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Peruvian Female Sex Workers' Ethical Perspectives on Their Participation in an HPV Vaccine Clinical Trial

Brandon Brown,

Program in Public Health, University of California, Irvine

Mariam Davtyan, and

Program in Public Health, University of California, Irvine

Celia B. Fisher

Center for Ethics Education, Department of Psychology, Fordham University

Abstract

This study examined female sex workers' evaluation of ethically relevant experiences of participating in an HPV4 vaccine clinical trial conducted in Lima, Peru (the Sunflower Study). The Sunflower Study provided all participants with HPV testing, treatment for those testing positive, and access to the vaccine for all testing negative. Themes that emerged from content analysis of interviews with 16 former participants included the importance of respectful treatment and access to healthcare not otherwise available and concerns about privacy protections, the potential for HIV stigma, and poststudy abandonment.

Keywords

ethics; vaccine trials; female sex workers; informed consent; confidentiality; risks and benefits

Public awareness of Human Papillomavirus (HPV) is generally very low. This is especially true in groups with high HPV exposure, including female sex workers (FSWs; Brown et al., 2012; Brown, Carcamo, Blas, Valderrama, & Halsey, 2010; Brown, Blas, Heidari, Carcamo, & Halsey, 2013). Knowledge of HPV as a risk factor for cervical cancer varies widely, and people often confuse HPV with other sexually transmitted infections (Brown et al., 2010; Klug, Hukelmann, & Blettner, 2008; Malta et al., 2007; Tarimo et al., 2011). Even with the availability of vaccines, vast improvements in education about HPV and intervention programs for implementing the vaccine are necessary (Brown et al., 2010; Tarimo et al., 2011). In addition, studies that assess participant perceptions of vaccine trials are lacking despite their importance for identifying barriers to studying implementation (Moodley, Pather, & Myer, 2005).

Decisions regarding appropriate human subjects protections for socially vulnerable populations often rely on the moral compass of researchers and interpretations of regulations by ethics committees (Fisher, 1999). The true experiences of study subjects may be distinct

from these perspectives and can inform researchers, public health officials, and ethics committees on providing true informed consent and ensuring participants' dignity, respect, and justice during their research experience (Fisher, 1999, 2004, 2011, 2015/*this issue*; Kim, Holloway, Frank, Wilson, & Kiebertz, 2008; Moodley et al., 2005). For example, ethics committee members may approve informed consent materials based on an erroneous perception of "forms of trust" that include the expectation that participants have an optimistic and trusting view of research (Kim, Holloway, Frank, Wilson, & Kiebertz, 2008) when research on the perspectives of social minority populations document HIV "experimental mistrust" as a major barrier to participation in HIV vaccine and medical and drug use treatment trials (Fisher, 2010; Fisher et al., 2008; McDonald, Townsend, Cox, Paterson, & Lafrenière, 2008; Mills et al., 2004). Moreover, investigator and ethics review committee assumptions regarding participants' understanding of vaccines in general and sexual health vaccine trials in particular may not adequately reflect participant misconceptions (Fisher, 2010). In addition, there are significant differences in the way ethical treatment is perceived among research participants and researchers, because understanding of participants' rights varies across countries, as does availability of approved treatment options (Angell, 1997; Jenkins et al., 2000; Klitzman, 2008; Singh, Govender, & Mills, 2007).

Although several studies have evaluated participants' understanding of the informed consent process, voluntary participation, and reasons for participating in HIV vaccine trials in the United States and in developing countries (Allen et al., 2005; Buchbinder et al., 2004; Excler et al., 2008; Fisher, 2010; Grady et al., 2008; Maek et al., 2003; Mills et al., 2006), to date little is known about participant perspectives on social value and personal risks and benefits of participation in HPV vaccine trials (Lindsey, Shah, Siberry, Jean-Philippe, & Levin, 2013).

Involving FSWs in sexual health preventive and treatment research also involves unique concerns of privacy and confidentiality because of the stigma associated with commercial sex work and the global marginalization of this group (Pedrosa, Yoshida, Faulhaber, Costa, & Schechter, 2009; Shoepf, 1991). Lack of understanding of the privacy protocol of a research study and in some cases lack of confidence in government authorities can cause distrust, perceived intrusiveness, and skepticism for FSWs to participate in research (Urada & Simmons, 2014). These feelings can place social and structural constraints on FSW participation in research studies. To facilitate participation of this population in research, FSWs must feel respected and perceive that their confidentiality and privacy are being maintained (Reed, Khoshnood, Blankenship, & Fisher, 2014). Furthermore, feelings of respect and trust in confidentiality is influenced by the consent process, staff gender and demeanor, the study environment, time requirements for study participation, survey content, and perceived community support for FSW involvement in research (Reed et al., 2014). Key benefits of participation perceived by FSWs participating in sexual health research includes access to HIV prevention and testing as well as positive and trusting relationships between sex workers and research teams (Goldenberg, Rivera Mindt, Rocha Jimenez, Brouwer, Morales Miranda, & Fisher, 2015/*this issue*).

To bridge this gap and to add to the existing knowledge, we assessed how Peruvian FSWs who previously participated in an HPV vaccine trial (the Sunflower Study) perceived their study participation. Using qualitative interviews we explored the role of participant mistrust, access to health care, understanding of informed consent, voluntary participation, motivation to participate, and the unique confidentiality and privacy concerns of FSWs.

METHOD

The purpose of this study was to examine the ethically relevant perspectives of Peruvian FSWs on their participation in the Sunflower Study, a Phase 4 clinical trial of the HPV vaccine (Brown et al., 2012; Brown et al., 2013; Brown et al., 2010; Shroff et al., 2013). The Sunflower Study included 200 healthy registered FSWs ages 18 to 26 years, living in Lima, with no known immune deficiency. All participants were provided with the HPV vaccine, HIV testing and counseling, cervical screening, condoms, lubricant, and syndromic treatment for sexually transmitted infections (STIs) over a period of 7 months. Most (92%) participants received three doses of vaccine, whereas at baseline, 23% of participants tested positive for any of the HPV4 vaccine genotypes with DNA testing.

Participants

Sixteen women, who had been previously enrolled in the Sunflower Study agreed to participate in the study following word-of-mouth recruitment. Recruitment for this study was done at a nongovernmental organization Via Libre among women who continued attending the clinic approximately one year following the completion of the Sunflower Study. A community advisory board of FSWs was created to help establish the study materials and identify ways to best remind participants of the previous study. We enrolled the first 16 women who came to the clinic and agreed to participate. Participants were between 23 and 29 years of age ($M = 25.8$, $SD = 1.74$). The majority had attended high school; six completed secondary school and two completed primary school. Most ($n = 11$) reported being single, two participants were either separated or divorced, and three participants were living with a partner. First sexual experience ranged from 12 to 19 years old ($M = 16.2$ years), and women reported they first received money for sex at ages ranging from 12 to 22 years ($M = 18.5$ years). Frequency of sex work ranged from 0 to 7 days per week, with an average of 5 days per week. Participants reported having conducted sex work for 3 to 11 years, with a monthly income ranged from 130 to 2,000 soles (\$47–\$720 USD) per month. Approximately half of the FSWs were brothel based and half outside brothels (44% and 56%, respectively), and their number of clients varied from one to 200 clients per month, with an average of 50 clients per month.

Procedures

This study was approved by the Institutional Review Board at the University of California, Irvine, and the institutional ethics committee of Asociación Civil Impacta Salud y Educación in Peru. Data were collected through a brief demographic survey and 1- to 2-hr semistructured interviews conducted in the participants' primary language, Spanish. Prior to informed consent, the women were refamiliarized with the Sunflower Study through the original Sunflower recruitment materials. The surveys collected basic demographic data

such as educational level, marital status, sexual health history, contraceptive use, history of health insurance, substance use, and sex-worker-specific information. Surveys also asked participants about their knowledge of HPV, any health services they had utilized since the completion of the Sunflower Study, and medical history of STIs. The final section of the surveys included a series of 4-point Likert scale questions regarding understanding of consent, participation experience, voluntariness, access to medical care, participant opinion on health care, and view of the small tokens of appreciation as compensation for participation in the clinical trial.

To obtain data on the participants' experiences, we conducted semistructured interviews that lasted 1 to 2 hr each. Individual interviews were conducted in Spanish, audio-recorded, transcribed verbatim, and translated into English. Transcripts were coded in Atlas.ti using open and axial coding. Codes were collapsed, combined, and developed into concepts and representative quotes. To protect confidentiality, no personal identifiers were collected and each participant was assigned and referred to using a specific color. An experienced focus group facilitator, who had previously worked with FSWs, facilitated the interviews.

Although measures were taken to ensure participant confidentiality, privacy, and ethical treatment in the Sunflower Study, it is not certain how participants perceived these constructs and whether they were sufficient in quelling fears, developing trust, and building a safe and informed environment during the study. The interviews began with questions regarding participants' initial motivation for study participation, their feelings about the method of recruitment, and whether a trust within the setting was established and if it changed throughout the course of the study. Questions then moved to examine participants' reflections on the informed consent procedures and whether the information was easy to understand, and whether their initial expectations of research risks and benefits were congruent with their actual experiences during and after the study. Participants were also queried about their expectation of vaccine efficacy. The interview then turned to initial concerns regarding privacy and confidentiality and whether they felt their concerns were addressed after having participated in the trial. The last set of questions focused on the influence of incentives on voluntary participation. Participants were asked if they were concerned that withdrawal from the study would mean loss of healthcare options and asked for their response to the small study incentive.

RESULTS

Responses to the preliminary questionnaires indicated that 1 year following completion of the Sunflower Study, most of the participants appeared to be knowledgeable about HPV and sought poststudy health care. Nearly all participants (94%) understood that HPV was sexually transmitted and that it was the main cause of cervical cancer (81%). Condoms were seen as the primary means of preventing HPV (87%). The majority of the participants (81%) had previously been to the health facility where the Sunflower Study was conducted, and 87% of participants were aware of a public health facility that offered medical care to FSWs following the Sunflower Study. On average, the women had visited a health facility for STI testing within the last 9.5 months.

Responses to our preliminary survey questions were consistent with opinions expressed about the Sunflower Study in the qualitative interviews described below. All responded that the primary reason for participating in the Sunflower Study was to obtain cervical cancer screen. All also reported that their participation in the original study was voluntary, although as described next, 81% believed they could withdraw at any time. A majority (87%) thought the study was well described in the consent, and enjoyed participating in the study (94%), and a minority (19%) thought they should have been paid for participation.

Qualitative data collected through interviews were coded and analyzed using Atlas.ti, and quantitative data were entered into a database and analyzed using Stata v13. Several ethically relevant themes emerged from our content analysis of the transcribed data. The most salient themes included motivation to participate, trust and dignity, respect, benefits and risks, stigma, access to healthcare, and privacy concerns. The semistructured interviews revealed that participants' motivation to participate was primarily to receive cervical screening. They felt that participation was completely voluntary and components of the informed consent were adequately understood. Similarly, participants' expectations of research risks and benefits were largely consistent with their experiences during and after the study, and they disclosed that trust was established and maintained throughout the study. Privacy and confidentiality were reported as critical aspects of research risks and were adequately addressed by study staff. Participants also expressed concerns about losing care provided in the study when the study ended, emphasizing feelings of abandonment. Most participants also stated that their participation was appreciated and they felt that they contributed greatly to science and to the scientific community.

Voluntariness, Study Access to Care, and Community Responsibility

All participants “agreed” or “strongly agreed” that participation in the current study was voluntary and that their primary motivation for participation was to receive cervical screening. The following remarks were made in regards to voluntary participation and access to care:

It was voluntary, definitely — Lilac

Absolutely, my participation was voluntary. — Brown

Yes, I knew [I could withdraw] but I wanted to continue. — Green

I was afraid of having an illness and since I saw care was available there, I called to see what it was about. I joined because of curiosity, more than anything. ... I felt anxious when I received my Pap and NIC III result; that was when I felt a bit of concern ... they took me, I had a biopsy and after this, a colposcopy and ‘cononizacion,’ something called a cone. ... They did not charge me anything. — Blue

However, some indicated that they did not feel they could withdraw from participation, and this was due to the potential importance of the study results to their communities and the access to the medical care provided by the study. For example, one participant explained that they knew they were free to withdraw from the study but did not want to withdraw, stating the research was “important” to themselves and their peers:

No never, to the contrary, I wanted to stay in the project. This type of project is important for my peers—colleagues who always stay in contact one way or another, and when new women enter [our profession] we always are informing them how we exchange information. . . . Actually all women should be a part of these types of studies, which are important because many people do not know or understand the environment. Those who are completely informed will be vigilant to the report [or results]. — Turquoise

Informed Consent Process

The majority of participant comments indicated that they had thoroughly understood the HPV trial risks and benefits as originally communicated through the Sunflower Study informed consent. Benefits included receipt of FDA-approved HPV4 vaccine at no cost, free Pap smears and treatment when indicated, and a small gift for attending each study visit. Risks included discomfort and a potential bruise from the blood draw; discomfort during Pap smear; discomfort in answering survey questions; and possibility of a “fainting” feeling, nausea, headache, or possibly allergic reactions after receiving the vaccine. The following responses conveyed their understanding:

Yes, at the first moment, I was a little scared but they explained that they would not say our names, and they aren’t going to take pictures, or asking for a lot of data, and they treated us well and they told us that they would not publish our names or anything, then I accepted. — Pink

Yes, at the beginning I did not know what a consent was, and they explained the project, the vaccine, and perhaps some consequences that it was going to bring step by step, but yes I had doubts I asked and they answered honestly. Yes I felt well informed. — Red

Yes, the girl, that day, explained everything to me, we have read a few pages [of the consent form] and she said how were going to do all the things that we were doing, about the tests, and they are not going to publish our names anything and everything that would happen, yes, she explained well, that’s why I accepted, I found it easy. — Pink

Other participants felt that their understanding of the consent as it applied to specific study procedures was less thorough but it would undoubtedly protect them from cancer:

More or less I thought it would protect me. — Green

They explained to me that I will be fully protected, if I understood well. — Sky
Blue

Well, I feel good, because I know I’m protected with the cervical cancer vaccine and now I’m waiting for other projects, to prevent other diseases. — Brown

Comments by two of the 16 participants suggested that they disagreed that the study was well described during the informed consent:

At some point I didn’t understand, I had questions. — Turquoise

That was like an experiment, I am not sure, I don’t know. — Fuchsia

Trust and Dignity

Sunflower Study staff met with a community advisory board of former FSW peer health promoters on how to best interact with potential study participants. This included training on how to present the study and how to respectfully respond to questions, and background into the daily life of FSWs. Participants expressed sentiments of gratitude and feelings of respect in the way they were treated by study staff during the trial. Each participant conveyed feeling respected and felt they were contributing to a worthwhile and important cause that could potentially impact the lives of other women like themselves. This is most poignantly illustrated in the following comment:

If nothing else, they always treated me as a human. — Blue

Participants noted that they perceived protocol and study procedure clarification by staff as displaying respect for them, thereby earning their trust, specifically if it was not initially gained. The staff members' attentiveness and thoughtfulness toward participants conveyed their good intentions, helping them shift their perspective from having fears to trusting staff. Many of the participants conveyed this even if some staff members were less respectful toward them:

At first I did not completely trust the study and staff, later I certainly did. —
Turquoise

I had a bit of fear but they earned my trust — Orange

I did trust/confide in all the staff members, especially one, but I did have a problem with one of the obstetricians. She treated me poorly, sometimes the speculum [during the cervical screenings] hurt me when she put it in, and I told her 'be careful.' She would say 'it may hurt you sometimes.' She treated us poorly and I didn't like the way she treated us ... but I did not feel she treated us this way because we are sex workers. I think that with any person she would have responded similarly. It is a lack of respect on her part and unprofessional, unlike the other staff members. — Fuchsia

Many expressed initial concern that the research staff would perpetuate the community discrimination and stigmatization they experienced as against FSWs:

At first when they explained everything to me I was a bit afraid, because sometimes bad people would get close to us, they would insult us, treat us poorly, discriminate against us, but when [the staff members] explained the study to us, I saw that they were good people that meant well. They explained risks we were generally unaware of in our professions, then I felt I could trust them and that's when I felt more a part of the study and would frequent the study more often. — Red

Their service was so friendly, for example, if you say that you work in a brothel or in any bar, you go to a regular hospital, they treat you very ugly, very ugly treatment. They don't look at you, and do not treat you well, however in Girasol [the Sunflower Study], I was treated very well. — Lilac

Personal and Community Benefits

The survey responses indicated that as a result of their participation in the Sunflower Study most women (13 of 16) understood that HPV can cause cervical cancer. All participants indicated that women can be infected with HPV, and 12 of 16 understood that the vaccine can protect against HPV and cervical cancer. In addition to the benefits of enhanced sexual health knowledge, the following statements were made in regards to study benefits:

Now I have learned how it [HPV] works and this has helped prevent that. I am very happy that I participated and have the vaccine now so I won't get sick. That makes me very happy. — Pink

I feel good, calm because I know I am protected with the vaccine for cervical cancer and I hope there are other protections like this to prevent other illnesses. — Brown

The trust gained from participation in the HPV trial fostered positive perceptions of clinical trials as important for improving the health of FSWs. Participants exhibited sentiments of being healthier and the importance of scientific research with the following comment:

All sex workers should be in a study like this and those who aren't sex workers, well it would be good if they were in it too. It's for the best. But in my case, I think that all the workers, like me, should definitely participate in studies like this. — Violet

Research Risks

In addition to benefits, participants also perceived the risks of study participation, and they included potential vaccine side effects. The following statements were in this context:

I thought I'll have some consequences, effects or something, maybe suddenly get a fever, it can give me some effect, any effect of the drugs that they put in it me. — Pink

Yes, I was afraid, and I thought it was not safe, and maybe they suddenly could transmit something, I don't know. — Fuchsia

Later, participants indicated that these perceived risks of vaccine side effects were not causes for distrust or reasons to withdraw from the study. They stated that the benefits of the vaccine, especially in protecting them from cervical cancer and genital warts, outweighed any potential risks. This comparison of potential risks and benefits was conveyed by several participants by the following comment:

Within the work that I have I take a unique risk and the truth I don't want cancer, never, I don't want it for anyone and it is for this reason that I accept and willingly decided as it is said to take the risk. — Grey

Privacy and Confidentiality

Concerns of privacy and confidentiality were prominent in the study population, and this was due to the social stigma experienced as FSWs. Some participants feared that family and

friends would discover they were engaged in sex work and therefore did not want any study information to potentially identify them as such. One participant noted,

Yes, I care about something, if someone recognized me in the place of my attention
— Green

Another stated that she needed to be told multiple times that her confidentiality and privacy would not be threatened. She had also asked specific questions about what type of information would be published in the study:

... They are not going to publish our names anything and everything that would happen, yes, she explained well, that's why I accepted, I found it easy, that I found it easy, yes. — Pink

Study participants appreciated the detailed information the staff provided about how their specific private information would be managed:

... Even our codes of each document, gave us a number and our names were only initial. There is trust between the girls who knew us. In the office what we were there was a woman and yes I felt that there were privacy, they revealed nothing of the results that we were. — Red

Postexperimental Attitudes: Gratitude and Abandonment

The majority of participants stated that they enjoyed participating in the study. Many also felt as though the visibility of sex workers as an important high-risk group for cervical cancer increased after the study. Participants indicated feeling grateful for the chance to participate in the study and to contribute to important research that may benefit others in their position. In addition, participants felt a sense of caring and understanding from study staff members and that studies like the Sunflower should occur more frequently. The following remarks were made in this context:

I gained trust and confidence in the study and staff members. ... I still retain that feeling towards them, well after the study is over. — Blue

I think that it would be good to try to come seek us out more, there should be more outreach because I think that there are a number of workers and female friends of mine who have not been able to have access [to vaccine and services]. This is the case in Lima, I do not know how it is elsewhere in other neighborhoods. — Red

Postexperimental attitudes and perceptions also came with some sense of abandonment and anxiety, particularly due to a fear of losing medical treatment and the sense of community fostered by the study once the study ended. The following statements were made in this regard:

I was in a lot of pain, because I wanted to keep continuing with the treatments, with advice of the doctors I know and trust. — Pink

After it was finished, I thought that they would forget about me. I never thought that afterwards they would return to visit. Now that I know that is not true, that they are looking after me I feel a lot better. — Red

Perceptions of Incentives

As a form of appreciation for participating in the Sunflower Study, participants were given the choice of several small gifts, such as small purse. The end of the study also elicited various differing attitudes regarding incentives and compensation. The following statements were made:

In every visit they gave us gifts, incentives, and I felt important. ... It was just right. My health was of more importance to me. — Green

We received gifts and I was grateful, and if they had not given me anything like this, I would have been grateful to them for keeping me in mind and making me part of the vaccines [study], that was enough. — Pink

I was surprised, I didn't think that I would be given anything, everything was free, so when I was given stuff I was rather glad that they had given me something, all that attention too, because I did not expect anything. — Yellow

Even though nearly half of the participants (seven of 16) responded that they should have been paid to participate in the study, interview responses indicated that other incentives and overall benefits from the study were sufficient and made them feel important. Examples were as follows:

We do not need the vaccine, but I most sincerely thought that at the end of all this they would give us money or something, but no, nothing, whenever I went, they just gave me a few things, combs, pillows, maybe they think I had no combs and pillows in my house, no, no, the truth is that I thought to receive many things, but no, it wasn't what I expected — Purple

In every visit they gave us gifts, incentives, and I felt important — Green

These things, the pocketbook, the memories they give us and our reimbursement we like also, therefore, yes it was OK and they would always give me something, I wouldn't return home empty handed — Red

DISCUSSION

High-risk and marginalized populations recruited for study participation are far more vulnerable to fear and distrust because they feel uncertain about voluntary commitment, their role as study participants, and what the researchers intend to do (Maek et al., 2003). However, when participants feel that they are respected, appreciated, and well informed by research personnel, their perceptions shift away from distrust (Maek et al., 2003; Mills et al., 2006). In the current study, most participants experienced empathy and fairness from study staff and developed trusting relationships as shown in other studies (Goldenberg et al., 2015/this issue). We also worked with brothel managers to gain their buy-in for the study, so that women had permission to participate. Seeking this permission has been shown to be required in other studies and helps facilitate retention as well (Goldenberg et al., 2015/this issue; Mills et al., 2006).

Participants of the current study provided an array of responses with respect to their individual experiences, and the themes arising from the in-depth interviews were centered around trust, access to health care, motivation to participate, and concerns regarding confidentiality and privacy. Overall, study participants felt they had benefited from having participated in the Sunflower Study because it increased their education about the HPV virus, provided vaccine protection from HPV, and motivated them to continue to seek cervical screening and generally be more vigilant about their healthcare.

All Sunflower Study participants received the HPV4 vaccine in this Phase 4 clinical study. This is distinctly different from Phase 3 vaccine studies that traditionally required a placebo control plus standard of care and that often lack the participation of participant representatives in the design and implementation of procedures (Ditmore & Allman, 2011; Lindsey et al., 2013). The uniform provision of services, the community engagement approach, and staff training in culturally appropriate and respectful practices taken by the Sunflower Study most likely led to early development of participant trust in a study and the study staff as well as an absence of fear, a salient and important theme mentioned by participants.

Despite the general positive evaluation, participants in our study had several privacy and confidentiality concerns related to both internal and community stigmatization of sex work. They feared being recognized at the study site and that their participation and test results would become public. Previous studies with FSWs illustrated similar concerns that public awareness by police or media could result in arrest or job loss, that family would discover the sexual nature of their work, and that community stigma would be exacerbated if it became known that they have a chronic infection (Reed et al., 2014; Urada & Simmons, 2014). The Sunflower Study sought to minimize such concerns. Participants were reassured about confidentiality protections both verbally by study staff and by actually viewing the records that contained subject identification numbers rather than personal identifiers.

The majority of respondents were satisfied with the informed consent process, the incentives provided, and the protection of their privacy and confidentiality. They felt as though their participation was valuable and that they were contributing to science in a meaningful and socially valid way. With respect to financial incentives, seven of 16 participants of the current study stated that they should have been paid to participate in the study. These findings are consistent with those of other researchers who found that financial motivation was only one among other important reasons for participation, including personal health benefits and contributions to science and to the health of others (Stunkel & Grady, 2011).

Along with the perceived benefits gained from participation in the Sunflower Study were feelings of desertion and abandonment when the study team completed the project. Such reactions are consistent with other studies involving participants in low healthcare resource settings (Wootten, Abbott, Siddons, Rosenthal, & Costello, 2011). Such findings suggest that future studies should include an increased effort to maintain closer attention to follow-up healthcare and examine the potential benefits of increasing participants' comprehension of study timetables (beginning and ending of clinical trials) in reducing this perception of abandonment (Wootten et al., 2011).

Challenges and Limitations

A contribution of the current study is that it illuminated FSWs' ethics-relevant attitudes toward their actual research participation rather than in response to hypothetical research vignettes (Buchbinder et al., 2004). A limitation of this qualitative work is generalizability. First, the Sunflower Study is unique in terms of clinical trials in that it provided all participants with equal access to HPV testing, treatment if testing was positive, and the HPV vaccine, a vaccine known to be effective. Thus positive reactions of participants need to be understood within this special context. In addition, the opinions and perceptions of the 16 individuals from the original Sunflower Study of 200 individuals may not be consistent with that of other FSWs who participated in the study itself or similar clinical trials. Moreover, because participants self-selected as opposed to being randomized, they may have been more likely to have had a positive experience in the original Sunflower clinical trial. As with other forms of qualitative research, small sample size, nonrandom selection of participants, and unique cultural contexts community history of participants limits generalizability but lends itself to transferability—providing sufficient detail to allow future investigators to determine if the themes transfer to their particular populations and research settings (Fisher & Wallace, 2000; Guba & Lincoln, 1982). At the same time, our participants' comments regarding fears about stigma and the importance of respectful treatment by research staff are consistent with studies exploring ethically relevant FSWs' attitudes toward HIV conducted in India, the Philippines, and Guatemala

Conclusions

The Sunflower Study inspired trust and gratitude among study participants due to the health benefits, confidentiality protections, and respect provided by study staff during the trial and efforts to ensure understanding of study procedures throughout. The continued interest in the study population following the initial study that the present ethics investigation illustrated fostered an additional sense that the investigators had an ongoing interest in the well-being of the participants. Based on the current study results and other literature on the topic, additional studies assessing postclinical trial perceptions are necessary to ensure that research participants are treated ethically and are aware of the importance of scientific research and its potential impact. Furthermore, researchers may also need to develop navigation plans to properly transition participants out of research projects once studies have ended. Continuation of treatment outside the scope of the research will help address the issue of abandonment and ensure a positive impact of participating in the research. With respect to engaging and motivating marginalized communities to participate in clinical trials, Malta et al. (2007) suggested reducing perceptions of stigma about sexually transmitted infections and health.

Studies related to sexual health risk can often increase anxiety among participants related to the potential diagnosis and treatment of sexually transmitted illnesses, which in turn can be a hindrance in recruiting participants and potentially contribute to participant mistrust (Maw, Reitano, & Roy, 1998). Working with health promoters and brothel managers and identifying peer leader participants may help to allay such fears and facilitate study participation and retention (Shroff et al., 2013). In addition, previous studies conclude that participants expect a certain atmosphere from clinical trials, particularly professionalism and

good organization (Fisher, 2010; Kost, Lee, Yessis, Coller, & Henderson, 2011). These participant expectations were met in the current study and lend themselves to the themes of trust, postexperimental perceptions, and stigma. Participants appear to better understand their roles and feel positively toward clinical research participation when their interaction with researchers is considered a social situation with active, consistent negotiation of participant roles (Morris & Balmer, 2006).

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