



HCV Treatment in Injection Drug Users

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Project ECHO HCV Collaborative

Conflict of Interest Disclosure Statement

No conflicts of interest to disclose.



Disclosures

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Faculty:

CME Committee: David Couch; Kathleen Clanon, MD; Johanna Rosenthal, MPH; Pat Blackburn, MPH; Richard Fischer, MD; Sharon Adler, MD

CNE Committee: David Stephens, BSN, RN; Jessica Leston, MPH; Erin Edelbrock MPA; Ginny Cassidy-Brinn MSN, ARNP

Disclosures

Richard Fischer, MD is a member of an Organon speaker's bureau. Dr. Fischer does not participate in planning in which he has a conflict of interest, and he ensures that any content or speakers he suggests will be free of commercial bias.

Dr. Jorge Mera has been on advisory boards for Gilead Sciences and AbbVie Pharmaceuticals.

Neither of these company's products will be discussed in this presentation.

None of the other planners or presenters of this CE activity have disclosed any conflict of interest including no relevant financial relationships with any commercial companies pertaining to this CE activity.

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Objectives

By the end of this session, you should be able to:

1. Explain the relationship between HCV and persons who inject drugs (PWID)
2. Describe the rationale for treating HCV in the PWID population
3. Identify best practices for treatment of HCV in the PWID population.



HCV in PWID

- Injection drug use = greatest HCV risk factor
 - >50% of all US cases
- HCV epidemic among PWID
- Multiple recent outbreaks of HCV
 - Especially in non-urban areas with high opioid prescribing
- High transmission risk
- Reinfection is common
- Co-existing social problems/barriers

Clin Infect Dis. 2013;57(Suppl 2):S32–S38.

hepatitisc.uw.edu

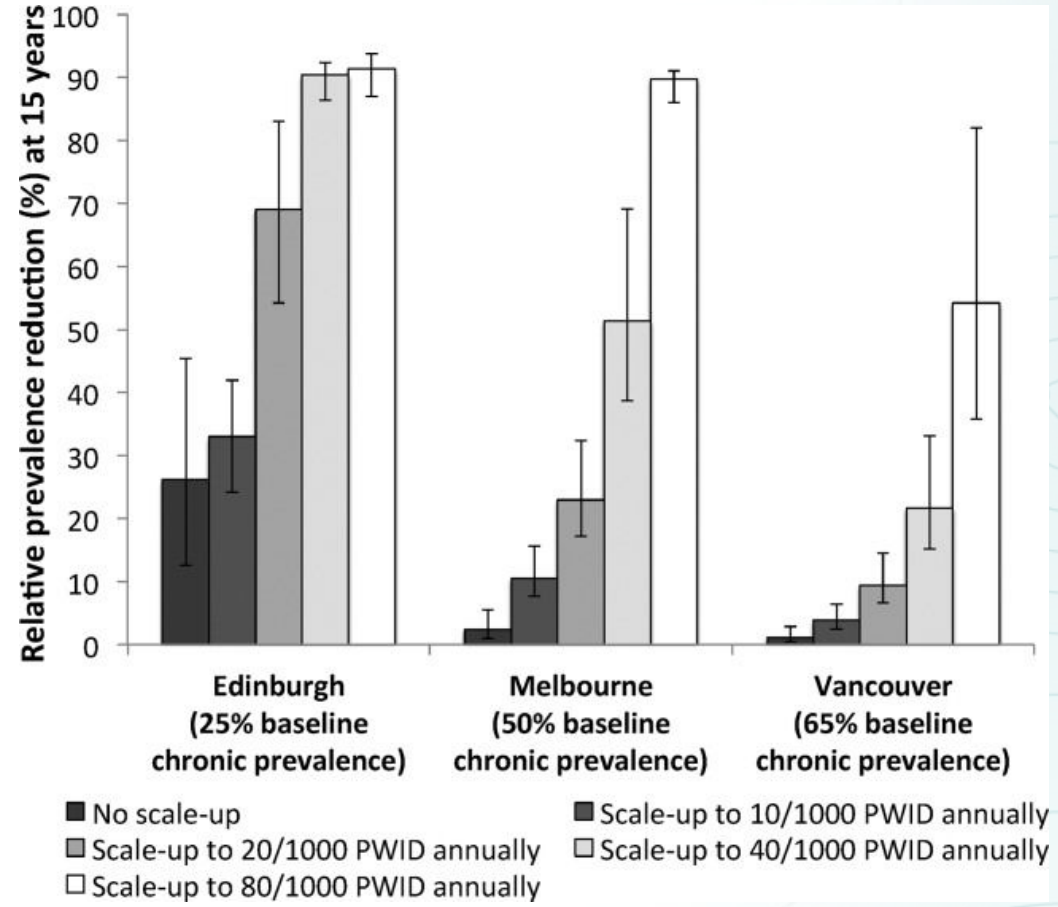
Guideline Recommendations

- “...recent and active IDU should not be seen as an absolute contraindication to HCV therapy.”
- “...no data to support the utility of pretreatment screening for illicit drug or alcohol use...they create barriers to treatment, add unnecessary cost and effort...”
- “Scale up of HCV treatment in persons who inject drugs is necessary to positively impact the HCV epidemic in the United States and globally.”

AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C. <http://www.hcvguidelines.org>. Accessed May 12, 2017.

Modeled Treatment Studies in PWID

- Treatment leads to decreased prevalence/incidence
- Cost-effectiveness
 - Driven by the projected “prevention benefit”
- No current epidemiological evidence



Curr Opin Infect Dis. 2015;28(6):576–82.
Hepatology. 2013;58(5):1598–1609.

Early Studies in PWID

- Multiple interferon-based clinical trials have shown that HCV treatment in PWID is effective
 - Despite active injection drug use
 - Despite psychological comorbidities
 - Despite side effect profile of interferon
- Overall good treatment uptake, but still room for improvement
 - Refusal of medical screening and lost to follow-up
- Treatment rates mirrored the non-IVDU population
- Expected improvement in cure rate with DAAs

Euro J Gastroent & Hepatol. 2011;23:23–31.

Int J Drug Policy. 2015;26(10):1014–19.

HCV Treatment at Needle Exchange Program

- HCV Treatment In People Who Inject Drugs Co-located Within A Needle Syringe Program
 - Presented at CROI 2017
- Patient population
 - 26 patients currently injecting drugs and utilizing a needle exchange program were started on treatment
 - ~45.9 yoa, 92% male, 46% homeless, ~25 injections/month, 58% on OAT, 92% treatment naïve, 54% genotype 1
- Interventions – on-site HCV treatment with DAAs
- Endpoint – SVR12

Eckhardt B. CROI 2017. Feb 14-17; Seattle, WA .

Eckhardt et al. Study Results

- SVR12
 - 23 / 26 completed treatment
 - 2 patients failed to achieve SVR12
 - Both were re-infections with genotypes not covered by original regimen

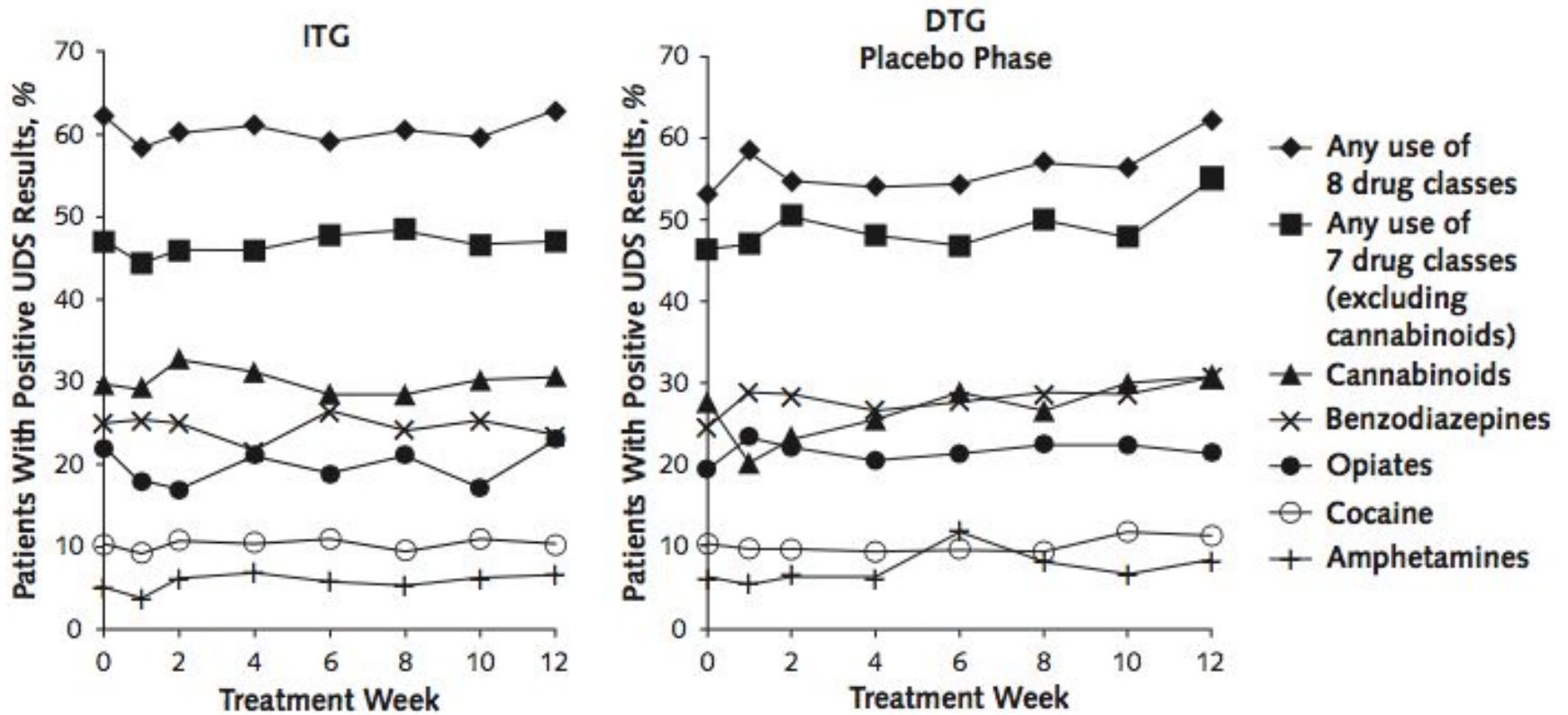
Eckhardt B. CROI 2017. Feb 14-17; Seattle, WA .

CO-STAR Trial

- Randomized, placebo-controlled, multisite, double-blind
- Patient population
 - 301 treatment-naive patients with chronic HCV GT1, GT4, or GT6
 - Opioid agonist therapy (OAT) at least 3 months before enrollment
- Interventions
 - Elbasvir / grazoprevir
 - Immediate treatment group (ITG)
 - Delayed treatment group (DTG) – 12 week placebo pre-treatment
 - Urine drug screening (UDS) was conducted at each study visit
- End Points
 - Proportion of patients in the ITG achieving an SVR

Ann Intern Med. 2016;165:625-634.

CO-STAR: Drug Use



Ann Intern Med. 2016;165:625-634.

CO-STAR: Results

		ITG N = 201	DTG N = 95
SVR12	Assuming reinfections are failures (%)	184 (91.5)	85 (89.5)
	Assuming reinfections are responses (%)	189 (94.0)	85 (89.5)
	Recurrence	7	3
	Reinfection	5	0
	Loss to follow-up / Discontinuation	3 / 2	7 / 0
SVR24	Assuming reinfections are failures (%)	170 (84.6)	81 (85.3)
	Assuming reinfections are responses (%)	175 (87.1)	82 (86.3)
	Recurrence	9	3
	Reinfection	5	1
	Loss to follow-up / Discontinuation	15 / 2	10 / 0

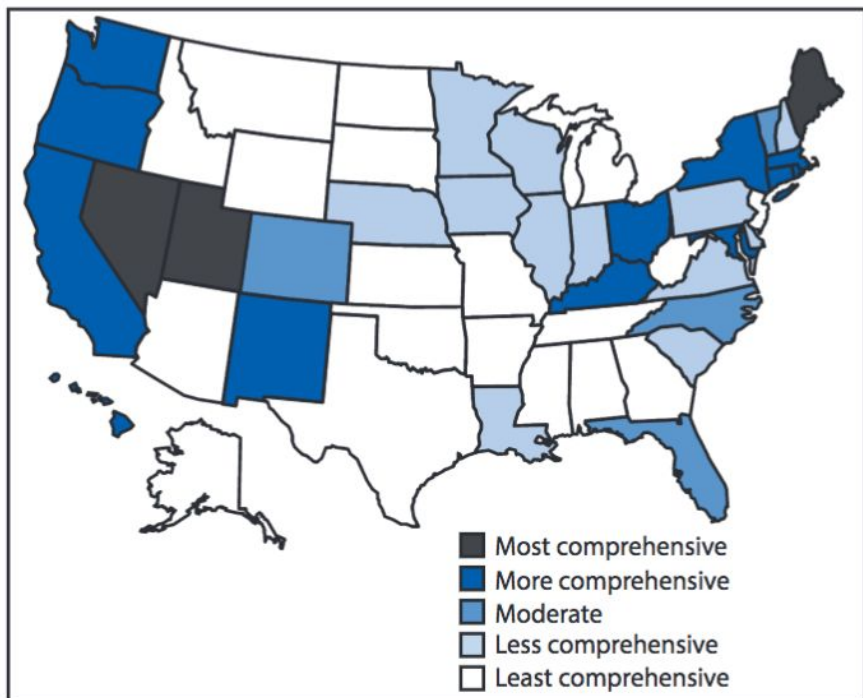
Ann Intern Med. 2016;165:625-634.

Patient Counseling

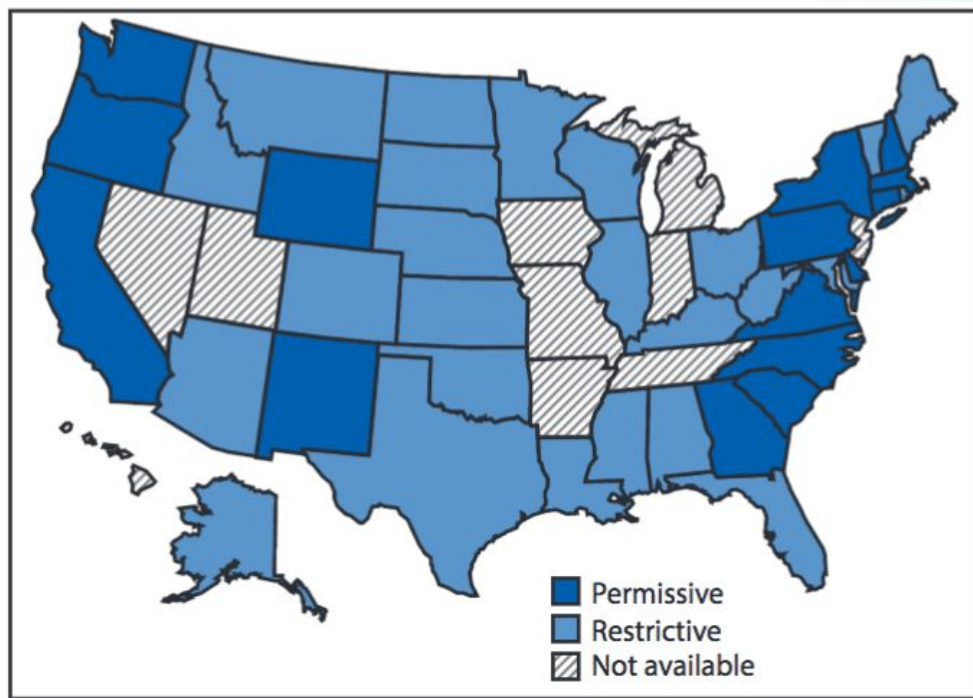
- Offer annual HCV screening to PWID
- Emphasize importance of treatment
 - Educate regarding consequences of untreated HCV
- Decrease transmission and reinfection
 - Do NOT share needles/syringes/preparation equipment
 - New syringe and equipment with each injection
- Assist with linkage to behavioral health and drug treatment programs

cdc.gov/hepatitis

Legal Barriers



Comprehensiveness of state laws pertinent to prevention of HCV infection among PWID.



State Medicaid fee-for-service HCV treatment policy restrictions.

MMWR Morb Mortal Wkly Rep. 2017;66:465-9.

Conclusions

- HCV guidelines recommend treating PWID
- Preliminary data indicates treatment is effective in this population
- Needle exchange facilities appear to be effective facilities for engaging PWID into care
- Treating beyond HCV □ Multidisciplinary approach
- Reinfection?
- Ending the HCV epidemic will likely require a focus on this at risk population

DHHS. Guidance to Support Certain Components of Syringe Services Programs. 2016.



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End of Presentation

Questions?

