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HPTN 052 Named Top Scientific Breakthrough of 2011

December 22, 2011—The HIV Prevention Trials Network (HPTN) is honored to have its HPTN 052 study named Breakthrough of the Year by [Science](#) magazine, the world's leading journal of scientific research, global news and commentary. According to *Science*, the study was selected for its, "profound implications for the future response to the AIDS epidemic." *Science* Editor-in-Chief Bruce Alberts writes, "In combination with other promising clinical trials, the results have galvanized efforts to end the world's AIDS epidemic in a way that would have been inconceivable even a year ago." The complete top 10 list of 2011 scientific breakthroughs appears in the December 23 issue of *Science*.

"To receive this honor is both exciting and humbling," said HPTN 052 lead investigator Dr. Myron Cohen. "While this study provides definitive proof that treatment as prevention works, the study team recognizes this is not the end of the journey but the beginning. It is imperative that we continue to build on these results and evaluate strategies that can provide guidance on the use of treatment as prevention."

The HPTN 052 study, funded by the National Institute of Allergy and Infectious Diseases, National Institutes of Health (NIAID/NIH), was the culmination of the tireless work of the thirteen sites that participated, along with the central resources of the HPTN—the Operations Center at FHI360, the Statistical and Data Management Center at the Statistical Center for HIV/AIDS Research and Prevention (SCHARP) at the Fred Hutchinson Cancer Research Center, and the HPTN Network Laboratory at Johns Hopkins University, as well as the commitment of the study participants.

Results from HPTN 052 are being used to generate new World Health Organization (WHO) policies related to management of HIV discordant couples. HPTN 052 results support ongoing and planned research in the HPTN network portfolio that include the use of treatment of HIV infection as part of a cohesive, combination HIV prevention strategy. HPTN 065 (Test, Link, and Care-Plus or TLC-Plus) is a study currently being conducted in the U.S., and HPTN 071 (PopART) is another pivotal study that will contribute to the understanding of the impact of enhanced coverage of treatment on HIV transmission at a population level in an international setting.

HPTN 052 was the first randomized clinical trial to show that providing early antiretroviral therapy to an HIV infected person can reduce the risk of sexual transmission of HIV to an uninfected partner by 96 percent. In addition to evaluating the prevention benefits of early ART, HPTN 052 was able to demonstrate a positive impact of early ART on clinical outcomes of the HIV infected partners. HIV infected partners in the early treatment arm had a 41 percent lower risk of adverse clinical events compared to those for whom treatment was delayed.

A total of 1763 HIV serodiscordant couples were enrolled between April 2005 and May 2010 (866 couples were randomly assigned to the early ART arm and 877 were randomly assigned to the delayed ART arm). Five countries in sub-Saharan Africa participated in the trial, as well as Brazil, India, Thailand, and the United States. On April 28, 2011, an independent Data Safety and Monitoring Board (DSMB) concluded the trial had demonstrated the benefit of early ART with respect to HIV transmission, and recommended that the primary study results be announced as soon as possible. "Prevention of HIV-1 Infection with Early Antiretroviral Therapy" was published August 11, 2011 in the [New England Journal of Medicine](#). Antiretroviral therapy is now provided to all willing seropositive participants; the study is continuing in order to measure the durability of the prevention and treatment effects.

The principal investigator of the HPTN, Sten Vermund from Vanderbilt University, cited the team effort, "HPTN leadership salutes the 3526 study participants, the field site staff, the network's central resource groups, and the HPTN 052 protocol team under Dr. Cohen's leadership for their tireless efforts. The steady support provided by the National Institutes of Health, endorsement from Ministries of Health around the world, guidance from our community advisory groups, and donations of antiretroviral medicines from the pharmaceutical industry were all essential in the success of the trial."

The HIV Prevention Trials Network (HPTN) is a worldwide collaborative clinical trials network that develops and tests the safety and efficacy of primarily non-vaccine interventions designed to prevent the acquisition and transmission of HIV. The HPTN research agenda is focused primarily on reduction of HIV transmission and acquisition through the use of ART for HIV-infected persons and ARVs as pre-exposure prophylaxis (PrEP) for HIV-negative persons for HIV prevention, reducing the impact of behavioral and biologic co-factors that increase risk of infection, treatment of substance use (particularly injection drug use), behavioral risk reduction interventions, and structural interventions. The highest priority of the HPTN is to develop and implement combination prevention strategies that demonstrate a significant and measurable reduction in HIV incidence in a variety of populations and epidemic settings.