amfAR AIDS RESEARCH The Foundation for AIDS Research

July 2011

ISSUE BRIEF

Ending the HIV/AIDS Epidemic: A Moment of Decision

For the first time, there is real hope we can begin to end the global HIV/AIDS pandemic. Capping a year of dramatic scientific breakthroughs, researchers at the National Institutes of Health (NIH) announced in May 2011 the results of the HPTN 052 study, which found that early initiation of antiretroviral therapy reduced the risk of HIV transmission to uninfected partners by 96%.[1] Several other recently announced research findings have confirmed the potential of antiretroviral pills and gels to help prevent HIV infection.

Investing now to capitalize on scientific advances such as these, while expanding deployment of the public health tools that are already available to us, will not only save millions of lives but will also significantly reduce human suffering, new HIV infections, and healthcare costs in the years to come.

An intensified approach to AIDS that takes advantage of recent research breakthroughs will advance the overall goals of the Obama Administration's Global Health Initiative (GHI), including the GHI's focus on the health and wellbeing of women and girls. With AIDS the leading killer of women of reproductive age globally, an effective response to eradicating this disease is critical to improving maternal and child health, and to creating a platform for implementing broader health services.[2]

In the United States a strengthened approach to HIV will enable the National HIV/AIDS Strategy to achieve its goals of reducing HIV incidence, increasing access to care, and eliminating HIV-related health disparities.

Reducing HIV Transmission with Earlier Treatment

- As HIV transmission is strongly related to the infected partner's viral load[3], it has long been thought that antiretroviral therapy might reduce the infectiousness of people living with HIV. (Treatment significantly reduces viral replication – often to the point that the virus cannot be detected by standard tests.) Previous studies in serodiscordant couples (i.e., couples in which one partner is positive and the other negative) have suggested that treatment is associated with reduced transmission risk.[3, 4] In San Francisco, expanded treatment access has been accompanied by a reduction in the rate of new HIV infections.[5] Until the HPTN 052 results in 2011, however, no randomized controlled clinical trial had clearly assessed the role of treatment in preventing new HIV infections.
- The HPTN 052 clinical trial was designed to assess the prevention role of treatment and to determine the best time to initiate therapy. The study enrolled 1,763 serodiscordant couples, 97% of whom were heterosexual, in nine countries. Researchers randomized the couples into two trial arms – one (immediate arm) in which HIV-positive individuals started therapy early in the course of HIV infection, and the other (delayed arm) in which therapy was delayed until there was evidence of significant HIV-related immune suppression.
- After monitoring the number of new infections in the two trial arms, researchers concluded that **early initiation of therapy lowered the risk of infection in serodiscordant couples by 96%**. The trial also found that individuals who were started earlier on therapy were less likely to be diagnosed with tuberculosis, the leading cause of death globally for people living with HIV.
- **The HPTN 052 results have potentially momentous consequences for the HIV/AIDS response**. The results underscore the importance of the earliest possible diagnosis of HIV, as well as the extraordinary prevention benefits of early treatment. From the standpoint of program planning and service delivery, HPTN 052 confirms that the historic separation between prevention and treatment programs is counterproductive. Indeed, it is now clear that HIV treatment should be a core component of efforts to reduce HIV incidence.
- A variety of questions require further study, including how to address implementation challenges in HIV testing and treatment delivery, improve adherence among those receiving therapy, better understand population-level impacts of treatment on prevention, and assess the role of HIV transmission in the "acute" stage of HIV infection when most newly infected individuals will not yet be on treatment.[6]

amfAR Public Policy Office 1150 17th Street, NW • Suite 406 • Washington, DC 20036 • T: +1 202.331.8600 • F: +1 202.331.8606 **www.amfar.org**

Additional New Approaches for Reversing the Epidemic

- Clinical trials in sub-Saharan Africa indicate that **voluntary medical male circumcision** reduces the risk of HIV infection in men by about 60%.[7, 8, 9] Implementation of this new prevention strategy in countries with high HIV prevalence and low rates of circumcision[10] needs to be accelerated.
- Although hundreds of thousands of children worldwide begin their lives each year with HIV infection (370,000 in 2009 alone[17]), it is now clear that the world has the means to **eliminate vertical transmission (from pregnant women to newborns) by 2015**. Globally, dramatic gains have been made in expanding coverage of antiretroviral prophylaxis to prevent transmission from pregnant women to their infants, with sharp reductions in new infections among children reported in countries that have brought such services to scale.[10]
- Other new prevention tools are on the immediate horizon. In 2010, researchers announced that a U.S.-supported trial found that a vaginal **microbicide gel reduced women's risk of HIV infection by 39%.**[11]
- In 2010 and 2011 three separate research studies found that a daily combination of two antiretrovirals as pre-exposure prophylaxis (or PrEP) can **significantly reduce** the risk that heterosexual men and women, and gay/bisexual men will become infected with HIV.[12, 13]
- Used in combination with current, proven approaches to HIV prevention, such as male and female condom distribution, needle exchange and HIV education, these new tools can substantially reduce global HIV infection rates.

Important Choices at This Moment of Opportunity

- Both in the U.S. and globally, expanded access to lifesaving HIV/AIDS therapies is urgently needed to treat the illness as well as to help prevent further spread of HIV. In the U.S., the continued high rates of HIV infection stem in part from inadequate suppression of viral load in as many as three out of four people living with HIV.[14]* Globally, even while HIV treatment access has risen 22-fold since 2001, an estimated nine million people still do not have access to treatment.[10] To translate the HPTN 052 clinical trial results into concrete gains, it will be essential to expand early and regular HIV testing, link individuals who test HIV-positive to high-quality care, ensure continuity of care, and help patients adhere to treatment regimens.[15]
- Changes will also be needed in how HIV/AIDS resources are allocated. Based on a comprehensive analysis of the cost-effectiveness and long-term impact of various HIV interventions, recommendations from an international blue-ribbon panel of experts published in *The Lancet* in June 2011 urged the **prioritization of a handful of high-impact, high-value approaches**, including antiretroviral treatment, prevention of mother-to-child transmission, male circumcision, and focused programs for populations at elevated risk. The authors estimated that by investing in high priority strategies now, it is possible to avert 7.4 million deaths and save an additional 29.4 million life-years between 2011 and 2020. Although this more strategic approach will require greater investments of resources in the near term, it is projected that future spending needs would begin to decline by 2015 as a result of the gains achieved by these interventions.[16]

Recommendations: Implications of Scientific Breakthroughs for U.S. AIDS Policy

The U.S. Epidemic: Achieving National HIV/AIDS Strategy goals

- Congress and the Administration should take immediate steps to eliminate waiting lists, cutbacks, and restrictions in the AIDS Drug Assistance Program (ADAP). In anticipation of the implementation of the Affordable Care Act, Medicaid expansion should be accelerated to ensure universal coverage of antiretroviral treatment for people living with HIV infection.
- The federal government urgently needs to transition to a more proactive approach to HIV testing, with expanded targeted HIV testing programs, as well as implementation of CDC recommendations for routine HIV testing in health and social service settings. Sexually active gay and bisexual men should be tested regularly, as should others who are at high risk for infection. The Administration should include coverage for HIV testing services as a covered preventive care service under regulations implementing the Affordable Care Act.

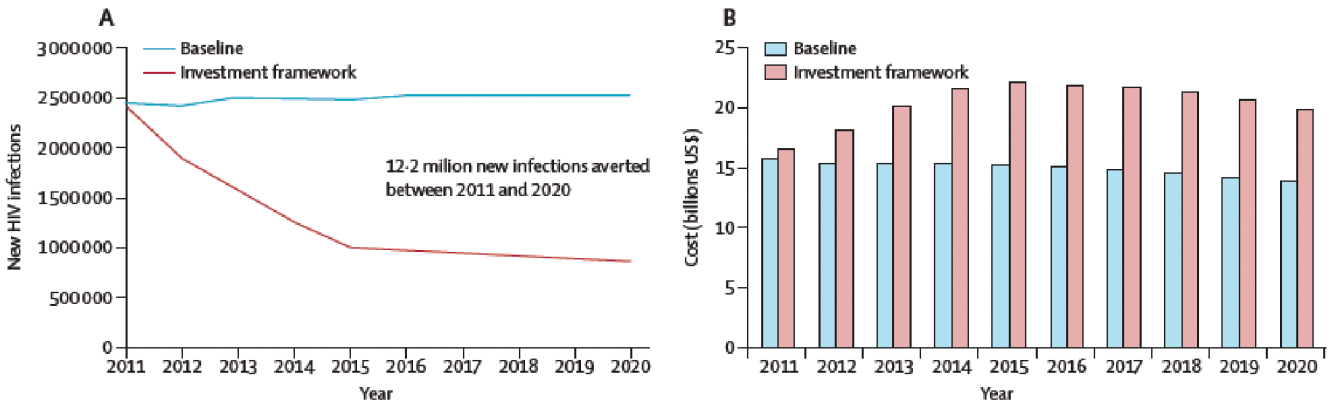
* Poor rates of viral suppression stem from a combination of late diagnosis of HIV, inadequate access to care, discontinuity of care, and sub-optimal treatment adherence (which allows drug resistance to develop and the virus to rebound).

- Consistent with the National HIV/AIDS Strategy, the federal government should ensure seamless planning and coordination among all federal agencies involved in the HIV/AIDS response. In particular, CDC and other agencies of the U.S. Department of Health and Human Services, including the Health Resources Services Administration (HRSA) and the Centers for Medicare and Medicaid Services, should collaborate closely to capture the prevention benefits of antiretroviral treatment. State and local public health agencies should seriously consider merging their planning for HIV prevention, treatment, and care, which are currently handled separately in many jurisdictions.
- Congress and the Administration should provide additional resources to CDC to help the agency support strengthened, more integrated surveillance programs at the state and local level.

The global epidemic: Achieving dramatic reductions in HIV infections and mortality

- To end the AIDS pandemic, new and more strategically allocated resources are needed through the President's Emergency Plan for AIDS Relief (PEPFAR), the Global Fund to Fight AIDS, TB and Malaria, other international donors, and the governments of countries heavily affected by AIDS.
- PEPFAR should undertake a priority review to align its portfolio to support approaches that will have the greatest possible impact on reducing HIV incidence and mortality, including AIDS treatment, medical male circumcision, prevention of vertical transmission, condom distribution, behavioral interventions, and other approaches.
- U.S.-supported programs, the Global Fund, UNAIDS, and the World Health Organization should move toward earlier initiation of HIV treatment, both to promote the health of people living with HIV and to realize the tremendous prevention benefits of HIV treatment.
- Continued treatment scale-up should be complemented by support for innovative testing promotion strategies, including door-to-door campaigns, the use of mobile phones for education, and the integration of HIV testing in all health settings in high-prevalence countries. Treatment programs supported through PEPFAR should integrate peer-based programs to improve adherence to therapy. Specific initiatives are needed to ensure full and equal treatment access for populations most at risk, including gay and bisexual men and other men who have sex with men, sex workers, injection drug users, and women and girls who are vulnerable to HIV infection.
- PEPFAR country offices should actively work to bring voluntary medical male circumcision to scale. PEPFAR should also redouble its efforts to help countries achieve saturation coverage for services to prevent vertical transmission (from pregnant women to newborns) through universal access to treatment for women and PMTCT services.
- Congress and the Administration should continue ramping up PEPFAR support to developing nations. Investing now in life-saving treatment scale-up will reduce the epidemic's long-term burden on heavily affected countries and the global community as a whole.
- With a significant percentage of patients on antiretroviral therapy dropping out of care within the first two years of treatment[17], CDC should increase its financial and technical

Potential decline in HIV incidence with new and more strategic investment



New investment framework to address global AIDS as proposed in The Lancet. *With new and more strategic investments, global HIV incidence is brought down significantly and overall costs begin to fall within several years. (Schwartländer B, et al,* Lancet, *vol. 377, June 11, 2011)*

support to countries to strengthen patient monitoring and tracking systems.

- Given the long-term role that treatment will play in controlling HIV/AIDS, NIH should prioritize research to develop more affordable treatment regimens. These could include less costly (weekly or once-a-month) regimens, creation of a polypill containing multiple medicines, treatments that are longer lasting and less prone to resistance, and simple, inexpensive, diagnostic tools for use in poor countries to identify HIV-infected individuals so that they can receive early treatment.
- American diplomacy should prioritize efforts to mobilize additional donor support for the short-term investments needed to bring treatment as prevention and other new tools to scale. All high-income countries should join with the U.S. to ensure that heavily affected countries have the means to capitalize on recent scientific advances to avert millions of new HIV infections in the future.
- U.S. leaders should take advantage of broad support for a revitalized effort to end the AIDS epidemic. For example, a statement signed by hundreds of organizations globally calls on bilateral donors, international institutions, and governments of heavily affected countries to move towards earlier and expanded HIV treatment access to reduce both HIV incidence and mortality globally.[15]

The results of HPTN 052 and other recent research advances mean that AIDS need not be an epidemic that plagues the world for generations. Policy makers now face a choice: investing strategically today to accelerate the end of AIDS, or paying for the response to this pandemic for generations to come.

Ending HIV/AIDS: A National and Global Imperative

In the U.S., HIV/AIDS today is a serious public health challenge. Nearly 1.2 million Americans are living with HIV.[18] Each year, an estimated 56,000 are newly infected with HIV[19], and more than 17,000 die annually of HIV-related causes. HIV/AIDS is the third leading cause of death among Black men and women aged 35–44[20, 21] and the fourth leading cause of death among Black women aged 25–34 and 45–54.

Globally, more than 33 million people are living with HIV, including 2.6 million people newly infected in 2009.[17] HIV/AIDS is the world's leading infectious disease killer, and the leading cause of death of women of childbearing age.[22] Although global HIV incidence has fallen gradually over the last decade, new HIV infections are on the rise in Eastern Europe and Central Asia, in the Middle East and North Africa, and in many populous Asian countries.[17]

References and Notes

1 HIV Prevention Trials Network, Initiation of Antiretroviral Treatment Protects Uninfected Partners from HIV Infection (HPTN Study 052). Press Release. May 12, 2011. http://www.hptn.org/web%20documents/PressReleases/HPTN052PressReleaseFINAL5_12_118am.pdf.
2 amfAR. HIV/AIDS Investments: Building blocks for global heatlh? Issue brief. July 2010. www.amfar.org/uploadedFiles/In_the_Community/Publications/amfAR-IDSA-global-July2010.pdf?n=1678
3 Quinn TC, et al. (2000). Viral Load and Heterosexual Transmission of Human Immunodeficiency Virus Type 1. *New Eng J Med* 342:921-929.
4 Bunnell R, et al. (2006). Changes in sexual behavior and risk of HIV transmission after antiretroviral therapy and prevention interventions in rural Uganda. *AIDS* 20:85-92.
5 Das M, et al. (2010). Decreases in Community Viral Load Are Accompanied by Reductions in New HIV Infections in San Francisco. *PLoS ONE* 5:e11068.
6 Smith, K, et al. (2011). HIV-1 treatment as prevention: the good, the bad and the challenges. *Current Opinion in HIV and AIDS 2011* 6:315-325
7 Auvert B, et al. (2005). Randomized, controlled intervention trial of male circumcision for reduction of HIV infection risk: the ANRS 1265 trial. *PLoS Med* 2:e298.
8 Bailey RC, et al. (2007). Male circumcision for HIV prevention in young men in Kisumu, Kenya: a randomized controlled trial. *Lancet* 369:643-656.
9 Gray RH, et al. (2007). Male circumcision for HIV prevention in men in Rakai, Uganda: a randomized trial. *Lancet* 369:657-666.
10 UNAIDS. AIDS at 30: *Nations at the crossroads.* 2011.
11 Karim QA, et al. (2010). Effectiveness and Safety of Tenofovir Gel, an Antiretroviral Microbicide, for the Prevention of HIV infection in Women. *Science* 329:1168-1174.
12 Grant RM, et al. (2010). Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men. *New Eng J Med* 363:2587-2599.
13 CDC. CDC Trial and Another Major Study Find PrEP Can Reduce Risk of HIV Infection among Heterosexuals, July 13, 2011.
14 Dieffenbach CW. Treatment as Prevention. PEPFAR Expert Consultation: Unresolved Issues in HIV Prevention Programming in Generalized Epidemics. November 8, 2010.
15 AVAC (2011). We CAN End the AIDS Epidemic. Accessed on July 3, 2011 at http://www.avac.org/ht/d/sp/a/GetDocumentAction/i/34312.
16 Schwartlander B et al. Towards an improved investment approach for an effective response to HIV/AIDS. *Lancet* 377:2031-2041.
17 UNAIDS. *Report on the Global AIDS Epidemic.* 2010.
18 CDC. HIV Surveillance – United States, 1981-2008. *Morbidity and Mortality Weekly Report* 2011;60:689-693.
19 Hall HI, et al. Estimation of HIV Incidence in the United States. JAMA 2008;300:520-529.
20 CDC. Leading Causes of Death by Age Group, Black Males, 2006. http://www.cdc.gov/men/lcod/2006/BlackMales2006.pdf.
21 CDC. Leading Causes of Death by Age Group, Black Females, 2006. http://www.cdc.gov/women/lcod/06_black_females.pdf.
22 WHO (2009). *Women and health: today's evidence, tomorrow's agenda.*