

HPTN 067

The ADAPT Study: **A**lternative **D**osing to **A**ugment **P**re-Exposure Prophylaxis **P**ill **T**aking

What is HPTN 067 (The ADAPT Study)?


HPTN 067, also known as The ADAPT Study, is a unique study looking at the use of non-daily pre-exposure prophylaxis (PrEP). PrEP is a new HIV prevention method in which people who are HIV-negative take HIV treatment drugs (antiretrovirals – ARVs) daily to reduce their risk of becoming HIV-infected. The study is designed to identify PrEP pill-taking schedules that participants are more likely to follow and determine if these schedules influence healthier sexual practices. HPTN 067/ADAPT is coordinated by the HIV Prevention Trials Network (HPTN) and is sponsored and funded by the National Institute of Mental Health (NIMH), a division of the National Institutes of Health (NIH).

How does PrEP work?

The idea behind PrEP is that if an HIV-negative person takes certain ARV pills on a regular schedule before they are exposed to HIV through sex, they may be protected from HIV infection. When used daily as PrEP the ARV drug Truvada® has been shown to be 44% effective in reducing the risk of becoming HIV-infected among gay and bisexual men and transgender women. At least seven PrEP studies have either recently been completed or are underway in 13 countries involving over 20,000 people with diverse risk behaviors.

In 2010, the iPrEx study published results that showed the daily use of oral Truvada® reduced the risk of HIV infection by 44% in HIV-negative men who have sex with men (MSM). The study found participants who had more Truvada® in their body were better protected than those who did not take the pills daily. In 2011, two additional studies also found PrEP effective in reducing HIV infection among heterosexual men and women. In July, 2012 the FDA approved daily oral Truvada® for PrEP use based on study findings to date. Truvada® was the first ARV approved by the FDA for HIV prevention in adults.

What do we hope to learn from HPTN 067/The ADAPT Study?



HPTN 067/ADAPT is an important first step in determining whether taking PrEP less frequently can be an effective HIV prevention strategy and lower the overall cost of PrEP. While it is not yet known if non-daily dosing of PrEP will ultimately prove effective, this study will provide valuable information to help inform future research. Study participants will be contributing to important research by helping to determine if different schedules of PrEP might reduce side effects, and increase the willingness to take PrEP as instructed.

The study will also provide important new information about how tests of samples of blood and hair may be used to better monitor PrEP use and evaluate the potential influence of PrEP usage on changes in sexual behavior.

Who is participating in the study?

HPTN 067/ADAPT study will enroll 540 HIV-negative volunteers. The Silom Community Clinic in Bangkok, Thailand and the Harlem Prevention Center in New York will each enroll 180 MSM and transgender women. The Emavundleni Centre in Cape Town, South Africa will enroll 180 women who have sex with men (WSM).

To enroll in the study participants must be at least 18 years old, literate in one of the local study languages, and able to provide written informed consent. They must also be able to provide weekly phone updates to local clinic staff. The earliest recruitment and screening for HPTN 067/ADAPT began in the Fall of 2011. The total duration of the study at each site is estimated to be less than two years.

What will happen during this study?

The ARV that will be used in HPTN 067/ADAPT is Truvada®. Study participants will be randomly divided into three groups:

Group 1: Truvada® once a day

Group 2: Truvada® twice per week and another Truvada pill after sex

Group 3: Truvada® only before and after sex

Participants will take no more than seven pills per week. All study participants will be clearly informed that non-daily PrEP schedules have not yet been proven to be effective. All participants will therefore be offered HIV risk reduction counseling and condoms.

What is HPTN?

The HIV Prevention Trials Network (HPTN) is a partnership between scientists and communities around the world to develop, evaluate, and implement cutting-edge biomedical, behavioral and structural interventions to reduce the transmission of HIV. HPTN uses randomized controlled clinical trials, designed and conducted according to the highest scientific and ethical standards, to identify the best combinations of interventions for the populations at highest risk of HIV infection worldwide. HPTN is largely funded by the National Institute for Allergy and Infectious Diseases with additional funding from the National Institute on Drug Abuse and National Institute for Mental Health, at the U.S. National Institutes of Health.

To learn more about HPTN 067/The ADAPT Study** and the HIV Prevention Trials Network, visit www.hptn.org or follow us on Facebook: <http://facebook.com/HIVptn> or Twitter: www.twitter.com/HIVptn.**

