

Frequently Asked Questions About TLC-Plus:

A Study to Evaluate the Feasibility of an Enhanced Test, Link to Care, Plus Treat Approach for the Prevention of HIV Transmission in the United States (HPTN 065)

Why is HIV prevention important in the United States?

HIV continues to spread. The Centers for Disease Control and Prevention (CDC) reports that in 2006 an estimated 56,300 new HIV infections occurred in the United States. That estimate is roughly 40 percent higher than previous estimates of annual new infections in the United States. The CDC also reports that some populations are experiencing a disproportionate number of new infections. Of all new HIV infections, 53% occur in men who have sex with men (MSM), nearly 45% occur in Blacks, and roughly 17% occur in Hispanics.¹ Better strategies for prevention are needed. New strategies that involve entire communities and that focus on those populations who are most affected by the HIV epidemic are especially important.

What is the Test, Link to Care, Plus Treat approach?

The “Test, Link to Care, Plus Treat” approach is a new, promising strategy for HIV prevention that aims to decrease new HIV infections in an entire community. It builds on what other people call the “Test and Treat” approach. Evidence supports the value of people knowing their HIV status (that is whether they are HIV-positive or negative). For people found to be HIV-positive, treatment has been shown to have important beneficial effects. Early evidence supports the possibility that treatment of persons with HIV can decrease the risk of transmitting HIV from them to their sexual partners. However, this has not yet been proven.

The “Test and Treat” approach is based on the idea that new HIV infections in a community can be reduced if 1) all community members get tested for HIV, 2) all individuals who are HIV-positive are quickly linked to medical care, 3) HIV-positive individuals begin appropriate medications (antiretroviral therapy - ART) and consistently take these medications (adherence) to reduce the levels of virus in their system (suppression). The biggest difference between the “Test and Treat” and the “Test, Link to Care, Plus Treat” approach is that in the “Test and Treat” approach, all HIV-positive individuals are treated with ART, but in the “Test, Link to Care, Plus Treat” approach, only HIV-positive individuals who qualify for ART per current guidelines are treated with ART.

Why is the Test, Link to Care, Plus Treat approach important in the United States?

The current strategies to prevent HIV transmission in the United States have not succeeded in stopping the HIV epidemic. The Test, Link to Care, Plus Treat approach involves addressing several areas in the healthcare system that need to be improved in order to both to help HIV-positive individuals live longer, healthier lives, and to hopefully reduce transmission of the virus to others.

What are the key goals of the Test, Link to Care, Plus Treat approach?

The key goals of the Test, Link to Care, Plus Treat approach are:

- Providing HIV testing to as many people as possible within a community.
- Helping people who are HIV-positive get linked to HIV medical care.
- Assisting HIV-positive individuals who are started on ART to be take the medicines regularly so they improve their health by keeping the virus under control.

What is the Test, Link to Care, Plus Treat Study?

The Test, Link to Care, Plus Treat Study (TLC-Plus), also called HPTN 065, is a three-year research project that was developed by the HIV Prevention Trials Network (HPTN) in collaboration with the CDC to find out if the Test, Link to Care, Plus Treat approach can work in the United States. The ‘TLC’ part of the name refers to the study’s goals of improving HIV testing, improving linking of HIV-positive individuals to medical care. The ‘Plus’ in the study’s name refers to treatment for those in medical care who qualify for ART per current guidelines with support for improving adherence to this medicines. The “Plus” also refers to a program to help HIV-positive individuals prevent transmission through behavioral change. The research project will also seek feedback from both care providers and patients on topics

¹ CDC HIV/AIDS Facts Sheet: Estimates of New HIV Infections in the United States. August 2008

such as use of medications for HIV in patients and methods that are used to assist people link to care and to improve ART adherence.

TLC-Plus is a feasibility study. “Feasibility” refers to the process of learning whether it is possible to carry out the types of community-level activities that are necessary to achieve the goals of TLC-Plus.

What communities will be included in TLC-Plus?

Two communities, the Bronx, New York and Washington, D.C., will participate in TLC-Plus. These communities were invited to participate because of their high reported rates of HIV and because they have already begun an ambitious campaign to increase HIV testing and linkage to care.

What will happen when TLC-Plus starts?

TLC-Plus will include several activities:

- Expanding HIV testing: HIV testing will be offered to all people who either go to emergency departments (EDs) or are admitted to hospitals in both the Bronx and Washington, D.C. In addition, TLC-Plus will help the study communities develop additional effective messages to encourage community members to get tested at other places where HIV testing is offered including at community testing sites. All efforts to promote HIV testing will be coordinated with the local health departments.
- Improving linking HIV-positive people to care: The study will work with testing sites and care sites to build on their existing strategies and develop new strategies that might help connect HIV-positive people with quality medical care.
- Increasing starting of ART and improving ART adherence: The study will provide training of health providers on the new guidelines for use of ART. The study will also explore several methods to help patients who are taking ART to take their medication regularly (good adherence) so they can lower the levels of virus in their system and keep those levels low (suppression). In addition, sites will provide patients with referrals and assistance in accessing support services, such as housing, mental health, and substance use services that may help increase their ability to adhere to their prescribed ART.
- Finding new ways to help decrease transmission of HIV: Some of the patients at both the Bronx and Washington, D.C. care sites will be invited to use a computer-based program designed to help HIV-positive people avoid transmitting the virus to other people.
- Seeking information from patients and providers: Individuals who are receiving HIV care and their care providers will be asked to provide information regarding their knowledge and opinions regarding treatment services and about some of the strategies that are being used in the TLC-Plus study. The information gathered will be used to shape future HIV prevention efforts.

How will TLC-Plus attempt to improve linkage to care and ART adherence?

TLC-Plus will use several strategies. HIV care providers and other planners in both the Bronx and Washington, D.C. communities have expanded efforts to help patients link with and remain in care. Financial incentives, such as coupons, vouchers, or cash payments have previously been used with many types of patients to improve their health behaviors, for example, to help in stopping smoking and weight loss. TLC-Plus will explore whether financial incentives can further help increase HIV-positive individuals link to care and adhere to treatment.

Prior research has shown that HIV-positive persons who are not engaged in medical care either do not have an established relationship with a medical provider or are unable to overcome barriers limiting access to care. As part of TLC-plus some of the HIV test sites in each study community will be provided with coupons to give individuals who test positive for HIV. Individuals who receive coupons will be told that once they establish medical care at a clinic (that is complete two visits); they will be able to redeem the coupon. TLC-Plus will also explore whether incentives encourage patients to actively work with their healthcare providers so that they are able to take their medicines regularly and keep HIV suppressed in their system. Some of the HIV care sites will therefore be provided with financial incentives for patients who are able to keep HIV suppressed.

All patients will be provided with additional information about support services that may help them link to medical care and remain in care and adhere to ART during and after the TLC-Plus study. The study will assess the effectiveness of use

of financial incentives on linkage to medical care and suppression of the virus by comparing the effects at testing and care sites providing coupons versus those not providing coupons.

How will ART be prescribed during the TLC-Plus study?

ART will be administered according to the Department of Health and Human Services treatment guidelines that were updated in December 2009. TLC-Plus will train clinicians on those guidelines and, if the guidelines are updated during the course of the study, TLC-Plus will adapt the new guidelines and provide clinicians with additional training.

What are the unique features of TLC-Plus?

- TLC-Plus focuses on individuals as well as the community
- TLC-Plus has sought guidance from providers, community members, and advocates during the study's development.
- TLC-Plus represents a close collaboration with the National Institutes of Health, the CDC, and local health departments in several cities in the United States.
- TLC-Plus will simultaneously evaluate several innovative strategies to increase HIV testing, improve linkage of HIV-positive persons from HIV test sites to HIV care sites, and improve HIV suppression with HIV treatment.