

# The Doc Is In

*Prescribing,  
Managing and  
Billing for PrEP  
for HIV  
Prevention*

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Today's webinar is brought to you by AVAC's PxROAR program and the LA County PrEP Workgroup.

Featuring presentations from Matthew Rose, Dr. Tony Mills, Dr. Nika Seidman and Shannon Weber.

A recording of the webinar will be available at [avac.org/meetingreports](http://avac.org/meetingreports).

## Welcome to today's webinar!

If you are not already, make sure you are dialed in to the toll-free audio conference line:

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### AGENDA

**Welcome:** Kieta Mutefpa

**Intro to Truvada as PrEP in the US:** Matthew Rose

### **Provider Presentations:**

- Dr. Tony Mills, UCLA
- Dr. Nika Seidman and Shannon Weber, BAPAC

**Discussion:** Moderated by Cassie Warren

AVAC

Global Advocacy for HIV Prevention

*The Doc Is In*  
Intro to Truvada as PrEP in the US

Matthew Rose, PxROAR member

*Doc Is In* webinar

April 3, 2014

# What is PrEP?

- Pre-exposure prophylaxis is a concept where people take medicine to *prevent* rather than to treat a disease or condition
- PrEP for HIV prevention involves HIV-negative individuals taking ARVs (drugs currently used to treat people with HIV/AIDS) to reduce risk of HIV infection



# Oral PrEP Data

- Three large-scale trials (in gay men and transgender women; serodiscordant couples; heterosexual men and women) have shown evidence of HIV risk reduction—tenofovir-based PrEP works if you take it
- Adherence matters—those who were able to follow the PrEP regimen as prescribed had lower risk
- Taking PrEP does not mean that you're 100 percent protected from getting HIV
- PrEP is not a “vaccine” or a “morning-after” pill

## PrEP Study Results

Study	Population	N	Treatment(s)	Results
iPrEx Brazil, Ecuador, Peru, South Africa, Thailand, US	Gay men, other MSM, transgender women	2499	Daily oral Truvada	44% efficacy
TDF2 Study Botswana	Men and women	1200	Daily oral Truvada	62% efficacy
Partners PrEP Study Kenya, Uganda	Serodiscordant couples	4758	Daily oral Tenofovir Daily oral Truvada	67% efficacy 75% efficacy
Bangkok Tenofovir Study Thailand	IDUs	2400	Daily oral Tenofovir	49% efficacy
FEM-PrEP Kenya, South Africa, Tanzania	Women	1950	Daily oral Truvada	No effect
VOICE South Africa, Uganda, Zimbabwe	Women	5029	Daily oral Tenofovir Daily oral Truvada Daily vaginal TFV gel	No effect

# Adherence

## PrEP Works...If You Take It

Trial	Efficacy	Adherence
CAPRISA 004 <sup>6</sup>	1% tenofovir gel: 39%	51%
iPrEx <sup>7</sup>	Oral daily Truvada: 42%	51%
Partners PrEP <sup>8</sup>	Oral daily tenofovir: 67% Oral daily Truvada: 75%	83% 81%
TDF2 <sup>9</sup>	Oral daily Truvada: 62%	81%
FEM-PrEP <sup>10</sup>	Oral daily Truvada: No Protection	24%
VOICE <sup>2</sup>	TFV gel: No protection Oral daily tenofovir: No protection Oral daily Truvada: No protection	23% 28% 29%

*The point estimate of efficacy for each study is listed and adherence estimates were determined by measuring drug levels from participant samples collected at varying time points.*

# PrEP Guidelines

- CDC [interim guidance](#) on prescribing PrEP for adults at risk of HIV via sexual exposure and injection drug use; expanded US Public Health Service Guidelines expected in 2014
- Some clinics/DOHs have clinician guidelines (e.g., Massachusetts DOH released guidelines and FAQs in May 2013)

# Regulatory Approval

- US Food and Drug Administration approved use of Truvada as PrEP in July 2012; Truvada is indicated in combination with safer sex practices for pre-exposure prophylaxis to reduce the risk of sexual acquired HIV-1 infection in adults at high risk
- Gilead REMS guidelines:  
<https://www.truvadapreprems.com/#>



## When Prescribing Truvada for a PrEP indication, Healthcare Providers must

- Prescribe Truvada as part of a comprehensive px strategy
- Counsel individuals to adhere to daily dosing schedule
- Confirm a negative HIV-1 test immediately prior to initiating PrEP
  - If clinical signs or symptoms consistent with acute viral infection are present and recent (<1 month) exposure are suspected.
    - Delay starting PrEP for at least one month and reconfirm HIV-1 status or
    - Use a test approved by the FDA as an aid in diagnosis of HIV-2 infection, including acute or primary HIV-1 infection

## ...Prescribing continued

- While using Truvada for PrEP, HIV-1 screening tests should be repeated at every 3 months
- If symptoms consistent with acute HIV-1 infection developed following a potential exposure event. PrEP should be discontinued until negative infection status is confirmed using an approved by the FDA as an aid in the diagnosis of HIV-1, including acute of primary HIV-1 infection

# What is a REMS?

- Risk Evaluation and Mitigation Strategy
- FDA program to manage a known or potential risk associated with a drug
  - Designed to ensure the benefits of a drug outweigh its risks
- Goals of REMS for Truvada for PrEP is to educate prescribers and individuals about
  - The importance of adherence
  - The importance of regular monitoring of HIV-1 serostatus
  - Truvada for PrEP must be part of a comprehensive prevention strategy

# Truvada as PrEP REMS

Gilead REMS guidelines: [www.truvadapreprems.com/#](http://www.truvadapreprems.com/#)

- Dear Healthcare Provider Letter
- Training Guide for Healthcare Providers
- Important Safety Information for Healthcare Providers
- Safety Information Fact Sheet
- Agreement Form
- Checklist for Prescribers
- Medication Guide
- Important Safety Information for Uninfected Individuals
- Full Prescribing Information

# Truvada for PrEP Utilization in the US

- Geographically prescribers of Truvada for PrEP are located in 49 states and distributed across approximately 700 cities
- Only 37% also prescribed Truvada for HIV treatment
- Overall 6 specialties initiated 75.6% of PrEP

## Prescriptions

- Family Practice 16%
- Internal Medicine 15%
- Emergency Medicine 14%
- Infectious Diseases 12%
- Nurse Practitioners 9%
- Physician Assistants 8%

# ...Utilization continued

- When compared to HIV positive patients a uninfected individuals receiving TVD for PrEP were:
  - 1.4 times more likely to be from the South
  - 1.8 times more likely to be female
  - 1.4 times more likely to be younger than 25 years old
  - 3.8 times more likely to be treated by a non-ID physician (95

# Providers Prescribing

- Only 1 in 5 US HIV physicians surveyed in 2011 used antiretrovirals for preexposure prophylaxis (PrEP)
- Among the 189 respondents, 90% knew about iPrEx results and 78% were familiar with CDC interim guidance on PrEP for MSM. But only 19% of respondents had prescribed PrEP
- Among PrEP prescribers, 78% prescribed PrEP for MSM, but 31% prescribed it for heterosexual men and 28% for women
- Among PrEP prescribers, 58% said HIV discordance in a couple most influenced their decision to prescribe PrEP for the HIV-negative partner

*Only 1 in 5 US HIV Doctors Surveyed Uses PrEP, Despite High Awareness Author: Mark Mascolini <http://www.iasociety.org/Default.aspx?pageId=5&elementId=15599>*

Dr. Tony Mills

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**Positive Reproductive Outcomes for Men**



**BAPAC**

Bay Area Perinatal  
AIDS CENTER

Initiative launched by BAPAC at SFGH's Ward 86 HIV clinic:

- Aimed at the ~500 HIV+ men who have sex with women
- Supporting HIV+ men's sexual & reproductive health intentions
- Integrating sexual & reproductive health care into a primary care
- HIV- female partners can receive care at BAPAC
- [hiv.ucsf.edu/care/perinatal/pro\\_men.html](http://hiv.ucsf.edu/care/perinatal/pro_men.html)

# PRO Men Patient resources

Monthly support group; Spanish to launch this year

4 patient brochures

- *Is PrEP right for me? A primer for HIV-women*
- *Preventing HIV transmission & Pregnancy: A guide for men*
- *Safer conception options for HIV+ men with an HIV-female partner*
- *Safer conception options for HIV- women with an HIV-positive male partner*

*Spanish translations in progress*

2 patient videos on timed ovulation for safer conception

*Spanish translations in process*

4-minute Adherence Video english/spanish

4- minute Disclosure Video

[hiv.ucsf.edu/care/perinatal/pro\\_men.html](http://hiv.ucsf.edu/care/perinatal/pro_men.html)

# Provider resources

- 3 hour provider training in partnership with PAETC
- Provider algorithm
  - *Decision tree for sexually active men and women*



# Discussion

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## To ask a question:

- Enter your question on the ReadyTalk webinar interface
- Press \*7 to unmute and ask your question on the line
- Email your question to [avac@avac.org](mailto:avac@avac.org)

For more on PrEP, visit PrEP Watch at [www.prepwatch.org](http://www.prepwatch.org)

Reminder that the recording will be posted to the AVAC website ([www.avac.org](http://www.avac.org)), and webinar registrants will receive a follow-up email with link to the slides and recording.

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