Hepatitis C in the United States: Preparing for the Test and Cure Era

Division of Viral Hepatitis
National Center for HIV/AIDS, Viral Hepatitis, STD & TB Prevention
Centers for Disease Control and Prevention
November 14, 2013
Estimated Incidence of Acute Hepatitis C in the United States, 1982 - 2009

- Decline among transfusion recipients
- Decline among injection drug users
- Surrogate testing of blood donors
- Anti-HCV test (1st generation) licensed
- Anti-HCV test (2nd generation) licensed

Source: Sentinel Counties Study of Viral Hepatitis and State Disease Surveillance, CDC
Persons Who Inject Drugs Are at Highest Risk for HCV Infection

- Accounts for 60–70% of new infections in U.S.
- IDU incidence is highest among new injectors.\(^2,3\)
- HCV transmission has declined but remains substantial.
  - In Baltimore, HCV incidence 7.8% (2005–2008).\(^4\)
  - In Seattle, HCV + prevalence 32% (2004).\(^5\)
- Prevention requires a combination of strategies.\(^6\)
- Reinfection incidence after HCV clearance: 1.8–47/100 PYs.\(^7-15\)

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### HCV Screening & Testing at Venues Serving PWID

**CDC Demonstration Projects**

**January--June 2013**

<table>
<thead>
<tr>
<th>Locations</th>
<th>One-Year Testing Goals</th>
<th># of Tests in 6 month period</th>
<th>% anti-HCV+</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wisconsin</td>
<td>2000</td>
<td>362</td>
<td>15</td>
</tr>
<tr>
<td>Maine</td>
<td>1000</td>
<td>50</td>
<td>24</td>
</tr>
<tr>
<td>New York City</td>
<td>5000</td>
<td>500</td>
<td>26</td>
</tr>
<tr>
<td>Los Angeles</td>
<td>3000</td>
<td>816</td>
<td>10</td>
</tr>
<tr>
<td>Seattle, WA</td>
<td>1000</td>
<td>76</td>
<td>52</td>
</tr>
<tr>
<td>Oakland, CA</td>
<td>1000</td>
<td>146</td>
<td>40</td>
</tr>
<tr>
<td>Chicago</td>
<td>1000</td>
<td>221</td>
<td>25</td>
</tr>
<tr>
<td>Virginia</td>
<td>1400</td>
<td>87</td>
<td>28</td>
</tr>
</tbody>
</table>

Venues Include: Syringe Exchange Programs; Drug Treatment Centers; Health Departments; Methadone Clinics; Corrections; Shelters

*Preliminary Data*
Increases in Reports of New HCV Infection
HCV Case Reports- 2007-2011

- 44% increase in 2011
- ~17,000 cases/ yr.
- ~ 70% IDU
- Young (18-29 years)
- Predominantly white
- Equally female: male
- Non-urban, suburban areas
- Previous prescription narcotic users
Healthcare-associated HCV Transmission

- A larger risk in past
  - Before screening of blood/plasma donations in 1992
  - Before universal precautions for infection control pre-1990s
- Disease outbreaks continue to occur
  - 16 reported to CDC (1998–2008)\(^6,7\)
  - Diverse settings associated with transmission
    - Poor infection control (e.g., dialysis, anesthesia, chemotherapy)
    - Illicit drug diversion

References:
HCV Sexual Transmission among HIV+ MSM

• First reported from multiple European, Australian cities
• Rising HCV seroconversions among 4295 EuroSIDA participants
  – 0.47 in 2002
  – 2.34 in 2010
  – 63% were MSM only

• In New York City, HCV incidence associated with unprotected rectal intercourse, non-IDU (ketamine, meth)

• In Boston, HCV incidence 1.63/100 person years; 70% reported only sexually transmitted infections
### Persons Living With Viral Hepatitis - United States

<table>
<thead>
<tr>
<th>Virus</th>
<th>Prevalence</th>
<th>% Unaware of Infection</th>
<th>Deaths (2010)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCV</td>
<td>2.7 – 3.9 million</td>
<td>45%-60%</td>
<td>16,600</td>
</tr>
</tbody>
</table>

* National Vital Statistics System
<table>
<thead>
<tr>
<th>Population</th>
<th>Population Size</th>
<th>Prevalence</th>
<th>Antibody Positive</th>
<th>Chronically Infected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Homeless</td>
<td>643,000</td>
<td>35.0%</td>
<td>225,050</td>
<td>168,788</td>
</tr>
<tr>
<td>Incarcerated</td>
<td>1,614,000</td>
<td>30.0%</td>
<td>484,200</td>
<td>363,150</td>
</tr>
<tr>
<td>Veterans</td>
<td>22,916,000</td>
<td>7.5%</td>
<td>1,718,700</td>
<td>1,289,025</td>
</tr>
<tr>
<td>Active Military</td>
<td>1,418,000</td>
<td>0.5%</td>
<td>7,090</td>
<td>5,318</td>
</tr>
<tr>
<td>Healthcare Workers</td>
<td>7,201,000</td>
<td>2.0%</td>
<td>144,020</td>
<td>108,015</td>
</tr>
<tr>
<td>Nursing home residents</td>
<td>1,414,000</td>
<td>4.5%</td>
<td>63,630</td>
<td>47,723</td>
</tr>
<tr>
<td>Chronic hemodialysis</td>
<td>263,820</td>
<td>7.8%</td>
<td>20,578</td>
<td>15,433</td>
</tr>
<tr>
<td>Haemophiliacs with transfusions &lt; 1992</td>
<td>17,000</td>
<td>85.0%</td>
<td>14,450</td>
<td>10,838</td>
</tr>
<tr>
<td>Remainder of US population. (Adjusted NHANES)</td>
<td>214,513,180</td>
<td>1.5%</td>
<td>3,217,698</td>
<td>2,413,273</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>250,000,000</strong></td>
<td><strong>2.4%</strong></td>
<td><strong>5,895,416</strong></td>
<td><strong>4,421,562</strong></td>
</tr>
</tbody>
</table>
Most Americans Living with HCV Were Born During 1945-1965

- 81% of 2.7 M (2.2-3.2m) HCV+ adults
- 75% of HCV related mortality
- Prevalence five fold higher than others (3.29% vs 0.55%) \(^1,2\)
- 39% report previous IDU \(^1\)
- 49% do not report a risk

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HCV-related Mortality On the Rise

Rate per 100,000 Persons

Year

Hepatitis B
Hepatitis C
HIV

HCV-related Mortality On the Rise
Future Burden of Hepatitis C Related Morbidity and Mortality in the US

- Markov model of health outcomes
  - Of 2.7 M HCV infected persons in primary care
    - 1.47 M will develop cirrhosis
    - 350,000 will develop liver cancer
    - 897,000 will die from HCV-related complications

Monitor Case Reporting and HCV Mortality
Years to Death from the Date of HCV Diagnosis
Massachusetts: 1992-2009

A total of 76,122 HCV diagnoses were reported to the MDPH between 1992 and 2009, 8,499 of these reported HCV cases died and are represented in the figure.

- Median interval: 3 years
- Median age: 53 years

N=8,499

Lijewski, D Church, MA Dept of Health
Trends in Hepatitis C Disease and Costs

- **HCV is a major cause of liver disease.**
  - 40,000 (36%) of persons on liver transplant waitlist
  - 50% of persons with liver cancer; 2.5% annual increase

- **Substantial HCV-related costs**
  - Three-fold higher disability days (1.36 vs. 0.34) than others
  - $21,000 in annual health costs vs. $5500 for others
  - From 2002-2010, HCV + patients age 50-59 yrs had largest increases in hospital admissions (164%) and charges (341%)

- Successful hepatitis C treatment reduces health costs ($900 vs. $1378 per patient per month)

References:
Limited Effectiveness of Risk-based HCV Testing Strategies

- CDC recommendations since 1998 included:
  - Injection drug use
  - Blood transfusion before 1992 and other blood exposures
  - HIV
- Many clinicians are not aware of HCV testing guidelines.
- Clinicians may be reluctant to ask about risks.
- Patients may be reluctant to disclose or may not recall risks.
- At least 45-60% are unaware of their HCV infection.

NEW CDC Recommendation

- Adults born during 1945 through 1965 should receive one-time testing for HCV without prior ascertainment of HCV risk factor

- Benefits of therapy
  - Reduces risk of liver cancer by 70%
  - Reduces risk of all-cause mortality by 50%
CDC Recommendations for HCV Testing Based on Birth Cohort, Risk, and Medical Indications

- One Time testing for persons born 1945-1965
- Past or present injection drug use
- Signs of liver disease (persistently elevated ALT)
- Received blood/organs prior to June 1992
- Received blood products made prior to 1987
- Ever on chronic hemodialysis
- Infants of HCV-infected mothers
- HIV infection
NEW CDC Algorithm to Detect Current HCV Infection

Recommended Testing Sequence for Identifying Current Hepatitis C Virus (HCV) Infection

- **HCV antibody**
  - **Nonreactive**
    - No HCV antibody detected
      - STOP*
  - **Reactive**
    - **HCV RNA**
      - **Not Detected**
        - No current HCV infection
      - **Detected**
        - Current HCV infection
        - Link to care

* For persons who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended. For persons who are immunocompromised, testing for HCV RNA can be considered.

† To differentiate past, resolved HCV infection from biologic false positivity for HCV antibody, testing with another HCV antibody assay can be considered. Repeat HCV RNA testing if the person tested is suspected to have had HCV exposure within the past 6 months or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.

### Screening for HCV infection in Adults: USPSTF Recommendations

<table>
<thead>
<tr>
<th>Population</th>
<th>Persons at high risk for infection and adults born between 1945 and 1965</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Recommendation</strong></td>
<td>Screen for HCV infection. Grade: B (Moderate net benefit)</td>
</tr>
<tr>
<td><strong>Risk Assessment</strong></td>
<td>Most important risks: IDU; Additional risks: blood transfusion&lt; before 1992, long-term hemodialysis, born to an HCV-infected mother, incarceration, intranasal drug use, unregulated tattoo, and other percutaneous exposures.</td>
</tr>
<tr>
<td><strong>Screening tests</strong></td>
<td>Anti–HCV antibody testing followed by confirmatory polymerase chain reaction testing</td>
</tr>
<tr>
<td><strong>Screening interval</strong></td>
<td>Periodic: Ongoing risks One-time: persons born 1945-1965</td>
</tr>
<tr>
<td><strong>Implementation</strong></td>
<td>Voluntary; patient knowledge and understanding; receive information about HCV and testing; Can decline (opt-out) screening</td>
</tr>
</tbody>
</table>
Medicare Coverage Determination

- Process to formalize support for HCV testing as a preventive service in Medicare
- Based on USPSTF recommendations
  - Birth cohort
  - Risks

Mr. Ryan Clary
Director of Public Policy and Programs
National Viral Hepatitis Roundtable
P.O. Box 1662
Rohnert Park, CA 94927

Dear Mr. Clary:

Thank you for your letter regarding Medicare coverage for Hepatitis C screening for at-risk beneficiaries.

Medicare coverage for preventive services (such as screening Pap smears, pelvic exams, mammography, and colorectal cancer screening tests) is covered under the Medicare program and has been authorized by various statutory provisions. Additionally, Section 1861(ddd) of the Social Security Act (authorized in 2008 by the Medicare Improvements for Patients and Providers Act) allows Medicare to cover “additional preventive services” if certain statutory requirements are met, including if the Secretary determines through the national coverage determination process that the service is all of the following:

1. Reasonable and necessary for the prevention or early detection of illness or disability.
2. Recommended with a grade of A or B by the United States Preventive Services Task Force (USPSTF).
3. Appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

The current USPSTF recommendations for this topic are:

- The USPSTF recommends screening for hepatitis C virus (HCV) infection in persons at high risk for infection
- The USPSTF also recommends offering 1-time screening for HCV infection to adults born between 1945 and 1965. (B recommendation)

We thank you for bringing this important issue to our attention and we intend to open an NCD on this topic.

Sincerely,

Patrick Conway, M.D., M.S.
CMS Chief Medical Officer
Director, Center for Clinical Standards & Quality

[Signature]

Patrick Conway, M.D., M.S.
Governor Cuomo signs bill to promote Hepatitis C testing in New York state

October 2013

- Mandates HCV testing of persons born 1945-1965
- On hospital admission
- In primary care settings
Hepatitis C, a Silent Killer, Meets Its Match

November 5, 2013
Improving the HCV Test and Cure Continuum

~ 3 million persons living with HCV

- All HCV infected: 1.6 M (50%)
- anti-HCV tested: 1.2 M (38%)
- HCV care: 750,000 (23%)
- HCV RNA: 360,000 (11%)
- Treated: 200,000 (6%)

Improving the HCV Test and Cure Continuum

• Educate the public and providers
• Guide best practice
  – Demonstration projects for testing
  – Care models (e.g., Project ECHO)
  – Performance measures and clinical decision tools

• Monitor implementation and impact

• Create partnerships (public health, clinical, community)
TILT-C testing and linkage to care: October 2012-August 2013 - Grady Hospital, Atlanta GA

- 2,634 – HCV Ab ordered
- 1,762 – HCV Ab drawn
- 123 – HCV Ab Positive (7.0%)
- 101 – HCV RNA positive
- 83 – Scheduled for linkage visit (82%)
- 73 – Attended linkage visit to date (72%)

Data: Courtesy of Lesley Miller, MD. Principal investigator
HCV Antibody Results for Persons born 1945-1965
University of Alabama- Birmingham
9/3/13 - 10/17/13

- 1,287 (74.8%) HCV Status Unaware
  - 117 (9.2%) Declined
  - 2,087 (74.8%) Accepted Test Offering
    - 164 (14.3%) Anti-HCV Tests Not Performed
      - 866 (88.0%) Anti-HCV -
        - 20 HCV RNA Not Yet Performed
      - 118 (12.0%) Anti-HCV +
        - 27 (27.5%) HCV RNA -
        - 71 (72.5%) HCV RNA +

Summary

- Requires comprehensive primary and secondary prevention strategies
- Risk-based prevention strategies to detect and prevent new HCV infections
- One time HCV testing of persons born 1945-1965 to reduce HCV morbidity and mortality
- HCV testing and linkages to care and treatment must improve to realize health gains from anticipated new therapies
- Collaborations are essential among public health, clinical care providers, and payers to improve HCV testing, care and treatment
BORN FROM 1945-1965?
CDC RECOMMENDS YOU
GET TESTED FOR HEPATITIS C.