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Prospective Use of Urine Tenofovir Assay to Monitor Adherence to PrEP

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Conflict of Interest Disclosure

Helen C. Koenig, MD, MPH

- Consulting Fees: Gilead Sciences, Inc
- Contracted Research: Gilead Sciences, Inc



Background

- Adherence to PrEP is critical, but current adherence measurements are inadequate
- Young MSM of color and transwomen are at greatest risk yet adherence has not been adequate in this group
- We previously developed and validated a non-invasive, inexpensive, and highly acceptable urine assay to measure tenofovir (TFV) in HIV-negative subjects



Objectives

For a high-risk yMSM of color and transwomen population over a 48 week study period:

- 1) Assess adherence to PrEP using the urine assay
- 2) Assess retention in care, defined as
 - a) Completed >50% medication pick-up visits
 - b) Had a visit at 48 weeks (within study window)
- 3) Assess changes in rates of STIs
- 4) Assess attitude toward PrEP by study subjects



Methods: Urine Assay

- Uses liquid chromatography/mass spectrometry
- Assay has high sensitivity and specificity for TFV
- 100% concordance btw TFV in blood & urine
- TFV detected >7d in urine

Urine [TFV] ng/ml	Adherence Level	Date Last Dose	Implication
>1000	Recent adherence	Within 48 hrs	HIV protection
>10 to >100	Low adherence	2-7 days ago	Suboptimal HIV protection, at risk of resistance
<10	Non-adherence	> 7 days ago	No HIV protection, low risk of resistance



Methods: Study Design

- 48w prospective study of retention/adherence
- Subjects recruited from “I Am Men’s Health” PrEP Program at Y-HEP for high-risk youth
- PrEP administered weekly, biweekly, or monthly at Y-HEP with intensive adherence support
- Inclusion criteria: age 18-30, male sex at birth
- Risk behaviors were assessed through STI rates and Risk Assessment Battery (RAB) survey



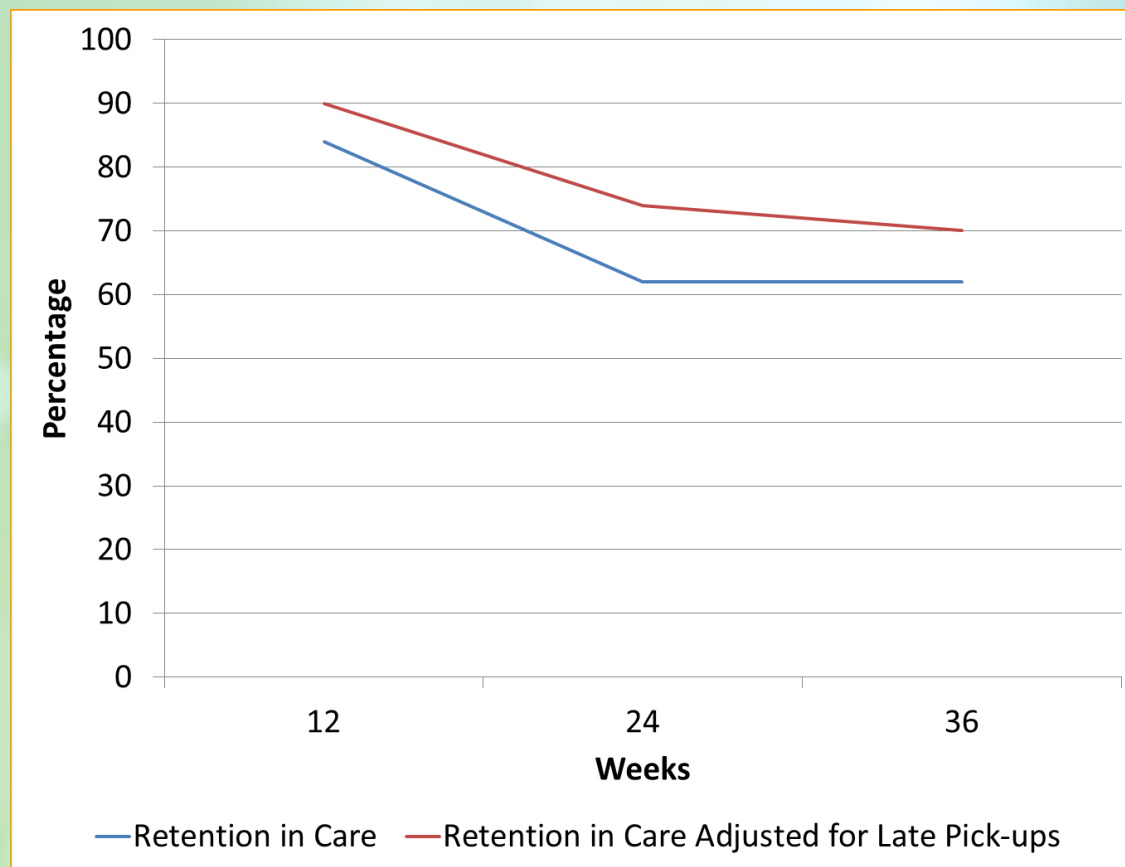
Weeks	Screening Visit	Study Visits						
	-2 to -0	0	4	8	12	24	36	48
Informed Consent	√							
4 th gen HIV Ab/Ag test	√				√	√	√	√
Rapid HIV Test			√	√				
Plasma TFV level						√		√
Urine TFV level			√	√	√	√	√	√
Adapted Risk Assessment Battery		√				√		√
STI Test if Symptomatic	√	√	√	√	√	√	√	√
STI Screening	√				√	√	√	√
Risk-reduction Counseling		√	√	√	√	√	√	√
Condom Provision		√	√	√	√	√	√	√
Patient Assistance App for Uninsured Patients	√							
Acceptability Survey								√



Baseline Characteristics (n = 50)	
Age, y, range	22.4 (18-29)
African-American Race	32 (64)
Ethnicity Hispanic/Latino	9 (18)
Transgender (Male to Female)	5 (10)
Self-identified Sexual Orientation	
Straight/Heterosexual	2 (4)
Gay/Homosexual	35 (70)
Bisexual	13 (26)
Education	
Some High School	8 (16)
Graduated High School/GED	17 (34)
Some College/Trade School	16 (32)
Graduated College/Prof. Degree	9 (20)
Annual Income < \$10,000	33 (66)
Risk Factors for HIV	
HIV+ partner	4 (8)
Inconsistent Condom Use	40 (80)
History of STI	29 (58)
Exchange of Sex for Commodities	9 (18)
Drug/Alcohol Use	37 (74)
History of Incarceration	11 (22)
Partner(s) of Unknown HIV Status	27 (54)
4 or More Partners in last 6 mo	15 (30)



Retention in Care, 36 weeks

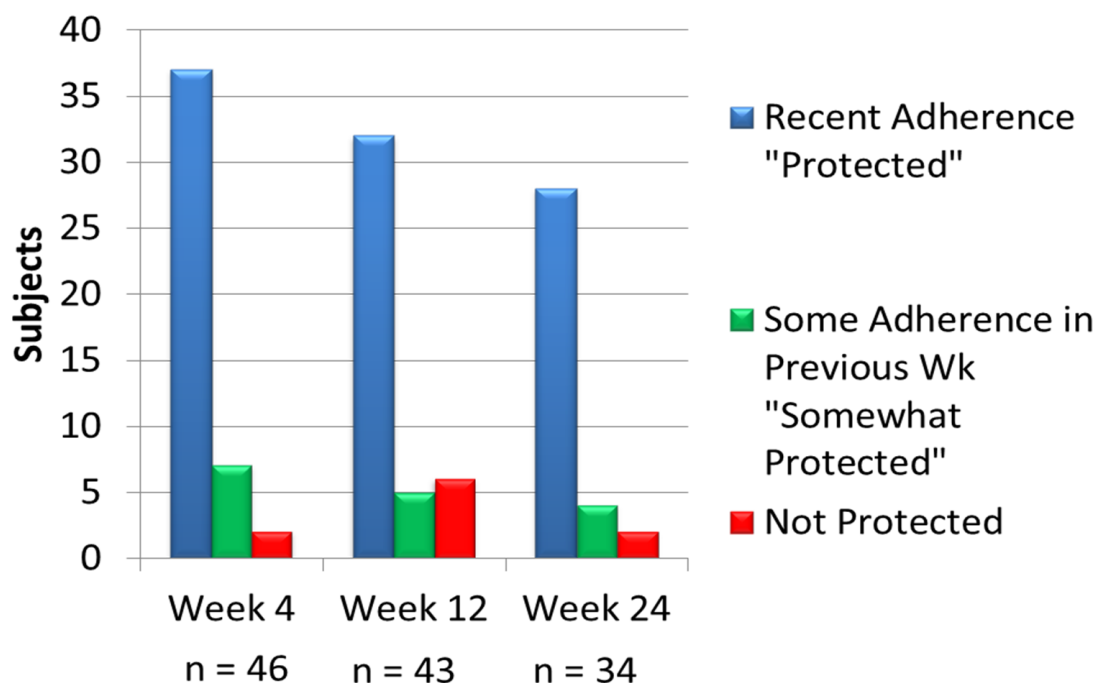


70% subjects
retained in
care at 36
weeks



Adherence to PrEP

Urine TFV Concentrations



At 24 wks:

83% subjects with **protective** urine TFV values

12% subjects with low-positive (not protective) urine TFV values

5% subjects with negative values (not protective)



In Practice: Patient with Consistent Adherence

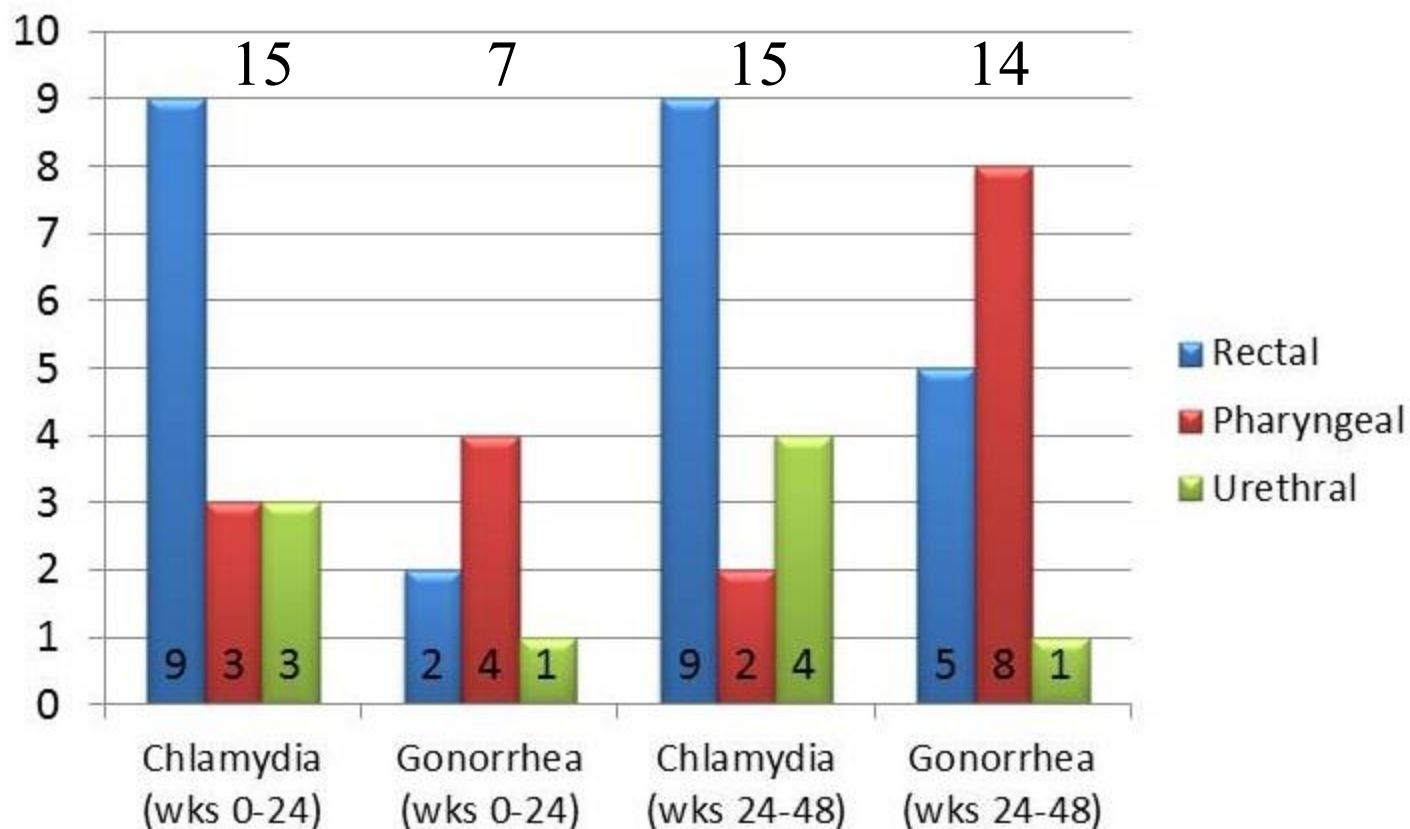
		2/3/2015	4/1/2015	5/1/2015	6/1/2015	6/1/2015	6/26/2015	7/23/2015
Tenofovir Level			>1000 ng/mL (Protected)	>1000 ng/mL (Protected)	>1000 ng/mL (Protected)		>1000 ng/mL (Protected)	>1000 ng/mL (Protected)
HIV viral load								
HIV-1 RNA by PCR					<20			
log10 HIV-1 RNA					COMMNT			
HIV testing								
HIV Rapid Test			Negative	Negative	Negative			
HIV AG/AB, 4TH GEN								
HIV Screen 4th Gen								
Hepatitis Panel								
HCV Ab					<0.1			
HEPATITIS B SURFACE								
Hep B Core Ab, Tot								
STD screening								
RPR (MONITOR) W/					Reactive A			
RPR, Quant					1:32 H			
NEISSERIA GONORRHOEA					Negative	Negative		

PreP log

[Add Results](#)[illegible]



STI Rates



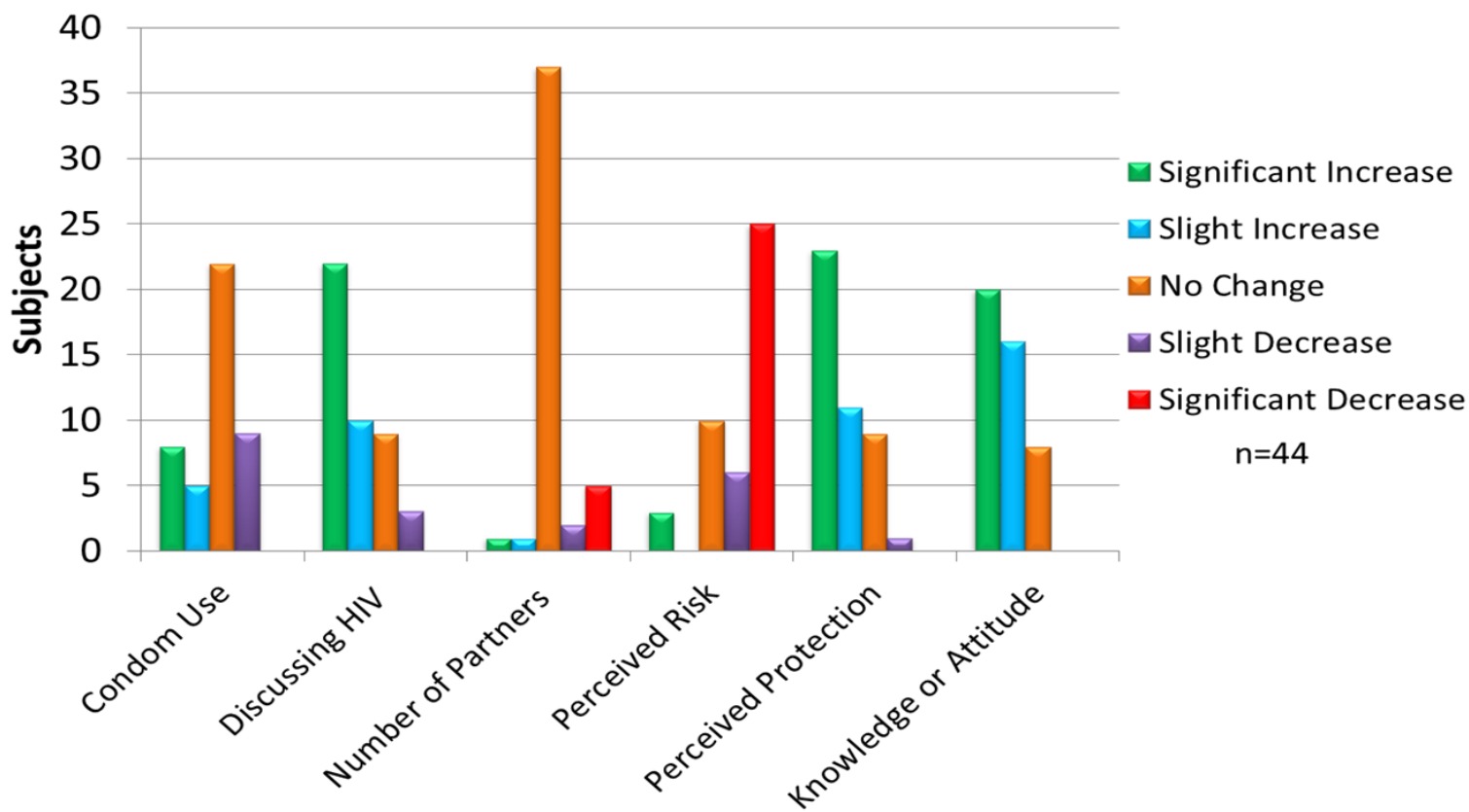
★ Additional STIs diagnosed:

2 diagnoses of Syphilis in wks 0-24, 0 cases wks 24-48

1 diagnosis of genital Herpes in wks 0-24, 0 cases wks 24-48



Perspectives on PrEP





Conclusions

- Urine TFV testing allowed us to monitor PrEP adherence among high-risk youth in a CBO
- Adherence > 83% at 24 wks by urine
- Retention 70% at 36 weeks
- High rates of other STIs throughout study period
- Future Directions
 - Demonstrate urine assay increases adherence
 - Develop urine assay into point-of-care test



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