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HIGH UPTAKE AND REDUCED -1 INCIDENCE IN AN OPEN-LABEL TRIAL OF THE DAPIVIRINE RING

Epidemiology/Public Health: (T) Prevention Interventions

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Background: Two phase III clinical trials (MTN-020/ASPIRE & IPM 027/The Ring Study) demonstrated that a monthly vaginal ring containing dapivirine was safe and reduced HIV-1 incidence by approximately 30% compared to placebo. For tenofovir pre-exposure prophylaxis (PrEP), adherence and HIV-1 prevention effectiveness have often been greater in open-label studies than in earlier placebo-controlled trials. We are conducting MTN-025/HOPE, a phase IIIb open-label extension trial of the dapivirine vaginal ring; a planned interim analysis of data was conducted in October 2017.

Methods: HIV-1 uninfected women who had participated in ASPIRE are offered 12 months of access to the dapivirine vaginal ring in HOPE at 14 sites in Malawi, South Africa, Uganda, and Zimbabwe. Used rings are returned at each study visit (monthly for 3 months, then quarterly) and are tested for residual levels of dapivirine. HIV-1 incidence in HOPE was compared to that expected by weighted bootstrap sampling of the placebo arm of ASPIRE, selecting 10,000 times for a subset of women matched on trial site, age, and presence of a curable sexually transmitted infection at trial entry.

Results: Between August 2016 and October 2017, 1407 women enrolled into HOPE, 57% of those HIV-1 uninfected at completion of ASPIRE. The median age was 31 years (IQR 27-37), with 13% aged 20-24 and 28% 25-29 years; 16% had a curable sexually transmitted infection. Of 1407 enrollees, 1299 (92%) accepted the dapivirine vaginal ring. 89% of returned rings had residual dapivirine levels consistent with some use during the prior month. A total of 12 HIV-1 infections in 616 person-years of follow-up have been observed (incidence 1.9 per 100 person-years, 95% CI 1.0-3.4). Given the site, age, and sexually transmitted infection distribution of the population enrolled, HIV-1 incidence was expected to be 4.1 per 100 person-years (95% CI 3.2-5.1) in the absence of access to the dapivirine vaginal ring, and an incidence of 1.9 would be expected to occur with a frequency of less than 1 in 10,000 samplings.

Conclusion: Interim results from this open-label extension trial of the dapivirine ring demonstrate high uptake and adherence, and HIV-1 incidence has been half of the expected rate. These findings are limited by the lack of a contemporaneous placebo group and prior participation of the study population in ASPIRE, but they suggest important HIV-1 prevention effectiveness of the dapivirine vaginal ring when used by African women in an open-label setting.