Preference for Daily versus Intermittent PrEP Dosing among Substance Using High-Risk MSM

J.A. Mitty^{1,2}, E.F. Closson², B. Rowley², K. H. Mayer^{1,2}, and M.J. Mimiaga^{2,3,4}

¹Beth Israel Deaconess Medical Center/ Harvard Medical School ²The Fenway Institute, Fenway Health, ³Massachusetts General Hospital/Harvard Medical School ⁴Harvard School of Public Health

HARVARD MEDICAL SCHOOL



FENWAY INSTITU





MASSACHUSETTS GENERAL HOSPITAL Pre-exposure prophylaxis (PrEP) has the potential to significantly reduce HIV infection among high risk MSM

- The safety and efficacy of PrEP was recently established in the multinational "iPrEx" study
 - A double-blind, RCT comparing a once-daily FTC-TDF to placebo in 2,499 MSM, where FTC-TDF resulted in a 44% reduction in the incidence of HIV infection
- A model to simulate the impact of PrEP in high-risk MSM in the US showed that 50% PrEP efficacy could reduce lifetime risk of HIV infection from 44% to 25%; and 90% could reduce to 5.8%



Among MSM, 'club drugs' are frequently used in gay-oriented nightclubs, bars, and circuit parties

 Club drugs include: *Cocaine/crack Ecstasy GHB*

Crystal methamphetamine Ketamine Alcohol

- Club drugs are used as an enhancement to sexual encounters and are highly associated with unprotected anal sex and HIV infection among MSM
- The disinhibitory effects contribute to:
 - Greater number of partners
 Increased sexual encounters
 - Decreased condom use
 - Increased condom failure while 'high'

P. Halkitis, Parsons, & Wilton, 2003; P. N. Halkitis & Parsons, 2002; Mansergh G., 2001; Mattison, Ross, Wolfson, & Franklin, 2001; Ross, Mattison, & Franklin, 2003



What we know about substance using MSM and PrEP...

- A study of MSM with recent club drug use raised concerns with regards to behavioral disinhibition as well as potential risk compensation associated with the implementation of PrEP
- At this time there is no post-iPrEX data looking at PrEP implementation specifically among club drug using MSM who may be ideal candidates for this modality



Golub, Kowalczyk et al. 2010

Understanding PrEP Implementation among Club Drug Using MSM

<u>Multiple PIs</u>: Drs. Matthew Mimiaga and Jennifer Mitty Funding for this study is supported by the National Institute of Mental Health (R21MH085314-01)

Study Aims



701

- To identify potential strategies to enhance access and acceptance of this harm reduction strategy
- To gauge dosing preferences in order to design the most optimal adherence package for this population
- If high-risk behaviors are frequent or unplanned, daily dosing more appropriate^{1 –} What do substance users prefer?

¹van Griensven 2010

Methods

Participants (n = 40) completed a brief interviewer-administered quantitative assessment

Semi-structured interviews were conducted addressing topics related to:

- Substance use
- Healthcare
- Logistics of PrEP use
- Knowledge of PrEP
- Employment and housing
- Social supportSexual risk

Participants (n= 40)

Inclusion Criteria:

- 18 years of age or older
- HIV uninfected
- Biological male who has sex with other men
- Has used club drugs while engaging in unprotected anal sex with a casual male partner OR an HIV infected main partner in the past 3 months

SEX + DRUGS!

Fenway Health is seeking HIV-negative men who have sex with men and who use drugs to participate in a confidential survey and interview. We want to learn more about what you think about PrEP.

E THE FENWAY INSTITUTE

- Participants were categorized according to substance use pattern: infrequent use versus those who met DSM-IV diagnostic criteria for drug abuse/dependence
- Men were recruited from gay-oriented bars, nightclubs, dance parties in the greater-Boston area

Data analysis and measures

- Interviews were recorded, transcribed, and examined using thematic-analysis (NVIVO)
- Analysis focused on:
 - Dosing preferences among MSM with varied club drug use
 - Strategies to enhance access and acceptance of PrEP
- Quantitative assessment data were analyzed SAS v 9.1.3 software



Substance use and UAS past 3 months



Participant characteristics

Demographics

- Mean age: 39 (SD 11.1)
- 37% ethnic/racial minority
- 25% self-reported sex with both men and women
- 55% reported income <\$24,000/year

Sexual risk past 3 months

- Mean number of partners: 10 (SD = 16.2)
- UAS with a HIV infected partner: 20%
- UAS with a casual partner of unknown HIV serostatus: 85%

PrEP knowledge and experience

Have taken PrEP in the past

Very likely to use PrEP

Previously heard about PrEP



Dosing Preferences

ways:

Participants preferred to take PrEP one of three

Once daily

Immediately before or after sex On specific days of the week (i.e. Tuesdays and Thursdays)

Dosing Preferences (cont'd)

- Overall, 90% of participants preferred use of PrEP on a daily basis as compared to the 2 intermittent options
- Intermittent dosing was thought to increase the occurrence of missing doses due to "heavy" drug use and forgetfulness
- Few (5%) preferred the use of a rectal microbicide PrEP gel over a pill taken orally



PrEP Dosing: Emergent Themes

Daily dose of PrEP facilitates ease of use

Ease of integrating PrEP into existing medication regimen/daily routines

Limited ability to plan ahead for sex

Discomfort with brining pill out for the night

Substance use as perceived adherence barrier

Ease of integration into medication regimen

"I would prefer to take it everyday. Because I would just fit it in with my regular routine. It would be another pill to help me stay healthy. If I took it daily with my regular meds, in my regular pill container, I would see it. I would remember."

-35 year-old infrequent cocaine user

"To get up and take it and know that you took it and not have to worry about being in the heat of the moment...It'd just be easier. If you were going to start taking it just like a daily regimen, like your heart medication, your bipolar drugs...whatever plethora of medication you take, just to add that in there. -65 year-old (DSM-4 dependence) crystal user

Preferences for daily dosing of PrEP for "hard" drug users

"I would rather do the daily... it would be part of my routine. It's something I would do automatically as opposed to having to worry about carrying it around." -40 year-old (DSM-4 dependence) crack user

> "Thinking of taking a pill right before sex is illogical for me... Your chances of taking it right before sex is probably 50/50. If I was getting high I wouldn't take it (before sex). I would have to take it everyday."

-42 year-old (DSM-4 dependence) crystal user

Taking PrEP right before sex for infrequent substance users

"Given the aging process there are other drugs and stuff that you have to take. So I wouldn't want to be on another pill once a day. I would be apt to take it going into risky behavior -48 year-old popper user (infrequent)

> "If they are all equally efficacious, I'd prefer to take it right before sex...You wouldn't have to take as may drugs... Why would you want to bombard your body all the time with medication if you don't need it?" -51 year-old alcohol user (infrequent)

PrEP, cost and adherence

- When asked to prioritize PrEP against daily living expenses and other medications, most described PrEP as a relatively low priority:
 - Many reported (80%) lower perceived PrEP utilization and ability to adhere should the expense limit their ability to afford costs associated with their continued substance use / sex life (e.g., being able to afford to go out to meet guys)



Conclusions

- Among "hard" drug using, high-risk MSM, daily dosing of PrEP may enhance acceptability and adherence
- Infrequent substance using, high-risk MSM appear to prefer taking PrEP right before sex or on specific days of the week
- In order to optimize PrEP uptake in this high-risk population considerations related to cost and insurance must be addressed, as this was a prominent perceived utilization and adherence barrier

Acknowledgements

Source of support:

National Institute of Mental Health - R21MH085314-01

Research and recruiter staff:

- Elizabeth (Rose) Closson
- Blake Rowley
- John Trinidad
- Samuel Cohen
- Benjamin Hersch

Community partners:

- Club Café
- Paradise Nightclub
- Chris Harris Presents
- And other bars and nightclubs in Boston

THANK YOU

Matthew J. Mimiaga, ScD, MPH Assistant Professor, Harvard University mmimiaga@hsph.harvard.edu