Hepatitis C Screening Recommendations and the Care Cascade

C Change: A Leadership Summit on Hepatitis C Policy in Pennsylvania
May 1, 2015

Claudia Vellozzi, MD, MPH
Chief, Prevention Branch
Division of Viral Hepatitis
Centers for Disease Control and Prevention

Role of Public Health in HCV Prevention

Public Health Core Functions - Institute of Medicine, 1988
Guided by research…

- Assessment
- Policy Development
- Assurance
Outline

- Assessment and policy development leading to recommendations
- Public health strategies to provide assurance in implementing recommendations

Assessment and Policy Development for the Viral Hepatitis C Testing Recommendations for Persons Born 1945-1965
Impact of Prevention Measures on Hepatitis C Virus (HCV) Infection in U.S.

- Discovery of HCV: 1989
- Indirect blood screening for HCV and HIV prevention measures: 1986
- Anti-HCV test licensed: 1992
- Needle stick Safety and Prevention Act: 2001
- 22,000 new acute HCV cases reported in 2012

Prevalence of Current HCV Infection Among Persons in the United States

| Prevalence Civilian, Non-Institutionalized Populations (NHANES) | 2.7 million (2.2-3.2 million) 1.0% (0.8%-1.2%) |
| Estimated HCV Infection Among Homeless and Incarcerated Persons (Not Included in NHANES) | 360,000-840,000 22%-52% |
Two of Three Americans Living with HCV Were Born During 1945-1965

- Reflects historical high HCV incidence before viral discovery in 1989
- Five-fold higher prevalence than other US adults (3.39% vs 0.55%)
  - 81% of all HCV+ US adults
  - Of all HCV-related mortality in US, 73% were born in this cohort

Adjusted Odds Ratios for the Presence of HCV RNA: NHANES 2003-2010

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Odds Ratios Age 20-59</th>
<th>Odds Ratios Age ≥ 60</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age Categories (20-39 referent)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age 40-49</td>
<td>6.0 (3.2-11.1)</td>
<td></td>
</tr>
<tr>
<td>Age 50-59</td>
<td>9.5 (5.3-16.8)</td>
<td></td>
</tr>
<tr>
<td>Race-Ethnicity (all others referent)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-Hispanic Black</td>
<td>1.6 (1.1-2.3)</td>
<td>10.0 (4.9-20.1)</td>
</tr>
<tr>
<td>High School Education (high school or more referent)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than High School/GED</td>
<td>2.0 (1.2-3.3)</td>
<td></td>
</tr>
<tr>
<td>Family Income (&gt;2.0 times poverty level referent)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤2.0 times poverty level</td>
<td>3.7 (2.6-5.3)</td>
<td></td>
</tr>
</tbody>
</table>

Denniston M, Ann Int Med 2014
The Growing Burden of Hepatitis C in the United States

- Of 2.7 million HCV-infected persons in primary care
  - 1.47 million will develop cirrhosis
  - 350,000 will develop hepatocellular carcinoma (HCC)
  - 897,000 will die from HCV-related complications

Rein D, Dig Liver Dis 2010.

Increases in Hepatitis C Mortality

Reported Deaths 19,368
Median age - 59 years
Advances in HCV Therapy

- 1991: 6% IFN
- 1999: 16% IFN/RBV
- 2001: 34% IFN/RBV
- 2002: 42% Peg-IFN (PEG)
- 2011: 54% - 56% Peg/RBV
- 2014: >90% All oral DAA


HCV Deaths Averted with Birth Cohort Testing Using Different Treatments

- PR = Pegylated Interferon plus Ribavirin for all genotypes
- PRPI = PR plus a protease inhibitor for genotype 1
- PRS/R = pegylated interferon, ribavirin, and sofosbuvir for genotype 1, and sofosbuvir plus ribavirin for genotypes 2 and 3
- SS/SR = Sofosbuvir and Simeprevir for genotype 1, and sofosbuvir and ribavirin for genotypes 2 and 3

Risk-based Recommendations for HCV Screening

- Since 1998, CDC recommendations included risk-based screening
  - Injection drug use
  - Blood transfusion before 1992 and other blood exposures
  - HIV infected persons

- 45%-85% of infected persons remained unidentified

Barriers to testing
- Lack of clinician awareness of HCV testing guidelines
- Clinician reluctance to ask about risks
- Patient reluctance to disclose or failure to recall risks

Combined Birth-cohort and Risk-based Testing Effectively Identify HCV-infected Patients

CDC and USPSTF Updated Recommendations for HCV Testing

- **One time screening test for persons born 1945-1965**
- **Major risk**
  - Past or present injection drug use
- **Other risks**
  - Received blood/organs prior to June 1992
  - Received blood products made prior to 1987
  - Ever on chronic hemodialysis
  - Infants born to HCV infected mothers
  - Intranasal drug use
  - Unregulated tattoo
  - History of incarceration
- **Medical**
  - Persistently elevated ALT
  - HIV (annual testing)

Assurance for the Viral Hepatitis C Testing Recommendations for Persons Born 1945-1965
HCV Test, Care, and Cure Continuum, United States

- 3.2 million persons living with HCV

- 1.6 M (50%)
- 1.2 M (38%)
- 750,000 (23%)
- 360,000 (11%)
- 200,000 (6%)

Hepatitis C treatment costs that yield cost-effectiveness thresholds stratified by fibrosis level

<table>
<thead>
<tr>
<th>Treatment scenario</th>
<th>$0/QALY Cost-saving</th>
<th>$50,000/QALY</th>
<th>$100,000/QALY</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients</td>
<td>2000</td>
<td>22200</td>
<td>42400</td>
</tr>
<tr>
<td>F2 or higher</td>
<td>14900</td>
<td>128800</td>
<td>242800</td>
</tr>
<tr>
<td>F3 or higher</td>
<td>84200</td>
<td>713600</td>
<td>1,343000</td>
</tr>
</tbody>
</table>

Holmberg S, et al, NEJM 2013

## Cost-effectiveness and Health Impact of Birth Cohort Testing and Treating in the Era of Direct Acting Antivirals

**Interferon Free Regimens**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>PegINF-Riba</th>
<th>PegINF-Riba + Sofosbuvir</th>
<th>Sofosbuvir-Simeprevir</th>
<th>Sofosbuvir-ledipasvir³ (Harvoni®)</th>
<th>Ombitasvir,Paretaprevir, Ritonavir, Dasabuvir⁴ (Viekira Pak®)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCV deaths averted²</td>
<td>49,916</td>
<td>156,106</td>
<td>320,646</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>ICER, Cost per QALY gained²</td>
<td>$59,792</td>
<td>$45,524</td>
<td>$59,333</td>
<td>$35,000</td>
<td>$32,000</td>
</tr>
</tbody>
</table>

1. Greater benefits result from both higher tolerability and more treated patients as well as higher pharmaceutical effectiveness
2. Compared to no treatment
3. Assumes equal effectiveness and tolerability as Sof/Sim but at the package cost ($94,500) of Harvoni®
4. Assumes equal effectiveness and tolerability as Sof/Sim but at the package cost ($83,319) of Viekira Pak®


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## Educating Communities: *Know More Hepatitis* Campaign materials & how to use them

- Website
- Fact sheets
- Infographics
- Posters
- Video PSAs
- Live read radio scripts
- Buttons & Badges
- Shareable digital content
- Resources for providers
Online Viral Hepatitis Risk Assessment

- Personalized recommendations based on CDC’s hepatitis testing and vaccination guidelines

![Image of Online Viral Hepatitis Risk Assessment]

Recommendations

Based on your answers, CDC recommends the following for you:

- Get a blood test for Hepatitis C. [Click for explanation]

Because you answered “not sure” or “prefer not to answer” to at least one question, your recommendations may be incomplete. If you have any questions about your situation or risk, please talk to your health care professional.

For more information about hepatitis A, hepatitis B, and hepatitis C, please visit [www.cdc.gov/hepatitis].


Testing Algorithm for Identifying Current Hepatitis C Virus (HCV) Infection (2013)

![Testing Algorithm Diagram]

- HCV antibody
  - Reactive
    - Detected
      - Current HCV Infection
      - Link to care
      - Additional testing as appropriate†
    - Not detected
      - No current HCV infection
      - STOP*
  - Nonreactive
    - No HCV antibody detected
      - No current HCV infection
      - STOP*

* 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.
During 9/2012 – 2/2014
- Trained 66 PCP predominantly from rural settings
- Most PCP (93%) with no experience in HCV care
- Of 280 patients, 129 (46%) received treatment
  - More than twice that observed in other CDC studies

Community-based Programs to Test and Cure Hepatitis C: 9/2014 – 9/2018
- Goal: develop package of services to improve healthcare capacity to test and cure
  - Identify and educate target population
  - Incorporate HCV testing in primary care practices
  - Implement regular consultation of primary care provider with HCV specialists
  - Case management
  - Monitor outcome and community impact via data system
  - Leverage Affordable Care Act: free testing, insurance enrollment, and improve quality of care through use of EMR
Health Care Reform
Impact on Viral Hepatitis Prevention

- Insurance coverage for those with preexisting, chronic disease
- Testing covered as a non-copay preventive service
- Incentive for adoption of health information technology to care for patients
- Emphasis on quality of provider care: use of performance measures
- Forcing a reinvention of public health surveillance, prevention research, and service delivery

American Medical Association
Performance Measures Updated

- **Screening**
  - One-time screening: patients at risk (injection drug use ever, blood transfused prior to 1992, or born during 1945–1965)
  - Annual HCV screening: patients who are active injection Drug Users

- **Care and treatment**
  - Referral to treatment for patients identified with HCV Infection
  - Sustained Virologic Response (SVR)
  - Confirmation of Hepatitis C viremia
  - Hepatitis C RNA and genotype testing before initiating treatment
  - HCV RNA testing between 4-12 weeks after treatment start
  - Discontinuation of antiviral therapy if inadequate response
  - Screening for HCC in patients with Hepatitis C Cirrhosis

- **Additional performance measures on prevention** (vaccination, alcohol consumption counseling, HCC screening)
Role of Public Health in HCV Prevention

Public Health Core Functions - Institute of Medicine, 1988

Guided by research…
- Assessment
- Policy Development
- Assurance

Epidemiologic Profiles Project

- Building state health department capacity
- Epi profiles document, interpret, and frame viral hepatitis burden in local terms to heighten awareness and drive decision making
  - States used novel data sources
  - States engaged critical stakeholders
  - States maximized dissemination opportunities
- Pilot project with three states - Arkansas, Oregon, Wisconsin
  - [www.dhs.wisconsin.gov/publications/P0/p00860.pdf](http://www.dhs.wisconsin.gov/publications/P0/p00860.pdf)
  - [http://www.healthy.arkansas.gov/programsServices/infectiousDisease/hivStdHepatitisC/Documents/HepC/HCVEpidemiologicProfile.pdf](http://www.healthy.arkansas.gov/programsServices/infectiousDisease/hivStdHepatitisC/Documents/HepC/HCVEpidemiologicProfile.pdf)
Frequency of Hepatitis C Virus tests* in U.S. States/Province by test type and quarter

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Q2 2012</th>
<th>Q3 2012</th>
<th>Q4 2012</th>
<th>Q1 2013</th>
<th>Q2 2013</th>
<th>Q3 2013</th>
<th>Q4 2013</th>
<th>Q1 2014</th>
<th>Q2 2014</th>
<th>Total 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>All HCV antibody tests</td>
<td>30,962</td>
<td>32,111</td>
<td>29,653</td>
<td>29,653</td>
<td>29,959</td>
<td>31,942</td>
<td>31,556</td>
<td>32,761</td>
<td>37,289</td>
<td>285,867</td>
</tr>
<tr>
<td>Proportion antibody positive</td>
<td>2,275</td>
<td>2,102</td>
<td>1,841</td>
<td>1,802</td>
<td>1,849</td>
<td>1,926</td>
<td>1,829</td>
<td>1,994</td>
<td>2,248</td>
<td>17,866</td>
</tr>
<tr>
<td>Proportion of NATs</td>
<td>9.4%</td>
<td>6.6%</td>
<td>6.1%</td>
<td>6.2%</td>
<td>6.0%</td>
<td>5.8%</td>
<td>6.1%</td>
<td>6.0%</td>
<td>6.2%</td>
<td>9.176</td>
</tr>
</tbody>
</table>

Data from a large commercial laboratory

Hepatitis C Incidence by Urbanicity and Year of Diagnosis

Suryprasad AG, et al. CID 2014
Incident HCV Infection: Summary of the Evidence

- IDU is the current driver of the HCV epidemic in the United States
- Seems to be a “constant” number of acute cases still occurring in urban predominantly heroin users
- New phenomenon of young, white nonurban IDU who start on oral prescription opioids and progress to injection.

Local Strategies to Enhance HCV Testing and Care

- Gather community data to guide service delivery and inform policy
- Improve reporting
- Update professional training/public awareness
- Assist in the expansion of HCV testing
- Target providers and health systems with interventions to promote delivery of HCV testing and care
  - Promote development of clinical decision tools and performance measures
    - Use to monitor and report back to providers and health systems
- Convene stakeholders
  - Meetings with Medicaid, other payers,
  - Presentations to providers, public health officials, others
- Participate in policy development
- Work in conjunction with the state Viral Hepatitis Prevention Coordinator
Using the National Viral Hepatitis Action Plan to Guide Pennsylvania’s Response

Michelle Moses-Eisenstein, MPH
Office of HIV/AIDS and Infectious Disease Policy
U.S. Department of Health and Human Services
May 1, 2015
Overview

- Impact
- Response
- Challenges and Opportunities
- Importance of Stakeholders
- A CALL TO ACTION
# 2013 Viral Hepatitis Surveillance, U.S.

<table>
<thead>
<tr>
<th></th>
<th>Hepatitis A (HAV)</th>
<th>Hepatitis B (HBV)</th>
<th>Hepatitis C (HCV)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Incident cases</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>(annual estimated)</strong></td>
<td>3,473</td>
<td>19,764</td>
<td>29,718</td>
</tr>
<tr>
<td></td>
<td>14%↑ in reported</td>
<td>5.4%↑ in reported</td>
<td>151.5%↑ in</td>
</tr>
<tr>
<td></td>
<td>cases compared to</td>
<td>cases compared to</td>
<td>reported acute</td>
</tr>
<tr>
<td></td>
<td>2012</td>
<td>2012</td>
<td>cases from 2010 to</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2013</td>
</tr>
<tr>
<td><strong>Chronic infections</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>(prevalent cases)</strong></td>
<td></td>
<td>700,000 – 1.4</td>
<td>2.7-3.9 million</td>
</tr>
<tr>
<td></td>
<td></td>
<td>million</td>
<td></td>
</tr>
<tr>
<td><strong>Est. perinatal</strong></td>
<td></td>
<td>800 – 1,000</td>
<td></td>
</tr>
<tr>
<td><strong>(annual estimated)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Deaths (2013)</strong></td>
<td>80</td>
<td>1,873</td>
<td>19,368</td>
</tr>
<tr>
<td><strong>(annual reported)</strong></td>
<td></td>
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</tbody>
</table>

*Between 45% to 65% of chronically infected persons are unaware of their infection status.*


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## Response
The Evolution of Our National Response

2010

2011

2014

Viral Hepatitis Action Plan
(Updated 2014-2016)

6 Priority Areas

- Educating providers and communities
- Improving testing, care, and treatment
- Strengthening surveillance
- Eliminating transmission of vaccine-preventable viral hepatitis
- Reducing viral hepatitis cases associated with drug-use behaviors
- Protecting patients and workers from health-care-associated viral hepatitis
2020 Goals of the Viral Hepatitis Action Plan

- Increase the proportion of persons who are aware of their HBV infection from 33% to 66%
- Increase the proportion of persons who are aware of their HCV infection from 45% to 66%
- Reduce the number of new HCV infections by 25%
- Eliminate mother-to-child HBV transmission

Federal Collaborators – Viral Hepatitis Implementation Group (VHIG)

Members without logos: Office of HIV/AIDS and Infectious Disease Policy, Regional Health Administrators
State and Local Collaboration

- National and State professional associations
- State and Local Departments of Health
- Advocacy Organizations
- School and Programs of Public Health
- Medical schools and other provider training organizations

Challenges and Opportunities
The New Generation Exposed to HCV

151% increase in reported acute HCV cases from 2010-2013

Recent studies show

- ~ 70% HCV prevalence among People Who Inject Drugs (PWID)
- History of using oral prescription opioids
- Highest rates among ages 18 to 29 years
- Predominantly white
- Equally female and male
- Non-urban and suburban

PWID: People who inject drugs; CDC/hepatitis.gov; MMWR 2011; MMWR 2014; CDC unpublished data.

Changes in Rates of New Acute HCV Cases Reported by State, United States, 2006 vs. 2012

Between 2006 and 2012

- 30 states reported increases
- 17 states had > 200% increase

In 2012

- Nearly 50% of reported cases ≤ 30 yrs.

Suryprasad AG, et al. CID 2014

www.aids.gov/hepatitis • #ViralHepAction
Preventing HCV among People Who Inject Drugs: Webinars, Fact Sheets, and other resources

- Drug use is an increasing problem in rural and semi-rural America
- Multi-component prevention strategies are needed

 Archived webinar and slides available at aids.gov/webinars.

Viral Hepatitis and the ACA

- The Affordable Care Act provides opportunities for prevention and screening
  - Hepatitis B screening for individuals at risk will be a covered preventive service in May 2015
  - Hepatitis C screening is a covered preventive service (includes Medicare)
  - Hepatitis A and B vaccines are covered preventive services
  - Protections from exclusion due to preexisting conditions such as viral hepatitis
HCV Therapy Has Undergone a Revolution

Current HCV Treatment (2014 to present)
- 90-100% cure rate
- 8-24 weeks long
- All oral medications
- Few side effects (approximately 2% of people discontinue)
- Few contraindications

Previous HCV Treatment (before 2011)
- 50-70% cure rate
- 48 weeks long
- Injections and oral medications
- Multiple side effects
- Many contraindications
Stages of the HCV Continuum of Care

Importance of Stakeholders
Federal Resources

Hepatitis C: An Introductory Guide for Patients

Viral Hepatitis. Are you at risk?
Take this 5 minute Hepatitis Risk Assessment developed by the CDC and get a personalized report.

Begin

Materials available at www.cdc.gov/hepatitis

Courtesy of CDC DVH Education, Training, & Communications Team

Know More Hepatitis

National Educational Campaign

News/Media Advocacy
Opinion Leader Outreach
Digital Media
Professional Education
Broadcast (Radio/TV Public Service Advertising)
Partnership Engagement
Social Media

Materials available at www.cdc.gov/hepatitis

Courtesy of CDC DVH Education, Training, & Communications Team
Get social. Expand your reach.

U.S. Viral Hepatitis Action Plan and Stakeholders’ Workbook

Visit http://aids.gov/hepatitis
Guide for Strategic Planning

The Stakeholders’ Workbook

Facilitate opportunities to talk through potential viral hepatitis activities, challenges, tools, resources, and partnerships related to each priority area.

1) Discuss the questions, e.g.,
- What are the best ways to identify persons with chronic viral hepatitis who do not know they are infected? What can your organization do to promote this?

2) Individualize the hepatitis planning sheet to prioritize, set timeframes, & goals

Available at www.AIDS.gov/hepatitis

Exploring Vital Roles and Opportunities for Stakeholders

- Health departments
- Community-based organizations
- Patient advocacy organizations

Includes key messages and specific opportunities for:
- Health care providers
- Patients, Advocates, and Individuals
- Professional organizations and associations
- Schools and training programs

Available at www.AIDS.gov/hepatitis
Community Leadership and the Stakeholders’ Workbook

We Have the Tools!

- Centers for Disease Control and Prevention
  - Educational materials, training resources, and guidelines
    - www.cdc.gov/hepatitis

- U.S. Department of Health and Human Services
  - Viral Hepatitis Action Plan, Stakeholders’ Workbook, updates & reports, and blogs
    - www.AIDS.gov/hepatitis

- U.S. Department of Veterans Affairs
  - Patient and Provider education and tools
    - http://www.hepatitis.va.gov/

- American Association for the Study of Liver Disease
  - Primary healthcare provider training on viral hepatitis
    - http://www.aasld.org/act-first-free-online-cme-course-primary-care provid ers
CALL TO ACTION

Thank You!

Contact:
Michelle Moses-Eisenstein, MPH
michelle.moses-eisenstein@hhs.gov