

Factors Associated with PrEP Coverage among MSM and TGW in NYC

HPTN 067/ADAPT Study

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BACKGROUND

- Factors associated with adherence to Pre-Exposure Prophylaxis (PrEP) for prevention of HIV infection are not well understood
- This analysis assessed factors associated with PrEP coverage of sex acts among men who have sex with men (MSM) and transgender women (TGW) in HPTN 067 in New York City (NYC)
- Coverage** was defined as PrEP (at least 1 FTC/TDF pill) taken within 4 days pre- and at least 1 FTC/TDF pill taken within 24 hours post-sex
- Understanding factors associated with coverage among U.S. MSM and TGW can inform future PrEP support interventions

HPTN 067 / ADAPT

- ADAPT: **A**lternative **D**osing to **A**ugment **P**rEP pill **T**aking
- A Phase II, Randomized, Open-label Study of Intermittent Oral Emtricitabine/Tenofovir Disoproxil Fumarate (FTC/TDF) Pre-Exposure Prophylaxis (PrEP)
- Primary Harlem results presented at **IAS 2015** (Mannheimer S, oral presentation: MOAC0305LB), including:
 - Daily dosing resulted in better coverage of sex acts
 - Coverage 66% among participants in Daily arm vs. 47% in Time-driven arm and 52% in Event-driven arm
 - For non-daily PrEP, incomplete coverage of sex acts was mostly related to lack of post-sex dosing

Table 1. Baseline Participant Characteristics

Characteristic	N=179	Study Arm	N=179
Age, median (years)	30		
Race/Ethnicity		Daily	59 (33%)
White	19 (11%)	Time-driven	60 (33.5%)
Black	107 (60%)	Event-driven	60 (33.5%)
Hispanic	43 (24%)	Education, higher than high school	76 (42%)
Other, non-Hispanic	10 (6%)	Employment, full- or part-time employed	56 (31%)
Self-identified gender		Depressive symptoms (CES-D ≥ 16)	38 (21%)
Man	174 (97%)	Hazardous alcohol use (AUDIT score ≥ 8)	37 (21%)
Transgender woman	3 (2%)	Heroin use	10 (6%)
Gender queer	2 (1%)		

METHODS

METHODS FOR HPTN 067 (OVERALL STUDY)

- Harlem, New York City (NYC) one of three sites for HPTN 067
- NYC site enrolled men (MSM) and transgender women (TGW) who reported anal intercourse with men
- Participants randomized 1:1:1 to 24 weeks of one of three self-administered **FTC/TDF PrEP dosing strategies**:
 - Daily**: 1 pill daily
 - Time-driven**: 1 pill twice a week plus 1 pill within 2 hours after sex
 - Event-driven**: 1 pill 24-48 hours before and 1 pill within 2 hours after sex
- Each HPTN 067 site powered independently for separate analyses to compare regimens for **coverage** of sex acts
- Coverage** (at least 1 FTC/TDF pill taken within 4 days pre- and at least 1 pill dose taken within 24 hours post-sex) – assessed by: self-reported sexual and pill taking behavior collected in detailed weekly interviews using participant’s electronic drug monitoring (EDM) data

DATA COLLECTION

- Demographics collected by research staff
- Other baseline data collected via computer assisted self-interview (CASI) including education, employment, depressive symptoms via CES-D (score >16 suggestive of symptomatic depression), AUDIT alcohol use scale (score > 8 considered hazardous), other substance use including stimulants, opiates
- Information, Motivation & Behavioral Skills (IMB) related to PrEP use*** assessed via CASI at 12 and 24 weeks post-randomization, based on modified IMB model of health behavior adoption

METHODS FOR CURRENT ANALYSIS

Data from NYC HPTN 067 participants were analyzed to assess for factors associated with PrEP coverage

DATA ANALYSIS

- Logistic regression for clustered data (clustering on participant) was used to estimate odds ratios and adjusted odds ratios for coverage outcome
- Characteristics significant at p<0.05 were retained in final model

LIMITATIONS

- Coverage measure was subjective - relied on participant recall of PrEP adherence and of sexual events, after discussion with participant of available EDM data on pillbox openings
- Definition of coverage used may not be adequate for full PrEP efficacy given FTC/TDF dosing regimens used in HPTN 067/ ADAPT Study

RESULTS

- Baseline characteristics of NYC HPTN 067 / ADAPT Study participants summarized in **Table 1**
 - Participants were predominantly U.S. MSM of color
- Results of univariate and multivariate analyses of factors associated with coverage are shown in **Table 2**
- In multivariate (adjusted) analyses:**
 - Factors significantly associated with **higher coverage** included: **Daily dosing arm, older age, employment, and higher PrEP motivation**
 - Factors significantly associated with **lower coverage** included: **Black race and heroin use**

Table 2. Factors Associated with Coverage

Characteristic	Unadjusted OR	p value	Adjusted OR	95% CI	p value
Age	1.03	0.01	1.03	1.01-1.05	0.001
Race/Ethnicity		0.08			0.02
White	Ref		Ref		
Black	0.35	0.01	0.49	0.25-0.97	0.04
Hispanic	0.47	0.10	0.64	0.31-1.30	0.22
Other, Non-Hispanic	0.90	0.88	1.40	0.62-3.14	0.42
Higher than high school education	2.09	0.002	NA		
Employment	2.39	0.006	1.67	1.07-2.59	0.03
Depression	0.54	0.05	NA		
Hazardous alcohol use	0.49	0.006	NA		
Number of condomless receptive anal intercourse	1.06	0.39	1.04	0.98-1.10	0.20
Reported heroin use	0.45	0.06	0.34	0.17-0.69	0.005
Study Arm (overall 3-way comparison)		0.04			0.03
Daily	Ref		Ref		
Time-driven (vs. Daily)	0.50	0.05	0.49	0.29-0.83	0.008
Event-driven (vs. Daily)	0.53	0.01	0.62	0.38-1.01	0.05
PrEP Information*	1.26	<0.001	NA		
PrEP Motivation*	1.04	0.008	1.03	1.00-1.05	0.02
PrEP Behavioral Skills*	1.04	0.004	NA		

CONCLUSION

- This analysis identified factors that may require interventions to optimize adherence to PrEP among similar populations of U.S. MSM, including younger age, unemployment, lack of motivation for PrEP, and heroin use
- Further study is needed to assess determinants of racial differences
- Daily dosing of PrEP was associated with the best coverage of sex acts, when compared to the non-daily dosing arms