The Twin Epidemics of Hepatitis C Virus (HCV)
Transmission and Disease

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The Silent Epidemic of HCV

- HCV is a common infection with high incidence, prevalence, morbidity, and mortality
  - Untreated, 40% of people will die from their infection
- Many factors keep it under appreciated, including:
  - Long asymptomatic incubation
  - No powerful advocacy
  - Perceptions of cost

Twin Epidemics of HCV
Transmission and Disease

- Seroprevalence highest in 1945-1965 cohort
  - 6X prevalence (3.4%) than others
  - 81% of HCV + adults; 73% of deaths
- Health disparity for blacks, AI/AN

These persons who inject drugs (PWIDs) are mainly:
- Young (aged 20-29 yrs);
- White, roughly equal gender distribution
- Non-urban (suburban, rural); and
- Previous oral prescription opioid users

Sources used:
Surveillance, CID 2014; Denniston Ann Int Med 2014, Smith, MMWR 2012,
HCV Modes of Transmission and Prevalence

- **Injection drug use**
  - Predominant current transmission mode
  - Risks: injection frequency, duration, equipment sharing
  - Incidence: 10-15% per year

- **Unsafe health care**
  - More common risk prior to HCV discovery

- **Other modes**
  - Perinatal: 5-15%, mothers with HIV at highest risk
  - Sexual transmission: rare; HIV infected MSM at highest risk
  - Also reported (e.g., inhaled drugs, unregulated tattooing)

Prevalence

<table>
<thead>
<tr>
<th>civilian, non-institutionalized populations (NHANES)</th>
<th>2.7 million (2.2-3.5 million)</th>
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<tbody>
<tr>
<td>1.6% (9.8%-1.3%)</td>
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Estimated HCV infection among homeless and incarcerated persons (not included in NHANES)

<table>
<thead>
<tr>
<th>Estimated HCV Infection Among Homeless and Incarcerated Persons</th>
<th>340,000-840,000</th>
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<tr>
<td>21%-52%</td>
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Natural History of HCV Infection

Estimated Burden of HCV-Related Morbidity and Mortality if diagnosis and treatment not expanded

- Markov model of health outcomes
  - Of 2.7 M HCV infected persons in primary care
    - 1.4M will develop cirrhosis
    - 350,000 will develop liver cancer
    - 897,000 will die from HCV-related complications
Increasing HCV-Related Morbidity and Mortality

Hospitalizations in Adults with Principal Diagnosis of HCV, HBV, or HIV, Nationwide Inpatient Sample, 2004-2011

Deaths from HCV and All Other Nationally Notifiable Infectious Conditions*, U.S., 2003-2013


Hospitalizations in Adults with Principal Diagnosis of HCV, HBV, or HIV, Nationwide Inpatient Sample, 2004-2011

Impact of HCV Testing, Care, and Curative Treatment

• Test:
  – Persons born 1945-1965
  – Persons who inject drugs

• 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

Barriers Limit Access to HCV Testing, Care, and Treatment

• Policies to guide HCV testing
• Poor provider knowledge
• Lack of clinical decision tools
• Limited public health data to monitor performance
• Few patient navigators per volume
• Denial of CMS reimbursement for testing (e.g., ED, in-patients) and treatment
• Cost of HCV therapy

Holmberg et al., N Engl J Med 2013
Key Strategies to Improve Access to HCV Testing, Care, and Curative Therapy

- 34 CDC funded programs identified practices to remove barriers:
  - Data to monitor care cascade
  - Provider/public education
  - Clinical decision tools
  - Care models
  - Negotiated affordable diagnostics
  - Target health disparities

Results of HCV Testing Program for Homeless and Public Housing Clients, Philadelphia, PA

- 11% anti-HCV+
- 92% tested for RNA
- Of HCV RNA+
  - 89%
  - 75%
  - 63% RNA +

Birth Cohort Testing for HCV in the Indian Health Service (2012-2015)

- Provider education
- Clinical decision prompts

Birth Year Group

Percent HCV Antibody Tested by Birth Year Group
MarketScan Insurance Claims Data, 2005-2014
New Hepatitis C Treatments
- New therapies and others in development
  - Shorter treatment time
  - Easier to take
  - Fewer side effects
  - More effective (curing 95% of cases)
- Treatment access
  - Inpatient clinic formulary (e.g., Alaska Native Medical Center)
  - Patient assistance programs (e.g., AbbVie, Gilead, Janssen, Merck, and Patient Access Network Foundation)
- Affordability
  - Prices are declining from first market prices of $86K-$94K/ course
  - Negotiated prices
    - $32K-56K range for health plans
    - Might be as low as $17K for USG program (VA, IHS)

Cost of Treatment and Influence on Access
Recent Actions
- CMS cautions states about restrictive HCV treatment policies, November 5, 2015
- Approval of ZEPATIER with list price $54,600, January 2016
- Report of lower prices; for VA (~$17K)
- Legal actions (WA) removing restrictions based on disease severity

Medicaid Fibrosis Requirements for HCV Therapy, 2014 vs 2016
- 14 (36%) of 36 state Medicaid programs lowered their requirements

Changes in HCV Cost and Cost Effectiveness

<table>
<thead>
<tr>
<th>Model</th>
<th>Cost to implement</th>
<th>Savings in Health Costs</th>
<th>ICER</th>
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<tr>
<td>2014 Initial market price</td>
<td>$65.9b</td>
<td>$14.3b</td>
<td>$36,687</td>
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<tr>
<td>2016 Current cost estimates</td>
<td>$44.0b</td>
<td>$44.4b</td>
<td>$41</td>
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Potential Impact on Future Burden of Hepatitis C Related Mortality in the US

Reported Cases of Hepatitis C, by County, United States, 2013 and 2014 Combined

Change in HCV Incidence is Associated with Increases in Injection Drug Use

CDC.gov/hepatitis; Superseded: CID 2014; Zibbell MMWR 2015.
Reports of infants Born to HCV Infected Women: Kentucky, United States, 2011-2014

Number of Persons Born After 1984 with a Positive HCV Antibody or RNA Test Result, by Place of Residence and Testing Laboratory

2012
N= 24,206

2015
N= 52,308
Incidence of Acute HBV Infection—United States and Kentucky, Tennessee, and West Virginia, 2006–2013

Hepatitis B Vaccination Coverage 2012-2014

Results of HCV and HIV Testing in Scott County and Other Areas, Feb.- Sept. 2015

Total tests 1537
• HCV positive- 599 (39%)
  – HIV Positive- 116 (19%)
  – HIV Negative- 483 (81%)
• HIV positive - 125 (8%)
  – HCV Positive- 116 (92%)  
  – HCV Negative- 9 (8%)
  813 HCV/HIV negative specimens

- HCV positive - 599
  - HIV Positive - 116 (19%)
  - HIV Negative - 483 (81%)
- HIV positive - 125
  - HCV Positive - 116 (92%)
  - HCV Negative - 9 (8%)

100 persons; 50 with mixed genotypes
Multiple introductions of HCV and super infections

Overlay of HIV Contact Tracing and HCV Genetic Networks

Counties at Risk for HIV and HCV Outbreaks in PWID, U.S.

Syringe Services Program (SSP) Coverage, U.S., June 2014

Van Handel, JAIDS, 2016; Des Jarlais MMWR 2015
Impact of HCV Treatment As Part of Prevention Services for PWID: Scott County-Like Outbreak

Impact at 10 years

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<th>Year</th>
<th>Chronic prevalence (%)</th>
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<td>2012-2014</td>
<td>50%</td>
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<tr>
<td>2016-2018</td>
<td>50%</td>
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<td>2020-2022</td>
<td>50%</td>
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<tr>
<td>2024-2026</td>
<td>50%</td>
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<tr>
<td>2028-2030</td>
<td>50%</td>
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NSP = needle exchange program
OST = oral treatment

Fraser H, et al. manuscript in preparation

CDC Activities to Improve HCV Prevention Among Persons Who Inject Drugs

- Implement CDC SSP guidance
  - Assist state/local HD establish ‘determination of need’
  - Assist local programs implement an SSP
  - Communication materials

- Support state/local planning and response
  - Appalachian region training mtg – July 26-27
  - Participates in town hall, E. KY July 28
  - Support NACCHO local planning grant - SW Virginia

- Support state/local surveillance and investigation
  - Epi-AID, HCV in E. TN, July 2016
  - Prioritize surveillance funds for states with high HCV incidence (FY17)
  - Report HCV trends among pregnant women; assist HHS develop reporting criteria

- Prevention research
  - Study of HIV, HCV testing and prevention in non-urban areas (NIDA, collaborator)
  - RCT of HCV therapy strategies for PWID (PCORI)

Global and Domestic Strategies and Plans to Eliminate Viral Hepatitis Transmission and Disease

- World Health Assembly (WHA) encourages global elimination goals(2014)
- CDC Elimination Project- Overseas Notice (2014)
- CDC TA: CDCF project
- With support WHO global hepatitis strategy and hepatitis elimination goals
- CDC/MHA
- Global HCV Elimination Project (2015)
- CDC TA, CDCF project
- CDC/AA
- With support WHO hepatitis strategy and hepatitis elimination goals
- CDC/MHA
- Global HCV Elimination Project (2015)
- CDC TA, CDCF project
- CDC/AA
Our hope is to eliminate this disease entirely through Cherokee Nation Health Services. As Native people and as Cherokee Nation citizens, we must keep striving to eliminate hepatitis C from our population.

Feb. 22, 2016

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

- 50% reduction in new cases of chronic HBV and HCV infection
- 65% reduction in deaths from chronic HBV and HCV

 Decrease HBV and HCV Incidence by 60% to Reach Goals for 2020

- 6.2 million infections in 2015 to 900,000 infections by 2030
- 1.4 million deaths in 2015 to under 500,000 deaths by 2030

*Note that AK, AZ, CT, DE, HI, IA, MS, NH, RI, and WY did not provide data to CDC on HCV incidence but did provide data on HBV incidence

State did not provide data

State is above the national goal (HBV)

State is above the national goal (HCV)

State is above the national goal (HBV and HCV)
Simple, Effective, but Out of Reach? Public Health Implications of HCV Drugs

John W. Ward, M.D., and Jonathan W. Martin, M.D., M.P.H.

“The availability of simple, safe, and curative regimens creates opportunities for improving the health of the millions of patients living with HCV infection. At a population level, the effect of HCV medications will be determined by affordability and equitable access to HCV testing, care, and treatment. Only through these improvements can our focus be directed to what matters most: reducing the morbidity and mortality associated with HCV infection, stopping HCV transmission, and ultimately eliminating HCV as a public health threat in the United States and worldwide.”

Thank You