



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

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Disclaimer

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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.



Get Tested. Get in Care. Stay in Care.
Be Healthy.



HHS HIV Initiative 2019

ENDING THE HIV EPIDEMIC: A PLAN FOR AMERICA



Diagnose HIV as early as possible



Treat HIV quickly and effectively



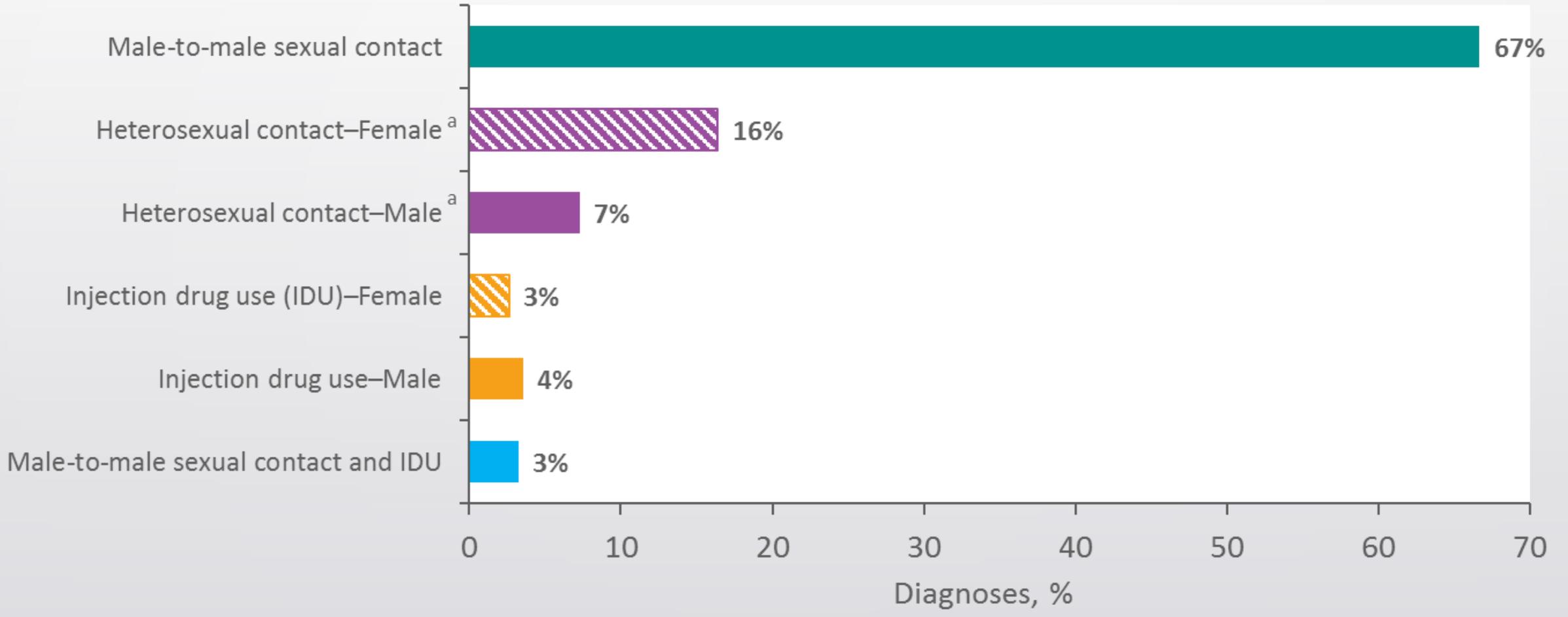
Protect people at risk



Respond quickly to clusters of new cases



HIV transmissions (2017 CDC)



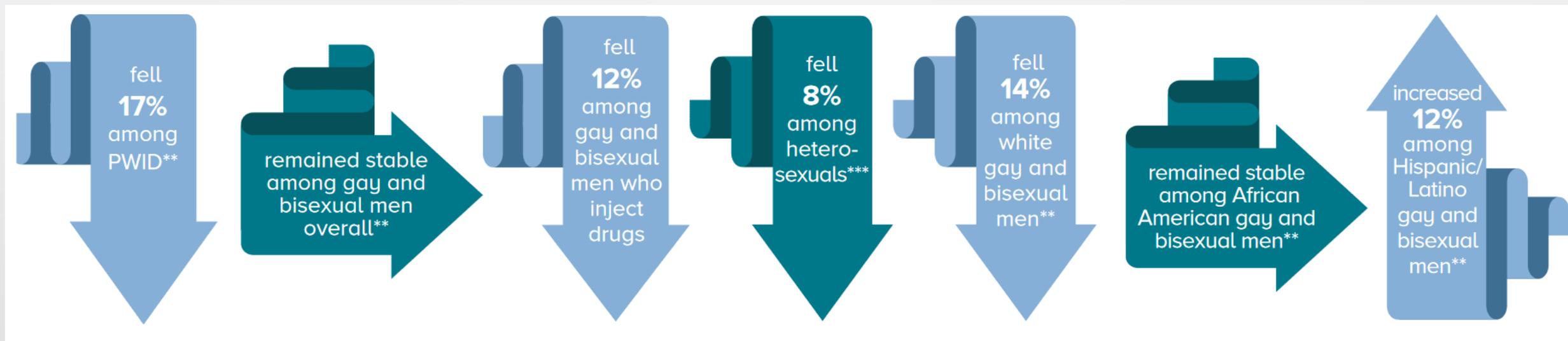
HIV Transmission Risk (2017 CDC)

Lifetime Risk of HIV Diagnosis by Transmission Group



Source: Centers for Disease Control and Prevention

HIV Diagnoses in the U.S. and Dependent Areas, 2012–2016





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**

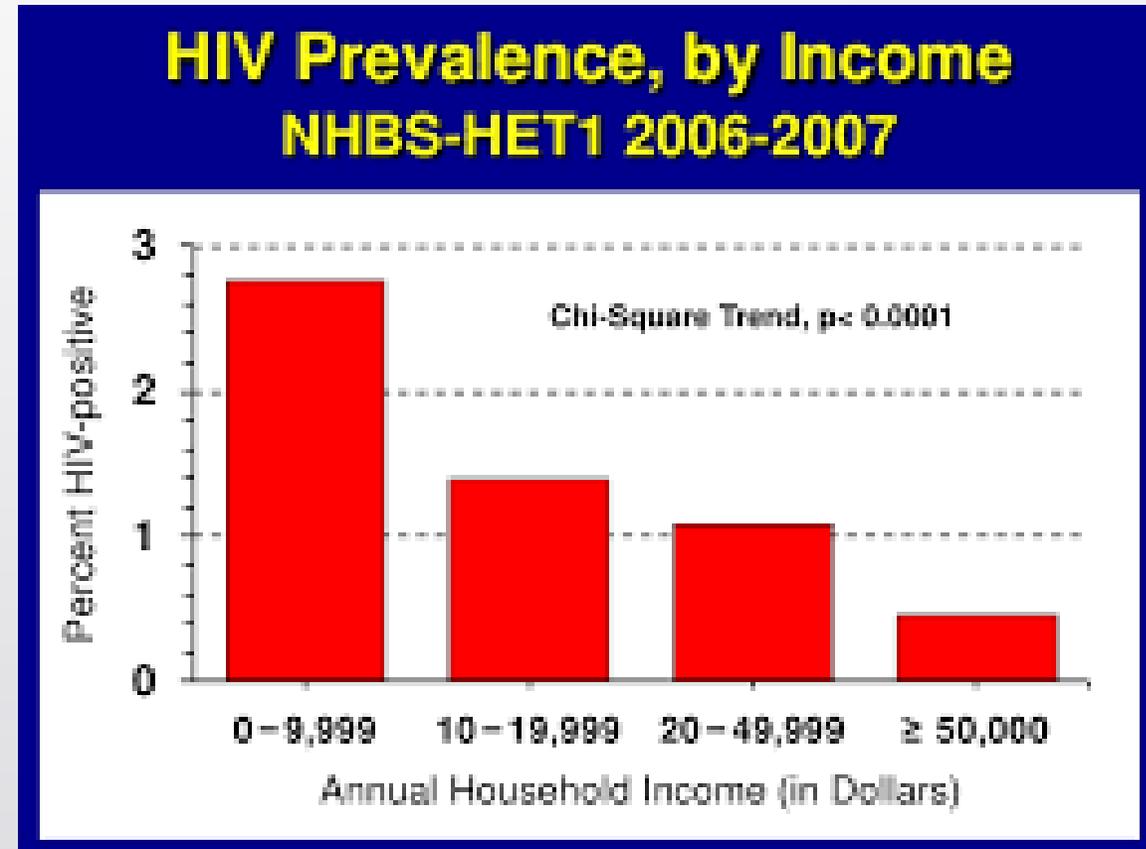
- Homeless individuals report low rates of barrier protection (~25%)

➤ **Injection Drug Use**

- 30-50% of homeless individuals report use at some point

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





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



Partners



Practices



Past History
of STIs



Protection
from STIs



Pregnancy
Plans

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?

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?

Have you ever had an STI, like syphilis?

Have any of your partners had STIs?

Are you concerned about getting an STI?

How do you protect yourself from STIs and HIV?

How often do you use this protection? With which partners?

Do you plan to have a child in the future?

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%

Study Names	Risk Reduction in HIV Acquisition
iPrEx (TDF/FTC)	92% (40-99%)
Partners PrEP	90% (58-98%)
TDF2 (TDF/FTC)	TDF detected: 85%
BTS (TDF)	74% (17-94%)

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

	Men Who Have Sex With Men	Heterosexual Women and Men	Injection Drug Users
Detecting substantial risk of acquiring HIV infection:	<ul style="list-style-type: none"> Sexual partner with HIV Recent bacterial STD High number of sex partners History of inconsistent or no condom use Commercial sex work 	<ul style="list-style-type: none"> Sexual partner with HIV Recent bacterial STD High number of sex partners History of inconsistent or no condom use Commercial sex work Lives in high-prevalence area or network 	<ul style="list-style-type: none"> HIV-positive injecting partner Sharing injection equipment Recent drug treatment (but currently injecting)
Clinically eligible:	<ul style="list-style-type: none"> 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:	<ul style="list-style-type: none"> 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 		
	<ul style="list-style-type: none"> Do oral/rectal STD testing 	<ul style="list-style-type: none"> Assess pregnancy intent Pregnancy test every 3 months 	<ul style="list-style-type: none"> Access to clean needles/syringes and drug treatment services

Source: US Public Health Service. Preexposure prophylaxis for the prevention of HIV infection in the United States —2014: a clinical practice guideline.

MONITORING				23
Laboratory test/Clinical Assessment	Baseline	Every 3 months	Every 6 months	Notes
HIV screening assay	✓	✓		Consider need for HIV RNA PCR
HIV symptoms	✓	✓		fever, fatigue, swollen glands, sore throat, rash
HBV serology	✓			Offer HBV vaccination if not immune; Consider recheck HBV yearly if at risk
HCV antibody	✓			Recheck HCV yearly if at continued risk
Serum creatinine	✓		✓	Avoid PrEP if CrCl <60 mL/min
STI screen (syphilis, gonorrhea, chlamydia)	✓	✓ if high risk	✓	Include oral/rectal GC/CT screen if high risk (previous STI, no condoms) or symptomatic
Pregnancy test (women)	✓	✓		Urine beta-HCG
Assess side effects / Adherence		✓		Headache/nausea; take daily, not just after sex
Risk reduction counselling	✓	✓		Condoms, clean needles, behavior change, SUD



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

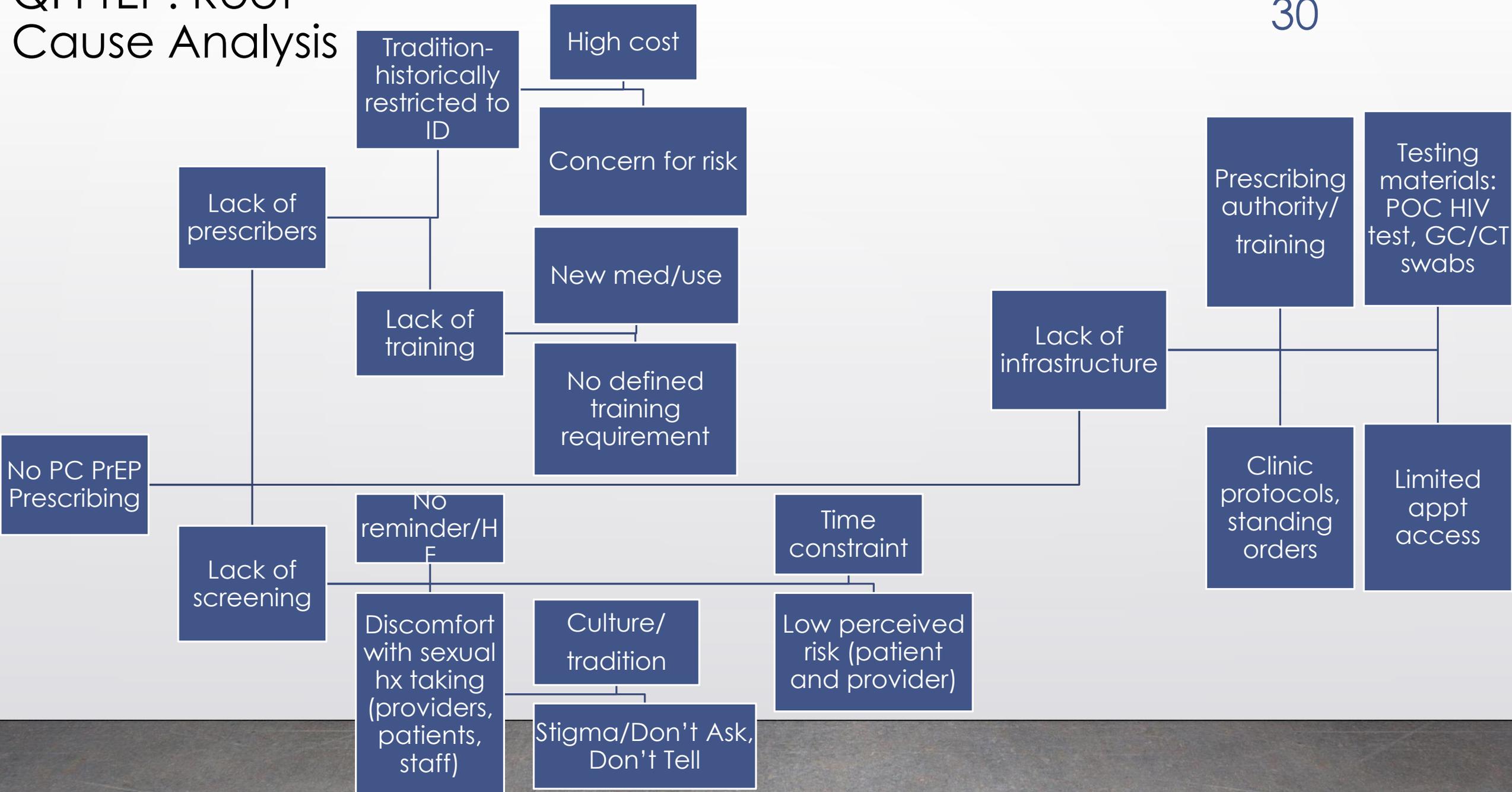
Obtain PrEP prescribing privileges for primary care providers and pharmacists in HPACT

Better identification of patients eligible for PrEP

Initiate PrEP therapy in 10% of eligible patients not already on PrEP by February 2020

QI PrEP: Root Cause Analysis

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



Addressing System Barriers

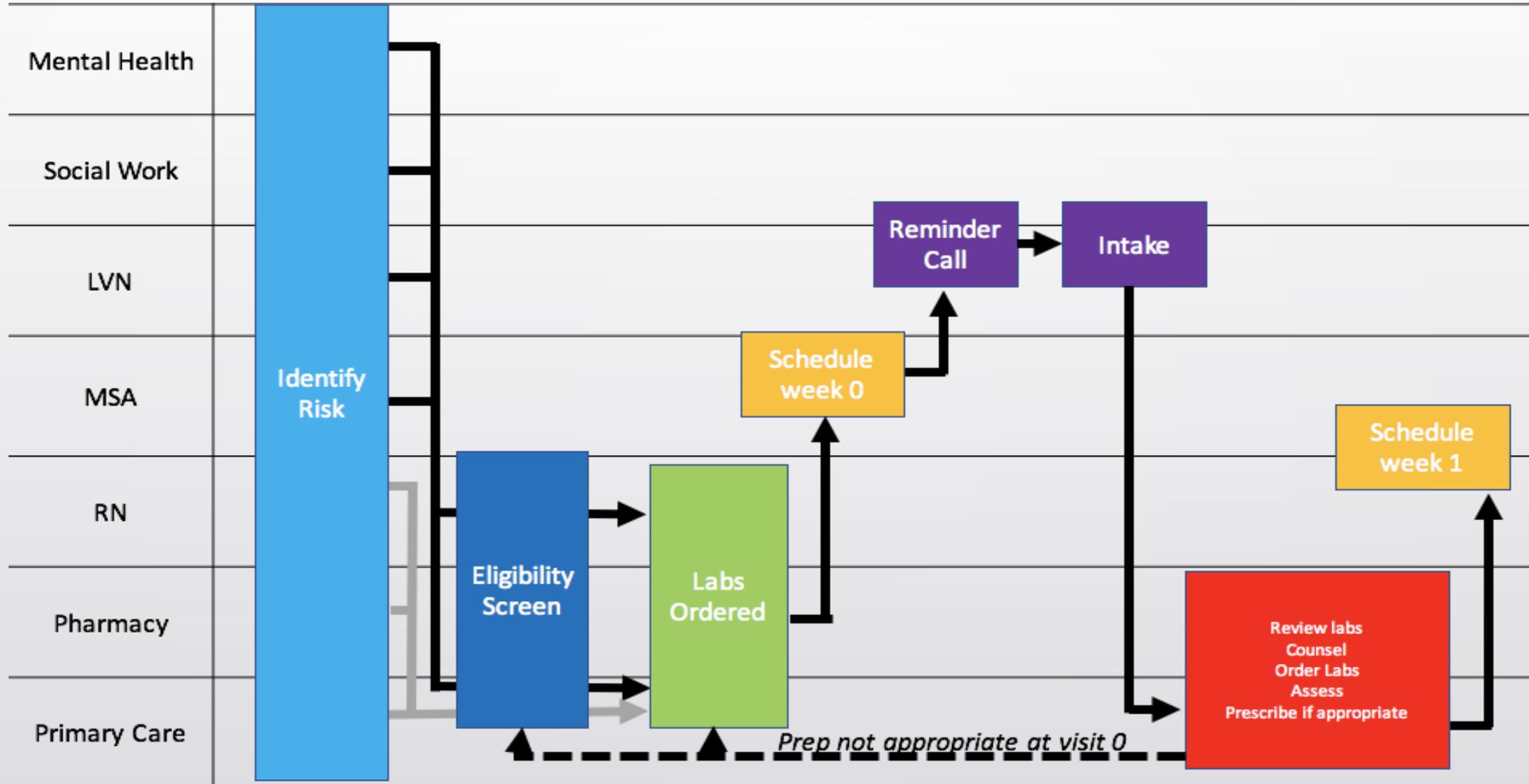
- Truvada restricted to Infectious Disease -> Standardized training to approve primary care providers to prescribe PrEP
- No Point of Care HIV tests or Gonorrhea/Chlamydia (GC/CT) swabs in clinic -> Lab approved rapid processing of HIV tests and self-collection of GC/CT swabs
- EMR Tools
 - Automatic 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





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>



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