Estimating HIV Risk Reduction Attributable to PrEP Access and Proper PrEP Usage
Among Black Men Who Have Sex With Men in the United States

1. Background (*Provide a brief description of the rationale for the study, including key references.*)
Using a potential outcomes framework, we aim to estimate the reduction in HIV risk (measures of relative risk and relative risk reduction) resulting from access to pre-exposure prophylaxis (PrEP) among black men who
have sex with men (BMSM) in the United States.

Estimating the effect of access to PrEP and proper usage of PrEP in reducing HIV incidence among BMSM in the U.S

While HIV incidence is reducing nationwide in the United States (US), Black men who have sex with men (BMSM) remain to be at high risk of HIV infection. In spite of growing research exploring barriers to high quality healthcare, there is a general consensus that BMSM do not have the same quality health
care than other at-risk populations. Current guidelines recommend pre-exposure prophylaxis (PrEP) for
HIV prevention: In randomized clinical trials (RCTs), PrEP has been shown to help reduce rates of new
HIV infections. The iPrex trial showed reduction in HIV among gay and bisexual men and transgender
women across several countries; the partners PrEP trial and the TDF2 trials showed reduction in HIV
among heterosexual couples in Africa; and the Bangkok Tenofovir Study demonstrated that PrEP works
for people who inject drugs. We hypothesize that (i) mere access to PrEP reduces HIV risk in the population of BMSM in the U.S. and (ii) effective use of PrEP also reduces HIV risk in the population of
BMSM in the U.S. However, there are no RCTs comparing effectiveness of access to PrEP and/or
effective use of PrEP in reducing HIV incidence among BMSM in the U.S. (while the iPrex trial did
include a number of BMSM in the US, the number of participants is not enough for any statistical
comparison.)
Treating the HIV uninfected cohort in HPTN 061 as an external control arm for the HPTN 073 cohort,
we plan to develop a potential outcomes framework to estimate the effect of PrEP access and PrEP use
on reducing HIV incidence among BMSM in the US. HPTN 061 was a research study that examined
feasibility and acceptability of a multifaceted intervention for slowing the spread of HIV among Black
MSM, and enrolled HIV infected and uninfected participants in six U.S. cities. HPTN 061 was conducted before FDA approval of PrEP. HPTN 073 was a demonstration study designed to see if

BMSM are willing to use a daily oral pill for PrEP, and gathered feedback about willingness to use PrEP
as well as acceptability and adherence from the individuals who elected to initiate PrEP. In contrast to
the HPTN 061 population, all participants in HPTN 073 did have access to oral PrEP.

2. Specific Aims and Hypotheses

(1) Access to PrEP reduces HIV incidence in BMSM in the US
(2) Proper usage of PrEP reduces HIV incidence in BMSM in the US

Black men who have sex with men (BMSM) remain to be at high risk of HIV infection. In spite of
growing research exploring barriers to high quality healthcare, there is a general consensus that BMSM
do not have the same quality health care than other at-risk populations. Following efficacy results from
several randomized clinical trials (RCTs), pre-exposure prophylaxis (PrEP) is currently recommended
for HIV prevention. However, none of the RCTs leading to PrEP licensure specifically studies BMSM
in the U.S. We hypothesize that not only does proper use of PrEP reduce HIV incidence in this
population as well, but also mere access to PrEP can be effective in reducing HIV incidence.

4. Study Design and Analysis (include data analysis plan and/or table shells as appropriate)

We seek to develop statistical methodology to estimate the counterfactual reduction in incidence in
the absence of RCTs. We use a potential outcomes framework to remove the effects of confounders
through propensity score matching, i.e. ‘replicating an RCT’ using data from HPTN 061 and HPTN 073.