

CROI 2024: HIV PrEP Update

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Disclosures

Dr. Corcoran has no financial conflicts of interest or disclosures.

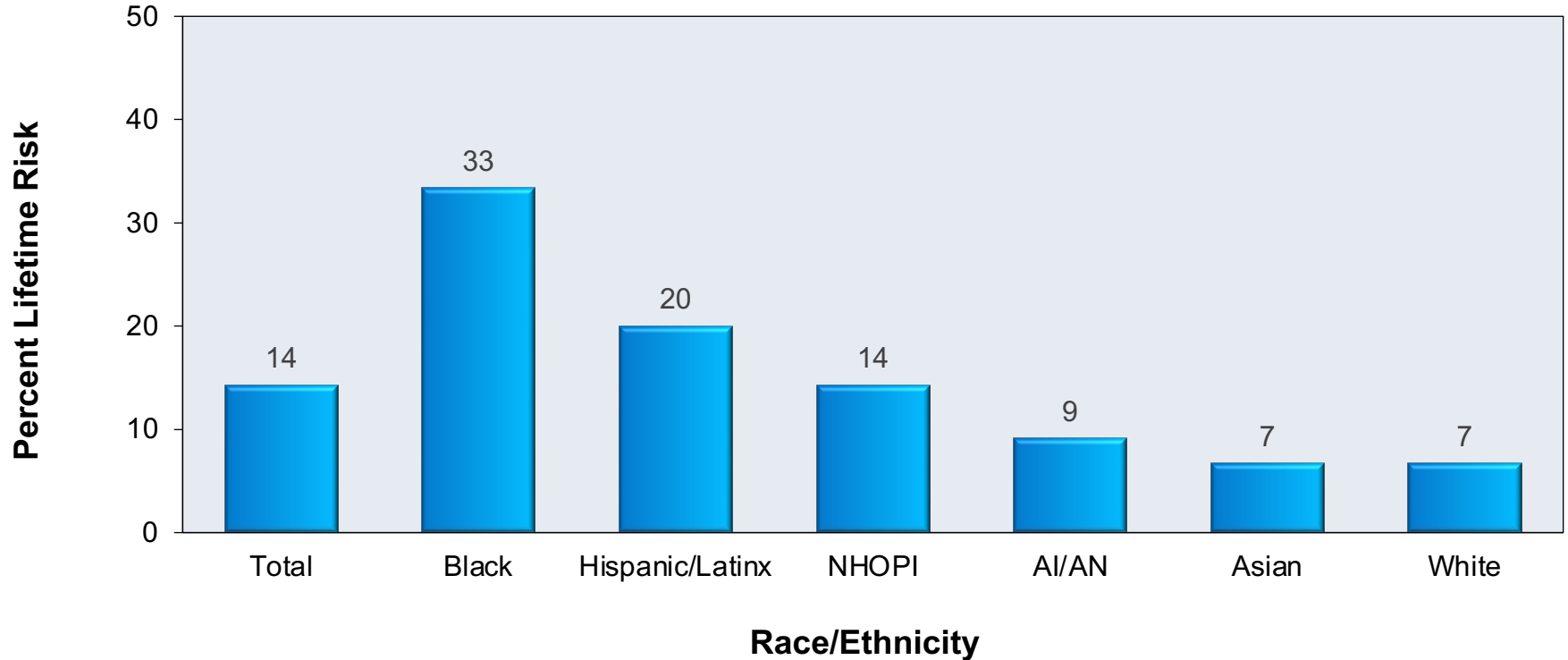
Estimating Lifetime Risk of HIV Diagnosis Among MSM in the US, 2017 - 2021

Singh S. Estimating Lifetime Risk of a Diagnosis of HIV Infection Among MSM: United States, 2017 – 2021. CROI 2024 #193

Methods

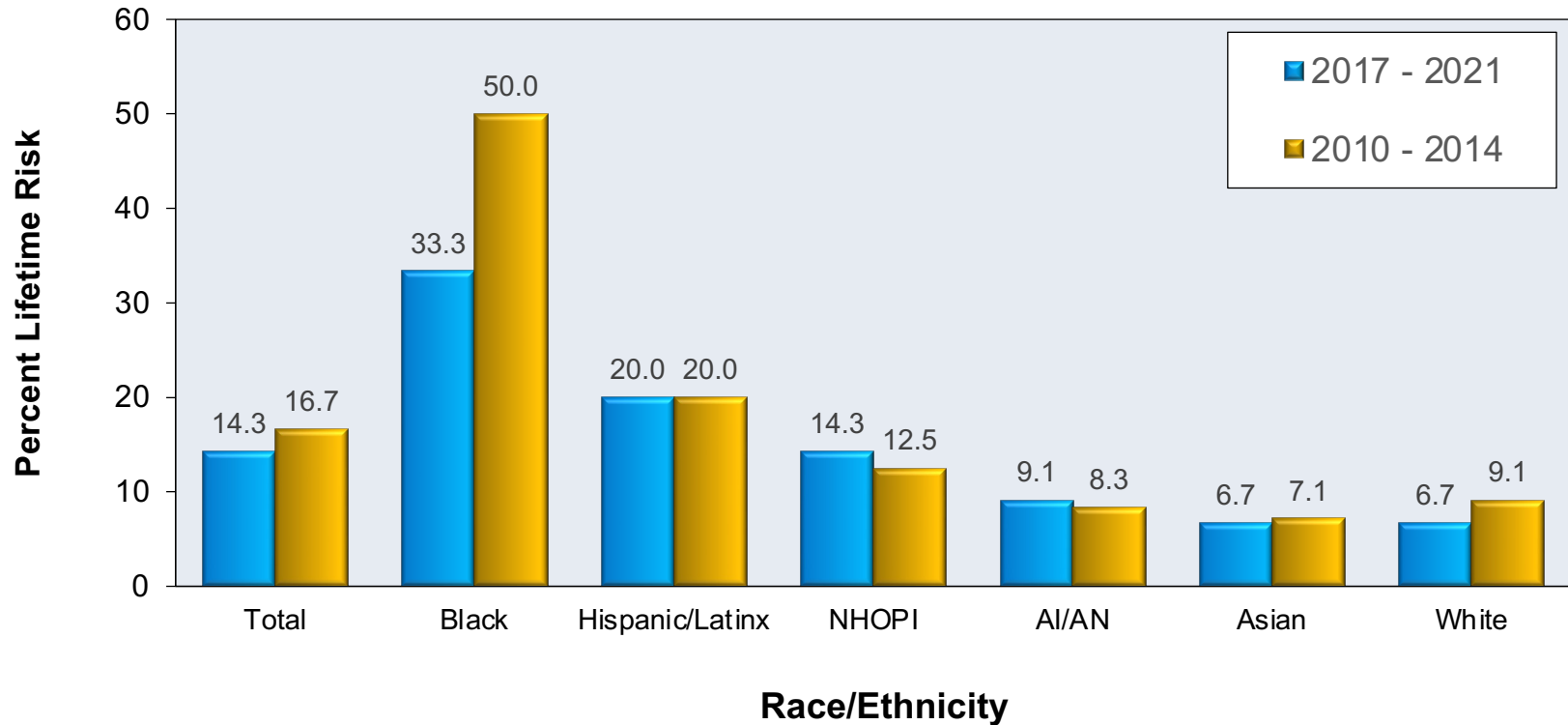
- CDC investigators used data from the following sources (2017 – 2021) to estimate lifetime risk of HIV acquisition among MSM.
 - National HIV Surveillance System (NHSS) → Number of HIV diagnoses
 - Mortality Data – National Center for Health Statistics → Number of non-HIV deaths
 - Census Data → Population
- The number of HIV diagnoses and non-HIV deaths were used to calculate the probability of an HIV diagnosis at a given age using a competing risk model.
 - Probabilities applied to a hypothetical cohort to obtain risk estimates
- Lifetime risk was defined as the cumulative probability of an HIV diagnosis

2017 - 2021 Lifetime Risk of an HIV Diagnosis Among MSM by Race / Ethnicity



Source: Singh S. CROI. 2024. Abstract #193.

Lifetime Risk of an HIV Diagnosis by Race/Ethnicity, 2010 – 2014 vs. 2017 - 2021



Association of State-Level PrEP Coverage and State-Level HIV Diagnoses, US 2012-2021

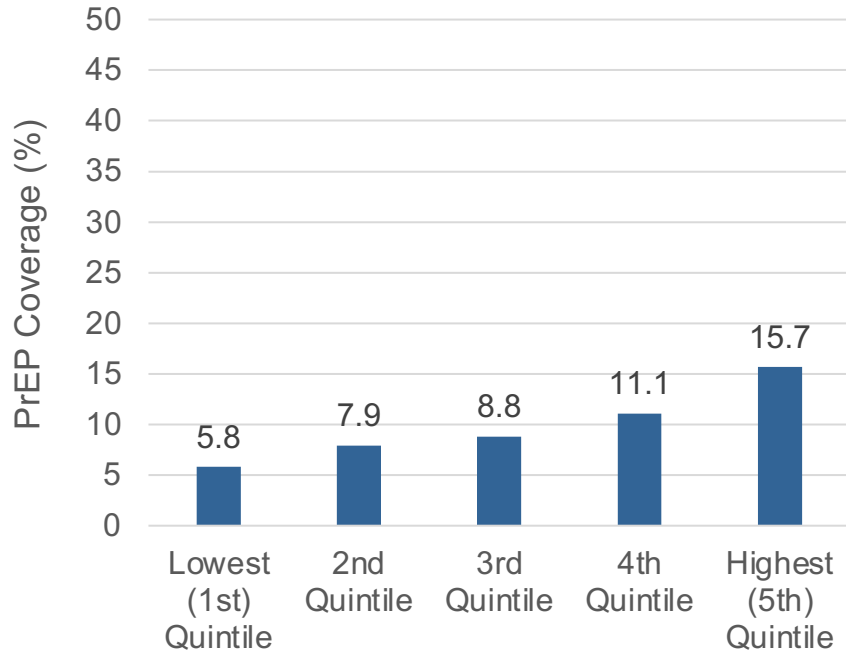
Sullivan P. et al. Association of State-Level PrEP Coverage and State-Level HIV Diagnoses, US, 2012-2021. CROI 2024 #165

Methods

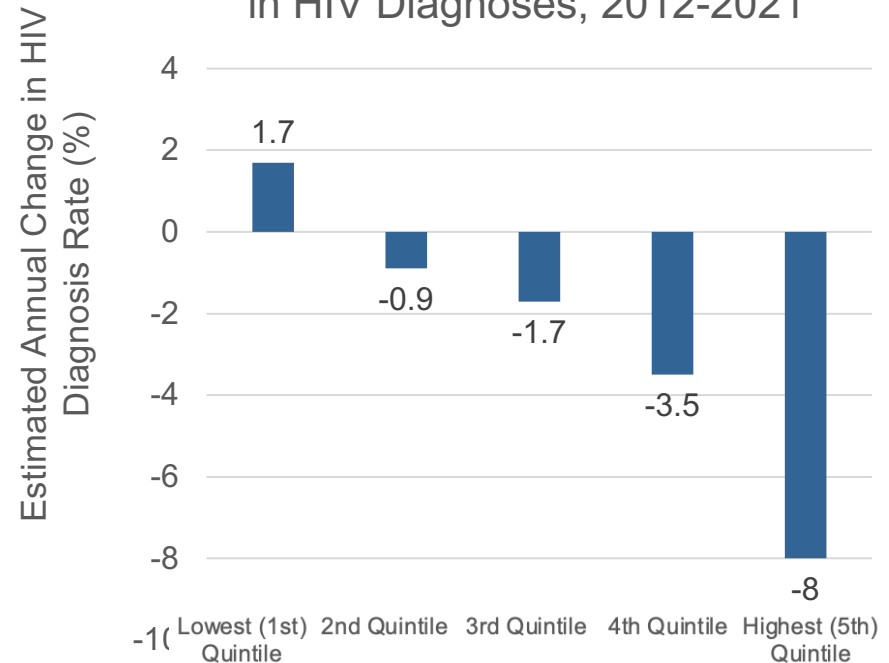
- Authors used data from AIDS Vu.org and CDC to estimate the number of people with a PrEP indication.
- Commercial pharmacy data was used to estimate the number of PrEP prescriptions by state.
- $\text{PrEP coverage} = \frac{\# \text{ of PrEP uses}}{100 \text{ persons with indications}}$.
- Estimated annual percent change in PrEP coverage, controlling for jurisdictional-specific viral suppression rates.

Mean PrEP Coverage and Changes in New HIV Infections among 50 US States, 2012-2021

Quintiles of Mean PrEP Coverage



Estimated Annual Percent Change in HIV Diagnoses, 2012-2021



Site-Based HIV Testing Assay Performance for Cabotegravir and TDF-FTC PrEP Failure in HPTN 083

Landovitz R, et al. Site-Based HIV Testing Assay Performance for Cabotegravir and TDF-FTC PrEP Failure in HPTN 083. CROI 2024: Denver, CO;Abstract 128.

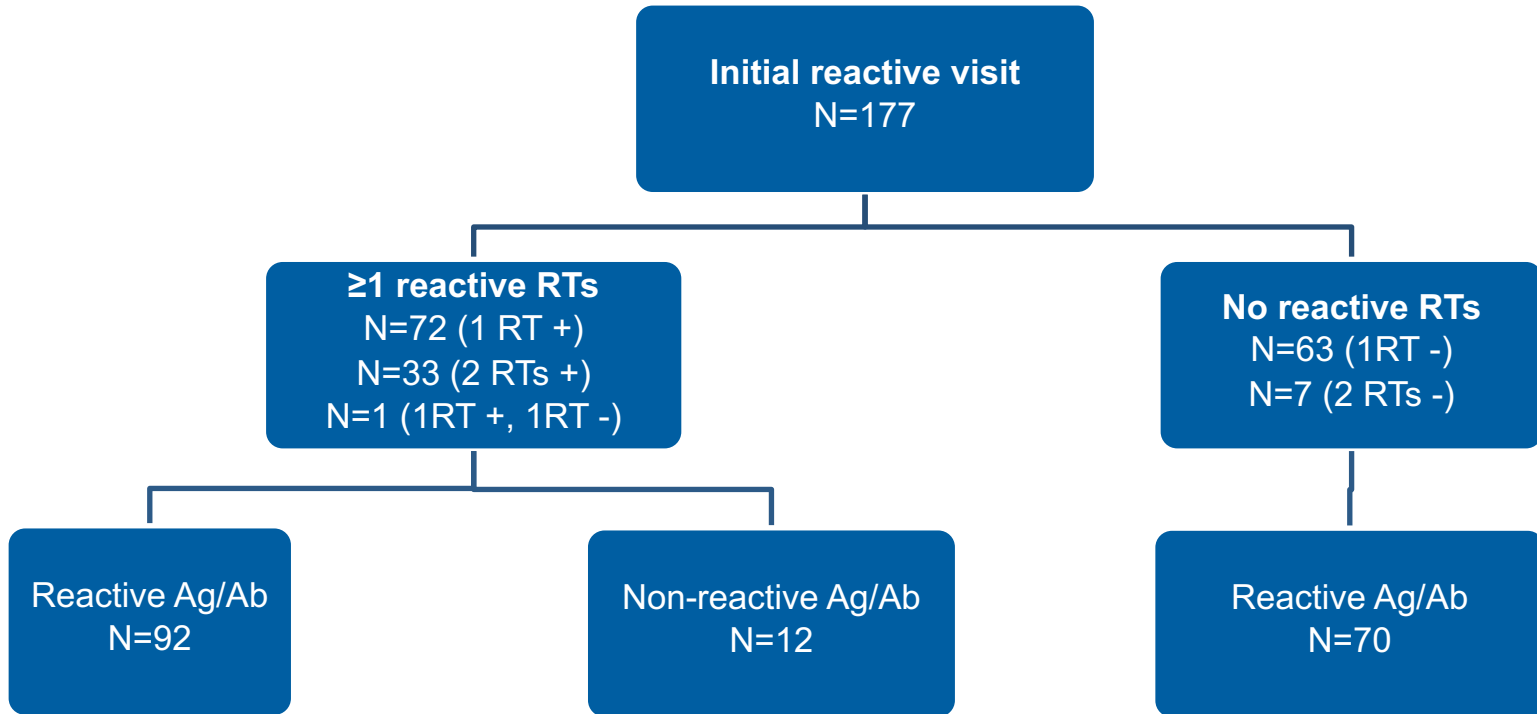
Background

- HPTN 083 is an ongoing phase 3 RCT evaluating the efficacy of CAB-LA vs. daily oral TDF-FTC for HIV PrEP in cisgender men and transgender women.
- During the blinded phase of the study, researchers used rapid HIV antibody testing (RT) and laboratory-based HIV antigen/antibody testing (Ag/Ab) to evaluate for HIV infection.
- Post-hoc observations identified delays in HIV ag/ab test reactivity in the setting of CAB-LA PrEP failures, leading to the CDC recommendations for viral load testing in patients on CAB-LA for PrEP.
- Optimal HIV testing algorithm to screen for long-acting PrEP failure remains undefined.

Methods

- Aim to evaluate the PPV of different RT and Ag/Ab HIV testing combinations for cisgender men and transgender women on CAB-LA for PrEP.
- RTs and Ag/Ab tests were performed at all study visits, with some sites conducting 2 RTs prior to HIV PrEP administration per local practice.
- Researchers analyzed data from the blinded period and first unblinded year of follow-up.
- PPVs with 95% CIs were calculated for different testing approaches.

Positive Testing Results



3 participants were missing 1 or more protocol-specific tests

Results

	CAB-LA		TDF/FTC	
Test Type	HIV+/Total Reactive	PPV (95% CI)	HIV+/Total Reactive	PPV (95% CI)
RT+	38/45	84% (71%, 94%)	86/94	91% (84%, 96%)
Ag/Ab+	42/64	66% (53%, 77%)	85/99	86% (77%, 92%)
RT+ and Ag/Ab+	27/27	100% (87%, 100%)	65/65	100% (94%, 100%)
RT+ and Ag/Ab-	0/5	Insufficient data	0/7	Insufficient data
RT+ and RT+	10/12	83% (52%, 98%)	20/21	95% (76%, 100%)
RT- and Ag/Ab+	14/36	39% (23%, 57%)	20/34	59% (41%, 75%)
RT+ or Ag/Ab+	43/70	61% (49%, 73%)	86/107	80% (72%, 87%)

Source: Landovitz R. CROI 2024. Abstract #128.

HIV PrEP in the Pipeline

CAPRISA: 1-yr TAF Implant for HIV PrEP

- Silicone implant with 110mg TAF free-base micro tablets.
- Tested in 30 healthy HIV negative women, ages 18 to 40 years, in South Africa.
- There were no serious adverse events, but the implant was poorly tolerated with a high frequency of ISRs.
 - 31% removed early, median of 19 weeks.
- TAF release from implants was low and plasma concentrations were lower than prespecified targets.

Weekly Dosed Novel NRTTI in Adults without HIV

- MK-8527 = novel oral nucleoside reverse transcriptase translocation inhibitor (NRTTI) in clinical development.
- Two phase 1 trials evaluating safety and pharmacokinetics.
 - Mild AE's presents in 15-34% of patients
 - No serious AE's
- PK data supports once weekly dosing.

CAB-LA Formulations Supporting ≥ 4 Month Dosing Intervals

- 2 phase 1 studies presented looking at longer acting injectable CAB
 - Part A (CAB200 + rHuPH20) stopped due to poor tolerability
 - Part C (CAB-ULA) progressing into later stage PrEP and HIV treatment trials
- Part C evaluated different doses of CAB (800mg – 1600mg), given either SQ or IM
- Half-life of SQ and IM injections estimated to be 6x and 2x that of regular CAB-LA, respectively.
 - IM injections better tolerated

Acknowledgement

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