HEPATITIS C: UPDATE AND MANAGEMENT

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Associate Director, Kern Institute
STAR Center Director
José Franco, MD

Disclosures

• I have no disclosures relevant to this presentation

• I will only be speaking regarding FDA-approved therapies
HEPATITIS C UPDATE AND MANAGEMENT: OBJECTIVES

• Explain the prevalence and natural history of hepatitis C
• Identify which cohorts should be tested for hepatitis C
• Recognize the currently available therapies for the treatment of hepatitis C
HEPATITIS C TREATMENT: PREDICTION

The majority of non-cirrhotic patients and compensated cirrhotics will be treated by primary care physicians.
Nearly Everyone With HCV Can Now Be Treated Successfully

- Very high SVR rates; therapies highly tolerable
- All-oral therapy for almost every patient
- Treatment generally just 12 weeks

References in slidenotes.
CHRONIC VIRAL HEPATITIS IN USA: 2013

Hepatitis B: 1.2 MILLION
Hepatitis C: 3.2 MILLION

CDC
Incidence of acute hepatitis C, by year
United States, 1982-2013

Reported Number of Cases

Year

WISCONSIN HCV REPORTING - 2013

• Reported cases: 2638
  – 22% in Milwaukee county
  – 10% Correctional institutions

• 43% female (up from 30% in 2003)

• 27% now in those under 30 (up from 5% in 2003)
HEPATITIS C RISK FACTORS

• Risk behaviors
  – Current or past injection drug use
  – Intranasal illicit drug use

• Risk exposures
  – Long-term hemodialysis
  – Unregulated percutaneous/parenteral exposure
  – Healthcare providers with needlesticks or mucosal exposures to HCV-infected blood
  – Children born to HCV-infected women
  – Transfusions prior to 1992, clotting factors prior to 1987
  – Incarcerated individuals
HEPATITIS C TESTING

One time testing also recommended for individuals born between 1945-1965, without prior ascertainment of risk
Recommended Testing Sequence for Identifying Current Hepatitis C Virus (HCV) Infection

- **HCV antibody**
  - Nonreactive
    - No HCV antibody detected
    - Nonreactive
    - STOP*
  - Reactive
    - Reactive
    - HCV RNA
    - Not Detected
      - No current HCV infection
      - Additional testing as appropriate†
    - Detected
      - Current HCV infection
      - Link to care

* For persons who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended. For persons who are immunocompromised, testing for HCV RNA can be considered.

† To differentiate past, resolved HCV infection from biologic false positivity for HCV antibody, testing with another HCV antibody assay can be considered. Repeat HCV RNA testing if the person tested is suspected to have had HCV exposure within the past 6 months or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.

HCV INFECTION: WORLDWIDE GENOTYPE DISTRIBUTION

HEPATITIS C
GENOTYPES IN U.S.

- Genotype 1A 37%
- Genotype 1B 30%
- Genotype 2 10%
- Genotype 3 6%
- Other or mixed 9%
- Indeterminate 5%
NATURAL HISTORY OF HCV INFECTION

Exposure
Acute Phase ➔ Chronic 85% ➔ Cirrhosis 20%

- Resolved 15%
- Cirrhosis:
  - ESLD 6%/yr
  - HCC 4%/yr
- Transplantation 3-4%/yr

0 yrs  10 yrs  20 yrs  30 yrs

Di Bisceglie
<table>
<thead>
<tr>
<th>Host Factors</th>
<th>Viral Factors</th>
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<tbody>
<tr>
<td>Non-Modifiable</td>
<td>Co-infection with HBV or HIV</td>
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<tr>
<td>Fibrosis stage</td>
<td></td>
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<tr>
<td>Inflammation grade</td>
<td></td>
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<tr>
<td>Older age at time of infection</td>
<td></td>
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<tr>
<td>Male sex</td>
<td></td>
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<tr>
<td>Organ Transplant</td>
<td></td>
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<tr>
<td><strong>Modifiable</strong></td>
<td></td>
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<tr>
<td>Alcohol consumption</td>
<td></td>
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<tr>
<td>Nonalcoholic fatty liver disease</td>
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<tr>
<td>Obesity</td>
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<td>Insulin resistance</td>
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</table>
STAGES OF FIBROSIS

Stage 0  Stage 2  Stage 3  Stage 4

CIRRHOSIS
FIBROSCAN
FIBROSCAN SCORING

SCORING CARD

CORRELATION BETWEEN LIVER STIFFNESS (kPa) & FIBROSIS STAGE

- Hepatitis B*
- HCV-HIV co-infection*
- Hepatitis C recurrence after liver transplantation*
- Hepatitis C*
- Chronic cholestatic diseases*
- Alcohol***
- NAFLD***

LIVER DISEASE

0 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 75

LIVER STIFFNESS (kPa)
HCV in the US: Gaps in Current Practice

- Chronic HCV Infected: 3,500,000
- Diagnosed and Aware: 1,743,000
- Access to Care: 1,514,667
- HCV RNA Confirmed: 952,726
- Liver Biopsy: 581,632
- Prescribed HCV Treatment: 555,883
- Achieved SVR: 326,859

WHO SHOULD PRIMARY CARE PHYSICIANS NOT TREAT?

- Decompensated cirrhosis
- HIV/HCV co-infection
- Patients with renal impairment
- Acute HCV
- Recurrent HCV after liver transplant
# Child-Pugh Scoring Criteria

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<tr>
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<tr>
<td><strong>Albumin (g/dL)</strong></td>
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<tr>
<td><strong>Bilirubin (mg/dL)</strong></td>
<td>&lt;2</td>
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<tr>
<td><strong>INR (PT prolongation)</strong></td>
<td>&lt;1.70 (&lt;3 seconds)</td>
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<tr>
<td><strong>Ascites</strong></td>
<td>None</td>
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<tr>
<td><strong>Encephalopathy</strong></td>
<td>None</td>
</tr>
<tr>
<td><strong>Child-Pugh Class</strong></td>
<td>A = 5-6 Compensated</td>
</tr>
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</table>

HEPATITIS C ERADICATION:

DEFINITION

Absence of hepatitis C viral RNA at least 12 weeks following completion of antiviral therapy (SVR-sustained virological response)
HEPATITIS C VIRUS

C  E1  E2  NS2  NS3  NS4b  NS5a  NS5b

Structural  Non-structural

Neumann, Science, 1998
Rosenberg, J Mol Biology, 2001
Lauer, NEJM, 2001
Approved DAAs From Multiple Classes: Basis of 2016 Combination HCV Regimens

Structural Domain
- 5'UTR
  - Core
  - E1
  - E2
  - P
  - 7

Nonstructural Domain
- NS2
- NS3
- NS4A NS4B
- NS5A
- NS5B
- 3'UTR

Protease
- Ribavirin (RBV)
- NS3 Protease Inhibitors
  - Grazoprevir (GZR)
  - Paritaprevir/Ritonavir (PTV/RTV)
  - Simeprevir (SMV)
  - Voxilaprevir (VOX)*
  - Glecaprevir (GLE)*

NS5A Replication Complex Inhibitors
- Daclatasvir (DCV)
- Elbasvir (EBR)
- Ledipasvir (LDV)
- Ombitasvir (OBV)
- Velpatasvir (VEL)
- Pibrentasvir (PIB)*

NS5B NUC Inhibitors
- Sofosbuvir (SOF)

NS5B Non-NUC Inhibitors
- Dasabuvir (DSV)

*Possible approval in 2017.

Slide credit: clinicaloptions.com
### Recommended and Alternative Regimens by evidence level and alphabetically for:

**Genotype 1a, Treatment-naive Patients, Without Cirrhosis**

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</tr>
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<td>Daily daclatasvir (60 mg*) plus sofosbuvir (400 mg)</td>
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LEDISPAVIR/SOFOSBUVIR

- First approved 11/2014
- Can be used in
  - compensated cirrhosis
  - decompensated cirrhosis
  - post-liver transplant
- Well tolerated
- Few drug-drug interactions
Approved DAAs From Multiple Classes: Basis of 2016 Combination HCV Regimens

*Possible approval in 2017.
Ledipasvir-Sofosbuvir for 8 or 12 Weeks in Treatment-Naïve HCV GT 1
ION-3 Study: Results

ION-3: SVR 12* by Treatment Duration and Regimen

Abbreviations: LDV-SOF = ledipasvir-sofosbuvir; RBV = ribavirin
*Primary end-point by intention-to-treat analysis

Elbasvir/Grazoprevir (Zepatier)

All-oral, once-daily regimen

- Approved 1/2016 for GT 1 and 4

Approved DAAs From Multiple Classes: Basis of 2016 Combination HCV Regimens

- **Structural Domain**
  - 5'UTR
  - 3'UTR
  - Core E1 E2 P7 NS2 NS3 4A NS4B NS5A NS5B

- **Nonstructural Domain**
  - Protease
  - Polymerase

- **Ribavirin (RBV)**
- **NS3 Protease Inhibitors**
  - Grazoprevir (GZR)
  - Paritaprevir/Ritonavir (PTV/RTV)
  - Simeprevir (SMV)
  - Voxilaprevir (VOX)*
  - Glecaprevir (GLE)*
- **NS5A Replication Complex Inhibitors**
  - Daclatasvir (DCV)
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*Possible approval in 2017.

Slide credit: clinicaloptions.com
SVR12: Immediate and Deferred Treatment Groups

![Bar chart showing SVR12 results for immediate and deferred treatment groups.](chart.png)

<table>
<thead>
<tr>
<th></th>
<th>Full analysis set</th>
<th>Modified full analysis set</th>
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</thead>
<tbody>
<tr>
<td>Immediate treatment</td>
<td></td>
<td></td>
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<tr>
<td>Relapse</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>D/c unrelated to study medication</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td>Deferred treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relapse</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>D/c unrelated to study medication</td>
<td>3</td>
<td>0</td>
</tr>
</tbody>
</table>

D/c = discontinued; MFAS = primary efficacy analysis; Tx = treatment.
FAS was a secondary analysis.
†Noncirrhotic, interferon-intolerant patient with HCV GT1b infection relapsed at FUW12.
‡Lost to follow-up (n = 2); n = 1 each for death, noncompliance, withdrawal by subject, and withdrawal by physician (owing to violent behavior).
§Two patients in the DTG, both with G1a infection, relapsed at FUW4 and FUW12.
‖Withdrawal by subject, n = 1; AE, n = 1; death, n = 1.
PTV/r/OBV+DSV (Viekira Pak)

- Approved 12/2014 for GT 1
- GT 1a and cirrhotics require Ribavirin which increases pill Burden and side effects
- Contraindicated in advanced cirrhosis
Approved DAAs From Multiple Classes: Basis of 2016 Combination HCV Regimens

**Structural Domain**
- 5'UTR
- Core
- E1
- E2
- P
- 7

**Nonstructural Domain**
- NS2
- NS3
- 4A NS4B
- NS5A
- NS5B
- 3'UTR

**Protease**
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- NS5B Non-NUC Inhibitors
  - Dasabuvir (DSV)

*Possible approval in 2017.

Slide credit: clinicaloptions.com
Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir +/- RBV in GT1
PEARL-III and PEARL-IV: Results

3D = Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir
RBV = Ribavirin

Sofosbuvir/Velpatasvir (Epclusa)

- Velpatasvir, an NS5A inhibitor and Sofosbuvir, an NSEB inhibitor, once daily single tablet regimen
  - FDA approval 2016
  - Pangenotypic
Approved DAAs From Multiple Classes: Basis of 2016 Combination HCV Regimens

**Structural Domain**
- 5'UTR
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  - E2
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*Possible approval in 2017.

Slide credit: clinicaloptions.com
Sofosbuvir/Velpatasvir: SVR12 by Genotype

ASTRAL-1: SOF/VEL STR for 12 Weeks in GT 1, 2, 4, 5, 6 HCV-Infected Patients

SVR12 (%)

<table>
<thead>
<tr>
<th>Genotype</th>
<th>Total</th>
<th>1a</th>
<th>1b</th>
<th>2</th>
<th>4</th>
<th>5</th>
<th>6</th>
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<tbody>
<tr>
<td></td>
<td>618/624</td>
<td>206/210</td>
<td>117/118</td>
<td>104/104</td>
<td>116/116</td>
<td>34/35</td>
<td>41/41</td>
</tr>
</tbody>
</table>

1 relapse  2 LTFU  1 WC  1 relapse  1 death

LTFU=lost to follow up; WC=withdraw consent

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### Recommended Regimens by evidence level and alphabetically for:

**Genotype 1b, Treatment-naive Patients, Without Cirrhosis**

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<td>release regimen or plus twice-daily dosed dasabuvir (250 mg)</td>
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**Genotype 1b, Treatment-naive Patients, with Compensated Cirrhosis**

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### Genotype 2, Treatment-naive Patients, Without Cirrhosis

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</table>

### Genotype 2, Treatment-naive Patients, with Compensated Cirrhosis

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Recommended Regimens by evidence level and alphabetically for:
Genotype 3, Treatment-naive Patients, Without Cirrhosis

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<tr>
<td>Daily daclatasvir (60 mg*) plus sofosbuvir (400 mg) with or without weight-based ribavirin</td>
<td>24 weeks</td>
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**Genotype 4, Treatment-naive Patients, Without Cirrhosis**

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**Genotype 4, Treatment-naive Patients, with Compensated Cirrhosis †**

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<td>12 weeks</td>
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<tr>
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<td>12 weeks</td>
</tr>
<tr>
<td>Generic Name</td>
<td>Brand Name</td>
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<tr>
<td>sofosbuvir</td>
<td>Sovaldi</td>
</tr>
<tr>
<td>ledipasvir/sofosbuvir</td>
<td>Harvoni</td>
</tr>
<tr>
<td>simeprevir</td>
<td>Olysio</td>
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<tr>
<td>ombitasvir/paritaprevir/ritonavir</td>
<td>Viekira Pak</td>
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<td>ombitasvir/paritaprevir/ritonavir</td>
<td>Technivie</td>
</tr>
<tr>
<td>daclatasvir</td>
<td>Daklinza</td>
</tr>
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WHAT DRUGS ARE CHOSEN FOR HCV THERAPY?

Medicaid coverage guidelines:
- Genotype 1: Zepatier or Viekira XR
- Genotype 2 & 3: Epclusa
- Genotype 4: Zepatier or Technivie

Medicare Part D and Commercial Insurance trends (each plan has a different formulary):
- Genotype 1: Harvoni
- Genotype 2: Epclusa
- Genotype 3: Epclusa or Daklinza+Sovaldi
- Genotype 4: Harvoni
HCV THERAPY:
RECENT MEDICAID CHANGES

Summary of major updates:
- Treatment coverage will be available to stage 0 & 1 fibrosis patients
- Fibroscan/fibrosis staging is not required unless advanced fibrosis/cirrhosis is suspected
- Patients with “recent” (not defined in guideline) drug use must be participating in a recovery program and must no longer be actively using IV drugs for at least 3 months prior to and during HCV therapy
- Medicaid will now provide approval for the full course of HCV therapy, and not require renewals/labs throughout treatment as before
HEPATITIS C TREATMENT:

SUMMARY

• Hepatitis C treatment is highly effective with greater than 95% sustained virological response
• Hepatitis C treatment is well tolerated
• Current treatment options are costly
• Multiple barriers to therapy persist including identifying infected individuals and performing appropriate testing