High SVR Rates, Regardless of Race or Socioeconomic Class, in Patients Treated with HCV DAAs in Community Practice Using a Specialized Pharmacy Team (E0481)

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BACKGROUND

- Virologic cure of HCV (i.e., sustained virologic response (SVR)), defined as undetectable levels of HCV RNA in the blood 12 weeks after completion of therapy, has reached as high as 99% with approved direct-acting antiviral (DAA) therapies in clinical trials.
- Socioeconomic factors have been significant determinants of access to HCV treatments.
- HCV Health Outcomes Centers (HOC) Network was designed to allow for:
  - Comprehensive patient management for patients with chronic hepatitis C infection including liver disease staging and assessment of comorbid medical conditions
  - Dedicated pharmacy support team with expertise in liver disease
    - Expertise in prior authorization process
    - Copay assistance pathways
    - Comprehensive review of concomitant medications to avoid drug interactions
    - Ongoing review of dosing adherence and compliance
  - Telehealth management including patient contact weekly/bimonthly depending on the level of concern relating to patient compliance.

OBJECTIVES

- This study assesses socioeconomic factors, differences in insurance coverage, and the drug prior authorization process in HCV-infected patients managed in Texas community practices partnered with a dedicated pharmacy team with expertise in liver disease.
- The aims of this cohort analysis are to:
  - Characterize the patient population and define SVR rates in patients in community practice
  - Identify any socioeconomic factors, including race, predictive of lack of response
  - Assess the DAA approval process when managed by a dedicated pharmacy team with expertise in liver disease
  - Assess patient compliance in HOC community GI/hep practices

METHODS

- Protocol inclusion criteria: This IRB-approved, observational protocol captures SVR and pharmacy support data. Inclusion criteria: Patient is ≥18 years, has chronic hepatitis C (any genotype) and is treated with a DAA regimen selected by the provider. Insurance carrier and prior authorization process data were also captured.
- Patient population: The analysis is based on a cohort of 2480 patients from community practices who started on therapy between January 2017 and September 2021.
- DAA treatment: Prescribed treatment selected by the provider ranged from 8-24 weeks, was based on FDA approved labeling and depended on drug regimen, genotype, baseline viral load, and/or presence/absence of cirrhosis.
- Patient management/Data collection: The HOC health care team provides an educational session (live or via telehealth) at the time of enrollment. All follow up management is telehealth with contact made weekly/bimonthly depending on patient compliance. Dosing compliance/adherence as well as drug/drug interaction potentials are reviewed. Median income is based on home zip code. Race is patient defined. Standard of care clinical data and pharmacy data are captured in a RedCap database.

RESULTS

- HOC cohort baseline characteristics: 2480 patients met inclusion criteria.
  - Mean age was 56.0 years old (range 18-91 years old), 60.1% were male, 49% were White Hispanic, 37% were White Non-Hispanic and 14% were Black.
  - Genotype:
    - The major of patients were infected with GT1a (61%) with a higher % of Blacks (67%) vs White Non-Hispanics (58%) or White Hispanics (61%).
    - Very few Blacks were infected with GT3 (2%) compared to White Non-Hispanics (14%) and White Hispanics (15%).
  - 6.2% previously failed an interferon-based HCV regimen; 7.1% previously failed a DAA regimen and the percentage was similar across racial groups.
- Significant medical history:
  - Although 2% of White Non-Hispanics and 3% of White Hispanics had a prior history of liver transplant, none of the patients in the Black cohort did.
  - 7% of White Hispanics had a history of hepatocellular cancer compared to 3% in White Non-Hispanics and 2% in Blacks.
  - 4% of White Hispanics and Blacks were dialysis dependent; however, only 1% of the White Non-Hispanics were.

Table 1. Degree of Fibrosis/Cirrhosis by Racial Group

	White Hispanic (n=1214)	White Non-Hispanic (n=916)	Black (n=350)	All (n=2480)
F0	11%	18%	12%	14%
F1	12%	16%	14%	14%
F2	9%	10%	9%	10%
F3	26%	22%	30%	25%
F4	42%	33%	35%	38%

- A higher percent of Blacks (65%) and White Hispanics (68%) had advanced fibrosis/cirrhosis at time of treatment compared to Non-Hispanic Whites (55%).

Table 2. Distribution of Socioeconomic Characteristics by Racial Group

	White Hispanic (n=1214)	White Non-Hispanic (n=916)	Black (n=350)	All (n=2480)
Employment Status				
Full Time	28%	32%	26%	29%
Disability	42%	35%	47%	40%
Retired	12%	17%	19%	15%
Unemployed or Part Time	18%	16%	8%	16%
Insurance Type				
Private	35%	43%	28%	37%
Medicare	32%	32%	42%	34%
Medicaid	33%	24%	30%	29%
Income, Median	$34,456	$43,108	$32,202	$37,477

- A higher percent of Blacks (47%) and White Hispanics (42%) were on disability compared to Non-Hispanic Whites (35%). This paralleled higher rates of Medicare/Medicaid coverage as well as lower median income.

RESULTS (CON'T)

Figure 1. Household Income Distribution by Racial Group

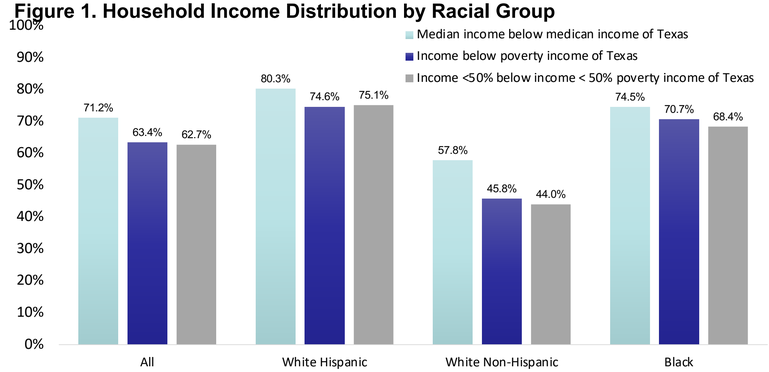

Table 3. HCV Medication Approval Process by Racial Group

	White Hispanic (n=1214)	White Non-Hispanic (n=916)	Black (n=350)	All (n=2480)
Approved with first prior authorization request	92%	92%	91%	92%
Percentage of appeals approved	100%	86%	92%	93%
Days from RX to medication shipment (mean)	17	18	18	17

- Prior authorization was granted in 92% patients upon first request, regardless of race. Appeals were successful for nearly all patients and time to receive medication was consistent across all racial groups.

Table 4. Virologic Response by Racial Group

	White Hispanic (n=1214)	White Non-Hispanic (n=916)	Black (n=350)	All (n=2480)
Undetectable HCV RNA at Week 4	88.8%	86.5%	86.3%	87.7%
Undetectable HCV RNA 12 Weeks Post-Treatment Sustained Virologic Response (SVR)	94.8%	96.5%	94.0%	95.3%

SUMMARY/CONCLUSIONS

- A higher percent of Blacks and White Hispanics were of lower socioeconomic class than Non-Hispanic Whites.
- In our study, Blacks and White Hispanics were found to be equally eligible for HCV treatment contrary to what has been historically reported.
- Despite having more advanced disease and more negative socioeconomic factors, >94% of Blacks and White Hispanics patients were cured.
- Continued patient education and communication with the healthcare team can lead to high adherence regardless of race/ethnicity or underlying socioeconomic factors in the community setting.

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