Policy Statement: Pre-Exposure Prophylaxis (PrEP)

The National Alliance of State and Territorial AIDS Directors (NASTAD), on behalf of state and territorial health officials responsible for HIV/AIDS and viral hepatitis programs, believes science should guide HIV prevention efforts. Based on the recommendations of the Antiviral Drugs Advisory Committee (AVDAC) of the U.S. Food and Drug Administration (FDA), NASTAD supports the approval of a label change for Truvada to be used as a pre-exposure HIV prophylaxis (PrEP) among HIV-uninfected men who have sex with men (MSM) and transgender women; partners in serodiscordant couples; and other individuals who are documented to be at an elevated risk of acquiring HIV through sexual activity.

This policy statement reinforces NASTAD’s Statement of Urgency: Crisis Among Gay Men, and the core objectives of the National HIV/AIDS Strategy (NHAS) to reduce HIV incidence and intensify HIV prevention efforts in communities where HIV is most heavily concentrated. The NHAS directs that current prevention approaches must be coupled with research on new and innovative methods that can have a long-term impact on preventing new infections. Such strategies may include PrEP, the use of antiretroviral (ARV) therapy by high-risk, uninfected individuals to prevent HIV acquisition. Data from studies to date emphasize that PrEP should not be used as the sole means of HIV prevention by at-risk individuals but must be used in conjunction with condom use, routine HIV testing, timely STI screening and treatment and behavioral counseling.

The opportunities afforded by PrEP are unprecedented in the public health response to the epidemic. The daily utilization of Truvada as a mechanism to prevent HIV acquisition would allow for an individually-controlled, moderately effective prevention tool that could be used alongside other proven prevention methods, with or without the knowledge and cooperation of a sexual partner. In the scope of prevention science it may be the closest we have come to a vaccine.

Recent data (i.e., Global iPrEx, CDC TDF 2 and Partners PrEP) on PrEP demonstrate that the strategy can provide an evidence-based option to prevent new HIV infections among HIV-negative individuals, especially among MSM, transgender women and other individuals who are at an elevated risk to acquire HIV through sexual exposure. There is a potential for this intervention to reduce HIV transmission in other impacted population groups in the U.S. more broadly, such as Blacks and Latinos, but this potential is not yet established through study results. NASTAD encourages ongoing implementation research and demonstration projects to monitor the safety and efficacy of adopting a PrEP regimen within populations other than those indicated on the proposed label as well as within real-world situations, including public health settings.

Additional studies should focus on identifying:

- Most appropriate persons for PrEP (i.e., those individuals who would most benefit)
- Approximate length of time an individual would require PrEP
- Additional interventions and support including behavioral interventions and referrals to substance abuse, mental health or other care services that may be required to support sustainable behavior change that allows for the discontinuation of PrEP
- Use of PrEP in serodiscordant couples where the positive partner is on treatment and virally suppressed

Implementing PrEP in public health settings may prove challenging. While private insurance and some programs (e.g., Medicaid) may cover the cost of PrEP medications (e.g., Truvada), there is no categorical funding within public health programs to pay for these medications and costs associated with assessment and care engagement (i.e., counseling and adherence support) of PrEP clients. Funding for necessary enhanced clinical services such as frequent HIV/STI screening, STI treatment and/or partner services will also be very limited in public health settings due to an already overburdened system. And while not specifically a part of PrEP interventions, there is no funding available for monitoring of acute HIV infections for clients on PrEP who test positive as well as administration of non-occupational post-exposure prophylaxis (nPEP), when indicated. With many cost-containment measures in place for access to medications for HIV-positive individuals in the AIDS Drug Assistance Programs (ADAP) across the country, implementing PrEP using categorically funded public health resources poses an ethical dilemma for health departments.

NASTAD reaffirms its PrEP Issues for Consideration, which outlines eight areas for health departments to consider related to implementing PrEP: cost, effectiveness, financing, safety, risk compensation, behavioral effects, drug resistance, and adherence.

In conjunction with new and existing partners, NASTAD members pledge to:

- Emphasize the importance of providing comprehensive prevention and care services for individuals at high-risk for HIV acquisition and transmission
- Utilize existing planning funds (e.g., PS12-1201) and examine alternative funding streams for the planning and implementation of PrEP
- Ensure an opportunity to accomplish implementation research for PrEP in a range of priority populations, venues and regions so as to inform optimal strategies for PrEP administration
- Strategize to ensure that PrEP implementation does not further health disparities among Black and Latino communities, particularly since private insurance coverage may provide access to PrEP and public health settings may not be able to do so
- Initiate efforts to educate medical providers, HIV testers and counselors, and community stakeholders on opportunities to access PrEP, including potential medication assistance programs which may be initiated by pharmaceutical companies

NASTAD will also work with federal partners to identify appropriate funding streams for implementing PrEP in public health settings and to provide technical assistance to health departments. Finally, NASTAD will continue to monitor the PrEP landscape and other biomedical advances that will increase the availability of evidence-based interventions in order to reduce new HIV infections.

*Approved by NASTAD’s Executive Committee on June 14, 2012*