

**NIH COMMON FUND HIGH-RISK HIGH-REWARD RESEARCH SYMPOSIUM**  
**DECEMBER 15 – 17, 2014**  
**POSTER ABSTRACTS – SESSION 1 (DEC. 15, 2014)**

**The Better THAN Study: Targeting Heavy Alcohol use with Naltrexone**

**Awardee:** Glenn-Milo Santos

**Award:** Early Independence Award

**Awardee Institution:** San Francisco Department of Public Health

**Background:**

Binge drinking (defined for men as drinking five or more drinks on one occasion), also known as heavy episodic drinking, is highly prevalent in the US. Binge drinking accounts for more than half of the 80,000 annual deaths attributed to excessive alcohol consumption. In 2006, the economic costs of binge drinking exceeded \$170 billion in the US. National HIV Behavioral Surveillance data indicate that 57% of men who have sex with men (MSM) reported binge drinking (past 30 days).

Binge drinking among MSM has been independently associated with unprotected sex and HIV infection. Binge drinking is by far the most prevalent exposure attributed to HIV infections among MSM, who comprise over half of the 56,300 new HIV infections in the US in 2006. Thus, effective interventions to reduce binge drinking among MSM may function as an important HIV prevention intervention by reducing alcohol-related sexual risk behaviors. Despite the high prevalence of binge drinking and the continued domestic HIV epidemic among MSM, few alcohol interventions have been proven to be effective in this population.

Oral naltrexone is a low-cost FDA-approved medication for alcohol dependence with few toxicities. Naltrexone is a  $\mu$ -opioid receptor antagonist that attenuates the rewarding effects of alcohol. The standard daily regimen for oral naltrexone hampers compliance and alternate regimen schedules have been proposed to increase effectiveness of the drug and expand the population that may benefit from this pharmacologic intervention. One promising approach is the intermittent, targeted administration of naltrexone, whereby individuals take the medication as-needed, in anticipation of heavy drinking.

**Research Design:**

This project, entitled The Better THAN Study, will evaluate the efficacy of targeted dosing of oral naltrexone among non-dependent binge-drinking MSM at risk for acquiring or transmitting HIV. This is a double-blind, placebo-controlled trial of 120 binge-drinking MSM to 12 weeks of naltrexone 50mg, to be taken in anticipation of heavy drinking. MSM will be seen weekly for alcohol-metabolite urine testing, study drug dispensing and brief counseling for alcohol use. Safety assessments and behavioral surveys will be completed monthly. Efficacy on alcohol consumption and alcohol-associated sexual risk behaviors (Aims 1-3) will be assessed using weekly time-line follow-back, screening for ethyl glucuronide (EtG)-positive urines, and computer administered monthly interviews. Tolerability and acceptability (Aim 4) will be assessed through tracking of adverse events and medication adherence. GEE models will be fitted to estimate treatment effects on repeated study outcomes.