HEPATITIS C
IN THE PRIMARY CARE SETTING

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DISCLOSURES

• This talk will include information about investigational drugs that have not yet been approved by the FDA.

• Neither speaker has any commercial or financial interests to disclose.
HEPATITIS C MANAGEMENT IN THE PRIMARY CARE SETTING

**Primary Care Provider**

- HCV Ab
- HVC RNA
- HCV Genotype Labs – Liver Fxn

**Screening**

**Diagnose**

- Ultrasound
- Hep A/B IZ
- ETOH
- Drug Use

**Staging**

- Drug Regimen Monitoring?

**Treatment**

**Follow Up**

- Specialist
- Liver Biopsy
- Fibroscan
- IL28b, Q80K

- Cancer Surveillance?
- -AFP
- -Liver U/S

- Cancer Surveillance
HEPATITIS C IN PRIMARY CARE

• HCV screening is recommended for all baby boomers.
• Hepatitis C is curable.
• Screening for Hepatitis C will NOT swamp your clinic with large numbers of antibody positive patients.
• Hepatitis C treatment medications are NOT too complex to prescribe at the primary care level.
• Hepatitis C treatment medications are accessible to our patients.
CONSEQUENCES OF HEPATITIS C AND LIVER CIRRHOSIS

Decreased Quality Of Life
- Fatigue
- Weight Loss
- Depression
- Muscle Wasting
- Impaired Cognition

Liver Transplantation
- HCV is the most frequent indication
- 30% develop cirrhosis 5-7 yrs post-transplant

Complications
- GI bleeding (varices, gastropathy)
- Ascites
- Bacterial Infections
- Encephalopathy
  - Overt
  - Minimal
- Hepatocellular carcinoma

Death
- ~12,000 deaths per year (based on death certificate documentation)
- Likely an underrepresentation
HEPATITIS C: DISEASE PROGRESSION TO LIVER CIRRHOSIS AND CANCER

HCV infection

- Chronic HCV
  - 60%-85%

Cirrhosis

- 20%-50%
  - 1-4%/yr

Liver Cancer

- ~ 20%

Liver Failure

Liver Transplant

Time: 20-30 years
IN THE US, PREVALENCE OF HCV HIGHER THAN HIV OR HBV

Number of infected individuals and number aware they are infected (diagnosed)

HEPATITIS C IN NATIVE AMERICAN COMMUNITIES

In 2011, Sacramento Native American Health Center evaluated our Hepatitis C patient population:

- In the previous 2 years we had seen 285 patients with Hepatitis C
  - Native Patients: 86 (30.2%)
  - Non-Native Patients: 199 (69.2%)

Hepatitis C Treatment Program Participants (2011):

- Total Treatment Program Participants: 28
- Average age: 51.5 years
- Males: 60.7%
- Females: 39.3%
- Native Patients: 18%

Hepatitis C Genotype
Hep C Treatment Group Patients (N=28)

- Genotype 1: 75%
- Genotype 2: 17%
- Genotype 3: 8%
WHO SHOULD BE SCREENED?

- Adults born between 1945-1965
- A history of recreational drug use
- A history of transfusion of blood or blood products prior to 1992
- Patients on hemodialysis.
- Patients with elevated aminotransferase enzymes (AST/ALT)
- Patients who are HIV positive
- Children born to an HCV positive mother (check HCV antibody after 6 months of age)
- Even for patients with none of the above risk factors, an annual anti-HCV test is recommended for all patients over the age of 18 that are being screened for other STDs or blood-borne infections.
HEPATITIS C DIAGNOSIS AND WORKUP

**Diagnosis of Hepatitis C**

- Approximately 15-45% of people exposed to HCV will clear the virus and not progress to chronic infection. This population does not need treatment or further workup concerning Hepatitis C infection.

- The test of choice for diagnosis of HCV infection is **HCV RNA by PCR**.
HEPATITIS C DIAGNOSIS AND WORKUP

Evaluation of the HCV patient

Once active infection has been determined by PCR, the following tests are recommended to be drawn or performed:

• HCV RNA by PCR (if not previously performed)
• HCV Genotype
• Comprehensive Metabolic Panel (CMP)
• CBC with differential
• Hepatitis A & B surface antibody (to test for previous exposure to Hep A and Hep B Viruses)
• HIV screening
• Abdominal Ultrasound with specific attention to the spleen, common bile duct, and liver
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Primary Care Provider

Screening

Diagnose

Staging

Treatment

Follow Up

HCV Ab

HVC RNA
HCV Genotype
Labs – Liver Fxn

Ultrasound
Hep A/B IZ
ETOH
Drug Use

Drug Regimen
Monitoring?

Cancer
Surveillance?

-AFP
-Liver U/S

Specialist

Liver Biopsy
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Drug Regimen
Monitoring

Cancer
Surveillance
SHOULD I RECOMMEND THAT MY PATIENT PURSUE TREATMENT FOR HEPATITIS C?

• Not everyone is a good candidate for immediate treatment.
• Not everyone needs to be immediately referred to a specialist.
• Patient education is key.

Considerations
• Compensated Cirrhosis
• Patients with signs of liver decompensation such as: ascites, persistent jaundice, wasting, hepatic encephalopathy, or variceal bleeding.
• Active alcohol use or IV drug use
• Bone marrow suppression, marked anemia, thalassemia major, or sickle cell anemia
• Autoimmune Hepatitis
• Comorbid conditions that markedly limit life expectancy
• Patients with prior treatment failure or relapse
• Co-infection with HIV
HEPATITIS C TREATMENT IS RAPIDLY EVOLVING AND IMPROVING

SVR Rates in Patients With HCV

<table>
<thead>
<tr>
<th>Year</th>
<th>IFN 6 mo</th>
<th>IFN 12 mo</th>
<th>IFN/RBV 6 mo</th>
<th>IFN/RBV 12 mo</th>
<th>PEG-IFN 12 mo</th>
<th>PEG-IFN/RBV 12 mo</th>
<th>PI/PEG-IFN/RBV 6-12 mo</th>
<th>SOF/PEG-IFN/RBV 3 mo</th>
</tr>
</thead>
<tbody>
<tr>
<td>1986</td>
<td>6</td>
<td>16</td>
<td>34</td>
<td>42</td>
<td>39</td>
<td>54-56</td>
<td>68-75</td>
<td>89-90†††</td>
</tr>
</tbody>
</table>

1SVR12 rate of 90% among patients in Group A (GT 1) in the Phase 2 ATOMIC trial (12 weeks of SOF+PEG-IFN+RBV)
1SVR12 rate of 89% among GT 1 patients in the Phase 3 NEUTRINO trial (12 weeks of SOF+PEG-IFN+RBV)
**SOFOSBUVIR 2014: FDA APPROVED INDICATIONS**

<table>
<thead>
<tr>
<th>HCV and HCV/HIV Co-Infected</th>
<th>Treatment</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotypes 1, 4</td>
<td>Sofosbuvir + Peginterferon + Ribavirin</td>
<td>12 weeks</td>
</tr>
<tr>
<td>Genotype 2</td>
<td>Sofosbuvir + Ribavirin</td>
<td>12 weeks</td>
</tr>
<tr>
<td>Genotype 3</td>
<td>Sofosbuvir + Ribavirin</td>
<td>24 weeks</td>
</tr>
</tbody>
</table>
CURRENT STATUS OF HCV THERAPY

• **Genotype 1**
  • New standard of care is 90% SVR
  • Shorter duration: 12 weeks (Sofo+PR)
  • Potential for single pill a day regimen
    • Sofosbuvir+Ledipasvir
    • 95% SVR
    • Filed with FDA in February 2014
CURRENT STATUS OF HCV THERAPY

• **Genotype 2**
  • Short and simple
  • Sofosbuvir 400mg qd with food + Weight based Ribavirin BID
  • 12 weeks for everybody
  • Monitoring: Pregnancy, Anemia, Viral Load
    • At 4 weeks
  • Fibroscan to decide cancer screening
CURRENT STATUS OF HCV THERAPY

• **Genotype 3**
  - Sofosbuvir 400mg PO Daily with food + Weight Based Ribavirin BID
  - 24 weeks
  - 12 weeks with Peg+Ribavirin for Cirrhostics with previous failure on PR
  - Monitoring: Pregnancy, Anemia, Viral Load
    - At 4 weeks
  - Fibroscan to decide cancer screening
FUTURE OF HCV THERAPY

• **Genotype 1**
  • Standard of care will be >95% SVR
  • Without Interferon and without Ribavirin
  • At least 2 direct antiviral agents (DAA)
CURE IMPROVES OUTCOMES IN PATIENTS WITH HCV-ASSOCIATED ADVANCED FIBROSIS

In the HALT-C trial, achieving SVR significantly reduced HCV-associated complications and mortality
• Median follow-up 96 months for patients with SVR, 79 months for nonresponders

TREATMENT EXPERIENCES AT SAC NATIVE HEALTH/CASE PRESENTATIONS
WHERE CAN I START?

• Implement screening guidelines.
• Start a Hepatitis C support group
  • find community partners to work with
  • utilize patient volunteers
• There are teleconferences/training available through IHS
  • Project ECHO
• Work with your local pharmaceutical representative
• Moving Mountains – Sacramento Area
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Ultrasound
Hep A/B IZ
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Drug Use

Monitoring?
QUESTIONS?

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• AASLD/IDSA HCV guidelines:
  • http://hcvguidelines.org

• Project ECHO [medical consultation, training and no cost CME]:
  • http://echo.unm.edu/

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