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Barriers and Facilitators in the Recruitment and Retention of Peruvian Female Sex Workers in a Randomized HPV Vaccine Trial

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Abstract

Objective: To share the lessons learned when recruiting and retaining Peruvian female sex workers (FSWs) in a clinical trial.

Methods: Peruvian FSWs 18-26 years of age were asked to join a clinical study of HPV vaccine starting in August 2009. Condoms, lubricants, and health services were given as an incentive to join the study, as well as a gift valued at three US dollars at each study visit for retention purposes.

Results: 120 participants completed the survey. Barriers to non-enrollment recruiting included the false association of our clinical trial with an ineffective HIV vaccine study, plans to become pregnant during the vaccine study, not identifying as sex workers, pushback from husbands with fear of vaccine related birth defects, questioning motives for a free vaccine, not wanting to use birth control, lack of high perceived value of incentives, and limited time availability. Barriers to retention included periodic travel out of Lima, high costs for commuting, the requirement of no clients one day before the visit, and misinformation by health care providers regarding associations between the vaccine and illnesses.

Conclusions: Working with health promoters and brothel managers, making periodic phone call reminders of appointments, and identifying participants who were peer leaders helped facilitate study participation and retention. Despite hardships in recruiting and retaining female sex workers, this group will participate in a study they deem useful for their health. Before recruiting female sex workers in clinical trials, potential barriers need to be addressed by study investigators.

Keywords: Cervical cancer; HPV Vaccines

Introduction

Cervical cancer is the second most common cancer in women worldwide, with 250,000 deaths per year, and persistent human papillomavirus (HPV) infection is found in nearly all cases [1]. Female sex workers (FSWs) are at higher risk of HPV infection and subsequent development of cervical cancer and HIV infection than the general population due to exposure to multiple sexual partners [2]. Vaccination of new brothel-based FSWs at routine HIV/STI screening visits could increase completion rates and lower the risk of HPV-related disease to bridge populations [3].

Recruitment and retention of participants in clinical trials is crucial to reach study objectives, but is often more difficult with marginalized and stigmatized populations. A number of studies have explored willingness to participate in HPV clinical trials among women and mothers of adolescents in the U.S. and Mexico [4-7]. Barriers identified included fear of side effects, effectiveness, cost, lack of information regarding the link between HPV infection and cervical cancer, needing to speak to their partner first, concerns that the vaccine would promote adolescent sexual behavior, and fear of experimentation [2]. The present study examines the barriers to recruitment and retention in a HPV clinical trial, and is an extension of project that provided HPV vaccines to FSWs in Lima, Peru [3]. Our goal is to evaluate the barriers and motivators of recruitment and retention in the HPV vaccine trial conducted among FSWs in Peru.

Methods

FSWs aged 18-26 years from 49 different brothel based locales in Lima, Peru, were asked to participate in an HPV clinical trial starting in August, 2009. Women who passed initial eligibility screening were given an appointment to undergo full written informed consent and study participation. Inclusion criteria for the study were age 18-26 years old, no reported immunodeficiency including HIV, presence of a uterus, not pregnant or planning a pregnancy in the next 7 months, and not previously received HPV vaccine. Participants who were eligible were randomized in a 1:1 ratio to receive the HPV4 vaccine in the standard (0,2,6 months) or a modified schedule (0,3,6 months) which paired more closely with the three month clinic visits to receive STI testing. The study sample size of 200 participants was built around vaccine dose completion. Having 57 women in each study condition provided over 80% power to detect a 25% total improvement in vaccine dose completion among those on the modified (0,3,6 month) schedule. Participants were randomized to each group in block sizes of 8 when they opened individually sealed envelopes which detailed their assignment. The trial was registered at clinicaltrials.gov with

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registration number NCT00925288. Ethics approval was obtained from Johns Hopkins Bloomberg School of Public Health IRB Committee, the Bioethics Committee of via Libre, and the Institutional Bioethics Committee of Universidad Peruana Cayetano Heredia.

Study visits included STI screening, counseling, surveys, and procurement of contraceptives. Incentives such as condoms, lubricants, and small gifts including a purse, beauty products, watches, and sarongs were given to participants at their appointments. Interviewer administered face to face surveys included both open-ended questions and yes/no questions assessing barriers and motivators to study retention. A database with each participant's contact information was created and updated after each visit. Additional details of study visit procedures are published elsewhere [3]. Survey data were double entered into EpilInfo 3.5.1 and checked for logic and range. Stata 9.0 was used for quantitative data analysis. Chi-square and Fisher's exact tests were used for comparison of categorical variables. Differences in means were computed by F test.

Results

Of the 200 participants enrolled, 182 (91%) received the last dose of vaccine, and completed the final survey (Figure 1). One hundred and twenty participants completed the 12 month extension study with results herein. The mean age of participants was 23.8 years, and the majority were either single or separated/divorced (68.3%). Participants 19-23 had significantly more difficulties attending their appointment ($p<0.01$). Eighty percent reported a prior pregnancy. Almost all participants reported residing in Lima (95.8), and 81.7% did not reside in the city where they worked. Participants between the ages of 24-28 had significantly more difficulties in attending appointments compared to those between the ages of 19-23 ($p<0.01$). Over 95% of participants reported less risky behavior following their participation in the study. When asked about differences in behavior, 38.3% of participants reported being more careful and cautious of their personal health, 26.7% reported increased self-esteem, self-control, and being more cautious of clients, 23.3% reported use of condoms, and 9.2% gained more information about HPV and HIV.

Barriers to the recruitment process included the association of our clinical trial with an ineffective HIV vaccine, non-identification as a sex worker, pushback from husbands with fear of vaccine-related birth defects, questioning motives for a free vaccine, lack of high perceived value of incentives, and not having the time to attend appointments. A majority of women who had difficulty attending appointments listed time constraints and exhaustion as a primary factor for non-participation. Other responses included child care responsibilities, lack of permission from work, questions from family, and long commute to study site.

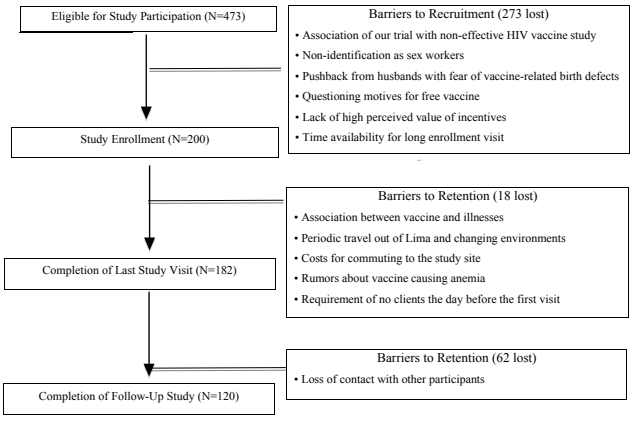

Figure 1: Flow-chart of recruitment and retention process in HPV vaccine clinical study.

Figure 1 illustrates reasons for loss to follow-up among study participants. Among those who reported difficulties coming to appointments (N=37) via survey, 18.9% reported lack of time, 48.6% reported being tired, and 32.4% reported various responses including lack of child care, no permission to miss work, questions from family, and a long commute to the study site. Motivators to retention included high levels of community and peer support for participating in the study. When asked for specific ways to increase FSW participation in clinical trials, over 75% suggested the researchers to visit the site directly. Other participants reported a need for increased study advertisement (10.8%), encouragement from recruiters (9.2%), with the remainder listed use of alternative locations and providing more incentives.

Discussion

When recruiting high-risk populations for clinical trials, barriers and motivators must be addressed to ensure maximal participation. In our study, nearly 2/3 of potential participants were ineligible, yet only 9% of study participants were lost due to barriers to retention thus indicating that many of the methods used to retain participants in the study were successful.

Factors that helped facilitate study participation and retention in our study included working with health promoters, providing periodic appointment reminders, working with brothel managers, and identifying FSWs who were peer leaders. Peer leaders have the potential to form a liaison between the research committee and the FSW community due to their reputation as a credible role model and can therefore serve as a powerful recruitment tool [8]. Furthermore, peer leaders are viewed as empowering, hold the reputation as positive role models, and are more successful at giving the target population information than professional health care providers [9].

Some participants were misinformed by physicians that HPV vaccine causes anemia. Misinformation must be controlled for in future studies to ensure retention of participants. Other barriers identified, including time constraints for appointments and lack of transportation are difficult to address with in person visits and limited budget for transportation reimbursement. On one occasion during this study, Peruvian sex workers in one brothel attacked their foreign peers and forced them out of their work location. Other participants left for home outside of Peru and then were unable to return due to political instability and closed borders. Unfortunately these factors cannot be controlled for directly by the study researchers.

A HIV vaccine trial conducted in Rio de Janeiro, Brazil attempted to recruit FSWs [10]. The primary barriers for recruitment included fear of being tested for HIV, lack of understanding of vaccines, illiteracy, unreliable contact information, and lack of money for transportation [10]. In our study, we noted similar barriers, and obtaining reliable and updated contact information was a priority. At each study visit, participant information sheets were updated to record changes in contact information. All phone calls were logged in an Excel file. Each participant was contacted a minimum of five times between visits to ensure retention.

One major limitation in this study is that all behavioral data were self-reported and subject to response bias. Another limitation is the

small sample size. There are an estimated 88,640 FSWs in Peru, and 18,000 in Lima—thus, our results may not be generalizable to all FSWs [3]. A final limitation is the cutoff in participation in the extension study from the original cohort. Two hundred women participated in the baseline study, whereas 120 of those women participated in the 12 month extension study.

Understanding and addressing proper recruitment and retention strategies can significantly increase participation of special high-risk populations. Incorporating new and effective strategies is a critical factor in the research design process. We found that FSWs were willing to participate and complete clinical trials that they deem useful for their health. Trends and patterns emerging from the results of this study should be taken into account and applied to future studies that involve Peruvian FSWs, or other high-risk populations. Future interventions should include formative work to ensure high participation of high risk populations.

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