Poster #660

# Identifying and Prioritizing Hepatitis C Treatment for HIV-Hepatitis C Co-Infection

For additional information please contact: Amanda D. Castel, MD, MPH at acastel@gwu.edu

School of Public Health & Health Services
THE GEORGE WASHINGTON UNIVERSITY

THE DC COHORT
Advancing HIV Care and Treatment in the District of Columbia

Castel AD, Kalmin MM, Hart RLD, Greenberg AE, Masur H, on Behalf of the DC Cohort Executive Committee

George Washington University, Milken Institute School of Public Health

## BACKGROUND

- In Washington, DC an estimated 9% of HIV-infected persons have a diagnosis of chronic Hepatitis C infection (HCV).
- HCV management guidelines recommend:
  - Most patients receive treatment unless they have limited life expectancy due to a co-morbidity; and
  - Prioritization of treatment based on host factors including co-infections and degree of liver fibrosis.
- Drug cost for directly acting agents is substantial ($84-100K/patient) and the number of experienced U.S. healthcare providers is insufficient to treat all patients immediately.

## OBJECTIVES

- To describe the prevalence and incidence of HCV, and risk factors for disease progression and transmission in incident HCV cases among a large urban cohort of HIV+ patients.

## METHODS

### DC COHORT

- A longitudinal observational cohort study of HIV-infected persons in care in Washington, DC at 13 participating clinical sites.
- Data abstracted from participants' electronic medical records manually and through electronic exports.
- Included participants enrolled 1/2011 -12/2014 with an HCV diagnosis either at baseline or during the follow-up period.

### ANALYSIS

- Categorized patients into treatment categories according to the IDSA/AASLD HCV treatment guidelines.
- Conducted descriptive analysis to identify differences among HIV only and HIV-HCV patients.

## RESULTS

**Table 1. Characteristics of DC Cohort Participants by HCV Status (N=6,479)**

| Characteristics | HIV mono-infection | | Prevalent HIV/chronic HCV co-infection[1] | | Incident HCV diagnoses[2] | | P-value[3] |
|---|---|---|---|---|---|---|---|
| **Total in analytic cohort** | **5,614** | | **865** | | **198** | | |
| | **median (IQR)** | | **median (IQR)** | | **median (IQR)** | | |
| **Person months of follow-up since consent** | 30.7 (16.6, 39.9) | | 34.2 (17.0, 41.0) | | 39.4 (27.0, 42.9) | | **<0.001** |
| **Age (years)** | 45.2 (35.0, 52.8) | | 55.9 (50.8, 59.9) | | 52.6 (46.2, 58.9) | | **<0.001** |
| **Years HIV positive** | 8.9 (4.0, 15.9) | | 14.0 (6.9, 20.2) | | 13.6 (7.5, 20.4) | | **<0.001** |
| | **N** | **%** | **N** | **%** | **N** | **%** | |
| **Sex** | | | | | | | **0.0469** |
| Male | 4,070 | 72.5 | 655 | 75.7 | 159 | 80.3 | |
| **Race/ethnicity** | | | | | | | **<0.001** |
| Non-Hispanic black | 4,219 | 75.2 | 753 | 87.1 | 150 | 75.8 | |
| Non-Hispanic white | 821 | 14.6 | 77 | 8.9 | 30 | 15.2 | |
| Hispanic | 257 | 4.6 | 13 | 1.5 | 7 | 3.5 | |
| Other | 115 | 2.0 | 10 | 1.2 | 1 | 0.5 | |
| Unknown | 202 | 3.6 | 12 | 1.4 | 10 | 5.1 | |
| **HIV transmission risk** | | | | | | | **<0.001** |
| MSM | 2,281 | 40.6 | 138 | 16.0 | 71 | 35.9 | |
| High risk heterosexual | 1,721 | 30.7 | 190 | 22.0 | 49 | 24.7 | |
| IDU | 142 | 2.5 | 302 | 34.9 | 37 | 18.7 | |
| MSM and IDU | 55 | 1.0 | 24 | 2.8 | 7 | 3.5 | |
| Other/Unknown | 1,415 | 25.2 | 211 | 24.4 | 34 | 17.2 | |
| **Housing status** | | | | | | | 0.0543 |
| Permanent/stable | 4,550 | 81.0 | 669 | 77.3 | 151 | 76.3 | |
| Temporary/unstable | 408 | 7.3 | 70 | 8.1 | 16 | 8.1 | |
| Homeless | 122 | 2.2 | 30 | 3.5 | 7 | 3.5 | |
| Other | 37 | 0.7 | 7 | 0.8 | 1 | 0.5 | |
| Unknown | 497 | 8.9 | 89 | 10.3 | 23 | 11.6 | |
| **Employment status** | | | | | | | **<0.001** |
| Employed | 1,773 | 31.6 | 199 | 23.0 | 54 | 27.3 | |
| Unemployed | 1,591 | 28.3 | 406 | 46.9 | 60 | 30.3 | |
| Retired | 152 | 2.7 | 37 | 4.3 | 2 | 1.0 | |
| Student | 149 | 2.7 | 2 | 0.2 | 0 | 0.0 | |
| Disabled | 18 | 0.3 | 7 | 0.8 | 0 | 0.0 | |
| Other | 134 | 2.4 | 5 | 0.6 | 5 | 2.5 | |
| Unknown | 1,797 | 32.0 | 209 | 24.2 | 77 | 38.9 | |
| **Insurance status** | | | | | | | **<0.001** |
| Private | 1,650 | 29.4 | 121 | 14.0 | 48 | 24.2 | |
| Public | 3,638 | 64.8 | 709 | 82.0 | 138 | 69.7 | |
| Other | 146 | 2.6 | 15 | 1.7 | 2 | 1.0 | |
| Unknown | 180 | 3.2 | 20 | 2.3 | 10 | 5.1 | |
| **Co-morbid conditions** | | | | | | | |
| Mental health | 1,904 | 33.9 | 427 | 49.4 | 84 | 42.4 | **<0.001** |
| Substance abuse | 638 | 11.4 | 110 | 12.7 | 26 | 13.1 | 0.2466 |
| Alcohol abuse | 749 | 13.3 | 119 | 13.8 | 26 | 13.1 | 0.7384 |
| **HIV Viral load (copies/ml)[4,5]** | | | | | | | 0.1955 |
| 0-199 | 4,012 | 71.5 | 659 | 76.2 | 145 | 73.2 | |
| 200-299 | 104 | 1.9 | 13 | 1.5 | 1 | 0.5 | |
| 300-399 | 70 | 1.2 | 4 | 0.5 | 3 | 1.5 | |
| 400-999 | 167 | 3.0 | 28 | 3.2 | 4 | 2.0 | |
| 1,000-9,999 | 354 | 6.3 | 41 | 4.7 | 9 | 4.5 | |
| 10,000-49,999 | 338 | 6.0 | 31 | 3.6 | 5 | 2.5 | |
| 50,000-99,999 | 140 | 2.5 | 21 | 2.4 | 3 | 1.5 | |
| ≥100,000 | 230 | 4.1 | 29 | 3.4 | 6 | 3.0 | |
| Unknown | 199 | 3.5 | 39 | 4.5 | 22 | 11.1 | |
| Median (IQR) | 20 (10, 230) | | 20 (10, 84) | | 20 (10, 66) | | 0.8559 |
| **Site of care** | | | | | | | 0.8101 |
| Community based clinic | 2,757 | 49.1 | 421 | 48.7 | 117 | 59.1 | |
| Hospital based clinic | 2,857 | 50.9 | 444 | 51.3 | 81 | 40.9 | |

[1] Defined as co-infected with HCV if had ICD9 diagnosis code indicating chronic or unspecified HCV or a positive HCV Ab or viral load lab test ≤7 days post consent date.
[2] Participants were considered to have an incident diagnosis of HCV if they had an ICD9 diagnosis code indicating chronic or unspecified HCV or a positive HCV Ab or viral load lab test dated >7 days after consent date and had no prior indication of HCV.
[3] P-values are comparing HIV mono and HIV/HCV co-infected participants at baseline. P-values for categorical variables were obtained from chi-square tests or Cochran-Armitage tests for trend; p-values for continuous variables were obtained from Wilcoxon rank sum tests.
[4] Closest value within six months prior to consent and one month after consent. Undetectable viral loads were assigned a value of one-half the lower limit of detection.
[5] For incident HCV diagnoses, closest value within six months prior to HCV diagnosis and one month after HCV diagnosis. Undetectable viral loads were assigned a value of one-half the lower limit of detection.

**Figure 1. HCV RNA Distribution among Persons with Incident HCV Infection (N=54)**

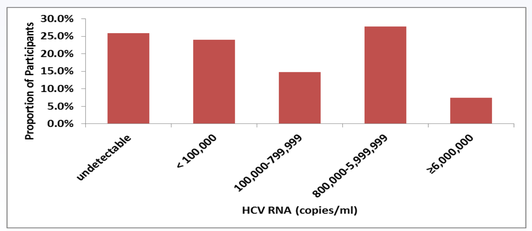


**Figure 2. Treatment Regimens for Participants with Incident HIV/HCV Co-Infection (N=14)**

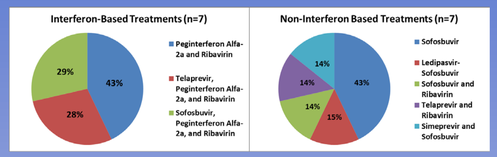


**Table 2. Categorization of Untreated HCV among DC Cohort Participants (N=293)**

| IDSA/AASLD Treatment Category | N (%) |
|---|---|
| **Highest Priority** | |
| Advanced fibrosis or compensated cirrhosis (F3,F4) (defined by APRI (>1.0) or FIB4 scores (>3.25)) | 65 (22.2) |
| Organ transplant[1] | 0 (0.0) |
| Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (eg, vasculitis) | 2 (0.7) |
| Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis | 9 (3.1) |
| **Pts who meet any of the above criteria** | **71 (24.2)** |
| | |
| **High Priority** | |
| Fibrosis (APRI 0.5-1.0 or FIB4 1.45-3.25)(F2) | 138 (47.1) |
| Hepatitis B virus coinfection | 17 (5.8) |
| Other coexistent liver disease (eg, [NASH]) | 1 (0.3) |
| Debilitating fatigue | 25 (8.5) |
| Type 2 diabetes mellitus (insulin resistant) | 44 (15.0) |
| Porphyria cutanea tarda | 0 (0.0) |
| **Pts meeting any of the above criteria not already in the highest risk group** | **136 (46.4)** |
| | |
| **Elevated Risk of HCV transmission** | |
| Men who have sex with men (MSM) with high-risk sexual practices | 92 (68.6) |
| Active injection drug users | 87 (29.7) |
| Incarcerated persons[1] | 0 (0.0) |
| Persons on long-term hemodialysis[1] | 0 (0.0) |
| HCV-infected women of child-bearing potential wishing to get pregnant[1] | 0 (0.0) |
| **Pts who meet any of the above criteria and not already in the highest or high-risk groups** | **47 (16.0)** |
| | |
| **Untreated pts not in any of the above three groups, i.e. low risk group** | **39 (13.3)** |

[1] Information is not collected in the DC Cohort regarding organ transplants, incarcerations, long-term hemodialysis, or intended pregnancies thus these items could not be measured.

### RESULTS

- 865 (13.3%) participants had a diagnosis of chronic HCV at the time of enrollment in the DC Cohort. (Table 1)
- 198 (3.5%) participants had a new diagnosis of HCV co-infection; a rate of 1.56 infections per 100-person years. (Table 1)
- Among incident HCV infections, most were male, black, MSM, publically insured, HIV virally suppressed, and receiving care at a community-based clinic. (Table 1)
- 35% of participants had HCV RNA levels over 800,000 copies/ml. (Figure 1)

## RESULTS (CONT'D)

- Few participants (n=14; 7.1%) with incident HCV infections were treated for their HCV. (Figure 2)
- Median APRI score was 0.4 (IQR 0.3, 0.8); median FIB4 score was 1.7 (IQR 1.1, 2.8).
- In addition to their HIV, 71% of co-infected participants met IDSA/AASLD priority treatment criteria with an additional 16% meeting treatment criteria due to elevated transmission risk. (Table 2)

## CONCLUSIONS

### SUMMARY

- HIV/HCV co-infection is relatively common with a remarkably high rate of incident infections.
- The majority of new infections are receiving HIV care at community based clinics.
- Most HIV/HCV co-infected patients have factors placing them at highest priority for treatment according to the current guidelines.

### LIMITATIONS AND STRENGTHS

- Limitations include missing HCV RNA levels, lack of HCV genotype data, and use of ICD9 and serologic estimates of fibrosis to characterize risk.
- Strengths include the large, representative sample of the DC Cohort.

### DISCUSSION

- With few participants previously treated for their HCV infection, providing prompt therapy will require substantial financial and workforce resources.
- Estimated treatment costs for this cohort are $28-54 million, which if extrapolated to all HIV/HCV infected persons in DC will cost an estimated $134-261 million.
- HIV care providers should regularly screen for HCV infection, identify persons at high priority for treatment, and ensure treatment access to those in need.

Acknowledgements: This work was supported by the National Institute of Allergy and Infectious Diseases at the National Institutes of Health [UO1 AI69503-03S2]. DC Cohort Executive Committee Members: Data in this manuscript were collected by the DC Cohort investigators and research staff located at: Cerner Corporation (Jeffrey Binkley, Harlen Hays, Thilakavathy Subramanian, Kathy Wood); Children's National Medical Center Adolescent (Lawrence D'Angelo) and Pediatric (Natella Rakhmanina) clinics; The Senior Deputy Director of the DC Department of Health HAHSTA (Michael Kharfen); Family and Medical Counseling Service (Angela Wood); Georgetown University (Princy Kumar, Mary Young); George Washington Medical Faculty Associates (David Parenti); George Washington University Department of Epidemiology and Biostatistics (James Peterson, Lindsey Powers Happ, Maria Jaurretche); Howard University (Maya Bryant, Saumil Doshi); La Clinica Del Pueblo (Ricardo Fernandez); MetroHealth (Annick Hebou); National Institutes of Health (Carl Dieffenbach); Unity Health Care ( Stephen Abbott); Veterans Affairs Medical Center (Debra Benator); Washington Hospital Center (Maria Elena Ruiz); Whitman-Walker Health (Rick Elion). We would also like to acknowledge Dr. Sarah Kattakuzhy for her assistance with the preparation of the data, the Research Assistants at all of the participating sites, the DC Cohort Community Advisory Board and GW Research Assistant, Sally Behan.