Implementing PrEP in a High-Risk Primary Care Clinic serving Homeless Veterans

Presentation of the quality improvement efforts of the VA Greater Los Angeles Center of Excellence Interprofessional Academic HPACT Team

Presentation to the NHCHC June 19th, 2019
Disclaimer

- This project was supported by the Health Resources & Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) under grant number U30CS09746, a National Training and Technical Assistance Cooperative Agreement for $1,625,741, with 0% match from nongovernmental sources. This information or content and conclusions are those of the presenters and should not be construed as the official position or policy of, nor should any endorsements be inferred by HRSA, HHS or the U.S. Government. NHCHC is a nonpartisan, noncommercial organization.
PrEP QI Team Members

QI Trainees
Elizabeth Gregg, FNP-C; Emma Nace, FNP-C; Carrie Linn, PharmD; Sonja Jefferson, ASW; Noah Ravenborg, MD; Marielle Bolano, MD; and Kieran Holzhauer, MD

QI Faculty Advisors
Brianna Cowan, MD; Lillian Gelberg, MD, MSPH; Kristin Kopelson, FNP-C

Special Thanks
Peter Capone-Newton, MD; Carole Warde, MD; Pamela Belperio, PharmD; Jennifer Fulcher, MD; all of the VAGLAHS Center of Excellence in Primary Care Education faculty and trainees; and all of HPACT staff.
Objectives

• Brief review of HIV and the development of pre-exposure prophylaxis (PrEP) for HIV

• Review HIV acquisition risk factors that may be over-represented in the homeless population

• Provide up-to-date recommendations to initiate PrEP in the primary care setting

• Describe the QI project in a primary care clinic serving Homeless Veterans (West LA VA Homeless Patient Aligned Care Team (HPACT))
HIV History and Epidemiology

• 1930s-1940s: Earliest cases of human immunodeficiency virus (HIV)

• 1940s-1970s: Slow spread of disease through Africa and to other parts of the world

• 1970s-1980s: Rapid increase in infection rates

• Early 1980s: Rare cases of pneumonia, cancer, and opportunistic infections led to characterization and identification of HIV and AIDS. Initial cases always fatal.

• Late 1980s: Development of first HIV antiretroviral medications.

• Late 1990s: Improved therapies that suppressed viral load and allowed HIV to begin to be considered a chronic disease in those with access to treatment

• Today: 1.1M persons in the US live with HIV infection; including 162,500 persons who do not know they have HIV (2015 CDC)
HIV in the United States

Not all people with HIV are getting the care they need.

1.1 million people living with HIV in the US in 2015

- 86% diagnosed
- 63% received care
- 49% retained in care*
- 51% virally suppressed**

* Had 2 tests at least 3 months apart to measure level of virus in the body. ** Virus at low enough level to stay healthy and reduce transmission risk. Based on most recent test. Based on the most recent data available in November 2018.

HHS HIV Initiative 2019

ENDING THE HIV EPIDEMIC: A PLAN FOR AMERICA

Diagnose HIV as early as possible

Treat HIV quickly and effectively

Protect people at risk

Respond quickly to clusters of new cases
HIV transmissions (2017 CDC)

- Male-to-male sexual contact: 67%
- Heterosexual contact—Female: 16%
- Heterosexual contact—Male: 7%
- Injection drug use (IDU)—Female: 3%
- Injection drug use—Male: 4%
- Male-to-male sexual contact and IDU: 3%
HIV Transmission Risk (2017 CDC)

![Chart showing lifetime risk of HIV diagnosis by transmission group.]

- **MSM**: 1 in 6
- **Women Who Inject Drugs**: 1 in 23
- **Men Who Inject Drugs**: 1 in 36
- **Heterosexual Women**: 1 in 241
- **Heterosexual Men**: 1 in 473

Source: Centers for Disease Control and Prevention
HIV Diagnoses in the U.S. and Dependent Areas, 2012–2016

Source: CDC, HIV in the United States and Dependent Areas, Jan. 2019.
Risk Factors for Acquiring HIV

• Via sexual transmission:
  • Anyone who is:
    • **NOT** in a mutually-monogamous relationship with a partner who recently tested HIV-negative
    • **AND** who does not regularly use condoms during sex with partners of unknown HIV status.

• Via IV transmission:
  • Anyone who has injected any substance in the past 6 months and who has ever shared injection equipment

• Other:
  • Anyone having unprotected sex with a partner who has the above risk factors
  • Occupational risks for medical providers (rare)
HIV Risk Factors and the Homeless Community

➢ LGBT
  ➢ 11-40% of homeless individuals

➢ Survival Sex
  ➢ Up to 40% of homeless individuals report having engaged in survival sex at least once during their period of homelessness

➢ Risky Sex
  ➢ Homeless individuals report low rates of barrier protection (~25%)

➢ Injection Drug Use
  ➢ 30-50% of homeless individuals report use at some point

Wenzel et. al 2016; Caton et al. 2013; Roberton et al. 2004
Homeless Persons have Higher HIV Rates

- Homeless persons are 5 - 10 times more likely to have HIV than the stably-housed population
- Rates of HIV infection among homeless persons in the US: 2% - 10%
- Overall higher HIV acquisition rates among homeless persons who have substance use and mental illness

Wenzel et. al 2016; Caton et al. 2013; Roberton et al. 2004
HIV Prevention Strategies

- Barrier protection (condoms, dental dams)
- Clean needles (Needle exchange programs/not sharing needles, etc.)
- Post-exposure prophylaxis (PEP)
- **Pre-exposure prophylaxis (PrEP)**
- Routine STD Screening and Treatment
PrEP Background

• FDA approved for PrEP in July 2012
  • Tenofovir disoproxil fumarate 300mg (TDF)/emtricitabine 200mg (FTC) (Truvada) taken orally daily

• USPTF now recommends screening and offering PrEP to all at-risk individuals (Grade A)
What is HIV Pre-exposure Prophylaxis (PrEP)?

- PrEP is the use of an antiretroviral medication for the *prevention* of HIV
- PrEP indication: HIV- *negative* individuals who are at *risk* for contracting HIV
Assessing Sexual Risk Factors

Taking a good sexual health history: start with the five “Ps”

I am going to ask personal questions to help me protect you against sexually transmitted infections

<table>
<thead>
<tr>
<th>Partners</th>
<th>Practices</th>
<th>Past History of STIs</th>
<th>Protection from STIs</th>
<th>Pregnancy Plans</th>
</tr>
</thead>
</table>

**Partners**
- Are you currently sexually active?
- Do you have sex with men, women, or both?
- In the last 12 months, how many sexual partners have you had?

**Practices**
- What part of the body do you use for sex? Do you have oral sex? Anal? Vaginal?
- Do any of your sex partners use injection drugs?

**Past History of STIs**
- Have you ever had an STI, like syphilis?
- Have any of your partners had STIs?

**Protection from STIs**
- Are you concerned about getting an STI?
- How do you protect yourself from STIs and HIV?

**Pregnancy Plans**
- Do you plan to have a child in the future?
- How often do you use this protection? With which partners?
- Do you use birth control?
Assessing Injection Use Risk Factors

• Put questions in context: “Some of my patients have used drugs, such as heroin, cocaine or methamphetamine--- have you ever used drugs?”

• Elicit prior, recent and current drug use history:
  • “In the last six months, have you used any of these drugs?”

• Determine type of drug that is being used:
  • “Do you use heroin, meth, cocaine, or another drug?”

• Determine how it is being administered
  • “Please tell me how do you use the drug. “

• Determine harm reduction practices
  • “Where do you get your needles from? Tell me about your needle practices.”
How effective is HIV PrEP?

- Daily use of PrEP reduces HIV acquisition from sexual transmission by more than 90% and from IVDU by more than 70%

<table>
<thead>
<tr>
<th>Study Names</th>
<th>Risk Reduction in HIV Acquisition</th>
</tr>
</thead>
<tbody>
<tr>
<td>iPrEx (TDF/FTC)</td>
<td>92% (40-99%)</td>
</tr>
<tr>
<td>Partners PrEP</td>
<td>90% (58-98%)</td>
</tr>
<tr>
<td>TDF2 (TDF/FTC)</td>
<td>TDF detected: 85%</td>
</tr>
<tr>
<td>BTS (TDF)</td>
<td>74% (17-94%)</td>
</tr>
</tbody>
</table>

Table Adapted from: CDC PrEP 2017 Update
Contraindications for PrEP

• Inability to successfully take a daily medication
• HIV-positive individuals
• Creatinine clearance (Cr/Cl) <60 mL/min
• HIV exposure within the past 72 hours
  • Evaluate for non-occupational post-exposure prophylaxis (nPEP)
Additional Considerations Prior to Prescribing PrEP

- Hepatitis B virus infection
- Pregnancy plans:
  - Currently pregnant
  - Plan to become pregnant
  - Plan to conceive with one’s partner
  - Breastfeeding
## Summary of Guidance for PrEP Use

<table>
<thead>
<tr>
<th>Diagnosis of risk of acquiring HIV infection:</th>
<th>Men Who Have Sex With Men</th>
<th>Heterosexual Women and Men</th>
<th>Injection Drug Users</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Sexual partner with HIV</td>
<td>• Sexual partner with HIV</td>
<td>• HIV-positive injecting</td>
<td></td>
</tr>
<tr>
<td>• Recent bacterial STD</td>
<td>• Recent bacterial STD</td>
<td>partner</td>
<td></td>
</tr>
<tr>
<td>• High number of sex partners</td>
<td>• High number of sex</td>
<td>• Sharing injection</td>
<td></td>
</tr>
<tr>
<td>• History of inconsistent or no condom use</td>
<td>• History of inconsistent</td>
<td>equipment</td>
<td></td>
</tr>
<tr>
<td>• Commercial sex work</td>
<td>• or no condom use</td>
<td>• Recent drug treatment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Commercial sex work</td>
<td>(but currently injecting)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Lives in high-prevalence area or network</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Clinically eligible:

- Documented negative HIV test before prescribing PrEP
- No signs/symptoms of acute HIV infection
- Normal renal function, no contraindicated medications
- Documented hepatitis B virus infection and vaccination status

### Prescription

- Daily, continuing, oral doses of TDF/FTC (Truvada), ≤90 day supply

### Other services:

- Follow-up visits at least every 3 months to provide:
  - HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STD symptom assessment
  - At 3 months and every 6 months after, assess renal function
  - Every 6 months test for bacterial STDs

- Do oral/rectal STD testing

- Assess pregnancy intent
- Pregnancy test every 3 months

- Access to clean needles/syringes and drug treatment services

---

<table>
<thead>
<tr>
<th>Laboratory test/Clinical Assessment</th>
<th>Baseline</th>
<th>Every 3 months</th>
<th>Every 6 months</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV screening assay</td>
<td>✔</td>
<td>✔</td>
<td></td>
<td>Consider need for HIV RNA PCR</td>
</tr>
<tr>
<td>HIV symptoms</td>
<td>✔</td>
<td>✔</td>
<td></td>
<td>fever, fatigue, swollen glands, sore throat, rash</td>
</tr>
<tr>
<td>HBV serology</td>
<td>✔</td>
<td></td>
<td></td>
<td>Offer HBV vaccination if not immune; Consider recheck HBV yearly if at risk</td>
</tr>
<tr>
<td>HCV antibody</td>
<td>✔</td>
<td></td>
<td></td>
<td>Recheck HCV yearly if at continued risk</td>
</tr>
<tr>
<td>Serum creatinine</td>
<td>✔</td>
<td></td>
<td>✔</td>
<td>Avoid PrEP if CrCl &lt;60 mL/min</td>
</tr>
<tr>
<td>STI screen (syphilis, gonorrhea, chlamydia)</td>
<td>✔</td>
<td>✔ if high risk</td>
<td></td>
<td>Include oral/rectal GC/CT screen if high risk (previous STI, no condoms) or symptomatic</td>
</tr>
<tr>
<td>Pregnancy test (women)</td>
<td>✔</td>
<td></td>
<td></td>
<td>Urine beta-HCG</td>
</tr>
<tr>
<td>Assess side effects / Adherence</td>
<td>✔</td>
<td></td>
<td></td>
<td>Headache/nausea; take daily, not just after sex</td>
</tr>
<tr>
<td>Risk reduction counselling</td>
<td>✔</td>
<td></td>
<td></td>
<td>Condoms, clean needles, behavior change, SUD</td>
</tr>
</tbody>
</table>
Discontinuation of PrEP

- **New HIV Diagnosis**
  - Stop PrEP if HIV acquired during PrEP use
  - Link patient to an HIV specialist

- **Self-discontinuation of PrEP or PrEP no longer indicated**
  - Check HIV status at end of PrEP treatment
  - Clarify reason for PrEP discontinuation
Side Effects of PrEP

- Most common short-term side effects (which usually lessen after first few weeks):
  - headache, nausea
- Other, less common side effects:
  - diarrhea, abdominal pain, myalgia
- Decreased creatinine clearance
  - Small decrease; typically reverses when PrEP discontinued
- Decrease in bone mineral density
  - Approximately 1% decrease with no increase risk of fractures; typically reverses when PrEP is discontinued
Current status of PrEP in the community

• Of the more than one million people at high risk for contracting HIV, only ~10 percent are currently receiving PrEP.

• Insurance generally covers PrEP, but it’s expensive (~$2000/month).
  • Lifetime medical costs if one becomes HIV infected at age 35: > $325,000
  • Estimated medical costs saved by avoiding one HIV infection: $230,000

• As a PREVENTION tool, PrEP belongs in primary care. Screening for risk factors and initiating PrEP when indicated IS the standard of care.
Background: West Los Angeles (WLA) VA Homeless Patient-Aligned Care Team (HPACT)

• There are more than 50 HPACT clinics across the country serving >17,000 homeless Veterans

• The Greater Los Angeles VA Healthcare System has three HPACT sites serving ~3600 homeless Veterans at our Sepulveda, Downtown, and WLA sites
  • As of June 2019, 2200 homeless Veterans are assigned to the WLA site
  • WLA HPACT employs 58 staff and 26 trainees (Internal Medicine, Nurse Practitioner, PharmD, SW, Psychology, and Psychiatry)

• Interprofessional group of trainees and faculty
QI PrEP: The Problem Statement

• In fall 2018, a multi-disciplinary team of residents representing Internal Medicine, Nurse Practitioners, Clinical Pharmacy, and Social Work convened to address the low rate of initiation of PrEP for eligible patients in a high-risk clinic serving homeless Veterans.

• Identified barriers to prescribing PrEP to homeless Veterans at WLA HPACT:
  • PrEP prescribing privileges restricted to specialists
  • Eligible patients were not routinely identified
  • No current clinic workflow for PrEP prescribing and management
QI PrEP: The Goals

Obtain PrEP prescribing privileges for primary care providers and pharmacists in HPACT.

Better identification of patients eligible for PrEP.

QI PrEP: Root Cause Analysis

No PC PrEP Prescribing

Lack of prescribers

Lack of training

Tradition—historically restricted to ID

High cost

Concern for risk

New med/use

No defined training requirement

Lack of screening

No reminder/HF

Discomfort with sexual hx taking (providers, patients, staff)

Culture/tradition

Stigma/Don’t Ask, Don’t Tell

Time constraint

Low perceived risk (patient and provider)

Lack of infrastructure

Prescribing authority/training

Testing materials: POC HIV test, GC/CT swabs

Clinic protocols, standing orders

Limited appt access
<table>
<thead>
<tr>
<th>Root Cause</th>
<th>Solution</th>
<th>Due</th>
<th>Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inability of PCPs to prescribe PrEP</td>
<td>Work with ID and pharmacy to change PrEP prescribing privileges</td>
<td>June 2019</td>
<td><strong>Complete:</strong> Providers can now complete PrEP TMS training for prescribing privileges</td>
</tr>
<tr>
<td>Difficulty identifying patients eligible for PrEP</td>
<td>Utilize existing clinical dashboard to identify eligible HPACT patients</td>
<td>June 2019</td>
<td><strong>Complete:</strong> Using 5/2019 data, 49 HPACT patients have been identified who may be eligible for PrEP</td>
</tr>
<tr>
<td></td>
<td>Increase staff awareness with PrEP toolkit</td>
<td>June 2019</td>
<td><strong>In Progress:</strong> All-staff and discipline-specific trainings are ongoing</td>
</tr>
<tr>
<td></td>
<td>Add opt-in CPRS clinical reminders</td>
<td>July 2019</td>
<td><strong>In Progress:</strong> Work with local team to adapt PrEP reminder for local use</td>
</tr>
<tr>
<td></td>
<td>Update PrEP clinical dashboard to include additional HIV risk factors</td>
<td>June 2020</td>
<td><strong>Future:</strong> Work with local and national VA team to think through how to capture IVDU in the absence of an ICD-10 code</td>
</tr>
<tr>
<td>No current process for PrEP management</td>
<td>Create HPACT clinic workflow for initiating PrEP</td>
<td>June 2019</td>
<td><strong>In Progress:</strong> Initial PrEP workflow has been proposed to administration</td>
</tr>
<tr>
<td></td>
<td>Implement HPACT clinic workflow for initiating PrEP</td>
<td>July 2019</td>
<td>Future</td>
</tr>
<tr>
<td></td>
<td>Create a process for monitoring patients on PrEP</td>
<td>June 2020</td>
<td><strong>In Progress:</strong> Model after pharmacy-led HCV medication management</td>
</tr>
</tbody>
</table>
Addressing System Barriers

• Truvada restricted to Infectious Disease -> Standardized training to approve primary care providers to prescribe PrEP

• No Point of Care HIV tests or Gonorrhea/Chlamydia (GC/CT) swabs in clinic -> Lab approved rapid processing of HIV tests and self-collection of GC/CT swabs

• EMR Tools
  • Automatic reminder (trackable)
  • Order sets
  • Note templates
  • Dashboard
Addressing Cultural Barriers

• Multiple targeted trainings and presentations:
  • All Staff:
    • Increase awareness of PrEP
    • Risk factor education
  • Prescribers:
    • Sexual and drug history taking, pocket tool
    • Emphasize role as prevention (primary care scope)
    • Monitoring, risks, side effects, contraindications—enhance provider confidence

• Workflows
• Discipline champions
• Dashboard data
• Management buy-in
Proposed clinic workflow for initiating PrEP

- Mental Health: Identify Risk
- Social Work
- LVN
- MSA
- RN
- Pharmacy
- Primary Care

流程步骤:
1. 识别风险
2. 评估资格
3. 安排第一周实验室检测
4. 预约第二周

备注:
- 预防性治疗不适宜在第一周

备注:
- 审查实验室结果
- 指导
- 订购实验室
- 评估
- 开药 (如适宜)
Next Steps

- Still in progress: EMR tools, workflows
- Incoming trainees
- Expand RN/LVN role in follow-up
- Disseminate: Women’s Health, SUD Clinic, PACC
Questions?
Resources

- HHS initiative: https://www.hiv.gov/
- CDC HIV/AIDS: https://www.cdc.gov/hiv/default.html
- Gilead Patient Assistance: https://www.truvada.com/how-to-get-truvada-for-prep/truvada-cost
Contact Information

Brianna Cowan, MD – Brianna.Cowan@va.gov
Center of Excellence
West Los Angeles HPACT
11301 Wilshire Boulevard; Building 402
Los Angeles, CA 90073
310-478-3711