

**U.S. Policy and Funding on AIDS Should Follow the Science:  
A Policy Statement on the Implications of HPTN 052 for the U.S. Response to Domestic and Global AIDS  
Approved September 9, 2011**

*The following policy statement responds to the results of the HPTN 052 study, sponsored by the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health (NIH), which found that HIV-infected men and women with relatively healthy immune systems who received immediate oral antiretroviral therapy (ART) were more than 96 percent less likely to sexually transmit the infection to their uninfected partners and were more than 40 percent less likely to experience a clinical event than those whose treatment was delayed. The findings from the HPTN 052 study provide further urgency to the quest to expand access to HIV treatment. These policy recommendations will be updated to reflect significant scientific discoveries related to the prevention, care and treatment of HIV disease.*

### **HPTN 052 Study Overview**

Although the benefits of HIV treatment on prevention of HIV transmission from HIV-infected individuals to their sexual partners have long been surmised, the HPTN 052 study represents the first large-scale, randomized controlled trial – the gold standard in medicine – showing that ART reduces the risk of sexual transmission of HIV to an uninfected partner. Findings from the study indicate that HIV treatment decreased the risk of HIV transmission by 96 percent. Moreover, earlier initiation of HIV treatment resulted in better health outcomes for the HIV-infected person.

The study enrolled 1,763 stable, HIV discordant couples – one partner HIV-infected, the other uninfected – starting in 2007 at 13 study sites in nine countries, including Botswana, Brazil, India, Kenya, Malawi, South Africa, Thailand, the United States and Zimbabwe. HIV-infected participants were eligible for the study if they had a CD4+ cell count between 350 and 550 cells/mm<sup>3</sup>. All participants were at least 18 years of age, and the median age was 33 years at the time of enrollment; 52 percent of the participants were male, 97 percent of the couples were heterosexual, and the couples agreed to participate in the trial for five years.

The couples joined one of two study groups: 886 were randomly assigned to the early arm where the HIV-infected partners began receiving a three-drug HIV treatment combination. The remaining 877 delayed the start of HIV treatment until their CD4 count dropped below 250 cells/mm<sup>3</sup> or they developed an AIDS-related condition.

The Phase-3 clinical trial is set to run until 2015. However, in response to the results, all HIV-infected subjects in the delayed treatment arm have been offered ART. The use of early ART by relatively healthy, HIV-infected patients provided substantial protection to their partners from acquiring the virus. Of the 28 HIV transmissions that occurred within the study couples, 27 occurred in the delayed treatment group and only one in the early HIV treatment group. Additional analysis suggested that the latter transmission occurred very early in treatment before suppression of the virus had occurred. Sixty-four percent of the HIV transmissions were from infected women to their male partners. Notably, 61 percent of the linked HIV infections were transmitted from partners with CD4 counts greater than 350 cells/mm<sup>3</sup>.

In addition to evaluating the prevention benefits of ART, HPTN 052 also served as an evaluation of the impact of early ART on clinical outcomes of the HIV-infected partners. The findings on this question were also clear—HIV-infected partners in the early treatment arm had a 41 percent lower risk of clinical events compared to those for whom treatment was delayed. The most common clinical event in both arms was tuberculosis, and there was an 84 percent reduction in the incidence of extrapulmonary tuberculosis between the immediate and the delayed treatment arms.

This finding was most encouraging: early ART can prevent transmission between discordant couples and, at the same time, reduce disease progression in the infected partner. Prevention and treatment are synergistic!

### **HIV Treatment Access in the Global Context**

In June 2011, the United Nations General Assembly adopted a declaration that called for access to lifesaving HIV treatment for 15 million people in low and middle-income countries by the end of 2015. To date, only 6 million people in low and middle-income countries are receiving HIV treatment, less than half of the number who need such treatment. The effects of HIV treatment are evident especially in sub-Saharan Africa – the epicenter of the epidemic – where an estimated 2 million fewer people died of AIDS-related causes in 2009, as access to ART increased in that region, than died in 2004. Nevertheless, according to the Joint United Nations Program on HIV/AIDS 2010 Global Report, fewer than 40 percent of people in the region who need treatment today based on recommendations of the World Health Organization had access to treatment in 2009. Only a quarter of children with HIV infection in sub-Saharan Africa who need treatment had access to such treatment. Thus, there is an urgent need to expand access to HIV treatment for the many millions of men, women and children who need treatment today.

The HIV prevention benefits of ART and the impact of ART on tuberculosis and other life-threatening opportunistic infections further strengthen the case for HIV scale-up and the prioritization of treatment funding in these difficult fiscal times. The impact of ART on prevention of tuberculosis in HIV-infected individuals has been well documented—an 80-92 percent reduction in risk—and scientific models suggest that initiating ART in all HIV/TB co-infected individuals would reduce the number of TB cases, TB mortality rates, and population-level TB transmission.

Treatment funding under the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) is declining just as science has demonstrated that HIV treatment is not only lifesaving for individuals but is also the most effective form of HIV prevention, which, in combination with other prevention modalities, could ultimately end the AIDS pandemic. PEPFAR funding for adult and pediatric treatment represents just 27 percent of overall spending and has declined significantly since 2008. An analysis of the PEPFAR Country Operational Plans through fiscal year 2010 shows that absolute treatment funding declines differed by country – with some showing flat treatment expenditures, while others such as Namibia, Mozambique, Kenya and Tanzania showing a reduction between 10 and 30 percent of their total treatment budgets by 2010. This reduction is occurring just as we have proven that treatment offers so much promise for stemming the epidemic.

Although the Office of the Global AIDS Coordinator has shown outstanding leadership in identifying efficiencies to reduce the cost of treatment, savings garnered from cost reductions associated with expanded generic medication procurement and shipping cost reductions should clearly be reinvested in scaling up access to treatment to achieve individual and public health benefits. Additional resources also must be invested in activities aimed at retaining individuals in care and reducing loss-to-follow-up.

#### *Policy Recommendations:*

- Expand HIV counseling and testing through PEPFAR, including health facility-based, community-based, and home-based testing. Expand access to couples HIV testing and counseling in all of these venues.
- Scale-up HIV treatment to reflect a higher proportion of the PEPFAR budget, perhaps 50 percent.
- Evaluate all PEPFAR prevention expenditures based on scientific evidence of their efficacy. Shift resources from less efficacious interventions to those with documented efficacy in reducing HIV incidence, including ART.
- Include HIV treatment as a key prevention intervention in all demonstration projects or evaluation studies of combination prevention strategies.

- Work urgently to provide country guidance encouraging the strategic use of treatment as prevention throughout PEPFAR programs. This includes integration of HIV treatment as a key component of “combination prevention” efforts that might include expanded medical male circumcision and other evidence-based behavioral, biomedical, and structural prevention interventions.

## **HIV Treatment Access in the United States**

In the U.S., almost a quarter of people with HIV disease remain unaware of their HIV infection and the annual number of new HIV cases has remained stable at about 50,000 without evidence of abatement in transmission. Current data indicate that many individuals with diagnosed HIV in the U.S. initiate HIV treatment at an advanced stage of infection, far later than is recommended by the federal treatment guidelines. A quarter of persons with HIV in need of HIV treatment in the U.S. are not receiving it. Up to 30 percent of people with HIV in the U.S. are uninsured, and a majority of people with HIV rely on the coverage available through publically-funded programs such as the Medicaid (40 percent) and/or Medicare (20 percent) programs. Tragically, as of August 2011, more than 9,000 low-income people with HIV in need of lifesaving HIV treatment were on waiting lists to receive it through the Ryan White AIDS Drug Assistance Program. Demand for care at HIV clinics serving uninsured and underinsured people with HIV has increased by 60 percent since 2001, while funding available to these clinics through the Ryan White program clinics has increased by 10 percent during the same period.

In 2010 the President’s National HIV/AIDS Strategy provided the first comprehensive framework for reducing HIV incidence, improving access to care, and reducing HIV-related disparities in the U.S. The passage of the Patient Protection and Affordable Care Act (ACA) authorized a historical expansion of health care coverage beginning in 2014. Together these important policy milestones offer an unprecedented opportunity to make significant progress against the HIV epidemic. Providing universal and uninterrupted access to HIV care and treatment to everyone in the U.S. who needs it will save the lives of people with HIV disease and dramatically reduce new HIV infections as demonstrated by the HPTN 052 study results. Federal and state budget constraints compounded by efforts to expeditiously cut the federal budget deficit and to repeal the ACA seriously threaten our ability to make progress by transferring the science to the frontlines where it is urgently needed.

### *Policy Recommendations:*

- Prioritize domestic HIV funding for early HIV diagnosis with reliable and ongoing linkage and access to HIV care and treatment.
- Fully fund the Ryan White program and address state waiting lists for ART.
- Ensure an equitable and balanced approach to the federal deficit reduction process that protects funding for health care programs serving vulnerable populations, such as the Ryan White program, and maintains the federal commitment to the Medicaid program.
- Fully fund and implement the Patient Protection and Affordable Care Act.

*The HIV Medicine Association (HIVMA) of the Infectious Diseases Society of America (IDSA) is the professional home for more than 4,600 physicians, scientists and other health care professionals dedicated to the field of HIV/AIDS. HIVMA promotes quality in HIV care and advocates policies that ensure a comprehensive and humane response to the AIDS pandemic informed by science and social justice. More information at: [www.hivma.org](http://www.hivma.org).*

*The Center for Global Health Policy, established by the Infectious Diseases Society of America’s Education & Research Foundation in 2008, supports and promotes U.S. efforts to combat HIV/AIDS and tuberculosis around the world. The Center provides scientific and policy information to U.S. policymakers, federal agencies, nongovernmental organizations and the news media, linking decision-makers to the latest evidence-based input and guidance from physician/scientists and other professionals from both developing and developed countries. More information at: [www.idsaglobalhealth.org](http://www.idsaglobalhealth.org).*

*The Infectious Diseases Society of America (IDSA) is an organization of physicians, scientists, and other health care professionals dedicated to promoting health through excellence in infectious diseases research, education, prevention, and patient care. The Society, which has more than 9,000 members, was founded in 1963 and is based in Arlington, VA. More information at: [www.idsociety.org](http://www.idsociety.org).*