An Overview of NYS Hepatitis C Testing Law

Statewide Stakeholder Meetings
Agenda

- Overview of Hepatitis C virus (HCV)
- CDC HCV screening recommendations
- Review of HCV screening and diagnostic tests
- CDC HCV screening algorithm
- NYS HCV testing law
- Additional resources
Why is this legislation so important?

- 4.1 million persons ever infected; 3.2 million chronic infections
  - Up to 75% unaware of status
- Transmitted through percutaneous exposure to infected blood
  - Injection drug use (IDU) is the principle risk for transmission
- Major cause of liver disease
  - Leading indication for liver transplants
  - Leading cause of HHC (approx. 50% of HHC incident)
- HCV-related deaths doubled from 1999-2007 to over 16,000/year
  - In 2007, HCV related deaths began to exceed HIV related deaths
- No vaccine available
- Changing landscape of HCV:
  - New CDC expanded screening recommendations
  - Newer screening technologies are available
  - More effective treatments
    - HCV is curable
Why Baby Boomers?

- Persons born between 1945-1965 are five times more likely to be infected with HCV
  - HCV Prevalence 3.25% among 1945-1965 birth cohort vs. 0.88% among individuals outside the birth cohort.
- 1.94 million chronically infected
- Represent 73% of all HCV-associated mortality
- 31.5% lacked health insurance
- 57.8% reported drinking an average of two or more alcoholic drinks per day.
- 80% lack Hepatitis A/B vaccination
NYS-HCV-Baby Boomers*

Data Source: NYSDOH, Bureau of Communicable Disease Control and NYCDOHMH, Bureau of Communicable Disease Control and Prevention

*Data through 2011
Benefit of HCV Diagnosis and Care

• Reduce the risk of transmission to others
• Early clinical evaluation and ongoing monitoring
  – Treatment response decreases as liver disease progresses
• Take measures to protect their liver from further harm
  – Vaccination against Hepatitis A and B
  – Decrease or eliminate alcohol consumption
  – Counseling on interactions between herbal supplements, over the counter, and prescription medications
Benefits of HCV treatment

• Hepatitis C is curable
  – Elimination of HCV infection is possible - known as Sustained Virologic Response (SVR)
• SVR associated with:
  – Reduction in all-cause mortality
  – Lower rates of liver related death and decompensated cirrhosis
• HCV therapy is shorter in duration (12 weeks) and side effects more tolerable
• All oral interferon-free therapy for GT 2 and 3
• HCV therapy shown to be effective
  – Genotype 1*: = 89%
  – Genotype 2 and 3**: 67% overall
    • Genotype 2: 95%
    • Genotype 3: 56%
• Many more therapies in phase I/II trials

*Sofosbuvir + PEG + RBV, treatment naive; ** Sofosbuvir + RBV, treatment naive
CDC Risk and Medical Indication-Based Guidelines

- October 1998
- Had ever injected illegal drugs
- Were ever on chronic hemodialysis
- Received blood transfusions or solid organ transplants before July 1992
- Received clotting factor concentrates made before 1987
- Known exposure to Hepatitis C
- Living with HIV
- Has signs or symptoms of liver disease (persistent abnormal ALT)
- Children born to mothers who have Hepatitis C
Expanded CDC Recommendations for HCV testing

- August 2012
- Adults born from 1945 through 1965 should receive one-time testing for HCV without prior ascertainment of HCV risk factor status
- All persons with identified HCV infection should receive a brief alcohol screening and intervention as appropriate, followed by referral to appropriate care and treatment service for HCV infection and related conditions.
Rationale for augmenting HCV screening recommendations

- Limited effectiveness of current testing strategies
  - 45-85% of adults with chronic hepatitis C are unaware of their infection
  - 45% of persons ever infected with HCV report no known risk
  - ALT screening misses > 50% of chronic cases
- Increasing morbidity and mortality of chronic HCV infection
- Benefits of diagnosis and care
- Benefits of HCV treatment
HCV antibody test

- HCV screening test
- Several FDA approved assays
  - One CLIA approved rapid HCV antibody test
- Antibody test result can be either reactive or non-reactive
- A reactive result can indicate:
  - Current HCV infection
  - Past (resolved HCV) infection
- If result is reactive for HCV antibodies, an HCV RNA test should be performed next
  - No additional test to confirm antibodies
- Antibodies are usually detectable 8-9 weeks after exposure

Slide courtesy of Monica Parker, PhD, NYSDOH Wadsworth Laboratory
HCV RNA test

- Necessary to confirm, current infection status
- Several FDA approved RNA tests available
  - Qualitative and Quantitative
- Reflex testing is available
- RNA test results can be detectable or undetectable
- If RNA is detected
  - Indicates active infection
  - Conduct genotype testing
  - Evaluate for treatment eligibility
- If RNA is not detected
  - No current infection
  - No further testing unless
    - Exposure within past 6 months is suspected
    - Clinical signs of HCV
    - Improper specimen handling occurred
  - If any exceptions exist, repeat HCV RNA testing
CDC HCV screening algorithm

## Coverage for HCV testing

<table>
<thead>
<tr>
<th>Payer</th>
<th>Testing Covered</th>
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<tbody>
<tr>
<td>Medicaid</td>
<td>Yes</td>
</tr>
<tr>
<td>Medicare</td>
<td>No - currently under review</td>
</tr>
<tr>
<td>Private</td>
<td>Refer to policy</td>
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- USPSTF - Grade B
- No co-pay as a result of ACA
- Medicare - Working to formalize support for HCV testing as a preventive service
## Billing for HCV testing

<table>
<thead>
<tr>
<th>Test Type</th>
<th>CPT Code(s)</th>
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<tbody>
<tr>
<td>Hepatitis C antibody</td>
<td>86803</td>
</tr>
<tr>
<td>HCV RNA testing (Qualitative and Quantitative)</td>
<td>87521, 87522</td>
</tr>
<tr>
<td>HCV genotype testing</td>
<td>87902</td>
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NYS Hepatitis C Testing Law

- Signed by Governor Cuomo on October 23, 2013
- First in the Nation
- Effective January 1, 2014

KEY PROVISIONS of the law

- An hepatitis C screening test be offered to every individual born between 1945 and 1965
  - Inpatient of a hospital or
  - Receiving primary care services in the outpatient department of a hospital or
  - In a freestanding diagnostic and treatment center or
  - From a physician, physician assistant, or nurse practitioner providing primary care regardless of setting type.
NYS Hepatitis C Testing Law (2)

• KEY PROVISIONS- continued
  – If an individual accepts the offer and the screening test is reactive, the health care provider must offer the individual follow-up health care or refer the individual to a health care provider who can provide follow-up health care.
    • The follow-up health care must include a hepatitis C diagnostic test (i.e., HVC RNA test)
  – The offer of testing must be culturally and linguistically appropriate.
Key definitions

- Hepatitis C screening test
  - Any laboratory screening test that detects the presence of HCV antibodies
- Hepatitis C diagnostic test
  - Any laboratory test that detects the presence of hepatitis C virus in the blood and that provides confirmation of whether or not the individual has HCV infection
- Primary care
  - Medical fields of family medicine, general pediatrics, primary care, internal medicine, primary care obstetrics or primary care gynecology
Exceptions to the law

– When the individual is being treated for a life threatening emergency.

– When the individual has previously been offered or has been the subject of a hepatitis C related test (unless otherwise indicated due to risk factors).

– When the individual lacks the capacity to consent (though in these cases the offer may also be made to an appropriate person who is available to provide consent on behalf of the patient).
Other parts of the law

• Report to the Governor
  – On or before January 1, 2016, the commissioner of health shall evaluate and report on the impact
    • Number of persons who are screened for hepatitis C
    • Number of persons who have accessed care following a positive test

• Sunset Date
  – The law expires and is deemed repealed on January 1, 2020
Implementation of the law

• Provide guidance
• Stakeholder meetings
• Dear Colleague letter
• Host statewide webcast
• Provide briefings to various groups, councils and task forces
• Develop and execute an evaluation plan
Additional resources

• Additional information on NYS testing law
  – www.health.ny.gov/hepatitis
    • Click on Hepatitis C Testing
• Additional information on Hepatitis C
  – www.health.ny.gov/hepatitis
  – www.cdc.gov/hepatitis
  – www.aasld.com
• Additional laboratory information
  – http://www.questdiagnostics.com
  – https://www.labcorp.com
  – http://www.bioreference.com
Tools available to promote law

Don’t say “I’m all good” just because you don’t have symptoms.

Hepatitis C can lead to liver cancer. Most people with Hepatitis C do not feel sick. Yet liver damage may be silently taking place. Even if you think you’re fine, talk to your doctor about getting tested.

www.cdc.gov/hepatitis
Additional questions?

hepatabc@health.state.ny.us