

Oral presentation

## **OA01-06 LB. HIV-1 plasma RNA and risk of HIV-1 transmission**

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### **Background**

Non-sterilizing HIV-1 vaccines may provide public health benefits if they significantly reduce plasma HIV-1 RNA, thus potentially reducing infectiousness. Quantification of reduction in plasma HIV-1 RNA needed to decrease HIV-1 transmission is useful for design of efficacy trials of candidate HIV-1 vaccines. We modeled the relationship between plasma HIV-1 RNA and HIV-1 transmission using data from a prospective study of African heterosexual HIV-1 serodiscordant couples.

### **Methods**

3408 HIV-1-infected participants with CD4 counts  $\geq 250$  cells/mm<sup>3</sup> enrolled in the Partners in Prevention HSV/HIV Transmission Study and their partners were followed for  $\leq 24$  months. HIV-1 transmission events were assessed for viral genetic linkage within the enrolled partnership by determining HIV-1 *env* and *gag* sequences from partners. The relationship between plasma HIV-1 RNA over time and risk of genetically linked HIV-1 transmission was evaluated with a Cox model with a natural cubic spline.

### **Results**

84 post-enrollment linked HIV-1 transmissions were observed. HIV-1 incidence increased rapidly and non-linearly with higher plasma HIV-1: from 0.53 transmissions per 100 person-years for plasma HIV-1 RNA  $< 10,000$  copies/mL to 6.2 for HIV-1 RNA  $> 1,000,000$  copies/mL ( $p < 0.0001$ ). Baseline HIV-1 RNA in men was, on average,

0.4 log<sub>10</sub> higher than in women; no significant difference in risk of transmission for a given HIV-1 level was observed between men and women ( $p = 0.17$ ). Given the distribution of plasma HIV-1 RNA in this population of stable cohabiting couples, our modeling predicts that a 0.74 log<sub>10</sub> reduction in average plasma HIV-1 RNA in the population would be required for a 50% reduction in HIV-1 transmission risk.

### **Conclusion**

This analysis provides a detailed description of the relationship between plasma HIV-1 RNA and risk of heterosexual HIV-1 transmission. These findings suggest targets for reduction in HIV-1 RNA for use in evaluating non-sterilizing HIV-1 vaccine candidates in HIV-1 infected persons to reduce risk of heterosexual HIV-1 transmission.