But, will they use it?

Examining Microbicide Use in the Context of the HPTN 059 Tenofovir Gel Safety Trial

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Why examine use without a proven product?

- Reasons to believe self reported use data are inaccurate
  - But...
- Data on use behavior essential to interpreting trial results, including:
  - determination of effectiveness
  - generalizability to other populations
What do we know about use behavior?
Taking stock of the field...

Within clinical trials:
- Perfect adherence not achieved
- Acceptability generally high
- Influence of trial context on use not examined

Acceptability Research:
- Product attributes
- Perception of Risk
- Partners
- Power
- Privacy
Examining Microbicide Use: an integrated approach

I. HPTN 059 trial measures

II. Enhanced acceptability in Pune, India site

III. Qualitative, in-depth interviews in Pune and US sites
I. HPTN 059: Expanded Safety and Acceptability of Tenofovir 1% Gel

- **Screening**
- **Enrollment**
  - Daily-Tenofovir
  - Daily-Placebo
  - Coitally-Tenofovir
  - Coitally-Placebo

**059 CT Assessments**
1 2 4 8 12 16 20 24

- India (Pune): 100 women
- US (AL/NY): 100 women
Clinical Trial Acceptability and Use Measures

- Sexual Risk Behavior
  - Vaginal sex (last week, last time)
  - Anal sex (ever, last week)
  - Number of sexual partners (last month)

- Adherence
  - % sex acts with gel and/or condom use
  - Correct use: timing of insertion, douching, other vaginal product use

- Acceptability
  - Product attributes
  - Sexual pleasure

- Study Burden
  - Problems: wait time, reimbursement, following instructions, other
Research Questions:

1. How consistently/correctly do participants report using their study gel?
   - Does adherence vary by gel use arm?
   - Does it vary by sexual risk behavior?
   - (How) does gel adherence change over time?

2. Overall, how much do participants like using their study gel?
   - Does acceptability vary by gel use arm?
   - Which product attributes best predict acceptability?
   - Are participants in the daily use arm more likely than those in the coitally-dependent arm to report increased sexual pleasure for themselves? For their partners?

3. What proportion of participants identified problems with trial participation?
II. Enhanced Acceptability Study: Pune, India

- Community pre-screening & screened out
- Women and Male Partners Ineligible/Uninterested in 059 CT
  - B 8 16 24
- 059 CT Assessments
  - B 4 12 24
- Cohort participating in 059 CT and male partners
  - B 8 16 24
Enhanced Acceptability Measures

- **Outcome variables:**
  - % of sex acts with gel and/or condoms (last week)
  - Perceived consistency of gel/condom use (5 point scale)
  - Interest in gel use outside trial setting (6 point scale)

- **Predictors**
  - Couple Harmony
  - AIDS Fatalism (HIV risk perception / sexual power)
  - Protection Efficacy
  - Motivation to comply with trial

- **Socio-demographic characteristics**
  - privacy
Research Questions:

1. What factors best predict women’s reports of consistent gel use during the clinical trial? Their partner’s reports?

2. Are these factors similar or different to factors predicting consistent condom use outside a trial setting?

3. What predicts interest in using a microbicide gel outside of a clinical trial for women? For their partners?
## Participant Characteristics

<table>
<thead>
<tr>
<th>Socio-demographic Variables</th>
<th>CT Women (N = 81)</th>
<th>Non-CT Women (N = 61)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age (years)</td>
<td>33.2 (24-43)</td>
<td>32.9 (18-46)</td>
</tr>
<tr>
<td>Current Marital Status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not married</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Married</td>
<td>100 (81)</td>
<td>100 (61)</td>
</tr>
<tr>
<td>Average # of Children</td>
<td>2.4 (1-5)</td>
<td>2.3 (0-5)</td>
</tr>
<tr>
<td>Educational Level</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No schooling</td>
<td>6 (5)</td>
<td>5 (3)</td>
</tr>
<tr>
<td>Some primary (1-4)</td>
<td>30 (24)</td>
<td>25 (15)</td>
</tr>
<tr>
<td>Some secondary (5-10)</td>
<td>47 (38)</td>
<td>55 (34)</td>
</tr>
<tr>
<td>&gt; 10 years</td>
<td>17 (14)</td>
<td>15 (9)</td>
</tr>
<tr>
<td>Earn Income</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>44 (36)</td>
<td>44 (27)</td>
</tr>
<tr>
<td>Yes</td>
<td>56 (45)</td>
<td>56 (34)</td>
</tr>
<tr>
<td>Average Income/Month (Rs.)</td>
<td>1,561 (500-3,500)</td>
<td>1,131 (300-3,000)</td>
</tr>
</tbody>
</table>
## Baseline Data on Condom Attitudes and Use

<table>
<thead>
<tr>
<th>Condom Attitudes and Use</th>
<th>CT Cohort %</th>
<th>Non-CT Cohort %</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Women (N=81)</td>
<td>Partners (N=50)</td>
</tr>
<tr>
<td><strong>Consistent Condom Use/ 2 months</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never/Rarely</td>
<td>50%</td>
<td>52%</td>
</tr>
<tr>
<td>Sometimes/Frequently</td>
<td>28%</td>
<td>24%</td>
</tr>
<tr>
<td>Always</td>
<td>22%</td>
<td>24%</td>
</tr>
<tr>
<td><strong>Attitudes towards Condoms</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Like somewhat/a lot</td>
<td>38%</td>
<td>70%</td>
</tr>
<tr>
<td>Neutral</td>
<td>50%</td>
<td>18%</td>
</tr>
<tr>
<td>Dislike somewhat/a lot</td>
<td>12%</td>
<td>12%</td>
</tr>
</tbody>
</table>
## Mean Scale Scores, by Cohort and Gender

<table>
<thead>
<tr>
<th>Predictors of Microbicide Acceptability</th>
<th>CT Women (n=81)</th>
<th>Male Partners/CT (n=50)</th>
<th>Non-CT Women (n=61)</th>
<th>Male Partners/Non-CT (n=27)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Couple Harmony</td>
<td>5.14 (0.81)</td>
<td>5.28 (0.42)</td>
<td>5.10 (0.68)</td>
<td>5.30 (0.31)</td>
</tr>
<tr>
<td>Partner Abuse</td>
<td>2.78 (1.18)</td>
<td>1.95 (0.62)</td>
<td>2.90 (1.31)</td>
<td>1.92 (0.41)</td>
</tr>
<tr>
<td>Perception of Partner Infidelity</td>
<td>1.54 (1.02)</td>
<td>1.30 (0.69)</td>
<td>1.70 (1.00)</td>
<td>1.29 (0.67)</td>
</tr>
<tr>
<td>AIDS Fatalism</td>
<td>3.30 (0.92)</td>
<td>3.14 (0.84)</td>
<td>3.38 (0.90)</td>
<td>3.49 (0.88)</td>
</tr>
<tr>
<td>Protection Efficacy</td>
<td>5.65 (0.56)</td>
<td>5.77 (0.33)</td>
<td>5.34 (0.73)</td>
<td>5.13 (1.22)</td>
</tr>
</tbody>
</table>
III. Qualitative In-Depth Interviews (repeated or at exit)
Qualitative Research Questions:

- How adherent are participants to gel and condom use?
- How do individual and couple factors influence adherence to protocol and product?
  - Women’s perceptions of HIV risk
  - Her control of decisions affecting trial participation and gel use
  - Her control over sex
  - Her own and her partner’s attitudes towards product attributes
- How does the clinical trial context influence gel use?
  - Women’s and their partners understanding of clinical research and their expectations about trial participation
  - Motivations to comply with the clinical trial protocol
- (How) do experiences with trial participation and product use vary by gel administration arm (coital or once-daily)?
- In what ways do sexual partners influence trial participation and adherence to gel or condom use?
Summary:

- Mix of qual/quant data collection increases reliability of self reported use behavior
- Increased attention on how partner, power and privacy influence adherence
- Context of clinical trial (including motivation to comply) actively examined
- Addition of non-trial cohort increases generalizability
- Male partner perspective included
Thanks!

For further information, contact:

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