Screening and Treatment of Hepatitis C in Corrections

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Faculty Disclosure

“I do not have any relevant financial relationships with any commercial interests.”
Educational Objectives

Demonstrate understanding of Hepatitis C virus (HCV) epidemiology

Describe proper HCV screening, staging and monitoring processes

Understand the economical climate of HCV treatment
Agenda

- Epidemiology of HCV
- Screening for HCV
- Initial Evaluation
- Assessment for Cirrhosis/Decompensation
- Assigning Priority for HCV Treatment
- Recommended Treatment
- Monitoring
- Economics of HCV Management
What is Hepatitis C Virus (HCV)?

- Discovered in 1989, RNA virus, family Flaviviridae
- 9,600 nucleotide genome-single polyprotein
  - High genetic diversity leads to intra-host variants “quasipecccies”
  - 7 major genotypes that predict treatment response
  - No vaccine candidates for licensure
Approximately 3.5 million people in the United States are chronically infected with HCV (1.3%)\(^1,a\)
- Including populations excluded from NHANES (e.g., the incarcerated, homeless, institutionalized, and those living on Native American reservations) brings the total estimate to 4.6 million\(^2\)

Seroprevalence is higher in\(^1\)
- 1945-1965 birth cohort (3.5%)
- Non-Hispanic blacks (2.2%)
- Males (1.9%) vs females (1.1%)

Approximately 9% of all diagnosed individuals have been successfully treated\(^3,b\)

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NHANES=National Health and Nutrition Examination Survey.
\(^a\)NHANES data as of 2010.
\(^b\)NHANES data, 2001-2008.
HCV Genotypes by Geographic Region

HCV genotypes in the United States
- GT 1 is most common, accounting for ~78% of HCV infections\(^2a\)
- GT 1a subtype is twice as common as GT 1b

GT=genotype.
\(^a\)Derived from HCV RNA–positive participants in NHANES III conducted 1988 to 1994 (N=275).
Recent Increases in HCV Infection

- **Between 2007 and 2012**
  - 50% increase in case reporting
  - 200% increase in 17 states

- **Risk factors**
  - ~70% persons who inject drugs
  - Previous oral prescription narcotic use
  - Equally male to female
  - Young, ages 18 to 29 years
  - Rural and suburban
  - White

Map showing % change incidence with color coding:
- Insufficient Data
- No change or decrease
- <100% increase
- 100-199% increase
- ≥200% increase
Transmission

**Most Common**
- Sharing needles, syringes, other equipment
- Needlestick injuries
- Maternal to fetus transmission

**Less Common**
- Sharing personal care items
  - Razors, toothbrushes
- Sexual contact
- Tattooing/piercing

**Not Transmitted**
- Sharing eating utensils
- Breastfeeding
- Hugging, kissing, coughing, sneezing
- Mosquitos

*HCV can survive outside the body at room temperature, on surfaces for up to 3 weeks.*
Natural History of HCV Infection

- **Acute HCV infection**
  - 14%-46%
  - 54%-86%
  - <1%

- **Chronic hepatitis C**
  - 0.8% per year<sup>a</sup>
  - 15%-51%

- **Liver cirrhosis**
  - 1%-5% per year
  - 3%-6% per year

- **Hepatocellular carcinoma (HCC)**
- **Hepatic decompensation**

- **Fulminant hepatitis**

**20 years**

- Annual mortality rate of 2%-4% in CHC-infected patients with cirrhosis

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<sup>a</sup>0.8% of those with CHC may develop HCC without having developed cirrhosis.

Mortality from HCV is Increasing

- From 1999 to 2010, HCV deaths increased by 50%
  - In 2010, 16,600 deaths
  - Mean age at death was 59 years

- Two-fold increased mortality risk
  - Black non-Hispanic
  - American Indian/Alaskan Natives

- Mortality is under estimated
  - Only 33% of liver-related deaths among HCV infected persons are reported on Vital Records

- At least 45-60% are not aware of their HCV infection
Number of Local Jail Inmate Deaths, Liver Dz, AIDS-Related
2000-2013

<table>
<thead>
<tr>
<th>Year</th>
<th>HCV</th>
<th>HIV</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>24</td>
<td>57</td>
</tr>
<tr>
<td>2001</td>
<td>27</td>
<td>59</td>
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<td>2006</td>
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<td>2007</td>
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<td>2008</td>
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<td>2009</td>
<td>32</td>
<td>35</td>
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<tr>
<td>2010</td>
<td>32</td>
<td>32</td>
</tr>
<tr>
<td>2011</td>
<td>29</td>
<td>32</td>
</tr>
<tr>
<td>2012</td>
<td>29</td>
<td>29</td>
</tr>
<tr>
<td>2013</td>
<td>29</td>
<td>29</td>
</tr>
</tbody>
</table>

HCV Can Be Cured

- Unlike HIV and HBV, **HCV is curable**
  - HCV RNA remains in the cytoplasm and does not integrate into host DNA

- HCV is highly genetically variable due to its:
  - High replication rate: On average, 1.3 x 10^{12} HCV virions are produced in each infected individual per day
  - High mutation rate: The HCV polymerase lacks a proofreading function and is error prone

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HBV=hepatitis B virus; HIV=human immunodeficiency virus; 
*Cure, also known as SVR, is defined as no detectable HCV in the blood at 12 or more weeks after therapy is complete.*

SCREENING FOR HCV INFECTION

Acute HCV Infection

14 – 46%

Spontaneous Clear

55-85%

Chronic HCV Infection
Screening Criteria

Testing for HCV infection is recommended for:

• All **sentenced** inmates
• All inmates with certain clinical conditions
• All inmates who request testing

**AASLD, CDC. USPSTF recommend risk factor-based and birth cohort screening for HCV infection.**

Risk Factors for HCV

**Risk Exposures**
- Ever incarcerated
- Long-term hemodialysis
- Percutaneous exposures in unregulated setting
- HCPs after needlesticks, or mucosal exposures to HCV-infected
- Children born to infected mother
- Transfusion before 1992
- Clotting factor before 1987

**Risk Behaviors**
- Injection-drug use (once)
- Intranasal illicit drug use

**Other Considerations**
- HIV infection
- Sexually active about to start PreP
- Unexplained chronic liver disease
- Solid organ donors

http://www.hcvguidelines.org
Screening for HCV

• Preferred **SCREENING** test is immunoassay, Ab to HCV antigens (HCV Ab or anti-HCV)
  – (+) means history of exposure to HCV

• Screening of **Nonsentenced** Inmates
  – *Unless clinically indicated, screening should ordinarily not be pursued for asymptomatic, highly mobile, nonsentenced inmates.*
  – *Referrals to community HCV testing sites should be made when appropriate.*

Screening to Evaluation

- Acute HCV Infection
- Chronic HCV Infection

14 – 46%
55-85%

+ HCV Ab

STAGING Of HCV Disease

Spontaneous Clear
Initial Evaluation of HCV (+)

- Baseline H&P
- Lab Tests
- Calculation of the APRI score (fibrosis)
- Preventive health interventions
  - Vaccines, screenings for other conditions
- Information on HCV infection

Baseline Evaluation

• Targeted H&P
  – S/S of liver disease
  – Quantify ETOH consumption, risk factors for HCV
  – Evaluate other causes of liver disease (ETOH, NASH, iron overload, autoimmune hepatitis.)
  – Prior Tx for HCV infection

• Labs
  – HCV Viral load
    • No genotype yet
  – CBC, PT/INR, Liver panel, Cr, GFR.
  – HBsAg, HIV Ab

Extrahepatic Manifestations of HCV

Strongly associated
- Mixed cryoglobulinemia
- Sjögren (sicca) syndrome
- Lymphoproliferative disorders
- Porphyria cutanea tarda
- Neuropathy
- Membranoproliferative glomerulonephritis
- Cryoglobulinemic (leukocytoclastic) vasculitis

Possibly associated
- Corneal ulcers (Mooren’s ulcer)
- Thyroid disease
- Lichen planus
- Pulmonary fibrosis
- Chronic kidney disease
- Type 2 diabetes
- Systemic vasculitis (polyarteritis nodosa, microscopic polyangiitis)
- Arthralgias, myalgias, inflammatory polyarthritis
- Autoimmune thrombocytopenia
- Neurocognitive dysfunction

Esophageal Varices
Hepatic Encephalopathy Pathogenesis

- Failure to metabolize NH₃
- NH₃ Shunting
- Toxins
- GABA-BD receptors
- Bacterial action
- Protein load
Progression of Fibrosis
Guideline Recommendations for Fibrosis Assessment

- Although **liver biopsy is the diagnostic standard**, sampling error and observer variability limit test performance, particularly when inadequate sampling occurs
  - Serious complications such as **bleeding**, although rare, are well recognized

- The most efficient approach is to **combine direct biomarkers and vibration-controlled transient liver elastography (ie. Fibroscan)**
  - A biopsy should be considered for any patient who has discordant results between the 2 modalities that would affect clinical decision making

- **Alternatively, if direct biomarkers or vibration-controlled transient liver elastography are not available, APRI and FIB-4 tests can help identify those most likely to have F3 or F4 fibrosis stage.**
  - Biopsy should be considered in those in whom more accurate fibrosis staging would impact treatment decisions

Calculation of APRI score: Degree of Liver Damage

- AST to Platelet Ratio Index
- Less invasive than liver biopsy
- Less expensive than liver biopsy
- \[
  \frac{[(\text{AST/AST ULN}) \times 100]}{\text{platelet count (10}^9/\text{L)}}
\]

- Calculator
  - http://www.hepatitis.uw.edu/page/clinical-calculators/apri
Assess for Hepatic Cirrhosis

APRI \geq 2

• APRI Score (preferred method for assessment of fibrosis and cirrhosis)
  – \textbf{APRI} \geq 2.0 predicts presence of cirrhosis
    • (48\% sensitivity, 94\% specificity)
    • Abdominal ultrasound to identify other findings of cirrhosis

• Liver Bx no longer required

• \textbf{Cirrhosis}:
  – Signs/Symptoms
    • Low albumin, low platelets, incr bilirubin, ascites, esophageal varices, hepatic encephalopathy

Cirrhosis
Assess for Compensation

- Acute HCV Infection (55-85%)
- Spontaneous Clear (14-46%)
- Chronic HCV Infection
- Mild Fibrosis
- Moderate To Severe Fibrosis (15-51%)
- Cirrhosis
  - Decompensated Cirrhosis (3-6%/yr)
  - Hepatocellular Carcinoma (1-5%/yr)
  - Death (2-4%)

- Death
Assess Hepatic Compensation

- **Why?**: determines tx regimen to be used
- **Compensated vs. Decompensated**
- **Child-Pugh Score**
  - Uses the following parameters:
    - Albumin, bili, INR, ascites, hepatic encephalopathy
    - Score of 1, 2 or 3

<table>
<thead>
<tr>
<th>CTP Score</th>
<th>CTP Class</th>
<th>Cirrhosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>5-6</td>
<td>Class A</td>
<td>Compensated</td>
</tr>
<tr>
<td>7-9</td>
<td>Class B</td>
<td>Decomppensated</td>
</tr>
<tr>
<td>≥ 10</td>
<td>Class C</td>
<td></td>
</tr>
</tbody>
</table>

http://www.hepatitis.uw.edu/page/clinical-calculators/ctp

Decompensated Cirrhosis:
Child-Pugh ≥ 7

- **Decompensated cirrhosis**
  - Should be managed in consultation with a clinician experienced in the Tx of this condition
  - Child-Pugh Class C cirrhosis
    - Reduced life expectancy
    - Should be considered for Reduction in Sentence/Compassionate Release

Cirrhosis: Additional Interventions

- Pneumococcal vaccine
- Hepatocellular Carcinoma Screening
  - Liver ultrasound every 6 months for pts with both cirrhosis and chronic HCV
- Esophageal varices screening
  - EGD
- Other Interventions:
  - Beta blockers for prevention of variceal bleeding
  - Abx prophy for SBP
  - Diuretic Tx for ascites
  - Lactulose and rifaximin Tx for encephalopathy

Where Are We Now?

• The burden of HCV-related disease is large
• Reports of new HCV infections are increasing
• CDC and USPSTF recommend HCV testing for persons
  – Born during 1945 and 1965
  – Who inject drugs, past or present
  – Others at risk
• At least ½ of HCV-infected persons are unaware of status
• Access to HCV testing, care and treatment must improve for patients to benefit from advances in therapy

Goal of Treatment

- Virologic cure
- Reduce all-cause Mortality
  - End stage liver disease
  - Hepatocellular Carcinoma
Recommendations for When and in Whom to Initiate Treatment

• “Treatment is recommended for all patients with chronic HCV infection, except those with short life expectancies that cannot be remediated by treating HCV, by transplantation, or by other directed therapy.”

http://www.hcvguidelines.org
Considerations in Specific Populations

• “Despite the recommendation for TX of nearly all patients with HCV infection, it remains important for clinicians to understand patient and disease-related factors that place individuals at risk for HCV-related complications as well as for HCV transmission. Although these groups are no longer singled out for high prioritization for treatment, it is nonetheless important that practitioners recognize the unique dimensions of HCV disease and its natural history in these populations. The discussions offered below may assist clinicians in making compelling cases for insurance coverage of treatment when necessary.”
  – Persons with advanced liver disease
  – Persons who have undergone liver transplantation
  – Persons at greater risk for rapidly progressive fibrosis and cirrhosis
  – HIV coinfection
  – HBV coinfection and other coexistent liver diseases
  – Persons with extrahepatic manifestations of chronic HCV infection

http://www.hcvguidelines.org
Recommended Assessments Prior to Starting AV Therapy

- Staging of fibrosis
  - Liver biopsy
  - Imaging
  - Noninvasive markers

- Assessment of potential drug-drug interactions
  - carbamazepine, phenytoin, phenobarbital
  - Some statins
  - HIV drugs
  - Amiodarone
  - rifampin

Labs within 12 wks of starting
- CBC
- INR
- Hepatic Function
- GFR
- TSH (if INF is used)
- HCV genotype and subtype
- HCV Viral Load
- HBsAg, anti-HBs, anti-HBc
- Resistance-associated variants (RAV) prior to tx
Priority Level 1: Highest Priority

- **Cirrhosis**
  - Known or clinical findings
    - Decompensated Cirrhosis (Child-Pugh 7 to 9) highest
  - Isolated APRI ≥ 2 with no other clinical findings of cirrhosis are Priority Level 2
- **Liver Transplant Candidates or Recipients**
- **Hepatocellular Carcinoma (HCC)**
- **Comorbid Conditions** (cryoglobulinemia, etc.)
- **Chronic Kidney Disease** (GFR <30 mL/min, including dialysis pts.)
- **Immunosuppressant Medication**
- **Continuity of Care** (already started on Tx)

Priority Level 2: High Priority

- APRI score $\geq 2$
- Advanced fibrosis on liver bx (Metavir 3)
- HBV coinfection
- HIV coinfection
- Comorbid Liver Disease
- Chronic Kidney Disease (GFR 30-59 mL/min)

Priority Level 3: Intermediate Priority

- Stage 2 fibrosis on liver biopsy
- APRI score 1.5 to <2
- Diabetes mellitus
- Porphyria cutanea tarda

Priority Level 4: Routine Priority

- Stage 0 to 1 fibrosis on liver biopsy
- All other cases of HCV infection meeting eligibility for criteria for treatment, as noted below....
  - No contraindications
  - Not be pregnant
  - Sufficient time remaining on sentence to complete course of treatment (now 12 weeks in majority of cases)
  - Demonstrate willingness and ability to adhere to a rigorous Tx regimen and to abstain from high-risk activities while incarcerated.

Recommended Treatment Regimens

• **Depend on:**
  – HCV genotype
  – Prior HCV treatment history
  – Compensated vs. Decompensated Liver Disease

• **3 Classes of DAAs** (Direct acting Antivirals)
  – Polymerase inhibitors (-buvir)
  – Protease inhibitors (-previr)
  – NS5A Replication Complex Inhibitors (-asvir)

Recent advances in HCV therapeutic options provide high cure rates (>90%) with direct-acting antiviral options that are IFN-free.

## Improvements in HCV Therapy: Overall SVR Rates in the Pre-DAA and DAA Eras

<table>
<thead>
<tr>
<th>Era</th>
<th>Standard of Care</th>
<th>Overall SVR(^a) Rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-2011 (Pre-DAA)</td>
<td>Peg-IFN + RBV</td>
<td>47%-54(^{1,2})</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(^{a})SVR=24-week follow-up</td>
</tr>
<tr>
<td>2011-2013 (Early DAA)</td>
<td>DAA + Peg-IFN + RBV</td>
<td>67%-75(^{3,4})</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(^{a})SVR=24-week follow-up</td>
</tr>
<tr>
<td>2013-present (all-oral DAA regimens)</td>
<td>DAA regimen ± RBV</td>
<td>(\geq 90%)^{5-9}</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(^{a})SVR=12-week follow-up</td>
</tr>
</tbody>
</table>

By Genotype...

**Genotype 1a (51%)**
- Daclatasvir/sofosbuvir
- Daclatasvir/sofosbuvir with riba
- Viekira Pak (lidipasvir/sofosbuvir)
- Simeprevir/sofosbuvir
- Simeprevir/sofosbuvir with riba
- Zepatier (elbasvir/grazoprevir)
- Harvoni (ledipasvir/sofosbuvir) with riba

**Genotype 1b (27%)**
- Daclatasvir/sofosbuvir
- Daclatasvir/sofosbuvir with riba
- Harvoni (ledipasvir/sofosbuvir)
- Paritaprevir/ritonavir/omnibit asvir/dasabuvir
- Simeprevir/sofosbuvir
- Simeprevir/sofosbuvir plus riba
- Zepatier (elbasvir/grazoprevir)
By Genotype...

**Genotype 2 (13%)**
- Daclatasvir/sofosbuvir
- Sofosbuvir + riba

**Genotype 3**
- Daclatasvir/sofosbuvir
- Daclatasvir/sofosbuvir with riba
- Sofosbuvir + riba + PEG-IFN
- Sofosbuvir + riba

**Genotype 4**
- Harvoni (ledipasvir/sofosbuvir)
- Zepatier (elbasvir/grazoprevor)
- Paritaprevir/ritonavir/ombitasvir/dasabuvir + riba
- Sofosbuvir + riba
- Sofosbuvir + riba + PEG IFN
- Harvoni with riba

**Genotype 5 or 6**
- Harvoni (ledipasvir/sofosbuvir)
By Genotype...

Epclusa (sofosbuvir/velpatasvir)

**Indicated for ALL HCV Genotypes**

1, 2, 3, 4, 5 or 6 without cirrhosis

**Indicated for ALL HCV Genotypes**

1, 2, 3, 4, 5, or 6 with riba for decompensated cirrhosis
Recommended Monitoring During AVT

- **Clinic Visits as clinically indicated**
  - Medication adherence
  - AE monitoring
  - Drug –drug interactions

- **4 Weeks of Therapy**
  - CBC, Cr, GFR, Hepatic panel
  - HCV viral load
  - TSH every 12 wks for IFN

Recommendations for Discontinuation of Tx Because of Lack of Efficacy

• HCV VL is **detectable** at **week 4**
  – Repeat VL after 2 additional wks (wk 6)
  – If repeat VL has increased > 10-fold (>1log_{10}) then discontinue

• Significance of (+) VL at week 4 that remains (+), but lower, at week 6 or week 8 is unknown. No recommendation to stop therapy or extend therapy can be provided at this time.

Recommended Follow-up for Pts Who Achieve SVR (cure)

- Metavir F0-F2, recommended follow-up is the same as if they were never infected.
- Assess for Reinfection pt has ongoing risk for HCV infection or unexplained hepatic dysfunction.
- Metavir F3-F4, ultrasound twice yearly for surveillance of hepatocellular carcinoma
- Persistently abnl LFTs after SVR
Factors Associated with Accelerated Fibrosis Progression

Host

• **Nonmodifiable**
  – Fibrosis stage
  – Inflammation grade
  – Older age at time of infection
  – Male sex
  – Organ transplant

• **Modifiable**
  – Alcohol consumption
  – Nonalcoholic fatty liver disease
  – Obesity
  – Insulin resistance

Viral

• HCV Genotype 3
• Coinfection with HBV or HIV

SO..................

WHY DON’T WE TREAT EVERYONE WHO HAS CHRONIC HCV VIRAL DISEASE?
ECONOMICS OF HCV
# Average WAC Costs

## Wholesale Acquisition Cost (WAC) of Direct Acting Antiviral Agents used to Treat HCV

<table>
<thead>
<tr>
<th>Medication</th>
<th>Trade Name</th>
<th>Manufacturer</th>
<th>WAC for 1 Day</th>
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<tbody>
<tr>
<td>Daclatasvir</td>
<td>Daklinza</td>
<td>Bristol-Myers Squibb</td>
<td>$750</td>
</tr>
<tr>
<td>Elbasvir-Grazoprevir</td>
<td>Zepatier</td>
<td>Merck &amp; Co., Inc.</td>
<td>$650</td>
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<tr>
<td>Ledipasvir-sofosbuvir</td>
<td>Harvoni</td>
<td>Gilead Sciences</td>
<td>$1125</td>
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<tr>
<td>Ombitasvir-Paritaprevir-Ritonavir</td>
<td>Technivie</td>
<td>AbbVie</td>
<td>$912</td>
</tr>
<tr>
<td>Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir</td>
<td>Viekira Pak</td>
<td>AbbVie</td>
<td>$992</td>
</tr>
<tr>
<td>Simeprevir</td>
<td>Olysio</td>
<td>Janssen</td>
<td>$790</td>
</tr>
<tr>
<td>Sofosbuvir</td>
<td>Sovaldi</td>
<td>Gilead Sciences</td>
<td>$1000</td>
</tr>
<tr>
<td>Sofosbuvir-Velpatasvir</td>
<td>Epclusa</td>
<td>Gilead Sciences</td>
<td>$890</td>
</tr>
</tbody>
</table>

**Average Cost for 12 Weeks of Therapy:** $63,000 - $94,500
Nearly One-Half of All Prescriptions for HCV Treatment Were Denied by Medicaid

Incidence of absolute denial of HCV treatment by insurance

![Chart showing incidence of absolute denial by insurance type.]

- Overall: 16%
- Medicaid: 46%
- Medicare: 5%
- Commercial Insurance: 10%

Extends to Which Payers Restricted Access to HCV Treatment Evaluated in 4 States Utilizing Data From a Specialty Pharmacy from 11/1/14 - 4/30/15.

Excludes 21 patients with incomplete prior authorization after 60 days.

Lo Re. AASLD, 2015. #LB-5
Affordability

• An intervention that is cost effective is not necessarily affordable.

• Affordability refers to whether a payer has sufficient resources in its annual budget to pay for a new therapy for all who might need or want it within that year.

http://www.hcvguidelines.org
Affordability: Cost Effectiveness Analysis

• **Perspective on Cost**
  – Seeks to inform decisions about how society should prioritize healthcare spending.
  – Insurers considers **ONLY** its own revenues

• **Time Horizon**
  – CEA uses “lifetime” time horizon
  – Business budget planning uses 1-year to 5-year
  – Savings that may accrue 30 yrs from now have little impact on spending decisions today.

• **Weak Association between willingness to pay and the real-world bottom line**

http://www.hcvguidelines.org
Affordability

- No mathematical formula that provides a good means of integrating the concerns of value and affordability.
- Cost effective = provide excellent benefits for the resources invested in their use and
- Determining the total resources that can be spent on HCV treatment, however, depends on political and economic factors that are not captured by cost-effectiveness determinations.
Cost-effectiveness of All-oral Regimens for HCV Tx

• Treating patients with more advanced fibrosis or cirrhosis provided better value.

• Although the WAC costs of HCV drugs often make tx appear unaffordable, the reality is that insurers, PBMs, and gov’t agencies negotiate pricing and few actually pay the much publicized WAC (retail).

• Negotiated pricing and cost structure for pharmaceutical products in the U.S. are NOT TRANSPARENT – difficult to estimate the true cost effectiveness

http://www.hcvguidelines.org
Conclusions

• HCV screening for all “sentenced inmates”
• HCV Ab (+)
  – Confirm
  – “Stage the Disease”
• HCV Infection is “curable”
• Treatment regimens easier/shorter
• Affordable Treatment remains an issue