PrEP for Indian Country: Moving HIV Acquisition to Zero

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Introduction by Jonathan Iralu, MD
IHS ID Chief Clinical Consultant

Greg

26 yo man who has sex with men who presents to primary care for skin rash

- Waiting tables and going to night school for accounting
- Social History:
  - Not in a stable relationship currently
  - Uses condoms with some partners, but not all
  - Versatile for anal sex
- Past History:
  - Rectal gonorrhea 2014, NGU 2011
  - Currently on no daily medications
- Uninsured
- Physical Exam:
  - Reveals lesions c/w secondary syphilis
    - Confirmed with blood testing

Questions to Discuss

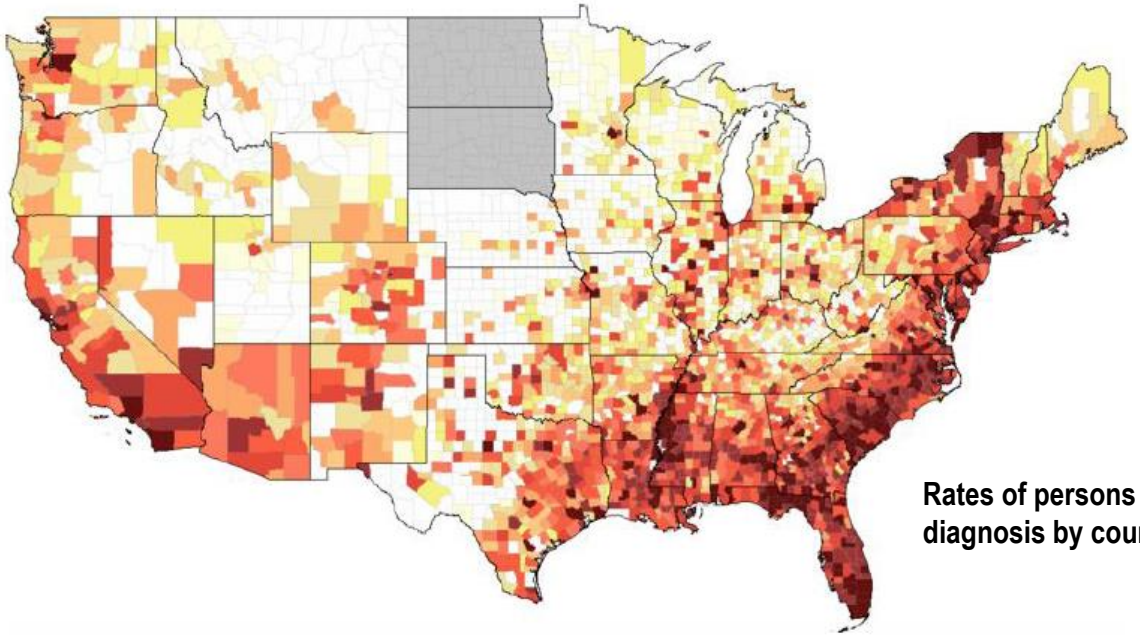
- Is Greg a good candidate for PrEP?
- What should the condom messaging be?
- What tests/assessments are needed before starting PrEP?
- Who will pay for all this?

PrEP: 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 <u>and</u> 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.

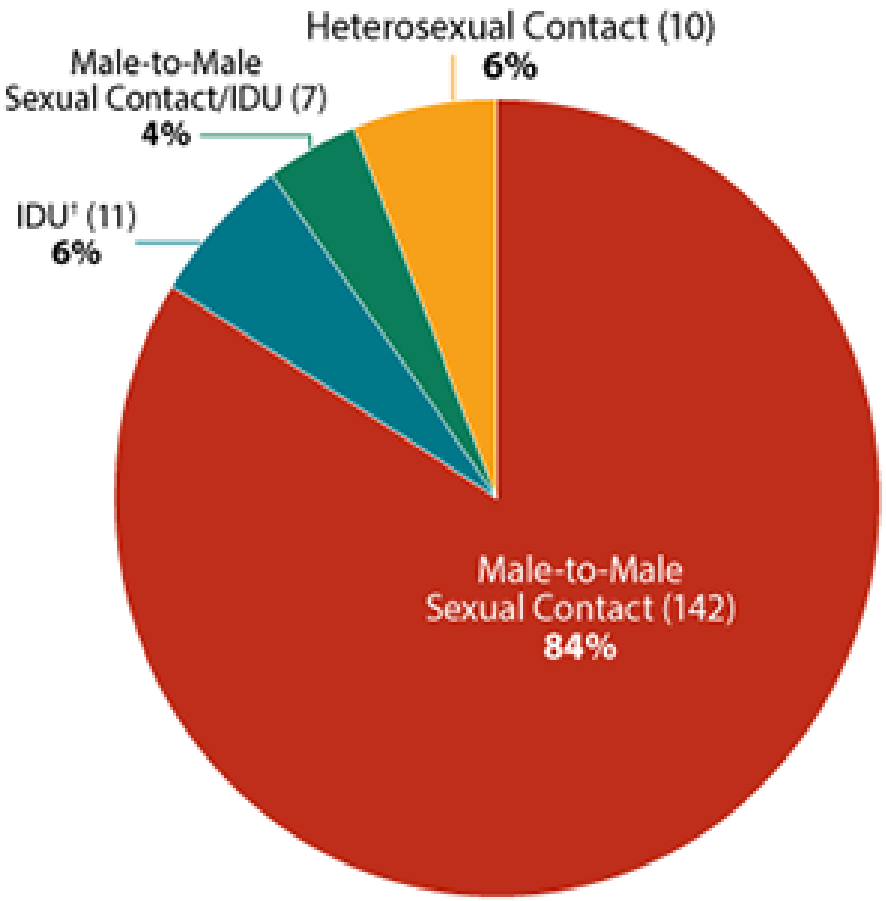
New Cases of HIV, USA, AI/AN

(CDC surveillance, 2010-2014)

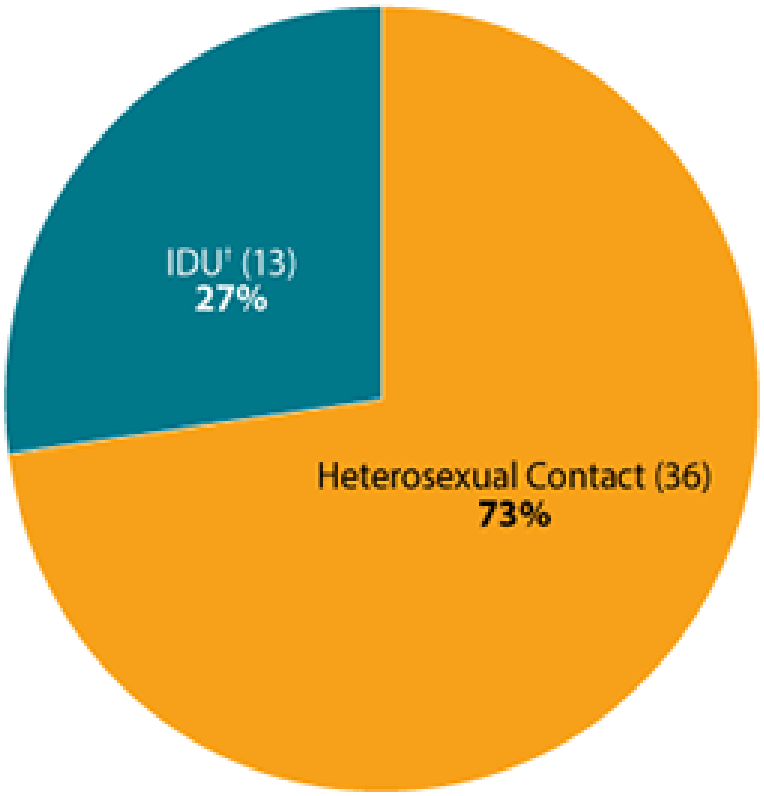
- Approximately 44,000 new cases/year in the USA
- HIV incidence among AI/AN patients has increased from 174 cases (7.9/100,000) in 2010 to 222 in 2014 (9.5/100,000)
- In 2014, an estimated 84% of new HIV cases were transmitted via sexual contact among Men Who Have Sex with Men (MSM)

Centers for Disease Control and Prevention. *HIV Surveillance Report, 2014*; vol. 26. http://www.cdc.gov/hiv/library/reports/surveillance/ Published November 2015. Accessed March 28, 2016

Main Transmission routes, Indian Country



Males (N-170)



Females (N-49)

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

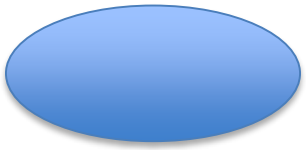
Tenofovir is the most studied agent for PrEP

- 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)

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

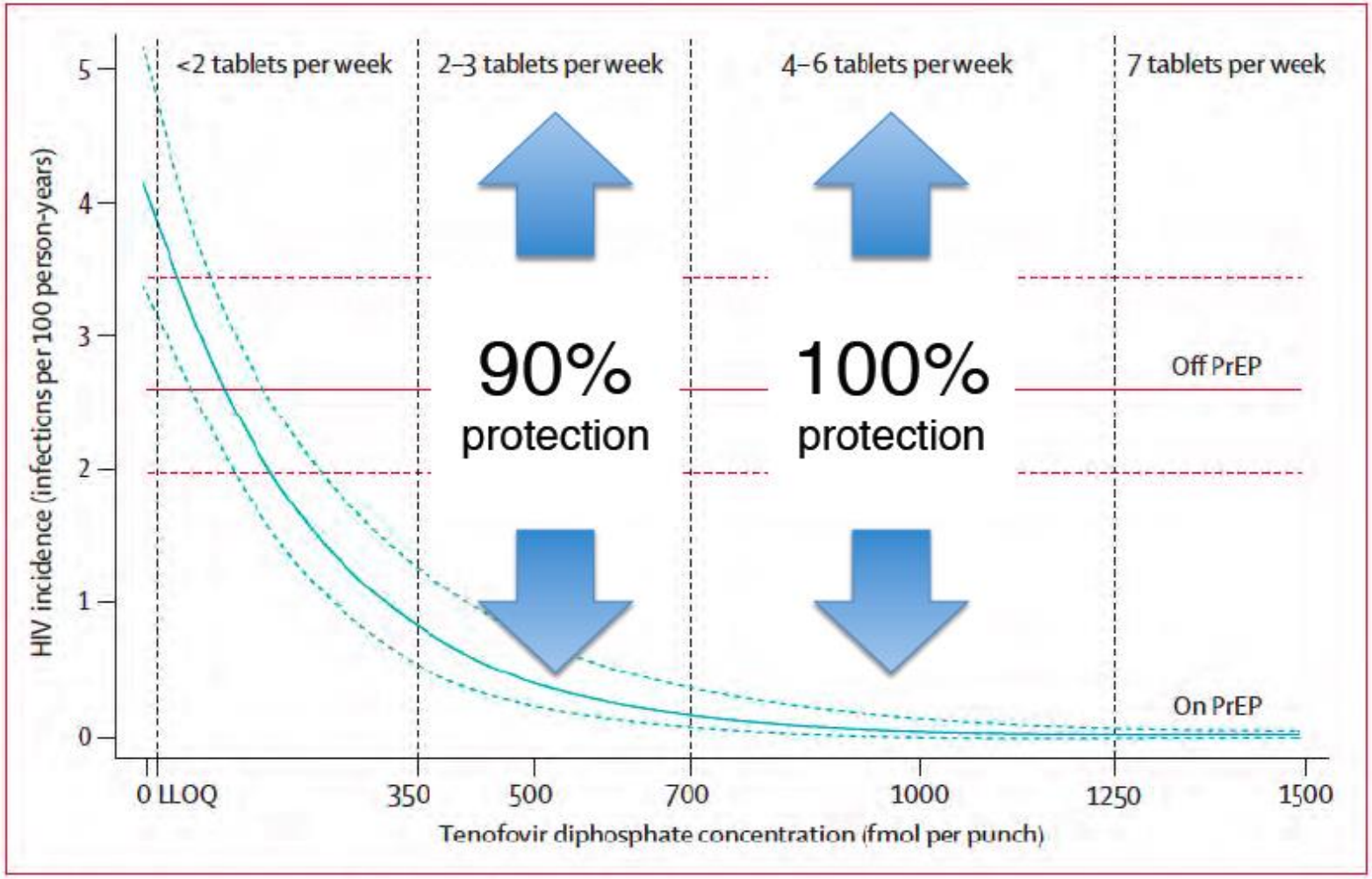
Adherence is critical

Protective efficacy (%)

	All participants		High adherers
iPrEx	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

BRIEF REPORT HIV/AIDS

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

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(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.

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 $P < .05$.

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DOI: 10.1093/cid/civ778

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

Of the 801 participants, 657 (82%) opted to start PrEP. 144 people (18%) decided not to do so.

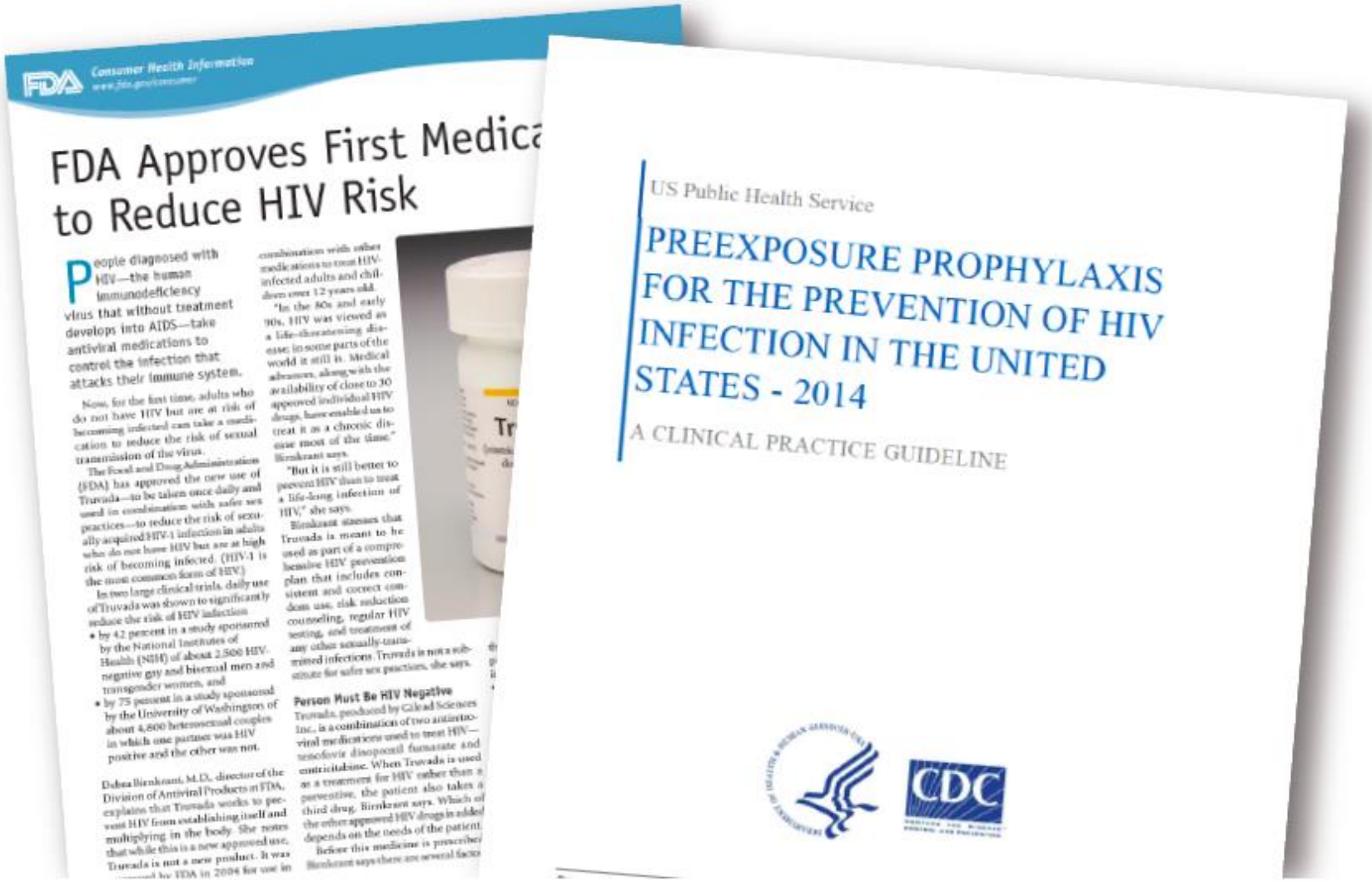
No new HIV diagnoses occurred among PrEP users during 388 person-years of follow-up.

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
www.fda.gov/consumer

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 at 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 approved 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 medicines used to treat HIV—tenofovir disoproxil fumarate and emtricitabine. When Truvada is used as a treatment for HIV rather than as 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 factors

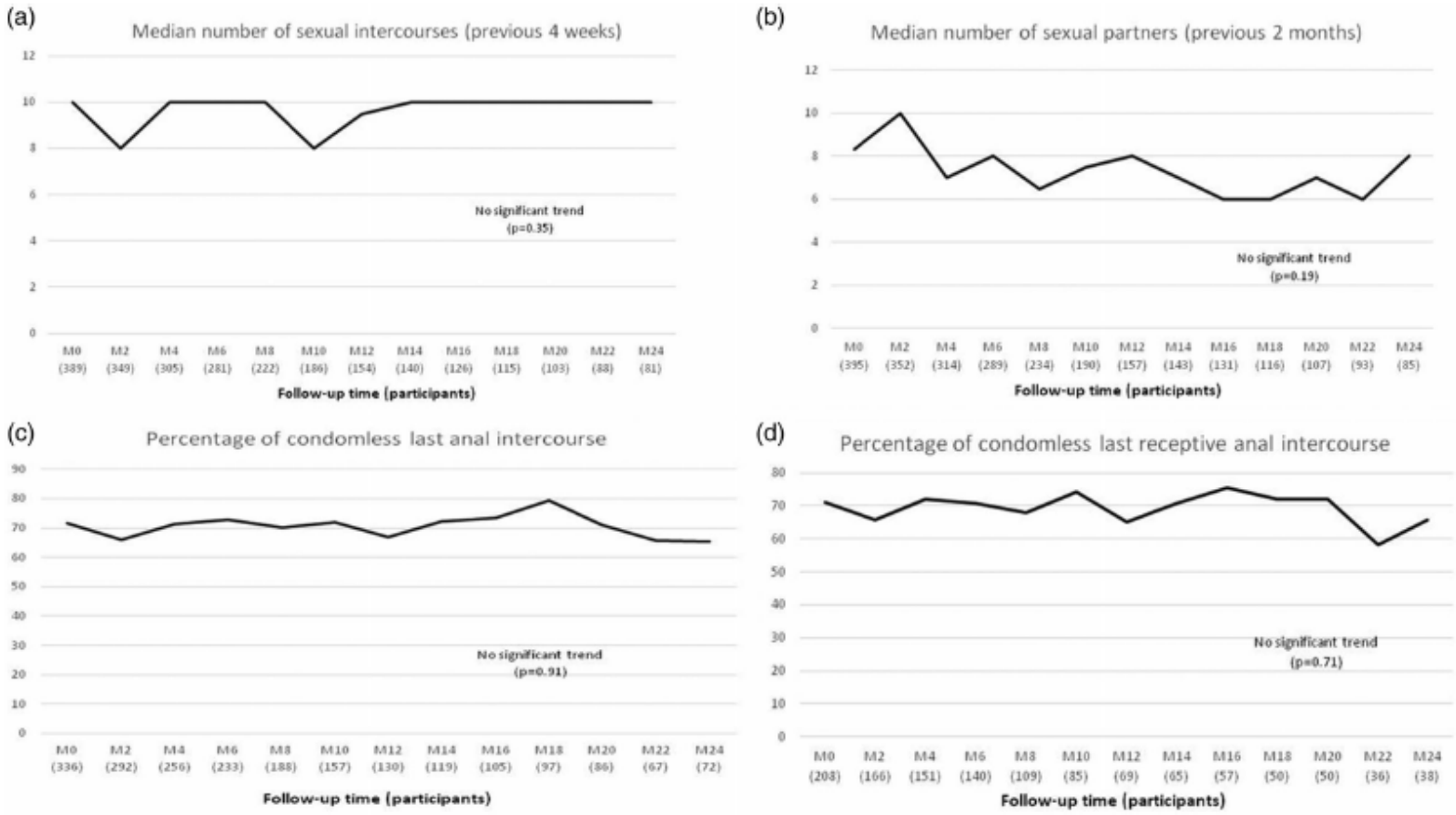
US Public Health Service

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

A CLINICAL PRACTICE GUIDELINE

CDC

MSM Risk Behavior During ANRS IPERGAY Trial



Sagaon-Teyssier, L. AIDS Care 2016;28:48-55

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

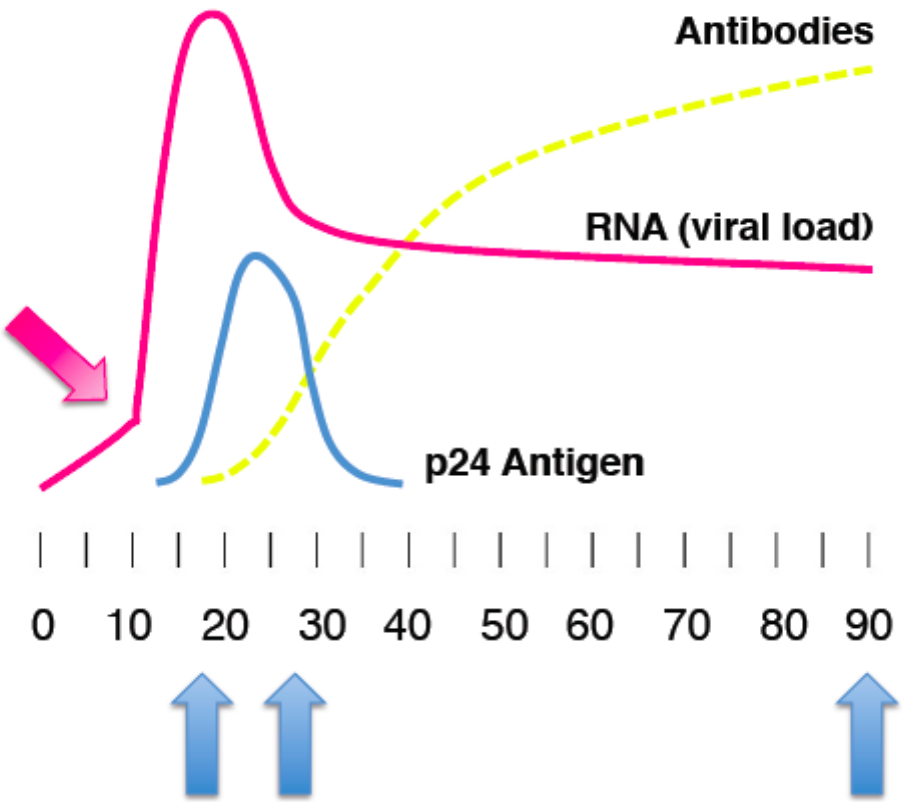
- Get to know your patient and her/his risk(s)
- Ask lots of embarrassing questions!
- Educate about signs & symptoms of STIs
- Don't forget about drug use around sex
- Don't forget about shared drug paraphernalia

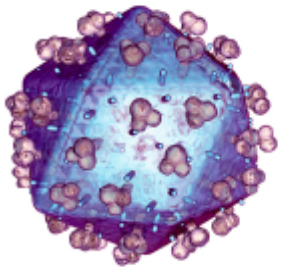
Step 1: Assess need

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

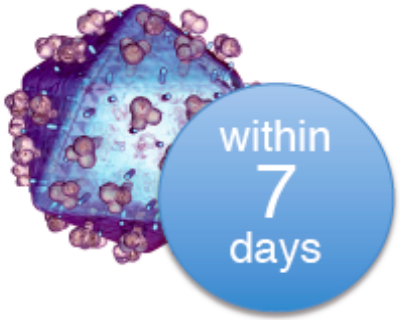
- ❑ HBsAg
- ❑ HBsAb
- ❑ HCV Ab

CAUTION if active HBV!

Renal function

- ❑ Creatinine
- ❑ eCrCl

eCrCl must be ≥ 60 mL/min



HIV status

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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)**

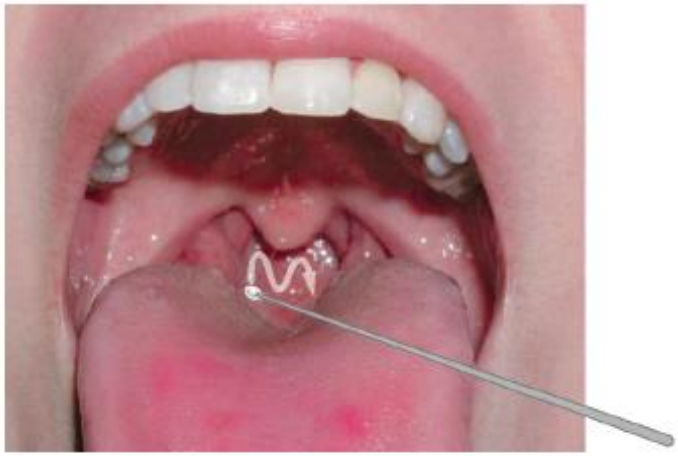
US Public Health Service. PrEP Guideline – 2014.

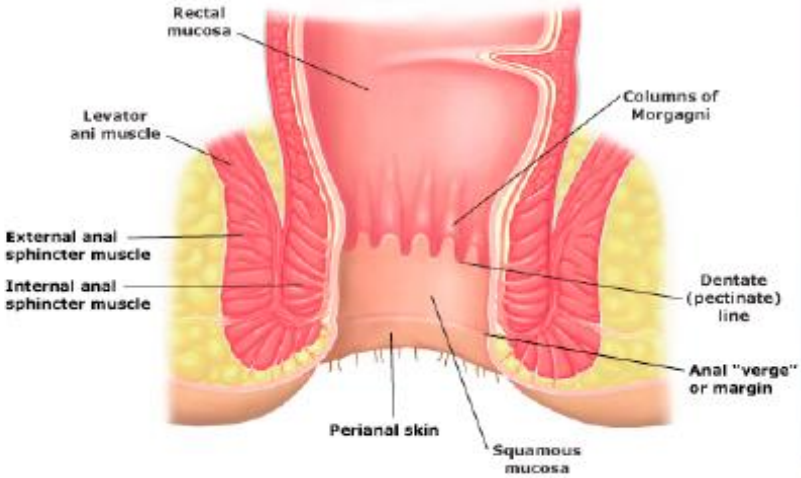
Step 3: Screen for STIs

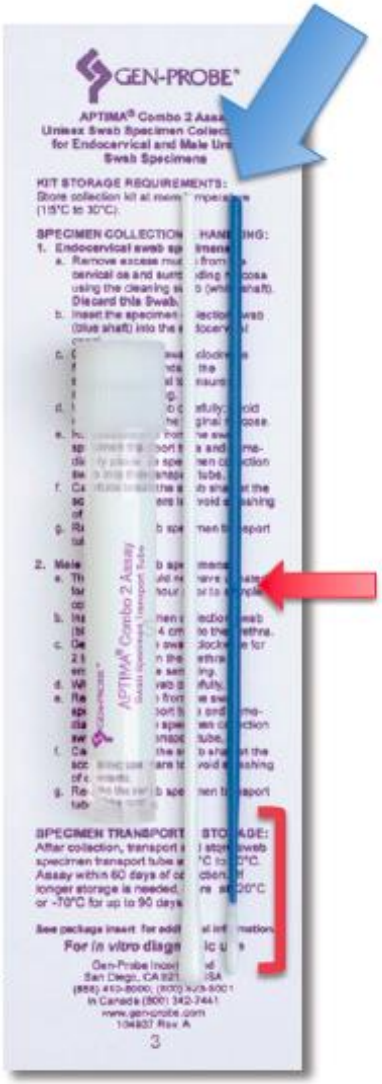
If not already done in prior 3-6 months:

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

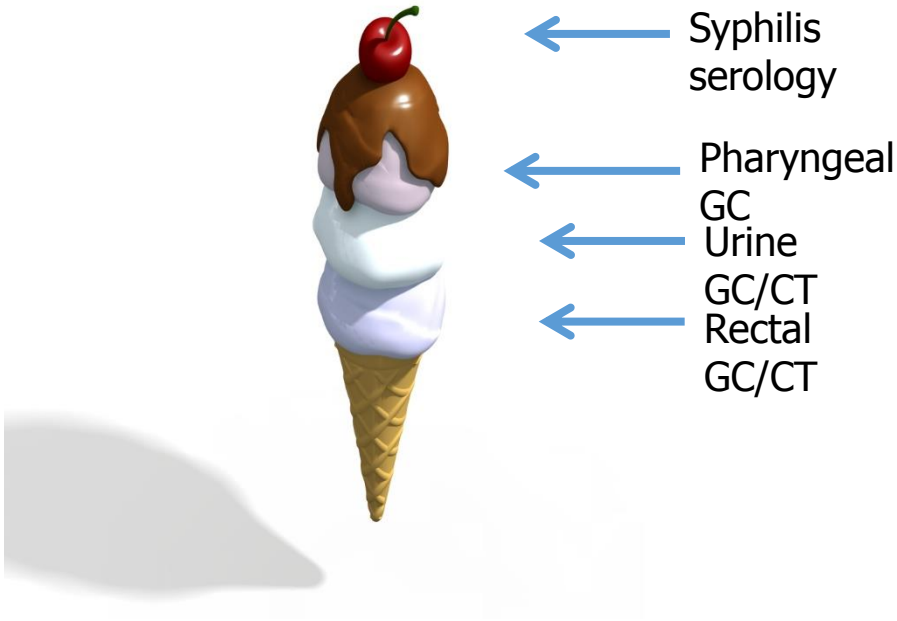
Step 3: Screen for STIs







Don’t forget the triple dip



NCSD
National Coalition of STD Directors
Promoting Sexual Health Through STD Prevention

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.

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

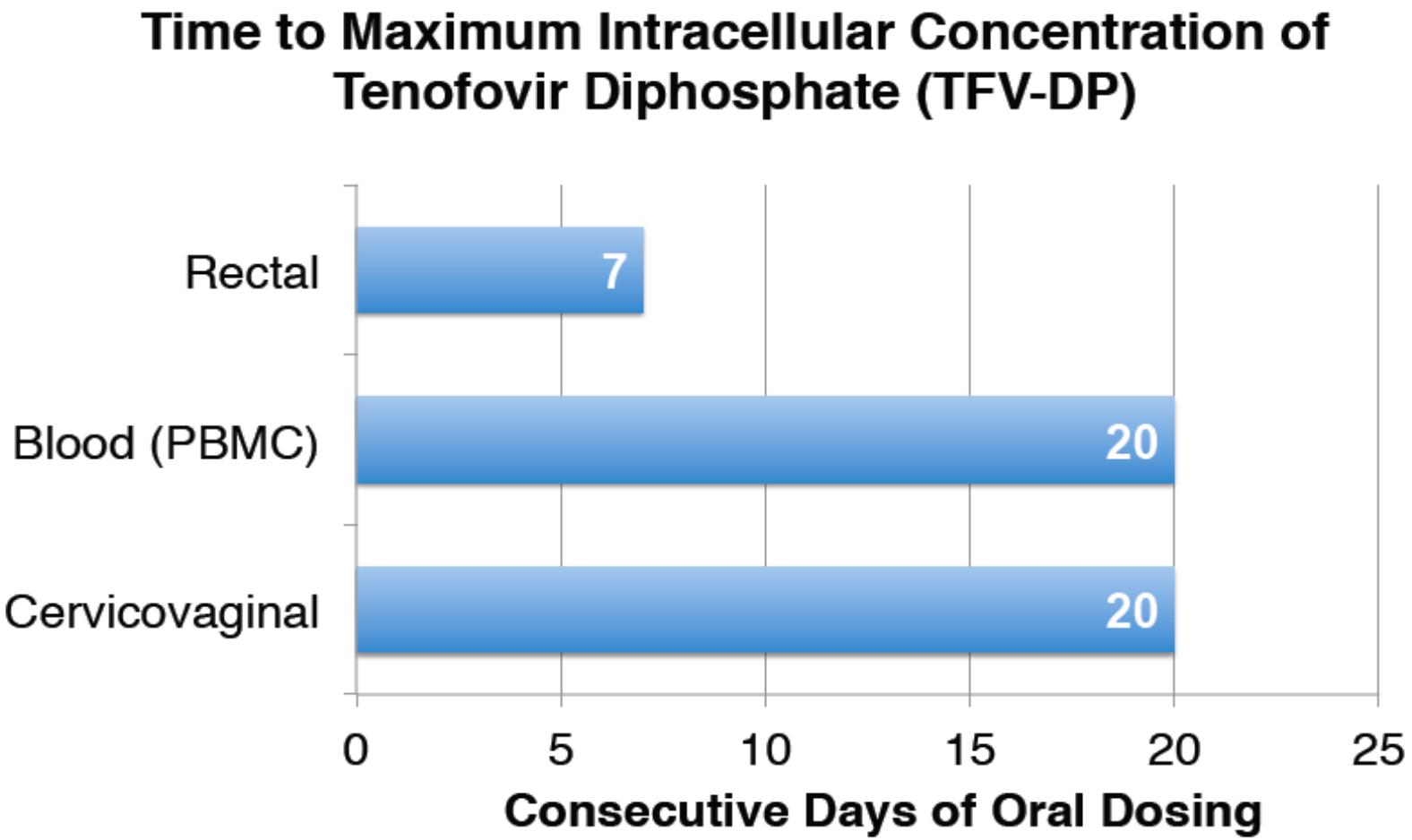
Won't PrEP encourage riskier sex?

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.

What prevents PrEP from being adopted?

- Awareness/Education
  - Provider
  - Patients
- Resistance to departure from condom-centric prevention counseling
- Integration into primary care and STI treatment settings
- Cost

What prevents PrEP from being adopted?

- Identification of at Risk Populations
  (History, Biologic markers, Self Identified)
- Access to screening and monitoring tests
  (extra-genital NAT, serum Cr, CBC, etc.)
- Fear of Sex……. Need to reframe to Sexual Health Message
- Should IHS make PrEP a covered service?

The Arizona Experience

Paul Bloomquist, MD, AAHIVS

The HIV Center of Excellence for American Indians/Alaska Natives

Phoenix Indian Medical Center

Estimate of PrEP Eligible Individuals

- 90,000 active user population
- 45,000 males
- 33,750 adult males

Estimate of PrEP Eligible Individuals

- 2.9% of adult men describe male sexual contact in last 12 months- 979 people (1)
- 4.5% of adult men identify as “gay” – 1516 people (2)
- CDC estimates that 24.7% of all MSM meet criteria for indication of PrEP (3)

1. **Gates, GJ (2006). Same Sex Couples and the Gay, Lesbian, Bisexual Population: New Estimates for the American Community Survey, 25. accessed at http://escholarship.org/uc/item/8h08t0zf**
2. **Purcell, Johnson, Lansky, Prejan, Stein, Denning, Crepaz. (2012). Estimating the Population size of men who have sex with men in th US to obtain HIV and syphilis rates. The Open AIDS journal, 6, 98-107.**
3. **CDC. Preexposure Prophylaxis for the Prevention of HIV Infection in the US-2014. A Clinical Practice Guideline. US Public Health Service.**

Estimate of PrEP Eligible Individuals

- 241-375 MSM are eligible for PrEP
- This does not include IDU or high risk heterosexual people

- $750 / month/individual-wholesale
- $2.17-3.38 M expense for medication

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 for 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 Cent 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.

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