

# Future of PrEP and Microbicide Research: Setting the Stage



Kenneth H. Mayer  
January 7<sup>th</sup>, 2013



**Forum for  
Collaborative HIV Research**



Beth Israel Deaconess  
Medical Center



A teaching hospital  
of Harvard  
Medical School

# Evidence for PrEP Efficacy with Tenofovir-Based Regimens, circa 1/13

Study	Population	N	Efficacy (%)
<b>CAPRISA 004</b> <i>South Africa</i>	Women	889	<b>39%</b> <b>Vaginal TFV gel</b> <b>Pericoital dosing</b>
<b>iPrEx</b> <i>Brazil, Ecuador, Peru, South Africa, Thailand, US</i>	Men Having Sex with Men	2499	<b>44%</b> <b>Daily oral FTC/TDF</b>
<b>TDF2 Study</b> <i>Botswana</i>	Young men & women	1200	<b>62%</b> <b>Daily oral FTC/TDF</b>
<b>Partners PrEP Study</b> <i>Kenya, Uganda</i>	Heterosexual couples	4758	<b>67% daily oral TDF</b> <b>75% daily oral FTC/TDF</b>

# PrEP (Like ART) Works When Taken

	Blood Samples With Tenofovir Detected, %	HIV Protection Efficacy in Randomized Comparison,%
Partners PrEP*[1]	81	75
TDF2[2]	79	62
iPrEx[3]	51	44
FEM-PrEP[4]	26	6

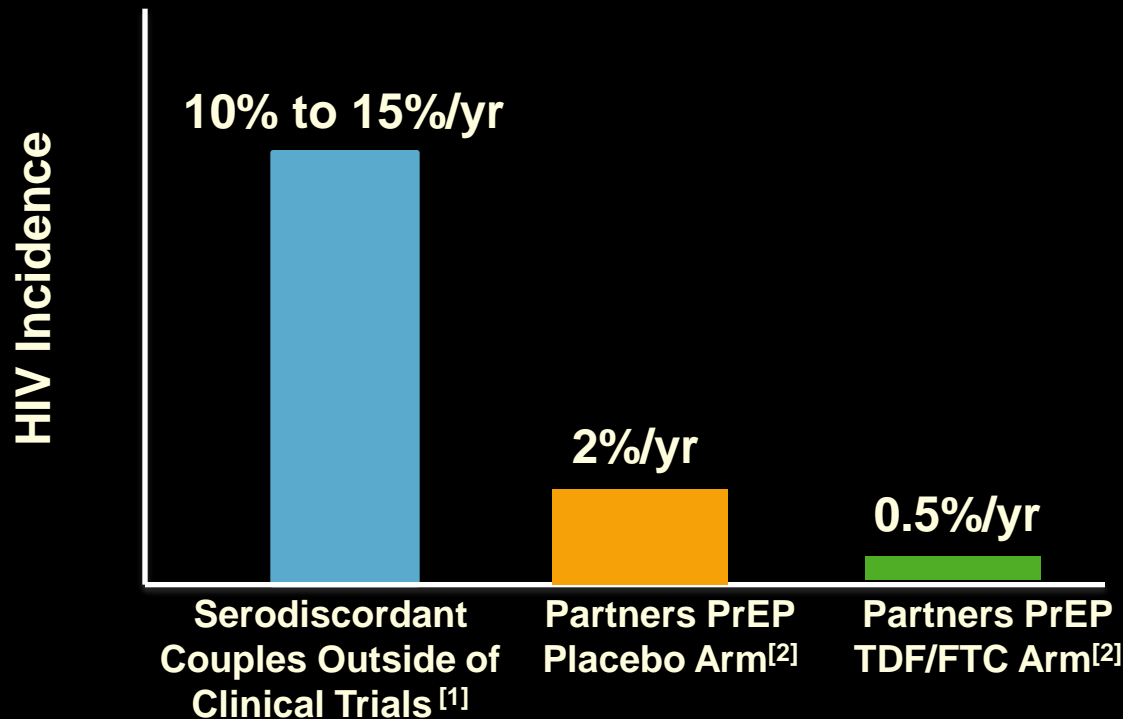
\*TDF/FTC arm

**Dose-response  
between evidence of PrEP use and efficacy**

1. Baeten JM, et al. N Engl J Med. 2012. 2. Thigpen MC, et al N Engl J Med. 2012;  
3. Grant RM, et al. N Engl J Med. 2010; 4. Van Damme L, et al N Engl J Med. 2012;[

# PrEP Works Together With Other HIV Prevention Strategies

Ongoing HIV counseling and testing, condoms, risk reduction, male circumcision, treatment of STIs *plus PrEP* synergize to maximally reduce HIV risk

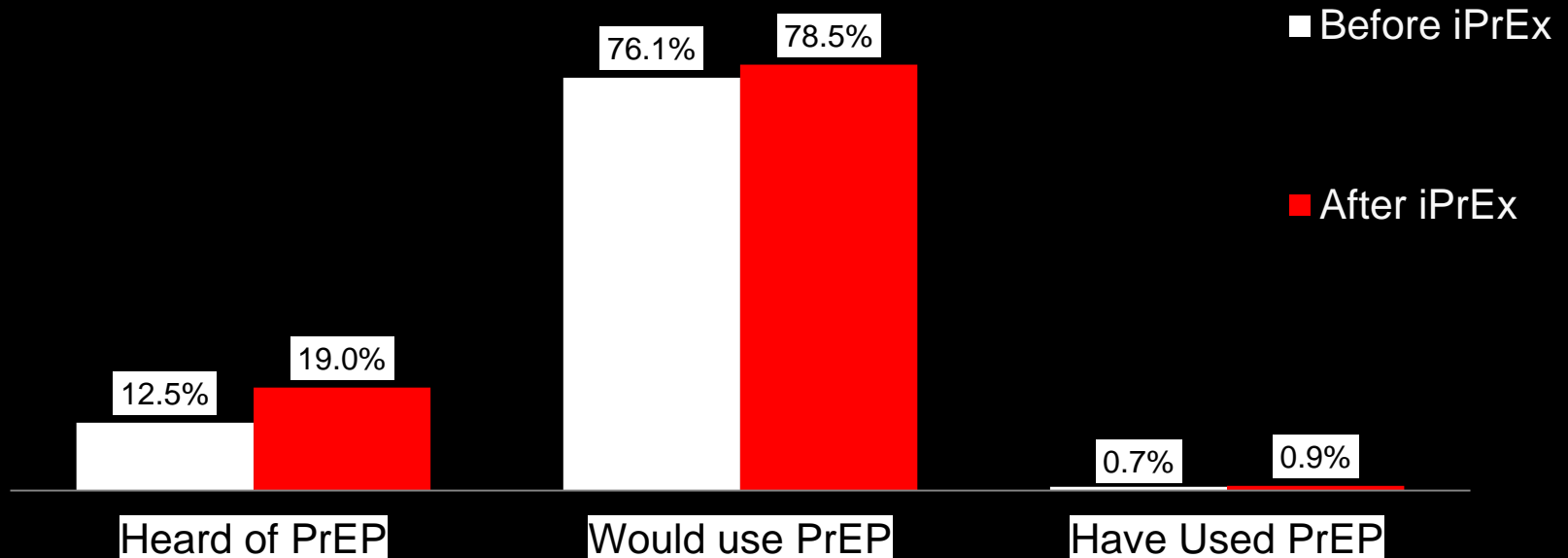


1. Quinn TC, et al. N Engl J Med. 2000;342:921-929. 2. Baeten JM, et al. N Engl J Med. 2012;[Epub ahead of print]. .

# Immediately after iPrEx, PrEP awareness increased But rapid uptake did not happen

## Changes in PrEP Awareness, Interest, and Experience after iPrEx among MSM

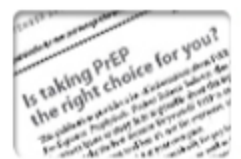
(Krakower et al, PLoS ONE, 2012)



## HIV PREVENTION PILL FOR NEGATIVE MEN: Another choice for staying HIV free?

Manhunt Cares is proud to commemorate this year's World AIDS Day by promoting the [Gladstone Institutes](#), [The Fenway Institute](#), and our own [OLB Research Institute's](#) research in advancing the U.S. FDA's recently approved HIV prevention pill for HIV negative men (and women).

Take a minute to celebrate these advances by learning more:



**Download**  
the Fact Sheet  
and Research >>



**Watch**  
a Short Video from  
Huffington Post Live >>



**Read** PositiveFrontiers.com's  
excellent series called  
"My Life On PrEP" >>



# 2012 World AIDS Day Metrics: Manhunt Cares PrEP Page

## November 30, 2012 - January 1, 2013

Unique Page views:	34,149
Huffington Post Video Views:	9,518
Positive Frontiers “My Life On PrEP” Visits:	3,698
CDC Fact Sheet Downloads:	3,040
Project Inform Fact Sheet Downloads:	1,294
Research Article Downloads:	882

Sources: Google Analytics and YouTube Analytics



**Carl Sandler**

CEO, MISTER app

GET UPDATES FROM CARL SANDLER



## A Pill to Prevent HIV

Posted: 11/06/2012 2:35 pm



React > [Amazing](#) [Inspiring](#) [Funny](#) [Scary](#) [Hot](#) [Crazy](#) [Important](#) [Weird](#)

Follow > [HIV/AIDS](#), [HIV Pre-Exposure Prophylaxis](#), [HIV Prevention](#), [HIV/AIDS Prevention](#), [Hiv](#), [Hiv Pill](#), [Prep](#), [Truvada](#), [Gay Voices News](#)

### SHARE THIS STORY

Like 2,006 people like this. Be the first of your friends.

498

85

56

4

share

tweet

email

+1

Submit this story

Last week a friend posted on Facebook: "It's been an interesting life. HIV + (positive). 10/9/2012." He is 24.

Later, I asked my young friend if he had heard of Truvada, the drug recently approved by the FDA for use as pre-exposure prophylaxis, or PrEP, against HIV. It's a pill to prevent HIV transmission. Like most people I know, he hadn't ever heard about PrEP and didn't understand that it was an option available to him.

Sadly, I'm not surprised. The information that has come out about PrEP over the past year has been so vague or confusing that millions of gay men at risk for getting HIV may not understand it. The fact is, a daily dose of Truvada *can* statistically protect against contracting HIV.

If taken properly and consistently over a period of time prior to an exposure, an HIV-negative person is protected in roughly equivalent rates of protection provided by a condom, or **over 90 percent**. Researchers have **estimated** that for gay men, taking Truvada daily (7 pills per week) may be 99-percent effective; four pills a week might be as good as consistent condom use (96 percent).\*

So why isn't there a more expansive conversation happening in the gay community about this drug? Where are the front-page headlines? I spoke to some of my own friends about PrEP and quickly realized that many people, both HIV-positive and HIV-negative, have a knee-jerk *negative* reaction to PrEP, a combination of healthy skepticism, fear, misinformation and confusion.

I'm writing this piece because I don't want to read any more Facebook postings like that of my young friend. I want people of all ages to have the information they need to decide for themselves about the risks and benefits of Truvada and PrEP.

### The Condom Conundrum

Despite decades of safer sex messages, over 50,000 Americans are still newly infected with HIV

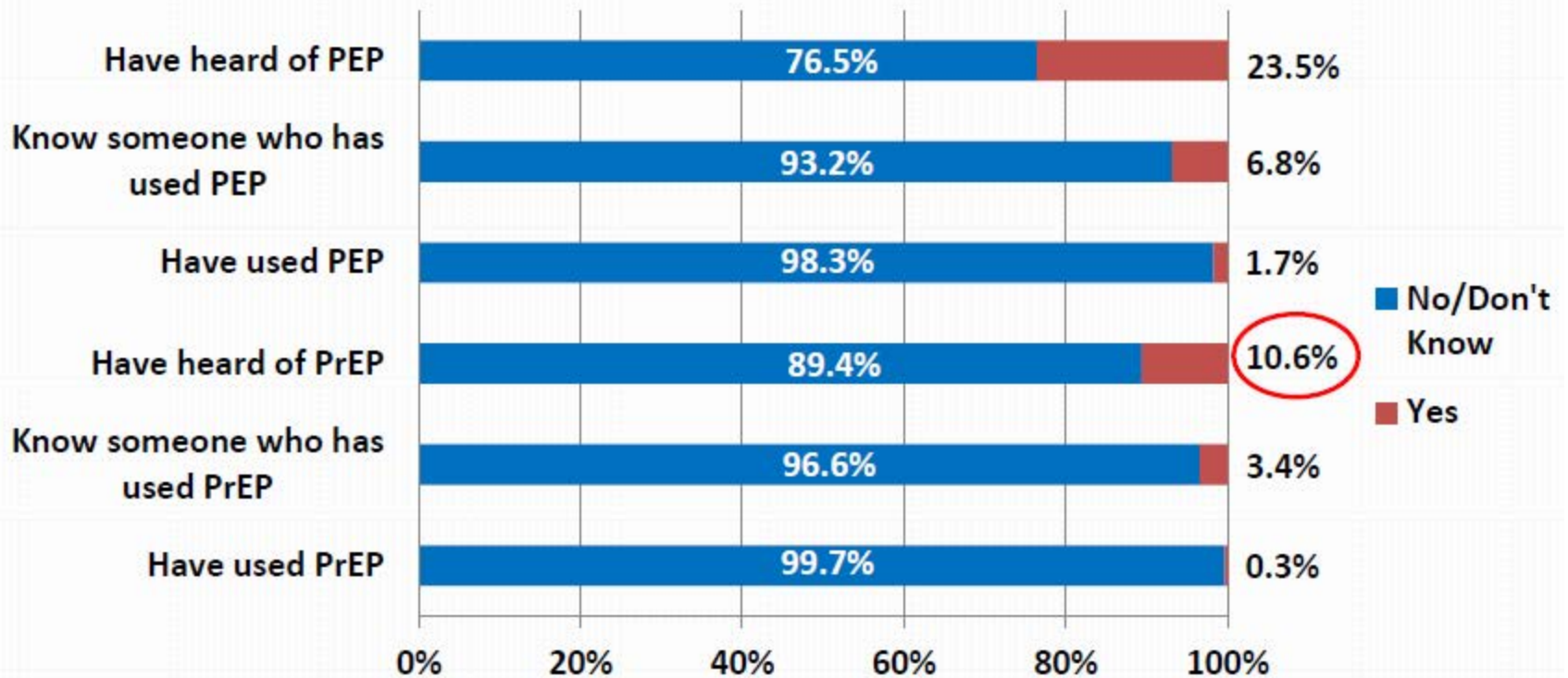


# Development of a PrEP Candidate Screening Tool: An Assessment of PrEP Knowledge and Health Behaviors among Individuals at High- Risk for HIV

**Amanda D. Castel, MD, MPH**

**George Washington University School of Public  
Health and Health Services**

# Knowledge of PEP and PrEP



# Massachusetts Physicians Survey

## 12/10-4/11 (N=115)

---

- 60% HIV specialists, 40% generalists
- 64% heard of iPrEX and 57% CAPRISA 004
- 70% thought the gel, and 40% thought pills should be available to at risk persons
- 28% felt that pills should not be available to at risk persons
- Providers who felt that behavioral interventions were safer/more effective, and/or that PrEP use would result in a ↓ in federal funds for other prevention activities were less likely to endorse PrEP

White et al, AIDS Pt Care, 2012

# What Primary Care Providers Need to Know About Preexposure Prophylaxis for HIV Prevention

## A Narrative Review

Douglas Krakower, MD, and Kenneth H. Mayer, MD

As HIV prevalence climbs globally, including more than 50 000 new infections per year in the United States, we need more effective HIV prevention strategies. The use of antiretrovirals for preexposure prophylaxis (PrEP) among high-risk persons without HIV is emerging as one such strategy. Randomized, controlled trials have demonstrated that once-daily oral PrEP decreased HIV incidence among at-risk men who have sex with men and African heterosexuals, including serodiscordant couples. An additional randomized, controlled trial of a topical pericoital antiretroviral microbicide gel decreased HIV incidence among at-risk heterosexual South African women. Two other studies in African women did not demonstrate the efficacy of oral or topical PrEP, raising concerns about adherence patterns and efficacy in this population.

The U.S. Food and Drug Administration (FDA) Antiviral Drugs Advisory Committee reviewed these studies and additional data in May 2012 and voted to advise the approval of oral tenofovir-emtricitabine for PrEP in high-risk populations. On 16 July 2012,

the FDA recommended that this combination medication be approved for use as PrEP in high-risk persons without HIV. Patients may seek PrEP from their primary care providers, and those receiving PrEP require monitoring. Thus, primary care providers should become familiar with PrEP. This review outlines current knowledge about PrEP as it pertains to primary care, including identifying persons likely to benefit from PrEP; counseling to maximize adherence and reduce potential increases in risky behavior; and monitoring for potential drug toxicities, HIV acquisition, and antiretroviral drug resistance. Issues related to cost and insurance coverage are also discussed. Recent data suggest that PrEP, combined with other prevention strategies, holds promise in helping to curtail the HIV epidemic.

*Ann Intern Med.* 2012;157:490-497.

For author affiliations, see end of text.

This article was published on [www.annals.org](http://www.annals.org) on 22 July 2012.

[www.annals.org](http://www.annals.org)

[www.truvadapreprems.com](http://www.truvadapreprems.com)

# AMERICAN JOURNAL OF Preventive Medicine

VOLUME 44(1S2)

www.ajpmonline.org

JANUARY 2013

## Introducing PrEP Implementation

- S59** **Introducing Wicked Issues for HIV Pre-Exposure Prophylaxis Implementation in the U.S.**  
DK Smith, JW Dearing, T Sanchez, RH Goldschmidt
- S63** **Antiretroviral Prophylaxis for Sexual and Injection Drug Use Acquisition of HIV**  
JD Campbell, JH Herbst, RT Koppenhaver, DK Smith
- S70** **Designing for Diffusion of a Biomedical Intervention**  
JW Dearing, DK Smith, RS Larson, CA Estabrooks
- S77** **Primary Care and Public Health Partnerships for Implementing Pre-Exposure Prophylaxis**  
WE Norton, RS Larson, JW Dearing

## Lessons for PrEP from Other Health Interventions

- S80** **Preparing for HIV Pre-Exposure Prophylaxis: Lessons Learned from Post-Exposure Prophylaxis**  
SE Cohen, AY Liu, KT Bernstein, S Philipp
- S86** **Moving HIV Pre-Exposure Prophylaxis Into Clinical Settings: Lessons from Buprenorphine**  
EJ Edelman, DA Fiellin
- S91** **Adherence to Antiretroviral Medications for HIV Pre-Exposure Prophylaxis: Lessons Learned from Trials and Treatment Studies**  
LJ Koenig, C Lyles, DK Smith
- S99** **Applying Chronic Illness Care, Implementation Science, and Self-Management Support to HIV**  
MK ElZarrad, ET Eckstein, RE Glasgow

## Policy Issues for PrEP Implementation

- S119** **State Adolescent Consent Laws and Implications for HIV Pre-Exposure Prophylaxis**  
L Culp, L Caucchi
- S125** **Financial Policy Issues for HIV Pre-Exposure Prophylaxis: Cost and Access to Insurance**  
M Horberg, B Raymond
- S129** **HIV Pre-Exposure Prophylaxis Diffusion and Implementation Issues in Nonclinical Settings**  
SG Hosek
- S133** **Disseminating HIV Pre-Exposure Prophylaxis Information in Underserved Communities**  
MJ Dutta
- S137** **Social Justice, Public Health Ethics, and the Use of HIV Pre-Exposure Prophylaxis**  
S Philipp

## Getting Practice-Based Evidence for PrEP

- S141** **A Proposed Framework to Monitor Daily Oral Antiretroviral Pre-Exposure Prophylaxis in the U.S.**  
DK Smith, J Beltrami
- S147** **Providing HIV Pre-Exposure Prophylaxis: Lessons Learned from the Ryan White HIV/AIDS Program**  
S Trent-Adams, LW Cheever
- S151** **Using Registries to Monitor HIV Pre-Exposure Prophylaxis Safety in Clinical Settings**  
HH Tilson
- S156** **Next Steps in Designing for Diffusion of Pre-Exposure Prophylaxis: Demonstration Projects**

# **Chemoprophylaxis: A work in progress**

---

- **What have we learned since FDA approval?**
- **What may new demonstration projects tell us?**
- **What are we learning from community responses?**
- **Are there other regimen candidates for PrEP?**
- **Are there other delivery systems for PrEP?**

**Later: How do we best get the answers we need?**