



Pre-exposure Prophylaxis for HIV Prevention

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**Urban Indian
Health Institute**
A Division of the Seattle Indian Health Board



Adapted from a presentation developed
by

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for use by the AIDS Education Training
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Topics To Be Covered

1. HIV epidemiology in AI/AN
2. Efficacy and Safety
3. Prescribing Recommendations/Protocols
4. Common concerns about PrEP
5. Barriers to PrEP in AI/AN

HIV Epidemiology Case numbers and rates

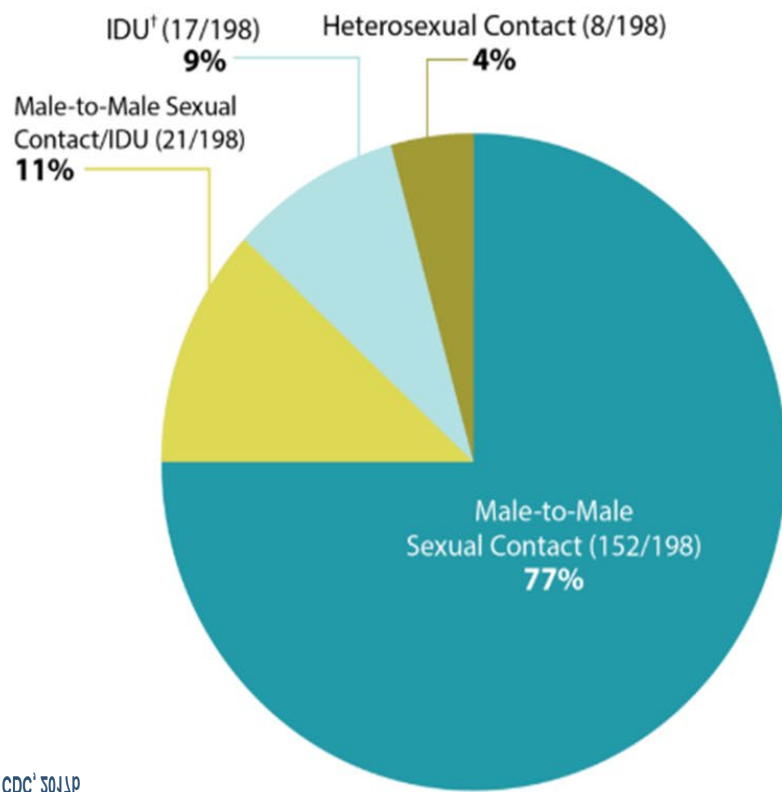
2016

HIV	Cases	Rate/100,000 persons
AI/AN	243	10.2
Non-Hispanic White	10,345	5.2

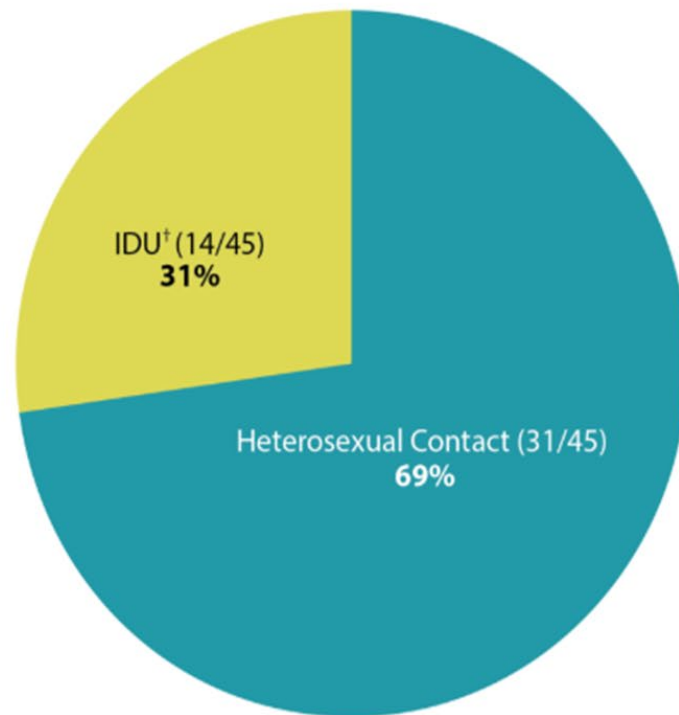
AIDS	Cases	Rate/100,000 persons
AI/AN	102	4.3
Non-Hispanic White	4442	2.2

Racial misclassification and under-counting likely

HIV Epidemiology (2016) Diagnoses within AI/AN by sex & transmission category



Men/Males (N=198)



Women/Females (N=45)

CDC 3013P

HIV Epidemiology Disparities

2015


3,500 AI/AN estimated living with HIV

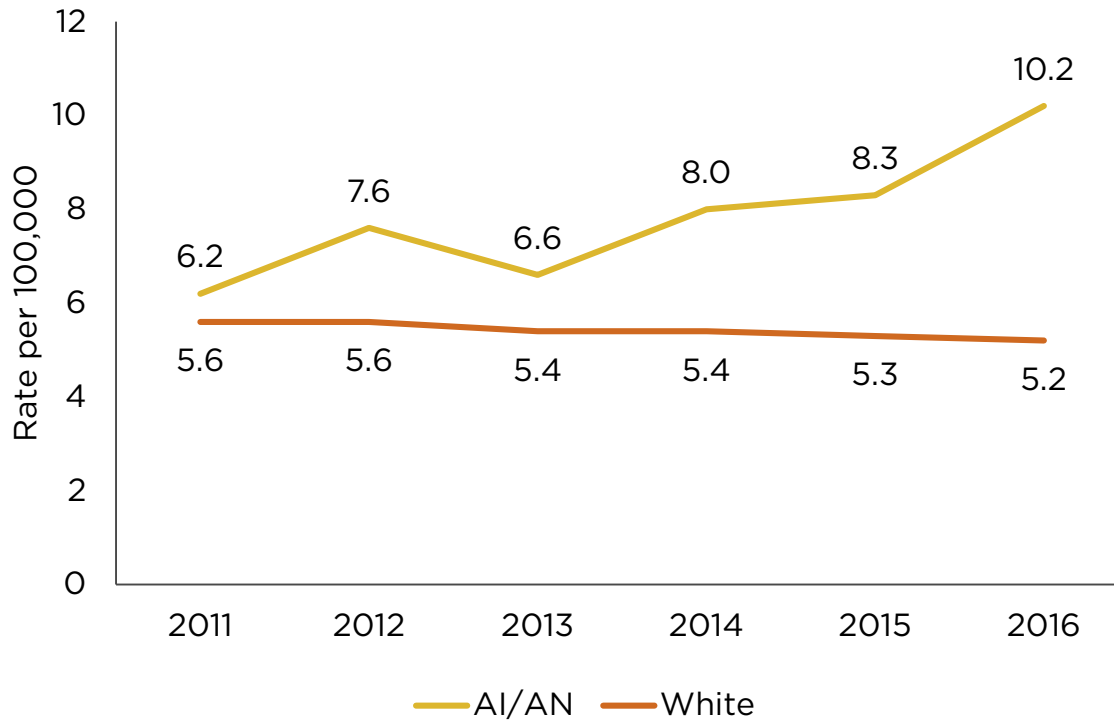
18% undiagnosed

overall US: 15% undiagnosed

Source: CDC, 2016b; CDC, 2017b; Reilley, B. et al. Public Health Reports. 2018

HIV Epidemiology Disparities

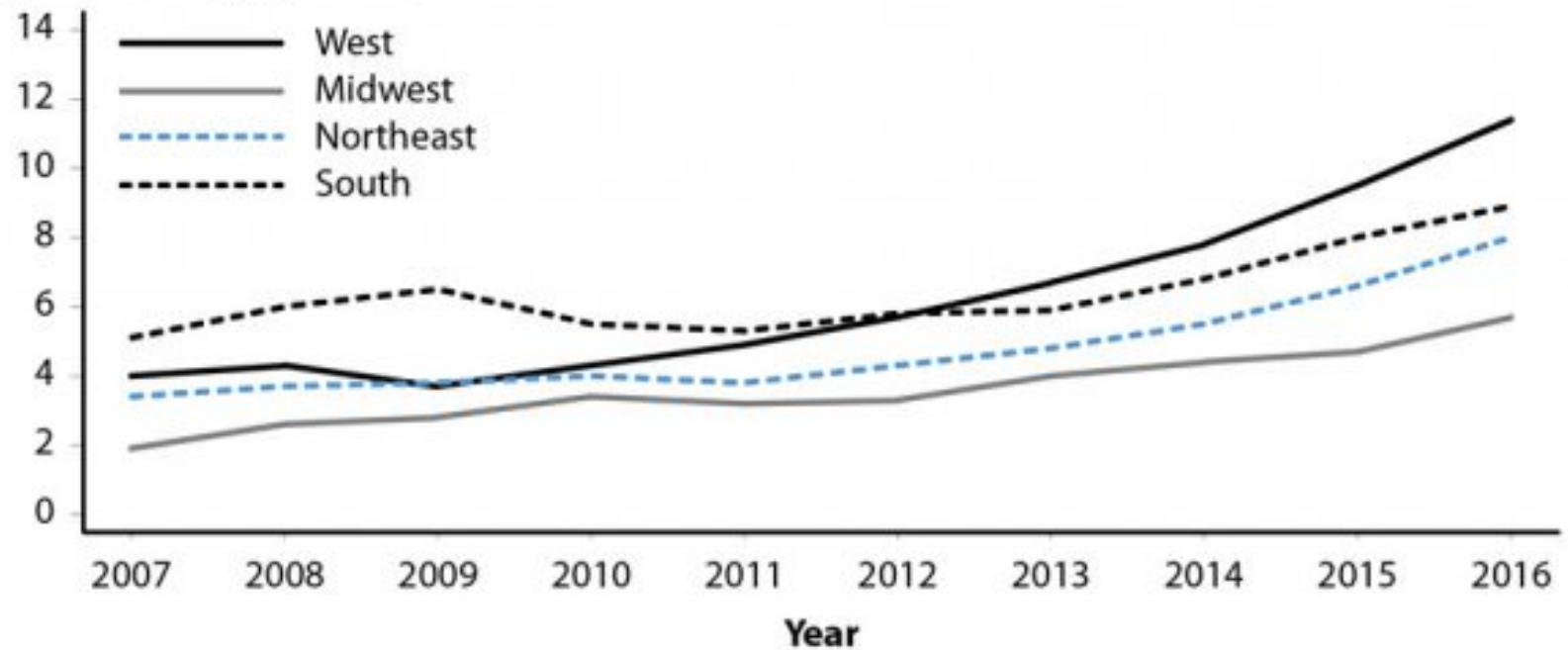
AI/ANs  in HIV cases diagnosed
Most other groups  cases



Syphilis Rates Continue to Rise

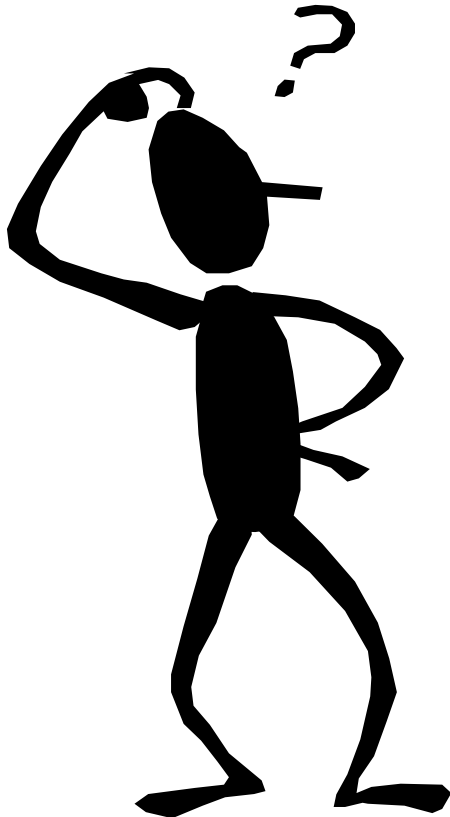
2016 CDC Surveillance Data

Rate (per 100,000 population)



<https://www.cdc.gov/std/stats16/Syphilis.htm>

Question



What barriers have you observed that contribute to HIV/HCV/STI rates within AI/AN communities?

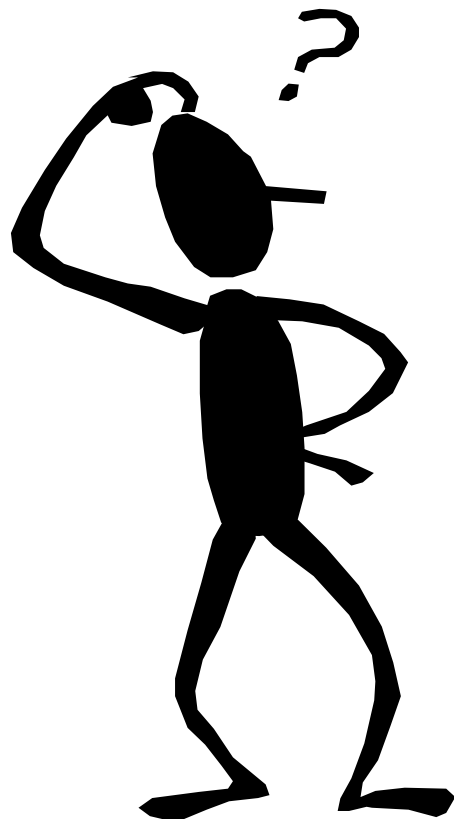
Prevention challenges in AIs/ANs

- AIs/ANs had 2nd highest rates of GC/CT.
- Lack of awareness of status – 1 in 5 HIV+ AIs/Ans
- Stigma and discrimination – on so many levels.
- Mistrust and lack of support from healthcare system
- Cultural diversity – 560 federally recognized tribes w >170 languages

Prevention challenges in AIs/Ans (Con.)

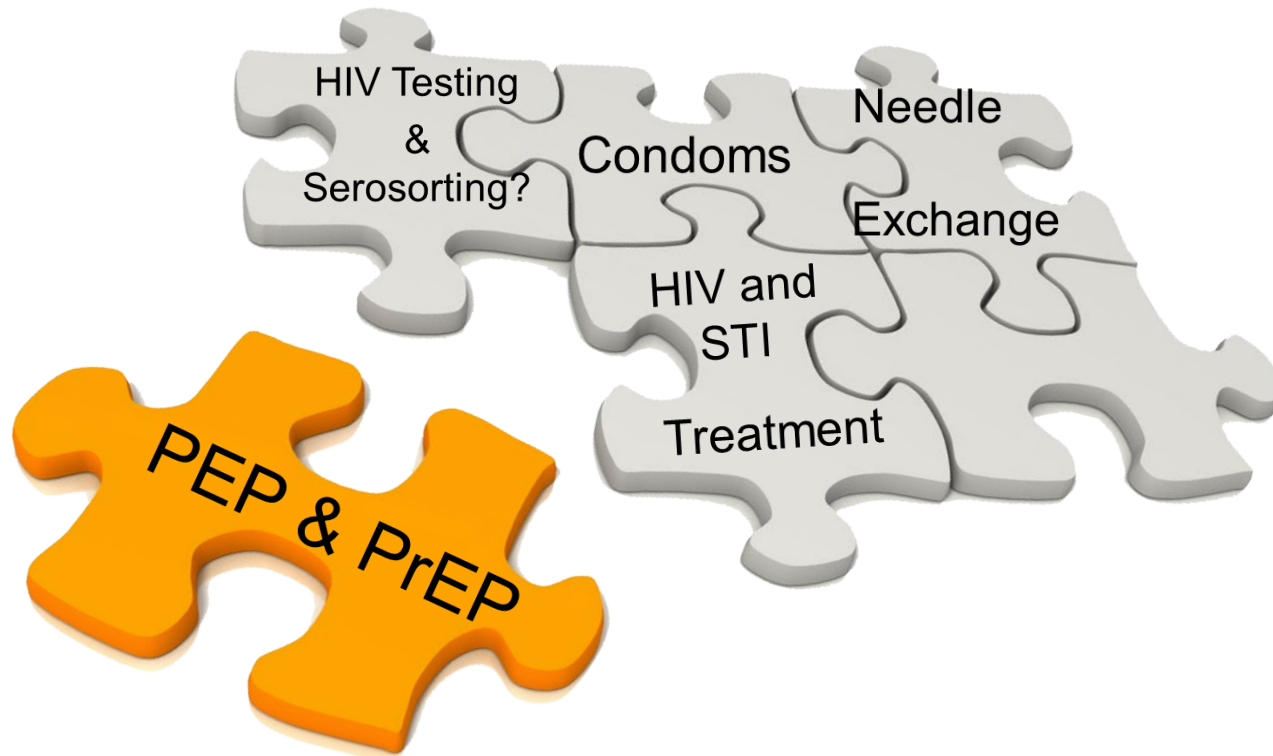
- Poverty, education, employment, healthcare, addiction
- Comorbidities – diabetes, depression, anxiety
- Data limitations – racial misidentification and undercounting leads to underfunding
- Limited funding, resources, services

Question



Name several HIV/HCV/STI
prevention interventions

Sexual Health Tools of Prevention



Pre Exposure Prophylaxis (PrEP)



The Latest Addition to the prevention toolkit

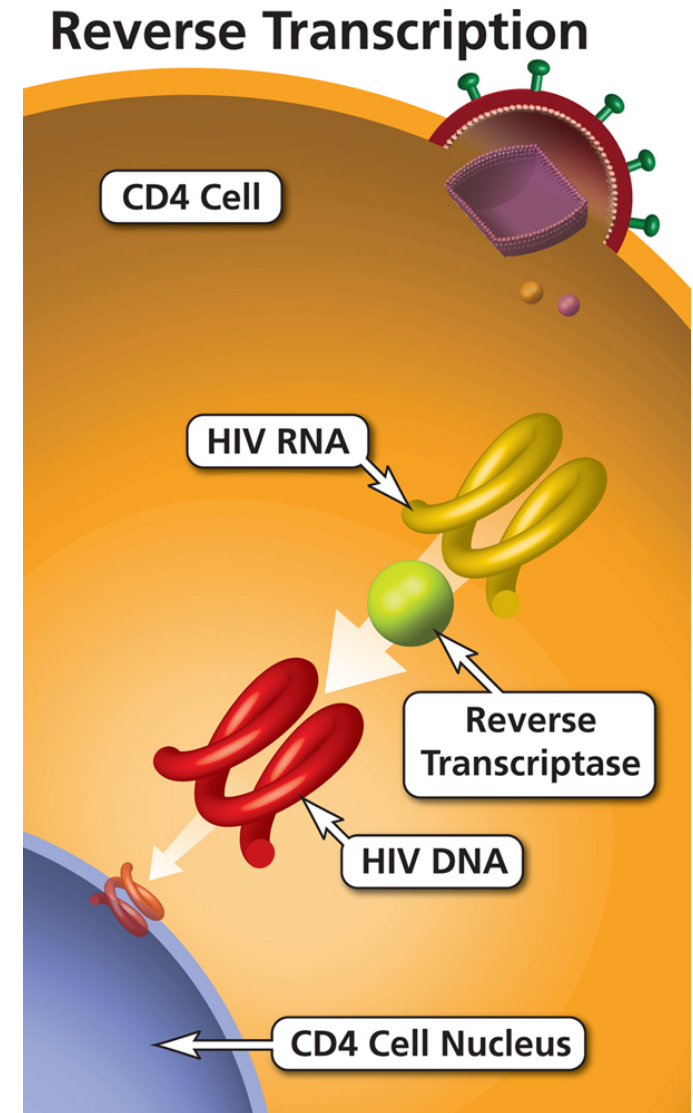
What is PrEP?



- PrEP (Pre-Exposure Prophylaxis) = Daily medication to prevent HIV infection
- Truvada is the only approved medication
- Chemical Composition
 - **Emtricitabine (200 mg) FTC**
 - **Tenofovir disoproxil fumarate (300 mg) TDF**

Biochemical Prevention

- Antiretroviral – Nucleoside Reverse Transcriptase Inhibitor (NRTI) “Nuke”
- Protects CD4 cells from being infected following introduction of virus



PrEP Timeline

- 2004 – Truvada approved for ARV Therapy
- 2007 – IPrEx Study launched – 2,499 individuals
- 2008 - Partners Study launched - 4,758 couples
- 2012 – FDA approves Truvada as PrEP
- 2014 – CDC issues recommendation for PrEP
- 2015 – WHO issues recommendation for PrEP

Key HIV PrEP Trials Using Oral Tenofovir (TDF) or Tenofovir-Emtricitabine (TDF-FTC)

Study	Study Population	Study Randomization	HIV Incidence Impact
IPrEx (Brazil, Ecuador, South Africa, Thailand, US)	2499 MSM and transgender women	Daily oral TDF-FTC or placebo	TDF-FTC: 44% ↓
Partners PrEP Study (Kenya, Uganda)	4147 heterosexual HIV discordant couples	Daily oral TDF, TDF-FTC, or placebo	TDF: 67% ↓ TDF-FTC: 75% ↓
TDF2 Study (Botswana)	1219 heterosexual men and women	Daily oral TDF-FTC or placebo	TDF-FTC: 63% ↓
FEM-PrEP (Kenya, South Africa, Tanzania)	2120 women	Daily oral TDF-FTC or placebo	TDF-FTC: no protection
VOICE (South Africa, Uganda, Zimbabwe)	5029 women	Randomized to daily oral TDF, TDF-FTC, oral placebo, TDF vaginal gel, or gel placebo	TDF: no protection TDF-FTC: no protection TDF gel: no protection
Bangkok TDF Study (Thailand)	2413 injection drug users	Randomized to daily oral TDF or placebo	TDF: 49% ↓
IPEGAY (France, Quebec)	400 MSM	Randomized to “on-demand” TDF-FTC or placebo	TDF-FTC: 86% ↓
PROUD (United Kingdom)	545 MSM and transgender women	Randomized to daily oral TDF-FTC immediately or delayed	Immediate TDF-FTC: 86% ↓

Efficacy of PrEP

When taken daily and as directed, PrEP is highly effective at reducing transmission of HIV

- Sexual Transmission **>90%**
- IDU Transmission **>70%**

PrEP Side Effects and Safety

“Startup Syndrome”

- Nausea, headache, or fatigue may occur in first 2-4 weeks

Renal Safety

- Renal insufficiency

Bone Effects

- TDF-FTC associated with small change (~1%) in bone density
- No increase in fractures seen

Hepatic Effects (RARE)

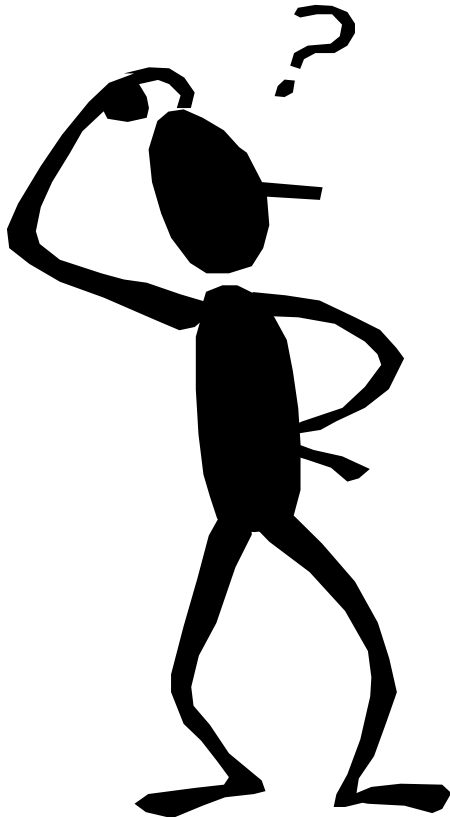
- HBV Flare
- Small risk of TDF related cancer

Important Information on PrEP

- Initial screen for STI's, HIV status, and metabolic function. Continued screening every 3-6 months
- Minimum of 7 days required for effective tissue saturation of anal tissues; 14 days for penile; 21 days for vaginal
- Continued daily adherence for ongoing protection
- Does not prevent against other STI's. Most effective when used in combination with barrier protection
- Patients starting PrEP with acute or established HIV infection need to be on standard ARV tri-therapy

Question

Who do you feel would be appropriate candidates for PrEP?

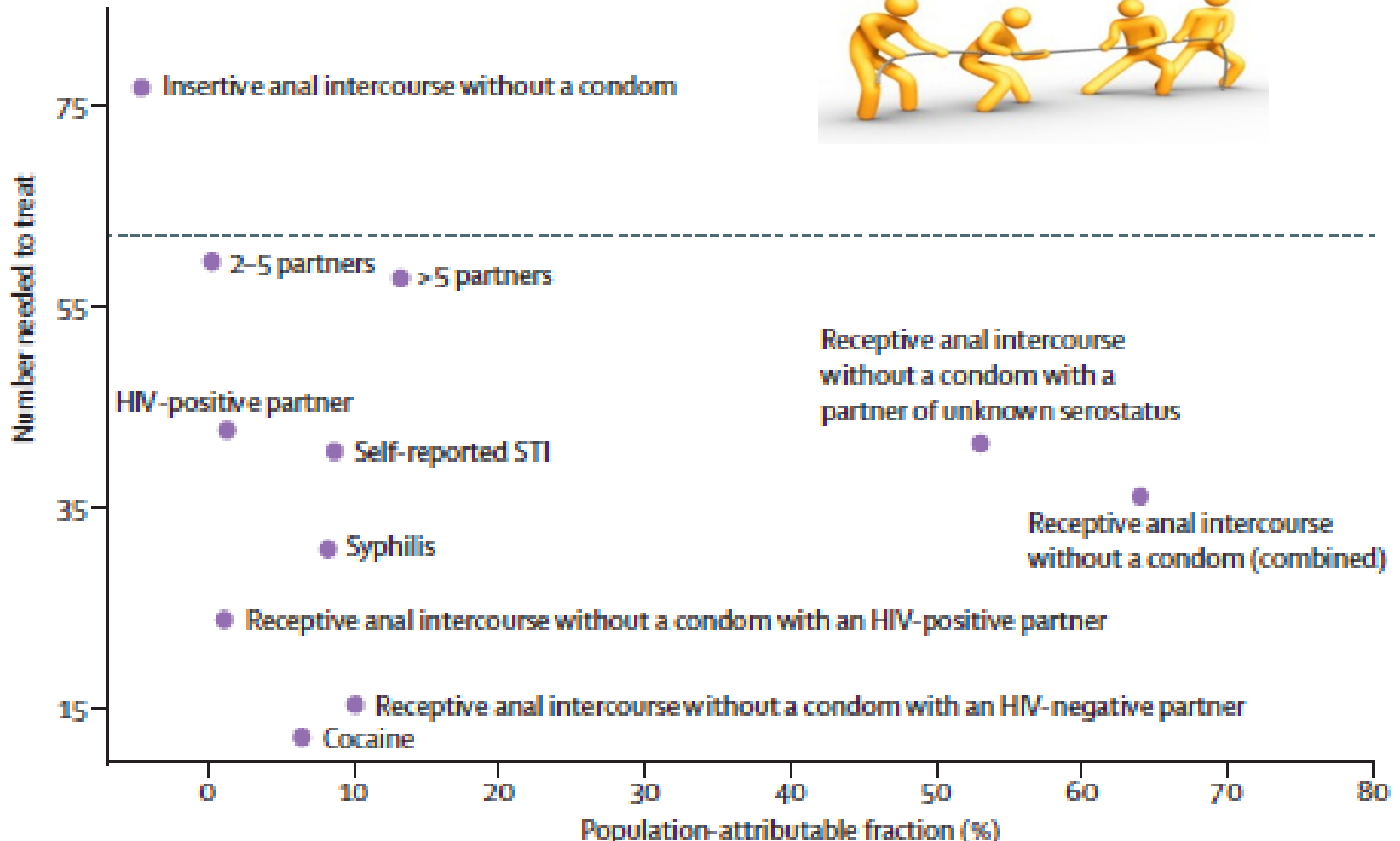


Who is an Ideal Candidate for PrEP?

Individuals at substantial risk” for HIV

- MSM w/multiple partners, have condomless anal sex, and a recent STI
- Heterosexual partners of MSM
- Partners of unknown HIV or IDU status
- Transgender Women
- PWID
- Sex Workers
- Partners of HIV+

Who is an Ideal Candidate for PrEP?



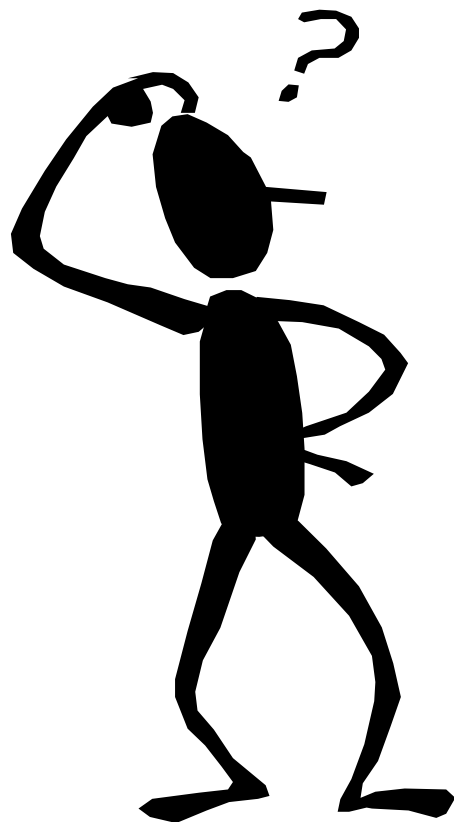
PrEP Management: Simpler than Diabetes

- Assess sexual health history and risk for HIV
- Determine appropriateness of biomedical intervention
- Able to adhere to a daily medication
- Able to adhere to follow-up visits
- Insurance coverage and/or ability to pay
- Initial screening tests
 - HIV (Must be negative; if reactive, begin ARV treatment)
 - HBV (if unvaccinated – If reactive, treat)
 - General STI Screen (CT/GC/Syphilis – If reactive, treat)
 - Kidney Creatinine Function (> 60 mL/min)
 - Pregnancy Test (if applicable)
- Follow-up STI and kidney function tests 3-6 months

PrEP and Hepatitis (B/C)

- HBV + should be evaluated for treatment or by linkage to an experienced HBV care provider. Potential life threatening hepatic flare if suddenly stopped
- HCV testing is recommended for:
 - PWID (With annual testing)
 - MSM starting PrEP
 - Anyone born 1945-1965
 - History of incarceration
 - Non-professional tattoos
- HCV treatment can occur simultaneously

Question



What are some concerns you
have about PrEP?

PrEP: Commonly Cited Concerns

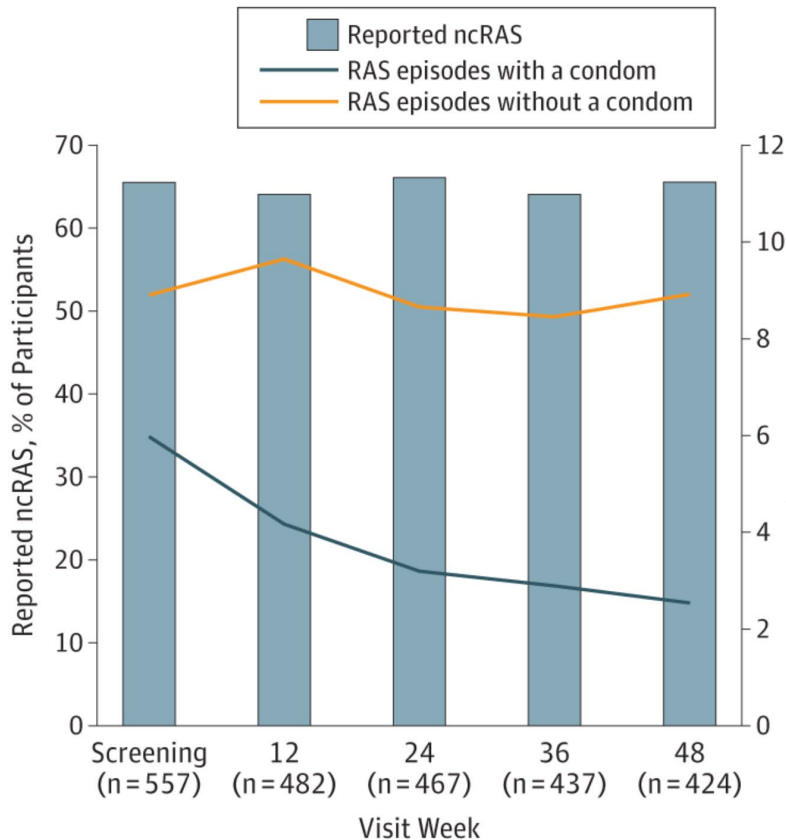
- Behavioral Disinhibition
- Increased STI outbreaks
- Too complicated for primary care providers
- Adherence

PrEP and Behavioral Disinhibition

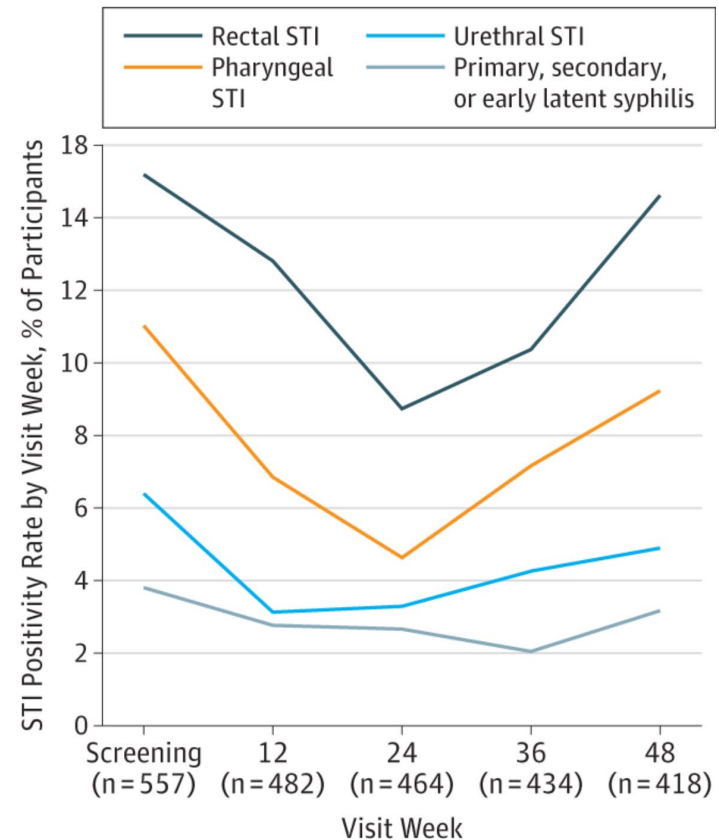
Could “risk compensation” negate the prevention benefits of PrEP?

Behavior change and STIs in Demo Project (San Francisco, Miami, Washington D.C.)

A Receptive anal sex

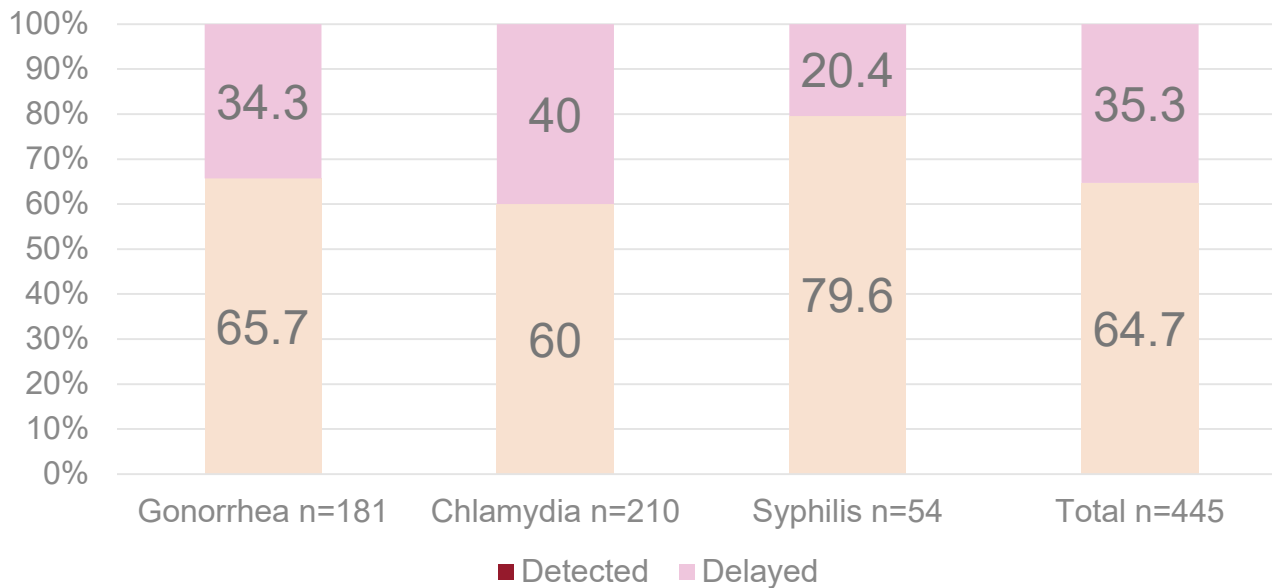


B Positive results of STI testing



Asymptomatic STIs of Persons on PrEP

Proportion of infections for which treatment would have been delayed with q6 month screening



Contradictory Studies on STIs and PrEP?

- STI incidence among MSM PrEP users is high
- PROUD - No difference in STI incidence
- Kaiser Permanente - 44% men ↓ condom use with PrEP
- Meta-analysis suggests ↑ STI risk in MSM using PrEP
- Possible reduced incidence d/t frequent screening

PrEP and STI incidence

Study results are inconclusive and contradictory

BUT...

- ❖ Birth control has not led to increased sexual risk
- ❖ Needle exchange has not led to increased IDU.
- ❖ HPV vaccine has not led to earlier sexual introduction

PrEP: Applying Harm Reduction



We prescribe lipid-lowering agents to reduce MI risk for people who continue to eat French fries...

WHY SHOULD SEX/SUBSTANCE USE BE ANY DIFFERENT?

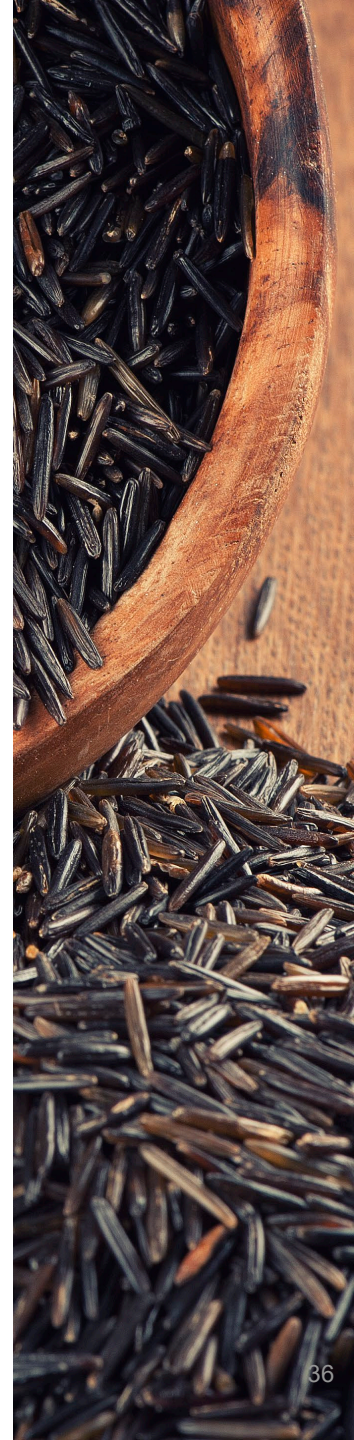
Sexual Behavior is Part of a Broader Puzzle

- Not Static
- Fluctuates
- Driven by conscious AND subconscious decisions
- Interconnected with other life domains



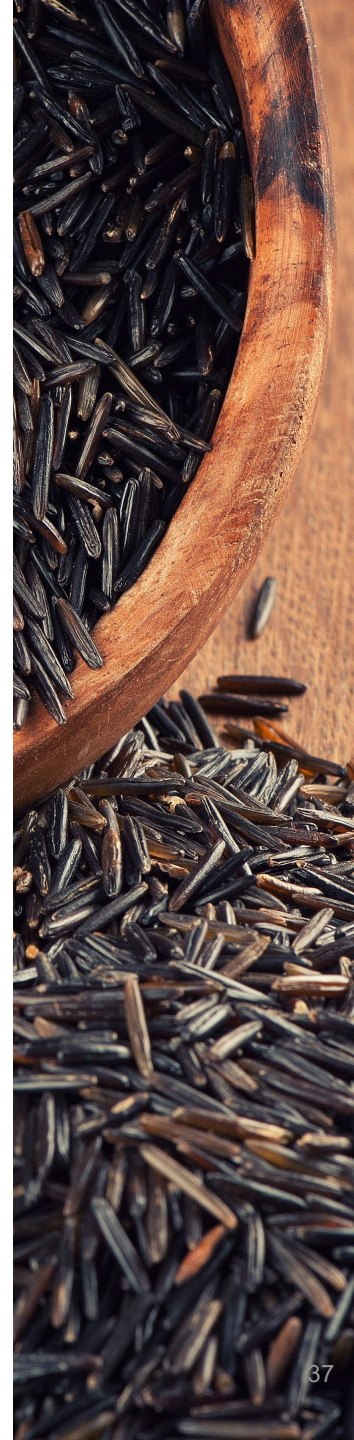
Health Value of PrEP

- Increased STI screening/treatment
- Reframing sexual health in a positive framework
- Decreased anxiety
- Increased communication and disclosure partners
- Normalization of preventative medical care



Ethical Values of PrEP

- Holistic
- Patient centered
- Respects right to choose and free will
- Addresses realistic expectations for behavior modification
- Harm reduction
- Protects the health of partners



Adherence

- Must be taken daily (“Birth control” metaphor)
- Adherence can change along with changes in habits, routines, etc
- Provider should be monitoring
- Side effects can cause patients to stop

Provider to Patient: Addressing Adherence

- Initial Appointment
 - Educate and stress importance of adherence
 - Establish dosing routine and reminder systems
 - Address broader health (ex. mental health, etc.)
- Followup Appointments
 - Assess adherence and identify barriers
 - Assess and help manage side-effects

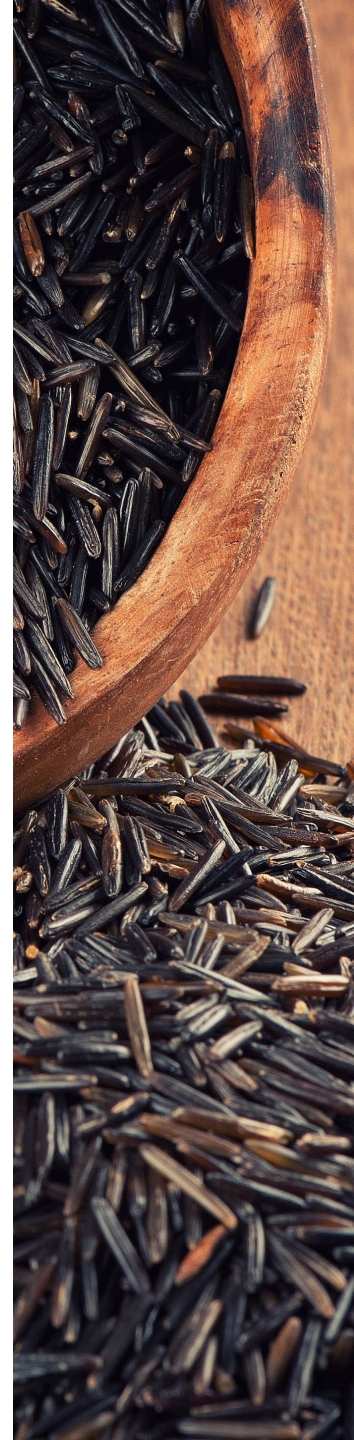
PrEP And Adolescents

- FDA-approved for adolescents > 35kg.
- Challenges
 - Adherence
 - Consent without parental approval varies by state
 - Medication/insurance coverage without parental notification

Prevention challenges in AIs/ANs

Specific data to AIs/ANs are limited


- Knowledge about PrEP?
- PrEP uptake?
- Barriers and facilitators to PrEP uptake?
- Culturally appropriate promotional material?



PrEP Access for AIs/ANs

- Truvada is now on IHS National Core Formulary
- UHP access varies and is a facility-level decision
- Some pharmacies carry PrEP
- Some providers prescribe PrEP

Culturally Appropriate Materials



Is PrEP right for you?

If you are HIV negative and answer "yes" to any of the questions below, talk to your doctor about PrEP:

- Is your sexual partner(s) living with HIV or of unknown status?
- Has your partner threatened or forced sexual activity?
- Do you/your sex partner(s) use or inject drugs?
- Do you [sometimes or always] have anal, vaginal, or frontal sex without a condom?
- Are you and your partner who lives with HIV trying to get pregnant?
- Do you/your sex partner(s) exchange sex for money, housing, drugs, or other needs?
- Have you been treated recently for an STD, such as gonorrhea, chlamydia, or syphilis?

PROJECT INFORM

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Is PrEP? Resources

PrEP (PreExposure Prophylaxis) is a daily pill that can reduce your risk of getting HIV by more than 90% if you take it every day. It is also effective for people who have sex with men and women, and for people who inject drugs.

To find a doctor that prescribes PrEP:
preplocator.org/

To learn more:
cdc.gov/hiv/basics/prep.html

To tell your provider about PrEP:
cdc.gov/hiv/pdf/PrEPguidelines2014.pdf

National Clinician PrEPLine: 855-448-7737

Ask Your Doctor Payment

If your current doctor is unable to prescribe PrEP, ask for a referral to another doctor or facility.

If taking PrEP, visit your doctor every three months for repeat HIV tests, refills, and follow-up.

See your doctor if you have side effects that become severe or don't go away.

Some urban Indian health clinics, tribal clinics, and IHS facilities currently do not cover PrEP, so you may be referred to another doctor or facility. Most private insurance and state Medicaid plans cover PrEP.

If PrEP isn't fully covered for you, patient assistance can help:
uihi.org/projects/hiv-sti-and-hepatitis-c-prevention-project/prep-payment-assistance/

Conclusions and Next Steps

- PrEP is safe and easy to prescribe
- PrEP is covered by many insurance plans
- PrEP reduces risks of transmission of HIV
- PrEP has already helped to reduce HIV rates

PrEPare to Become an Advocate

- Self-Educate
- Support expanded Medicaid
- Support expansion of access to more providers and pharmacies

How can I learn more?

General Information

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

www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf

www.facebook.com/groups/PrEPFacts

www.prepfacts.org

www.pleaseprepme.org

UCSF Clinician Consultation Center

1-855-HIV-PrEP (1-855-448-7737), M-F 11-6 EST

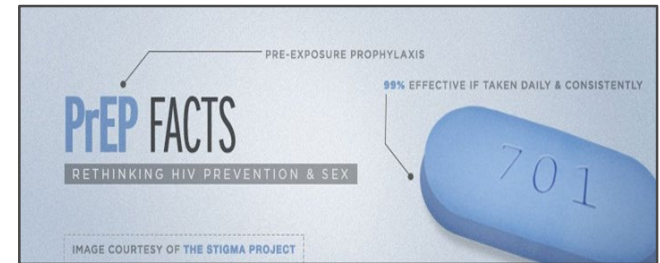
IHS Clinical Guidelines

<https://www.ihs.gov/hivaids/clinicalinfo/guidelines>

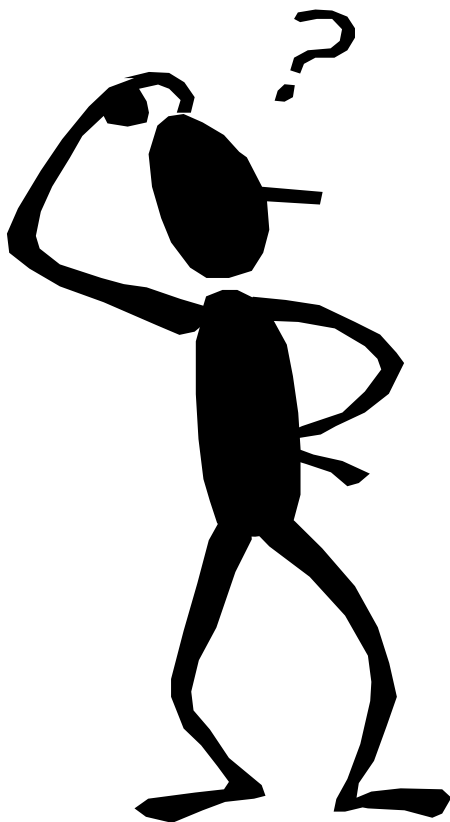
Financial Assistance for PrEP

Gilead's Medication Assistance Program

<http://www.gilead.com/responsibility/us-patient-access/us%20advancing%20access>



Questions?





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