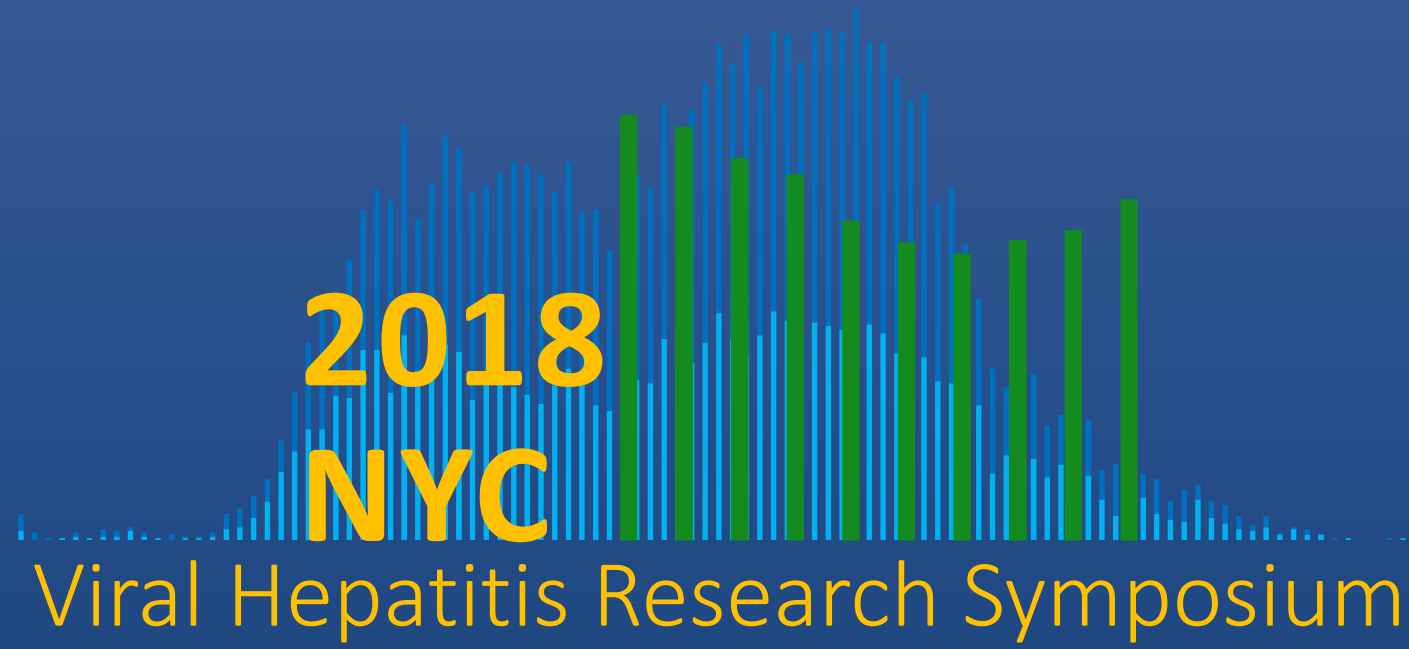




2018

NYC

Viral Hepatitis Research Symposium

Late Presenters among Minority Patients with Chronic Hepatitis C Infection

Calvin Q. Pan, M.D.¹, Charles Rabinovich², Vijay Gayam, M.D.³, Milana Normatov, Pham.D.², Bazhena Fidman, Pham.D.², Dan Wang⁴

1. Division of Gastroenterology and Hepatology, NYU Langone Health, New York University School of Medicine, NY
2. Quality Specialty Pharmacy, 1611 University Ave, Bronx, New York
3. Interfaith Medical center, SUNY Downstate University Hospital, Brooklyn, New York
4. St. John's University, Jamaica, New York

Disclosure

All authors have no financial conflict of interest related to the study to be disclosed

Background of Our Study

HCV prevalence in 2017: 2.8 millions

Validated HEP-SIM model

Infections associated with incarcerated persons

Among HCV viremic: 43%

Among those unaware of being infected: 47%

HCV burden is shifting from NHANES* to non-NHANES populations

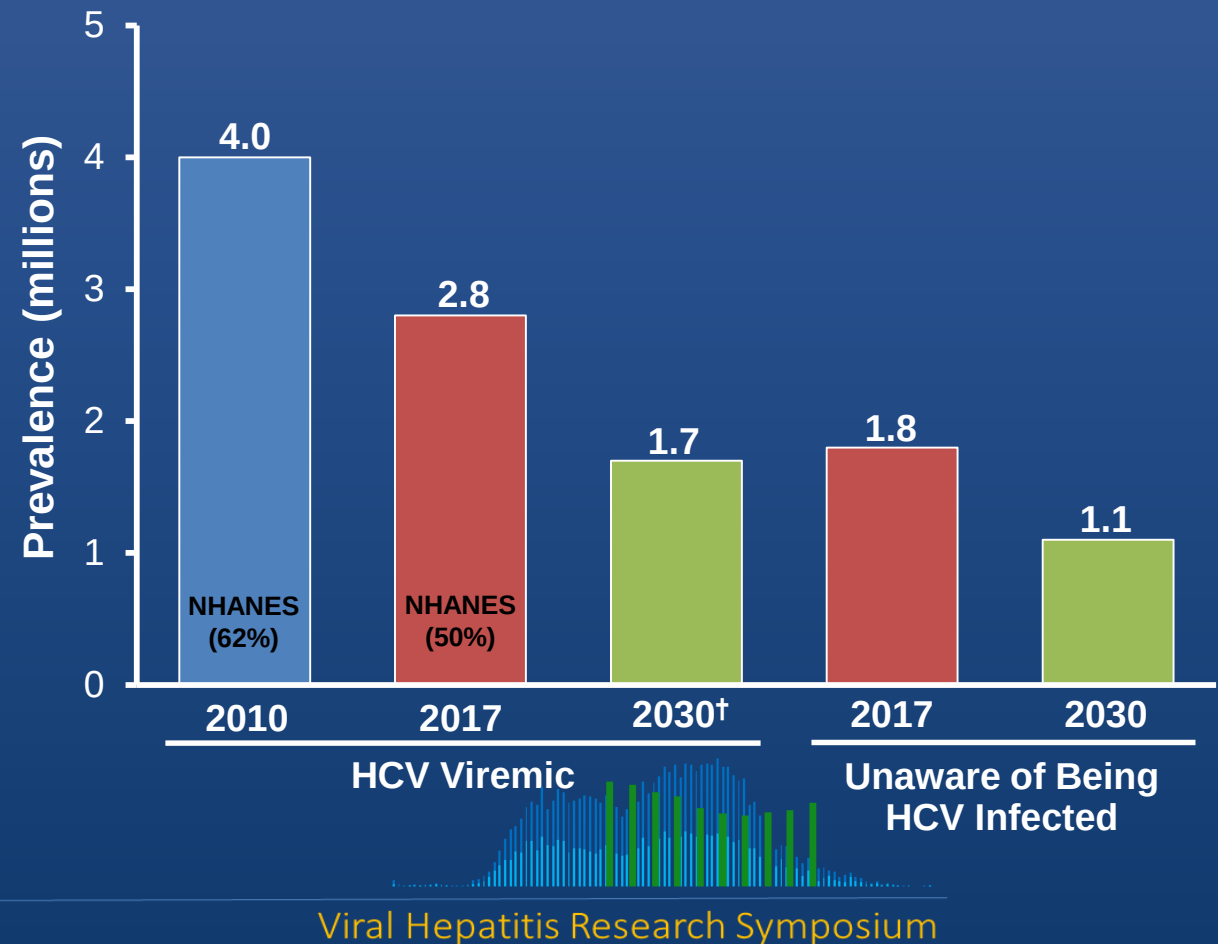
Incarcerated, homeless, hospitalized, nursing home, Indian reservation, immigrants

*NHANES plus non-NHANES populations (2010 estimates), CDC data used to update 2017 estimates. From 2013 onwards, risk-based and birth-cohort screening incorporated.

†Assumes current clinical practice management policy.

Chhatwal J, et al. *Hepatology*. 2017;66(suppl S1):529A-530A. Abstract 989.

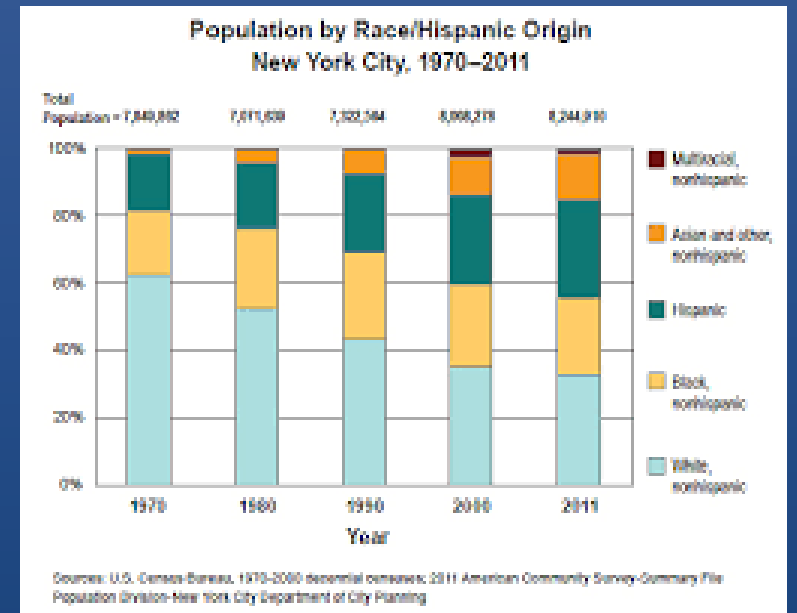
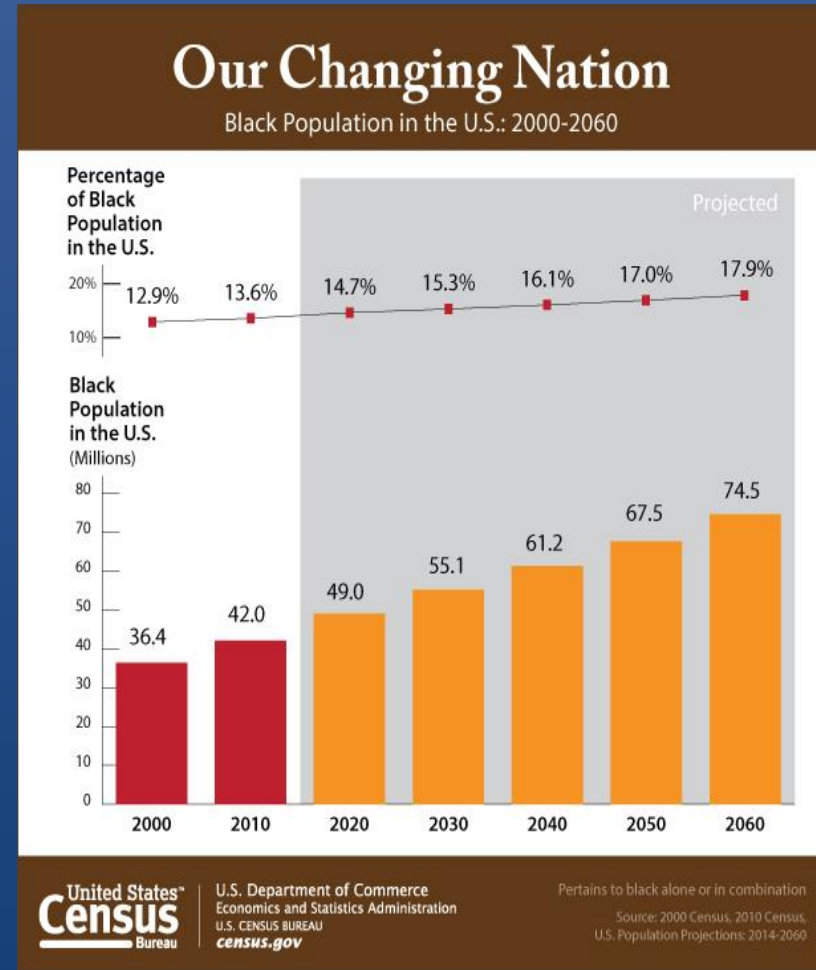
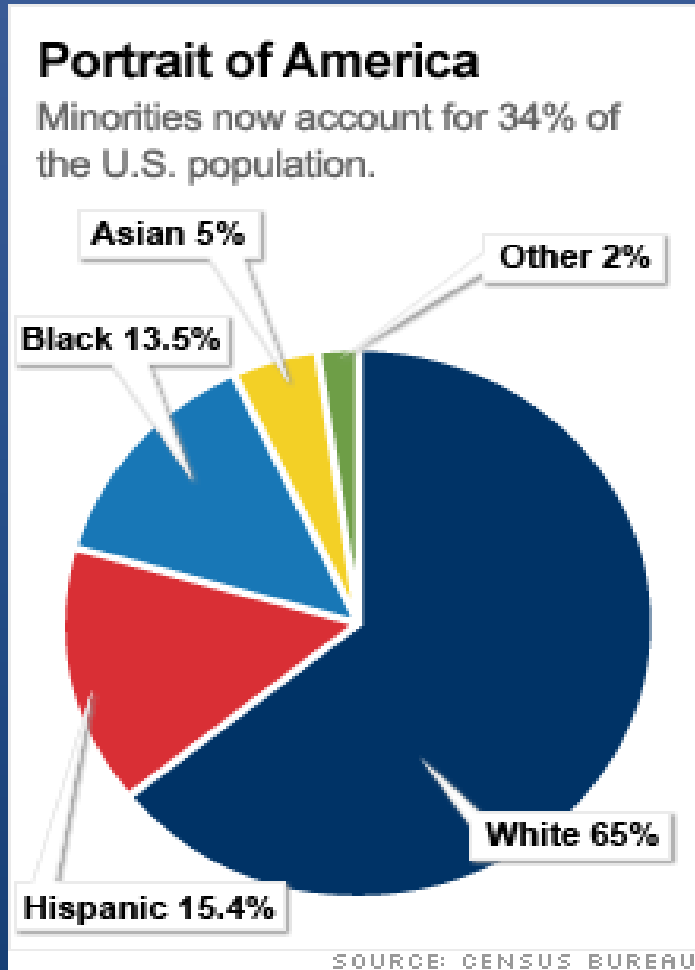
Viremic and Unaware of Infection: 1.8 millions



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Increasing Minorities in the US Population



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Black Americans Have Higher Risk of Chronic Hepatitis C Infection

Transmission:

- Percutaneous exposure to blood
- Vertical (mother-to-infant)
- Sexual

Risk factors for CHC:

- History of illicit drug use other than marijuana
- Male gender
- Black race
- Low family income
- High-school education or less
- 10 lifetime sexual partners
- Incarceration (30% are HCV Ab +)

Chronic Hepatitis Cohort Study (CHeCS): Mortality and Progression to Decompensated Cirrhosis in F3 and F4

Population-based cohort (2001-2012)

4 large health systems

Patients who underwent liver biopsy (n=2799)

Median observation time: 5.0 years

Clinical endpoints for never treated and non-SVR patients after biopsy

All-cause death, HCC, liver transplant, decompensated cirrhosis

Liver progression in never treated and non-SVR patients

Substantial liver disease progression among patients meeting high or highest recommendation for treatment by the AASLD-IDSA guidelines (Fibrosis F3 and F4)

Geisinger Health System (Danville, PA), Henry Ford Health System (Detroit), Kaiser Permanente (Honolulu and Portland).

Xu F, et al. *Clin Infect Dis*. 2016;62:289-297.

Clinical Outcomes (median 5 years) by Baseline Biopsy Stage

	F2 (n=849)	F3 (n=509)	F4 (n=408)
Ever treated after biopsy (%)	49	74	69
Achieved SVR (%)	75	55	47
Outcomes in never treated/ non-SVR patients (%)			
HCC	0.7	3.1	8.8
Decompensated cirrhosis	2.6	10.4	26.5
Liver transplant	0.6	1.0	4.9
Death	5.9	9.8	23.3

$P < 0.001$ for all outcomes across baseline biopsy stage.

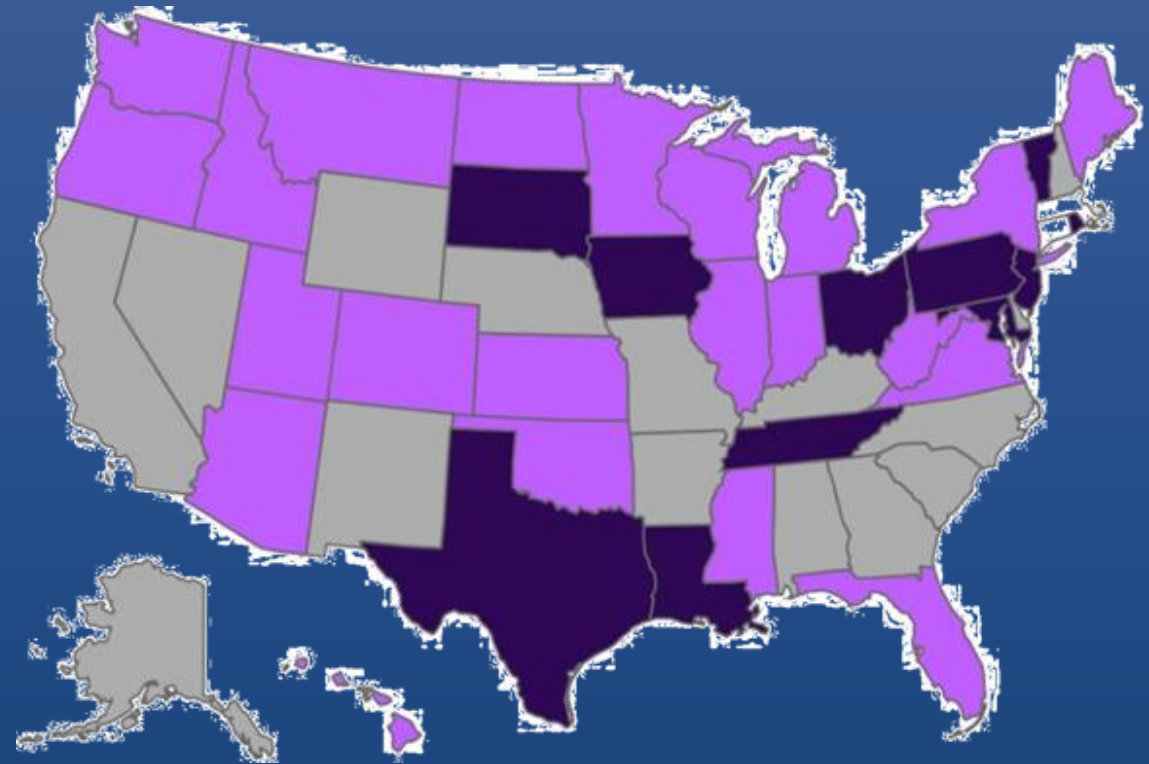
Higher Percentage of Medicaid Recipients are Minority: Treatment Restrictions

Distribution of the Nonelderly with Medicaid by Race/Ethnicity in 2016 in the US[#]

- White 43%
- The Minorities 57% (Black 18%, Hispanic 30% Others 9%)

Prescriber Requirements*

□	No restrictions	■	By or in consultation with a specialist
■	Restrictions unknown	■	Specialist must prescribe



Kaiser Family Foundation, assessed in May 2018

(<https://www.kff.org/medicaid/state-indicator/distribution-by-raceethnicity-4>)

*2016 Medicaid FFS; †Adjusted for age, sex, race, HIV status, and cirrhosis status.

Hepatitis C: The State of Medicaid Access (Preliminary Findings: National Summary Report). www.chlpi.org. Accessed May 2018

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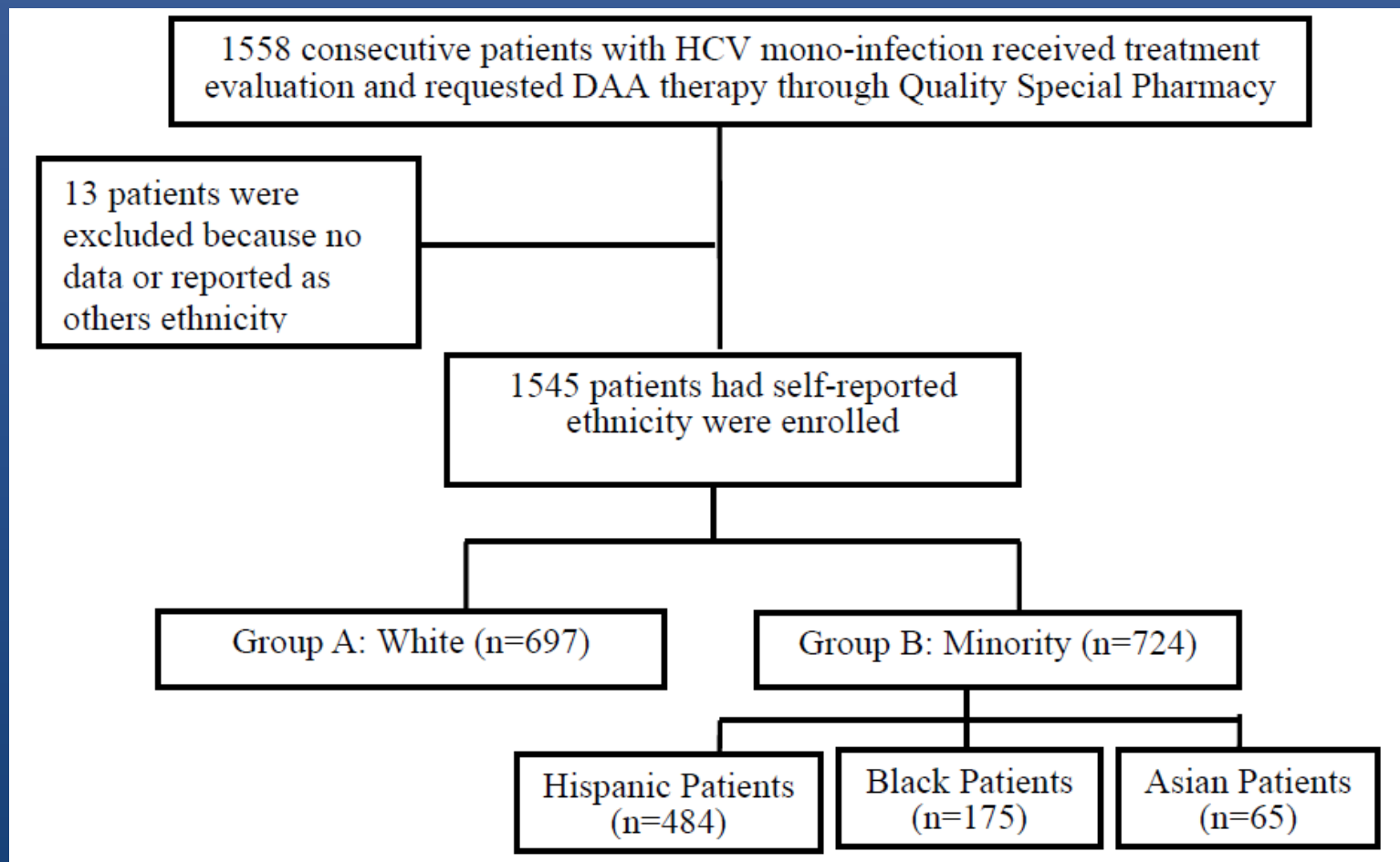
The Goal of Our Study

- Minority patients are under screened for chronic hepatitis C (CHC) in the US, it is possible that the majority of minority patients were diagnosis at the late disease stage of their infection. They also have access barrier to treatment through Medicaid in most of the states
- Fewer data exists for minority patients with advanced fibrosis.
- We aim to study the histological staging of minority patients when they came for initial treatment evaluation, and compared with those in White.
- Our data will provide the evidence to address the health care gap on the need of early assess to HCV treatment in minority patients with CHC.

Study Methods

- This is a cross sectional study on patients with mono-infection of CHC in the US
- Quality Specialty Pharmacy is a US specialty pharmacy network. Pertinent data for patients prescribed DAA in 2017 and 2018 were obtained through the network.
- Subjects were divided into White patients and the minority group.
- The liver fibrosis staging (scores 0 to 4) by serum markers, fibroscan or biopsy. Advance fibrosis in current study refers to the histological stage of fibrosis at stage 3 or stage 4.
- The mean fibrosis scores and percentages of patients with advanced fibrosis, i.e. the late presenters for care were compared between groups.

Patients Enrolled in the Study



Characteristics and Viral Features of Study Patients

Variable n (%)	General Cohort (n=1421)	Minority (n=724)	White (n=697)	P values*
Age in years				
<50, n (%)	270 (19%)	141 (19%)	129 (19%)	0.642
≥50, n (%)	1151 (81%)	583 (81%)	568 (81%)	
Mean ± SD	58.65+12.14	59.30+12.01	57.98+12.24	0.040
Male, n (%)	844 (59%)	450(62%)	394(57%)	0.031
BMI in kg/m2*				
>30	237 (17%)	137 (19%)	100 (14%)	0.127
20-30	520 (36%)	260 (36%)	260 (37%)	
<20	57 (4%)	30 (4%)	27 (4%)	
Unknown	607(43%)	297 (41%)	310 (45%)	
Mean ± SD	27.59+6.16	29.22.+5.97	27.36+6.03	0.011
Place of residence				
New York	789 (56%)	405(56%)	384(55%)	<0.001
California	320 (22%)	192(26%)	128(18%)	
Florida	224 (16%)	91(13%)	133(19%)	
Other areas	88 (6%)	36(5%)	52(8%)	
Genotype				
1a	784 (55%)	405 (56%)	379 (54%)	0.553
1b	312 (22%)	141 (20%)	171 (25%)	0.021
mixed 1a/1b	30 (2%)	15 (2%)	15 (2%)	1.000
2	131 (9%)	72 (10%)	59 (9%)	0.335
3	102 (7%)	45 (6%)	57(8%)	0.152
4,5, 6, mixed/unknown	62 (5%)	46 (6%)	16 (2%)	<0.001

Significantly Higher Mean Fibrosis Scores and Higher Percentage of Patients with F3/F4 in the Minority Group

Self Reported Race	Cohort Size (n)	Mean Fibrosis Score $\pm$ (SD)	Late Presenters (Fibrosis stage 3 or 4)
Hispanic	484	2.58 $\pm$ 1.38	54.55%
Black	175	2.28 $\pm$ 1.41	46.28%
Asian	65	2.28 $\pm$ 1.40	42.53%
All minority cases	724	2.48 $\pm$ 1.39 *	51.24% #
White	697	2.15 $\pm$ 1.39 *	40.09% #

* P <0.001; # P<0.001

Conclusions

- Minority patients with CHC in the US experience disparities in access to hepatitis C treatment in early fibrosis stages.
- The strategies in public health to address the disparity are urgently needed, as late presenters are at high risk of hepatocellular carcinoma and progression to liver decompensation.

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