

Peruvian FSW Perspectives on Ethics-Relevant Experiences of Participating in an HPV Vaccine Clinical Trial

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Aims of study

- Examine Peruvian female sex workers' (FSWs) evaluation of participation
 - Retrospective look
 - social and health risks/benefits
 - informed consent
 - Incentives
 - fair treatment
- All following participation in a vaccine study
 - Phase 4 clinical trial
 - Quadrivalent HPV vaccine



Rationale

- Participant post-trial trust, fears, and feelings not addressed in published lit.
 - Investigators fearful to find this out?
- Understanding participant wants/what works best helps us conduct appropriate studies
- Little known about participant perspectives on social value and personal risks and benefits of participation in HPV vaccine trials

Background-FSWs in Peru

- 18,000 FSWs in Lima
- Selling sex legal
 - requirement 3 months
 - Not always practiced
 - One time 'card'
- High stigma
- higher risk of STIs



Background-HPV vaccine

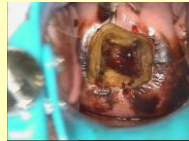
- HPV vaccine completion
 - borders 30% among girls in the US
 - Little to no data in Peru
- At the time, no previous studies of HPV vaccine completion in high risk groups
- We conducted a clinical trial of HPV vaccine with a highly exposed group
 - Female sex workers
 - Sunflower Study

Background-Original Study Details

- Sunflower Study took place in 2009
 - Longitudinal study of HPV prevalence
 - Cervical HPV DNA and cytology
 - HPV antibody testing
 - **randomized trial of HPV vaccine**
 - 2 schedules (0,3,6) or (0,2,6)-Merck vs GSK
 - 0,3,6 match with STI testing
 - **All participants received vaccine**
 - 92% completed all 3 doses

Background-Benefits

- HPV vaccine
 - approved for use in Peru
- Condoms, lubricants
- Cervical cancer screening, wart removal, STI trtx, HIV testing
- LEEP procedure-cervix
- Small token of appreciation



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Research Design

- Retrospective look
 - participation in Sunflower study
- Mixed methods approach
 - Semi structured interviews
 - 1-2 hours
 - experiences and impressions
 - Quantitative survey
 - 5 min
 - Demographics and scale questions



Measures/Methods

- Quantitative Measures (survey):
 - Age, current status in sex work, income level, access to health care, continued cervical health care
 - Longitudinal HPV/vaccine knowledge
 - Scale questions
- Qualitative Measures (4 major areas):
 - Participant recruitment
 - Understanding of the study
 - Incentives given in the study
 - Long term impact of the study

Identifying Participants

- Recruitment strategy
 - Asked women who came to the FSW clinic we established at NGO
 - Did you participate in Sunflower study?
 - Small amount of cash to cover transportation
- IRB approval; Informed consent
 - UC Irvine IRB and the Impacta IRB approved study protocol and verbal consent process
 - No names/signatures recorded
 - Colors to keep track of individual responses

Results: Demographics/knowledge

- 16 total participants
 - mean age: 25.8 years
 - Education: High school only most common
- Mean age of first sex: 16.2 years
- Mean frequency of sex work: 5 days/week
 - 50 clients/month
- 93.75% agreed HPV is sexually transmitted
 - 75% claimed to know of a vaccine that protects against HPV

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Quantitative Results-study experience

Measure	Agreed	Disagreed
Study well described in consent	14	2
Participation is voluntary	16	0
Felt they could withdraw at anytime without loss	13	3
Enjoyed participating	15	1
Primary reason for participating was CC screening	16	0
Study should have paid us	3	13

Themes and Representative Quotes

- Balancing fear and trust
 - 'Yes I had a little bit of fear, but it seemed they were sincere people'
 - **Red** (regarding doubts about the study)
 - 'Yes, if my family found out where I work. I accepted because everything was coded'
 - **Lilac** (regarding fears about the study)

Themes and Representative Quotes

- Gratitude and respect
 - '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** (regarding incentives)
 - 'Gifts, and I was grateful, and if they had not given me anything like this, I would have been grateful for keeping me in mind and making me part of the vaccines, that was enough'
 - **Pink** (regarding incentives)

Themes and Representative Quotes

- Fair treatment and dignity
 - '...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** (on treatment)
 - 'If nothing else, they always treated me as a human'
 - **Blue** (on treatment)

Themes and Representative Quotes

- Becoming more visible
 - 'All sex workers should be in this.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.
 - **Red** (on advice for future studies)
- Abandonment and security
 - '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** (on feelings about hearing the study would end)
 - '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** (on feelings after the vaccine trial ended)

Conclusions

- Participants generally content with all aspects of study and emphasized its non-coercive attributes
- Participants expressed gratitude for professional treatment despite normalized stigma
- Further work may be needed to reduce feelings of abandonment
 - navigation plans to properly transition participants out of research projects once studies have ended
- Need more research like this to ensure ethical treatment of research participants

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