

What if there were a pill that could help prevent HIV?

There is.

Ask your doctor if PrEP is right for you.

Pre-exposure prophylaxis: A daily pill to reduce risk of HIV infection

www.cdc.gov/hiv/basics/prep.html



Pre-Exposure Prophylaxis (PrEP) for HIV Infection

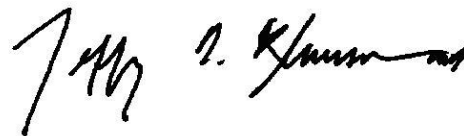
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Disclosures

- Dr. Klausner is a faculty member of the University of California Los Angeles
- Dr. Klausner is a guest researcher with the US CDC Mycotics Diseases Branch
- Dr. Klausner is a member of the WHO STD Guidelines group
- Dr. Klausner is a board member of YTH, Inc, non-profit
- Dr. Klausner is unpaid medical advisor for Healthvana.com
- In the past 12 months, Dr. Klausner and UCLA Regents have received:
 - Research funding, supplies or unrestricted gifts from the NIH, CDC, US Navy, Hologic, Gilead Sciences, Cepheid, Standard Diagnostics, MedMira, AIDS Healthcare Foundation, and Sentient Research



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Learning Objectives

- Increase participant's knowledge of the effectiveness and safety of Truvada for PrEP
- Enhance participant's capacity to identify those who would benefit from Truvada for PrEP
- Understand when to prescribe Truvada for PrEP and manage drug and behavioral side effects



Outline

- What is PrEP?
- How does it work?
- Is it safe?
- Offering PrEP
- Cases
- Resources

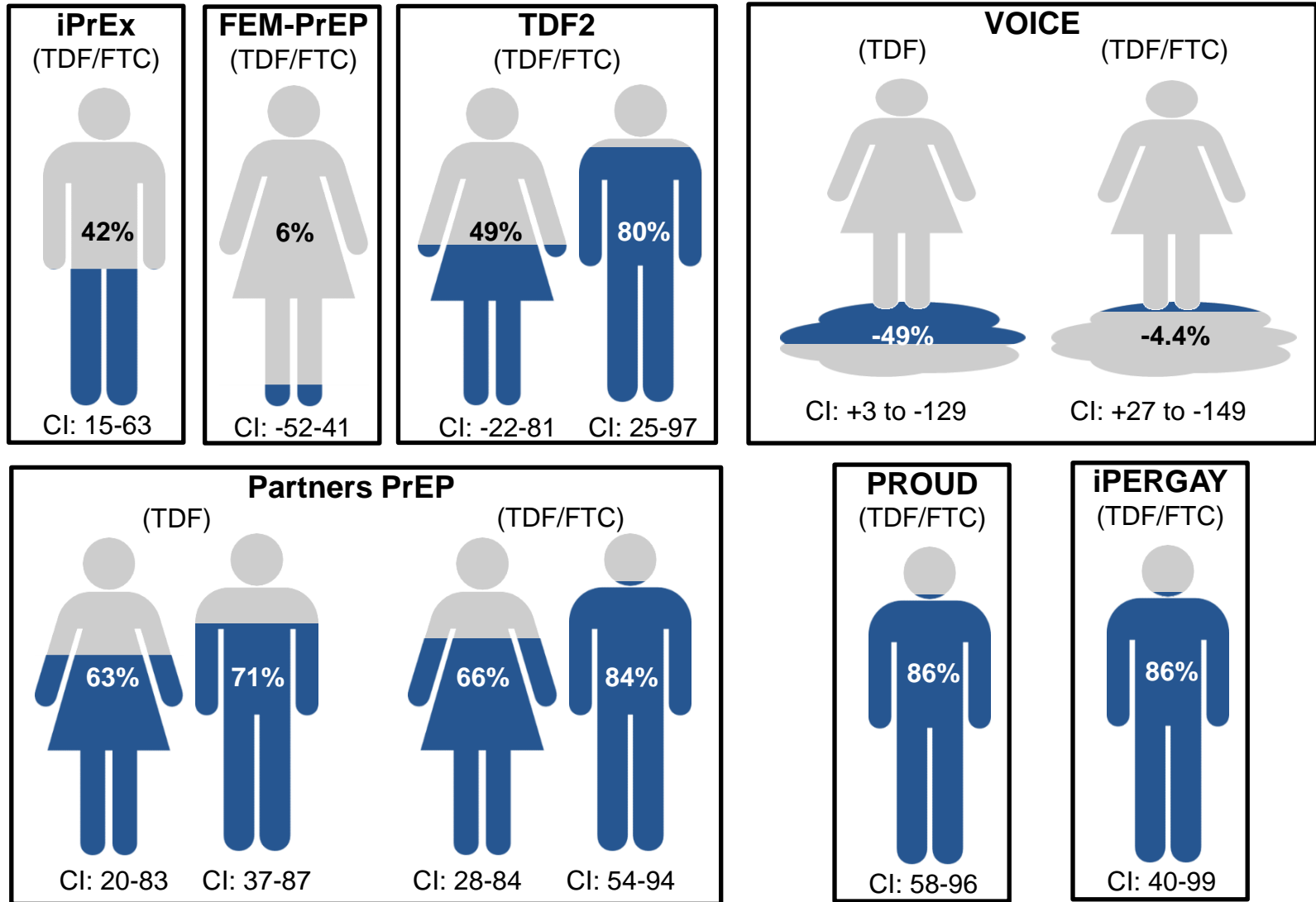


What is PrEP?

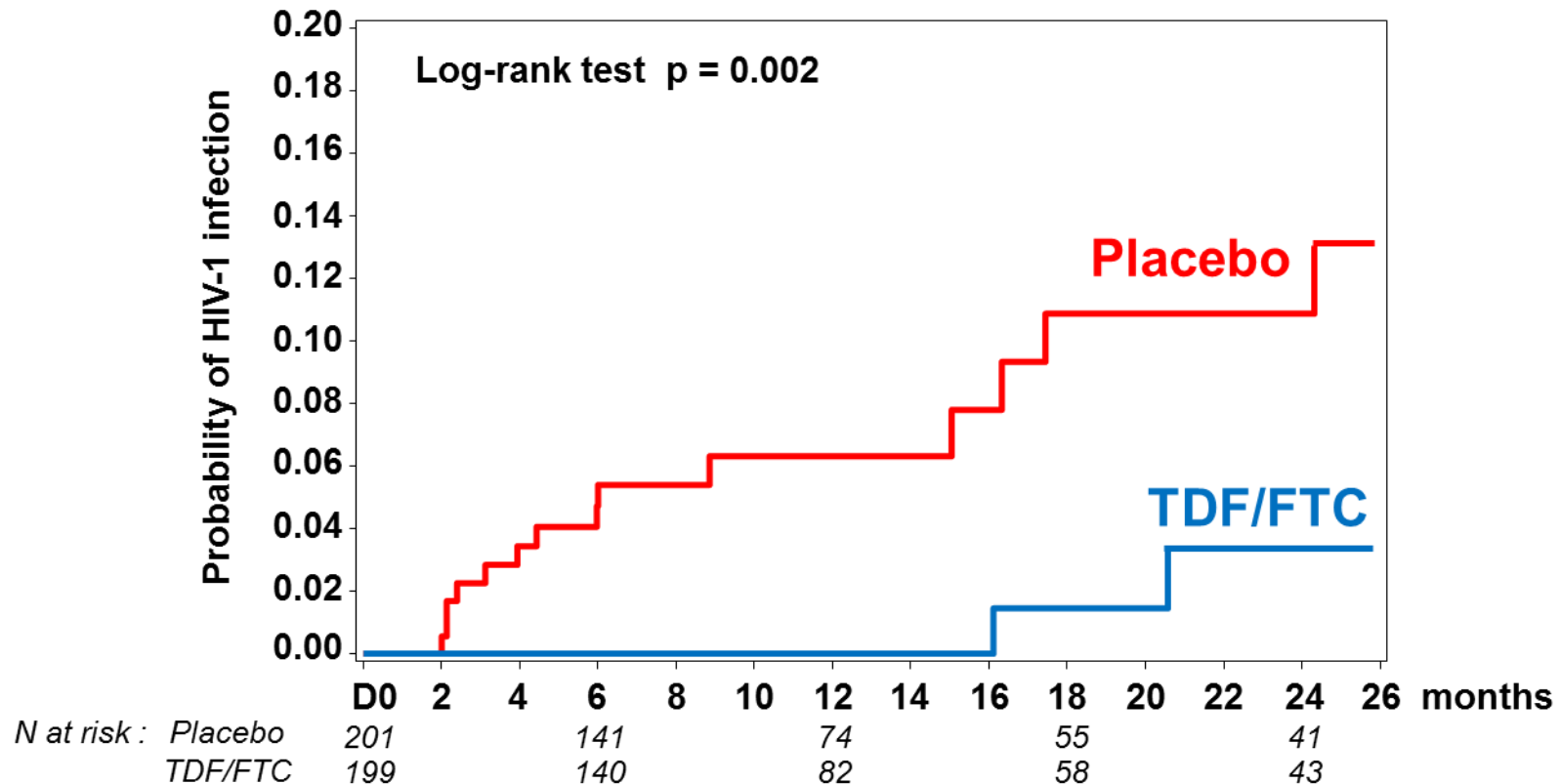
- Truvada (emtricitabine/tenofovir) (FTC-3TC)
- One pill, once a day
- FDA-approved, July 2012



Effectiveness of Truvada



Effectiveness in iPERGAY study



Mean follow-up of 13 months: 16 subjects infected

14 in placebo arm (incidence: 6.6 per 100 PY), **2 in TDF/FTC arm** (incidence: 0.94 per 100 PY)

86% relative reduction in the incidence of HIV-1 (95% CI: 40-99, $p=0.002$)

NNT for one year to prevent one infection : 18

Safety of Truvada

- Clinical
 - Mild short-term nausea +/- diarrhea (10%)
 - Decreased appetite + weight loss (5-10%)
 - Reversible small decrease in bone density (1%)
 - Reversible small decrease in kidney function (0.5%)
- Sexual health
 - Decrease in condom use
 - Increase in syphilis and rectal gonorrhea and chlamydia



Key Steps in a PrEP Program

- Identify the population at risk – young men who have sex with men, men who have sex with men of color, men who have sex with men attending STD clinics, sex workers, sex partners of injection drug users
- Identify the clinical setting for care
- Assemble a multi-disciplinary team—medical provider (MD, NP, PA), social worker, phlebotomist, other health workers
- Create protocols for inclusion, exclusion, quarterly follow-up and testing (clinical and STD)
- Educate and outreach to target community
- Enrollment—informed consent
- Adherence support—e.g., OregonReminders.org
- Monitoring and evaluation



Identify those at HIV risk

- **Men who have sex with men**
 - Ask every man if they have had sex with men, women or both in past 12 months
 - If sexually active with men, ask about types of partnerships, relationships and HIV status of partners:
 - Steady, main partner
 - If has main partner, ask about monogamy or sexual agreement
 - Regular, occasional partners
 - Casual, anonymous partners
 - Ask about where he meets partners—clubs, online, etc.
 - Any exchange of money/drugs for sex



CDC Recommended Indications for PrEP Use by Men who have Sex with Men

- Adult man
- Without acute or established HIV infection
- Any male sex partners in past 6 months (if also has sex with women, see heterosexual criteria)
- 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
- Any STI diagnosed or reported in past 6 months
- Is in an ongoing sexual relationship with an HIV-positive male partner

CDC 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 MSM 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 (IDU or bisexual male partner)
- Is in an ongoing sexual relationship with an HIV-positive partner



CDC 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

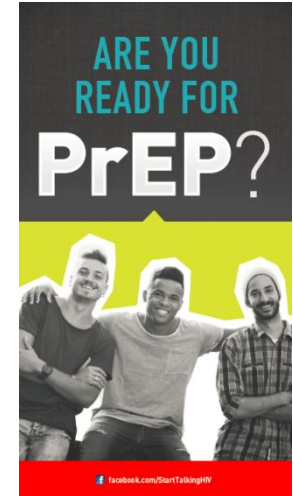
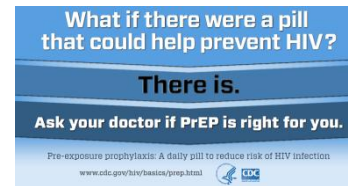
AND at least one of the following

- 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 MSM and heterosexual criteria)



Clinical setting and team

- Routine primary care
 - Create PrEP friendly environment
 - Use CDC infographics
- PrEP champion
- Add tools into e-health system
 - Best practice advisories
 - Patient self-completed risk assessment
- Social worker or benefits expert



Typical Clinical Evaluation

- Baseline
 - 4th generation HIV Ab/Ag or HIV RNA testing
 - STI screening for syphilis, rectal chlamydia, gonorrhea and pharyngeal gonorrhea
 - Hepatitis B & C screening
 - HBV vaccine if negative
 - Kidney function testing
 - Pregnancy test
- Every 3 month follow-up
 - HIV testing
 - Pregnancy test
 - STI screening for syphilis, rectal chlamydia, gonorrhea and pharyngeal gonorrhea
 - Kidney function testing (at 3 months then 6-monthly)
 - Bone scan not recommended



Prescribe Truvada

- Truvada 1 tab daily by mouth, #30, refills x 2
- Follow-up visit at 1 month to review dosing, adherence, side-effects
- Manage other interventions, vaccinations, etc.
- Risk-reduction counseling
 - How do you keep yourself at low risk from STIs?
 - Any substance use issues?
 - How does substance use impact sexual behavior?
 - Identify a concrete step to reduce risk



Medication Assistance

- Gilead will provide Truvada for PrEP at no cost for individuals who qualify for the assistance program (< 500% poverty level)
- Gilead will provide Co-Pay assistance for insured patients

Program Element	Truvada PrEP Medication Assistance Program
Eligibility Criteria	US resident, uninsured or no drug coverage, HIV-negative, low income
Drug Fulfillment	Product dispensed by Covance Specialty Pharmacy, labeled for individual patient use and shipped to prescriber (30 day supply); no card or voucher option
Recertification Period	6 months, with 90 day status check

www.start.truvada.com



Programmatic Support

CDC

Gilead

US Public Health Service

PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES - 2014

A CLINICAL PRACTICE GUIDELINE



Preexposure Prophylaxis for the Prevention of HIV Infection in the United States - 2014 Clinical Practice Guideline

US PUBLIC HEALTH SERVICE

PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES - 2014

CLINICAL PROVIDERS' SUPPLEMENT



Preexposure Prophylaxis for the Prevention of HIV Infection in the United States - 2014 Clinical Providers' Supplement Page 1 of 40

Checklist for Prescribers: Initiation of TRUVADA® for Pre-exposure Prophylaxis (PrEP)

Instructions: Complete checklist at each visit and file in individual's medical record.

I have completed the following prior to prescribing TRUVADA for a pre-exposure prophylaxis (PrEP) indication for the individual who is about to start or is taking TRUVADA for a PrEP indication:

Lab Tests/Evaluation

- ☐ Completed high-risk evaluation of uninfected individual
- ☐ Confirmed a negative HIV-1 test immediately prior to initiating TRUVADA for a PrEP indication
- ☐ If a clinical syndrome consistent with acute viral infection are present and recent (< 1 month) exposure is suspected, delay starting PrEP for at least 1 month and retest HIV-1 status or use a test approved by the FDA as an aid in the diagnosis of HIV-1 infection, including acute or primary HIV-1 infection, then TRUVADA for a PrEP indication is contraindicated in individuals with unknown HIV-1 status or who are HIV-1 positive

Perform HIV screening test

- ☐ Confirmed estimated creatinine clearance (CrCl) > 40 mL/min prior to initiation and periodically during treatment to assess risk for renal dysfunction, assess estimated CrCl, serum phosphorus, serum glucose, and serum protein before initiation of TRUVADA and periodically while TRUVADA is being used. If a decrease in estimates is observed in uninfected individuals while using TRUVADA for a PrEP indication, evaluate potential causes at response potential risks and benefits of continued use
- ☐ Confirmed that the uninfected individual at high risk is not taking other HIV-1 medications or HIV medication
- ☐ Evaluated risk/benefit with women who may be pregnant or may want to become pregnant

Counseling/Follow-up

- ☐ Discussed known safety risks with use of TRUVADA for a PrEP indication
- ☐ Counselled on the importance of scheduled follow-up every 2 to 3 months, including regular HIV-1 screening at least every 2 months, while taking TRUVADA for a PrEP indication to monitor HIV-1 negative status
- ☐ Discussed the importance of discontinuing TRUVADA for a PrEP indication if seroconversion has occurred, to the development of resistant HIV-1 variants
- ☐ Counselled on the importance of adherence to daily dosing schedule
- ☐ Counselled that TRUVADA for a PrEP indication should be used only as part of a comprehensive prevention strategy
- ☐ Educated on practicing safer sex consistently and using condoms correctly
- ☐ Discussed the importance of and performed screening for sexually transmitted infections (STIs), such as syphilis and gonorrhea, that can facilitate HIV-1 transmission
- ☐ Discussed the importance of and performed screening for sexually transmitted infections (STIs), such as syphilis and gonorrhea, that can facilitate HIV-1 transmission
- ☐ Offered HIV vaccination as appropriate
- ☐ Provided education on where information about TRUVADA for a PrEP indication can be accessed
- ☐ Discussed potential adverse reactions
- ☐ Reviewed the TRUVADA Medication Guide with the uninfected individual at high risk

Truvada
emtricitabine/tenofovir disoproxil fumarate

GILEAD
Sciences

Individual Label

Agreement Form for Initiating TRUVADA® for Pre-exposure Prophylaxis (PrEP)

Individual Label

Instructions: Review form with an HIV-negative person who is about to start or is taking TRUVADA for a PrEP indication at each visit. File form in the person's medical record.

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. The following factors may help to identify individuals at high risk:

- Has partner(s) known to be HIV-1 infected, or
- Engages in sexual activity within a high prevalence area or social network and one or more of the following:
 - Inconsistent or no condom use
 - Diagnosis of sexually transmitted infections
 - Exchange of sex for commodities (such as money, shelter, food, or drugs)
 - Use of illicit drugs, alcohol dependence
 - Incarceration
- Partner(s) of unknown HIV-1 status with any of the factors listed above

Healthcare Provider Agreement

By signing below, I certify my understanding of the risks and benefits of TRUVADA for a PrEP indication and my obligation to the individual at high risk of HIV-1 infection.

HIV-Negative Person Agreement

By signing below, I acknowledge that I have taken with my healthcare provider about the risks and benefits of TRUVADA for a PrEP indication and my obligation to the individual at high risk of HIV-1 infection.

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Sciences

Truvada® for Pre-Exposure Prophylaxis (PrEP)
Medication Assistance Program

Application to be used for TRUVADA (emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) for PrEP only

Fax 1-855-330-5478 to begin enrollment

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CLEAR FORM

1 Applicant Information		ENGLISH	SPANISH	OTHER
Applicant Name: _____		Applicant Language: <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		
Address: _____				
City: _____ State: _____ Zip: _____ Phone #: (____) _____				
Social Security #: _____	MM DD YYYY	Gender: _____	Resides in U.S./A.L. territory: <input type="checkbox"/> M <input type="checkbox"/> F <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/>	
Primary Contact: _____ Relationship: _____ Phone #: (____) _____				
Applicant Financial Information				
Current Annual Household Income: \$ _____ Number in Household (select one): 1 2 3 4 5 6				
Please include current documentation for all sources of income (e.g., tax return, W2, last 2 pay stubs, etc.)				
<input type="checkbox"/> Applicant is insured (Please fill out all the applicable insurance information below. Attach copy front and back of applicant insurance card.)				
<input type="checkbox"/> Applicant is uninsured (No health insurance through any public or private payer). Complete "Additional Insurance Information" below.				
Primary Payer Name: _____ Is this a Medicare Part D plan? <input type="checkbox"/> YES <input type="checkbox"/> NO				
Plan Name: _____ Payer Phone #: (____) _____				
Subscriber Name: _____ Policy #: _____ Group #: _____				
<input type="checkbox"/> Check box if applicant has secondary insurance coverage and fax insurance cards, if available.				
Additional Insurance Information				
Has the applicant applied for Medicare Part D? <input type="checkbox"/> YES <input type="checkbox"/> NO				
If YES, date of application: _____				
If NO, provide reason: _____				
Has the applicant applied for Medicaid? <input type="checkbox"/> YES <input type="checkbox"/> NO				
If YES, date of application: _____				

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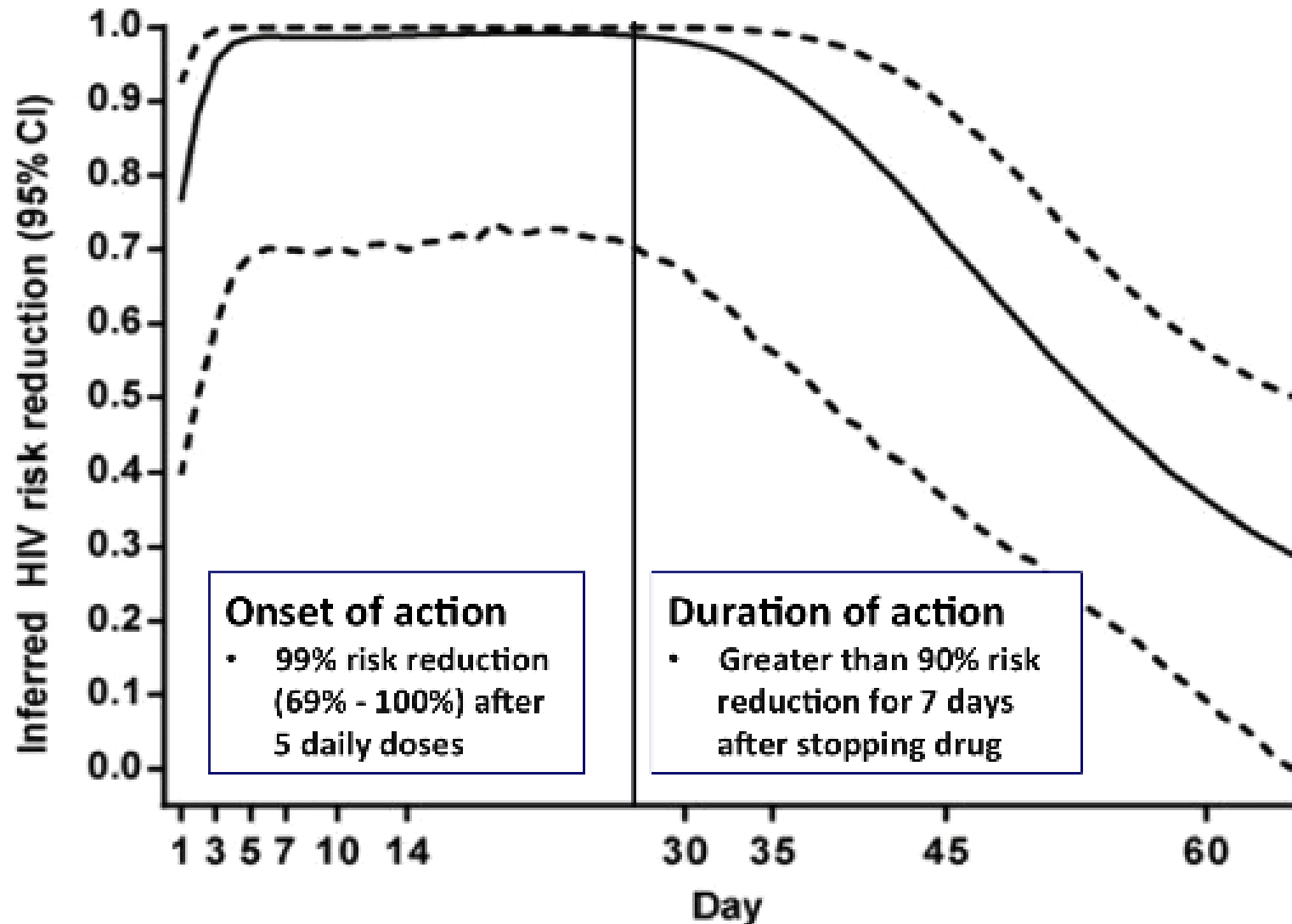
For inquiries, call TRUVADA for PrEP at 1-855-330-5479

Case 1

- 22 year old man, recent syphilis treatment, reports sex with other men
- Tested HIV-negative 2 months ago
- What additional history is needed?
- What tests are needed?
- Should Truvada for PrEP be prescribed?
- When will protection occur?



PK Insights to Guide Starting and Stopping PrEP (MSM)



Case 2

- 36 year old man with fever, chills, mild rash
- Reports condomless receptive anal sex 3 weeks ago at a sex club
- Interested in PrEP



Signs and symptoms of acute HIV

- Fever
- Rash
- Sore throat
- Headache
- Swollen glands
- Diarrhea



Source: www.etsu.edu

Truvada for PrEP and Resistance

TRIAL	RESISTANCE AMONG THOSE INFECTED AT ENROLLMENT	RESISTANCE AMONG THOSE INFECTED LATER IN THE STUDY
iPrex	1 of 8 in the placebo arm 2 of 2 in the PrEP arm	0 of 64 in the placebo arm 0 of 36 in the PrEP arm
Partners PrEP	0 of 6 in the placebo arm 2 of 8 in the PrEP arms	0 of 52 in the placebo arm 0 of 30 in the PrEP arms
TDF2	0 of 2 in the placebo arm 1 of 1 in the PrEP arm	1 of 24 in the placebo arm 0 of 9 in the PrEP arm
TOTAL	1 of 16 in placebo arms 5 of 11 in PrEP arms	1 of 140 in placebo arms 0 of 75 in PrEP arms

7 with resistance: 5 of 7 with HIV before starting Truvada

Case 3

- 42 year old woman with HIV-infected partner
- Partner's viral load is unknown
- Has condomless sex when he's in town
- Is Truvada for PrEP indicated?
- Risks vs. benefits?
- Baseline history and testing?



Future Directions—Long-Acting PrEP

Table 2. Summary of cabotegravir long-acting SHIV prevention results in nonhuman primate models

Species	Viral challenge route	SHIV162p3 challenge dose (TCID ₅₀)	Result (% protection)
Rhesus	Intrarectal	50	100
Rhesus	Intravaginal (with Depo)	300	90
Pigtail	Intravaginal	50	100

Clinical Resources

- Jeffrey D. Klausner, MD, MPH
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Online Resources

<https://start.truvada.com/>

www.truvadapreprems.com


www.cdc.gov/hiv/guidelines/preventing.html

www.projectinform.org/order/prepbooklets/

http://www.thebody.com/index/treat/tenofovir_prevention.html




<http://prepfacts.org/>

Where do you fit in?



Are you a guy who has sex with guys? **Are you a woman who has sex with guys?** **¿Habla usted español?**

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