Hepatitis C Virus (HCV): An Overview for the Primary Care Provider

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Objectives:

At the end of this presentation participants will be able to:

1. Understand the epidemiology of HCV
2. Describe the clinical manifestations of HCV
3. Develop a plan to evaluate and treat patients with current HCV in their practice

Outline

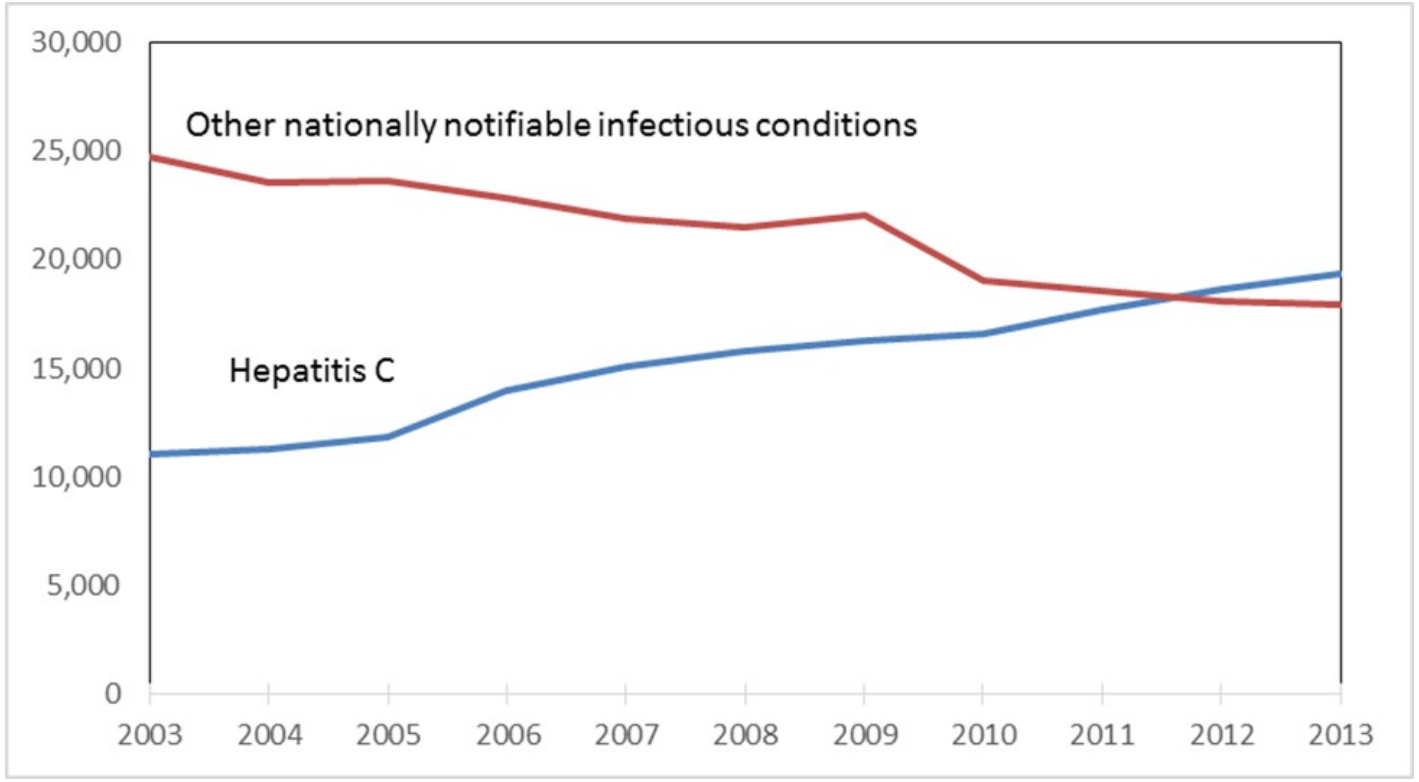
The Problem

Epidemiology

Clinical presentation

Diagnosis, evaluation treatment

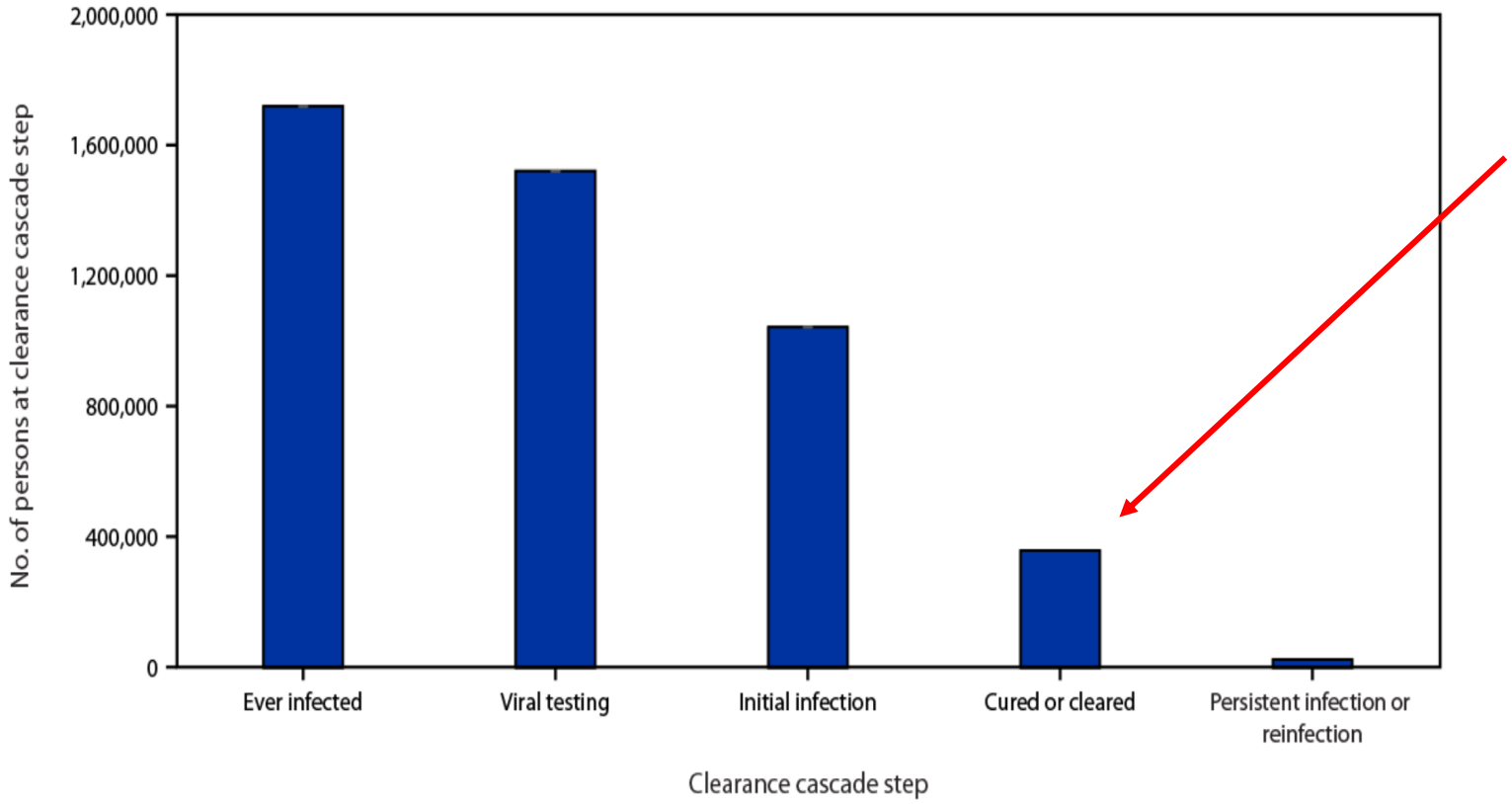
HCV Deaths and Deaths from Other Nationally Notifiable Infectious Diseases,* 2003- 2013



* TB, HIV, Hepatitis B and 57 other infectious conditions reported to CDC

Division of Viral Hepatitis

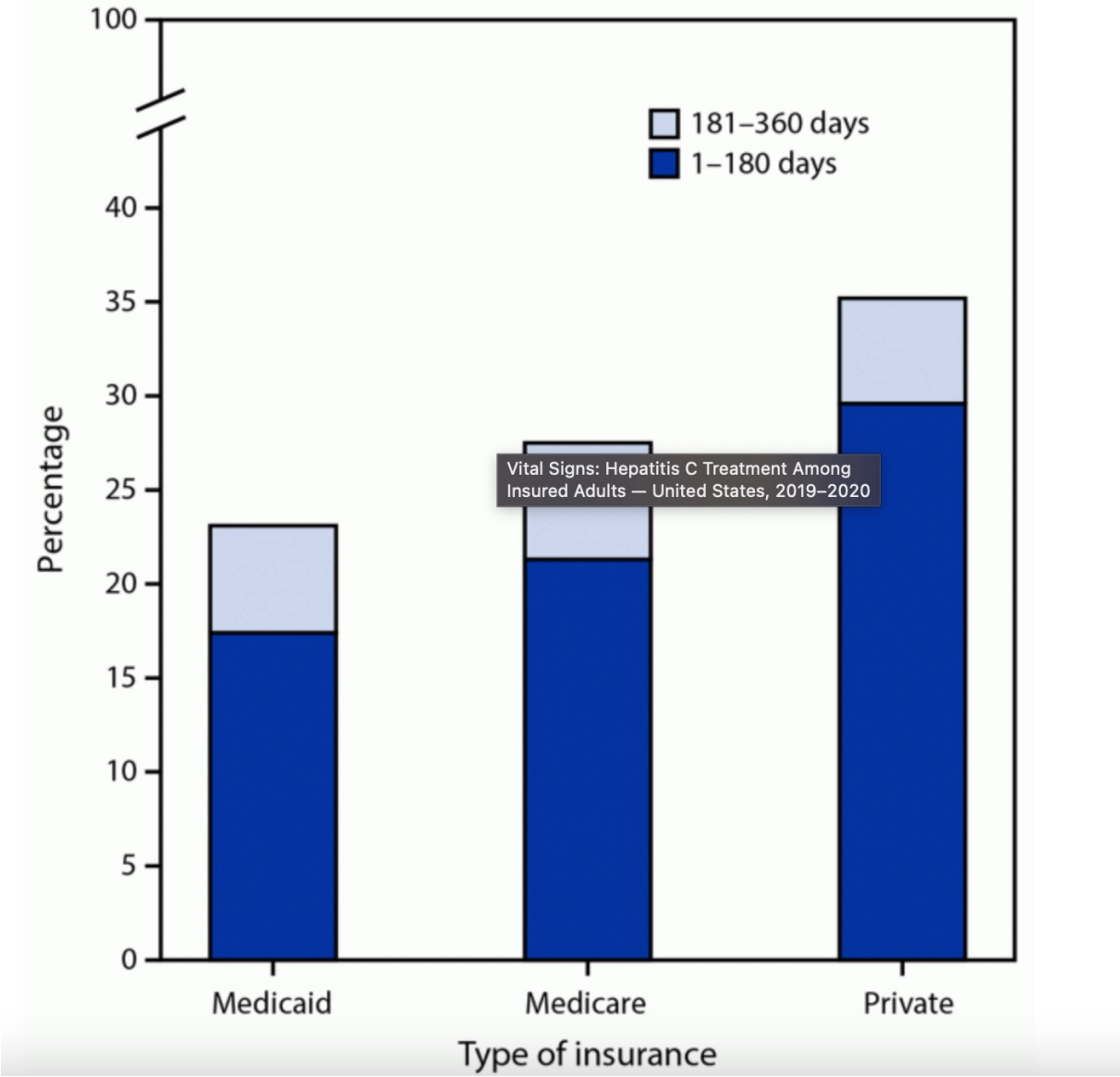
Hepatitis C virus clearance cascade using national commercial laboratory data — United States, 2013–2022



- The prevalence of viral clearance among persons with diagnosed hepatitis C was only 34% overall
- This clearance was even lower (16%) among persons aged 20–39 years with other payor (client or self-pay) insurance.

Wester C, Osinubi A, Kaufman HW, et al. Hepatitis C Virus Clearance Cascade — United States, 2013–2022. MMWR Morb Mortal Wkly Rep 2023;72:716–720

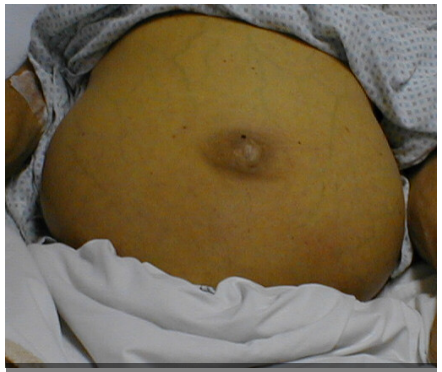
Percentage of adults with hepatitis C initiating direct-acting antiviral treatment within 360 days of diagnosis, by number of days after diagnosis and insurance type — United States, 2019–2020



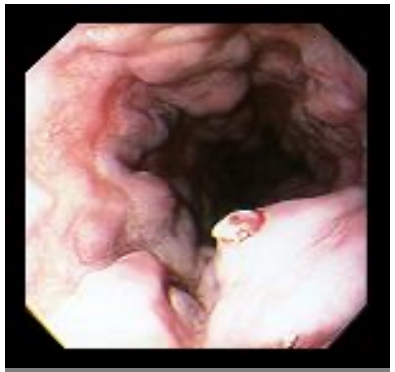
Thompson WW, Symum H, Sandul A, et al. *Vital Signs:* Hepatitis C Treatment Among Insured Adults — United States, 2019–2020. MMWR Morb Mortal Wkly Rep 2022;71:1011-1017.

What Are We Trying To Achieve?

At the individual level



Ascites



Esophageal Varices

End Stage Liver Disease

At Public Health Level

Decrease	Decrease Mortality by 65%*
Decrease	Decrease Incidence by 90%*
Eliminate	Eliminate HCV as a Public Health Problem*

* WHO 2030 goals for HCV Elimination

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HCV FACTS in the United States, 2020

- **41 states reported a total of 107,300 newly identified chronic HCV cases**
  - 40.7 chronic hepatitis C cases per 100,000.
- **HCV-associated deaths increased 4%**
  - 3.45 deaths per 100,000 people, compared to 2019 (3.33 deaths per 100,000 people).
- **Death rates were higher among AI/AN and non-Hispanic Black persons**
  - (3.2 times and 1.8 times, respectively) than among non-Hispanic White persons.

2x

The incidence rate of acute hepatitis C has more than doubled since 2013, a 124% increase

American Indian/Alaska Native

Rates of acute hepatitis C are highest among American Indian / Alaska Native persons

20-39 years

Persons aged 20-39 years had the highest incidence of acute hepatitis C

66%

66% of cases with risk information reported injection drug use

During 2020, rates of acute hepatitis C were highest among males, persons 20-39 years of age, American Indian/Alaska Native persons, those who reported using injection drugs, and those living in the eastern and southeastern states.

Acute HCV on the Rise: Younger People Affected

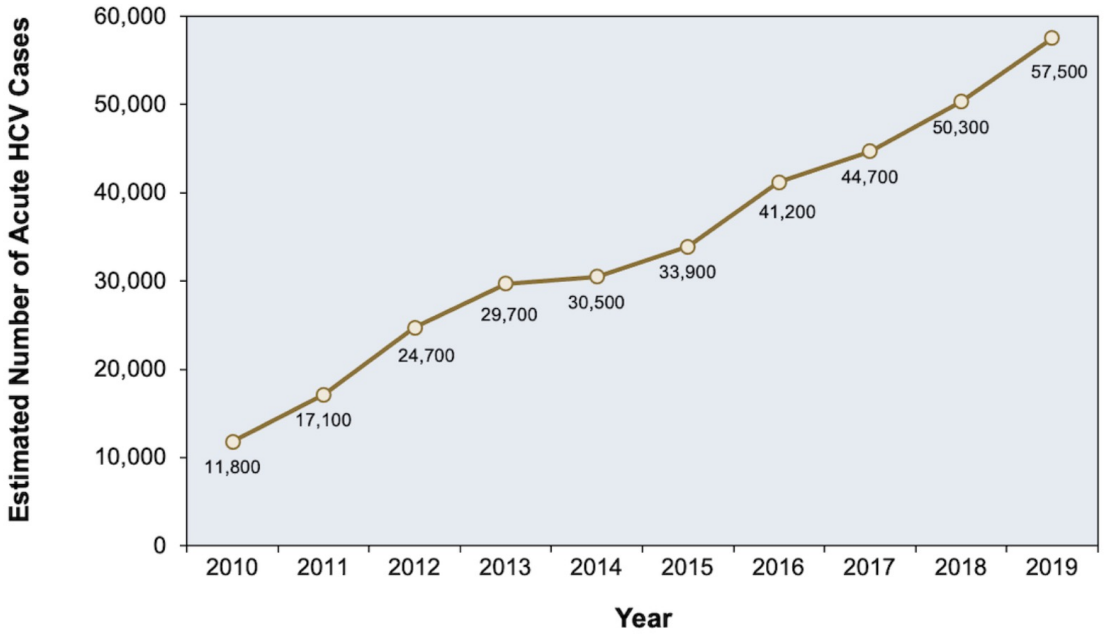


Figure 1 - Estimated Number of Acute Hepatitis C Cases, United States, 2010-2019

Source: Centers for Disease Control and Prevention (CDC). 2019 Viral Hepatitis Surveillance Report—Hepatitis C. Published May 2021.

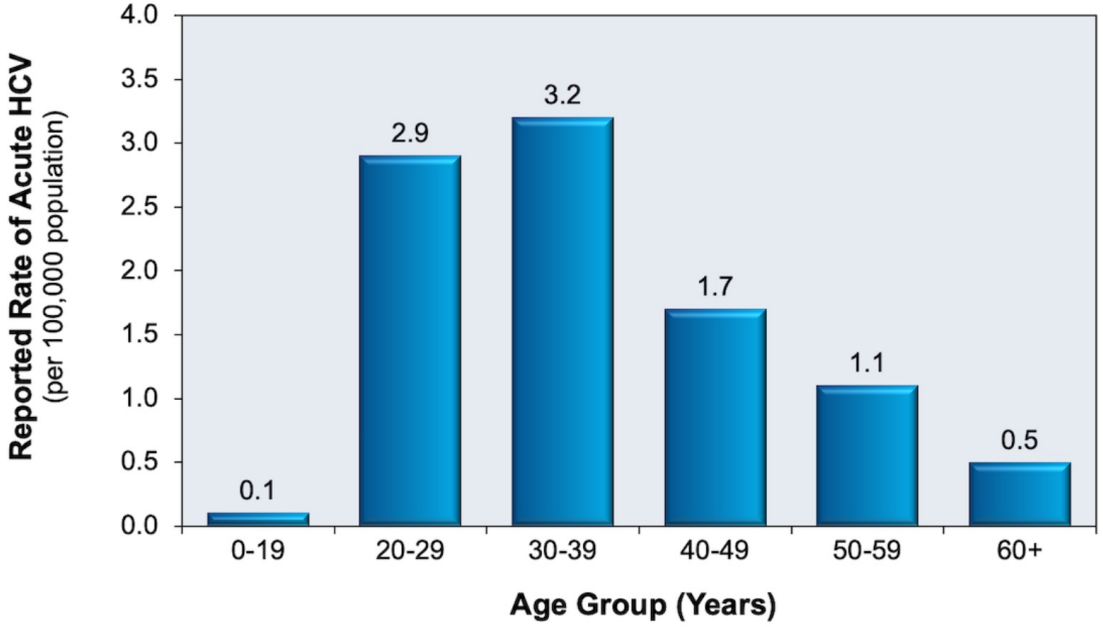
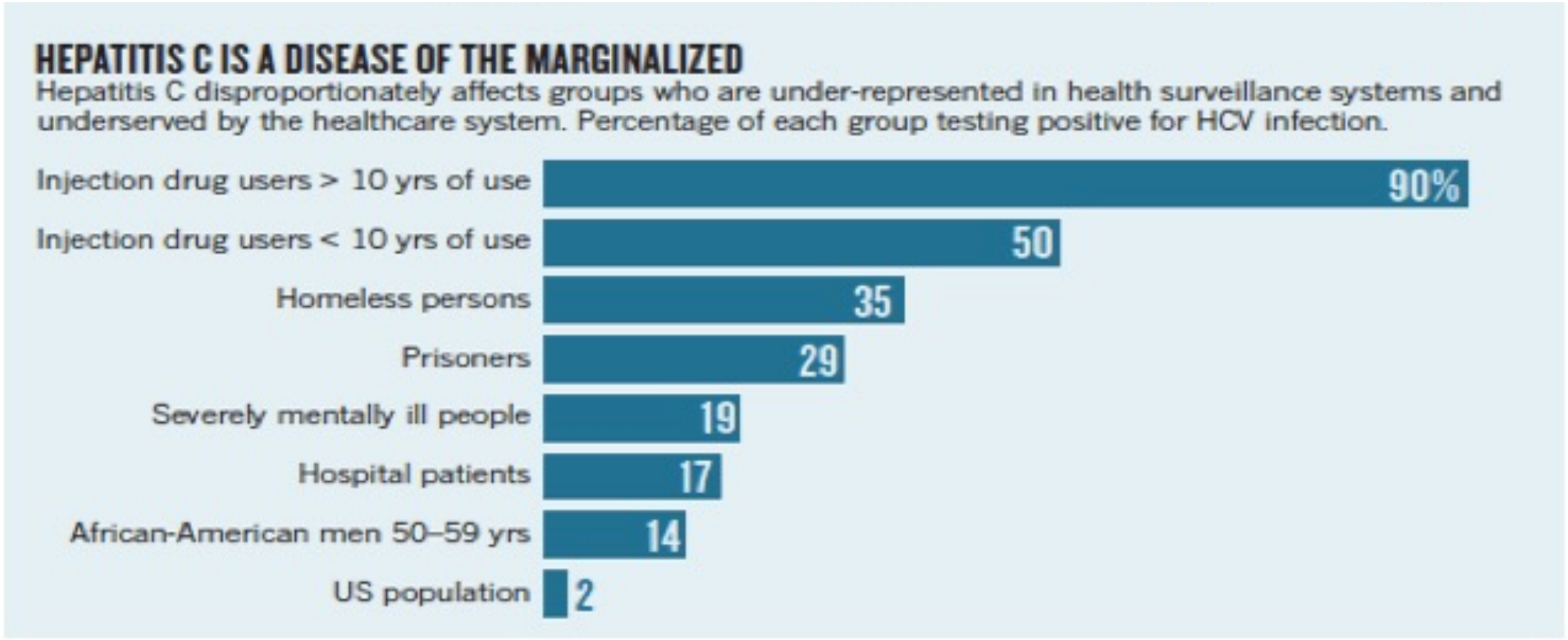


Figure 2 - Reported Rate of Cases of Acute Hepatitis C, United States, by Age Group, 2019

Source: Centers for Disease Control and Prevention (CDC). 2019 Viral Hepatitis Surveillance Report—Hepatitis C. Published May 2021.

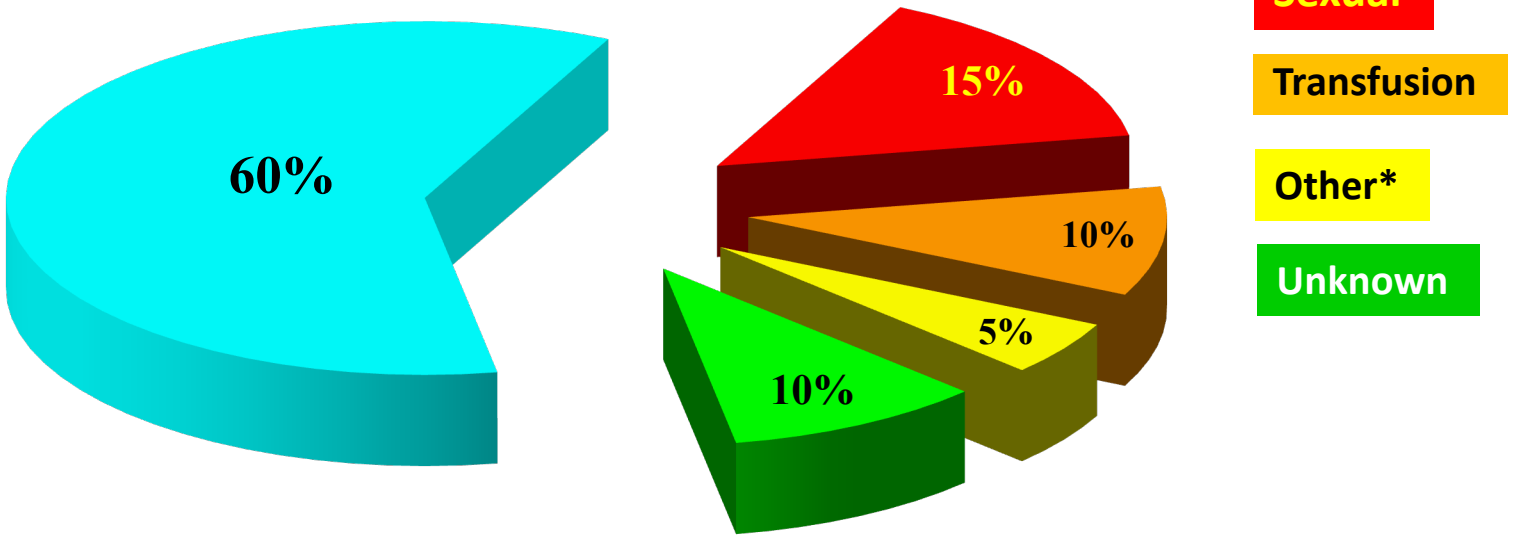
Estimated Number of Acute Hepatitis C Cases, United States, 2010-2019 and Reported Rate of Cases of Acute Hepatitis C, United States, by Age Group, 2019
Source: Centers for Disease Control and Prevention (CDC). Viral Hepatitis Statistics and Surveillance—United States, May 2021. (www.hepatitisc.uw.edu)



Edlin, B.R., 2011. Perspective: test and treat this silent killer. Nature 474 (7350),S18–S19.

HCV: Transmission

- **Blood**
  - IVDU is the leading cause in the United States
    - Snorting
  - Percutaneous injuries
  - Dental
  - Tattooing
  - Blood transfusion (Before 1992)
- **Sexual contact**
  - Rare in heterosexual
  - More frequent in HIV + MSM
- **Mother-to-child**
  - The rate is 1.7% - 4.3 %
  - *Increased in IVDU, HIV co-infection, VL (?)*



*Nosocomial; Health-care work; Perinatal

Centers for Disease Control and Prevention. Viral Hepatitis Surveillance—United States, 2016. Atlanta: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2018. Available at: https://www.cdc.gov/hepatitis/statistics/2016surveillance/index.htm.

HCV Transmission and Injection Drug Use

- **Today, > 80% Occurs in PWID**
- **All paraphernalia are involved in Transmission**
  - Needle
  - Syringe
  - Cooker
  - Table
  - Tourniquet

PWID: People Who Inject Drugs

~20 to 30% of PWID become infected with within the first 2 years of starting to inject drugs

- 50% within 5 years

Transmission risk is greatest with "direct sharing" of needles and syringes

- But may also occur indirectly via sharing of injection paraphernalia

Palmateer N, Hutchinson S, McAllister G et al. Risk of transmission associated with sharing drug injecting paraphernalia: analysis of recent hepatitis C virus (HCV) infection using cross-sectional survey data. J Viral Hepatol 2014 Jan;21(1):25-32

Outline

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Symptoms of HCV

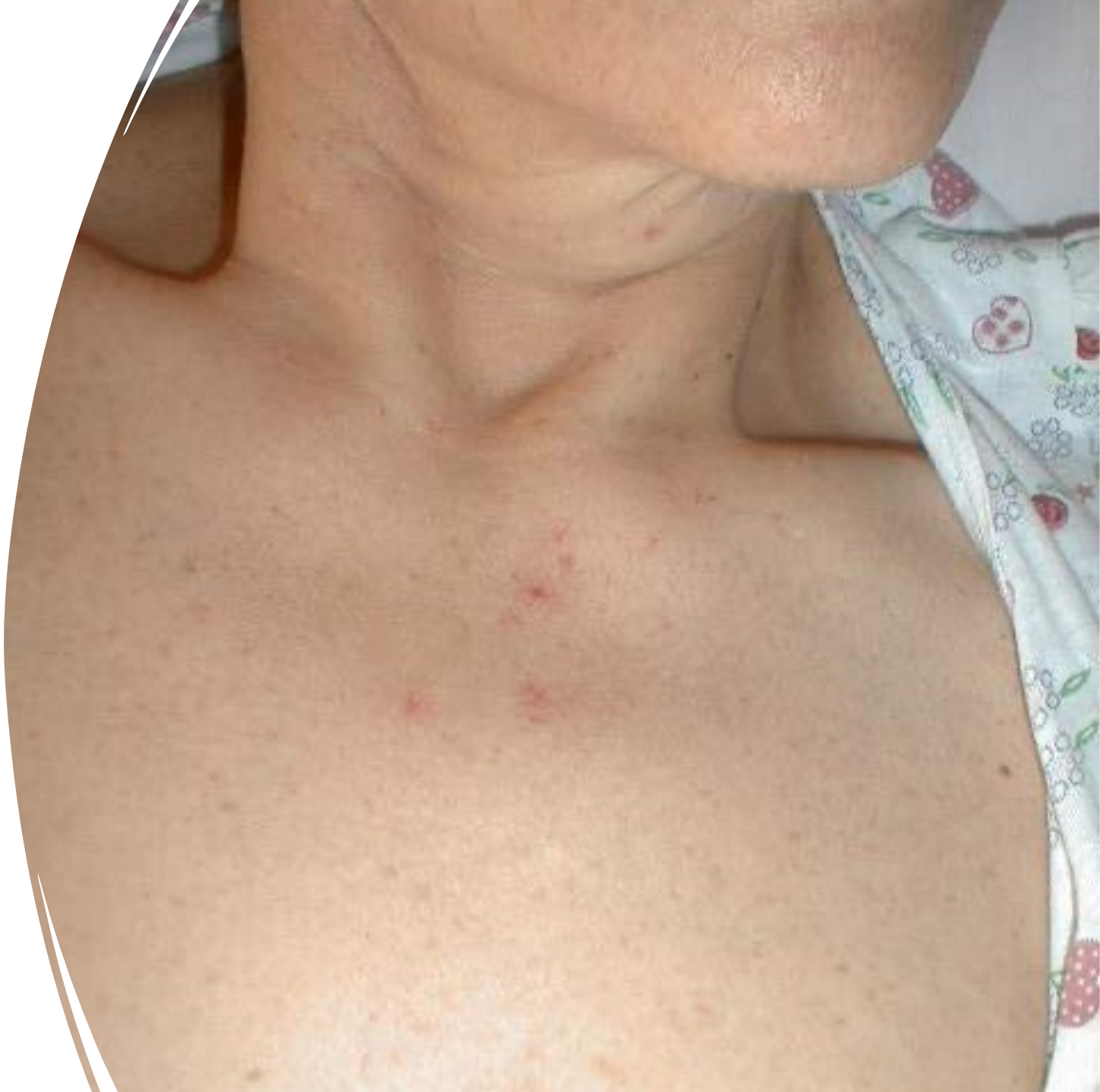
Most patients are asymptomatic

Common symptoms

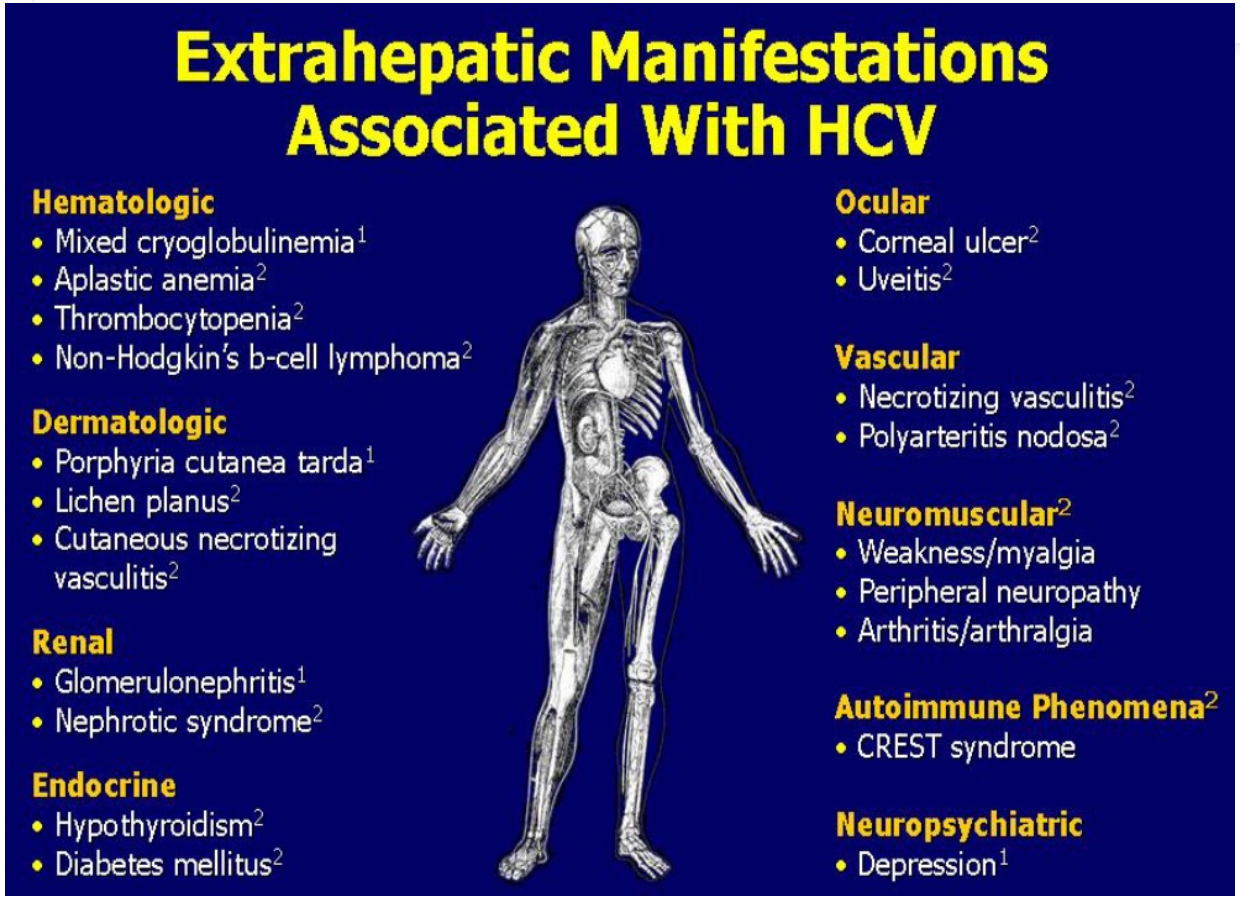
- Fatigue
- Impaired Cognitive Function - "Brain Fog"
- Migratory arthralgia/myalgia
  - Often misdiagnosed as rheumatoid arthritis
- Depression

Physical Findings

- **Most Patients do not have any abnormal physical findings**
- In patients with cirrhosis, you may find
  - Spider angiomas
  - Palmar erythema
  - Gynecomastia
  - Testicular atrophy
  - Jaundice
  - Firm liver
  - Parotid hypertrophy



HCV Extrahepatic Manifestations



40% of people with HCV will develop at least 1 extrahepatic manifestation often not clinically recognized

Extrahepatic manifestations can occur at any stage of disease

High index of suspicion is needed for these conditions regardless of the presence of cirrhosis

Consider HCV as a potential etiology of these conditions in patients who do not carry an HCV diagnosis

[1]NIH. *NIH Consens State Sci Statements*. 2002;19(3):1-46.
[2]Sene et al. *Metab Brain Dis*. 2004;19(3-4):357-381.

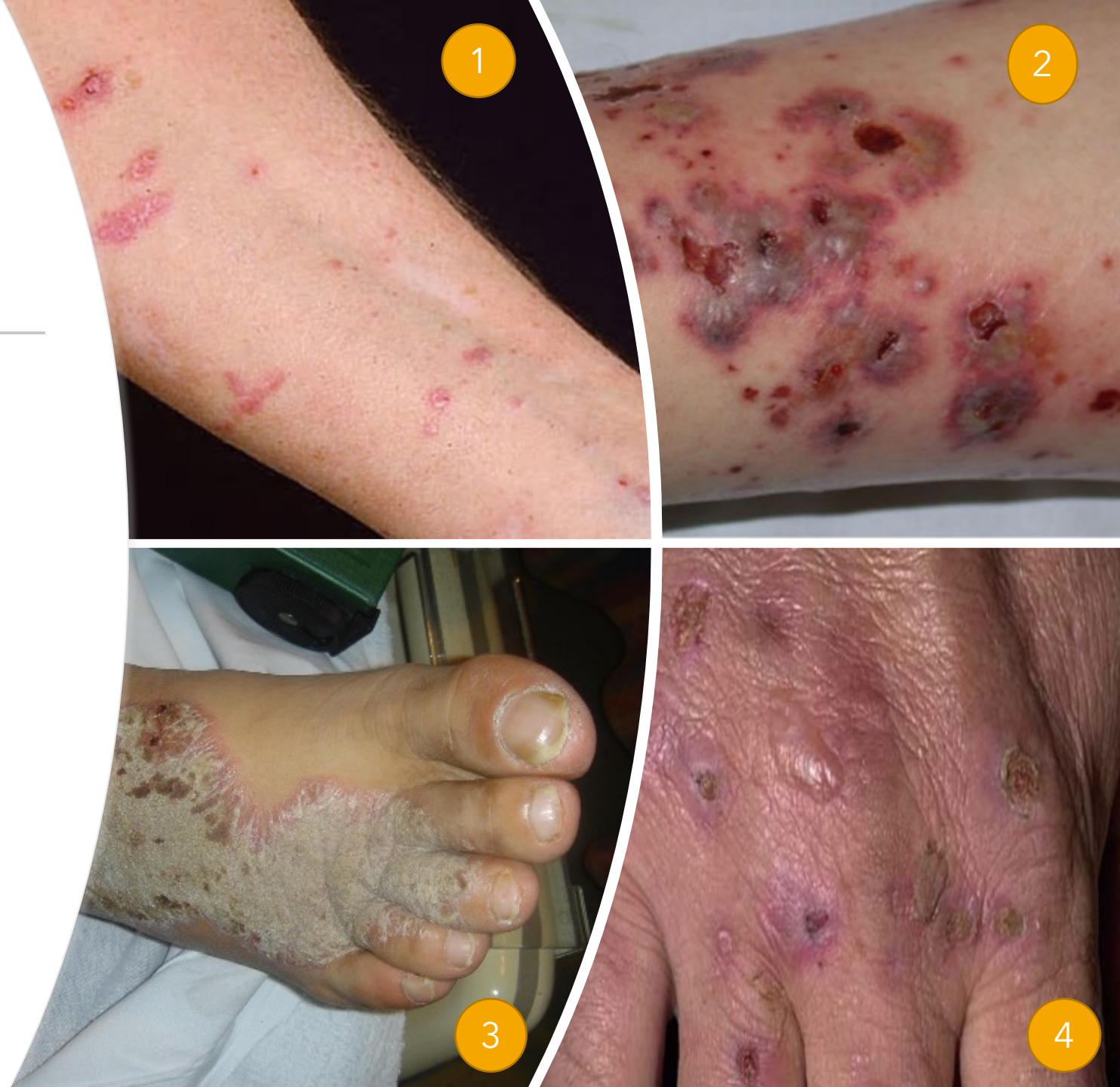
Dermatologic Manifestations

1: Lichen planus

2: Leukocytoclastic vasculitis

3: Necrolytic acral erythema

4: Porphyria cutaneous tarda



CDC is Augmenting Previous Guidance With Two New Recommendations:

1) Hepatitis C screening at least once in a lifetime for all adults aged ≥18 years, except in settings where the prevalence of HCV infection is <0.1% and
2) Hepatitis C screening for all pregnant women during each pregnancy, except in settings where the prevalence of HCV infection is <0.1%.
3) The recommendation for HCV testing that remains unchanged is regardless of age or setting prevalence, all persons with risk factors should be tested for hepatitis C, with periodic testing while risk factors persist.
4) Any person who requests hepatitis C testing should receive it, regardless of disclosure of risk, because many persons might be reluctant to disclose stigmatizing risks.

Schillie S, Wester C, Osborne M, Wesolowski L, et al. MMWR Recomm Rep 2020;69(No. RR-2):1–17.

Considerations to Improve HCV Screening

1

Think outside of traditional screening sites

2

Incentivize screening rate improvements

- Include nurses, pharmacists, medical assistants, providers

3

Utilize point of care testing when possible

- Allows for immediate engagement in care

4

Reflex RNA testing

5

Develop site specific “lab-triggered” screening

HCV Screening: Beyond Baby Boomers and Primary Care

Universal Screening

- Age-based
- Without regard for risk factors

Expanded Sites

- Opioid treatment programs
- Behavioral health clinics
- Emergency department/Urgent cares
- Prisons/Jails
- Homeless Shelters
- Clinics on the move – mobile units
- Community events
- Surgery centers

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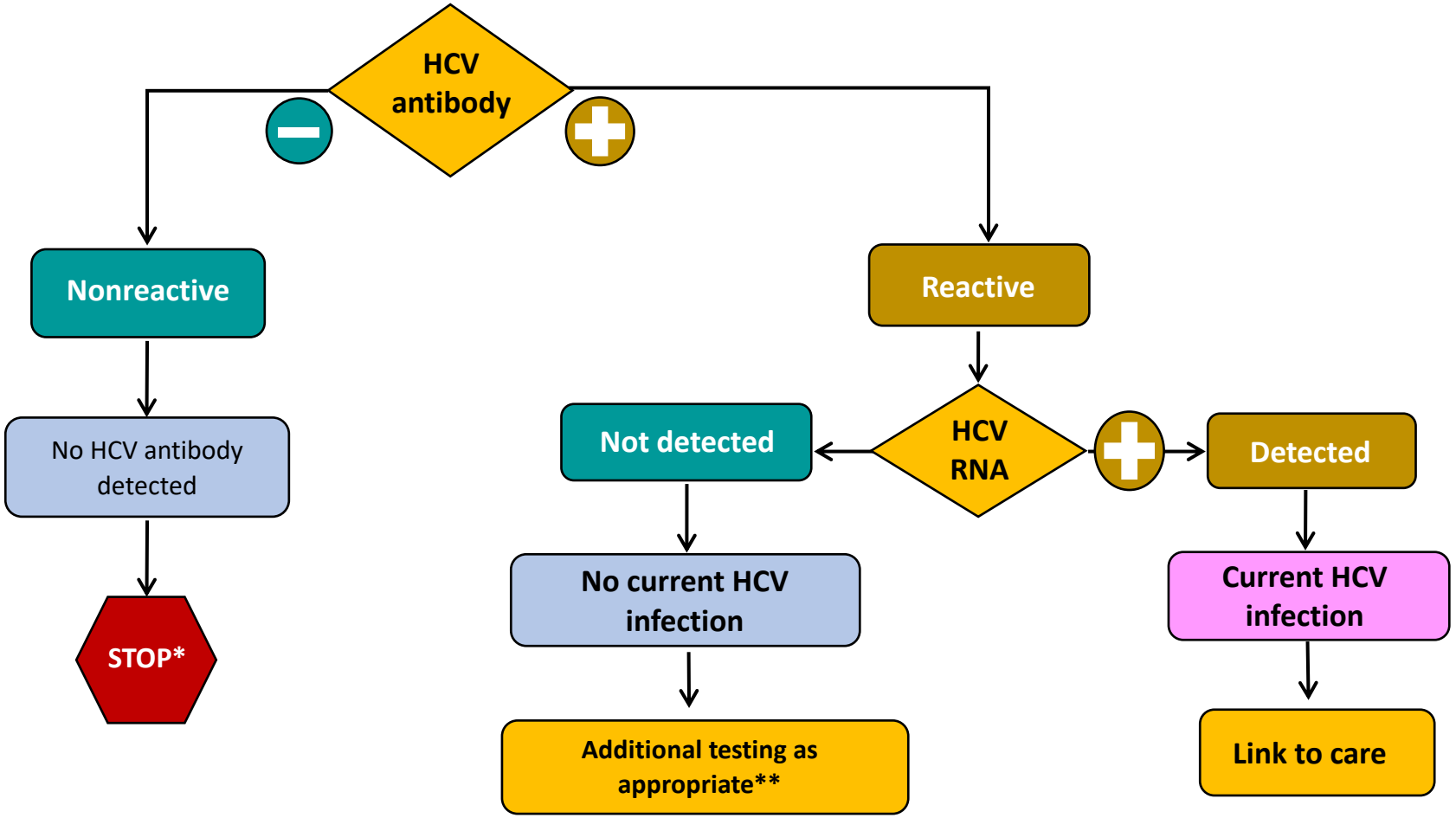
HCV Workflow

- Confirm Diagnosis
- Lab/Imaging workup
- Fibrosis Staging
- Critical Information
- Treatment
  - Cure
  - Surveillance

Confirm the Diagnosis



* For persons who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended. For persons who are immunocompromised, testing for HCV RNA can be considered.

** 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. CDC. Testing for HCV infection. *MMWR*. 2013;62(18).

HCV antibody False Negative

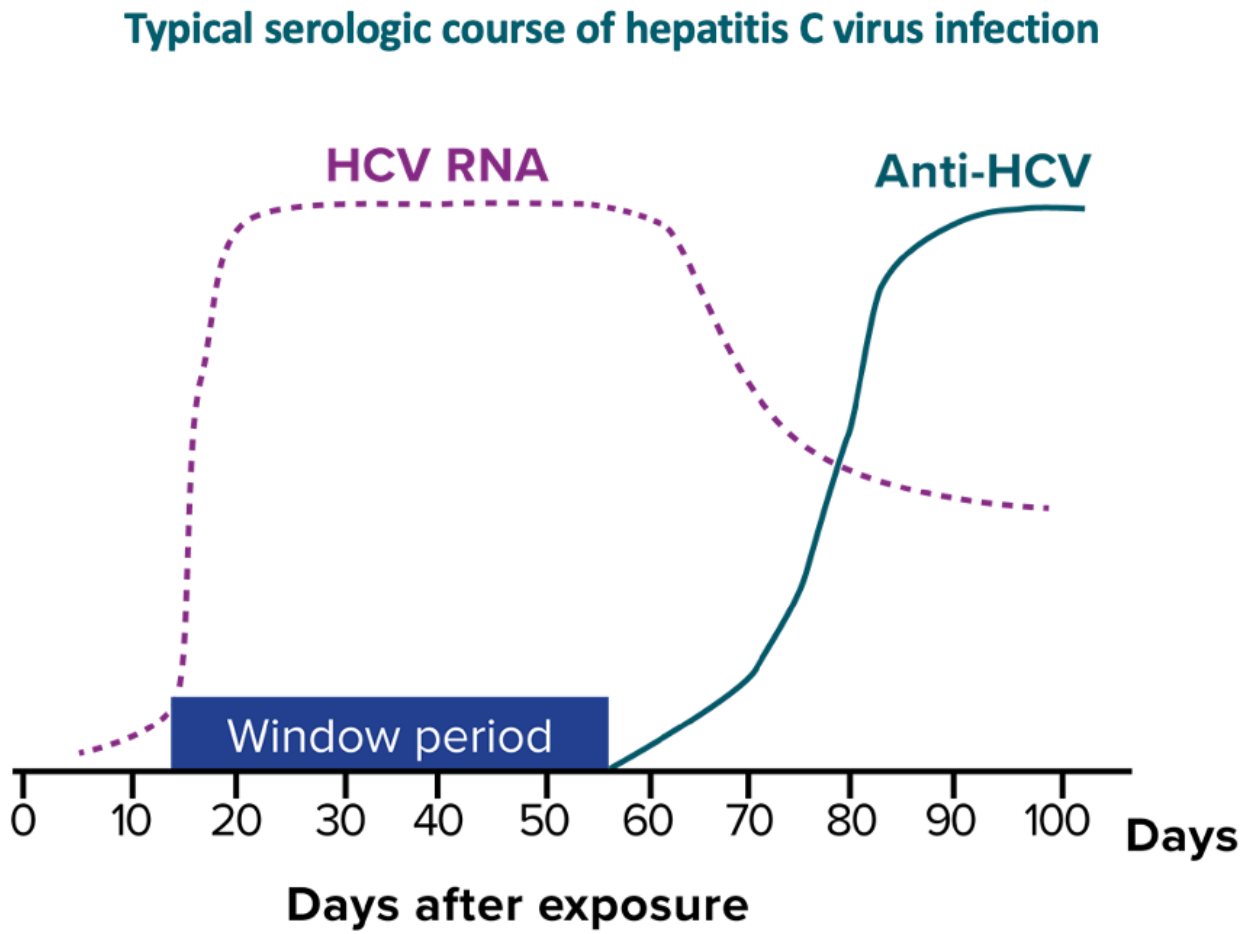
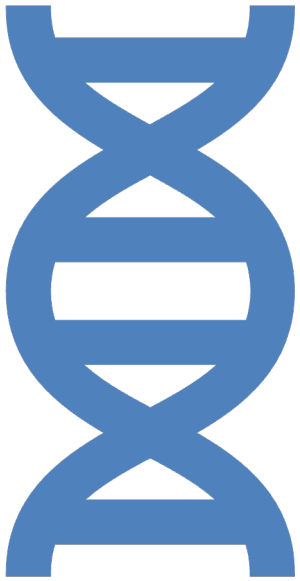


Figure obtained from https://www.aphl.org/aboutAPHL/publications/Documents/ID-2019Jan-HCV-Test-Result-Interpretation-Guide.pdf.

HCV RNA: Viral Load



- **Number of virus particles** (RNA) per mL of blood
- **Confirms current infection**
  - 15-30% of acutely infected patients spontaneously resolve
- **It defines cure**
  - When the viral load is not detected 12 weeks after treatment is complete - sustained virological response **(SVR 12)**
- **Does not predict liver disease progression**

HCV Workflow

- Confirm Diagnosis
- Lab/Imaging workup
- Fibrosis Staging
- Critical Information
- Treatment
  - Cure
  - Surveillance

Laboratory Workup

Genotype

- Determines treatment in certain cases
- Three main genotypes in the US: GT1, GT2 and GT3

Hep A serology

- Order Hep A total antibody or IgG antibody
- If non-reactive, patient needs vaccination

Hep B serology

- Immunization and to monitoring reactivation
- Order HBsAg, HBcAb (total or IgG) and HBsAb

HIV serology

- Important to treat HIV
- Important to treat HCV (interaction with some HIV medications)

Laboratory Workup

CBC

- Platelets are critical for liver fibrosis staging

Comprehensive metabolic panel

- ***ALT/AST*** are important for liver fibrosis staging
- ***Bilirubin*** is Important for Child Pugh Score if necessary
- ***GFR***
  - May point to urgent treatment if it is due to HCV related nephropathy

Urinary Drug Screen

- Important to address and refer to
  - Behavioral health
  - Harm reduction program if available
  - Medication assisted treatment if needed

What is the Earliest Laboratory Marker for Cirrhosis?

a) Low albumin level
b) Elevated AST
c) Elevated ALT
d) Thrombocytopenia
e) Anemia
f) Leucopenia

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a) Low albumin level
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Imaging

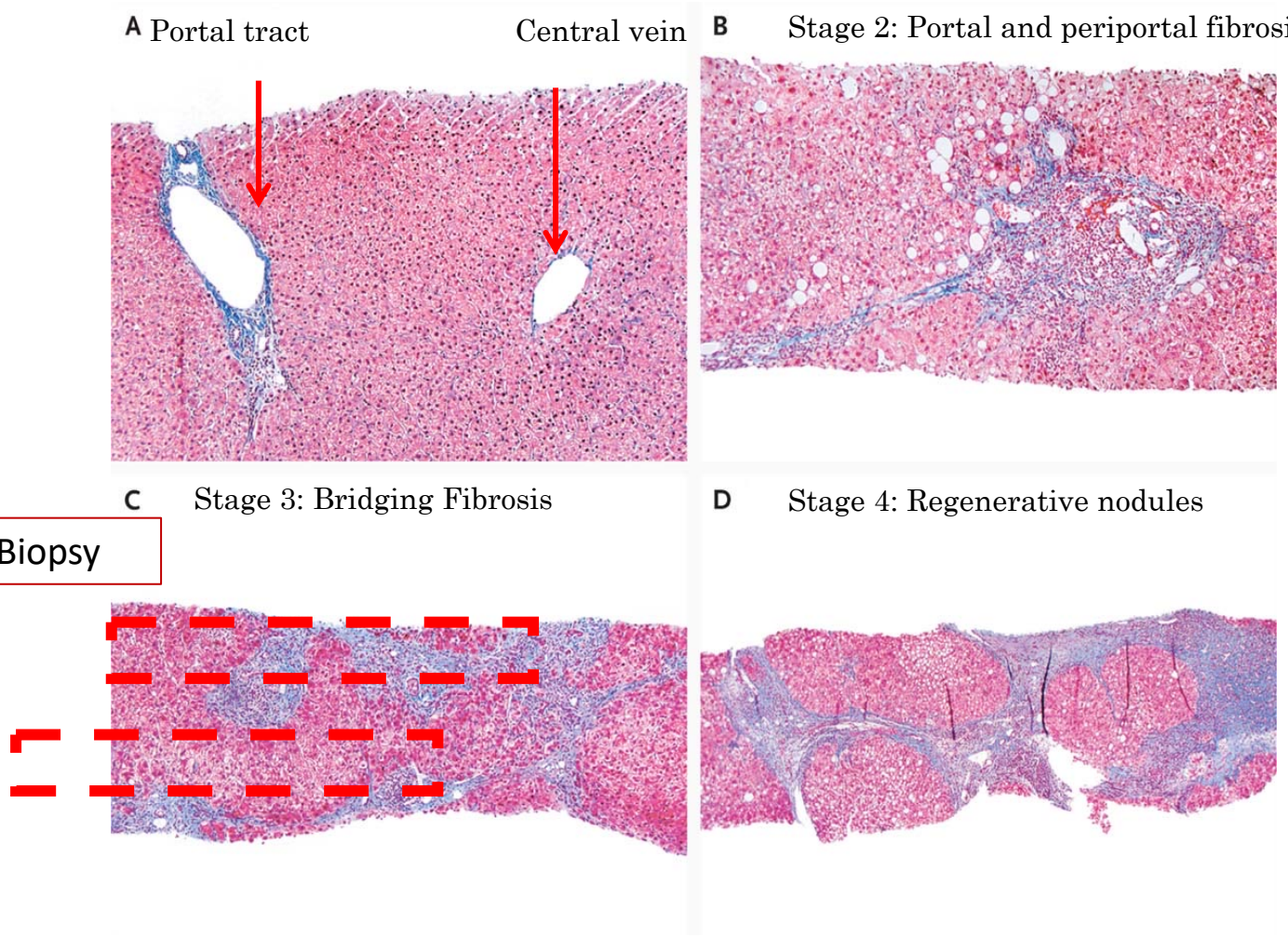
Ultrasound

- Specific for advanced liver disease but ***not sensitive***
  - Nodular liver
  - Ascites
  - Splenomegaly
  - Portal vein flow
- Screens for liver cancer
- May find other comorbidities such as fatty liver

Fibroscan

- Used for liver fibrosis staging

Liver Biopsy



Liver Biopsy

- **F0: No fibrosis**
- **F1: Scattered portal fibrosis**
- **F2: Diffuse periportal fibrosis**
- **F3: Bridging fibrosis**
- **F4: Cirrhosis**
  - ***Compensated***
  - ***Decompensated***
    - History or presence of ascites
    - History of esophageal bleeding due to esophageal varices
    - History or presence of hepatic encephalopathy

The NEW ENGLAND JOURNAL of MEDICINE

Rosen HR. N Engl J Med 2011;364:2429-2438

Non-Invasive Liver Fibrosis Staging in the Office

APRI: AST to Platelet Ratio Index

$$APRI = \frac{\frac{\text{AST Level (IU/L)}}{\text{AST (Upper Limit of Normal) (IU/L)}}}{\text{Platelet Count } (10^9/L)} \times 100 = 2.084$$

AST Level (IU/L): 126
AST (Upper Limit of Normal) (IU/L): 39
Platelet Count (10^9/L): 155

An APRI score greater than 1.0 had a sensitivity of 76% and specificity of 72% for predicting cirrhosis. APRI score greater than 0.7 had a sensitivity of 77% and specificity of 72% for predicting significant hepatic fibrosis.

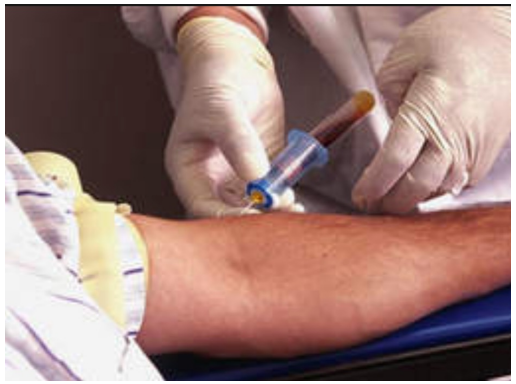
FIB–4 Index

$$FIB\text{-}4 = \frac{\text{Age (years)} \times \text{AST Level (U/L)}}{\text{Platelet Count } (10^9/L) \times \sqrt{\text{ALT (U/L)}}} = 3.76$$

Age (years): 56
AST Level (U/L): 129
Platelet Count (10^9/L): 196
ALT (U/L): 96

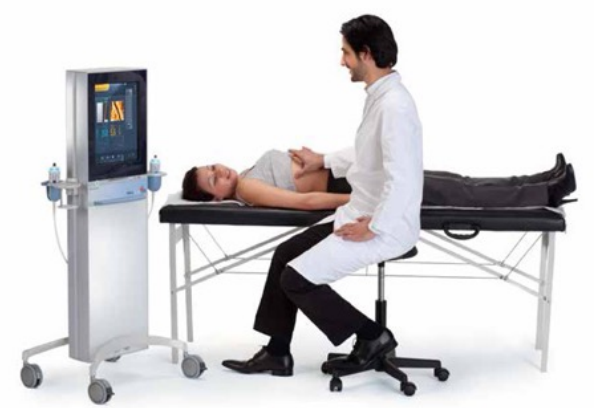
A FIB-4 score <1.45 has a negative predictive value of 90% for advanced fibrosis A FIB-4 >3.25 has a 97% specificity and a positive predictive value of 65% for advanced fibrosis.

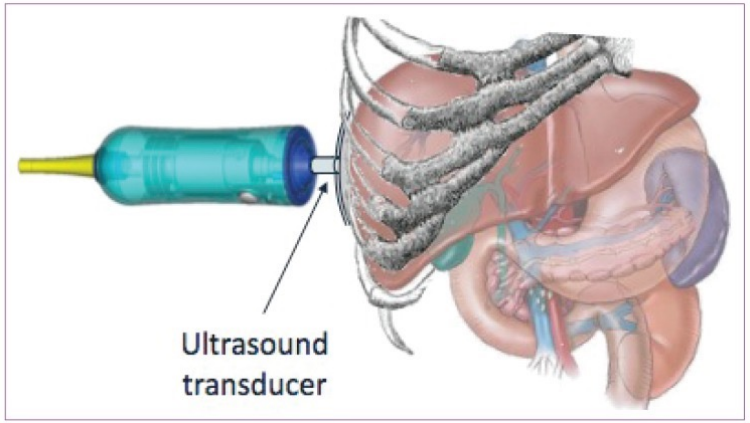
Fibrotest/Fibrosure

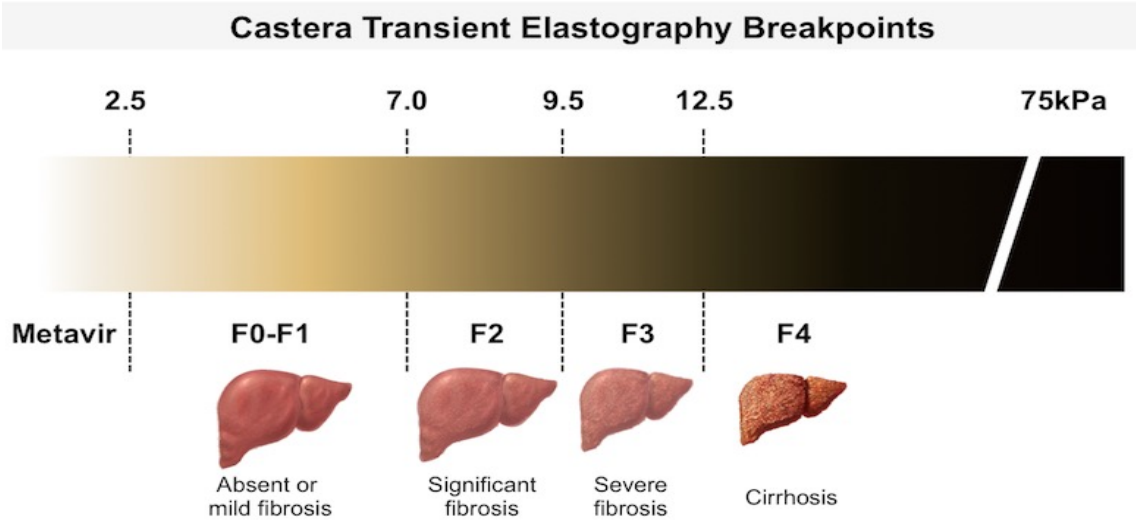


Lin ZH, Xin YN, Dong QJ, et al. Hepatology. 2011;53:726-36
Sterling RK, Lissen E, Clumeck N, et. al. Hepatology 2006;43:1317-1325
University of Washington: Hepatitis C Online www.hepatitisc.uw.edu/

Liver Fibrosis Staging by Imaging: Transient Elastography







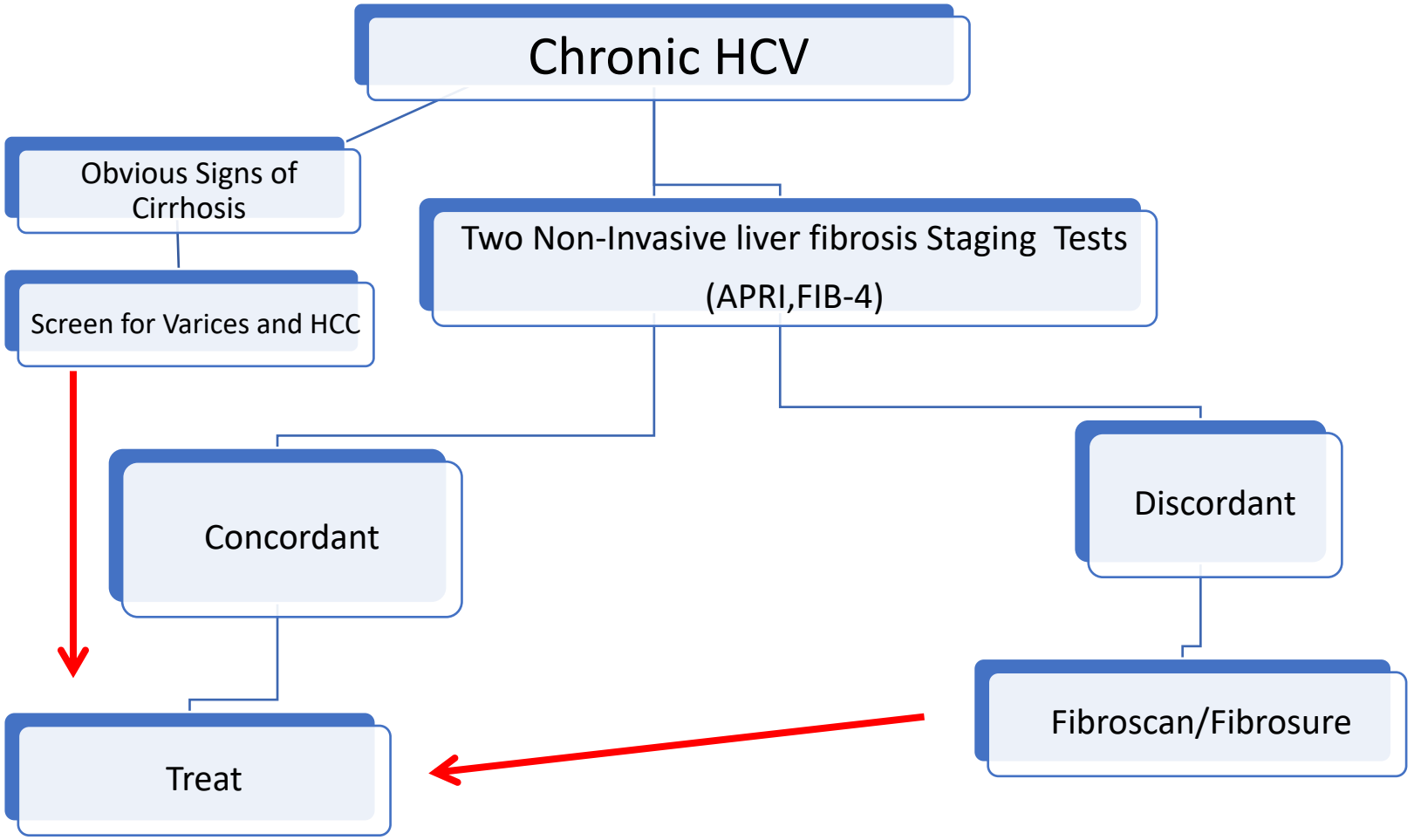
The probe of the Fibroscan device is positioned in an intercostal space near the right lobe of the liver, and a 50-MHz wave is passed into the liver from a small transducer on the end of the probe. The device then measures the velocity of the shear wave (in meters per second) as this wave passes through the liver, and this measurement is converted to a liver stiffness measurement.

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3594956/

Fibrosis Staging Interpretation

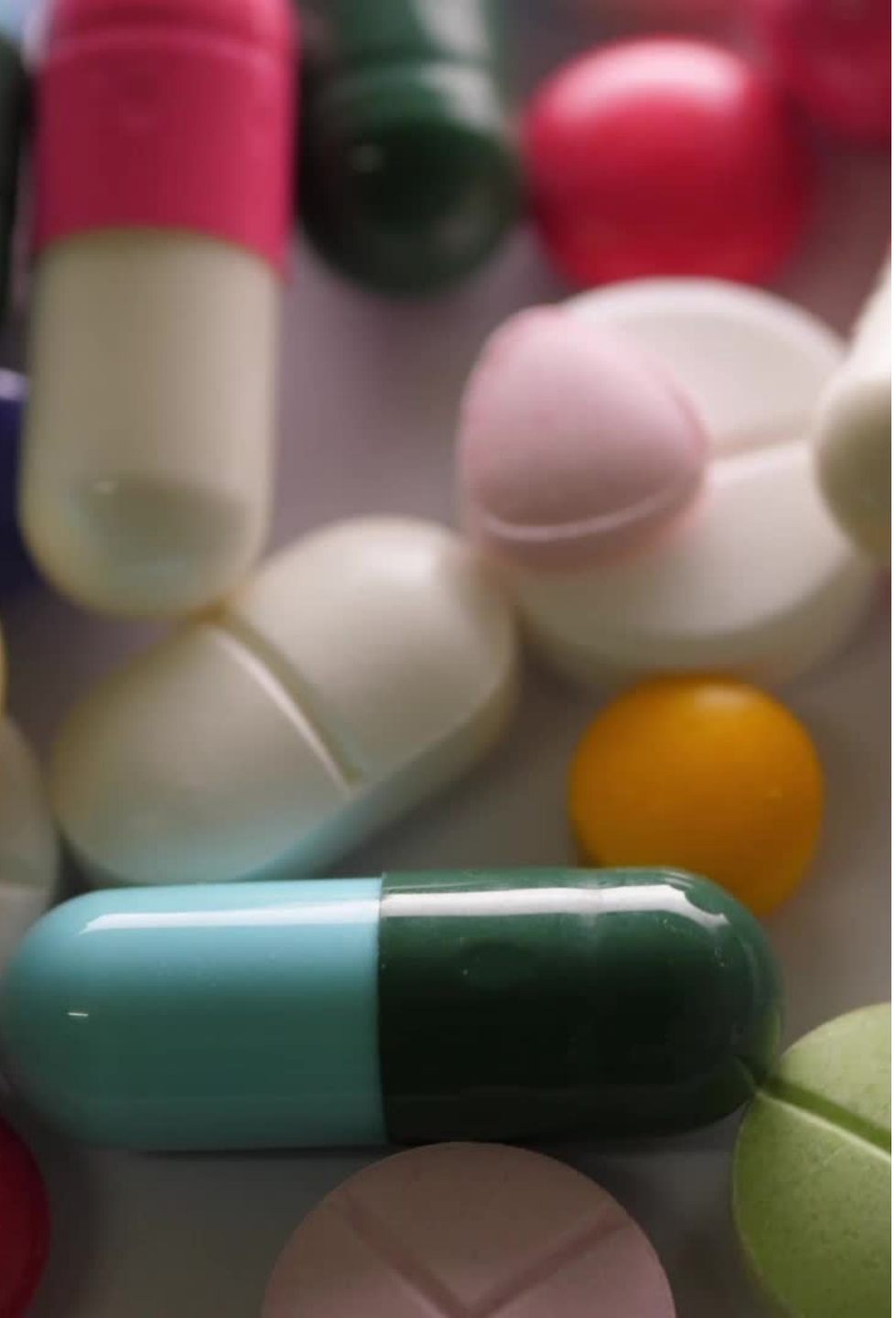
Metavir	Biopsy	Fibroscan	Fibrosure	APRI	FIB-4
F4	F4	≥ 12.5 kPa	≥ 0.75	≥ 1.0	> 3.25
F3	F3	9.6 12.4 kPa	0.58 – 0.74		
F2	F2	7.1-9.5 kPa	0.49 – 0.57	< 1.0	< 1.45
F1	F1	≤ 7.0 kPa	0.23 – 0.48		
F0	F0		≤ 0.22		

Fibrosis Staging Algorithm



HCC: Hepatocellular Carcinoma

Adapted from Boghal H, Sterling RK, Infect Dis Clin N Am 26 (2012) 839-847



Why is it important to stage Liver Fibrosis?

- Treatment ***may be different between*** cirrhotic and non cirrhotic patients and ***will be different*** in patients with decompensated cirrhosis vs non decompensated cirrhosis

- All patients with liver fibrosis (F3 or F4) will need:
  - Liver cancer surveillance

- All patients with liver fibrosis F4 (Cirrhosis) will need:
  - Upper GI Endoscopy: For esophageal varices screening
  - Screening for hepatic encephalopathy

- Patients with decompensated cirrhosis need to be referred to a liver transplant center

HCV Workflow

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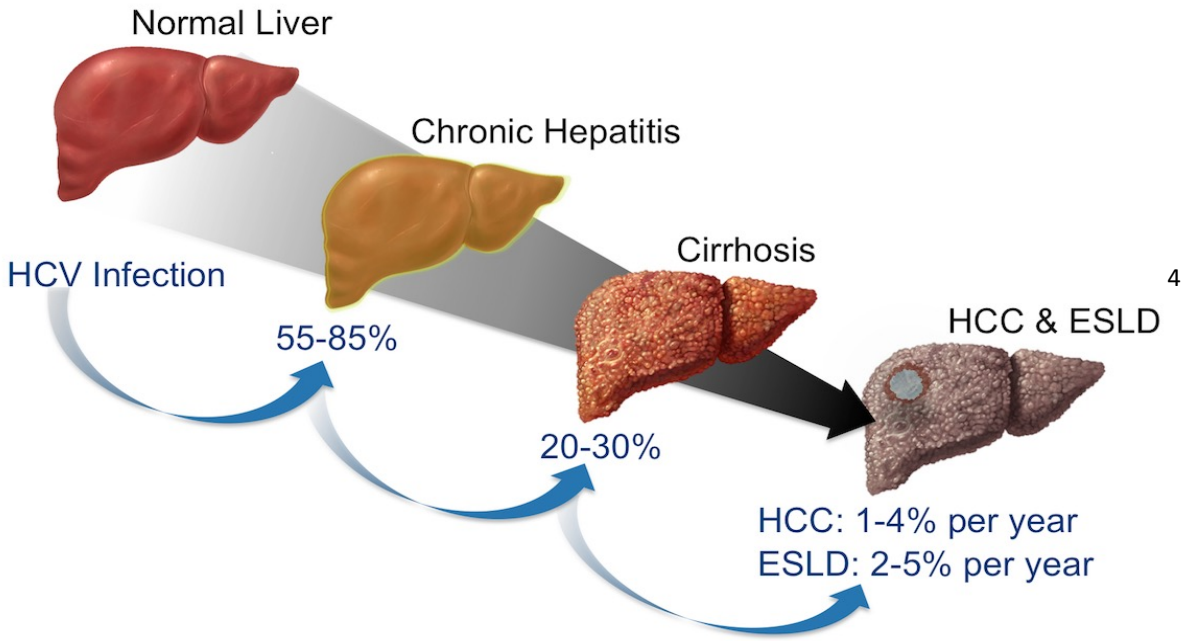
Natural History Following Initial Infection with HCV



[4]

Abbreviations: ESLD = end-stage liver disease HCC = hepatocellular carcinoma

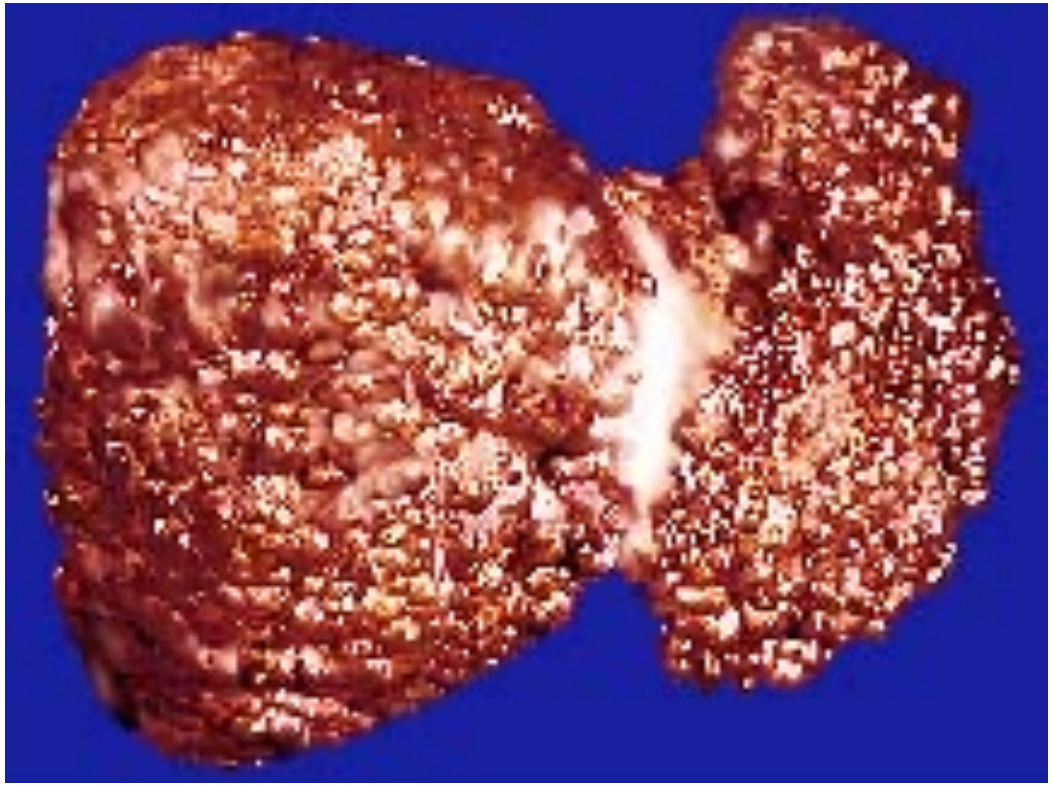
Rates of progression to cirrhosis are increased in the presence of a variety of factors, including:

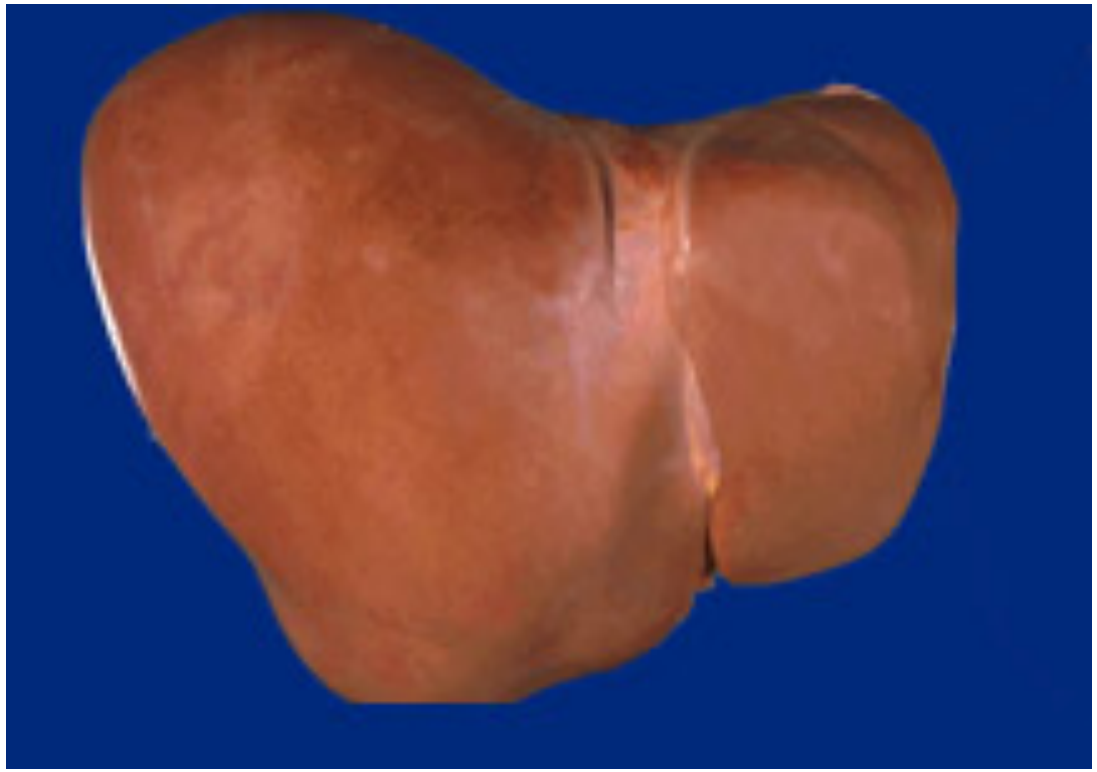
- Being male
- Being age >50 years
- Consuming alcohol
- Having nonalcoholic fatty liver disease, hepatitis B, or HIV coinfection
- Receiving immunosuppressive therapy[1,2,3]

1.Liang TJ, Rehermann B, Seeff LB, Hoofnagle JH. Pathogenesis, natural history, treatment, and prevention of hepatitis C. Ann Intern Med. 2000;132(4):296-305. 2. Thomas DL, Seeff LB. Natural history of hepatitis C. Clin Liver Dis. 2005;9(3):383-98. 3. Westbrook RH, Dusheiko G. Natural history of hepatitis C. J Hepatol. 2014;61(1 Suppl):S58-68. 4. Lingala S, Ghany MG. Natural History of Hepatitis C. Gastroenterol Clin North Am. 2015;44:717-34.

What Does HCV Treatment and Cure Accomplish?

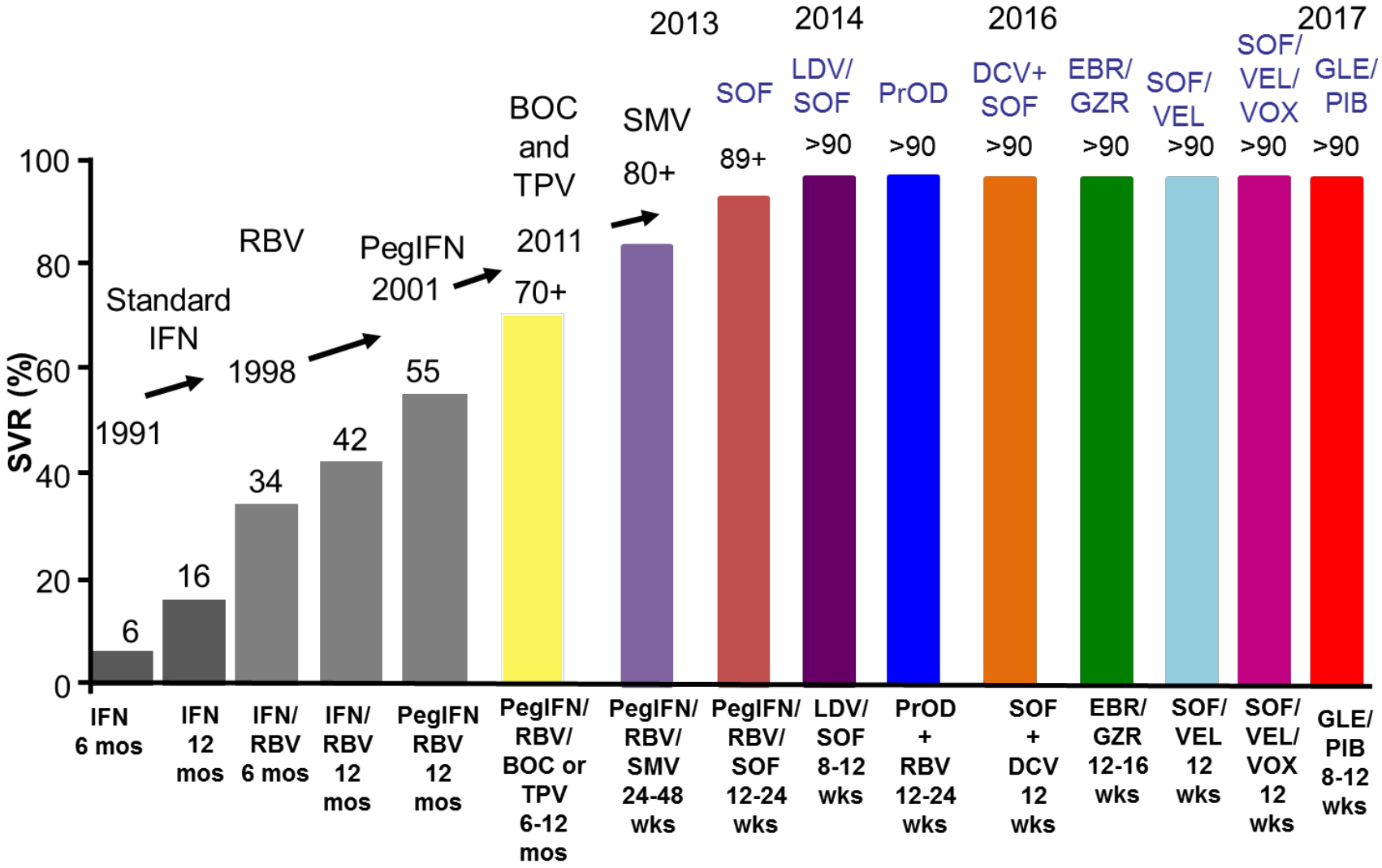
- 70% Reduction of Liver Cancer
- 50% Reduction in All-cause Mortality
- 90% Reduction in Liver Failure





- Lok A. NEJM 2012; Ghany M. Hepatol 2009; Van der Meer AJ. JAMA 2012

The Evolution of Highly Effective Treatment



HCV Therapies – Direct Acting Antivirals (DAAs)

Medication	NS5B Inh	NS5A Inh	NS3/4A PI	Other
Epclusa®	sofosbuvir	velpatasvir		
Mavyret®		pibrentasvir	glecaprevir	

NS5B Inh – Nonstructural protein 5B Polymerase Nucleotide Analog Inhibitor
NS5A Inh – Nonstructural protein 5A Inhibitor
NS3 PI – Nonstructural protein 3/4A Protease Inhibitor

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 (Without Cirrhosis)

Patients who have any of the following characteristics:

- Prior hepatitis C treatment
- Cirrhosis (see simplified treatment for treatment-naive adults with compensated cirrhosis)
- HBsAg positive
- Current pregnancy
- Known or suspected hepatocellular carcinoma
- Prior liver transplantation

(see HCV guidance for treatment recommendations for these patients)

Simplified HCV Treatment Algorithm for Treatment-Naive Adults With Cirrhosis

Who Is Eligible for Simplified Treatment

Adults with chronic hepatitis C (any genotype) who have compensated cirrhosis (Child-Pugh A) and have not previously received hepatitis C treatment
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/mm^3, etc)
- Prior liver biopsy showing cirrhosis

Who Is *NOT* Eligible for Simplified Treatment (With Cirrhosis)

Patients who have any of the following characteristics:

- Current or prior episode of decompensated cirrhosis, defined as Child-Turcotte-Pugh (CTP) score ≥7 (ascites, hepatic encephalopathy, total bilirubin >2.0 mg/dL, albumin ≤3.5 g/dL, or INR ≥1.7)
- Prior hepatitis C treatment
- End-stage renal disease (ie, eGFR <30 mL/min/m^2) (see Patients with Renal Impairment section)
- HBsAg positive
- Current pregnancy
- Known or suspected hepatocellular carcinoma
- Prior liver transplantation

(see HCV guidance for treatment recommendations for these patients)

https://www.hcvguidelines.org/

A Patient has Cirrhosis if any of the following are present:

FIB-4 > 3.25

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/mm^3**, etc)

Prior liver biopsy showing cirrhosis

https://www.hcvguidelines.org/

Simplified Pretreatment Laboratory Testing in Patients with HCV and Without Cirrhosis

Within 6 months of initiating treatment:

- Complete blood count (CBC)
- Comprehensive metabolic panel (CMP) Hepatic function panel (ie, albumin, total and direct bilirubin, alanine aminotransferase [ALT], 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.

https://www.hcvguidelines.org/

Simplified Pre-Treatment Assessment in Patients With or Without 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.
  - Drug-drug interactions are particularly important in HIV co-infection
  - In those with HIV, the simplified treatment approach should not be used in those on TDF containing regimens with eGFR <60 ml/min because of the need of additional monitoring.

Education:

- Educate the patient about proper administration of medications, adherence, and prevention of reinfection.

https://www.hcvguidelines.org/

Recommended Regimens in Patients Without Cirrhosis

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

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

Monitoring During Treatment

- No laboratory or clinical monitoring is required for the majority of patients
- **Monitor for hypoglycemia** In diabetic patients
- **Monitor INR** in patients taking warfarin
- Consider in-person or telehealth/phone visit if needed for patient support

NOTE: Patients with genotype 3 require baseline NS5A resistance-associated substitution (RAS) testing. Those without Y93H can be treated with 12 weeks of sofosbuvir/velpatasvir. If Y93H is present, see HCV guidance for treatment recommendations.

https://www.hcvguidelines.org/

Post-Treatment Assessment of Cure (SVR12) in Patients With or Without Cirrhosis

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.

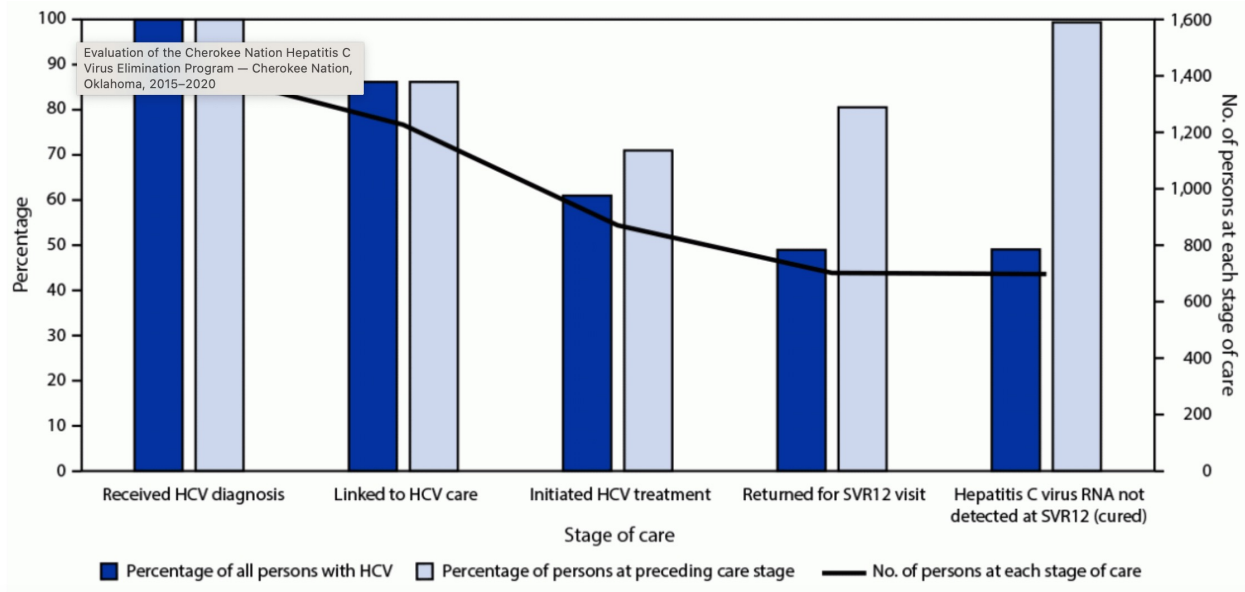
Patients with ongoing risk for HCV infection (eg, intravenous drug use or MSM engaging in unprotected sex) should be counseled about risk reduction, and tested for HCV RNA annually and whenever they develop elevated ALT, AST, or bilirubin.

Advise patients to avoid excess alcohol use.

Assessment for other causes of liver disease is recommended for patients with elevated transaminase levels after achieving SVR.

https://www.hcvguidelines.org/

Cascade of care among persons with hepatitis C virus infection (N = 1,423) — Cherokee Nation Health Services, Oklahoma, November 2015–October 2020



Abbreviations: HCV = hepatitis C virus; SVR12 = sustained virologic response >12 weeks after treatment completion.

- Five years after implementing a hepatitis C elimination program, Cherokee Nation Health Services (CNHS) had diagnosed hepatitis C in 1,423 persons
  - 86% of whom were linked to care.
  - 61% initiated treatment
  - 99% of those who completed treatment were cured.

Essex W, Feder M, Mera J. Evaluation of the Cherokee Nation Hepatitis C Virus Elimination Program — Cherokee Nation, Oklahoma, 2015–2020. MMWR Morb Mortal Wkly Rep 2023;72:597–600.

Syndemic

Cherokee Nation Comprehensive HCV Care Model

Universal Screening
All patients aged 18 and older

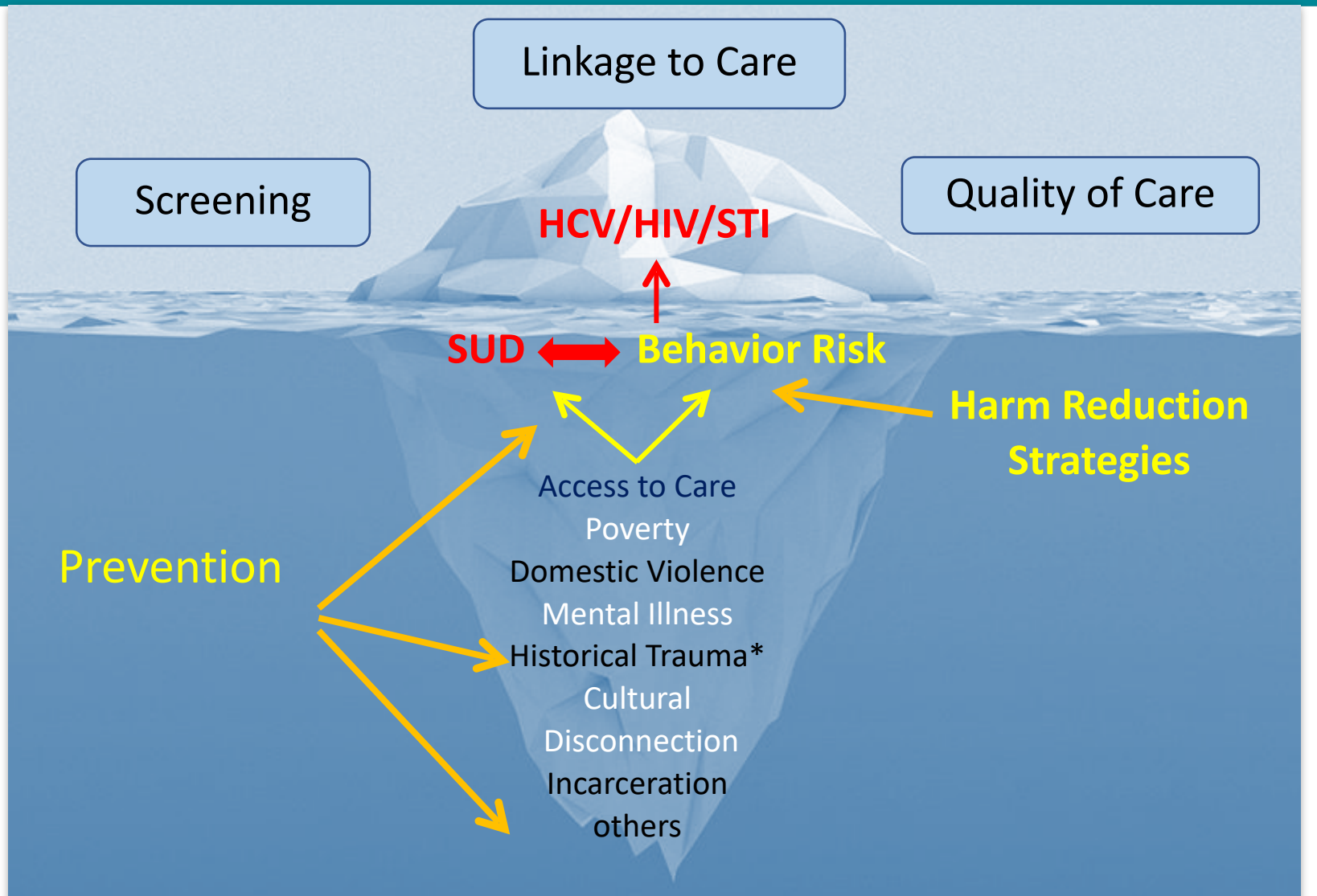
Patient Navigator
Staff contacts HCV+ individuals and arranges follow-up testing and evaluation

HCV Evaluation and Non-Adherence Risk Assessment
Nurse, BH counselor, HCV provider, case manager, pharmacist, community health worker

HCV Treatment
All patients offered treatment

Community Health Worker
Home visits for patients at high risk of non-adherence

Maria Yellow Horse Brave Heart Journal of Psychoactive Drugs Vol. 35, Iss. 1, 2003



Conclusions

- Hepatitis C can be cured and eliminated
- Simplified treatment algorithms are available
- Eliminating HCV as a public health problem will require a multipronged approach
- HCV evaluation and treatment should be integrated into primary care
- Primary care providers should be at the forefront of HCV treatment, If they are not, nobody will be.

Helpful Resources

http://www.npaihb.org

Text HCV 97779

http://www.hcvguidelines.org/

http://www.hepatitisc.uw.edu/

On-line curriculum on liver disease and HCV, includes clinical studies, clinical calculators, slide lectures

ProjectECHO HCV guidelines