STOP HCC-HCV

HEPATITIS CVIRUS (HCV) CARE CASCADE TO CURE

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DISCLOSURES

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OVERVIEW OF HCV EPIDEMIOLOGY AND CARE CASCADE

HEPATITIS CVIRUS (HCV)

- An enveloped virus First identified in 1989
- with single-stranded RNA genome
 - Flaviviridae family of viruses along with Zika and Dengue
 - Research into HCV replication led to development of novel anti-viral drugs
- Direct Acting Antivirals (DAA)
 - Target specific sites of the HCV RNA replication process
 - Protease inhibitors (anti-NS3/4A)
 - RNA-dependent polymerase inhibitors (anti-NS5B)
 - NS5A inhibitors (Anti-NS5A)



DEMAND FOR HCV CARE

- Approximately 3 million persons in U.S. with chronic HCV infection but half don't know it
- Most are low income, and an increasing proportion are uninsured who have not yet been screened
 - Major barriers to accessing specialty care
- Insufficient specialist supply to meet demand for care
- Important role for primary care

HCV EPIDEMIOLOGY

- 20 40% of persons infected with HCV spontaneously clear the infection
 - More likely if young when infected
- Chronic infection is typically asymptomatic
- 75% proceed to develop cirrhosis
 - Disease progression faster with HIV infection, alcohol use, and Hispanic ethnicity
- Among those with cirrhosis, I-4% develop hepatocellular carcinoma (HCC) annually

Kamal SM. Acute hepatitis C: a systematic review. Am J Gastroenterol. 2008 May;103(5):1283-97; quiz 1298. doi: 10.1111/j.1572-0241.2008.01825.x. PMID: 18477352.

DIAGNOSING CHRONIC INFECTION – RISK GROUPS

- Baby boomers (born 1945-65) 70% of all chronic infections
- All Adults aged 18 years and older
 - Screening endorsed by the USPSTF

Other risk groups

- Injection drug use
- Homelessness
- Unsafe injections
- MSM

- Prisoners
- Hemodialysis
- Tattoos in unsafe settings
- # sex partners
- Transfusion <1992</p>



LEARNING OBJECTIVES

List 7 steps in care cascade for uninsured patients with chronic HCV

Identify 5 laboratory tests to evaluate and stage chronic HCV

List 3 commonly prescribed DAAs and most common side effects

Select appropriate test and medications: case studies

CARE CASCADE FOR INSURED PATIENTS WITH CHRONIC HCV

Diagnosis of chronic HCV

Counseling about HCV

Referral to Specialist for evaluation and treatment

Shared care for comorbidities

HCV CARE CASCADE FOR UNINSURED

Diagnosis of chronic HCV	
Counseling about HCV	
Laboratory and imaging tests]
Structured case review with specialist during 'office hours''	
Management of comorbidities	
Applications – Medicaid (rejected) then Prescription Assistance Program	
DAA treatment and final HCV RNA 12 weeks after completed	

CASE

- 55 yo Hispanic male comes to establish care and reports nonspecific fatigue
- His BMI is 41. He drinks 2-3 beers on the weekend. He has no insurance
- You order HCV screening
 - HCV Ab with reflex to HCV RNA Quant
 - HCV antibody is positive and HCV RNA is 15.1 million
- He returns worried and upset about this unexpected finding.

What are your next steps?

COUNSELING PATIENTS WITH CHRONIC HCV

- Counseling to engage patients in care
- Focus groups with low-income patients diagnosed with chronic HCV reveal barriers that need to be addressed:
 - I. Social stigma, shame, fear and dealing with risky behaviors such as alcohol use
 - 2. Concerns about infecting others
 - 3. Poor understanding about HCV and how to evaluate and treat the disease
 - 4. Barriers to care and costly treatment while dealing with comorbidities

OFFER HOPE FOR CURE!

HCV CARE CASCADE -- REMEMBER

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LABORATORY TESTS FOR CHRONIC HCV INFECTION FOCUSING ON RESOURCE-LIMITED PRACTICES

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TESTS FOR CHRONIC HCV FOR MR HERNANDEZ

- HCV RNA Quantitative
- Genotype (+/-)
- Fibrosis staging with labs and imaging
- CMP liver function, renal function, albumin, glucose
- CBC –hemoglobin and platelets
- Liver imaging (ultrasound)

Other Tests

- Hepatitis A antibody
- Hepatitis B virus (HBV) surface Ag, HBV surface Ab, HBV core Ab
- HIV screen
- Hgb Alc

HCV GENOTYPE

Infection by HCV genotype



HCV Genotype (% of total)



□ la most common

 May not be needed if treatment naïve and planning to prescribe pangenotypic DAAs

N=512

Stages of liver fibrosis



Mild fibrosis F2

Severe Fibrosis: Cirrhosis F4

Photo courtesy of Tom Smyrk, MD

LIVER DISEASE STAGING

- Influences DAA duration, response, relapse
- Advanced liver fibrosis and cirrhosis = poorer response to therapy
- Liver cirrhosis primary risk factor for hepatocellular carcinoma (HCC) – so affects monitoring long-term
 - 5-year risk of developing HCC: 22% with cirrhosis vs. 3.2% without cirrhosis
- Fibrosis also associated with risk of HCC
 - 5-year risk of HCC: 13.4% with fibrosis vs. 1% without fibrosis

STAGING LIVER DISEASE

- Liver biopsy has been gold standard but noninvasive estimates of liver fibrosis increasingly reliable
- Laboratory test algorithms useful in distinguishing no fibrosis from fibrosis
 - Fibrosis4 (FIB-4), APRI
- Imaging helpful with liver ultrasound
- Alternatives for imaging less available
 - FibroSure (# 550123 thru Labcorp)
 - Fibroscan in special centers
 - MRI elastography but not widely available, costly

CALCULATING FIB-4

Fibrosis-4 (FIB-4) Calculator

The Fibrosis-4 score helps to estimate the amount of scarring in the liver. Enter the required values to calculate the FIB-4 value. It will appear in the oval on the far right (highlighted in yellow).



Interpretation:

Using a lower cutoff value of 1.45, a FIB-4 score <1.45 had a negative predictive value of 90% for advanced fibrosis (Ishak fibrosis score 4–6 which includes early bridging fibrosis to cirrhosis). In contrast, a FIB-4 >3.25 would have a 97% specificity and a positive predictive value of 65% for advanced fibrosis. In the patient cohort in which this formula was first validated, at least 70% patients had values <1.45 or >3.25. Authors argued that these individuals could potentially have avoided liver biopsy with an overall accuracy of 86%.

Source: Sterling RK, Lissen E, Clumeck N, et. al. Development of a simple noninvasive index to predict significant fibrosis patients with HIV/HCV co-infection. Hepatology 2006;43:1317-1325.

http://www.hepatitisc.uw.edu/page/clinical-calculators/fib-4

FIB-4 PREDICTING SEVERE FIBROSIS OR CIRRHOSIS IN HIV

Figure 3. ROC analysis of the ability of FIB-4 to predict severe fibrosis or cirrhosis (95% CI represented by dash-dot lines).



Karic J Infect Dev Ctries 2018; 12(3):178-182

TEST COMPARISON

Serologic Test	Stage	Sensitivity	Specificity	Limitations
FIB-4	F3-F4	74.3%-87%	65-80.1%	
APRI	F3-F4	61%-76%	38%-64%	Obesity, Inflammation

Non-serologic Test	Validity	Limitations	
Fibroscan®	validated	Inflammation, passive congestion	
Ultrasound (US)	Commonly used, Reliable	Operator qualifications, Obesity	
Combination test (serum markers plus imaging)	Common clinical practice		
These techniques do not accurately differentiate moderate stages of fibrosis Hagen et al., (2015) p. 1252			

Grgurevic et al., Post Grad Med J (2019) Hagen et al., (2015); Trivedi et al., 2018 Digestive and Liver Disease

MR. HERNANDEZ'S LABS

D	emographics	Test Results	Date	
Patient Identifier	CPRIT# NB15	HCV Antibody >11.0	5/30/2018	
Clinic	Atascosa CHC	HCV Quantitative 15,600,00	0 5/30/2018	
Age 45		Genotype 1a	5/30/2018	
Gender	M	ALT 5	7 5/30/2018	
PCP F. Rajlakshmi		AST 3	6 5/30/2018	
Insurance	Insurance Self-Pay		.1 5/30/2018	
Race/Ethnicity	Hispanic	Albumin 4.	.5 5/30/2018	
Last Updated	8/3/2018	Total Bilirubin 0.	.2 5/30/2018	
Chronic Diseases	Current Medications	Alakaline phosphatase 10	2 5/30/2018	
Anxiety	Viagra 25mg Tablet	Glucose 9	0 5/30/2018	
Essential Htn	Vistril 25mg	Creatinine 0.9	1 5/30/2018	
Sexual Dysfunction	Paroxetine 20mg tablet	eGFR 10	1 5/30/2018	
HCV	Metoprolol Tartrate 50mg Tablet	Platelet count 29	2 5/30/2018	
Back Pain w/o sciatica	Atorvastatin 10mg Tablet	Hemoglobin from CBC 14.	.3 5/30/2018	
	Amlodipine 5mg Tablet	INR	1 5/30/2018	
		MELD Score	6 8/3/2018	
		Fib-4 Score 0.7	3 8/3/2018	
		Hemoglobin A1c 5.	.5 2/20/2018	
		Hepatitis A antibody Positive	5/30/2018	
		Hepatitis B surface antibody Non-Reactive	5/30/2018	
		Hepatitis B antigen Negative	5/30/2018	
		Hepatitis B Core antibody Negative	5/30/2018	
Si	ubstance Use	HIV screen Non-Reactiv	e 5/30/2018	
Tobacco (ppd x years)	Never Smoker	Treatment Naïve? Yes X	No	
Alcohol	No Alcohol			
Average drinks per day				
		Signs of cirrhosis? Yes No_X U	ncertain	
Average days per week		Ultransured Describe 5/24/40. The lives in sec		
Max drinks per day (binging)		measuring 15 2cm It is noemal in echogenicity	and smooth in	
Illicit drug use - (which) Social History		 countour without focal mass. Evaluation is limited due to overlying soft tissue and bowel gas. No definite findings of 		
BMI	7/11/18- 41.97			
Last Blood pressure	7/11/2018-119/80			

FINDINGS FROM MR HERNANDEZ'S EVALUATION

- Low risk for advanced fibrosis with low FIB-4, and no abnormalities seen on U/S
- High viral load >6 million
- BMI of 41 still at risk for NAFLD and NASH in terms of long term management
- Alcohol use should be counseled to reduce on weekends because even small amounts can continue liver damage after treatment
- IMMUNIZE AGAINST HBV

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TREATING AND CURING HCV INFECTION

FOCUSING ON UNINSURED PATIENTS

LEARNING OBJECTIVES

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DIRECTLY ACTING ANTIVIRALS

NS5A polymerase inhibitors (-asvir)

- High potency, pan-genotypic, but inhibition by genotype may vary by molecule
- Intermediate barrier to resistance (Barrier is how many mutations it takes to develop resistance; low barrier is 1 mutation and high barrier is multiple mutations)

NS5B polymerase inhibitors (-buvirs)

- Intermediate potency, some are pan-genotypic, others not
- High barrier to resistance but with exceptions
- NS3/4A Protease Inhibitors (-previrs)
 - High potency, limited genotypic coverage
 - Low barrier to resistance



SVR= no HCV RNA at 12 weeks post completion of treatment

EVOLUTION OF HCV TREATMENT SUSTAINED VIRUS RESPONSE (SVR) = HCV CURE



Commonly Used DAA Therapies

Combination Therapies	Abbreviation	Trade name	Genotype
Ledipasvir/Sofosbuvir	LED/SOF	Harvoni®	1,4,5,6
Sofosbuvir/Velpatasvir	SOF/VEL	Epclusa ®	I-6
Glecaprevir/Pibrentasvir	GLE/PIB	Mavyret®	I-6

LEDIPASVIR/SOFOSBUVIR LED/SOF

HARVONI®

LEDIPASVIR/SOFOSBUVIR LED/SOF (HARVONI®)

- Sofosbuvir = nucleoside NS5B inhibitor and pangenotypic
- Ledipasvir = NS5A inhibitor with activity for genotypes I, 4, 5, and 6
- Combination for genotypes 1, 4, 5, and 6
- One pill, once a day
- Cannot use with Cr Cl <30 ml/min</p>



LEDIPASVIR/SOFOSBUVIR: DURATION OF THERAPY

Treatment naïve or non-cirrhotic treatment experienced:

- I2 weeks
 - Exception: 8 weeks for genotype I with HCV RNA <6 million and early stage disease</p>
 - Risk of relapse if patient has advanced fibrosis
 - Do not use in patients with HIV
- Treatment-experienced cirrhotic:
 - I2 weeks with weight-based ribavirin


■ Sof/LDV 12 wk ■ Sof/LDV 8 wk ■ Sof/LDV+ RBV 12 wk ■ Sof/LDV 24 wk

LEDIPASVIR/SOFOSBUVIR LED/SOF: PRUGSINTERACTIONSIS

(Prilosec or Nexium) reduce efficacy

- Alt: H2 blockers I2 hours from LED/SOF
- Hold Statins (atorvastatin and rosuvastatin): increase statin level
- Anticonvulsants: decrease efficacy
- Antimycobacterial therapy (including rifamycins): decrease efficacy

- St. John's Wort: decrease efficacy
- Amiodarone bradycardia (Black box warning)
- HIV medications (Refer to Specialist)
 - Truvada and boosted PI combination
 - Increases tenofovir levels
 - Tipranavir

LEDIPASVIR/SOFOSBUVIR. SIDE EFFECTS

- ➢ Fatigue (13-18%)
- Headaches (11-17%)
- > Nausea (6-9%)
- Diarrhea (3-7%)
- Insomnia (3-6%)

- > Other side effects not in package insert
- Increased appetite
- > Occasional increase in creatinine

SOFOSBUVIR/VELPATASVIR SOF/VEL EPCLUSA®



SOFOSRI IVIR/VELPATASVIR SOF/VEL·(FPCI LISAR)

- Sofosbuvir is nucleoside NS5B inhibitor
- Velpatasvir is NS5A inhibitor
- Pangenotypic 1, 2, 3, 4, 5, 6
- One pill once a day



SOFOSBUVIR/VELPATASVIR SOF/VEL: DURATION OF THERAPY

 Without cirrhosis or with compensated cirrhosis (Child-Pugh A): 12 weeks (regardless of genotype)

- Decompensated cirrhosis (Child-Pugh B and C) + ribavirin (weight-based) for 12 weeks (Refer to Specialist)
- Cannot use with Cr Cl <30 ml/min</p>



Genotype Ia Genotype Ib Genotype 2 Genotype 3 Genotype 4 Genotype 5 Genotype 6

Epclusa 12 wk sof + RBV 12 wk Sof + RBV 24 wk

SOFOSBUVIR/VELPATASVIR SOF/VEL: DRUG INTERACTIONS (SEE LIVERPOOL HEP INTERACTIONS)

- No PPI
- Antacids: >4 hours from SOF/VEL dose
- H2 blockers: take 12 hours from SOF/VEL dose
- Amiodarone symptomatic bradycardia
- Rifampin, St. John's wort, carbamazepine: may decrease concentration of SOF/VEL

- Check interactions with medications including herbals
- Other common interactions
 - Hold Statins (Lipitor, Crestor)
 - Anti-convulsants
 - Antimycobacterials
 - HIV anti-retroviral drugs (Refer Specialist)
 - Monitor Digoxin dose



SOFOSBUVIR/VELPATASVIR SOF/VEL: SIDE EFFECTS

- Headache (22%)
- Nausea (9%)
- Fatigue and low energy (9%)
- Insomnia (5%)
- Irritability (≥5%)

MAVYRET®

GLECAPREVIR/PIBRENSTAVIR GLE/PIB (MAVYRET®)

- Glecaprevir is a NS3/4a inhibitor
- Pibrentasvir is a NS5A inhibitor
- Pan-genotypic: 1, 2, 3, 4, 5, 6
- Take 3 tablets once a day, with food
- Do not use with Rifampin (contraindicated)
- No contraindication for creatinine clearance <30</p>

GLECAPREVIR/PIBRENSTAVIR GLE/PIB: DURATION OF THERAPY

- Treatment naïve or experienced with <u>no</u> cirrhosis: 8 weeks
- Treatment naïve or experienced with cirrhosis, compensated (Child Pugh A): 12 weeks





GLECAPREVIR/PIBRENSTAVIR GLE/PIB: DRUG INTERACTIONS AND CONTRAINDICATIONS

Statins

- atorvastatin, lovastatin, simvastatin
- Ethinyl estradiol (OCPs)
 - increased risk of ALT elevation
- Anti-convulsants
- Rifamycins

- St. John's Wort
- Cyclosporine
- HIV Medications (refer to specialist)

GLECAPREVIR/PIBRENSTAVIR GLE/PIB: SIDE EFFECTS

- Headache (up to 17%)
- Fatigue (up to 16%)*
- Nausea (up to 12%)
- Diarrhea (up to 10%)
- Pruritis (up to 17%)*

* More common with severe renal dysfunction

EVALUATION AND MANAGEMENT OF CHRONIC HCV – ROLE FOR PRIMARY CARE

- Primary care providers increasingly treating HCV infection
- Newer direct acting antiviral (DAA) drugs for HCV are well tolerated and safe for most patients
- Cure rates (defined as sustained viral response at 12 weeks post treatment) for patients treated in primary care are similar to specialists' rates
 - San Francisco General Hospital Network 91% of 762 patients cured, most treated in primary care
 - South Texas practices 95.5% of 67 patients cured

Kim NJ et al. JGIM 2018 in press

UNINSURED PATIENTS NOT ELIGIBLE FOR PRIMARY CARE MANAGEMENT

- Cirrhosis with decompensation
- Hepatocellular carcinoma
- Refer to specialist if insured

THREATS TO A CURE TO ADDRESS

>Alcohol or substance abuse

- Poor adherence to medications for other diseases (e.g. diabetes)
- Poor social support or unstable housing
- > Upcoming incarceration
- >Unstable mental health
 - But depression not a contraindication
- Cirrhosis
- Treatment with a proton pump inhibitor
 - Terrault et al .Gastroenterology. 2016;151(6):1131-1140 Parlati L, Pol S. Gastroenterol Hepatol. 2018;12(12):1245-1250.

NS5A mutations

ADHERENCE SUPPORT

- Critical not to miss any doses
- Plan ahead engage the family
- Stable environment as much as possible
- Pill box
- Reminders phone, stickers
- Structure day to take at the same time
- Try not to change schedule or travel during treatment

MONITORING DURING DAA THERAPY

- No cirrhosis No need to monitor labs during therapy if no symptoms
- HCV RNA at end of treatment and 12 weeks after
- Cirrhosis check liver function tests at 4 weeks
- Check CBC if on ribavirin

HCV TREATMENT AND PREGNANCY

> HCV infection increasing in women of childbearing age

From 15,500 in 2006 to 31,000 in 2014

> DAA's are currently contraindicated in pregnancy

- Serum pregnancy test recommended
- > Treat before pregnancy (with contraception)
- > Counsel to delay pregnancy for at least 6 months post-treatment
- > Test both infant and mother after delivery and treat if needed

Kushner T, Terrault NA. Hepatol Commun. 2018 Nov 30;3(1):20-28. doi: 10.1002/hep4.1282. Boucher & Gruslin, 2017

• Worldwide HBV-HCV coinfection is estimated to be 1-15%

- Risk of HBV reactivation with DAA's
- Treat if HBV Surf Ag positive
- Monitor LFTs monthly if HBV Core Ab + (even if Surf Ag neg) and if increasing check HBV DNA
- Entecavir (Baraclude), tenofovir (Viread), lamivudine (Epivir), adefovir (Hepsera) or telbivudine (Tyzeka)
- Start with or before HCV drugs

Blackard & Sherman (2018), Rev Med Virol; Mavilia & Wu, 2018; Journal of Clinical and Translational Hepatology

coinfection

HBV

HCV

Treatment naïve TREATMENT PLAN FOR MR HERNANDEZ

- But viral load >6 Million
- Genotype Ia Good candidate for LED/SOF
 - I2 weeks because of high viral load (>6 million)
 - Hold the statin
- Counseling about diet and alcohol use this is a teachable moment
- Adherence support for 100% compliance with DAAs

LEARNING OBJECTIVES

List 7 steps in care cascade for uninsured patients with chronic HCV

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Select appropriate test and medications: case studies 60 yo man with HTN on amlodipine, hyperlipidemia on statin, and CGSRD on PPI

Hepatitis C RNA- 1.5 million

- What test is not indicated?
 - A. CMP
 - B. CBC with platelets

C. Ferritin D. Hepatitis A and B studies, HIV screen

E. Ultrasound



- HCV genotype is Ia
- HCV RNA 1.5 million, HAV and HBV tests negative
- What is the next step for this <u>uninsured</u> patient?
 - A. Obtain liver biopsy
 - B. Stage liver disease by using fibrotest
 - C. Stage liver disease by using FIB-4 score and ultrasound

D. No further tests needed

CASE I



Fib-4 over 3.25 so higher likelihood of advanced fibrosis

Genotype Ia CASE US shows fatty infiltration and slight nodularity

- Fib-4 3.49 (likely fibrosis/cirrhosis)
- eGFR = 70 so stage 2 CKD
- What is the best treatment option?
 - A. Order ledipasvir/sofosbuvir 8 weeks
 - B. Order ledipasvir/sofosbuvir 12 weeks
 - C. Order ombitasvir, paritaprevir, and dasaburvir 12 weeks
 - D. Order glecaprevir/pibrentasvir 8 weeks

CASE TO ADDRESS from DAA dose Hold the statin

- Adherence supports
- Immunize against HAV and HBV
- Counsel about stopping alcohol to prevent liver damage
- At risk of NAFLD that can cause ongoing liver damage
 - DASH diet or other dietary intervention
- Advanced liver disease ultrasound every 6 mos to monitor for HCC

HCV TREATMENT RESOURCE



HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C



wwv

Home



Test, Evaluate, Monitor

Treatment-Naive

Treatment-Experienced

Unique & Key Populations

About

Start Here:

Start Here: Choose a patient profile from the menu above. Υ

Welcome to HCVGuidelines.org

Contents and Introduction - Select a Page

The AASLD and IDSA in partnership with the panel have created an updated web experience to facilitate easier and faster access to this important resource. Please select a patient profile from the menu above, click on a guidance section below, or use the search box to begin.

New and updated:

'HCV in Pregnancy' Updated With the current increases in HCV among young adults, including women of childbearing age, there is now discussion about universal screening of pregnant women.

Search the Guidance

Enter your keyword: Search

. . . .

+ Testing, Evaluation, and Monitoring of Hepatitis C - Browse Topics

Initial Treatment of HCV Infection - Choose Patient Genotype

Retreatment of Persons in Whom Prior Therapy Has Failed - Choose Patient Genotype

HEPATITIS C WEBSITE

<u> ΗΤΤΡΟ·//\ΛΛΛΛΛ/ΟΤΟΡΙΕΡΑΤΙΤΙΟΟ ΟΟΜ/</u>

HC\

HCC

HOME

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Home

Hepatitis C virus (HCV) causes liver cancer and liver failure. Millions of people in the US have HCV infection, but many don't know they have it. Why does this matter? There is a cure!

Contact us »



Helping Texans Prevent Liver Cancer

Sole MithRMCV Ab and if + HCV RNA

- Counsel patients with chronic HCV to engage in care
- Laboratory and imaging tests to stage disease and comorbidities
- Immunize if needed against HAV and HBV
- Know indications, drug interactions, side effects of commonly used medications in HCV treatment
 - Havoni (LED/SOF), Epclusa (SOF/VEL), Mavyret (GLE/PIB).
- Follow-up to address substance use and comorbidities that increase liver damage
- U/S for cirrhotics every 6 mos for HCC



For more info on HCV, visit: <u>StopHepatitisC.com</u>





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STOP HCC BY TREATING HCV



