A Pill for HIV Prevention
An Overview of Pre-Exposure Prophylaxis for New Providers

Christopher Hurt, MD
Assistant Professor of Medicine
Division of Infectious Diseases

UNC
INSTITUTE FOR GLOBAL HEALTH & INFECTIOUS DISEASES
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The views expressed are not necessarily those of the NIH.
What is pre-exposure prophylaxis?

Use of antiretroviral medications before an exposure, to reduce the risk of becoming infected

Tenofovir disoproxil fumarate (TDF) is the most studied agent for PrEP

- Properties of drug allow infrequent dosing
- Few drug-drug interactions
- Safe and well tolerated

FDA approved in 2012
USPHS guideline in 2014

(emtricitabine / TDF = Truvada)
Change may be difficult for many of us
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Adapted from HPTN
You’re seeing Demetrius in clinic

- 19 year-old freshman at UT
- Presenting for new discharge from penis
  - Dysuria preceded discharge
  - Symptoms for about 36 hours
- No constitutional symptoms
- Anxious – first-ever episode
Demetrius, cont’d

• Has sex with men
• Not in a relationship currently
• Meets partners at clubs and online
• Uses condoms “most of the time”
  o (in response to “How often do you…?” question)
• Finished PEP regimen 2 months ago
Pop quiz

Consistent use of condoms reduces the risk of HIV acquisition by how much?

50-60%  70-80%  90-100%
Pop quiz

Consistent use of condoms reduces the risk of HIV acquisition by how much?

50-60% 70-80% 90-100%


MSM (EXPLORE & VAX 004 trials): Smith DK et al. JAIDS 2015;68(3):337-44
Condoms only work if you use them

55% of MSM didn’t use condom with most recent anal sex

~90% of heterosexuals had some condomless sex in the prior year

30% of heterosexuals didn’t use condom with most recent anal sex

Demetrius, cont’d

• Has tried to be consistent with condoms
• Sex is less enjoyable with them
• Doesn’t always have one handy
• “They just get in the way of the moment”
Pop quiz, part 2

Consistent use of PrEP* reduces the risk of HIV acquisition by how much?

50-60%  70-80%  90-100%

*added to existing prevention methods
Pop quiz, part 2

Consistent use of PrEP* reduces the risk of HIV acquisition by how much?

50-60%  70-80%  90-100%

*added to existing prevention methods

Clinical trials leading to PrEP approval

**Prevention of sexual transmission**

- **Partners PrEP – daily oral TDF/FTC**
  (Serodiscordant couples – Kenya, Uganda)
  - Effect size (CI): 75% (55; 87)
- **Partners PrEP – daily oral TDF**
  (Serodiscordant couples – Kenya, Uganda)
- **TDF2 – daily TDF/FTC**
  (Heterosexual men and women – Botswana)
  - Effect size (CI): 67% (44; 81)
- **iPrEx – daily oral TDF/FTC**
  (MSM – North and South America, South Africa, Thailand)
  - Effect size (CI): 62% (22; 84)
- **FEM-PrEP – daily oral TDF/FTC**
  (Women – Kenya, South Africa, Tanzania)
  - Effect size (CI): 44% (15; 63)
- **MTN-003/VOICE – daily oral TDF/FTC**
  (Women – South Africa, Uganda, Zimbabwe)
  - Effect size (CI): 6% (-52; 41)
- **MTN-003/VOICE – daily oral TDF**
  (Women – South Africa, Uganda, Zimbabwe)
  - Effect size (CI): -4% (-49; 27)
  - Effect size (CI): -49% (-129; 3)

**Prevention in people who inject drugs**

- **Bangkok Tenofovir Study – Daily oral TDF**
  (IDUs – Thailand)
  - Effect size (CI): 49% (10; 72)
Clinical trials leading to PrEP approval

5 studies showed protective benefit of daily TDF-based PrEP
Clinical trials leading to PrEP approval

Prevention of sexual transmission

- **Partners PrEP** – daily oral TDF/FTC (Serodiscordant couples – Kenya, Uganda)
- **TDF2** – daily TDF/FTC (Heterosexual men and women – Botswana)
- **iPrEx** – daily oral TDF/FTC (MSM – North and South America, South Africa, Thailand)
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Prevention in people who inject drugs

- **Bangkok Tenofovir Study** – Daily oral TDF (IDUs – Thailand)

Effect size (CI)

- **Partners PrEP**: 75% (55; 87)
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- **Bangkok Tenofovir Study**: 49% (10; 72)

3 studies showed no protective benefit from TDF-based PrEP

http://www.avac.org/report2013
But didn’t you just say the efficacy was 90-100%?
It’s all about adherence
Trials of oral and topical tenofovir-based PrEP show that these strategies reduce risk of HIV infection if they are used correctly and consistently. Higher adherence is directly linked to greater levels of protection.

Source: Salim S. Abdool Karim, CAPRISA
What’s “consistent” PrEP use?

Data depicted reflect protective efficacy among MSM and TGW (i.e., principally anal sex)

- <2 tablets per week: 90% protection
- 2–3 tablets per week: 100% protection
- 4–6 tablets per week: 100% protection
- 7 tablets per week: Off PrEP

Time to optimal protection varies…

Days to Maximum Intracellular Concentration of Tenofovir Diphosphate (TFV-DP)

What I tell patients:
• For receptive anal sex 14 days
• For receptive vaginal sex 30 days
• For insertive sex or PWID 30 days

Key points

Daily dosing affords greatest protection

Occasional missed dose probably OK (less OK for cisgender women…)

Nonadherence creates opportunities for infection
Moving PrEP into practice

FDA Approves First Medication to Reduce HIV Risk

People diagnosed with HIV—the human immunodeficiency virus that without treatment develops into AIDS—take antiretroviral 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 safe sex practices—to reduce the risk of sexually acquired HIV infection in adults who do not have HIV but are at high risk of becoming infected. (HIV) 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 43 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 Antivirals, Products of 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 previously approved by FDA for use in combination with other medications to treat HIV-infected adults and children over 12 years old.

"In the 1980s 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 more than 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 lifelong 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 submitted for sale as a drug, she says.

US Public Health Service

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

A CLINICAL PRACTICE GUIDELINE
Demetrius, cont’d

• Aware of the term “PrEP”

• Remembers reading something about a study in San Francisco?

• Overall pretty skeptical

• “I’ve heard these medications are toxic…”
Kaiser Permanente

SF Bay area, July 2012 - Feb 2015

1045 referrals for PrEP

80% evaluated in person

82% started PrEP (62% of those referred)

388 person-years of follow-up

187 new STIs among PrEP users

0 new HIV infections among PrEP users

PROUD Study

London, Nov 2012 - Apr 2014

544 MSM & trans women

½ started immediately

½ delayed initiation

DSMB halt (Oct 2014)

PROUD Study

London, Nov 2012 - Apr 2014

544 MSM & trans women 1/2 started immediately 1/2 delayed initiation 86% protective effectiveness (95% CI: 58, 96)

13 at-risk MSM need to be treated for 1 year to prevent 1 infection (95% CI: 9, 23)

For primary prevention: aspirin 1667 x 1Y statin 104 x 5Y

What are the side effects of PrEP?

“Startup syndrome”

- Flatulence (3-4%)*
- Nausea (8-20%)*
- Mild headache (6-22%)*
- Symptoms resolve within first 30d, for most

* post-marketing reported frequencies (Lexi-Comp)

What are the side effects of PrEP?

**Proximal tubular toxicity**
- Fanconi syndrome
- Hypophosphatemia
- Phosphaturia (FE Phos)
- Glucosuria (plasma normal)
- Proteinuria
- Proximal RTA

Of 10,343 HIV+ starting tenofovir

2% had any renal function abnormality

Of 183 starting with normal function
- 59% Normalized (after median 17m) n=108
- 9% Improved n=18
- 31% No change n=57


What are the side effects of PrEP?

Loss of bone mineral density

FTC/TDF on study vs Off FTC/TDF

18-22 years old (n=72)

Percent change BMD

Baseline | Week 24 | Week 48 | Ext Phase | Ext Phase

Spine
P=0.03 vs W48
P=0.04 vs BL

Whole Body
P=0.01 vs W48
P=0.7 vs BL

Hip
P=0.04 vs W48
P=0.5 vs BL

* P < 0.05 vs BL

Mulligan K, et al. 18th Int’l Workshop on Comorbidities and Adverse Drug Reactions in HIV.
Demetrius, cont’d

• Doesn’t think side effects sound bad

• “People say PrEP is for sluts… and I don’t hook up that much…”

• “Is this still something you’d recommend?”
Won’t PrEP encourage riskier sex?

Slut shaming and stigma are all too real.

I see, so if I don't have sex with you I'm a prude bitch, if I use the pill I'm a slut, if I get pregnant I'm an idiot and if I choose abortion I'm Satan. Yay.

US News and World Report, 1966
Won’t PrEP encourage riskier sex?

Shaming of PrEP users is also real

Rethinking HIV Prevention and Sex

Hi all, finally updated my Grindr to say I’m on prep and I can safely say I have never seen so many guys suddenly lose interest or just stop talking/block me. Has anyone else dealt with this? Made it clear with one guy that I take it as extra precaution, still use condoms, and he said he ‘didn’t think I was that kinda guy’... what?!

Your protecting yourself and others. Thankfully you are that “type of guy”.

Prep. F**k in disgusting

Dirty breeder. Prep is to stop HIV only. Not other vile STD
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

Who should get PrEP?

HIV uninfected, plus:
- Any HIV+ partner(s)
- Condomless sex in past 6m
- Any STI in past 6m
- High number of sex partners
- In high-prevalence area or sexual network
- Commercial sex work
- Shared injection equipment
- Recent drug treatment & current relapse
Who should get PrEP?

HIV uninfected, plus:
- Any HIV+ partner(s)
- Condomless sex in past 6m
- Any STI in past 6m
- High number of sex partners
  - In high-prevalence area or sexual network
- Commercial sex work
- Shared injection equipment
- Recent drug treatment & current relapse
HIV prevalence in the Southeast, 2012
Prevalence by race/ethnicity, 2012

Hispanic/Latino

White
Prevalence by race/ethnicity, 2012
PrEP is not reaching those at greatest risk

US Population 2015

- Black: 62%
- Hispanic: 18%
- Asian: 13%
- Multi/Other: 13%
- White: 26%

New Infections 2015 (estimated)

- Black: 44%
- Hispanic: 24%
- Asian: 26%
- Multi/Other: 10%
- White: 13%

Mera Giler R. et al. IAS Paris 2017, abstract #WEPEC0919
https://www.poz.com/article/estimated-136000-people-prep-us
PrEP users per 100,000 population, 2016

More than half of new HIV diagnoses in US in 2016, but only 30% of all PrEP users

Data from AIDSVu: http://map.aidsvu.org/map?prep=1
PrEP is really a matter of social justice
Demetrius, cont’d

- Won over by the compelling evidence

- “What do I have to do to get started?”
Step 1: Determine clinical eligibility

Viral hepatitis
- HBsAg
- HBsAb
- HCV Ab

Renal function
- Creatinine
- eCrCl

Caution if active HBV

eCrCl must be \( \geq 60 \text{ mL/min} \)

Step 1: Determine clinical eligibility

HIV status

- Ag/Ab (over rapid)
- POC (on blood)
- ELISA / EIA

Must be HIV(–)

→ Maybe RNA, too?

Step 1: Determine clinical eligibility

Viral hepatitis
- HBsAg
- HBsAb
- HCV Ab

Caution if active HBV

Renal function
- Creatinine
- eCrCl

eCrCl must be $\geq 60$ mL/min within 30 days

HIV status
- Ag/Ab
- POC (on blood)
- ELISA / EIA

Must be HIV(⁻) → Maybe RNA, too?

Step 1: 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)**
Step 2: 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: 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
Step 4: Prescribe & follow-up

First Rx: 30-90 days, NO refills

Return to clinic in 30-90 days

- Adherence?
- Side effects?
- Behavior changes?

2nd Rx: 90 days’ worth
Step 5: Maintenance & reassessment

**At least every 3 months (i.e., each visit)**
- Assess adherence, side effects, behaviors
- Repeat HIV testing
- Prescription renewal

**At least every 6 months, also…**
- Check creatinine and eCrCl
- Screen for STIs, if not already done
- Determine need – “seasons of risk”
The big picture

PrEP is a **proven**, **well-tolerated**, **highly effective** tool for HIV prevention when taken every day.
I am a 30-something African-American gay man in New York. H.I.V. is constantly on my mind. Not so much my H.I.V.-negative status. Rather, even though I watched my parents die of AIDS when I was young, I still struggle with whether I should take the drug Truvada, a pre-exposure prophylaxis (PrEP) that can protect almost completely against H.I.V.
Questions?

Please email me!

Christopher Hurt, MD
churt@med.unc.edu
PrEP for Special Populations

Persons Who Inject Drugs, Transgender Persons, and Cisgender Women Trying to Conceive

Christopher Hurt, MD
Assistant Professor of Medicine
Division of Infectious Diseases
PrEP is not just for MSM

Vital Signs: Estimated Percentages and Numbers of Adults with Indications for Preexposure Prophylaxis to Prevent HIV Acquisition — United States, 2015

Dawn K. Smith, MD; Michelle Van Handel, MPH; Richard J. Wolitski, PhD; Jo Ellen Stryker, PhD; H. Irene Hall, PhD; Joseph Prejean, PhD; Linda L. Komig; Linda A. Valeroy, PhD

On November 24, 2015, this report was posted as an MMWR Early Release on the MMWR website (http://www.cdc.gov/mmwr).

Abstract

Background: In 2014, approximately 40,000 persons in the United States received a diagnosis of human immunodeficiency virus (HIV) infection. Preexposure prophylaxis (PrEP) with daily oral antiretroviral medication is a new, highly effective intervention that could reduce the number of new HIV infections.

Methods: CDC analyzed nationally representative data to estimate the percentages and numbers of persons in the United States, by transmission risk group, with indications for PrEP consistent with the 2014 U.S. Public Health Service’s PrEP clinical practice guideline.

Results: Approximately 24.7% of sexually active adult men who have sex with men (MSM) (492,000 [95% confidence interval (CI) = 212,000–772,000]), 18.5% of persons who inject drugs (115,000 [CI = 45,000–185,000]), and 0.4% of heterosexual active adults (624,000 [CI = 404,000–846,000]), had substantial risks for acquiring HIV consistent with PrEP indications.

Conclusions: Based on current guidelines, many MSM, persons who inject drugs, and heterosexual active adults have indications for PrEP. A higher percentage of MSM and persons who inject drugs have indications for PrEP than heterosexual active adults, consistent with distribution of new HIV diagnoses across these populations.

Implications for Public Health Practice: Clinical organizations, health departments, and community-based organizations should raise awareness of PrEP among persons with substantial risk for acquiring HIV infection and their health care providers. These data can be used to inform scale-up and evaluation of PrEP coverage. Increasing delivery of PrEP and other highly effective HIV prevention services could lower the number of new HIV infections occurring in the United States each year.

Introduction

Approximately 40,000 persons in the United States received a diagnosis of HIV in 2014. PrEP is a complementary strategy to other effective HIV prevention methods, including early diagnosis and treatment of HIV, achieving viral suppression and consistent condom use.
PrEP is not just for MSM

492,000
sexually active MSM

115,000
persons who inject

624,000
heterosexually active adults

Smith DK et al. MMWR 2015 64(46):1291-1295
Bangkok Tenofovir Study
Persons who inject drugs

June 2005 - June 2012 (endpoint reached Nov 2011)

- 2413 injectors randomized (9665 P-Y of f/u)
- 17 infections on TDF (among 1204)
- 33 infections on placebo (among 1207)
- 49% efficacy mITT (95% CI: 9.6, 72.2)

- 83.5% preventive efficacy among 849 participants with ≥97.5% adherence

Efficacious, but may be too expensive...

Scaling up services to 50% coverage among US PWID...

- **OAT**: 22,000 infections averted, $18,000 / QALY
- **NSP**: 35,000 infections averted, $25,000 / QALY
- **Test & Treat**: 6,700 infections averted, $27,000 / QALY
- **PrEP**: 37,000 infections averted, $300,000 / QALY
FTC/TDF among transgender persons

No interactions\(^1\) with:
- Estradiol
- Progestins
- Spironolactone

No predicted interaction with testosterone\(^2\)

Effectively no data on TGM\(^3\)
- HIV risk for TGM affected by:
  - Vaginal thinning/atrophy
  - Loss of self-lubrication

2 https://hiv-druginteractions.org/interactions/77395
“One strategy is... viral suppression... for the male partner, with intercourse... around ovulation, while the female partner is taking... PrEP.”

Kawwass JF, et al. MMWR. 2 June 2017;66(21):554-7
CDC acknowledges PrEP in conception planning

“[PrEP]… can also reduce the risk for a woman who is attempting conception with an HIV-infected man, especially if his viral load is not known or is detectable.”
Safety of FTC/TDF in pregnancy is clear

FTC/TDF is category B

No evidence of birth defects among babies born to mothers taking TDF for HIV

No data suggesting PrEP is unsafe in pregnancy or lactation

Efficacy of PrEP in pregnancy is unknown

Risk of HIV acquisition higher during pregnancy & post-partum

Women who became pregnant in PrEP trials stopped FTC/TDF

CDC/USPHS 2014
- Ensure male partner undetectable
- Begin PrEP 1 month before, continue for 1 month after conception attempt

2 Mofenson LM. *PLoS Med*. Sep 2016;13(9):e1002133
3 CDC/USPHS 2014 PrEP Guideline – Clinical Providers’ Supplement
Potential impact of interventions, 2015-2020

Scenario 1: Projected new HIV infections by 2020 at current testing and treatment rates

265,330
Potential impact of interventions, 2015-2020

Scenario 1: Projected new infections by 2020 at current testing and treatment rates

Scenario 2: If PrEP use increases among high-risk populations at current testing and treatment rates

- **New infections**: 265,330
- **HIV infections prevented due to expanded testing and treatment**: 217,109
- **HIV infections prevented due to PrEP (assumes PrEP use among high-risk populations = 40% MSM; 10% PWID; 10% HET)**: 48,221

Yaylali E et al. CROI 2016, abstract #1051
Graphic from CDC
Potential impact of interventions, 2015-2020

Scenario 1:
Projected new infections by 2020 at current testing and treatment rates

265,330 total new infections

Scenario 2:
If PrEP use increases among high-risk populations at current testing and treatment rates

217,109 total new infections

48,221 infections prevented through PrEP

Scenario 3:
If 85% of people diagnosed are linked to care, 60% achieve viral suppression, plus PrEP use

144,434 total new infections

31,988 infections prevented through PrEP

88,908 infections prevented through testing and treatment

Legend:
- New infections
- HIV infections prevented due to expanded testing and treatment
- HIV infections prevented due to PrEP (assumes PrEP use among high-risk populations = 40% MSM; 10% PWID; 10% HET)

Yaylali E et al. CROI 2016, abstract #1051
Graphic from CDC
Potential impact of interventions, 2015-2020

**Scenario 1:**
Projected new infections by 2020 at current testing and treatment rates

- New infections: 265,330

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- New infections: 217,109
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**Scenario 3:**
If 85% of people diagnosed are linked to care, 60% achieve viral suppression, plus PrEP use

- New infections: 144,434
- HIV infections prevented through testing and treatment: 31,988

**Scenario 4:**
Achieving NHAS goals – if 85% of people diagnosed are linked to care, 80% achieve viral suppression, plus PrEP use

- New infections: 80,270
- HIV infections prevented through testing and treatment: 16,928
- HIV infections prevented due to PrEP: 168,132

Yaylali E et al. CROI 2016, abstract #1051
Graphic from CDC
Questions?

Please email me!

Christopher Hurt, MD
churt@med.unc.edu
EXTRA SLIDES
Post-exposure prophylaxis (PEP)

Key points

• Two classifications:
  • Occupational (sometimes “oPEP”)
  • Nonoccupational (“nPEP”)

• Effective if given within 72h (earlier = better)

• Historically, 28d of: Combivir $^2$NRTIs + Kaletra PI
  • Suboptimal completion rates due to side effects

• 2013 – CDC oPEP guidelines updated
Post-exposure prophylaxis (nPEP)
As of 2016, recommended regimen is **28 days** of:

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<th>Alternative</th>
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<td><strong>emtricitabine/tenofovir DF</strong></td>
<td><strong>ritonavir</strong></td>
</tr>
<tr>
<td>Truvada (Gilead)</td>
<td>Norvir (AbbVie)</td>
</tr>
<tr>
<td>QD</td>
<td>QD</td>
</tr>
<tr>
<td><strong>raltegravir</strong></td>
<td><strong>dolutegravir</strong></td>
</tr>
<tr>
<td>Isentress (Merck)</td>
<td>Tivicay (ViiV)</td>
</tr>
<tr>
<td>BID</td>
<td>QD</td>
</tr>
</tbody>
</table>

**Preferred Alternative**

CDC is on board with “U=U”

“[P]eople who take ART daily… and maintain an undetectable viral load have effectively no risk of sexually transmitting the virus to an HIV-negative partner.”