Acceptability of a Dapivirine Vaginal Ring among US Adolescent Females
In a Phase 2a Safety Trial (MTN 023/IPM 030)
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Background
- Most risk reduction against HIV-1 infection for women over age 25 in sub-Saharan Africa has been reported in recent Phase III trials of a vaginal ring (VR) containing the antiretroviral drug dapivirine.
- No risk reduction was found for women under 21 years likely due to low adherence.
- MTN 023/IPM 030 is a collaboration between the Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN), the International Partnership for Microbicides (IPM), and the Microbicide Trials Network (MTN).
- The ring has been found to be safe and acceptable by standard self-report questionnaires in this trial.
- Qualitative research expands on the acceptability of the ring in this population.

Methods
- Ninety-six adolescents (15-17 years old) were enrolled in a Phase 2a randomized placebo-controlled safety trial of the Dapivirine Vaginal Ring (VR) in 2013.
- Informed consent was signed by adolescents, legal guardians, and study personnel.
- Participants were enrolled at five U.S. sites (Birmingham [n=3], Boston [n=4], NYC [Bronx] [n=6], Denver [n=6], and Pittsburgh [n=6]) and were recruited from adolescent and primary care health clinics, family planning clinics, gynecology clinics, and community-based locations.
- Study participants self-administered a VR at the initial study visit, and at each subsequent monthly clinic visit when a new VR was dispensed. They all attended clinic visits every four weeks, to week 24, and received a new VR at each clinic visit until week 24 when the VR was removed and not reapplied.
- A subset of 21 were randomly selected for in-depth semi-structured interviews (ISI) at their final clinic visit. The participants used the VR for either 12 (n=11) or 24 (n=10) weeks.
- Trained interviewers conducted visual web-interviews at week 25.
- Open-ended questions examined participant overall experiences and feelings using the VR, and participant reports of partner attitudes and experiences with the ring, risks during sexual intercourse, and comfort with use.
- Interviews were digitally recorded, transcribed verbatim, entered into Atlas TI, and analyzed using thematic content analysis based on the conceptual model of acceptability and adherence shown in Figure 1.
- Verbatim quotations illustrative of each theme are in the tables, with quotes from each site for each theme.

Results

Table 1: Demographics of ISI Participants (n=21)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Age (years)</th>
<th>Repartition</th>
<th>Black (%)</th>
<th>White (%)</th>
<th>Other (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>37 (17-76)</td>
<td>39% (9)</td>
<td>52% (11)</td>
<td>42% (8/2)</td>
<td>13% (2)</td>
</tr>
</tbody>
</table>

Table 2: Perceived partnership, sex, and product-related barriers to VR acceptability and adherence

- **Perceived partnership:**
  - Participants felt that their partners were supportive and that the ring was acceptable to them.
  - Some reported that their partners were not supportive, but the participants continued to use the ring.
- **Perceived sex:**
  - Participants reported that the ring did not interfere with their sexual activities.
  - Some reported that the ring was uncomfortable to use, but continued to use it.
- **Perceived product-related barriers:**
  - Participants reported that the ring was easy to put in and take out, and did not interfere with their daily activities.

Table 3: Perceived partnership, sex, and product-related barriers to VR acceptability and adherence

- **Partner’s support:**
  - Participants reported that their partners were supportive of their use of the ring.
  - Some reported that their partners were not supportive, but the participants continued to use the ring.
- **Sexual activities:**
  - Participants reported that the ring did not interfere with their sexual activities.
  - Some reported that the ring was uncomfortable to use, but continued to use it.
- **Product-related barriers:**
  - Participants reported that the ring was easy to put in and take out, and did not interfere with their daily activities.

Conclusions

High acceptability of VR as a HIV prevention method for US adolescent females was reported. Although initial concerns about product factors and other physical characteristics of the ring may have diminished with use, participants did not explicitly report a change in their opinions about product size and other characteristics. Principal concerns for young women are partners’ feeling the ring and menstrual hygiene issues – these may be managed proactively by clinic staff to help increase acceptability and adherence.

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