Women, Intimate Partner Violence, and HIV Prevention Trials

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for the Fordham HIV Prevention Research Ethics Training Institute
# Intimate Partner Violence

Percent of women reporting intimate partner violence:

<table>
<thead>
<tr>
<th>Location</th>
<th>Ever</th>
<th>Last 12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh province</td>
<td>61.7</td>
<td>31.9</td>
</tr>
<tr>
<td>Brazil province</td>
<td>36.9</td>
<td>14.8</td>
</tr>
<tr>
<td>Ethiopia province</td>
<td>70.9</td>
<td>53.7</td>
</tr>
<tr>
<td>Namibia city</td>
<td>35.9</td>
<td>19.5</td>
</tr>
<tr>
<td>Peru province</td>
<td>69.0</td>
<td>34.2</td>
</tr>
<tr>
<td>Samoa</td>
<td>46.1</td>
<td>22.4</td>
</tr>
<tr>
<td>Thailand province</td>
<td>47.4</td>
<td>22.9</td>
</tr>
<tr>
<td>Tanzania province</td>
<td>55.9</td>
<td>29.1</td>
</tr>
</tbody>
</table>

Source: WHO Multi-Country Study on Domestic Violence and Women’s Health
Lack of Sexual Autonomy

Percent of women who believe that a wife can refuse sex if ...

<table>
<thead>
<tr>
<th>Location</th>
<th>She doesn’t want it</th>
<th>Her husband mistreats her</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh province</td>
<td>54.4</td>
<td>44.6</td>
</tr>
<tr>
<td>Brazil province</td>
<td>23.9</td>
<td>7.7</td>
</tr>
<tr>
<td>Ethiopia province</td>
<td>53.8</td>
<td>43.7</td>
</tr>
<tr>
<td>Namibia capital</td>
<td>17.9</td>
<td>12.3</td>
</tr>
<tr>
<td>Peru province</td>
<td>51.4</td>
<td>27.8</td>
</tr>
<tr>
<td>Samoa</td>
<td>72.0</td>
<td>31.2</td>
</tr>
<tr>
<td>Thailand province</td>
<td>23.8</td>
<td>11.6</td>
</tr>
<tr>
<td>Tanzania province</td>
<td>74.3</td>
<td>51.4</td>
</tr>
</tbody>
</table>

Source: WHO Multi-Country Study on Domestic Violence and Women’s Health
Women, Violence and HIV

• Violent relationships put women at increased risk of HIV and other STIs through a variety of biological, economic and cultural factors:
  – Forced sex can cause bleeding and tearing of the genital lining;
  – Women in these relationships lack the power to negotiate condom use or leave partners who put them at risk;
  – Other factors.

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Female-Initiated Prevention Tools

• Female-initiated prevention tools could be used by women who cannot negotiate condom use or leave partners who put them at risk.

• Experimental female-initiated prevention tools being developed include:
  – Microbicides;
  – Cervical barriers;
  – Pre-exposure prophylaxis; and
  – Vaccines (??).
• Microbicides – vaginal gels, creams or films designed to block HIV – could offer women in violent relationships means of protection against HIV.

• Women in these relationships usually cannot negotiate condom use.

• They might, however, be able to use a user-initiated HIV prevention tool like a microbicide without their partner's knowledge.
New research suggests that most women can, would or should tell their partners.

- “Passive acquiescence” versus “active involvement.”
- Difficult to use consistently if covert.
- Difficult to hide covert use, with discovery also putting women at risk.
Female-initiated HIV prevention tools like microbicides thus offer both promise and peril for women in violent relationships.

All HIV prevention trials pose some risk of violence for women.

- Risks of disclosed participation;
- Risks associated with exclusion; and
- Risks associated with counseling and other services provided in the trial.
Basic design of a phase IIb/III HIV prevention trial (500 – 10,000+ participants):

1. Recruit Potential Participants
2. Screen Potential Participants
   - HIV positive
     - Refer for HIV treatment
     - Additional Screening and Testing
   - Pregnant
     - Refer for prenatal care
3. Enroll Potential Participants
   - Agree to participate?
     - Yes
       - Have STI
         - Provide STI treatment
       - No STI
         - Randomize Participants
           - Control Arm
             - Condoms, counseling, other prevention tools, and placebo
           - Experimental Arm
             - Condoms, counseling, other prevention tools, and test product
   - Refuse to participate?
     - Thank you and goodbye

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Because of the risk of violence for some participants, HIV prevention researchers face a number of logistical and ethical challenges:

- Ensuring confidentiality;
- Minimizing risks to “screen outs”;
- Minimizing risks to seroconverters;
- Determining the level of support services to offer all participants; and
- Responding to acts of violence associated with trial participation.
WHO Guidance

• WHO Ethics and Safety Recommendations for Research on Domestic Violence Against Women:
  – Actions must be taken to reduce the risks to women participating in research, particularly the risk of violent reprisal;
  – Efforts should be made to reduce the risk of psychological distress and to provide some form of crisis intervention if needed; and
  – Referrals to social support services be provided.
Empirical Research

• You want to look at the effectiveness of intimate partner violence-focused interventions for women enrolled in a microbicide trial.

• How might you ethically gather empirical data to:
  – Determine whether psychological distress among women reporting a history of intimate partner violence is a research-related harm?
Empirical Research

• You want to look at the effectiveness of intimate partner violence-focused interventions for women enrolled in a microbicide trial.

• How might you ethically gather empirical data to:

  – Determine whether psychological distress among women reporting a history of intimate partner violence is a research-related harm?

  – Identify and reduce barriers to access for social support services?

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• You are doing an HIV prevention study in a traditional and patriarchal resource-poor region where obtaining community consent is required.

• Based on your experiences, you are concerned about voluntary consent, particularly of women with a history of intimate-partner violence.

• How might you ethically gather empirical data that explores issues of voluntariness among women enrolled in this study?