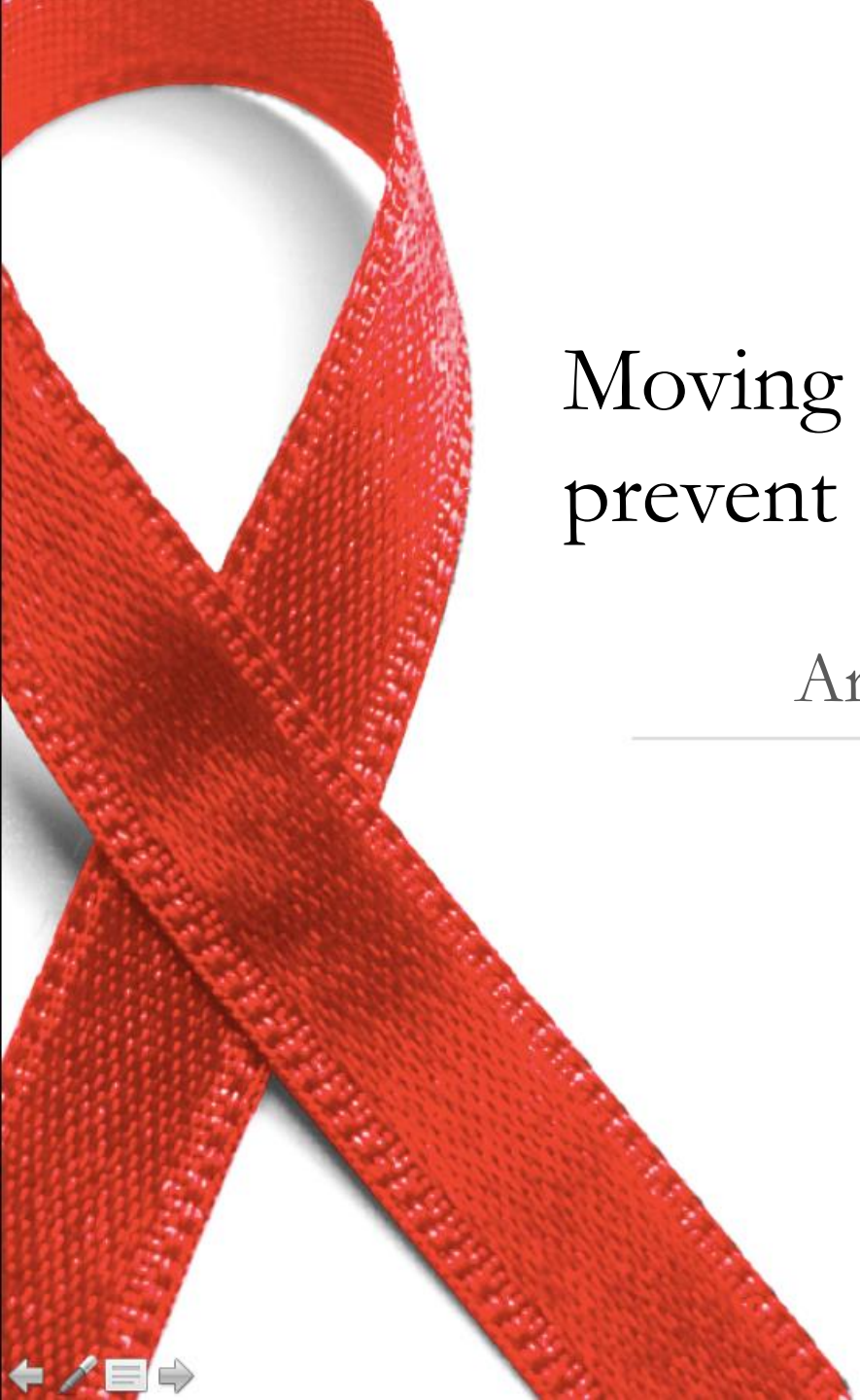


UNC SCHOOL OF MEDICINE

Moving beyond condoms to prevent HIV transmission

Are you Prepared for HIV PrEP?

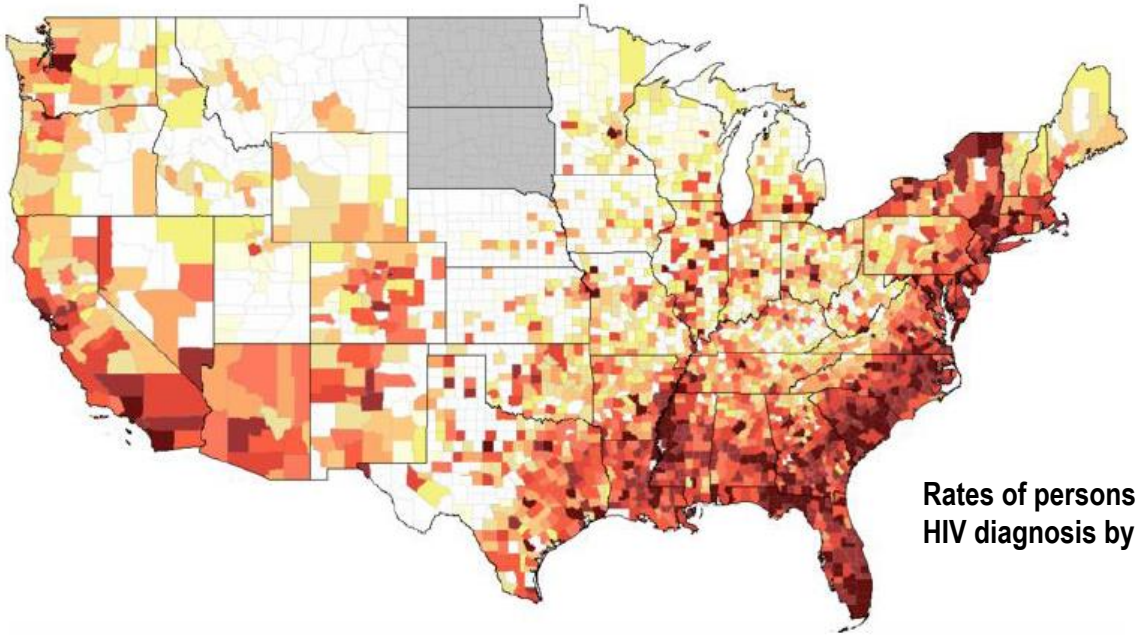
David Alain Wohl, MD
Associate Professor
Division of Infectious Diseases
UNC Chapel Hill

The Issues

- New HIV infections in the US continue
- Vast majority of infections are sexually acquired
- Condoms work but are not loved by all
- TDF/FTC PrEP has been demonstrated to be effective
- TDF/FTC PrEP is a reality
- How do we get PrEP to those who want it and can benefit from it

A Snapshot of HIV/AIDS in the United States

- Number of people living with HIV: 1.2 million
- Number of new infections: ~ 50,000 per year
- Percent of people who are infected and unaware: 14%



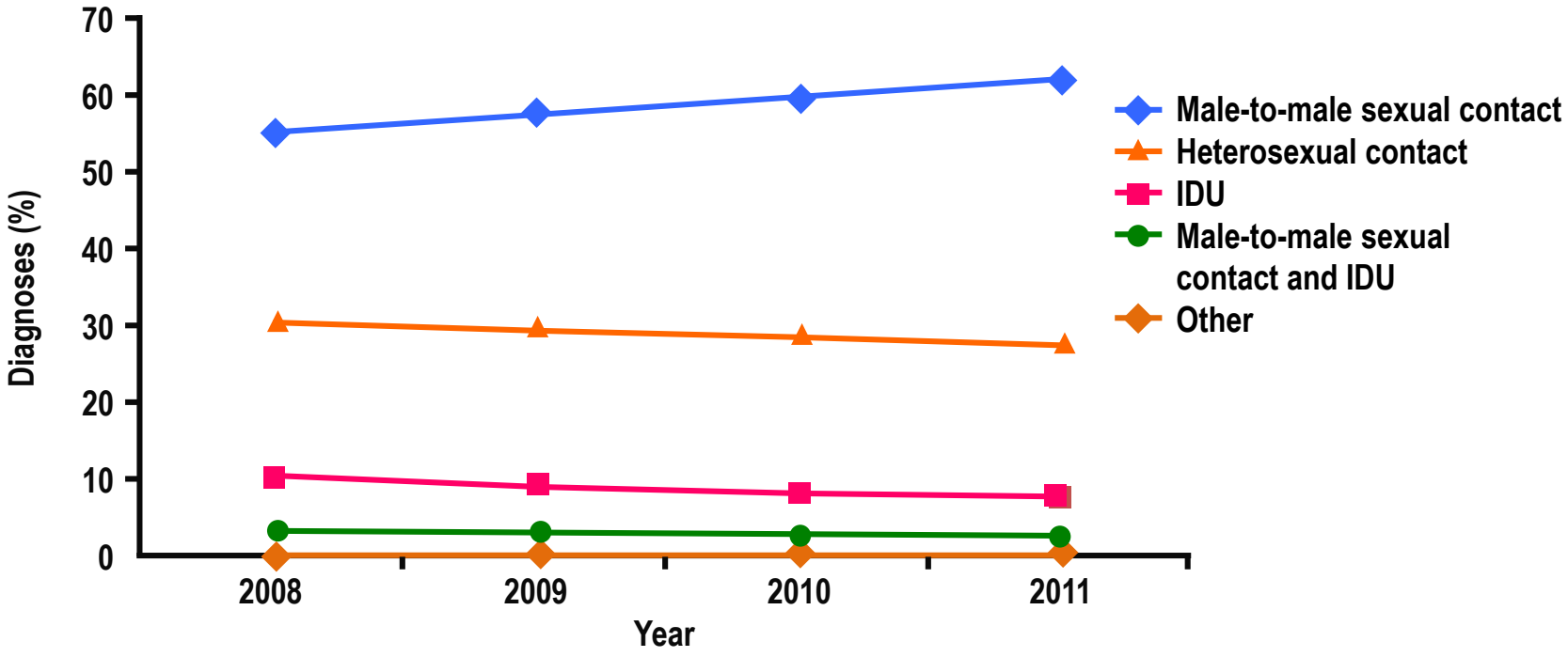
Rates of persons living with an HIV diagnosis by county, 2010

HIV = human immunodeficiency virus; AIDS = acquired immunodeficiency syndrome.

AIDSVu (www.aidsvu.org). Emory University, Rollins School of Public Health. Accessed 2/26/15;
Centers for Disease Control and Prevention (CDC). HIV in the United States: at a glance. www.cdc.gov/hiv/statistics/basics/ataglance.html. Accessed 2/26/15.

Current Prevention Methods Are Insufficient

Estimated New HIV Infections in the United States for the Most Affected Subpopulations (2008–2011)

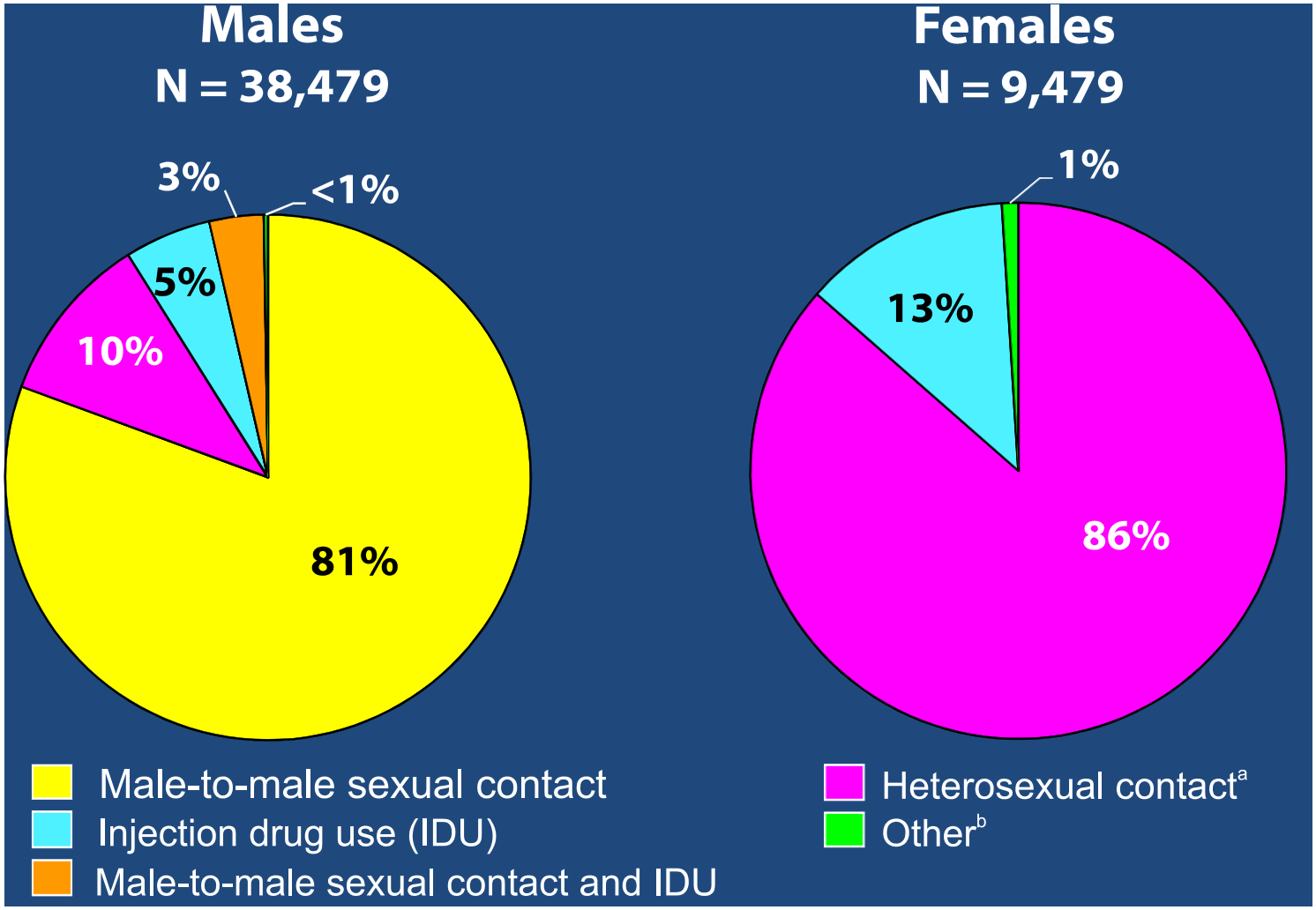


IDU = injection drug user.

CDC. HIV in the United States: 2013. www.CDC.gov. Accessed 2/26/15.

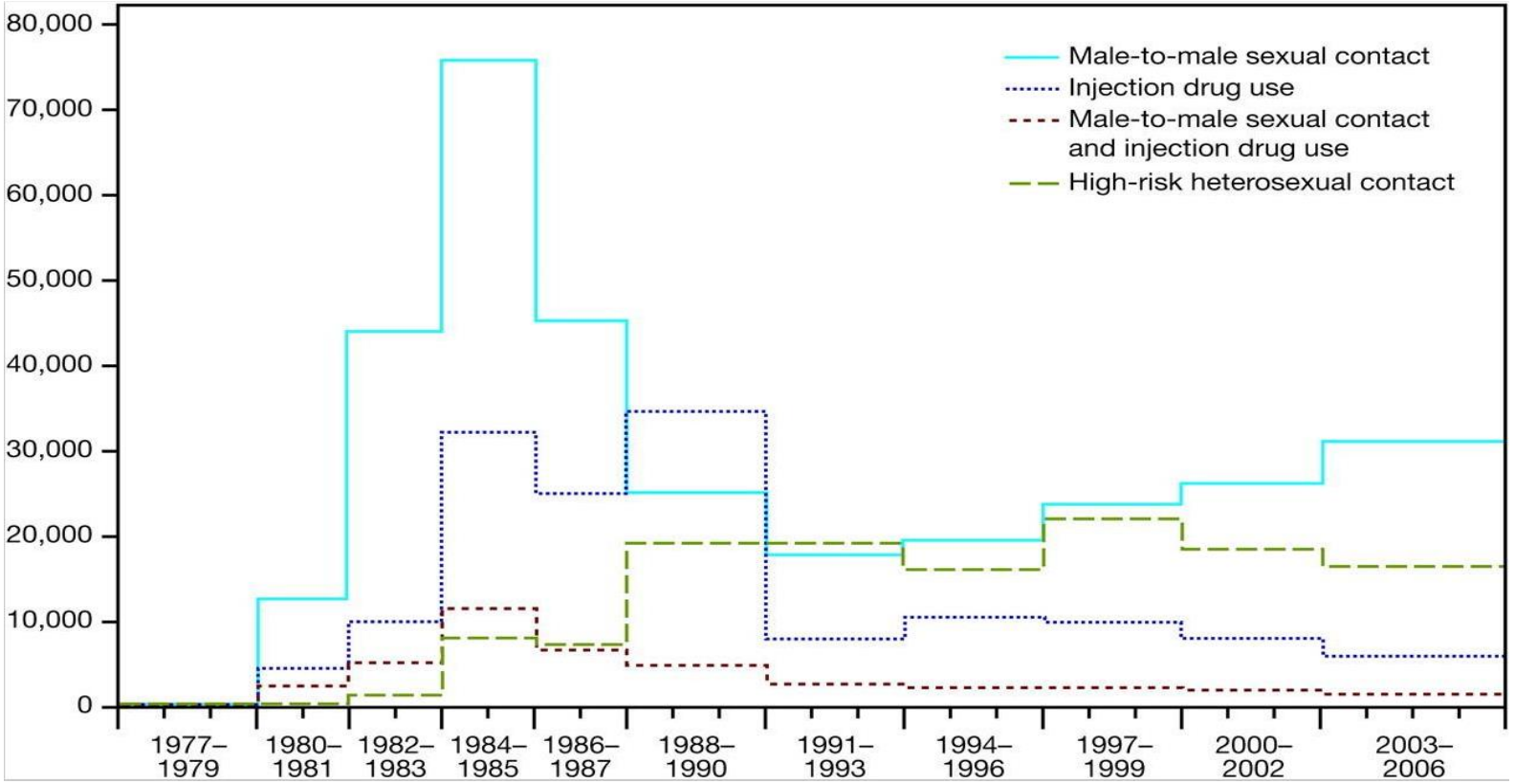
How are people getting HIV in the US?

CDC 2013 Surveillance data



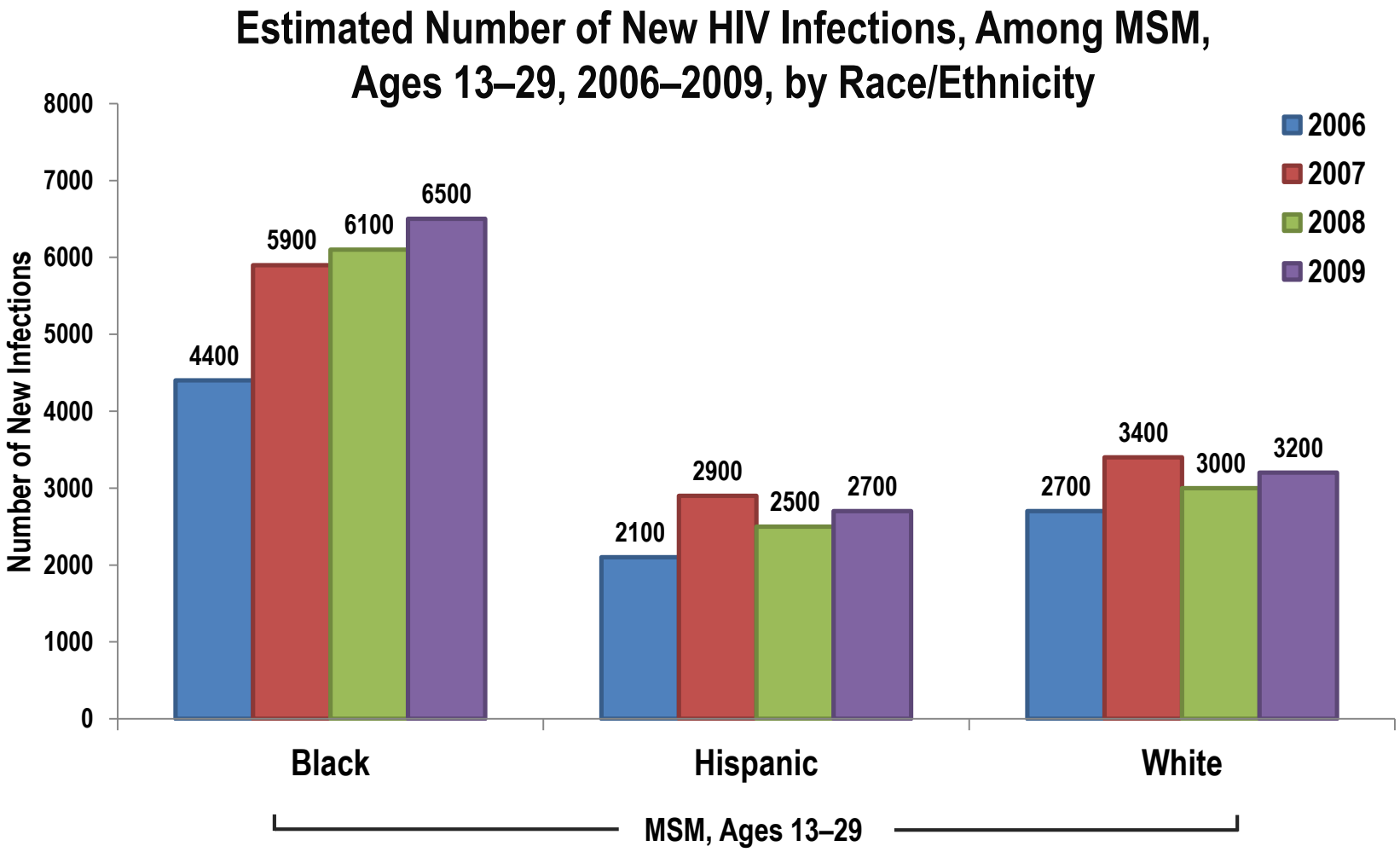
Current HIV Prevention Methods Are Insufficient

Estimated Number of New HIV Infections
Extended Back-Calculation Model, 1977–2006, by Transmission Category



Note: Estimates are for 2-year intervals during 1980–1987, 3-year intervals during 1977–1979 and 1988–2002, and 4-year interval for 2003–2006.
CDC Fact Sheet. Estimates of New HIV infections in the United States. Released August 2008.

Current Prevention Methods Are Insufficient (Cont.)



MSM = men who have sex with men.

CDC Fact Sheet. Estimates of New HIV Infections in the United States, 2006–2009. August 2011.

Multiple, proven prevention strategies

Evidence-Based HIV Prevention Strategies

- Condom access and distribution
- Health education and risk reduction counseling
- Needle and syringe exchange
- STI screening and testing
- HIV testing
- ART for prevention
- Post-exposure prophylaxis (PEP)
- Pre-exposure prophylaxis (PrEP)

What is PrEP?

Pre-exposure prophylaxis

Use of anti-HIV medications **before** an exposure, to reduce the risk of becoming infected

Tenofovir is the most studied agent for PrEP

- Pharmacokinetics allow infrequent dosing
- Few drug-drug interactions
- Safe and well tolerated
- Resistance less likely

CDC Guidance for Recommended Oral PrEP

Fixed-dose TDF/FTC is the recommended PrEP regimen* for MSM, heterosexually active men and women, and IDU who meet prescribing criteria:

- FDA approved indication
- Dosed as a single pill (300/200 mg) once daily

***MSM, heterosexually active men and women, and IDU who meet PrEP prescribing criteria.**

CDC. Pre-exposure Prophylaxis for the Prevention of HIV Infection in the United States: A Clinical Practice Guideline. May 2014. www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf. Accessed 2/26/15.

Concept rooted in 4 lines of evidence

Prophylactic use of anti-infectives

Concept rooted in 4 lines of evidence

Prevention of mother-to-child transmission

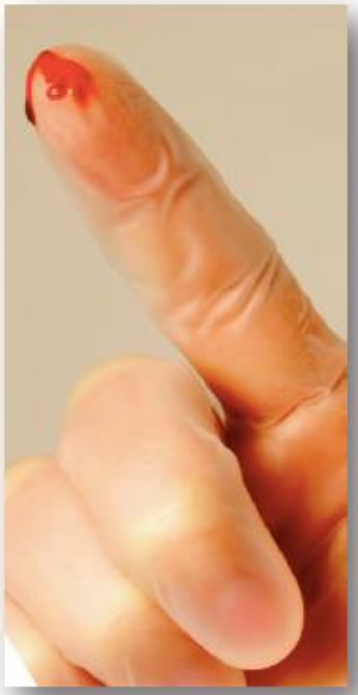
Concept rooted in 4 lines of evidence

Studies in animal models (macaques)

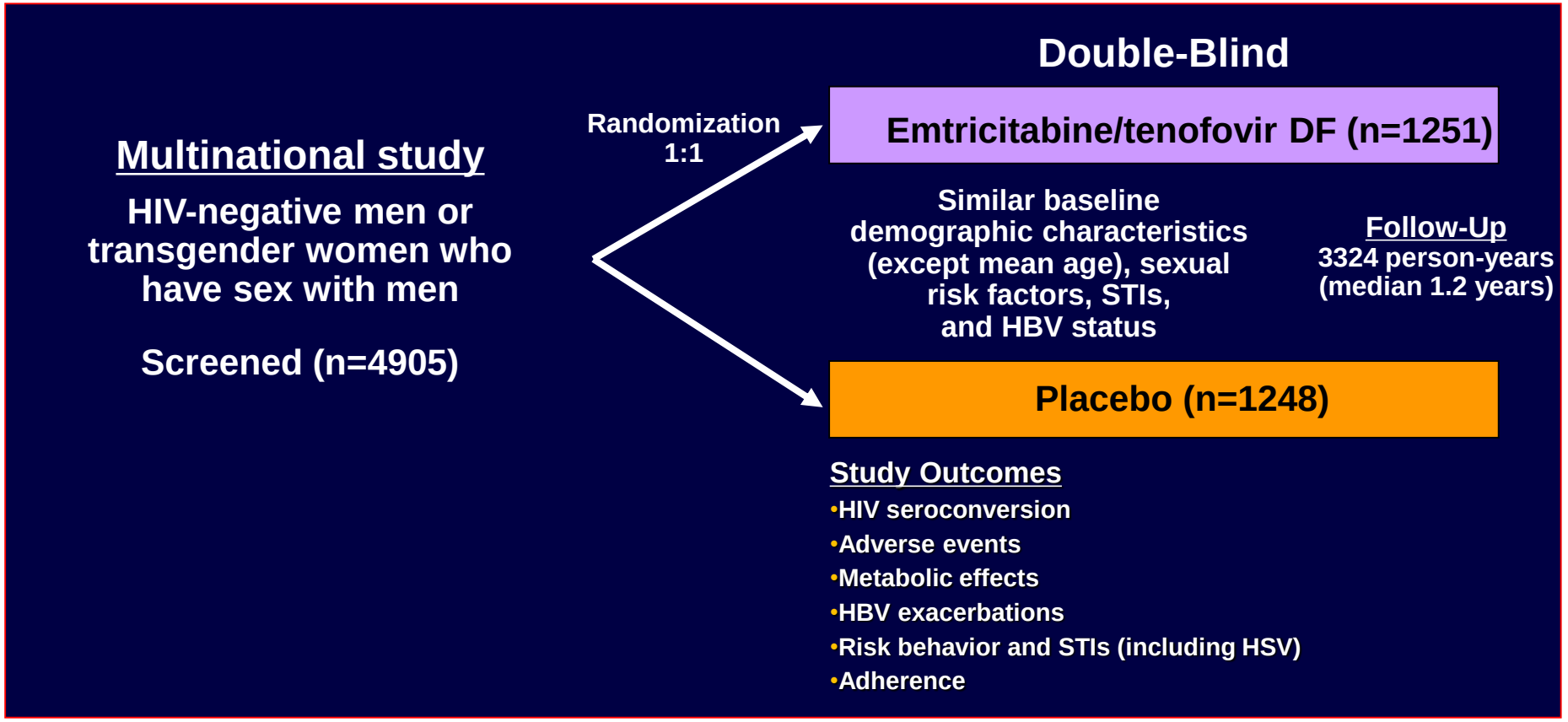
Concept rooted in 4 lines of evidence

Post-exposure prophylaxis (PEP)



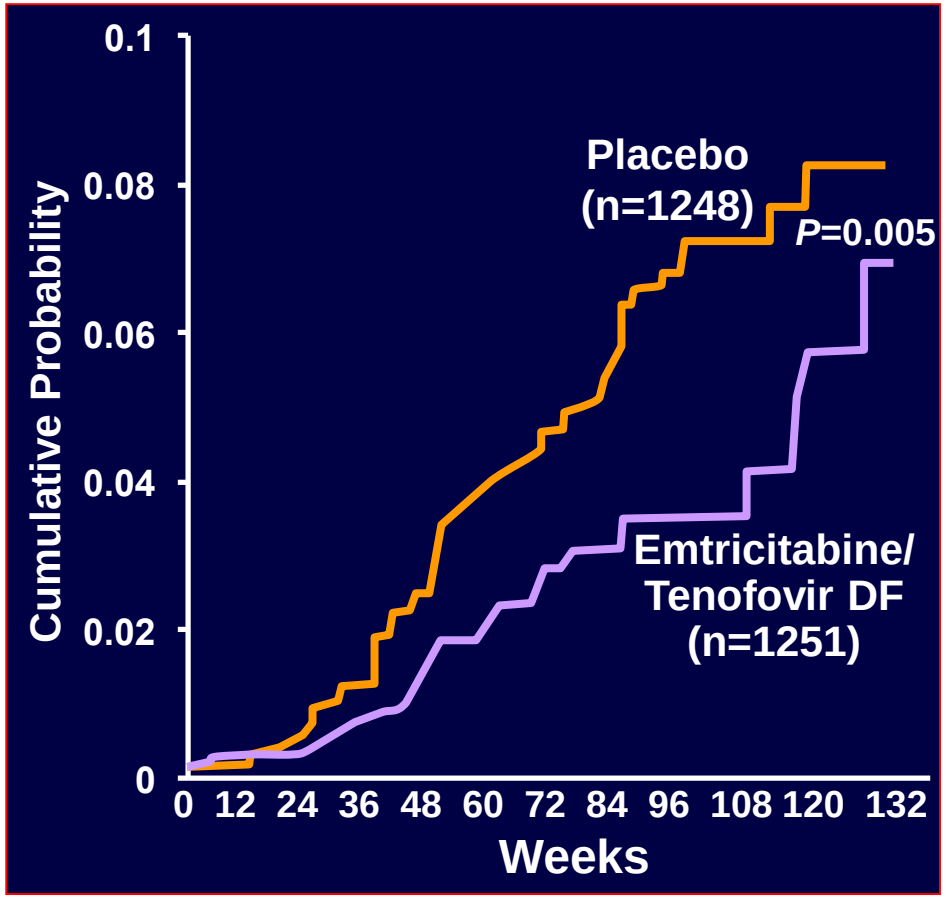
iPrEx Study: MSM and Transgender Women



Grant RM, et al. *N Engl J Med.* 2010;363:2587-2599.

iPrEx Study Results: MSM and Transgender Women

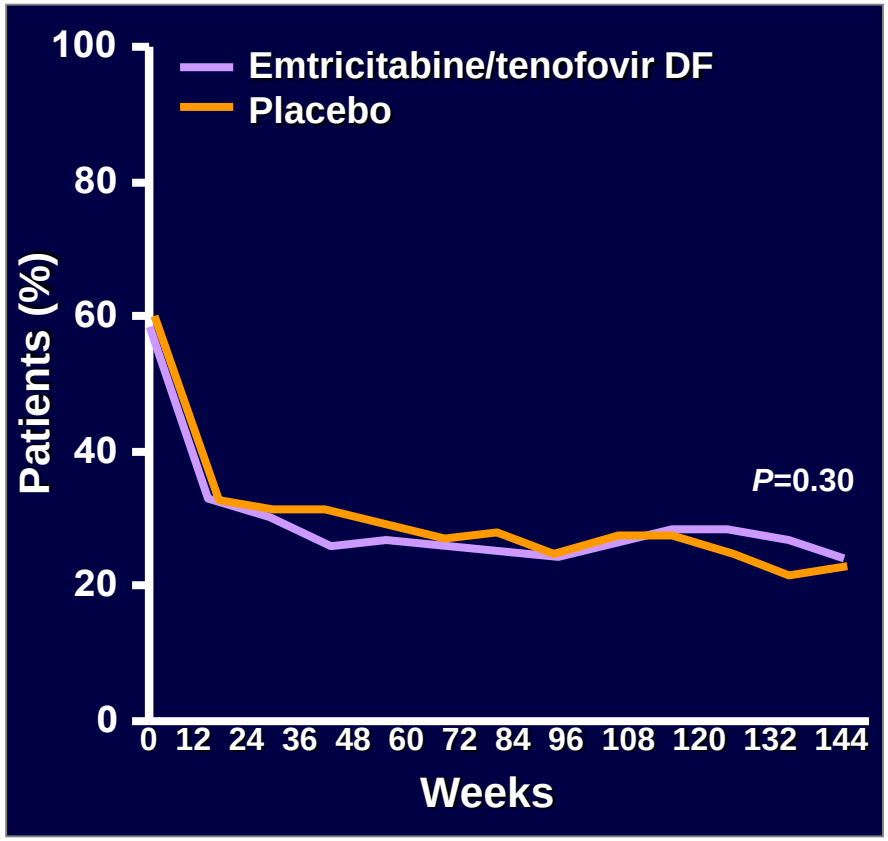
- **Multinational, randomized controlled trial (n=4905 MSM and transgendered women)**
- **HIV incidence**
  - **Placebo: 3.9/100 person years**
  - **PrEP provided 44% additional reduction in HIV incidence**
- **Risk reduction with PrEP**
  - **96% if drug concentrations indicated use of 4 tablets/week**
  - **99% if drug concentrations indicated use of 7 tablets/week**



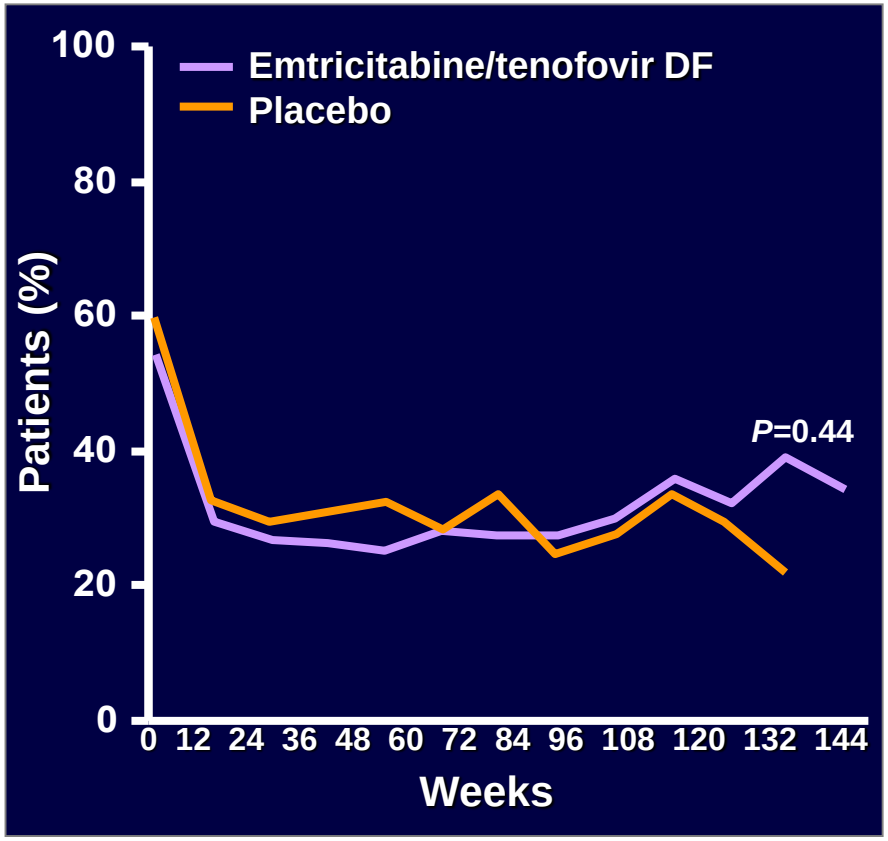
Grant RM, et al. *N Engl J Med.* 2010;363:2587-2599.
Grant RM, et al. 20th CROI. Atlanta, 2013. Abstract 27.

iPrEx Study: Unprotected Receptive Anal Intercourse

Overall Patient Population



Patients Who Believed They Were Receiving FTC/TDF



Grant R, et al. 6th IAS Conference. Rome, 2011. Abstract WeLBC04.

Five major studies demonstrated PrEP's preventive efficacy across risk groups

Study	ARV Used	Frequency	Group
CAPRISA 004	Tenofovir vaginal gel	Before & after sex	Heterosexual women
iPrEx	Truvada oral	Daily	MSM & transwomen
Partners PrEP	Tenofovir & Truvada oral	Daily	Heterosexual discordant couples
TDF2	Tenofovir & Truvada oral	Daily	Heterosexual men & women
Bangkok Tenofovir Study	Tenofovir oral	Daily	Injection drug users

Two major studies demonstrated a lack of efficacy among heterosexual women

Study	ARV Used	Frequency	Group
FEM-PrEP	Truvada oral	Daily	Heterosexual women
VOICE (MTN-003)	Tenofovir gel, tenofovir oral, Truvada oral	Daily	Heterosexual women

Adherence to PrEP Is Critical

Study	Overall Efficacy, %	Blood Samples with TFV Detected, %	Efficacy by Blood Detection of TFV, %
iPrEx	44	51	92
iPrEx OLE	49	71	NR
Partners PrEP	67 (TDF) 75 (TDF/FTC)	81	86 (TDF) 90 (TDF/FTC)
TDF2	62	80	85
Bangkok TFV	49	67	74
Fem-PrEP	No efficacy	< 30	NR
VOICE	No efficacy	< 30	NR

Grant RM, et al. *N Engl J Med*. 2010;363(27):2587-2599; Grant RM, et al. *Lancet Infect Dis*. 2014;14:820-829; Baeten JM, et al. *J Acq Defic Synd*. 2013;63(Supp 2):S122; Baeten JM, et al. *N Engl J Med*. 2012;367(5)399-410; Thigpen MC, et al. *N Engl J Med*. 2012;367(5):423-434; Choopanya K, et al. *Lancet*. 2013;381(9883):2083-2090; van Damme L, et al. *N Engl J Med*. 2012;367(5):411-422; Marrazzo J, et al. CROI 2013. Abstract 26LB; CDC. Pre-exposure Prophylaxis for the Prevention of HIV Infection in the United States: A Clinical Practice Guideline. May 2014. www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf. Accessed 2/26/15.

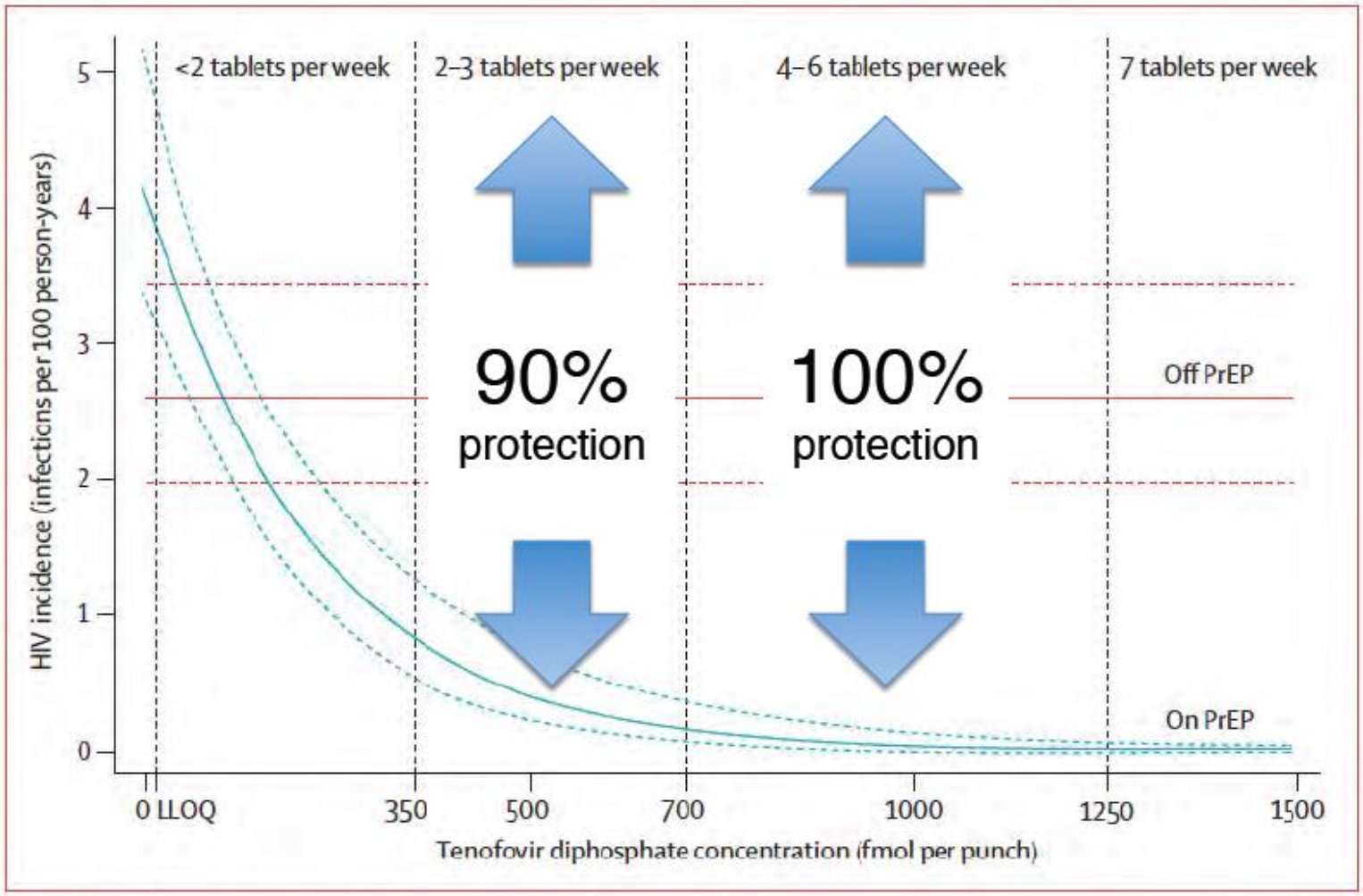
Adherence is critical

Protective efficacy (%)

	All participants	High adherers
	44	92
	62-73	~95

Grant RM, et al. *NEJM.* Dec 2010;363(27):2587-99
Baeten JM, et al. *NEJM.* Aug 2012;367(5):399-410

iPrEx OLE confirmed prior estimates



Grant RM, et al. *Lancet Inf Dis*. Sep 2014;14(9):820-9

Key points

Daily dosing affords greatest protection

Occasional missed dose probably OK

Nonadherence creates opportunities for infection

Two Recent PrEP Studies: A Comparison of IPERGAY and PROUD

PROUD Study (UK)

- High-risk MSM and transgender women (N = 545)
- Randomized; deferred arm
  - Immediate vs deferred PrEP*
- Daily dosing schedule
  - Whether or not they were sexually active
- All participants received full preventive services
- 86% reduced risk of HIV

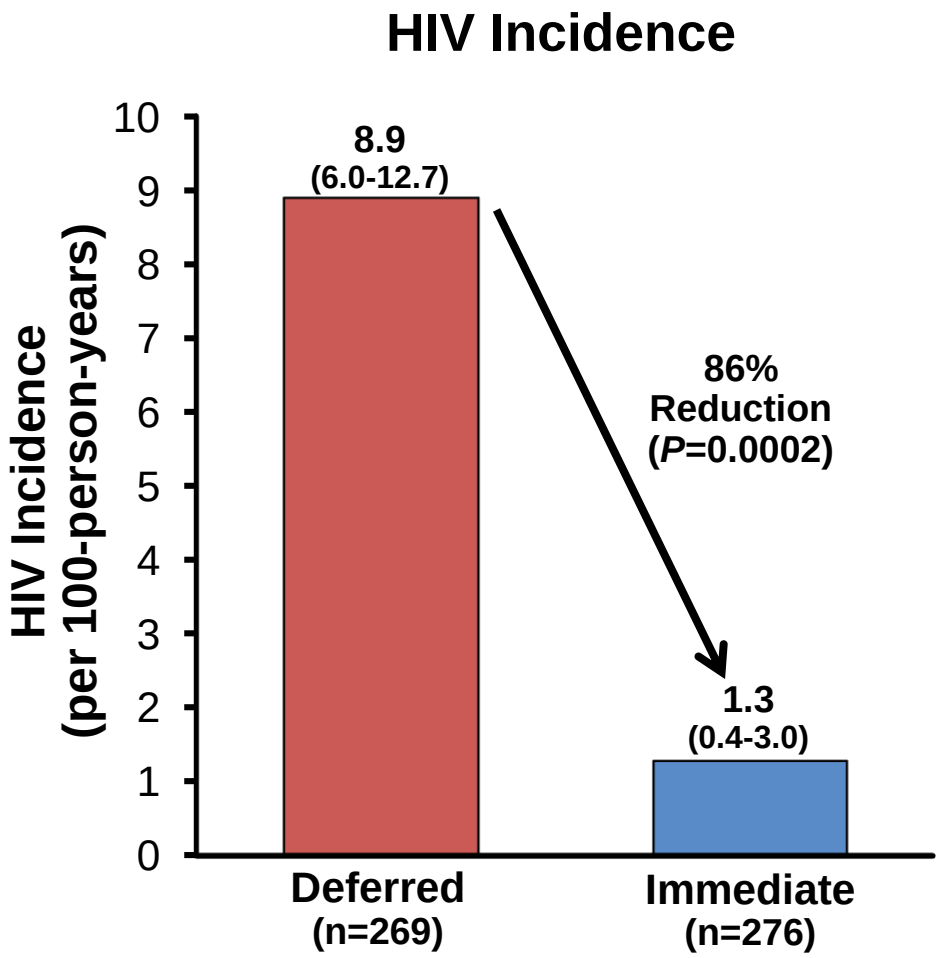
IPERGAY Study (Fr & Canada)

- High-risk MSM and transgender women (N = 400)
- Randomized; placebo arm
- Flexible dosing schedule*
  - "On demand"
    - 2 tabs taken 2-24 hrs before sex
    - 1 tab day after sex and another 1 tab day after that
- All participants received full preventive services
- 86% reduced risk of HIV

*adherence assessed by face-to-face interviews, pill counts, TDF/FTC plasma and hair concentrations
†PrEP given 1 year after enrolling.
McCormack S, et al. CROI 2015. February 23-24, 2015, Abstract 22LB; Molina JM, et al. CROI 2015. February 23-24, 2015, Abstract 23LB; Fonsart J, et al. AIDS 2014. July 20-25, 2014. Melbourne. Abstract TUAC0103; Antonucci S, et al. AIDS 2014. July 20-25, 2014. Melbourne. Abstract THPE197.

PROUD Study: Results

- Significantly fewer new HIV infections with immediate versus deferred PrEP (3 versus 19 cases)
  - 86% reduction (*P*=0.0002)
  - Number needed to treat to prevent 1 infection: 13
- PEP used by 31% in deferred arm
- Preliminary analysis found that risk behaviors were similar between the 2 arms

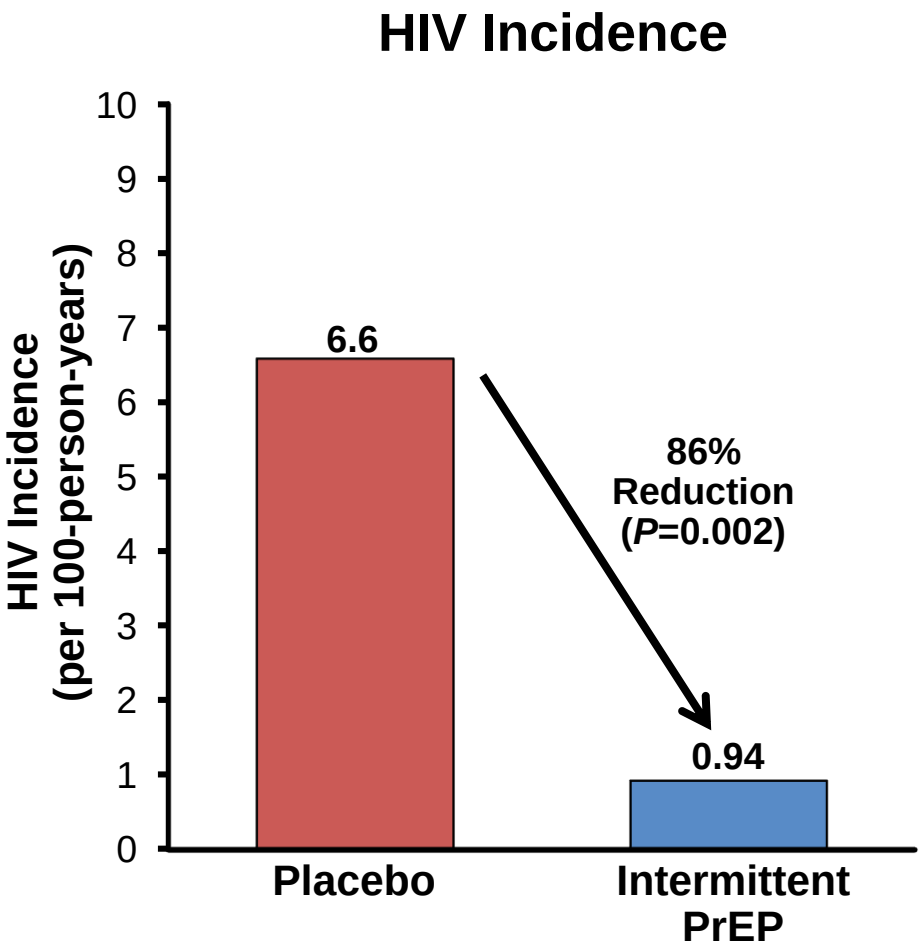


PEP: post-exposure prophylaxis.

McCormack S, et al. 22nd CROI. Seattle, 2015. Abstract 22LB.

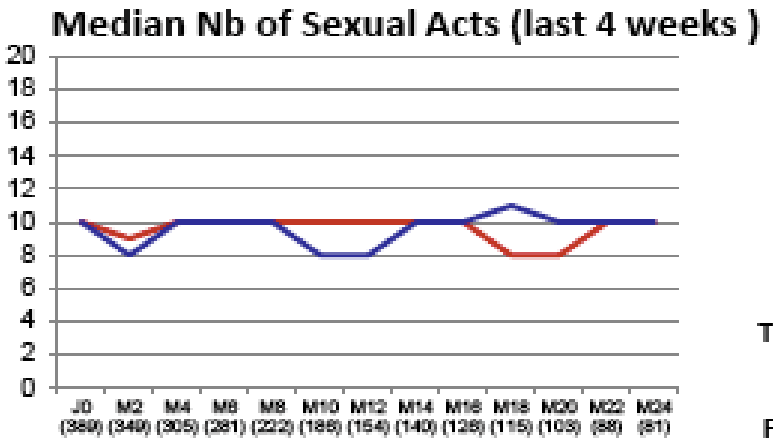
IPERGAY Trial: Results

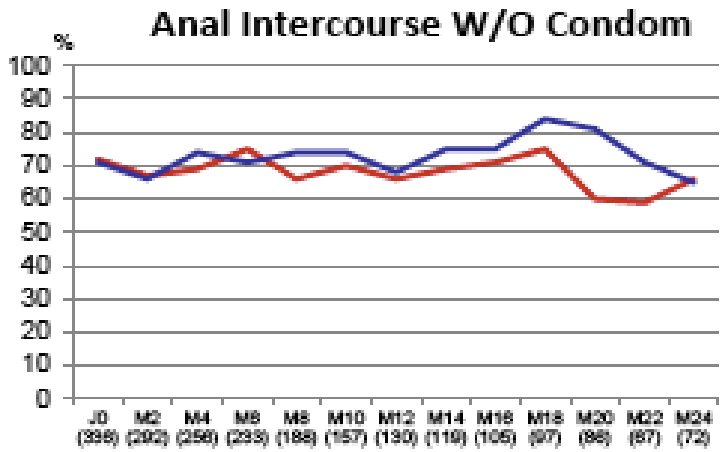
- Significantly fewer new HIV infections with intermittent PrEP versus placebo (2 versus 14 cases)
  - 86% reduction after a mean follow-up of 13 months (*P*=0.002)
- Safety of on-demand PrEP was similar to placebo except for GI adverse events
- Adherence to PrEP was good, supporting the acceptability of on-demand PrEP



Molina JM, et al. 22nd CROI. Seattle, 2015. Abstract 23LB.

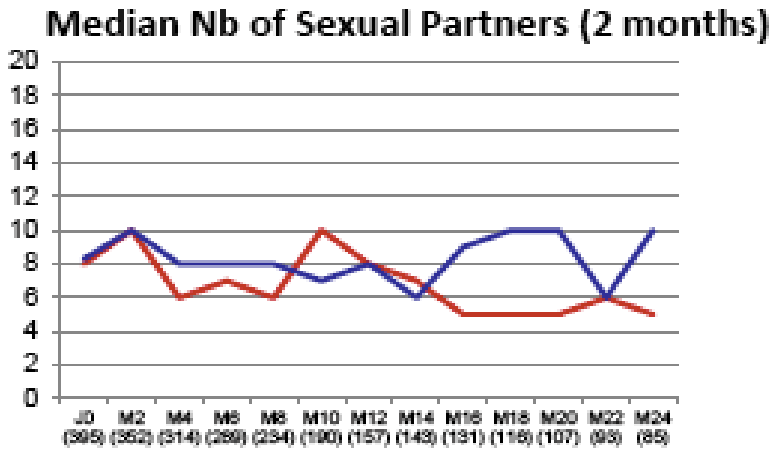
Risk Behavior during IPERGAY

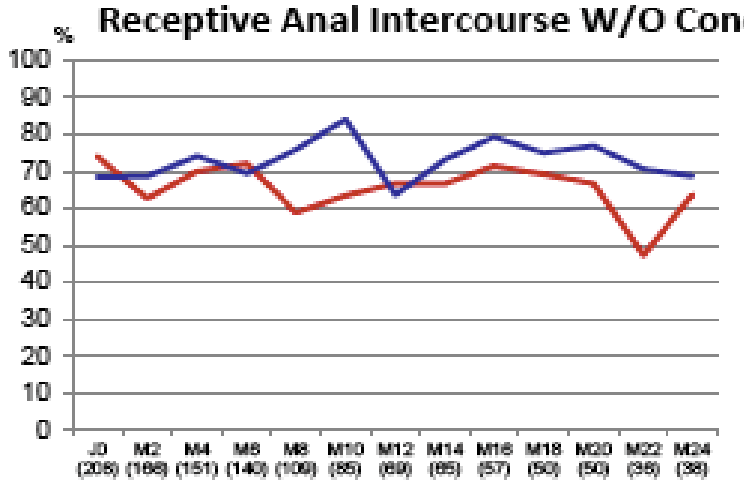




TDF/FTC

Placebo





Molina JM, et al. CROI 2015. February 23-24, 2015, Abstract 23LB

BRIEF REPORT HIV/AIDS

No New HIV Infections With Increasing Use of HIV Preexposure Prophylaxis in a Clinical Practice Setting

Jonathan E. Volk,[1] Julia L. Marcus,[2] Tony Phengrasamy,[1] Derek Blechinger,[1] Dong Phuong Nguyen,[1] Stephen Follansbee,[1] and C. Bradley Hare[1]

[1]Department of Adult and Family Medicine, Kaiser Permanente San Francisco Medical Center, and [2]Division of Research, Kaiser Permanente Northern California, Oakland, California

(See the Editorial Commentary by Koester and Grant on pages 1604–5.)

Referrals for and initiation of preexposure prophylaxis (PrEP) for human immunodeficiency virus (HIV) infection increased dramatically in a large clinical practice setting since 2012. Despite high rates of sexually transmitted infections among PrEP users and reported decreases in condom use in a subset, there were no new HIV infections in this population.

Keywords. preexposure prophylaxis; men who have sex with men; HIV; sexually transmitted infections; behavioral disinhibition.

The effectiveness of once-daily oral preexposure prophylaxis (PrEP) using tenofovir/emtricitabine for prevention of sexually acquired human immunodeficiency virus (HIV) infection has been demonstrated in trials and open-label studies [1, 2]; however, data on PrEP use outside of the research context are limited. Interest in PrEP was high among men who have sex with men (MSM) in a demonstration project in the United States [3], yet initial pharmacy data indicated that many at-risk individuals were not accessing PrEP [4]. In addition, despite reassuring data suggesting that sexual risk behavior and the incidence of sexually transmitted infections (STIs) did not increase in PrEP trials [5, 6], few data on sexual behavior or STIs have been reported among PrEP users outside of research settings.

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Correspondence: Jonathan E. Volk, MD, MPH, Kaiser Permanente San Francisco Medical Center, 2238 Geary Blvd, San Francisco, CA 94115 (jvolk@stanfordalumni.org).
Clinical Infectious Diseases® 2015;61(10):1601–3

DOI: 10.1093/cid/civ778

We aimed to characterize patterns of PrEP use among members of the Kaiser Permanente Medical Center in San Francisco (KPSF). We describe characteristics of individuals evaluated for and initiating PrEP, trends in PrEP referrals and initiation, incidence of HIV and other STIs among PrEP users, and self-reported changes in condom use and number of sexual partners after PrEP initiation.

METHODS

Kaiser Permanente is a large integrated healthcare system that provides comprehensive medical services to >170 000 adult residents in San Francisco. Our study population included all adult KPSF members evaluated for PrEP from July 2012 (the date of approval by the US Food and Drug Administration) through February 2015. At KPSF, primary care or other providers refer patients to a specialized PrEP program after assessment of risk or patient-initiated request. This program, created to meet the growing demand for PrEP, provides adherence support and clinical monitoring by infectious disease physicians, pharmacists, nurses, and administrative staff.

As part of the PrEP program, patients were screened for medical contraindications to the use of tenofovir/emtricitabine and for HIV antibody and viral load. Demographic data and reasons for starting or not starting PrEP were assessed during an in-person intake visit. Similar to PrEP trials [1], safety assessments and HIV/STI screening were repeated every 1–3 months after PrEP initiation. Testing for chlamydia and gonorrhea was done using nucleic acid amplification tests of urine and self-collected swabs of the throat and rectum. Beginning in July 2014, patients were surveyed by secure email after 6 months of PrEP use about changes in sexual behavior since starting PrEP.

We used descriptive statistics to compare PrEP initiators and noninitiators and those who did and did not report increases in risk behavior, with χ^2 tests for categorical variables and t tests for continuous variables. We used Kaplan–Meier analysis to compute the cumulative incidence of STIs and HIV after 6 and 12 months of PrEP use. Concurrent diagnosis of an STI at multiple anatomic sites (ie, pharyngeal, urethral, and/or rectal) was considered 1 infection, whereas diagnoses of gonorrhea and chlamydia in 1 anatomic site were considered multiple infections. Analyses were conducted using SAS software version 9.1 (SAS Institute, Cary, North Carolina). Statistical tests were 2-sided except where otherwise indicated, and statistical significance was defined as $P < .05$.

July 2012- February 2015: 1,045 referrals for PrEP, of which 835 (80%) led to an in-person evaluation.

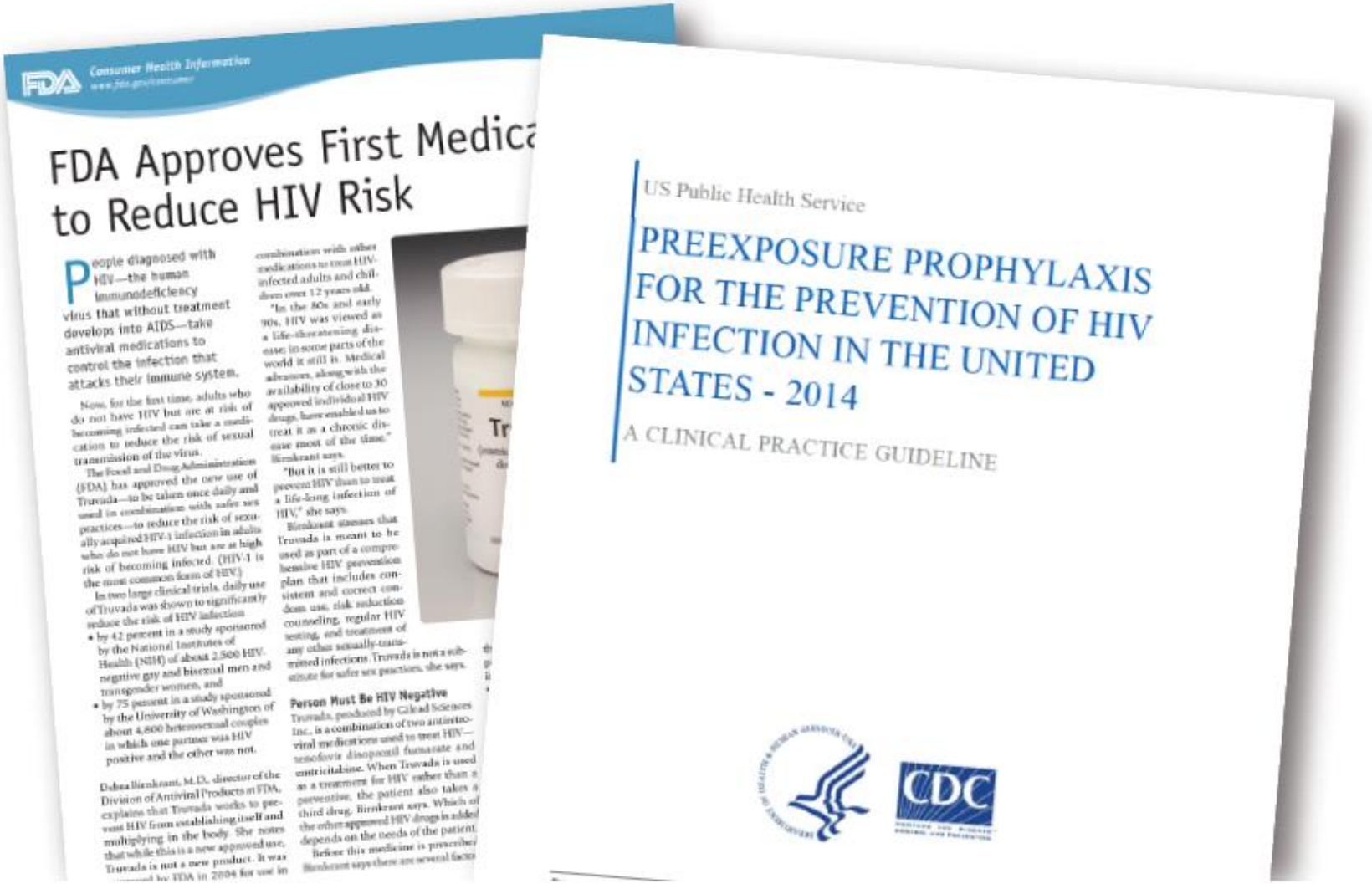
Of the 801 participants with at least 1 intake visit, 657 (82%) opted to start PrEP -- including 20 who restarted PrEP after discontinuing it. 144 people (18%) decided not to do so.

No new HIV diagnoses occurred among PrEP users during 388 person-years of follow-up.

After 6m 30% of diagnosed with any STI, 18% rectal STI, 17% chlamydia, 15% gonorrhea, and 3.3% syphilis; After 12 months, the corresponding percentages were 50%, 33%, 33%, 28%, and 5.5%, respectively.

Among the 143 PrEP users after 6m on PrEP, 56% said condom use unchanged, 41% reported a decrease, and 3% reported an increase; 74% said their number of sexual partners stayed the same, 15% reported a decrease, and 11% reported an increase

Moving PrEP into practice



FDA Consumer Health Information

FDA Approves First Medica to Reduce HIV Risk

People diagnosed with HIV—the human immunodeficiency virus that without treatment develops into AIDS—take antiviral medications to control the infection that attacks their immune system.

Now, for the first time, adults who do not have HIV but are at risk of becoming infected can take a medication to reduce the risk of sexual transmission of the virus.

The Food and Drug Administration (FDA) has approved the new use of Truvada—to be taken once daily and used in combination with safer sex practices—to reduce the risk of sexually acquired HIV-1 infection in adults who do not have HIV but are at high risk of becoming infected. (HIV-1 is the most common form of HIV.)

In two large clinical trials, daily use of Truvada was shown to significantly reduce the risk of HIV infection

- by 42 percent in a study sponsored by the National Institutes of Health (NIH) of about 2,500 HIV-negative gay and bisexual men and transgender women, and
- by 75 percent in a study sponsored by the University of Washington of about 4,800 heterosexual couples in which one partner was HIV positive and the other was not.

Debra Birnkrant, M.D., director of the Division of Antiviral Products in FDA, explains that Truvada works to prevent HIV from establishing itself and multiplying in the body. She notes that while this is a new approved use, Truvada is not a new product. It was [illegible] by FDA in 2004 for use in combination with other medications to treat HIV-infected adults and children over 12 years old.

"In the 80s and early 90s, HIV was viewed as a life-threatening disease; in some parts of the world it still is. Medical advances, along with the availability of close to 30 approved individual HIV drugs, have enabled us to treat it as a chronic disease most of the time," Birnkrant says.

"But it is still better to prevent HIV than to treat a life-long infection of HIV," she says.

Birnkrant stresses that Truvada is meant to be used as part of a comprehensive HIV prevention plan that includes consistent and correct condom use, risk reduction counseling, regular HIV testing, and treatment of any other sexually-transmitted infections. Truvada is not a substitute for safer sex practices, she says.

Person Must Be HIV Negative

Truvada, produced by Gilead Sciences Inc., is a combination of two antiretroviral medications used to treat HIV—tenofovir disoproxil fumarate and emtricitabine. When Truvada is used as a treatment for HIV rather than a preventive, the patient also takes a third drug, Birnkrant says. Which of the other approved HIV drugs is added depends on the needs of the patient.

Before this medicine is prescribed, Birnkrant says there are several facto[illegible]

US Public Health Service

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

A CLINICAL PRACTICE GUIDELINE

CDC

CDC PrEP Guidance: For Whom Is PrEP Recommended?

Daily oral PrEP is recommended for adults at substantial risk of acquiring HIV infection:

- Sexually active MSM
- Heterosexually active men and women
- Injection drug users

	MSM	Heterosexual Women and Men	IDUs
Detecting substantial risk of acquiring HIV infection	• HIV-positive sexual partner • Recent bacterial STI • High number of sex partners • History of inconsistent or no condom use • Commercial sex work	• HIV-positive sexual partner • Recent bacterial STI • High number of sex partners • History of inconsistent or no condom use • Commercial sex work • In high-prevalence area or network	• HIV-positive injecting partner • Sharing injection equipment • Recent drug treatment (but currently injecting)

CDC. Pre-exposure Prophylaxis for the Prevention of HIV Infection in the United States: A Clinical Practice Guideline. Section: Summary of Guidance for PrEP Use. May 2014. www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf. Accessed 2/26/15.

Step 1: Assess need

Open a dialogue about sexual health

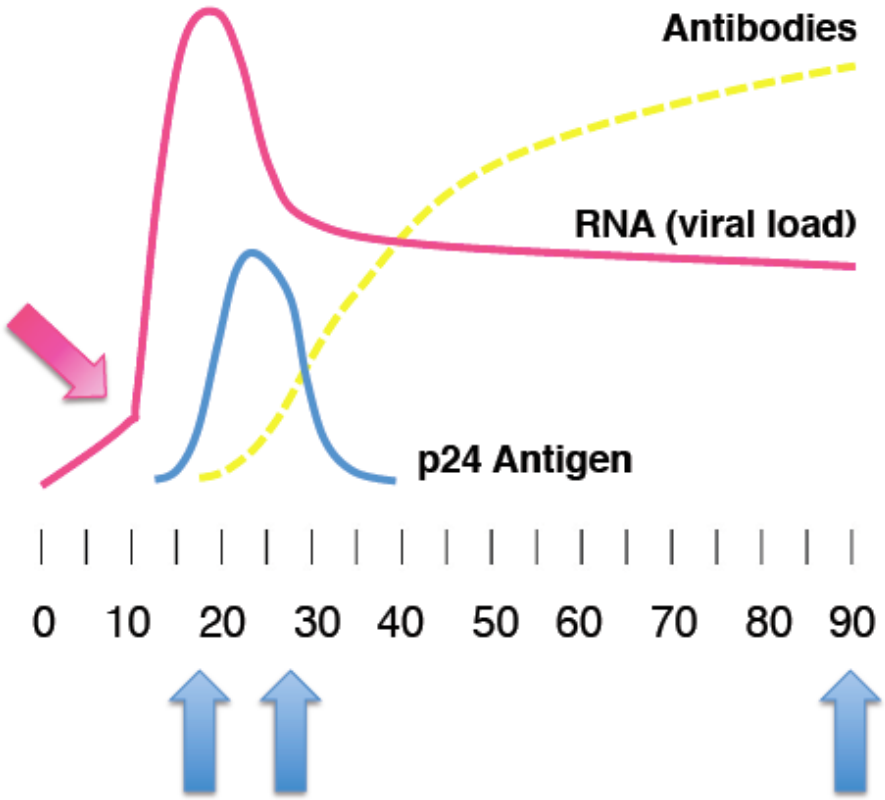
- Get to know your patient and her/his risk(s)
- Ask lots of embarrassing questions!
- Educate about signs & symptoms of STIs
- Don't forget about drug use around sex
- Don't forget about shared drug paraphernalia

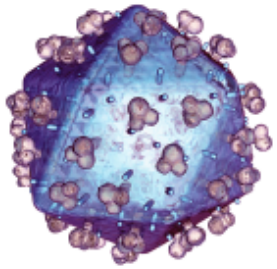
Step 1: Assess need

Tips for talking about sex with patients

- Avoid preface statements before inquiring
- Make sure definition of “sexually active” is clear
- It’s OK to use colloquial terminology
- My standard brief history:
  - “Do you have sex with men, women, or both?”
    - For MSM: “Do you top, bottom, or both?”
  - “Are you in a relationship with anyone?”
    - “Do you have sex with anyone (else)?”
  - “How often do you use condoms for… ?”

Step 2: Determine clinical eligibility





HIV status

- ❑ **Ag/Ab** (4th gen)
- ❑ Rapid **(blood)**
- ❑ ELISA / EIA

Must be HIV(–)

→ **Maybe RNA, too?**

US Public Health Service. PrEP Guideline – 2014.

Step 2: Determine clinical eligibility

Viral hepatitis

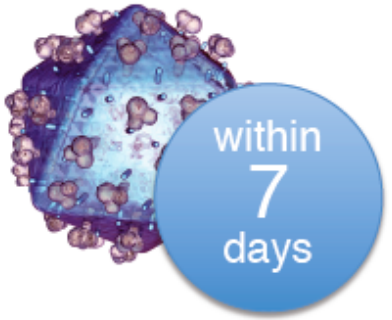
- ❑ HBsAg
- ❑ HBsAb
- ❑ HCV Ab

CAUTION if active HBV!

Renal function

- ❑ Creatinine
- ❑ eCrCl

eCrCl must be ≥ 60 mL/min



HIV status

- ❑ **Ag/Ab (4th gen)**
- ❑ Rapid **(blood)**
- ❑ ELISA / EIA

Must be HIV(–)

→ Maybe RNA, too?

US Public Health Service. PrEP Guideline – 2014.

Step 2: Determine clinical eligibility

Screen for symptoms of acute HIV

- Must be free of these, within prior **4 weeks**:
  - Fever (75%)
  - Fatigue (68%)
  - Skin rash (48%)
  - Pharyngitis (40%)
  - Cervical adenopathy (39%)
- Suspect acute HIV? **Send HIV RNA (viral load)**

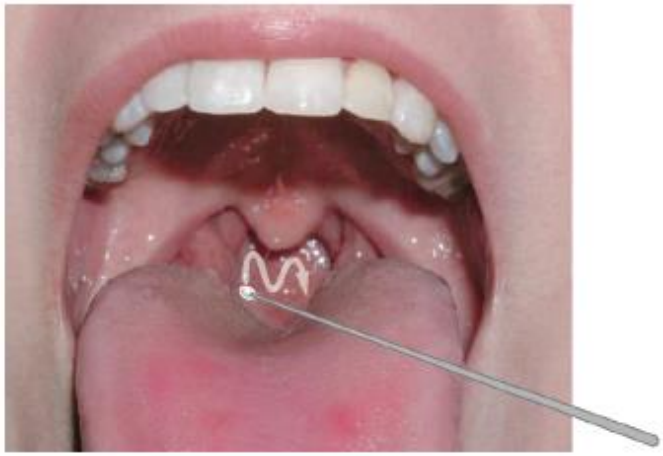
US Public Health Service. PrEP Guideline – 2014.

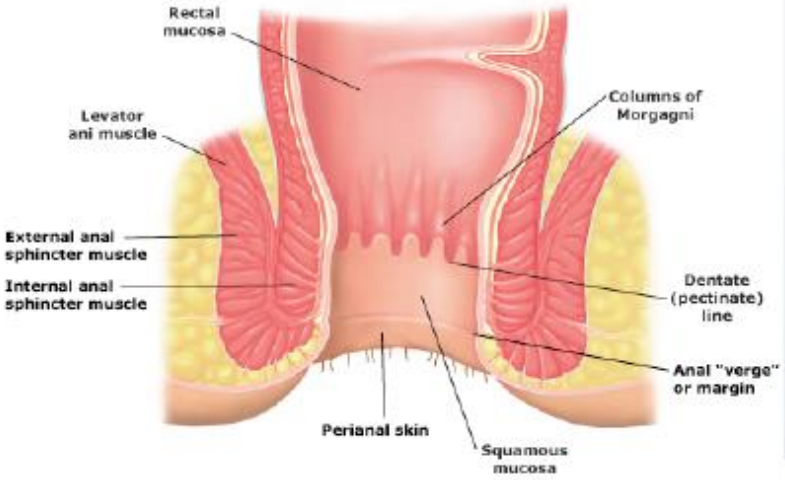
Step 3: Screen for STIs

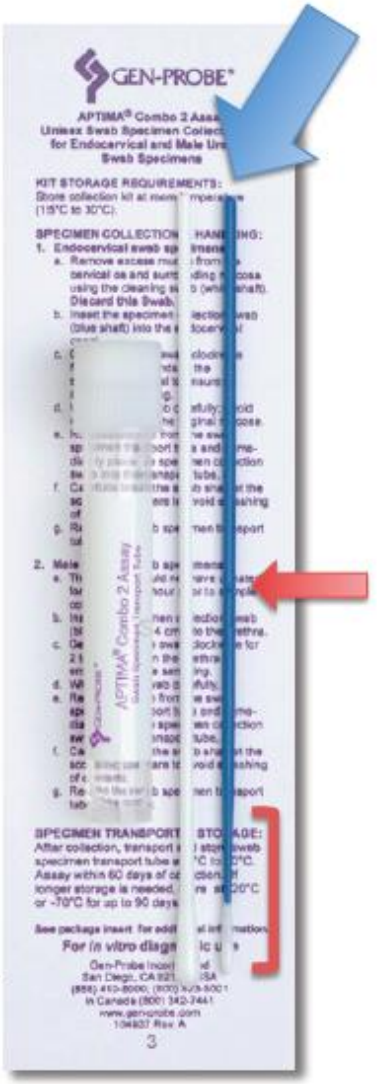
If not already done in prior 3-6 months:

- ❑ RPR for syphilis
- ❑ Gonorrhea and chlamydia
  - NAA testing preferred
  - **Extragenital sites too!**

Step 3: Screen for STIs







Step 4: Counsel the patient

Establish ground rules

- Ongoing relationship – **quarterly** visits
- No HIV test? No prescription!

"Startup syndrome"

- Flatulence, nausea / GI upset, headache
- Symptoms resolve within first 30d, for most

US Public Health Service. PrEP Guideline – 2014.

Would you sign a Contract?

Patient Section

It has been explained to me that:

- Taking a dose of PrEP medication every day lowers my risk of getting HIV infection
- If I miss doses of my PrEP medications, I am less protected against HIV infection
- This medication **does not** completely eliminate my risk of getting HIV infection
- This medication **does not** protect me from other sexually transmitted infections
- This medication may cause side effects, so I should contact my PrEP provider for advice if I have any health problems I think might be related to my medications
- It is important for my health to find out quickly if I get HIV infection while I'm taking this medication, so I will contact my PrEP provider right away if I have symptoms of possible HIV infection (fever, sore throat, rash, headache, or swollen glands)
- My PrEP provider will **not** prescribe me any medication unless I attend my scheduled appointments and have a negative HIV test at least once every 3 months
- I need to have a primary care provider for my general medical needs

Therefore, I will:

- Try my best to take my medication at about the same time every day
- Talk to my PrEP provider about any problems I have taking my medication every day
- Not share my medication with any other person
- Attend all scheduled appointments with my PrEP provider
- Call our clinic within 48 hours prior to any appointments I cannot attend, and ask to be rescheduled
- Not receive a prescription for any medication without first seeing my PrEP provider in the clinic and getting tested for HIV
- Work with my PrEP provider to identify a primary care provider for my general medical needs, if I do not already have one
- Not hold my provider responsible for any negative issues or outcomes resulting from my failure to abide with the terms of this agreement

_____ _____

Patient Signature Date

_____ _____

Provider Signature Date

North Carolina AIDS Training and Education Center. PrEP. For Providers. Patient/Provider Contract for PrEP. Available at: www.med.unc.edu/ncaidstraining/prep/for-providers/for-prep-prescribers. Accessed 3/10/15.

Step 4: Counsel the patient

Adherence strategies

- Pair pill-taking with daily task (even weekends!)
  - Plugging cell phone in before bedtime
- Set an alarm (clock, watch, or phone)
- Use a pill box
- Keep a dose on / near you

US Public Health Service. PrEP Guideline – 2014.

Step 5: Prescribe & follow-up

First Rx: Thirty days, NO refills

Return to clinic in 30 days

- ❑ Adherence?
- ❑ Side effects?
- ❑ Risk behaviors?

2nd Rx: Thirty days, 2 refills

Step 6: Maintenance & reassessment

At least every 3 months

- ❑ Assess adherence, side effects, risk behavior
- ❑ Repeat HIV testing
- ❑ Prescription renewal

At least every 6 months

- ❑ Check creatinine and eCrCl
- ❑ Screen for STIs, if not already done
- ❑ Determine need – "**seasons of risk**"

Frequently asked questions

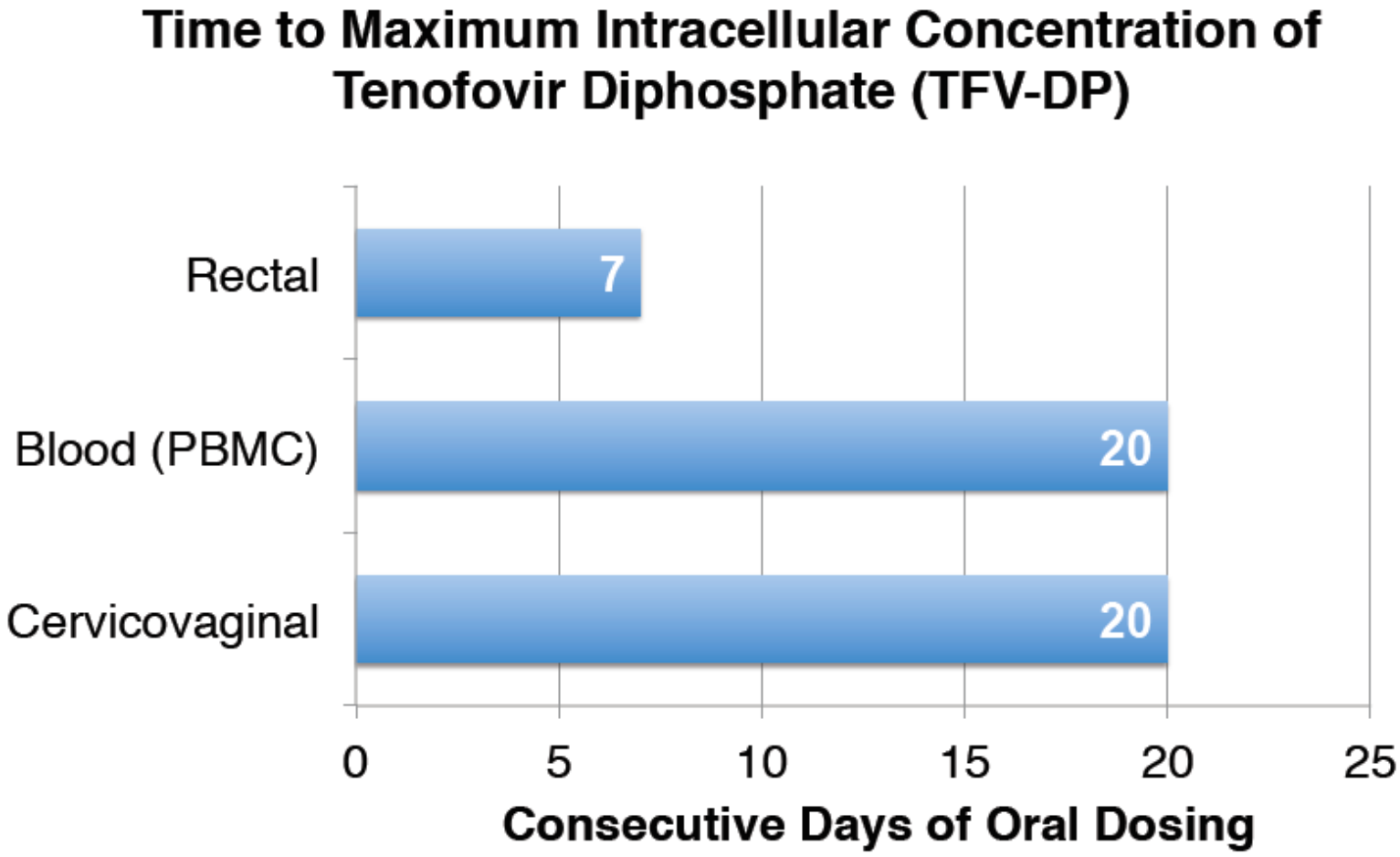
Won't PrEP encourage riskier sex?

Risk compensation

- Repeatedly examined in multiple trials
  - Indices of risk **stable or reduced**
    - Condomless sex
    - Number of partners
    - Bacterial STIs

Liu AY, et al. *JAIDS*. 2013;64:87-94. Marcus JL, et al. *PLoS ONE*. 2013;8(12):e81997. Guest G, et al. *Sex Transm Dis*. 2008;35(12):1002-8. Baeten JM, et al. *NEJM*. 2012; 367:399-410. Thigpen MC, et al. *NEJM*. 2012;367:423-34. Van Damme L, et al. *NEJM*. 2012;367:411-22.

How long before I'm protected?



US Public Health Service. PrEP Guideline – 2014.

Won't it be less effective in practice?

Effectiveness is often lower than efficacy

- Condoms (97% → 70-80%)
- Oral contraceptive pills (99% → 90%)

PROUD Study

- 545 MSM, transwomen in English GUM clinics
- Half got PrEP immediately, half waited 1 year
- Stopped early due to strong positive effect
- **Protective effectiveness 86%** (IRR; 95%CI 58, 96)

McCormack S, et al. CROI 2015. Abstract 22LB

Can my patient afford PrEP?

Cost to PrEP users

- Out-of-pocket (uninsured) = around $1300/mo.
- Insurance covers (even Medicaid) – **pre-auths**
- Access programs and co-pay assistance
- Potentially free from Gilead if income <$58K

- See NCATEC's **"For PrEP prescribers"** page

https://twitter.com/peterstaley/status/518554275501178882

Schackman BR, et al. *Curr Opin HIV/AIDS*. 2012;7:587
Juusola JL, et al. *Ann Intern Med*. 2012;156:541
Gomez GB, et al. *PLoS Med*. 2013;10(3):e1001401

Managing Side Effects

- Side effects reported in clinical trials
  - Uncommon and usually resolved within the first month of taking PrEP
    - iPrEx: significant increase in nausea and weight loss
    - Mild decrease in CrCl that was reversible
- Signs/symptoms that require urgent evaluation (renal injury, acute HIV infection)
- Inform about potential for drug-resistant HIV infection if PrEP taken inconsistently and HIV infection occurs

iPrEX = pre-exposure prophylaxis initiative.

CDC. Pre-exposure Prophylaxis for the Prevention of HIV Infection in the United States: A Clinical Practice Guideline. May 2014. www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf. Accessed 2/26/15; Grant RM, et al. *N Engl J Med*. 2010;363(27):2587-2599; Solomon MM, et al. *AIDS*. 2014;28(6):851-859.

More info: *www.med.unc.edu/ncaidstraining*

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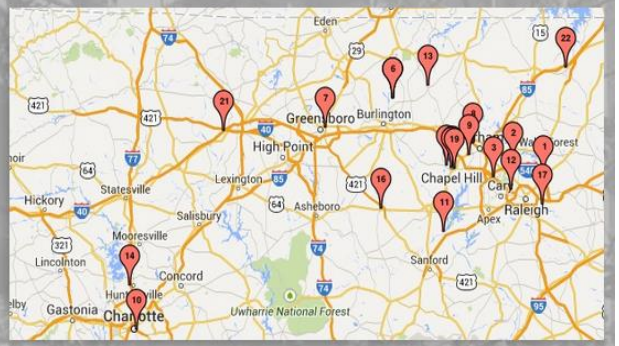
North Carolina AIDS Training and Education Center

Home | About Us | Request Training | Clinician Resources | PrEP | Videos/Slides/Webinars | Events | CAPUS | Pharmacy/Dentistry | Excellence in HIV Care

- For Providers
- Consumers Interested in or Currently Taking PrEP
- North Carolina DHHS PrEP Memorandum for World AIDS Day 2014

PrEP Resources

Pre-exposure prophylaxis (PrEP) is a new way of pr…oming infected with HIV. We have put together these resources to help you to l…ether you are a provider or a consumer.



HIV Training That Makes a Difference

NC ATEC

University of North Carolina at Chapel Hill
AIDS Training and Education Center

WHAT'S NEW

- Excellence in HIV Care Webinar Series
- Clinical Care in 2015: HIV, Hepatitis C and Vulnerable Populations
- Check out our new *PrEP resources page*.
- WOHL STREET JOURNAL: Becoming Less Super as a Specialist

NCATEC Clinician Line

855-UNC-ATEC

855-862-2832

Do you have clinical questions regarding the management of HIV?

Call Mon.-Fri. 9-5 to get connected to an HIV expert!

NCATEC has lots of resources

http://www.med.unc.edu/ncaidstraining/prep

For PrEP Prescribers

These resources are intended to help you initiate and manage y

On this page, we have condensed the 2014 US Public Health Se supplement into a step-by-step guide for providers managing pa

If after reviewing the information here you still have a specific q this page for contacts who can help.

Step-by-Step Guidance

To download this information in checklist form, click here.

The UNC Infectious Diseases Clinic's working group on PrEP ma which sets some "ground rules" at baseline.

- **Step 1: Assess Need for PrEP**
- **Step 2: Determine Clinical Eligibility**
- **Step 3: Consider STI Screening**
- **Step 4: Counsel the Patient**
- **Step 5: Initiate PrEP**
- **Step 6: Follow-Up**

Clinician Contacts for Help with PrEP

- Call PrEPline, a service of the **Clinician Consultation Cente 855-448-7737** (11 AM and 6 PM EST)
- Contact a UNC Infectious Diseases clinical fellow or attend **862-6264**. Between 8 AM and 5 PM on weekdays, you'll s

Consumers Interested in or Currently Taking PrEP

Pre-exposure prophylaxis (PrEP) is a new way of protecting yourself from becoming infected with HIV. We have put together these resources to help you to learn more about PrEP and to find a local provider who can prescribe PrEP and help you maintain your sexual health.

To the left is a short video from My PrEP Experience about PrEP basics.

Below, you'll find a list of frequently asked questions (FAQs) about PrEP, provided by the San Francisco AIDS Foundation. If you don't find an answer to a question you have here, feel free to check out their website, PrEPfacts.org, for more information. They have separate FAQ pages for women and for men (along with transwomen).

Map of North Carolina PrEP Providers

There is a search bar in the lower right-hand section of the map. You can search by zip code or city.