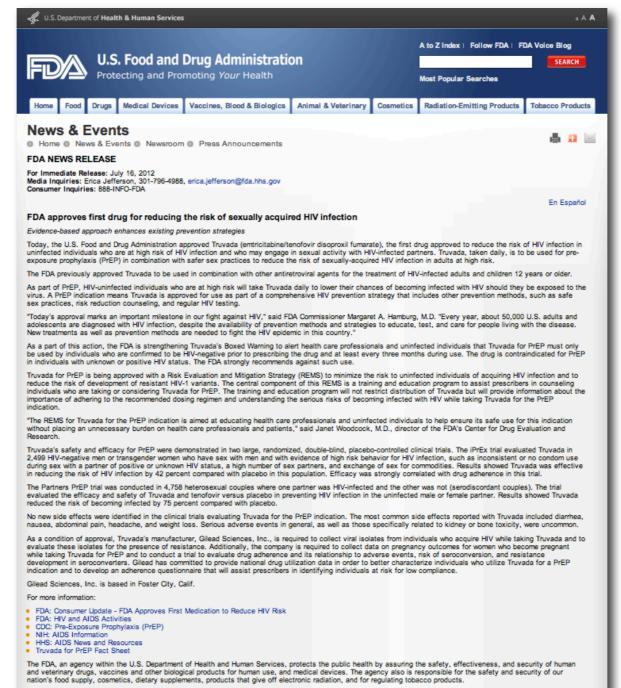
New Guidance on Daily Oral PrEP: What's out there and what does it mean for advocates?



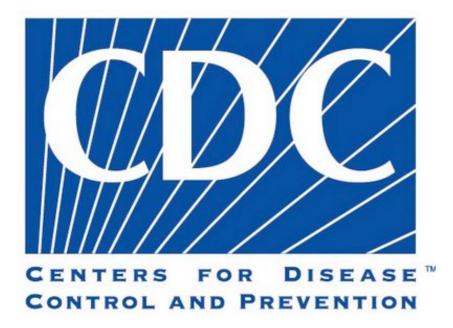
September 18, 2012

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

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



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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/mm6131a2.htm?s_cid=mm6131a2_w

Interim Guidance: Preexposure prophylaxis for the prevention of HIV infection in men who have sex with men

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



Guidance on pre-exposure oral prophylaxis (PrEP) for serodiscordant couples, men and transgender women who have sex with men at high risk of HIV

http://www.who.int/hiv/pub/guidance_prep/en/index.html

SA PrEP Guidelines



- Recognises
 - MSM a significant key population at risk for HIV in RSA
 - Evidence for an effective biomedical prevention
 - Must be combined with other behavioural and structural interventions
 - Can be formulated as a part of "package for MSM"
 - Truvada available in pharmacies in RSA.
 - Have an ethical and moral obligation to make sure guidance available for this to be prescribed for this indication safely.
 - Complete and on line....<u>saj**hiv**med.org.za</u>

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

http://www.bhiva.org/documents/Publications/PrEP2012.pdf

GUIDELINE

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

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Keywords: HIV, PrEP, pre-exposure prophylaxis, HIV prevention, guideline, UK

PURPOSE OF STATEMENT

care workers on the role of antiretroviral pre-exposure prophylaxis (PrEP) in the setting of the UK HIV epidemic, so that they can have an informed discussion with their patients. Recent results from clinical trials of PrEP have made it imperative to investigate whether this biomedical tool will have a useful part to play in HIV prevention in the UK. However, it is not possible to review the evidence for this biomedical intervention in isolation, as PrEP (systemic and topical) is one of several methods in the prevention package, and one of four biomedical tools available; the other three being medical male circumcision, postexposure prophylaxis following sexual exposure and early treatment of the positive partner.

We have therefore broadened the scope of the Position Statement to attempt to put the evidence for PrEP in context, both in terms of the characteristics of the UK epidemic and in terms of the evidence for other biomedical interventions. We took note of the current guidelines on the topic of HIV prevention, including those that are out for consultation.

METHODS

Feedback was obtained at the British HIV Association (BHIVA) annual conference, and subsequently through the UK PrEP Working eGroup, to which there is an open invitation to join. Two conference calls were arranged to solicit the opinions of organizations based in the community, and a meeting of stakeholders drawn from the eGroup was held on the 5 May 2011. Comments were solicited on the tables, and then the consensus statements. A further call was held on the 13 July 2011 to discuss the design of a randomized controlled trial (RCT). The tables and statements were updated to reflect new evidence that emerged in July, September and November 2011.

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CONSENSUS STATEMENTS

The intention of this Position Statement is to inform UK health- • HIV remains an infectious disease of major public health importance in the UK with an estimated 91,500 individuals living with HIV at the end of 2010.¹ The epidemic most affects Black African, gay and other men who have sex with men (MSM) communities. In 2010, 3000 new infections were diagnosed in MSM (the highest ever total) and 2440 (81%) of these were judged to have been acquired within the UK;1 on behaviour change, mainly the use of condoms and, more recently, testing behaviour. There is limited funding for initiatives to be implemented in accordance with national guide lines, and increasing pressure to make savings. While cross-sectional data-sets of outcomes and impact provide some insight, there has been no systematic approach to the evaluation of behavioural interventions on a national basis; Four randomized, placebo-controlled trials have now reported on the use of PrEP, providing evidence for the effeceness of daily oral Truvada (tenofovir and emtricitabine) in MSM,2 serodiscordant couples who were predominantly heterosexual,3 young heterosexual adults4 and coital tenofo vir 1% vaginal gel in women.5 A fifth trial of daily oral Truvada in women is conducting an orderly closure following an interim analysis which revealed equal numbers of HIV infections in the Truvada and placebo groups.⁶ A sixth trial in women is similarly to discontinue daily oral tenofovir (September 2011) and daily tenofovir 1% vaginal gel (November 2011), but will continue daily oral Truvada and their respective placebo.7 Other trials are underway or planned, one of these in the UK (Table 1), available online only at: http://www.ijsa.rsmjournals.com/cgi/content/ full/23/1/1/DC1;

· The momentum following these clinical trials creates the opportunity to re-think our overall strategy for HIV prevention at a time when the NHS is undergoing change. The con-tinued increase in infections being identified in MSM acquired within the UK underscores the urgent need to do so. Central to the prevention strategy is full engagement of the most affected communities;

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Gilead Sciences: Beyond FDA Approval

- Discussions are ongoing with regulatory agencies in other countries including Europe, Canada and Australia, but specific plans for filing have not yet been finalized
- Dossier for Truvada for treatment submitted in Peru during IAS
- Corporate grants program launched mid-September
- Support for demonstration projects ongoing

Truvada PrEP Educational Website

Truvada Remtricitabine-tenofovir disoproxil fumarate Re	Prescribing Information Medication Guide Important Safety Information and Boxed WARNINGS REMS Resources
TRUVADA for a Pre-Exposure Prophylaxis (PrEP) Indication TRUVADA is indicated, in combination with safer sex practices, for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults at high risk.	View Full Prescribing Information Including Boxed Warnings → View Medication Guide →
Click here for factors that place an uninfected adult at high risk \rightarrow Click here for factors to consider before prescribing TRUVADA for PrEP \rightarrow	Free
Resources for Healthcare Providers	For Uninfected Individuals
REMS Resources	Condoms
Download important Risk Evaluaton Mitigation S healthcare providers before prescribing TRUVAI uninfected individuals at high risk of sexually acc	If you are an uninfector individual at high risk taking TRUVADA for a PrEP indication, you can obtain condoms at no cost.
Read important REMS materials testing	Open condom ordering form ->
HIV Testing Read important information about safely prescribing TRUVADA for a PrEP	Safety Information for Uninfected Individuals
indication, and answer a post-training questionnaire to qualify to offer HIV testing at no cost to uninsured or financially needy individuals.	Review information for uninfected individuals at high risk.
Qualify to offer HIV testing at no cost to uninsured or financially needy individuals	Review material for uninfected individuals
Medication Assistance Program	
Help eligible uninfected individuals taking TRUVADA for a PrEP indication receive assistance paying for the medication.	

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Q&A

Thank you for joining today's webinar. To ask a question you can:

- Email your question to avac@avac.org
- Ask your question in the chatbox on the web interface if you're listening online
- Once the facilitator has opened the line for questions, press *7 to unmute yourself

Join us on October 3rd for another webinar — Beyond Daily TDF/FTC as PrEP: Exploring new drugs and regimens for PrEP.

Register here: http://bit.ly/Uhqh7i