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Exploring Barriers and Facilitators to Participation of Male-To-Female Transgender Persons in Preventive HIV Vaccine Clinical Trials

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Abstract

Observed seroincidence and prevalence rates in male to female (MTF) transgender individuals highlight the need for effective targeted HIV prevention strategies for this community. In order to develop an effective vaccine that can be used by transgender women, researchers must understand and address existing structural issues that present barriers to this group's participation in HIV vaccine clinical trials. Overcoming barriers to participation is important for ensuring HIV vaccine acceptability and efficacy for the MTF transgender community. To explore barriers and facilitators to MTF transgender participation in preventive HIV vaccine clinical trials, the HIV Vaccine Trials Network (HVTN) conducted focus groups among transgender women in four urban areas (Atlanta, Boston, Philadelphia and San Francisco). Barriers and facilitators to engagement of transgender women in preventive HIV vaccine clinical trials led to the following recommendations: (1) transgender cultural competency training; (2) creating trans-friendly environments; (3) true partnerships with local trans-friendly organizations and health care providers; (4) protocols that focus on transgender specific issues; and (5) data collection and tracking of transgender individuals. These results have implications for the conduct of HIV vaccine trials, as well as engagement of transgender women in research programs in general.

Keywords

HIV; vaccine; transgender women

Introduction

Transgender is a term used to describe a range of individuals with gender identities discordant from sex assignment at birth. Research on this population has been fairly limited and few studies address HIV prevention with male-to-female (MTF) transwomen (Bockting, Rosser, & Scheltema, 1999; Nemoto, Operario, Keatley, Han, & Soma, 2004; Nemoto, Operario, Keatley, Nguyen, & Sugano, 2005). Prevalence of HIV infection among transwomen in the United States has been reported to be as high as 52% in the general transfemale population (Edwards, Fisher, & Reynolds, 2007) and as high as 68% among transfemale commercial sex workers (Elifson et al., 1993). A recent national survey (Grant et al., 2011) found reported prevalence rates of HIV infection among transgender people (2.64%) were four times the national average (.45%), with rates higher among transgender people of color (25% of African Americans, 11% of Latino/as, 7% of American Indians, and 4% of Asian-Americans). Several studies have found HIV incidence (adjusted relative hazard ratio [HR], 5.0; 95% CI, 1.5–16.2 infections per 100 person-years) and prevalence (41% – 63%) rates to be highest among African American transwomen (Clements-Nolle, Marx, Guzman, & Katz, 2001; Kellogg, Clements-Nolle, Dilley, Katz, & McFarland, 2001; Nemoto et al., 2004; Simon, Reback, & Bemis, 2000).

Multiple risk behaviors contribute to HIV incidence among transwomen. Increased seroconversion rates are significantly associated with reported unprotected receptive anal sex (HR, 3.9; 95% CI, 1.2–13.1) (Kellogg et al., 2001). Correlates of HIV-positive serostatus among transwomen include: annual income of less than US\$12,000 (31%, $p < 0.01$) (Simon et al., 2000), less than 12 years of education (25%, $p < 0.01$) (Simon et al., 2000), multiple sex partners (OR, 2.64; 95% CI, 1.50–4.62) (Clements-Nolle et al., 2001; Nemoto, Luke, Mamo, Ching, & Patria, 1999), history of injection drug use (OR, 2.69; 95% CI, 1.56–4.62) (Clements-Nolle et al., 2001), and unsafe sex practices (e.g., sex without a condom (62.5%, $p < 0.05$), and sex work as a main source of income (26%, $p = 0.11$)) (Kellogg et al., 2001; Kenagy, 2002; Simon et al., 2000).

Observed seroincidence and prevalence rates among transwomen highlight the urgent need for effective targeted HIV prevention strategies and more inclusive HIV biomedical research studies for the transgender community. For example, in order to develop an effective HIV vaccine for transwomen, researchers must understand and address existing structural issues that present barriers to their participation in research. Overcoming barriers to participation can ensure HIV vaccine acceptability for transwomen. Several studies have examined barriers to access to healthcare for transgender individuals and can be utilized to inform these efforts. It is important to note that these barriers are multifactorial and include: lack of provider knowledge or interest in trans healthcare (Snelgrove, Jasudavicius, Rowe, Head, & Bauer, 2012); lack of trans-friendly health care providers (Sanchez, Sanchez, & Danoff, 2009); and discrimination (Kenagy, 2005) or fear of discrimination (Boyce, Barrington, Bolanos, Arandi, & Paz-Bailey, 2012).

Since the implementation of collecting transgender-specific demographic data, enrollment of transwomen participants in preventive HIV vaccine trials has been modest. Because of their high risk of HIV acquisition as compared to other groups, the HIV Vaccine Trials Network

(HVTN) recognizes the urgent need to include transgender individuals in vaccine research. Although there are several publications detailing barriers and facilitators to HIV vaccine trial participation experienced by other populations (Moutsiakis & Chin, 2007; Newman et al., 2006; Newman & Logie, 2010; Sobieszczyk, Xu, Goodman, Lucy, & Koblin, 2009; Voytek, Jones, & Metzger, 2011) little is known about variables impacting HIV vaccine clinical trial participation among transgender individuals. The formative data presented here provides important insight into barriers and facilitators to the participation of transwomen in preventive HIV vaccine clinical trials. Our presentation of data specific to transwomen, is not intended to exclude transgender men. Rather, recognizing the high HIV seroincidence and prevalence rates among transwomen, we strive to begin a dialogue on the inclusion of transwomen in preventive HIV vaccine research to increase awareness of the existing circumstances and special needs of all members of the transgender community. This article provides first person accounts from transwomen regarding barriers and facilitators to participation in preventive HIV vaccine clinical trials, and includes implications for addressing them, and directions for facilitating transwomen's research participation.

Methods

Procedures

Focus groups of transwomen were conducted in Atlanta, Boston, Philadelphia and San Francisco (one in each city). In each city, HVTN Clinical Research Site (CRS) staff assisted in reaching out to local community-based organizations (CBOs) serving transgender individuals to recruit participants. Potential participants responded to flyers posted at CBO venues by calling the local contact person (CRS or CBO staff) and were screened by phone. The eligibility criteria were: a) self-identified MTF transwoman; b) aged 18 to 55 years; c) has had sexual intercourse with a man without a condom in the last 12 months; and d) self-identified as HIV-negative or HIV serostatus unknown. Eligible participants were then scheduled for a two hour focus group held at the CBO and paid \$30 for their time. Focus groups were digitally recorded, transcribed verbatim and uploaded into Atlas.ti6 software. Human Subjects approval was obtained at the Fred Hutchinson Cancer Research Center (FHCRC) (HSD #4950).

Data Analysis

The focus group guide consisted of semi-structured open-ended questions that assessed four domains: a) attitudes and perceptions of research and research participation; b) attitudes and perceptions of preventive HIV vaccine research; c) perceptions and opinions regarding recruitment and engagement strategies; and d) key health issues for the MTF community. A team of three researchers (MA, RY, & JM) completed the qualitative data reduction.

Thematic analysis was utilized to review and code transcripts, including *in vivo*, line-by-line and focused coding, and a constant comparative method. The first step of horizontalization (Moustakas, 1994) involved independent review of each focus group for recurring statements across participants (e.g., societal marginalization; mistrust of the health care system). After independently coding the first focus group, researchers met to discuss corresponding themes, develop clusters of meaning (i.e., barriers vs. facilitators to

participation), and create a codebook to organize all identified themes. The codebook, which listed all facilitators and barriers identified in the text, was then utilized to analyze subsequent transcripts and generate new codes as they arose in an iterative process. After the three researchers independently reviewed the transcripts, they met as a team and differences in coding were resolved by consensus. To enhance the validity of the findings, we employed data source triangulation (comparing transcripts with memos and notes), investigator triangulation (using three independent coders), and peer debriefing (review by partners at transfriendly organizations and staff that work closely with the transgender community). The senior researcher reviewed coding on each transcript before entering the data into Atlas.ti6.

Results

Demographics

Table 1 lists the participants' major demographic characteristics. Forty-two individuals (N = 42) participated in these groups. The majority were African-American (57%). Forty-five percent reported annual incomes below the US poverty line for a one person household (\$10,890 annual income) and seventy-four percent reported annual incomes of less than \$20,000. Almost all (n = 41) participant¹ reported having sex with men and the majority (76%) considered themselves heterosexual. Others identified as homosexual or gay (5%), bisexual (12%), gender queer (2%), or chose not to identify a sexual orientation (5%). The median number of unprotected anal sex partners in the six months prior to the focus group was 1 (M = 6.5; range = 1–100). Fifty-two percent had never participated in behavioral or biomedical research. Seven (17%) were unsure of previous research participation and two (5%) chose not to answer. Among those with a history of biomedical research participation (n=11, 26%), two reported participating in a Pre-Exposure Prophylaxis (PrEP) clinical trial and one in a vaccine clinical trial.

Across the groups, five distinct themes regarding barriers and four distinct themes regarding facilitators emerged regarding participation in HIV vaccine research among transwomen. Barriers included: (1) stigma; (2) being unaware and misinformed; (3) exclusion from research; (4) mistrust of the scientific community; and (5) perceived possible vaccine side effects. Facilitators included: (1) increased information and awareness; (2) culturally competent research staff; (3) recommendation from a trusted trans-friendly health care provider; and (4) assistance with basic needs.

Stigma

Although many of the transwomen recognized HIV as a concern in their community, risk for HIV was often low on the list of the many challenges they face. All participants recounted experiences of discrimination, mistreatment and abuse as a result of their gender identity. Participants viewed HIV/AIDS as another source of stigma and discrimination for the transgender community. Transwomen felt that their already marginalized reality would be

¹Although all participants reported having sex with men during screening and were thus eligible to participate, one participant reported not having sex with men on the demographic form completed prior to the focus group.

negatively impacted by participation in a preventive HIV vaccine trial. The dual stigmatization of being transgender and being labeled as HIV seropositive was perceived as a formidable barrier to participation in HIV vaccine research.

That's a very stigma on the trans girls because we are very much stigmatized anyway. I have a whole lot of girlfriends that want to know about the vaccine, that's trans, but they too scared to go into certain places to learn about it because they don't want no one to think that they have it [HIV], which they don't have it. (Philadelphia)

Many of the women felt that society saw them as being HIV seropositive and participation in an HIV vaccine trial would provide additional evidence for this. A Boston participant explained why she would not participate, "If you ask me personally right now, the way I see it, it's like if you talk about HIV right now in society, they're just going to tag it to us." Furthermore, transwomen reported being suspicious of the motives of researchers as a result of past discrimination by health care professionals.

Well, I don't think your motive is where it should be. So therefore, I'm not going to put myself out there and make - it's already that we have people are mocking us for whatever reason. (Atlanta)

Several participants expressed annoyance at the assumption transgender individuals engage in high risk sexual behavior. While recognizing the HIV disparities in their community, participants felt this assumption further compromises their already marginalized social status.

Participants explained the stigma and discrimination experienced by transwomen often leads to a fragmented community. The struggle to ensure personal safety (e.g., efforts to avoid being identified as transgender) and to meet basic needs (i.e., housing, food) often leads to competition and division. The perception of competition among women and the need for leadership and direction in the community was a persistent theme across all focus groups. As one Atlanta participant explained, "You look more real [able to pass as a biological woman] than so and so and so and so. And that breeds competition so that too often...you get to the point where you automatically see another [transgender] girl that you don't know, and there's that disconnect right away." Another Philadelphia participant summed up the need for community solidarity by stating, "We definitely don't have no unity. Imagine that."

Unaware and Misinformed

The most frequently cited barrier to HIV vaccine trial participation was lack of exposure to information. Participants reported having either no exposure or limited exposure, which often translated into receiving inaccurate information. This general lack of awareness and information regarding preventive HIV vaccine clinical trials had the greatest impact on decisions to participate.

For some participants, the lack of information about HIV vaccine research led them to question its importance or relevance. The participants were well aware of HIV disparities in their community and many often received information on HIV, other STIs and health issues.

The absence of HIV vaccine literature in the materials and resources available to them was cause for concern and raised many questions.

Because what I'm hearing here is that we don't know nothing about the vaccine. We don't know what they're doing. Here is, I'm being honest with you, this is the first time I'm hearing about anything about the vaccine. And I feel like all the stuff that they can send me in the mail about a survey, about HIV, a doctor's appointment to get tested, and all that other good stuff, they can tell me exactly where they at, where they say we're going to try this, and we're just informing you. (Philadelphia)

Excluded from Research

The majority of participants perceived themselves as being excluded from research. Generally, they lamented over the absence of a research agenda or any focus in research on transwomen. Their perception was that research is either focused on MSM, and as transwomen they were lumped with this group, or they perceived research to be focused on biological women, and they were excluded. As one participant in Atlanta explained, "... It's all MSM's and most [transgender] people don't consider themselves men having sex with men. And I heard of one that was for women, but is it for the trans [women]?"

A common belief was that if a transwomen was accepted into a study, the research staff would consider her an MSM. As an Atlanta participant noted, "If you're accepted, they're going to consider you as an MSM." Transwomen felt that researchers did not prioritize them in the same way they did other populations (i.e., MSM and biological women) and if they were included, it was as an afterthought when researchers had exhausted all other possibilities. As one Philadelphia participant noted, "I'm quite sure this is not your first research on this. This is your first one with transgenders as one of the ladies said over here; we're always last on the list. We're last on the list to get asked. And then they run out of people, then hey, what about you? Get on the list. That's how they [researchers] do us."

Mistrust of the scientific community

Pervasive fear and myths about scientific research in general, lack of scientific literacy regarding ongoing HIV vaccine research, and socioeconomic, cultural and racial barriers deter the MTF community from participating in studies. Transwomen in the San Francisco and Philadelphia groups expressed not only mistrust, but a belief that the scientific agenda was at odds with their wellbeing. These participants viewed HIV prevention research as a money making enterprise wherein all of the risk was placed on them with negligible compensation. As one San Francisco transwoman explained, "The pharmaceutical companies make out like kings when you go through that study and you get peanuts. They give us peanuts not millions. They make billions from this."

Furthermore, the general lack of trust and confidence in the larger scientific community provided ample reason for lack of involvement. A Boston participant stated, "All of them - the vaccine, the shots. All of them. It's just like can you really trust what's inside of it? Like, is your doctor really telling you the truth that's inside of it?" This lack of trust led many to believe that once a vaccine was available there would be limited or no availability to them or

the larger transgender community. They perceived that their social standing would place them last in line and as such participating in an HIV vaccine clinical trial would not benefit their community.

We'll get the vaccine after half of us are dead, and then okay, we got the minority out. Now, let's give up the vaccine. It doesn't make sense for you to talk about a vaccine, and then you create a vaccine, and we're the tail end to get the vaccine. (Philadelphia)

Perceived possible vaccine side effects

Another barrier to participation is the fear of unknown side effects of the vaccine. According to one participant in Boston, "They ain't sticking none of that up in my body. I might get sick and never turn back. I might turn crazy or something, girl." Echoing this sentiment, a participant from San Francisco explained, "So if you take a shot from somebody else, you don't know what is this. What if it creates some other something incurable? Who is to say that's not how AIDS came about?"

Related to the fear of side effects is the fear that participants are being injected with live HIV virus, and that researchers have not done an adequate job of explaining the composition of the vaccines being tested.

[The] vaccine to me sounds like a flu shot. It's like you get injected with the flu, and then your body has time to start fixing it up and throw it out, right. So for me, when this vaccine research from the Department of Health, my understanding was they were going to shoot me with AIDS or HIV and see if your body can counteract it like a mouse to a scientist. (San Francisco)

Another barrier to participation in the MTF transgender community is fear of the unknown risks of vaccines interacting with hormone therapy or sexual reassignment surgery. As one Atlanta participant stated, "In order for us to get a point where a possible vaccine would work and not clash with our hormones, there would have to be one woman taking the study to create the vaccine so we'll know the side effects." All participants across the focus groups discussed either silicone or hormone use and there was concern about the lack of information and research about potential negative interactions.

Facilitators to Participation

Although many barriers to participation were reported, only a few participants indicated they would never participate in a preventive HIV vaccine trial. The large majority identified factors that would facilitate participation in a preventive HIV vaccine clinical trial.

Provision of information and increased awareness

Most participants who reported knowing very little or nothing about HIV vaccine research also expressed a desire to know more. As one Boston woman stated, "I honestly know nothing about the vaccine. I would like to know more about this vaccine and how these vaccines work." Participants felt that increasing HIV vaccine research awareness for transwomen and the larger transgender community would not only increase the knowledge

of the community but would facilitate participation in clinical trials. A Philadelphia participant captured the sentiment of the groups when she stated, “But for the trans community to be educated on it (HIV vaccine research), about the vaccine itself, that’s the whole key. You can’t get us (transwomen) into something if we know nothing about it.”

Culturally competent staff

As a result of past mistreatment and discrimination, participants were sensitized to reception and staff behavior that they perceived as judgmental toward the transgender community. Women highlighted the need for staff to “understand” the transgender community and what “life is like” for transgender women. Several women underscored the importance of establishing relationships with the larger transgender community and building rapport with individual transgender participants. Many women related past experiences as participants in research projects that left them wary of staff. As one San Francisco woman explained, “I just had the feeling of big time discrimination and the staff was just unsafe to be around.” Another San Francisco woman summarized the importance of competent staff stating, “But they need to establish a relationship with us. If they had a representative from our community that was hired to work for them and advocate to us on their behalf, then we could actually have some kind of relationship.”

Recommendation by a trusted trans-friendly primary care provider

All participants were very knowledgeable about health care providers who were trans-friendly. In each of the cities, with the exception of San Francisco (where there were many), there were only a handful (and in some cases (i.e. Atlanta) only one or two) of providers who fit this description. These providers were described as trusted allies and valuable resources for health care and other information. Many women actively sought advice and information from these providers. As one Boston woman explained, “My primary care provider could do a little research for me and get me something to really just learn more.” Several women stated that a recommendation from these providers would facilitate their participation in research. As an Atlanta participant pointed out, “If my doctor was talking to me about it [a clinical trial], I think it would stand out more. I’d probably be more inclined because then there would be someone actually talking to you about it and providing you with information. And right now, I don’t know too many doctors who typically have transgender patients. I know maybe two.”

Assistance with basic needs

The San Francisco and Atlanta focus groups focused on the “responsibility” of researchers and the research community to assist transwomen in meeting their basic needs. Several women noted that the effort needed to obtain basic every day needs often prevented research participation. The women noted that the majority of transgender women in their community spent most of their time securing basic needs. As such, there was little time for engaging in other activities such as research participation. The provision of resources and services would facilitate participation among transwomen. As one San Francisco woman explained, “Put transitional homes out there. Put educational scholarships so we can get educated. Make housing available readily because we’re going to be the last to be helped in the end. Why? Because we are at the bottom. Never had money, never had clothes, never had a house.”

Discussion

More participatory methods are needed to allow transwomen to voice their needs to researchers. Mixed methods data would help guide researchers in developing more trans-friendly and participant focused clinical trials. We hope this data provides a foundation for future research and helps elucidate existing barriers and facilitators. Although the data presented here focus on HIV vaccine research, it has implications for the larger research community working with transgender persons. Drawing from the literature and formative data, we have identified several best practices or recommendations that we believe may improve the engagement of transgender women in preventive HIV vaccine trials specifically and research generally.

Recommendations

1. Transgender cultural responsiveness training for all research site personnel—As a result of previous experiences with verbal abuse, discrimination or insensitivity many transwomen may not trust the health care system or health care providers. Many health care providers lack the knowledge or experience to adequately address health concerns relevant to the trans-community (Grant et al., 2011). This blind spot can often lead to trans-patients not feeling understood or respected by clinical staff. According to the National Transgender Discrimination Survey (Grant et al., 2011), lack of provider knowledge, refusal of care, and pervasive harassment were common among transgender persons seeking access to medical services. These issues were further exacerbated by racial and ethnic discrimination. Social marginalization, discrimination and stigma have been identified as factors contributing to lack of employment, limited employment and housing opportunities, living below the poverty threshold, and engagement in high risk sex work among MTF individuals (Bockting, Robinson, & Rosser, 1998; Nemoto et al., 1999; Nemoto, Sausa, Operario, & Keatley, 2006).

One of the most significant challenges transwomen face is the hostility they encounter from people who are uncomfortable with transgender individuals. This becomes a major obstacle for transwomen to access needed services and compromises their human rights and safety. To fully engage the trust and participation of transwomen, CRS personnel must be cognizant of and able to identify the special needs and experiences of this population. They must also have the necessary skills to effectively and sensitively work with the transgender community in HIV prevention and vaccine research. Implementing a cultural responsiveness training that addresses these topical issues may foster better relationships with the transgender community.

2. Creating trans-friendly environments—The inclusion of transwomen requires the provision of trans-friendly spaces that demonstrate concern for safety and provide support. To do this effectively Mottet and Tanis (2008) identify nine key areas that must be addressed and provide guidance for the creation of trans-friendly spaces. The nine keys to transgender inclusion are: (1) full integration of transpeople at every organizational level; (2) recruiting a broad range of transpeople; (3) creating a welcoming environment; (4) dealing with prejudice; (5) acknowledging past mistakes regarding trans-inclusion; (6)

offering trans-inclusive programming, services and advocacy positions; (7) understanding transgender experiences; (8) understanding one's role as an ally; and (9) having fair employment practices.

3. True partnership with local trans-friendly organizations and health care providers—The lack of information and awareness of HIV vaccine research suggests the need for targeted advertising and marketing in the transgender community. Furthermore, data presented here suggest the need to identify and reach out to transfriendly organizations and health care providers to build and maintain strong relationships and partnerships that include the provision of HIV vaccine information and updates as they become available.

With increased understanding of the transgender experience, CRS personnel have an enhanced capacity to identify and implement actions that are transgender-inclusive. In addition, site personnel are better equipped to recognize and demonstrate their role as transgender allies, which involve being aware of the challenges that transgender people experience, and actively working with the community to decrease these disparities. This may be done by establishing partnerships with local trans-friendly and LGBT organizations / allies. CRS sites might benefit from training in the utilization of Community-Based Participatory Research methods (CBPR, Israel, Eng, Schulz, & Parker, 2005; Minkler and Wallerstein, 2003) to assist in creating reciprocal and equitable partnerships with transgender community members, and trans-friendly organizations and health care providers. Finally, several joint activities have been proposed to strengthen partnerships and allow the research site and organizations to pool resources and collectively serve the needs of the community (Mottet & Tanis, 2008).

4. Protocols that focus on transgender specific issues (i.e., exploring vaccine interactions with hormones)—To adequately address the needs of the transgender community, transgender individuals need to be included in the larger research agenda. In a recent report providing guidance for research with LGBT populations, the Institute of Medicine (IOM, 2011) highlighted the importance of increasing participation of sexual and gender minorities in research and recommended that NIH and other funding agencies encourage researchers to include sexual and gender minorities explicitly in their samples.

One way to facilitate this is to explore the incorporation of ancillary studies that contribute to a wider understanding of the transgender community. These studies might address important gaps in our current understanding of transgender health and HIV, including: collecting data to establish lab norms for transwomen; exploring the correlates of HIV risk and injection (both substance and non-substance related) risk; identifying associations between self-reported adverse events or social harms and transgender identity; and identifying clinically relevant interactions between the use of hormone therapy and preventive HIV vaccine products. It may be challenging to recruit enough transgender participants to achieve adequate power for a completely transgender study. However, identifying transgender participants across protocols may allow for a substantial subsample to collect summary safety and efficacy estimates for this population.

5. Data collection and tracking of transgender individuals—Recent efforts in the scientific community to be more inclusive in the measurement of gender identity should be expanded. The historical gestalt of gender as a binary variable (male or female) has ignored the fluid nature of gender identity. Young and Meyer (2005) highlight the importance of recognizing variation with regard to self-identity labels and note that these labels are often fluid and may vary according to gender, culture, social class, ethnicity, and other factors. The CDC's recognition of transgender as a reportable gender identity, and the separation of transwomen from the MSM category in data reporting, provide a model for funding and research institutions. The IOM report (2011) highlighted the importance of collecting data on sexual orientation and gender identity in the same way that data on race and ethnicity are collected.

The HVTN is engaging in activities that will increase the Network's ability to accurately collect data on participants who identify as transgender, increase the CRS staff's current knowledge of the transgender community, and improve the overall experience of transgender individuals in preventive HIV vaccine trials. With the inclusion of questions distinguishing sex assigned at birth from current gender identity, the Network will for the first time be able to analyze gender identity data in a meaningful way and provide information regarding findings to the transgender community. To improve the quality and validity of gender data across all clinical research, research institutions should, at the very least, collect data that distinguishes sex assigned at birth from current gender identity and closely track adverse event reporting to determine side effects and drug interactions with hormone therapy in transgender individuals.

In addition to the current initiatives focused on capturing gender identity on demographic forms, a review of existing research templates or documents is needed to identify language that could be made more transgender inclusive and culturally responsive. One example is to specify that pregnancy tests are required only for those individuals born female who are engaging in sexual behavior that could lead to pregnancy.

Conclusion

The project and findings summarized in this report represent a first step in what must be an ongoing effort to understand the needs of the transgender community and effectively engage transgender individuals in preventive HIV vaccine trials. The data presented here is limited to transwomen recruited by CRS staff and CBOs serving transgender individuals in four US metropolitan areas. As such, it is not generalizable to the larger transgender community. To reflect the diversity of the transgender community, more formative research is required in different geographic areas, including rural and other non-urban metropolitan areas. Future research efforts should strive to increase racial and ethnic diversity of transgender participants. In addition, more data are needed regarding the experiences and perceptions of researchers working with the transgender community. Future studies with researchers must explore: attitudes, beliefs and perceptions of working with transgender community; training needs; and infrastructure and support needed to work with the transgender community.

Finally, more focused and continuous efforts to include transgender individuals more broadly in research activities are necessary. As with any vulnerable population, special steps need to be taken to ensure transgender community members are included and have access to information. Inviting transgender persons to join Community Advisory Boards (CABs), hiring transgender individuals as site staff or faculty, and recruiting transgender individuals to serve on external advisory committees are a few examples of steps that may be taken to increase involvement of the transgender community. These recommendations are critical first steps for the scientific community to demonstrate respect, inclusivity, and engagement with the transgender community.

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Table 1

Focus Group Participants' Demographics

Characteristics	% of participants (n)
Race / Ethnicity	
White	14.3 (6)
African American	57.1 (24)
Latina	9.5 (4)
Asian	2.4 (1)
Native Hawaiian	2.4 (1)
Multiracial	14.3 (6)
Age (years)	
18–24	16.7 (7)
25–29	19.0 (8)
30–39	28.6 (12)
40–49	21.4 (9)
>50	14.3 (6)
Self-identified Sexual Orientation	
Heterosexual	76.2 (32)
Homosexual or Gay	4.8 (2)
Bisexual	11.8 (5)
Gender Queer	2.4 (1)
Chose not to identify	4.8 (2)
Annual Income	
Below Poverty Line (\$10,890)	45.0 (19)
\$11,000 – \$19,999	28.6 (12)
\$20,000 – \$49,999	9.5 (4)
Chose not to answer	16.7 (7)