Duke Physician Assistant Program

Primary Care Approaches to Hepatitis C

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Objectives

Upon completion of this session, participants will be able to:

1. Discuss the epidemiology of chronic HCV infection in the US with specific focus on people with substance use disorders

2. Describe a group model for the treatment of chronic HCV infection that can be applied to multiple clinical settings

3. Apply a low-resource protocol for the treatment of HCV for patients with limited financial resources

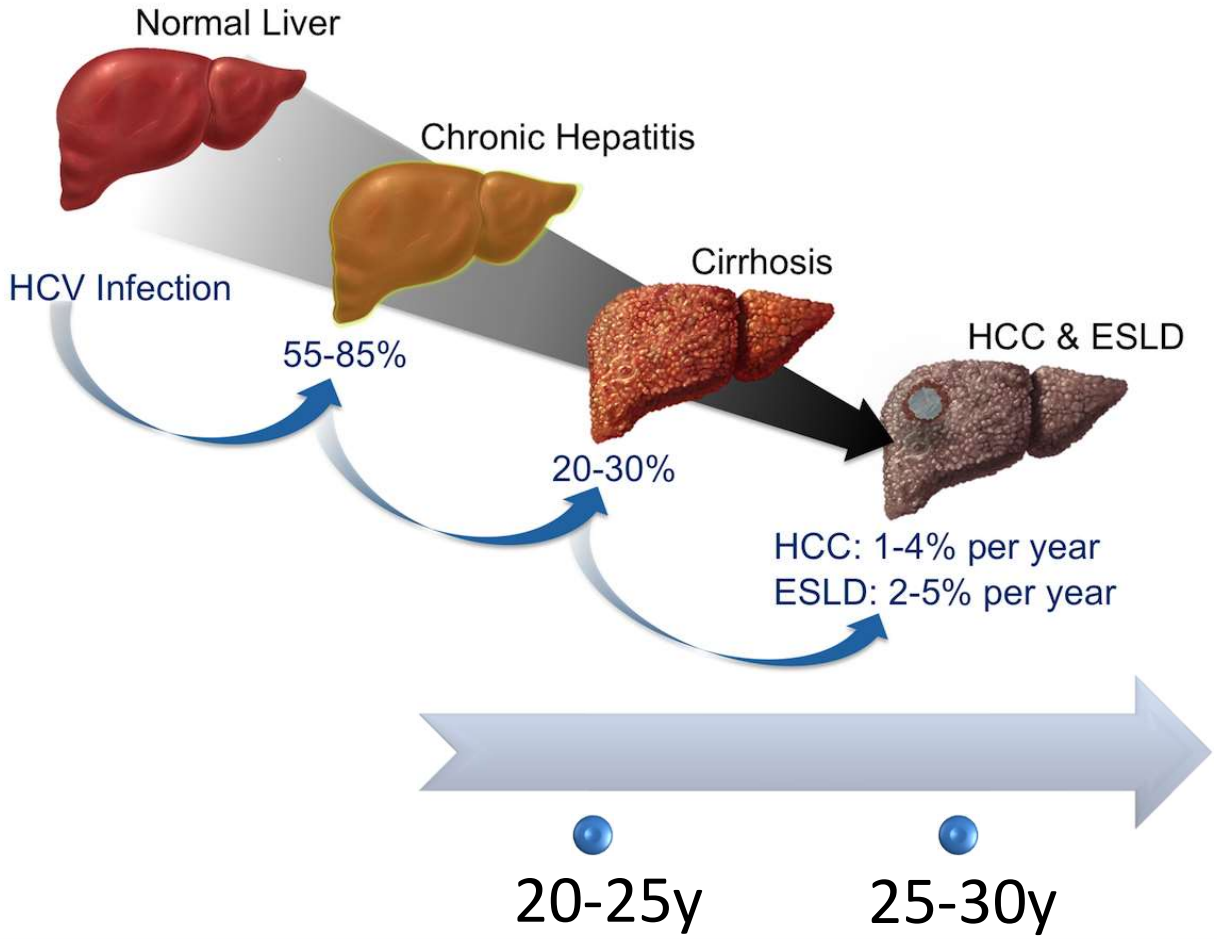
Hepatitis C Virus (HCV) Basics

- RNA virus
- 7 genotypes
  - 1a, 2, 3 most common in US
- Transmission through infectious blood
- No vaccine available
- Often asymptomatic at time of infection
- For every 100 infected, 5-25 will develop cirrhosis within 10-20 years
  - 1%-4% yearly risk of hepatocellular carcinoma

HCV Progression

- Fibrosis is scar tissue that develops in response to chronic liver injury
- Development requires several years of ongoing injury
- Reversible in its initial stages
- Progressive fibrosis can lead to cirrhosis (irreversible)
- Factors that lead to faster progression:
  - HIV/Hep B coinfection, DM, Age >50 at infection, Alcohol, Obesity, NAFLD, Male sex, immunosuppressive tx

Image Source: US Department of Veteran Affairs
https://www.hepatitis.va.gov/hcv/background/natural-history.asp

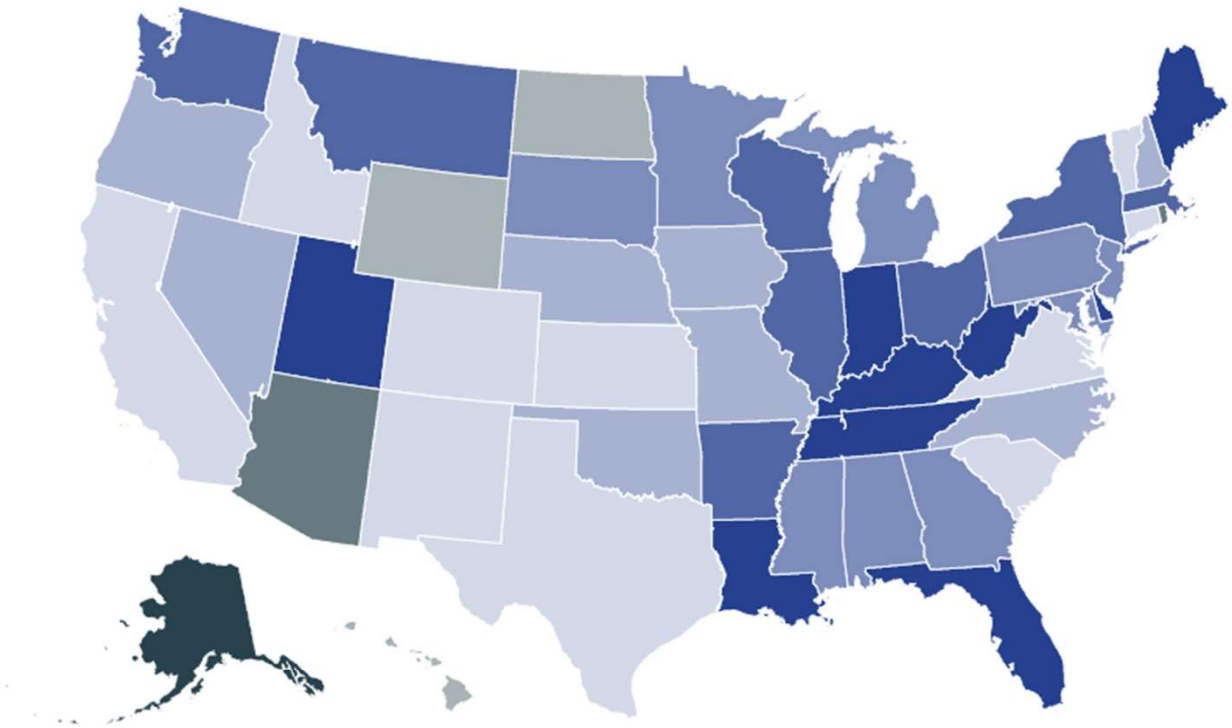


Epidemiology

- 58 million people living with HCV worldwide
- 1.5 million new infections occurring yearly
- Over 2.4 million in the US affected
- Leading cause of morbidity & mortality from liver disease in US
- Highest prevalence in people ages 20-39

Figure 3.3

Rates* of reported cases† of acute hepatitis C virus infection, by state or jurisdiction United States, 2020



Cases/100,000 Population

- 0.0–0.3
- 0.4–0.7
- 0.8–1.3
- 1.4–2.3
- 2.4–11.9
- No reported cases
- Data unavailable
- Not reportable

Color Key	Cases/100,000 Population	State or Jurisdiction
	0.0–0.3	NM, CA, ID, SC, TX, CO, VT, CT, KS, VA
	0.4–0.7	MO, NH, NV, IA, NE, OK, NC, OR
	0.8–1.3	MD, SD, AL, MN, PA, MI, GA, MS, NJ
	1.4–2.3	WA, IL, MT, OH, WI, NY, AR, MA
	2.4–11.9	TN, KY, UT, IN, DE, WV, LA, FL, ME
	No reported cases	HI, ND, WY
	Data unavailable	AZ, DC, RI
	Not reportable	AK

* Rates per 100,000 population.

† Reported cases that met the classification criteria for a confirmed case. For the case definition, see https://ndc.services.cdc.gov/conditions/hepatitis-c-acute/.

Source: CDC, National Notifiable Diseases Surveillance System.

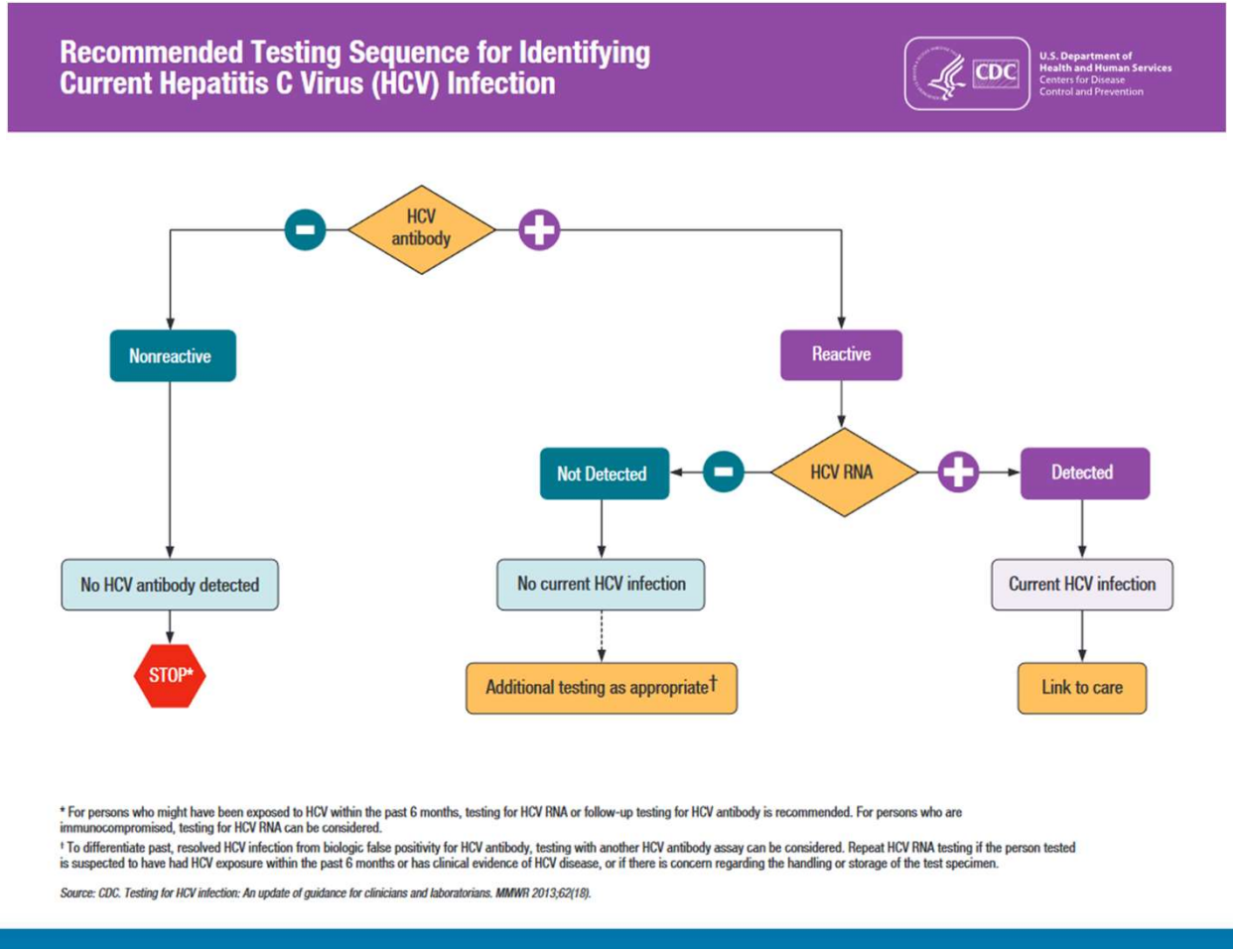
Centers for Disease Control and Prevention. Viral Hepatitis Surveillance Report – United States, 2020. https://www.cdc.gov/hepatitis/statistics/2020surveillance/index.htm. Published September 2022.

Poll Question

- How would you interpret these findings?

TEST	RESULT	REFERENCE
HCV Ab	Reactive	Non reactive
HCV RNA, NAA	Not detected	

HCV Testing & Diagnosis



HCV & Substance Use

- HCV prevalence is 53% among people with injection drug use
- People who use substances less likely to get screened or treated
- Stigma & discrimination
- Barriers
  - Cost of treatment
  - Location
  - Ongoing substance use

Group Treatment/Shared Medical Visits

- Group treatment or shared medical visits have been successful in chronic disease treatment
  - Diabetes
  - Hypertension
  - Obesity
- HCV Group Treatment
  - Hodges et al (2019) –at community health center
  - Stein et al (2012)- with methadone maintenance

Shared Medical Visits

- Shared medical visits may:
  - Improve access to care
  - Offer peer support
  - Reduce stigma
  - Improve education
  - Improve efficiency

HCV Group Treatment Model

Group visit 1	Group visit 2
✓ HCV education session ✓ Form completion (group consent, releases, medication patient assistance program) ✓ Overview of treatment process ✓ Order laboratory studies (CBC, CMP, PT/INR, HAV/HBV) ✓ Refer for HAV/HBV vaccines if indicated ✓ Schedule follow-up group visit in 4 weeks	✓ Questions and review HCV transmission, prevention, and treatment ✓ Medication education (adherence, side effects, drug interactions) ✓ Patients begin treatment with pangenotypic DAA ✓ Schedule follow-up group visit in 4–6 weeks
After visit 1: review laboratory results, calculate FIB-4/APRI scores, and review patient medications for potential interactions	

Group visit 3	Group visit 4
✓ Discuss treatment process ✓ Address side effects or medication-related concerns ✓ HCV education and prevention reminders ✓ Discard toothbrushes, razors, and other blood-containing products ✓ Schedule follow-up for 4–6 weeks	✓ Ensure and celebrate completion of treatment ✓ Ensure completion of HAV/HBV vaccines ✓ HCV education and prevention ✓ Order HCV RNA for 12 weeks after DAA completion

Image Source: Jones Quinnette B., Giemza Kristi, Anglin Lorraine, & Cottingham Sarah. (n.d.). Treating Hepatitis C in a Substance Use Recovery Program: A Limited-Resource Group Model. *NEJM Catalyst*, *3*(5), CAT.21.0453. https://doi.org/10.1056/CAT.21.0453

Group Treatment Opportunities

- Primary care
- Substance use disorder treatment programs
- Prisons
- Health departments
- Federally Qualified Health Centers (FQHCs) or Community Health Centers (CHC)

Potential Partners

- Academic institutions
  - Hepatology, Infectious Disease
- Health departments
- Non-profits
- Federally Qualified Health Centers (FQHCs) or Community Health Centers (CHC)
- Pharmaceutical companies

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Simplified HCV Treatment

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Simplified HCV Treatment

Eligibility

Who is eligible?

- ✓ Adults with chronic hepatitis C (any genotype) who do not have cirrhosis and have not received prior HCV treatment

Eligibility

Who is not eligible for simplified treatment?

- X Prior HCV treatment
- X Cirrhosis
- X Chronic Hep B (HBsAg Positive)
- X Currently pregnant
- X Known/suspected hepatocellular carcinoma (HCC)
- X Prior liver transplant

Pre-Treatment Assessment

Pretreatment Goals:

- Identify those who have more advanced disease
- Identify potential drug-drug interactions
- Educate the patient

Cirrhosis Assessment

- Everyone: Calculate a Fib-4 score
  - MDCalc; Hepatitis C Online
  - Requires input of age, AST, ALT, PLT count
  - Fib 4>3.25 = cirrhosis
- Optional alternative methods:
  - Transient elastography (“FibroScan”)
  - Serologic tests (e.g. Fibrosure, Enhanced Liver Fibrosis Test)
  - Liver biopsy

Poll Question

A patient is newly diagnosed with HCV. Their labs return as follows:

Test	Result	Reference
Bilirubin, Total	0.3	0.0 – 1.2 mg/dL
Albumin	4.3	3.8 – 4.8 g/dL
AST	37	0 - 40 IU/L
ALT	83	0 – 44 IU/L
PLT	254	150 – 450 x10E3/uL
Hepatitis B Surface Antibody	Reactive	
Hepatitis B Surface Antigen	Nonreactive	Negative
PT	9.9	9.1 – 12.0 sec
INR	1.0	0.9 – 1.2

Cirrhosis

- More likely cirrhotic if:
  - AST> ALT
  - Decreased platelet count
  - Decreased albumin levels
  - Increased bilirubin
  - Elevated PT-INR is a late finding
  - Fib 4>3.25 = cirrhosis

Pre-Treatment Labs

- Within 6 months of treatment initiation:
  - CBC
  - Hepatic function panel
  - eGFR
- Any time prior to starting treatment:
  - Quantitative HCV RNA (HCV viral load)
  - HIV antigen/antibody test
  - Hepatitis B surface antigen
- Before initiating antiviral treatment:
  - Pregnancy test

Medications

- Perform a medication reconciliation
  - Include over the counter medications and herbals/supplements
- Medications to watch out for:
  - Statins
  - Antacids
  - Ethinyl estradiol-containing contraceptives
  - University of Liverpool drug interaction checker

Education

- Pregnancy prevention
- Harm reduction
- Reinfection prevention
- Safe sex
- Avoid alcohol
- Hep A/B vaccines

Treatment

- Regimens- Direct Acting Antiviral (DAAs)
  - Glecaprevir/Pibrentasvir (Mavyret®) for 8 weeks
  - Sofosbuvir/Velpatasvir (Eplcusa®, generic) for 12 weeks
- Common side effects
  - Headache (6-22%), fatigue (6-15%), nausea (6-12%),
- Adverse Reactions
  - Hepatitis B reactivation
  - Hepatotoxicity

Treatment Monitoring

- In person or by phone
- Side Effects/Adverse effects
- Adherence
- Missed doses
- Replace personal hygiene items after a month
- No routine laboratory monitoring
- Hep A/B vaccine boosters

Treatment Resources

- Patient assistance programs
  - myAbbVie Assist
  - Gilead Support Path®
- Medicaid coverage
  - Prescriber, SUD, prior auth, & fibrosis restrictions *may* apply
- Medicare coverage
  - At least one DAA on formulary

Post-Treatment

- Assess for sustained viral response (SVR)
  - Hepatic function & HCV RNA 12 weeks post treatment
  - SVR achieved if HCV RNA is undetectable
  - Evaluate for other causes of liver disease if transaminases do not normalize
- If SVR achieved
  - No liver related follow up for non-cirrhotic patients
  - Yearly HCV RNA if ongoing risk
  - Avoid excess alcohol use
- If SVR not achieved
  - Refer to specialist

Clinical Pearls

- If you know about one kind of hepatitis, you know about one kind of hepatitis
- Young people tend to have higher elevations of aminotransferases
- Normal LFTs ≠ normal liver
- Don’t forget about Hep A/B vaccination
- Shared medical visits are efficient

Resources

- AASLD/IDSA HCV Guidelines: https://www.hcvguidelines.org/
- CDC Viral Hepatitis https://www.cdc.gov/hepatitis/hcv/index.htm
- University of Liverpool drug interaction checker
- MDCalc; Hepatitis C Online

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