ACCEPT

Addiction & Co-morbid Conditions: Enhancing Prevention & Therapeutics

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Session Date: Friday, May 19, 2023

Didactic Topic and Presenter:
HIV Pre-exposure Prophylaxis (PrEP) in Addiction Medicine

Virginia Richey, DO, FAAFP
Addiction Medicine Fellow
UW Dept of Family Medicine & Community Health

- 12:15 PM: Attendance text-in – Introductions
- 12:25 PM: Case Presentation and Discussion
    - Presenters:
        - Joe Galey - *Peer Support Specialist, Recovery Coach, Safe Communities, MDC. / UW Health*
        - Meggan Kohel – Behavioral Health Registered Nurse Case Coordinator
- 1 PM: Didactic Presentation
    - Presenter: Virginia Richey, DO, FAAFP
- 1:15 PM End of Session

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Interprofessional Continuing Education Partnership UNIVERSITY OF WISCONSIN–MADISON | School of Medicine and Public Health, School of Nursing, School of Pharmacy

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ECHO ACCEPT
Addiction & Co-morbid Conditions: Enhancing Prevention & Therapeutics
2022-2024
HIV Pre-exposure Prophylaxis (PrEP) in Addiction Medicine
5/19/23
Didactic Presenter: Virginia Richey, DO, FAAFP
Case Presenter: Joe Galey and Megg Kohel

Provided by the University of Wisconsin–Madison Interprofessional Continuing Education Partnership (ICEP)

Intended Audience:

Nurses, Nurse Practitioners, Pharmacists, Physicians, Physician Assistants, Pharmacy Technicians, Psychologists, Social Workers, Patient/Caregivers, Students

Objectives:

As a result of this educational regularly scheduled series, learners as members of the healthcare team will be able to:

1) Identify HIV and PrEP trends impacting the care of people who use drugs (PWUD) and disparities in HIV prevention and care.
2) Summarize HIV PrEP recommendations, guidelines, prescribing, monitoring and medications
3) Discuss measures to increase PrEP utilization in PWUD

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Name	Role	Financial Relationship Disclosures	Discussion of Unlabeled/Unapproved uses of drugs/devices in presentation?	COI completion date
Randall Brown	RSS Chair	Usona Institute (Grant / Contract), multi-disciplinary association for psychedelic studies (Grant / Contract)	Yes	1/30/2023
Nada Rashid	RSS Coordinator	No relevant financial relationships to disclose	No	1/31/2023
Kathleen Maher	RSS Coordinator	No relevant financial relationships to disclose	No	1/30/2023
Ritu Bhatnagar	Planner	No relevant financial relationships to disclose	Yes	1/29/2023
Paul Hutson	Planner	No relevant financial relationships to disclose	Yes	1/28/2023
Susan Mindock	Planner	No relevant financial relationships to disclose	No	1/31/2023
Sheila Weix	Planner	No relevant financial relationships to disclose	No	2/3/2023
Kellene Eagen	Planner	No relevant financial relationships to disclose	No	1/27/2023
Joseph Galey	Planner	No relevant financial relationships to disclose	Yes	1/27/2023
David Leinweber	Planner	No relevant financial relationships to disclose	No	4/13/2023
Virginia Richey	Presenter	No relevant financial relationships to disclose	No	5/1/2023

Joseph Galey	Presenter	No relevant financial relationships to disclose	No	5/8/2023
Meggan Kohel	Presenter	No relevant financial relationships to disclose	No	5/2/2023

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Case Presentation

Joe Galey CPS, Doula, Recovery Coach
Megg Kohel BHRNCC

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Case Introduction

One-liner (including age/sex):

40 years old male (PWID) with history of polysubstance use disorder, currently being treated with Buprenorphine Sub-Q in primary care.

Primary questions for discussion:

- When would it be appropriate to start Prep?
- How would you approach the conversation?
- Would you feel comfortable continuing Sub-Q Buprenorphine?

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Medical & Behavioral Health Diagnosis:	Current Medications:
Hospital Infection-osteomyelitis **Non-Hospital** Anxiety and depression Depression ADHD Opioid use disorder, severe, in early remission, dependence Tobacco use disorder Bipolar I disorder with depression PTSD (post-traumatic stress disorder)	Sublocade 300mg x 2 Buprenorphine HCl-Naloxone HCl (Suboxone) 8-2 MG per sublingual film Gabapentin (Neurontin) 300 MG cap Naloxone HCl (Narcan) 4 MG/0.1ML nasal spray QUEtiapine Fumarate (SEROquel) 50 MG tab

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Substance Use

History:

- 20-year history of substance use experiences

Consequences of Substance Use:

Social/occupational/educational:

- Reports not having stable friends and family relationships
- Unable to keep or maintain employment
- Started use in High School no further education.
- No housing for years
- Loss custody of children
- Judicial

Physical (including evidence of tolerance/withdrawal):

- Poly substance use - cross addiction – problem substance changes
- Multiple hospitalizations
- Infections Hep-C
- malnutrition

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Treatments

- IOP
- DOC
- Methadone
- Buprenorphine Sublingual
- Buprenorphine Sub-Q

Social History:	Family History:
➢ Lack of housing / Homelessness ➢ No employment ➢ Fly's cardboard for money ➢ Friends in active use	➢ loss of custody of children ➢ Partner in active use ➢ No information on other family use

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Patient strengths & protective factors:	Risk factors:
➢ Resourceful / needs meet ➢ Trusting / providers ➢ Accepting of help/ seeks help ➢ MOUD ➢ BHRNCC ➢ Peer Support ➢ RN- Community Resource	➢ Lack of consistent housing ➢ Malnutrition / Food insecure ➢ Infections/ Abscesses ➢ Overdose / Injection ➢ No income ➢ Legal ➢ Partner in active use/ Codependent

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Labs

- Hep-C / Liver
- Urine Drug Screens
- HIV
- STI

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Patient Goals & Motivations for Treatment

- Not dying
- Risk of amputation from infection
- Getting children back
- Not suffering through withdrawal
- Maintain longer sobriety

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Proposed Diagnoses

- Opioid use disorder with dependance
- Depression

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Proposed Treatment Plan

- Continue Buprenorphine Sub-Q injections 300mg
- Encourage higher level of care
- Start Hep-C medication
- Conversation around Prep

Discussion:

- When would it be appropriate to start Prep?
- How would you approach the conversation?
- Would you feel comfortable continuing Sub-Q Buprenorphine?
- High Risk of mortality-Harm reduction

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DSM-5 Substance Use Disorder ("Addiction")

- Tolerance
- Withdrawal

Physical Dependence ≠ Use Disorder

- Larger amts/longer periods than intended
- Persistent desire/failed attempts to quit/control use
- Much time obtaining/using/recovering
- Important activities sacrificed
- Continued use despite known adverse effects
- Failure to fulfill major obligations
- Recurrent hazardous use
- Craving
- Ongoing use despite interpersonal problems

2-3 = mild
4-5 = moderate
≥ 6 = severe

By initialing here _______ you have acknowledged that Project ECHO case consultations do not create or otherwise establish a provider-patient relationship between any ECHO clinician and any patient whose case is being presented in a teleECHO clinic.

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HIV Pre-exposure Prophylaxis (PrEP) in Addiction Medicine

Virginia Richey, DO
Addiction Medicine Fellow
Univ of WI - Dept of Family Medicine & Community Health
Family Medicine Physician

May 19, 2023

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Disclosures

- None

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Objectives

- Identify HIV and PrEP trends impacting the care of PWUD (People Who Use Drugs) in the US
- Identify disparities in HIV prevention & care
- Describe components of HIV prevention in PWUD
- PrEP 101: Overview of PrEP - guidelines, prescribing, medications, monitoring
- Measures to increase PrEP utilization in PWUD

HIV PrEP Utilization – What we know

- People who use drugs (PWUD) are disproportionally affected by HIV
  - Globally 20% of people who inject drugs are living with HIV
  - US ~10% new infections attributed to injection drug use (IDU)
  - New HIV diagnoses among PWUD are increasing
  - From 2016 to 2019, HIV diagnoses increased 13% among PWID
  - Wisconsin ~10% of new cases attributed to IDU or both IDU + male-male sexual contact
  - Many disparities exist in HIV prevention, screening, treatment
  - Structural & social factors - housing, incarceration, poverty, stigma, discrimination, access
- PrEP utilization in PWUD lags far behind other groups **< 3%**
- PWUD are at increased risk for HIV infection and should be considered high priority for PrEP use
- Interventions addressing barriers to care can improve PrEP uptake

1. https://www.dhs.wisconsin.gov/publications/p00484-20.pdf
2. Centers for Disease Control and Prevention. HIV Surveillance Report, 2020; vol. 33. http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html. Published May 2022. Last accessed 4/28/23
3. Mistler CB, Copenhaver MM, Shrestha R. The Pre-exposure Prophylaxis (PrEP) Care Cascade in People Who Inject Drugs: A Systematic Review. AIDS Behav. 2021 May;25(5):1490-1506

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Lifetime Risk of HIV Infection among PWID

	Male	Female
PWID (total)	1 in 42	1 in 26
Black/African American	1 in 11	1 in 7
Hispanic/Latinx	1 in 26	1 in 25
American Indian/Alaska Native	1 in 49	1 in 19
Native Hawaiian/Other Pacific Islander	1 in 65	1 in 269
Asian	1 in 196	1 in 215
White	1 in 108	1 in 49

UCSF National Clinician Consultation Center. (2022). *Barriers & Best Practices to HIV Prevention and Treatment for People Who Use Drugs* [Video]. https://nccc.ucsf.edu/2022/06/08/webinar-barriers-and-best-practices-to-hiv-prevention-and-treatment-for-people-who-use-drugs/

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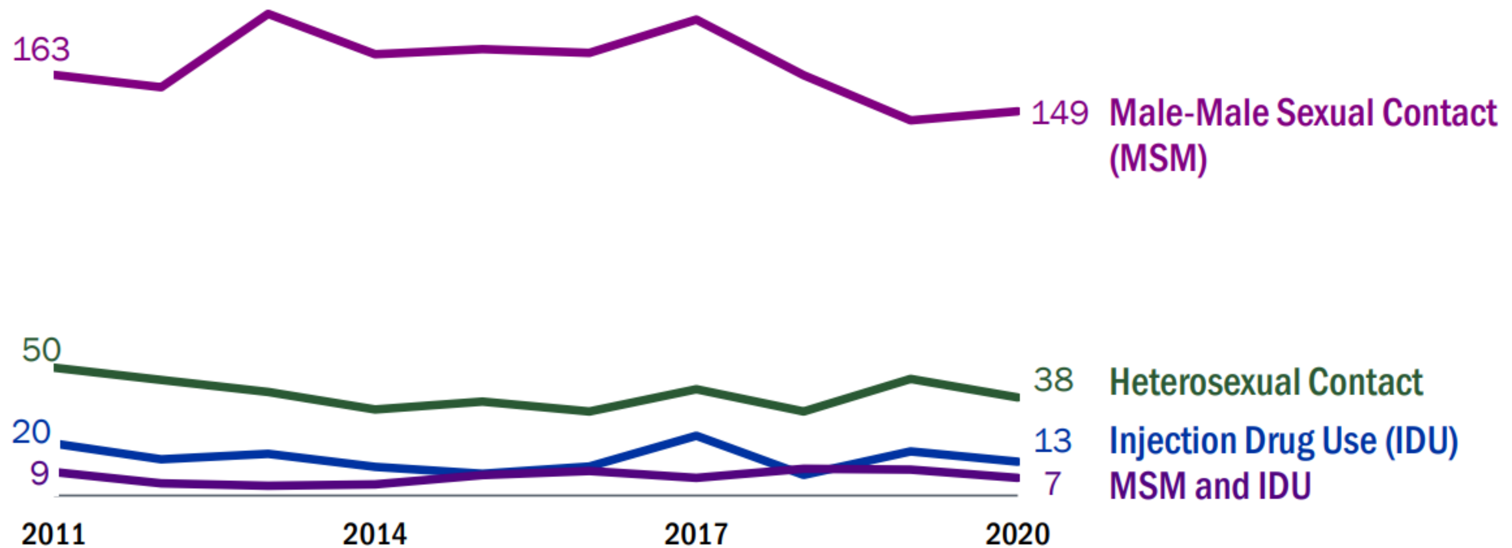
Wisconsin HIV (2020)

During 2011–2020, the estimated number of diagnoses attributed to male-male sexual contact, injection drug use, and male-female sexual (heterosexual) contact were stable (Figure 9).



https://www.dhs.wisconsin.gov/publications/p00484-20.pdf

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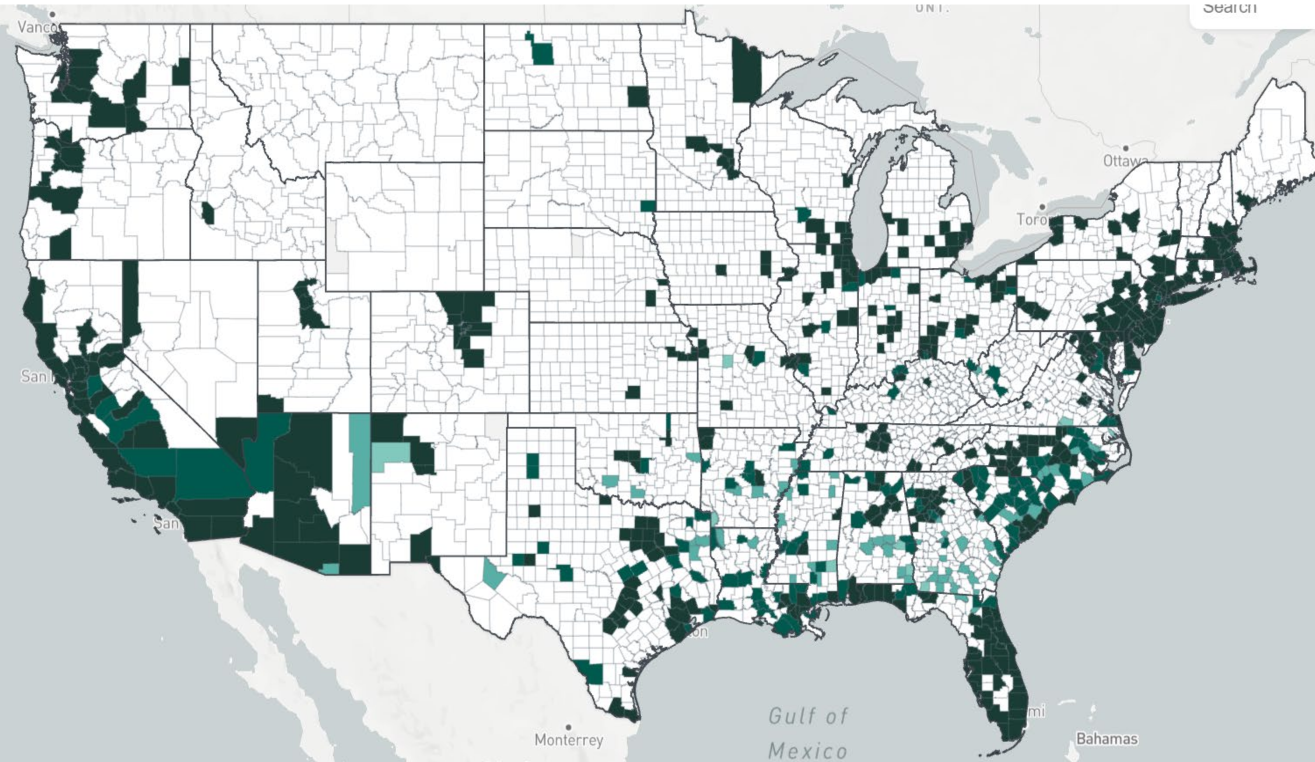
PrEP to Need Ratio (PNR) in the US



PrEP-to-Need Ratio (PNR) = ratio of PrEP users in 2021 to the number of people newly diagnosed with HIV in 2020

Lower PNR = more unmet need

PrEP-to-Need Ratio (PNR, or the number of PrEP users to the number of people newly diagnosed with HIV), 2021	0.00 - 0.43	0.44 - 1.0	1.01 - 2.22	2.23 - 5.27	5.28+

© Mapbox © OpenStreetMap Improve this map

https://map.aidsvu.org/map
last accessed 4/18/23

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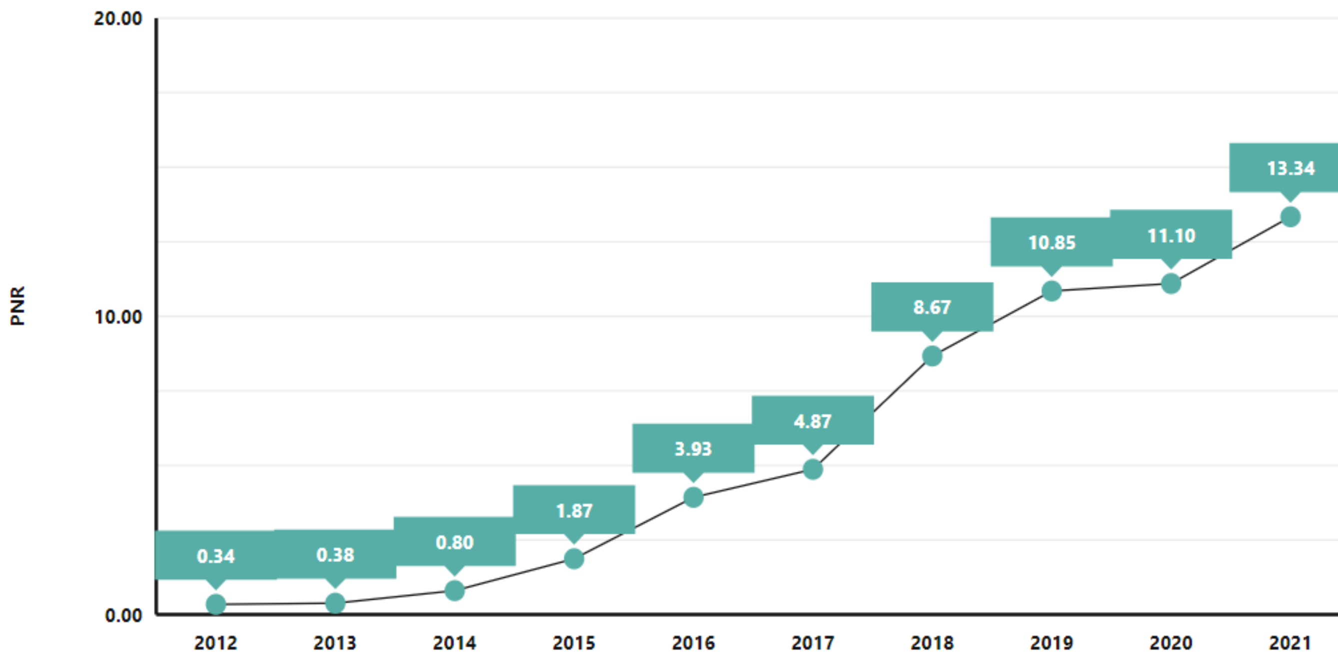
PrEP to Need Ratio - Wisconsin



PNR, 2021

13.34

PNR, by Sex, 2021

Male: 15.71

Female: 4.00

PNR, by Race/Ethnicity, 2021

Black: 2.98

Hispanic/Latinx: 4.05

White: 29.24

PNR, by Age, 2021

Aged 13-24: 11.74

Aged 25-34: 13.56

Aged 35-44: 12.54

Aged 45-54: 17.42

Aged 55+: 13.85

PrEP-to-Need Ratio (PNR) = ratio of PrEP users in 2021 to people newly diagnosed with HIV in 2020

Lower PNR = more unmet need

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https://aidsvu.org/local-data/united-states/midwest/wisconsin/#prep – last accessed 4/18/23

HIV Testing and Screening

- Almost 40% of new HIV infections are transmitted by people who do not know they are infected
- Of ~1.2 million people living with HIV in the US in 2019, 1 in 7 (13%) unaware of diagnosis
- When dx is known, can start tx

  U = U

  Un-detectable = Un-transmittable
- CDC & USPSTF recommend HIV testing at least once in lifetime as routine care for all people age 13-64
- Annually for those with higher risk, including PWUD

Centers for Disease Control and Prevention. HIV Surveillance Report, 2020; vol. 33.
http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html
Published May 2022. Accessed 5/2/23

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What is HIV PrEP?

- Medication for HIV negative individuals that can help prevent HIV transmission
- Biomedical intervention that may be part of a larger prevention tool kit (harm reduction)
- Opportunity to reduce HIV disparities
- Potential gateway to accessing other health services
- Highly effective - when taken consistently, can reduce risk of contracting HIV by 99%
- First approved in 2012 for use in the US

https://www.cdc.gov/hiv/basics/prep.html

Who may benefit from PrEP?

- Anyone who self-identifies a need for PrEP
- Men who have sex with men (MSM)
- People with partners with or at risk for HIV
- Transgender women
- People who have had an STI, condomless anal sex, or transactional sex
- PWID or use stimulants like methamphetamine during sex

Recommendation Summary

Population	Recommendation	Grade
Adolescents and adults at increased risk of HIV	The USPSTF recommends that clinicians prescribe pre-exposure prophylaxis with effective antiretroviral therapy to persons who are at increased risk of HIV acquisition to decrease the risk of acquiring HIV infection. See the "Practice Considerations" section for more information about identification of persons at increased risk and about effective antiretroviral therapy.	A

https://www.uspreventiveservicestaskforce.org/uspstf/draft-recommendation/prevention-human-immunodeficiency-virus-hiv-infection-prep

https://www.uspreventiveservicestaskforce.org/uspstf/draft-recommendation/prevention-human-immunodeficiency-virus-hiv-infection-prep (2019)

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PrEP Eligibility & Guidance – CDC 2021

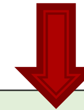

Table 1a: Summary of Clinician Guidance for Daily Oral PrEP Use

	Sexually-Active Adults and Adolescents[1]	Persons Who Inject Drug[2]
Identifying substantial risk of acquiring HIV infection	Anal or vaginal sex in past 6 months AND any of the following: • HIV-positive sexual partner (especially if partner has an unknown or detectable viral load) • Bacterial STI in past 6 months[3] • History of inconsistent or no condom use with sexual partner(s)	HIV-positive injecting partner OR Sharing injection equipment
Clinically eligible	**ALL OF THE FOLLOWING CONDITIONS ARE MET:** • Documented negative HIV Ag/Ab test result within 1 week before initially prescribing PrEP • No signs/symptoms of acute HIV infection • Estimated creatinine clearance ≥30 ml/min[4] • No contraindicated medications	
Dosage	• Daily, continuing, oral doses of F/TDF (Truvada®), ≤90-day supply OR • For men and transgender women at risk for sexual acquisition of HIV; daily, continuing, oral doses of F/TAF (Descovy®), ≤90-day supply	
Follow-up care	**Follow-up visits at least every 3 months to provide the following:** • HIV Ag/Ab test and HIV-1 RNA assay, medication adherence and behavioral risk reduction support • Bacterial STI screening for MSM and transgender women who have sex with men[3] – oral, rectal, urine, blood • Access to clean needles/syringes and drug treatment services for PWID **Follow-up visits every 6 months to provide the following:** • Assess renal function for patients aged ≥50 years or who have an eCrCl <90 ml/min at PrEP initiation • Bacterial STI screening for all sexually-active patients[3] – [vaginal, oral, rectal, urine- as indicated], blood **Follow-up visits every 12 months to provide the following:** • Assess renal function for all patients • Chlamydia screening for heterosexually active women and men – vaginal, urine • For patients on F/TAF, assess weight, triglyceride and cholesterol levels	

[1] adolescents weighing at least 35 kg (77 lb)

[2] Because most PWID are also sexually active, they should be assessed for sexual risk and provided the option of CAB for PrEP when indicated

[3] Sexually transmitted infection (STI): Gonorrhea, chlamydia, and syphilis for MSM and transgender women who have sex with men including those who inject drugs; Gonorrhea and syphilis for heterosexual women and men including persons who inject drugs

[4] estimated creatine clearance (eCrCl) by Cockcroft Gault formula ≥60 ml/min for F/TDF use, ≥30 ml/min for F/TAF use

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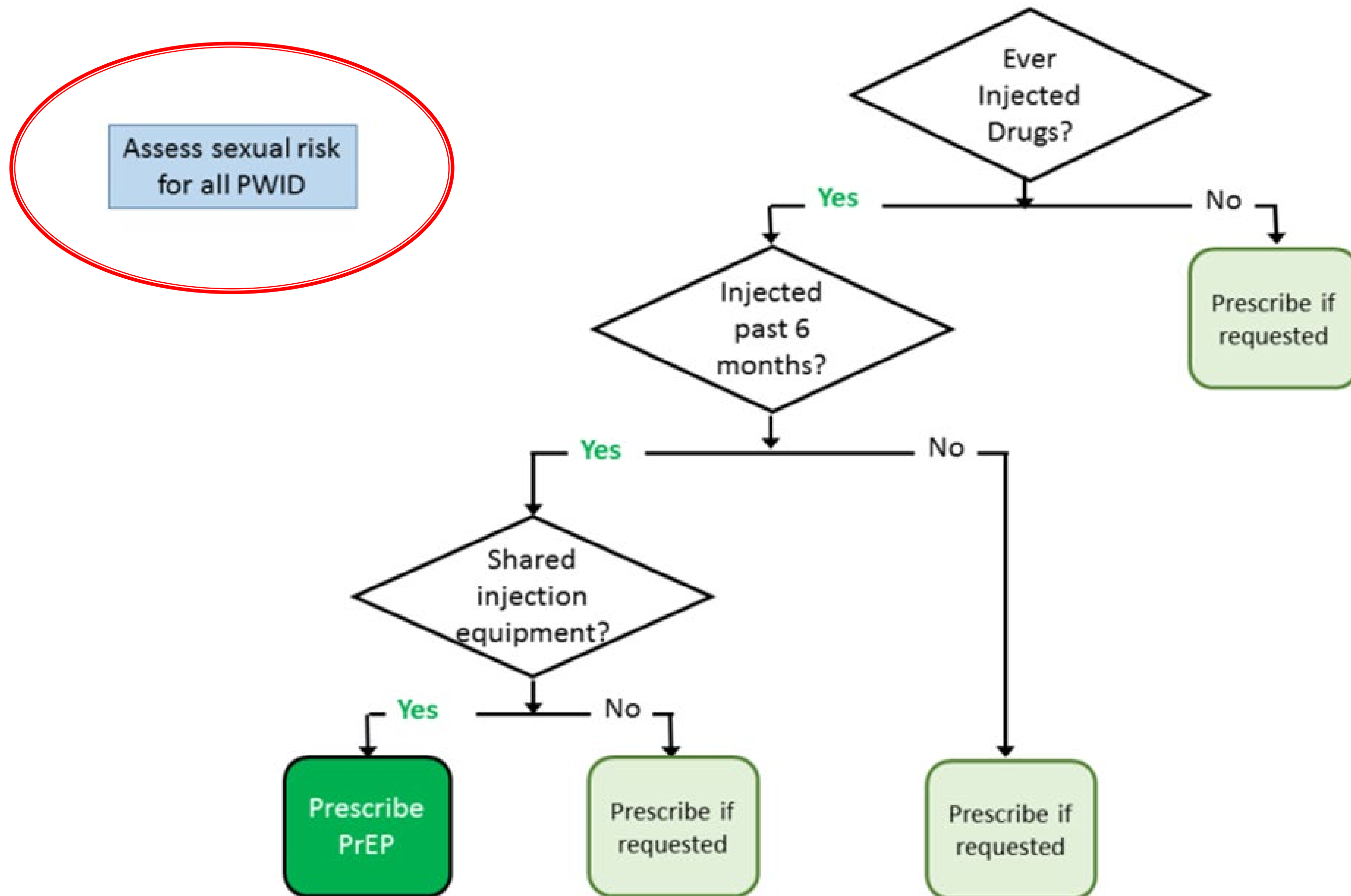
https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

PrEP for People Who Inject Drugs (PWID)



https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

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PrEP – FDA approved agents

TDF/FTC tenofovir disoproxil fumarate/emtricitabine (Truvada)

- FDA approved 2012
- Once daily tablet
- For ALL sexually active individuals and PWID – now generic!

TAF/FTC tenovofir alafenamide/emtricitabine (Descovy)

- FDA approved 2019 (Discover Trial)
- Once daily tablet
- Cisgender men who have sex with cisgender men (MSM) & transgender women

Cabotegravir (CAB, Apretude)

- FDA approved 2021
- Cisgender MSM & transgender women
- Injectable, long-acting, 600 mg IM - initial dose
- 2nd dose given 1 mo after 1st dose, then Q 2 months

****All 3 are approved for adults and adolescents weighing at least 35 kg**

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Possible Side Effects

Oral PrEP (F/TDF, F/TAF)

- Nausea, diarrhea, headache - usually mild and resolves within 1 mo
- Renal impairment - typically reversible if PrEP stopped (risk greater with F/TDF)
- Slight (1%) loss of bone mineral density over 1 yr; no increased risk of fractures; risk greater with TDF
- F/TAF (Descovy: possible weight gain (ave 2-3 lb)

Injection PrEP (CAB) - injection site reactions

PrEP time to effectiveness

TDF/FTC (Truvada)

- Rectal tissue 7 days
- Cervicovaginal tissue 20 days

TAF/FTC (Descovy) and **cabotegravir**

- No data yet available

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Lab monitoring

Baseline (within 7 days of starting PrEP)

- HIV test (ideally HIV Ag/Ab)
  - HIV RNA (if concern for infection within the past 4 weeks)
- HBV and HCV serology
- STI testing: GC/CT (throat, rectum, genital/urine based on sites of exposure), syphilis
- Oral PrEP: creatinine (CrCl)
  - TDF/FTC (Truvada) contraindicated if CrCl < 60ml/min
  - TAF/FTC (Descovy) can be used CrCl > 30ml/min
- TAF/FTC: lipids

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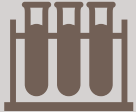
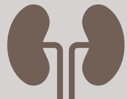
Labs: Oral PrEP

1 month: optional, appropriate in some cases to ensure patient is still HIV negative)



Every 3 months: HIV Ag/Ab, HIV RNA, screen for STIs (see baseline labs), pregnancy test



Every 6 months: CrCl for persons age ≥ 50 or eCrCl < 90
Every 12 months: cholesterol. HCV Ab for MSM, transgender women, and PWID

https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf. Published XXX 2021

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Labs: Injection PrEP (CAB)

- 1 month: HIV RNA
- Every 2 months: HIV Ag/Ab and HIV RNA
- Every 4 months: HIV RNA, STI testing (see baseline list)
- Pregnancy test as appropriate

Follow up visits

Oral PrEP

- 1 week (optional): Call, check if Rx filled, assess adherence and side effects
- 1 month (optional)
- At least **every 3 months, Rx 90-day supply**

Injection PrEP

- 1 month (time of 2nd injection)
- Every 2 months (subsequent injections)

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Counseling - PrEP

- Importance of close adherence
- Other infection & HIV prevention (condom use/risk reduction)
- Safer injection use practices
- Need for regular follow-up visits & labs
- Reproductive goals/contraception
- Symptoms of acute HIV infection
- Risks of stopping (HIV infection) and cautions for restarting (need for HIV testing, risk of inadequate treatment if HIV infected)
- Oral PrEP: risk of flare of HBV (if infected)
- For CAB: slow decline in CAB levels after stopping (risk of CAB resistance if infected with HIV during this time)
- Insurance/medication assistance
- Procedures for refills

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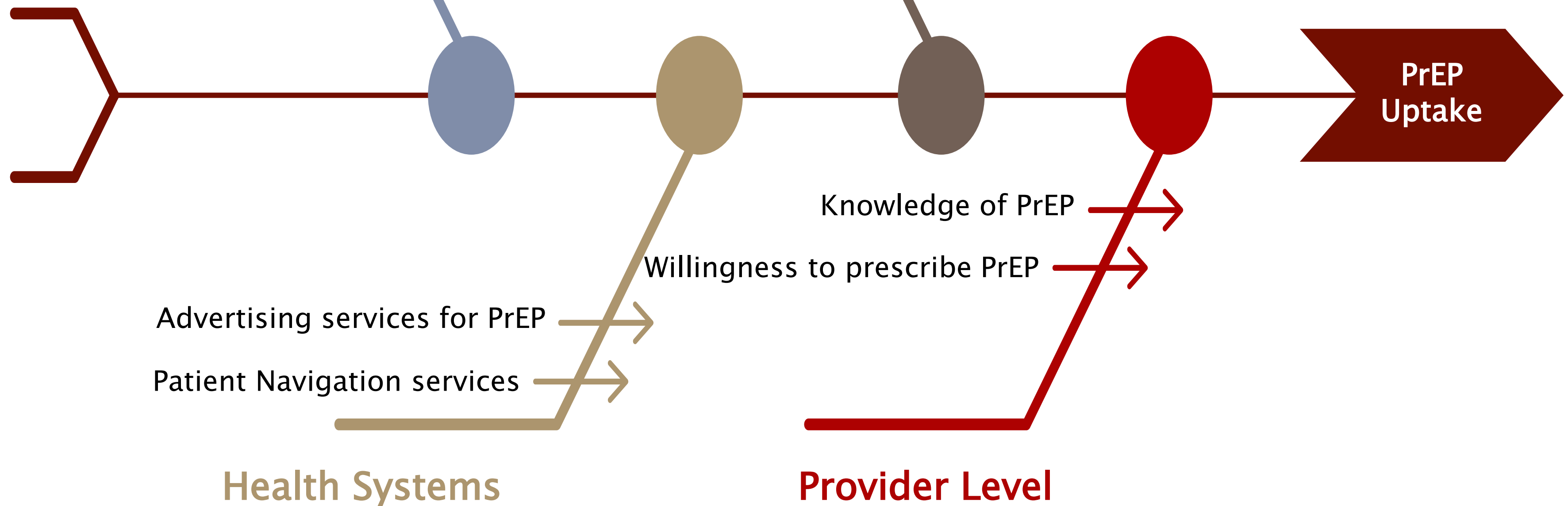
Barriers to PrEP



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Daud, M. and Gergen, M. (2022, December 8). *A QI Project: Increasing Access to PrEP at Northport Family Medicine Reidency Clinic* [PowerPoint slides]. University of WI DFMCH Fellowship Symposium.

Improving PrEP Use in PWUD

- Talk about PrEP - incorporate with harm reduction conversations
- Assess sexual related risk
- Address structural & logistical barriers
  - Same day PrEP
  - PEP to PrEP
  - Sync SUD tx visits with PrEP visits
  - Case management, PrEP navigation
  - Integrated care with SUD Tx and harm reduction services

Improving PrEP Use in PWUD (cont)

- Think of PrEP as another harm reduction measure
- "Are you interested in hearing more about a medication that can prevent HIV?"
- EHR PrEP dot-phrases/templates for substance use & sexual health risk screening
- Offer provider & team education on:
  - Taking a sexual health hx and counseling
  - Health equity
  - Implicit biases
  - Delegate a PrEP "captain" to help other providers with education and clinical consultations

Conclusions

- PWUD are disproportionally affected by HIV
- PrEP utilization in PWUD lags far behind other groups
- PWUD are at increased risk for HIV infection and should be considered high priority for PrEP use
- Assess sexual related risks in addition substance use and injection related risks
- USPTF & CDC recommend universal screening for HIV and discussing PrEP with all sexually active adolescents and adults
- Interventions addressing barriers to care can improve PrEP uptake, such as integrating care with SUD Tx and harm reduction services

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References and Resources

- Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf
- https://map.aidsvu.org/map
- Biello, K.B., Bazzi, A.R., Mimiaga, M.J. *et al.* Perspectives on HIV pre-exposure prophylaxis (PrEP) utilization and related intervention needs among people who inject drugs. *Harm Reduct J* 15, 55 (2018)
- Mistler CB, Copenhaver MM, Shrestha R. The Pre-exposure Prophylaxis (PrEP) Care Cascade in People Who Inject Drugs: A Systematic Review. AIDS Behav. 2021 May;25(5):1490-1506
- Kennedy AJ, Hassan I, Cameron FA, Gobao V, Edelman EJ, Ho K, Fisk S, Hamm M, Merlin JS. Barriers and Facilitators to Providing HIV Preexposure Prophylaxis Among Buprenorphine Prescribers: A Pilot Qualitative Study. J Addict Med. 2021 May-Jun 01;15(3):261-263
- University of California San Francisco. National Clinician Consultation Center. https://nccc.ucsf.edu/
- AETC Program PrEP Toolkit: https://aidsetc.org/prep

nPEP (Non-Occupational Post-Exposure Prophylaxis)

Known *or* potential exposure to HIV

AND

≤72 hours after exposure that presents substantial risk for HIV acquisition

Baseline labs

- HIV Ag/Ab
  - If HIV is reactive, do NOT use nPEP → link to HIV care
- STI tests
- Urine pregnancy
- Serum creatinine, ALT, AST
- HBV serology
- Hepatitis C Ab

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nPEP Medications

- 1st dose of nPEP ASAP after a negative rapid HIV *or* a non-rapid HIV test is sent
- TDF/FTC (Truvada) 300/200 mg + dolutegravir (Tivicay) 50 mg
  1 tablet of each PO daily x **28 days**
- May use TAF/FTC (Descovy) in place of TDF/FTC, and bictegravir in place of dolutegravir. Bictegrav available as coformulation with TAF/FTC (bictegravir/TAF/FTC, Biktarvy)

nPEP Follow up

- 72 hours
- 4-6 weeks after initiating nPEP
  - HIV Ag/Ab test after initial non-reactive test
  - Syphilis test at 4-6 weeks and 3-6 months
- HBV & HCV serology at 6 months

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