Monitoring the HCV care cascade to inform public health action

Susan Hariri, PhD
Division of Viral Hepatitis
Centers for Disease Control and Prevention

NASTAD Hepatitis Technical Assistance Meeting
Washington D.C.
October 20, 2015
New opportunities to combat HCV “Silent Epidemic”

- **Improved treatment and management**
  - Safe, curative drugs

- **Enhanced screening recommendations**
  - One time testing in baby boomers (CDC/USPSTF)

- **Expanded access to health care since ACA**
  - Linkage to care and management

- **Increased awareness of HCV as public health problem**
  - Opioid and heroin abuse epidemic
  - HIV outbreak in Indiana
HHS Action Plan for the Prevention, Care and Treatment of Viral Hepatitis

- Updated for 2014-2016

- Goals (HCV-related)
  - Reduce new cases of HCV by 25%
  - Increase proportion of persons aware of HCV infection from 45% to 66%

- Priority areas (HCV-related)
  - Educate providers and communities
  - Strengthen surveillance
  - Improve testing, care, treatment
Division of Viral Hepatitis Strategic Plan

Vision: To eliminate viral hepatitis in the U.S. and worldwide

Mission: Bring together science and public-health to eliminate VH

Goals: Decrease incidence and prevalence of viral hepatitis
Decrease morbidity and mortality from viral hepatitis
Reduce viral hepatitis-related health disparities

Objectives: Assure all persons living with VH are identified and linked to recommended care and treatment services

Improve continuum of testing, care, and treatment (cascade)
Care cascade

- Approach to describe and quantify discreet, sequential steps in the spectrum of engagement in care from testing to treatment
- Developed to achieve benefits of antiretroviral therapy to prevent HIV and associated sequelae
- Important tool at national, state, and local levels
  - Measure progress toward goals
  - Monitor engagement in care
  - Identify gaps in services and barriers to progression
  - Implement evidence-based strategies and/or develop new approaches to address gaps
  - Strengthen education and advocacy to inform public health policy/action
HCV care cascade

1. Detect infection (antibody test)
2. Confirm diagnosis (RNA test)
3. Link to care and assessment (genotype, stage)
4. Treat (DAA)
5. Cure (SVR)

DAA, direct acting antiviral
SVR, sustained virologic response

~ 6-18 months depending on treatment response
Different ways to define the HCV care cascade

| HCV screening with antibody test | HCV antibody screening test  
|                                | HCV antibody positive        
|                                | Received screening test results |
| Chronic HCV diagnosis          | HCV RNA test accepted        
|                                | HCV RNA test positive        
|                                | Chronic HCV diagnosed and aware |
| Engagement and retention in HCV care | Had or obtained insurance     
|                                   | Had or obtained PCP          
|                                   | Saw a provider               
|                                   | Referred for HCV Treatment   
|                                   | Told Needed Regular Care     
|                                   | Linked to care               
|                                   | Retained in specialty care   
|                                   | Genotype Test                
|                                   | Liver biopsy                 
|                                   | Liver disease staging        
| HCV treatment                  | Told needed treatment        
|                                   | Initiated therapy            
|                                   | Adhered to therapy           
|                                   | HCV RNA follow up testing    
| HCV cure                       | Achieved SVR                 |
Different ways to display the HCV care cascade

- 3.2 million of U.S. population with chronic HCV infection
- 1.6 million (50%) had HCV detected
- 1.0–1.2 million (32–38%) were referred to care
- 380,000–550,000 (12–18%) underwent liver biopsy
- 630,000–750,000 (20–23%) had HCV RNA test
- 220,000–360,000 (7–11%) were treated
- 170,000–200,000 (5–6%) were successfully treated

Graphs showing different stages of the HCV care cascade:

- Estimated with chronic HCV infection
- Diagnosed with chronic HCV infection
- Linked to HCV care
- Treated with HCV antiviral medications
- Estimated to have SVR
Approaches to monitoring care cascade

- No single “correct” method
- Depends on needs, objectives, data sources

**Population level**
- Same denominator used in each step
  - Total number of persons with chronic HCV infection (including undiagnosed)
  - Total number of persons with chronic HCV diagnosis
- Cross-sectional representation of longitudinal process
- Can use different data sources for different steps
- Useful for monitoring progress nationally

**Cohort level**
- Numerator from each step used as denominator in following step
- Follow cohort of individuals along cascade
- Useful to identify gaps and opportunities for interventions
- Difficult to accomplish on large scale
HCV care cascade, United States

- Chronic HCV: 3.2 M (100%)
- Antibody tested: 1.6 M (50%)
- Linked to care: 1.2 M (38%)
- HCV RNA: 750 k (23%)
- Treated: 360 k (11%)
- SVR: 200 k (6%)

Meta-analysis 2006-2013

Birth Cohort demonstration project*  
Oct 2012 – June 2014

N=4,050

HCV Ab+  RNA tested  RNA+  Linked to care  Attended 1st appt

62  71  79  70

*conducted in venues serving high risk populations including health departments, hospitals, correctional facilities, substance abuse treatment centers, STD clinics, homeless shelters
DVH plan for monitoring the HCV care cascade

Established work group to:

- Develop methods
  - Based on purpose and level of evaluation
  - Tailored to population and setting (baby boomers priority)
  - Standardize as much as possible
    - Compare over time and across settings
    - Consistent messaging and reporting

- Identify data sources
  - Wherever possible, regional/state/local level data

- Define steps

- Select measurable indicators
Traditional public health data

- **Surveillance systems**
  - National Notifiable Diseases Surveillance System (NNDSS)

- **Vital records and registries**
  - State-based birth and death records
  - National Death Index
  - State-based cancer registries

- **Population surveys**
  - National Health and Nutrition Examination Survey (NHANES)
    - Specimens collected for testing
    - Best source for estimating viral hepatitis prevalence
  - National Health Interview Survey (NHIS)
  - Behavioral Risk Factor Surveillance System
Novel “big” data sources

- Commercial reference laboratories
- Insurance claims (pharmacy, ICD-9, CPT)
  - Can be stratified by state, MSA
- Medicare and Medicaid claims (national, state)
- Ambulatory electronic medical records (EMR)
  - Can be stratified by state
- Outpatient pharmacy claims
- Veterans Administration (national, state)
- Federally Qualified Health Center (FQHC) EMRs
Commercial laboratory data
LabCorp and Quest

- **Laboratory tests and results**
  - Hepatitis A, B, C, E*
  - Liver function tests
  - ICD9 codes submitted with test
  - Pregnancy indicator

- **2011 to 2015**
  - ~12 million people with a HCV test

- **National data**
  - Can stratify by state, 5- or 3-digit zipcode
  - Representation varies by region (e.g., few tests MN, WI, ND, SD)

- **Denominator: population served by LabCorp and Quest**

*Quest only*
Trends in HCV antibody testing, Quest laboratories, 2011-2015
<table>
<thead>
<tr>
<th>Pennsylvania</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Q1</td>
<td>Q2</td>
<td>Q3</td>
</tr>
<tr>
<td>Number of persons tested for</td>
<td>29,231</td>
<td>28,652</td>
<td>28,119</td>
</tr>
<tr>
<td>HCV antibody</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of persons who tested</td>
<td>2,188</td>
<td>2,007</td>
<td>1,972</td>
</tr>
<tr>
<td>positive for HCV Ab*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Percent positive</td>
<td>7.3%</td>
<td>7.0%</td>
<td>7.0%</td>
</tr>
<tr>
<td>Number of persons tested for</td>
<td>5,159</td>
<td>4,438</td>
<td>4,243</td>
</tr>
<tr>
<td>RNA by date of first test</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of persons who tested</td>
<td>2,944</td>
<td>2,669</td>
<td>2,595</td>
</tr>
<tr>
<td>positive for HCV RNA*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Percent positive</td>
<td>57.1%</td>
<td>60.1%</td>
<td>61.2%</td>
</tr>
</tbody>
</table>

*by date of first positive test
HCV antibody testing and positivity by county, Pittsburgh region, 2011-2015

Percent positive not shown for those zip codes with less than 100 tests
MarketScan

- Commercial insurance claims database
  - Includes most Medicare enrollees
- 1995 - 2013
- ~ 44 M persons in 2013
- National coverage
  - Can stratify by state and MSA
- Laboratory results for ~ 3M persons
  - Can be used for validating ICD9 codes
- Outpatient Rx data (inpatient Rx also exist)
- Medicaid data for few states (pooled) for some years
HCV antibody testing by birth year group, MarketScan commercial Insurance and Medicare claims data

Unpublished data
DVH data dissemination plans

- **Quarterly reports to states/jurisdictions**
  - More frequent/detailed as needed

- **DVH website**
  - National and state level data
  - Updated regularly

- **Published manuscripts**
  - Descriptive, trends by demographic characteristics
  - Predictors and barriers to progression
DVH assistance to develop state/local cascade

- Guidance on developing care cascade to monitor progress at local level

- Determine purpose of the cascade
  - Collaboration with surveillance partners and other stakeholders
  - Determine population and setting

- Define cascade steps and indicators
  - WG calls around each step
  - Calculation (numerator, denominator)

- Identify local data sources (years)
  - State vital records (birth, death)
  - State registries (cancer, immunization, organ transplant)
  - HIV/AIDS reporting system
  - Hospital discharge data
Acknowledgements

- Claudia Vellozzi
- Lauren Canary
- Craig Hales
- Cheryl Isenhour