

# Evaluating the Patient for Treatment/Readiness

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# Disclosure

I am a principal investigator for an ANTHC sponsored HCV treatment study funded in part by Gilead Sciences

# Who to Treat

Treatment is recommended for all patients who have chronic HCV infection except:

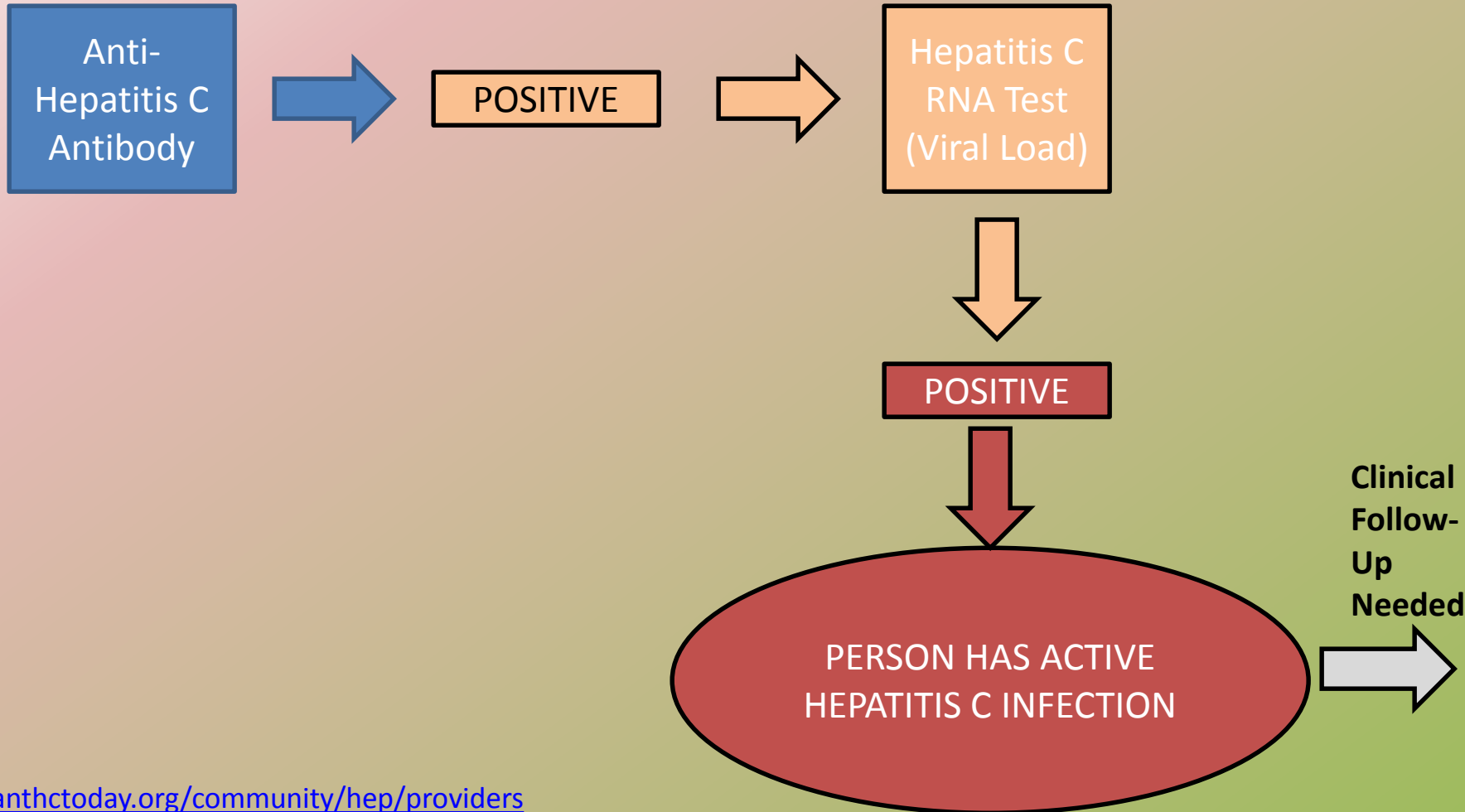
- Those with a short life expectancy that cannot be remediated by HCV treatment, liver transplantation, or another directed therapy

# Evaluation Essentials

- \_\_\_ Confirmation of HCV
- \_\_\_ Chronic vs. acute disease
- \_\_\_ Past treatment status
- \_\_\_ Fibrosis stage
- \_\_\_ Identify/address significant comorbidities
- \_\_\_ Immunizations as appropriate (Hep A&B)
- \_\_\_ Check drug interactions
- \_\_\_ Know pregnancy/plans/birth control
- \_\_\_ Determine patient readiness – any PTDs?
- \_\_\_ Insurance status/prior authorization



# Hepatitis C Virus Confirmation



# Acute vs Chronic HCV

- Acute HCV: defined as presenting within 6 months of exposure
- Approximately 20%-50% will clear HCV spontaneously- 2/3 within the first 6 months of infection
- Monitor HCV RNA and LFTs for at least 6 months to determine spontaneous clearance
  - If you decide to treat acute HCV, monitor HCV RNA for at least 12-16 weeks before beginning treatment
  - Same regimens given as chronic infection

# Pregnancy and HCV

- Guidelines recommend treating HCV prior to pregnancy
- Mother to child transmission is low- 5-15% with progression to chronic infection 3-5%
- Children born to mothers with HCV need antibody-based screening at or after 18 months
- Avoid use during pregnancy, no human data available

# What do you need to know?

- History
  - Risk factors for HCV acquisition (past and present)
  - Medical co-morbidities including coinfection with HBV or HIV
  - Alcohol and illicit drug use (past and present)
  - Psychiatric history





# What do you need to know?



- History continued
  - Social (stable housing, transportation, support of family/friends)
  - Allergies
  - Medications, herbs, supplements, OTC (potential drug/drug interactions)



# How healthy is the liver?

- Has the patient ever been treated for HCV?
  - Treatment naïve vs treatment experienced
- Any prior fibrosis testing?
  - History of a liver biopsy, Fibroscan or previous work-up? Important to document prior stage



# How healthy is the liver?

- Is there evidence in their medical history of complications from liver disease?
  - Decompensated cirrhosis: presence of ascites, jaundice, coagulopathy, presence of esophageal varices, splenomegaly/ portal hypertension, or hepatic encephalopathy
  - Prior hospitalizations for gastrointestinal bleed, ascites, history of paracentesis, AMS due to hepatic encephalopathy?
  - Refer these patients to Hepatology or GI

# How healthy is the patient?

- Are there other significant comorbidities?
  - Uncontrolled DM, active TB, chronic kidney disease, coinfection with HIV or hepatitis B, undiagnosed cancer, substance use disorder
- Are there any extra-hepatic manifestations of liver disease?
  - fatigue (most common), depression, arthralgias, neuropathy, nephropathy, glomerulonephritis, lichen planus, non-Hodgkin's lymphoma, porphyria cutanea tarda, and mixed cryoglobulinemia

# Physical exam

- A complete PE at baseline is important
- Height, weight and BMI should be documented
- Look for liver related physical findings that would indicate advanced liver disease
  - Icterus, jaundice, spider nevi (angioma), ascites
  - Other possible signs: Terry's nails, Caput medusa, gynecomastia, palmar erythema

# Spider angioma





# Icterus & Jaundice



# Ascites and Caput Medusa





# Testing for Asterixis

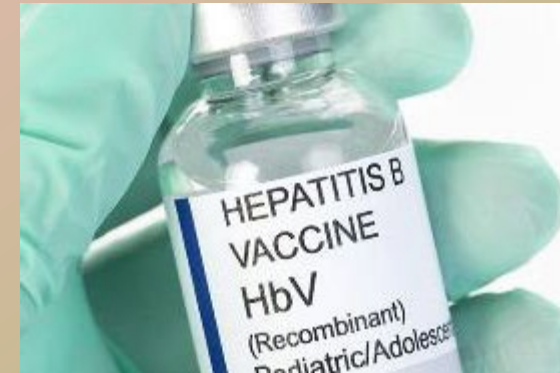


# General laboratory evaluation

- CBC, CMP, PT/INR
- HCV RNA quantitative level (viral load)
- HCV genotype
- HIV screen
- HAV total IgG, hepatitis B surface antigen (HBsAg), surface antibody (Anti-HBs), core antibody (Anti-HBc)
  - Checking for HAV/HBV immunity and determining HBV status
- Pregnancy status

# Immunizations

- All persons with HCV should be fully vaccinated for HAV and HBV
- Pneumococcal vaccination recommended for patients with cirrhosis or alcoholism
  - For more information, see handout
- Routine adult vaccines: influenza, TDaP, Shingrix after 50y



# Hepatitis A

- Order Hepatitis A antibody total/IgG to check for immunity (not IgM)
- If non-reactive, give hepatitis A vaccine series



# Potential Reactivation of Hepatitis B

RECOMMENDED	RATING
All patients initiating HCV direct-acting antiviral therapy should be assessed for HBV coinfection with HBsAg testing and for evidence of prior infection with anti-HBs and anti-HBc testing.	Ila,B

Consult Liver Disease or Infectious Disease Specialist if HBsAg+ or anti-HBc+

# Hepatitis B

- HBsAg+ Infection
- Anti-HBc+ Exposure. No need to vaccinate.
- Anti-HBs + Immunity

Check patient's vaccine history before initiating vaccine.

# Evaluating fibrosis

- Why is it important?
  - Determines appropriate treatment & duration of treatment
  - To identify those with advanced disease who will need hepatocellular carcinoma (HCC) screening and additional long term follow up after cure





# Metavir Scoring System for Liver Biopsy

## STAGES (fibrosis)

- F0- no fibrosis
- F1- mild fibrosis (portal fibrosis without septa)
- F2- moderate fibrosis (portal fibrosis with few septa)
- F3- advanced fibrosis (numerous septa without cirrhosis)
- F4- cirrhosis

## GRADES (inflammation)

- A0- no activity
- A1- mild activity
- A2- moderate activity
- A3- severe activity



# How do you evaluate fibrosis?

Follow a stepwise approach:

- Start with non-invasive markers
  - Indirect and direct markers of fibrosis
- Radiologic imaging
- Liver biopsy

# [www.anthc.org/hep](http://www.anthc.org/hep)

## Hepatitis C Treatment

We want to keep you informed of recent drugs, screenings, treatments, and other news pertaining to Hepatitis and other liver diseases. As news becomes available we will post content here. Check back often to stay informed!

### Treatment Tools

[Before Treatment](#)[Monitoring During and After Treatment](#)[Treatment Reference Tools](#)

### Staging Fibrosis

[Start Here – Staging Fibrosis Algorithm](#)[APRI and FIB-4 Interpretation](#)

### Treatment Naïve Decision Trees (click on Yes or No to begin)

Genotype 1

Cirrhosis?

[Yes](#)[No](#)

Genotype 2 or 3

Cirrhosis?

[Yes](#)[No](#)

Genotype 4

Cirrhosis?

[Yes](#)[No](#)

Genotype 5 or 6

Cirrhosis?

[Yes](#)[No](#)

### Treatment Experienced Patients

[Consult Liver Disease Specialist](#)

# Indirect markers of fibrosis

- APRI
  - Uses AST and platelets
- FIB-4
  - Age, AST and ALT, platelet count
- Both are good at excluding or confirming minimal or significant fibrosis but less valuable for those somewhere in between

[www.hepatitis.uw.edu](http://www.hepatitis.uw.edu) or [www.mdcalc.com](http://www.mdcalc.com)

# APRI

AST to Platelet Ratio Index:

$$\text{AST} \div \text{ULN of AST (40)} \div \text{Platelets (k/mL)} \times 100$$

- The lower the APRI score  $< 0.5$  the greater the negative predictive value to rule out cirrhosis.
- The higher the APRI  $> 1.5$  the greater the positive predictive value to rule in cirrhosis. APRI  $> 2.0$  is 91% specific for cirrhosis.
- APRI alone is not sufficiently sensitive to rule out significant disease.
- The use of multiple indices in combination may result in higher diagnostic accuracy than APRI alone.

# FIB-4

## Fibrosis-4 score

- $\text{Age (years)} \times \text{AST} \div \text{Platelets (k/mL)} \times \sqrt{\text{ALT}}$
- Score < 1.45 has a negative predictive value of 90% for advanced fibrosis
- Score > 3.25 has a 97% specificity and 65% positive predictive value for advanced fibrosis

<https://anthc.org/wp-content/uploads/2018/10/Staging-Fibrosis-Algorithm.pdf>

# Fibrosis Case Study

- 56 y.o. female screened as Baby Boomer and found to be HCV Ab+, confirmed viral load 2,352,000 IU/mL
- Blood transfusion in 1983
- Does not use drugs or drink alcohol
- Baseline labs: Hgb 14, Hct 42.2, plt 354k, ALT 76, AST 60, alk phos 96, albumin 4.0, total bilirubin 0.3

APRI = 0.4    FIB-4 = 1.09

# Interpretation of APRI and FIB-4

APRI Result	Fibrosis Interpretation
< 0.5	No – Moderate Fibrosis
$\geq 1.5$	Advanced fibrosis (bridging fibrosis to cirrhosis)
> 2	Cirrhosis
> 0.5 < 1.5	Indeterminate

FIB-4 Result	Fibrosis Interpretation
< 1.45	No-Moderate Fibrosis
> 3.25	Advanced Fibrosis
1.45 – 3.25	Indeterminate

# Serum Fibrosis Tests

- FibroTest/Quest
- Fibrosure LabCorps
- FibroSpect II/Prometheus
  - Use a proprietary algorithm that includes age, gender, and biochemical markers associated with hepatic fibrosis
    - Will give estimate of fibrosis stage
  - Contraindications to these tests: Gilbert disease, acute hemolysis, extrahepatic cholestasis, post-transplant, and renal insufficiency
  - 8-hour fast recommended





# FibroSure Results

## FibroSure Components

- Alanine aminotransferase (ALT)
- $\alpha$ 2-macroglobulin
- Apolipoprotein A1
- Bilirubin, total
- $\gamma$ -glutamyl transferase (GGT)
- Haptoglobin
- Patient's age and sex

For more information, please contact your local account representative.

Test Name	Hepatitis C Virus (HCV) FibroSure®
Test Number	550123

## METAVIR Group Scoring System

Fibrosis Stage (FibroTest)	Range
F0 – No fibrosis	0.00-0.21
F0-F1	> 0.21-0.27
F1 – Portal fibrosis	> 0.27-0.31
F1-F2	> 0.31-0.48
F2 – Bridging fibrosis with few septa	> 0.48-0.58
F3 – Bridging fibrosis with many septa	> 0.58-0.72
F3-F4	> 0.72-0.74
F4 – Cirrhosis	> 0.74-1.00
Activity Stage (ActiTest)	Range
A0 – No activity	0.00-0.17
A0-A1	> 0.17-0.29
A1 – Minimal activity	> 0.29-0.36
A1-A2	> 0.36-0.52
A2 – Moderate activity	> 0.52-0.60
A2-A3	> 0.60-0.63
A3 – Severe activity	> 0.63-1.00

For the most current information regarding test options, including specimen requirements and CPT codes, please consult the online Test Menu at [www.LabCorp.com](http://www.LabCorp.com).

## References

1. Poynard T, Imbert-Bisquit F, Munteanu M, et al. Overview of the diagnostic value of biochemical markers of liver fibrosis (FibroTest, HCV FibroSure) and necrosis (ActiTest) in patients with chronic hepatitis C. *Comp Hepatol*. 2004 Sept 23;3(8).
2. Poynard T, Morra R, Hallon P, et al. Meta-analysis of FibroTest diagnostic value in chronic liver disease. *JIMC Gastroenterology*. 2007 Oct 15;7(40).
3. Crockett SD, Kalishbach T, Keeffe EB. Do we still need a liver biopsy? Are the serum fibrosis tests ready for prime time? *Clin Liver Dis*. 2006;10(513-534).
4. Spadascini G, Vito A, Faldut M, et al. Stepwise combination algorithm of non-invasive markers to

# FibroTest Result



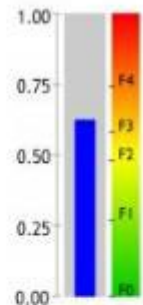
Report Status: Final  
TEST, PATIENT

Patient Information	Specimen Information	Client Information
<b>TEST, PATIENT</b>  <b>DOB: 01/01/1965    AGE: 50</b> Gender: F    Fasting: Y Phone: NG Patient ID: BH047903A	Specimen: BH047903A Requisition: 0422196 Lab Ref #: 0422196  Collected: 04/07/2015 / 11:28 EDT Received: 04/07/2015 / 11:29 EDT Reported: 04/07/2015 / 14:13 EDT	Client #: 97502840    AARRSSS COLMENAR, ANTONIO TEST CLIENT (HQ) AH1 1 MALCOLM AVE TETERBORO, NJ 07608-1011

COMMENTS: TEST PATIENT

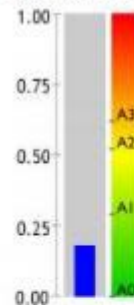
## Liver Fibrosis, FibroTest™ ActiTest™ Panel

**Fibro Test**  
Fibro Test assesses the fibrosis of the liver



Score : 0.62  
( F3 )  
advanced fibrosis

**Acti Test**  
Acti Test assesses activity (inflammation) in chronic viral hepatitis C or B



Score : 0.18  
( A0-A1 )  
no activity


### Biomarkers

Analyte	Result	Reference Range/Comments	Analyte	Result	Reference Range/Comments
Alpha2 Macroglobulin	301 H	106-279 mg/dL	Total Bilirubin	0.4	0.2-1.2 mg/dL
Haptoglobin	47	43-212 mg/dL	Gamma GT	63	3-70 U/L
Apolipoprotein A1	104	101-198 mg/dL	ALT	26	6-29 U/L

Lab: EZ

### Liver Fibrosis History

# FIBROSpect II Results



**PROMETHEUS<sup>®</sup>**  
Therapeutics & Diagnostics  
9410 Carroll Park Drive  
San Diego CA 92121  
Toll Free: 888/423-5227  
www.prometheuslabs.com

**Test Results**

**PROMETHEUS<sup>®</sup> FIBROSpect<sup>®</sup> II**

**SAMPLE REPORT**

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Patient & Order Information				Report Recipient	
Order ID	2081520			Undefined Physician MD Prometheus Laboratories Inc. 9410 Carroll Park Drive San Diego, CA 92121  858/824-0895 Phone    858/824-0896 Fax	
Patient	Test, Patient				
DOB	01/01/1950				
SSN	XXX-XX-6789	Sex	X		
Institution ID	XXXXXX	Prometheus ID	1406851		
Ordered	01/03/2011	Completed	01/04/2011		
Ordered By	Undefined Physician MD				
ICD9 Codes	276.8	787.03			
Sample ID: SM01030060		Collection Date: 12/29/2010 5:00AM (Serum)		Institution Sample ID: RE2R	

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**Test Result**

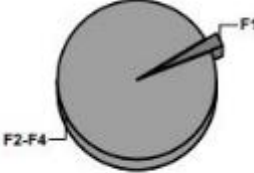
1. FIBROSpect II Index	2. Clinical Interpretation	3. FIBROSpect II Index Reference Range
99	Consistent with METAVIR <b>F2-F4</b>	0 - 41 Consistent with METAVIR F0-F1 42 - 100 Consistent with METAVIR F2-F4

**1. FIBROSpect II Index Interpretation**  
 In a study population of chronic HCV patients (n=696), 0.3% of patients with biopsy F0-F1 had a FIBROSpect II index of  $\geq 99$ . Of these, 0.0% were F0 and 100.0% were F1.

**2. Clinical Interpretation**  
 Based on this study population and these results, the chance of your patient having F2-F4 is 97.2%.\*  
 The chance of having F0 is 0.0% and the chance of having F1 is 2.8%.

\*These values will vary with prevalence of F2-F4 fibrosis

**2. FIBROSpect II Index  $\geq 99$  (N = 36)**



F0	0.0%
F1	2.8%
F2-F4	97.2%
Total	100.0%

**3. METAVIR Description (1,2):**

F0 - No fibrosis  
 F1 - Portal tract fibrosis  
 F2 - Septal fibrosis  
 F3 - Bridging fibrosis  
 F4 - Cirrhosis

**3. Reference Range Studies**  
 In a study population of chronic HCV patients (n=696) with a fibrosis (METAVIR F2-F4) prevalence of 51.7%, FIBROSpect II sensitivity at an index of 42 was 81% and the specificity was 71%. Tests performed to determine FIBROSpect II result:  $\alpha 2$ -macroglobulin (AMG) by nephelometry, Tissue inhibitor of metalloproteinases-1 (TIMP-1) by ELISA, Hyaluronic acid (HA) by ELISA. This test was developed and its performance characteristics determined by Prometheus Laboratories Inc. It has not been cleared or approved by the U.S. Food and Drug Administration.

# Staging Fibrosis in Untreated HCV

**Do not use this to stage fibrosis in those who have been treated and achieved SVR**

Calculate [APRI](#), [FIB-4](#)\*, and FibroScan if available.  
If FibroScan not available obtain:  
FibroSpect II (Prometheus), FibroSure (LabCorp)  
FibroTest (Quest)  
or available fibrosis test

Do Not Use APRI or FIB-4 if your patient is currently drinking EtOH (men > 3, women > 2 standard drinks daily), has acute HCV, or if your patient has known or suspected cirrhosis or advanced fibrosis, refer to liver specialist for fibrosis staging

Click here for table  
Interpreting APRI and FIB-4

Test results are concordant/unambiguous

Test results are discordant, indeterminant or unclear

No to moderate  
Fibrosis (Metavir  
F0-F2 equivalent)

Advanced  
Fibrosis (Metavir  
F3 equivalent)

Cirrhosis  
(Metavir F4  
equivalent)

Choose HCV  
treatment from  
Cirrhosis?  
"No" option

Choose HCV  
treatment from  
Cirrhosis?  
"No" option

Choose HCV  
treatment from  
Cirrhosis?  
"Yes" option

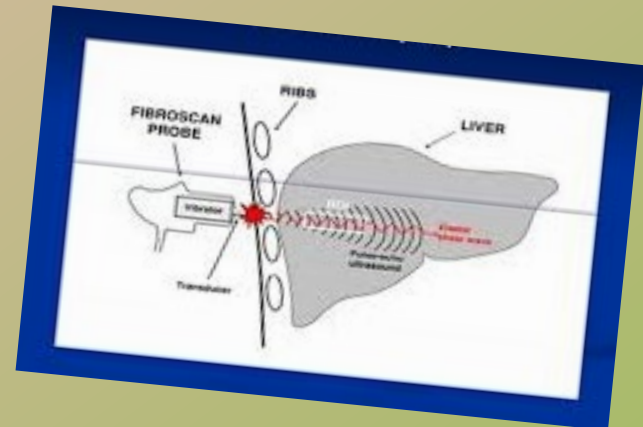
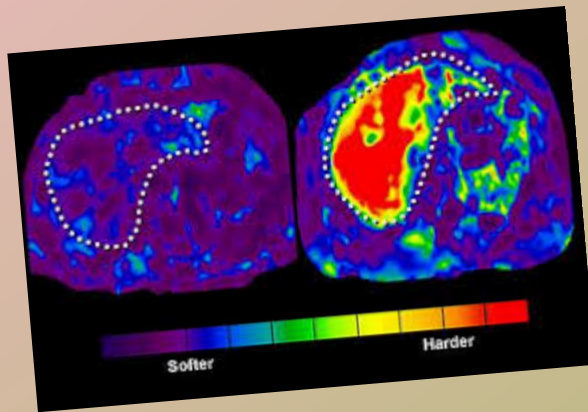
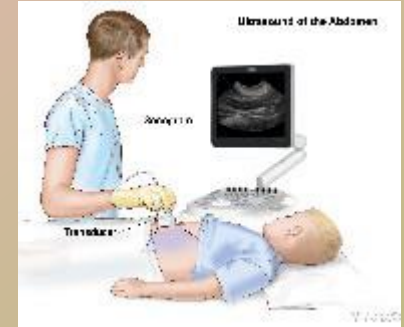
Consult liver  
specialist  
about fibrosis  
staging

RUQ US/AFP every 6 months for  
HCC screen. Consider referral to  
liver specialist.

\*<https://www.hepatitisc.uw.edu/page/clinical-calculators/>

# Imaging to Estimate Fibrosis

- Abdominal U/S
- Transient U/S Elastography
- Magnetic Resonance Elastography





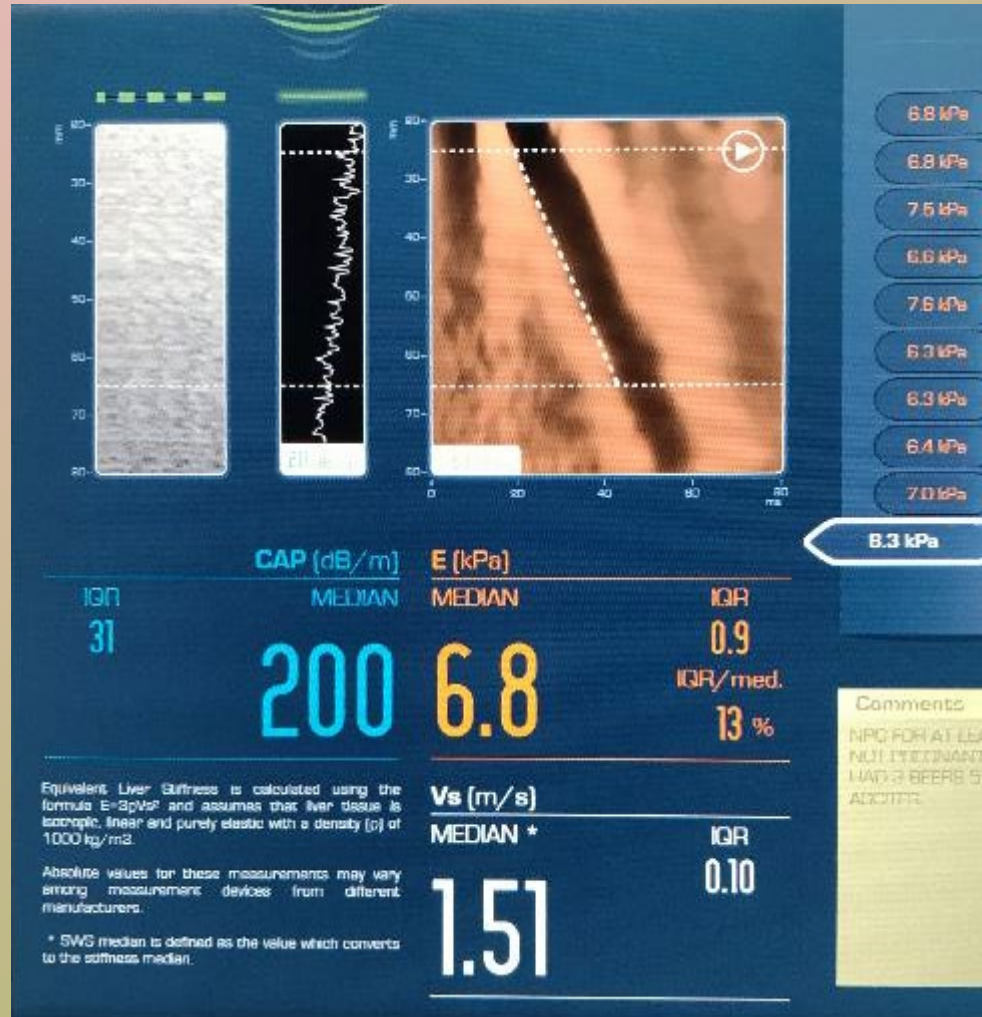
# Abdominal U/S

- Advantages
  - Non-invasive, lower cost, widely available
  - Potential to identify useful factors
    - Nodularity, ascites, spleen size
    - Coarseness of the liver parenchyma
    - Size of lymph nodes around hepatic artery
    - Patency and flow of veins and arteries
    - Lesions suspicious for HCC
- RUQ vs abdominal U/S

# Transient U/S Elastography

- Transient U/S Elastography Advantages
  - Measures liver stiffness with decent correlation with pathology
  - Painless, quick, easy to perform, reasonably accurate
  - Relatively inexpensive test
- FibroScan
  - Is a specific branded transient US elastography machine for measuring fibrosis, steatosis with limited availability in AK
  - Available at ANTHC and brought to tribal liver field clinics throughout the state
  - Has been studied for over 2 decades, starting in Europe

# FibroScan

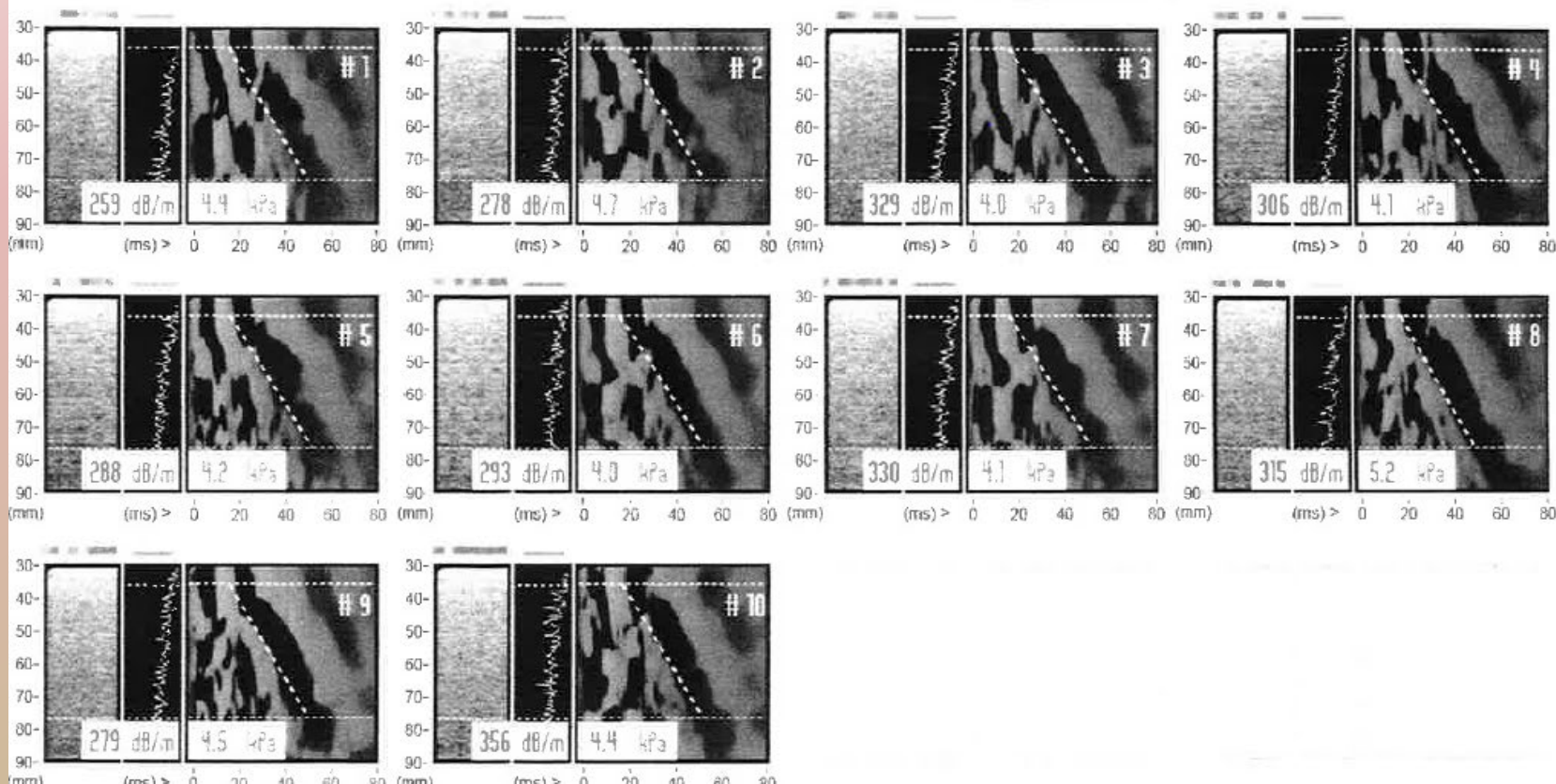




HCV  
Indication : HCV  
Referring physician : TOWNSHEND

CAP (dB/m)		E (kPa)	
IQR	MEDIAN	MEDIAN	IQR
44	300	4.3	0.4
			IQR/med. 9 %

Exam XL (Liver)  
Operator : tgh  
Valid measurements : 10  
Total measurements : 13  
SWS MEDIAN = 1.20 m/s  
SWS IQR = 0.05 m/s



# Interpretation of FibroScan with CAP

## CAP

### Performance By Steatosis Grade

Grade	CAP Cutoff dB/M	Sensitivity	Specificity	AUC
S0 <u>vs</u> S1-S3	<b>248</b>	0.69	0.82	0.82
S0-S1 <u>vs</u> S2-S3	<b>268</b>	0.77	0.81	0.86
S0-S2 <u>vs</u> S3	<b>280</b>	0.88	0.78	0.88

Steatosis Grade	Affected Hepatocytes
S1	$\leq 33\%$
S2	$\geq 33 - 66\%$
S3	$> 66\%$

## FibroScan

### Peer Review Cutoff Value Reference

Disease	F0-F1	F2	F3	F4
HBV	$\leq 6.0$	$> 6.0$	$\geq 9.0$	$\geq 12.0$
HCV	$\leq 7.0$	$> 7.0$	$\geq 9.5$	$\geq 12.0$
HCV-HIV	$\leq 7.0$	$\leq 10.0$	$\geq 11.0$	$\geq 14.0$
Cholestatic	$\leq 7.0$	$\geq 7.5$	$\geq 10.0$	$\geq 17.0$
NAFLD/NASH	$\leq 7.0$	$\geq 7.5$	$\geq 10.0$	$\geq 14.0$

Utilization of FibroScan in Clinical Practice; Bonder et al, Current Gastroenterology Rep, 2014 16-372

11 Study Meta-Analysis / 2076 Subjects  
Individual Patient Data Meta-Analysis of Controlled Attenuation Parameter (CAP) Technology for Determining Steatosis; Karlas et al, 2016

# Transient U/S Elastography

## Disadvantages

- Operator dependent
- Can be difficult on patient's with significant central adiposity
- Not meant to diagnose liver mass



# Magnetic Resonance Elastography

- When would you need this?
- Advantages
  - Good correlation with pathology results
  - More accurate b/c not operator dependent
  - Can be used in conjunction with contrast enhanced MRI
  - Will give more information about the liver, cirrhosis, and hepatomas

# Magnetic Resonance Elastography

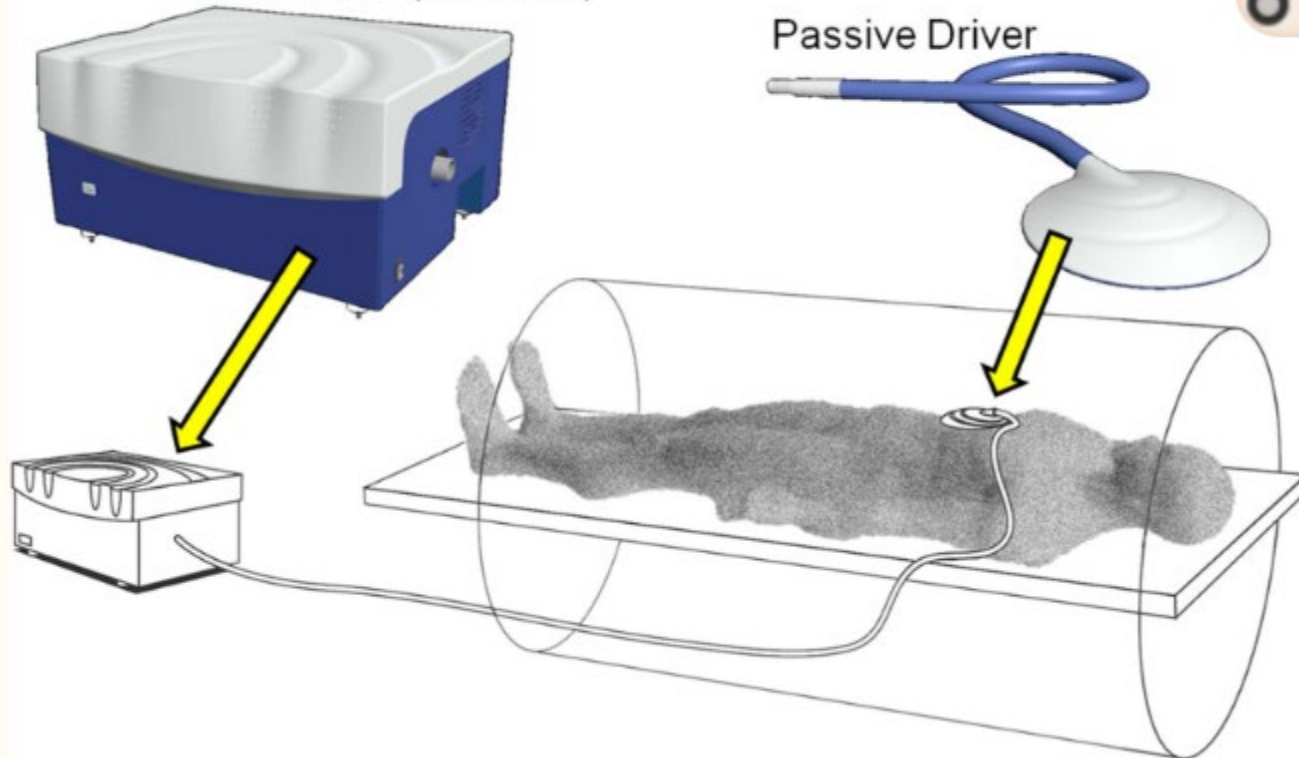
- Disadvantages
  - Limited availability
  - Cost

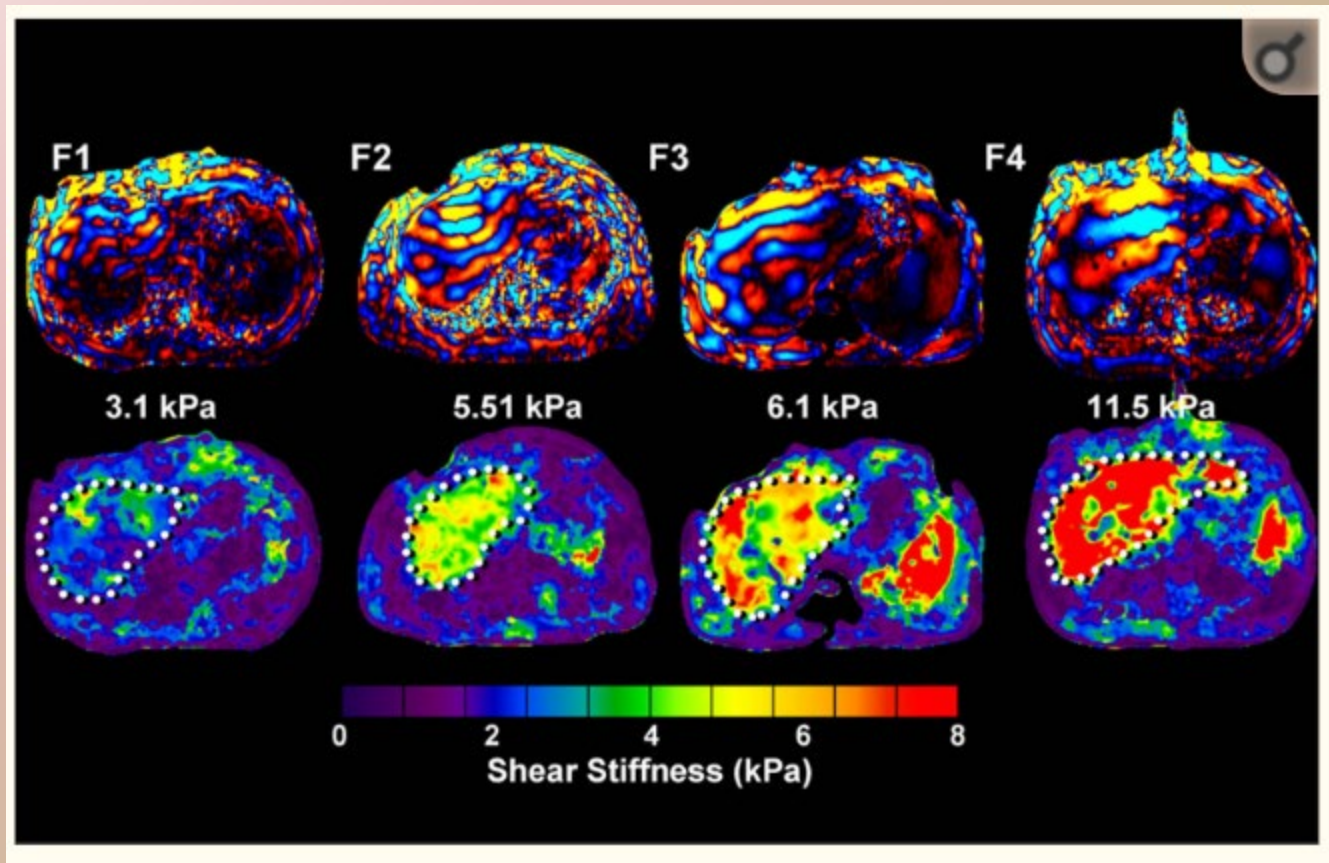




Active Driver (Acoustic)

Passive Driver







# Liver Biopsy

- Advantages
  - Gold standard
  - Measures grade (inflammation) and stage (fibrosis)
  - Diagnose co-existing liver diseases
- Disadvantages
  - Invasive, has associated risks, higher cost than U/S
  - Sampling variability
  - Can incorrectly stage fibrosis 20% of time

# Indications for MRE or Liver Biopsy

- If indirect, serum markers and TE/FibroScan show discordant results and the decision on how to manage patient with HCV depends on results (MRE)
  - To determine if patient requires lifelong surveillance for HCC
- When concurrent forms of liver disease in addition to HCV suspected (consider liver biopsy)

# Case Study 1

- A 59 yo (born 1959) male presented recently as a new patient
- Labs revealed elevated LFTs so follow up testing done, found to be HCV Ab+
- PMH: HTN, prediabetes, obesity, GERD
- Medications: lisinopril 20 mg daily and omeprazole 20 mg daily. No OTCs or herbals.
- Social hx: Doesn't use drugs or tobacco. He enjoys beer (in moderation) on the weekends.
- Family hx – Negative for liver disease. Father died of colon ca at age 64, mother, 80, alive & well

# Case Study 1

- Is there additional health or social history you do you need?
  - Are other health screenings up-to-date?
  - Housing/work/transportation issues



# PTDs?

## Potential Treatment Disruptors



# Case Study 1 Physical Exam

- BMI 34.7
- No icterus or jaundice
- Several spider nevi on upper chest
- Abd distended, truncal obesity
- No asterixis





# Case Study 1 Baseline Labs

- CBC: Hgb 14.1, Hct 41.5, plt 139
- CMP: Glucose 97, creatinine 0.8, eGFR 97, electrolytes normal, ALT 91, AST 112, alkaline phosphatase 114, total bilirubin 1.2, albumin 3.4
- PT/INR = 13.9, 1.1
- HCV RNA 1,974,000 international units/mL
- Genotype 1a
- HIV negative
- HBsAg negative, HBcAb negative, HBsAb negative
- HAV IgG reactive

APRI is 2.01 and FIB-4 is 4.98



# Interpretation of APRI/FIB-4 Link

- <https://anthc.org/wp-content/uploads/2018/08/Interpretation-of-APRI-and-FIB-4.pdf>

# Interpretation of APRI and FIB-4

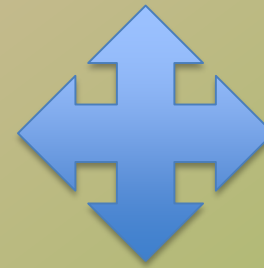
APRI Result	Fibrosis Interpretation
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$\geq 1.5$	Advanced fibrosis (bridging fibrosis to cirrhosis)
> 2	Cirrhosis
> 0.5 < 1.5	Indeterminate

FIB-4 Result	Fibrosis Interpretation
< 1.45	No-Moderate Fibrosis
> 3.25	Advanced Fibrosis
1.45 – 3.25	Indeterminate



It looks like my patient has cirrhosis,  
now what?

???



# Further Evaluation Needed

- Confirm finding with another test – serum fibrosis test or TE/FibroScan
- Baseline abd ultrasound then RUQ ultrasound to screen for hepatocellular carcinoma (HCC) every 6 months
- Calculate Child-Turcotte-Pugh (CTP) Score when someone has cirrhosis

# Case Study 1 Ultrasound

- Liver has increased hepatic echogenicity consistent with medical liver disease. No hepatic mass. Mild splenomegaly. Hepatopetal blood flow in the portal vein. Small amount of ascites present.



[www.anthc.org/what-we-do/clinical-and-research-services/hep/hep-c-treatment-information/](http://www.anthc.org/what-we-do/clinical-and-research-services/hep/hep-c-treatment-information/)



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## Hepatitis C Treatment

We want to keep you informed of recent drugs, screenings, treatments, and other news pertaining to Hepatitis and other liver diseases. As news becomes available we will post content here. Check back often to stay informed!

### Treatment Tools

Before Treatment

Monitoring During and After Treatment

Treatment Reference Tools

Treatment Checklist  
Health Summary  
Insurance Screening  
Patient Readiness Attestation  
Hep C Information  
Pre-Treatment Letter  
Alcohol Use Disorders Identification Test (Audit-C)  
Patient Health Questionnaire (PHQ-9)  
Child-Turcotte-Pugh (CTP) Calculator  
Hep Drug Interactions



# CTP Score to Determine if Patient Has Compensated or Decompensated Cirrhosis

LAB OR CLINICAL CRITERIA	POINTS*		
	1	2	3
Encephalopathy	None	Grade 1-2 (or precipitant-induced)	Grade 3-4 (or chronic)
Ascites	None	Mild/Moderate (diuretic-responsive)	Severe (diuretic-refractory)
Bilirubin (mg/dL)	<2	2-3	>3
Albumin (g/dL)	>3.5	2.8-3.5	<2.8
INR	<1.7	1.7-2.3	>2.3

Add score for each criteria.

CTP Class:

A = 5-6 points  
(compensated)

B = 7-9 points  
(decompensated)

C = 10-15 points  
(decompensated)

<http://www.hepatitis.va.gov/provider/tools/child-pugh-calculator.asp>

# Case Study 1 Baseline Labs

- CBC: Hgb 14.1, Hct 41.5, plt 139
- CMP: Glucose 97, creatinine 0.8, eGFR 97, electrolytes normal, ALT 91, AST 112, alkaline phosphatase 114, total bilirubin 1.2, albumin 3.4
- PT/INR = 13.9, 1.1
- HCV RNA 1,974,000 international units/mL
- Genotype 1a
- HIV negative
- HBsAg negative, HBcAb negative, HBsAb negative
- HAV IgG reactive

APRI is 2.01 and FIB-4 is 4.98

# This patient seems a little complicated...

## **Consult/AK Echo**

- Discordant fibrosis results
- Acute hepatitis C
- Compensated cirrhosis
- Other contributing factors to liver disease
- Failed prior HCV therapy
- Anyone who seems like a challenge but you think you can handle with a little guidance

## **Refer to GI, hepatology or ID**

- Co-infected with HIV or HBV
- HCC
- Decompensated cirrhosis
- Dialysis
- Prior or future transplant

# What else should you be aware of?

- HCV can co-exist with other forms of liver disease
  - Alcoholic hepatitis (history, AST/ALT ratio, GGT)
  - NAFLD and NASH
  - Alpha-1 Antitrypsin Deficiency
  - Hemochromatosis
  - Autoimmune hepatitis



Workup of elevated LFTs: <https://anthc.org/what-we-do/clinical-and-research-services/hep/for-providers/>



## In Summary



- HCV treatment evaluation needs to be wholistic
- Identifying fibrosis level is a key part of that evaluation
- Common barriers to consider are behavioral health issues, housing, transportation, and substance use disorders
- Are *you* ready? It takes a team to treat HCV



Thank you for your attention

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