PREP AND PEP

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- The CME planning committee, Osteopathic Founders Foundation and Saint Francis Health System CME departments have reviewed and resolved all conflicts of interest.

LEARNING OBJECTIVES

- To review non-occupational post-exposure prophylaxis guidelines
- To review occupational post-exposure prophylaxis guidelines
- To review pre-exposure prophylaxis guidelines
- To review the DISCOVER trial Week 96 results



Aidsinfo.nih.gov

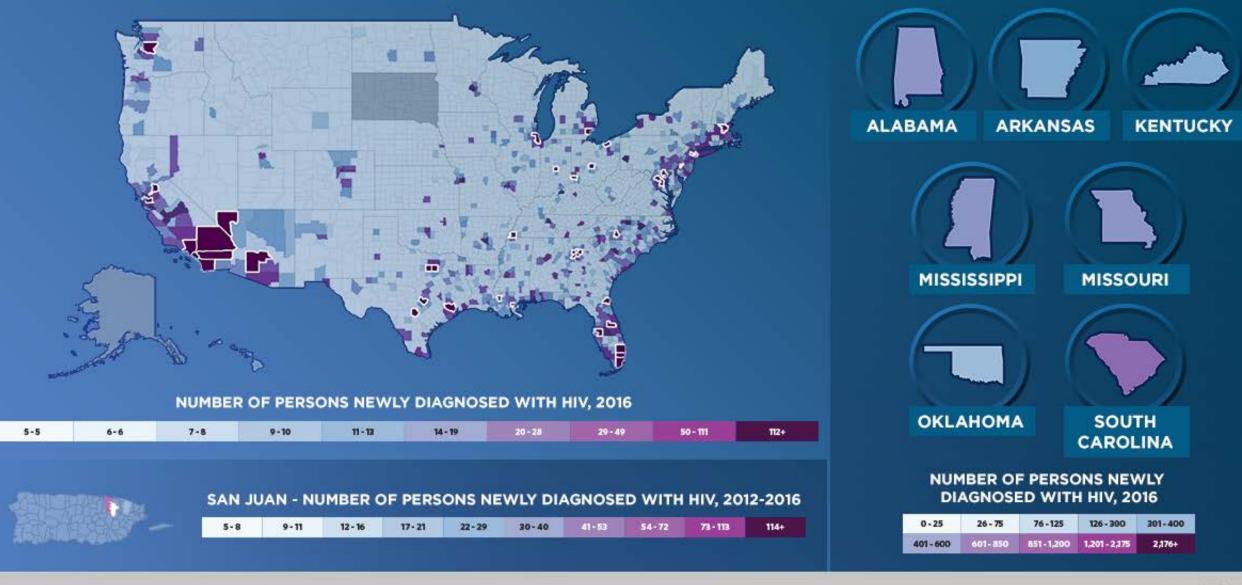
PrEP and PEP are methods for preventing HIV infection that involve taking HIV medicines. When you take steps to protect yourself against a disease, like HIV, it's called prophylaxis.

PrEP and PEP are for people who don't have HIV, but are at risk of getting it.



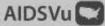
Ending the HIV Epidemic: A Plan for America

48 Highest Burden Counties + DC + San Juan + 7 States with Substantial Rural HIV Burden



AIDSVu.ORG

SOURCE: U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION



Key Strategies from Ending the HIV Epidemic: A Plan for America



DIAGNOSE

all individuals with HIV as early as possible after infection.



TREAT

the infection rapidly and effectively after diagnosis, achieving sustained viral suppression.

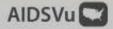
PREVENT

new HIV transmissions by using proven interventions, including pre-exposure prophylaxis (PrEP) and syringe services programs (SSPs).



RESPOND

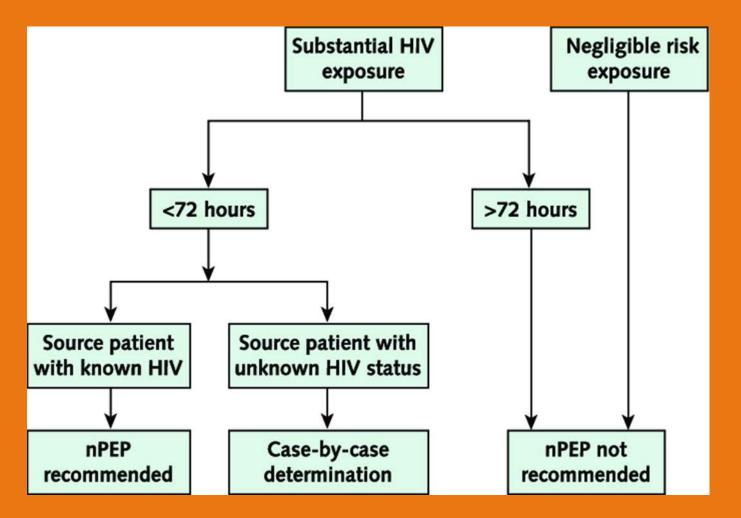
rapidly to detect and respond to growing HIV clusters and prevent new HIV infections.



NON-OCCUPATIONAL POST-EXPOSURE PROPHYLAXIS (nPEP)

<u>NPEP</u>

- Within 72 hrs of exposure
- With substantial risk of HIV
 - Source with known HIV
 - Body fluid
 - Exposure site



EVALUATION

- HIV testing
- Hepatitis B & C
- Other STI's
- HCG
- Creatinine
- AST/ALT

Table 1. Estimated per-act risk for acquiring HIV from an infected source, by exposure act

Exposure type	Rate for HIV acquisition per 10,000 exposures
Parenteral Blood transfusion Needle sharing during injection drug use Percutaneous (needlestick)	9,250 63 23
Sexual Receptive anal intercourse Receptive penile-vaginal intercourse Insertive anal intercourse Insertive penile-vaginal intercourse Receptive oral intercourse Insertive oral intercourse	138 8 11 4 Low Low
Other* Biting Spitting Throwing body fluids (including semen or saliva) Sharing sex toys	Negligible Negligible Negligible Negligible

*HIV transmission through these exposure routes is technically possible but unlikely and not well documented.

Notes: Factors that may increase the risk of HIV transmission include sexually transmitted diseases, acute and late-stage HIV infection, and high viral load. Factors that may decrease the risk include condom use, male circumcision, antiretroviral treatment, and pre-exposure prophylaxis. None of these factors are accounted for in the estimates presented in the table.

Source: Centers for Disease Control and Prevention¹

NPEP 28-DAY REGIMEN

Preferred (adults with CrCl >59)

- Tenofovir (TDF)300mg/Emtricitabine 200mg (Truvada) once daily
- + Dolutegravir (Tivicay) 50mg once daily or Raltegravir (Isentress) 400mg BID

	and the second	
	PRESCRIBING POST-EXPOSURE PROPHYLAXIS (PEP) Three antiretroviral drugs are recommended for PEP regimen:	
t t	Tenofovir DF (300mg)/Emtricitabine (200mg) daily + Raltegravir 400mg BID OR Tenofovir DF (300mg)/Emtricitabine (200mg) daily + Dolutegravir 50mg daily	
	 Potential HIV exposure within past 72 hours and patient has not taken PrEP for past 7 days Provide 28-day supply of PEP, and then transition to only PrEP There is no evidence that PEP "masks" HIV seroconversion 	
int.	• There is no evidence that PEP "masks" HIV seroconversion	

NPEP 28-DAY REGIMEN

• Alternative

- Tenofovir (TDF)300mg/Emtricitabine 200mg (Truvada) once daily
- + Darunavir (Prezista) 800mg and ritonavir (Norvir) 100mg once daily with food

• If CrCl < 60

- Use both zidovudine and lamivudine renally dosed instead of tenofovir TDFemtricitabine (Truvada) in the above regimens
- Risk reduction
- PrEP following nPEP



OCCUPATIONAL POST-EXPOSURE PROPHYLAXIS (PEP)

Preferred HIV PEP Regimen

US PUBLIC HEALTH SERVICE GUIDELINE

Updated US Public Health Service Guidelines for the Management of Occupational Exposures to Human Immunodeficiency Virus and Recommendations for Postexposure Prophylaxis

PEP is now recommended for ALL occupational exposures to HIV!

Raltegravir (Isentress: RAL) 400 mg PO twice daily Plus Truvada, 1 PO daily (Tenofovir [Viread; TDF] 300 mg + emtricitabine [Emtriva; FTC] 200 mg) Follow-Up Counseling and Monitoring for Occupational Postexposure Prophylaxis

Early Reevaluation after Exposure (within 72 hours)

Regardless of whether a health care provider is taking postexposure prophylaxis, reevaluation of exposed health care provider within 72 hours after exposure is strongly recommended, as additional information about the exposure or source person may be available.

Follow-up Testing and Appointments

Follow-up testing at a minimum should include the following:

- □ HIV testing at 6 weeks, 12 weeks, and 6 months after exposure; alternatively, if the clinician is certain that an HIV-1/2 antigen—antibody immunoassay is being utilized, then HIV testing could be performed at baseline, 6 weeks after exposure, and 4 months after exposure. HIV testing results should preferably be given to the exposed health care provider at face-to-face appointments.
- Complete blood counts (2 weeks after exposure; further testing may be indicated if abnormalities are detected)
- Renal and hepatic function tests (2 weeks after exposure; further testing may be indicated if abnormalities are detected)



LINICIAN CONSULTATION CENTER ational rapid response for HIV management and bloodborne pathogen exposures.

The Clinician Consultation Center is a free telephone advice service for clinicians by clinicians. Receive expert clinical advice on HIV, hepatitis C, substance use, PrEP, PEP, and perinatal HIV.

See <u>nccc.ucsf.edu</u> for more information.

HIV/AIDS Warmline 800-933-3413	Perinatal HIV Hotline 888-448-8765	
HIV treatment, ARV decisions,	Pregnant women with HIV or at-risk	
complications, and co-morbidities	for HIV & their infants	
Hepatitis C Warmline 844-HEP-INFO	PrEPline 855-HIV-PrEP	
844-437-4636	Pre-exposure prophylaxis for persons	
HCV testing, staging, monitoring, treatment	at risk for HIV	
Substance Use Warmline 855-300-3595 Substance use evaluation and management	PEPline 888-448-4911 Occupational & non-occupational exposure management	

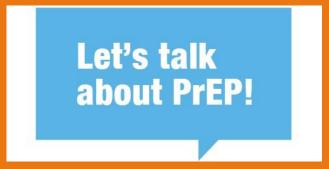
THIS VISIT WAS FOR AN STI...

THE NEXT COULD BE FOR HIV

Truvadahcp.com







PRE-EXPOSURE PROPHYLAXIS





Recommendation Summary

Population	Recommendation	Grade (What's This?)
Persons at high risk of HIV acquisition	The USPSTF recommends that clinicians offer preexposure prophylaxis (PrEP) with effective antiretroviral therapy to persons who are at high risk of HIV acquisition.	A

WHAT IS PREP?

- Pre-exposure prophylaxis
- Tenofovir disoproxil fumarate-emtricitabine (TDF-FTC)/Truvada
- Tenofovir alafenamide-emtricitabine(TAF-FTC)/Descovy
- Nucleoside reverse transcriptase inhibitors (NRTI)
- Prevents HIV-1 from replicating as it enters the body
- Helps prevent the virus from establishing permanent infection











PrEP Recommendations: Daily Use vs On-Demand Use

United States

CDC^[1]

- Recommended for daily use only
- Not recommended as coitally timed or other noncontinuous use

FDA^[2]

 TDF/FTC indicated for PrEP once daily

European Union^[3]

- Recommended for daily use
- Optional recommendation for on-demand use for high-risk MSM
- On-demand use: 2-1-1 dosing
 - Double dose before sex,
 1 dose 24 hrs after first dose,
 - 1 dose 48 hrs after first dose

IAS-USA^[4]

- Recommended for daily use
- Optional recommendation for on-demand use for MSM with infrequent sex

CANDIDATES FOR PREP

- At substantial risk of HIV acquisition and 1 of the following:
 - Sexually-active adult MSM (men who have sex with men) IA
 - Sexually-active adult heterosexual men and women IA
 - Adult persons who inject drugs (PWID) IA
- Uninfected partner in HIV-discordant couples during conception and pregnancy – IIB
- Insufficient data in adolescents IIIB

SUBSTANTIAL RISK OF HIV ACQUISITION

- HIV-positive sexual partner
- Recent bacterial STI/sexually transmitted infection (syphilis, gonorrhea, chlamydia)
- High number of sex partners
- History of inconsistent or no condom use
- Commercial sex work
- PWID who have HIV-positive injecting partner(s)
- PWID who are sharing injecting equipment



TABLE. CDC Criteria for PrEP Use ⁶				
TARGET POPULATION	MEN WHO HAVE SEX WITH MEN	HETEROSEXUAL MEN AND WOMEN	PEOPLE WHO INJECT DRUGS	
Substantial risk factors for acquiring HIV infection (if at least 1 is present, PrEP should be considered)	 Sexual partner with HIV Recent bacterial STI Inconsistent condom use Commercial sex work 	 Sexual partner with HIV Recent bacterial STI Inconsistent condom use Commercial sex work Residence in high- prevalence area or sexual network 	 HIV-positive injection partner Sharing of injection equipment Recent drug treatment (but currently injecting) 	
Clinical eligibility	 Documented negative HIV test before PrEP prescription No signs/symptoms of acute HIV infection Normal renal function 			

CDC indicates US Centers for Disease Control and Prevention; PrEP, pre-exposure prophylaxis; STI, sexually transmitted infection. Adapted from CDC's Preexposure Prophylaxis for the Prevention of HIV Infection in the United State—2017 Update.⁶

Identifying eligible patients

CDC guidance document¹

- Ask questions about sexual and injecting risk taking
- Clues: recent STIs or pregnancy in the past 6/12

BOX A1: RISK BEHAVIOR ASSESSMENT FOR MSM³⁶

In the past 6 months:

- Have you had sex with men, women, or both?
- (if men or both sexes) How many men have you had sex with?
- How many times did you have receptive anal sex (you were the bottom) with a man who was not wearing a condom?
- How many of your male sex partners were HIV-positive?
- (if any positive) With these HIV-positive male partners, how many times did you have insertive anal sex (you were the top) without you wearing a condom?
- Have you used methamphetamines (such as crystal or speed)?

May be difficult for patients to provide Box A2: RISK BEHAVIOR ASSESSMENT FOR HETEROSEXUAL MEN AND WOMEN

questions?

- Risk of disappointing doctors/ losing
- Risk of criminal liability in some jurisc

1.CDC PrEP for prevention of HIV in the United States, 2014 Clinical Practice Guideline

In the past 6 months:

- Have you had sex with men, women, or both?
- (if opposite sex or both sexes) How many men/women have you had sex with?
- How many times did you have vaginal or anal sex when neither you nor your partner wore a condom?
- How many of your sex partners were HIV-positive?
- (if any positive) With these HIV-positive partners, how many times did you
 have vaginal or anal sex without a condom?

BOX B1: RECOMMENDED INDICATIONS FOR PREP USE BY MSM²

- Adult man
- Without acute or established HIV infection
- Any male sex partners in past 6 months (if also has sex with women, see Box B2)
- Not in a monogamous partnership with a recently tested, HIV-negative man

AND at least one of the following

- Any anal sex without condoms (receptive or insertive) in past 6 months
- A bacterial STI (syphilis, gonorrhea, or chlamydia) diagnosed or reported in past 6 months

BOX B3: RECOMMENDED INDICATIONS FOR PREP USE BY INJECTION DRUG USERS

- Adult person
- Without acute or established HIV infection
- Any injection of drugs not prescribed by a clinician in past 6 months

AND at least one of the following

- Any sharing of injection or drug preparation equipment in past 6 months
- Been in a methadone, buprenorphine, or suboxone treatment program in past 6 months
- Risk of sexual acquisition (also evaluate by criteria in Box B1 or B2)

BOX B2: RECOMMENDED INDICATIONS FOR PREP USE BY HETEROSEXUALLY ACTIVE MEN AND WOMEN

- Adult person
- Without acute or established HIV infection
- Any sex with opposite sex partners in past 6 months
- Not in a monogamous partnership with a recently tested HIV-negative partner

AND at least one of the following

- Is a man who has sex with both women and men (behaviorally bisexual) [also evaluate indications for PrEP use by Box B1 criteria]
- Infrequently uses condoms during sex with 1 or more partners of unknown HIV status who are known to be at substantial risk of HIV infection (PWID or bisexual male partner)
- Is in an ongoing sexual relationship with an HIV-positive partner
- A bacterial STI (syphilis, gonorrhea in women or men) diagnosed or reported in past 6 months

ASSESSMENT OF RISKS

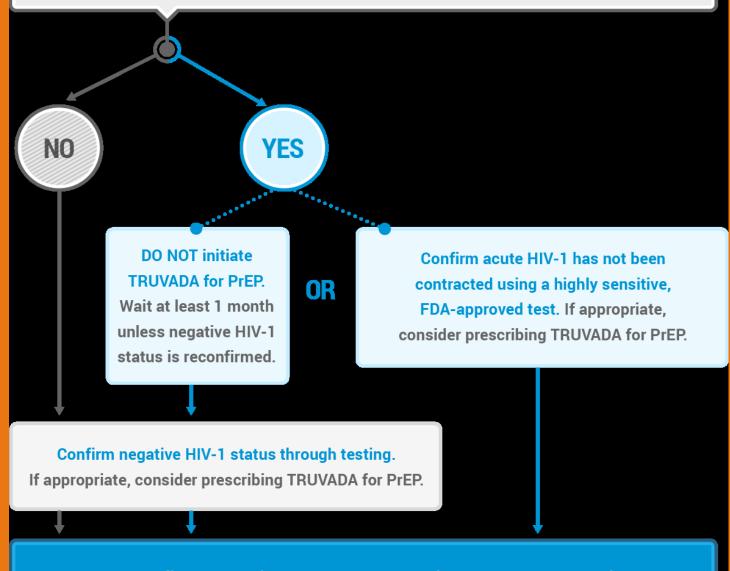
- HIV testing negative and no signs of acute HIV
- Renal function
 - eGFR > 60
- Hepatitis B status negative and vaccinated
- Hepatitis C status (esp PWID and MSM)
- Sexually transmitted infections (syphilis and gonorrhea, chlamydia if MSM)
- Pregnancy

ACUTE HIV INFECTION

- Within 1-2 months
- Flu-like illness
 - Fever
 - Rash
 - Headache
 - Lymphadenopathy
 - Diarrhea
 - Fatigue
 - Myalgias
 - Night sweats



Are there signs or symptoms of acute HIV-1 infection, OR is recent exposure (<1 month) to HIV suspected?



Re-confirm negative HIV-1 status at least every 3 months.

TIME TO ACHIEVING PROTECTION

- Time from initiation of PrEP to maximal protection against HIV is unknown
- Pharmacokinetics of TDF and FTC vary by tissue
- Preliminary data to achieve steady state and maximum intracellular concentrations of tenofovir diphosphate
 - Blood: ~20 days
 - Rectal tissue: ~7 days
 - Cervicovaginal tissues: ~20 days
 - Penile tissues: no data

PRESCRIPTION

- Tenofovir disoproxil fumarate-emtricitabine (TDF-FTC)/Truvada
- Tenofovir alafenamide-emtricitabine (TAF-FTC)/Descovy
 - Indicated for MSM or transgender women only (excludes receptive vaginal sex)
- Once daily
- No food requirements
- Dispense 90-day supply
- Renew only after HIV testing is negative

Co-pay card program

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HV CO-PVP ASSISTANCE PROGRAM INSTRUCTIONS

Gilead Sciences HIV Co-Pay Assistance Program

What is the Eliesd HIV En-Pay Assistance Program?

B is a program to belg people pay for Elited NF medicities. – The Galaci HB Co-Pay Program covers up to \$250 per mentils for 1 year on-year prescriptions. for these HB medicines. TVE232* Institution/administration/acceleric disaprend fearmate). BURY 24: Introduction/data/acceleric disaprend fearmate).

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MONITORING

- Follow up appt in 1 month and q 3 months
- Labs q 3 months
 - HIV testing
 - Serum creatinine (CMP)
 - Every 6 months
 - Every 3 months if renal risks
 - HCG test
 - STI testing (GC/CL, RPR)
- Re-assessment q 12 months for need for PrEP

Recommended Laboratory Testing and Frequency for Patients Taking PrEP				
Laboratory test	Baseline	At least every 3 months	At least every 6 months	Notes
HIV screening assay	\checkmark	\checkmark		Consider need for HIV RNA PCR
HBV (panel [#]) and HCV antibody	\checkmark			Offer HBV vaccination if not immune
Serum creatinine	\checkmark		\checkmark	^CrCl decrease may require stopping PrEP
STI testing	\checkmark	\checkmark	\checkmark	Include oral/rectal screen for MSM if risk
Pregnancy test for women*	\checkmark	\checkmark		Safety of PrEP in pregnancy not known

Abbreviations: eCrCl = estimated creatinine clearance; STl = sexually transmitted infections #Includes HBsAg, anti-HBc, and anti-HBs

^Do not start tenofovir DF-emtricitabine if CrCl <60 mL/min; do not start tenofovir alafenamide-emtricitabine if CrCl <30 mL/min

*For women who may become pregnant

COUNSELING



- Medication dosage and schedule
- Potential side effects
- Adherence and efficacy
 - Anal: minimum 4 doses per week for efficacy
 - Vaginal: 6-7 doses per week for efficacy
- Reduction of barriers to adherence
- Education on symptoms of acute HIV
- Risk reduction behaviors (condoms, other STIs, sharing needles)

PERSONS WITH NEW HIV INFECTION

- Confirmatory HIV testing
- CD4, HIV viral load, genotypic HIV resistance
- Convert PrEP to an HIV regimen without awaiting lab results
- Refer to HIV Specialist
- Counseling for their HIV status and risk management
- Notify local health dept for confidential partner notification and testing



Prep Efficacy Trials

Study Name	Population	N	Results	Efficacy By Detection of Drug
Partners PrEP	Heterosexual couples	4,758	TDF: 67% efficacy FTC/TDF: 75% efficacy	86% 90%
TDF2 Study	Heterosexual Men and Women	1,219	FTC/TDF: 62% efficacy	85%
iPrEx	MSM/trans women	2,499	FTC/TDF: 44% efficacy	92%
FEM-PrEP	Women	1,951	FTC/TDF: futility	NR
VOICE	Women	5,029	TDF, TDF/FTC, Vaginal TFV gel: futility	NR
Thai IVDU	IVDU	2,413	TDF: 49% efficacy	74%

Kahle E, et al. 19th IAC; Washington, DC; July 22-27, 2012; Abst. TUAC0102.



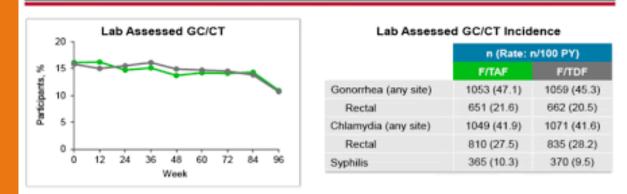
www.croiconference.org

Introduction

- The DISCOVER study (ClinicalTrials.gov NCT02842086) is an ongoing Phase 3, randomized, controlled trial evaluating the efficacy and safety of F/TAF for PrEP among cisgender men and transgender women who have sex with men (MSM, TGW) at high risk of HIV infection
- Interim data analysis was conducted when 100% of participants completed Week 48 and 50% completed Week 96, and demonstrated that¹:
 - F/TAF was noninferior to F/TDF in preventing HIV infection
 - Both drugs were well tolerated, with low rates of AE-related discontinuations
 - F/TAF had significantly better bone and renal safety outcomes vs F/TDF
- Here we present longer term results conducted after all participants completed the Week 96 visit

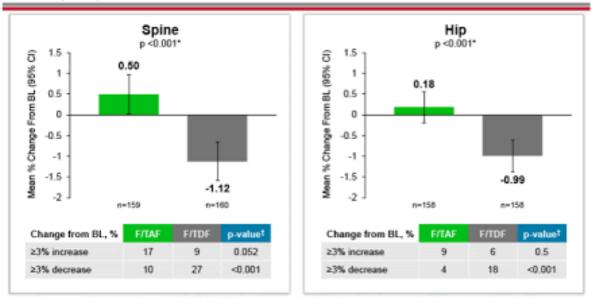


DISCOVER Sexually Transmitted Infections Through Week 96



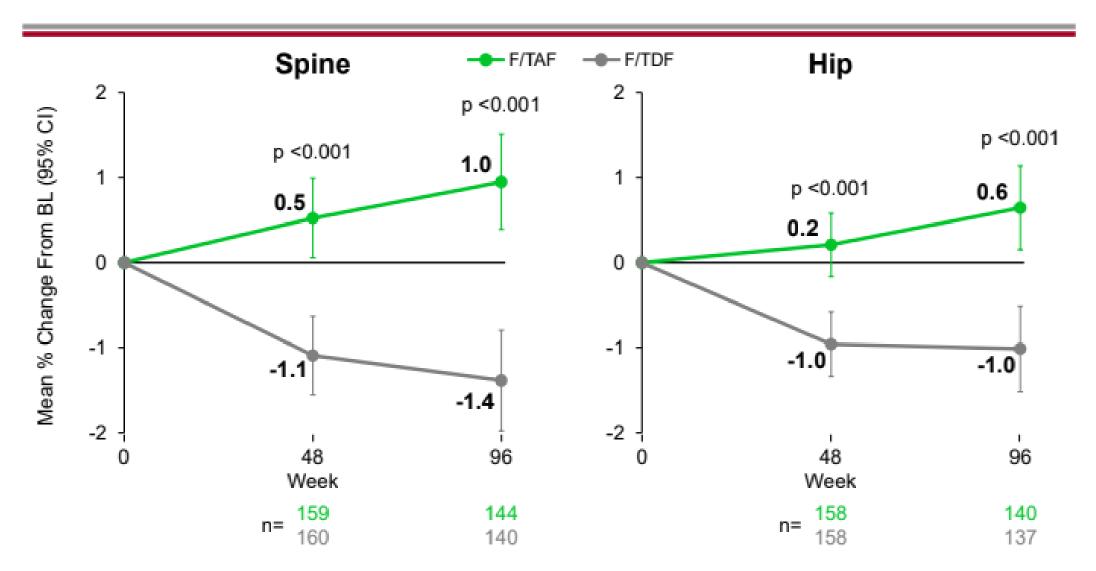
- · Incidence of gonorrhea, chlamydia, or syphilis while on study (based on AE reporting)
 - F/TAF = 145.1/100 PY
 - F/TDF = 138.8/100 PY

Bone Safety at Week 48: Bone Mineral Density Sub-study (n=383) Secondary Endpoint



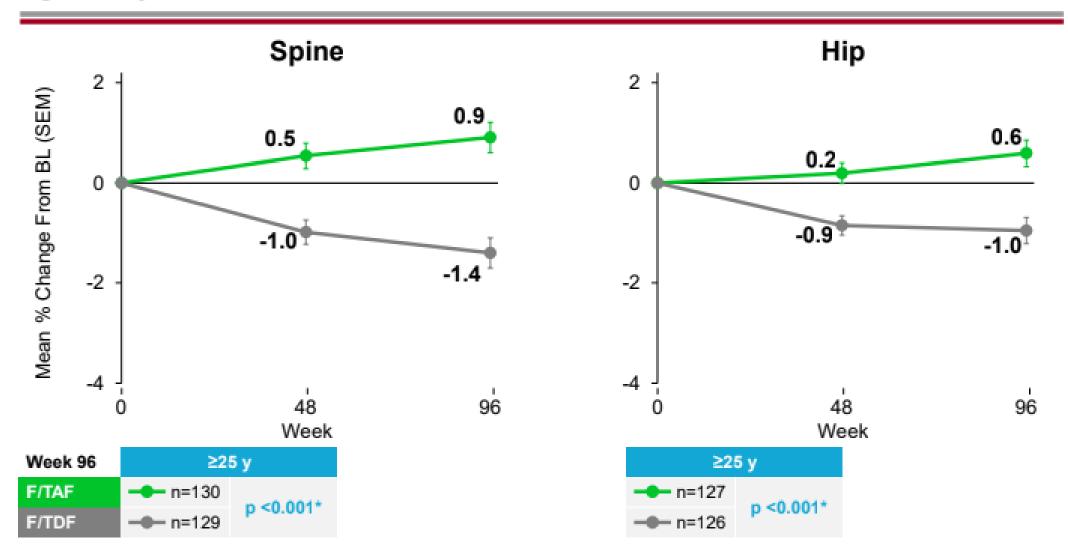
'p-values from analysis of variance model with baseline F/TDF for PrEP and treatment as fixed effects, 'p-value was based on a dichotomized response (ie, >3% vs <3%) from Cochran-Mantel-Haenszei test for nominal data (general association statistic) adjusting for baseline F/TDF for PrEP. BL, baseline.

Bone Safety: BMD Substudy (n=375)*



Bone Safety: BMD Substudy (n=375)*

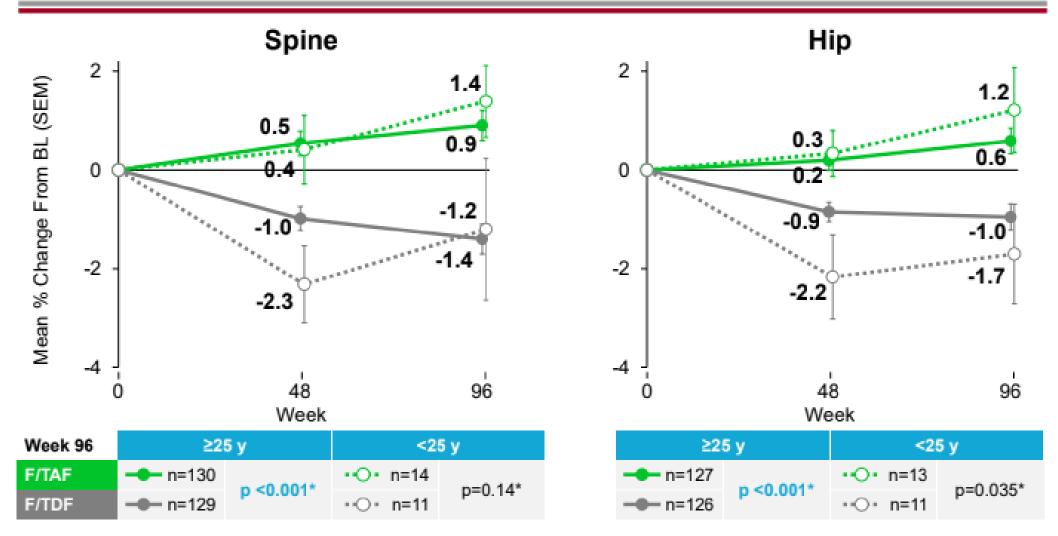
Aged ≥25 y



*p-values from analysis of variance model with BL F/TDF for PrEP and study arm as fixed effects. SEM, standard error of mean.

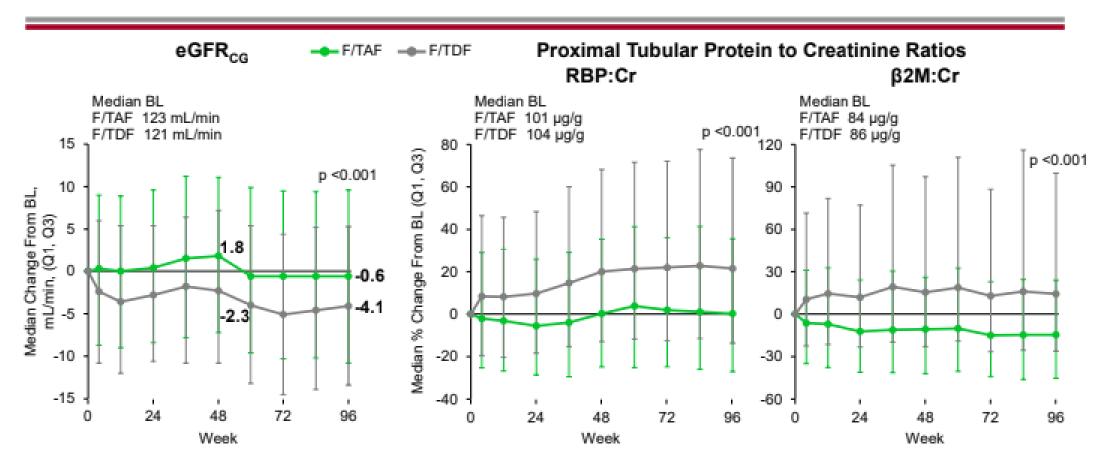
Bone Safety: BMD Substudy (n=375)*

Aged ≥ and <25 y



*p-values from analysis of variance model with BL F/TDF for PrEP and study arm as fixed effects. SEM, standard error of mean.

Renal Safety

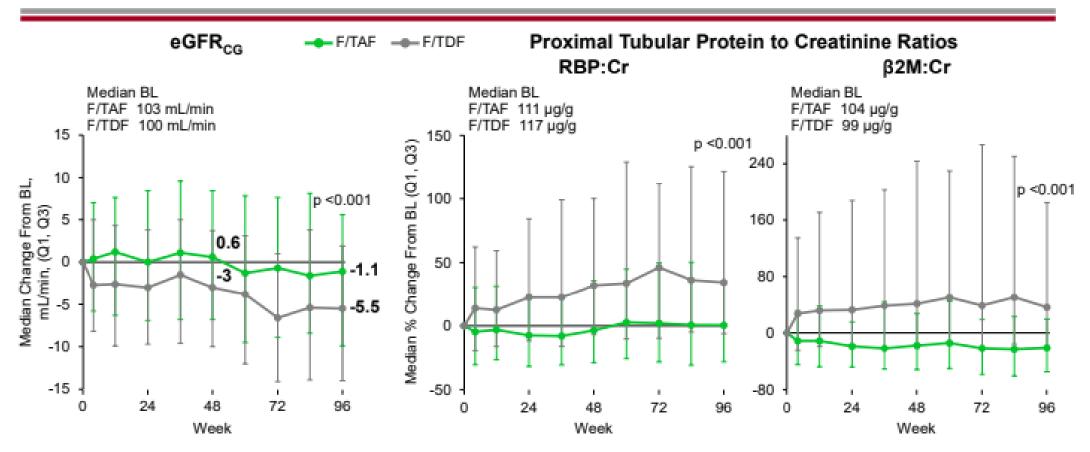


- Renal discontinuations: F/TAF, n=2; F/TDF, n=6
- Fanconi syndrome: F/TAF, n=0; F/TDF, n=1

*p-values from Van Elteren test stratified by BL F/TDF for PrEP to compare 2 study arms. β2M, β2-microglobulin; Cr, creatinine; Q, quartile; RBP, retinol-binding protein.

Renal Safety

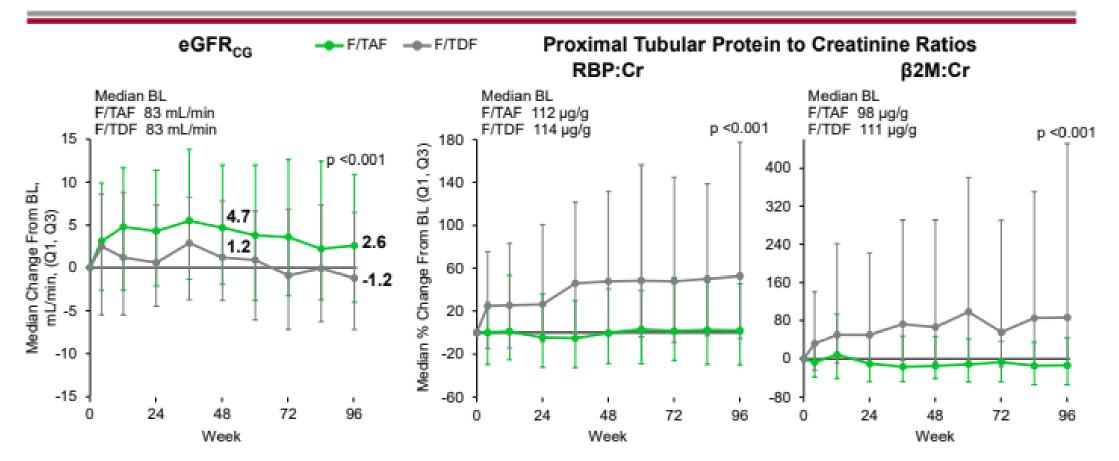
Aged ≥50 y



Renal discontinuations: F/TAF, n=0; F/TDF, n=3

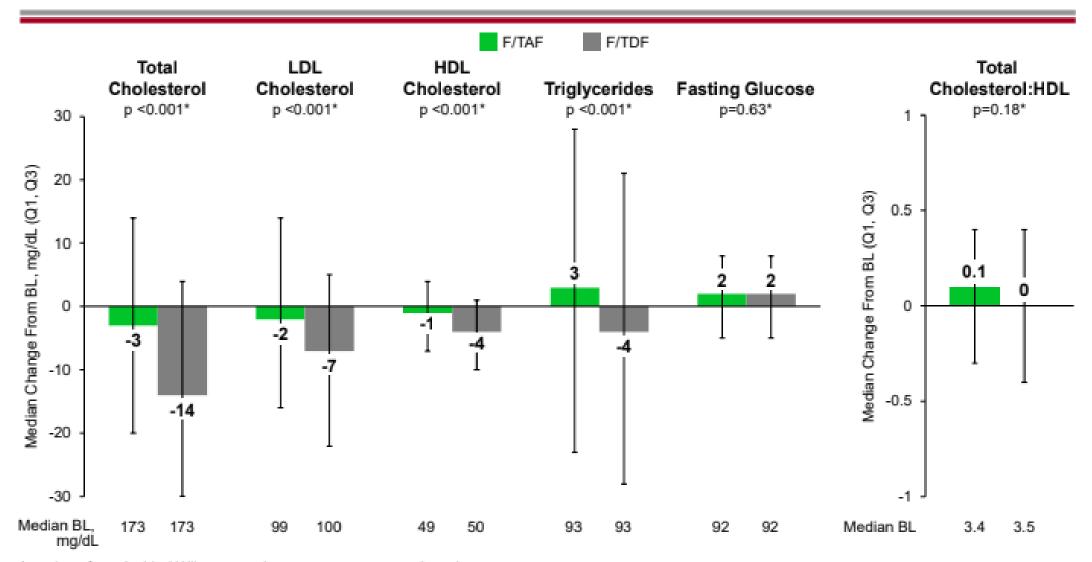
Renal Safety

BL eGFR 60-≤90 mL/min



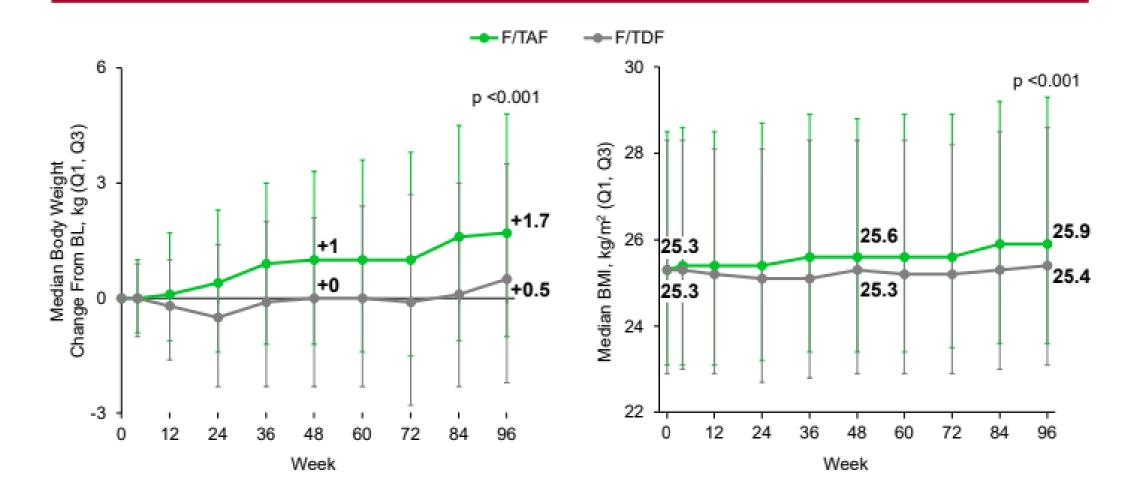
Renal discontinuations: F/TAF, n=0; F/TDF, n=4

Fasting Lipids and Glucose at Week 96



*p-values from 2-sided Wilcoxon rank sum test to compare 2 study arms.

Body Weight and BMI



p-values for changes from baseline from analysis of covariance model including BL F/TDF for PrEP and study arm as fixed effects and BL body weight or body mass index (BMI) as a covariate.

Conclusions

- F/TAF remained noninferior to F/TDF for HIV PrEP through 96 weeks
- DISCOVER provides the largest, single variable comparison of bone and renal safety parameters between TAF and TDF in the absence of underlying HIV or third antiretroviral agents:
 - Differences in BMD between F/TAF and F/TDF increased at week 96; BMD declines of ≥3% were more common in participants taking F/TDF, with more pronounced differences in younger participants
 - Renal biomarker changes remained more favorable in participants taking F/TAF, including in older participants and those with reduced eGFR
- F/TDF was associated with greater declines in both LDL and HDL but total cholesterol: HDL ratios or fasting glucose remained similar across both study arms at 96 weeks.
- Weight gain was observed in both arms at 96 weeks, and was approximately 1kg greater in participants taking F/TAF. The weight gain in F/TAF arm was similar to that observed in the placebo arm of iPrEx PrEP trial and the general population^{1,2}
- F/TAF is a safe, longer term option for PrEP

1. Glidden DV, et al. Clin Infect Dis 2018;67:411-9. 2. Hill JO, et al. Science 2003;299:853-5.



LINICIAN CONSULTATION CENTER ational rapid response for HIV management and bloodborne pathogen exposures.

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HCV testing, staging, monitoring, treatment	at risk for HIV	
Substance Use Warmline 855-300-3595 Substance use evaluation and management	PEPline 888-448-4911 Occupational & non-occupational exposure management	

"It is frustrating to hear experts say that prescribing Truvada to someone could give them an unrealistic sense of safety from becoming HIV+. I'm sure that's true for some...but judging from my own REAL (not hypothetical) experience, it makes me more aware of the risks I'm taking. I am reminded of those risks on a daily basis, every time I open that bottle and swallow that blue pill. I don't take them lightly. If I did, I wouldn't go through the trouble of using Truvada."

Woman with HIV+ partner who started PrEP
 ecause they wanted to have a child



Thread reader



THREAD BY ADAM C LAKE MD (@ACLAKEMD)

Welcome to my first tweetorial! A patient comes in with an STI or asks for #PrEP. You test for #hiv, #hbv (vaccinate prn), round out the sti testing and get a BMP. Talk (safer) sex for a bit. You give them TDF/FTC #30 x2 refills (and unlimited condoms)....



Read all 16 tweets on threadreaderapp.com



RESOURCES

- aidsinfo.nih.org
 - PEP and PrEP guidelines
- AIDSVu.org
- croiconference.org
 - Onyema O, et al. CROI 2020, Longer Term Efficacy and Safety of F/TAF and F/TDF For HIV PrEP: DISCOVER Trial Week 96 Results.
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