Ending the Epidemic Task Force
Committee Recommendation
CR43

Recommendation Title: Offer Hepatitis C Virus (HCV) Screening and Testing to all HIV-positive Individuals and Offer HCV Treatment to All HIV/HCV Co-Infected Individuals

1. **For which goal outlined in the Governor's plan to end the epidemic in New York State does this recommendation apply?** *1 and 2*

2. **Proposed Recommendation:** Approximately 30% of people with HIV in New York State (NYS) have HCV co-infection due to overlapping modes of HIV and HCV transmission. The greatest burden is among people who inject drugs. Clusters of acute HCV have also been reported among men having sex with men in the New York City (NYC) area. Given the large burden of HCV-related disease among co-infected persons and an aging population, assessment of HCV and the progression of liver disease is a critical component of care for co-infected persons. Accelerated liver disease progression, in addition to an inferior response to previous interferon-based HCV therapies, has resulted in increased morbidity and mortality among persons co-infected with HIV and HCV. Advances in HCV diagnostic testing and more effective HCV treatments, even among HIV-infected persons, present a tremendous opportunity to cure more co-infected persons of their HCV disease. However, barriers exist at many levels and almost half of the HIV-infected persons who are diagnosed with HCV are not referred for HCV treatment.

   These barriers include:

   1) Limited knowledge of HCV, including HCV testing and treatment.

   2) Limited accessibility to HCV testing.

   3) Limited capacity for HCV care and treatment.

   4) Limited numbers of providers with knowledge, skills and experience to treat HCV.

   5) Restrictions on access to HCV medications.

   6) Lack of inclusion of people with HCV in the development and monitoring of treatment programs.

   7) Payer variability in terms of prior authorization, patient selection and access to anti-HCV drugs.

Offering (HCV) screening and testing to all HIV-positive individuals, and offering HCV treatment to all HIV/HCV co-infected individuals will help to reduce HCV transmission and new HCV infections among HIV-positive persons, and will also raise the bar on eliminating HCV-related morbidity and mortality among HIV/HCV co-infected persons. Conversely, HCV mono-infected persons are at high risk for HIV infection, making HCV mono-infected patients a target group for HIV prevention.

We recommend strongly:

1) That patients with HIV/HCV co-infection have access to interferon-sparing HCV treatment.

2) That a streamlined prior authorization process should be in place to ensure appropriate and uninterrupted access to HCV therapies, regardless of payer. The process should be based on clinical evidence and not be a deterrent to prescribing HCV medication. To achieve this, current Medicaid guidance should be revised so that:
   - Undetectable HIV RNA for six months and abstaining from drug and alcohol use are relative, not absolute, contraindications
   - Treatment decisions relative to HIV ribonucleic acid (RNA) and drug and alcohol use should be driven by provider clinical judgment
   - Costs of care are driven by evidence-based cost-benefit analyses and not based solely on drug costs

3) Increased emphasis on the importance of HCV cure as prevention (CasP).

4) Developing/maintaining an HCV Treatment Cascade.

5) Ensuring HIV/HCV co-infection screening, testing and interferon-sparing treatment (automatically included under Medicaid) be available to all HIV/HCV co-infected patients.

6) Unrestricted access to HIV/HCV co-infection screening, testing and treatment by leveraging NYS Medicaid managed care purchasing power and securing pharmaceutical discounts/rebates. This negotiation must be modelled after the discounts secured for HIV medications under the NYS AIDS Drug Assistance Program (ADAP). Negotiation must also take place with other payers, including Pharmacy Benefit Managers, so that all insurance providers remove barriers to patient access to highly effective, interferon-sparing treatment.

7) Routinely offering annual and risk-based HCV testing.

8) Conducting HCV RNA testing followed by genotyping if HCV-infection is confirmed after a reactive HCV antibody test in all HIV-positive persons.

9) Including HIV/HCV co-infected consumers in policy and program development.

10) HCV screening, care and treatment be provided according to current and evolving IDSA/AASLD and NYS DOH AIDS Institute HCV mono-infection and HIV/HCV co-infection guidelines.
    - As noted in the IDSA/AASLD guidelines section "When and in Whom to Initiate HCV Therapy," current evidence clearly supports treatment in all HCV-infected patients, except those with limited life expectancy (less than 12 months) due to non-liver-related comorbid condition”

11) Increasing current HCV funding stream to support and enhance current efforts:
    - HCV education among HIV-infected persons, especially people who inject drugs [PWID] and men who have sex with men (MSM)
    - Access to HCV testing through integration into programs providing HIV services
    - Prevention services (syringe exchange, condoms, Suboxone, drug/alcohol treatment, behavioral health)
    - Effective models to better link and engage co-infected persons in care, especially those at highest risk (i.e., PWID)
    - Increased capacity and infrastructure for HCV care and treatment using the model of currently funded HIV/HCV co-infected persons
    - Models to allow providers to gain the knowledge, skills and experience to provide quality HCV care and treatment (i.e., telemedicine; see CR10, Innovative, digital/electronic care coordination models that improve rates of adherence)
    - Programs to monitor HCV quality of care (modeled after current HIVQual initiative)
    - Effective policies that foster access to HCV medications for all
    - Improving and standardizing surveillance activities
    - Expand availability of rapid HCV testing

Key individuals, stakeholders, or populations who would benefit from this recommendation

- People with HIV-infection
- People diagnosed with HIV/HCV co-infection
- Other at-risk individuals (MSM, injection drug users (IDUs), HIV-positive persons, persons born 1945-1964)
- Providers caring for and treating persons with HIV/HCV co-infection

Measures that would assist in monitoring impact

By health program:

- People with an HIV diagnosis who have been screened (anti-HCV) for HCV. Of those people who have a positive HCV screening test, the number and percentages that have been diagnosed with HCV (HCV RNA test)
- Of those diagnosed with HCV, the number of people who have received an HCV genotype test prior to treatment initiation

- People diagnosed with HIV/HCV co-infection that have been linked to HCV care
- People diagnosed with HIV/HCV co-infection that have been treated for HCV
- People diagnosed with HIV/HCV who have been cured (sustained virological response) of their HCV disease

Footnotes or References

Grebely J et al. Breaking down the barriers to hepatitis C treatment among individuals with HCV/HIV coinfection: Action required at the system, provider and patient level. J Infect Dis 2013; 207(S1):S19-25.

Cachay ER et al. The hepatitis C cascade of care among HIV-infected patients: a call to address ongoing barriers to care. PLoS One. 2014 Jul 18; 9(7):e102883. doi: 10.1371/journal.pone.0102883. http://www.ncbi.nlm.nih.gov/pubmed/25036553.

Medicaid Update, October 2014: see page 9 for criteria for HCV treatment: https://www.health.ny.gov/health_care/medicaid/program/update/2014/oct14_mu.pdf.

Hagan LM et al. Cost analysis of sofosbuvir/ribavirin versus sofosbuvir/simeprevir for genotype 1 hepatitis C virus in interferonineligible/intolerant individuals. Hepatology. 2014 Jul; 60(1):37-45. doi: 10.1002/hep.27151. http://www.ncbi.nlm.nih.gov/pubmed/24677184.

Holmberg SD et al. Hepatitis C in the United States. N Engl J Med 2013; 368:1859-1861. http://www.nejm.org/doi/full/10.1056/NEJMp1302973.

Linas BP et al. The hepatitis C cascade of care: identifying priorities to improve clinical outcomes. PLoS One. 2014 May 19; 9(5):e97317. doi: 10.1371/journal.pone.0097317. http://www.ncbi.nlm.nih.gov/pubmed/24842841.

Yehia BR et al. The treatment cascade for chronic hepatitis C virus infection in the United States: a systematic review and metaanalysis. PLoS One. 2014 Jul 2; 9(7):e101554. doi: 10.1371/journal.pone.0101554. http://www.ncbi.nlm.nih.gov/pubmed/24988388.

Yehia BR et al. Hepatitis C virus testing in adults living with HIV: a need for improved screening efforts. PLoS One. 2014 Jul 17; 9(7):e102766. doi: 10.1371/journal.pone.0102766. http://www.ncbi.nlm.nih.gov/pubmed/25032989.

Infectious Diseases Society of America and American Association for the Study of the Liver. Recommendations for Testing, Managing, and Treating Hepatitis C http://www.hcvguidelines.orgAASLD.

AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org.

New York State Department of Health AIDS Institute. http:// www.hivguidelines.org.

AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org/full-report/when-and-whom-initiate-hcv-therapy.

Note: pharmacy access is included also in CR9. This recommendation includes language to ensure uninterrupted access to medication. That recommendation:

- Defines the role of “expert pharmacist”
- Eliminates prior authorization and specialty pharmacies for antiretroviral drugs

3. **Would implementation of this recommendation be permitted under current laws or would a statutory change be required?** Permitted under current law.

4. **Is this recommendation something that could feasibly be implemented in the short-term (within the next year) or long-term (within the next three to six years)?** Within the next year/ Within the next three to six years.

5. **Please list the TF numbers of the original recommendations that contributed to this current version**: TF101.