

Poster presentation

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## **P13-05. Factors associated with pregnancy during the HVTN 503/Phambili trial, a phase IIB HIV trial of the Merck Ad-5 multi-clade HIV vaccine**

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### **Background**

To maximize safety, women in HIV vaccine trials should avoid pregnancy, but pregnancy often occurs. We evaluated baseline risk factors for pregnancy in this trial.

### **Methods**

Women who were unsterilized, non-pregnant, and agreed to avoid pregnancy for at least 1-month after her final vaccination ("vaccination period") were analyzed. Each woman's vaccination period was calculated based on her final vaccination, regardless of whether she completed all three vaccinations (trial unexpectedly halted). At two of five sites, hormonal contraception was required and provided for free. We calculated pregnancy rates overall and by vaccination period, and used Cox regression to examine baseline contraceptive availability, partner, and personal variables for associations with pregnancy.

### **Results**

Of the 352 women (mean age 23.9 yrs; 98.9% black) in the six months prior to enrollment, 83.2% had a main partner, 48.9% had partners of unknown HIV-status, 83.8% had vaginal sex only; 6.2% anal sex; 9.9% oral sex, and 58.5% and 57.1% reported injectable contraception and consistent condom use, respectively. At this writing 17 4.8%(17/352) pregnancies occurred; updated analysis

forthcoming. The pregnancy rate was 0.53/100-women-months (0.33–0.85) and did not differ by vaccination period, site, nor by use of condoms or hormonal methods. In multivariable analysis, having a partner of unknown HIV-status was inversely associated with pregnancy Hazard Ratio(95%CI) 0.2(0.1–0.8), and was positively associated with engaging in oral sex 2.9(1.0–8.5) and marijuana use 3.3(0.7–14.9). Associations with oral sex were not mediated by condom use; null associations with contraception may be explained by non-adherence and misclassification.

### **Conclusion**

Pregnancy was not reduced during the vaccination period, despite women's professed commitment to avoid such pregnancies. Pregnancy depended on a specific high-risk participant profile and HIV-status disclosure within sexual partnerships. More discerning methods for determining pregnancy intent and understanding partnership dynamics are needed to minimize pregnancies in South African trials.