April 3, 2014

Hepatitis C – New Legal Requirements for Physicians

Why is this legislation so important?

- 3.6 million persons ever infected; 2.7 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

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
- Referral resources
- Answers to Frequently Asked Questions
- Additional resources

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***

<table>
<thead>
<tr>
<th>Year</th>
<th>Born before 1945</th>
<th>Baby boomers</th>
<th>Born after 1965</th>
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<tbody>
<tr>
<td>2001</td>
<td>2,000</td>
<td>4,000</td>
<td>6,000</td>
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<td>2,000</td>
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</tr>
<tr>
<td>2011</td>
<td>2,000</td>
<td>4,000</td>
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</tbody>
</table>

*Data through 2011

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

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**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 relate death and decompensated cirrhosis
  - HCV therapy is shorter in duration and side effects more tolerable
  - All oral interferon-free therapy for GT 2 and 3
  - New HCV therapies with greater efficacy
    - Genotype 1*: 89%
    - Genotype 2 and 3**: 67% overall
      - Genotype 2: 95%
      - Genotype 3: 56%
  - Many more therapies in phase III trials

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**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

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**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.

Coverage for HCV testing

<table>
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<tr>
<th>Payer</th>
<th>Testing Covered</th>
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<tbody>
<tr>
<td>Medicaid</td>
<td>Yes</td>
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<tr>
<td>Medicare</td>
<td>Currently – No, Draft proposed decision - Yes</td>
</tr>
<tr>
<td>Private</td>
<td>Refer to policy</td>
</tr>
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</table>

- USPSTF – Grade B
- No co-pay as a result of ACA
- Medicare –
  - Currently - No
  - Proposed decision as of March 2014 is yes, HCV testing will be covered.
  - Final decision by June.

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

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>87520, 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.

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

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., HCV RNA test)
  - The offer of testing must be culturally and linguistically appropriate.

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

Referral Resources – SDOH HCV Funded Sites

- Programs for HCV mono-infected persons:
  - Albert Einstein College of Medicine MMTP
  - Mount Sinai Medical Center
  - Anthony L. Jordan Health Center (Rochester)
  - Daytop Village, Inc. (Dutchess and Sullivan)
  - Hudson River Health Care (Amenia, Beacon, Poughkeepsie, Monticello, Yonkers)

- Programs for HIV/HCV coinfected persons:
  - Montefiore Medical Center
  - Harlem United
  - Northshore University Hospital
  - St. John's Riverside Hospital
  - Albany Medical Center
  - SUNY Upstate
  - AIDS Care (Rochester)
  - Erie County Medical Center

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

Referral Resources – CHCANYS HCV Collaborative Sites

- Community Health Center of Buffalo
- Whitney M Young (Albany)
- Open Door Family Medical Center (Hudson Valley)
- Morris Heights Health Center (NYC)
- Acacia Network (NYC)
- Community Healthcare Network (NYC)
Provider Reporting Responsibilities

- Reporting of acute and chronic hepatitis C cases is mandated under the NYS Sanitary Code (10NYCRR 2.10, 2.14)
- Physician (or designee) report using the Universal Reporting Form
  - NYC use PD-16 form and rest of state use DOH-38g
  - Report to the local Health Department in the county where the client lives
- Laboratories will report via the Electronic Clinical Laboratory Reporting System (ECLRS)

New HCV materials

Tools available to promote law

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
Are Emergency Departments required to offer the HCV test?
- No. EDs were not included as a required setting.

Will the NYSDOH be updating their 2005 hepatitis C clinical guidelines?
- Yes, the NYSDOH began the process of updating the hepatitis C clinical guidelines in January 2014.
- The audience for the guidelines will be primary care providers.
- The guidelines will include the newly approved hepatitis C therapies.
- Guidelines will be posted at: www.hivguidelines.org

How often does the offer of testing have to be repeated?
- The NYS law requires a one time offer only.
  - No additional offer of screening is required
  - However, patients who report new or ongoing risk may be offered screening based on CDC risk-based screening recommendations.

Does the law require documentation that the offer was made?
- No requirement to document the offer HCV screening in the medical record.
- Documentation may be helpful to track that the offer has been made and avoid duplication of the offer.
Patient Consent to HCV Screening

- No specific consent form required.
  - May use of general medical consent
  - The “exception” as stated in the law - When the individual lacks the capacity to consent ...
    - Refers to the individual lacking the capacity to accept the offer.
    - The reference to 'capacity to consent' does not imply written, informed consent for the Hepatitis C test.

Additional questions?

hepabc@health.state.ny.us

Are Partner Notification Services available for persons testing positive for hepatitis C?

- No. Unlike HIV, there is no requirement to offer partner services for those testing positive for hepatitis C.
- Providers should counsel the individual and recommend that their sexual and needle sharing partners also get tested.

Contact

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