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Expanded Analysis of HPTN 052 Study Results Show Cost-Effectiveness of Early Treatment of HIV

When the HIV Prevention Trials Network (HPTN) 052 investigators released their landmark study results last year showing that treatment can reduce HIV transmission by 96% in serodiscordant couples, questions were raised about the cost of early antiretroviral therapy (ART) and if it should be universally implemented. Data presented today at the XIX International AIDS Conference in Washington, D.C. show that treatment as prevention is "very cost-effective". Using an HIV microsimulation model (CEPAC-International) to further expand analysis of HPTN 052 data, study investigators were able to project the clinical impact, costs, and cost-effectiveness of early ART. They found that this strategy increases survival, prevents costly opportunistic infections, averts early transmissions and is very cost-effective.

Commenting on the findings, Rochelle Walensky, MD, MPH, Associate Director of the Program in Epidemiology and Outcomes Research at the Harvard Center for AIDS Research said, "Early ART is a triple winner: HIV-infected patients do better, their partners are protected and it is very cost-effective. Regardless of the country setting, over the long term treatment as prevention offers excellent return on investment across a wide range of assumptions about transmission and treatment effects."

The cost-effectiveness analysis was modeled in South Africa and India using trial-derived data. These two geographic locations were selected to illustrate how regional economic distinctions may, or may not, change the conclusions. Early ART was designated as very cost-effective or cost-effective if its cost-effectiveness ratio is < 1x or < 3x *per capita* GDP (GDPs: $8,100 [South Africa]; $1,400 [India]). In making the distinctions between cost-effective and cost-saving it is important to note that interventions need not save money to be cost-effective and worth implementing. Widely accepted international standards exist to help define when the health benefits of an intervention justify the additional costs. Using those standards, early ART is very cost-effective.

"This expanded analysis of the HPTN 052 study results provides more evidence that treatment as prevention is a strategy we can't afford to ignore," said Myron Cohen, MD, Co-Principal Investigator of HPTN, and the HPTN 052 Protocol Chair. "Clearly the results of the model indicate there is a great return on this important health investment."

HPTN 052 is an ongoing randomized clinical trial. A total of 1763 HIV serodiscordant couples were enrolled in HPTN 052 between April 2005 and May 2010.The study is being conducted at 13 sites in Africa, Asia, and North and South America. The majority of couples (97%) are heterosexual. All participants receive couples risk-reduction counseling, free condoms and testing and treatment for sexually transmitted infections. Primary HIV care is also provided to the HIV-infected partner. Following the public announcement of results in May 2011, all HIV infected participants in the study were offered ART. All participants will continue to be followed until the planned study end in April 2015 to assess the durability of the prevention and clinical benefits.

The release of the initial prevention and clinical study results of HPTN 052 in 2011 led to the revision of both World Health Organization (WHO) and U.S. treatment guidelines.

HPTN 052 is funded by the Division of AIDS (DAIDS)/U.S. National Institute of Allergy and Infectious Diseases (NIAID)/U.S. National Institutes of Health (NIH). HPTN 052 is conducted in collaboration with the AIDS Clinical Trials Group (ACTG). Study drugs are donated by Abbott Laboratories; Boehringer Ingelheim Pharmaceuticals, Inc.; Bristol-Myers Squibb; Gilead Sciences, Inc.; GlaxoSmithKline/ViiV Healthcare; and Merck & Co., Inc.

To learn more about the HIV Prevention Trials Network, visit www.hptn.org.

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.*

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