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
- HIV and syphilis
  - 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

**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

**Quantitative Results-study experience**

<table>
<thead>
<tr>
<th>Measure</th>
<th>Agreed</th>
<th>Disagreed</th>
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</thead>
<tbody>
<tr>
<td>Study well described in consent</td>
<td>14</td>
<td>2</td>
</tr>
<tr>
<td>Participation is voluntary</td>
<td>16</td>
<td>0</td>
</tr>
<tr>
<td>Felt they could withdraw at anytime without loss</td>
<td>13</td>
<td>3</td>
</tr>
<tr>
<td>Enjoyed participating</td>
<td>15</td>
<td>1</td>
</tr>
<tr>
<td>Primary reason for participating was CC screening</td>
<td>16</td>
<td>0</td>
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<tr>
<td>Study should have paid us</td>
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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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- For questions contact Brandon Brown

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