

NEAR-PERFECT ADHERENCE IN US iPrEx RCT SITES: FREQUENCY AND CORRELATES

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for the iPrEx investigators



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Background

- iPrEx RCT of daily TDF/FTC
 - 2499 MSM and transgender women
 - 44% efficacy at primary cut off date
 - Efficacy varied significantly by product use
 - Among those with drug levels:
94% reduction in HIV risk (95% CI: 79 to 99%)
 - Product use varied significantly by region/sites
 - 94% (US) vs. 43% (non-US) had detectable drug level

Objective

To characterize product use and identify factors that associated with it in US (Boston, San Francisco) participants [223].



METHODS

- **How to operationalize product use....**

- **Drug Levels?**

- Gross level (drug there or not)
- Fewer data points available; none for control arm

- **Self Report?**

- Best spread of data collection [3143 assessments]
- Closest face validity to what we want to know (Did you miss doses?)
- Across full cohort, poor positive predictive value



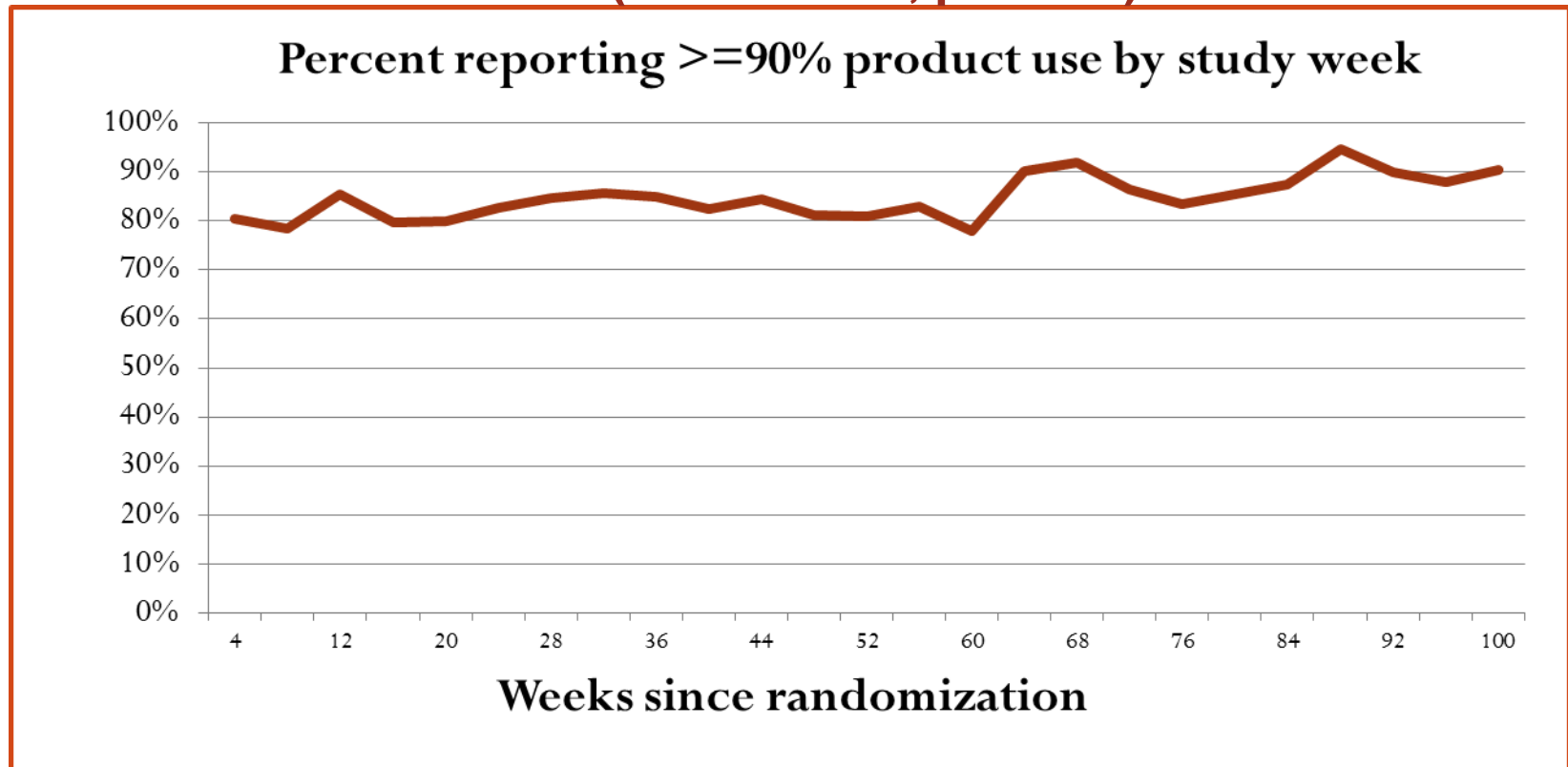
METHODS

- **Self report and drug levels in US**
 - **Subsample n=34**
 - 97% had drug levels.
 - **Positive predictive value of self-report: 97%**
- **Supported use of self-report as reasonable estimate of product use.**
 - **Modeled near-perfect ($\geq 90\%$) reported product use to characterize over time rates, overall rates and correlates.**

Results

Self-reported near perfect adherence over study week
N=223

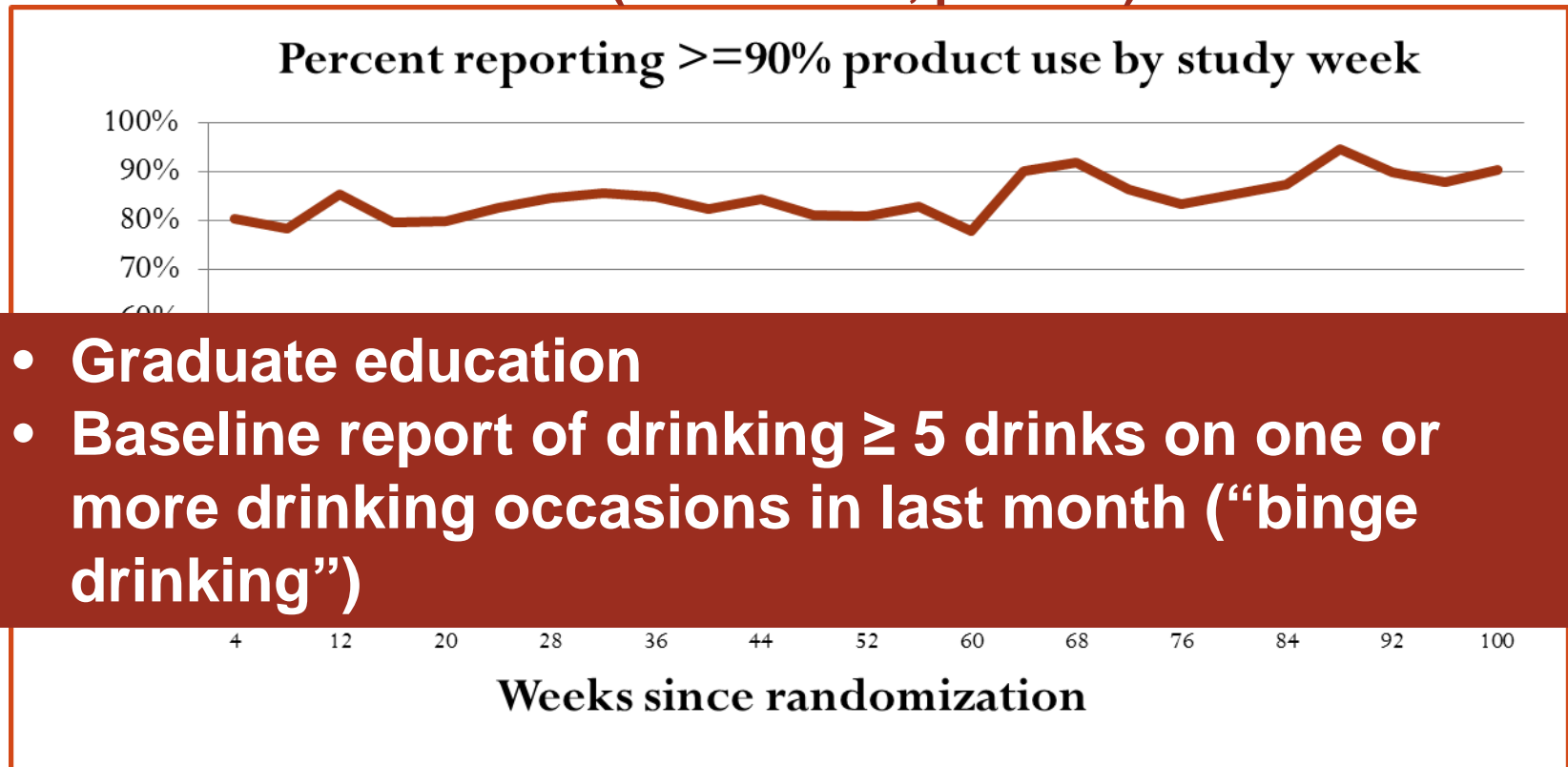
Significant increase in reported near perfect use over time (Beta= 0.005, p=0.048)



Results

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N=223

Significant increase in reported near perfect use over time (Beta= 0.005, p=0.048)



Results

3143 self-reported adherence assessments

Mean adherence

93%

(mdn 100%; IQR 93-100)

Near-perfect ($\geq 90\%$)

83%

Results

GEE **UNIVARIABLE** MODELS [controlling for participant [n=223] and site]

CORRELATES

- Graduate education
- Belief that FTC/TDF is 60-100% effective
- Recent report of receptive anal sex without condom use with partner thought to be HIV+ (past 3-months)
- Age (younger)
- Recent report of nausea, vomiting, diarrhea or flatulence
- Drank alcohol daily in past month
- Drank ≥ 5 drinks on one or more drinking occasions in last month (“binge drinking”)
- Use of meth or cocaine in past month

Results

GEE **MULTIVARIABLE** MODEL [controlling for participant [n=223] and site]

CORRELATES

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Conclusions

- Product use among US iPrEx RCT participants was high
 - By self-report
 - Supported by drug levels

- demography (age)
- medication (“side effects”)
- alcohol use (“binge drinking”)
- sexual behavior/beliefs/risk appraisal (anal sex without a condom with HIV+ partner)

- Factors influencing open label PrEP use are under investigation in iPrEx OLE

The iPrEx Study: Safety, Efficacy, Behavior, and Biology



**Gladstone Institute
of Virology and
Immunology**

