Exploring Current & Emerging Treatments for Chronic Hepatitis C (HCV): Cost & Effectiveness

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SUN CITY

Elderly people
Objectives

• Learn the current and emerging treatment strategies for HCV and their cost effectiveness
• Understand the epidemiology and natural history of HCV
• Learn how to diagnose and screen for HCV
Hepatitis C Virus (HCV)

- Single-stranded RNA virus
- Only member of genus *Hepacivirus* in the Flaviviridae family
- Humans are the only known natural host
- Unlike the DNA viruses HIV and HBV, cure of HCV infection is possible

Hepatitis C Differs from HIV and HBV: HCV can be Cured!

- HBV:
  - Host cell
    - cccDNA
    - Proviral DNA
    - Viral RNA
  - TREATMENT: Long-term suppression of viral replication
- HIV:
  - Host cell
    - cccDNA
    - Proviral DNA
    - Viral RNA
  - TREATMENT: Long-term suppression of viral replication
  - 2, 3
- HCV:
  - Host cell
    - Viral RNA
  - TREATMENT: Viral Eradication = Cure

References:
1. Pawlotsky JM. J Hepatol 2006;44:S10-S13
EPIDEMIOLOGY OF HCV

Chronic HCV: A Global Health Problem

Weekly Epidemiological Record. N° 49, 10 December 1999, WHO
HCV Genotypes

6 HCV genotypes that differ from each other by 31-34% in their nucleotide sequences.

Genotype and Viral Load in U.S. Patients

- Genotype 1 HVL: 49.5%
- Genotype 1 LVL: 24.5%
- Genotype 2,3 HVL: 14.7%
- Genotype 2,3 LVL: 7.3%
- Genotype 4,5,6 HVL: 2.7%
- Genotype 4,5,6 LVL: 1.3%
- Genotype 4,5,6 LVL: 1.3%

HIGH VIRAL LOAD: >800,000 IU/ML
LOW VIRAL LOAD: <800,000 IU/ML

**Current Prevalence of HCV**

- 200 million persons have been infected with HCV worldwide (anti-HCV positive)\(^1\)
- 170 million have chronic disease worldwide (HCV RNA positive-currently infected)\(^1\)
- 3.5 million Americans have been infected with HCV (anti-HCV positive)\(^2\)
  - True prevalence at least 5.2 million\(^3\)
- 2.7 million Americans have chronic disease (HCV RNA positive-currently infected)\(^2\)
  - True prevalence at least 3.9 million\(^4\)

1. Edlin BR. Hepatology 2005;42(suppl 1):213A.
3. Chak E, Talai AH, Sherman KE, Schiff ER, Saab S. Liver International 2011; 31:1090-1101

**Chronic HCV Infection in the US**

- Chronic HCV cases not included in NHANES estimate:
  - Homeless
  - Incarcerated
  - Veterans
  - Active military
  - Healthcare workers
  - Nursing home residents
  - Chronic hemodialysis
  - Hemophiliacs

Chak E, Talai AH, Sherman KE, Schiff ER, Saab S. Liver International 2011; 31:1090-1101
Prevalence of HCV in the U.S. (NHANES 2001-2010)

Overall prevalence: 1% (2.7 million)
75% were born between 1945 and 1965 (age 49-69)
“Baby Boomers”


Chronic HCV in U.S.

2.7-3.9 million infected
50-75% HCV detected
32% to 38% referred for care
7% to 11% treated

Natural History of HCV: A Chronic Progressive Liver Disease

HCV Natural Disease Progression

- **Acute HCV**: 75%-85% (>6 months)
- **Chronic HCV**: 15%-25% (>6 months)
- **Fibrosis**: 60%-70%
- **Cirrhosis**: 1%-4% per year (20-40 years)
- **Hepatocellular Carcinoma (HCC)**: 75%-85% (>6 months)
- **Virus Cleared**:Anti-HCV (+) HCV-RNA (-)

Chronic HCV: Progression to Cirrhosis

Factors Associated With Disease Progression

- ETOH consumption: >30 g/day in males
  >20 g/day in females
- Disease acquisition at > 40 years
- Male
- HIV or HBV co-infection
- Hepatic Steatosis and insulin resistance

Shiffman ML. Viral Hepatitis Rev. 1999;5:27-43
Swain et al. EASL 2006.
Factors Not Influencing Progression

- Transaminase level (ALT)
- Viral load
- Mode of transmission
- Genotype

Swain et al. EASL 2005.

Diagnosis & Screening of HCV
Importance of Diagnosing HCV

- The Primary Care Provider (PCP) has a unique window of opportunity to make a diagnosis of HCV and refer for treatment prior to the development of cirrhosis and its complications.

Chronic HCV in U.S.

- 2.7-3.9 million infected
- 50-75% HCV detected
- 32% to 38% referred for care
- 7% to 11% treated

HCV Patients Are Undiagnosed Because of Screening Barriers to Diagnosis

- Patient Barriers
  - Persons infected with HCV are usually asymptomatic and unaware of their infection
  - Persons infected with HCV are usually unaware of the risk factors for HCV


I hope I don’t have Hepatitis C
The Lack of Symptoms in Chronic HCV Infection

The most common symptom is fatigue

HCV Patients Are Undiagnosed Because of Screening Barriers to Diagnosis

- Primary Care Provider Barriers
  - Routine HCV risk factor assessment not current PCP practice
  - Elevated LFTs, not risk factors, is current marker for PCPs ordering a liver panel
    - Normal ALT in males is up to 30
    - Normal ALT in females is up to 19


Common Risk Factors for HCV

HCV is spread through contact with infected blood

- IV drugs use now accounts for 2/3 of HCV in US
- Received blood or blood products or solid organ transplant before 1992
- Hemodialysis patients before 1992
- Needle Sticks
- Intranasal cocaine with shared implements
- Body piercing with contaminated needles
- Tattooing with contaminated needles or ink
- Incarceration
Less Common Risk Factors

- Sharing of household items that could carry infected blood: razors, toothbrushes, manicure implements
- Traumatic contact with blood: cuts, nose-bleeds, menstrual blood
- Perinatal transmission: 5% of deliveries from HCV positive mothers
- Sexual transmission: accounts for less than 5% of all cases: Seen in high-risk sexual behavior (multiple sex partners, prostitutes, man to man sex) where there is trauma to the mucosa
  - The risk in monogamous partners without any other risk factors is extremely low

The Role of the PCP: Look for Risk Factors

It’s been up to the PCP to identify and screen all their patients with risk factors for HCV
Risk-based Screening is not Working: You Can’t Treat What You Haven’t Diagnosed

Diagnosed HCV cases

Undiagnosed HCV cases

75% of HCV found in BABY BOOMERS: those born 1945-1965 who contracted HCV in the 1970’s-1980’s: The Era of Sex, Drugs and Rock And Roll
Screening Guidelines for Diagnosing Chronic HCV

• Screen all baby boomers and all patients with risk factors regardless of age and all patients with ↑ LFT’s with anti-HCV (>99% sensitivity)
• In patients with ↑ LFT’s, look for other causes of ↑ LFT’s:
  – HAAb, HBsAg, HBcAb, HBsAb
  – Iron, TIBC, ferritin
  – Antinuclear, antimitochondrial, and antismooth muscle antibodies
  – Ultrasound
Diagnosis of HCV

• Confirm positive anti-HCV with **quantitative** HCV RNA PCR
  – Positive within 1-3 weeks after exposure
  – Denotes active disease and infectivity
  – Quantitative assays detect to low levels: Quest Heptimax (5 IU/ml) or LabCorp Quanta-Sure (10 IU/ml)

• Check HCV genotype at the same time

Treatment of Hepatitis C: 2014

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HEPATITIS C
Why Treat HCV Now?

• Chronic HCV is a progressive disease that increases morbidity and mortality (with resultant increasing substantial healthcare costs), all of which can be reduced with successful treatment

• The cost for treating HCV is significantly higher for those with more severe disease due to increased direct health care costs

Benefits of Treating and Achieving Viral Eradication (SVR)1-4

• Reduction in liver-related deaths
• Reduction in all-cause mortality
• Reduction in HCC
• Reduction in liver decompensation and need for liver transplant
• All of the above will reduce the economic burden of HCV and result in cost savings

Chronic HCV: The Epidemic has Just Begun

At least 2.7 million persons are chronically infected with HCV

Between 2010-2030 if NO treatment is provided

1,040,000 will have developed cirrhosis
254,664 will have developed HCC
537,928 will die


Estimated Prevalence of Chronic HCV and Cirrhosis

- Acute infections peaked between 1970 and 1990
- The peak of chronic HCV prevalence was 2001
- The highest prevalence of cirrhosis is projected to be between 2010 and 2030

The Tsunami of HCV Cirrhosis Complications: Decompensation and HCC

Hepatic decompensation

- Portal hypertension
- Ascites
- Variceal bleed
- Encephalopathy

Mortality Rates in the US, 1999-2007

Positive HCV RNA Associated With Higher All-Cause Mortality

All Causes

- Anti-HCV seropositives, HCV RNA detectable
- Anti-HCV seropositives, HCV RNA undetectable
- Anti-HCV seronegatives

*P* < .001 for comparison among 3 groups
*P* < .001 for HCV RNA detectable vs undetectable

Follow-up (Yrs)

 Cumulative Mortality (%)

0 2 4 6 8 10 12 14 16 18 20

VA Cohort Study

HCV Increases Risk of Liver Cancer

Hepatocellular Carcinoma

Proportion With Diagnosis

Follow-Up (Years)

HCC Incidence in Cirrhotic Patients: SVR vs No SVR


HCV Accounts for ~ 50% of Liver Transplants in the United States

Goals of Treatment of HCV

- Primary Goal:
  - Achieve Sustained Viral Response (SVR)
  - Undetectable HCV RNA 6 months after completion of treatment with past treatment regimes
  - Undetectable HCV RNA 3 months after treatment with the newer HCV combinations
  - SVR is synonymous with “cure”

Whom to Treat

“Successful hepatitis C treatment results in sustained virologic response (SVR) which is tantamount to virologic cure, and as such, is expected to benefit nearly all chronically infected persons. Evidence clearly supports treatment in all HCV-infected persons, except those with limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions.”
Whom to Treat
www.hcvguidelines.org
10/24/14

• Highest priority for treatment owing to highest risk for severe complications
  – Advanced fibrosis (Metavir F3) or compensated cirrhosis (Metavir F4)
  – Organ transplant
  – Type 2 or 3 essential mixed cryoglobulinemia with vasculitis
  – Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis

Whom to Treat
www.hcvguidelines.org
10/24/14

• High priority for treatment owing to high risk for complications
  – Fibrosis (Metavir F2)
  – HIV-1 or HBV coinfection
  – Other coexistent liver disease (eg, NASH)
  – Debilitating fatigue
  – Diabetes mellitus (insulin resistant)
  – Porphyria cutanea tarda
Up to 2011, the Treatment of HCV GT1 was Pegylated Interferon and Ribavirin

- The unsatisfactory response rate in genotype 1 with peginterferon and ribavirin (54-56%) led to the development of a new class of HCV drugs called Direct Acting Antivirals (DAA’s) that directly inhibit viral replication.
HCV Life Cycle and DAA Targets


HCV Genome and DAA Targets

Emergence of Pre-existing Resistant Mutants During Treatment with DAA Monotherapy

Baseline HCV RNA

Before Treatment

Time on Treatment with DAA Alone

Viral breakthrough

HCV RNA

Resistant virus

Sensitive virus

Use of Multiple Drugs Prevent Selection of Resistant Variants

Baseline HCV RNA

Before Treatment

Time on Treatment with DAA + PegIFN + RBV

All DAA’s now and in the future are used in combination with other HCV drugs to prevent viral resistance

Resistant virus

Sensitive virus
The First DAAs were 2 Protease Inhibitors: Telaprevir and Boceprevir each given with PegINF and Ribavirin

Limitations:
• They are only approved for genotype 1
• Efficacy: SVR of only 68-75%
• Tolerability
• Complicated Regimes
• Serious drug-drug interactions

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Second Generation DAA’S

• Goal:
  – Increase genotype 1 SVR
  – Shorten the duration of treatment
  – Avoid serious side effects

• The first FDA approved 2nd generation DAAs are sofosbuvir and simeprevir
  – Both taken with peginterferon and ribavirin for genotype 1
Sofosbuvir

- NS5B Polymerase Nucleoside Inhibitor
- Potent antiviral activity against HCV GT1–6
- Oral once a day tablet with no food effect
- No clinically significant drug interactions
- Generally safe and well-tolerated in clinical studies to date (> 3,000 patients)
  - Low incidence of fatigue and headache

NEUTRINO: Sofosbuvir + P/R for 12 Weeks in Treatment-Naive GT 1/4/5/6

Limitations of Sofosbuvir/PegINF/RBV for Genotype 1

- Requires peginterferon and ribavirin
- 81% SVR in cirrhosis

VALENCE: SVR12 With SOF + RBV in GT2 and GT3

GT2 12-Wk Treatment

- Naive, Noncirrhotic: 97/30 = 94%
- Naive, Cirrhotic: 100/2 = 100%
- Exp’d, Noncirrhotic: 91/33 = 84%
- Exp’d, Cirrhotic: 88/7 = 88%

GT3 24-Wk Treatment

- Naive, Noncirrhotic: 90/23 = 94%
- Naive, Cirrhotic: 92/13 = 100%
- Exp’d, Noncirrhotic: 87/10 = 87%
- Exp’d, Cirrhotic: 60/5 = 80%

AASLD/IDSA Recommendations for Treatment of Genotype 2 and Genotype 3

- Genotype 2: Sofosbuvir and ribavirin for 12 weeks
- Genotype 3: Sofosbuvir and ribavirin for 24 weeks

Simeprevir

- 2nd Generation once a day NS3/4A Protease Inhibitor
- FDA approved for use in genotype 1 only
- No Benefit if Q80K Positive: NS3 Q80K is a naturally occurring polymorphism that occurs in 48% of US genotype 1a
- 61 drug-drug interactions (CYP3A4)
- Adverse reactions: Photosensitivity, rash, pruritus, nausea, myalgia, and dyspnea
Simeprevir Naïve Genotype 1 SVR: Pooled Quest 1 and 2 Studies

No Benefit if Q80K Positive

Simeprevir Treatment Experienced Genotype 1 SVR (Promise Study)

No Benefit if Q80K Positive
Simeprevir Uses Response-Guided Therapy and Peg/RBV Tail

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<th>12</th>
<th>24</th>
<th>48</th>
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HCV RNA
- Undetectable
- Undetectable
- Undetectable

SIM + PEG/RBV

PEG + RBV

Treatment naïve and prior relapsers: 12 weeks SMV/PEG/RBV + 12 weeks PEG/RBV

Prior non-responders: 48 weeks (12 weeks SMV/PEG/RBV + 36 weeks PEG/RBV)

Limitations of Simeprevir/Peg/RBV for Genotype 1

- Requires peginterferon and ribavirin
- Simeprevir has a complicated response-guided regime, 61 drug interactions, not effective with Q80K mutations, multiple side effects, and a SVR <90%
Interferon Free Treatment for Genotype 1 HCV

The Holy Grail of Hepatology

WHAT ARE THE PROBLEMS WITH PEGYLATED INTERFERON

Requires an injection
Peginterferon Side Effects

- Psychiatric symptoms:
  - Depression, anxiety, mood changes, suicidal ideation
- Hematologic side effects:
  - Anemia, neutropenia, thrombocytopenia
- Flu-like symptoms:
  - Headache, fatigue, chills, myalgias, arthralgias
- GI symptoms:
  - Nausea, diarrhea, dyspepsia
- Retinopathy
- Thyroid toxicity

Contraindications to Peginterferon

- History of/or ongoing poorly controlled psychiatric disease (depression, bipolar)
- Decompensated cirrhosis
- Autoimmune disease
- Active substance abuse
- Kidney and heart transplants
“Treatment of HCV is at a moment of “revolution,” one on par with the mid-1990’s wave of antiretroviral combinations that converted HIV from a death sentence to a chronic illness. This one of those moments in time when a revolution is taking place in terms of a disease state”

Nezam H. Afdahl, Chief of Hepatology, Beth Israel Deaconess Medical Center, Harvard Medical School, The American Journal of Managed Care, April 2014

Interferon Free Treatment of G1 2014

• Sofosbuvir and ledipasvir
• Sofosbuvir and simeprevir
• 3 D plus ribavirin
**Sofosbuvir + Ledipasvir (NS5A Inhibitor)**

- First FDA approved interferon free tx for G 1
- Single tablet once a day
- Low incidence of fatigue and headaches

**ION 1: SVR12 With 12 or 24 Wks**
**SOF/LDV ± RBV in Tx-Naive GT 1 Pts**

- Adding RBV and/or extending LDV/SOF treatment duration to 24 weeks did not increase SVR12 rates

ION 1: SVR12 for LDV/SOF for 12 Weeks in GT 1 by Race and Ethnicity


ION 2: SVR12 in GT 1 PegIFN+RBV and PI+PegIFN+RBV Failures

Adding RBV and/or extending treatment to 24 weeks did not increase SVR_{12}
ION 2: SVR12 With 12 or 24 Wks of SOF/LDV ± RBV in GT 1 by Cirrhosis Status

24-week treatment in previously treated cirrhotic patients increased SVR12.


ION-3 (GT 1, Treatment-Naive, Non-Cirrhotic: 8 or 12 weeks of LDV/SOF with Baseline HCV RNA <6Million IU/ml)

In patients with HCV RNA < 6M IU/ml extending treatment to 12 weeks did not increase SVR12.

ION-3 (GT 1, Treatment-Naive, Non-Cirrhotic: 8 or 12 weeks of LDV/SOF with Baseline HCV RNA >6 Million IU/ml)

In patients with HCV RNA > 6M IU/ml extending treatment to 12 weeks increased SVR$_{12}$


FDA Approved Dosage of LED/SOF

- 8 week can be considered in treatment-naïve patients without cirrhosis who have pre-treatment HCV RNA less than 6 million IU/mL
- 12 weeks in treatment-naïve patients with or without cirrhosis
- 12 weeks in treatment-experienced patients without cirrhosis
- 24 weeks in treatment-experienced patients with cirrhosis

Harvoni Package Insert 10/14
Simeprevir + Sofosbuvir: Cosmos Phase II Study


**SMV/SOF ± RBV**

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<th>Cohort 1 (F0-F2 Nulls)*</th>
<th>SMV/SOF</th>
<th>SMV/SOF + RBV</th>
<th>SMV/SOF + RBV Overall</th>
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*Excluding patients who discontinued for nonvirologic reasons.

Simeprevir and Sofosbuvir

- FDA approved for 12 weeks without cirrhosis and 24 weeks with cirrhosis
- Limitations:
  - Based on a small phase II study with limited data
  - 61 drug interactions with simeprevir (CYP3A)
  - Because of potential cross resistance with HCV protease inhibitors, should not used with prior protease inhibitor based regimen failure
  - SVR <90% in real world experience
3D plus Ribavirin Combination
(Due to be FDA Approved 12/14)

• ABT-450 (protease inhibitor boosted with ritonavir)
• Ombitasvir (NS5A inhibitor)
• Dasabuvir (non-nucleoside polymerase inhibitor)

• Weight dosed ribavirin twice a day

SAPPHIRE I: SVR12 With 3 DAAs + RBV in Treatment-Naive Non-Cirrhotic GT 1 Pts

The overall efficacy of 12-week treatment and 24-week treatment did not differ significantly except for prior 1a null responders where 24 weeks was more effective.
The Cost of Achieving a Cure vs The Cost of NOT Treating

Estimated Cost of Untreated HCV for 2010 to 2019

- 208,500 HCV-related deaths over a 10-year period
- $10.7 billion in direct medical cost
- $75.3 billion societal costs from premature disability and mortality
- Total of $86 billion in direct and indirect costs

The Cost of Untreated HCV

- The cost of **not treating** patients is high
  - Patients with compensated cirrhosis may live for over a decade accruing over $270,000 in expense prior to developing end-stage liver disease
  - The cost of treating cirrhosis and HCC is $30,000-$70,000 annually for 5-10 years
  - The cost for liver transplantation is ~$577,100 per transplant + $145,000 year
  - More costs will be incurred both short-term and long-term

Younossi ZM et al. J Hepatology 2014;60:530-537
Pockros P. 29th Annual New Treatments in Chronic Liver Disease, La Jolla, March 29, 2014

Increasing Health Care Costs Associated With Progressive Liver Disease in the Aging HCV-Infected Population

- While the prevalence of HCV infection is declining from its peak, the incidence of advanced liver disease and associated health care costs continue to rise

Healthcare Costs Associated with HCV are Substantial and Increase with Disease Severity


HCV is a Progressive Disease and HCV-Related Healthcare Costs are Directly Related to Disease Severity


HCV Therapy Is Associated with Lower Healthcare Costs and Curing HCV Should Lower Downstream Health Care Costs


NCD=non-cirrhotic disease
CC=compensated cirrhosis
ESLD=end-stage liver disease

![Graph showing predicted costs for different liver disease severities and treatment statuses.]

SVR With PegIFN + RBV is Significantly Associated With Reduction in All-Cause Mortality

Benefits of Achieving a SVR

Viral eradication leads to improved outcomes

• ↓ in cirrhosis
• ↓ in decompensation
• ↓ in HCC
• ↓ in liver transplants
• ↓ in liver-related deaths

Wong JB. Pharmacoeconomics 2006; 24(7):661-672

Treatment with Oral IFN-free Regimens will be the Most Cost-Effective Strategy

• Treatment is short term and curative in almost all patients
• There are not as many costs associated with INF-free treatment compared to INF treatment (cost of managing side effects plus $5,000/12 weeks for visits, labs, etc)
• Fewer costs will be incurred not only in the short-term, but also in the lifetime of a patient

Younossi ZM et a. J Hepatology 2014;60:530-537
Pockros P. 29th Annual New Treatments in Chronic Liver Disease, La Jolla, March 29, 2014
Reau, NS, Jenson DM. Hepatology 2014:59:1246-1249
The Price of a Cure: Cost Per SVR

Total Costs Accrued in one year per patient

SVR Rate

- Costs include:
  - Drug regimen costs
  - Managing adverse event costs
  - Monitoring costs (labs and office visits)


The Price of a Cure: Cost Per SVR

Administering a therapy with a lower cost per successfully treated patient will mean:
- Fewer patients will relapse and have to be treated again
- Fewer patients will progress to more advanced fibrotic states as well as end stage liver disease states, and therefore: Fewer costs will be incurred
The Price of a Cure: Cost Per SVR

- The most costly drug is the one that does not lead to treatment success despite initial investment due to lack of efficacy or premature discontinuation (i.e., AEs, adherence)

2. Saab J et al. APF June 2014 p 1-19
4. Afdhal N et al. NEJM May 2014 p 1889-1897
5. Afdhal N et al. NEJM April 2014 p 1483-1493
6. Kowdley KV et al. NEJM May 2014 p1879-1887

Genotype 1 Cost Per SVR: Treatment-Naïve Without Cirrhosis (F0-F3)

Genotype 1 Cost Per SVR: Treatment-Naïve With Cirrhosis


Genotype 1 Cost Per SVR: Treatment-Experienced (PR+PI) Non Cirrhotic and Cirrhotic

Costs of Other Chronic Diseases

- **Heart Disease and Stroke**: $193.4 billion in direct medical costs/y and $122 billion/y in indirect costs
- **Diabetes**: $176 billion/y in direct medical costs and $69 billion/y in decreased productivity
- **Arthritis**: $81 billion/y for direct medical costs and $47 billion/y for indirect costs
- **Cancer Care Costs**: $157 billion/y

HCV Treatment

- Shorter treatment duration: 4 weeks?
- SVR rates close to 100% including in cirrhosis
- Few adverse events
- Single oral drug combination for all genotypes
Conclusions

• HCV is a major cause of chronic liver disease, cirrhosis and hepatocellular carcinoma
• Screen all patients with risk factors, and all baby boomers for HCV
• We are undergoing a dramatic paradigm shift in HCV treatment with new DAA combinations that promise higher cure rates, shorter treatment duration and fewer side effects
• The cost of all oral therapy should be offset by future savings through the prevention of liver-related complications

Your tests show that what happened in Vegas didn't stay in Vegas
Questions ?