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Latino Beliefs about Biomedical Research Participation: A Qualitative Study on the US-Mexico Border

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Abstract

Latinos are under-represented in biomedical research conducted in the United States (US), impeding disease prevention and treatment efforts for this growing demographic group. We gathered perceptions of biomedical research and gauged willingness to participate through elicitation interviews and focus groups with Latinos living on the US-Mexico border. Themes that emerged included a strong willingness to participate in biomedical studies and suggested that Latinos may be under-represented due to limited formal education and access to health information, not distrust. The conflation of research and clinical care was common and motivated participation. Outreach efforts and educational interventions to inform Latinos of participation opportunities and clarify harms and benefits associated with biomedical research participation will be essential to maintain trust within Latino communities.

Keywords

Biomedical research; Latino; ethnicity; recruitment; qualitative; community perceptions; therapeutic misconception

Introduction

Latinos living in the United States (US) face numerous health disparities ranging from higher incidence and mortality from human immunodeficiency virus (HIV) and diabetes to lower access to health care resources compared to non-Latino Whites (CDC, 2012). Yet, Latinos are significantly under-represented as participants in biomedical research—defined as the study of underlying disease processes and distinct from clinical trials of diagnostic,

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treatment, or preventative intervention strategies (Grann, 2010; James et al., 2008; National Research Council, 2011). The Latino population currently makes up 17% of the US population, representing a 43% increase over the past 10 years (Ennis, Rios-Vargas, & Albert, 2011). This percentage is expected to grow to an estimated 30% of the population by 2050 (Passel & Cohn, 2008). As such, the need to improve Latinos' representation in biomedical research and ensure biomedical research works to improve rather than deepen health disparities is critical. While barriers to clinical trial participation for underserved populations, including Latinos, have been comprehensively studied, what Latinos believe and think about biomedical research in which individual results are not necessarily available or clinically significant has not been well-studied (Ford et al., 2013). Further, as outlined in the Belmont Report (1979), biomedical researchers have a responsibility to ensure the principles of beneficence, justice, and respect for persons are applied to all populations, with particular attention paid to those identified as vulnerable and underserved. To ensure the Belmont Report's central principles are met, insight into Latino beliefs and experiences are necessary to inform biomedical research design and build trust and collaboration with Latino communities.

The few studies that have assessed Latino attitudes regarding participation in biomedical research, including genetic studies, have found high levels enthusiasm (Arar, Hazuda, Steinbach, Arar, & Abboud, 2005), but also revealed that Latino respondents may experience more fear and skepticism about biomedical research than non-Latino whites (Katz et al., 2006; Katz et al., 2007). Additionally, there is evidence that logistical factors such as lack of transportation, limited access to medical resources, and concern about needing to pay for research services can act as barriers to Latinos' research participation (Ulrich et al., 2013). Cultural factors have been found to contribute to differential recruitment and retention of minority racial and ethnic populations in clinical trials (Eggerth DE & Flynn MA, 2010; Sheppard et al., 2005), but there is limited data on whether cultural factors similarly influence Latinos' decisions to take part in biomedical research. Finally, studies conducted in non-Latino White populations have revealed concerns about biomedical research with regard to privacy and confidentiality and sharing of biological data (Trinidad et al., 2010, 2011). These issues have not been well-examined in the Latino population. In an effort to address these gaps in the current literature, this study interviewed Latinos living in an underserved US-Mexico *colonia* to better understand their perceptions of biomedical research. Using one-on-one interviews and focus groups conducted by *promotores* (lay health workers), we asked participants about factors that would influence their decision to take part in a biomedical research study and explored participant perceptions about why Latinos are under-represented in such studies. Additionally, we estimated understanding of key issues related to biomedical research, such as the goals of biomedical studies, purpose of informed consent, and potential risks related to participation. Finally, we asked participants about their expectations and preferences around the processes of conducting biomedical research, such as the biological sample collection, storage and future use of samples, and communication about study procedures and results.

Method

Design

This qualitative study was part of a larger mixed-methods research project aimed at creating an evidence-based questionnaire suitable for measuring understanding and receptivity to biomedical research participation in underserved Latino communities. Here we present data gathered during the first phase of the project. This included 35 one-on-one elicitation interviews exploring factors influencing research participation and three confirmatory focus groups conducted with self-identified Latinos living in the US-Mexico border region in the state of New Mexico. The Fred Hutchinson Cancer Research Center Institutional Review Board reviewed and approved the project and its instruments.

Setting

Colonias are described by the US Department of Housing and Urban Development (HUD) as marginalized communities that develop due to a need for affordable housing (HUD, 2014). Specifically, *colonias* are defined as communities within 150 miles of the US-Mexico border, including Arizona, California, New Mexico, and Texas. However, recent research indicates the appearance of *colonias* in non-border states such as Georgia and North Carolina (Housing Assistance Council, 2012). These communities are informal homesteads with limited infrastructure and services (e.g., water, sewage, safe and sanitary housing). They may exist as dispersed rural dwellings or more dense modular housing (e.g. trailer parks). *Colonias* include incorporated or unincorporated subdivisions that may be under the jurisdiction of and receive some support from city or county government. In New Mexico there are over 140 designated *colonias* with over 70,000 residents. The majority of these residents are US citizens (85%) and have an average income of $5,000 a year (HUD, 2008). Latinos living in *colonias* tend to be primarily from a Mexican-origin, younger in age compared to Latinos in urban areas, and of low income and education however, the pattern of poverty and low education tend to be more sustained in *colonias* compared to other rural areas due to lack of infrastructure (Office of Border Health & Public Policy Research Institute, 2000).

Promotores

Promotores are bilingual and bicultural members of the community trained as lay health workers (also known as community health workers). Use of *promotores* to access the local community is a well-established in community-based participatory research (CBPR) approach (Livaudais et al., 2010). *Promotores* possess a connectedness with the general population that engenders trust and provides a level of familiarity with participants that often unattainable by researchers. Further, training of *promotores* expands both individual and community capacity to provide services (CDC, 2011).

Recruitment and Participants

Participants were recruited from primarily Latino, rural, underserved US-Mexico border *colonias* through *promotores* from a local health clinic. Recruitment fliers advertising the study were posted in local community organizations and other facilities, including grocery

stores, laundromats, and gas stations. The *promotores* answered questions about the study and screened potential participants for eligibility via telephone. Eligibility criteria included being over 18 years of age, a resident of a US-Mexico border *colonia* in New Mexico, Spanish speaking, and self-identification as Latino. The one-on-one elicitation interviews were held in participant homes or another venue suggested by the participant (e.g., library, clinic). Informed consent was obtained at the beginning of all interviews and basic socio-demographic information was collected through a brief pen and paper survey. If participants needed assistance with the demographic survey *promotores* were trained to ask each survey question verbally and indicate the participant's response on their behalf. Interviews took between 30 and 60 minutes to complete. Participants were provided a $20 gift card upon completion of the interview. Only three elicitation interviews were conducted in English and the remainder were held in Spanish.

Similar methods were used to recruit participants for the confirmatory focus groups. Focus groups were held in the social area of a local church or a conference room at a local health clinic. Focus groups were conducted in Spanish by a Native Spanish-speaking primary investigator and one or two research staff. Each focus group included between seven and eight participants. Focus group participants provided written informed consent, completed the demographic survey, and received a small incentive ($20) for their participation. Focus groups lasted between 90–105 minutes. All materials (fliers, interview guides, surveys) were available in both English and Spanish and participants were free to use the language with which they felt most comfortable communicating.

Elicitation interviews

Elicitation interviews motivate interviewees to reveal attitudes, beliefs, and behaviors relevant to a phenomenon of interest through intensive one-on-one sessions that build trust while minimizing the influence of social desirability (Denzin & Lincoln, 2000). The elicitation interviews followed an open-ended, semi-structured approach and utilized an interview guide that covered key content areas related to biomedical research participation. All interviews were audio-recorded for later transcription and translation. The *promotores*, who are skilled at interacting with community members to communicate health-related information in a culturally competent manner, underwent a one-day training in which they rehearsed how to elicit candid and complete information through the use of probes and recurrent questioning. The investigators intermittently reviewed the audio-recordings and field notes to ensure compliance and consistency. After completion of the first five interviews, the study team reviewed the interview guide and responses to ensure that all content areas were adequately addressed. In cases where more detailed information on a topic was desired, target probes were added to the interview guide.

The *promotores* opened the interview with ice-breaker questions to familiarize participants with the interview process and develop rapport. Questions then moved on to assess knowledge and perceptions of biomedical research, including previous participation and general interest in participating in biomedical research studies. Interviewees were asked to describe what 'biomedical research' and 'informed consent' meant to them. Next barriers and facilitators to participation were examined in addition to views of harms and benefits

associated with participation in research studies. Participants were also asked what they believed were the reasons Latinos have lower rates of representation than non-Latino Whites. Biological knowledge, specifically knowledge of genetics and genetic research and the health effects of providing biological samples (urine, stool, saliva), was explored next. Participants were asked what types of biological samples they would be comfortable providing, to whom, and at what location (i.e. home or hospital). Then, participants discussed expectations about how the results of research studies would be used, including what information participants expected to learn, or would like to learn, after taking part in a biomedical research study. Finally, the interview closed by examining perceptions and attitudes around the sharing and future use of biological samples after a study's completion. All interviews ended with the opportunity for participants to express any additional thoughts they had about biomedical research.

All of the interviews were audiotaped, transcribed, and reviewed by the interviewer for completeness. For interviews that were conducted in Spanish, transcripts were translated into English by bilingual members of the study team with extensive experience working in collaboration with primarily Spanish-speaking communities. Using Atlas.ti® software and following principles developed by Morgan (1997), three members of the study team independently coded a sample (n=5) of the elicitation interview transcripts, identifying key words, ideas, and common concepts that appeared during the discussions (open coding). Using a constant comparative method, the concepts that emerge through open coding were compared to each other both within and between participants in order to generate codes describing central phenomenon and their interrelationships (Cresswell, 1998). From this initial analysis, a codebook was created and reviewed by the larger study team. Two members of the study team then coded the remaining interviews. Three times during the coding process the same transcript was independently coded and analyzed to determine inter-rater reliability. Any disagreements were discussed among the study team and the codebook was updated (codes added, modified, or clarified) as needed, resulting in high inter-rater reliability (over 90% across all codes). After coding reliability and data saturation (no new themes emerged) were established, counts of the number of passages assigned to a code were created. The codes were then grouped by key topics covered in the interview guide and ordered by count to aid in discerning broad themes and analyzing patterns within and across topics following a thematic networks approach (Attride-Stirling, 2001). By examining the final network of inter-related themes, the study team identified key global themes related to participation in biomedical research as well as remaining areas of ambiguity warranting clarification using the focus group data.

Focus groups

Focus groups are useful for confirming observations from one-on-one settings as they use group interactions to extract information and insights that may not emerge during individual interviews. Additionally, when topics are unclear or contested, dialogue among participants can bring about common understanding of concepts and perceptions (Denzin & Lincoln, 2000). The goals of the focus groups in this study were to confirm our understanding of the key attitudes, beliefs and behaviors related to participation in biomedical research that were developed through the elicitation interviews and to clarify the previously identified

ambiguous and vague statements from research participants. Focus groups also allowed for discussion of issues identified in the literature that did not arise in elicitation interviews (e.g. being a guinea pig as a reason for not participating in biomedical research studies).

We developed the guide for the focus group discussions using the results of the elicitation interview analysis. The questions covered many of the same topics as the elicitation interview guide, but specific attention was given to probing perceptions of biomedical research as an extension of standard medical care as well as relevant cultural beliefs that emerged during the one-on-one interviews. Following similar methods as with the elicitation interviews, all focus groups were audio recorded. Of the 3 focus groups, the first two were transcribed and translated into English for coding. The first transcript was coded by two members of the study team using the original codebook, to which new codes were added when needed. The modified codebook was reviewed by the study team and then used to code the remaining two focus groups. Again, after assessing coding reliability and generating counts of passages, codes were grouped by the key topics identified in the elicitation interviews and sorted by count. The third focus group was audio recorded and coding occurred auditorily as the purpose of the third focus group was to clarify or confirm details that were unclear from the interview and first two focus groups.

Results

Focus groups confirmed and elaborated the experiences and perceptions identified in the elicitation interviews. Therefore, study results are presented as a summary of the two modes of data collection and include data from both the interviews and focus groups. The overarching global themes that emerged include: willingness to participate, few perceived harms and many perceived benefits, information and education as perceived primary barriers to participation, preferences for the conduct of biomedical research, and the conflation of biomedical research with providing a clinical medical service.

Participants

The 35 participants in the elicitation interviews included 28 (80%) women and 7 (20%) men. The average age of respondents was 37 (±11.5) years. Participants had an average of 12 (±3.1) years of education, 63% of respondents were not employed, 74% were born in Mexico, and greater than 90% had parents born in Mexico. Fifty-four percent did not have health insurance, but 66% reported having a medical home. Three focus groups were conducted with 20 females and 4 males with demographic characteristics similar to the elicitation interview participants.

Willingness to participate

Participants expressed high willingness to participate in biomedical research. Only one individual said that they would not join a biomedical study if invited, while the majority of participants said that they would want to take part regardless of the study's specifics. This enthusiasm extended to providing biological samples as well as participating in genetic research and is reflected in the words of this participant:

> '…it seems very interesting to me, and the truth is, yes if I had the opportunity to participate in something like this, I'd love to.'

A few participants stated that their willingness to take part in a biomedical study would depend on certain factors. Specifically, these individuals were primarily concerned with the study's purpose, research design, and participant burden. As one individual described:

> 'Well, it depends on what they're going to do to me. If they're just asking me questions like this, then it doesn't matter, but if it's something physical, then no.'

These respondents also explained that their decision to take part in a study could depend on the type of sample that would be required. One individual illustrated this initial hesitation about providing biological samples, saying:

> 'Because one thinks that their body will be intruded upon…and that they're going to take samples and pieces– that's what…I have in mind. Yes. It's that, well one doesn't know, that maybe because it's something as simple as blood, or as simple as urine…Mm hmm – I don't think – well my first thought is like that they're going to take pieces from me.'

Almost all of the respondents were willing to provide researchers with any type of biological sample brought up during the interviews—neither blood, urine, saliva, stool, nor buccal swab samples were more or less acceptable, overall.

Few harms and many benefits

When asked about what would deter them from participating in a biomedical research study, few respondents could come up with any reason to forgo participation. When initially probed about potential harms associated with biomedical research, nearly all participants responded that there were none. During the interviews, only 12 participants (34%) mentioned a harm that could result from taking part in a biomedical study at any point during the interview process. Of those that mentioned harms during the interviews and focus groups, a few individuals were concerned about pain associated with providing blood samples. As one participant described:

> 'And also – I'm really scared of needles. Because of that no, no…'

Another participant worried that members of the study team may not be properly trained:

> 'Um, well yes, again because if a person doesn't know the consequences and maybe, um if they take a blood sample and maybe the person isn't trained for that, then there's a risk that, or maybe they don't use sterilized instruments or the person doesn't know what s/he is doing.'

The most frequently expressed concern was the possibility of learning about high risk for or current existence of disease. This worry was particularly evident in discussions of genetic research. As described by one participant:

> 'Well, yeah…maybe it would turn out that I'm sick, and I didn't even know.'

Overall, however, participants rarely mentioned these harms and described many more benefits to participation in biomedical research. When asked to describe the benefits or

value of biomedical research, the most frequent response was that it helped produce knowledge that would allow researchers and doctors to better understand disease:

> 'The benefits would be that we are um, we'd be better informed about diseases, and what diseases there are in the human body.'

During the interviews a total of 30 participants (86%) mentioned generalizable knowledge as a benefit or source of value resulting from biomedical research. Many participants also believed that such knowledge about disease would better enable diagnosis, prevention, and treatment efforts. At other times, value of biomedical research was not described in terms of health benefits, but rather as a means of generating knowledge, or a method of discovery, that was important or interesting in its own right:

> 'Well, that it's something very important – to research, to know, to learn.'

The value of biomedical research as something that could improve the lives of future generations was mentioned by a small number of participants in the interviews, but was strongly supported during the focus groups. As one individual described:

> 'Well the benefits are for the future, for future generations, so that this works to help our children, our grandchildren, our relatives that are younger than me.'

Finally, some participants articulated that the value of biomedical research was that it could particularly benefit Latinos:

> 'I think it's something, biomedical research, is something that's going to help, not just me, but all Latinos in general and the entire community.'

Information and education as barriers to participation

None of the Latinos we interviewed had ever taken part in a biomedical study. When asked why they thought Latinos are not as well-represented in biomedical research studies as non-Latino Whites, low health literacy and general awareness of biomedical research stemming from limited formal education were seen as the major contributing factors. The majority mentioned informational barriers resulting from low levels of formal education as a major contributor to disparities in participation. One participant explained, saying:

> 'I think it's because the majority of Latinos who are here in the United States, not all of us had the opportunity to study. We lack education in our country, we lack help, and I think it's because of ignorance. Because they don't know – they're afraid.'

Interestingly, language barriers were only mentioned as an obstacle to participation by two participants during the interviews. As the participant quoted below highlights, issues with language, when mentioned, were described as an additional impediment to existing knowledge and informational gaps faced by Latino communities:

> 'Well sometimes because we lack information. Sometimes it is due to the language itself that sometimes we don't know about things. I think that would be it.'

As illustrated in the first quote in this section, fear was also mentioned as a barrier to participation by a few of the participants. This fear was attributed to lack of understanding

of what participation entailed, but also to racism and discrimination faced by Latinos living in the United States. As described by this individual,

> 'Well, I think because of fear, because well, I think there's still racism and people are afraid of participating because perhaps they/we don't understand well, or things aren't clear – what's being dealt [what the study deals] with, or what's going to be done with the samples.'

Despite the strong enthusiasm for taking part in biomedical research that we observed during the interviews, many of our participants believed that contributing to science or medicine through research was not a priority in their culture. They suggested that Latinos may not be taking part in biomedical studies because they are not committed to investing the time and effort it would require to become informed about biomedical research and seek out participation opportunities.

Preferences for the conduct of biomedical research

The high rates of willingness to take part in biomedical research and the low levels of perceived harm resulting from participation did not mean that our interview participants were indifferent to the conduct of biomedical research. In fact, strong preferences for how biomedical research should be carried out emerged during the interviews. Recognizing the informational barriers faced by Latinos living in the US, it is not surprising that most preferences were related to the provision of information before, during, and after the study. When asked what participants would want to know before agreeing to participate in a biomedical study, most wanted details about the study itself. For example, in the interviews, 20 participants (57%) wanted to know the specific disease or diseases that were being studied and a similar number of participants wanted to know the purpose of the study. In the words of this individual:

> 'The purpose, I think that's the most important thing to know – the 'why'. Why they're doing the research. Mmm, I'd like to know … what disease [is being studied], and if they're dealing with more than one. And what they're focusing on.'

Other participants were more interested in the basic logistical information. They wanted to know whether or not they would receive individual results back from the research team if they agreed to participate in the study. As one participant explained:

> 'Uh, what it's about, what they're going to investigate, about whom, and for example, if they're going to give some type of information, results, about what they're doing…just what it is they need from me, and I'd like for them to give me information about the results and what they found.'

Many of the interview participants were interested in getting individualized study results. This desire reflected the information-seeking behavior that was driving some individuals to participate in biomedical studies, as illustrated in this quote:

> '…I would like to know and be in agreement, to know, um, to understand my body better, to know the 'why' I have a high risk of a certain disease or how to prevent it…I think that for me, it would be a good idea, for them to tell me if I'm, if I

> personally at high risk for some disease, or something bad that might happen to me. If they can't help me, then help another person- a future generation let's say.'

After a biomedical study is completed, samples are often stored for future studies and shared among researchers. Knowledge and preferences around these practices were probed during the interviews. When asked what they thought happens to biological samples after a research study has finished, a strong majority thought the samples were thrown away. On finding out that sometimes samples are stored for future studies, all but one of the participants were comfortable with that practice. As one individual described:

> 'It's fine, I don't see that… It doesn't bother me.'

When specifically asked how they would feel if the same scientist used their remaining sample for a different study without their consent, 21 participants (60%) in the of interview continued to agree that would be fine and members of the focus group tended to do the same. As described by this participant:

> 'Well, no. No that wouldn't matter to me, because it's just a sample – how's that sample going to affect me? If they can continue using it, if it helps them out, well that's fine.'

However, the remainder of participants expressed concern about this practice and were opposed to not being informed about future use of their biological sample. One participant described their feelings, saying:

> '…I would like more information about that, like about it…Yes, just like they talked to me the first time and told me, I would like to again, to know, what is it that they are going to do… I think I would not like that…No, because I was explained everything the first time and I was told everything very well and then for the second time wanting to use it without not even calling me or anything. I don't think so, that is not right.'

Participants had even more concerns about the practice of sample sharing of stored samples by researchers. When asked how they would feel if a scientist other than the one who initially obtained consent used their sample to study something else, many participants said that they would be distressed and disappointed, as illustrated in this quotation:

> 'No, well, I'd be upset…I would feel sad, annoyed because it isn't, because it isn't the one who has my case, and someone who arrives to take a sample, isn't going to know what I, what I feel, what I gave my consent for what could be done [with] that sample.'

In addition to the participants that expressed concern about sample sharing between researchers, 13 interview participants (37%) were clear they would not want a second researcher to use a sample they had provided in another study, regardless of the circumstances. This sentiment was echoed during the focus groups. Additionally, participants were unwilling to sign a blanket consent form allowing researchers to use their samples however they chose without re-informing them. As one individual described:

> ‘No. I don’t agree with that – if I sign something, things need to be specified – what the sample is for, and what they’re going to use it for, what the purpose is, and what the research is that’s going to be done with it.’

Conflation of biomedical research and clinical care

Confusion between participating in a biomedical research study and receiving a clinical service was present in almost all of the 35 interviews. Many participants conflated providing a biological sample for a research study and undergoing a clinical evaluation, despite information delineating the differences between the two throughout the interview guide. This confusion influenced almost every over-arching theme identified during analysis, from the harms and benefits of research to the motivations for taking part in a study. At the very outset of the interview, several participants began by describing biomedical research as a type of clinical interaction, as illustrated in this quote:

> ‘Biomedical. Well, yeah, something having to do with studies, it could be about humans - about us, um physicals, physical exams, something like that…’

Additionally, when asked what they thought researchers do with biological samples after they are collected as part of a biomedical study, many assumed they were examined in order to make diagnoses. As this individual described:

> ‘They study it and um to see if a person’s got an illness and if it can be cured, so that it isn’t transmitted to other people.’

During the interviews 12 participants (34%) articulated the benefits and value of biomedical research in terms of receiving clinical services, individualized health information, or medical care. One individual described the importance of biomedical research, saying:

> ‘The importance is that it’s a way of doing our check-ups to see if we’re in time to [detect] diseases… Mm, well one would learn if he had… a disease or not, or which ones in order to prevent.’

This confusion was especially present in discussion of genetic research, where individuals saw a primary benefit of genetic studies as alerting them to what diseases they had or were at risk of developing. In the words of one individual:

> ‘But…well, I guess they check me – that would be the benefit – that they’re going to check me.’

In addition to benefits, many of the harms that participants thought could come from participating in biomedical studies were related to clinical-trial like situations where they would be receiving treatment. For example, one individual expressed their concerns about participating by saying:

> ‘No, but that’s just saying it, I wouldn’t like to take anything they would give me that my body would reject or that they were experimenting on me.’

Finally, a few participants indicated that receiving clinical services or clinical information were the primary reasons why they would participate in biomedical research, as seen in this exchange:

INV: ‘Why would you participate?’

P: ‘Mm because, mm I think it would do me good…In, to see how things turn out in my blood or if I’ve got a disease or not.’

Despite receiving information distinguishing between biomedical research and clinical trials as well as biomedical research and medical care, the perception that providing a biological sample or participating in a study was akin to undergoing a clinical evaluation was a common misperception during these interviews.

Discussion

This study evaluated willingness to participate in biomedical research and assessed perceptions and preferences for biomedical research methods and conduct using semi-structured interviews and focus groups with Latinos living in US-Mexico border communities. Overall, results corroborate previous research revealing Latinos’ strong willingness to participate in biomedical research and the logistical and cultural factors acting as barriers to participation (Ulrich et al., 2013). Novel study findings in this Latino community included: research participants’ lack of understanding of biomedical research as distinct from clinical research, participants’ expectations for both general and personalized information as a result of their participation, and participants’ concerns about sample sharing between researchers without their knowledge.

As a whole, participants conveyed a strong willingness to participate in biomedical research. These findings are consistent with a meta-analysis of biomedical and clinical trial participation rates conducted by Wendler et al. (2006), which noted little difference in the rates at which non-Latino Whites and minorities agreed to participate in health-related research. In our study, when motivation behind high willingness to participate was examined, two primary themes emerged. First, benevolence-a desire to contribute to biomedical research for the purpose of helping others in their own community and beyond--was salient throughout the interviews. The opportunity to advance the prevention, diagnosis, and treatment of disease was highlighted as one of the key benefits of biomedical research. The second reason for participation in biomedical studies, however, highlighted participants’ misunderstanding of the purpose and process of most forms of purely biomedical research. Specifically, participation in biomedical studies was misconstrued as an opportunity to receive clinical care, disease diagnoses, and treatments. The misconception of study goals in biomedical research is similar to the concept of ‘therapeutic misconception’ found in the clinical trials literature, where participants overestimate the personal benefits and underestimate the risks of the research to which they have agreed to participate. The misinterpretation of benefits serves as a call to researchers for careful evaluation of a study’s informed consent process. To ensure the principles of beneficence, justice, and respect for persons are adhered to, a clear explanation of a study’s goals and explicit notification of the information participants will receive before, during, and after participating in a biomedical research study needs to be included as part of informed consent process (Arar et al., 2005; Flory & Emanuel, 2004). It is possible that if Latinos understand biomedical research often does not include individual results, they may be less likely to participate even with the recognition of potential benefits to humanity (Wallace, 2013). However, a recent study in a

community of similar ethnic and socioeconomic status in Washington State suggests motivations to participate in biomedical research (among participants in a pesticide exposure study) included the idea of therapeutic misconception, a desire to benefit their own children who may have been exposed to pesticides as well as advancing general scientific knowledge (Hohl, Gonzalez, Carosso, Ibarra, & Thompson, 2014). In this sense the findings were similar to the current study's and may be indicative of a willingness to participate in biomedical research for the purpose of benevolence and the greater society, despite a lack of individualized health information. In either respect, education dispelling myths about receiving clinical information during biomedical research participation, while emphasizing benevolent motives could be particularly effective in preventing participant misunderstanding of potential outcomes and still result in the participation of Latinos in biomedical research. Future studies should explore the willingness of low income, low literacy Latinos to participate in biomedical research while explicitly stating the exclusion of receiving individualized health information.

When asked about the low rates of representation among Latinos, many of our participants expressed beliefs that low participation was due to low levels of formal education, low health literacy, and lack of motivation to seek out information. In contrast to previous studies (Davis, Bynum, Katz, Buchanan, & Green, 2012; Ulrich et al., 2013) a limited number of participants noted a lack of access to participation opportunities, simply "not being asked", or a lack of trust as additional barriers. Interpretation of these particular findings, however, should be done with caution as some of the perceptions about community members' level of motivation, interest in health-related information, and level of education may be the result of internalized racism as opposed to accurate portrayal of educational or motivational barriers to participation among Latinos in this community. The contributions of internalized racism vs. actual educational barriers need to be further investigated. But, these perceptions about the Latino ability or willingness to seek out and understand health information, when considered in combination with the clear participant expressed desire to receive information about general health-related issues, suggests there is an opportunity to provide health education and engage Latino communities in biomedical research. Specifically, providing general health education (e.g., through short informal educational sessions provided at the time of recruitment, especially with trusted members of the community who also act as health professionals, i.e. *promotores*) may be a way of providing benefit to participants and, consequently encourage Latino participation.

When the issues of sample re-use for other studies were discussed by participants, responses appear to shift as more specific scenarios were described. While participants seemed somewhat surprised that biological samples were stored for potential future use, they were generally open to their sample being used by the same researcher that had collected their sample—although many did express a preference for being contacted before the sample were reused. Interestingly, when the scenario involved samples being shared with secondary investigators, i.e. researchers that the participant did not have an established relationship with, participants tended to have a more negative response. Indeed, most stated that they would expect to be contacted to approve any new analyses using their sample. Among Caucasian populations to which this type of question has been posed, there appears to be

more openness to sample sharing although there remained a wide range of responses and more explicit concerns about privacy (Trinidad et al., 2010, 2011). In one study of genomic data participants expressed a desire for a tiered informed consent process and, as stated by the authors, 'participants…valued "being asked" about new uses of existing study data, including sharing with other researchers and their use in other investigations' (Trinidad et al., 2010).

However, among our sample of participants, many expressed strong expectations for contact and consent prior to use of their sample by another researcher. It is not clear if the reasons for this preference derive from differing privacy concerns and cultural influences such as *personalismo* (the desire for personal relationships with providers), or instead reflect a more general concern about how other researchers might use their biological samples without their permission or knowledge. *Personalismo* is an important concept along with *respeto* (respect or deference to person of authority) that must be considered when working with Latino communities of all subgroups (Larkey, Ogden, Tenorio, & Ewell, 2008). More in-depth investigation of concerns about sample sharing and the potential influence of cultural constructs important to Latino communities is warranted.

Best Practices

While the need to ensure participants are fully informed should be the case for all populations, it is particularly relevant for building the relationships necessary to encourage participation in Latino communities. Studies that have shown success with recruitment and retention of Latinos for clinical and behavioral research have identified relationship building between researchers and members of the community as one of the primary mechanisms of their success (Diehl et al., 2011; Warner et al., 2013). In particular these examples highlight the use of CBPR, which allows for cultural adaptation of study protocols and the involvement of culturally competent research staff, like *promotores.* As the role of *promotores* expands within health care reform (U.S. Congress, 2009; U.S. Department of Health and Human Services & Office of Minority Health, 2011), there is also an opportunity to impact communities through a researcher's relationship with *promotores.* However, these relationships must be mutually respectful, reciprocal, and long-term. For example, in this study the relationship between the University research team and *promotores* was well-established, *promotores* provided their expertise about the accessibility and cultural appropriateness of the interview and focus group guides, *promotores* received training in conducting interviews and focus groups (capacity building), were provided opportunity to receive education and discuss issues of informed consent and biomedical vs. clinical research, and received financial compensation for their assistance with data collection. But it should be noted, the role of *promotores* in research can extend to all levels ranging from providing input during the initial design of the study to data analysis and presentation so as to represent the community interests at all levels and ensure growth in the cultural competency of the researcher.

The findings of this study suggest Latinos living in US-Mexico border communities are willing to participate in biomedical research. The assumption that Latinos are underrepresented in biomedical research because they choose not to participate due to fear

or distrust need to be reevaluated or may not apply in some Latino communities. Instead, Latinos' awareness of biomedical research, access to participation opportunities, and ability to follow-through on intentions to participate in the face of literacy and logistical barriers warrant greater attention. Considering Latinos' desire to contribute to scientific knowledge, the role of science policy and researcher responsibility in determining the recruitment needs of vulnerable populations must be considered (Durant et al., 2007). As federally-funded investigators already face both legal and ethical mandates for increasing participant diversity, our data suggest that improving outreach to underserved communities to inform them about opportunities to participate in biomedical research and providing in-depth information about research protocols and outcomes may improve recruitment and retention of participants from this otherwise underrepresented population.

Generalizability of these findings may be limited to *colonias*. Although there are some similarities between Latinos living in *colonias* and other Latino populations (rural and urban), the findings of this study may not relevant to communities that are a greater mix of Latino subgroups or wider breadth of educational and income levels. Nevertheless, as there is an estimated 3.4 million Latinos currently living in border *colonias* (Housing Assistance Council, 2012) there is noteworthy relevance in being able to take these initial steps toward improved communication and inclusion of rural Latinos in biomedical research.

Research Agenda

Our study findings add to the limited literature on Latinos beliefs about biomedical research participation, but are subject to a number of limitations that need to be addressed with future research. For example, it was difficult to decipher if participants who referenced educational barriers to research participation were focusing on formal academic education, health-specific education, or both. In some cases we were left with the impression that pursuing these types of education was limited by logistics or obligations such as family and work that limited interest or opportunity to pursue such information. The distinction between the role of formal education and health-related education in biomedical research participation requires more in-depth examination in future studies. Additionally, the low number of perceived harms associated with biomedical research participation that were mentioned during the interviews, led us to question of whether or not participants knew enough about biomedical research to begin to question potential harms. All participants in this study responded that they had never participated in biomedical research. Their perspectives on such research need to be understood in this light. It is possible that actual negative (or positive) experiences with participation in biomedical research may change perspectives. Finally, given participants' surprise at learning about common practices of biomedical research studies like sample sharing among researchers, we believe our ability to gather insights about potential harms was limited and should be explored in populations who have previously participated in biomedical research studies. It should be noted that although the *promotores* who conducted the interviews and focus groups are members of the community themselves and have a well-regarded relationship with the study participants, the concept of *respeto* may have influenced some of the expressed willingness to participate in biomedical research that we observed. Studies that compare intentions to participation in biomedical studies and actual participation decisions are needed to address this limitation. Future studies

should evaluate knowledge and beliefs about biomedical research in other geographic areas and among Latino sub-populations to assess generalizability of these findings.

Importantly, developing informed consent documents that address the issues will contribute to ethical and non-exploitative research practices in historically underserved and marginalized communities. For example, this may include an informed consent process in which *promotores* review the consent with every participant and ask participants to answer questions upon completion to verify comprehension (Mexas et al., 2014). Additionally, including community members in the development of research materials, i.e. conduct cognitive interviewing or involve community members in verifying the accessibility of informed consents to low literacy participants may help to address therapeutic misconception (Tamariz, Palacio, Robert, & Marcus, 2013).

Educational Implications

This study has important implications for biomedical researchers, science policy-makers, and ethics committee members. Specifically, our data indicates that Latinos living on the US-Mexico border are highly willing to participate in biomedical research, but that key misperceptions of the purpose and practices of biomedical research as well as the potential individual benefits of participation are pervasive. Thus, the criteria for informed consent will likely not be achieved in some Latino communities without targeted, culturally appropriate educational interventions to inform participants about goals and procedures of biomedical research studies. Ideally, this education will be carried out by trusted members of the community who also act as health professionals. Ensuring that all participants fully understand the potential harms and benefits of a biomedical study before making a decision to take part is both an ethical obligation of researchers, policy-makers, and review board members, and a pathway to promoting biomedical research participation in Latino communities by building trust.

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Biographies

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