

# Prep for PrEP: *Biomedical Advances in HIV Prevention*

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## ***Mission***

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*NASTAD strengthens state and territory-based leadership, expertise and advocacy and brings them to bear on reducing the incidence of HIV and viral hepatitis infections and on providing care and support to all who live with HIV/AIDS and viral hepatitis*

## ***Vision***

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*NASTAD's vision is a world free of HIV/AIDS and viral hepatitis*

- Review of HIV/AIDS Toolkit
- Update on Vaccine Development
- Antiretroviral Medications as Prevention
- PrEP Guidelines
- NASTAD Efforts Related to PrEP

## Prior to Exposure

- Education and behavior change
- Male circumcision
- Pre-exposure prophylaxis (PrEP)
- Preventive vaccines
- **HSV2 suppression or vaccine**

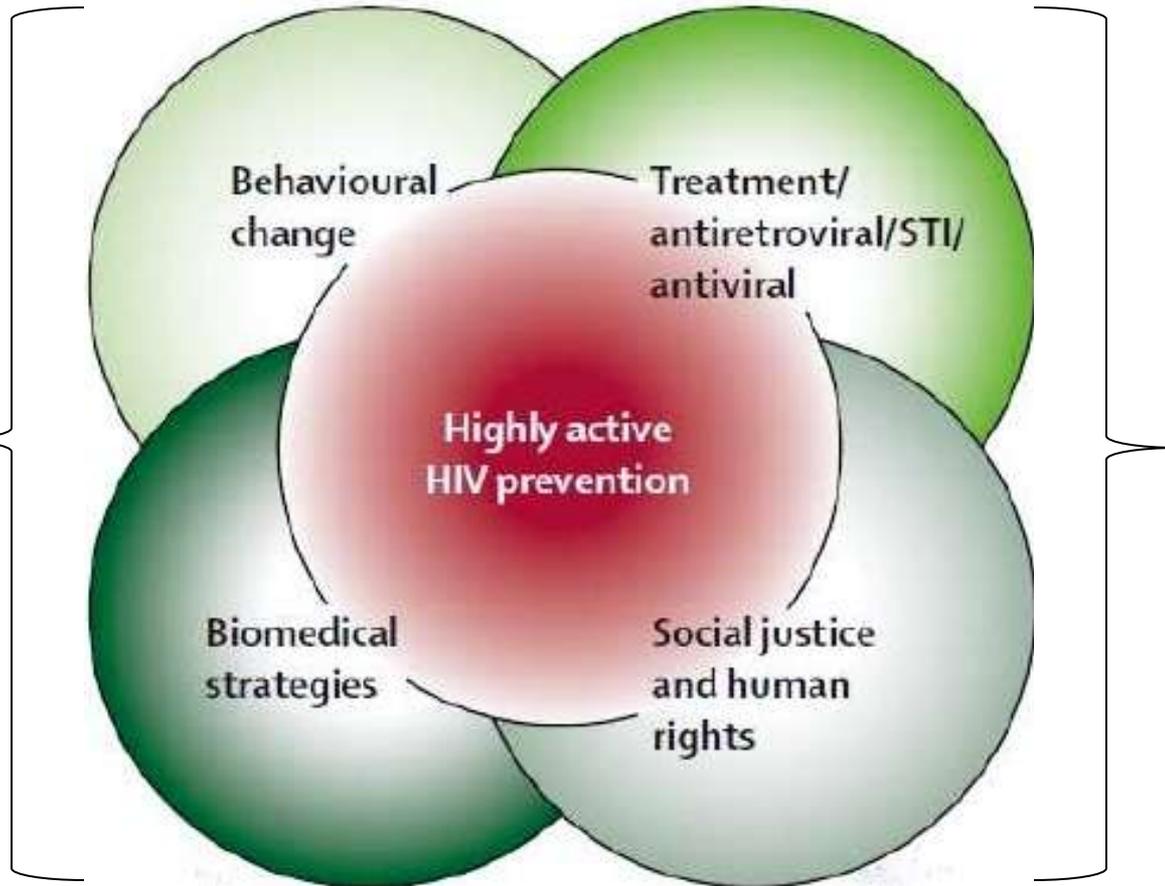
## Point of Transmission

- Male and female condoms
- Antiretroviral therapy (mother-to-child)
- Post exposure prophylaxis (PEP)
- Microbicides

## After Infection

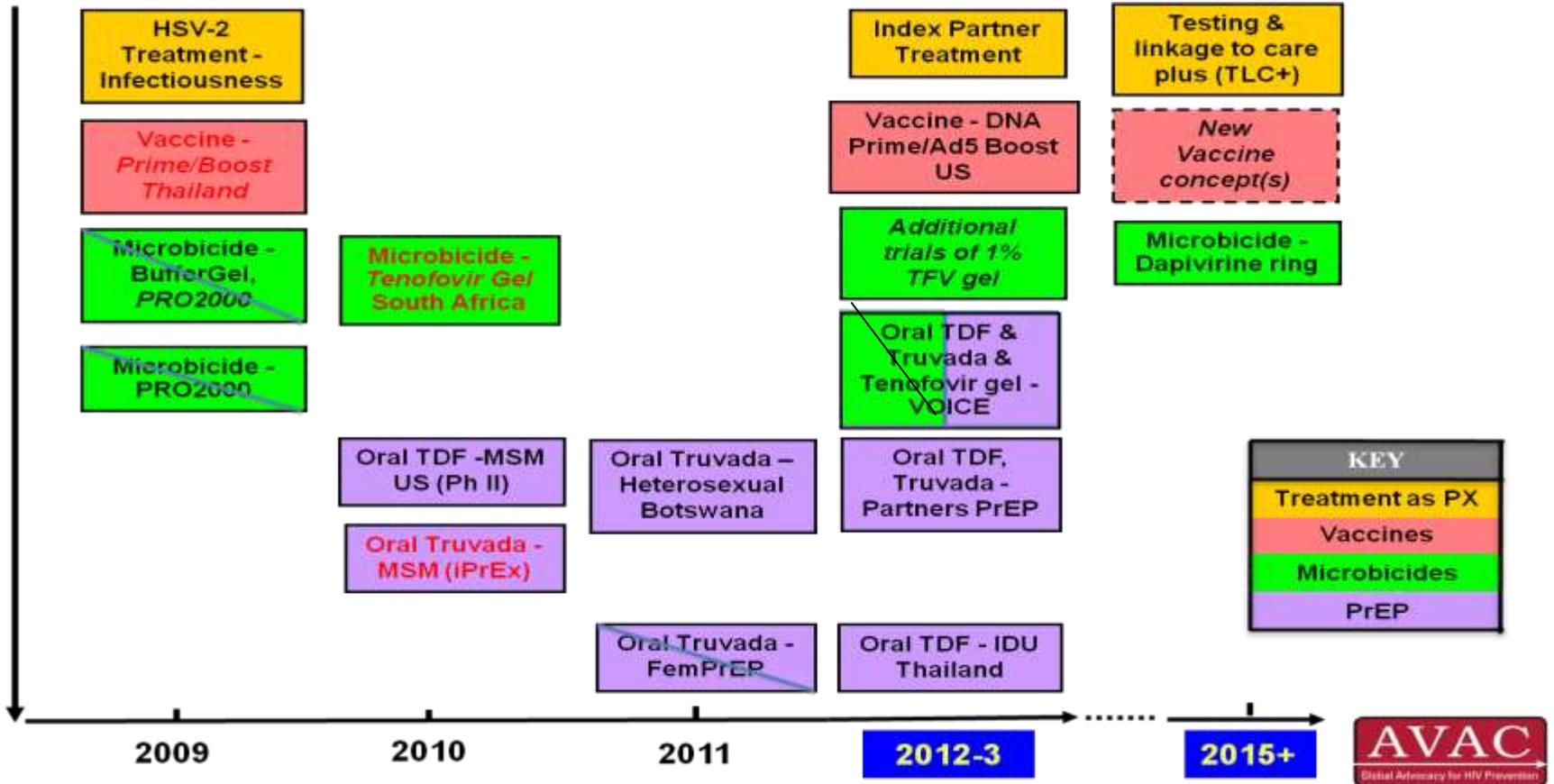
- Antiretroviral therapy
- Care
- Education and behavioral change
- **Therapeutic vaccines**

**Leadership and scaling up of  
treatment and prevention efforts**

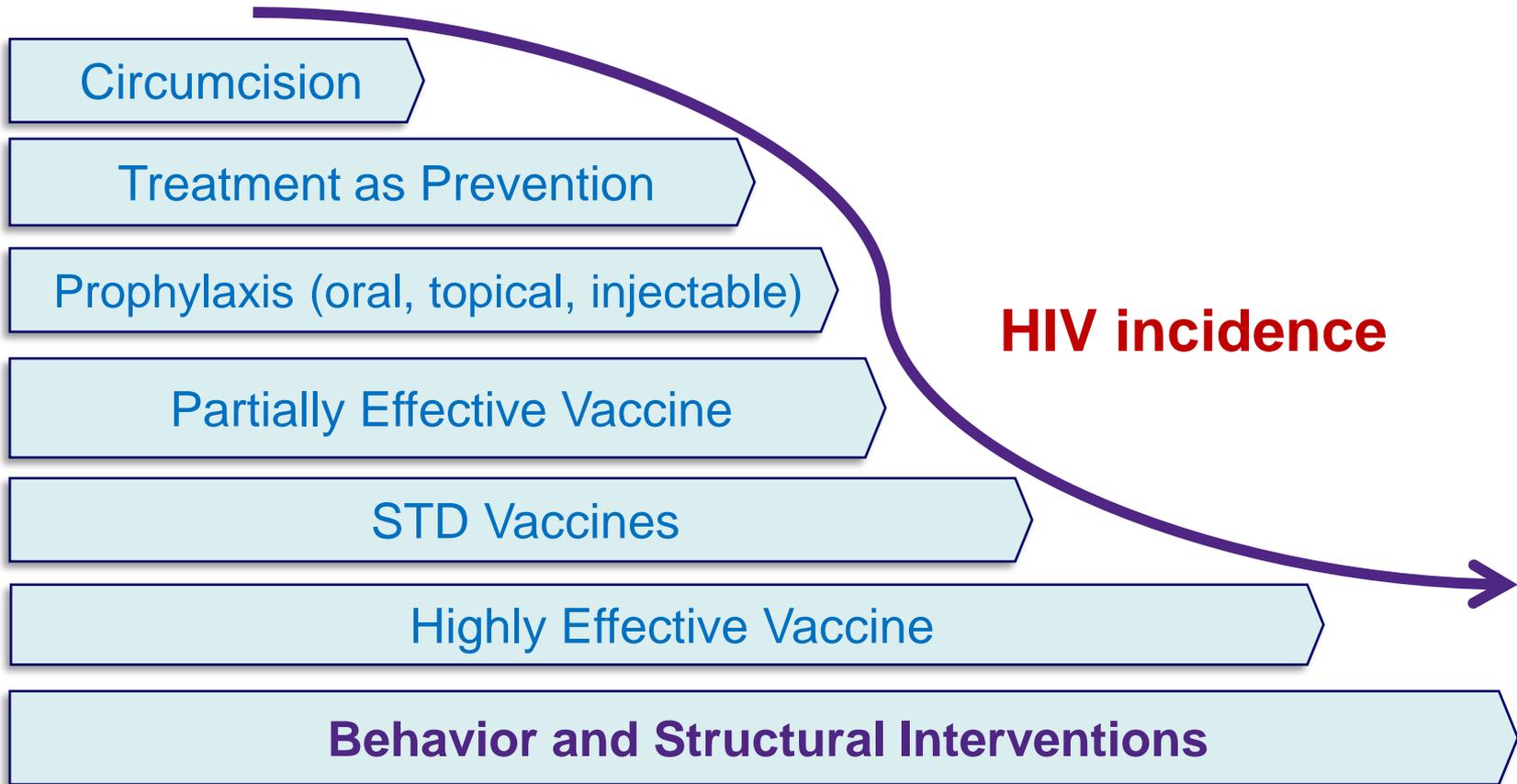


Source: Coates et al., Lancet 2008

# HIV Prevention Research Landscape



# Shattock's Pathway to Reversing the Epidemic



Source: Science, 2011; 333: 42-3

Virus or Bacteria	Year Discovered	Year Vaccine Licensed	Year Elapsed
<b>Typhoid</b>	1884	1989	105
<b>Haemophilus Influenzae</b>	1889	1981	92
<b>Malaria</b>	1893	None	-
<b>Pertussis</b>	1906	1995	89
<b>Polio</b>	1908	1955	47
<b>Measles</b>	1953	1995	42
<b>Hepatitis B</b>	1965	1981	16
<b>Rotavirus</b>	1973	1998	25
<b>HPV</b>	1974	2007	33
<b>HIV</b>	1983	None	-

Source: AIDS Vaccine Handbook, AVAC, 2005

- **PMTCT:** ARVs are given to HIV-positive mothers and their infants to help reduce the risk of HIV transmission to the infant
- **PEP:** Post-exposure prophylaxis is an HIV risk-reduction method in which someone takes a short-course ARV regimen to reduce the risk of HIV infection within 72 hours from a possible exposure
- **PrEP:** Pre-exposure prophylaxis is the use of ARVs in HIV-negative individuals who maybe at higher risk of infection
- **Treatment as Prevention:** Evidence that low viral load in an HIV-positive individual decreases transmission rate to HIV-negative partners

# Post-Exposure prophylaxis (PEP)

- PEP is the short term use of ARV medications to reduce the risk of HIV infection
- Must be started within 72 hours of exposure
- Originally used for occupational exposures (e.g., needle sticks, bodily fluid exposures)
- CDC does have guidelines for use in non-occupational exposures (e.g., sexual assaults, high risk sexual behaviors, or injecting drug use)

# Pre-Exposure Prophylaxis (PrEP)

- ARV medication prior to exposure in the attempt to stop HIV infection
- FDA approved the fixed-dose combination pill tenofovir/emtricitabine (Truvada) for adult men who have sex with men (MSM) and heterosexually active males and females at very high risk for HIV
- Taking PrEP does not mean that you're 100 percent protected from getting HIV
- PrEP is not a “vaccine” or a “morning-after” pill

- iPrEx designed to determine effectiveness of daily oral Truvada in safely and effectively prevent HIV infection among MSM and Transgendered Women.
- Investigators found that study participants who took the daily dose of oral ARVs experienced an average 44 percent fewer HIV infections than those who received the placebo pill.
- Those who took the drug on 50 percent or more days as measured by pill count, bottle count and self-reporting experienced 50.2 percent fewer infections.
- Those who took the drug on 90 percent or more days had 72.8 percent fewer HIV infections.

# Partners PrEP and CDC TDF2

- Partners PrEP was the use of Truvada and Viread in discordant heterosexual couples. The Viread group had an efficacy average of 68 percent for women and 55 percent for men, while the Truvada group had 62 percent efficacy for women and 83 percent for men compared to the placebo group.
- CDC TDF 2 show the efficacy of oral Truvada was 73 percent overall in heterosexual men and women, similar to the efficacy found in Global iPrEx study among MSM reporting pill use on 90 percent of days.

- The study 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.
- The Data Safety Monitoring Board has 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.
- Strategies for scaling up knowledge of HIV status and increasing treatment coverage are critical next steps to realizing the public health benefits of this finding.

- **Centers for Disease Control and Prevention**
  - Interim Guidance: Pre-exposure Prophylaxis for the Prevention of HIV Infection in Men Who Have Sex with Men
  - Interim Guidance for Clinicians Considering the Use of Pre-exposure Prophylaxis for the Prevention of HIV Infection in Heterosexually Active Adults
  - 2012 PrEP Program Guidance for HIV Prevention for Health Department Grantees
  
- **World Health Organization**
  - Guidance on Oral Pre-exposure Prophylaxis (PrEP) for Serodiscordant Couples, Men and Transgender Women who have Sex with Men at High Risk of HIV

# NASTAD PrEP Policy Statement



## 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 (ADAC) 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 PrEP](#), [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

Approved by NASTAD's Executive Committee on June 14, 2012, the statement supports the approval of a label change for Truvada to be used as PrEP among high-risk, HIV negative individuals. In addition, the statement calls for continued research to examine PrEP in real world situations and identifies five action items for health departments.



# NASTAD Members Pledge Five PrEP Action Items

1. Emphasize the importance of providing comprehensive prevention and care services for individuals at high-risk for HIV
2. Utilize existing planning funds (e.g., PS12-1201) and examine alternative funding streams for the planning and implementation of PrEP
3. Ensure an opportunity to accomplish implementation research for PrEP in a range of priority populations, venues and regions
4. Strategize to ensure that PrEP implementation does not further health disparities among Black and Latino communities
5. Initiate efforts to educate medical providers, HIV testers and counselors, and community stakeholders

- **Eight issues for consideration when planning to include PrEP into your prevention plans**
  - Cost
  - Effectiveness
  - Financing
  - Safety
  - Risk compensation
  - Behavioral effects
  - Resistance
  - Adherence

## **Webinar: State HDs Implementing PrEP Monday, November 5, 2012, 4-5 p.m. ET**

NASTAD will facilitate a discussion with health departments about PrEP and incorporating PrEP into prevention plans. Two jurisdictions will share how they have “implemented” PrEP and answer questions about lessons learned.

**This webinar will be for NASTAD members only.**

- **AVAC**  
[www.avac.org/prep](http://www.avac.org/prep)
- **Project Inform**  
[www.projectinform.org/prep](http://www.projectinform.org/prep)
- **Centers for Disease Control and Prevention (CDC)**  
[www.cdc.gov/hiv/prep](http://www.cdc.gov/hiv/prep)
- **Gilead**  
<https://start.truvada.com/>

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