REVIEW OF PREP GUIDELINES:
A PRIMER FOR THE PRIMARY CARE PRACTITIONER

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Disclosure

- Speaker's Bureau: Gilead, VIIV, BMS, Merck, Serono

Learning Objectives:

1. Review the timeline for major PrEP Studies

2. Define the role of the primary care provider in screening patients for PrEP

3. Describe the follow up visits required for PrEP

FDA Approval

- In July 16, 2012, FDA approved the use of tenofovir (300mg) + emtricitabine (200 mg) (TDF/FTC or Truvada®) for HIV PrEP in adults who are at high risk for becoming HIV-infected
  - **Dosage:** One tablet once daily taken orally with or without food

- Four trials found PrEP to be effective for preventing HIV infection when taken as prescribed[1,2,3,6]

- FEM-PrEP and VOICE trials in *females* did not show a benefit, likely because of poor adherence[4,5]

- All trials found PrEP to be safe

1. Grant RM, et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *N Engl J Med*2010;363:2587-2599.
2. Baeten JM, et al. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. *N Engl J Med* 2012;367:399-410.
3. Thigpen MC, et al. Antiretroviral preexposure prophylaxis for heterosexual HIV transmission in Botswana. *N Engl J Med* 2012;367:423-434.
4. Van Damme L,et al. Preexposure prophylaxis for HIV infection among African women. *N Engl J Med* 2012;367:411-422.
5. Marrazzo J et al. *Pre-exposure prophylaxis for HIV in women: Daily oral tenofovir, oral tenofovir/emtricitabine or vaginal tenofovir gel in the VOICE study (MTN 003).* 20th Conference on Retroviruses and Opportunistic Infections, Atlanta, abstract 26LB, 2013.
6. Choopanya K, Martin M, Suntharasamai P, et al. Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): A randomized, double-blind, placebo-controlled phase 3 trial. *Lancet* 2013;381:2083-2090.

PrEP Efficacy Trials

Study Name	Population	N	Results	Efficacy By Detection of Drug
Partners PrEP	Heterosexual couples	4,758	TDF: **67%** efficacy FTC/TDF: **75%** efficacy	**86%** **90%**
TDF2 Study	Heterosexual Men and Women	1,219	FTC/TDF: **62%** efficacy	**85%**
iPrEx	MSM/trans women	2,499	FTC/TDF: **44%** efficacy	**92%**
FEM-PrEP	Women	1,951	FTC/TDF: **futility**	NR
VOICE	Women	5,029	TDF, TDF/FTC, Vaginal TFV gel: **futility**	NR
Thai IVDU	IVDU	2,413	TDF: **49%** efficacy	**74%**

Kahle E, et al. 19th IAC; Washington, DC; July 22-27, 2012; Abst. TUAC0102.

US Public Health Service PrEP Guidelines Background

- On May 14th, 2014, CDC released clinical, practice guidelines for PrEP:
  - Provide clear criteria for determining a person's HIV risk and indications for PrEP use
  - Require that patients receive HIV testing to confirm negative status before starting PrEP
  - Underscore importance of counseling about adherence and HIV risk reduction, including encouraging condom use for additional protection

http://www.cdc.gov/hiv/prevention/research/prep/

CDC Defines Substantial Risk

- For **sexual transmission**, this includes anyone who is in an ongoing relationship with an HIV-positive partner.
- It also includes anyone who (1) is not in a mutually, monogamous relationship with a partner who recently tested HIV-negative, and (2) is a:
  - Gay or bisexual man who has had anal sex without a condom or been diagnosed with an STD in the past 6 months or
  - Heterosexual man or woman who does not regularly use condoms during sex with partners of unknown HIV status who are at substantial risk of HIV infection
    - For example, people who inject drugs or have bisexual male partners

http://www.cdc.gov/hiv/prevention/research/prep/

CDC Defines Substantial Risk

- For **people who inject drugs**, this includes those who have injected illicit drugs in the past 6 months and who have shared injection equipment or been in drug treatment for injection drug use in the past 6 months.
- Providers should also discuss PrEP with HIV discordant couples during conception and pregnancy
  - *As one of several options to protect the HIV-negative partner*
- PrEP is only for people who are at ongoing, substantial risk of HIV infection.
  - Post exposure prophylaxis (PEP) should be offered to people who present after a single high-risk event of potential HIV exposure

http://www.cdc.gov/hiv/prevention/research/prep/

NYS DOH Guidance for the Use of PrEP

- On Jan 14th, 2014 NYS DOH published Guidance for the Use of PreP to Prevent HIV transmission
  - www.hivguidelines.org

http://www.hivguidelines.org/clinical-guidelines/pre-exposure-prophylaxis/guidance-for-the-use-of-pre-exposure-prophylaxis-prep-to-prevent-hiv-transmission/

NYS DOH Guidance
Candidates for PrEP:

- PrEP is indicated for individuals who have a documented negative HIV test *and* are at ongoing, high risk for HIV infection
  - Negative, HIV test result needs to be confirmed as close to initiation of PrEP as possible
- PrEP is not meant to be used as a lifelong intervention, but rather as a method of increasing prevention during "high risk" periods

http://www.hivguidelines.org/clinical-guidelines/pre-exposure-prophylaxis/guidance-for-the-use-of-pre-exposure-prophylaxis-prep-to-prevent-hiv-transmission/

NYS DOH Guidance
Candidates for PrEP

- Providers need to obtain a thorough sexual and drug use history and regularly discuss risk-taking behaviors
  - For example, How many episodes of "condomless" intercourse or unsafe injecting practices have occurred?
  - Encourage safer-sex practices and safer injection techniques
- Individuals who do not have continued risk, should be educated about non-occupational post exposure prophylaxis

http://www.hivguidelines.org/clinical-guidelines/pre-exposure-prophylaxis/guidance-for-the-use-of-pre-exposure-prophylaxis-prep-to-prevent-hiv-transmission/

NYS DOH Guidance
Candidates for PrEP

MSM who engage in unprotected anal intercourse [1,2]	Stimulant drug use, especially methamphetamine [4]
Individuals in a sero-discordant sexual relationship, especially during attempts to conceive	Individuals with ≥ 1 ano-genital STI per year[5]
Transgender individuals	Individuals who have been prescribed nPEP with continued high-risk behavior or multiple courses [6]
IDUs, including injecting hormones [3]	Individuals engaging in transactional sex

1. Smith DK, et al. Development of a clinical screening index predictive of incident HIV infection among men who have sex with men in the United States. *J Acquir Immune Defic Syndr* 2012;60:421-427.
2. Grov C, et al. HIV risk in group sexual encounters: An event-level analysis from a national online survey of MSM in the U.S. *J Sex Med* 2013;10:2285-2294
3. Choopanya K, et al. Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand.
4. Zule WA, et al. Methamphetamine use and risky sexual behaviors during heterosexual encounters. *Sex Transm Dis* 2007;34:689-694
5. Menza TW, et al. Prediction of HIV acquisition among men who have sex with men. *Sex Transm Dis* 2009;36:547-555.
6. Heuker J, et al. High HIV incidence among MSM prescribed postexposure prophylaxis, 2000-2009: Indications for ongoing sexual risk behaviour. *AIDS* 2012;26:505-512

NYS DOH Guidance
Contraindications to PrEP

- Psycho-Social
  - Lack of readiness and/or ability to adhere
  - Efficacy of PrEP is dependent on adherence to ensure that plasma drug levels reach a protective level
- Medical
  - Documented HIV Infection
    - Drug resistant HIV has been identified in patients with undetected HIV who subsequently received TDF/FTC for PrEP
    - Kidney Dysfunction
      - CrCl <60 mL/min

http://www.hivguidelines.org/clinical-guidelines/pre-exposure-prophylaxis/guidance-for-the-use-of-pre-exposure-prophylaxis-prep-to-prevent-hiv-transmission/

NYS DOH Guidance
Contraindications to PrEP

- Although consistent condom use is a critical part of a prevention plan for all persons prescribed PrEP

- Lack of use of barrier protection *is not a contraindication to PrEP*

http://www.hivguidelines.org/clinical-guidelines/pre-exposure-prophylaxis/guidance-for-the-use-of-pre-exposure-prophylaxis-prep-to-prevent-hiv-transmission/

NYS DOH Guidance
Pre-Prescription: Assessment Checklist

- Symptoms of Acute HIV Infection
  - Febrile, "flu", or "mono"-like illness in last 6 weeks
- Medication List
- Substance Use and Mental Health Screening
- Knowledge about PrEP
  - Patient understanding and misconceptions
  - Health Literacy
- Readiness and Willingness to adhere to PrEP
- Primary Care
  - Does the patient have a PCP?
- Partner Information
  - Determine status of partners
- Domestic Violence Screening
- Housing Status
- Means to Pay for PrEP
  - Is patient insured?
- Reproductive Plans (for Women)

http://www.hivguidelines.org/clinical-guidelines/pre-exposure-prophylaxis/guidance-for-the-use-of-pre-exposure-prophylaxis-prep-to-prevent-hiv-transmission/

NYS DOH Guidance
Pre-prescription: Lab Tests

- HIV Test
  - Obtain 3rd or 4th generation HIV test
  - Perform viral load test for HIV for:
    - Patient with sxs of AHI or whose HIV AB is negative but reports unprotected sex in last month
- Basic Metabolic Panel
    - Do not start PrEP if CrCl <60 mL/min
- Urinalysis
    - Identify pre-existing proteinuria
- Serology for Hep A, B and C (Immunize for A and B if not immune)
  - Screen for sexually transmitted infections, GC and chlamydia (genital, rectal, pharyngeal)
    - RPR for syphilis
  - Consider vaccinations for HPV and meningococcus, if indicated
- Pregnancy Test

http://www.hivguidelines.org/clinical-guidelines/pre-exposure-prophylaxis/guidance-for-the-use-of-pre-exposure-prophylaxis-prep-to-prevent-hiv-transmission/

NYS DOH Guidance
Prescribing PrEP

- The first prescription of TDF/FTC should only be for 30 days
- At the 30 day visit (after assessing adherence, tolerance and commitment), a prescription for 60 days may be given
    - Creatinine and CrCl for patients with borderline renal function or at increased risk for kidney disease (>65 years of age, black race, HTN or DM)
- After 3 month visit, prescriptions can be given for 90 days *provided that patient is adherent*
- Patient should then return for 3-month visits for HIV testing and other assessments:

http://www.hivguidelines.org/clinical-guidelines/pre-exposure-prophylaxis/guidance-for-the-use-of-pre-exposure-prophylaxis-prep-to-prevent-hiv-transmission/

TABLE 8. PREP: FOLLOW-UP VISITS

At each visit:

- Assess **adherence**
- Provide **risk-reduction counseling**
- Offer **condoms**
- Manage **side effects**, *follow up 2 weeks after initiation to assess side effects (in person or by phone)*

Laboratory Testing: Follow-Up and Monitoring

Laboratory Test	**Frequency**
HIV Testing	
• 3rd generation or higher rapid antibody test *List of 3rd and 4th generation tests is available here.*	○ Every 3 months, *and* ○ Whenever there are symptoms of acute infection (serologic screening test + HIV RNA test)
STI screening	
• Ask about symptoms	○ Every visit
• NAAT to screen for gonorrhea and chlamydia, based on exposure sites • Rapid plasma reagin (RPR) for syphilis • Inspection for anogenital lesions	○ At least every 6 months, even if asymptomatic (*Note:* Monogamous discordant couples may not need STI screening as frequently), *and* ○ Whenever symptoms are reported
Hepatitis C screening	
• Hepatitis C IgG	○ At least annually for injection drug users, MSM, and those with multiple sexual partners
Renal function	
• Serum creatinine and calculated creatinine clearance	○ 3 months after initiation, then every 6 months
• Urinalysis	○ Annually
Pregnancy testing	○ Every 3 months

NYSDOH Guidance
Discontinuation of PrEP

- Immediately, if patient receives a positive HIV test result
  - Big risk of resistance if patient is maintained on TDF/FTC only
  - Obtain a genotypic assay and refer and link to HIV care
  - Discontinuation of TDF/FTC in patients with chronic active hepatitis B can cause exacerbations of hepatitis B
- Develops renal disease
- Non-adherent to medication or appointments after attempts to improve
- Using medication for purposes other than intended
- Reduce risk behaviors to the extent that PrEP is no longer needed

http://www.hivguidelines.org/clinical-guidelines/pre-exposure-prophylaxis/guidance-for-the-use-of-pre-exposure-prophylaxis-prep-to-prevent-hiv-transmission/

Summary

- PrEP is now part of a menu of evidence-based interventions to prevent HIV transmission.
- Although the overall number of new HIV infections is decreasing in NYS, subpopulations such as young MSM continue to increase--especially in young, black men.
- PrEP may be an effective option to augment behavior change in these high-risk populations.

Questions?

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To set up training on HIV, Hepatitis C, PEP or PrEP please contact Terri Wilder at twilder@chpnet.org

http://www.ceitraining.org/

Promotion and Implementation of PrEP: Utilizing social workers in practice

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NYS Department of Health • AIDS Institute
WWW.CEITRAINING.ORG

Mount Sinai Institute for Advanced Medicine

DISCLOSURE

There are no disclosures

Clinical Education Initiative
NYS Department of Health • AIDS Institute
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Learning Objectives:

1. Discuss the social work role as an addition to the provider role in the PrEP protocol

2. Define a social work role in PrEP promotion

3. Cite social work opportunities in PrEP implementation

Social worker role vs. provider role

- Additional time to spend with patients
  - Ability to weigh pros and cons of PrEP with patient
  - Discuss patient feelings/perceptions of PrEP
  - Counsel on use and process
- Counseling training and experience
  - Can provide sexual health counseling, adherence counseling
  - Can counsel patients who are unsure about PrEP, assist patients in making their right decision

Promotion of PrEP

- Introduce concept of PrEP
- Inform about PrEP, process and requirements
- Recognize benefits and concerns of PrEP
- Decide if PrEP is relevant to individual
- Connect patient with PrEP if interested/able
- If not interested, maintain availability PrEP

Introducing PrEP

- HIV testing/PEP/in context of sexual health counseling
- Has patient ever heard of PrEP?
  - If so, what does patient know about PrEP?

- Differentiate PrEP vs. PEP
  - PEP (Post):
    - "I think I may have been exposed to HIV, so I will take 1 month of medications to try to prevent becoming infected
  - PrEP (Pre):
    - "I haven't yet been exposed, but I'm worried I might be at risk, so I will take a medication daily to try to prevent infection"

Describing PrEP

- 1 pill once a day - Truvada
- Adherence is essential
  - Discuss efficacy with adherence
- Monitoring is part of PrEP
  - Frequency of visits
  - Benefits of having a PCP
- Ensuring negative status
- Evaluating timeline for being on PrEP

PrEP access

- If patient uninsured, can they obtain Medicaid/an exchange plan?
- No access program for uninsured to pay for full protocol (meds, labs, medical visits)

- Covered by NYS Medicaid
- Covered by some commercial/ACA plans
  - Explore medication/provider visit co-pays
- Gilead PrEP Patient Assistance Program
  - Covers Truvada only (cannot access medical visits/labs)
  - For patients without insurance/significant insurance barriers

PrEP pros and cons

- Ask what patient sees as the benefits and risks of PrEP:
  - Do you feel this could be a relevant tool for you?
  - Why or why not?

- Pros: lowered risk HIV, health promoting for patient and partners, maintaining negative status, strategy removed from encounter (differs from condoms)
- Cons: medication side effects, needing to take medication daily, stigma (concept of promiscuity)

PrEP stigma

- Pervasive in practice
- Belief of PrEP as promiscuity-inducing medication
  - "Truvada whore"
- Fear of being "found out" as on PrEP
- Fear of side effects or fear of taking medications

- Discuss the literature
- Discuss personal choice
  - Does this work for your health and your life?
- Discuss NOT going on PrEP
  - What would it mean for you to test positive for HIV?
- Address self-stigmatizing beliefs
  - Do you feel you would pursue risky behaviors if you went on PrEP? And if so, would this be a concern for you?

Connecting patient to PrEP

- If patient has expressed willingness to pursue PrEP, ensure connection to services
- Can patient schedule an appointment at the clinic, be referred, or discuss with outside PCP?
  - Assist patient in scheduling/referral if needed
  - Inform of clinic process to become a new patient
- Review process
  - Ensure patient understands what must be established before they can begin first dose
- For patients disinterested in PrEP, ensure patients are aware of how to access PrEP services if interest arises

Implementation of PrEP

- Ensure that first visit is scheduled in clinic or advise patient to discuss w/outside PCP
  - Assist patient with barriers, e.g. what can patient do if outside PCP refuses
- Ask patient, if willing, to meet again with SW to follow up after PCP appointment when PrEP is prescribed
- Ensure SW availability to patient for insurance issues, other issues related to accessing PrEP, or sexual health counseling

Meeting with patients on PrEP

- Ask patient how their experience on PrEP has been
  - Any barriers to accessing medication or provider?
- Assess adherence
  - When was your last missed dose?
  - Reiterate why adherence is important
- Discuss patient sexual encounters
  - Have encounters changed in any way once patient started PrEP?
  - Counsel patient on any goals related to sexual health
- For patients continuing on PrEP
  - Continue visits if adherence/other issues, or as needed
  - Counsel patients weighing PrEP timeline: how do you see your PrEP use moving forward?

QUESTIONS?

Please remember to fill out your evaluations! Thank you!