February 23, 2010

Dear colleagues,

We are delighted to introduce the first issue of Prevention Now!—an e-newsletter developed to provide up-to-date information on the HIV Prevention Trials Network (HPTN).

Established by the Division of AIDS (DAIDS) of the U.S. National Institute of Allergy and Infectious Diseases (NIAID), the HPTN is a worldwide collaboration supported by NIAID, the National Institute of Mental Health (NIMH), and the National Institute on Drug Abuse (NIDA). Our mission is to develop and test the safety and efficacy of non-vaccine HIV prevention interventions. A strong network of expert scientists and investigators from more than two dozen international sites engages a central leadership team to conceptualize and conduct these high priority clinical trials. Several of the studies deeply involve the Centers for Disease Control and Prevention (CDC).

We would like to share our news with colleagues both inside and outside of the network, so please share this issue of the newsletter widely. We hope you enjoy learning more about the HPTN, and we welcome your comments both about the newsletter and about the HPTN itself.

Best regards,

Sten H. Vermund and Quarraisha Abdool Karim
Co-Principal Investigators, HPTN Coordinating and Operations Center

What's New in the HPTN?

HPTN 065 to Launch Soon
We are happy to report that HPTN 065 is nearing its launch! The study will determine the feasibility of using a new approach for preventing HIV transmission in the United States—dubbed TLC-Plus—that combines HIV testing, linkage to care, plus treatment according to current guidelines. In the TLC-Plus approach, HIV testing is used to determine who is HIV positive. Individuals who are positive are linked to HIV care, and those who qualify for antiretroviral treatment (ART) are offered medication. HPTN

Making Progress

HPTN 052 on Schedule
The HPTN 052 study team is marching toward its final recruitment goal! More than 1,550 of the targeted 1,750 serodiscordant couples have been enrolled in the Phase III trial, which will compare ART plus HIV primary care versus HIV primary care alone for preventing sexual transmission of HIV. Thanks to all the
065 is a collaboration among the HPTN, the U.S. Centers for Disease Control and Prevention (CDC), and the Departments of Health in New York and Washington, DC. Dr. Wafaa El-Sadr of Columbia University and Dr. Bernard Branson of the CDC are the study’s principal investigators.

Guidance Document Available
We encourage site investigators and staff to take advantage of the HPTN’s revised guidance document, Ethics Guidance for Research. Special thanks to Dr. Stuart Rennie of the University of North Carolina at Chapel Hill, Dr. Jeremy Sugarman of Johns Hopkins University, and the HPTN Ethics Working Group for updating the document to include the most recent and relevant scientific findings and ethical considerations for HIV prevention research.

In the Community

Facebook and Twitter!
The HPTN is now on Facebook and Twitter! News about HIV prevention research in the United States is spreading faster than ever before and reaching many new communities, thanks to the HPTN’s presence on these two popular social networking sites. Visit us on Facebook or Twitter for information and updates on specific trials. Enjoy the sites, and help spread the news!

Black Men Stand Together
The newly launched website BlackMenStandTogether.org is helping to recruit participants for HPTN 061. Also known as the BROTHERS study, HPTN 061 is being conducted in six major U.S. cities and will evaluate several prevention strategies for lowering the disproportionate rate of HIV infections among Black men who have sex with men. Visit the site today to learn more about how we can fight the HIV epidemic in the United States and to see how interested Black men can join the study.

HPTN 066 Under Development
HPTN 066 is a pharmacokinetic study of the active drug concentrations of Truvada (a combination of tenofovir and emtricitabine) in blood and tissue cells. The study will compare these drug concentrations when taken at different dosing intervals, ranging from daily to weekly. This information is needed to plan studies for using drug concentrations to measure adherence. HPTN 066 will be conducted at the University of North Carolina at Chapel Hill and Johns Hopkins University, in the United States.

HPTN 067 Under Development
HPTN 067 will determine whether intermittent use of PrEP (self-administered both before and after the first sexual act in a given day) and daily use of PrEP are associated with equivalent coverage of sex events. It will also determine whether intermittent PrEP is associated with fewer pills needed for coverage and with fewer self-reported symptoms or side effects. The study will last 30 weeks and will be conducted among 180 South African women who have sex with men and 180 Thai men who have sex with men and transgendered people.
A Closer Look

HPTN 052 Site in Harare, Zimbabwe

Nearly 1,750 serodiscordant couples have been recruited from eight developing countries to participate in HPTN 052—a Phase III clinical trial comparing two strategies for preventing sexual transmission of HIV. One of the study sites is in Harare, Zimbabwe.

"Serodiscordant couples are a special group of people for which the generic ABC message of HIV prevention does not seem relevant, and HPTN 052 is helping to address this," says Mrs. Jimijika Batani, study coordinator at the Harare site.

Serodiscordant couples in Zimbabwe have access to individual HIV voluntary counseling and testing (VCT) in designated VCT centers. However, before HPTN 052 began, few of them knew that they could be tested as couples and receive specific information on how to prevent transmission within discordant relationships.

"A couple's knowledge of their discordance was not translating into safer sex practices," says Mrs. Batani. "However, because of HPTN 052, couples HIV counseling and testing has now been introduced, and couples are being encouraged to use it." The study has played a critical role in advocating for this service in VCT centers in Zimbabwe.

Coming Soon

2010 National STD Prevention Conference
March 8–11, 2010
Atlanta, GA

16th International Symposium on HIV and Emerging Infectious Diseases
March 24–26, 2010
Marseille, France

Hot Off the Press


This is just a sampling of recent publications by members of the network. Don't forget to follow the operating policy for HPTN publications, to correctly acknowledge the HPTN in your manuscripts, and to submit your work to the manuscript review committee. We will include more recent publications next time!
The HPTN 052 study staff are enrolling HIV-infected individuals with CD4+ cell counts of 350–550 cells/mm³ along with each individual's HIV-negative partner. The HIV-infected individuals will be randomized to receive either immediate ART plus HIV primary care or HIV primary care alone. Each participant in the HIV primary care only arm will also receive ART when his or her CD4+ cell count falls within or below 200–250 cells/mm³. All participants will receive couples HIV counseling and HIV primary care throughout the entire study, and the HIV-negative partners will be tested regularly for HIV. The scientists will then compare HIV transmission rates between the study arms to see how ART affects transmission over time.

Research from Africa and Thailand has shown a correlation between the viral load of HIV in the blood and the risk of transmission during sex. The higher the viral load, the higher the chance of transmission. Because ART reduces the viral load in the blood and in the genital secretions of infected people, scientists have long wondered whether ART can prevent sexual transmission.

"This study may also help us clarify the important issue of when an infected partner should start ART," Mrs. Batani says.

Because participants in the primary care arm will also receive ART if their CD4+ cell counts drop, the scientists will be able to examine the long-term safety of starting ART immediately versus starting it after the cell counts drop. Other secondary objectives of the study include characterizing patterns of drug resistance, evaluating the usefulness of different measures to detect drug resistance, and assessing factors associated with adherence to the two ART strategies.

Mrs. Batani's role in meeting the study's objectives is complex. She is supervising all staff at the Harare site, making sure the study protocol is implemented properly, ensuring that all data and laboratory samples are collected and reported accurately, and—among many other duties—seeing that recruitment at the site runs smoothly.

The Harare site easily met its target of 200 enrolled couples by December 2009 and has been asked to recruit an additional 30 couples by April 2010. The study is expected to last five more years.

"Aside from answering all of its important scientific questions, HPTN 052 should make the public more aware that discordant couples exist," says Mrs. Batani. "Hopefully it will also encourage discordant couples to be responsible for each other and to learn how to prevent the transmission of HIV to their loved ones."