

# SUBSTANCE-USING MSM ON HIV PRE-EXPOSURE PROPHYLAXIS HAVE BETTER ADHERENCE

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General Abstract

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Background:

The effectiveness of tenofovir/emtricitabine (TDF/FTC) for HIV preexposure prophylaxis (PrEP) strongly depends on maintaining adherence. We hypothesized that among men who have sex with men and transgender women enrolled in a randomized controlled PrEP trial, substance users would have lower levels of PrEP adherence.

Methods:

CCTG 595 was a randomized controlled trial of individualized texting versus standard care for adherence to daily TDF/FTC. We examined alcohol and substance use over 48 weeks for association with dried blood spot (DBS) intracellular tenofovir diphosphate (TFV-DP) levels at weeks 12 and 48 (i.e., composite outcome, see Table; cutoff  $\geq 719$  fmol/punch that approximates  $\geq 4$  doses in the past week). Substance use was assessed (for the past 3 months) at all study visits using a SCID screening questionnaire for "No use", "Some use" (1-4 times) and "Heavy use" (5 or more times) of any substance of abuse combined (marijuana and alcohol excluded) and also for each substance separate. Problematic use was assessed using the DAST-10 and AUDIT. We also assessed whether alcohol and substance use impacted study completion and incident sexually transmitted infections (STIs). Fisher's exact test and logistic regression were used.

Results:

Of 394 subjects at baseline, any substance use was reported by 73% and alcohol use by 83% of participants. Overall, 71% of the 394 participants had TFV-DP levels  $\geq 719$  fmol/punch at week 48. Ongoing "Heavy" substance use (any) and "Some" or "Heavy" alcohol use were significantly associated with better adherence in logistic regression (Table), while problematic use had no significant impact on adherence. No particular substance contributed more to this association and notably METH users did not have worse adherence than non-METH users. In general, intensity of alcohol or substance use at baseline was not associated with study completion. Any

substance use, but not alcohol use, was strongly associated with incident STI on study (Odds ratio of 2.5 and 2.6 for "Some" and "Heavy" use compared to "No" use;  $p < 0.001$ ).

### Conclusion:

While substance users had increased STI rates, indicating higher risk behavior, PrEP adherence was not lowered by substance or alcohol use. In fact, likelihood to reach TFV-DP levels above the cut-offs appeared to be higher in participants with substance use suggesting that these individuals may have insight into HIV risk and appropriately be more diligent with PrEP adherence.

### Epidemiology/Public Health:

(T) Prevention Interventions

### Keywords:

Adherence

Adherence Monitoring

Men who have sex with men (MSM)

Preexposure prophylaxis (PrEP)

Substance use

<b>Table 1: Effect of Substance Use and Alcohol Use on PrEP Adherence</b>			
<b>Variables for Predicting Primary Adherence Endpoint<sup>#</sup></b>	<b>OR</b>	<b>95% CI</b>	<b>p value</b>
<b><i>Model 1*</i></b>			
<b>Intervention Arm (i.e. receiving individualized texting for adherence to daily TDF/FTC)</b>	1.117	0.713-1.749	0.6297
<b>White Race</b>	1.678	1.000-2.818	0.0502
<b>Patient Health Questionnaire (PHQ9)</b>	0.953	0.909-0.999	0.0470
<b>Ongoing 'Some' Substance Use (Any)</b>	1.512	0.884-2.585	0.1309
<b>Ongoing 'Heavy' Substance Use (Any)</b>	2.076	1.189-3.624	0.0102
<b><i>Model 2*</i></b>			
<b>Intervention Arm</b>	1.149	0.728-1.814	0.5496
<b>White Race</b>	1.730	1.019-2.937	0.0423
<b>Patient Health Questionnaire (PHQ9)</b>	0.952	0.909-0.998	0.0431
<b>Ongoing 'Some' Alcohol Use</b>	3.200	1.705-6.008	0.0003
<b>Ongoing 'Heavy' Alcohol Use</b>	3.430	1.954-6.022	<0.0001

# Adherence determined by DBS samples from two visits (week 12 visit and the last on-drug visit on or over the 48 week visit). Both visits are required to have a detectable TFV-DP level >719 fmol/punch (consistent with taking four or more doses per week). If the last on-drug DBS visit was at week 12 adherence only that visit counted. If they discontinued before week 12 the subject was considered non-adherent.

\* Predictors evaluated in logistic regression included ongoing "Some" and "Heavy" substance use (Any, excludes alcohol and marijuana use; model 1) / alcohol use (model 2), study arm, race, and baseline PHQ9. "Ongoing" was defined as 50% or more study visits (study consisted of total 6 regular visits) with reported use.

([https://ww2.aievolution.com/cro1701/files/content/abstracts/abs\\_1268/Table1CCTG595finalend.png](https://ww2.aievolution.com/cro1701/files/content/abstracts/abs_1268/Table1CCTG595finalend.png))

