Review of HCV Labs and Screening Guidelines

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# AASLD Screening Recommendations

## One-Time Hepatitis C Testing

### Recommendations for One-Time Hepatitis C Testing

<table>
<thead>
<tr>
<th>RECOMMENDED</th>
<th>RATING</th>
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</thead>
<tbody>
<tr>
<td>One-time, routine, opt out HCV testing is recommended for all individuals aged 18 years or older.</td>
<td>I, B</td>
</tr>
<tr>
<td>One-time HCV testing should be performed for all persons less than 18 years old with activities, exposures, or conditions or circumstances associated with an increased risk of HCV infection (see below).</td>
<td>I, B</td>
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<tr>
<td>Prenatal HCV testing as part of routine prenatal care is recommended with each pregnancy.</td>
<td>I, B</td>
</tr>
<tr>
<td>Periodic repeat HCV testing should be offered to all persons with activities, exposures, or conditions or circumstances associated with an increased risk of HCV exposure (see below).</td>
<td>IIA, C</td>
</tr>
<tr>
<td>Annual HCV testing is recommended for all persons who inject drugs, for HIV-infected men who have unprotected sex with men, and men who have sex with men taking pre-exposure prophylaxis (PrEP).</td>
<td>IIA, C</td>
</tr>
</tbody>
</table>
Risk activities

- Injection drug use (current or former, including those who injected only once)
- Intranasal illicit drug use
- Use of glass crack pipes
- Male engagement in sex with men
- Engagement in chem sex (defined as the intentional combining of sex with the use of particular nonprescription drugs in order to facilitate or enhance the sexual encounter [Bourne, 2015])
Risk exposure

• Persons on long-term hemodialysis (ever)
• Persons with percutaneous/parenteral exposures in an unregulated setting
• Healthcare, emergency medical, and public safety workers after needlestick, sharps, or mucosal exposure to HCV-infected blood
• Children born to HCV-infected women
• Recipients of a prior transfusion or organ transplant, including persons who:
  • Were notified that they received blood from a donor who later tested positive for HCV
  • Received a transfusion of blood or blood components, or underwent an organ transplant before July 1992
  • Received clotting factor concentrates produced before 1987
• Persons who were ever incarcerated
Other conditions and circumstances

- HIV or HBV infection
- Sexually active persons about to start pre-exposure prophylaxis (PrEP) for HIV
- Chronic liver disease and/or chronic hepatitis, including unexplained elevated alanine aminotransferase (ALT) levels
- Solid organ donors (living and deceased) and solid organ transplant recipients
Routine HCV tests

- Hepatitis C antibody (HCV Ab)
- Quantitative Hepatitis C RNA (HCV PCR)
- Hepatitis C genotype (HCV GT)
Screening for hepatitis C

- Hepatitis C Antibody testing (HCV Ab)
  - Sensitivity and specificity approaching 100%
  - First positive around 8 weeks after exposure
  - Positive for life
  - Option to order with reflex PCR
Point of care testing

- FDA approved test - OraQuick rapid HCV antibody test
- Rapid results - 20 minutes
- Equivalent efficacy and specificity
  - Tester dependent
- No rapid confirmatory testing available in the US at this time
Confirmatory testing

- Hepatitis C PCR (HCV PCR)
- Results
  - Quantifiable 15 -100,000,000 IU/mL
    - may be detectable below 15
HCV genotypes

• 6 main genotypes (1-6)
  • Subtypes (ex. GT1a, GT1b)
• GT 1 is the most prevalent genotype in the USA
• Higher prevalence of GT 3 in intravenous drug users
• Relevance
  • Treatment outcomes
  • Re-infection vs treatment failure
## Recommendations for Initial HCV Testing and Follow-Up

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<tr>
<td>HCV-antibody testing with reflex HCV RNA polymerase chain reaction (PCR) testing is recommended for initial HCV testing.</td>
<td>I, A</td>
</tr>
<tr>
<td>Among persons with a negative HCV-antibody test who were exposed to HCV within the prior 6 months, HCV-RNA or follow-up HCV-antibody testing 6 months or longer after exposure is recommended. HCV-RNA testing can also be considered for immunocompromised persons.</td>
<td>I, C</td>
</tr>
<tr>
<td>Among persons at risk of reinfection after previous spontaneous or treatment-related viral clearance, HCV-RNA testing is recommended because a positive HCV-antibody test is expected.</td>
<td>I, C</td>
</tr>
<tr>
<td>Quantitative HCV-RNA testing is recommended prior to initiation of antiviral therapy to document the baseline level of viremia (ie, baseline viral load).</td>
<td>I, A</td>
</tr>
<tr>
<td>HCV genotype testing may be considered for those in whom it may alter treatment recommendations.</td>
<td>I, A</td>
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<tr>
<td>Persons found to have a positive HCV-antibody test and negative results for HCV RNA by PCR should be informed that they do not have evidence of current (active) HCV infection but are not protected from reinfection.</td>
<td>I, A</td>
</tr>
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Confirming chronic infection

Two positive HCV PCR’s 6 months apart or more
Figure 1. CDC-Recommended Testing Sequence for Identifying Current HCV Infection

- **HCV Antibody**
  - Nonreactive
    - No HCV Antibody Detected
      - Stop
  - Reactive
    - HCV RNA
      - Detected
        - Current HCV Infection
          - Link to Care
      - Not Detected
        - No Current HCV Infection
          - Additional Testing as Appropriate
Additional labs following confirmation of active infection

- Hepatic panel
- BMP
- CBC with plt
- HIV
- Hepatitis B surface antibody
- Hepatitis B surface antigen
- Hepatitis B core antibody total
- HAV IgG (if vaccine status unknown)
Labs needed for treatment

<table>
<thead>
<tr>
<th>AASLD recommends</th>
<th>Medicaid</th>
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<td>• In the past 6 months</td>
<td>• In the past 3 months</td>
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<tr>
<td>• Hepatic function panel, CBC, INR, eGFR</td>
<td>• HCV PCR</td>
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<tr>
<td>• Anytime prior to starting</td>
<td>• HBV labs</td>
</tr>
<tr>
<td>• HCV RNA</td>
<td>• HIV screening</td>
</tr>
<tr>
<td>• HBV labs</td>
<td>• Pregnancy test</td>
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<tr>
<td>• HIV labs</td>
<td></td>
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<tr>
<td>• Before initiating therapy</td>
<td>• Anytime prior to starting</td>
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<td>• Pregnancy testing</td>
<td>• HCV genotype</td>
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</table>
Labs for fibrosis staging

**FIB 4**
- Age
- AST
- ALT
- Platelet count

**APRI**
- AST
- ALT
- Platelet count
Lab requirements while on treatment
On treatment labs:
AASLD simplified guidelines

• Non cirrhotic
  • None

• Compensated cirrhosis without prior treatment
  • Provider discretion
Post treatment assessment for cure: AASLD simplified guidelines

• After completion of 12 weeks of treatment
  • Liver panel
  • HCV PCR
Follow up after achieving SVR: AASLD simplified guidelines

• Non cirrhotic
  • Ongoing risk factors
    • Yearly HCV PCR and repeat whenever liver tests are elevated
  • No ongoing risk factors
    • No follow up needed

• Cirrhosis
  • Needs ongoing monitoring for liver health and HCC screening
  • Screen for reinfection if needed
SVR not achieved: AASLD simplified guidelines

- Non cirrhotic
  - Labs every 6-12 months
    - Hepatic panel
    - CBC with plt
    - INR
Questions?