ACCEPT

Addiction & Co-morbid Conditions: Enhancing Prevention & Therapeutics

Agenda

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For attendance, purposes please text the following code: RUVFAW to 608-260-7097

Session Date: Friday September 18, 2020

Didactic Topic and Presenter:
Primary Care-Based Hepatitis C Treatment
Kellene Eagen, MD - Assistant Professor, UW Department of Family Medicine and Community Health

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- 12:15 PM: Attendance text-in – Introductions
- 12:25 PM: Case Presentation
  - Presenter: Rebecca Kellum, MD
- 1 PM: Didactic Presentation
  - Presenter: Kellene Eagen, MD
- 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

Project ECHO
University of Wisconsin

ACCEPT
Addiction & Co-morbid Conditions: Enhancing Prevention & Therapeutics
2020-2022

Primary Care-Based Hepatitis C Treatment

Friday September 18, 2020

Kellene Eagen, MD - Assistant Professor - UW Department of Family Medicine and Community Health
Rebecca Kellum, MD – Case Presenter

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 will be able to:

1. Implement appropriate opioid prescribing and monitoring practices.
2. Effectively participate in office-based, collaborative management of substance use disorders.
3. Consistently provide in overdose prevention education to appropriate patients.
4. Identify the role of medication assisted therapies, such as methadone, naltrexone, and buprenorphine, and contributions of different members of the healthcare team to the management of substance use disorders.

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Randall Brown, RSS Chair	No relevant financial relationships to disclose	Yes	4/8/2020
Briana Kleinfeldt, RSS Coordinator	No relevant financial relationships to disclose	No	4/8/2020
Kathleen Maher, RSS Coordinator	No relevant financial relationships to disclose	No	4/18/2020
Nada Rashid, RSS Coordinator	No relevant financial relationships to disclose	No	7/1/2020
Ritu Bhatnagar, Planner	No relevant financial relationships to disclose	Yes	4/15/2020
Richard Crawford, Planner	No relevant financial relationships to disclose	No	4/9/2020
Paul Hutson, Planner	No relevant financial relationships to disclose	No	4/9/2020
Susan Mindock, Planner	No relevant financial relationships to disclose	No	4/6/2020

Lindsey Peterson, Planner	No relevant financial relationships to disclose	No	4/6/202
Alyssa Tilhou, Planner	No relevant financial relationships to disclose	No	4/13/2020
Sheila Weix, Planner	No relevant financial relationships to disclose	No	4/6/2020
Kellene Eagen, Speaker/Author	No relevant financial relationships to disclose	No	8/3/2020
Rebecca Kellum, Speaker/Author	No relevant financial relationships to disclose	No	9/14/2020

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ACCEPT

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Patient Case Presentation

***Please do not attach any patient-specific files or include any Protected Health Information.**

1. Date: 9/18/2020
2. Presenter Name: Rebecca Kellum, MD
3. Presenter Organization: SSM Dean Clinic East, Internal Medicine Primary Care
4. ECHO ID: 2436
5. Have you presented this patient during this teleECHO clinic before? ☒ Yes ☐ No

6. **Please state your main question for this case:**
   - **Best management approach: Patient requesting switch from naltrexone PO to IM for treatment of OUD has transaminases 9 times the UNL and is found to have HCV infection. Also, differentiating naltrexone vs hepatitis-induced liver injury.**

Patient Demographic Information: (limited as patient seen only once, a 30 minute appointment with focus on MOUD)

7. Age: 33
8. Gender: female
9. Education/Literacy: unk
10. Income source: unk. previously employed in industrial field.
11. Social Factors/History:
    - at the time of her first visit, 5/11/20, pt was living at ARC house. She was on probation, having been released from jail about six weeks prior. was to be at ARC house through September, after which she anticipated moving into sober living
    - both parents with histories of drug and alcohol use disorders. Currently, they are both present in her life and supportive of her recovery. Father continues to drink heavily.
    - she reports a history of physical and sexual abuse as a child
    - she has 50% custody of her 13 year-old son, who is currently living with his father. On reasonably good terms with her son's father and new partner.

12. <u>Substance Use History:</u>

- Began using heroin about 6 years prior, when her boyfriend at the time was using. was eventually injecting 1.5-2gm per day. Had stopped heroin 4 times before, all within the context of going to jail.
- was given drug court for her first felony possession. Was doing well for awhile after that, but then lost someone close to her in drug court to an OD and she relapsed.
- Had received vivitrol upon leaving jail and found it helpful. Relapse on vivitrol occurred in the context of multiple social stressors and once, when missing a ride to her injection appointment. No prior history of buprenorphine or methadone treatment.
- One prior overdose, reversed with by-stander Naloxone.
- has injected cocaine, but not regularly. denied methamphetamine use.
- minimal alcohol use and prior marijuana use

- 5/2020: in IOP at ARC house. Received vivitol before leaving jail. Then, was receiving naltrexone 50mg po daily through ASAP clinic. Denied current opioid or other substance use.
- 5/6/2020: called our office (has PCP at Dean) requesting to resume vivitrol. Felt that naltrexone pills were not as effective as vivitrol. She was instructed to come in before her visit for lab testing.
- 5/11/20 first OV: Confirmed status with case manager at ARC house. Rapid UDS negative for opioids. Administered first naltrexone injection. Planned to return in 4 weeks. Later that day, CMP results returned showing elevated AST and ALT.

<u>Hepatitis C history</u>

- 4/2016 HCV RNA detected. Referred to ID at Dean. She expressed frustration with needing to return for labs. 9/2016 HCV RNA undetectable and she was notified that she cleared the infection. Recommended retest in six months.
- 5/11/20 after OV, CMP results demonstrated AST/ALT 9 times above the ULN and above the recommended levels for safely administering naltrexone IM. Nursing called pt and requested she return in a few days for repeat liver testing plus HIV and HCV testing.
- 5/14: AST/ALT slightly improved. HCV Ab positive. Nursing instructed pt to have labs drawn a week before next naltrexone injection. Also referred to ID clinic. Their routine HCV lab panel ordered.
- 5/29 she came in for labs. ALT/AST improved enough to warrant continuation of vivitrol in two weeks.

	5/11	5/13	5/29
AST	494	488	180
ALT	188	172	74

- 6/11: she did not arrive for her vivitrol appointment and did not answer phone when called.
- 6/15: she called my office asking about the HIV result. this was provided to her, but staff was not aware of her missed appointment and did not inquire into naltrexone follow-up.
- 6/29: she called her PCP about a "chemical burn" on her face from using methamphetamine. She informed that nurse that she was no longer receiving naltrexone injections because she has liver issues from Hep C. she was given same-day appointment, to which she did not come.

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- 7/1: my office still unable to reach the patient. She was no longer at ARC house. I spoke with the her mother, who said she didn't know how to reach her daughter. Knew that her daughter had only 2 more weeks left at ARC house when she "walked off." Because there was an active warrant out for her arrest, her mother also knew that she'd have to inform the police if her daughter informed her of her own whereabouts. Pt's older sister had also not heard from the patient for weeks.
- 8/26: per public records, arrested for probation violation. No scheduled release date.

5/13 HCV RNA quantitative: 1,500,750

5/29 Liver fibrosis panel: no fibrosis, severe actitest activity (0.75, A3); INR 0.9, HBV s Ab positive, HCV genotype 1a or 1b, HAV Ab negative, HIV negative

	6	5	4	3	2	1
	1/16/2015 1429	4/25/2016 1300	5/2/2016 1126	9/19/2016 0918	5/13/2020 0836	5/29/2020 1008
HEPATITIS RESULTS						
Hepatitis A Virus ...			Negative *			Negative *
Hepatitis B Core V...						Negative *
HBc Antibody Total			Negative			
Hepatitis B Virus ...			Positive * !			Positive *
Hepatitis B Virus ...						457.87 *
Hepatitis B Virus ...	Negative *		Negative *			Negative *
Hepatitis C Antibody					Reactive * !	
HCV Quant by NAAT ...					1,500,750	
HCV Quant by NAAT ...					6.18	
HCV Quant by NAAT ...					Detected * !	
Hepatitis C Genotype				Undetected *		1a or 1b *
Hepatitis C Virus ...				Undetected *		
Hepatitis C Virus ...		DETECTED !				

secondary observations and learning points for me:

- Challenges for OBOT in primary care setting:
  - primary care triage/scheduling staff and other providers may not be well-versed in priorities for caring for people with SUDs:
    - recognizing need for timeliness when pts are requesting treatment and/or having difficulty with treatment
    - importance of communicating about follow-up appointments, issues with treatment

13. <u>Consequences of Substance Use:</u>

- Social/occupational/educational:
- has been in jail multiple times

- Physical (including evidence of tolerance/withdrawal):
- reports one overdose, reversed with by-stander naloxone

14. <u>Interventions that have been tried:</u>

- vivitrol upon leaving incarceration
- drug court

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- residence and IOP at ARC house

15.

Current Addiction and Mental Health-related Medications:	Medical/Behavioral Health Diagnosis:
● naltrexone 50mg po daily (at time of first visit) ● mirtazapine 30mg nightly	● h/o abnormal pap smear ● anxiety, depression, PTSD, insomnia

16.

Patient Strengths/protective factors:	Risk factors:
● living at ARC house with behavioral health treatment and close monitoring. She expressed that ARC house was helping her with better coping skills. ● had already experienced benefit from IM naltrexone ● local family supportive	● isolation with lockdown at ARC house ● identified lack of coping skills as a reason for prior relapse

17. <u>Labs (as indicated), include summary of urine testing or last urine drug screen results:</u>

see above

18. <u>Patient Goals/Motivations for Treatment:</u>

wants to "get her life back."

19. <u>Proposed Diagnoses:</u>

- OUD
- potential cocaine use disorder
- tobacco use disorder
- anxiety, depression, PTSD

20. <u>Proposed Treatment Plan:</u>

- OBOT vivitrol injection monthly
- referred to ID clinic for HCV infection
- psychiatric care through PCP
- behavioral health through ARC house for the time being

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By initialing here __RK_____ 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.

DSM 5 Criteria for Substance Use Disorder

A use disorder is characterized by maladaptive use resulting in repetitive consequences over the previous 12 months. A minimum of 2-3 criteria is required for a mild substance use disorder diagnosis, while 4-5 is moderate, and 6-7 is severe (American Psychiatric Association 2013)

1. Taking the substance in larger amounts and for longer than intended
2. Wanting to cut down or quit but not being able to do it
3. Spending a lot of time obtaining the substance
4. Craving or a strong desire to use
5. Repeatedly unable to carry out major obligations at work, school, or home due to use
6. Continued use despite persistent or recurring social or interpersonal problems caused or made worse by use
7. Stopping or reducing important social, occupational, or recreational activities due to opioid use
8. Recurrent use in physically hazardous situations
9. Consistent use despite acknowledgment of persistent or recurrent physical or psychological difficulties from using
10. *Tolerance as defined by either a need for markedly increased amounts to achieve intoxication or desired effect or markedly diminished effect with continued use of the same amount. (Does not apply for diminished effect when used appropriately under medical supervision)
11. *Withdrawal manifesting as either characteristic syndrome or the substance is used to avoid withdrawal (Does not apply when used appropriately under medical supervision)

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Primary Care-Based Hepatitis C Treatment

Kelly Eagen, MD

September 18, 2020

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Disclosures

- I have no financial disclosures.

"Guess what Doc! I repotted all my bonsai plants and finally moved my couch this weekend.
I haven't had energy like this in years!"

Question for the Audience:

What medical intervention has the remarkable effect to allow for bonsai repotting and furniture rearranging?

Answer…

Hepatitis C ~~Treatment~~ CURE

** Disclaimer: HCV cure is not guaranteed to provide boundless energy for gardening but will have a significant positive effect on health nonetheless.*

*Adding HCV Treatment to your practice as a caregiver for underserved and vulnerable populations will bring **JOY** to your practice.*

Project ECHO University of Wisconsin

Overview

- My (real quick) story that brought me here
- What do you really need to know to treat HCV?
- A plug for upcoming UW Addiction Medicine Grand Rounds

"They don't treat people like me."

– My patient (2012)

Primary care–based HCV Treatment

- Patient-centered
- Efficient
- Satisfying (to staff and patients alike)
- Increases access for vulnerable populations
- Eliminates specialty care bottlenecks
- Safe
- Effective

"In a real-world cohort of patients at urban FQHCs, HCV treatment administered by nonspecialist providers was as safe and effective as that provided by specialists."
(Kattakuzhy et al. 2017)

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Who is an HCV treatment candidate?

Recommendations for when and in whom to initiate treatment

Treatment is recommended for all patients with chronic HCV infection, except those with short life expectancies that cannot be remediated by treating HCV, by transplantation, or by other directed therapy. Patients with short life expectancies owing to liver disease should be managed in consultation with an expert.

Rating: Class I, Level A

AASLD
AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES

IDSA

Project ECHO
University of Wisconsin

Who is appropriate for treatment in primary care (or by SUD provider)?

- Suggested reasons to refer:
  - **Decompensated liver failure** ***(strong rec)*** ***(* Do not treat with protease-inhibitors)***
  - HBV co-infection *(strong rec)*
  - Prior treatment failure with Direct Acting Antivirals
  - End Stage Renal Disease (eGFR < 30)
  - HCC
  - Pregnancy
  - h/o liver transplant

- Note I did not say…
  - Active substance use, HIV-infection, experiencing homelessness, severe mental illness

Assessing treatment readiness

- Is patient *relatively* stable from a substance use, mental health, social situation standpoint?
  - **Can they engage for a consistent 8-12 weeks?**
- Does your patient
  - Want treatment? Take meds regularly?
  - Have *relative* control of other medical issues?
  - Have consistent engagement with your program?
    - Partner with case managers, shelter staff, SUD treatment
- Can patient articulate a plan to avoid reinfection?

New!!

Simplified Treatment Guidelines

(www.hcvguidelines.org)

Simplified HCV Treatment Algorithm for Treatment-Naive Adults Without Cirrhosis

WHO IS ELIGIBLE FOR SIMPLIFIED TREATMENT

Adults with chronic hepatitis C (any genotype)
who do not have cirrhosis
and have not previously received hepatitis C treatment

WHO IS *NOT* ELIGIBLE FOR SIMPLIFIED TREATMENT

Patients who have any of the following characteristics:

- Prior hepatitis C treatment
- Cirrhosis (see simplified treatment for treatment-naive adults with compensated cirrhosis)
- End-stage renal disease (ie, eGFR <30 mL/min/m²) (see Patients with Renal Impairment section)
- HIV or HBsAg positive
- Current pregnancy
- Known or suspected hepatocellular carcinoma
- Prior liver transplantation

PRETREATMENT ASSESSMENT*

- **Calculate FIB-4 score.**
- **Cirrhosis assessment**: Liver biopsy is not required. For the purpose of this guidance, a patient is presumed to have cirrhosis if they have a FIB-4 score >3.25 **or** any of the following findings from a previously performed test.
  - Transient elastography indicating cirrhosis (eg, FibroScan stiffness >12.5 kPa)
  - Noninvasive serologic tests above proprietary cutoffs indicating cirrhosis (eg, FibroSure, Enhanced Liver Fibrosis Test, etc)
  - Clinical evidence of cirrhosis (eg, liver nodularity and/or splenomegaly on imaging, platelet count <150,000/mm³, etc)
  - Prior liver biopsy showing cirrhosis
- **Medication reconciliation:** Record current medications, including over-the-counter drugs, and herbal/dietary supplements.
- **Potential drug-drug interaction assessment:** Drug-drug interactions can be assessed using the AASLD/IDSA guidance or the University of Liverpool drug interaction checker.
- **Education:** Educate the patient about proper administration of medications, adherence, and prevention of reinfection.
- **Pretreatment laboratory testing**

  Within 6 months of initiating treatment:
  - Complete blood count (CBC)
  - Hepatic function panel (ie, albumin, total and direct bilirubin, alanine aminotransferase [ALT], and aspartate aminotransferase [AST])
  - Calculated glomerular filtration rate (eGFR)

  Any time prior to starting antiviral therapy:
  - Quantitative HCV RNA (HCV viral load)
  - HIV antigen/antibody test
  - Hepatitis B surface antigen

  Before initiating antiviral therapy:
  - Serum pregnancy testing and counseling about pregnancy risks of HCV medication should be offered to women of childbearing age.

RECOMMENDED REGIMENS*

Glecaprevir (300 mg) / pibrentasvir (120 mg)
taken with food for a duration of 8 weeks

Sofosbuvir (400 mg) / velpatasvir (100 mg)
for a duration of 12 weeks

ON-TREATMENT MONITORING

- Inform patients taking diabetes medication of the potential for symptomatic hypoglycemia. Monitoring for hypoglycemia is recommended
- Inform patients taking warfarin of the potential for changes in their anticoagulation status. Monitoring INR for subtherapeutic anticoagulation is recommended.
- No laboratory monitoring is required for other patients.
- An in-person or telehealth/phone visit may be scheduled, if needed, for patient support, assessment of symptoms, and/or new medications.

POST-TREATMENT ASSESSMENT OF CURE (SVR)

- Assessment of quantitative HCV RNA and a hepatic function panel are recommended 12 weeks or later following completion of therapy to confirm HCV RNA is undetectable (virologic cure) and transaminase normalization.
- Assessment for other causes of liver disease is recommended for patients with elevated transaminase levels after achieving SVR.

FOLLOW-UP AFTER ACHIEVING VIROLOGIC CURE (SVR)

- No liver-related follow-up is recommended for noncirrhotic patients who achieve SVR.
- Patients with ongoing risk for HCV infection (eg, intravenous drug use or MSM engaging in unprotected sex) should be counseled about risk reduction, and tested for HCV RNA annually and whenever they develop elevated ALT, AST, or bilirubin.
- Advise patients to avoid excess alcohol use.

FOLLOW-UP FOR PATIENTS WHO DO *NOT* ACHIEVE A VIROLOGIC CURE

- Patients in whom initial HCV treatment fails to achieve cure (SVR) should be evaluated for retreatment by a specialist, in accordance with AASLD/IDSA guidance.
- For patients unable to be retreated, assessment for disease progression every 6 to 12 months with a hepatic function panel, CBC, and INR is recommended.
- Advise patients to avoid excess alcohol use.

AASLD

*More detailed descriptions of the patient evaluation process and antivirals used for HCV treatment, including the treatment of patients with cirrhosis, can be found at www.hcvguidelines.org. Updated: December 10, 2019

IDSA

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Simplified treatment – no cirrhosis

- Pre-treatment labs
  - Anytime prior
    - Quantitative HCV RNA viral load
    - HIV Ag/Ab
    - Hep serologies → vaccinate if not immune!
  - Within 6 mos
    - CBC, hepatic function panel, eGFR
  - Before initiating
    - Pregnancy test (with counseling for women of childbearing age)

Note:
- If no cirrhosis, imaging not required
- No genotype required (however insurance may require)

- Cirrhosis assessment
  - Calculate Fib4: if > 3.25 → presumed cirrhosis (serum calculation)
  - Cirrhosis diagnosis by prior testing:
    - By imaging (U/S, CT, MRI)
    - Platelets < 150k
    - Transient elastography
    - Non-invasive serum tests (proprietary – ie. "FibroTest")

Full details at: https://www.hcvguidelines.org/treatment-naive/simplified-treatment

Simplified treatment – no cirrhosis

- Regimens (pan-genotypic)
  - *Glecaprevir (300 mg) / pibrentasvir (120 mg) x 8 weeks (Mavyret)*
    - *3 pills daily*
    - *Often formulary preferred due to cost*
  - *Sofosbuvir (400 mg) / velpatasvir (100 mg) x 12 weeks (Epclusa)*
    - *1 pill daily*
- *Complete med reconciliation and review drug-drug interactions*
  - *University of Liverpool (www.hep.druginteractions.org) - GREAT*
- *Education*
  - *Med effects (fatigue, HA, nausea)*
  - *Adherence*
  - *Reinfection*

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Full details at: https://www.hcvguidelines.org/treatment-naive/simplified-treatment

Simplified treatment – no cirrhosis

- Monitoring on treatment
  - No laboratory monitoring required on treatment

    → *(Not guideline based but can opt for TW4 HCV VL if concern for adherence)*
  - Consider telemedicine or in-person visit for medication adherence/prn

- After treatment
  - SVR12 (sustained viral response) lab (HCV VL 12 weeks after treatment)
    - If undetectable → CURE!
    - If detectable, work-up and consider retreatment (may need specialty consult)
  - No liver-related f/u indicated if no cirrhosis
  - Reinfection education and advise regarding risks of alcohol use

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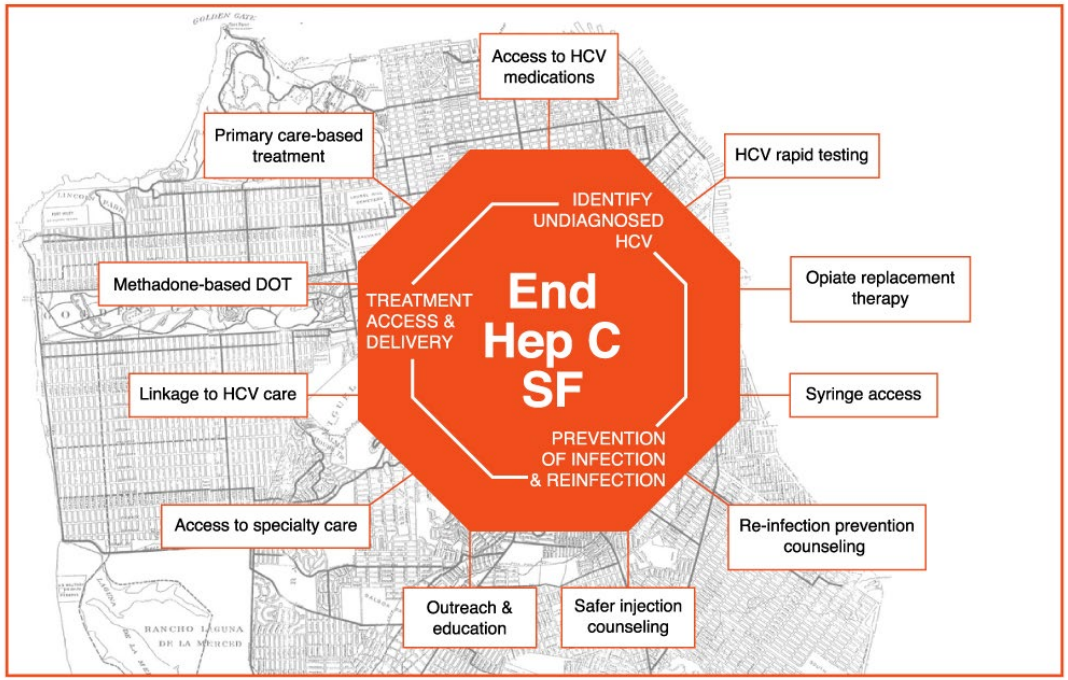
Full details at: https://www.hcvguidelines.org/treatment-naive/simplified-treatment

Conclusions

- Treat HCV - It's fun and the right thing to do!
  - Contact me for questions - *kellene.eagen@fammed.wisc.edu*
- www.hcvguidelines.org = GREAT resource
- *Patients with SUDs deserve treatment and are effectively cured of HCV*
- November 4th
  - *UW Addiction Medicine Grand Rounds* - Me!
  - "The Road to HCV Elimination: San Francisco"



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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