TV-104-091919-47

SYLLABUS AND COURSE GUIDE

A Grassroots Approach to Weed Out HIV and HCV in Special OUD Populations

A Free, 90-Minute CME/CNE/CPE/MIPS/ABIM MOC Live and On Demand Activity

Premiere Date: Thursday, September 19, 2019

12:00 p.m.–1:30 p.m. ET (live)

Credit Expiration Date: Saturday, September 19, 2020

On the Web: http://bit.ly/TV104

LIVE FACULTY: Carlos Malvestutto, MD, MPH; Jaimie P. Meyer, MD, MS, FACP

MODERATOR: David A. Wohl, MD

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INFORMATION FOR PARTICIPANTS

Statement of Need

Injection drug use (IDU) has been fueled by the opioid crisis, resulting in a dramatic increase in hepatitis C virus (HCV) and human immunodeficiency virus (HIV) infections. People with opioid use disorder (OUD) are 28 times more likely to contract HIV, and one in 10 new HIV infections is attributed to IDU. Further, the CDC reported a 233% increase in new HCV infections between 2010-2016.

Although effective treatments for HIV and HCV exist and are readily available, barriers related to OUD make treatment difficult in this population, especially in the rural, correctional, and VA (Veterans Affairs)' settings.

In this CME Outfitters Live and On Demand, expert faculty discuss strategies for HIV and HCV testing in special OUD populations, applying evidence-based treatment approaches, as well as prevention strategies, including PrEP, for patients with OUD at high risk for HIV infection.

Learning Objectives

At the end of this CE activity, participants should be able to:

- Implement strategies for HIV and HCV testing in special OUD populations in correctional, VA, and rural settings.
- Apply evidence-based treatment approaches in patients with OUD with HIV or HCV infection or HIV/HCV co-infection.
- Identify patients with OUD at high risk for HIV infection who are candidates for HIV prevention strategies, including PrEP.

The following learning objectives pertain only to those requesting CNE or CPE credit:

- Discuss strategies for HIV and HCV testing in special OUD populations in correctional, VA, and rural settings
- Describe evidence-based treatment approaches in patients with OUD with HIV or HCV infection or HIV/HCV co-infection.
- Identify patients with OUD at high risk for HIV infection who are candidates for HIV prevention strategies, including PrEP.

Target Audience

OUD specialists, primary care physicians, psychiatrists, mental health specialists, physician assistants, nurse practitioners, nurses, and pharmacists

Financial Support

Supported by an educational grant from Gilead Sciences, Inc.

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Enduring: 0376-0000-19-032-H01-P
Type: knowledge-based

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Learning Formats:

Live activity

Enduring Material

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FACULTY BIOS & DISCLOSURES

David A. Wohl, MD (Moderator)

In response to the HIV pandemic, Dr. Wohl has focused his career on optimizing the treatment of HIV infection, including identifying the most effective therapeutic approaches and minimizing the adverse effects of therapy. Cognizant that HIV disproportionately affects the most vulnerable, he has worked to improve HIV care and prevention for often marginalized individuals such as the incarcerated, men who have sex with men, and those living in poverty.

Dr. Wohl is active within the U.S. AIDS Clinical Trials Group (ACTG) and HIV Prevention Trials Network (HPTN), and served two terms as a member of the U.S. Department of Health and Human Services (DHHS) Panel on Antiretroviral Guidelines and was recently invited to serve on the DHHS Panel on Opportunistic Infection Guidelines.

As part of the response to the 2013-2016 Ebola outbreak in West Africa, Dr. Wohl led UNC clinical research efforts to test interventions for Ebola Virus Disease in Liberia and now is a principal investigator of a clinical cohort that longitudinally follows Ebola survivors, as well as a study to determine the natural history of Lassa fever.

In addition to his research and administrative activities, Dr. Wohl maintains a large HIV continuity clinic at UNC.

Carlos Malvestutto, MD, MPH

Dr. Malvestutto completed his Bachelor of Science in Biology at Yale University in 1996 and a Master of Public Health at Johns Hopkins University College of Hygiene and Public Health in 2000. He obtained his MD at Ponce School of Medicine in Ponce, Puerto Rico in 2005 and completed residency in internal medicine at Mount Sinai Medical Center in New York, NY in 2008 and his fellowship in Infectious Diseases at New York University Medical Center in 2010. He remained on faculty at NYU until 2014 when he moved to Columbus, OH and joined the faculty at the Ohio State University Wexner Medical Center.

Dr. Malvestutto is Assistant Professor in the Division of Infectious Diseases at the Ohio State University Wexner Medical Center. He is the former Director the Infectious Diseases Fellowship Training Program at OSU and is the former Medical Director of the Family AIDS Clinic and Education Services (FACES) program at Nationwide Children's Hospital. Dr. Malvestutto is an investigator at the OSU AIDS Clinical Trials unit and is involved in multiple HIV and hepatitis C clinical trials. His areas of clinical research include improving linkage to prevention and treatment care for underserved populations, cardiovascular complications of HIV, new modalities of HIV PrEP, and use of broadly neutralizing antibodies for the treatment and cure of HIV.

Jaimie P. Meyer, MD, MS, FACP

Dr. Jaimie Meyer graduated from Dartmouth College and attended medical school at the University of Connecticut. She completed a residency in Internal Medicine at NY Columbia Presbyterian and fellowships in Infectious Diseases at Yale and Interdisciplinary HIV Prevention Research at Yale School of Public Health. She also completed a Master of Science in Biostatistics and Epidemiology at Yale School of Public Health.

Dr. Meyer is currently an Assistant Professor of Medicine at Yale School of Medicine AIDS Program and a Clinical Assistant Professor at Yale School of Nursing, where she maintains board certifications in Internal Medicine, Infectious Diseases, and Addiction Medicine, along with DEA certification to prescribe buprenorphine. Her clinical work and research focus on HIV prevention and treatment for women involved in criminal justice and drug treatment settings.

As a clinical researcher, she develops and implements interventions to address the unique needs of women involved in criminal justice systems through probation, parole, prison, and jail, in terms of diagnosing, treating, and preventing HIV, hepatitis C, sexually transmitted infections, substance use disorders, and homelessness. She has been continuously funded for this work through NIDA, SAMHSA, the Doris Duke Charitable Foundation, and other foundational and industry sources. Dr. Meyer's research is motivated by the patients she cared for as an HIV provider at the only women's prison in the state of Connecticut.

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Dr. Malvestutto reports that he serves on the advisory committee for ViiV Healthcare.

Dr. Meyer reports that she recieves research support from Gilead Sciences, Inc.

Jeffrey Helfand, DO (Peer Reviewer) has no disclosures to report.

Mae Ochoa, RPh (peer reviewer) has no disclosures to report.

Kavitha Ramachandran (planning committee) has no disclosures to report.

Jan Perez (planning committee) has no disclosures to report.

Sharon Tordoff (planning committee) has no disclosures to report.

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A Grassroots Approach to Weed Out HIV and HCV in Special OUD Populations

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CME Outfitters, LLC, gratefully acknowledges educational grants from Gilead Sciences, Inc. in support of this CME/CE activity.

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David A. Wohl, MD

Professor of Medicine
Site Leader, Global HIV Prevention & Treatment Research Site
Co-Director, North Carolina AIDS Training & Education Center
Co-Director, Viral Hemorrhagic Fever Clinical Research Group
Institute for Global Health & Infectious Diseases
The University of North Carolina (UNC) at Chapel Hill School of Medicine
Chapel Hill, NC

David A. Wohl, MD

Disclosures

- ***Research Support:*** Gilead Sciences, Inc.; Merck & Co., Inc.; ViiV Healthcare
- ***Advisory Committee:*** Gilead Sciences, Inc.; Janssen Pharmaceuticals, Inc.; Merck & Co., Inc.; ViiV Healthcare
- ***Consultant:*** Gilead Sciences, Inc.

Carlos Malvestutto, MD, MPH

Assistant Professor, Division of Infectious Diseases
Ohio State University
Wexner Medical Center
Columbus, OH

Carlos Malvestutto, MD MPH
Disclosures

- ***Advisory Committee:*** ViiV Healthcare

Jaimie P. Meyer, MD, MS, FACP

Assistant Professor of Medicine, Department of Internal Medicine,
Section of Infectious Disease,
AIDS Program Yale University School of Medicine
Clinical Assistant Professor,
Division of Primary Care/Health Systems in Nursing
Yale School of Nursing
New Haven, CT

Jaimie P. Meyer, MD, MS, FACP
Disclosures

- ***Research Support:*** Gilead Sciences, Inc.

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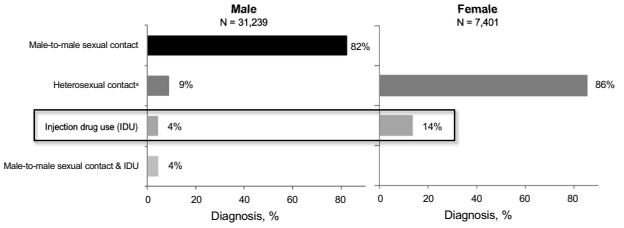
Learning Objective 1

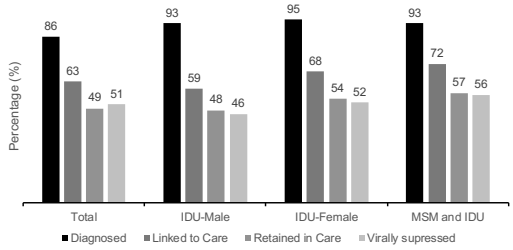
Implement strategies for HIV and HCV testing in special OUD populations in correctional, VA, and rural settings.

Diagnoses of HIV Infection Among Adults and Adolescents, by Sex and Transmission Category, 2017: United States and Six Dependent Areas



Note: Data for the year 2017 are considered preliminary and based on 6-month reporting delay. Data have been statistically adjusted to account for missing transmission category. "Other" transmission category not displayed as it comprises less than 1% of cases.
[a]Heterosexual contact with a person known to have, or to be at high risk for, HIV infection.
Centers for Disease Control and Prevention (CDC). *HIV Surveillance – Persons Who Inject Drugs*. 2017. https://www.cdc.gov/hiv/pdf/library/slidesets/cdc-hiv-surveillance-persons-who-inject-drugs-2017.pdf.

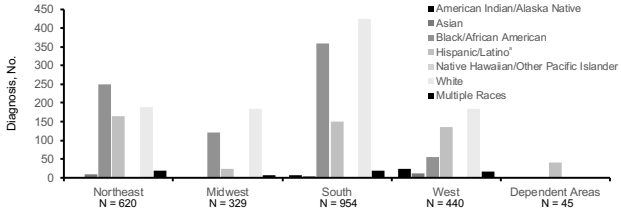
HIV Care Continuum Outcomes Among PWID, 2015 – United States



Linked to care = ≥ 1 test (CD4 or VL); retained in care = ≥ 2 tests (CD4 or VL) ≥ 3 months apart; virally suppressed = < 200 copies/mL on the most recent VL test; MSM = men who have sex with men.

CDC. *Selected National HIV Prevention and Care* Outcomes. https://www.cdc.gov/hiv/pdf/library/slidesets/cdc-hiv-prevention-and-care-outcomes.pdf.

HIV Diagnoses Among PWID, by Region and Race/ Ethnicity 2017: United States and 6 Dependent Areas



Note: Data for the year 2017 are considered preliminary and based on 6 months reporting delay. Data have been statistically adjusted to account for missing transmission category. Data exclude men with HIV infection attributed to male-to-male sexual contact and injection drug use.
[a]Hispanics/Latinos can be of any race.
CDC. *HIV Surveillance – Persons Who Inject Drugs*. 2017. https://www.cdc.gov/hiv/pdf/library/slidesets/cdc-hiv-surveillance-persons-who-inject-drugs-2017.pdf.

HIV and HCV Risk in Rural U.S.

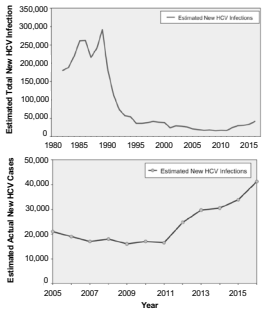
- 220 counties at greatest risk for IDU-associated HIV outbreaks mostly rural[1]
- Outbreak of 181 new HIV infections among PWID in rural Scott County, IN in 2014-2015[2]
  - Rapidly spreading HIV outbreak enabled by existing HCV transmission networks[3]
  - Lack of access to syringe services programs
  - Limited HIV[4] and HCV testing availability

Counties with highest vulnerability to rapid spread of HIV and new or continued high numbers of HCV infections in PWID[1]

IDU = injection drug use.
1. van Handel MM, et al. *J Acquir Immune Defic Syndr*. 2016;73(3):323-331. 2. Peters PJ, et al. *N Engl J Med*. 2016;375:229-239. 3. Ramachandran S, et al. *EBioMedicine*. 2018;37:374-381. 4. Gonsalves GS, et al. *Lancet HIV*. 2018;5(10):e569-e577.

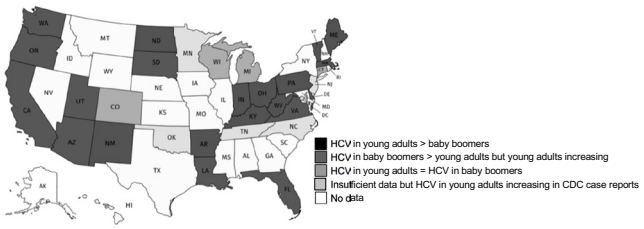
Hepatitis C in PWID

- 3.5 million people live with chronic HCV in the U.S.[1]
- Only 50% aware of their diagnosis[2]
- 300,000 new hepatitis C virus (HCV) infections every year
- 1.3 million PWID in the U.S. - highest risk for HCV infection
- Steady decline in new infections between 1990 and 2005
- Steady increase in new HCV infections since 2011 driven by opioid epidemic
- Disproportionate increase in HCV cases in rural areas[3]
- Prevalence of chronic HCV almost 6x higher in homeless veterans compared to non-homeless veterans[4]



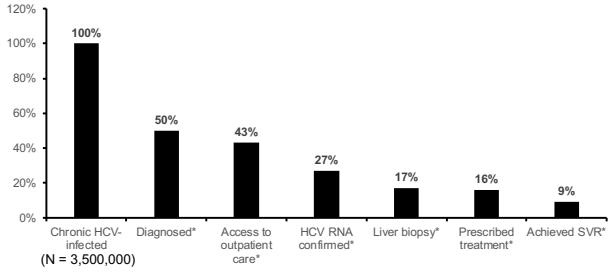
1. CDC. *Viral hepatitis Statistics and Surveillance—United States*. 2016. https://www.cdc.gov/hepatitis/statistics/2016surveillance/pdfs/2016HepSurveillanceRpt.pdf. 2. Denniston MM, et al. *Hepatology*. 2012;55(6):1652-1661. 3. Suryaprasad AG, et al. *Clin Infect Dis*. 2014;59(10):1411-1419. 4. Noska AJ, et al. *Clin Infect Dis*. 2017;65(2):252-258.

HCV Prevalence Increasing in Young Adults



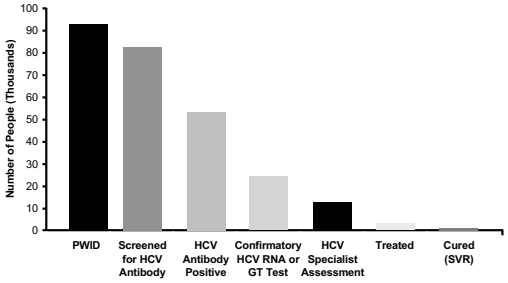
Terrault, N. *F1000Research*. 2019;8(F1000 Faculty Rev):54. https://f1000research.com/articles/8-54.

HCV Treatment Cascade



*Calculated as estimated chronic HCV-infected X estimated percentage. Yehia BR, et al. *PLoS ONE*. 2014;9(7):e101554.

HCV Care Cascade Among PWID



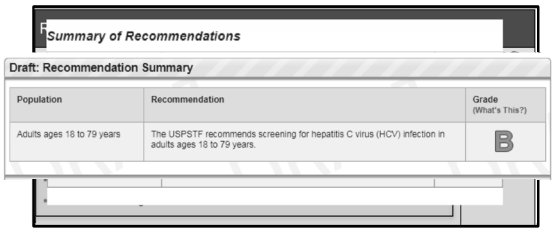
Grebely J, et al. *Nat Rev Gastroenterol Hepatol*. 2017;14(11):641-651. Iversen J, et al. *Int J Drug Policy*. 2017;47:77-85.

CDC HIV Screening Recommendations

- Routine HIV screening of adults, adolescents, and pregnant women in health care settings in the United States
  - Reduce barriers to HIV screening
- One-time screening for all individuals between age 13 and 64
- Once-a-year screening for high-risk individuals

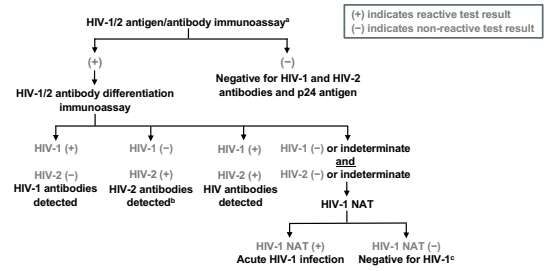
CDC. *HIV Testing*. 2019. https://www.cdc.gov/hiv/testing/index.html.

HCV Screening Recommendations



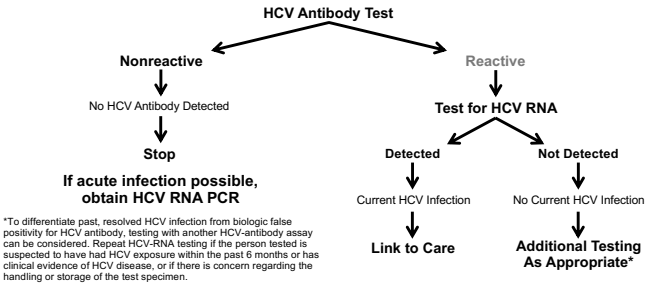
American Association for the Study of Liver Diseases (AASLD)-Infectious Diseases Society of America (IDSA). *HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C*. http://www.hcvguidelines.org. U.S. Preventive Services Task Force (USPSTF). *Hepatitis C: Screening*. http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/hepatitis-c-screening.

Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens



NAT = nucleic acid test.
CDC. *2018 Quick reference guide: Recommended laboratory HIV testing algorithm for serum or plasma specimens*. 2018. https://stacks.cdc.gov/view/cdc/50872.

CDC Recommended Testing Sequence for Identifying Current HCV Infection



*To differentiate past, resolved HCV infection from biologic false positivity for HCV antibody, testing with another HCV-antibody assay can be considered. Repeat HCV-RNA testing if the person tested is suspected to have had HCV exposure within the past 6 months or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.

AASLD-IDSA. http://www.hcvguidelines.org/full-report-view. Version May 24, 2018.

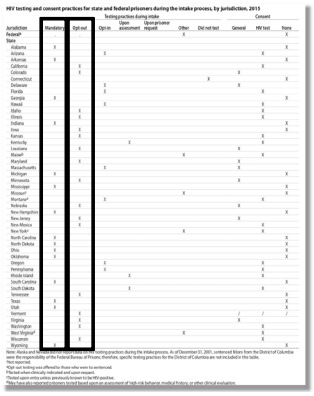
Infectious Diseases in the Correctional System

Each year:

- **14%** of all people in the US with **HIV**
- **33%** of those with **HCV**
- **40%** of those with **Tuberculosis**

pass through correctional facilities

Spaulding AC, et al. *PLoS One* 2009;4(11):e7558.; 2. Hammett TM, et al. *Am J Public Health.* 2002;92 (11):1789-1794.



HIV testing and consent practices for state and federal prisoners during the intake process, by jurisdiction, 2015

- Most state prisons perform mandatory or opt-out HIV screening at entry
- Some also test during incarceration and at release
- Rate of new HIV diagnoses is unclear
  - One study from NC from 2008-9 found very few persons who tested HIV+ at prison entry were not already known to be infected by state DHHS

Interventions to Increase HIV and HCV Testing in PWID

- Routine rapid HCV testing is cost-effective[1]
- Point-of-care (POC) HIV testing has shown high level of consent to testing in young PWID[2]
- Access to HIV testing, antiretroviral therapy (ART), medication-assisted therapy (MAT), and psychosocial counseling[3]
- Mobile technology is promising[4]
- Use of CLIA-waived POC HIV and HCV tests in community pharmacies[5,6]

1. Assoumou SA, et al. *Clin Infect Dis*. 2018;66(3):376-384. 2. Lazarus L, et al. *PLoS ONE*. 2016;11(12):e0166942. 3. Miller WC, et al. *Lancet*. 2018;392(10149):747-759. 4. Aronson ID, et al. *Front Public Health*. 2017;5:217. 5. Weber NC, et al. *Expert Rev Mol Diagn*. 2016;16(2):253-264. 6. Steltenpohl EA, et al. *J Pharm Pract*. 2018;31(6):629-635.

Strategies to Increase HIV and HCV Screening Among PWID

- **Enhanced screening** or scale-up of direct-acting antiviral (DAA) therapy could lead to decline in HCV incidence and prevalence[1,2]
- Identification of **missed opportunities for testing** (e.g., urgent care, emergency department)
- **"Hot spot"** zip codes for HCV and HIV transmission in urban settings can be identified through surveys of PWID[3]

1. Echeverria D, et al. *PLoS ONE*. 2015;10(8):30135901. 2. Durham DP, et al. *Clin Infect Dis*. 2015;62(3):298-304.
3. Des Jarlais DC, et al. *PLoS ONE*. 2018;13(3):e0194799.

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Learning Objective 2

Apply evidence-based treatment approaches in patients with OUD with HIV or HCV infection or HIV/HCV co-infection.

Justine

- 39-year-old woman presents to clinic for HIV and HCV care following 5-month stay in state prison
  - Comes with envelope containing a 1-page hand-written referral

Justine

- Patient says she was diagnosed with HIV infection in 2007 when she entered a residential treatment program for injected heroin addiction
  - Has been on and off ART since; was off when entered prison
  - Darunavir/cobicistat + TAF/FTC started during her recent incarceration; reports taking every day since release
  - Says her prior treatment was a single pill she took before bed that made her have weird dreams
  - While in prison, ALT and AST both noted to be above upper limits of normal; HCV antibody was positive; no further testing noted

ALT = alanine aminotransferase; AST = aspartate aminotransferase; FTC = emtricitabine; TAF = tenofovir alafenamide.

Justine

- She was released 3 weeks ago
  - Living with ex-boyfriend "for now"
  - Has used heroin three times since release using clean needles her ex gave her
  - No other illicit drugs or alcohol

Justine

To Do:

Labs:	
HIV RNA	< 20 c/mL
CD4+ cell count	438/mm^3
Safety labs	ALT = 124, AST = 111
HCV RNA	256,000 c/mL (GT1a, F2 fibrosis score)
HBV serologies vaccinate if not immune	Hepatitis B surface antigen (HBsAb) positive
Lipids	Low HDL
STI screening	Neg RPR, NAAT GC/Chlamydia throat, urine, rectal
Secure source of ART	State ART program forms submitted
Psycho-social:	
Screen for mental illness depression, anxiety, PTSD	Patient Health Questionnaire (PHQ)-9 = 15
Consider substance abuse treatment	Says interested but that she has been through them all
Housing options	SW says shelter is only option
Other assistance programs	Application for hospital assistance program
Transportation	Medical Uber application submitted
Food security	Food bank location provided

CD4 = cluster of differentiation 4; GC = *Gonococcus*; HBV = hepatitis B virus; HDL = high-density protein; NAAT = nucleic acid amplification test; PTSD = post-traumatic stress disorder; RNA = ribonucleic acid; RPR = rapid plasma regain; STI = sexually transmitted infection.

Justine

- No debate that Justine needs to stay on her ART
  - Opportunities to simplify to single tablet
- But what about her HCV?

AASLD/IDSA Guidelines: Recommendations for Treatment of HCV in PWID

Recommendations for Screening and Treatment of HCV Infection in People Who Inject Drugs (PWID)

RECOMMENDED	RATING
Annual HCV testing is recommended for PWID with no prior testing, or past negative testing and subsequent injection drug use. Depending on the level of risk, more frequent testing may be indicated.	IIa, C
Substance use disorder treatment programs and needle/syringe exchange programs should offer routine, opt-out HCV-antibody testing with reflexive or immediate confirmatory HCV-RNA testing and linkage to care for those who are infected.	IIa, C
PWID should be counseled about measures to reduce the risk of HCV transmission to others.	I, C
PWID should be offered linkage to harm reduction services when available, including needle/syringe service programs and substance use disorder treatment programs.	I, B
Active or recent drug use or a concern for reinfection is not a contraindication to HCV treatment.	IIa, B

AASLD IDSA. September 2017. *HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C.* https://www.hcvguidelines.org/treatment-naive.

Guideline-Recommended First-Line Treatment Regimens

Genotype	DAA Regimen
Genotype-Specific	
1,4	Elbasvir/Grazoprevir
1,4,5,6	Ledipasvir/Sofosbuvir
Pangenotypic	
1-6	Sofosbuvir/Velpatasvir
1-6	Glecaprevir/Pibrentasvir

AASLD IDSA. September 2017. *HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C.* https://www.hcvguidelines.org/treatment-naive.

Guideline Recommendations for the Treatment of HIV-HCV Co-Infection

- **HIV treatment**[1]
  - ART may slow the progression of liver disease
    - ART should be initiated in all patients with HCV/HIV co-infection, regardless of CD4 T lymphocyte cell count
  - Initial ART regimens same as those recommended for individuals without HCV infection
    - Drug-drug interactions and overlapping toxicities between ART and DAAs to be considered
- **HCV treatment**[2]
  - Same general approach for treating HCV as with HCV mono-infection
    - 8-week regimen of ledipasvir-sofosbuvir contraindicated
  - Recognize and manage drug-drug interactions between DAAs and ART
  - Screen and monitor for HBV infection

1. Panel on Antiretroviral Guidelines for Adults and Adolescents. *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV*. Department of Health and Human Services. https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf. 2. AASLD IDSA. September 2017. *HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C.* https://www.hcvguidelines.org/treatment-naive.

Drug-Interaction Potential Between Selected HIV Antiretroviral and Preferred HCV Direct-Acting Antiviral Agents

	Glecaprevir/ Pibrentasvir	Sofosbuvir/ Velpatasvir	Ledipasvir/ Sofosbuvir	Elbasvir/ Grazoprevir	Sofosbuvir/Velpatasvir/ Voxilaprevir
Atazanavir + RTV or COBI	x	≈	≈	x	x
Darunavir + RTV or COBI	x	≈	≈	x	≈
Lopinavir/ritonavir	x	≈	≈	x	x
Doravirine	√	√	√	√	√
Efavirenz	x	x	√	x	x
Rilpivirine	√	√	√	√	√
Raltegravir	√	√	√	√	√
Elvitegravir/COBI/FTC/TAF	≈	√	√	x	≈
Dolutegravir	√	√	√	√	√
Bictegravir/FTC/TAF	√	√	√	√	√
Tenofovir DF	√	≈	≈	√	≈
Tenofovir TAF	√	√	√	√	√
Abacavir	√	√	√	√	√
Lamivudine	√	√	√	√	√

*t*no clinically significant interaction expected; Potential interaction may require adjustment to dosage, altered timing of administration, or additional monitoring; Combination should be avoided

HEP Drug Interactions. https://www.hep-druginteractions.org/.

Team-Based Strategies to Improve Linkage and Retention in Care

- Improved communication
  - Motivational interviewing
  - Cultural competence
- POC treatment
- Comprehensive care and improved care coordination
  - Substance use disorder
  - Mental health
  - HIV
  - HCV
  - Syringe exchange programs

Wilkinson M, et al. *Aliment Pharmacol Ther.* 2009;29(1):29-37. Roncero C, et al. *Hepat Med.* 2018;11:1-11. Norton BL, et al. *J Subst Abuse Treat.* 2017;75:38-42. Lucas GM, et al. *Ann Intern Med.* 2010;152:704-711.

Justine

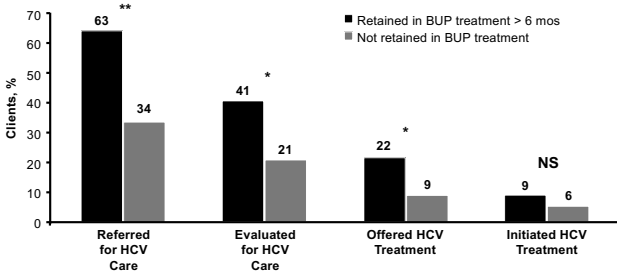
"Complicated"

What are the priorities?

Ours
- Keeping on HIV treatment
- Starting HCV treatment
- Getting to stop injecting heroin or use clean needles if continues
- Address depression

Hers
- Money
- Finding a place to live
- No transportation so dependent on others for rides
- Seeing a dentist

Buprenorphine Treatment Retention May Improve HCV Care



*$p < 0.5$; **$p < 0.01$; NS = not significant. Norton BL, et al. *J Subst Abuse Treat*. 2017;75:38-42.

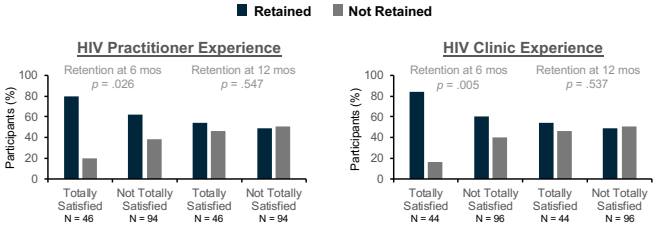
Barriers to Care Among Participants in a Public Health HIV Care Relinkage Program

Barriers to HIV Care (N=247)	N (%)
No insurance	124 (50)
Forget appointments	83 (34)
Trouble getting appointments	79 (32)
Costs not covered by insurance are too high	75 (30)
No transportation	70 (28)
At least one healthcare organization and delivery barrier	**184 (74)**
Homelessness	59 (24)
Using drugs	56 (23)
Don't need a doctor	48 (19)

Healthcare organization & delivery barriers are the most common "important" barriers

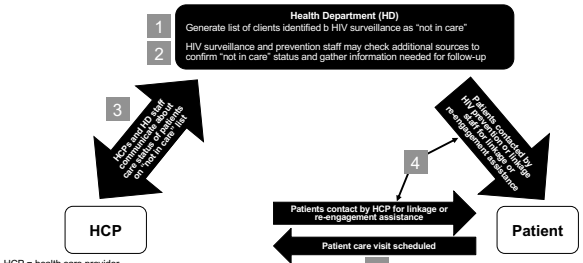
Note: 69% screened positive for depression, 54% reported substance use.
Dombrowski JC, et al. *AIDS Patient Care STDS*. 2015;29(5):279-287.

Patient Satisfaction Matters



Dang VN, et al. *AIDS Behav*. 2016;20(10):2477-2487.

Data to Care Combination Health Department/Health Care Provider Model

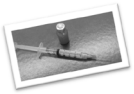


HCP = health care provider.
CDC. *Data to Care: Using HIV Surveillance Data to Support the HIV Care Continuum.* https://effectiveinterventions.cdc.gov/docs/default-source/data-to-care-d2c/pdf-of-important-considerations.pdf.

New and Emerging Therapies May Improve Treatment Adherence

HIV

Single tablet regimens with high resistance barrier



Long-acting injected ART

Long-acting implantable ART

HCV

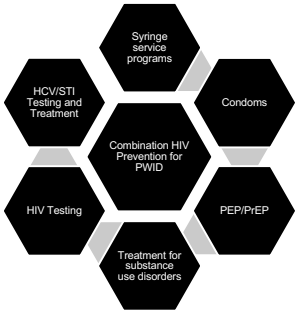
SVR in as less as 8 weeks

Treatment of acute infection

Learning Objective 3

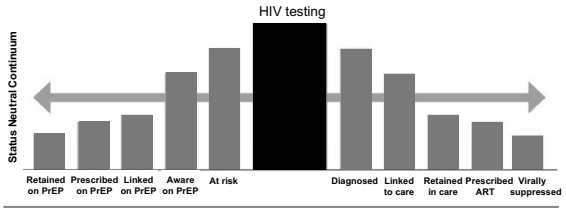
Identify patients with OUD at high risk for HIV infection who are candidates for HIV prevention strategies, including PrEP.

Combination HIV Prevention for PWID



PEP = post-exposure prophylaxis; PrEP = pre-exposure prophylaxis; STI = sexually transmitted infections.
Shrestha R, et al. Pre-exposure prophylaxis (PrEP) for people who inject drugs (PWID). In: Brianna Norton, Ed. *The Opioid Epidemic and Infectious Diseases*. 2019. MacArthur G, et al. *BMJ*. 2012;345:e5945. Vickerman P, et al. *Addiction*. 2014;2019(12):2060-2061. Wodak A, et al. *Subst Use & Misuse*. 2006;41:777-813. Abdul-Quader AS, et al. *AIDs Behav*. 2013;17(9):2878-2892. Schranz AJ, et al. *Curr HIV/AIDS Rep*. 2018;15(3):245-254.

The Status Neutral Continuum



Buchbinder SP and Liu AY. *Top Antivir Med*. 2018;26:1-16. Conference on Retroviruses and Opportunistic Infections (CROI). 2018. Abstract 61. www.nastad.org.

PrEP Indications for PWID

Adult person or adolescent ≥ 35 kg
Without established HIV infection
Meets at least one of the following sets of HIV risk criteria:

Risk from injection drug use	Risk from MSM	Risk from heterosexual sex
Any injecting of non-prescribed substance in past 6 months	A man with any male sex partners in the past 6 months	A man or woman with any opposite sex partners in the past 6 months
AND shared injecting or preparation equipment	Not monogamous with an HIV-man	Not monogamous with an HIV-partner
At high risk for relapse, including among people on MAT	AND any anal sex (receptive or insertive) without condoms in past 6 months	AND infrequently uses condoms with a partner of unknown HIV status, HIV+, or at high risk of HIV (PWID, MSM)
	Recent bacterial STI	Recent bacterial STI
	Any transactional sex	Any transactional sex

Shrestha R, et al. Pre-exposure prophylaxis (PrEP) for people who inject drugs (PWID). In: Brianna Norton, Ed. *The Opioid Epidemic and Infectious Diseases*. 2019. CDC. *Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2017 Update*. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf.

When taken consistently, oral PrEP reduces risk of HIV infection by

90-100%

among cisgender MSM, heterosexual men & women, and transgender women.

84% among PWID

1. Grant RM, et al. *NEJM*. Dec 2010;363(27):2587-99.; 2. Baeten JM, et al. *NEJM*. Aug 2012;367(5):399-410.; 3. Grant RM, et al. *Lancet Inf Dis*. 2014;14(9):820-829.; 4. Martin M, et al. *AIDS*. 2015;29(7):819-24

Adherence is Critical

Protective efficacy (%)

	All participants	High adherers
iPrEx	44	92
	62-73	~95

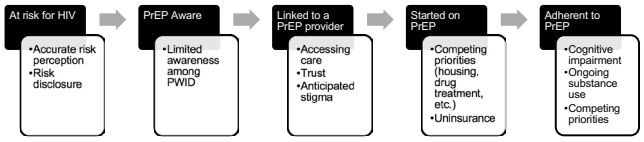
1. Grant RM, et al. *NEJM*. 2010;363(27):2587-99.; 2. Baeten JM, et al. *NEJM*. 2012;367(5):399-410.

Efficacy-Effectiveness Gap

Had Indications for PrEP (2014-2015)[1,2]	Received PrEP (2012-2016)[3,4]
● 1.1 million adults ● 176,670-468,000 U.S. women ● 72,510-115,000 PWID	● Overall: 11,000 new initiations every quarter 2016 ● 75% non-Hispanic White ● 15,060 U.S. women ● ?PWID (low)

1. Smith DK, et al. CROI. 2018. Abstract 86. 2. Smith DK, et al. *Morbidity and Mortality Weekly Report*. 2015;64(46):1291-1295. https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6446a4.htm?s_cid=mm6446a4_w. 3. Mera Giler R, et al. IAS. 2017. Abstract 1614. 4. Kuo I, et al. CROI. 2018. Abstract 1030.

PrEP Care Continuum and Key Challenges for PWID



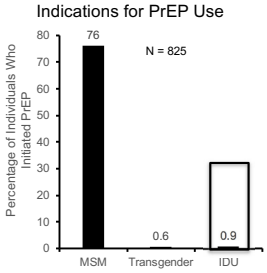
Shrestha R, et al. Pre-exposure prophylaxis (PrEP) for people who inject drugs (PWID). In: Brianna Norton, Ed. *The Opioid Epidemic and Infectious Diseases*. 2019.

↓ PrEP Awareness Among PWID

- 2015 National HIV Behavioral Surveillance System
- Among PWID with PrEP indication (n = 181/516):
  - 7.4% ever heard of PrEP
  - < 1% had received a PrEP prescription
  - None were taking PrEP

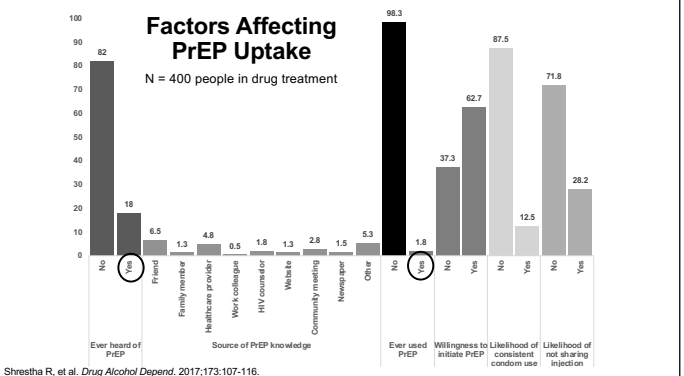
Kuo. CROI. 2018. Abstract 1030.

PrEP Uptake in the VA



- Low rates of PrEP initiation in the Southeast (10 per 100,000)
- > 2/3 of PrEP prescriptions were issued by specialists

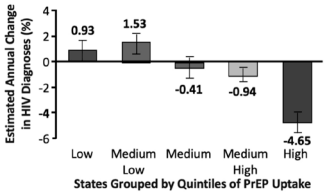
Garner W, et al. *Am J Public Health*. 2018;108(Suppl 4):S305-S310.



Shrestha R, et al. *Drug Alcohol Depend*. 2017;173:107-116.

Effect of PrEP Uptake on HIV Diagnoses: US

- Comparison of HIV diagnoses in people >13 years old* vs. PrEP uptake rates** from 2012-2016



- For 38 jurisdictions with available viral suppression data, significant association between PrEP uptake and decrease in HIV diagnoses persisted after controlling for state viral suppression level

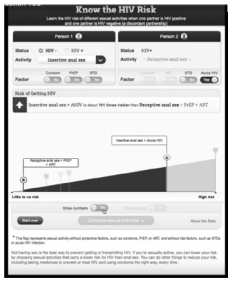
*Calculated using data from the National HIV Surveillance System, US Census, and intercensenal estimates.
**CC method estimated PrEP indications; national database covering > 83% of prescriptions supplied via commercial pharmacies and validated algorithms excluding non-PrEP FTC/TDF quantified unique persons using PrEP.
Sullivan PS, et al. AIDS 2018. Abstract LBPEC063.
Slide credit: clinicalcareoptions.com

Strategies to Increase PrEP Uptake Among PWID

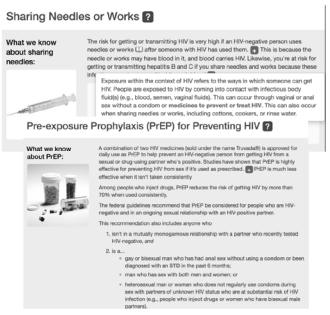
- Increase PrEP awareness
  - Inclusive messaging
  - Realign perceptions about risk
- Lower barrier to entry settings for HIV testing and PrEP linkage/initiation

(Community outreach model):
  - Drug treatment programs
  - STD clinics
  - Syringe service programs
  - Emergency departments
  - Primary care
  - Prisons or jails
- Low-threshold PrEP initiation:
  - Rapid start
  - Same-day start
- Peer navigation models

CDC HIV Risk Estimator (Interactive Tool)



CDC. *Know the HIV Risk.*
https://wwwn.cdc.gov/hivrisk/estimator.html.



Putting PrEP into Practice

Step 1: Determine clinical eligibility

HIV status

- ❑ **Ag/Ab**

→ **Maybe RNA, too?**

PrEP users must be HIV-NEGATIVE

US Public Health Service. PrEP Guideline – 2014.

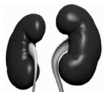
Putting PrEP into Practice

Step 1: Determine clinical eligibility

HIV status

- ❑ **Ag/Ab**
- ❑ Rapid **(blood)**
- ❑ ELISA / EIA

Must be HIV(–)
→ Maybe RNA, too?



Renal function

- ❑ Creatinine
- ❑ eCrCl

For TDF/FTC eCrCl must be ≥ 60 mL/min

US Public Health Service. PrEP Guideline – 2014.

Putting PrEP into Practice

Step 1: Determine clinical eligibility

HIV status

- ❑ **Ag/Ab**
- ❑ Rapid **(blood)**
- ❑ ELISA / EIA

Must be HIV(–)
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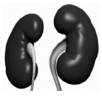


Renal function

- ❑ Creatinine
- ❑ eCrCl

For TDF/FTC eCrCl must be ≥ 60 mL/min

Viral hepatitis

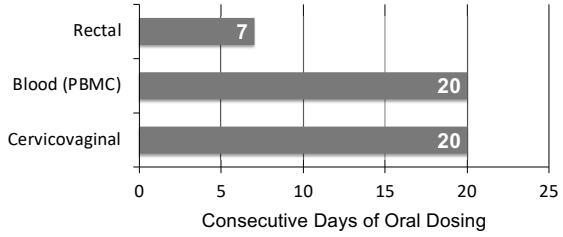
- ❑ HBsAg
- ❑ HBsAb
- ❑ HCV Ab **nice to have**

Awareness if active HBV

US Public Health Service. PrEP Guideline – 2014.

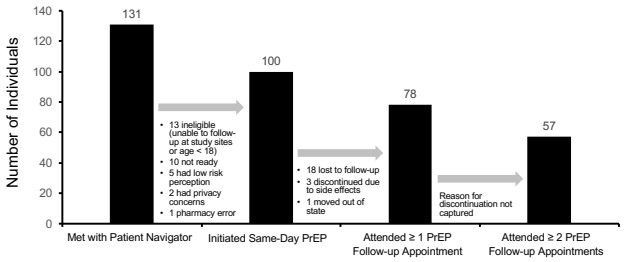
How Long Before I'm Protected?

Time to Maximum Intracellular Concentration of Tenofovir Diphosphate (TFV-DP)



US Public Health Service. PrEP Guideline – 2014.

Same-Day PrEP Initiation



Kamis KF, et al. *Open Forum Infectious Diseases*. 2019;6(7):ofz310.

SMART Goals

Specific, **M**easurable, **A**ttainable, **R**elevant, **T**imely

- Implement strategies to improve HIV and HCV testing within the clinical work flow
- Apply guideline recommendation to optimize HIV and HCV treatment
- Implement best practices to promote linkage and retention in care
- Develop strategies to improve PrEP awareness and uptake

To receive CME/CE credits for this activity, participants must complete the post-test and evaluation online.

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3. Be sure to fill in your **ABIM ID number** and **DOB** (MM/DD) on the evaluation, so we can submit your credit to ABIM.

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Type a question in the box under the presentation

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Activity Title and Faculty:

A Grassroots Approach to Weed Out HIV and HCV in Special OUD Populations

with David A. Wohl, MD; Carlos Malvestutto, MD, MPH; Jaimie P. Meyer, MD, MS, FACP

Site/Institution Name: ______________________________

Practice Setting: ❑ Office-based ❑ Hospital ❑ Clinic ❑ Managed Care ❑ Small Group Practice (less than 5) ❑ Large Group Practice (more than 5) ❑ Other: ______________________________

Address: ______________________________

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Site Coordinator: ______________________________ Phone: ______________________________

Fax: ______________________________ Email: ______________________________

Completion Date: ____________ We participated in a: ______________________________

Attendee Name (please print)	Please Circle Discipline						
______________________	MD	DO	PA	NP	RN	Pharm	Other: ______________
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______________________	MD	DO	PA	NP	RN	Pharm	Other: ______________
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