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A Historic Time for the HPTN



An HIV-positive beneficiary receives antiretroviral medications during a regular home visit in Africa. Recent results from HPTN 052 prove that early treatment with antiretroviral drugs can benefit both HIV-infected individuals and their sexual partners. © 2005 David Snyder, Courtesy of Photoshare.

Within the span of about a week, two large-scale HPTN studies have reported impressive results that will help propel the field of HIV prevention research forward.

HPTN 052 was the first randomized clinical trial to show that treating an HIV-infected individual with antiretroviral therapy (ART) can reduce the risk of sexual transmission of HIV to an uninfected partner. And just a week earlier, in the journal *The Lancet Infectious Diseases*, the National Institute of Mental Health (NIMH) Project Accept (HPTN 043) reported that adding community mobilization and support services to a mobile HIV counseling and testing program can improve rates of testing in rural communities.

Antiretrovirals for treatment and prevention

Previous observational and epidemiological studies had suggested that ART could make HIV-infected individuals less infectious to their sexual partners, but HPTN 052 has provided the definitive proof. The study, which evaluated the effect of immediate use of ART (when CD4⁺ cell counts are between 350 and 550 cells/mm³) versus delayed use (when

A Message from HPTN Principal Investigator Dr. Sten Vermund

It is with great pride that we announced the results of both HPTN 052 and NIMH Project Accept (HPTN 043) in May 2011. As we commemorate the 30th anniversary of the first reported cases of AIDS in the United States, we also celebrate how far we have come in preventing the spread of HIV around the world. HPTN 052 has demonstrated in a rigorous and randomized clinical trial that appropriate early treatment of HIV with oral antiretroviral drugs can prevent transmission of HIV from an HIV-positive individual to his or her uninfected sexual partner. NIMH Project Accept has demonstrated that a huge increase in the acceptance of HIV testing is feasible in highly diverse rural settings in Africa and Asia. An essential component of any prevention effort is to provide benefit for both HIV-infected and uninfected individuals, which both of these efforts did. These vital and dramatic clinical trial discoveries provide yet another reason to support global efforts to offer ART to everyone who needs it. They further give us hope that effective prevention and treatment programs can reach many more people who know their HIV status thanks to innovative and effective testing outreach.

Sten Vermund, MD, PhD, is HPTN principal investigator and Amos Christie Chair of Global Health at the Vanderbilt University School of Medicine.

Reflections on HPTN 052

This is exciting news. It is amazing how

CD4+ cell counts drop to less than 250 cells/mm³), enrolled 1,763 HIV-serodiscordant couples at 13 sites in Africa, Asia, and the Americas.

"The study was designed to evaluate the benefit to the sexual partner as well as the benefit to the HIV-infected person," says Dr. Myron "Mike" Cohen, the principal investigator of HPTN 052 and director of the Institute for Global Health and Infectious Diseases at the University of North Carolina at Chapel Hill.

Results showed that when compared with starting ART at lower cell counts, initiating ART when cell counts were between 350 and 550 cells/mm³ reduced the risk of HIV transmission by 96 percent—a remarkable benefit for uninfected individuals. Early use also significantly reduced the risk of extrapulmonary tuberculosis, demonstrating an added health benefit for HIV-infected participants.

Increasing testing rates

[NIMH Project Accept](#) was conducted in 32 communities in three African and Asian countries. Communities in each setting were paired according to demographic characteristics. One of each pair was randomized to receive clinic-based voluntary counseling and testing, and the other was randomized to receive a combination of clinic-based testing and community-based testing.



Photo credit: Perinatal HIV Research Unit.

The community-based testing intervention included mobile HIV testing along with both community mobilization and post-test psychosocial support services. The interim results of the study showed that the proportion of people who received their

first HIV test during the study was higher in areas that received the "combination" testing than in those areas that received only clinic-based testing. Repeat testing also increased in the combination-testing areas throughout the trial. Further results, including how the intervention affects the rate of new HIV infections, will be available in 2012.

"Project Accept is an important demonstration that effective strategies, such as we developed and implemented, can encourage HIV testing and identification of persons with HIV and referral into care," said Dr. Thomas Coates, the protocol chair of the study and the director of the AIDS Institute at the University of California, Los Angeles.

Combining approaches

The next logical step after evaluating the components of testing and treatment separately is to evaluate a combination of prevention strategies, which the recently launched **[HPTN 065](#)** study is doing.

Also known as TLC-Plus—short for test, link to care, plus treat—HPTN 065 is testing the community-level impact of implementing five synergistic study components: 1) expanded HIV testing, 2) linkage to care, 3) viral suppression through adherence to ART, 4) prevention for

our seemingly minute efforts have made significant contributions to history. This study has taught us a lot, and continues to show us that there is hope for those affected and infected by the virus.

Faustin Matchere
Study Coordinator
Blantyre, Malawi

The good results of the study brought willpower and hope for people who live with HIV to live with their families. Besides this, the study helped and provided information on how to live with HIV that was essential for HIV-infected people. This also brought me hope and willpower, and I was proud of being a representative of HIV-infected people in the HPTN 052 study... Communities and society can help, look after people who live with HIV/AIDS, and live together happily, peacefully.

Samran Tagun
Community Advisory Board Member
Chiang Mai, Thailand

The HPTN 052 study gives hope to many broken hearts, provides answers to the challenges of the 21st century and the future, and greatly bridges the practical and theoretical gap of the HIV epidemic.

Lloyd Chilikutali
Community Education Coordinator
Blantyre, Malawi

HPTN 052 is a study that looks after the health of both the infected person and the not yet infected person. It is a good study that not only takes care of study participants but also gives good follow-up health treatment, which is different from the care received at hospitals. Hospitals give only medication and care but do not provide the close individual care that study participants received in HPTN 052. I feel very glad about the successful results, which will be good for people living with HIV/AIDS and for serodiscordant couples. I hope there will be more studies for discordant couples in the future.

Anonymous
Study Participant
Chiang Mai, Thailand

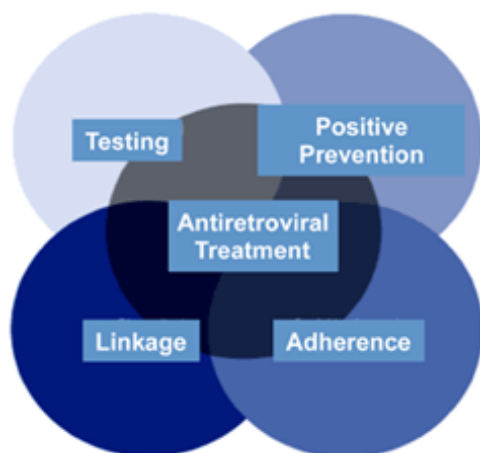
I am very happy about the positive study results...I am also very proud to be part of the study since I have worked on it from the very beginning and have learned a lot from the study staff on the U.S. side. My main concern now is about referring the study participants back to our health system, which will need a lot of cooperation

positives through risk-reduction counseling, and 5) patient and provider surveys. The HPTN, the U.S. Centers for Disease Control and Prevention, and state and municipal health departments are collaborating on the study, which is expected to last approximately three years.

What Else Is New in the HPTN?

HPTN a Leader in Treatment as Prevention

In early May, HIV/AIDS researchers from around the world convened to discuss the state of "treatment for prevention" at the three-day [International Treatment for Prevention Workshop](#) in Vancouver. HPTN 065 Principal Investigator Dr. Wafaa El-Sadr represented the HPTN at the international event, which was hosted by the British Columbia Centre for Excellence in HIV/AIDS.



Antiretroviral therapy for prevention will require a multi-component strategy.

early ART for people living with HIV, gaps in knowledge, challenges for implementation, and ways to move the research forward.

"Now there is a need for population-level studies to determine the feasibility and the effectiveness of ART as a prevention intervention," she said. "[HPTN 065](#) is under way to address this question, other feasibility studies are being developed, and more studies need to be planned urgently."

The workshop was co-hosted by the International AIDS Society, the Joint United Nations Programme on HIV/AIDS, the World Health Organization, and the National Institute on Drug Abuse. Access the agenda, webcasts, and more information [here](#).

New HPTN Study to Be Decided Soon

On behalf of the National Institute of Allergy and Infectious Diseases (NIAID), the Office of the United States Global AIDS Coordinator, and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), the HPTN solicited and is now reviewing proposals for a new study to test the effectiveness of a combination HIV prevention strategy.

The new study will evaluate the impact of a combination prevention strategy on HIV incidence in countries that are supported by PEPFAR programs. It will also need to assess the population-level coverage of the proposed interventions and estimate the cost per HIV infection averted by the prevention strategy. A decision is expected in the coming months about which proposed study will become part of the

with community hospital staff. We are using a lot of care in developing this referral plan.

Cholticha Ruangyuttikarn
Study Coordinator
Chiang Mai, Thailand

The HPTN 052 research has great value for vulnerable groups, infected patients and their partners, as well as children and adolescents. My work is to protect the rights for these groups and to provide them with information, data, and important knowledge including the facts of life. The results from this research make me proud. Every problem has a solution if there is wisdom.

Kreangkrai Chaimuangdee
Community Advisory Board Member
Chiang Mai, Thailand

It was very gratifying to be part of this important study and, above all, have known and shared the life of the protagonists of this victory—the serodiscordant couples.

Cintia Silva
Lead Counselor
Rio de Janeiro, Brazil

The commitment of the team and participants contributed to this excellent result. Congratulations to all.

Ana Claudia Rodrigues
Study Coordinator
Rio de Janeiro, Brazil

I feel comforted. In the past years the study team was anxious about participants allocated to the delayed antiretroviral therapy arm. The results released after the recent meeting of the data and safety monitoring board reinforces a transparent and unequivocal commitment of the clinical research to the welfare of the patients.

Tânia Brum
Team Leader
Rio de Janeiro, Brazil

HPTN 052 results will have an enormous impact on the antiretroviral policy in countries where antiretroviral therapy is provided free of charge to HIV infected people, if these findings are to be used as one more strategy in HIV prevention amongst serodiscordant couples... This revolutionary study was the first randomized prospective clinical trial able to confirm, with scientific rigor, the empiric observational findings that treatment is able to prevent HIV transmission between

HPTN's distinguished scientific portfolio.

What's New in Prevention?

Results from the FEM-PrEP Study

An independent data monitoring committee recently advised that it would be highly unlikely that the USAID-funded [FEM-PrEP](#) clinical trial would be able to demonstrate the effectiveness of Truvada (a combination of tenofovir disoproxil fumarate and emtricitabine) in preventing HIV infection in the study population, even if it continued to its originally planned conclusion.

The Phase III trial—implemented by FHI in partnership with research centers in three African countries—was designed to study whether HIV-negative women who are at higher risk of being exposed to HIV can safely use a daily dose of Truvada to prevent infection.

The FEM-PrEP outcome is surprising and disappointing, given a number of earlier studies suggesting the promise of pre-exposure prophylaxis (PrEP). However, as the FEM-PrEP trial undergoes an orderly closure, additional studies continue to evaluate the safety and effectiveness of a variety of PrEP regimens. Final analyses of the FEM-PrEP data will be conducted when the trial is completed, and primary results will be shared toward the end of this year.

The HPTN has three trials in development or in the field. These trials have different designs and are recruiting in different study populations than the FEM-PrEP trial.

HPTN Trials of Pre-Exposure Prophylaxis

Study	Description	Countries
HPTN 066	Phase I pharmacokinetic trial of Truvada in blood and tissue cells when taken at different dosing intervals	United States
HPTN 067	Phase II trial to determine the feasibility of using intermittent dosing of Truvada to prevent HIV in heterosexual women and in men who have sex with men	South Africa Thailand
HPTN 069	Phase II trial evaluating the safety and tolerability of adherence to maraviroc alone and in combination with other antiretroviral drugs among men who have sex with men	United States

In the Community

HPTN 052 Results Reach Communities Around the World
Results of the landmark HPTN 052 trial are being celebrated as an HIV

spouses in serodiscordant couples.

Breno Riegel Santos
Site Leader
Porto Alegre, Brazil

Thirty years after the first news story about HIV, after three decades of slow painful progress against the virus, it seems we are finally getting the upper hand. Thanks to all the study participants all over the world.

Fatima Zulu
Community Engagement Coordinator
Blantyre, Malawi

Hot Off the Press

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Coming Soon

[National HIV Testing Day](#)
June 27, 2011
United States

prevention breakthrough by news media around the world. At least 337 unique media outlets in 32 countries have run stories mentioning both the trial and the HPTN. Many others are likely spreading the good news that early treatment with antiretroviral drugs can help prevent HIV transmission within serodiscordant couples.

HPTN leadership including Dr. Sten Vermund, Dr. Quarraisha Abdool Karim, Dr. Wafaa El-Sadr, and HPTN 052 Principal Investigator Dr. Myron "Mike" Cohen are among those who have been interviewed by the media. Read selected coverage of the trial at [allAfrica.com](http://www.allAfrica.com), the [British Medical Journal](http://www.britishtimes.com), [The Lancet](http://www.thelancet.com), the [New York Times](http://www.nytimes.com), and the [Times of India](http://www.timesofindia.com).

A Closer Look

Commemorating 30 Years of AIDS

Just three decades ago, the virus causing AIDS had not been identified or named, and scientists and medical doctors were struggling to understand what was happening inside the bodies of patients who were infected. Flash forward 30 years, and remarkable achievements have been made in the identification, treatment, and prevention of the silent enemy we now know as HIV.



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The first cases of AIDS were published on June 5, 1981, in the U.S. Centers for Disease Control and Prevention's *Morbidity and Mortality Weekly Report*. Over the next year, the National Institutes of Health (NIH) saw its first AIDS patients. Dr. Anthony Fauci, who now directs

the National Institute of Allergy and Infectious Diseases (NIAID), was there from the beginning.

"It's totally transforming. Probably the best way to describe it to people is that when I began admitting patients, the median survival of those individuals was 26 weeks," says Dr. Fauci. But today, if a 20-year-old with HIV begins antiretroviral therapy in time, and gets the correct medicines, he or she could live an additional 50 years.

Great strides have also been made in HIV prevention, particularly in recent months. The Centre for the AIDS Programme of Research in South Africa ([CAPRISA](http://www.caprisa.org)) showed that 1% tenofovir formulated as a microbicide gel could reduce a woman's risk of acquiring HIV. The [iPrEX](http://www.iprex.org) team provided the first evidence that pre-exposure prophylaxis (PrEP) with oral antiretroviral drugs could help prevent HIV infection. And the [FEM-PrEP](http://www.fem-prep.org) results have reminded us that there is no room for complacency in science.

Most recently, the National Institute of Mental Health (NIMH) Project

[19th International Society for Sexually Transmitted Diseases Research \(ISSTD\) Meeting](http://www.isstdr.org)

July 10–13, 2011
Quebec City, Canada

[6th International AIDS Society \(IAS\) Conference on HIV Pathogenesis, Treatment and Prevention](http://www.iasociety.org)

July 17–20, 2011
Rome, Italy

[National HIV Prevention Conference](http://www.nhpc.org)

August 14–17, 2011
Atlanta, GA

Want to Read More?

HPTN 052

http://www.hptn.org/web%20documents/PressReleases/HPTN052PressReleaseFINAL5_12_118am.pdf

HPTN 043

<http://www.hptn.org/web%20documents/PressReleases/HPTN043Final3May2011.pdf>

HPTN 065

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

30 Years of AIDS

<http://aids.gov/thirty-years-of-aids/>

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Accept ([HPTN 043](#)) showed that community mobilization can boost HIV testing rates in remote areas, and HPTN 052 demonstrated that treating an HIV-infected person with antiretroviral therapy can dramatically reduce the risk of sexual transmission to an uninfected partner. The [HPTN 052](#) data have expanded an already robust HIV prevention toolbox, significantly breaking down the false dichotomy between treatment and prevention. So where do we go from here?

"To fully realize the public health potential of advances in treatment and prevention, more efforts will need to focus on scaling up what we know works, in ways that are appropriate for different epidemic settings and that demonstrate impact at a population level," says Dr. Quarraisha Abdool Karim, co-principal investigator of the HPTN and associate scientific director of CAPRISA. "At the same time, we need to continue our efforts to find a vaccine, test novel strategies for preventing new infections, and expand HIV prevention options for women."