

Estimation of counterfactual HIV incidence in young women

HPTN 082

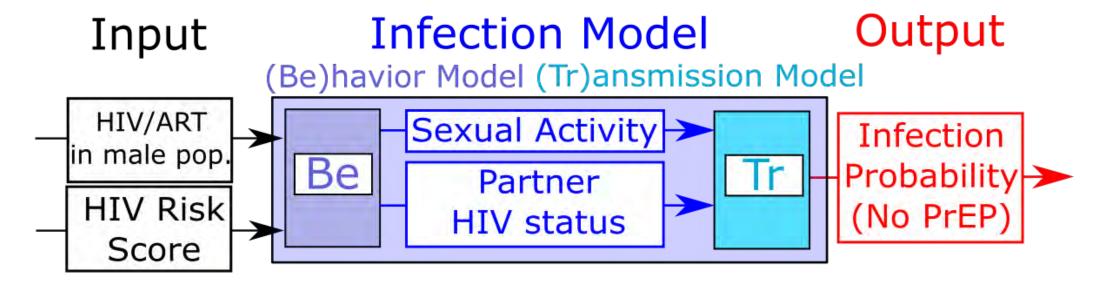
James R. Moore PhD
Fred Hutchinson Cancer Research Center
Seattle, WA
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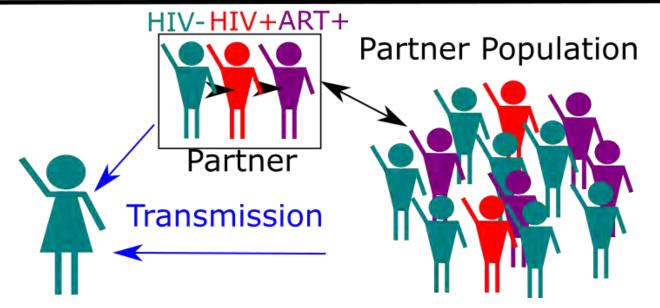


Overview

- HPTN 082 is a clinical trial aimed at increasing PrEP adherence among young women in sub-Saharan Africa.
 Enrollment is targeting high risk women informed by VOICE risk score. Almost all participants receive PrEP so there is no control.
- Modeling Goal: Provide counterfactual incidence in HPTN 082 in the absence of PrEP to be used in effectiveness evaluations.
- <u>Key conclusion:</u> Participant risk factors alone are not predictive of incidence and must be combined with site specific data on HIV and ART prevalence.







Key Parameters:

- -ART/HIV prevalence of male partner
- -Must be site/study specific

Model Calibrated To:

- -HIV incidence by risk score (VOICE)
- -Sexual activity by risk score (HPTN082)



VOICE HIV Risk Score

- Composite of six risk factors (see right):
- Scores range from 0-10.
- Derived from seroconversions in VOICE trial
- HPTN 082 participants screened for score ≥ 5
- Judging by risk scores, we might expect higher untreated HIV incidence in HPTN 082 cohort

MP: Not living with partner (+2)

FN: No financial support (+1)

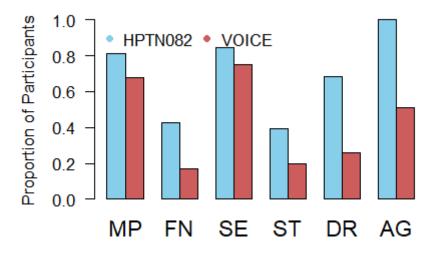
SE: Main ptnr. has other ptnrs. (+2)

ST: Treatable STI (+2)

DR: Any Alcohol Consumption (+1)

AG: Age 25 or less (+2)

Frequency of Risk Factors

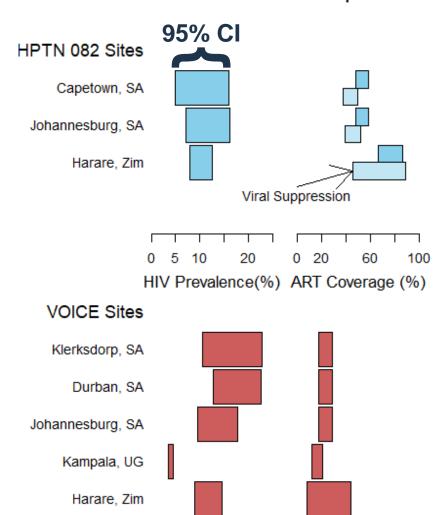




VOICE vs HPTN 082

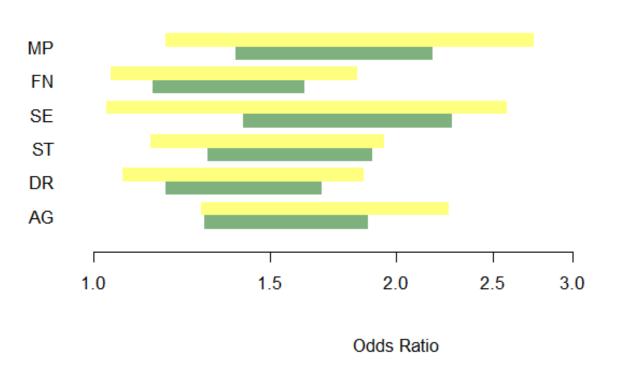
- Both tested PrEP in women in Southern Africa
- Years of study: 2009-2016 vs 2016-Present
- In local male population,
 - HIV Prevalence (%): 12-18 vs 8-13
 - ART Coverage (%): 18-26 vs 57-65
 - Viral Suppression (%): ???? vs 46-60
- Participant Age Range: 21-29 vs 16-25
- Annual HIV incidence: 5.3-6.7 vs ?????
- Sources: UNAIDS, Phia, SA HIV National Behavioral Survey, Uganda HIV Progress Report

Male Partner Comparison



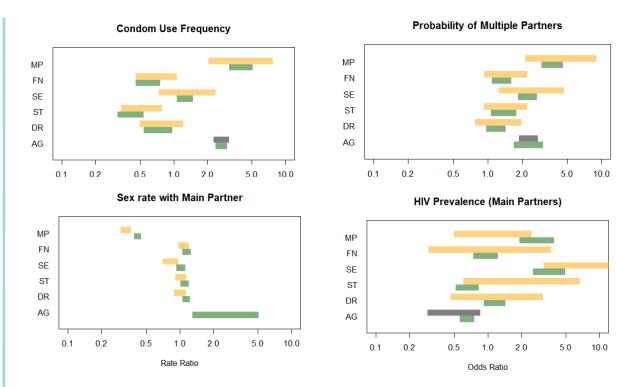


Calibration to HIV infection OR by risk factor in VOICE



Odds Ratio of HIV infection in VOICE (95%CI)
Range Predicted by Model (95%CI)

Association between risk factors and risk behaviors in HPTN 082

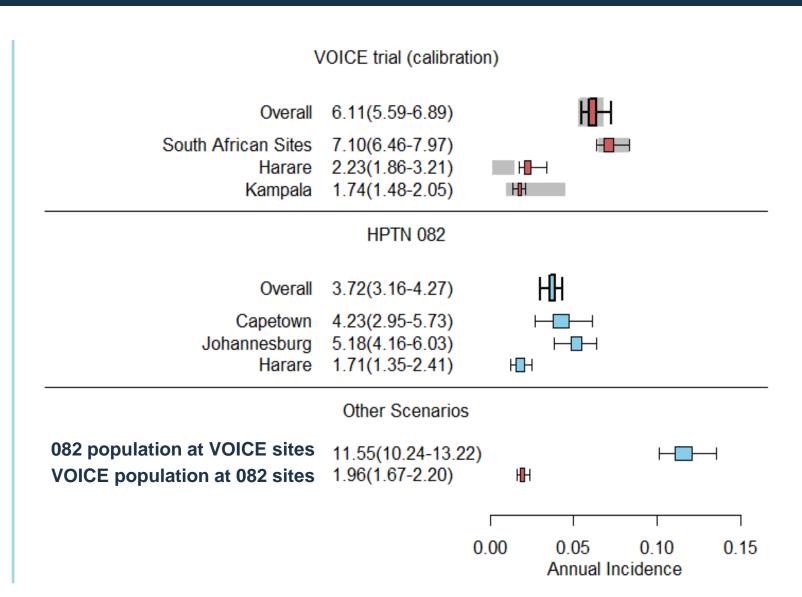


Behavioral Associations from HPTN082 ACASI or literature sources (95%CI) Range Predicted by Model (95%CI)



Main results

- Calibrated Model provided a good match to VOICE data (Model/Data)
 - We project a 3.7% (3.1-4.3) HIV incidence in HPTN 082 without PrEP
 - Both adjusting risk scores or study sites influence results significantly





Summary

- Counterfactual incidence in HPTN 082 in the absence of PrEP: 3.7% (95% CI 3.2-4.3)
 - Without accounting for changes in HIV/ART prevalence since 2012: 11.6% (10.2-13.2)
 - Without accounting for the high risk screening in HPTN 082: 2.0% (1.7-2.2)
- Participant risk factors alone are not predictive of incidence and must be combined with site specific data on HIV and ART prevalence
- Limitations:
 - Assumed that relationship between risk factors and risk behaviors is consistent between populations (of young women in Southern Africa).
 - Other risk-associated factors may change over time
 - Changes in condom usage over time
 - Changes in sexual behavior of HIV+ men due to increased testing



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