



Initiation of Antiretroviral Treatment Protects Uninfected Sexual Partners from HIV Infection (HPTN Study 052)

96% reduction in HIV transmission, according to study conducted by HIV Prevention Trials Network

Men and women infected with HIV reduced the risk of transmitting the virus to their sexual partners through initiation of oral antiretroviral therapy (ART), according to findings from a large multinational clinical study conducted by the HIV Prevention Trials Network (HPTN), a global partnership dedicated to reducing the transmission of HIV through cutting-edge biomedical, behavioral, and structural interventions.

The study, known as HPTN 052, was designed to evaluate whether immediate versus delayed use of ART by HIV-infected individuals would reduce transmission of HIV to their HIV-uninfected partners and potentially benefit the HIV-infected individual as well. Findings from the study were reviewed by an independent Data and Safety Monitoring Board (DSMB). The DSMB recommended that the results be released as soon as possible and that the findings be shared with study participants and investigators. The DSMB concluded that initiation of ART by HIV-infected individuals substantially protected their HIV-uninfected sexual partners from acquiring HIV infection, with a 96 percent reduction in risk of HIV transmission. HPTN 052 is the first randomized clinical trial to show that treating an HIV-infected individual with ART can reduce the risk of sexual transmission of HIV to an uninfected partner.

“This is excellent news,” said Dr. Myron Cohen, HPTN 052 Principal Investigator and Associate Vice Chancellor for Global Health and Director of the Institute of Global Health and Infectious Diseases at the University of North Carolina at Chapel Hill. “The study was designed to evaluate the benefit to the sexual partner as well as the benefit to the HIV-infected person. This is the first randomized clinical trial to definitively indicate that an HIV-infected individual can reduce sexual transmission of HIV to an uninfected partner by beginning antiretroviral therapy sooner.

HPTN 052 began in April 2005 and enrolled 1,763 HIV-serodiscordant couples (couples that have one member who is HIV-infected and the other who is HIV-uninfected), the vast majority of which (97 percent) were heterosexual. The study was conducted at 13 sites across Africa, Asia and the Americas. The HIV-infected person was required to have a CD4 cell count between 350-550 per cubic millimeter (cells/mm³) at enrollment, and therefore did not require HIV treatment for his or her own health. Couples were randomized to one of two groups. In one group, the HIV-infected person immediately



began taking ART (immediate ART group). In the other group, the HIV-infected person began ART when his or her CD4 cell count fell below 250 cells/mm³ or if he/she developed an AIDS-related illness (the delayed ART group).

Throughout the study, both groups received HIV-related care that included counseling on safe sex practices, free condoms, treatment for sexually transmitted infections, regular HIV testing, and frequent evaluation and treatment for any complications related to HIV infection. Each group received the same amount of care and counseling. Any HIV-uninfected person who became HIV-infected during the course of the study was referred to local services for appropriate medical care and treatment.

Among the 877 couples in the delayed ART group, 27 HIV transmissions occurred. This was in contrast to only one (1) transmission that occurred in the immediate ART group. This difference was highly statistically significant. The viruses transmitted in these 28 cases were confirmed to be linked by genetic analysis, confirming that the source of the new infection was the previously HIV-infected partner.

In the originally HIV-infected individuals themselves, 17 cases of extrapulmonary tuberculosis occurred in the delayed ART group, compared with three (3) cases in the immediate ART group, also a statistically significant finding. There were also 23 deaths during the study. Thirteen (13) occurred in the delayed ART group and 10 in the immediate ART group. Study participants and investigators are being informed of the results, and HIV-infected participants in the delayed ART group will be offered ART. All study participants will continue to be followed for at least one more year.

“Previous data about the potential value of antiretrovirals in making HIV-infected individuals less infectious to their sexual partners came largely from observational and epidemiological studies,” said NIAID Director Anthony S. Fauci, M.D. “This new finding convincingly demonstrates that treating the infected individual — and doing so sooner rather than later — can have a major impact on reducing HIV transmission.”

In India this study was carried out at YRGCARE Medical Centre, VHS in Chennai and at National AIDS Research Institute (NARI) in Pune. Dr.N.Kumarasamy, Chief Medical Officer of YRGCARE and the study Principal Investigator for the Chennai site mentioned that this landmark trial clearly states that Antiretroviral therapy should be initiated early in Indian HIV infected persons.

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