HCV Elimination in Oregon – Primary Care is Key

Kent Benner, MD, FAASLD
The Oregon Clinic

HCV: Diagnosis to Elimination

1989
Discovery of HCV Virus

1989
NANB - Interferon

2019
Elimination of HCV Virus

2019
Advanced fibrosis / cirrhosis

2019
Treatment side-effects / Limited efficacy

2019
Interferon/Ribavirin

2019
Mild liver injury

2019
Few SE’s / high efficacy

2019
HCV DAA’s

2019
Primary Care / Public Health

2019
GI/Hepatology/ID

2019
Industry / Academic Centers
Chronic Hepatitis C - Treatment Challenge

- A 24-year-old man with opioid use disorder (OUD) who screened positive for HCV antibody in jail would like to be treated for HCV.
  - He began experimenting with prescription drugs ("percs," "oxys") at age 15, snorting heroin at 19 and first injected at age 21.
  - He uses a needle-syringe program (NSP) but is not currently engaged in medication-assisted treatment (MAT).
  - HCV RNA testing confirms active HCV infection and non-invasive testing suggests mild liver fibrosis.

- Would you treat him?

Global HCV Burden of Disease

- **Prevalence:** HCV: 71 million (1%)
  - 2/3 living in Europe, south Asia, north Africa
  - Seven countries (China, Pakistan, India, Egypt, Russia, United States, and Nigeria) account for half of the global population of HCV infected persons.
- **Countries with >3% prevalence**
  - Mongolia, Egypt, Georgia, Pakistan, Russia

- **21% of hepatocellular carcinoma deaths**

- **Deaths** 420,000 deaths (2016)
Current All-Oral Therapies Highly Effective, Simple, Well Tolerated

References in slides notes

THE LATEST HEP C TREATMENTS

TALK TO YOUR DOCTOR, NURSE OR CLINIC ABOUT THE NEW CURES FOR HEP C

WHO ARE THEY FOR? ADULTS WHO HAVE HEP C AND A MEDICARE CARD

1. MOST PEOPLE HAVE NO OR VERY MILD SIDE EFFECTS
2. FOR A SMALL NUMBER OF PEOPLE, TREATMENT MAY LAST LONGER

IMPORTANT NOTE: TO MAKE SURE YOU ARE CURED, YOU NEED TO GET A FORBLOOD TEST AT LEAST 12 WEEKS AFTER YOU FINISH YOUR TREATMENT.
Elimination Programs Improve Access in Country of Georgia

- ~150,000 HCV RNA+ persons; 5.4% prevalence
- Goal: 90% diagnosed; 95% treated; 95% cured by 2020

Key tools:
- National planning
- Data to guide and evaluate program
- Health system strengthening
- Political support
- Partnerships – Gilead, Abbott, CDC, State, WHC

- Number treated 40,000 (April/15 – Oct/17)
- Reduced prevalence by 21% to 4.0%

Nasrullah M, Nat Rev Gastroenterol Hepatol. 2017 Jul

HCV Cascade of Care in VA

68% of the people in VA care in 2018 who previously had known chronic HCV have been cured

*Estimated from diagnosed ratio of prevalence in birth cohort strata in those treated in prior two years applied to those still untreated.
†Diagnosed with chronic HCV defined as ever had a detectable HCV RNA or genotype.
‡Linked to HCV care required an out-patient visit in the year, entry in the VHA’s HCV registry and HCV entered on the patient’s medical record problem list.
◊Treated with HCV antivirals defined as ever received HCV antivirals from VHA as of 31 December of the year.
●Achieved SVR defined as undetectable HCV RNA on all tests after end of treatment including at least one test at least 12 weeks after the end of treatment

Population Health Service 10P4A; data as of 12/31/2018
Goals for Elimination of HBV and HCV by 2030

Prevent 7.1 million deaths by 2030

Endorsed by World Health Assembly and International Task Force for Disease Eradication

HCV Prevalence – USA 2018

- NHANES 2013-2016 data adjusted to the state level, considering the addition of homeless and institutionalized populations
- Data was further adjusted using state specific HCV mortality and narcotic overdose rates
- Oregon is a high prevalence state (2013-2016)
HCV-Related Deaths
Oregon Exceeds the National Rate


Age-Adjusted Rate Per 100,000 Persons

<table>
<thead>
<tr>
<th>Year</th>
<th>Oregon</th>
<th>US</th>
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<tbody>
<tr>
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<td>2004</td>
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<td>2005</td>
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<td>2006</td>
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<td>2008</td>
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<tr>
<td>2011</td>
<td>5.3</td>
<td>5.2</td>
</tr>
<tr>
<td>2012</td>
<td>5.6</td>
<td>5.5</td>
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</table>

Age-Adjusted Mortality Rates for HIV and HCV: Oregon and US, 1999–2013

Year

<table>
<thead>
<tr>
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<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>OR HCV</td>
<td>5.2</td>
<td>5.5</td>
<td>5.8</td>
<td>6.1</td>
<td>6.4</td>
<td>6.7</td>
<td>7.0</td>
<td>7.3</td>
<td>7.6</td>
<td>7.9</td>
<td>8.2</td>
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<td>US HCV</td>
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<td>5.7</td>
<td>6.0</td>
<td>6.3</td>
<td>6.6</td>
<td>6.9</td>
<td>7.2</td>
<td>7.5</td>
<td>7.8</td>
<td>8.1</td>
<td>8.4</td>
<td>8.7</td>
</tr>
<tr>
<td>OR HIV</td>
<td>2.5</td>
<td>2.8</td>
<td>3.1</td>
<td>3.4</td>
<td>3.7</td>
<td>4.0</td>
<td>4.3</td>
<td>4.6</td>
<td>4.9</td>
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<td>5.8</td>
<td>6.1</td>
<td>6.4</td>
</tr>
<tr>
<td>OR HIV/HCV</td>
<td>1.9</td>
<td>2.2</td>
<td>2.5</td>
<td>2.8</td>
<td>3.1</td>
<td>3.4</td>
<td>3.7</td>
<td>4.0</td>
<td>4.3</td>
<td>4.6</td>
<td>4.9</td>
<td>5.2</td>
<td>5.5</td>
<td>5.8</td>
</tr>
</tbody>
</table>

Incidence New HCV Infections: Back-calculated to Fit the Total Number of Infections

- Assumed Oregon incidence mirrors US incidence
Changing HCV Demographics

An Increasingly Bimodal Age Distribution:
Oregon, 2015 vs 2018

Age Distribution of Newly Reported Chronic HCV Cases

2015: N=5993

2018: N=1946 (as of May 1, 2018)

Rising HCV Incidence Related to Increases in Injection Drug Use

- In 2016, 41,200 new HCV infections in U.S.
- 80% related injection drug use
- Three-fold increase since 2010
- Parallel increases in injection of prescription opioids and heroin
- Increasing HCV among pregnant women and newborns

Drug use by State: 2019’s “Problem Areas”

- Oregon Rank 12th overall
  - Highest % adult drug users
  - 3rd highest % teenage drug users
  - 5th fewest treatment facilities per 100,000 drug users

- Based on ranking 50 States in 3 areas (lower rank worse):
  - “Drug use and addiction” - Oregon 8
  - “Law enforcement” - Oregon 37
  - “Drug health issues” - Oregon 5

- WalletHub Sources: Data used to create this ranking were collected from U.S. Census Bureau, Bureau of Labor Statistics, Centers for Disease Control and Prevention, Federal Bureau of Investigation, Substance Abuse and Mental Health Services Administration, U.S. Drug Enforcement Administration, Child and Adolescent Health Measurement Initiative, Project Know, the Pew Charitable Trusts, Guttmacher Institute, OHS Health & Safety Services, CVS Health, IMS Institute for Healthcare Informatics and Recovery.org.

Public health impact of a population-based approach to HCV treatment in Oregon

This is a summary of the key outcomes of a hepatitis C virus (HCV) disease burden analysis undertaken by the CDA Foundation’s Polaris Observatory, in collaboration with ASTHO, CDC, Oregon Health Authority, Oregon Health and Science University, The Oregon Clinic, Oregon Department of Corrections, Oregon Medicaid Program, and the Portland Area Indian Health Board.

- In early 2018, ~57,200 HCV-RNA positive (viremic) infections in Oregon
  - ~ 60% (35,800) were diagnosed by year end
  - ~11% of total infections among active PWID
  - ~20% of infected individuals enrolled in Medicaid (~ 11,500 currently infected)
Population-based Approach: Projected Course of HCV in Oregon

This is a summary of the key outcomes of a hepatitis C virus (HCV) disease burden analysis undertaken by the CDA Foundation’s Polaris Observatory, in collaboration with ASTHO, CDC, Oregon Health Authority, Oregon Health and Science University, The Oregon Clinic, Oregon Department of Corrections, Oregon Medicaid Program, and the Portland Area Indian Health Board.

Population-based approach: Current Estimated HCV Burden in Oregon

This is a summary of the key outcomes of a hepatitis C virus (HCV) disease burden analysis undertaken by the CDA Foundation’s Polaris Observatory, in collaboration with ASTHO, CDC, Oregon Health Authority, Oregon Health and Science University, The Oregon Clinic, Oregon Department of Corrections, Oregon Medicaid Program, and the Portland Area Indian Health Board.

• In 2018 ~57,200 HCV-RNA positive (viremic)
  – ~1,400 Oregonians acquired new HCV
  – ~ 4,000 new diagnoses of HCV infection
  – ~3,600 (6% of infected persons) were treated with a 95% cure rate = ~3,400 cured
HCV Infection
A Serious Health Consequence of Injection-Drug Use

HCV prevalence among PWID is estimated to be 70%–77%\(^1\)


1 of 3 people who inject drugs acquires HCV infection in the first year of injecting\(^3\)

45% to 85% of individuals chronically infected with HCV are unaware of their status\(^4\)

Chronic HCV in Oregon, by County
2011–2015

Mean Annualized Rates per 100,000 Persons, by County\(^1\)

HCV and HCV-Treatment Status: OR-HOPE, 2019\(^2\)

Self-Reported Positive, Not Treated 21%
Self-Reported Positive, Treated 5%
New Positive 24%
Negative 50%

OR-HOPE, Oregon HIV/HCV and Opioid Prevention and Engagement (study).
Viral Hepatitis Elimination: Oregon

- Public Policy
  - 2017:
    - OHP: F Grade from Viral Hepatitis Round Table - Barriers to treatment among CCO’s
    - Viral Hepatitis Collective: Patients, advocates, physicians
    - Oregon Law Project: MOA 2016 with the Oregon Health Authority
  - 2019 Oregon Health Division Action
    - OHP eliminates fibrosis, substance use and prescriber restrictions for HCV Rx
    - OHP Sponsored the HCV Learning Collaborative 4/8/2019
      - CCO Medical Directors, Public health specialists, PWID providers, hepatologists
    - Successful Strategies and Best Practices for HCV Elimination in Oregon
    - Modeling the Burden of HCV in Oregon: Chronic Disease Assessment Foundation Grant
      - Public Health Specialists, OHD representatives, Epidemiologists, Hepatologists, ID Specialists, Primary Care Providers
      - Model development: 3/19 – 7/19

Medicaid Prescriber Restrictions: OHP Eliminated in 3/19

2014

2018

2019

No restrictions
By or in consultation with a specialist
Specialist must prescribe
Restrictions unknown

Slide credit: clinicaloptions.com

CHLPI and NVHR at https://stateofhepc.org/.
Medicaid Disease Severity Restrictions: OHP Eliminated in 3/19

Medicaid Substance Use Restrictions: OHP Eliminated in 3/19

Slide credit: clinicaloptions.com CHLPI and NVHR at https://stateofhepc.org/.
Who to Screen

CDC, USPSTF, and AASLD/IDSA
HCV Screening Recommendations

<table>
<thead>
<tr>
<th>Population</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>One-time screening is recommended for persons born between 1945 and 1965, without ascertainment of HCV risk[^1-3]</td>
</tr>
<tr>
<td>Risk</td>
<td>One-time screening is recommended for persons with these risk factors[^1,3]:</td>
</tr>
<tr>
<td></td>
<td>• History of illicit injection drug use (IDU) or intranasal illicit drug use</td>
</tr>
<tr>
<td></td>
<td>• History of long-term hemodialysis</td>
</tr>
<tr>
<td></td>
<td>• Receiving a tattoo in an unregulated facility/setting</td>
</tr>
<tr>
<td></td>
<td>• Healthcare workers upon accidental exposure</td>
</tr>
<tr>
<td></td>
<td>• Children born to anti-HCV–positive mothers</td>
</tr>
<tr>
<td></td>
<td>• History of transfusion with blood or organ transplantation before July 1992</td>
</tr>
<tr>
<td></td>
<td>• Were ever in prison</td>
</tr>
<tr>
<td></td>
<td>• HIV infection</td>
</tr>
<tr>
<td></td>
<td>• Chronic liver disease/hepatitis with unknown cause, including elevated liver enzymes</td>
</tr>
</tbody>
</table>

Annual screening is recommended for current IDUs and HIV-infected MSM[^3]

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Screening: Experience with the BPA

<table>
<thead>
<tr>
<th>Region</th>
<th># screened at Baseline</th>
<th># screened as of 9/30/17</th>
<th>% change from baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alaska</td>
<td>674</td>
<td>1,435</td>
<td>9.70%</td>
</tr>
<tr>
<td>EWA–WMT</td>
<td>7,670</td>
<td>20,408</td>
<td>17.50%</td>
</tr>
<tr>
<td>LA</td>
<td>5,771</td>
<td>17,130</td>
<td>25.60%</td>
</tr>
<tr>
<td>Oregon</td>
<td>16,902</td>
<td>43,157</td>
<td>22.60%</td>
</tr>
<tr>
<td>WWA*</td>
<td>41,436</td>
<td>60,311</td>
<td>14.90%</td>
</tr>
<tr>
<td>System Total</td>
<td>72,453</td>
<td>142,441</td>
<td>19.00%</td>
</tr>
</tbody>
</table>

*Swedish Medical Center Hep C screen BPA started Feb 2015
Primary Care Clinicians Have a Critical Role in Hepatitis C Care

US prevalence of hepatitis C virus infection\(^1\)  
\[1%\]

Average pt load for primary care clinician\(^2\)  
\[x 2000\] pts

Average primary care clinician has 20 pts with hepatitis C virus infection in his/her practice


Hepatitis C Virus (HCV) in the US: Gaps in Practice

DHHS Goal for 2020\(^2\)

- Chronic HCV Infected\(^1\): 3,500,000
- Diagnosed and Aware\(^1\): 1,743,000
- Access to Outpatient Care\(^1\): 1,514,667
- Treated\(^1\): 555,883
- Cured\(^1\): 326,859

Moving Toward a Single-Visit Hepatitis C Diagnosis


Hepatitis C in Oregon
A Closer Look

Risk Factors Among Acute Cases of HCV Oregon, 2009–2013

- Injection Drug Use
- Other Blood Exposure
- Multiple Sex Partners
- Other Risk
- Incarcerated
- Health Care–Associated

Prevalence of HCV in Current Injection Drug Users by Age, Oregon, 2007–2013

Overall, 21% Positive for HCV

*Includes needlesticks, tattoos, and piercings; †Includes transfusions, infusions, dialysis, or surgery; ‡Oregon Adult High-Risk screening Project.

HCV DAA Therapy Is Effective Among PWID, Even in the “Real-World”

- In meta-regression, clinical trials significantly associated with higher SVR rates vs observational studies
  - aOR: 2.18 (95% CI: 1.27-3.75; \( P = .006 \))
- Difference due to loss to follow-up, not virologic failure

Recent IDU

<table>
<thead>
<tr>
<th>Study</th>
<th>SVR, % (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bielen 2017</td>
<td>83.3 (60.8-94.2)</td>
</tr>
<tr>
<td>Boglione 2017</td>
<td>93.9 (89.1-96.6)</td>
</tr>
<tr>
<td>Boscaillou 2017</td>
<td>80.4 (73.0-86.2)</td>
</tr>
<tr>
<td>Conway 2017</td>
<td>96.7 (88.8-99.1)</td>
</tr>
<tr>
<td>Grebely 2018</td>
<td>94.2 (87.9-97.3)</td>
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<tr>
<td>Mazhnaya 2017</td>
<td>64.0 (44.5-79.8)</td>
</tr>
<tr>
<td>Milne 2017</td>
<td>87.4 (80.2-92.2)</td>
</tr>
<tr>
<td>Valencia 2017</td>
<td>74.4 (59.8-85.1)</td>
</tr>
<tr>
<td>Overall</td>
<td>87.4 (82.0-92.8)</td>
</tr>
</tbody>
</table>

Treatment Adherence Among Persons With Recent IDU: SIMPLIFY - 12 Wks. of SOF/VEL

- 97% (100/103) completed treatment; median treatment adherence: 94%
- 32% had < 90% adherence (nonadherent)
- SVR rate 94% in adherent and nonadherent group (\( P = .944 \))

Sample Daily Adherence for 4 Participants
The Challenge to Elimination of HCV Transmission Prevention Services for Persons Who inject Drugs

- Drug treatment + safe injection equipment reduces transmission risk by 74%
- Only 86 and 93 countries have these services, respectively
- WHO target -200 needle/syringe exchanges per PWID annually—
  - Global – 33
  - US- 30
- PWID HCV prevalence is lowest in countries with greatest access to prevention services
  - e.g. Australia, Netherlands

Larney S, Lancet Glob Health. 2017

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Reinfection Rates in PWID Following DAA Treatment

A Meta-Analysis and Systematic Review

EASL, April 2019

- Overall conclusions (n=22 studies; 5112 total PYFU)
  - Posttreatment HCV reinfection rates
    - Receiving MAT with no recent IDU: 1.3 per 100 PYFU (95%CI: 0.5, 3.2)
    - Recent IDU and receiving MAT: 3.6 per 100 PYFU (95%CI: 1.5, 9.1)
    - Recent IDU, not receiving MAT: 4.6 per 100 PYFU (95%CI: 2.1, 10.3)
  - Lower rate in studies with long-term follow-up suggested higher risk of reinfection early posttreatment
  - Harm reduction services are needed to reduce the reinfection risk, while regular posttreatment HCV assessment is needed to detect and treat reinfection early

PYFU, person years follow-up.
*Stratified analysis.
Treatment as Prevention
If We Treat More High-Risk Patients, We’ll Eliminate HCV Sooner

- Modeling the Effect of HCV Treatment on Reinfection in PWID

But, we must concomitantly scale up harm-reduction measures
- Medication-assisted treatment
- Syringe services programs
- Increased intensity of HCV management
- Patient education and counseling

- Increase HCV treater workforce:
  - OHSU Telemedicine Network: Hepatitis C and Liver Care Project ECHO


Task Shifting to Address Barrier of Lack of Access to Specialists

- Many different types of providers can deliver HCV treatment:
  - PCPs, addiction medicine specialists, PAs, NPs, Clinical pharmacists
  - Specialists can contribute by facilitating mentorship, education, training

- Many different settings can deliver HCV treatment
  - FQHCs, drug Rx centers, prisons, mental health clinics, clinical pharmacies
  - Utilize embedded models of care

- Hepatologists/other subspecialists are only needed for select cases (advanced liver disease, other complicating comorbidities)


Adapted from Slide credit: clinicaloptions.com
**Project ECHO: Extension for Community Healthcare Outcomes**

- Addresses critical gap in availability of specialty care for patients with complex health conditions in rural and underserved settings

![Diagram of ECHO model]

- Expert team constitutes the “hub”
- Community-based primary care teams are the “spokes”
- Patients receive specialty care services where they need them
- Hub provides training in specialty care
- Trained PCPs deliver specialty care

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**Recommendations for When and in Whom to Initiate HCV Treatment**

- **Treatment for all:** Unless pts already have short life expectancy, treatment is recommended for all pts with chronic HCV infection, regardless of genotype and fibrosis level\(^1\)
  - Treatment even at lower-stage fibrosis (F0-F1) improves survival\(^1\)
  - No special population: injections drug use, chronic kidney disease, HCV/HIV, HCV/HBV

- **Decreasing barriers to access:**
  - Medicaid, Medicare and private insurers have substantially removed barriers to access
  - Costs per treatment course have dropped to WAC ~ $25,000; negotiated costs as low as 50% of WAC (confidential)
  - Cost effectiveness of HCV treatment very favorable - <$10,000/QLY gained

Pre-HCV Treatment Management

- HCV RNA Quantitative
  - genotype (optional)
- CBC, CMP and Urine HCG
- HIV, HAV, HBV screening and vaccination as appropriate
- Assessment of degree of fibrosis
  - Noninvasive testing (serologic or US elastography) or biopsy
  - If evidence of cirrhosis
    - Screen for HCC
    - Screen for varices
- Review addiction treatment plan
- Prevention messaging
  - HIV prevention
  - Limit hepatotoxins, including alcohol
  - HCV transmission prevention
  - Harm reduction

How to assess fibrosis without a biopsy

**Non-Invasive Techniques**

- **Chemical assessment (blood test)**
  - Direct markers of fibrogenesis (proprietary)
    - Fibrotest (Fibrosure®)
    - ELF (European liver fibrosis) panel
  - Indirect markers of fibrosis (routine lab)
    - APRI score
    - Fib-4
    - Forn’s index
    - Fibrometer

- **Physical assessment (Liver stiffness measurement)**
  - US transient elastography (Fibroscan®)
  - US acoustic radiation force impulse (ARFI) elastography
  - MR elastography

Physical measures tend to outperform chemical assessment
MR > U/S (Fibroscan) ~ ARFI > Direct > Indirect
Combination?

Currently in use
Pretreatment: Look for Potential Drug–Drug Interactions

- Review all herbals/supplements, prescription and OTC medications, including contraceptives, proton pump inhibitors, statins
- Ask about PRN usage of other drugs
- Consult with clinical pharmacist with questions

Key resource: www.hep-druginteractions.org

Adverse Events

- Newer hepatitis C medications do not have same adverse events as interferon and are generally well tolerated
- Discuss most common adverse events and management strategies in pre-education session
  - Headaches: nonpharmacologic management strategies, limits of OTC pain relievers and liver disease
  - Anemia: still a concern when ribavirin needed
  - Other common adverse events: fatigue, nausea, diarrhea
- Encourage pts to report bothersome or unusual adverse events
Downloadable Resources

aasld.org

Phone App: HCV treatment path

www.clinicaloptions.com/HCVUpdates
University of Washington: Hepatitis C Online
https://www.hepatitisc.uw.edu/

When to Refer to an Experienced Hepatitis C Treater

- No previous treatment
- No advanced fibrosis
- Hepatitis C reinfection
- Prior treatment with peginterferon/ribavirin
- Renal impairment
- Active substance use
- Compensated cirrhosis
- If required by insurance
- Recurrent hepatitis C virus infection after liver transplantation
- Decompensated cirrhosis (e.g., ascites, jaundice, encephalopathy, bleeding varices)
Hepatitis C Elimination in Oregon
Conclusions

• Oregon has among the highest incidence of HCV infection in America
• Insurance obstacles to HCV treatment in Oregon are disappearing
  » Primary care can treat all stages of HCV regardless of substance use history
• HCV treatment with direct acting antivirals is easy and highly effective
  » Online resources, local champions, ECHO Programs and expert consultation are available
• Elimination of HCV will require expansion of screening and treatment settings
  » Diagnose at initial contact and treat persons where they are
• Interruption of HCV transmission requires treatment of PWID
  » Reinfection rates are acceptable
  » Reduction of HCV infection in PWID with direct acting antivirals is most effective and cheapest in combination with medication-assisted treatment and needle and syringe programs