

Overall Study Fact Sheet

HPTN 065 (TLC-Plus): A Study to Evaluate the Feasibility of a Community-Focused Approach for HIV Prevention in the United States

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HPTN 065, also known as the Test, Link-to-Care Plus Treat (TLC-Plus) study, was a three-year research study evaluating the feasibility of a community-focused strategy to expand HIV testings, diagnose HIV infection, link HIV-positive individuals to medical care, initiate treatment according to current guidelines, and ensure that patients adhere to their treatment regimens.¹ This continuum, which begins with HIV testing and ends with viral suppression, is essential for a successful community-wide strategy centered on the use of antiretroviral therapy for HIV prevention. HPTN 065 (TLC-Plus) was designed with the aim to increase testing, linkage and viral suppression, key steps of the continuum.

The test, link-to-care plus treat model for HIV prevention explored in this study is based on three principles:

- Most people who know they are infected with HIV adopt behaviors to prevent transmitting the virus to their sexual partners.
- When linked to medical care and given effective treatment, including antiretroviral medications, people with HIV can live longer, healthier lives.
- Antiretroviral medications can significantly reduce the level of HIV in the blood (known as viral load) and prevent the transmission of HIV to sexual partners.²

The two intervention communities (Bronx, New York and Washington, D.C.) were selected because of their high rates of HIV and because they had intensive, ongoing efforts to increase HIV testing and linkage-to-care. In addition there were four non-intervention communities included in the study—Chicago, Houston, Miami, and Philadelphia—where expanded testing and linkage activities were also underway. Observations in the four non-intervention communities helped assess the influence of changing trends in HIV testing and care expansion in the United States.

HPTN 065 provides key information for programs in the United States that aim to decrease the transmission of HIV through expanded HIV testing and treatment, and also for the design of future research. This study is unique because it used routinely reported HIV surveillance data to measure key outcomes. The study, however, was not designed to measure changes in the number of new cases of HIV infection in the communities where the study took place.

Study Design:

HPTN 065 consisted of five interrelated study components.

1. **Expanded HIV Testing** involved social mobilization activities to promote HIV testing in the community and efforts to increase HIV screening of patients seen at participating hospitals in the intervention communities. The goal was to increase the proportion of patients admitted to hospital emergency rooms and inpatient units who were tested for HIV. Activities to expand hospital-based testing took place in 16 participating hospitals (9 in the Bronx and 7 in DC). Social mobilization, which targeted men who have sex with men (MSM) and encouraged HIV testing at least twice a year, took place via various media outlets (print, radio, web, social media) in both DC and the Bronx.
2. **Linkage-to-Care** used a site-randomized design to evaluate whether financial incentives would increase the likelihood that individuals would be linked with medical care after receiving an HIV diagnosis. A total of 37 HIV testing sites participated in the study (18 in Bronx and 19 in DC). Half of the sites, selected at random (by chance), gave coupons to people who tested positive for HIV. These coupons could be redeemed for \$25 and \$100 gift cards once they received medical care at HIV care sites. The other half of the test sites continued their usual methods for linking HIV-positive individuals to HIV clinics.
3. **Viral Suppression** used a site-randomized design to evaluate whether financial incentives would increase the number of patients who take their HIV medication consistently in order to achieve and maintain an undetectable viral load, also referred to as viral suppression. Viral suppression is defined as having an undetectable amount of HIV virus in the blood. A total of 39 HIV care clinics participated in the study (20 in Bronx and 19 in DC). Half of the HIV clinics, selected at random (by chance), gave financial incentives (\$70 gift cards every three months) to patients who maintained an undetectable viral load. The other half of the HIV clinics continued their usual methods to help patients take their HIV medications regularly.
4. **Prevention for Positives** used an individual randomized design to evaluate whether a computerized prevention intervention would reduce risk behaviors, such as unsafe sex or injection drug use more than the standard-of-care prevention services offered by HIV care sites. This study component was conducted at 11 sites (5 in the Bronx and 6 in DC) and enrolled a total of 948 patients.
5. **Patient and Provider Surveys** assessed the knowledge and attitudes of patients receiving HIV care and HIV care providers about (1) the use of antiretroviral medications for both treatment and prevention of HIV and (2) the use of financial incentives.

Collaborating Partners:

HPTN 065 was conducted by a collaborative team of researchers associated with the HIV Prevention Trials Network (HPTN), the U.S. Centers for Disease Control and Prevention (CDC), the departments of health in the intervention (New York City and Washington, D.C.) and non-intervention communities (Chicago, Houston, Miami, and Philadelphia), clinicians and other key personnel at HIV test and care sites, with support from a study-specific community advisory group. The study was funded by the National Institute of Allergy and Infectious Diseases (NIAID) and the National Institutes of Mental Health (NIMH) at the National Institutes of Health (NIH). NIAID funds the HPTN.

For More Information:

For more information about HPTN 065 visit:

http://www.hptn.org/research_studies/hptn065.asp

References

1. El-Sadr WM, Affrunti M, Gamble T, Zerbe A. Antiretroviral therapy: a promising HIV prevention strategy? *J Acquir Immune Defic Syndr* 2010;55 Suppl 2:S116-21.
2. Cohen MS, Chen YQ, McCauley M, et al. Prevention of HIV-1 infection with early antiretroviral therapy. *The New England journal of medicine* 2011;365:493-505.