, & Mooney, 2006; Ford et al., 2008; Killien et al., 2000; Powell, Fleming, Walker-McGill, & Lenoir, 2008). Participants were confused by the translated term *clinical trial* (*estudio clínico*) and the concept behind it and reported having limited or no educational resources about the topic in Spanish; recent studies have documented many Hispanic cancer patients feel intimidated by medical terminology (Garbers & Chiasson, 2004; Shokar, Vernon, & Weller, 2005) and desire culturally relevant information in Spanish (Ellington et al., 2006; Ford et al., 2008). Our audience responded negatively toward the video in which the audio was dubbed; when communicating health-related information to an audience who speaks a foreign language, it is necessary to completely transcreate, rather than simply translate, the materials in order to have the most potent effect on the targeted audience. Transcreation in health education is the process of not only adapting the text of written or oral materials but also infusing culturally relevant context, photos, and themes [27–29].

There were a number of barriers to clinical trials that focus group participants reported. With respect to fear, many studies have documented that fear is an important barrier to clinical trial participation among all patients, regardless of race, ethnicity, or gender (Ford et al., 2008; Giuliano et al., 2000), leading to information/decision-avoidance in some cases (Miles et al., 2008). It is not surprising cost was a barrier cited by participants in each group. Expenses involved in clinical trials are commonly reported as a barrier by cancer patients of all ethnic backgrounds (Ellington et al., 2006; Ford et al., 2008; McCaskill-Stevens, McKinney, Whitman, & Minasian, 2005).

The focus groups also pointed to cultural aspects of decision making that were important to address in the intervention materials. Our study found that a patient's family plays an integral role in health care decision making and course of treatment. This is a similar finding to other studies with cancer patients in general (Albrecht et al., 2008; Elit et al., 2009). In addition, patients reported an expectation for the doctor to guide them in health care decisions. These findings are similar to previous studies reporting that Spanish-speaking patients prefer group decision making involving opinions of family members in addition to recommendations made by the physician (Ellington et al., 2006). Latino culture puts strong value in the central role of the family even in everyday life; thus, during an illness, the family fulfills a crucial role (Vega, Kolody, Valle, & Weir, 1991). It is not surprising then that patients wanted the opportunity to take the video home and discuss it with their family. Furthermore, Latinos value the following traditions: communitarism, solidarity, and therole of the extended family. Given the importance of these traditions, health professionals may be



seen as figures of authority, with the expectation that they would provide advice, guidance, and recommendations about medical matters (Penchaszadeh, 2001). Patients described the video compilation as “respectful,” which seems to be important for this group of Hispanic patients. In Hispanic culture, the concept of respect implies an adherence to lines of authority and the importance of showing it to others (Penchaszadeh, 2001). The spokespeople chosen for the video were physicians and patients, which is consistent with a study conducted by Quinn et al., in which participants stated that health care providers would be the most reliable source of information in an educational campaign. The same study also found participants wanted to see patient testimonials as part of the campaign because it would appeal to them on a personal level (Quinn, McIntyre, & Vadaparampil, XXXX).

### **Limitations of the Study**

It is important to note that the majority of participants were female and self-identified as Puerto Rican so the results are not representative of the entire Hispanic population. Although the study was open to all cancer patients, the majority who chose to participate were of self-reported Puerto Rican ethnicity. Another limitation of this study is the combination of cancer patients and caregivers in the focus groups. There may have been some distinctions between the answers given by the cancer patients and caregivers if they had been interviewed in separate focus groups, however patients did not wish to be separated from their caregivers. In addition, we did not collect data on the socioeconomic levels of this participants and this information may have an influence on the knowledge and seeking of clinical trials.

### **Conclusion**

Results show a need to present culturally tailored information for specific audiences. These results guided the development of a Spanish video specifically focused on meeting the information and cultural needs of Hispanic cancer patients and addressing the barriers to participation in clinical trials. The DVD and booklet intervention is currently undergoing a randomized control trial to evaluate its effectiveness in improving patients’ perceptions regarding clinical trials.

## **Appendix A: Preliminary Logic Model for Cancer Clinical Trials Video**

### **Target audience**

- Hispanic cancer patients and care givers

### **Desired behavior**

- Increase cancer clinical trial participation

### **Behavioral determinants to address**

- Increase knowledge
- Increase awareness

- Dispel myths about clinical trials

### Benefits to promote

- Enable patients to make informed decisions about health
- Provide most advanced treatment to cancer patients
- Contribute to development of new treatment options

### Product/service placement

- Clinics, hospitals, cancer centers

### Information placement

- New cancer patient information packet

## Appendix B: Focus Group Guide

### Section I: General: Perception of Clinical Trials

1. When I say the words, “clinical trial” what comes to mind? (*Probe:- images, ideas, thoughts, etc ....*).
2. What kinds of research studies or clinical trials have you heard about? (*If none, skip to question #3*)
  - 2a. Where did you hear about these kinds of studies? (*Probe:., media, family, friend, MD ...*)
3. In your own words how would you describe a clinical trial to a friend? / What would be the best way to describe this type of research study to other patients or caregivers? Are there certain words that would help more people understand?
 

[If respondents do not have a good understanding of clinical trials [based on responses to questions #1–3] skip to question Section II]
4. In your opinion, why are clinical trials done?
5. Who usually takes part in research studies or clinical trials? (Let respondent reply; then probe:., only sick, healthy and sick, women/men, as last resort, etc ...).
 

Probe: Why do you think a patient would be offered a clinical trial/what are some of the reasons a patient might be offered a clinical trial?
6. What are some of the reasons that you might not want to take part in a research study or clinical trial? (*Barriers*)
7. What are some of the reasons that you might want to take part in a research study or clinical trial? (*Benefits*)
8. Where do you think you can find out information about taking part in a research study/clinical trial (*e.g., MD, clinic, nurse, television, etc.?*)

## Section II: Experience with Clinical Trials/Decision Making

9. Have you ever been asked to participate in a clinical trial or medical research study?

**If YES,**

9a. Please describe how you made the decision to take part/or not take part in this trial.

9b. What are some of the reasons that made you decide to/or not to take part in this trial?

(Probe: What were the things you took into consideration?/What were the things you considered?)

9c. When you made your decision to take part/or not take part in the clinical trial, who or what helped you to make your decision? (*Probes: Certain people, books, other print material, Internet serve as helpful in decision-making?*)

9d. If the person has participated in clinic trial ask: What was the experience like?

**If NO, Skip to next section, Section III .**

## Section III: Review Sample Videos

### Interviewer

We'd like you to watch a brief video about clinical trials. Afterward we will ask you some questions about it. Please use this note pad to jot down any questions or comments that come to mind as you watched it. If you feel like you need a break, please tell me so and we'll do so.

### PLAY VIDEO/DVD PLAYER

10. What is your overall impression of the clips you just saw?

10a. What do you think is the main message of this video?

10b. What did you like best about the video?

(After response also probe for: family, music, religion & setting-[house or hospital/clinic])

10c. What did you like least about the video?

(After response also probe for: family, music, religion & setting-[house or hospital/clinic])

11. Does this video help you to understand what a clinical trial is?

11a. If you have participated in a research study or clinical trial, does this video accurately portray your experience?

12. What did you think about the message of the video?

12a. Was the video asking you to do anything?

12b. Is there anything about the message that bothers you?

12c. Is there anything about the message and the way it is presented that you don't like?

12d. What better way might we show this information?

12e. Would you want to watch an informational video like this?

13. Which of these words best describes the feeling of the video?

13a. Was it serious? Light-hearted? technical? Boring? What word would you use?

13b. Does the feeling of video fit with the message?

13c. What should *be the* overall feeling of an informational video about clinical trials?

14. Were the people in the video believable?

14a. Was the information credible/trustworthy?

If yes, what made it so? If no, why not?

14b. Who is the best person to give information about clinical trials? / Who would you like to see present this information (*probe for patients, doctors, variety*)

15. Was there a good balance of personal stories and facts?

15a. Which would you rather see more of?

16. What other things would you like to see in a video that would help patients understand more about clinical trials?

17. Please tell me about the types of information that would be most helpful to include in the video (facts, personal stories, etc).

## Appendix C: Working Logic Model for Cancer Clinical Trials Video

### Target audience

- Hispanic cancer patients and care givers with low levels of knowledge about clinical trials

### Desired behavior

- Talk to health care provider about clinical trials
- Ask questions
- Make health care decisions with family

### Behavioral determinants to address

- Increase knowledge
- Increase awareness
- Build confidence about health care decision making

- Role of the family

### **Benefits to promote**

- Resources to learn more about clinical trials
- Ability to make informed decisions about clinical trial participation
- Methods to include family involvement in health care decisions

### **Product/service placement**

- Oncologist appointment

### **Information placement**

- Hispanic cancer patient's information packet

## **Appendix D: DVD Description**

### **Chapter 1: Clinical trials: Consider all your options**

In this chapter, patients are informed about the existence and availability of clinical trials. Patients are informed that researchers are able to explore alternative treatments for cancer using data obtained in clinical trials. This content is covered in the video through the use of patient's stories and real physicians describing, in interview style, what a clinical trial entails.

### **Chapter 2: What is a clinical trial?**

Two Moffitt physicians provide definitions of a clinical trial. They describe it as an opportunity for a better treatment, or as an alternative treatment for cancer.

### **Chapter 3: Is a clinical trial equivalent as a diagnostic exam?**

One physician emphasizes the difference between a clinical trial and a diagnostic exam by providing definitions of each term and examples.

### **Chapter 4: How do I know if a Clinical Trial is harmless?**

The process of designing new treatments and medicines toward cancer are explained in this chapter. One physician explains ethical considerations taken in clinical trials by which research protocols that test medicines and treatments must undergo approval by the Institutional Review Board (IRB) before reaching patients. Moreover, the physician explains that if a research design is harmful to patients, the IRB will decline the study. In this chapter, patients are reminded that their safety is our priority.

## Chapter 5: What is an informed consent?

The significance of an informed consent is explained by physicians. Patients are told that an informed consent can be reviewed at home, with their family members. Patients have the opportunity to decline a clinical trial if not interested; participation in a clinical trial is optional and ultimately is the patient's decision. If a patient signs an informed consent, and later decides not to participate, the patient can withdraw from the research study.

## Chapter 6: What should I do?

In this chapter, our video encourages patients to ask questions regarding a clinical trial and emphasizes that participation is optional and ultimately a personal decision. This chapter shows testimonies of some patients who agreed to participate in a clinical trial and some who chose not to. Survivor stories encourage patients and family members to ask questions and advocate for themselves. This chapter shows silent images families looking at the computer together, researching information, and reading a bible as they reflect on decisions.

## Chapter 7: What should I expect from my doctor?

Our video explains physicians and researchers responsibilities. This chapter focuses on patients' testimonies regarding clinical trial participation. Patients' testimonies indicate that good communication with physicians plays a key component in deciding about clinical trial participation.

## Chapter 8: What should I expect, if I decide to participate in a clinical trial?

During testimonies, patients explain the support they received from their physicians in deciding whether or not to participate. Chapter 8 describes costs related to clinical trials, and explains that costs should not be an impediment to clinical trial participation. Patients are encouraged to speak to their physicians if cost is an inconvenience. Our video highlights patient's reactions towards clinical trial participation and encourages patients to ask and seek information about clinical trials.

## References

- Aaronson N, Visser-Pol E, Leenhouts G, Muller M, Van Der Schot A, Van Dam F. Telephone-based nursing intervention improves the effectiveness of the informed consent process in cancer clinical trials. *Journal of Clinical Oncology*. 1996; 14:984. [PubMed: 8622050]
- Albrecht T, Ruckdeschel J, Riddle D, Blanchard C, Penner L, Coovert M. Communication and consumer decision making about cancer clinical trials\* 1. *Patient Education and Counseling*. 2003a; 50(1):39-42. [PubMed: 12767583]
- Albrecht T, Ruckdeschel J, Riddle D, Blanchard C, Penner L, Coovert M. Discussing clinical trials with cancer patients. *Medical Encounter*. 2003b; 15:26-30.
- American Cancer Society. *Cancer Facts & Figures for Hispanics/Latinos*. (XXXX).
- Bender D, Harbour C, Thorp J, Morris P. Tell me what you mean by "si": Perceptions of quality of prenatal care among immigrant Latina women. *Qualitative Health Research*. 2001; 11:780. [PubMed: 11710077]

- Borrayo E. Where's Maria? A video to increase awareness about breast cancer and mammography screening among low-literacy Latinas. *Preventive Medicine*. 2004; 39(1):99–110. [PubMed: 15207991]
- Brown D, Fouad M, Basen-Engquist K, Tortolero-Luna G. Recruitment and retention of minority women in cancer screening, prevention, and treatment trials. *Annals of Epidemiology*. 2000; 10(8 Suppl):S13. [PubMed: 11189088]
- Cox K, McGarry J. Why patients don't take part in cancer clinical trials: An overview of the literature. *European Journal of Cancer Care*. 2003; 12:114–122. [PubMed: 12787008]
- Cull A, Miller H, Porterfield T, Mackay J, Anderson E, Steel C. The use of videotaped information in cancer genetic counselling: A randomized evaluation study. *British Journal of Cancer*. 1998; 77:830. [PubMed: 9514066]
- Ellington L, Wahab S, Sahami Martin S, Field R, Mooney K. Factors that influence Spanish and English speaking participants' decision to enroll in cancer randomized clinical trials. *Psycho Oncology*. 2006; 15:273–284. [PubMed: 15973647]
- Ellis P, Butow P, Tattersall M. Informing breast cancer patients about clinical trials: A randomized clinical trial of an educational booklet. *Annals of Oncology*. 2002; 13:1414. [PubMed: 12196367]
- Eng M, Taylor L, Verhoef M, Ernst S, Donnelly B. Understanding participation in a trial comparing cryotherapy and radiation treatment. *The Canadian Journal of Urology*. 2005; 12:2607. [PubMed: 15877944]
- Ford JG, Howerton MW, Lai GY, Gary TL, Bolen S, Gibbons MC. Barriers to recruiting underrepresented populations to cancer clinical trials: a systematic review. *Cancer*. 2008; 112:228–242. [PubMed: 18008363]
- Garbers S, Chiasson M. Inadequate functional health literacy in Spanish as a barrier to cervical cancer screening among immigrant Latinas in New York City. *Preventing Chronic Disease*. 2004; 1(4):1–10.
- Giuliano A, Mokuau N, Hughes C, Tortolero-Luna G, Risendal B, Ho R. Participation of minorities in cancer research: the influence of structural, cultural, and linguistic factors. *Annals of Epidemiology*. 2000; 10(Suppl. 8):S22. [PubMed: 11189089]
- Hutchison C, Campbell S. Evaluation of an information booklet for patients considering participation in phase I clinical trials in cancer. *European Journal of Cancer Care*. 2002; 11:131–138. [PubMed: 12099949]
- Hutchison C, Cowan C, McMahon T, Paul J. A randomised controlled study of an audiovisual patient information intervention on informed consent and recruitment to cancer clinical trials. *British Journal of Cancer*. 2007; 97:705–711. [PubMed: 17848908]
- Killien M, Bigby J, Champion V, Fernandez-Repollet E, Jackson R, Kagawa-Singer M. Involving minority and underrepresented women in clinical trials: the National Centers of Excellence in Women's Health. *Journal of Women's Health & Gender-Based Medicine*. 2000; 9:1061–1070.
- Kreuter M, Wray R. Tailored and targeted health communication: Strategies for enhancing information relevance. *American Journal of Health Behaviour*. 2003; 27(Suppl. 3):227–232.
- McCaskill-Stevens W, McKinney M, Whitman C, Minasian L. Increasing minority participation in cancer clinical trials: The Minority-Based Community Clinical Oncology Program experience. *Journal of Clinical Oncology*. 2005; 23:5247. [PubMed: 16051967]
- Melisko M, Hassin F, Metzroth L, Moore D, Brown B, Patel K. Patient and physician attitudes toward breast cancer clinical trials: developing interventions based on understanding barriers. *Clinical Breast Cancer*. 2005; 6(1):45–54. [PubMed: 15899072]
- Miles A, Voorwinden S, Chapman S, Wardle J. Psychologic predictors of cancer information avoidance among older adults: The role of cancer fear and fatalism. *Cancer Epidemiology Biomarkers & Prevention*. 2008; 17:1872.
- Mills E, Seely D, Rachlis B, Griffith L, Wu P, Wilson K. Barriers to participation in clinical trials of cancer: a meta-analysis and systematic review of patient-reported factors. *The Lancet Oncology*. 2006; 7:141–148. [PubMed: 16455478]
- Mills N, Donovan J, Smith M, Jacoby A, Neal D, Hamdy F. Perceptions of equipoise are crucial to trial participation: a qualitative study of men in the Protect study. *Controlled Clinical Trials*. 2003; 24:272–282. [PubMed: 12757993]

- Myers J. Segmentation and positioning for strategic marketing decisions. 1996
- O'Brien K, Cokkinides V, Jemal A, Cardinez C, Murray T, Samuels A. Cancer statistics for Hispanics, 2003. *CA: A Cancer Journal for Clinicians*. 2003; 53:208–226. [PubMed: 12924775]
- Penchaszadeh VB. Genetic counseling issues in Latinos. *Genetic Testing*. 2001; 5:193–200. [PubMed: 11788084]
- Powell J, Fleming Y, Walker-McGill C, Lenoir M. The project IMPAclinical trial experience to date: Increasing minority participation and awareness of clinical trials. *Journal of the National Medical Association*. 2008; 100:178–187. [PubMed: 18300535]
- Quinn G, Bell B, Bell M, Caraway V, Conforte D, Graci L. The guinea pig syndrome: improving clinical trial participation among thoracic patients. *Journal of Thoracic Oncology*. 2007; 2:191. [PubMed: 17410041]
- Quinn G, Hauser K, Bell-Ellison B, Rodriguez N, Frias J. Promoting pre-conceptual use of folic acid to Hispanic women: A social marketing approach. *Matern Child Health Journal*. 2006; 10:403–412.
- Quinn G, McIntyre J, Vadaparampil ST. Preferences for hereditary breast and ovarian cancer information among Mexican, Cuban and Puerto Rican women at risk. *Public Health Genomics*. (XXXX).
- Ramirez R, de la Cruz G. The Hispanic population in the United States: March 2002. *Federal Register*. 1997; 62:280.
- Redding C, Rossi J, Rossi S, Velicer W, Prochaska J. Health behavior models. *International Electronic Journal of Health Education*. 2003; 3:180–193.
- Rodgers S, Chen Q, Duffy M, Fleming K. Media usage as health segmentation variables. *Journal of Health Communication*. 2007; 12:105–119. [PubMed: 17365354]
- Sateren W, Trimble E, Abrams J, Brawley O, Breen N, Ford L. How sociode-mographics, presence of oncology specialists, and hospital cancer programs affect accrual to cancer treatment trials. *Journal of Clinical Oncology*. 2002; 20:2109. [PubMed: 11956272]
- Shokar NK, Vernon SW, Weller SC. Cancer and colorectal cancer: Knowledge, beliefs, and screening preferences of a diverse patient population. *Family Medicine*. 2005; 37:341–347. [PubMed: 15883900]
- Solomon F, Eberl-Lefko A, Michaels M, Macario E, Tesauro G, Rowland J. Development of a linguistically and culturally appropriate booklet for Latino cancer survivors: lessons learned. *Health Promotion Practice*. 2005; 6:405. [PubMed: 16210682]
- Strevel E, Newman C, Pond G, MacLean M, Siu L. The impact of an educational DVD on cancer patients considering participation in a phase I clinical trial. *Supportive Care in Cancer*. 2007; 15:829–840. [PubMed: 17177040]
- Thomas R, Daly M, Perryman B, Stockton D. Forewarned is forearmed. Benefits of preparatory information on video cassette for patients receiving chemotherapy or radiotherapy: A randomised controlled trial. *European Journal of Cancer*. 2000; 36:1536–1543. [PubMed: 10930801]
- Urban, G. *Digital marketing strategy: text and cases*. Upper Saddle River, NJ: Prentice Hall; 2003.
- U.S. Census Bureau. Population Projection Program Population Division (NP-D1-A). Washington DC: Author; 2000. Projections of the resident population by age, sex, race, and Hispanic origin: 1999 to 2100.
- U.S. Census Bureau. Hispanic population of the United States. 2008. Retrieved from <http://www.census.gov/population/www/socdemo/hispanic/hispanic.html>
- Vega WA, Kolody B, Valle R, Weir J. Social networks, social support, and their relationship to depression among immigrant Mexican women. *Human Organization*. 1991; 50:154–162.
- Verheggen F, Nieman F, Jonkers R. Determinants of patient participation in clinical studies requiring informed consent: Why patients enter a clinical trial. *Patient Education and Counseling*. 1998; 35:111–125. [PubMed: 10026554]
- Weston J, Hannah M, Downes J. Evaluating the benefits of a patient information video during the informed consent process. *Patient Education and Counseling*. 1997; 30:239–245. [PubMed: 9104380]
- Williams J, Flora J. Health behavior segmentation and campaign planning to reduce cardiovascular disease risk among Hispanics. *Health Education & Behavior*. 1995; 22(1):36.



Yun H, Govender K, Mody B. Factoring poverty and culture into HIV/AIDS campaigns. *International Communication Gazette*. 2001; 63(1):73.

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**Table 1**Sociodemographic characteristics of study participants, *n* (%)

	All ( <i>N</i> = 36)	Tampa, Florida ( <i>n</i> = 15)	Puerto Rico ( <i>n</i> = 21)
<i>Sociodemographic characteristics</i>			
Age (years)			
18–30	2 (5.6)	0 (0)	2 (9.5)
31–49	9 (25.0)	3 (20.0)	6 (28.6)
50+	25 (69.4)	12 (80.0)	13 (61.9)
Gender			
Male	9 (25.0)	3 (20.0)	6 (28.6)
Female	27 (75.0)	12 (80.0)	15 (71.4)
Country of origin			
Puerto Rico	28 (77.8)	8 (53.3)	20 (95.2)
Colombia	3 (8.3)	3 (20.0)	0 (0)
United States	1 (2.8)	0 (0)	1 (4.8)
Nicaragua	1 (2.8)	1 (6.7)	0 (0)
Ecuador	1 (2.8)	1 (6.7)	0 (0)
El Salvador	1 (2.8)	1 (6.7)	0 (0)
Cuba	1 (2.8)	1 (6.7)	0 (0)
Education			
Less than high school	7 (19.4)	2 (13.3)	5 (23.8)
High school or more	27 (75.0)	11 (73.3)	16 (76.2)
Not available	2 (5.6)	2 (13.3)	0 (0)
<i>Medical characteristics</i>			
Patient	16 (44.4)	6 (40.0)	10 (47.6)
Caregiver	20 (55.6)	9 (60.0)	11 (52.4)
Type of cancer diagnosis			
Pelvic/stomach	4 (11.1)	4 (26.7)	0 (0)
Breast	10 (27.8)	4 (26.7)	6 (28.6)
All	1 (2.8)	1 (6.7)	0 (0)
Prostate	3 (8.3)	1 (6.7)	2 (9.5)
Colorectal	2 (5.6)	0 (0)	2 (9.5)
Lymphatic	2 (5.6)	1 (6.7)	1 (4.8)
Pulmonary with metastasis to bone	2 (5.6)	0 (0)	2 (9.5)
Pancreas	2 (5.6)	0 (0)	2 (9.5)
Ovarian	2 (5.6)	0 (0)	2 (9.5)
Multiple myeloma	2 (5.6)	0 (0)	2 (9.5)
Brain	2 (5.6)	0 (0)	2 (9.5)
Leukemia	1 (2.8)	1 (6.7)	0 (0)
Bones and stomach	1 (2.8)	1 (6.7)	0 (0)
Colon	1 (2.8)	1 (6.7)	0 (0)
Not available	1 (2.8)	1 (6.7)	0 (0)

	All (N = 36)	Tampa, Florida (n = 15)	Puerto Rico (n = 21)
Year of cancer diagnosis			
1980–1994	3 (8.3)	1 (6.7)	2 (9.5)
1995–1999	2 (5.6)	2 (13.3)	0 (0)
2000–2004	5 (13.9)	4 (26.7)	1 (4.8)
2005–2010	26 (72.2)	8 (53.3)	18 (85.7)

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