High Initiation of PrEP and ART in a Demonstration Project among African HIV Discordant Couples

Renee Heffron,1 Connie Celum,1 Nelly Mugo,1,2 Elly Katabira,3 Elizabeth Bukusi,1,2 Elioda Tumwesigye,4 Jessica Haberer,5 and Jared M. Baeten,1 for the Partners Demonstration Project Team

1University of Washington, Seattle, USA; 2Kenya Medical Research Institute, Nairobi, Kenya; 3Makerere University, Kampala, Uganda; 4Kabwohe Clinical Research Center, Kabwohe, Uganda; 5Harvard University & Massachusetts General Hospital, Boston, USA

Poster #949. For more information, please contact: Renee Heffron, RHeffron@uw.edu

BACKGROUND

• Antiretrovirals – as antiretroviral therapy (ART) for HIV-infected persons and pre-exposure prophylaxis (PrEP) for HIV-uninfected persons – are powerful interventions for reducing HIV transmission among HIV discordant couples.
• A primary implementation question for HIV prevention is how to deliver PrEP and ART for HIV discordant couples.
• Targeting high risk couples during periods of highest vulnerability is important for widescale PrEP implementation to be cost effective.

METHODS

• Prospective observational study with a target to enroll 1,000 high risk HIV discordant couples with quarterly follow up for 2 years (enrollment began November 2012)
• Set in Kenyan and Ugandan HIV testing and care centers
• Open-label PrEP (co-formulated emtricitabine/tenofovir, e.g. Truvada®) is available to all participants
• PrEP is offered as a “bridge” to ART use and PrEP discontinuation is encouraged after 6 months of ART use by the HIV-infected partner
• PrEP adherence is measured through self-report, medication event monitoring system (MEMS), and periodic drug level testing in stored plasma
• HIV infected partners are not using ART at enrollment; ART provision during follow up is based on national guidelines
• ART adherence is captured through viral load measurements
• All couples receive counseling about HIV prevention strategies, ART benefits, ART and PrEP adherence counseling, and semiannual CD4 testing
• Data are as of February 2014

PRELIMINARY RESULTS

Participant characteristics (as of February 2014), 589 couples enrolled

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Couples with HIV-infected female</th>
<th>Couples with HIV-infected male</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age of HIV-uninfected partner, Median (IQR)</td>
<td>29 (26.36)</td>
<td>29 (24, 34)</td>
</tr>
<tr>
<td>Number of children together, Median (IQR)</td>
<td>0 (0,1)</td>
<td>1 (0, 2)</td>
</tr>
<tr>
<td>Any income, N (%)</td>
<td>389 (97.5%)</td>
<td>188 (98.9%)</td>
</tr>
<tr>
<td>Number of sex acts in the past month, Median (IQR)</td>
<td>7 (4,12)</td>
<td>5 (3, 10)</td>
</tr>
<tr>
<td>Any unprotected sex in the past month, N (%)</td>
<td>264 (66.2%)</td>
<td>112 (58.9%)</td>
</tr>
<tr>
<td>CD4 count of HIV-infected partner, Median (IQR)</td>
<td>453 (285, 641)</td>
<td>430 (217, 583)</td>
</tr>
<tr>
<td>Viral load (log10) of HIV-infected partner, Median (IQR)</td>
<td>4.41 (3.85, 4.85)</td>
<td>4.87 (4.39, 5.26)</td>
</tr>
</tbody>
</table>

CONCLUSIONS

• PrEP uptake is 95% at enrollment and 75% of ART eligible participants have initiated ART
• More follow up will provide key data on HIV prevention preferences, uptake of and adherence to ART and PrEP, and risk behavior among high risk HIV discordant couples

ACKNOWLEDGEMENTS

We are grateful to all the research participants for their dedication to this study
University of Washington Coordinating Center
Jared Baeten, Connie Celum, Deborah Donnell, Renee Heffron, Ruanne Barnabas, Harald Haugen, Lara Kodaguchi, Susan Morrison, Jennifer Morton, Caitlin Scoville, Roger Ying
Site teams and partners
Kabwohe, Uganda (KCRC): Elioda Tumwesigye, Steven Asiimwe, Edna Tindimwebwa
Kampala, Uganda (Makerere Univ.): Elly Katabira, Edith Nakku-Joloba, Nulu Bulya
Kisumu, Kenya (KEMRI): Elizabeth Bukusi, Josephine Odoyo
Thika, Kenya (Kenyatta National Hospital/KEMRI, UW): Nelly Mugo, Kenneth Nigure
MGH/Harvard: David Bangsberg, Jessica Haberer, Norma Ware
Johns Hopkins University: Craig Hendrix
DF/Net Research (data management)
Gilead Sciences (donation of PrEP drug)