



SHOULD PrEP BE OFFERED TO ALL WOMEN?

8th International Workshop on HIV and Women
March 2, 2018



HANDS UP FOR PrEP !!!!

VOLTAIRE WOULD APPROVE...

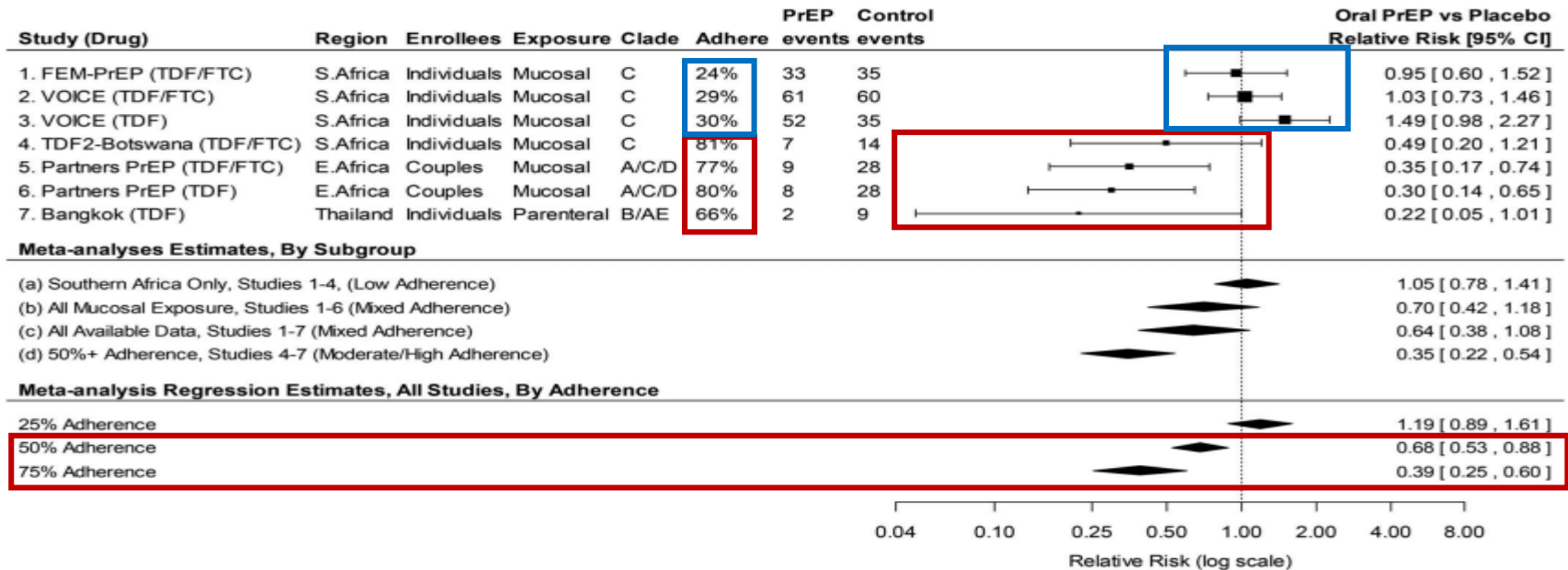




REVISITING THE ADHERENCE BASED META-ANALYSIS

Hanscom B et al. JAIDS 2016;73:606-8

- Included 5 studies.
- Oral PrEP effective with moderate/high adherence

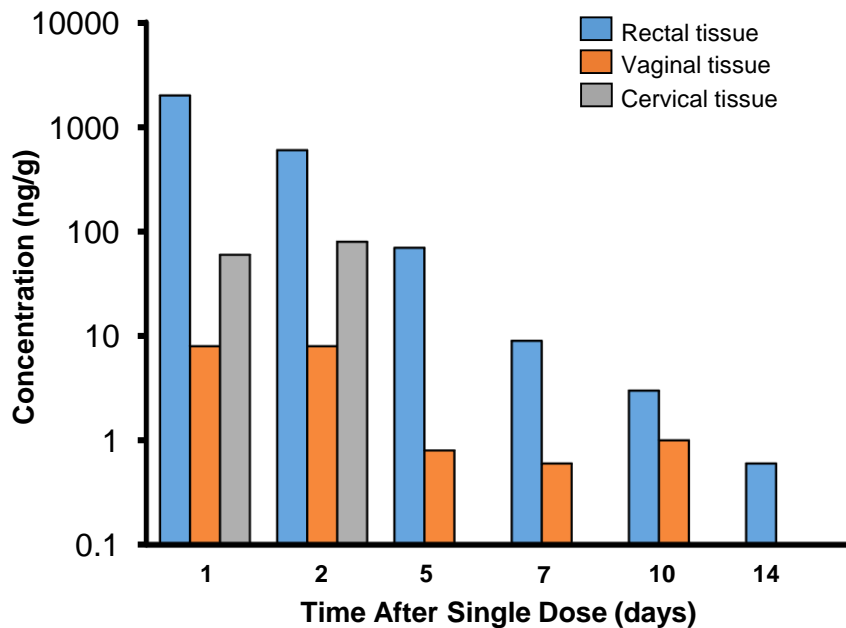


DAILY PrEP WORKS IF PATIENTS USE IT...

Study	Efficacy overall	Drug detected overall	Estimated Risk reduction with drug detection
MSM and Transgender Women (iPrEx)	42%	~50%	92%
Heterosexual Serodiscordant Couples (Partners PrEP)	67-75%	82%	90% (FTC/TDF) 86% (TDF)
Heterosexual Men and Women (TDF2)	62%	80%	78%
Persons who Inject Drugs (Bangkok Tenofovir Study)	49%	N/A	74%
Young Women (Fem-PrEP)	No efficacy	26%	“adherence too low to assess efficacy”
Young Women (VOICE)	No efficacy	29%	“ ”

PrEP and women :Varying Concentrations in Mucosal Tissues and Adherence Complicate Efficacy

Tenofovir DF



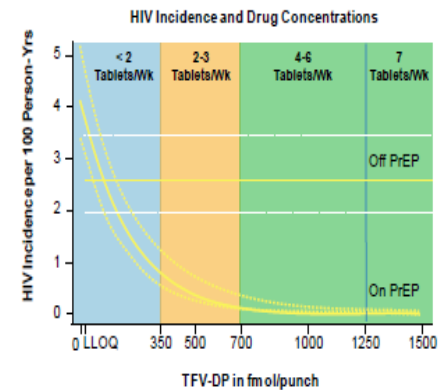
Open-label, 14-day pharmacokinetic study in HIV-negative female (n=7) and male (n=8) volunteers. Entry criteria included: 18-50 years of age; BMI 18-30 kg/m²; weight ≥50 kg; no HCV or HBV; nonpregnant women who were premenopausal and had regular menstrual cycles.

Patterson KB, et al. *Sci Transl Med.* 2011;3:112re4.

iPrEX OLE: PrEP Reduces Incidence of HIV Even With Incomplete Adherence

Slide 8 of 31

- Open-label extension of iPrEX trial; N = 1603 (75% receiving PrEP)
- 100% adherence was not required to attain full benefit from PrEP
- Benefit of 4-6 tablets/wk similar to 7 tablets/wk
- 2-3 tablets/wk also associated with significant risk reduction
- Higher levels of sexual risk taking at baseline associated with greater adherence to PrEP



Grant R, et al. IAC 2014. Abstract TUAC0105LB.
Grant R, et al. *Lancet Infect Dis.* 2014;14:820-829.

Slide credit: clinicaloptions.com

Harder for women...

“PrEP”CEPTION

Effects of Antiretroviral Therapy to Prevent HIV Transmission to Women in Couples Attempting Conception When the Man Has HIV Infection — United States, 2017

John T. Brooks, MD¹; Jennifer F. Kawwass, MD^{2,3}; Dawn K. Smith, MD¹; Dmitry M. Kissin, MD^{2,3}; Margaret Lampe, MPH¹; Lisa B. Haddad, MD^{2,3}; Sheree L. Boulet, DrPH²; Denise J. Jamieson, MD^{2,3}

WOMEN MAY BE AT HIGHER RISK OF INFECTION DURING CONCEPTION, PREGNANCY, AND BREASTFEEDING

- Biological Susceptibility
 - Elevated hormonal levels associated with cervical inflammation
 - Untreated STI's associated with cervical inflammation
 - Changes in the vaginal microbiome associated with inflammation
 - Nutritional deficiency and lowered immunity
- Behavioral exposure
 - Behavior changes in women and male partners during the pregnancy and postpartum period
 - Less condom use



SOME SUGGESTION OF IMPROVED ADHERENCE DURING THIS HIGH RISK TIME

PrEP : First do no harm...



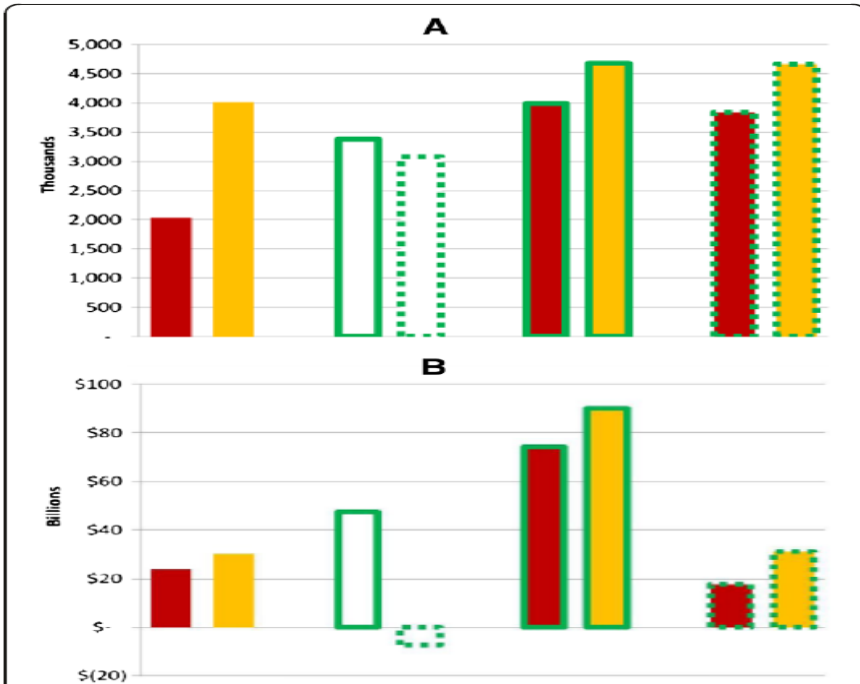
- Evidence from HIV negative pregnant women taking PrEP
 - No significant differences in maternal and infant outcomes
 - (In Partners Prep they had to discontinue taking prep when found to be pregnant but had taken it early on)
 - Evidence from HIV negative pregnant women taking TDF to treat HBV
- Evidence from HIV positive pregnant women on ARV's
 - Data on TDF or TDF/FTC during pregnancy and breastfeeding, even early on in pregnancy show no increased concerns.
 - TDF/FTC levels in breast milk: Very low levels (approx .3-2% of treatment levels)
 - Interaction with hormonal contraception?
 - Decline in bone density and renal function
 - Resistance in new infections
 - Risk compensation

Other Concerns

Cost-effectiveness : It depends...

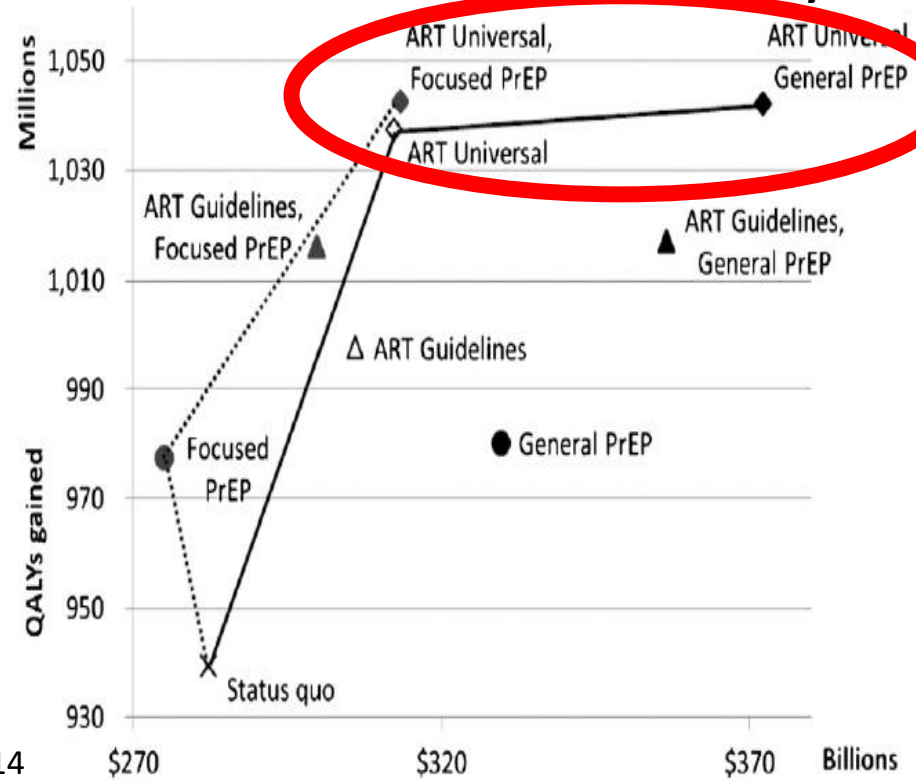


INFECTIONS AVERTED AND INCREMENTAL COST



ALISTAR ET AL, BMC MEDICINE, 2014

QALY VS TOTAL COST OVER 20 years



“PERFECT IS THE ENEMY OF THE GOOD”



- **Adherence Matters!!!** -Voltaire
- Women at high HIV risk are often medically underserved
- Recognize “seasons of risk”
- Should be part of a Comprehensive Package
 - Access encourages accessing all sexual health services
 - more equitable access will reduce future treatment costs
 - Decrease stigma by promoting prep as a positive choice
 - Careful monitoring will identify new infections and hopefully get them c



• Questions for the Future:



- We need episodic dosing or more forgiving regimens, combination topical and oral
- How long will PrEP remain effective in a population?(adherence fatigue, population resistance, menopause)
- What effect does PrEP have on risk taking in the future?
- Revisit cost effectiveness in the era of U=U

• **DEVELOPING SERVICES THAT ARE SUITED TO YOUNG PEOPLE IS ESSENTIAL FOR SUCCESS.**

WHY SHOULD MEN BE THE ONLY ONES WITH THE LITTLE BLUE PILLS ?



GET INFORMED.
MAKE THE RIGHT
CHOICE FOR YOU.



VOTE YES TODAY... !