

Pre-Exposure Prophylaxis (PrEP) for HIV Prevention:
Evidence, Guidelines & Applications to Clinical Practice



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Outline

- What is PrEP?
- Overview of HIV epidemiology
- PrEP efficacy
- How to prescribe PrEP
- Risks and benefits of PrEP
- PrEP “controversies”
- PrEP Pipeline

Cases

Case #1

- 46 yo MSM
- Long term, stable, open relationship with male partner
- Multiple recent sexual encounters with acquaintances
- Recent negative HIV test, remote history of syphilis
- PE unremarkable, uncircumcised
- Asks whether he should get PrEP

Case #2

- 18 yo heterosexual woman in South Africa
- Recently became sexually active
- Presents for voluntary HIV testing
- Unknown HIV status of male partners
- Requesting OCPs
- Hep B surface Ag negative, HIV negative, no STDs

Clinical Question

- What is the evidence for use of preexposure prophylaxis (PrEP) to prevent HIV infection?

What is PrEP?

ARE YOU READY FOR PrEP?

PrEP 101

PrEP Basics

PrEP stands for **Pre-Exposure Prophylaxis**

The word “prophylaxis” means to prevent or control the spread of an infection or disease

PrEP can help prevent you from getting HIV if you are exposed to the virus

PrEP is an HIV prevention option that works by taking **one pill every day**

1 PILL A DAY

CDC 2016

Rationale for PrEP for HIV prevention

- There is a well-established history of prophylaxis to reduce the risk of an infectious disease
 - E.g.: Malaria for travelers
- Evidence for HIV prevention based on
 - Prevention for mother-to-child transmission

Slide courtesy of S. Assoumou

One FDA approved drug

■ Truvada (TDF/FTC) : one pill with 2 antiretrovirals

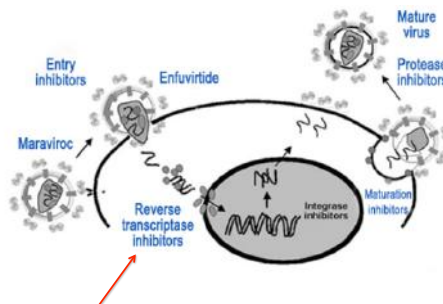
- Tenofovir 300mg
- Emtricitabine 200mg



- Some research has examined oral tenofovir alone for people who inject drugs (PWID), but this is not FDA approved

Choopanya et al, *Lancet* 2013

HIV Targets for Therapy



Rutgers.edu 4/2016

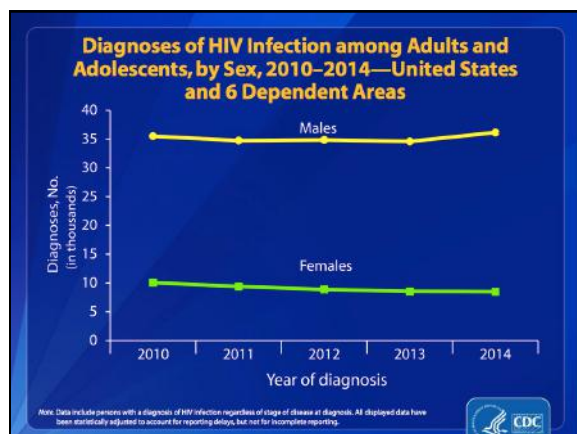
TDF/FTC dosing and prevention

- Based on modeling:
 - 7 days of daily dosing is needed to achieve protective concentrations for receptive anal sex
 - 21 days of daily dosing is needed for receptive vaginal sex.

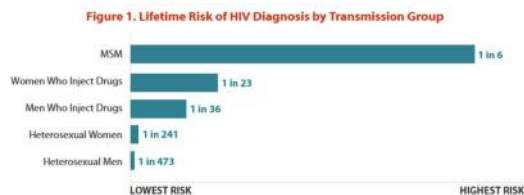
www.hivguidelines.org

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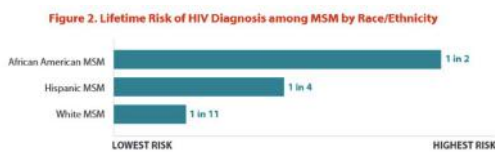


Lifetime HIV risk by Transmission Group



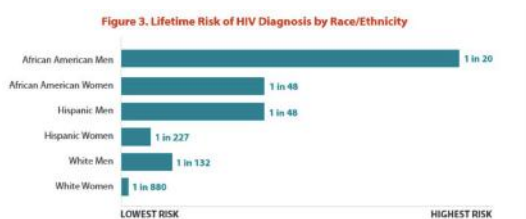
CDC Feb 2016

Lifetime HIV risk among MSM by Race/Ethnicity



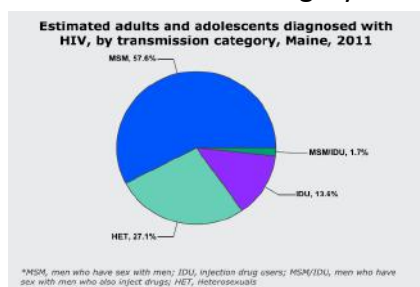
CDC Feb 2016

Lifetime HIV risk by Race/Ethnicity



CDC Feb 2016

HIV Prevalence in Maine, by transmission category



In 2011, 59 adults and adolescents diagnosed with HIV in Maine
(48 cases in 2015)

cdc.gov

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PrEP Guidelines January 2011 - MSM

“PrEP has the potential to contribute to effective & safe HIV prevention for MSM if it is:

- Targeted to MSM at high risk for acquiring HIV
- Delivered as part of a comprehensive set of prevention services
- Accompanied by monitoring of HIV status, side effects, adherence, & risk behaviors at regular intervals”

MMWR. Weekly. January 28, 2011.

PrEP guidelines - heterosexual adults August 2012

- 1) TDF/FTC is **contraindicated** for PrEP in persons with unknown or positive HIV status
- 2) Daily doses of TDF/FTC can be safe and effective
- 3) PrEP is 1 option to protect the HIV-negative partner in discordant couples during attempts to conceive
- 4) Women of reproductive age should have a documented pregnancy test before beginning PrEP and if not pregnant at initiation, at regular intervals while being prescribed PrEP.

MMWR. Weekly. August 2012

Background Studies			
Study	Population	N	Results
Caprison 004 South Africa	Women	889	39% efficacy vaginal TFV gel
VOICE S Africa, Uganda, Zimbabwe	Women	5029	28% TDF 23% Vaginal TFV gel 29% FTC/TDF
FACTS001 S Africa	Women	2200	TVF gel fertility
TDF2 Study Botswana	Young men and women	1200	62% efficacy FTC/TDF
Partners PrEP Study Kenya, Uganda	Heterosexual couples	4758	67% efficacy TDF 75% efficacy FTC/TDF
FEM-PrEP Kenya, S Africa, Tanzania	Women	1950	24% FTC/TDF
Bangkok Tenofovir Study Thailand	PWID	2400	TDF 49% efficacy
IPrEx Brazil, Ecuador, Peru, South Africa, Thailand, US	MSM	2499	44% efficacy FTC/TDF
Ipergay France, Quebec	MSM, transgender wom	400	86% efficacy FTC/TDF
PROUD UK	MSM, transgender wom	595	86% effectiveness FTC/TDF
Partners Demo Project	Heterosexual couples	4758	96% efficacy FTC/TDF

Back to the cases...how are these PrEP studies relevant?

- Two studies showed no efficacy in young African women
 - Fem-PrEP study
 - VOICE study
- Iprex study - 44% efficacy in MSM pts

Why such difference in results?

- Adherence is key

Dose Response Relationship between Adherence and PrEP

Study	Reported Efficacy	Adherence*
FTC/TDF Partners PrEP	75%	81%
TDF Partners PrEP	67%	
TDF2	63%	79%
Bangkok TDF	49%	67%
IPrEx	44%	51%

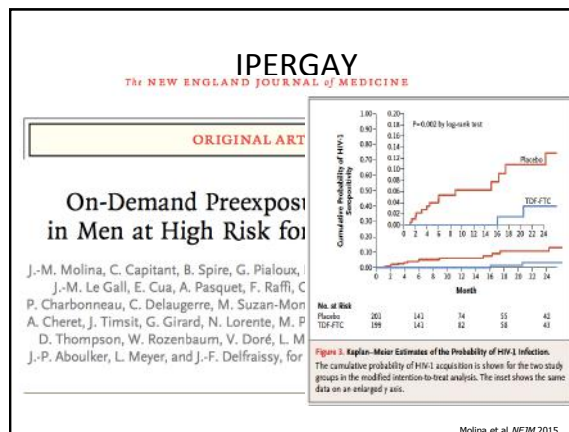
Risk reduction
76% 2 doses/wk
96% 4 doses/wk
99% 7 doses/wk

* Based on tenofovir blood levels in non-seroconverters.

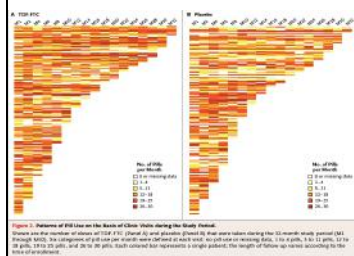
Modified from Barten JM, Haberer JE, Liu AY, Sista N. J Acq Defic Syndr 2013; 63(Suppl 2):S122-9
Grant R et al, NEJM. Dec 2010

More recent studies with better adherence

- IPERGAY trial in France
- PROUD trial in the U.K
- Partners Demonstration Project



PrEP Pill count: IPERGAY



Median # of pills
per month
= 15 (IQR 11 – 21)

17% \geq 26 days/month

31% \leq 11 days/month
(i.e. <2.5 days/week)

Molina et al. NEJM 2015

PROUD trial

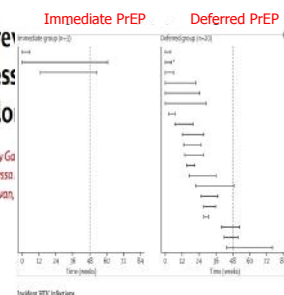
Pre-exposure prophylaxis to prevent HIV infection (PROUD): effectiveness of a pragmatic open-label randomised controlled trial

Sheena McCormack*, David T Dunn*, Monica Desai, David I Dalling, Mitzy Go, Gabriel Schembri, Nicola Mackie, Christine Bowman, Charles J Lacey, Vanessa Saye H Khoo, James Rooney, Anthony Nardone, Martin Fisher, Alan McOwan,

threshold; daily PrEP recommended for everyone

– No difference in STI's

- 50 vs. 57% STI during study



McCormack et al, Lancet 2016

Partners Demonstration Project

- N= 1,013 couples in Kenya and Uganda
- Serodiscordant 'high risk' couples given PrEP for 6 mos, or ART if indicated, historical control
- 96% reduction in HIV incidence

Baeten et al, CROI 2015, abstract 24

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How do you prescribe PrEP?

Initial visit checklist

- Assess for possible acute HIV infection
- HIV risk assessment/sexual history to determine whether PrEP is indicated
- Laboratory screening
- Counseling on condom use/other risk reduction
- Discuss adherence
- Information on PrEP during conception/pregnancy
- Tenofovir/Emtricitabine Rx
- Follow up appointment



CDC.gov

How do you assess patient risk?

Table 2. Estimated Per-Act Probability of Sexual Acquisition of HIV From an Infected Source Without the Use of Condoms*

Type of Intercourse	Probability
Receptive anal	138/10 000
Insertive anal	11/10 000
Receptive penile-vaginal	8/10 000
Insertive penile-vaginal	4/10 000
Receptive oral	Low
Insertive oral	Low

Reynolds E, *Annals* December 2015

How do you assess patient risk?

Original Investigation

July 12, 2016

Sexual Activity Without Condoms and Risk of HIV Transmission in Serodifferent Couples When the HIV-Positive Partner Is Using Suppressive Antiretroviral Therapy

Allison J. Rodger, MD¹, Valentina Cambiano, PhD², Tina Braun, RN³, et al

> Author Affiliations

JAMA. 2016;316(2):177-181. doi:10.1001/jama.2016.5148

- Among 1,166 enrolled couples, 888 couples provided 1,238 couple-years of follow-up
- Heterosexual and MSM couples; HIV-positive partner was using suppressive ART and who reported condomless sex
- There were no documented cases of within-couple HIV transmission (upper 95% confidence limit, 0.30/100 couple-years of follow-up).

Rodger et al, *JAMA* 2016

Indication for PrEP --MSM

- Adult man
- Without acute or established HIV infection
- Any male sex partners in past 6 months (if also has sex with women, see Box B2)
- Not in a monogamous partnership with a recently tested, HIV-negative man

AND at least one of the following

- Any anal sex without condoms (receptive or insertive) in past 6 months
- Any STI diagnosed or reported in past 6 months
- Is in an ongoing sexual relationship with an HIV-positive male partner

CDC. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States, 2014 Clinical Practice Guideline.

Indication for PrEP --heterosexually active men and women

- Adult person
- Without acute or established HIV infection
- Any sex with opposite sex partners in past 6 months
- Not in a monogamous partnership with a recently tested HIV-negative partner

AND at least one of the following

- Is a man who has sex with both women and men (behaviorally bisexual) [also evaluate indications for PrEP use by Box B1 criteria]
- Infrequently uses condoms during sex with 1 or more partners of unknown HIV status who are known to be at substantial risk of HIV infection (IDU or bisexual male partner)
- Is in an ongoing sexual relationship with an HIV-positive partner

CDC. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States, 2014 Clinical Practice Guideline.

Indication for PrEP --PWID

- Adult person
- Without acute or established HIV infection
- Any injection of drugs not prescribed by a clinician in past 6 months

AND at least one of the following

- Any sharing of injection or drug preparation equipment in past 6 months
- Been in a methadone, buprenorphine, or suboxone treatment program in past 6 months
- Risk of sexual acquisition (also evaluate by criteria in Box B1 or B2)

CDC. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States, 2014 Clinical Practice Guideline.

Laboratory testing before initiating PrEP

- ✓ HIV Ag/Ab (4th generation) test within one week of prescribing

- ✓ HIV viral load if concerns for acute HIV

- ✓ Creatinine clearance (>60 mL/min)

- ✓ Consider UA

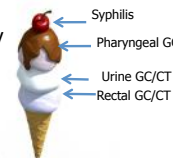
- ✓ Screen for Hep A, B, and C

- Vaccinate for HAV, HBV if indicated

- ✓ Screen for and treat STI's – NAATs GC/CHL

- Includes pharyngeal, rectal GC/CHL for MSM

- Syphilis screening



Counseling before initiating PrEP

- ✓ Adherence = efficacy
- ✓ Discuss need for regular HIV testing, review signs/symptoms of acute HIV
- ✓ Behavioral risk reduction
- ✓ Review side effects

Prescribing PrEP

- ✓ Initial 1 mo. supply, no refills, 2 wk phone check in
- ✓ ~ 1 month follow up visit, then 60 day supply
- ✓ 90-day supply, no refills thereafter
- ✓ Billing: usually “high risk sexual behavior”

ICD-10	Description
Z72.5	High risk sexual behavior
Z20.82	Contact with and (suspected) exposure to other viral communicable diseases
CPT	Description
99401	Preventive counseling (15 minutes)
99402	Preventive counseling (30 minutes)
99403	Preventive counseling (45 minutes)
99404	Preventive counseling (60 minutes)

http://prepfacts.org/assets/PrEP_Facts_16-paper_brochure_mech_FINAL.pdf
www.hivguidelines.org

Laboratory screening/follow-up

Before Prescribing PrEP	Follow-up Assessment	Frequency
Document negative HIV antibody	Serial HIV antibody testing	At least every 2-3 months; if HIV-infected, discontinue PrEP, obtain HIV resistance testing, and link to HIV care
Test for HIV RNA if signs/symptoms suggesting acute HIV infection are present		
Screen and test for STIs	Rescreening and treatment for STIs	With any signs/symptoms of STI; at least every 6 months if asymptomatic
Serologic testing for syphilis and NAATs for <i>Neisseria gonorrhoeae</i> and <i>Chlamydia trachomatis</i>		
Screen for HBV infection	Monitor for signs/symptoms of hepatic inflammation and increases in aminotransferase levels	At least every 2-3 months
If active HBV diagnosed, document baseline aminotransferase levels and consider using TDM-4TC for HBV treatment and PrEP		

cdc.gov

Laboratory screening/follow-up

Before Prescribing PrEP	Follow-up Assessment	Frequency
Document calculated CrCl ≥ 60 mL/min per 1.73 m ²	Repeat renal function testing	3 months after initiation, then every 6 months
Assess behavioral risk to confirm ongoing high risk for HIV acquisition	Repeat risk assessment, counseling, and provision of condoms	Every visit, at least every 2-3 months
Provide risk-reduction counseling and condoms		
Provide adherence counseling	Assess adherence; Provide counseling and support as needed	Every visit; at least every 2-3 months
Determine if women are planning to become pregnant, are currently pregnant, or are breastfeeding	Serial pregnancy testing	At every visit
Do not prescribe PrEP to women who are breastfeeding		

cdc.gov

PrEP for conception (“PrEP-ception”), PrEP during pregnancy & breastfeeding



Hot off the Presses! Use of PrEP in & Around Pregnancy

- Many women desire children w/ HIV + male partner
- Pregnancy is not a contraindication for PrEP
 - Start 1 month before, continue for 1 month after
- Little data on safety of PrEP in lactation; tenofovir secreted in breast milk, but infant levels extremely low; discuss risks/benefits

Seidman D, *Contraception* 2016

Outline

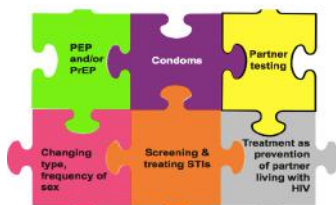
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PrEP is part of a prevention package

■ Prevention package

includes:

- PrEP (Tenofovir/emtricitabine)
- Behavior and adherence counseling
- Condom use
- STI screening



Modified slide courtesy of S. Assoumou

PrEP—Benefits



Preconception/antenatal visits



Sex education

■ Primary care benefits

- Hepatitis vaccination, reproductive health care

■ Cost-effective?

- Yes, if targeted at those with high incidence

NAM AIDSmap
Ouelett et al, *Can J Infect Dis Med Microbiol* 2015
Ong et al, *Lancet* 2015

PrEP—Risks

■ Resistance

- Uncommon

■ Toxicities/side effects

- Few, mild and transient (nausea, vomiting)
- Renal, bone toxicity → reversible

Bone density and PrEP

■ Substudy of iPrex trial, n=498 MSM/trans women

■ Compared bone mineral density (BMD) in placebo vs. low TDF/FTC drug level vs. normal TDF/FTC levels

■ BMD decreased by 1% hip, 1.8% spine in TDF/FTC normal level group

- Spine → BMD took 6 mos. to recover
- Hip → 12 mos to recover (>25 yo), 6 mos. if <25 yo

Grant et al, CROI 2016, abstract 48LB

■ What is PrEP?

■ Overview of HIV epidemiology

■ PrEP efficacy

■ How to prescribe PrEP

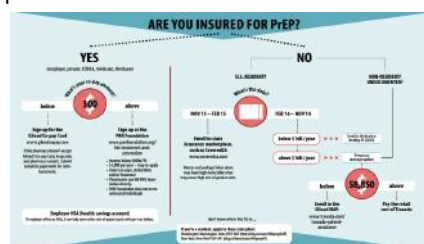
■ Risks and benefits of PrEP

■ PrEP “controversies”

■ PrEP Pipeline

Do insurance companies pay for it?

■ Yes...with some effort on patient/provider part.



PrEP “Controversies”

- Access to PrEP
 - Provider barriers:
 - Low awareness (1/3 PCPs and nurses unaware)
 - Concerns for toxicity, sexual risk behaviors, adherence, drug resistance
 - Not taking sexual histories
 - Populations not being reached well:
 - People under 19 years old
 - Blacks
 - Women

Loeb et al, J Gen Intern Med 2011
Scheer Set al. HIVR4P 2016, Abstract OA24.03.

PrEP “Controversies”

- High STI rates among MSM on PrEP supports more frequent monitoring
 - CDC PrEP guidelines: q 6 mos.
 - CDC STI guidelines: q3-6 months for MSM, esp those with prior STIs
- Spark PrEP Project – could miss substantial number of STIs if only screening asymptomatic PrEP patients q6 mos.

Golub S, et al CROI 2016, Abstract 869

PrEP “Controversies”

- “Almost-Certain Case of Truvada PrEP Failure Due to Drug Resistance Reported”
- Recent case of HIV reported in Chicago

– PrEP resistance not unexpected, but still quite rare

Knox et al, CROI 2016, Abstract 169aLB
Grossman et al, HIVR4P Grossman H et al, Abstract OA03.06LB

PrEP “Controversies”

- Modest Kidney Function Decline on Truvada PrEP supports need for monitoring
 - Pts >50 and pts with GFR<90 → more frequent monitoring?

Liu AY et al. CROI 2016, Abstract 867

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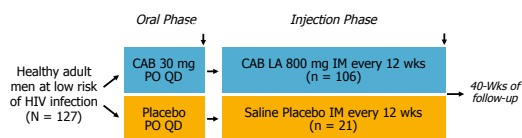
PrEP Pipeline: Strategies to improve delivery and adherence

- Injectable PrEP
 - Cabotegravir, Rilpivirine
- Intra-vaginal rings
- Maraviroc
- Alternative delivery systems (creams, gels, films, rectal and vaginal suppositories)



ÉCLAIR: Cabotegravir LA in HIV-Negative Men at Risk for HIV Infection

- Cabotegravir: potent integrase inhibitor formulated as oral tablet and for long-acting (LA) IM injection
- Randomized, double-blind phase IIa trial
 - Primary endpoint: safety, tolerability of CAB LA IM injections
 - 2 HIV seroconversions, none during CAB LA dosing period



Markowitz M, et al. CROI 2016, Abstract 106

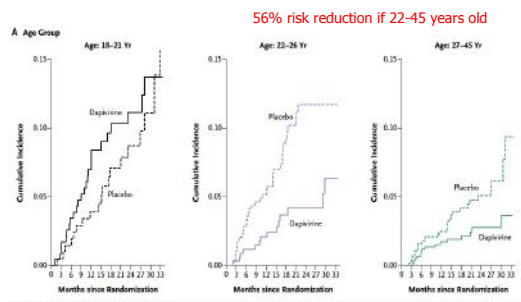
Slide credit: clinicaloptions.com

PrEP Pipeline: Intra-vaginal ring

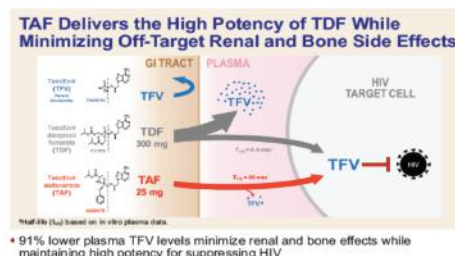
- Dapivirine (NNRTI)
- ASPIRE trial: 2,629 women 18-45 in sub-Saharan Africa, 15 sites total
 - Overall HIV reduction 27% (95% CI 1%-46%)
 - 37% if 2 sites w/ low adherence excluded
 - Lower adherence associated with:
 - IPV or other social harms (younger age, new primary partner, non-disclosure of study/ring use to partner)

Baeten et al, *NEJM* 2016

PrEP Pipeline: Dapivirine ring

Baeten et al, *NEJM* 2016

PrEP Pipeline: TAF (tenofovir alafenamide) **not** yet approved



Sax, P CROI 2015

PrEP Pipeline: TAF (tenofovir alafenamide) **not** yet approved

- TAF PrEP protects monkeys, but levels in humans may be too low
 - Tenofovir exposure in mucosal tissues was 2-10 fold lower after TAF vs. TDF
- TAF should NOT be used for PrEP until more research is available & it is approved for PrEP

Take-home Points

- PrEP is a prevention method in which HIV non-infected patients at high risk for HIV are prescribed antiretroviral medication to reduce their risk of developing HIV
- Offer PrEP to your at-risk patients
- PrEP is effective
- Monitor STI's regularly
- Adherence is key!



Other Resources

- UpToDate table on how to monitor patients on PrEP
- Clinicians' Consultation Center – PrEpline:
855-448-7737 (11am-6pm EST, M-F)
- Facebook group for patients/providers
- Project inform
- Local pharmacists can also help with financial assistance programs



Thanks

- Questions?
- kthakarar@mmc.org

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- Baeten J et al. Near Elimination of HIV Transmission in a Demonstration Project of PrEP and ART. 2015 Conference on Retroviruses and Opportunistic Infections (CROI), Seattle, USA, Abstract 24.

Question #1

Pt is a 23 yo heterosexual woman from South Africa with an HIV + male partner. She recently became sexually active and presents for voluntary HIV testing. She is requesting OCPs.

True or false:

PrEP will probably not be effective in this patient because several trials have shown it's ineffective in serodiscordant couples.

Question #2

Pt JB is a 46 yo MSM in a long term, stable, open relationship with HIV negative male partner. He has had multiple recent sexual encounters with acquaintances. Recent negative HIV test, + syphilis 3 mos ago. PE unremarkable, uncircumcised. Asks whether he should get PrEP.

Is this patient a candidate for PrEP?

- A Yes
- B No
- C Not sure, consult ID

Question #3a

You have decided JB may be candidate for PrEP. Some of the lab tests you will order are:

- A HBV surface Ag/Ab, HIV Ag/Ab, BUN/cr, STI testing
- B HBV surface Ag/Ab, HIV Ag/Ab, HIV viral load, BUN/cr, STI testing

Question #3b

For JB, besides HBV and HIV, appropriate STI testing would include:

- A Treponema Ab, urine GC/CHL, HCV Ab
- B Treponema Ab, urine GC/CHL, HCV Ab, pharyngeal and rectal GC/CHL
- C HBV and HIV testing is sufficient