



C.H.A.I.N. BRIEFING 2015-3

Hepatitis C Lifetime Prevalence and Treatment New York City & Tri-County 2009-2015

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Background

The current state of Hepatitis C (HCV) treatment is of interest because of recent advances in single and combination HCV drug regimens. In May 2011, the FDA approved two protease inhibitors as the first direct acting antivirals (DAAs) to treat HCV. When protease inhibitors are used in combination with interferon, they boost sustained virological response from 30% to over 90% (World Health Organization, 2014). Off-label use of an even newer generation of interferon-free drug regimens – Sovaldi (sofosbuvir) in combination with Olysio (simeprevir) – was first reported in the scientific literature in December 2013. The FDA approved Harvoni (Sovaldi plus ledipasvir) in October 2014, the Sovaldi/Olysio combination in November 2014 and Vieira Pak in December 2014 for treatment of HCV. The course of treatment for the newest regimens is shorter, with minimal side effects, low pill burden, and sustained virological response rates approaching 100% (Lam, Jeffers, Younoszai, Fazel, & Younossi, 2015).

Briefing Questions:

What is the lifetime prevalence of Hepatitis C co-infection among CHAIN participants? How many HCV-infected CHAIN participants are currently being treated for their co-infection? Are CHAIN participants being treated for HCV infection with the newest generation of interferon-free medications?

The CHAIN Project

The CHAIN Project is an ongoing prospective cohort study of persons living with HIV (PLWH) in NYC and the Tri-County region of Westchester, Putnam, and Rockland Counties. CHAIN interviews track self-reported information on HCV lifetime prevalence and current treatment. Interview questions are worded to limit self-reports to conditions that are diagnosed by a health care professional. Questions used for this briefing can be found in the appendix. More complete information on recruitment and sample design is included in CHAIN Report 2013-6: Prevalence of Non-HIV Comorbid Health Conditions in the CHAIN Cohort 2009-2015.

Findings

HCV infection is common among CHAIN participants. Among 706 NYC CHAIN participants interviewed between November 2009 and December 2015, 38% (n=270) have at some point in their lives tested positive for HCV. Among 366 Tri-County participants interviewed between March 2010 and December 2015, 32% (n=118) have tested positive for HCV. Lifetime risk of

HCV infection within the CHAIN cohort is associated with older age, being male, injection drug use, pre-1990 diagnosis of HIV infection, and less than a high school education.

Among NYC CHAIN participants with lifetime HCV co-infection, 44% (n=119) have been treated for the infection since 2009. Among co-infected Tri-County participants, 50% (n=59) have been treated for the infection since 2010.

Since December 2013, when off-label use of interferon-free drug regimens was first reported in the scientific literature, CHAIN completed interviews with 429 PLWH; 40% (n=171) reported HCV co-infection. Among co-infected individuals interviewed between December 2013 and October 2014, before FDA began approving interferon-free medications, 54 reported taking HCV medications, but only two reported taking the new generation of interferon-free medications (Sovaldi). After FDA began approving interferon-free medications, CHAIN interviewed another 54 HCV-infected individuals. A rapid shift to the new generation of interferon-free medications followed FDA approval, with a third of this group (n=19) taking HCV medications and 15 taking the interferon-free medications (Sovaldi or Harvoni).

In summary, among the 171 HCV co-infected CHAIN participants interviewed since the introduction of off-label use of interferon-free drug regimens,

- 17 reported taking the new generation of interferon-free medications;
- 56 reported taking interferon-based medications.

This leaves as many as 154 CHAIN participants or 90% of HCV infected participants who may benefit from the new medications. The actual pool of individuals benefiting from the new medications is likely to be smaller because of cases of successful treatment among the 56 who have taken interferon-based medications and cases in which the infection cleared on its own during the acute phase of the disease. If all 56, who reported taking interferon-based medications, were successfully treated this would still leave 98 untreated infected individuals or a lower bound estimate of 57% (98/171) of all infected individuals who might benefit from the interferon free medications.

Discussion

HCV co-infection is common among PLWH. A new generation of highly effective, interferon-free medications is now available to treat HCV co-infection. Since FDA approval began in October 2014, there has been a rapid uptake of these newer medications among CHAIN participants treated for HCV infection. Among those treated for HVC post FDA approval, 79% received the newest generation of interferon-free medications. Medicaid covered the cost of HCV treatment for all CHAIN participants.

However, the great majority of HCV co-infected CHAIN participants reported either untreated HCV infections or taking the harsher interferon-based medications and may benefit from access to these newer, easier to take medications. A more complete assessment of these individuals than is possible for CHAIN interviews is needed to confirm the precise number of CHAIN participations who continue to harbor HCV infection and would benefit from treatment with one of the newer regimens.

Efforts to increase the current low level of HCV treatment will also need to address various behavioral and medical contraindications. These include active substance use disorders, severe mental illnesses, and other social issues that may interfere with regular follow-up appointments and medication adherence. Additionally, potential drug-to-drug interactions with HIV medication regimens need to be addressed before starting on a course of HCV medication.

Methods Appendix

Data Sources

Data were obtained from in person interviews conducted between November 2009 and December 2015

CHAIN Interview Questions

Section B:

- Has a doctor or other medical provider EVER told you that you had Hepatitis (disease of the liver)?¹
- Specify Type: A B C D¹
- Was that in the past 6 months?¹
- Are you currently being treated for it?¹

Section H:

- Have you ever been tested for Hepatitis C?²
- Since our last interview, have you been tested for Hepatitis C?³
- Have you ever tested positive for Hepatitis C?¹
- Have you ever received any treatment for Hepatitis C, such as Interferon or other medications? Specify...²
- Since our last interview, have you received any treatment for Hepatitis C, such as Interferon or other medications? Specify...³

For more information about the findings of this brief report, consult the forthcoming: *CHAIN Report 2013-6, Prevalence of Non-HIV Comorbid Health Conditions in the CHAIN Cohort*

¹ Asked at baseline, follow-up, and cross-sectional interviews

² Asked at baseline and cross-sectional interviews

³ Asked at follow-up interviews

References

- Lam, B. P., Jeffers, T., Younoszai, Z., Fazel, Y., & Younossi, Z. M. (2015). The changing landscape of hepatitis C virus therapy: Focus on interferon-free treatment. *Therapeutic Advances in Gastroenterology*, 8(5), 298–312.
<http://doi.org/10.1177/1756283X15587481>
- World Health Organization. (2014). *Guidelines for the screening, care and treatment of persons with hepatitis C infection*. Switzerland: Global Hepatitis Programme. Retrieved from http://apps.who.int/iris/bitstream/10665/111747/1/9789241548755_eng.pdf?ua=1