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Hepatitis C

About the Guideline

- This guideline was developed for practitioners and is intended to guide the diagnosis, management, and treatment of adults with hepatitis C virus (HCV).
- This guideline was developed from the best available evidence and was preceded by a very thorough literature review process; the recommendations were rated based on level of evidence.
- The panel consisted of members from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA). The members were selected based on their expertise in diagnosis, management, treatment, research, and patient care.
- This guideline focuses on universal screening, management of incomplete treatment adherence, expanded eligibility for simplified chronic HCV treatment, updated treatment and retreatment recommendations, and management and treatment recommendations in the setting of transplantation.

Key Clinical Considerations

Become familiar with the recommendations and best-practice statements provided in this guideline, especially if you work in an acute care setting.

Universal HCV Screening

- A one-time screening test is recommended for all individuals 18 years and older and for all pregnant persons during each pregnancy (except in settings where HCV prevalence is less than 0.1%). This testing is recommended by the Centers for Disease Control and Prevention (CDC), and the U.S. Preventive Services Task Force.
- Initial HCV screening with an FDA-approved HCV-antibody test with reflex HCV RNA polymerase chain reaction is recommended to detect presence of active infection.

Management of Incomplete Direct-Acting Antiviral (DAA) Adherence

- For treatment interruptions before receiving 28 days of direct-acting antiviral (DAA) therapy, the following is recommended:
    - If treatment is missed for 7 days or less, immediately restart DAA therapy. Complete therapy as originally planned for prescribed duration (8 or 12 weeks).
    - If treatment is missed for 8 days or more, immediately restart DAA therapy, and obtain an HCV RNA test as soon as possible after restarting (preferably the same day).
        - If HCV RNA is negative, complete the originally planned treatment course. For patients with genotype 3 infection and/or compensated cirrhosis, it is recommended to extend treatment for an additional 4 weeks.
        - If HCV RNA is positive or was not obtained, extend treatment for an additional 4 weeks.
- For treatment interruptions after receiving 28 or more days of therapy, the following is recommended:

- If treatment is missed for 7 days or less, restart treatment immediately.
- If treatment is missed for 8 to 20 consecutive days, restart treatment immediately, and obtain an HCV RNA test as soon as possible after restarting (preferably the same day).
  - If HCV RNA is negative, complete the originally planned treatment course. For patients with genotype 3 infection and/or compensated cirrhosis, it is recommended to extend treatment for an additional 4 weeks.
  - If HCV RNA is positive or was not obtained, stop treatment and retreat.
- If treatment is missed for 21 or more consecutive days, stop treatment and assess for sustained virologic response 12 weeks after completion of therapy (SVR12). If SVR12 is not achieved, retreat.

Initial Treatment

- Universal treatment with DAA is strongly recommended for all patients with acute or chronic HCV.
  - Eligibility for simplified treatment for adults with chronic HCV infection (including those with HIV) include the following:
    - Individuals infected with any genotype
    - Individuals who have not previously received treatment for HCV infection
    - Individuals without cirrhosis or those with compensated cirrhosis
  - Exclusion from simplified treatment for adults with chronic HCV infection include the following:
    - Those who have previously received HCV treatment
    - Those who are hepatitis B surface-antigen positive
    - Those with compensated cirrhosis with end-stage renal disease
    - Those with current or previous decompensated cirrhosis
    - Those who are currently pregnant
    - Those with known or suspected hepatocellular carcinoma
    - Those with prior liver transplantation

Counseling and Care for Persons with Active HCV Infection

- Individuals with current HCV infection should be evaluated, treated, and educated about disease management; antiviral therapy should be initiated for patients with active and chronic infections, except those with short life expectancy who cannot be remediated by HCV therapy, liver transplant, or direct therapy.
- If resources are limited, patients at higher risk for disease complications but without cirrhosis and those who have not previously received HCV treatment should have prioritized, simplified treatment.
- Noninvasive testing or liver biopsy is recommended to identify the presence of hepatic fibrosis. Staging is usually determined by liver biopsy, but the potential for sample errors must be taken into account.
- Hepatitis B (HCB) and HIV testing should be completed, as well as an evaluation for other conditions that can accelerate liver fibrosis.
- Hepatitis A and hepatitis B vaccination is recommended for patients with HCV infection.
- Pneumococcal vaccine is recommended for patients with cirrhosis.

Treatment

- Recommendations for treatment are focused on treatment-naïve patients and treatment for those with prior therapy failure.
    - Treatment is further guided by the patient's HCV genotype, which is identified as genotype 1a, 1b, 2, 3, 4, 5, or 6.
- Recommended HCV treatment includes medications from the following classes: ribavirin (RBV), direct-acting antivirals (DAAs), and nonstructural protein 5A (NS5A) inhibitors.
    - Many treatment regimens include combinations of different medication classes. Some examples are as follows:
        - Glecaprevir/pibrentasivir
        - Sofosbuvir/velpatasvir, with or without ribavirin
        - Ledipasvir/sofosbuvir, with or without ribavirin
        - Elbasvir/grazoprevir
        - Sofosbuvir/velpatasvir/voxilaprevir
    - The combination of medication, dosage, frequency, and length of treatment is dependent upon the HCV genotype.
    - Adherence to the treatment regimen is an important contributing factor in its success.

Retreatment of Persons with Prior Therapy Failure

- Retreatment options are available and should be evaluated by a specialist.
- The combination of medication, dosage, and frequency are dependent upon the HCV genotype and prior treatment regimens.

Monitoring Patients before, during, and after Antiviral Therapy

- Prior to starting therapy, the following assessments/tests are recommended:
    - Cirrhosis assessment through calculation of FIB-4 score, transient elastography, noninvasive serologic tests, clinical evidence of cirrhosis, prior liver biopsy
    - Medication reconciliation
    - Education about proper medication administration, adherence, and prevention of reinfection
    - Drug-to-drug interaction with current medications
    - Laboratory tests: complete blood count (CBC), international normalized ratio (INR), liver function panel, total and direct bilirubin, and a calculated glomerular filtration rate (GFR)
    - HCV genotype and subtype
    - Hepatitis B surface antigen
    - HIV antibody test
    - Serum pregnancy testing and counseling for women of childbearing age
    - Quantitative HCV viral load
- The following recommendations should be observed during antiviral therapy:
    - Ensure routine follow-up with the provider.
    - Laboratory tests should be evaluated during therapy to monitor for liver injury or worsening results. These include a CBC, liver function panel, serum creatinine, and calculated GFR.

    - Monitor patients for hypoglycemia, if taking diabetes medication.
    - Monitor INR for patients taking warfarin to evaluate subtherapeutic anticoagulation.
    - Hepatotoxic and nephrotoxic effects should be evaluated for and tested as indicated clinically.
    - Quantitative HCV RNA and hepatic function panels are recommended 12 weeks or more after the completion of therapy.
- Patients who have failed therapy should be evaluated by a specialist for retreatment.
- Patients with cirrhosis should have an ultrasound performed every 6 months, with or without an alpha-fetoprotein level, to monitor for hepatocellular carcinoma (HCC).
- Review AASLD guidance for recommendations for evaluating varices.
- Individuals with disease progression should be assessed with a hepatic function panel, CBC, and INR every 6 to 12 months.
- Assessment for other causes is recommended in individuals with elevated transaminase levels after sustained virological response has been accomplished at 12 weeks or more posttreatment.
- Individuals with ongoing IV drug use or men who engage in unprotected sex with men should be counseled about risk reduction and tested annually for HCV RNA.
- Patients undergoing immunosuppressive treatment or chemotherapy may experience reactivation of hepatitis; therefore, routine HCV RNA testing or antiviral therapy is not recommended.

Unique Patient Populations

- Referral to an HCV and/or liver specialist is recommended for patients who have developed decompensated cirrhosis.
- Patients who have decompensated cirrhosis, Child-Turcotte-Pugh (CTP), or severe hepatic impairment with genotype 1a, 1b, 2, or 3 are not recommended for liver transplant and should be referred to a medical practitioner who specializes in the treatment of liver diseases.
- The length of treatment for HCV with decompensated cirrhosis may continue from 12 to 48 weeks, depending on the occurrence of complications. Recommended medications include ledipasvir and sofosbuvir.
- No dosage adjustment of DAA therapy is required for patients with mild or moderate renal impairment (a creatinine clearance [CrCl] of 30 to 80 mL/min).
- For patients with decompensated cirrhosis and/or recurrent HCV infection post-liver transplantation, DAA may be beneficial.
    - Consultation with a liver transplant center is strongly recommended.
    - Use protease inhibitor-containing regimens with extreme caution in this population due to the risk of potential toxicity.
- DAA treatment with approved regimens is recommended for all children ages 3 years and older with HCV infection.
- DAA treatment may be considered during pregnancy, after a risk assessment has been performed.
- All children born to HCV-infected women should be tested for HCV infection at or after 18 months of age.

HIV/HCV Coinfection

- HIV-infected patients have a higher rate of HCV infection and a faster progression to liver disease and end-stage liver disease. HIV/HCV patients should be treated the same way as HCV patients without HIV infection, with consideration for potential drug-to-drug interactions with HIV drugs.
- Interruption of antiviral therapy is not recommended for HCV patients. Drug interactions must be evaluated with HIV antiviral therapy prior to initiating treatment.

Acute HCV Infection

- Acute hepatitis C infection encompasses the first 6 months after initial infection. Spontaneous resolution occurs in 20% to 50% of cases.
- Treatment for acute hepatitis C infection is the same as for chronic HCV infection.

Education

- Educate all patients with confirmed HCV about the risk and routes of HCV transmission and about the techniques for avoiding blood exposure to reduce risk of HCV transmission to others.
- Teach patients to avoid sharing toothbrushes, razors, and nail clippers and to use gloves and diluted bleach to clean up blood.

Reference:

Bhattacharya, D., Aronsohn, A., Price, J., Lo Re, V., & AASLD-IDSA HCV Guidance Panel (2023). Hepatitis C Guidance 2023 Update: AASLD-IDSA Recommendations for Testing, Managing, and Treating Hepatitis C Virus Infection. *Clinical infectious diseases: an official publication of the Infectious Diseases Society of America*, ciad319. Advance online publication. https://doi.org/10.1093/cid/ciad319