

HCV Management in The Primary Care Setting: Assessment, Treatment, Post Treatment Monitoring

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Faculty/Presenter Disclosure

- ▶ **Faculty:** Dr. Susan Nouch
- ▶ **Relationships with financial sponsors:**
 - ▶ **Speakers Bureau/Honoraria:** Gilead (Advisory Board)

HCV Diagnosis

- ▶ **HCV Ab:** lifelong positivity, exposure to the virus, ever
- ▶ **HCV RNA:** active infection
- ▶ **Always add the RNA and genotype!**

Assessment of the HCV+ patient



Screen for co-infections and
comorbidities

Assess liver fibrosis

- APRI, Fib-4
- Fibroscan (stage 0-4)
 - 9.5-12 kpa: Advanced fibrosis (stage 3)
 - >12 kpa: Cirrhosis (stage 4)
- But does the patient really NEED the fibroscan?

I should probably do an U/S ... ?

- No clear recommendation
- **Unless** advanced fibrosis/cirrhosis
- (but I often do one anyway)

APRI Score

$$\text{APRI} = \frac{\frac{\text{AST Level}}{\text{AST (Upper Limit of Normal)}}}{\text{Platelet Count (10}^9\text{/L)}} \times 100$$

► Interpretation

- **APRI < 1.0:** reasonable to rule out cirrhosis
- **APRI 1.0-2.0:** potential for extensive fibrosis, fibroscan to assess
- **APRI > 2.0:** cirrhosis likely, fibroscan to confirm
- Less reliable HIV/HCV

1. <https://www2.gov.bc.ca/assets/gov/health/practitioner-pro/special-authority/fibrosis-info-sheet.pdf>

2. Lin, Zhong-Hua, et al. Performance of the aspartate aminotransferase-to-platelet ratio index for the staging of hepatitis C-related fibrosis: An updated meta-analysis. *Hepatology* 53:3 (2011): 726-736.

Fib-4 Score

$$\text{FIB-4} = \frac{\text{Age (years)} \times \text{AST Level (U/L)}}{\text{Platelet Count (10}^9\text{/L)} \times \sqrt{\text{ALT (U/L)}} = \text{[]}$$

► Interpretation

- **< 1.45**: unlikely to have significant fibrosis
- **> 1.45**: potential for extensive fibrosis, fibroscan to assess
- **> 3.25**: cirrhosis likely, fibroscan to confirm

HCV

19-0306.1306

Problem code 070.54 already in problem list for (RNA+ or -)

HCV labs/investigations

| | | |
|-----------|---|-------------|
| HCV | < 12 IU/mL * Not calculated HCV RNA detected | 20 Feb 2019 |
| RNA: | No HCV RNA detected | 13 Jun 2017 |
| | No HCV RNA detected | 10 Mar 2017 |
| HCV | Test not performed. A specimen | 11 Mar 2016 |
| Genotype: | from this patient was found to be genotype 1A COLLECTED | |

| | | |
|-------------|-----------------------|-------------|
| Hemoglobin: | 122 g/l | 20 Feb 2019 |
| Platelets: | 90 10 ⁹ /L | 20 Feb 2019 |
| ALT: | 32 U/l | 20 Feb 2019 |
| AST: | 55 U/l | 20 Feb 2019 |
| Creatinine | 50 umol/l | 20 Feb 2019 |
| GFR: | 115 | 20 Feb 2019 |
| Albumin: | 36 g/l | 20 Feb 2019 |
| Bili: | 8 umol/l | 20 Feb 2019 |
| INR: | 1.1 | 20 Feb 2019 |

Fibrosis Staging

| | | |
|------------|--|-------------|
| APRI: | 1.75 | 20 Feb 2019 |
| | <i>Suggests cirrhosis, recommend fibroscan to confirm</i> | |
| Fibroscan: | 20.9 | 04 Dec 2015 |
| (n kPa) | <i>Suggests cirrhosis, consider need for HCC screening and endoscopy</i> | |

Hepatitis A/B Status

| | | |
|----------------|--|-------------|
| Hep B Sfc Ag: | Non-Reactive | 28 Aug 2018 |
| Hep B Core Ab: | Reactive | 28 Aug 2018 |
| Hep B Sfc Ab: | < 2 IU/L | 28 Aug 2018 |
| Hep B DNA: | <20 The test now in use is the Roche COBAS | 29 Dec 2015 |
| Anti HAV: | | |

Abdominal U/S

Most Recent Abdo U/S

Comments: Date Completed:

Existing Interventions for Abdo U/S

Intervention: HCC screening Abdominal U/S every 6 Date: 05 Mar 2019

Date:

Use this button to add a manual abdominal U/S intervention with selected due date. When you close the form, you can edit the <reason> in interventions. To add an intervention for regular q6/12 HCC screening, use the button to the left, which will appear if criteria is met for advanced fibrosis or cirrhosis.

Problem code 571 (cirrhosis) already in problem list

HCV Treatment Preparation

- ▶ **Consider all RNA+ patients eligible for treatment**
- ▶ Can they reliably get through taking pills (*mostly*) daily x 8-12 weeks?
- ▶ Patient education on risk reinfection
- ▶ Special Authority process - Always order the bili and albumin!
- ▶ Consider dispensing, adherence
- ▶ Choose a regimen, **check drug interactions**
 - ▶ **Hep-druginteractions.org**
- ▶ Who you should refer/when to speak to experienced colleague
 - ▶ Cirrhosis, HIV/HBV co-infections, treatment experienced, complex drug interactions, multiple complex comorbidities

Choosing a regimen

Pangenotypic options

- **Sofosbuvir/velpatasvir (Epclusa)**
 - 12 weeks, one pill daily
- **Glecaprevir/Pibrentasvir (Maviret)**
 - 8 weeks for most, 3 pills ONCE daily

Other options

- Sofosbuvir/ledipasvir (Harvoni)
- Elbasvir/Grazoprevir (Zepatier)
- Sof/vel/vox (Vosevi) - DAA failures

Which pan-genotypic regimen to choose?

Glecaprevir/ Pibrentasvir

300/120

3 Tablets with food daily

8-12 weeks of treatment

Drug interactions: some
statins, ethinylestradiol
atazanavir or rifampin

Avoid in decompensated
cirrhosis (Child-Pugh B, C)

Can be used in all renal
impairment

Similarities

Pan-genotypic

Risk of reactivating
HBV

Adverse Reactions:
Headache and
Fatigue

Sofosbuvir/ Velpatasvir

400/100

1 Tablet +/- food daily

12 weeks of treatment

Drug interactions: some
statins, acid suppression,
amiodarone

Can be used in all cirrhosis
(Child-Pugh A, B, or C)

Not recommended in
eGFR <30 mL/min

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Advanced Fibrosis/Cirrhosis

▶ Screening for Hepatocellular Carcinoma

- ▶ q 6/12 abdo U/S
- ▶ For ALL patients with cirrhosis and consider for advanced fibrosis (stage 3, fibroscan 10-12 kpa)
- ▶ Risk Factors: diabetes, male, EtOH, older age at SVR, obesity, portal HTN
- ▶ U/S pre-treatment to rule out early HCC **before** starting DAAs



Advanced Fibrosis/Cirrhosis

- ▶ Consider Referral for **endoscopy** (plts <150, portal HTN on U/S, fibroscan > 20)
- ▶ If cirrhosis: Adjustments to treatment regimens (*sof/vel+rbv for geno 3a, glec/pib 12 weeks)
- ▶ What is **decompensated cirrhosis**?
 - ▶ Ascites, variceal bleed, encephalopathy, jaundice
 - ▶ Impairment of synthetic function (low albumin, platelets <100, elevated bili, INR)



On
treatment:

Now
What?

Monitor adherence

But don't they need lab work?

- Not really
- **Unless:**
 - Cirrhosis– especially decompensated
 - On Ribavirin
 - Hep B+ (maybe Hep B core +)
- End of-treatment Labs

Post-Treatment Follow-up

- ▶ SVR 12 testing, 12 weeks after EoT
- ▶ Continue to monitor based on risk of reinfection
- ▶ **Cirrhosis/Advanced Fibrosis**
 - ▶ Indefinite q6/12 HCC screening U/S
 - ▶ Consider Endoscopy

Case 1

- ▶ 53 yo male, new to your clinic
- ▶ Presents for OAT and hx HCV
- ▶ From out of province, no past records
- ▶ Not seen any doctors in several years
- ▶ Told many years ago he had HCV, but that it was “inactive”
- ▶ Current heavy EtOH use
- ▶ No known co-infections
- ▶ Do baseline labs, see in follow -up in 2 weeks

HCV\

SAVE

SAVE and CLOSE

2019.0405.1109

Problem code 070.54 already in problem list for (RNA+ or -)

HCV labs/investigations

HCV RNA: 2283785 IU/mL (6.36 log₁₀ IU/mL) 29 Jul 2019

HCV Genotype: Hepatitis C Virus genotype 1a This is a validated laboratory developed test. Performance characteristics are available at 29 Jul 2019

Hemoglobin: 129 g/l 29 Jul 2019

Platelets: 166 10⁹/L 29 Jul 2019

ALT: 121 U/l 29 Jul 2019

AST: 197 U/l 29 Jul 2019

Creatinine: 66 umol/l 29 Jul 2019

GFR: 109 29 Jul 2019

Albumin: 46 g/l 29 Jul 2019

Bilir: 17 umol/l 29 Jul 2019

INR: 0.9 29 Jul 2019

Order HCV Baseline/Pre-treatment Lab Set

Fibrosis Staging

APRI: 3.39 29 Jul 2019

Suggests cirrhosis, recommend fibroscan to confirm

Fibroscan: 6.8Kpa (n kPa) 13 Aug 2019 + View All (2)

Add Reminder to Refer for Baseline Screening Endoscopy

Add Intervention for q5/12 HCC Screening U/S

Problem code 571 (cirrhosis) already in problem list

Hepatitis A/B Status

Hep B Sfc Ag: Non-Reactive 29 Jul 2019

Hep B Core Ab: Non-Reactive 29 Jul 2019

Hep B Sfc Ab: < 2 IU/L 29 Jul 2019

Hep B DNA: 29 Jul 2019

Anti HAV: Nonreactive. Not immune to HAV 29 Jul 2019

Abdominal U/S

Most Recent Abdo U/S

Comments: Date Completed:

Existing Interventions for Abdo U/S

Intervention: Date:

Add Intervention for Abdo U/S Date:

Use this button to add a manual abdominal U/S intervention with selected due date. When you close the form, you can edit the <reason> in interventions. To add an intervention for regular q5/12 HCC screening, use the button to the bottom left, which will appear if criteria is met for advanced fibrosis or cirrhosis.

What do you do next?

Trust the fibroscan, go ahead and treat as non-cirrhotic

Trust the APRI, treat as cirrhosis

11%

Order abdo U/S and reassess

84%

None of the above

5%

Assessment

- ▶ U/S shows nodular liver, enlarged spleen
- ▶ **Cirrhosis**
- ▶ HCC screening, consider referral for screening endoscopy
- ▶ Needs HCV Treatment
 - ▶ Ongoing EtOH
 - ▶ Consult with colleagues re: medication selection and monitoring

Case 2

- ▶ 29 yo male
- ▶ New patient with OUD initiating OAT
- ▶ New intake labwork:
 - ▶ HCV Ab+, HCV RNA +
- ▶ Neg HCV Ab documented 1 year ago
- ▶ No hx of liver disease, no significant EtOH hx
- ▶ No Sig PMHx
- ▶ Trazodone for sleep, starting SROM for OUD

HCV\

SAVE

SAVE and CLOSE

2019.0405.1109

Problem code 070.54 already in problem list for (RNA+ or -)

HCV labs/investigations

| | | | |
|---------------|---|-------------|---|
| HCV RNA: | 125325 IU/mL (5.10 log10 IU/mL) | 21 Jul 2019 | - |
| HCV Genotype: | Hepatitis C Virus genotype 1a This is a validated laboratory developed test. Performance characteristics are available at | 21 Jul 2019 | - |
| Hemoglobin: | 127 g/l | 21 Jul 2019 | |
| Platelets: | 262 10 ⁹ /L | 21 Jul 2019 | |
| ALT: | 372 U/l | 21 Jul 2019 | |
| AST: | 136 U/l | 21 Jul 2019 | |
| Creatinine: | 78 umol/l | 21 Jul 2019 | |
| GFR: | 115 | 21 Jul 2019 | |
| Albumin: | 44 g/l | 21 Jul 2019 | |
| Bill: | | | |
| BNR: | | | |

Order HCV Baseline/Pre-treatment Lab Set

Fibrosis Staging

APRI: 1.48 21 Jul 2019

May suggest significant fibrosis, recommend fibroscan

Fibroscan: (+)
(n kPa)

Hepatitis A/B Status

| | | |
|----------------|--------------------------------|-------------|
| Hep B Sfc Ag: | Non-Reactive | 21 Jul 2019 |
| Hep B Core Ab: | Non-Reactive | 21 Jul 2019 |
| Hep B Sfc Ab: | 13 IU/L | 21 Jul 2019 |
| Hep B DNA: | | |
| Anti HAV: | Nonreactive. Not immune to HAV | 21 Jul 2019 |

Abdominal U/S

Most Recent Abdo U/S

Comments: Date Completed:

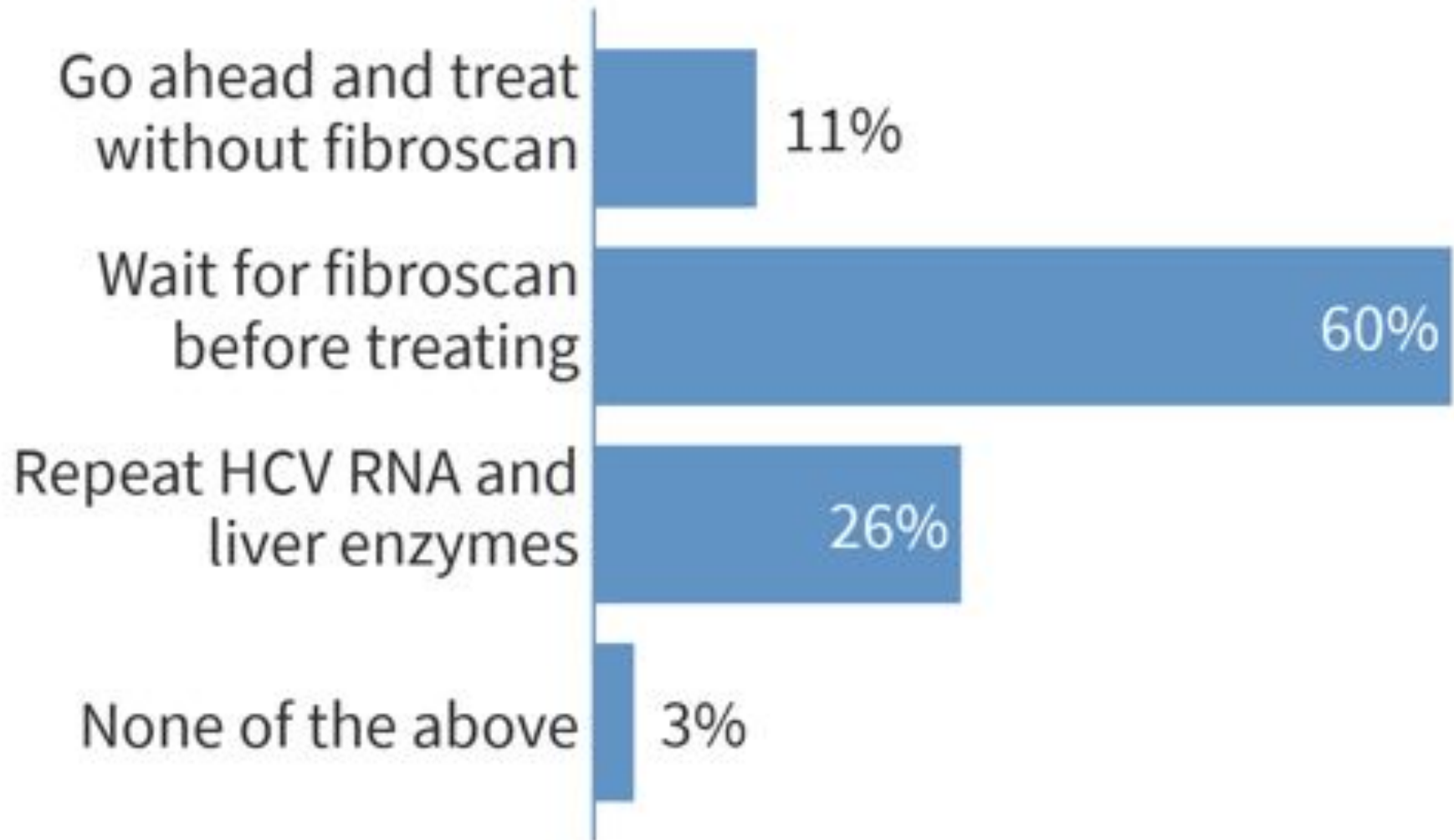
Existing Interventions for Abdo U/S

Intervention: Date:

Date:

Use this button to add a manual abdominal U/S intervention with selected due date. When you close the form, you can edit the <reason> in interventions. To add an intervention for regular q6/12 HCC screening, use the button to the bottom left, which will appear if criteria is met for advanced fibrosis or cirrhosis.

What do you do next?



Case 2: Follow- up

- ▶ Labs repeated in 1 Month
- ▶ HCV RNA increased
- ▶ AST and ALT still elevated, but lower than last month
- ▶ APRI now 0.69
- ▶ Patient now stable on OAT, wants treatment

Choosing a regimen

Ask the patient!

Hep-druginteractions.org

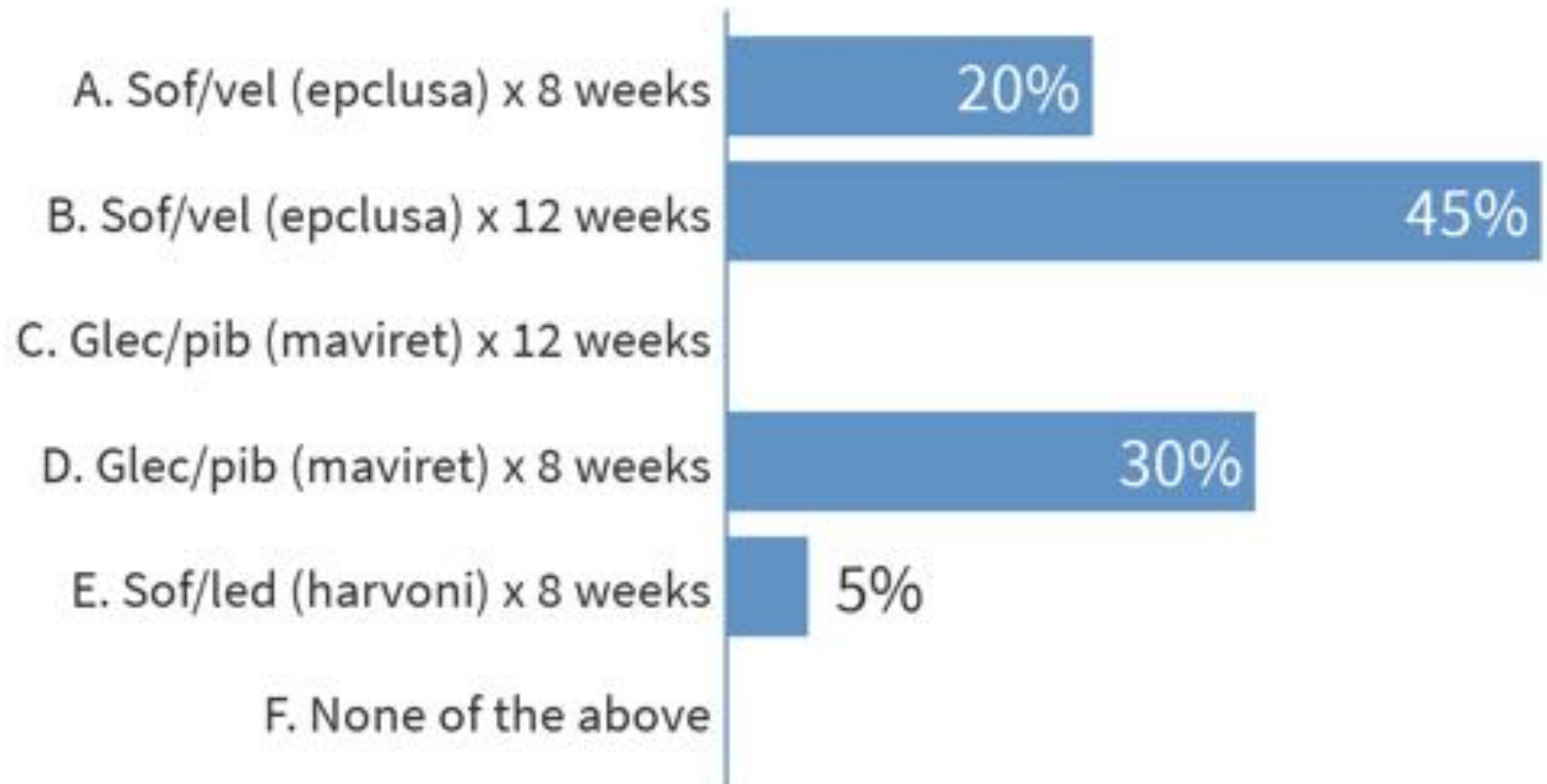
Apply for Special Authority

Adherence/Dispensing Plan

Patient education

Go!

What treatment regimen do you choose? (more than 1 correct)



Pearls

- ▶ Always add the RNA
- ▶ Always do the bili, albumin
- ▶ Fibroscan > 10 , or other signs cirrhosis – consider lifelong q6/12 HCC screening U/S, even after treatment
- ▶ If cirrhosis, do the U/S pre-tx
- ▶ Low APRI, short duration infection/young - can treat without f-scan,U/S if it is a barrier
- ▶ Use the HCV form!



Questions?

ADDITIONAL HCV LEARNING:

[HTTP://WWW.INHSU.ORG/EDUCATION-PROGRAM/](http://www.inhsu.org/education-program/)

[HTTPS://WWW.HEPATITISC.UW.EDU](https://www.hepatitisc.uw.edu)