WORKSHOP SESSION:
MAKING PREEXPOSURE PROPHYLAXIS AVAILABLE IN THE CLINIC:
CONSIDERATIONS AND PATHWAYS FORWARD

PRE-REGISTRATION IS REQUIRED
PLEASE SEE THE CPt INFORMATION DESK IF THIS IS NOT YOUR
SELECTED WORKSHOP
Wednesday, August 24, 2016
3:10 PM – 4:10 PM

Daily CPt evaluations will be e-mailed to attendees to the e-mail account they used to register for the CPt. On THURSDAY, you will receive a final e-mail with the Thursday session and the overall conference evaluation, the post-CPt test questions, and a link to claiming education credit.

To obtain CME, nursing, or pharmacy credits, or a Certificate of Participation for the CPt, this final evaluation must be completed by Friday, September 30, 2016.

Once you complete the evaluation form you will be taken to the electronic claim form; Details are in the e-syllabus.
Learning Objectives

After attending this presentation, participants will be able to:

- Describe the challenges with setting up preexposure prophylaxis (PrEP) services in a clinical setting
- Monitor PrEP uptake in a clinical setting
- Describe pathways to development of successful PrEP implementation in the participant’s own clinical setting

Special Thank You to Sarit Golub, PhD & Demetre Daskalakis, MD MPH

Clinical Trial Evidence for HIV Prevention Options (February 2016)
Sexually Transmitted Infections

Baseline
Week 12
Week 24
Week 36
Week 48

0.0%
5.0%
10.0%
15.0%
20.0%
25.0%
30.0%

Syphilis
Chlamydia
Gonorrhea

PrEP Delivery

• Help us reflect on our values
• Empower receptive partners to take control of prevention
• Reduce the burden of HIV anxiety
• Reboot conversations about prevention
• Connect patients to primary care and insurance
• Improve our approach to sexual health

Who Should be offered PrEP?

• CDC Guidelines
  • Age 18 and up, HIV negative (no acute or established HIV infection)
  • Not in a monogamous HIV-negative partnership
  • AND ONE OF:
    • MSM reporting nAI in past 6 months
    • MSM with STI in past 6 months
    • Infrequent condom use with MSM or IDU partner
    • Ongoing sexual relationship with HIV+ partner*

  Potential indicators of substantial risk of acquiring HIV infection

  • HIV-infected or HIV-positive sexual partner
  • Recent bacterial STI
  • High number of sex partners
  • History of inconsistent or no condom use
  • Commercial sex work

  Clinically eligible

  • Documented negative HIV test result; no signs/symptoms of acute HIV infection
  • Creatinine clearance ≥ 60 mL/min; no contraindicated medications
  • Documented hepatitis B virus infection and vaccination status

Golub, SA. Developing a PrEP Program for your Practice. NYCDOMH. 2015

That's a lot of people!

- Clinical Decisions
  - Reactive vs. Proactive
  - Formal “eligibility” at the clinic level?
  - Patients for whom your clinic CANNOT provide PrEP
  - Then what?
  - Should all providers see PrEP consultations?
  - Who should constitute the “team”?
  - Monitoring and Evaluation
  - Clinic capacity?
  - Referrals

Guidelines are for Guidance

- Caution with sexual history taking
  - “Slut shaming”
  - Moralizing
  - Harm reduction
  - Stigmatizing the concept of “high risk”

- CDC 5Ps of sexual health
  - Partners
  - Practices
  - Protection
  - Past history
  - Pregnancy

The Order Matters

- S. Golub found that young MSM of color better understood PrEP education AFTER being engaged in a sexual history
It Ain’t Just a Pill

- New York State has developed a 9-point checklist
- How PrEP Works
- Limitations of PrEP
- PrEP use (dosing)
- Safety
- Baseline tests and schedule for monitoring
- Criteria for discontinuing PrEP
- Possible symptoms of seroconversion
- Risks and benefits during pregnancy

Three Universal Truths at the Exact Same Time

- Verify HIV-negative status
  - 4th generation test or 3rd VL
  - S/Sx of acute infection (VL if positive or recent exposure)
  - What if no insurance?
- Creatinine screening
  - Cr (eGFR > 60 mL/min)
  - Some advocate urinalysis for pre-existing proteinuria
- STI/Pregnancy Testing

What do you need to feel comfortable prescribing PrEP?

- Can PrEP be prescribed “same day”?
- Prescription
  - 1 month only (first prescription)
  - 3 months thereafter (some prefer 2 months x 1, then Q3 months thereafter)
- Who needs Cr more often than every 6 months?
- Other services
  - Hepatitis, HPV, meningococcal vaccination
  - HCV screening


Get tested before starting PrEP.
Adherence Support

- Sigh.
- Need for daily adherence?
- Onset of “maximal” protection?
- Missed dose instructions
- Using refill timing and/or self-report
- Guidance
  - Be clear
  - Routinize daily dosing
  - Discuss common AEs up-front
  - Plan for disclosure
  - Seasons of Risk


STI testing

- Every 3 months, even if asymptomatic
- S. Golub showed as many as 15% of participants will have an asymptomatic STI on PrEP at 3 months that would have gone undetected with only 6 month testing
- In our project, 22% of participants had an asymptomatic incident STI at 3 months


“Purview Paradox”

HIV Providers’ Perceived Barriers and Facilitators to Implementing Pre-exposure Prophylaxis in Care Settings: A Qualitative Study

Douglas Krakower - Norine Wane - Jennifer N. Cherry - Kevin Muloney - Kenneth H. Mayer

Krakower D et al, AIDS Behav. 2014.
Contrasting Models of PrEP Provision for HIV Specialist

• Consultation – refer “back” to primary

• Service Provision

Assignment of Important Tasks

Retention/Persistence
Adherence Support
Interim Visits
Insurance/Co-Payment Navigation
Prescription (initial and refills)
Medical Screening
PrEP Education and Decision-making
Ownership

PrEP Payment 101

INSURED TO COVER COST FOR PrEP?

YES

NO

Gilead Advancing Access Co-pay Card
Patient Advocate Foundation (PAF)

US Resident
Enroll in insurance marketplace (Nov 1 – Jan 31)
If ≥138% FPL/yr
If <138% FPL/yr check eligibility for state Medicaid

Non-Resident/Undocumented
FQHC that serves undocumented pts

Enroll in Gilead MAP

Patient Access Network Foundation

Retail Cost of TDF/FTC

What is your income?
$33,850 ($100% FPL)

IF $2,138 (50% FPL)

IF $1,138 (30% FPL)

IF $2,138 (50% FPL)

IF $1,138 (30% FPL)

IF $58,850 (500% FPL)

IF $33,850 (100% FPL)

IF $17,850 (50% FPL)

IF $8,850 (30% FPL)
PrEP Payment 101

- Medicaid and Private Insurance
- PrEP and the ACA
- Gilead Co-pay Assistance Card
- Patient Access Network (PAN)
- Gilead Medication Assistance Program (MAP)
- New York State and Washington State have PrEP assistance programs

Medicaid
- Varies state-by-state
- In many Medicaid expansion states, PrEP visit/Rx/labs covered
- Requirements for pre-authorizations vary

Private Insurance
- Most private insurance will cover PrEP
- Coverage of medications costs highly variable
- HIV-testing, STI-testing, lab tests may require copays
- Gilead co-pay card can help with medication costs but neither visit nor lab costs

ACA

<table>
<thead>
<tr>
<th>Bronze Level</th>
<th>Silver, Gold, or Platinum</th>
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<tbody>
<tr>
<td>• Should expect co-pay of 50% for TDF/FTC</td>
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<tr>
<td>• (approx. $600 per month)</td>
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<tr>
<td>• Fixed prescription co-pays</td>
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<tr>
<td>• $25 to $100 per month</td>
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**Gilead Co-Pay Assistance Card**

- Covers up to $3600 of patient’s prescription copay or co-insurance per year
- Must be insured
- US or Puerto Rico resident
- Expires after 12 months
- Option for reapplications
- Cannot use with Medicare/Medicaid
- www.gileadcopay.com

**Patient Access Network (PAN)**

- $4000 over one year for prescription payments
- Commercial insurance, Medicare, or Medicaid
- US or Puerto Rico residents
- <500% of FPL ($58,850 per individual)

**Gilead Medication Assistance Program (MAP)**

- >12 years old
- Uninsured or insurance covers no prescription costs
- Resident of US or Puerto Rico, <500% of FPL
- Reapply every 6 months
- Independent pharmacy FedEx’s TDF/FTC to patient’s home
**We can do it! Basics**

- Education for staff at all levels
- Scripts/guides for clinics
- Training on PrEP Protocols
- Bullet points for phone and front desk staff
- Guides for nurses and counselors

![Graph showing Awareness of PrEP by Age](image)

Sanchez T et al, JMIR Pub Health Surveill. 2016.

**We can do it! Staffing**

- PrEP “Champion”
- PrEP Coordinator
- PrEP Providers
- PrEP Counselors

**We can do it! Resources**

- Education materials
- Provider checklists and/or EMR templates
- Tracking databases
- Funds to support un-/under-insured patients
We can do it! Monitoring and Evaluation

Feedback
- Protocols
- Patient conferences
- Challenges

Monthly Reporting
- Snapshot
- Quality Assurance

Can we do it?

- Identify PrEP Champion and Coordinator
- Draft Policies and Procedures
- Identify Needed Materials
- Identify Staff Training Needs
- Mechanisms for communication
- Method to ensure protocols are followed