

Adherence to PrEP among HIV negative women attempting conception with HIV positive male partners in the US

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Conflict of Interest Disclosure

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Contracted Research: Gilead Sciences Inc has provided support for the following Research Initiative: PrEPception – Expanding Reproductive Options for Serodiscordant Couples

Background

- ▶ Pre-exposure prophylaxis (PrEP) can protect heterosexual partners; although examined in other countries, little is known about the acceptability and feasibility of offering PrEP for HIV prevention during attempts to conceive in the US.
- ▶ The efficacy of PrEP is dependent on adherence. Examination of what motivates women to adhere to PrEP in the US is needed.
- ▶ We conducted a study to assess adherence rates measured by self-report and blood levels among HIV negative women who used PrEP for conception with HIV positive men at 4 medical centers in the US: Boston University, Drexel University College of Medicine, John Hopkins University, and Northwestern University.

Methods

- ▶ Preliminary results are presented from this observational study of HIV-positive male and HIV-negative female couples who have undergone preconception counseling and elected PrEP with condomless timed intercourse.
- ▶ Enrollment is ongoing with a target of 32 couples.
- ▶ Data collected included demographics, HIV serostatus, STI testing, prior conception history, and beliefs and motivations for pursuing PrEP for HIV prevention during conception.
- ▶ PrEP consisted of one pill of emtricitabine-tenofovir disoproxil fumarate daily for 30 days prior to condomless timed sex.
- ▶ PrEP was continued if pregnancy occurred and the woman was still at risk of contracting HIV from her partner.
- ▶ Women who opted to stop PrEP were advised to continue PrEP for at least 30 days after the last condomless sex episode.

Methods

- ▶ Self-reported (SR) measures were compared to dried blood spot (DBS) for tenofovir-diphosphate levels one month after starting emtricitabine/tenofovir disoproxil fumarate.
- ▶ The week 4 levels were adjusted to a steady state dosing based on a 17-day half-life. Dosing categories were:
 - ▶ ≤ 349 fmol/punch (< 2 tablets/wk),
 - ▶ 350-699 fmol/punch (2-3 tablets/wk), and
 - ▶ ≥ 700 fmol/punch (≥ 4 tablets/wk).
- ▶ Since participants fell into only two of these categories a Spearman correlation was used to assess the association between DBS and SR measured as continuous variables.
- ▶ Detectable FTC-TP was interpreted as evidence of recent dosing within the past 48 hours. This is similar to the information as detectable TFV/FTC in plasma.
- ▶ Liquid chromatography-mass spectrometry (LC-MS/MS) was the measurement tool.

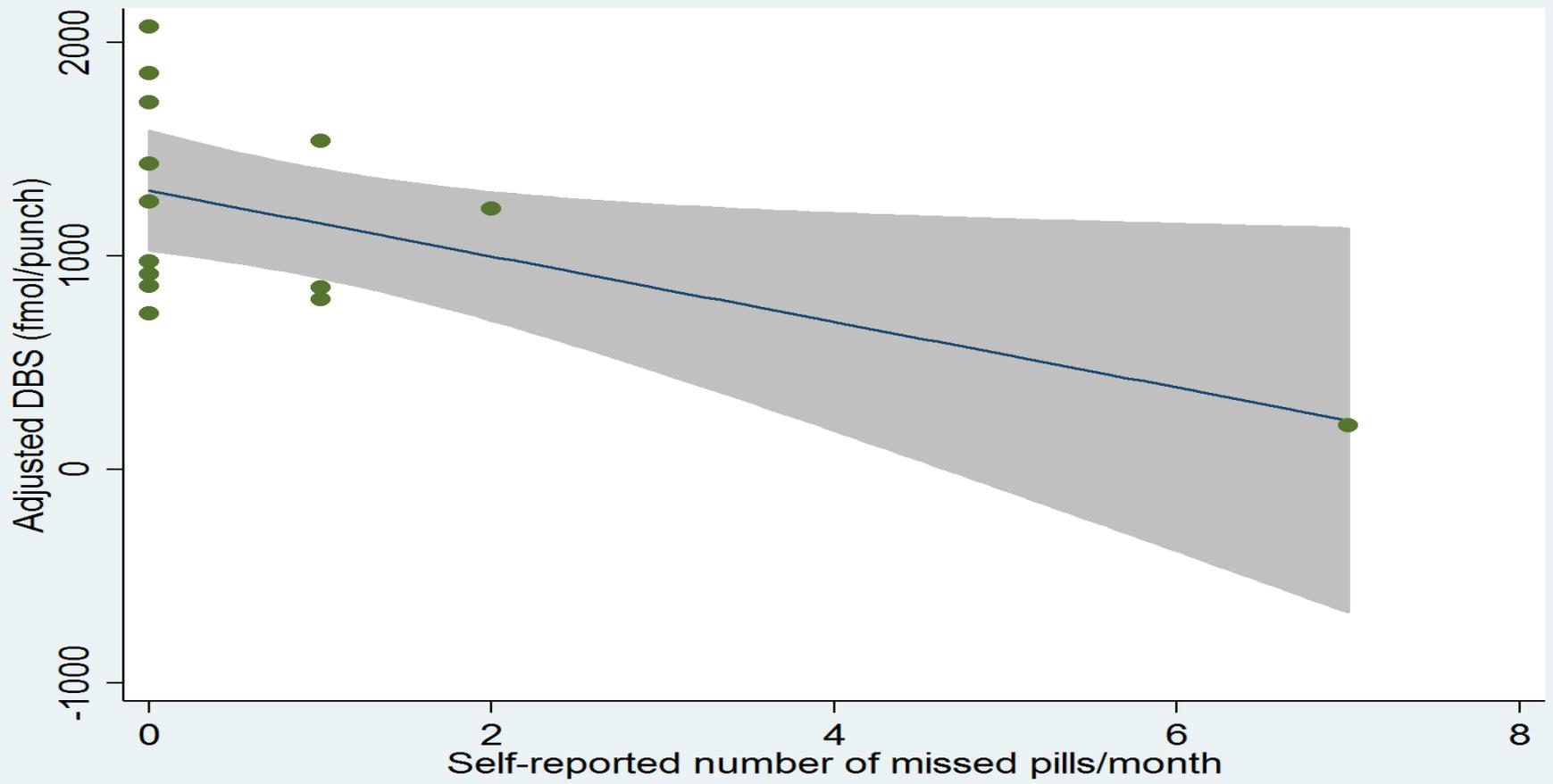
Results

- ▶ 16 HIV negative females were enrolled. 14 had DBS results at one month.
- ▶ Median age was 32 years, 63% were AA, 68% had some college or above education, and median length of current relationship was 2 years.
- ▶ 86% reporting ≤ 1 missed dose during the first month of taking PrEP (Mean= 29 days; Median= 30 days; IQR=1).
- ▶ The number of participants in each dosing category was:
 - 1/14 (7%) < 2 tablets/wk,
 - 0/14 (0%) 2-3 tablets/wk, and
 - 13/14 (93%) ≥ 4 tablets/week.
- ▶ The mean DBS level at drug steady state was 1172.96 +/- 508.41 (median= 1096.33; IQR=683.47) .

SELECTED DEMOGRAPHICS Female (n=16)

Characteristic	N	(Mean + SD) or n (%)
Age (at study enrollment)	16	34+/- 8 (Median: 34)
Race	16	
• African American		10 (62.5%)
• White/Caucasian		3 (18.8%)
• Hispanic/Latino		2 (12.5%)
• Asian		1 (6.3%)
Married	16	
• Yes		9 (56%)
• No		7 (43.8%)
Total length in relationship (months)	15	57 months +/- 60.8 months Median: 24 months
Highest education completed	16	
• Some high school, no diploma		2 (12.5%)
• High school graduate/GED equivalent		3 (18.8%)
• Some college		3 (18.8%)
• College graduate/post college		8 (50%)
Children (any children)	16	
• Yes		7 (44%)
• No		9 (56%)

Correlation of DBS and Self Reported Missed Pills



We found a moderate correlation between DBS and SR ($r=0.42$, $P=0.13$).

Gray area = 95% CI

Spearman correlation was used to assess the association between DBS and SR measured as continuous variables.

Acceptability of PrEP:

- ▶ 67% were worried/afraid of getting HIV from their partner
- ▶ 63% did not worry about getting HIV during intercourse
- ▶ 69% did not avoid having intercourse due to fear of acquiring HIV
- ▶ 69% said they are not afraid of getting HIV with PrEP

Fear of horizontal transmission of HIV

Characteristic	N	(Mean + SD) or n (%)
“Getting HIV from my partner worries/scares me” 15		
• Strongly disagree		2 (13.3%)
• Disagree		3 (20%)
• Agree		3 (20%)
• Strongly agree		7 (46.7%)
67% strongly agree/agree (Std. dev=0.49; variance=0.24) CI: +/- 23.8		
“Every time I have intercourse with my partner, I think about getting infected with HIV” 16		
• Strongly disagree		6 (37.5%)
• Disagree		4 (25%)
• Agree		5 (31%)
• Strongly agree		1 (6.3%)
63% (strongly disagree/disagree) did not worry about infection during intercourse (Std. dev=0.5; variance=0.25) CI: +/- 23.7		
“Sometimes I avoid intercourse with my partner because I am afraid I could get infected with HIV” 16		
• Strongly disagree		7 (43.8%)
• Disagree		4 (25%)
• Agree		4 (25%)
• Strongly agree		1 (6.3%)
69% (strongly disagree/disagree) did not avoid having intercourse due to fear of becoming infected (Std. dev=0.48; variance=0.23) CI: +/- 22.7		

Importance of childbearing to relationship

“If I do not have a child with my partner, I worry that we will not stay together” N=15

● Strongly disagree	7 (46.7%)
● Disagree	7 (46.7%)
● Agree	0
● Strongly agree	1 (6.7%)

93% (Strongly disagree/disagree) did not worry about their partner staying with them if they did not have a child together (Std. dev=0.26; variance=0.07) CI: +/- 12.91

Security with PrEP

“I am afraid that I could be infected with HIV by undergoing this method” N=16

● Strongly disagree	7 (43.8%)
● Disagree	4 (25%)
● Agree	5 (31.3%)
● Strongly agree	0

69% (strongly disagree/disagree) said they are not afraid of getting HIV with PrEP (Std dev=0.48; variance=0.23)
CI: +/- 22.66

Weakness of study

- ▶ **Due to low numbers** the spearman's correlation coefficient of 0.42 did not reach statistical significance, although there was a moderate association between adjusted DBS and SR.
- ▶ The DBS adherence categories for PrEP were developed in studies of men who have sex with men (iPrEx OLE), not in women. These interpretations were used in this study. Its important to note that the relevance of levels may be different in women.

Conclusions

- ▶ This study is unique in that it compares objective and subjective adherence to PrEP in women trying to conceive in the US.
- ▶ In contrast to published studies in females on PrEP to date this population was adherent and SR was moderately correlated with DBS.
- ▶ Future studies are needed to determine the clinical relevance of these adherence categories for PrEP in women as these categories were developed in studies of men who have sex with men.
- ▶ HIV serodiscordant couples are willing to engage in unprotected intercourse combined with PrEP to conceive. These findings are relevant for counseling of both partners when addressing intentions for conception in HIV serodiscordant couples.

Acknowledgement

- ▶ Ashley Ann Leech, PhD(c), MS, Boston University School of Public Health
- ▶ Peter Anderson, Pharm D, University of Colorado
- ▶ Emily Stinnett Miller, MD, Northwestern University
- ▶ Jenell Coleman, MD MPH, John Hopkins Medical Center
- ▶ Howard Cabral, PhD, MPH, Boston University School of Public Health
- ▶ Mari-Lynn Drainoni, Ph.D, Boston University School of Public Health
- ▶ Helen Koenig, MD MPH, Phila FIGHT
- ▶ Meg Sullivan, MD, **PI**: Boston Medical Center