HEPATITIS AWARENESS MONTH 2014

HepC CAP
HEPATITIS C ALLIES OF PHILADELPHIA
HOW CAN YOU CURE A VIRUS?
Make your own cure!

Cures were made with love
Time to put those cures to use…
A score means a cure!

Some went for the slam dunk
Others took the long shot
Even Oliver stopped by to “toss for a cure”

“B’ and ‘C’ unite!
A special thanks to our volunteers!
Hep C Advocate Training (May 5th)

• 38 people completed

• Why were people interested?
  • Work with clients who are infected/at-risk
    • “This would enhance my ability to help clients”
    • “Knowledge empowers people to have a better quality of life”
  • Want to know about new tx
    • “I completed tx and I have a lot of insight”
    • “One more advocate in the fight means more people will get tx”

• What action steps will participants take?
  • Speak to more people at risk; encourage them to get tested
  • Give info to co-workers, clients, and family members
  • Come to a HepCAP meeting

• Thanks to Office of HIV Planning for the space!
Storm City Council! (May 8th)
Storm City Council! (May 8th)
Hep B United National Summit in DC
Hep B United National Summit in DC
Other Events

- Tracy Swann at P-HOP
  - Treatment updates

- Hepatitis Testing Day at Prevention Point
  - Testing, vaccination
  - Education

- Up next…
  - World Hepatitis Day (Monday, July 28th)
Comparison of Confirmed and Unconfirmed antibody-positive Hepatitis C Cases in Philadelphia

Christine Marie Witt
Master of Public Health Candidate
Aims

• Aim 1: Determine if there was a significant difference between the risk factor profiles of HCV antibody only patients (cases) and HCV antibody and RNA tested patients (controls).

  ▫ Hypothesis: Cases are more likely to have behavioral risk factors associated with low SES (i.e. IDU, unlicensed tattooing, multiple sex partners)

  ▫ Hypothesis: Controls are more likely to have hospital-based risk factors that are not linked to SES (i.e. organ transplant/blood transfusion before 1992, long term hemodialysis)
Aims

• Aim 2: Determine if there was a significant difference between the facilities and providers that screen cases and controls
  - *Hypothesis:* Cases are more likely to be screened at federally qualified health centers (FQHCs) or district health centers (DHCs).
  - *Hypothesis:* Cases are more likely to be screened by primary care physicians
  - *Hypothesis:* Controls are more likely to be screened at private or specialty practices.
  - *Hypothesis:* Controls are more likely to be seen by liver specialists.
Aims

• Aim 3: Determine whether cases were aware of and plan to order/receive the confirmatory RNA test.

  ▫ Hypothesis: There will be an obvious gap in the knowledge of the cases and their providers regarding the confirmatory RNA test.
### Research Design & Methods

- **Case control study**
- **232 cases vs. 446 controls**

<table>
<thead>
<tr>
<th>Cases</th>
<th>Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inclusion</strong></td>
<td><strong>Inclusion</strong></td>
</tr>
<tr>
<td>▫ Philadelphia Resident</td>
<td>▫ Philadelphia Resident</td>
</tr>
<tr>
<td>▫ First HCV Antibody Test reported in 2013</td>
<td>▫ First HCV Viral Load or RNA test reported in 2013</td>
</tr>
<tr>
<td><strong>Exclusion</strong></td>
<td><strong>Exclusion</strong></td>
</tr>
<tr>
<td>▫ HCV Viral Load or RNA test</td>
<td>▫ Incarcerated</td>
</tr>
<tr>
<td>▫ Incarcerated</td>
<td>▫ Incarcerated</td>
</tr>
</tbody>
</table>

Inclusion criteria for cases and controls are based on being Philadelphia residents and having a first HCV test reported in 2013. Exclusion criteria include individuals with HCV viral load or RNA test and those who are incarcerated.
Data Collection

- Letters were sent to patients and ordering providers.

- Conducted interview via telephone
  - Verified date of birth to ensure confidentiality

- Four to six attempts to get in contact

- Field visits conducted by Hepatitis Investigators

- Medical Information could be released per the Pennsylvania Regulation Code § 27.152
Sample Size

232 cases
- 123 Previously reported
- 119 Incomplete investigation
- 56

446 controls
- 555 Previously reported
- 531 Incomplete investigation
- 378
## Demographics of Study Population

<table>
<thead>
<tr>
<th></th>
<th>Cases N = 56</th>
<th>Controls N = 378</th>
<th>Total N = 434</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N(%)</td>
<td>N(%)</td>
<td>N(%)</td>
<td></td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>31(55)</td>
<td>234(62)</td>
<td>265(61)</td>
<td>0.35</td>
</tr>
<tr>
<td>Female</td>
<td>25(45)</td>
<td>144(38)</td>
<td>169(39)</td>
<td></td>
</tr>
<tr>
<td><strong>Race/Ethnicity</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.64</td>
</tr>
<tr>
<td>African American</td>
<td>27(49)</td>
<td>197(52)</td>
<td>224(52)</td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>16(29)</td>
<td>110(29)</td>
<td>126(29)</td>
<td></td>
</tr>
<tr>
<td>Asian/Pacific Islander</td>
<td>3(5)</td>
<td>14(4)</td>
<td>17(4)</td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>1(2)</td>
<td>18(5)</td>
<td>19(4)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>8(15)</td>
<td>37(10)</td>
<td>45(10)</td>
<td></td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.07</td>
</tr>
<tr>
<td>&lt;45</td>
<td>17(30)</td>
<td>74(20)</td>
<td>91(21)</td>
<td></td>
</tr>
<tr>
<td>&gt;=45</td>
<td>39(70)</td>
<td>304(80)</td>
<td>243(79)</td>
<td></td>
</tr>
<tr>
<td><strong>Birth Country</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.12</td>
</tr>
<tr>
<td>U.S.A</td>
<td>40(77)</td>
<td>308(85)</td>
<td>348(84)</td>
<td></td>
</tr>
<tr>
<td>Other†</td>
<td>12(23)</td>
<td>53(15)</td>
<td>65(16)</td>
<td></td>
</tr>
</tbody>
</table>

† Cambodia, China, Cuba, Dominican Republic, Ecuador, Egypt, Georgia, Germany, Italy, Jamaica, Morocco, Pakistan, Philippines, Poland, Puerto Rico, Russian Federation, Trinidad & Tobago, UK, Vietnam
# Active vs. Passive Risk Factors

<table>
<thead>
<tr>
<th></th>
<th>Cases N=56</th>
<th>Controls N=378</th>
<th>Total N=434</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Passive Risk Factors</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>48 (86)</td>
<td>345 (91)</td>
<td>393</td>
<td>0.18</td>
</tr>
<tr>
<td>No</td>
<td>8 (15)</td>
<td>33 (9)</td>
<td>41</td>
<td></td>
</tr>
<tr>
<td><strong>Active Risk Factors</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>55 (98)</td>
<td>357 (94)</td>
<td>412</td>
<td>0.34</td>
</tr>
<tr>
<td>No</td>
<td>1 (2)</td>
<td>21 (6)</td>
<td>22</td>
<td></td>
</tr>
</tbody>
</table>
## Ordering Facility and Ordering Provider

<table>
<thead>
<tr>
<th>Location of Test</th>
<th>Cases N = 56 n(%)</th>
<th>Controls N=378 n(%)</th>
<th>Total N=434</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital</td>
<td>28(54)</td>
<td>140(39)</td>
<td>168(41)</td>
<td></td>
</tr>
<tr>
<td>District Health Center</td>
<td>2(4)</td>
<td>31(9)</td>
<td>33(8)</td>
<td>0.05</td>
</tr>
<tr>
<td>FQHC</td>
<td>5(10)</td>
<td>80(22)</td>
<td>85(21)</td>
<td></td>
</tr>
<tr>
<td>Private Practice</td>
<td>17(33)</td>
<td>108(30)</td>
<td>125(30)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ordering Provider</th>
<th>Cases N = 56 n(%)</th>
<th>Controls N=378 n(%)</th>
<th>Total N=434</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Care</td>
<td>23(47)</td>
<td>182(61)</td>
<td>205(59)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Liver Specialist</td>
<td>5(10)</td>
<td>58(19)</td>
<td>63(18)</td>
<td></td>
</tr>
<tr>
<td>Other Specialist</td>
<td>21(43)</td>
<td>59(20)</td>
<td>80(23)</td>
<td></td>
</tr>
</tbody>
</table>
### Follow-Up Care

<table>
<thead>
<tr>
<th></th>
<th>Cases N = 56</th>
<th>Controls N=378</th>
<th>Total N=434</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient aware they were tested?</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>29(52)</td>
<td>288(77)</td>
<td>317(74)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>No</td>
<td>27(48)</td>
<td>88(23)</td>
<td>115(26)</td>
<td></td>
</tr>
<tr>
<td><strong>Did you inform the patient?</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>27(75)</td>
<td>323(94)</td>
<td>350(92)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>No</td>
<td>9(25)</td>
<td>21(6)</td>
<td>30(8)</td>
<td></td>
</tr>
<tr>
<td><strong>Referred to specialist</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>13(30)</td>
<td>232(70)</td>
<td>244(65)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>No</td>
<td>31(70)</td>
<td>103(30)</td>
<td>134(35)</td>
<td></td>
</tr>
</tbody>
</table>
Conclusions

- Demographic and risk factor profiles were not indicators of whether an HCV patient would receive the confirmatory test.

- However, provider facility and provider type did differ between individuals who did and did not receive the confirmatory test.

- In addition, far fewer antibody-only cases were informed of their HCV test results or referred to a specialist than controls.

Potential reasons:
  - Patients were unaware they were tested
  - Providers were unable to contact patients
  - Providers were waiting for a follow up appointment
  - Providers were waiting for RNA test results
Value to the Community

- Provides an opportunity to educate providers on the importance of confirmatory testing and of initiating and maintaining provider-patient communication.

- Highlights a need to increase patient awareness around HCV testing and follow-up.
Recommendations

• Physicians should follow up with their patients who screen HCV antibody positive

• Increase awareness, decrease transmission, and extend longevity.

• Implement regulations for the reflex HCV RNA test


References


Thank you!
HCV Current Events and Updates
CMS will cover screening for HCV with the appropriate U.S. Food and Drug Administration (FDA) approved/cleared laboratory tests.

A screening test is covered for adults at high risk for Hepatitis C Virus infection.

“High risk” is defined as persons with a current or past history of illicit injection drug use; and persons who have a history of receiving a blood transfusion prior to 1992. Repeat screening for high risk persons is covered annually only for persons who have had continued illicit injection drug use since the prior negative screening test.

A single screening test is covered for adults who do not meet the high risk as defined above, but who were born from 1945 through 1965.
Summary Figure: Preferred Treatment Approach for HCV-Monoinfected and HIV/HCV-Coinfected Patients

**HCV Genotype**

1. **Tx Naïve**
   - **Not IFN eligible**
     - Not cirrhotic
       - Wait
         - Especially if GT1b
       - Or
         - 24 weeks Sofosbuvir + RBV
     - Cirrhotic
       - 12 weeks Sofosbuvir + PEG/RBV

2. **Tx Experienced**
   - **IFN eligible**
     - Not IFN eligible
       - 12 weeks Sofosbuvir + RBV
     - IFN eligible
       - 12 weeks Sofosbuvir + PEG/RBV
       - NOT FDA approved

3. **Tx Naïve**
   - **Not IFN eligible**
     - Not cirrhotic
       - Wait
         - Or
       - 24 weeks Sofosbuvir + RBV
     - Cirrhotic
       - 12 weeks Sofosbuvir + Simeprevir ± RBV
       - NOT FDA approved
   - **IFN eligible**
     - Not IFN eligible
       - 12 weeks Sofosbuvir + PEG/RBV
       - NOT FDA approved
     - IFN eligible
       - 24 weeks Sofosbuvir + RBV
Sofosbuvir for the Treatment of Hepatitis C and Evaluation of the 2014 American Association for the Study of Liver Diseases Treatment Guidelines

The recently published HCV treatment guideline published by AASLD and IDSA is of poor methodologic quality and does not adhere to international or US standards for guideline development. In addition, guideline authors had substantial and multiple conflicts of interest.
Arizona man Walter Bianco, twice denied Medicare coverage for two new drugs that together cost about $150,000.

Sean Cavanaugh, deputy administrator of the Centers for Medicare and Medicaid Services, told NPR: "Widely-accepted treatment guidelines for Hepatitis C have recently been updated, and it is our understanding that the Part D plan decided to overturn its denial of a particular Hepatitis C treatment based on guidance that was not available at the time of the initial decision."

But it's not clear whether Bianco's case does indeed set a precedent.