VANDERBILT UNIVERSITY MEDICAL CENTER

MeRIT Project: Optimizing the Hepatitis C Cascade of Care in the Direct-Acting Antiviral Era

Autumn Bagwell, PharmD, BCPS[1]; Karen Farris, PhD[2]; Cody A. Chastain, MD[3]

[1]Vanderbilt Specialty Pharmacy, [2]University of Michigan, Department of Clinical Pharmacy, [3]Division of Infectious Diseases, Department of Medicine, Vanderbilt University Medical Center

BACKGROUND

- Almost all patients with chronic hepatitis C virus (HCV) infection have a >90% chance of sustained virologic response (SVR) once treated with a direct-acting antiviral (DAA) regimen with or without ribavirin.
- Despite improved treatments for HCV, barriers remain in the HCV cascade of care, limiting the impact of DAA therapy.
- A systematic review and meta-analysis of the HCV treatment cascade in the United States prior to the DAA era reported that of the 3.5 million people estimated to have chronic HCV[1]:
  - Prescribed HCV treatment: 16%
  - Achieved SVR: 9%
- Estimates from the Centers for Disease Control and Prevention (CDC) Chronic Hepatitis Cohort Study (CHeCS)also prior to DAA era and estimated that of all patients estimated to have chronic HCV[2]:
  - Received HCV Treatment: 7-11% (220,000- 360,000)
  - Completed HCV treatment: 5-6% (170,000- 200,000)

AIMS

Aim 1:Frequency of Movement through the HCV Cascade of Care

Quantify the characteristics of patients that enter and are maintained in and complete the different levels of the cascade of care for HCV patients at Vanderbilt University Medical Center (VUMC) Infectious Diseases (ID) Clinic.

We anticipate that the largest disparity between a referral to clinic and treatment completion will be access to medication.

Aim 2: Patient Characteristics within the HCV Cascade of Care

Characterize patients that are maintained in each level of the cascade, with particular focus on Human Immunodeficiency Virus (HIV) coinfection, People Who Use Illicit Substances (PWUIS), patients with cirrhosis, patients with psychiatric disorders, and Medicaid recipients to identify barriers at each stage of the cascade of care between these cohorts and patients who do not have these characteristics.

We hypothesize groups with these characteristics will have lower treatment completion rates than patients without these characteristics.

SIGNIFICANCE

Advances in the treatment of HCV have allowed for a cure in most patients once treatment is initiated. However, barriers remain within the cascade of care for patients to obtain and complete HCV treatment that limit the impact of these agents in real world practice. Assessing the breakdown in this cascade will allow for more patients to access and complete treatment. Furthermore, identifying differences between patient populations who have historically been difficult to treat will help devise specific interventions targeted to improve care among these cohorts.

METHODS

- This is a single-center, retrospective cohort study of patients receiving care at the VUMC ID Clinic between October 2015 and September 2016.
- As defined below, the cascade of care will start with a referral to the VUMC ID clinic and represent the progression through achievement of clinical cure.

Cascade of Care	Required Element	Reason Required Element Not Met
HCV Treatment Evaluation	Initial HCV evaluation by a prescribing provider	Patient did not attend appointment for evaluation of HCV infection by a prescribing provider (MD/PA)
	Staging and baseline labs completed	Necessary work-up for a prior authorization including fibrosis staging and baseline labs were not completed
Prescribed Treatment	One of the following: --Benefits investigation with intent to prescribe therapy --Prescription generated for HCV treatment	Drug interactions preventing prescription
		Social barriers preventing treatment prescription
		Other (e.g. patient refusal, etc.)
Treatment Approved	One of the following: --Third Party approval --Patient Assistance Program (PAP) approval --Other means necessary to fiscally cover HCV treatment	Ineligible or not approved
Treatment Initiated	Fulfillment of a prescription and administration of at least one tablet of the prescribed medication	Patient lost to follow-up
		Social barriers preventing treatment initiation
		Other medical care priorities
		Other (patient refusal, etc.)
Treatment Completed	Administration of the entire prescribed treatment course	Discontinued treatment
		Unknown/lost to follow-up
		Adverse effects prevented completion
Clinic Cure	An undetectable HCV RNA at least 12 weeks after completing HCV treatment	Virologic failure
		Patient lost to follow-up

- **Primary endpoint:** completion of HCV treatment. **Secondary endpoints:** achievement of each stage in the treatment cascade.
- **Inclusion criteria:** diagnosis of chronic HCV with an appointment scheduled in the VUMC ID clinic. **Exclusion criteria**: active carcinoma; life expectancy of ≤6 months.
- Clinic visit data will be obtained from the Epic scheduling system while all other outcomes will be assessed in the electronic medical record (EMR) and stored in REDCap.

METHODS (continued)

Aim 1 analysis

- Evaluate the primary endpoint of cascade completion in all patients with HCV referred to the VUMC ID clinic
  - Frequency distributions and descriptive statistics for independent variables will be used to describe the patients achieving the primary endpoint.
- Chi square test to compare the percent of completion across all stages of the treatment cascade

Aim 2 analysis

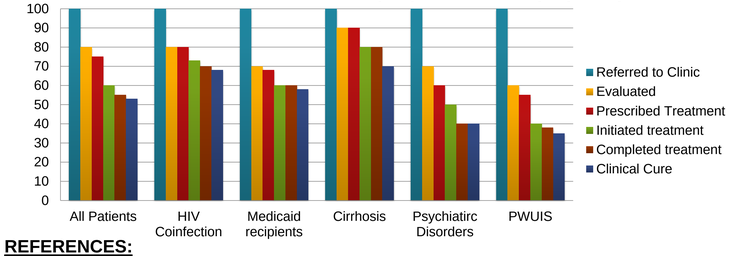
- Univariate analysis to identify differences between baseline characteristics and progression through the cascade of care
- Use logistic regression to compare patients with the characteristic of interest to those without predicting each stage separately, using baseline characteristics to adjust for confounders

Patient Populations of Particular Interest

Cohort	Definition
Medicaid	Primary Insurer for prescription coverage is Medicaid
HIV Coinfection	Diagnosed with Human Immunodeficiency Virus (HIV)
Cirrhosis	Any of the following criteria are met: --Ultrasound with or without elastography showing F4 fibrosis (including those with predicted F3-F4 fibrosis) or any abdominal imaging with anatomic changes consistent with cirrhosis --FIB-4 score ≥3.25 --Fibrosure ≥0.72 --Liver biopsy with Metavir score F4
Psychiatric Disorder	Diagnosis in EMR of any psychiatric history (ICD10 F01-F69 and F80-F99)
People Who Use Illicit Substances (PWUIS)	Self-reported use or a positive value for illicit substances used on common drug screen including methamphetamine, cocaine, opioids (not prescribed), benzodiazepines (not prescribed), tricyclics (not prescribed)

EXAMPLE OF ANTICIPATED RESULTS

Cascade of Care Example (for illustrative purposes)



REFERENCES:

1. Yehia BR, Schranz AJ, Umscheid CA, Lo Re V, 3rd. The treatment cascade for chronic hepatitis C virus infection in the United States: a systematic review and meta-analysis. PLoS One. 2014;9(7):e101554. doi:10.1371/journal.pone.0101554.
2. Holmberg SD, Spradling PR, Moorman AC, Denniston MM. Hepatitis C in the United States. N Engl J Med. 2013;368(20):1859-61. doi:10.1056/NEJMp1302973.