

New Guidance on Daily Oral PrEP: What's out there



September 18, 2012

Timeline

- July 2010: CAPRISA 004 presented at AIDS 2010 and published in *Science* that 1% tenofovir gel reduced risk in women by 39%
- Nov 2010: iPrEx publishes data that daily oral TDF/FTC reduced risk in MSM by 42%
- Jan 2011: US CDC publishes interim guidance on PrEP PrEP for clinicians considering use of PrEP in MSM
- April 2011: FEM-PrEP DSMB interim analysis – daily oral TDF/FTC had no effect on risk in women
- May 2011: HPTN 052 DSMB interim analysis – early treatment reduced transmission risk by 96% in serodiscordant couples – presented at IAS 2011 and published in *NEJM*
- July 2011: Partners PrEP DSMB interim analysis – daily oral TDF/ FTC reduced risk by 73%, and daily TDF reduced risk by 62%, in serodiscordant couples – presented at IAS 2011
- July 2011: TDF2 trial data presented at IAS 2011 that daily oral TDF/FTC reduced risk in heterosexual men and women by 63%
- Sept 2011: VOICE DSMB interim analysis – daily oral TDF had no effect on risk in women
- Nov 2011: VOICE DSMB interim analysis – daily 1% tenofovir gel had no effect on risk in women
- Dec 2011: Gilead files application for PrEP indication with US FDA
- Jan 2012: British HIV Association and British Association for Sexual Health publish Position Statement to inform UK healthcare workers on the role of PrEP
- May 2012: US FDA holds public Advisory Committee to consider PrEP; AdComm votes to recommend approval of PrEP for all sexually adults at risk of HIV
- June 2012: Southern African HIV Clinicians Society publishes guidelines for PrEP in MSM
- July 2012: Partners PrEP, TDF2 and FEM-PrEP data published in *NEJM*
- July 2012: US FDA approves daily oral TDF/FTC for deducing risk of sexually acquired HIV
- July 2012: WHO publishes guidance on PrEP with recommendations for use in demonstration projects
- Aug 2012: US CDC publishes interim guidance on PrEP for clinicians considering use of PrEP in heterosexual adults

US FDA Approves First Drug for Reducing Risk of Sexually Acquired HIV Infection



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FDA NEWS RELEASE

For Immediate Release: July 16, 2012

Media Inquiries: Erica Jefferson, 301-796-4988, erica.jefferson@fda.hhs.gov

Consumer Inquiries: 888-INFO-FDA

FDA approves first drug for reducing the risk of sexually acquired HIV infection

Evidence-based approach enhances existing prevention strategies

From: US Food & Drug Administration

When: 16 July 2012

For: Gilead Sciences oral TDF/FTC in the US

What: Regulatory approval in the US for daily oral TDF/FTC (Truvada) for PrEP in HIV-negative adults

www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm312210.htm

US CDC Issues Interim Guidance for MSM and Heterosexual Adults



Morbidity and Mortality Weekly Report

Weekly / Vol. 60 / No. 3

January 28, 2011

Interim Guidance: Preexposure Prophylaxis for the Prevention of HIV Infection in Men Who Have Sex with Men

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6131a2.htm?s_cid=mm6131a2_w



Morbidity and Mortality Weekly Report

MMWR / August 10, 2012 / Vol. 61 / No. 31

Interim Guidance for Clinicians Considering the Use of Preexposure Prophylaxis for the Prevention of HIV Infection in Heterosexually Active Adults

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6003a1.htm>

From: US Centers for Disease Control

When: 28 Jan 2011 for MSM; 10 Aug 2012 for heterosexuals

For: Clinicians in the US

What: Interim guidance for clinicians considering use of PrEP in MSM and heterosexual adults

World Health Organization Issues Guidance on PrEP



GUIDANCE ON PRE-EXPOSURE ORAL PROPHYLAXIS (PrEP)
FOR SERODISCORDANT COUPLES, MEN AND TRANSGENDER
WOMEN WHO HAVE SEX WITH MEN AT HIGH RISK OF HIV:
Recommendations for use in the context of demonstration projects

July 2012



From: World Health Organization

When: July 2012

For: National policy makers and
program managers

What: Recommendations for use of
oral PrEP in the context of
demonstration projects for
serodiscordant couples, men and
transgender women who have sex
with men at high risk of HIV

[www.who.int/hiv/pub/
guidance_prep/en/index.html](http://www.who.int/hiv/pub/guidance_prep/en/index.html)

Southern African HIV Clinicians Society



GUIDELINES

Southern African guidelines for the safe use of pre-exposure prophylaxis in men who have sex with men who are at risk for HIV infection

The Consensus Committee, Southern African HIV Clinicians Society, chaired by Linda-Gail Bekker and Kevin Rebe. MEMBERS: Ben Brown, Peter Budnik, Glenn de Swardt, Zoe Duby, Nathan Geffen, Brian Kanyemba, James McIntyre, Landon Myer, Andrew Scheibe, Laurie Schowalter, Mark Sonderup, Wendy Spearman, Carlos Toledo, Tim Tucker, Reon van Dyk, Gert van Zyl

SAJHIVMED June 2012, Vol. 13, No. 2

www.sajhivmed.org.za/index.php/sajhivmed/article/view/832

From: Southern African HIV Clinicians Society Consensus Committee

When: June 2012

For: Clinicians in Southern Africa

What: Guidelines for safe use of PrEP in men who have sex with men who are at risk for HIV infection

The British HIV Association/British Association for Sexual Health

The British HIV Association/British Association for Sexual Health and HIV Position Statement on pre-exposure prophylaxis in the UK

S McCormack MSc FRCP*, **S Fidler** PhD MRCP† and **M Fisher** MBBS FRCP‡

*MRC Clinical Trials Unit, London; †Department of Medicine, Imperial College London, London; ‡Department of HIV/Genitourinary Medicine, Brighton and Sussex University Hospitals NHS Trust, Brighton, UK

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[www.bhiva.org/documents/
Publications/PrEP2012.pdf](http://www.bhiva.org/documents/Publications/PrEP2012.pdf)

From: BHIVA/BASH (UK)

When: January 2012

For: UK healthcare workers

What: Position Statement on the role of PrEP in the setting of the UK HIV epidemic, so that clinicians can have an informed discussion with their patients.

Key Resources

- avac.org/prep – latest updates on PrEP research, policy, advocacy and demonstration projects from AVAC
- myprepexperience.blogspot.com – for real stories from people using PrEP as one way to protect themselves from HIV; you can also contribute your own story via audio, video or in writing
- prepfacts.org – consumer-friendly resource for gay and bisexual men and transwomen about PrEP from San Francisco AIDS Foundation and partners
- prepwatch.org – advocacy updates from a coalition of civil society partners in the US
- start.truvada.com – from Gilead Sciences with information for healthcare providers and potential PrEP users
- truvadapreprems.com – the Risk Evaluation and Mitigation Strategy (REMS) web site from Gilead Sciences as required by the US FDA