Screening, Diagnosing, and Treating Chronic Hepatitis C in Primary Care

A Patient-Centered Approach

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NJAFP New Jersey Academy of Family Physicians

Expert Panel

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Expert Panel Disclosures

- Cathryn Heath, MD, FAAFP and Ponni Perumalswami, MD report no financial relationships.
- Alain Litwin, MD has reported the he has received consulting fees from Merck and Co., Inc. and Gilead Pharmaceuticals.
- Theresa Barrett, PhD, Charles Goldthwaite, PhD (Planners) and Adity Bhattacharyya, MD (reviewer) report no financial relationships.

Conflicts have been resolved according to NJAFP policy.

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Speaker Disclosure

- **John Andazola, MD has indicated that he has nothing to disclose relevant to this presentation.**

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Learning Objectives

1. Screen appropriate individuals for HCV infection.
2. Interpret results of anti-HCV antibody and HCV RNA tests.
3. Explain the importance of sustained virologic response in the treatment of HCV.

Learning Objectives

4. Describe the appropriate use of new therapies for treating HCV infection.
5. Follow AASLD/IDSA/IAS-USA guidelines for treating individuals who have active HCV infection.
6. Use tenets of the patient-centered medical home to identify and manage factors that may impact therapy for individuals with HCV infection.

Epidemiology, Impact, and Risk Factors for HCV Infection

What is Hepatitis?

- Inflammation of the liver caused by viral infection, toxic agents, or autoimmune reactions
- In the US, hepatitis A virus (HAV), hepatitis B virus (HBV), and hepatitis C virus (HCV) account for most viral hepatitis infections
- Infected individuals often asymptomatic
- Vaccines available for HAV and HBV but not HCV

HCV: The "Silent Epidemic"

- ~185 million individuals are infected with HCV worldwide (350,000 deaths/year).[1]
- HCV is the most common chronic blood-borne infection in the US (2.7-3.2 million infections).[2]
- In the US, HCV causes more deaths than HIV.[3]
- 75% of infected individuals will develop chronic HCV.[2]

Sources: [1]World Health Organization. Guidelines for the screening, care and treatment of persons with hepatitis C infection (2014); [2]Ly KN, et.al. *Ann Intern Med.* 2012;156:271-278; [3]Armstrong GL, et.al. *Ann Intern Med.* 2006;144:705-714.

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The Impact of HCV

- Chronic HCV infection can lead to cirrhosis, end-stage liver disease, and hepatocellular carcinoma (HCC).
- HCV-associated disease is the leading cause of HCC and leading indication of liver transplantation in the US.[1]
- HCV-related mortality is projected to peak in 2030-2035 at ~36,100 deaths, 3,200 referrals for liver transplants, and 38,600 cases of end-stage liver disease.[2]

Sources: [1]Younossi ZM, et al. *Aliment Pharmacol Ther.* 2014;39:518-531; [2]Rein DB, et al. *Ann Intern Med.* 2012;156:263-270.

The Outcome of HCV Infection

100 persons infected w/ HCV

75-85 Chronic infection

60-70 Chronic liver disease

5-20 Cirrhosis

1-5 Death from HCC or cirrhosis

Source: CDC. Hepatitis C information for health professionals: Hepatitis C FAQs for health professionals. http://www.cdc.gov/hepatitis/HCV/HCVfaq.htm#section5.

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Risk Factors for HCV Infection

- Injection or intranasal illicit drug use‡
- Long-term hemodialysis
- Occupational exposure to HCV-infected blood
- Previous incarceration
- Transfusion/transplant prior to July 1992
- HIV infection
- Unexplained chronic liver disease

‡Intravenous drug use accounts for ≥ 60% of acute HCV infections in the US.

Source: American Association for the Study of Liver Diseases, Infectious Diseases Society of America, International Antiviral Society-USA. Recommendations for testing, managing, and treating hepatitis C. www.hcvguidelines.org.

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HCV Transmission

Yes

- Blood
- Contaminated drug paraphernalia
- Mother-to-infant
- Sexual intercourse (most likely among men who have sex with men)

No

- Casual contact
- Kissing/hugging
- Sneezing/coughing
- Breastfeeding
- Sharing food, utensils, glasses

Sources: AASLD/IDSA/IAS-USA. Recommendations for testing, managing, and treating hepatitis C. www.hcvguidelines.org; CDC. Know more hepatitis. http://www.cdc.gov/knowmorehepatitis/LearnMore.htm.

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Screening and Testing Individuals for Current HCV Infection

Screening for HCV Infection

- HCV testing is recommended at least once for persons born between 1945 and 1965.

- Other persons should be screened for risk factors for HCV infection.
- At least one-time testing should be performed for all persons at increased risk of HCV infection.

Supported by: CDC, USPSTF (Grade B recommendation), and AASLD/IDSA/IAS-USA.

Sources: Smith BD, et al. *MMWR Recomm Rep.* 2012;61(RR-4):1-31; Moyer VA, USPSTF. *Ann Intern Med.* 2013;159:349-357; AASLD/IDSA/IAS-USA. www.hcvguidelines.org.

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Screening for HCV Infection (2)

- Annual HCV testing is recommended for persons who inject drugs and for HIV-seropositive men who have unprotected sex with men.
- Periodic testing should be offered to other persons with ongoing risk for exposure to HCV.

Source: AASLD/IDSA/IAS-USA. www.hcvguidelines.org.

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Testing for HCV Infection

- Candidates identified from screening should be tested for HCV antibody to determine if the individual has ever produced HCV antibodies, regardless of whether the infection has been cleared.
- Antibody-reactive individuals should receive an HCV RNA test to measure current viral load.
- Tests can be performed in primary care or through referral.

Source: CDC. *MMWR Morb Mortal Wkly Rep* 2013;62:362-365.

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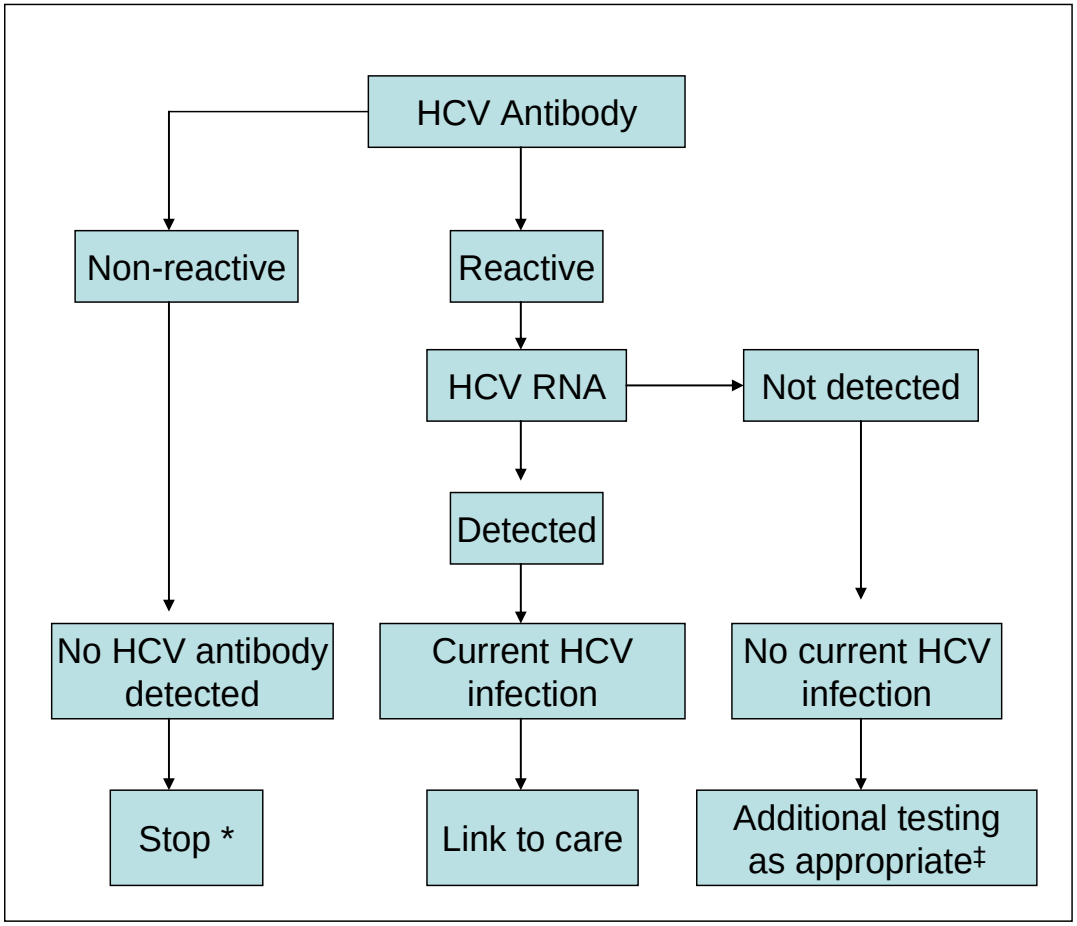
Identifying Current HCV Infection



Source: CDC. *MMWR Morb Mortal Wkly Rep* 2013;62:362-365.

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Informing Patients about Results

- Individuals who have positive results for an HCV antibody test but negative results for an HCV RNA test should be informed that they do not have evidence of current (active) HCV infection.
- Persons with current (active) HCV infection (e.g., positive results from both tests) should receive education and interventions aimed at reducing progression of liver disease and preventing HCV transmission.

Source: AASLD/IDSA/IAS-USA. www.hcvguidelines.org.

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Managing HCV Infection in the Patient-Centered Medical Home (PCMH)

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What to Do When a Patient Tests Positive for HCV

- Advise abstaining from alcohol consumption
- Advise interventions to facilitate cessation of alcohol consumption (if necessary)
- Evaluate for conditions that may accelerate liver fibrosis (e.g., HBV, HIV infection).
- Assess degree of liver fibrosis and the need for additional screening for conditions such as hepatocellular carcinoma
- Vaccinate against HAV and HBV

Source: AASLD/IDSA/IAS-USA. www.hcvguidelines.org.

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Advising HCV-Positive Patients*

- Caution against using non-steroidal anti-inflammatory agents (NSAIDs), which are associated with liver damage, in patients with cirrhosis.

- Avoid herbal supplements, which are unregulated and of unknown hepatic toxicity.
- Limit daily acetaminophen intake to 2,000 mg or less.
- Allow use of statins.

*Represents views of Panel faculty based on field consensus.

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Counseling Suggestions for HCV-Positive Individuals

- Inform about the low but present risk for HCV transmission with sex partners, particularly for men who have sex with men
- Avoid sharing personal items that may contain blood (e.g., toothbrushes, razors)
- Cover cuts and sores
- Consider joining a support group
- Consult with a health professional before taking any new medications or supplements.

Source: CDC. http://www.cdc.gov/hepatitis/HCV/HCVfaq.htm#section5.

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Treating and Managing HCV Infection:

Assessing Liver Health

Treatment Goals

HCV treatment should aim to:

Prevent or reduce long-term viral complications such as cirrhosis, liver failure, or HCC.

This goal can be achieved by:

- Eradicating the virus
- Promoting healthy liver function

Source: Chou R, et.al. *Ann Intern Med.* 2013;158:114-123.

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Sustained Virologic Response (SVR)

- Defined as complete eradication of the virus from the blood (e.g., the absence of detectable HCV RNA in serum 3 months after completing treatment)
  - Associated with lower all-cause mortality, incidence of HCC, liver failure, and transplantation.[1,2]
  - Reduces the risk of future liver damage and may, in some cases, reverse existing liver damage.[3]

Sources: [1]van der Meer AJ, et. al. *JAMA.* 2012;308:2584-2593; [2]Chou R, et.al. *Ann Intern Med.* 2013;158:114-123; [3]Lee YA, Friedman SL. *Antiviral Res.* 2014;107:23-30.

Staging Liver Disease

Fibrosis

↓

Compensated Cirrhosis

- Prolonged
- Asymptomatic

↓

Decompensated Cirrhosis

- Rapidly-progressing
- Symptomatic complications of liver dysfunction (ascites, GI bleeding, jaundice)

Source: D'Amico G, et.al. *J Hepatol.* 2006;44:217-231.

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Tools to Stage Liver Disease

- Biopsy
- Ultrasound
- Transient elastography
- Serum biomarker panel-based tests
- AST-to-platelet ratio index (APRI)
- Fibrosis-4 index (FIB-4)

Non-Invasive Staging: The APRI Index

$$\textbf{APRI} = \frac{\dfrac{\text{AST level (IU/mL)}}{\text{AST (Upper limit of normal)*}}}{\text{Platelet Count } (10^9/\text{L})} \times 100$$

*The upper limit of normal established by the laboratory that performed the test. An APRI score of 0.7 indicates significant fibrosis, whereas a score > 1.0 indicates cirrhosis.

Source: University of Washington. http://www.hepatitisc.uw.edu/page/clinical-calculators/apri.

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Non-Invasive Staging: The FIB-4 Index

$$\textbf{FIB-4} = \frac{\text{Age (yrs) X AST level (U/L)}}{\text{Platelet Count (109/L) x } \sqrt{\text{ALT (U/L)}}}$$

FIB-4 scores roughly correspond to liver biopsy METAVIR scores as follows: FIB-4 scores less than 1.45 correspond to an F0-F1 METAVIR score (no scarring/minimal scarring), whereas a FIB-4 score > 3.25 corresponds to an F3-F4 METAVIR score (e.g., extensive scarring without cirrhosis or cirrhosis).

Source: University of Washington. http://www.hepatitisc.uw.edu/page/clinical-calculators/fib-4.

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Assessing Treatment Readiness

- The decision to initiate treatment depends on:
  - Liver condition
  - Comorbid health conditions
  - Psychosocial readiness to undergo treatment regimens

HCV treatment is safe and effective for persons who inject drugs, with interventions focusing on behaviors to reduce the risk of reinfection and limit the spread of HCV in the community.[1]

Sources: [1]Robaeys G, et al. *Clin Infect Dis.* 2013; 57 Suppl 2: S129-S137.

Testing HCV Genotype

- Six distinct HCV genotypes (genotypes 1–6) and more than 50 subtypes have been identified.
- Genotype 1 is most common in the US.
- Some treatment regimens are most effective against a specific genotype.
- Identifying the infected individual's HCV genotype is essential to guide treatment.
- A single genotype test will suffice; genotypes do not change during the course of infection.

Treating and Managing HCV Infection

Pharmacology

An Overview

- Treatments for HCV are being developed and approved at an unprecedented pace.
- Development of direct-acting antiviral agents (DAAs) for genotype-based HCV treatment has dramatically changed paradigms.
- Oral DAAs are now the central feature of HCV treatment regimens, and numerous new agents and regimens are currently in clinical trials.
- All agents are indicated for combination therapy.

FDA-Approved HCV Agents

Interferon (IFN)/ Pegylated interferon (PEG IFN)	•Cytokines •Injectable
Ribavirin (RNV)	• Oral nucleoside inhibitor
•Boceprevir* •Simeprevir (SMV)*	•HCV NS3/4A protease inhibitors
Sofosbuvir (SOF)*	•HCV NS5B protease inhibitor
SOF/Ledipasvir* Fixed-Dose	•HCV NS5B/NS5A inhibitors
Ombitasvir*/Paritaprevir*/Ritonavir + Dasabuvir*	•HCV NS5A/NS3-4A/NS5B inhibitors

*Oral Direct-acting antiviral agents.

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The Interferons (IFN) and Ribavirin (RBV)

- Mainstay of HCV treatment prior to DAAs[1]
- IFN's mode of delivery and side-effect profile (e.g., fatigue, headache, neuropsychiatric effects, and flu-like symptoms) hamper adherence and dosing[2]
- PEG IFN and RBV are currently combined with DAAs in many current recommendations
- However, genotype-specific IFN-free regimens have been developed
- Field incentivized to develop effective oral, pan-genotype, IFN-free regimens

Sources: [1]Foster GR. *Drugs.* 2010;70:147-165; [2]Fried MW, et.al. *N Engl J Med.* 2002;347:975-982.

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Simeprevir (SMV)

- Approved in 2013 in combination with PEG IFN/RBV to treat chronic genotype 1 HCV infection
- Adding SMV to a PEG/RBV regimen improves SVR among treatment-naïve and relapsed individuals with chronic HCV genotype 1 infection
- Adverse events similar to those observed with PEG/RBV alone, with the exception being mild, reversible jaundice

Source: Kanda T, et.al. *Ther Clin Risk Manag.* 2014;10:387-394.

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Sofosbuvir (SOF)

- SOF + RBV/PEG IFN increases SVR relative to RBV/PEG IFN alone with minimal side effects[1-3]
- Approved to treat HCV genotypes 1-4[4]
- Approved for IFN-free regimens for genotypes 1-3[4]
- Treatment reduced to 12 weeks for certain regimens for genotypes 1, 2, and 4
- Indicated for HCV/HIV co-infected individuals

Sources: [1]Jacobson IM, et al. *N Engl J Med.* 2013;368:1867-1877; [2]Lawitz E, et al. *N Engl J Med.* 2013;368:1878-1887; [3]Zeuzem S, et al. *N Engl J Med.* 2014;370:1993-2001; [4]US FDA. http://www.fda.gov/forconsumers/byaudience/forpatientadvocates/ucm377920.htm.

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FDA-Recommended Regimens for SOF Combination Therapy

HCV Genotype	Treatment Regimen	Duration
1 or 4	SOF + PEG IFN + RBV	12 wks*
2	SOF + RBV	12 wks
3	SOF + RBV	24 wks
*SOF + RBV for 24 wks can be considered for IFN-ineligible HCV genotype 1.		

Source: US FDA.
http://www.fda.gov/forpatients/illness/hepatitisbc/ucm377920.htm

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Sofosbuvir/Ledipasvir Fixed-Dose Combination Tablets

- Approved by FDA on October 10, 2014
- Indicated to treat chronic HCV genotype 1 infection in adults
- Dosage: 1 tablet/day, with or without food
- First FDA-approved regimen that does not require administration with RBV or IFN

Source: US Food and Drug Administration. http://content.govdelivery.com/accounts/USFDA/bulletins/d4f738.

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FDA-Recommended Regimens for Fixed-Dose SOF/Ledipasvir Tablets

Patient Population	Recommended Duration
Treatment-naïve with or without cirrhosis	12 weeks*
Treatment-experienced without cirrhosis	12 weeks
Treatment-experienced with cirrhosis	24 weeks
*May be considered for 8 weeks in treatment-naïve patients without cirrhosis who have pre-treatment HCV RNA < 6 million IU/mL.	

Source: US Food and Drug Administration. http://content.govdelivery.com/accounts/USFDA/bulletins/d4f738.

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Ombitasvir/Paritaprevir/Ritonavir (OPR) + Dasabuvir Combo Pack

- Approved by FDA on December 19, 2014
- Indicated to treat chronic HCV genotype 1 infection in adults +/- compensated cirrhosis
- Dosage: 2 OPR tablets once daily + 1 dasabuvir tablet twice daily
- Does not necessarily require administration with RBV

Source: US Food and Drug Administration. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm427530.htm.

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FDA-Recommended Regimens for OPR + Dasabuvir Combo Pack

Patient Population	Add RBV?	Recommended Duration
Genotype 1a, no cirrhosis	Yes	12 weeks
Genotype 1a, with cirrhosis	Yes	24 weeks*
Genotype 1b, no cirrhosis	No	12 weeks
Genotype 1b, with cirrhosis	Yes	12 weeks
*May be considered with RBV for 12 weeks in some patients, based on treatment history.		

Source: AbbVie. Prescribing information for Viekira Pak. http://www.rxabbvie.com/pdf/viekirapak_pi.pdf.

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Treatment Regimens

- See AASLD/IDSA/IAS-USA guidelines for current genotype-specific recommendations[1]
- IFN-free oral regimens are current standard of care to treat HCV genotypes 2 and 3
- Such approaches eliminate IFN side effects, promote compliance, and reduce treatment duration and the need for ongoing viral load monitoring
- Expected to become standard of care for treating all HCV genotypes

Source: [1]AASLD/IDSA/IAS-USA. Recommendations for testing, managing, and treating hepatitis C. www.hcvguidelines.org.

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HCV Treatment: What's Next?

- Numerous investigational DAAs are currently in Phase III clinical trials
- FDA approving HCV products at rapid pace (4 drug products approved from Dec 2013-Dec 2014)
- Combinations are IFN-free (and in some cases IFN- and RBV-free) oral regimens
- Fixed–dose and single-tablet regimens under evaluation

Note: Recommendations for treating chronic HCV are constantly evolving.

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HCV Resources

CDC	·HCV management resources ·Patient fact sheets* ·Guidelines
Hepatitis C Online (Univ of Washington)	·CME ·Clinical calculators and guidelines
AASLD/IDSA/IAS-USA	Evolving evidence-based HCV management guidelines Online courses for primary care physicians
International Network on Hepatitis in Substance Users	Practice guidelines specific to substance users
*Spanish and/or other language materials available.	

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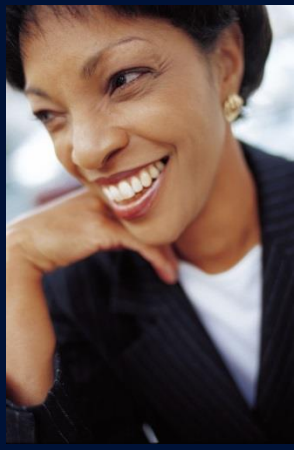
Case Study

Sharon

Case Study: Sharon



- 40-year-old African-American non-smoker with diabetes (BMI = 30.5 kg/m^2)
- Married with one child
- Family history of heart disease
- Received transfusion in 1994
- Takes metformin and an ACE inhibitor
- Used illicit drugs intra-nasally sporadically during a period of four years in late adolescence, with a one-time use of injectable drug

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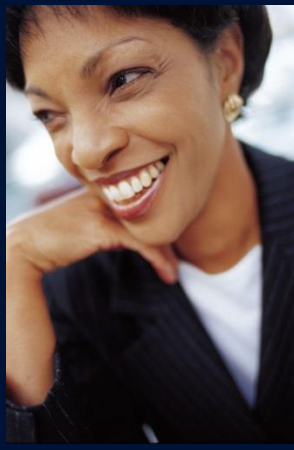
Case Study: Sharon

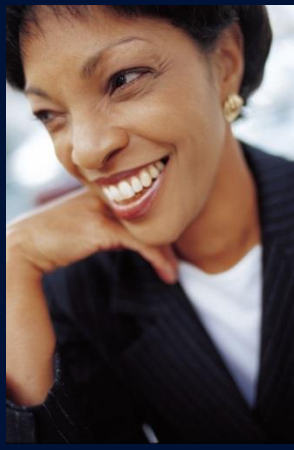


1. According to the latest screening recommendations from the CDC, should Sharon be screened because of her age?

a) Yes
b) No

(*Please mark your answer on your answer sheet)*

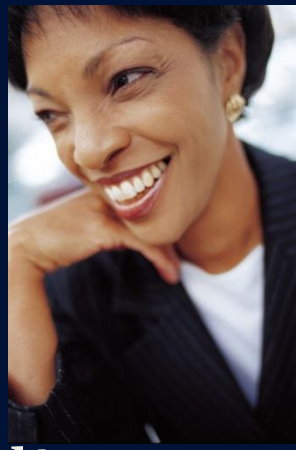
Case Study: Sharon



Sharon's laboratory workup values include:

- Total bilirubin: 0.8 mg/dL
- AST: 95 U/L
- ALT: 86 U/L
- Platelet count: 90 x 10^9/L
- Serum albumin: 3.4 g/dL
- International normalized ratio (INR): 1.1
- Encephalopathy: no symptoms

Case Study: Sharon



2. According to AASLD/IDSA/IAS-USA guidelines, which of Sharon's risk factors indicate that she should receive a hepatitis C antibody test? (select all that apply):

a) Previous intra-nasal illicit drug use
b) Transfusion received in 1994
c) One-time illicit injectable drug use
d) BMI > 30 kg/m^2
e) Family history of heart disease

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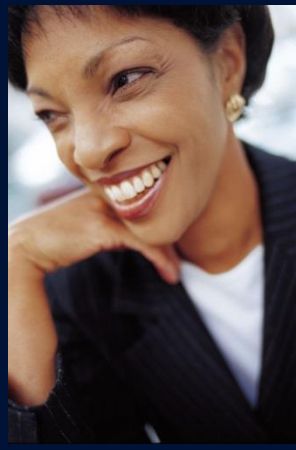
Case Study: Sharon



3. Sharon's HCV antibody test is positive. What should you do next?

a) Nothing at present; her ALT value suggests a "watch and wait" strategy
b) Repeat HCV antibody test
c) Order an HCV RNA test
d) Order an ultrasound
e) Refer to a specialist

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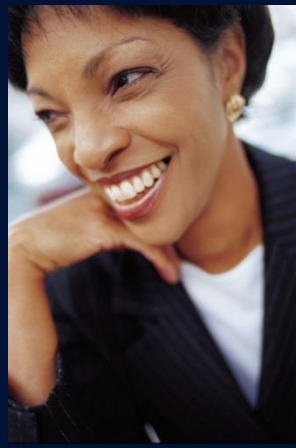
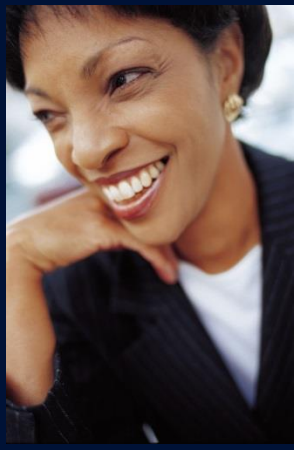
Case Study: Sharon



4. Sharon's viral load test indicates current HCV infection. You counsel her about the significance of chronic HCV infection. In light of her results and her general health, which of the following statements would **not** apply to Sharon?

Case Study: Sharon



4. Which of the following statements would **not** apply to Sharon?

a) Avoid/abstain from alcohol (less than two drinks/day)
b) Use a screen to perform a more thorough alcohol assessment
c) Recommend that she be vaccinated against influenza, hepatitis A, and hepatitis B
d) Incorporate diet and activity into her lifestyle
e) Practice barrier protection during sex to avoid infecting her husband with HCV (assuming a monogamous relationship).

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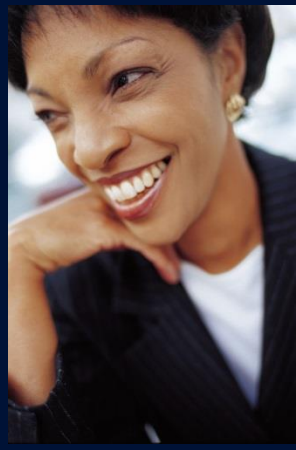
Case Study: Sharon



5. Based on Sharon's laboratory workup, which of the following are viable options to stage her liver disease?

a) Ultrasound
b) Biomarker-based tests (e.g., APRI or FIB-4)
c) Transient elastography
d) Liver biopsy
e) All of the above

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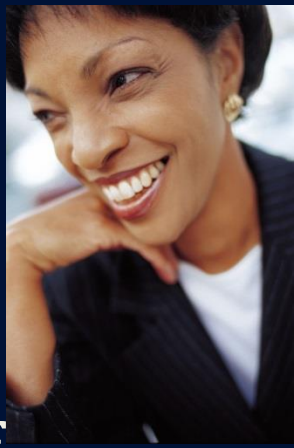
Case Study: Sharon



6. Based on Sharon's laboratory values (assuming an upper limit of normal for AST of 40 IU/L), Sharon's APRI score is 2.64. This score suggests:

a) Fibrosis
b) Cirrhosis
c) Hepatocellular carcinoma
d) Neither fibrosis nor cirrhosis

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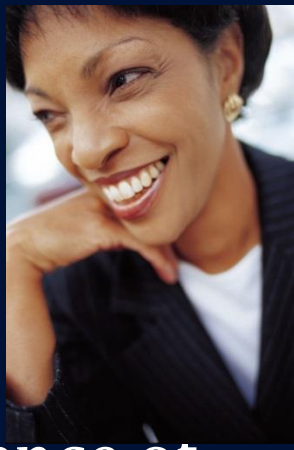
Case Study: Sharon



7. You order an ultrasound, which indicates that no ascites are present. In addition, there is no evidence of HCC or liver cancer. Based on these results, Sharon has:

a) No indications of cirrhosis
b) Compensated cirrhosis
c) Decompensated cirrhosis
d) Hepatocellular carcinoma
e) Advanced fibrosis

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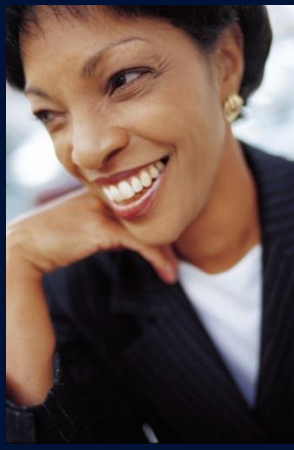
Case Study: Sharon



8. Sharon is HCV genotype 1. You put her on a treatment regimen using AASLD/IDSA/IAS-USA recommendations. Assuming that she completes her treatment and achieves SVR, what should you consider? (Select all that apply)

a) Monitor for signs of decompensated liver complications
b) Counsel on HCV risk reduction (e.g., continued abstinence from drug use)
c) Refer her to a transplant center
d) Retest for HCV antibody

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Conclusions

- Chronic HCV infection can lead to cirrhosis, end-stage liver disease, and hepatocellular carcinoma.
- Primary care clinicians can manage HCV infection by screening appropriate individuals, providing counseling, staging underlying liver disease, and treating infection using direct-acting antiviral (DAA) agents.

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Questions

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