

APPLICATION OF QUALITATIVE ANALYSIS PROCEDURES TO UNDERSTAND THE PERSPECTIVES OF HIV⁺ LATINAS ON PARTICIPATION IN CLINICAL TRIALS

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Currently, HIV+ Latinas are poorly represented in clinical trials. In order to improve recruitment of HIV+ Latinas in clinical trials it is important to learn about their concerns and perceptions towards clinical trials. One method of accessing such information is by collecting qualitative data through open-ended responses in surveys. The present study involves review of open-ended qualitative data from surveys conducted with HIV+ Latina women in San Diego County. Data analysis for this project applies qualitative analysis techniques that are used in research to identify themes, similarities, and trends in information that is in a text format versus numerical format. This project assessed potential causes of lack of HIV+ Latina participation in clinical trials with the goal of understanding barriers and facilitators of participation that may need to be considered in future research and recruitment activities.

HIV is a relatively new disease to human beings, having been identified in populations in the 1970's (Insel & Roth, 2001). It is one of the most serious health issues in the U.S. and around the world. It is estimated that more than 57 million people, that is almost 1% of the world's population, have been infected since the start of this epidemic. When the HIV/AIDS epidemic first began many did not understand the severity of the disease due to lack of information on its short and long-term health impact. As a result, various research studies and clinical trials have been designed and performed. The problem however, is that these research studies have predominantly been done with Non-Hispanic White males. Yet, HIV and AIDS are having an increasing impact on mortality and quality of life for women and minorities in the United States (Stone, Mauch, Steger, Janas, & Craven,). The Center for Disease and Control and Prevention (CDC) reported in 1995 that 15% of all reported AIDS cases in the U.S. were Hispanics. Just two years later, in 1997, that number went up to 18% (Lynch, Vincent J., 2000). Currently, AIDS is now the third leading cause of death for all U.S. women between the ages of 25 to 44 years (Stone, Mauch, Steger, Janas, & Craven,). As a result, we are now seeing health disparities in HIV and AIDS where researchers have noted differences in how the disease impacts different ethnic and racial minorities, differences in access to health care, and differences in representation of minority populations in clinical trials.

Disparities in health care exist when membership of a racial or other social group is associated with health care treatment or outcomes in a way that is unjustified by the fundamental need of the patient (Balsa & McGuire, 2003). In other words, health disparities exist because there is a lack of research and knowledge on the effects of health issues in different racial/ethnic groups and by gender and because we observe differences in health outcomes in affected communities.

There are many factors that contribute to the existence of health disparities. Some can be credited to social factors such as the high number of uninsured minorities, the lack of transportation to inner city medical clinics, or even over representation of minorities in Medicaid health plans that have limiting payment policies (Balsa & McGuire, 2003). Another factor is the lack of participation in clinical trials. For example, Roberson (1994) studied racial/ethnic groups' views and opinions about clinical trial participation and found that there are a large number of members of racial/ethnic groups that are underrepresented in cancer clinical trials. He concluded that there are cultural or other barriers that may affect the participation of members of these groups in clinical trials and suggests that to improve minority participation, researchers need to develop strategic planning that targets the study population (Roberson, 1994).

The under-representation of racial and ethnic minorities in clinical trials is very much evident in HIV and AIDS clinical trials. This is due to various reasons such as, not being informed about the trials, lack of interest, fears that arise due to the stigma that the word "experiment" carries, cultural differences, and language barriers. It is very important that participation increase so that studies can understand how the treatments may differ in different populations and so that a broader segment of the population can have better access to care and new treatments and not just a small proportion. In order for participation in clinical trials to increase researchers need to identify the key factors that keep patients from participating. This study focuses on the perspectives of HIV+ Latinas in the San

Diego region. A structured survey with a subset of open-ended questions to let women participants freely express themselves and their concerns through a qualitative approach was used in addition to using closed-ended questions.

The main goal of the present study is to use open-ended data to identify the concerns and perceptions about clinical trials in a group of HIV+ Latina women. In addition to that would be to evaluate open-ended qualitative data from surveys and to then identify themes and similarities within the women's responses.

Methods

This cross sectional study used an interviewer-administered survey with HIV+ Latinas to explore their knowledge, attitudes and experiences with participation in clinical trials. A trained interviewer who is both bilingual (English/Spanish) and bicultural read each participant a voluntary consent statement and administered the survey to volunteer participants. This project was approved by the UCSD Human Research Protections Program (<http://irb.ucsd.edu/>).

Participants

A total of forty HIV+ Latina women were recruited from three clinic sites in San Diego County. Recruitment sites included: University of California, San Diego (UCSD) Mother Child and Adolescent HIV Program the San Ysidro Health Center and the UCSD Owen Clinic. Potential participants were by a clinic staff liaison to the study, which made the initial contact with the potential participant. Each woman was read a voluntary consent statement in the language of her choice (English or Spanish) and was offered a token of appreciation of \$10 for her participation.

Procedures

As part of a broader study the following three open-ended questions were selected for analysis from a 29-item survey.

Question 1

What do you think a clinical trial is?

Question 7

What comes to mind when you hear the words "clinical trial," "drug study," or "medical study"?

Question 11

Of all the people who you are in touch with, who would you most trust to refer you to a clinical trial?

Codes

Upon thorough data analysis and review, the following codes were given to the following three questions.

Question 1: What do you think a clinical trial is?

- 1 = High level of knowledge of clinical trials
- 2 = Medium level of knowledge of clinical trials
- 3 = Low/No level of knowledge of clinical trials

Question 7: What comes to mind when you hear the words "clinical trial," "drug study," or "medical study"?

- 1 = Medication/Drugs
- 2 = Getting blood drawn
- 3 = Being experimented on/Guinea Pig

- 4 = Research
- 5 = Misc. responses

Question 11: Of all the people who you are in touch with, who would you most trust to refer you to a clinical trial?

- 1 = Doctor
- 2 = Nurse
- 3 = Case managers
- 4 = Clinic Staff
- 5 = Family/Friends
- 6 = Other

As a result of several responses given to question 11, it was decided by the study team to break down question 11 into three subgroups to avoid biases and preferences to specific responses. In this way, each response is recorded in the order it was given.

Once the questions had been selected, a review of the qualitative responses from each of the three questions was conducted. Patterns and similarities were identified and major themes were chosen. To assure quality assurance and avoid any biases, the study team reviewed the major themes and reached consensus on responses that may have been vague or difficult to understand. Upon thorough review of the qualitative data a coding scheme was developed for the three selected open-ended questions. Following the development of a coding scheme for each question, all forty responses to each question was coded, entered into a database, and analyzed.

Results

The population consisted of a predominantly Mexican-origin and Spanish-language dominant group of women. Of the forty participants 75% (30/40) chose to answer the survey in Spanish. The range of ages was between 21 to 60 years of age with an average age of 38 years. All forty participants answered all three questions. For one question, seven gave two responses and two participants gave three responses. Tables 1-5 show the results for the three questions analyzed.

Table 1. Q.1 What do you think a clinical trial is?

		Frequency	Valid Percent
Valid	High level of knowledge	30	75
	Medium level of knowledge	5	12.5
	Low/no level of knowledge	5	12.5
	Total	40	100

When participants were asked to describe what they thought a clinical trial was about, 70% of respondents (30/40) appeared to have a relatively high level of knowledge about clinical trials. About 12% (5/40) had a medium level of knowledge and the same amount of respondents appeared to have little or no knowledge.

Table 2. Have you ever participated in an HIV/AIDS clinical trial?

		Frequency	Valid Percent
Valid	Yes	24	60
	No	16	40
	Total	40	100

When participants were asked if they had participated in an HIV/AIDS clinical trial, 60% (24/40) of the respondents answered yes and 40% (16/40) answered no.

Table 3. Q7. What comes to mind?

		Frequency	Valid Percent
Valid	Medication/drugs	13	32.5
	Getting blood drawn	6	15
	Being experimented on/Guinea pig	4	10
	Research	8	20
	Other response	9	22.5
	Total	40	100

When participants were asked to express what they associate with clinical trials, 32.5% of the respondents (13/40) said medication and/or drugs. Approximately 15% of the respondents (6/40) gave an answer of getting their blood drawn. Only 10% (4/40) associate the term with being experimented on, 20% (8/40) referred to it as research, and finally 22.5% (9/40) gave miscellaneous responses.

Table 4. Q11. People trusted to refer

		Frequency	Valid Percent
Valid	Doctor	16	37.5
	Nurse	6	15
	Case manager/Social Worker	10	25
	Clinic personnel	3	7.5
	family	4	10
	other	2	5
	Total	40	100

When participants were asked who they trusted most to refer them to a clinical trial, 37.5% of the respondents (16/40) said they trusted their doctor, 15% (6/40) said they trusted their nurse/nurse practitioner, 25% (10/40) trust their case manager/social worker, 7.5% (3/40) trust the clinic personnel, only 10% (4/40) trust members of their family, and 5% (2/40) gave miscellaneous responses.

Table 5. Q11b. People trusted to refer

		Frequency	Percent	Valid Percent
Valid	Doctor	2	5	28.6
	Nurse	3	7.5	42.9
	Case manager/Social Worker	2	5	28.6
	Total	7	17.5	100
Missing	System	33	82.5	
Total		40	100	

This table shows that 17.5% of the respondents (7/40) gave two answers to question 11. Of those seven participants, 42.9% (3/7) said they trust their nurse/nurse practitioner as a second response. Approximately 28.6% (2/7) said they trust their doctor and the same goes for case manager/social worker.

Table 6. Q11c. People trusted to refer

		Frequency	Percent	Valid Percent
Valid	Nurse	1	2.5	50
	Other	1	2.5	50
	Total	2	5	100
Missing	System	38	95	
Total		40	100	

This table shows that only 5% of the respondents (2/40) gave a third response when asked who they trust most to refer them to a clinical trial. One said she trust the nurse/nurse practitioner and the other gave a miscellaneous response.

Discussion

The preliminary results show that for the most part, women in this study are very knowledgeable about clinical trials. Table 1 shows that 75% (30/40) of the participants gave responses that gave evidence of a high level of

knowledge about clinical trials. This can be explained by looking at Table 2 which shows that 60% (24/40) of the participants have participated in an HIV/AIDS clinical trial, which would imply that participants would be expected to be fairly well informed about clinical trials. Table 3 shows that of the forty participants 32.5%(13/40) associate the term "clinical trial" with medications and drugs. This may be due to the fact that because these women are HIV+ drugs and medications are important parts of their disease management and would be very familiar to them. As well, many of the clinical trials in which they have participated may have had to do with new HIV medications. Finally, Tables 4-6 show who the participants trust most to refer them to a clinical trial. It is noted that doctors, nurse, and case managers/social workers all appear to be trusted sources of information about clinical trials for patients.

Question 11 had to be broken down into three sub-groups due to participants providing more than one response to the question. Table 4 shows that all forty participants gave at least one response. We learned that when asked who they trusted most to refer them to a clinical trial, the majority of the participants 37.5% (16/40) said they trusted most in their doctor. After doctors, case managers and social workers appear to be the second most trusted person, 25% (10/40) gave such response. About 15% of the respondents (6/40) said they trust their nurse/nurse practitioner, 7.5% (3/40) trust the clinic personnel, only 10% (4/40) trust members of their family, and 5% (2/40) gave miscellaneous responses. Table 5 shows that seven of the forty women gave two responses and Table 6 shows that only two participants gave three responses.

Based on responses to these questions and the demographic data from our participants, we learned that the women of this study are highly knowledgeable of what a clinical trial is. Also, due to the fact that the majority of them have previously participated in an HIV/AIDS clinical trial it is evident to why most associate clinical trials with medications and drugs. Data also shows that doctors, case managers/social workers, and nurses all appear to be trusted sources for referrals to clinical trials. Thus, all three can collaboratively work together in raising the number of minority recruits for clinical trials. Future studies may need to look at a population who has had less experience with clinical trials so that researchers can get a better idea of what the misconceptions and fears are towards clinical trials.

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