The Path toward HCV Elimination by 2030

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WHO Impact Targets for Elimination of Hepatitis B and Hepatitis C as Public Health Threats

90% reduction in new cases of chronic HBV and HCV infection

65% reduction in deaths from chronic HBV and HCV

6-10 million infections (in 2015) to 900,000 infections (by 2030)

1.4 million deaths (in 2015) to under 500,000 deaths (by 2030)
Epidemic of HCV-Associated Morbidity and Mortality

- 3.5 M persons living with HCV
- 81% are persons born 1945-1965

70% of Baby Boomers have Moderate to Severe Liver Disease

Rising HCV mortality - 19,659 Deaths (2014)

Impact of HCV Testing, Care, and Curative Treatment

- **Test policy:** (2012)
  - Persons born 1945-1965
  - Persons who inject drugs
  - Others at risk

- **Care and Treatment:** ~90% cure with one to several pills/day for 8-12 weeks

- **Benefits:**
  - 73% reduction in liver cancer
  - 93% reduction in liver-related mortality

- **Impact:**
  - Prevention of 321,000 HCV deaths
  - Decreased HCV transmission to others

van der Meer JAMA 2012; Morgan Ann Int Med 2012; Rein CID 2015; Martin, CID 2013

<table>
<thead>
<tr>
<th>Stage</th>
<th>2001-2006</th>
<th>2007-2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aware of infection</td>
<td>50%</td>
<td>59%</td>
</tr>
<tr>
<td>Saw doctor for follow-up</td>
<td>41%</td>
<td>55%</td>
</tr>
<tr>
<td>Told by doctor additional follow-up needed</td>
<td>24%</td>
<td>35%</td>
</tr>
<tr>
<td>Told about treatment</td>
<td>16%</td>
<td>33%</td>
</tr>
<tr>
<td>Told treatment needed</td>
<td>12%</td>
<td>28%</td>
</tr>
<tr>
<td>Received treatment</td>
<td>7%</td>
<td>22%</td>
</tr>
</tbody>
</table>

Awareness and Medical Follow-Up

Foster, M, IDSA 2016; Holmberg, S, NEJM 2013
Strategies that Expand Access to HCV Testing, Care, Cure

- Testing policies
- Provider education
- Clinical decision tools
- Reflex RNA testing
- Performance indicators/incentives
- Case management
- Co-localization of HCV and primary care
- Accessible HCV therapies

Percent HCV Antibody Tested by Birth Year Group

Birth Year Group:
- 1945-1965
- Other birth years

Cost of HCV Treatment and Influence on Access

Recent Actions

- In 2014, most state Medicaid limited access: fibrosis score, provider type, sobriety criteria
- CMS cautions states about restrictive HCV treatment policies Nov. 2015
- Approval of new drugs (e.g., Zepatier, list price of $54,600, Jan. 2016)
- Negotiated lower drug prices (VA ~$17K)
- Legal actions (e.g., WA state)
- Therapy cost saving with < $70K drug costs (genotype 1) *

From 2014-2016, 16 states reduced fibrosis requirements. In 2016, 9 states have no fibrosis restriction- CT, FL, MA, NY, WY, AZ, GA, NV, WA (none in 2014)

In 2016, 23 states limited HCV treatment to those with severe fibrosis and cirrhosis (F3, F4)

HCV Patient Initiations on Sofosbuvir-Based Regimens

Patient Initiations in thousands

Q2 15 | Q3 15 | Q4 15 | Q1 16 | Q2 16 | Q3 16
---|---|---|---|---|---
60 | 14 | 35 | 31 | 19 | 31
52 | 26 | 30 | 27 | 15 | 21
37 | 14 | 30 | 30 | 15 | 21
158 | 151 | 139 | 146 | 133 | 119

Note: Graph illustrates the estimated number of patients that started therapy with a Gilead HCV drug for each quarter. Patient numbers are subject to adjustments. Rest of World is comprised primarily of Australia, Brazil, Egypt, and Canada.

Sofosbuvir was approved in the U.S. in December 2013 and in the EU in January 2014. Harvoni was approved in the U.S. in October 2014 and in the EU in November 2014. In Japan, Sofosbuvir launched in May 2015 and Harvoni launched in September 2015.
The US is on Track to Achieve WHO Goal for Elimination of HCV Mortality

- Annual Treatment Penetration = 280,000

- No treatment vs. Pre-DAA vs. DAA era

- Liver-related Deaths

Hepatology
Volume 64, Issue 5, pages 1442-1450, 1 JUN 2016 DOI: 10.1002/hep.28571
Priorities for Elimination of HCV Mortality

- **DIAGNOSIS**: Proportion of persons unaware of HCV status will increase over time
  - HCV testing with linkages to treatment will increase in importance
  - Expand adoption of HCV testing as routine clinical service (including reflex PCR)
  - Expand testing in diverse settings (e.g., ED, dialysis, corrections) and populations (e.g., age)

- **DISPARITIES**: HCV infected persons will be increasingly among marginalized populations (e.g., Medicaid, low SES, rural, racial/ethnic minorities, incarcerated)
  - Community education and partnership with key stakeholders
  - Case managers to engage persons in care and completion of treatment
  - Care models deemed affordable and effective for target populations

- **DATA**: Limited local capacity to track HCV cure cascade and health inequities
  - Track and document progress toward goals
  - Sustain focus on inequities in HCV testing/treatment access
  - Assist quality improvement at provider level
Change in HCV Incidence is Associated with Increases in Injection Drug Use

• ~31,000 new HCV infections in 2015

Suryaprasad, CID 2014, Zibbell MMWR 2015, CDC unpublished data
Rates of Infants Born to HCV Infected Women, Kentucky and the United States 2011, 2014

Koneru, A, MMWR 2016
Syringe Service Program (SSP) and Medication Assisted Treatment (MAT)

- SSP and MAT effective in reducing self-reported injecting risk behaviour
  - Limited evidence for effect on HCV transmission

- New Cochrane systematic review offers new data
  - MAT alone decreases risk by 50%
  - SSP alone decreases risk by 56% (in Europe)
  - MAT + SSP jointly decreases risk by 71%

<table>
<thead>
<tr>
<th>Reference</th>
<th>Risk Ratio (95% CI)</th>
<th>% Weight</th>
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<tbody>
<tr>
<td>High NSP coverage</td>
<td></td>
<td></td>
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<tr>
<td>Hope, 2011</td>
<td>0.17 (0.02, 1.54)</td>
<td>4.85</td>
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<tr>
<td>Bruneau, 2015</td>
<td>0.63 (0.37, 1.07)</td>
<td>20.26</td>
</tr>
<tr>
<td>Van Den Berg, 2007</td>
<td>0.15 (0.06, 0.40)</td>
<td>13.66</td>
</tr>
<tr>
<td>Palmateer, 2014</td>
<td>0.24 (0.10, 0.60)</td>
<td>14.81</td>
</tr>
<tr>
<td>Subtotal (I-squared = 64.4%, p = 0.038)</td>
<td><strong>0.29 (0.13, 0.65)</strong></td>
<td></td>
</tr>
<tr>
<td>Low NSP coverage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hope, 2011</td>
<td>1.08 (0.31, 3.82)</td>
<td>10.54</td>
</tr>
<tr>
<td>Van Den Berg, 2007</td>
<td>1.04 (0.53, 2.05)</td>
<td>18.03</td>
</tr>
<tr>
<td>Palmateer, 2014</td>
<td>0.48 (0.24, 0.95)</td>
<td>17.85</td>
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<tr>
<td>Subtotal (I-squared = 29.6%, p = 0.242)</td>
<td>0.76 (0.44, 1.33)</td>
<td>46.42</td>
</tr>
<tr>
<td>Overall (I-squared = 62.2%, p = 0.014)</td>
<td>0.47 (0.27, 0.80)</td>
<td>100.00</td>
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NOTE: Weights are from random effects analysis.
Distribution of HCV Among Young Persons and Location of Syringe Service Programs

Of 29,382 persons 15-29 yrs. with HCV, 20% lived within <10 miles of a syringe service program.
Impact of HCV Treatment As Part of Prevention Services for PWID in Rural Setting: Scott County-Like Outbreak

Decrease in HCV incidence

52% decrease in with MAT/SSP

69% with MAT/SSP/Treatment years.

Vikerman P, unpublished data
2016 Medicaid FFS Sobriety Requirements

12 states have no sobriety restrictions
29 states require 1 month to 1 year abstinence from drugs or alcohol
Priorities for Elimination of HCV Transmission

**DETECT** - HCV spreads quickly/quietly among persons who inject drugs
- Promote testing/reporting from target settings (e.g., drug treatment, corrections, ED, OB/GYN)
- Revise testing/reporting policies (e.g., age, perinatal)
- Investigate transmission networks (lab/epi/behavioral science tools)
- Provide data to target response

**RESPOND** - Evidence based interventions can stop transmission
- Need large increase in prevention capacity
- Safe injection programs (new permissive use of federal funds for syringe service programs)
- Substance abuse treatment (new SAMHSA funds)
- HCV testing and curative therapy as part of Cure and Prevention strategies
- Community engagement

**RESEARCH** - improve implementation of prevention strategies
- Engage persons who inject drugs in HCV prevention/care (CDC/NIDA/SAMHSA/ARC study)
- Begin and complete HCV treatment and prevent reinfection (PCORI study)
Eliminating the Public Health Problem of Hepatitis B and C in the United States

• 90% of HCV infections are curable; 80% of new HCV infections are preventable

• The elimination of hepatitis C and hepatitis B as public health threats is achievable

• Substantial issues must be addressed to meet elimination goals

• In early 2017, final report will be released with strategies to reach elimination goals

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