



HPTN

HIV Prevention
Trials Network

Uptake and Utilization of PrEP Among Black MSM: Why Race Matters (HPTN 073)

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HPTN 073 Study Design

- Demonstration project
 - 3 sites in the United States
- Study Sites:
 - Chapel Hill, NC
 - Los Angeles, CA
 - Washington, DC
- 225 HIV uninfected BMSM
- Offered once daily oral Truvada® as PrEP
- Client-centered care coordination (C4):
individualized prevention counseling, support,
and service coordination
- Participants followed for a total of 12 months

Client Center Coordinated Care (C4)

- Longitudinal management of client-identified health and psychosocial needs by an interdisciplinary team
- Acknowledges the unique experiences of BMSM in the U.S. with regard to biomedical interventions, psychosocial issues and barriers to accessing health care
- Informed by research experiences of HPTN
 - Extensive literature supporting the efficacy and cost-effectiveness of interdisciplinary team-based clinical care models
 - Years of clinical practice experience providing expert medical, nursing, social work and psychological care and treatment for BMSM

Client Centered Coordinated Care (C4)

- Intensive, individualized, client-centered counseling for adopting and maintaining HIV risk reduction behaviors
- Hybrid model based on Comprehensive Risk Counseling and Services (CRCS)
- Designed for HIV-negative BMSM who are at high risk for acquiring HIV
- Supports adherence for HIV-negative BMSM who decide to utilize Truvada as PrEP

C4 Theoretical Framework

- Needs supported counseling undergirded by self determination theory (SDT)
 - Socio-cultural factors facilitate or undermine a persons sense of volition and initiative
 - Assumption that humans have tendencies toward growing and mastering challenges, and integrating new experiences into a coherent sense of self
- Autonomy, competence, and relatedness
 - Engage in targeted behaviors (i.e., PrEP initiation, PrEP maintenance, and condom use)

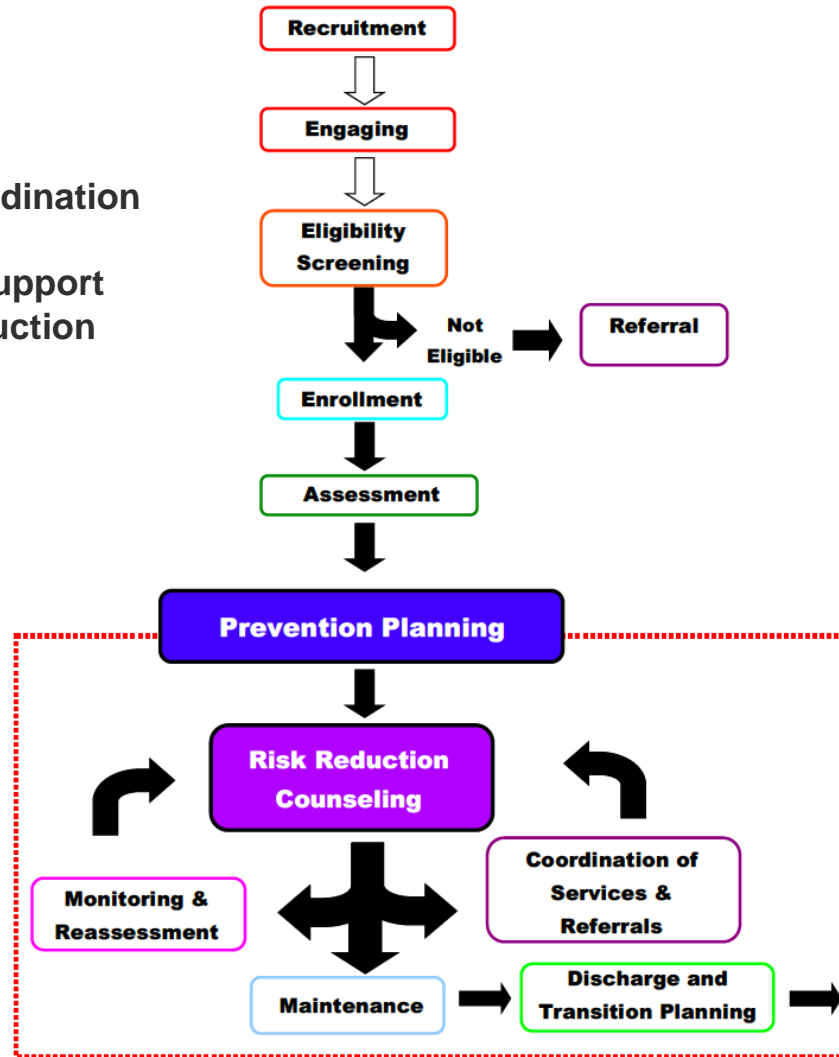
HPTN 073 Enrollment & Retention

- Study began Aug 2013
- Fully enrolled as of 26 Sept 2014
 - 226 total enrolled
 - UNC: 75; UCLA: 76; GWU: 75
- 40.2% of participants \leq 25 yrs of age
- Final visit Sept 2015
- Overall participant retention = 92%

HPTN 073

Client Centered Care Coordination (C4): A Culturally Specific Intervention Package to Support PrEP Use in HIV Risk Reduction Menu of Options

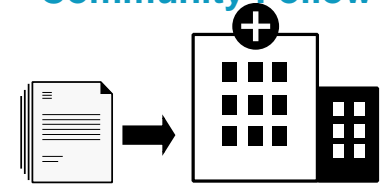
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C4 Core Components →
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PrEP Uptake: 79%

12-Month Retention: 92%

Transition to Community Follow-Up



Screened
344

118

Enrolled
226 (66%)

Major reasons

- 25 (21 %) Abnormal liver or kidney function
- 9 (8 %) Abnormal lab test results
- 9 (8 %) Withdrew consent
- 9 (8 %) Unwilling to adhere to study procedures
- 7 (6%) HIV+ rapid test
- 5 (4%) Unable to complete enrollment w/in 45 days
- 4 (3%) Current/prior study participation
- 4 (3%) Serious and active mental or medical illness
- 54 (46 %) Other reasons

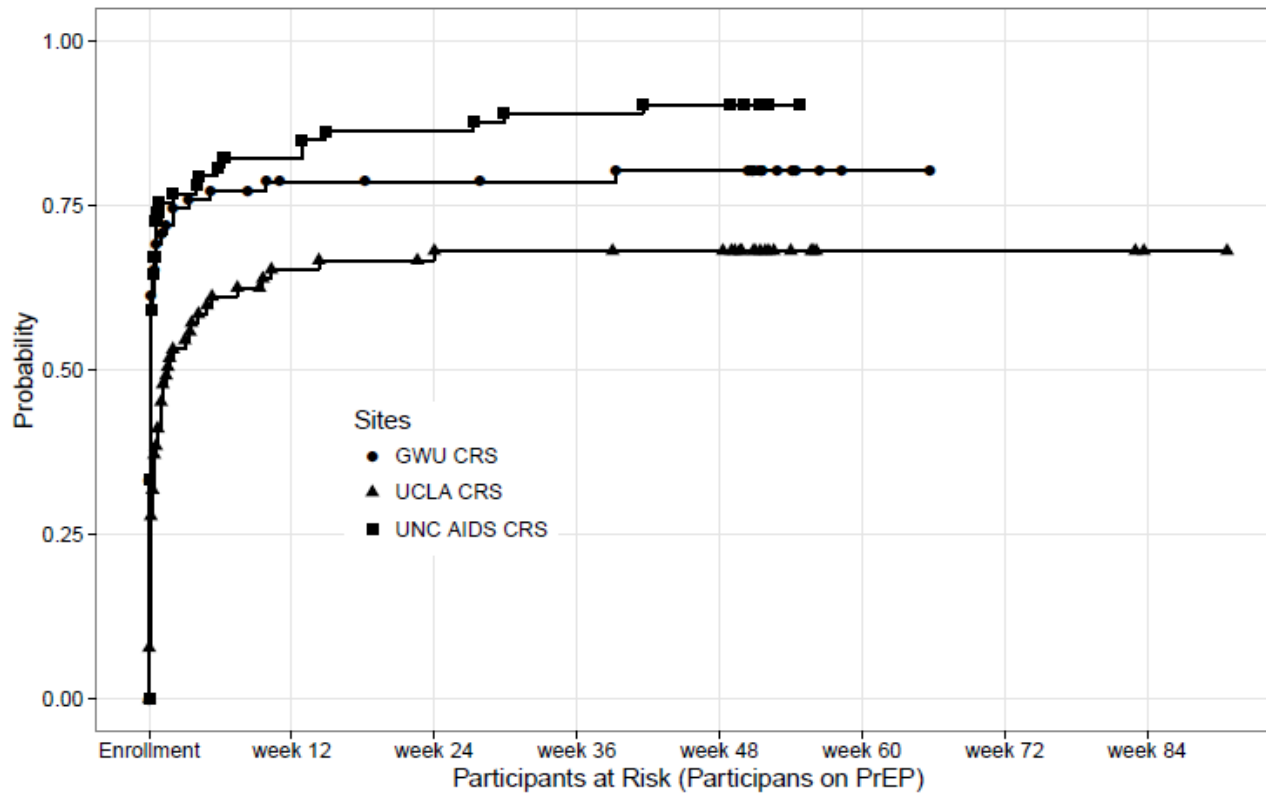
Demographics of participants enrolled in the study by PrEP Initiation

Demographics	Overall N	On PrEP	Not on PrEP
Site	226	79%	21%
Age			
<25	91	84%	16%
≥25	135	76%	24%
Gay	166	81%	19%
Bi-sexual	45	71%	29%
Marital Status			
Primary or main partner			
Male	74	78%	22%
Female	3	100%	-
Transgender	-	-	-
Ethnicity			
African-American/Black/Caribbean	204	78%	22%
Afro-Latino	17	82%	18%
Other	5	80%	20%

Demographics of participants enrolled in the study by PrEP Initiation

Demographics	Overall N	On PrEP	Not on PrEP
Site	226	79%	21%
Healthcare Coverage	155	77%	23%
Incarceration	69	74%	26%
Highest education level attained			
High School or less	56	77%	23%
Some college/vocational school	93	77%	23%
2yr/4yr or greater	77	82%	18%
Annual income (decline to answer 1%)			
<20k	108	74%	26%
20k – 49k	64	81%	19%
≥50k	51	84%	16%
Declined to answer			
Employment Status			
Unemployed/disability/other	61	66%	34%
Employed part-time/self-employed	80	84%	16%
Employed full-time	85	84%	16%

Cumulative Probability of PrEP Uptake



GWU CRS	75 (25)	14 (59)	13 (59)	12 (59)	11 (60)	1 (60)	0 (60)	0 (60)
UCLA CRS	77 (6)	25 (49)	23 (51)	22 (51)	21 (51)	4 (51)	4 (51)	1 (51)
UNC AIDS CRS	75 (25)	13 (61)	10 (64)	8 (66)	7 (67)	0 (67)	0 (67)	0 (67)

PrEP Uptake

- The median number of male partners in the prior 3 months was 3
- 33% reported a primary partner and 73% casual male partners
- 23 of 24 (96%) men reporting an HIV+ primary partner and 104/120 (86%) of men reporting casual partners with unknown or HIV+ status accepted PrEP
- Those agreeing to take PrEP utilized a median of 6 C4 sessions compared to men not accepting PrEP (median 4)

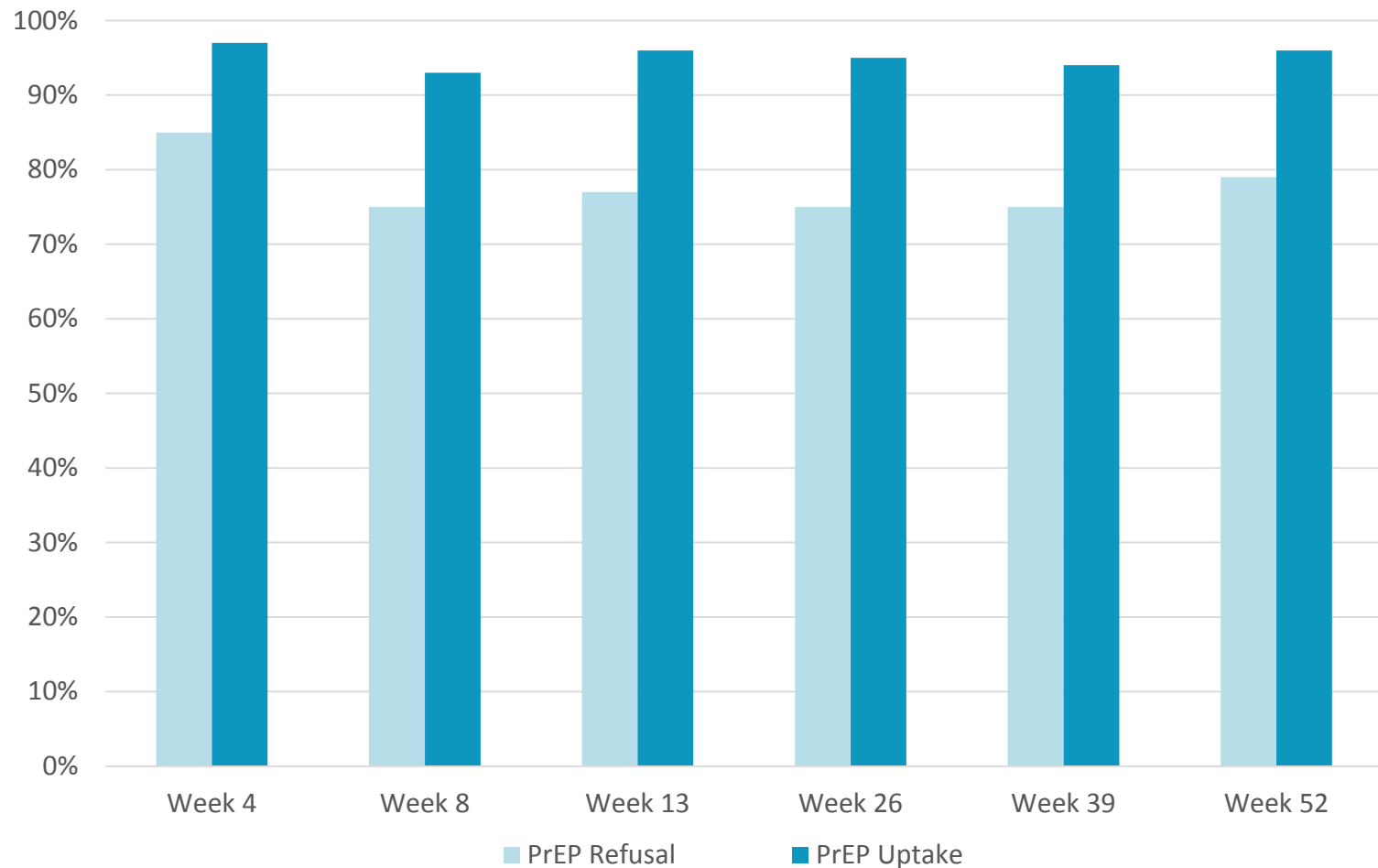
Self Reported PrEP Adherence

Week	Self –reported adherence \geq 50%	Self –reported adherence \geq 90%
4	85% (126/149)	67% (100/149)
8	82% (121/148)	67% (99/148)
13	87% (131/151)	70% (106/151)
26	81% (112/139)	62% (86/139)
39	85% (111/131)	70% (92/131)
52	86% (89/103)	67% (69/103)

HIV Seroconversions

- Among the 178 men who accepted PrEP as part of this study, 5 HIV infections occurred resulting in incidence=2.9 (95% CI (0.9-6.8)) compared to 3 in men who never accepted PrEP incidence=7.7 (95% CI (6-22.5))
- Of the 5 seroconverters who accepted PrEP, 2 reported discontinuing PrEP at 50 and 272 days prior to seroconversion.

Visit Completion by PrEP Initiation Status



Conclusions

- Providing theory-based, culturally tailored programs can potentially increase adherence, support program retention and prevent HIV in BMSM – attention to Race and unique needs matters!!!!
- HPTN 073 demonstrated high uptake of PrEP in BMSM utilizing C4 and led to data that could support a reduced rate of HIV-infection for BMSM on PrEP
- These findings help address a vital US public health gap in HIV prevention

- Confirmatory analyses
 - PBMC, DBS, PK
- Primary outcome paper
- Conference Presentations
 - CROI, AIDS2016, HIVR4P

U.S. Sponsors:

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HIV Prevention Trials Network (HPTN):

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Phaedrea Watkins, Scott Rose
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- Statistical and Data Management Center
SCHARP/Fred Hutch
- Network Leadership

Pharmaceutical Partner:

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- George Washington University CRS
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Site Staff and Study Participants