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Upon successful completion of this activity 1 contact hour will be awarded

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CONFLICT OF INTEREST

Dr. Jorge Mera is director of a program partially funded by Gilead.

Lisa Townshend-Bulson is a principal co-investigator on a grant that is partially funded by Gilead.

None of the other planners or presenters of this CE activity have any relevant financial relationships with any commercial entities pertaining to this activity.

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HCV Treatment in People Receiving MAT

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Antimicrobial Stewardship / Infectious Diseases Pharmacist
Lovelace Medical Center

June, 2018

Presentation prepared by: *Jacob Kesner*
Date prepared: *5/12/17*

Objectives

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

1. Explain the relationship between HCV and persons who receive medication assisted treatment (MAT)
2. Describe the rationale for treating HCV in people receiving medication assisted treatment (MAT)
3. Identify best practices for treatment of HCV in people receiving MAT.

idhp.com

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

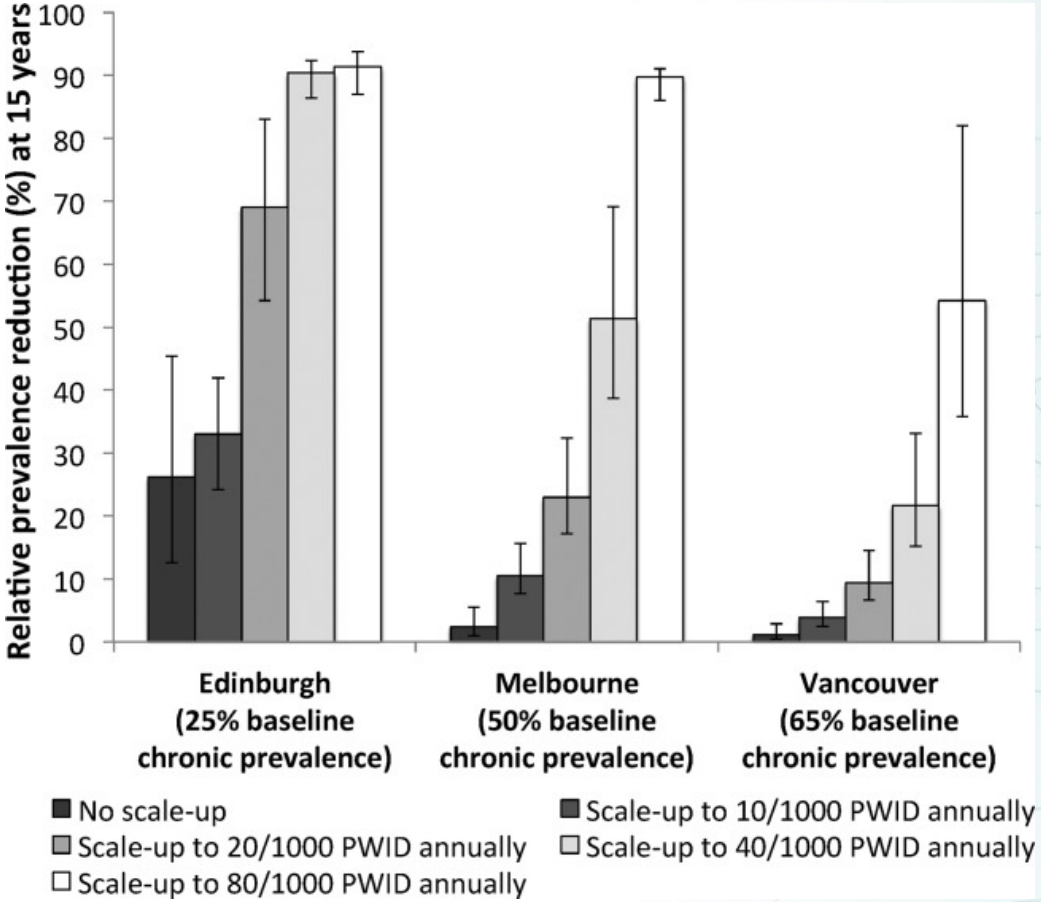
Guideline Recommendations

- "…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

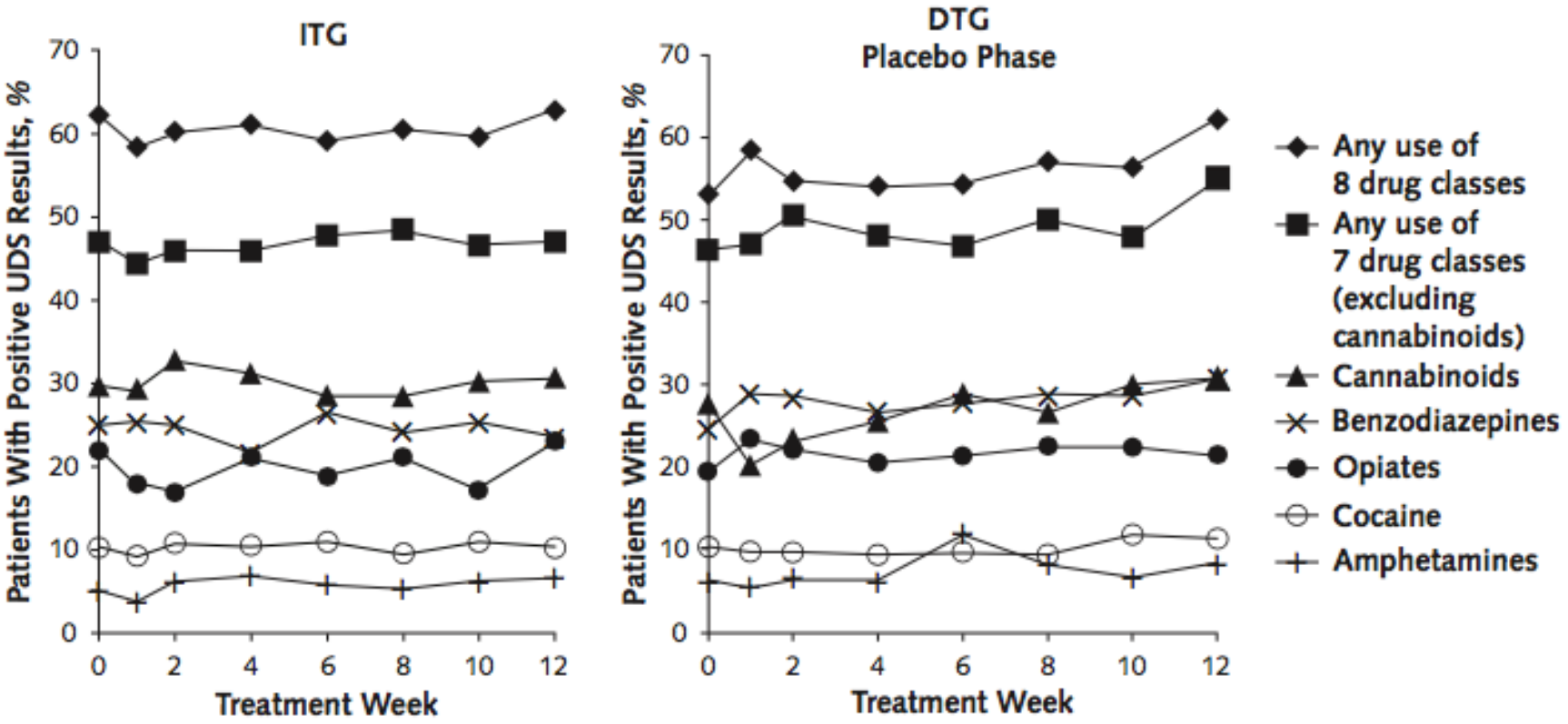
Eckhardt B. CROI 2017. Feb 14-17; Seattle, WA .

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.

SIMPLIFY Trial

- Open-label, single-arm, multicenter, Phase 4 trial
- Patient population:
  - 103 participants w/ GT 1-6 HCV
  - Self-reported injection drug use w/in 6 m
- Interventions: Sofosbuvir / velpatasvir x12 weeks
- End Points:
  - Primary: SVR12
  - Secondary: treatment completion, adherence, serious adverse event, discontinuation, therapy change, reinfection

Lancet Gastroenterol Hepatol. 2018;3:153-61.

SIMPLIFY Baseline Characteristics

Age (years)	48 (41–53)
Sex	
Male	74 (72%)
Female	29 (28%)
High school or higher education	50 (49%)
Unstable housing*	24 (23%)
Any drug use in the past 6 months	103 (100%)
Any injecting drug use in the past 6 months	103 (100%)
Any non-injecting drug use in the past 30 days	56 (54%)
Any injecting drug use in the past 30 days	76 (74%)
Heroin	57 (55%)
Cocaine	13 (13%)
Methamphetamines	31 (30%)
Other opioids	22 (21%)
Other	7 (7%)
Injecting drug use frequency in the past 30 days	
Never	27 (26%)
Less than daily	49 (48%)
At least daily	27 (26%)
Any alcohol use in the past 30 days	62 (60%)
Hazardous alcohol use in the past 30 days	18 (17%)
History of OST	84 (82%)

HCV genotype	
1a	35 (34%)
1b	1 (1%)
2	5 (5%)
3	60 (58%)
4	2 (2%)
HCV RNA load, log IU/mL	6·1 (5·3–6·7)
Alanine transaminase, IU/L	61 (39–84)
Stage of liver disease†	
No or mild fibrosis (F0–F1)‡	59 (61%)
Moderate or advanced fibrosis (F2–F3)‡	27 (28%)
Cirrhosis (F4)‡	9 (9%)
Study site distribution	
Canada or USA	40 (39%)
Europe	20 (19%)
Australasia	43 (42%)

Lancet Gastroenterol Hepatol. 2018;3:153-61.

SIMPLIFY Results

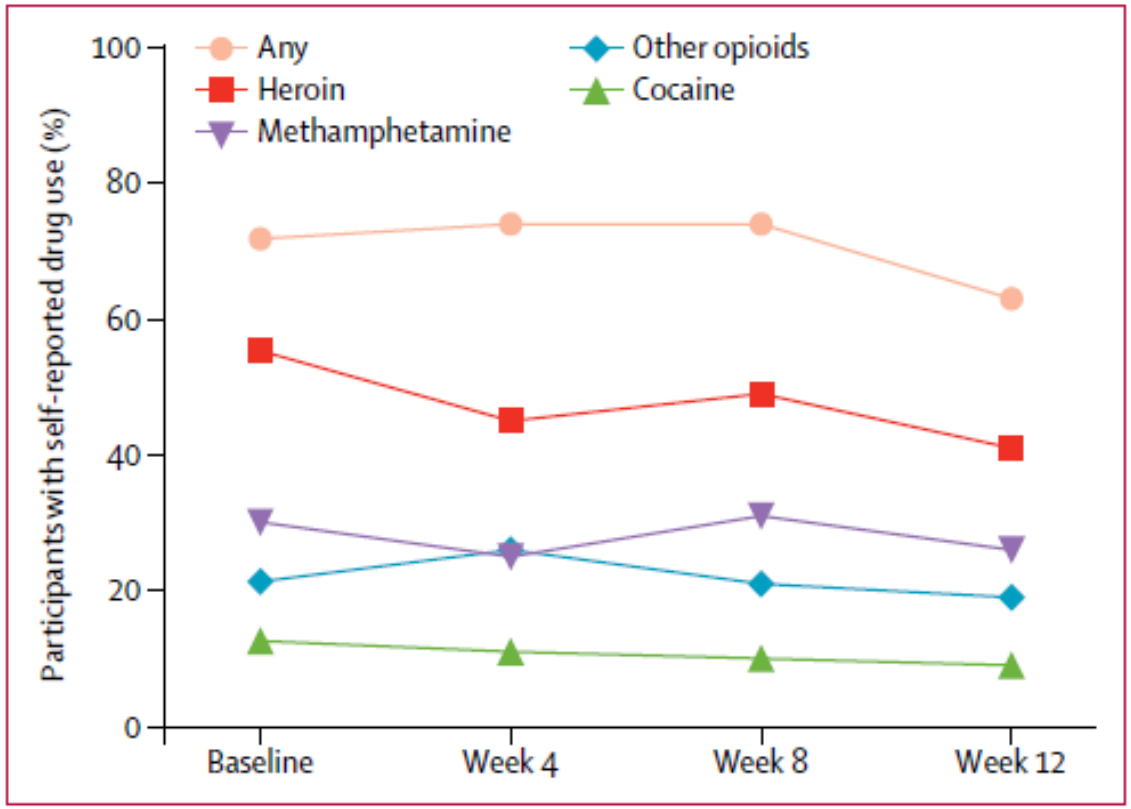


Figure 2: Self-reported injecting drug use during therapy

Lancet Gastroenterol Hepatol. 2018;3:153-61.

- Median adherence: 94%
- 68 of 103 were at least 90% adherent
- Therapy extended for 29 patients due to several interruptions in therapy

SIMPLIFY Results

- EOT response:
  - 99/103 (96%, 95%CI 90-99)
- **SVR12:**
  - **97/103 (94%, 95%CI 88-98)**
- No cases of virological failure or relapse
- 1 patient reinfected

Participants with any adverse event up to 28 days after last dose	
Grades 1–2	78 (76%)
Grade 3	6 (6%)
Grade 4	1 (1%)
Participants with a treatment-related adverse event up to 28 days after last dose	
Grades 1–2	47 (46%)
Grade 3	1 (1%)
Grade 4	0
Serious adverse event	7 (7%)
Treatment-related serious adverse event	1 (1%)

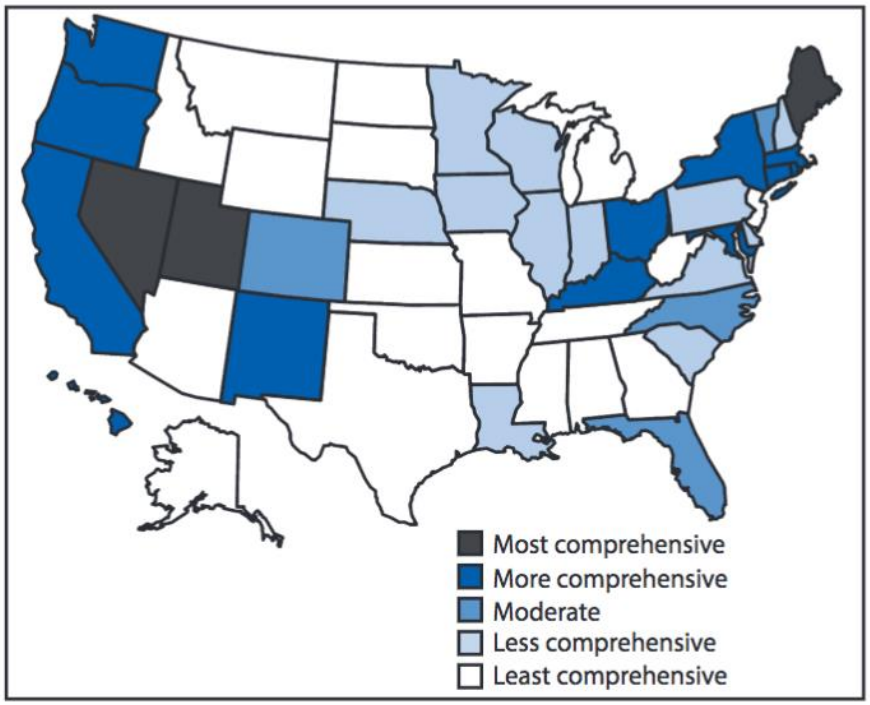
Lancet Gastroenterol Hepatol. 2018;3:153-61.

Patient Counseling

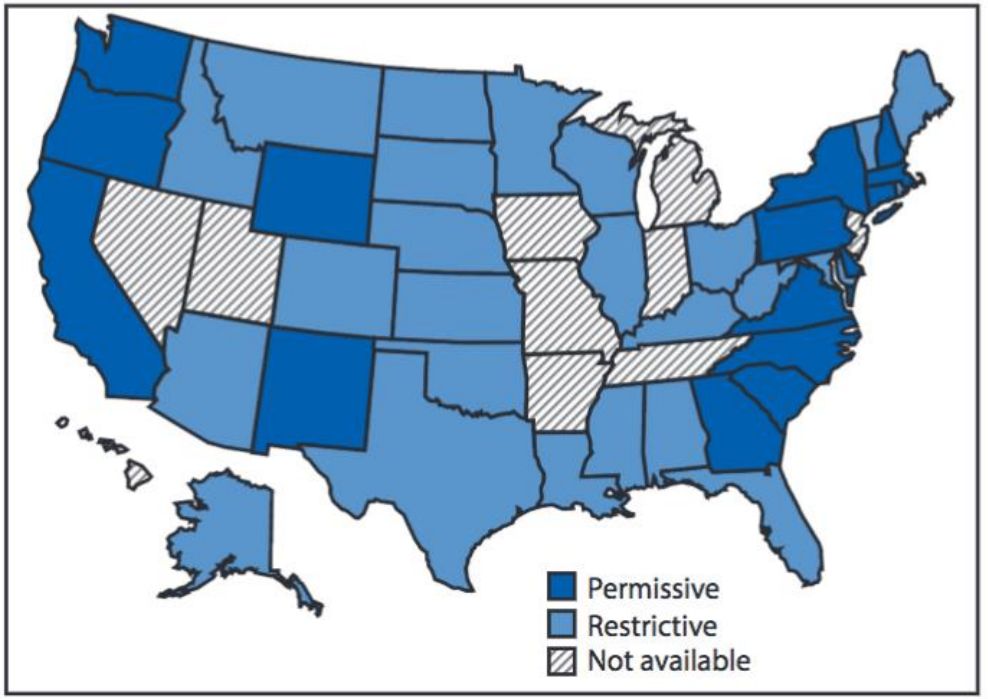
- Offer annual HCV screening to PWID
- Emphasize importance of treatment
  - Educate regarding consequences of untreated HCV
- Decrease transmission and reinfection
  - Do NOT share needles/syringes/preparation equipment
  - New syringe and equipment with each injection
- Assist with linkage to behavioral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

Project ECHO HCV Collaborative

End of Presentation

Questions?

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