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) continuously releasing the antiretroviral drug dapivirine.
- No risk reduction was found for women under 21 years likely due to low adherence.

MTN 023/IMP 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 at five centers in the US: Boston, Bronx, Pittsburgh, UAB, and the MTN 023 Protocol Team.
- Participants were enrolled at five U.S. sites (Binghamton, NY; Boston, MA; Bronx, NY; UAB, AL; and Pittsburgh, PA) and recruited from adolescent and primary care health clinics, family planning clinics, gynecology clinics, and community-based locations.
- Study participants self-rereported a VR at their initial study visit, and at each subsequent monthly clinic visit when a new VR was dispensed.
- They 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 no new VR inserted.

- A subset of 21 were randomly selected for in-depth semi-structured interviews (IDI) at their final clinic visit.
- Participants used the VR for 12 (11) or 24 (11) weeks.
- Trained interviewers conducted visual web-interviews at week 25.

- Open-ended questions examined participant overall experiences and feelings about the VR, and participant reports of partner attitudes and experiences with the ring, risk, role during sexual intercourse.

- 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.

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

<table>
<thead>
<tr>
<th>Theme</th>
<th>Bronx</th>
<th>Boston</th>
<th>Pittsburgh</th>
<th>UAB</th>
<th>MTN 023 Protocol Team</th>
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<tbody>
<tr>
<td>Partnership</td>
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<td>Product related</td>
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Results

- Acceptability of a Dapivirine Vaginal Ring among US Adolescent Females

Conclusions

- High acceptability of VR as a HIV prevention method for US adolescent females was reported. Although initial concerns around product characteristics 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 is too large and menstrual hygiene issues—these may be managed proactively by clinic staff to help increase acceptability and adherence.