

# ARV Therapies and Therapeutic Strategies

REPORTING ON IAS 2015

## *Comprehensive Expert Review and Discussion of Key Presentations*

An Independent CME Activity Jointly Provided by Postgraduate Institute for Medicine and ViralEd, Inc.  
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**Adherence, sexual behavior and HIV/STI incidence among men who have sex with men (MSM) and transgender women (TGW) in the US PrEP demonstration (Demo) project**

**An HIV pre-exposure prophylaxis (PrEP) demonstration project and safety study for young men who have sex with men in the United States (ATN 110)**

Abstract: TUAC0202 and TUAC0204LB

## US PrEP Demonstration Project Sites

**San Francisco  
City Clinic  
(N=300)**



**Miami-Dade County  
Downtown STD Clinic  
(N=157)**



**Whitman Walker  
Health  
(N=100)**



**Participants were either clinic referred (46%) or self-referred (54%)**

LiuA, et al; 8th IAS, Vancouver, Canada, July 19-22, 2015; Abst. TUAC0202.

## HIV Epidemics and Clinic Characteristics: SF, Miami and DC

	SF	Miami	DC
<b>City-wide</b>			
Persons living with HIV/AIDS	15,705	24,576	15,056
Male sex	92%	70%	72%
Race/ethnicity			
Black	13%	47%	75%
White	62%	15%	17%
Hispanic	17%	38%	6%
Asian	5%	<1%	2%
Proportion of new HIV cases among MSM	88%	75%	39%
<b>STD clinics/community health center</b>			
Annual visits	22,000	14,000	10,000
HIV seroconversion rate	2.3%	4%	2.3%

LiuA, et al; 8th IAS, Vancouver, Canada, July 19-22, 2015; Abst. TUAC0202.

## Methods

- ❖ HIV-negative MSM and transgender women enrolled between Oct 2012 - Jan 2014

- ❖ Behavioral risk criteria (last 12 mo):
  - ◆ Condomless anal sex with 2+ partners
  - ◆ 2+ episodes of anal sex with HIV+ partner
  - ◆ Syphilis, rectal gonorrhea or chlamydia

TFV-DP (fmol/punch)	Adherence Interpretation
700	≥4 doses/week
350 to 699	2-3 doses/week
<350	<2 doses/week
BLW	No recent dosing
Missed visit	Missed visit

- ❖ No serious medical conditions: CrCl ≥ 60 mL/min, negative/trace protein on urine dipstick, HbSAg negative
- ❖ Participants offered up to 48 weeks of TDF/FTC PrEP
- ❖ Follow-up at 1, 3, 6, 9, and 12 months for HIV/STI testing, counseling, clinical monitoring, PrEP dispensation

LiuA, et al; 8th IAS, Vancouver, Canada, July 19-22, 2015; Abst. TUAC0202.

## Baseline Characteristics of Enrolled Participants

Characteristic	%
Age (median)	35 years with 20% <25 years
Race/ethnicity	
White	48%
Latino	35%
Black	7%
Other	10%
Gender	
Male	98%
Transgender	1.3%
Education level	
≤ High School	15%
Some college or higher	85%
Any recreational drug use	74%
Popper, cocaine, meth, or club drug use	58%
Number of anal sex partners, past 3 months (mean)	11
Condomless receptive anal sex, past 3 months	67%
HIV+ primary partner	24%
STI (GC, CT, syphilis) at baseline	26%

LiuA, et al; 8th IAS, Vancouver, Canada, July 19-22, 2015; Abst. TUAC0202.

## Results: Adherence

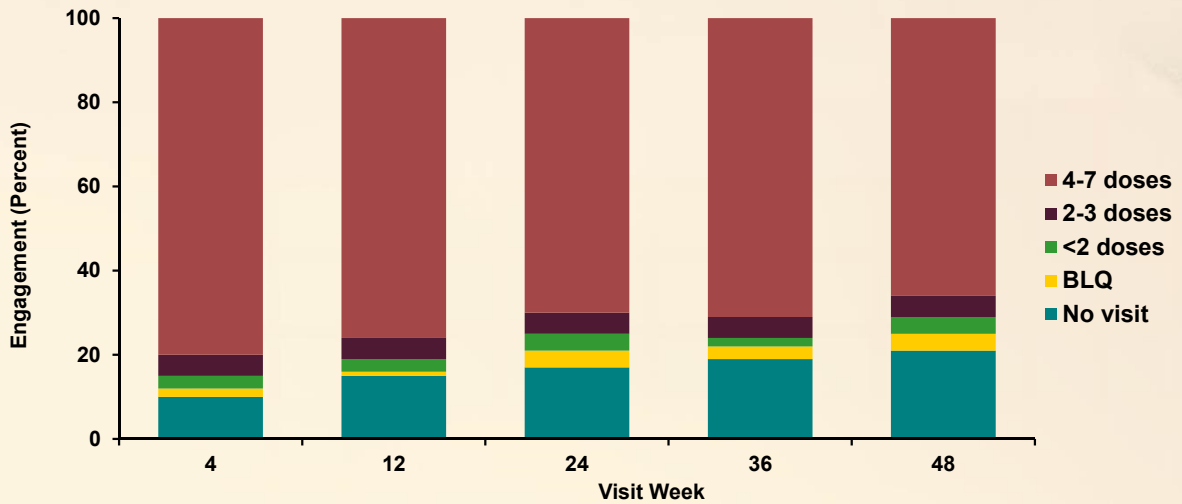


- 63% had protective DBS levels at all visits
- Retention 78% at 12 mos
- 3% always had DBS levels <2 doses/week
- PrEP dispensation interrupted in 15%: most commonly due to side effect concerns or low perceived risk

LiuA, et al; 8th IAS, Vancouver, Canada, July 19-22, 2015; Abst. TUAC0202.

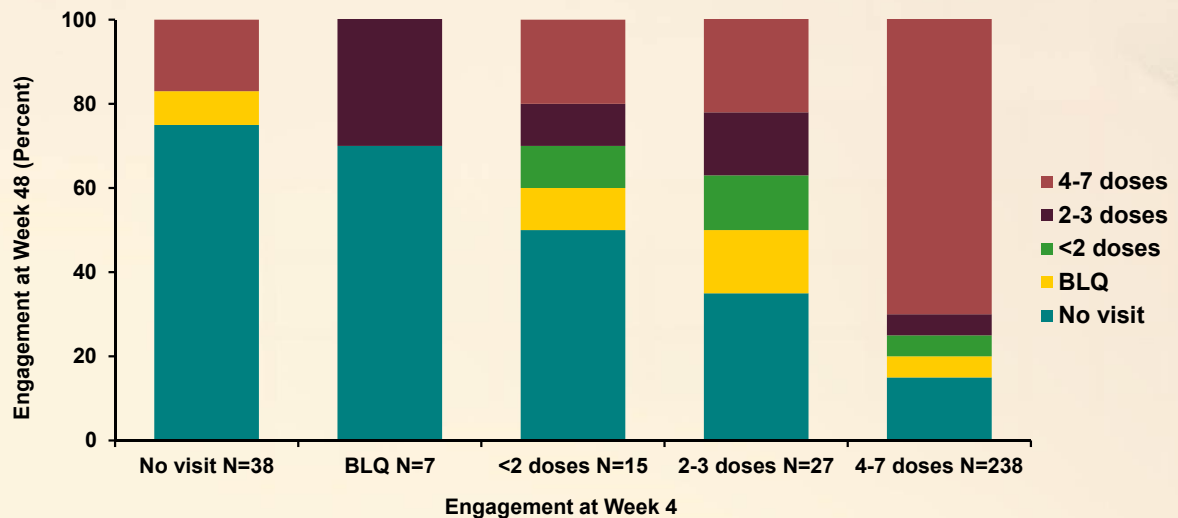
## Results: PrEP Engagement

❖ Lower engagement in Miami and among African-American participants



LiuA, et al; 8th IAS, Vancouver, Canada, July 19-22, 2015; Abst. TUAC0202.

## Early Engagement Predicts Later Engagement



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## Independent Predictors of Protective DBS Levels

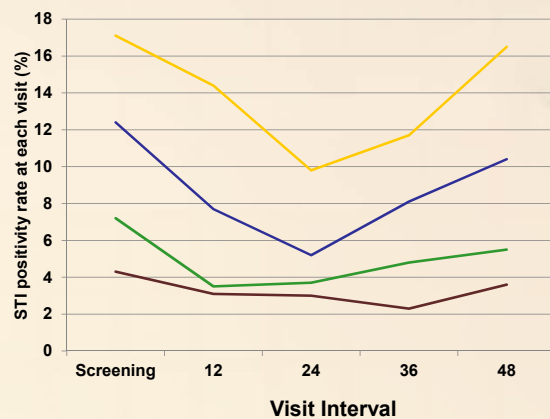
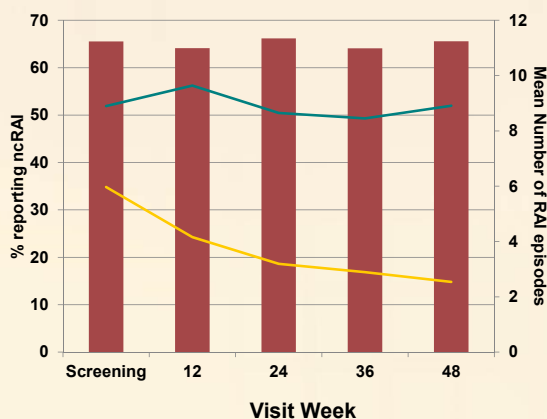
Characteristic	% PL*	AOR (95% CI)	P value
<b>Site</b>			
San Francisco	90	Ref	
Miami	65	0.32 (0.17-0.60)	<0.001
DC	88	1.08 (0.54-2.19)	0.82
<b>Race/Ethnicity</b>			
White	91	Ref	
Latino	77	0.81 (0.41-1.61)	0.55
Black	57	0.28 (0.12-0.64)	0.003
Asian	84	0.72 (0.17-3.03)	0.65
Other	82	0.42 (0.13-1.38)	0.15
<b>Living situation</b>			
Rent or own housing	87	2.02 (1.14-3.55)	0.02
Other	70	Reference	
<b># condomless anal sex partners, past 3 mo</b>			
0-1	75	Reference	
≥2	89	1.82 (1.14-2.89)	0.01

**Age, education, alcohol, or drug use were not associated with achieving protective levels**

\*PL = Protective DBS levels (TFV-DP in DBS consistent with ≥4 doses/week)  
Liu A, et al; 8th IAS, Vancouver, Canada, July 19-22, 2015; Abst. TUAC0202.

## Results: Sexual Behaviors

**Mean number of anal sex partners declined from 10.9 to 9.3 (P=0.04)**



**Overall STI incidence (90/100 person years) remained stable during follow-up (P>0.1)**

Liu A, et al; 8th IAS, Vancouver, Canada, July 19-22, 2015; Abst. TUAC0202.

## Results: HIV Seroconversions and Incidence

- ❖ 3 acute infections at enrollment
  - ◆ All had negative rapid and 4th gen HIV tests
  - ◆ 2 had positive pooled RNA, 1 positive individual RNA
  - ◆ FTC resistance developed in one ppt 1 week after enrollment: suppressed on combination ART
- ❖ Only 2 infections during follow-up
  - ◆ PPT #1: 19 weeks after enrollment:  
Reported last dose >1 month prior, TFV-DP levels < 2 doses/wk
  - ◆ PPT #2: 4 weeks after 48 week visit:  
TFV-DP levels < 2 doses/wk or undetectable after week 4
  - ◆ No evidence of HIV resistance
- ❖ HIV incidence = 0.43 / 100 py (95% CI 0.05-1.54)

LiuA, et al; 8th IAS, Vancouver, Canada, July 19-22, 2015; Abst. TUAC0202.

## Safety

- ❖ 19 serious adverse events: none related to TDF/FTC
- ❖ 23 creatinine elevations in 13 (2.3%) pts
  - ◆ All grade 1, except one grade 2
  - ◆ Only 3 confirmed on repeat testing, all resolved without stopping PrEP
- ❖ 12 bone fractures reported during the study: almost all trauma related; none related to TDF/FTC

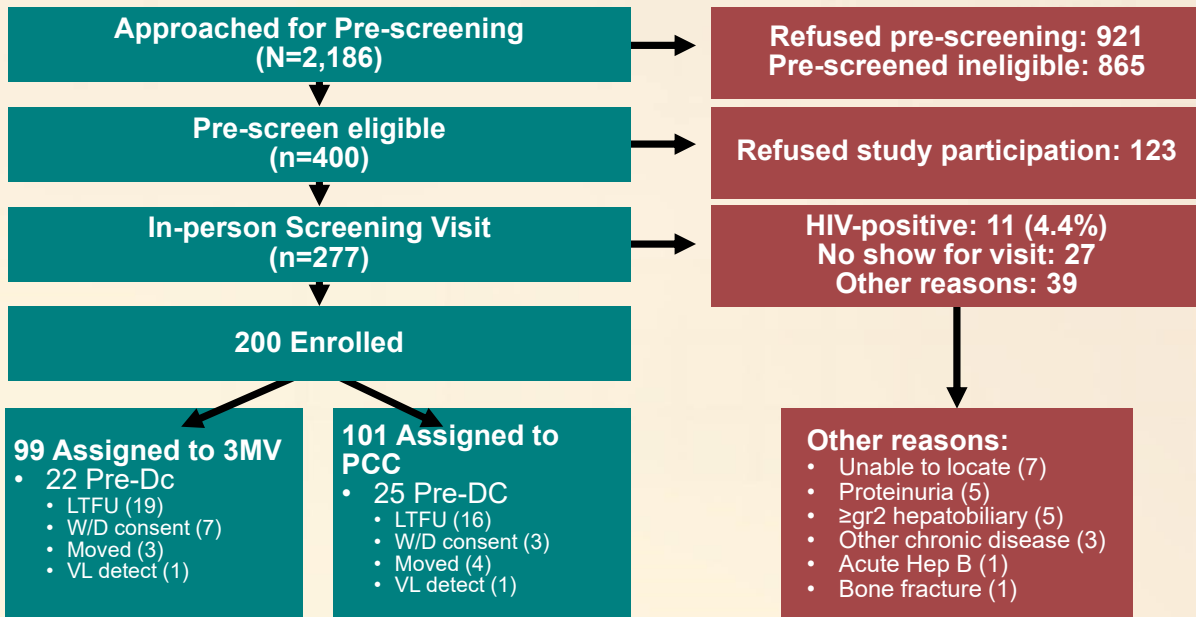
LiuA, et al; 8th IAS, Vancouver, Canada, July 19-22, 2015; Abst. TUAC0202.

# ATN 110 Study Sites



Hosek S, et al; 8th IAS, Vancouver, Canada, July 19-22, 2015; Abst. TUAC0204LB.

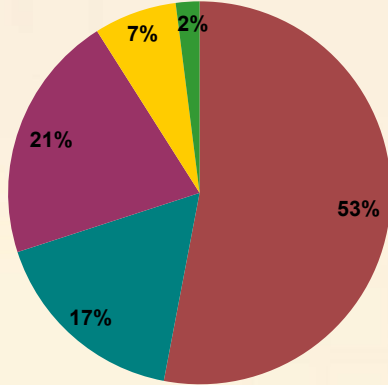
# Consort Diagram



Hosek S, et al; 8th IAS, Vancouver, Canada, July 19-22, 2015; Abst. TUAC0204LB.



## Baseline Demographics

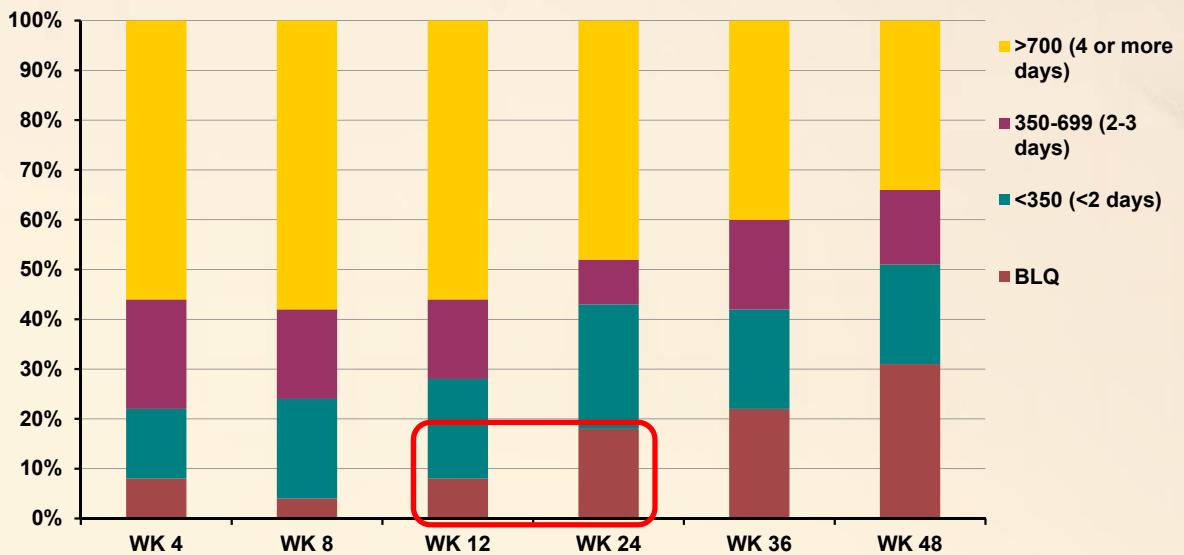


■ Black ■ Hispanic/Latino ■ White ■ Other/Mixed ■ Asian/PI

Mean age	20.18
Sexual Identity	Gay – 77.8% Bisexual – 13.7%
Highest grade completed	High School – 33.8% Some college – 45.5%
Not currently working	30.1%
Ever kicked out	17.2%
Ever paid for sex	28.6%
Partners in past mo	5
Condomless sex	81%
CRAI w/last partner	58%
Any positive STI test	22%

Hosek S, et al; 8th IAS, Vancouver, Canada, July 19-22, 2015; Abst. TUAC0204LB.

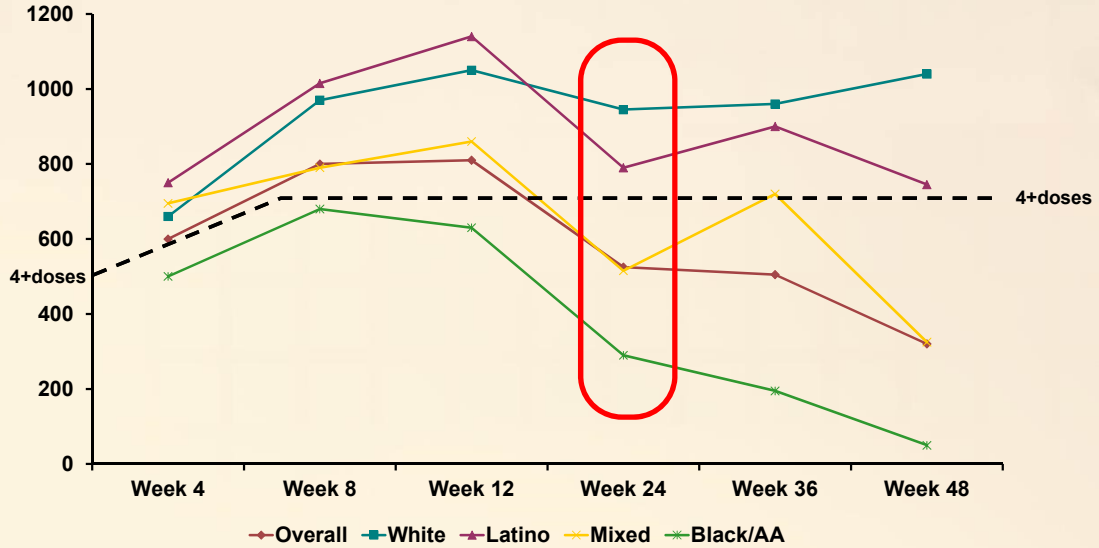
## Adherence: TFV-DP (fmol/punch) via DBS and Dosing Estimates



Hosek S, et al; 8th IAS, Vancouver, Canada, July 19-22, 2015; Abst. TUAC0204LB.



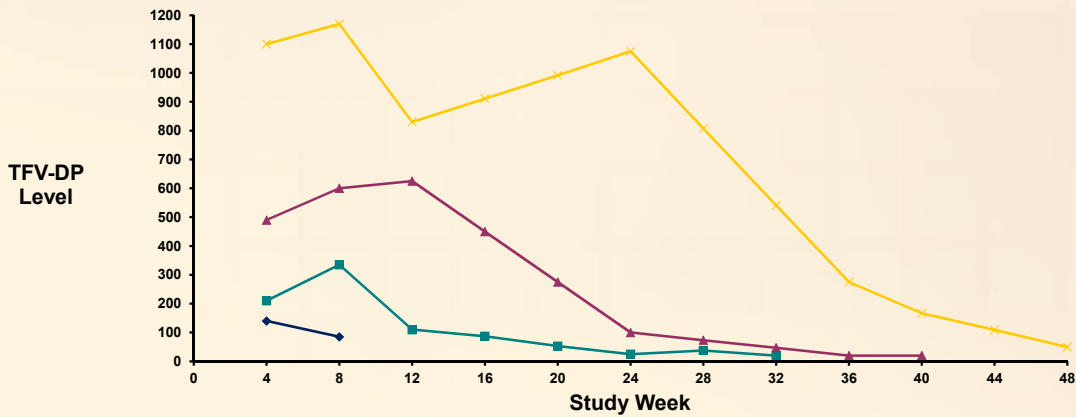
## Adherence: Median TFV-DP by Race/Ethnicity



Hosek S, et al; 8th IAS, Vancouver, Canada, July 19-22, 2015; Abst. TUAC0204LB.

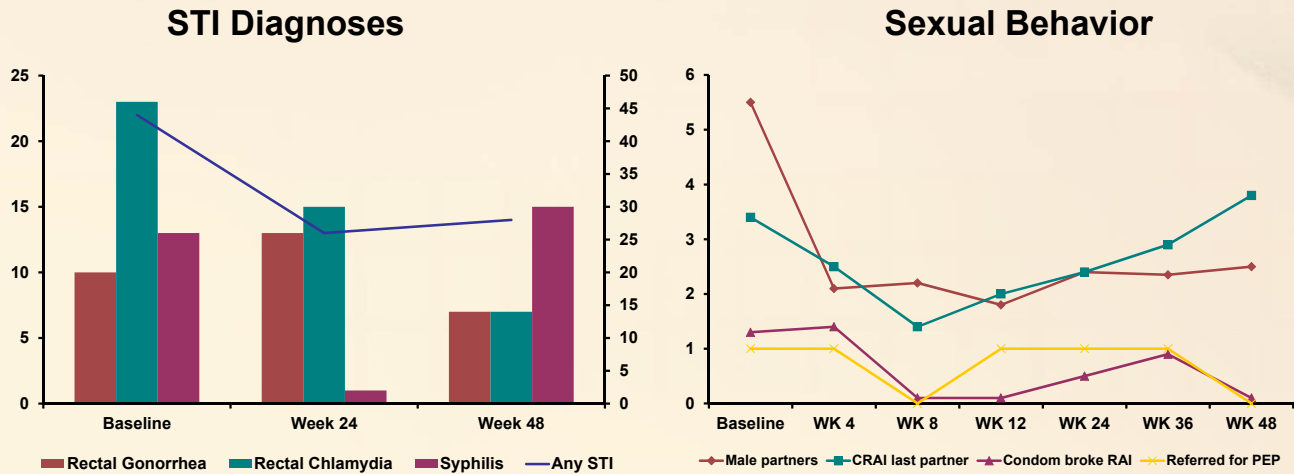
## HIV Incidence

- ❖ 4 seroconversions through week 48
- ❖ HIV incidence = 3.29 per 100 person-years
- ❖ No drug resistance found



Hosek S, et al; 8th IAS, Vancouver, Canada, July 19-22, 2015; Abst. TUAC0204LB.

## STIs, Sexual Behavior: No Evidence of Risk Compensation



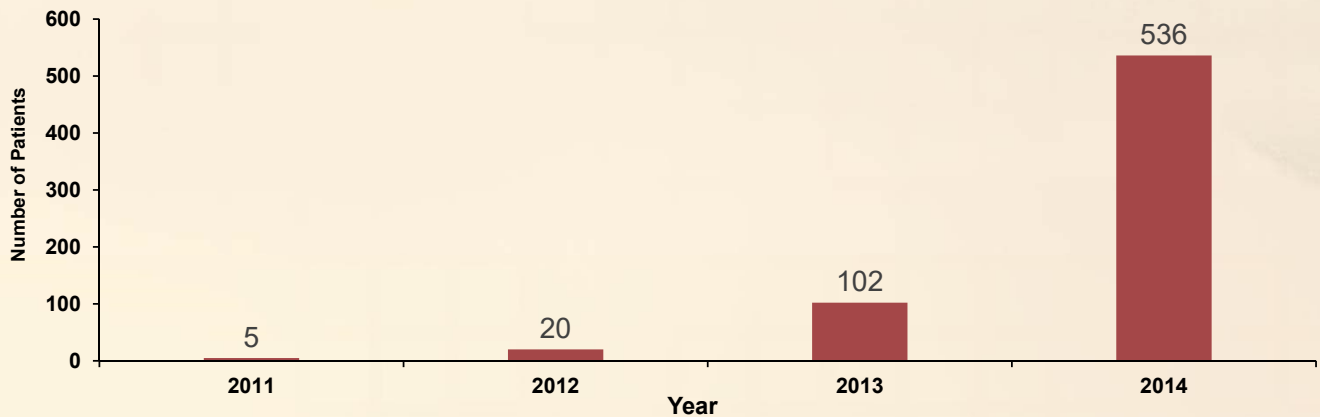
Hosek S, et al; 8th IAS, Vancouver, Canada, July 19-22, 2015; Abst. TUAC0204LB.

## Adherence and Sexual Behavior

- ❖ Participants that reported engaging in condomless sex had consistently higher levels of TFV-DP ( $p=0.005$ )
  - ◆ Remained consistent over course of the study
- ❖ Similarly, participants who reported CRAI with last partner demonstrated higher TFV-DP levels over course of the study
  - ◆ Trend not statistically significant

Hosek S, et al; 8th IAS, Vancouver, Canada, July 19-22, 2015; Abst. TUAC0204LB.

## RESULTS: Patients Initiating PrEP by Year



- ❖ Use of PrEP has increased five-fold in the past year alone
- ❖ In 2014, 25.2% of pts with a new bacterial STD, and 33.3% of pts using PEP, subsequently initiated PrEP
- ❖ As of 12/31/14, 88.5% are still using PrEP; longest duration: 3.8 Years