

Health Disparities in the Chronically Infected HCV Population

18 August 2022 AAIP

Brian Seagraves, Pharm.D.
UGA College of Pharmacy
Clinical and Administrative Pharmacy
Office: 706-542-5367
Cell: 706-424-1725

About Me

- Athens, GA Native
- 2004 Pharm.D. UGA College of Pharmacy
- Mentored in the ways of the Viral Hepatitis Force by Greg Smith, M.D. and Keyur Patel, M.D.
- Established Athens' 1st free viral hep treatment program at Mercy Health Center
- Established free viral hep treatment program at Athens Nurses' Clinic
- Established 1st Hep C community outreach program in Athens
- Assisted Good News Clinic in Gainesville, GA in developing free HCV clinic
- Assisted, and still consult with, Piedmont Athens Regional Community Care clinic in developing viral hep clinic (340B)
- 2016 Healthcare Georgia's Joseph D. Greene Community Service Award
- 2019 Georgia Society of Health-System Pharmacists Community Service Award
- 2022 ACCDC Humanitarian Award
- 2016 – present Faculty Member UGA College of Pharmacy

Disclosure

I have no real or apparent conflicts of interest

Objectives

Pharmacists:

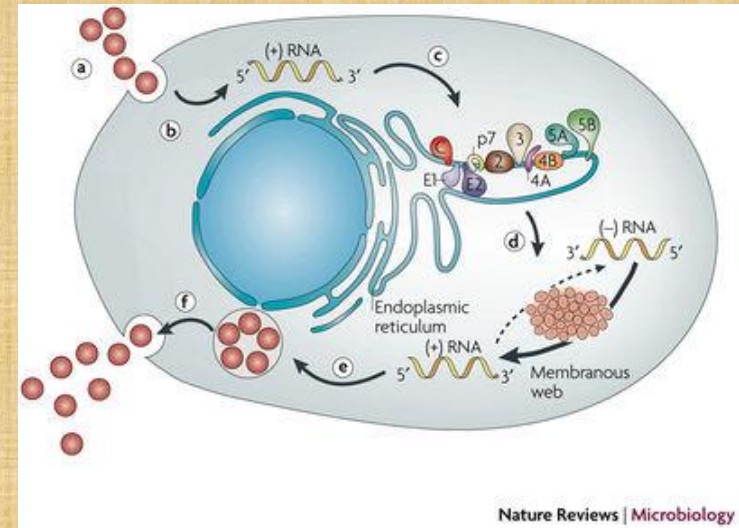
- 1. Review underlying physiology associated with HCV**
- 2. Describe the role of direct acting antivirals (DAAs) for use in HCV**
- 3. List what population should be screened for HCV**

Techs:

- 1. Review underlying physiology associated with HCV**
- 2. Recognize direct acting antivirals for use in HCV**
- 3. List what population should be screened for HCV**

HCV

- WHO estimates 150,000,000 chronically infected worldwide
- CDC estimates 2,400,000 in the US
 - RNA virus
 - Replicates in the cytoplasm
 - Makes numerous replication errors



<https://www.nature.com/articles/nrmicro1645>

Modes of Transmission

- Needle sticks
- Tattoos
- Body piercings
- Sharing razors, manicuring implements, toothbrushes
- Blood transfusion - - prior to 1990
- Sexual Transmission - - rare with monogamy*

* Vadenni C, Francesco R, et al. **Lack of Evidence of Sexual Transmission of Hepatitis C among Monogamous Couples: Results of a 10-Year Prospective Follow-Up Study.**

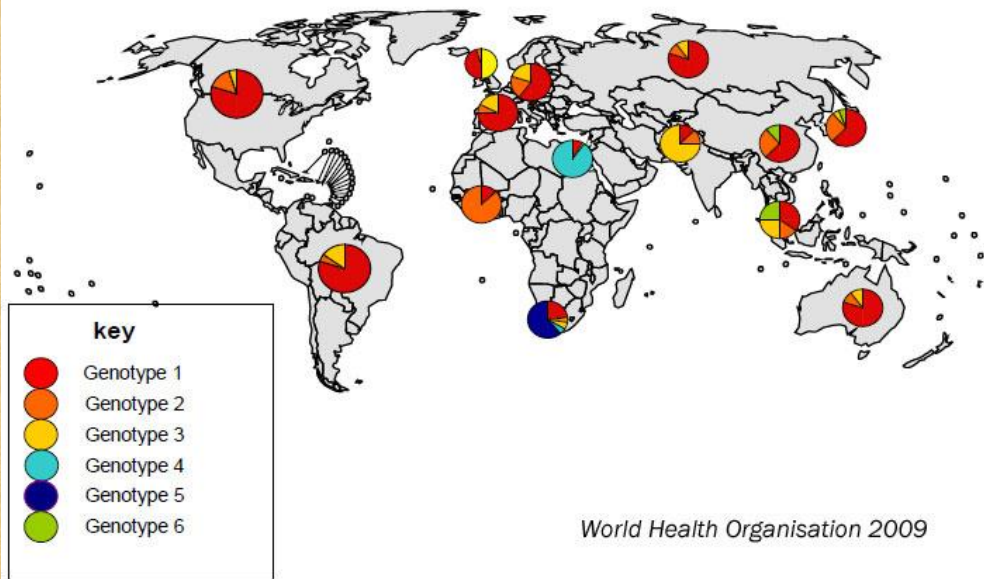
The American Journal of Gastroenterology (2004) **99**, 855–859

Risk Factors

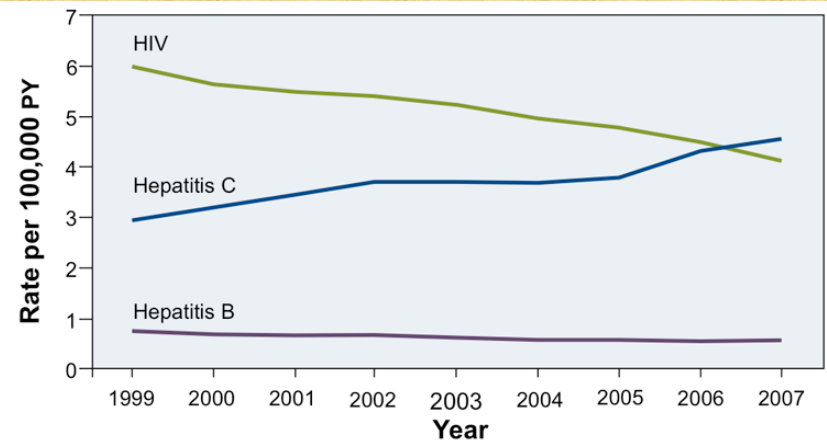
- IVDU - - Per CDC approximately 60% of CHC cases
- Healthcare workers - - Per CDC approximately 1.8%
- Intranasal Drug use
- Military Service
- Incarceration
- Multiple sex partners
- Unidentifiable - - approximately 10%
- **Baby Boomers.** However, CDC recommends “Hepatitis C screening at least once in a lifetime for **all adults** aged 18 years and older, except in settings where the prevalence of HCV infection (HCV RNA-positivity) is less than 0.1%”

<https://www.cdc.gov/hepatitis/hcv/guidelinesc.htm>

Global distribution of HCV genotypes



<http://hepctrust.org.uk/information/about-hepatitis-c-virus/genotypes-hepatitis-c>



*Mortality Rates = HBV, HCV, HIV listed as cause of death
Because of decedent can have multiple causes of death, a record listing more than 1 type of infection was counted for each type of infection

Source: Ly KN, Xing J, Klevens RM, Jiles RB, Ward JW, Holmberg SD. The increasing burden of mortality from viral hepatitis in the United States between 1999 and 2007. *Ann Intern Med.* 2012;156:271-8.

<https://www.acpjournals.org/doi/10.7326/0003-4819-156-4-201202210-00004>

HCV Screening Test



- **Finger prick**
- **Detects anti-HCV antibodies. Not definitive for HCV infection**
- **If positive, must have HCV by PCR (quant)**

STAGE (METAVIR)

Stage represents the amount of scarring or fibrosis

0 – 4

0 = No scarring

1 = Minimal scarring (usually portal)

2 = Scarring that extends outside the areas that contain blood vessels

3 = Bridging fibrosis (Spreading and connecting other fibrotic areas)

4 = Cirrhosis or advanced scarring

STAGING DETERMINATION

1. Needle Liver biopsy - - GOLD STANDARD

2. FibroSURE Analysis - - Blood Draw

3. FibroScan - - Transient elastography

CHILD-TURCOTTE-PUGH

- Scoring

| Measure | 1 point | 2 points | 3 points |
|---|--------------|--------------------------------|------------------------------------|
| Total bilirubin $\mu\text{mol/L}$ (mg/dL) | <24 (<2) | 24-50 (2-3) | >50 (>3) |
| Serum Albumin g/dL | >3.5 | 2.8-3.5 | <2.8 |
| PT, Prolongation OR INR | <4.0 <1.7 | 4.0-6.0 1.7-2.3 | >6.0 >2.3 |
| Ascites | None | Mild (or suppressed with meds) | Moderate to severe (or refractory) |
| Hepatic encephalopathy | None | Grade 1-2 | Grade 3-4 |

For example, a patient with the following: Total bilirubin = 3mg/dL; Serum albumin 2.2g/dL; INR=1.8; Mild ascites and no hepatic encephalopathy.

$$2+3+2+2+1 = 10$$

CHILD-TURCOTTE-PUGH

- Interpretation

| Points | Class | Status | One year survival | Two year survival |
|--------|-------|----------------------------|-------------------|-------------------|
| 5-6 | A | Compensated | 100% | 85% |
| 7-9 | B | Moderate Decompensation | 81% | 57% |
| 10-15 | C | Severe Decompensation | 45% | 35% |

HCV THERAPEUTICS TIMELINE

1989 - - HCV Identified

1989 - - Interferon alpha 2b

1996 - - Interferon alpha 2a

1998 - - Ribavirin

2001 - - Peg-Inf alpha 2b

2002 - - Peg-Inf alpha 2a

2011 - - Boceprevir and Telaprevir

2013 - - Sofosbuvir and Simeprevir

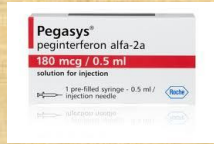
2014 - - Ledipasvir/Sofosbuvir and
Ombitasvir/Paritaprevir/Ritonavir/Dasabuvir

2015 - - Daclatasvir and Ombitasvir/Paritaprevir/Ritonavir

2016 - - Grazoprevir / Elbasvir and
Velpatasvir / Sofosbuvir

2017 - - Glecaprevir / Pibrentasvir and
Sofosbuvir/Velpatasvir / Voxilaprevir

INTERFERON



Subcutaneous injection

Adverse Reactions: May cause or aggravate fatal or life-threatening neuropsychiatric, autoimmune, ischemic, and infectious disorders. Hair loss, flu-like symptoms, thrombocytopenia, neutropenia, bone marrow suppression, cardiovascular disorders, pulmonary disorders, hepatic decompensation in cirrhotic patients.

Efficacy of monotherapy: 25% in non-cirrhotic genotype 1 patients

https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/103132s51901bl.pdf

RIBAVIRIN

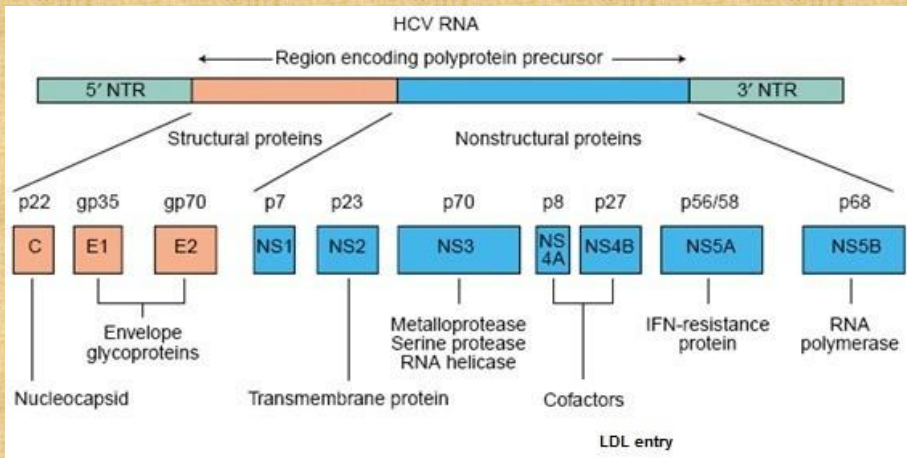
▶ A nucleoside analogue indicated for the treatment of chronic hepatitis C (CHC) virus infection in combination with peginterferon in adults with compensated liver disease not previously treated with interferon alpha, and in CHC patients coinfecting with HIV

▶ Ribavirin is also sometimes used to treat viral hemorrhagic fevers. In the event of biological warfare, ribavirin may be used to treat viral hemorrhagic fever that has been spread deliberately. Ribavirin is also sometimes used to treat severe acute respiratory syndrome.

▶ Dose: 15mg/kg/day in divided doses (BID)



https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021511s0231bl.pdf



<https://virologyj.biomedcentral.com/articles/10.1186/1743-422X-8-161>

Direct Acting Anti-virals (DAAs)

| NS3/4A | NS5A | NS5B |
|--|------------------------------------|-----------------------------------|
| Incivek (telaprevir) | | Sovaldi (sofosbuvir) |
| Olysio (simeprevir) | | |
| Victrelis (boceprevir) | Daklinza (daclatasvir) | |
| Viekira XR (paritaprevir/ritonavir) | Viekira XR (ombitasvir) | Viekira XR (dasabuvir) |
| Technivie (paritaprevir/ritonavir) | Technivie (ombitasvir) | |
| | Harvoni (ledipasvir) | Harvoni (sofosbuvir) |
| Zepatier (grazoprevir) | Zepatier (elbasvir) | |
| | Epclusa (velpatasvir) | Epclusa (sofosbuvir) |
| | Vosevi (voxilaprevir) | Vosevi (sofosbuvir) |
| | Mavyret (glecaprevir) | Mavyret (pibrentasvir) |

BLACK BOX WARNING FOR DAAs

WARNING: RISK OF HEPATITIS B VIRUS REACTIVATION IN PATIENTS COINFECTED WITH HCV AND HBV See full prescribing information for complete boxed warning. Hepatitis B virus (HBV) reactivation has been reported, in some cases resulting in fulminant hepatitis, hepatic failure, and death.

https://www.gilead.com/~media/files/pdfs/medicines/liver-disease/epclusa/epclusa_pi_old.pdf?la=en
https://www.gilead.com/~media/Files/pdfs/medicines/liver-disease/harvoni/harvoni_pi.pdf
https://www.rxabbvie.com/pdf/mavyret_pi.pdf
https://www.gilead.com/~media/Files/pdfs/medicines/liver-disease/vosevi/vosevi_pi.pdf



SOVALDI (SOFOSBUVIR)

- ▶ NS5B Nucleotide polymerase inhibitor
- ▶ Approved for Genotypes 1, 2, 3 or 4
- ▶ FDA approved dosing: 400mg PO QD with P / R with or without food
 - ❖ Genotypes 1 & 4: S/P/R x 12 weeks
 - Genotype 1 interferon ineligible – S / R x 24 weeks
 - ❖ Genotype 2: S / R x 12 weeks
 - ❖ Genotype 3: S / R x 24 weeks
- ❖ Hepatocellular carcinoma awaiting transplant: S / R up to 48 weeks

https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/204671s0021b1.pdf

SOVALDI

- ▶ Metabolism: Prodrug metabolized to GS-461203 hepatically - - “The metabolic activation pathway involves sequential hydrolysis of the carboxyl ester moiety catalyzed by human cathepsin A (CatA) or carboxylesterase I (CESI) and phosphoramidate cleavage by histidine triad nucleotide-binding protein I (HINTI) followed by phosphorylation by the pyrimidine nucleotide biosynthesis pathway.”

https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/204671s0021b1.pdf

SOVALDI

- Elimination: Renal Pathway

| Concomitant Drug Class: Drug Name | Effect on Concentration | Clinical Comment |
|---|---|---|
| Anticonvulsants: carbamazepine phenytoin phenobarbital oxcarbazepine | Decreased sofosbuvir Decreased GS-331007 | Coadministration of SOVALDI with carbamazepine, phenytoin, phenobarbital or oxcarbazepine is expected to decrease the concentration of sofosbuvir, leading to reduced therapeutic effect of SOVALDI. Coadministration is not recommended. |
| Antimycobacterials: rifabutin rifampin rifapentine | Decreased sofosbuvir Decreased GS-331007 | Coadministration of SOVALDI with rifabutin or rifapentine is expected to decrease the concentration of sofosbuvir, leading to reduced therapeutic effect of SOVALDI. Coadministration is not recommended. SOVALDI should not be used with rifampin, a potent intestinal P-gp inducer. |
| Herbal Supplements: St. John's wort (<i>Hypericum perforatum</i>) | Decreased sofosbuvir Decreased GS-331007 | SOVALDI should not be used with St. John's wort, a potent intestinal P-gp inducer. |
| HIV Protease Inhibitors: tipranavir/ritonavir | Decreased sofosbuvir Decreased GS-331007 | Coadministration of SOVALDI with tipranavir/ritonavir is expected to decrease the concentration of sofosbuvir, leading to reduced therapeutic effect of SOVALDI. Coadministration is not recommended. |

Serious Symptomatic Bradycardia When Coadministered with Amiodarone

https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/204671s0021b1.pdf

SOVALDI

- Missed dose - - take if 12 hours before next dose
- Adverse Events: Headache, N/V, fatigue

[/https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/204671s002lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/204671s002lbl.pdf)



HARVONI (LEDIPASVIR/SOFOSBUVIR)

- NS5A inhibitor with an NS5B Nucleotide polymerase inhibitor
 - Approved for Genotypes 1, 4,5 and 6
 - FDA approved dosing: 90mg/400mg PO QD
- Treatment-naïve with or without cirrhosis -- 12 weeks (may consider 8 weeks without cirrhosis and viral load less than 6 million)
 - Treatment experienced without cirrhosis – 12 weeks
 - Treatment experienced with cirrhosis – 24 weeks

https://www.gilead.com/~media/Files/pdfs/medicines/liver-disease/harvoni/harvoni_pi.pdf

HARVONI DRUG INTERACTIONS

- Same interactions as Sovaldi
- Antacids, H2 receptor blockers, PPIs - - decreases ledipasvir absorption
- Simeprevir – increased plasma concentrations of ledipasvir and simeprevir
- Rosuvastatin – increases plasma concentration of rosuvastatin

https://www.gilead.com/~media/Files/pdfs/medicines/liver-disease/harvoni/harvoni_pi.pdf

HARVONI

- Ledipasvir - - Biliary elimination (Renal elimination is less than 1%)
- Metabolism - - Mostly excreted unchanged (some slight oxidative metabolism)
 - Adverse Events: Headache, N/V, fatigue

https://www.gilead.com/~media/Files/pdfs/medicines/liver-disease/harvoni/harvoni_pi.pdf



EPCLUSA

(VELPATASVIR 100MG/SOFOSBUVIR 400MG)

Approved for HCV genotypes 1 through 6

No cirrhosis and compensated cirrhosis – 1 tablet daily for 12 weeks

Decompensated cirrhosis – 1 tablet daily with weight-based ribavirin for 12 weeks

https://www.gilead.com/~media/Files/pdfs/medicines/liver-disease/epclusa/epclusa_pi.pdf

EPCLUSA

(VELPATASVIR 100MG/SOFOSBUVIR 400MG)

Same drug interactions as Sovaldi.

Drugs that are inducers of P-gp and/or moderate to potent inducers of CYP2B6, CYP2C8, or CYP3A4 (e.g., rifampin, St. John's wort, carbamazepine) may decrease plasma concentrations of sofosbuvir and/or velpatasvir, leading to reduced therapeutic effect"

Acid suppression therapies decrease absorption of velpatisvir

http://www.gilead.com/~media/files/pdfs/medicines/liver-disease/epclusa/epclusa_pi.pdf?

EPCLUSA

(VELPATASVIR 100MG/SOFOSBUVIR 400MG)

Velpatasvir elimination: Biliary

Adverse Reactions: headache, fatigue, insomnia, nausea

https://www.gilead.com/~media/Files/pdfs/medicines/liver-disease/epclusa/epclusa_pi.pdf

MAVYRET

(GLECAPREVIR 100MG / PIBRENTASVIR 40MG)



Approved for genotypes 1 – 6

No cirrhosis and compensated cirrhosis

Contraindicated with moderate or severe decompensation

https://www.rxabbvie.com/pdf/mavyret_pi.pdf

MAVYRET (GLECAPREVIR 100MG / PIBRENTASVIR 40MG)

Dosing: 300mg/120mg daily (3 tabs)

| Treatment-Naïve Patients | | | |
|--------------------------|--------------------|--------------------------------------|--|
| HCV Genotype | Treatment Duration | | |
| | No Cirrhosis | Compensated Cirrhosis (Child-Pugh A) | |
| 1, 2, 3, 4, 5, or 6 | 8 weeks | 12 weeks | |

| Treatment-Experienced Patients | | | |
|--------------------------------|--|--------------------|--------------------------------------|
| HCV Genotype | Patients Previously Treated With a Regimen Containing: | Treatment Duration | |
| | | No Cirrhosis | Compensated Cirrhosis (Child-Pugh A) |
| 1 | An NS5A inhibitor ¹ without prior treatment with an NS3/4A protease inhibitor | 16 weeks | 16 weeks |
| | An NS3/4A PI ² without prior treatment with an NS5A inhibitor | 12 weeks | 12 weeks |
| 1, 2, 4, 5, or 6 | PR3 ³ | 8 weeks | 12 weeks |
| 3 | PR3 ³ | 16 weeks | 16 weeks |

Mavyret PI: https://www.rxabbvie.com/pdf/mavyret_pi.pdf

EXPEDITION-8 Study = 8 weeks naïve with compensated cirrhosis (2019)

MAVYRET (GLECAPREVIR 100MG / PIBRENTASVIR 40MG)

Contraindications:

- Severe hepatic impairment (Child-Pugh C)
- Coadministration with atazanavir and rifampin

Drug interactions:

- Carbamazepine, efavirenz, and St. John's wort
- Monitor INR in patients receiving warfarin

Adverse Reactions:

headache, fatigue, insomnia, nausea

https://www.rxabbvie.com/pdf/mavyret_pi.pdf

VOSEVI (SOFOSBUVIR 400MG / VELPATASVIR 100MG / VOXILAPRAVIR 100MG)



VOSEVI (SOFOSBUVIR 400MG / VELPATASVIR 100MG / VOXILAPRAVIR 100MG)

FDA approved for treatment experienced patients who previously failed an NS5A inhibitor, or genotypes 1a or 3 who were previously treated with sofosbuvir without an NS5A inhibitor.

Genotypes 1 – 6

Without cirrhosis or with compensated cirrhosis

Dose: 1 tablet daily for 12 weeks

https://www.gilead.com/~media/Files/pdfs/medicines/liver-disease/vosevi/vosevi_pi.pdf

Drug Interactions

Same as Sovaldi, Harvoni, and Epclusa

https://www.gilead.com/~media/Files/pdfs/medicines/liver-disease/vosevi/vosevi_pi.pdf

Sustained Virologic Response

SVR = Cure

Old Standard – SVR 24

New Standard – SVR 12

Lab at 12 weeks post treatment: CMP, CBC with diff., HCV by PCR (Quant)

Patients will always get positive test results with HCV antibody tests

Timely Hepatitis C Treatment* by Insurance Type

Medicaid

23%

77% not treated

Medicare

28%

72% not treated

Private

35%

65% not treated

0%

50%

100%

*Hepatitis C treatment started within 12 months of diagnosis during January 30, 2019 to October 31, 2020

Vitalsigns™

Source: August 2022 Vital Signs



CS331675

<https://stacks.cdc.gov/view/cdc/120092>

01/22, 03:09 PM | [View Full Report](#) | [Download Report](#) | [Print Report](#) | [Share Report](#)

CDC Center for Disease Control and Prevention

Early Release / August 9, 2022 / 71

William W. Thompson, PhD^{1*}, Hasan Syamum, PhD^{1*}, Amy Sandul, DHS¹, Neil Gupta, MD¹, Prvi Patel, MD¹, Noele Nelson, MD, PhD¹, Jonathan Mervis, MD¹, Carolyn Westler, MD¹ (View author affiliations)

View suggested citation

Summary

What is already known about this topic?

Direct-acting antiviral (DAA) treatment is recommended for nearly all persons with hepatitis C and cures ≥95% of cases. Treatment saves lives, prevents transmission, and is cost saving.

What is added by this report?

Treatment rates are low overall and vary by age and insurance payer. DAA treatment is lowest among young adults aged 18–29 years and Medicaid recipients, and within Medicaid, among persons reporting Black or other race and persons in states with treatment restrictions.

What are the implications for public health practice?

Timely initiation of DAA treatment, regardless of insurance type, is critical to reducing viral hepatitis-related mortality, disparities, and transmission.

Abstract

Introduction: Over 2 million adults in the United States have hepatitis C virus (HCV) infection, and it contributes to approximately 14,000 deaths a year. Eight to 12 weeks of highly effective direct-acting antiviral (DAA) treatment, which can cure ≥95% of cases, is recommended for persons with hepatitis C.

Methods: Data from HealthVerity, an administrative claims and encounters database, were used to construct a cohort of adults aged 18–69 years with HCV infection diagnosed during January 30, 2019–October 31, 2020, who were continuously enrolled in insurance for ≥60 days before and ≥60 days after diagnosis (47,687). Multivariable logistic regression was used to assess the association between initiation of DAA treatment and sex, age, race, payer, and Medicaid restriction status; adjusted odds ratios (aORs) and 95% CIs were calculated.

Results: The prevalence of DAA treatment initiation within 360 days of the first positive HCV RNA test result among Medicaid, Medicare, and private insurance recipients was 23%, 28%, and 35%, respectively; among those treated, 75%, 77%, and 64%, respectively, initiated treatment within 180 days of diagnosis. Adjusted odds of treatment initiation were lower among those with Medicaid (aOR = 0.54; 95% CI = 0.51–0.57) and Medicare (aOR = 0.62; 95% CI = 0.56–0.68) than among those with private insurance. After adjusting for insurance type, treatment initiation was lowest among adults aged 18–29 and 30–39 years with Medicaid or private insurance, compared with those aged 50–59 years. Among Medicaid recipients, lower odds of treatment initiation were found among persons in states with Medicaid treatment restrictions (aOR = 0.77; 95% CI = 0.74–0.81) than among those in states without restrictions, and among persons whose race was coded as Black or African American (Black) (aOR = 0.93; 95% CI = 0.88–0.99) or other race (aOR = 0.73; 95% CI = 0.62–0.88) than those whose race was coded as White.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3678712/>

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5610126/>

<https://stacks.cdc.gov/view/cdc/120092>

Increased risk of HCV in People with Lower Socioeconomic Status

[Danish Study.pdf](#)

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3678712/>

[NYC Study.pdf](#)

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5610126/>

U.S. Census Bureau QuickFacts: X +
 census.gov/quickfacts/table/US.GA.fultoncountygeorgia.clarkecountygeorgia/PE120220

QuickFacts
 United States; Georgia; Fulton County, Georgia; Clarke County, Georgia
 QuickFacts provides statistics for all states and counties, and for cities and towns with a population of 5,000 or more.

Enter state, county, city, town, or zip code Select a fact -- CLEAR TABLE MAP CHART DASHBOARD MORE

Table

| All Topics | United States | Georgia | Fulton County, Georgia | Clarke County, Georgia |
|--|---------------|------------|------------------------|------------------------|
| Persons in poverty, percent | 11.4% | 14.0% | 13.0% | 24.6% |
| PEOPLE | | | | |
| Population | | | | |
| Population Estimates, July 1, 2021, (V2021) | 331,893,745 | 10,799,556 | 1,065,334 | 128,711 |
| Population estimates base, April 1, 2020, (V2021) | 331,449,281 | 10,711,908 | 1,066,710 | 128,671 |
| Population, percent change - April 1, 2020 (estimates base) to July 1, 2021, (V2021) | 0.1% | 0.8% | -0.1% | Z |
| Population, Census, April 1, 2020 | 331,449,281 | 10,711,908 | 1,066,710 | 128,671 |
| Population, Census, April 1, 2010 | 308,745,538 | 9,687,653 | 920,581 | 116,714 |
| Age and Sex | | | | |
| Persons under 5 years, percent | 5.7% | 5.9% | 5.4% | 4.7% |
| Persons under 18 years, percent | 22.2% | 23.4% | 21.0% | 16.8% |
| Persons 65 years and over, percent | 16.8% | 14.7% | 12.4% | 12.1% |
| Female persons, percent | 50.5% | 51.2% | 51.5% | 52.5% |
| Race and Hispanic Origin | | | | |
| White alone, percent | 75.8% | 59.4% | 44.9% | 65.1% |
| Black or African American alone, percent (a) | 13.6% | 33.0% | 44.7% | 28.1% |
| American Indian and Alaska Native alone, percent (a) | 1.3% | 0.5% | 0.3% | 0.4% |
| Asian alone, percent (a) | 6.1% | 4.6% | 7.6% | 3.9% |
| Native Hawaiian and Other Pacific Islander alone, percent (a) | 0.3% | 0.1% | Z | 0.1% |
| Two or More Races, percent | 2.9% | 2.4% | 2.3% | 2.3% |
| Hispanic or Latino, percent (b) | 18.9% | 10.2% | 7.3% | 11.2% |
| White alone, not Hispanic or Latino, percent | 59.3% | 51.0% | 39.0% | 55.3% |

Barriers to Healthcare (Audience Participation)

DOCUMENT

Breaking Barriers

- Education - - Individual and Community
- Community Outreach Programs
- Solutions to Transportation Issues
- Telemed
- Free or Low-cost medications
- Persistence
- Compassion



Cases

Patient: John Crichton DOB: 12/11/1962

Medical History: Hypertension

Dyslipidemia

GERD

Bipolar disorder

Current Medications: Lisinopril 20mg

Rosuvastatin 40mg QD

Esomeprazole 40mg QD

Quetiapine 300mg QD

Carbamazepine 400mg BID

The above patient walks into your pharmacy asking if he should be screened for HCV.

Patient: John Crichton DOB: 12/11/1962

Medical History: Hypertension

Dyslipidemia

GERD

Bipolar disorder

Current Medications: Lisinopril 20mg

Rosuvastatin 40mg QD

Esomeprazole 40mg QD

Quetiapine 300mg QD

Carbamazepine 400mg BID

List risk factors for HCV:

IVDU, Intranasal drug use, Sharing razors / sharp hygiene devices,
Tattoos / piercings, Military service, incarceration, Blood transfusion
before 1990, Multiple sex partners

Patient: John Crichton DOB: 12/11/1962

Medical History: Hypertension

Dyslipidemia

GERD

Bipolar disorder

Current Medications: Lisinopril 20mg

Rosuvastatin 40mg QD

Esomeprazole 40mg QD

Quetiapine 300mg QD

Carbamazepine 400mg BID

What questions should you ask Mr. Crichton?

Illicit Drug use?

Tattoos?

Military service?

Prison /Jail?

Occupation (e.g. Healthcare worker)?

Received blood products?

Patient: John Crichton DOB: 12/11/1962

Medical History: Hypertension
Dyslipidemia
GERD
Bipolar disorder

Current Medications: Lisinopril 20mg
Rosuvastatin 40mg QD
Esomeprazole 40mg QD
Quetiapine 300mg QD
Carbamazepine 400mg BID

If Mr. Crichton reports no risk factors, should he be screened for HCV?
Why or why not?

Yes, absent any risk factor, Mr. Crichton's age qualifies him for screening. The CDC recommends Hepatitis C screening at least once in a lifetime for all adults aged 18 years and older, except in settings where the prevalence of HCV infection (HCV RNA-positivity) is less than 0.1%

Patient: John Crichton DOB: 12/11/1962

Medical History: Hypertension
Dyslipidemia
GERD
Bipolar disorder

Current Medications: Lisinopril 20mg
Rosuvastatin 40mg QD
Esomeprazole 40mg QD
Quetiapine 300mg QD
Carbamazepine 400mg BID

What does a positive HCV OraQuick screen indicate and how would you counsel Mr. Crichton?

A positive screen indicates exposure but not chronic infection. Approximately 15% of those infected with HCV will self-resolve. This should be carefully explained to Mr. Crichton and he should be referred to a GI, ID, or PCP for further evaluation.

Patient: John Crichton DOB: 12/11/1962

Medical History: Hypertension
Dyslipidemia
GERD
Bipolar disorder

Current Medications: Lisinopril 20mg
Rosuvastatin 40mg QD
Esomeprazole 40mg QD
Quetiapine 300mg QD
Carbamazepine 400mg BID

Mr. Crichton's physician, Dr. D'Argo, plans to start Mr. Crichton on ledipasvir 90mg/sofosbuvir 400mg once daily for 12 weeks to treat Mr. Crichton's chronic HCV infection.

Patient: John Crichton DOB: 12/11/1962

Medical History: Hypertension
Dyslipidemia
GERD
Bipolar disorder

Current Medications: Lisinopril 20mg
Rosuvastatin 40mg QD
Esomeprazole 40mg QD
Quetiapine 300mg QD
Carbamazepine 400mg BID

What drug interactions, if any, exist between this HCV medication and Mr. Crichton's current

**Ledipasvir/sofosbuvir and rosuvastatin - - markedly increased plasma levels of rosuvastatin
Ledipasvir/sofosbuvir and carbamazepine - - decreased absorption of ledipasvir (induction of P-gp)
Ledipasvir/sofosbuvir and esomeprazole - - decreased absorption of ledipasvir**

Patient: John Crichton DOB: 12/11/1962
Medical History: Hypertension
Dyslipidemia
GERD
Bipolar disorder

Current Medications: Lisinopril 20mg
Rosuvastatin 40mg QD
Esomeprazole 40mg QD
Quetiapine 300mg QD
Carbamazepine 400mg BID

What should you recommend to Dr. D'Argo about these drug interactions?

- D/C rosuvastatin - - there may be interactions with other statins as well. If statin therapy is required during the 12 weeks of HCV therapy, switch to simvastatin 20mg QD or other low dose statin
- D/C esomeprazole - - If acid suppression is required during the HCV therapy, switch to omeprazole 20mg QD taken simultaneously with ledipasvir/sofosbuvir or ranitidine 150mg 12 hours apart from ledipasvir/sofosbuvir. For breakthrough reflux, antacids may be used 4 hours apart from ledipasvir/sofosbuvir.
- D/C carbamazepine - - switch to and stabilize on levetiracetam before starting HCV therapy

Patient: John Crichton DOB: 12/11/1962
Medical History: Hypertension
Dyslipidemia
GERD
Bipolar disorder

Current Medications: Lisinopril 20mg
Rosuvastatin 40mg QD
Esomeprazole 40mg QD
Quetiapine 300mg QD
Carbamazepine 400mg BID

Mr. Crichton has no insurance, no assets, and is currently unemployed.
How can Mr. Crichton obtain the Harvoni?

Use the Patient Assistance Program available through the drug Manufacturer

**R.S. 57 year old WF. Former IVDU. Genotype 1 chronic HCV. Viral load: 700,000 IU/mL. Needle biopsy: S4. Child-Pugh C. Treatment experienced with Peg/riba x 24 weeks -
Plt: 47,000
HGB: 11.0
ANC: 750 cells/mm3**

Current Medications: Furosemide 40mg po BID, Spironalactone 200mg po QD, Rifamixin 550mg po BID

Regimen:

- Mavyret (Glecaprevir / pibrentasvir) QD for 8 weeks
- Mavyret (Glecaprevir / pibrentasvir) QD for 12 weeks
- Harvoni with ribavirin for 12 weeks ←
- Pegylated interferon 150mcg once weekly with 600mg ribavirin po BID

