Hep C
Link to Care
linking diagnosis to management
Hepatitis C Testing, Diagnosis and Linkage to Care

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Most Patients with Chronic Hepatitis C in the US Are Unaware that They Are Infected

- ~3,300,000 individuals are infected
- Only 825,000 are aware of their infection
- 2,475,000 are unaware of their infection

Complications from chronic hepatitis C develop slowly over a period of 20–30 years.

Disease Burden of Patients Infected 20 Years or More is Peaking Now

Patients infected
Infected > 20 y

Davis GL. *Rev Gastroenterol Disord* 2004;4:7-17.
HCV was the contributing or underlying cause of death for 15,106 individuals in 2007.
Deaths from HCV According to Age, 2007*
Those 45 to 64 Years Old Most Affected

n=15,106

- 55-64 years, 34.1%
- 65+ years, 19.2%
- 0-44 years, 7.5%
- 45-54 years, 39.3%

*Contributing or underlying cause
Change in Screening and Treatment Practices Were Warranted

• Without changes in previous identification and treatment practices:
  – Total medical costs for patients with HCV infection expected to more than double over the next 20 years
  – Deaths are forecasted to increase to 35,000/yr annually by 2030

CDC Evaluated Birth-Cohort Screening for Hepatitis C

- An estimated 75-80% of persons with chronic hepatitis C were born from 1945 – 1965
  - NHANES (1999 – 2002) found 4.5 times higher anti-HCV prevalence among persons born 1945 – 1965 vs. outside of that cohort (about 1 in 30 or 3.27% vs. 0.73%)
  - Most were infected 20 to 40 years ago; 1.25 – 1.75 million of these persons do not know they are infected
- Previous CDC risk-based screening recommendations resulted in low case identification
- New CDC birth cohort screening recommendations state that an HCV test be performed at least once in patients born between 1945 and 1965 regardless of risk factors

**New AASLD/IDSA/IAS–USA Recommendations for HCV Testing**

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, and one-time testing should be performed for all persons with behaviors, exposures, and conditions associated with an increased risk of HCV infection.

### Risk behaviors
- Injection-drug use (current or ever, including those who injected once)
- Intranasal illicit drug use

### Risk exposures
- Long-term hemodialysis (ever)
- Getting a tattoo in an unregulated setting
- Healthcare, emergency medical, and public safety workers after needle sticks, sharps, or mucosal exposures to HCV-infected blood
- Children born to HCV-infected women
- Prior recipients of transfusions or organ transplants, including persons who:
  - were notified that they received blood from a donor who later tested positive for HCV infection
  - 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 medical conditions
- HIV infection
- Unexplained chronic liver disease and chronic hepatitis including elevated alanine aminotransferase levels

New AASLD/IDSA/IAS–USA Recommendations for HCV Testing (cont’d)

- 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 factors for exposure to HCV.

CDC Recommended Testing Sequence for Identifying Current HCV Infection

## Initial Qualitative Serological Screening Tests for Anti-HCV

<table>
<thead>
<tr>
<th>Tests Approved for Clinical Use</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott HCV EIA 2.0 (Abbott Laboratories, Abbott Park, IL)</td>
<td>Enzyme immunoassay</td>
</tr>
<tr>
<td>Ortho® HCV Version 3 ELISA Test System (Ortho-Clinical Diagnostics, Raritan, NJ)</td>
<td>Enzyme-linked immunosorbent assay</td>
</tr>
<tr>
<td>Oraquick® HCV Rapid Antibody Test (Orasure Technologies, Bethlehem, PA)</td>
<td>Immunoassay</td>
</tr>
<tr>
<td>Vitros® Anti-HCV Assay (Ortho-Clinical Diagnostics, Raritan, NJ)</td>
<td>Immunometric assay</td>
</tr>
</tbody>
</table>

Rapid, Point of Care HCV Antibody Test

- OraQuick
  - Only test approved by FDA in the US for use in detecting HCV antibodies in venous whole blood specimens
  - Provides results in 20 minutes
  - Appropriate for use in physician offices, ERs, and public health clinics and facilities
  - Allows patient to not be lost to follow-up

A positive anti-HCV test result is not a diagnosis for chronic HCV infection.

Some individuals become infected with HCV and then spontaneously clear the infection.

Approximately 15%–25% of persons clear the virus without treatment and do not develop chronic infection; the reasons for this are not well known.

Positive HCV Ab Test Should be Confirmed With a HCV RNA Assay
# Interpreting Hepatitis C Test Results

<table>
<thead>
<tr>
<th>Anti-HCV</th>
<th>HCV RNA (PCR)</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>Negative</td>
<td>• No infection</td>
</tr>
<tr>
<td>Positive</td>
<td>Positive</td>
<td>• HCV present (acute or chronic infection)</td>
</tr>
<tr>
<td>Negative</td>
<td>Positive</td>
<td>• Chronic infection in immunosuppressed patient</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Early infection</td>
</tr>
<tr>
<td>Positive</td>
<td>Negative</td>
<td>• Resolved infection</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Treated infection, HCV below detectable levels (verify with qualitative HCV RNA PCR)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• False-positive anti-HCV test (&lt;1%)</td>
</tr>
</tbody>
</table>

Counseling Patients Newly Diagnosed with Chronic Hepatitis C

- There is a low but present risk for transmission with sex partners
- Sharing personal items that might have blood on them, such as toothbrushes or razors, can pose a risk to others
- Cuts and sores on the skin should be covered to keep from spreading infectious blood or secretions
- Donating blood, organs, tissue or semen can spread HCV to others

Counseling Patients Newly Diagnosed with Chronic Hepatitis C (cont)

• Avoid alcohol because it can accelerate cirrhosis and end-stage liver disease

• Check with a health professional before taking any prescription pills, over-the-counter drugs (such as analgesics), or supplements as these can potentially damage the liver

• Get vaccinated for HBV and HAV
Link to Care For Those Found to be HCV RNA Positive is Essential

- The first step in the management of HCV is appropriate linkage to care
- Link to care is evaluation by a practitioner who is prepared to provide comprehensive management, including consideration of antiviral therapy
- Treatment is recommended for patients with chronic HCV infection
- HCV-positive persons should be evaluated (by referral or consultation, if appropriate) for the presence of advanced fibrosis. This:
  - facilitates an appropriate decision regarding HCV treatment strategy
  - determines the need for initiating additional screening measures (eg, hepatocellular carcinoma [HCC] screening)

More Second Generation DAAs Available: PEG IFN not needed and Cure Rates Approach 100%

Average SVR Rates from Clinical Trials

- Standard Interferon
- Ribavirin
- Peginterferon

<table>
<thead>
<tr>
<th>Year</th>
<th>1st Generation DAAs</th>
<th>2nd Generation DAAs</th>
</tr>
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<tbody>
<tr>
<td>1991</td>
<td>6%</td>
<td>Peg-IFN/ RBV/ 2</td>
</tr>
<tr>
<td>1998</td>
<td>16%</td>
<td>2011 Peg-IFN/ RBV/ 2</td>
</tr>
<tr>
<td>2001</td>
<td>34%</td>
<td>2013 Peg-IFN/ RBV/ 2</td>
</tr>
<tr>
<td>2011</td>
<td>42%</td>
<td>2014 Peg-IFN/ RBV/ 2</td>
</tr>
<tr>
<td>2012</td>
<td>39%</td>
<td>Peg-IFN/ RBV/ 2</td>
</tr>
<tr>
<td>2013</td>
<td>55%</td>
<td>Peg-IFN/ RBV/ 2</td>
</tr>
<tr>
<td>2014</td>
<td>70%</td>
<td>Peg-IFN/ RBV/ 2</td>
</tr>
<tr>
<td>2015</td>
<td>99%</td>
<td>All Oral 2nd</td>
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</tbody>
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Adapted from US Food and Drug Administration, Antiviral Drugs Advisory Committee Meeting, April 27-28, 2011, Silver Spring MD.
Thank you for participating in Hep C Linkage to Care Update:

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