Treating Hepatitis C in Primary Care?
Yes we can!

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Panel

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Leandra Battisti, Pharm.D, Clinical Pharmacist
Objectives

- Describe a model to treat hepatitis C (HCV) in Primary Care
- Discussion: what are barriers to developing a program at your CHC?
- Present cases that illustrate common challenges in HCV treatment
The patient population at BMC has a higher prevalence of hepatitis C infection than the nationwide average.

A closer look at the BMC Hep C patient population identified:

- Patients at BMC are not screened consistently for Hep C infection
- Many patients have difficulty accessing and remaining engaged in care
- Wait times for specialty clinics for treatment are long
We have collaborated with other clinics to ensure patients are triaged appropriately.

- **Gastroenterology**
  - Decompensated cirrhosis
  - Other serious complications

- **Infectious Disease**
  - Co-infected HIV

- **Primary Care**
  - Others with chronic Hep C
We have designed a workflow to improve patient identification, linkage to care, and adherence.

**Identification and Referral**
- MD referral
- Automated lab referral
- Epic data targeting
- Peer referral

**Evaluation**
- Chart review for eligibility
- Clinical evaluation
- Bio-psycho-social intake
- Staging
- Re-evaluation

**Treatment**
- Prior authorization
- Medication teaching
- Adherence and lab check
- Treatment completion evaluation
- SVR evaluation
HCV Treater Role: Training

- Online American Association for the Study of Liver Diseases (AASLD) modules
- Alternate training: University of Washington modules
- Shadow a specialist in GI or ID
- Check out http://www.hcvguidelines.org/ for periodic updates
HCV Treater Role: Initial Evaluation

- Assess how infected with HCV
- Substance use
- Symptoms of Hepatitis C
- Medical comorbidity: uncontrolled DM-BMC health plan will cover F1
- Motivation for treatment
- PE
- Labs for staging
- Patient meets with care manager…
Case Manager Role
HCV Treater Role: Visit #2

- Review data, decide if should submit PA vs. discharge back to PCP
- Reassess sobriety/motivation for treatment
- If PA approved…
Pharmacist Role
HCV Treater Role: Visits #3 & 4

- End of treatment visit
- 12 weeks following treatment completion
- As needed visits during treatment
We have an interdisciplinary team of providers and staff

<table>
<thead>
<tr>
<th>Providers</th>
<th>Residents</th>
<th>Other staff</th>
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<tbody>
<tr>
<td>• Karen Lasser</td>
<td>• Gayatri Patel</td>
<td>• Glorimar Ruiz</td>
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<td>• Kristin Lee</td>
<td>• Vassiliki Pravodelov</td>
<td>• Alexandra Heinz</td>
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<td>• Theresa Kim</td>
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<td>• Sarah Kimball</td>
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<td>• Leandra Battisti</td>
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<td>• Jennifer Siegel</td>
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<td>• Jason Worcester</td>
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The results of the program so far are promising (data as of 3/30/16)

<table>
<thead>
<tr>
<th>Metrics</th>
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<tr>
<td>Total number of patients referred (MD, Lab, EMR, Peer)</td>
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<tr>
<td>Number of patients linked to care (completed initial medical evaluation)</td>
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<tr>
<td>Number of patients who completed staging (Fibroscan, US)</td>
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<td>Number of patients who were approved for treatment</td>
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<td>Number of patients who initiated treatment</td>
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<td>Number of patients who completed treatment</td>
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<td>Number of patients who achieved undetectable VL</td>
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<td>Number of patients who achieved SVR</td>
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<td>N of patients</td>
</tr>
<tr>
<td>316</td>
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<td>141</td>
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<td>10/11 eligible, 1 unknown</td>
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Discussion

Role of the 340b pharmacy in supporting this work.
Discussion

What are some of the barriers you have encountered in starting to treat HCV at your CHC?
Case 1

38 y.o. man with:
~Hepatitis C, no prior treatment
~Chronic Lower Back Pain
~Depression, untreated
~PTSD
~Opioid abuse – ~17 yr hx, multiple detox stays. Stopped heroin 2 mo ago, has been buying buprenorphine on the street

Referred by PCP for buprenorphine
Labs show:

AST/ALT – 96/112
Coags/CBC – nl
Hep C Ab – positive
VL/genotype (857,342/1a)
HIV – neg
Question

When is it medically indicated to start HCV treatment in patients with active or recent IDU?
What is the evidence?

- Limited data on treatment outcomes in active substance abuse
  - All is using older regimens
  - Observational data

- SVR can be obtained in reasonable rates in patients with active IDU

- ? Reinfection rates
NIH & AASLD Guidelines

- Treatment should not be withheld from those who currently use illicit drugs if pt:
  - Wants treatment
  - Can be monitored
  - Will practice contraception
Case 2.

64 y.o. man with:
Hepatitis C
HTN
EtOH use

Referred by PCP for evaluation/tx of Hep C
Case 2-continued

- Mode of transmission: IV heroin > 25 years ago
- Remote hx cocaine use
- Daily alcohol use: about a pint of vodka
- No prior treatment for hepatitis C
- ROS: fatigue, RUQ pain
Case 2-continued

- PE-normal
- Genotype 1b, viral load 1 million
- No coinfection
- WBC 8, Hct 40, plts 155
- AST 84, ALT 52
- INR 1
- Abdominal US – no cirrhosis
Question

What is the approach to evaluating/treating Hepatitis C in patients who currently use alcohol?
What is the evidence?

- Data do not support exclusion for hepatitis C treatment
- Prior studies of IFN based regimen: comparable SVR in injection drug users (Aspinall 2013)
- Provider bias - resistance to treating persons currently using illicit drugs or alcohol (Morrill 2005)
- Alcohol associated with more rapid fibrosis progression (Feld 2006)
How case was managed

- Ordered fibroscan – F3
- Decreased EtOH consumption to a couple of wine coolers a day
- Decided to start treatment with ledipasvir- sofosbuvir
- Prior authorization denied due to current alcohol use: require 6 months sobriety
- Encouraged abstinence and plan to reassess in 6 months
Case 3.

77 y.o. man with:
Hepatitis C
Anemia
Hemiplegia from CVA
HTN
“SOB”

Referred by PCP for evaluation/tx of Hep C
Case 3-continued

- Thinks contracted from IDU years ago
- Remote hx cocaine use
- No alcohol x 37 years
- Generally feels well
- PE-normal
- WBC 4, Hct 36, plts 236
- ALT 36/AST 56*
How I managed this case

- Ordered fibroscan
- “Due to age + comorbidity may not be appropriate candidate for tx, but will reassess once fibroscan results are back.”
- E-prognosis: 35% risk 5 year mortality, 70-82% risk of 10 year mortality
- Fibroscan was F0, insurance: Medicare-would cover treatment
What is the evidence?

• Few older (> 60) adults included in studies of antiviral tx
• Prior studies of PEG IFN/ribavirin: lower SVR in older patients
• All oral regimens: no evidence of decreased efficacy with increasing age
• All patients except those with limited life expectancy (< 12 mos) due to non Hep C conditions should be considered for tx
Guidelines

• Hepatitis C Guidance: AASLD-IDSA Recommendations for Testing, Managing, and Treating Adults Infected With Hepatitis C Virus

• “Antiviral treatment is recommended for all patients with chronic HCV infection, except those with limited life expectancy due to nonhepatic causes. (I-A: multiple RCTs or meta-analyses)”
Case 4

- 47 yo man, hx IDU, hx IFN tx
- c/o a little fatigue
- Drinks 2-3 beers/day; smokes 1 PPD
- NI PE
- Labs: GT 1a; AST 166, ALT 227, viral load 14 million
Question

In hepatitis C infected patients, when is it necessary to workup transaminitis for causes other than hepatitis C? What tests should we order?
How I managed patient

- Fibroscan: F4 c/w early cirrhosis
- Fe 184, TIBC 327, ferritin 387
- Actin (smooth muscle ab Igg), ANA, AFP
- UA: 4-10 RBCs
- Submitted PA for 12 weeks of Harvoni, referred to GI
Further workup/management in GI

- Treated with Harvoni x 3 months
- Negative for hereditary hemochromatosis mutations
- 12/2015: nl LFTs, HCV not detected, Ferritin 264
In the case of transaminitis, would it be appropriate to treat HCV first, then work up transaminitis if it doesn’t improve after treatment?
Guidelines

Assessment of other causes of liver disease for patients who have persistently abnormal liver function test results after achieving an SVR. (I-C: expert consensus, case studies, standard of care)
Summary

• Treating HCV in primary care settings is feasible, safe, and effective
• Caveats: need interdisciplinary team and specialty back-up