

Cross-Cultural Considerations in the Recruitment of Latinos of Mexican Origin into HIV/AIDS Clinical Trials in the U.S.-Mexico Border Region: Clinician and Patient Perspectives

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Despite increasing prevalence of HIV among U.S. Latinos, participation in HIV clinical trials is low. Barriers to HIV clinical trial participation in U.S. Latinos are not well understood. Using in-depth, semistructured interviews with HIV care providers serving HIV-positive Latinos and focus groups with HIV-positive Mexican-origin Latinos, we assessed cross-cultural barriers (e.g., stigma and linguistic) to HIV clinical trials in San Diego, California, bordering Mexico. Cross-cultural barriers were explored using grounded theory analytical techniques. Patient-provider concordance on the nature of HIV-related stigma, linguistic barriers, the impact of U.S.-Mexico border on Latino patients and participation in clinical trials were found. Providers described care access challenges faced by patients of Mexican-origin, particularly in light of immigration and U.S. border policy. HIV-related stigma and communication barriers among Latinos remain important obstacles to clinical trials participation and care access in the United States.

KEYWORDS *U.S.-Mexico border, immigrants, HIV/AIDS, health care access, clinical trials*

To live on the border is to live in the center: to be at the entrance and the exit; to inhabit two worlds, two cultures and to accept both.

—José Antonio Burciaga

INTRODUCTION

HIV prevalence is increasing in the U.S.-Mexico border region (Brouwer et al., 2006) and HIV has been identified as a health priority by the U.S.-Mexico Border Health Commission and Pan American Health Organization (United States-Mexico Border Health Commission, 2003; Pan American Health Organization [PAHO], 2007). National HIV surveillance data in the United States indicate a notable increase in the proportion of Latinos among new HIV infections and AIDS diagnoses, as well as increasing rate of HIV diagnosis among Latinos—three times higher than in non-Latino Whites in 2005 (Centers for Disease Control [CDC], 2006). Latino participation in HIV clinical trials, however, remains low (Gifford et al., 2002; Getz & Faden, 2008). Broadly defined, clinical trials are biomedical (e.g., development of new medications and treatment options or improvement of medication dosing) or behavior-related (e.g., assessment of new behavioral interventions to prevent disease transmission) research studies with individuals who are assigned by the investigator to a treatment or other intervention, and their outcomes are measured (U.S. National Institutes of Health [NIH], 2009).

Clinical trials are designed to determine new ways of improving patient health, including comparison of existing treatments to determine relative effectiveness.

Participation in clinical trials may allow for access to new therapies and treatment modalities, of particular importance for minority populations most affected by the HIV epidemic who may have limited access to care. Participation in clinical trials may not guarantee access to better treatment modalities; however, it improves a patient's access to monitoring of their disease state by clinicians specialized in the field of HIV. Equitable access to clinical trials may also improve generalizability of study findings to minority populations, and may reduce health disparities among those most affected by HIV. The National Institutes of Health (NIH) has issued a directive to promote recruitment of racial and ethnic minorities into research in order to identify potential differences in effects among ethnic/racial groups (NIH, 2001). Attention to ethnic and culturally-mediated barriers to HIV care and participation in clinical trials among Latinos in the U.S.-Mexico border region is warranted given the region's rapid demographic growth and substantial daily cross-border interaction (San Diego Association of Governments [SANDAG], 2003; U.S. Census Bureau, 2007).

Barriers to clinical trials include system-level barriers that may impede access to care and clinical trials (King et al., 2007). Examples of system-level barriers include provider preconceived notions or stereotypes about willingness to participate among Latinos and African Americans; language differences (e.g., clinicians are less likely to discuss clinical trials with patients who do not speak English); and level of effort that clinical trials personnel may make to recruit members of underrepresented communities (King et al., 2007; Stone, Mauch, Steger, Janas, & Craven, 1997; Stone, Mauch, & Steger, 1998; Stone, 2005). Ethical issues related to voluntary and informed consent, participation and coercion are appropriate areas of concern when enrolling members of traditionally underserved communities, including Latinos of Mexican origin living with HIV. To this end, Institutional Review Boards and NIH require detailed researcher explanation of how study recruitment will uphold the rights of participants including training of key personnel in protection of study participants (NIH, 2000). Provisions to improve linguistically-competent and ethically sound enrollment of traditionally disenfranchised ethnic groups include projects such as Project TRES (2009) an ethnically and linguistically-tailored ethics training course for Latino/a community-level research recruitment staff. Notwithstanding, continued attention is needed on potential ethical problems, particularly language-related issues, in recruitment of underserved populations. Our preliminary work in clinical trials participation barriers among Latinas living with HIV indicated that personal factors, such as fear, shame, and stigma are the most commonly perceived barriers to clinical trials participation (Zúñiga, Blanco, Martínez, Strathdee, & Gifford, 2007). This same study found that HIV service providers,

reported system-level barriers (Zúñiga et al., 2007). HIV-related stigma has been well documented in other studies as a significant barrier to HIV care and treatment in U.S. Latino populations (Zúñiga, Brennan, Scolari, & Strathdee, 2008; Venable, Carey, Blair, & Littlewood, 2006), yet its role in clinical trials participation for U.S. Latinos has not been well established. Furthermore, although HIV-related stigma has been implicated as a barrier to HIV vaccine clinical trials recruitment among uninfected populations (Brooks, Newman, Duan, & Ortiz, 2007) there is limited research on the role of HIV-related stigma in clinical trials recruitment of persons living with HIV. As the prevalence of HIV increases in Latino populations along the U.S.-Mexico border region, lack of access to HIV-related care, including clinical trials, may further widen observed disparities in health.

The current qualitative study was conducted in San Diego, California, which borders Tijuana, Baja California, Mexico. We examined barriers to HIV clinical trials participation among U.S. Latinos living with HIV and HIV care providers who serve Latino patients with a specific focus on stigma and system-level barriers. An in-depth understanding of patient and clinician contextual realities and perceived barriers to clinical trials is important to increase the effectiveness of clinical trials recruitment and inform the design of new approaches to improve access to HIV clinical trials and health care in Latino populations.

METHODS

Conceptual Framework

The behavioral model of health services utilization developed by Andersen, Aday, and others was adapted for the present study and served as the theoretical framework to explore and define factors associated with barriers to HIV clinical trials and HIV care in HIV-positive Latino populations in the U.S.-Mexico border region (see Figure 1; Phillips, Morrison, Andersen, & Aday, 1998; Andersen, 1995). Specifically, we applied the model's framework to include access to clinical trials as a factor of enabling resources within population characteristics (see Figure 1). The Behavioral model provides a framework in which factors associated with access to clinical trials can be contextualized within a broader access to care framework. This model has been used effectively to predict behavior in studies with HIV-positive persons and other vulnerable populations (Andersen, 1995; Gelberg, Andersen, & Leake, 2000; Dobalian et al., 2006) and was particularly well suited for the study as it has been successfully applied to access of vulnerable groups to antiretroviral therapy in the United States (Andersen, 1995).

The current study recruited two different populations (HIV providers and Latino patients living with HIV), employing sequential qualitative methods to first conduct in-depth interviews with HIV providers and later using

involved with HIV clinical trials, including study principal investigators and co-investigators. Low clinician response rate is common in busy clinical environments where schedules may make it difficult for clinicians and study staff to participate; King and colleagues indicated low response rates among HIV clinical trials study staff, with rates ranging from 56% to 58% in an internet-based survey (King et al., 2007).

Focus group participants were Latino patients living with HIV in the San Diego region. Eligibility criteria included: ≥ 18 years of age, Latino, English- or Spanish-speaking, and living with HIV. Thirty-seven persons participated in a total of four focus groups (two male and two female groups). Of the four focus groups, two focus groups (one female and one male group) were comprised of persons who had participated in a clinical trial, and two (one female and one male group) were conducted with persons who had never participated in a clinical trial. Focus group participants were recruited by volunteer peer advocates from a partner community clinic as well as by outreach workers from the UCSD HIV clinical trial research groups.

Data Collection

The in-depth interviews were conducted using a guide that included 29 open-ended and 6 closed-ended items, based on research generated from patients living with HIV and HIV service providers that indicated specific difference in perspectives on barriers to entry into clinical trials (Zúñiga et al., 2007). Questions such as: “Do you think low acculturation influences an HIV-positive Latino’s willingness or ability to participate in a clinical trial?” and “Do you think Latino patients are worried that someone will find out they are HIV-positive if they participate in a clinical trial?” were followed by prompts for the participants to expand on why or why not they thought the statement was correct. Trained study interviewers conducted the hour-long interviews with providers at a mutually convenient time and location. Providers did not receive an incentive for participating in the study.

Provider interview data were used to generate patient focus group questions and to ask patients about their perceptions of patient-provider communication, its role as a potential mediator of health choices, satisfaction with HIV medical services and care, and how these items may influence clinical trial participation. Draft focus group questions were presented in Spanish to a peer advocacy group for evaluation and feedback. Peer advocate review contributed to identification of errors and resulted in substantial improvements in clarity of questions in the interview measure. Focus group questions (12 total) were designed to provide participants with sufficient background information to understand the context of provider comments derived from key informant interviews and promote focus group reflection; elicit agreement or disagreement; and contribute their own thoughts on the

subject. Questions framed the issue and were followed by prompts for the participants to expand on their statements. Examples include: “For persons living with HIV who are undocumented, do you think that for those people their citizenship status is a barrier to participation in clinical trials?;” and “Do you think that the role of your family or partner could influence your participation in a clinical trial?” A 12-item demographic survey, including questions on education level, language preferences, and income, was also administered to study participants. All focus groups were conducted in Spanish and lasted between 1.5 and 2 hours; two were conducted at a collaborating community clinic and two at a UCSD clinical trial research office. Participants were read a consent form and allowed to ask questions during the entirety of the process. Participants received a \$25 grocery store voucher. (Study measures and protocols are available upon request from the study’s lead author).

DATA ANALYSIS

We followed the principle of *microanalysis* as described by Strauss and Corbin (1990), which is the detailed analysis of text that is necessary at the beginning of analysis to generate initial themes and suggest relationships between themes. Two members of the study team reviewed all interviews and focus group transcripts to identify themes.

Subsequent analysis was conducted independently by three study team members using open coding procedures on a sample of 5 of the 15 clinician/provider interviews to generate concepts, properties, and dimensions discovered in the data (Strauss & Corbin, 1990). The study team then met to discuss categories and reach consensus on coding themes. Next, the study team independently reviewed and coded two open-ended questions to reach consensus on how codes had been applied and whether there were emerging themes that merited new codes.

Using the revised coding scheme, two members independently coded five pages of two focus group transcripts. Coded questions were independently reviewed by third team member, who determined inter-rater reliability and met with study team to resolve coding discrepancies. Inter-rater reliability was >80%. The qualitative text analysis software, ATLAS.ti (version 7; ATLAS.ti Scientific Software Development GmbH), was used to facilitate visualization and organization of coded categories (concepts that stand for phenomena/central ideas in the data) and their properties, dimensions, and subcategories (Strauss & Corbin, 1990) as well as to facilitate generating frequencies of coded categories. Using the method of constant comparison, (Glaser & Strauss, 2006; Strauss & Corbin, 1990) a final coding taxonomy was reached through study team consensus.

RESULTS

Demographics

HIV care providers participating in in-depth interviews included 10 physicians, 3 nurses, and 2 pharmacists; were mostly non-Hispanic (66.7%), male (73.3%), and worked with HIV-positive Latinos for >10 years (73.3%). Slightly less than half of provider respondents were comfortable communicating in Spanish (47%), with one provider preferring to respond to the in-depth questions in Spanish.

Of 37 Latino focus group participants, 57% were male; and mean age was 43 years (range 22–59 years). Most participants were born in Mexico (92%) and about 60% of persons born outside of the United States had lived in the United States ≥ 10 years; 41% made at least one round-trip border crossing per month. About 38% had completed ≤ 8 years of schooling; nearly 70% reported an annual family income <\$15,000/year and 27% reported no medical insurance. Most (78%) preferred receiving health information in Spanish. Eighty-eight percent of participants were exposed to HIV through sexual contact and 50% had lived with HIV for ≥ 10 years; about half (49%) having been diagnosed in Mexico. Additional focus group sociodemographic data are provided in Table 1.

Key Emergent Themes

Major themes identified in both in-depth provider interviews and patient focus groups were: (a) HIV-related stigma, (b) Communication/language; (c) Cross-cultural issues; and (d) U.S.-Mexico border and immigration. Findings are presented by major theme with HIV provider perspectives first, followed by patient perspectives.

HIV-RELATED STIGMA

Providers described manifestations of HIV-related stigma as barriers to clinical trials participation among their Latino patients, noting the influence of individual-level stigma (e.g., fear of losing social support if seen entering an HIV research center) and community-level stigma (e.g., family adversely influenced their desire to seek medical care out of concern that others will learn of patient's status). Internalized stigma, both HIV-related stigma and stigma about sexual orientation, was expressed by providers who indicated that Latino patient discomfort with disclosure could serve as a barrier to participate in an HIV clinical trial. Providers conveyed that some patients felt guilty about being infected with HIV. Internalized stigma overlapped with patient concern about the number of additional clinic visits that clinical trials participation entails and having to explain to family members the reason for

TABLE 1 Demographics of Latino Focus Group Participants ($n = 37$)

Characteristics	N	%
Gender		
Male	21	56.8
Female	15	40.5
Transgender	1	2.7
Age		
18–35	7	18.9
36–51	23	62.2
52+	6	16.2
Missing	1	2.7
Family income per year		
<\$15,000	26	70.3
\$15,000–24,999	5	13.5
\$25,000–49,999	0	0
\$50,000+	1	2.7
Missing	5	13.5
Years of school completed		
0	1	2.7
1–8	13	35.1
9–12	14	37.8
>12	9	24.3
Missing	1	2.7
Country of birth		
United States	1	2.7
Mexico	34	91.9
Guatemala	1	2.7
Missing	1	2.7
Length of U.S. residency ^a		
0–5 years	7	19.4
6–9 years	6	16.7
10+ years	22	61.1
Missing	1	2.8
Monthly border crossings (round-trip)		
0	12	32.4
1–5	9	24.3
6–9	2	5.4
10+	4	10.8
Missing	10	27.0

^aAmong participants not born in the United States.

going to the doctor more often. Stigma was also raised in the context of trusting providers (e.g., patient concern over who will have access to their clinical trials information), although the broader influence of HIV stigma on the patient appeared to be more of a concern than patient mistrust of providers.

Providers felt that patients were concerned about being seen at sites where only persons living with HIV receive care. One provider indicated that a patient was anxious about being identified as someone living with HIV so the provider made recommendations as to other clinics where the patient could seek care. Co-occurring themes with HIV-related stigma were

disclosure and family social support. Although providers observed Latino patient reticence to be seen walking into an HIV research center, providers felt that it would be beneficial to have clinical trials centers closer to where Latinos reside. Some patients feared that they may be seen and somehow compromise the social support provided by their family if the patient's HIV status became known. As one provider described:

But the problem is that they [families] are supportive [and] they try to cover the issue; one of the young ones die of HIV they will say they die of pneumonia . . . or something other than complications related to HIV. If you tell them it is an HIV clinic then they will try to skip appointments. If you say that this is a place they do HIV studies they will be labeled and for sure try to avoid us.

The increase in number of care visits related to clinical trials participation was also perceived as problematic for patients who are concerned about stigma and having to explain to family and/or employer the reason for increase in visits. Increase in number of visits associated with clinical trials participation was specifically noted as a problem for employment, where patients feared having to disclose to employers the reason for needing time off for additional medical appointments and for school, where families may feel uncomfortable about explaining to teachers why the child will need to visit the doctor so often.

When the HIV-related stigma question was posed to Latino focus group participants, two individuals in different groups asked for clarification of the word *stigma*. The facilitator allowed participants who were familiar with this term to define it for their peers in order to observe how HIV-related stigma is understood and identified within the community. For example, in the women's group one participant stated, "Stigma is, for example, when you are ashamed to talk about it, you don't want to talk about it as if it were taboo for you or others."

Upon clarification of the term, participants engaged in discussion of their personal experiences with how perceived and felt HIV-related stigma and discrimination had affected their lives and that of their families. Female participants discussed how they have coped with HIV-related stigma over time. Upon reflecting on her experiences of living with HIV, navigating feelings of stigma, and HIV clinical research, one participant noted:

At first, HIV stigma makes one starts to become paranoid . . . you receive a letter, "we invite you to participate in a study of HIV," and you want to burn the page or rip it up due to fear of that . . . and then you start to close your doors, when it should not be like that. You should talk with your family and overcome that barrier, but I'm saying not with all the family, but with close family, we should do that.

Women in both focus groups discussed at great length their efforts to avoid HIV-related stigma, mentioning having to be dishonest with family or persons in their social and faith networks to avoid being stigmatized by family and their community. Latinas discussed naming other diseases they or their partners had to avoid HIV disclosure (e.g., cancer). Important to the discussion was past experiences with discrimination related to living with HIV and being singled out with questions about how they were infected; for married women this was a particularly difficult point, navigating both their partner's HIV status as well as their own. Men did not specifically mention masking their HIV infection by telling friends and family they had another disease. One male participant stated, "Almost all of my neighbors know I have AIDS; to me, it doesn't matter, it doesn't matter to me what people say." The same participant however did admit that the stigma related to having HIV was a problem and concern for many other people: "It depends on the person . . . but yes there are a lot of people it [stigma] affects . . ."

Focus group participants also mentioned they often avoided discussion of HIV because they were tired of sharing their experiences with others and having to field more questions. However, apart from one participant's general concern about maintaining the confidential nature of HIV-related medical appointments, focus group participants did not otherwise mention concern about being seen at an HIV medical clinic and were enthusiastically in favor of having clinical trials sites closer to where they live.

COMMUNICATION/LANGUAGE

Provider discussion of communication and language issues centered on the desire for improved access to bilingual staff and interpreters to facilitate enrollment of Latino patients with limited English language proficiency into clinical trials. Some providers expressed frustration with having a Spanish-speaking Latino patient, who was eligible for a study, but lacked access to an interpreter and having to ask the patient to wait. Some providers who did not speak Spanish were either learning or expressed interest in opportunities to improve Spanish-language skills.

Focus group participants talked about challenges to effective communication with health care providers as well as experiences that optimized communication. Although the importance of learning English was generally acknowledged, both men and women's groups expressed their preference communicating in Spanish during their medical appointments. Participants noted as well that although they may grasp working knowledge of English, their exposure to English medical terminology may be limited. In both male and female groups, language was also raised in the context of having trust in one's provider, and that a good relationship with the provider included ability to communicate in Spanish. Language was viewed by some as a

mediator of satisfactory clinical encounters, including availability of interpreter and patients expressed appreciation of clinician efforts to learn Spanish. As one patient expressed: “My doctor is learning Spanish and I love that . . .”

For some participants, limited English proficiency (speaking and reading) was a barrier to clinical trials participation, and one female participant stated this remained a barrier even when she offered to bring someone who could interpret during appointments, she stated:

For example, I wanted to enroll into a neuropathy study that interests me a great deal because I have neuropathy, and they told me: “you know what, um, but you need to be proficient in English.” I say: “what if I bring an interpreter? . . .” [provider response]: “No, you have to speak it.”

Language was not reported by men as a specific barrier to clinical trials, but the importance of having access to interpreters was very important to both male and female focus group participants. One male focus group participant described having had a highly satisfactory interaction with a clinician through an interpreter on a telephone; the interaction included a conversation about sensitive topics whereby the patient felt that a telephone interpreter was less obtrusive to effective communication than having an interpreter physically in the consultation.

Patients felt that communication with providers was compromised when providers stereotyped them and felt that their relationship with the provider was undermined when clinicians made assumptions that the patient did not feel were accurate. The issue of cross-cultural communication also emerged with reference to diet. One male focus group participant described the following comments made by his physician: “Because you Mexicans are accustomed to eating a lot of fats . . . it’s that your metabolism [of Mexicans] . . . since young children you eat many fats, then it is not like the Americans who eat a little less fat.” A similar sentiment was expressed by a female participant who felt that she was unable to communicate effectively with her provider that she was eating healthfully although she was experiencing weight gain.

CROSS-CULTURAL ISSUES

Providers mentioned the health belief of *fatalismo* [fatalism], or the idea that all things happen by fate or are destined to happen in relation to participation in clinical trials. According to one of the providers:

There is an element of fatalism sometimes in the Latino community about HIV. That now I have it, I’m going to die soon, and if they want me in a study that means that I really am going to die soon.

Another cultural consideration providers noted about their Latino patients is a deep respect some have for the physician. One provider reflected: “[There is] more of a dependence on provider recommendation . . . [Latinos] see [the] doctor as an authority figure . . . may feel some pressure to comply and participate.” Another provider mentioned: “[Latinos] are more likely to do what the doctor recommends . . . or want to participate [in clinical trials] to keep their doctor happy.” Male and female focus group participant reflections on culture included awareness of differences in communication styles and stereotyping of non-Latinos, as one Latino focus group participant stated:

We Latinos are accustomed to having people be a little warmer . . . “how are you? . . . how has it been going?” . . . even if it is a quick chat of two minutes. . . . the culture, the Germans, the Saxons, it is true, the culture is naturally colder, not because they are bad people or anything like that.

A second male focus group participant indicated a positive experience with care he received in the United States from physicians from Tijuana: “They understand us. They know our culture, our problems.” Discussion ensued on the patient’s responsibility to learn about the provider’s culture and one male participant recommended that U.S. providers learn about the health care delivery system in Mexico to better understand how Mexican immigrants in the United States experience care delivery in their country of origin.

U.S.-MEXICO BORDER ISSUES

Providers were aware of their Latino patients’ strong ties to Mexico, including residence or having family in Tijuana. Awareness included knowledge of long wait times to cross the border and patient ability to make appointments on time. Border and immigration-related concerns and patient experiences also included co-occurrence with HIV stigma:

The ones that live in Mexico. . . . the rest of the medical system doesn’t know of their diagnosis, they live in a constant state of fear that they might get sick and they might need emergency treatment, there they would be thrown in a hospital where they might have relatives, nurses or people that know them around them, they don’t want to trust them over there with their diagnosis, and unfortunately that creates an issue because physicians and nurses there deal with patients that are HIV-positive without knowing that they’re treating HIV. And, of course, that skews their intervention and biases their diagnostic ability.

Male and female focus group participants discussed many instances of how the U.S.-Mexico border and immigration policies impact their daily lives. Latino men discussed differential access to HIV care and medication

depending on one's ability to cross the border, and efforts to donate unused medication to HIV-positive persons living in Tijuana. Women also discussed this circumstance, adding that there was an anxiety for them when they were crossing back from Tijuana to San Diego. Women expressed fear that U.S. border patrol agents may ask what their personal medications are for, since current U.S. policy indicates that non-U.S. citizens living with HIV may be denied entry into the United States or denied U.S. visas (National Immigration Project, 2004). Women also discussed how reliance on public transportation and concern over border patrol "sweeps" on public transportation would influence their decision to participate in a clinical trial. This consideration of transportation as a barrier to care is unique to U.S. immigrants who hold certain types of visas or who are undocumented in the United States. Women also expressed keen awareness of the implications of deportation on their ability to access HIV care, indicating concern about a lack of knowledge about the types and location of HIV medical services in Tijuana. Deportation was also mentioned as a concern among women because it separates families and potential sources of support for persons living with HIV.

DISCUSSION

Our study has several important implications for Latino participation in clinical trials and access to HIV care that provide a deeper understanding of how HIV-related stigma, communication and language, and other related cross-cultural issues and the border region impact the lives of Mexican-origin immigrants living with HIV. With some important modifications to fit our border context, the behavioral model of health services utilization adapted for this study served well as an explanatory framework for participation in clinical trials (Figure 1). Model components such as health behavior (participation in clinical trials) and outcomes (patient satisfaction with the clinical encounter) indeed appear to be influenced by the environment (U.S.-Mexico border and access to HIV care in binational context); population characteristics/predisposing characteristics (e.g., patient language, immigration status) and enabling resources (e.g., patient-provider relationship, including trust and patient ability to understand what is being said during their appointments). Our findings indicate that participation in clinical trials in this population may be influenced by cross-cultural issues that span all components of the model. We also note that resolution of environmental barriers such as moving clinical trials centers closer to communities may not necessarily improve participation if patients or their families are concerned about HIV-related stigma associated with being seen at a health care facility for HIV, including clinical trials center.

Across the four focus groups there was general agreement with provider observations and in many cases, participants expanded in great length on

these observations, engaging in a lively dialogue and expressing their experiences and additional views on HIV-related coping strategies, including failed coping strategies. Patient discussions also offer insights on stereotyping; feeling stereotyped and how patients may stereotype non-Latinos, both of which enrich understandings of how patients may respond to different clinical encounters. Focus group discussions also revealed patient sensitivity to issues surrounding fear of deportation, raised specifically during discussion of transportation-related barriers to care. This finding may serve to improve provider communication with their Latino patients who rely on public transportation.

Our findings extend those of previous studies that have quantified barriers such as lack of information about clinical trials; lack of transportation; limited clinic hours; concern over being part of an experiment; and fear of adverse events from treatment (Stone et al., 1997; Zúñiga et al., 2008; Travieso, 2003). In the current study, HIV care providers articulated several instances of how HIV-related stigma directly impacted Latino patient participation in clinical trials, particularly when patients' families are either not aware of the person's HIV status, or are aware but want to protect the patient from HIV-related stigma and may discourage patient participation in a clinical trial. The role of family appears to have a potential duality in the context of clinical trials, where families who serve as a source of social support and protectors of persons living with HIV may in some cases not support participation when HIV-related stigma is a concern. The nature of HIV stigma and how it permeates the lives of Latino patient study participants provided a deeper understanding of the patient context in which care decisions, including clinical trials participation, are made. Our work indicates that HIV medical care providers are attuned to the impact of stigma on the lives of their patients, but further study is needed to raise awareness of how HIV-related stigma may play a direct role in clinical trials participation. Gender-based differences in the impact of HIV-related stigma and coping mechanisms are also important to explore. For example, women in our focus groups mentioned coping with HIV-related stigma by telling friends and/or family members that they had cancer, rather than HIV. Male focus group participants did not identify this as a coping strategy.

Both patients and providers underscored the impact of HIV-related stigma in immigrant patients who currently live in or frequently visit Mexico. Concerns about patient lack of disclosure to other health care providers in Mexico or fear of their HIV status being disclosed if care were received in Tijuana were raised by providers and not patients. However, wherever care is received, both patients and providers mentioned concern about being recognized at an HIV care facility. In contrast to other studies that identified provider language-mediated barriers to clinical trials participation (King et al., 2007; Stone et al., 1998), our study indicated a genuine earnestness on the part of some providers to accommodate for patient language needs.

Providers were aware of the barriers that limited English proficiency could place on patient ability to participate in clinical trials and provided recommendations on how to reduce these barriers. Patient resourcefulness to bring their own interpreter, however, was not necessarily a bridge for this barrier when clinical trials materials were available in English only.

Our finding on the role of patient-provider racial or ethnic concordance offers partial support to the observation of Sohler and colleagues (Sohler, Fitzpatrick, Lindsay, Anastos, & Cunningham, 2007), that patient-provider ethnic or racial concordance was not associated with trust in provider, that is, patients tended to trust their providers regardless of whether they were of the same race/ethnicity or not. Patients in our study were aware that culturally-effective clinical communication is enhanced when receiving care from clinicians who are of Mexican-origin and familiar with Latino culture, however they were particularly appreciative of efforts made by their non-Latino providers to learn Spanish.

We observed several instances of the seemingly paradoxical nature of improving inclusivity of Latino populations into HIV clinical research studies and HIV care provision in a border context. Paradoxical responses were found for clinical trials locations; the role of family in supporting clinical trials participation; and delivery of culturally-effective care (Zúñiga et al., 2006). Although providers and patients indicated enthusiastic endorsement of having clinical trials recruitment and care centers closer to where Latino communities reside, stigma, manifested as concern over being seen at a clinical trials site or clinic exclusively for persons living with HIV, was expressed during interviews with providers as a clear barrier to clinical trials participation.

Prior recommendations to reduce barriers to HIV clinical trials participation for traditionally underserved communities include improving patient satisfaction with the quality of the patient-provider relationship and improving physician referrals to clinical trials (Cargill & Stone, 2005). Based on our study findings, opportunities to move HIV clinical trial centers closer to communities may address logistical problems for many Latinos living with HIV. However, this will necessitate thoughtful consideration of how stigma can be mitigated, with the essential need for feedback from community members themselves. Community member perspectives on research, the research institution's reputation in the community, as well as the relationship between researchers and the target community are all important considerations for successful recruitment into research studies (Sullivan et al., 2001). Concern over immigration issues necessitates that clinicians who serve immigrant communities also consider this as a potential barrier to care and clinical trials access for their patients. Provider opportunities to mitigate this concern may include becoming informed about immigrant patient rights (National Immigration Project, 2004); being sensitive to the potential for

immigration-specific duress in immigrant populations (e.g., concern about taking public transportation to clinical trials site for fear of encountering immigration authorities); and reassuring patients that their relationship with providers will not be compromised through a violation of trust.

Because our populations were drawn from care centers affiliated with a university research center, our findings may not be generalizable to other providers and Latino subgroups or nonborder dwelling populations, or populations who have had less experience with clinical trials. Although study researchers made an effort to recruit persons living with HIV who had and had not participated in clinical trials, it was apparent, particularly in the men's groups, that most participants had some experience with and knowledge about clinical trials due to receiving care from providers affiliated with the academic medical center and perhaps also due to length of time living with HIV. Nevertheless, future study is needed to understand the relative importance of major barriers in Latino populations. We also wish to acknowledge potential bias in focus group study questions. For example, questions specific to documentation status as a barrier to care could have elicited biased responses. We found, however, that as a whole, our study measure elicited frank participant discussion of sensitive issues such as stress of crossing the border with HIV medications or fear of deportation which enriched the depth of understanding of their perceived barriers to clinical trials participation and care. Finally, our small sample size may have missed important issues that larger studies may have uncovered with patients and HIV clinicians. The qualitative nature of this work, however, provides us with an in-depth understanding of barriers to clinical trials that informs future interventions to improve clinical trials representation.

CONCLUSIONS

Understanding barriers to participation in clinical trials is fundamentally inseparable from barriers to HIV-related care faced by Latino populations overall. Efforts to decrease disparities in clinical trials participation among Latino populations will include many, if not all, of the same strategies to improve patient engagement into care. This study attempts to fill an important gap in our understanding of low Latino recruitment into clinical trials, and is worthy of attention in future patient-level or provider-level interventions to promote clinical trials participation. Efforts must be made to improve consciousness among HIV clinical trials clinicians and staff of the multiple barriers potentially faced by their Latino patients, including the profound impact of HIV stigma and limited English proficiency on clinical interactions and activities. That immigrants of Mexican origin comprise a large proportion of persons living with HIV/AIDS in California makes imperative the inclusion of

deportation anxiety and U.S. immigration policies in discussions of improving access to HIV care, including participation in clinical trials.

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