ID Week 2020:
Studies in HIV Primary Care

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Disclosures

No conflicts of interest or relationships to disclose.
Outline

1. Lung Cancer Screening in PWH

2. Practice Patterns in Hepatitis B Vaccination for PWH

3. *Heplisav-B* for PWH
Lung Cancer Screening in PWH
Background: Lung Cancer Screening

- In 2013, the USPSTF recommended low-dose CT chest if:
  - Aged 55-80
  - With a 30-pack year smoking history
  - Who currently smoke or
  - Who have quit within the past 15 years

- Compared to the general population, PWH have an overall increased risk of cancer and higher rates of lung cancer

- The USPSTF guidelines may not be applicable to PWH
Study Design: Lung Cancer Screening in PWH

• Retrospective chart review of patients aged 55-80 at a Midwestern HIV clinic between 7-1-2016 and 6-30-2018

• Of 341 patients, 256 were included in the analysis as eligible for lung-cancer screening (LCS) based on USPSTF criteria

• Exclusion criteria included those who never smoked, were deceased, had an unknown pack year history, or a prior diagnosis of lung cancer
Results: Lung Cancer Screening in PWH

- **Study Population**
  - Mean age 61 (range 55-78)
  - 75% male (193/256)

- **Results**
  - 104/256 (41%) met USPSTF criteria for LCS
  - Only 13% of those who met USPSTF LCS criteria were referred for low-dose CT chest
  - 55% of those referred completed the referral

- Patients who received tobacco cessation counseling (p=0.019) and with Hepatitis C (p=0.001) were more likely to receive LCS referral
In a small, single-center HIV Clinic, only 13% of PWH who smoke who met USPSTF criteria for LCS were referred for low-dose CT and approximately half completed the referral.

Take-Home Point: LCS rates are low among PWH. This is a reminder to assess USPSTF LCS criteria in all patients who smoke & refer if appropriate.
Practice Patterns in Hepatitis B Vaccination for PWH
Background: HBV Vaccination in PWH

- Individuals with HIV-Hepatitis B Virus (HBV) co-infection have higher rates of liver-related mortality compared with individuals without HIV

- HBV vaccine response rates in PWH are significantly lower (range 18-71%) than in adults without HIV (range 60-80%)\(^1\)

- HBV transmission continues to occur

- This is a topic of particular importance especially as we begin to prescribe more NRTI-sparing regimens
Study Design: HBV Vaccine Practices in PWH

- **Aim:** Evaluate current HBV screening, vaccination, and monitoring practices of physicians caring for PWH
- **Web-based survey with two sets of case-based questions disseminated to the ID division at UC San Diego, IDSA, and social media networks**
Results: HBV Vaccine Practices in PWH

• Study Participants
  - 74 clinicians from 26 states responded
  - 55% see > 20 PWH/month
  - 73% work at academic medical settings
Results: Timing and Choice of HBV Vaccination

| Preferred timing of HBV vaccination in a patient newly diagnosed with HIV getting started on ART |
|-------------------------------------------------|------------------------------------------------|
| Vaccinate immediately                            | 58 (78%)                                         |
| Postpone vaccination until HIV VL is suppressed   | 14 (19%)                                        |
| Defer vaccination since the patient is on ART     | 1 (1%)                                          |
| Other                                            | 1 (1%)                                          |

| Preferred initial HBV vaccination series for susceptible PWH |
|-------------------------------------------------------------|--------------------------------------------------|
| *Engerix-B or Recombivax-HB*                                 | 21 (29%)                                       |
| *Heplisav-B*                                                 | 31 (42%)                                       |
| Any of the above                                            | 21 (29%)                                       |

Hastie E, ID Week 2020, Abstract #27.
## Results: Management of Vaccine Non-Response

<table>
<thead>
<tr>
<th>Preferred intervention if patient does not seroconvert after first vaccination series</th>
<th>Numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>No further intervention</td>
<td>4 (6%)</td>
</tr>
<tr>
<td>Repeat with <em>Engerix-B</em> or <em>Recombivax-HB</em> at standard dose at 0, 1, and 6 months</td>
<td>15 (22%)</td>
</tr>
<tr>
<td>Repeat with <em>Engerix-B</em> or <em>Recombivax-HB</em> at double dose at 0, 1, and 6 months</td>
<td>19 (28%)</td>
</tr>
<tr>
<td>Repeat with <em>Engerix-B</em> or <em>Recombivax-HB</em> at standard dose at 0, 1, 2, and 6 months</td>
<td>2 (3%)</td>
</tr>
<tr>
<td>Repeat with <em>Engerix-B</em> or <em>Recombivax-HB</em> at double dose at 0, 1, 2, and 6 months</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Repeat with <em>Heplisav-B</em></td>
<td>29 (42%)</td>
</tr>
</tbody>
</table>
Results: Isolated HBV Core Antibody Management

<table>
<thead>
<tr>
<th>Preferred management of positive isolated hepatitis B core antibody</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>No further intervention</td>
<td>16 (22%)</td>
</tr>
<tr>
<td>Initiate hepatitis B vaccination</td>
<td>18 (24%)</td>
</tr>
<tr>
<td>Give a single dose of <em>Engerix-B</em> or <em>Recombivax-HB</em> with HBsAb titer check 1 month later</td>
<td>7 (9%)</td>
</tr>
<tr>
<td>Check HBV DNA level</td>
<td>33 (45%)</td>
</tr>
</tbody>
</table>
Summary: HBV Vaccine Practices in PWH

• In this survey study of 74 clinicians who care for PWH, there was significant practice variation regarding HBV vaccination, antibody monitoring, and management of a positive isolated hepatitis B core antibody.

• It appears that practitioners are interested in using Heplisav-B.

Take-Home Point: There is not a standard approach to HBV vaccination among those who care for PWH. We need to be vigilant in checking hepatitis B surface antibody at least one month after vaccine series completion.
Heplisav-B in PWH
Background: Hepatitis B Vaccination

• A two-dose recombinant HBV vaccine with a novel immunostimulatory adjuvant (HBV-ISS, *Heplisav-B*) was FDA approved in 2017 for adults 18 years and older.

• In immunocompetent adults, seroprotection with *Engerix-B* or *Recombivax-B* ranged from 65-80% versus 90-95% with *Heplisav-B*.

• Although many have adopted use of *Heplisav-B*, it has not been studied in PWH.
Study Design: *Heplisav-B* in PWH

- Retrospective cohort of 51 PWH ≥ 18 years without current HBV seroprotection (i.e. most recent anti-HBV surface Ab ≤ 10 mIU/mL)

- Primary outcome: seroprotection rate (SPR) at any point following the first *Heplisav-B* injection
Results: *Heplisav-B* in PWH

- **Study Population**
  - Mean age 59 (range 48-66)
  - 96% with HIV RNA < 200 copies/mL
  - 90% male (46/51)

- **Results**
  - 50/51 received both doses, 1/51 received one dose
  - SPR was 42/51 (82%)

- No significant difference in SPR based on age, sex, race/ethnicity, BMI, CKD, DM, smoking status, immunosuppression, prior HBV vaccination, history of prior + HBV sAb or cAb, or HIV RNA level
Results: Higher CD4 Cell Count Associated with SPR

Current and Nadir CD4+ Counts Are Associated with SPR

- **P for Trend <0.001**

<table>
<thead>
<tr>
<th>CD4+ Count</th>
<th>Seroprotection Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;100 (N=0)</td>
<td>N/A</td>
</tr>
<tr>
<td>100-199 (N=4)</td>
<td>25%</td>
</tr>
<tr>
<td>200-349 (N=10)</td>
<td>50%</td>
</tr>
<tr>
<td>≥350 (N=50)</td>
<td>92%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Nadir CD4+ Count</th>
<th>Seroprotection Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;100 (N=10)</td>
<td>40%</td>
</tr>
<tr>
<td>100-199 (N=15)</td>
<td>73%</td>
</tr>
<tr>
<td>200-349 (N=13)</td>
<td>85%</td>
</tr>
<tr>
<td>≥350 (N=26)</td>
<td>100%</td>
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Schnittman S, ID Week 2020, Abstract #21.
Summary: *Heplisav-B* in PWH

- This was a small, single center retrospective study of predominantly virally suppressed men in which safety data was not systematically collected.
- They concluded that SPR after *Heplisav-B* in PWH may be comparable to those without HIV and that higher CD4 cell counts were associated with higher seroprotection.

**Take away point:** Although *Heplisav-B* led to a high SPR in this cohort of PWH, *Heplisav-B* has not been formally studied in PWH, though will be soon.
Conclusions: Any comments?

1. Lung cancer screening rates among PWH were low. We need to assess for USPSTF LCS criteria in all patients who smoke and refer if appropriate.

2. Approaches to HBV vaccination in PWH are varied. Despite this, we need to be vigilant in checking HBV surface antibody levels ≥ 1 month after vaccine series completion.

3. Aside from a small retrospective cohort, *Heplisav-B* has not been formally studied in PWH, though will be soon.

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