

Mapping Disparities in Clinical Trial Enrollment Among HCC Patients: Insights from Social Determinants of Health

Mikin V. Patel¹, Alysha M. McGovern²; Amy Bolton^{2,3}; Abimbola O. Williams²; Osman Ahmed¹

¹ University of Chicago, Chicago, IL, USA; ² Boston Scientific, Marlborough, MA, USA ³ Tufts University School of Medicine and Friedman School of Nutrition Science and Policy, Boston, MA, USA

Boston
Scientific

BACKGROUND

- Hepatocellular carcinoma (HCC) is the most common primary liver malignancy and a leading cause of cancer-related mortality worldwide.
- Despite treatment advances, outcomes remain poor and may be a result of limited access to care.
- Understanding the factors influencing clinical trial enrollment among this population is critical to ensuring equitable access to emerging therapies.

OBJECTIVE

This study evaluated the demographic and socioeconomic characteristics associated with clinical trial participation among Medicare beneficiaries with HCC.

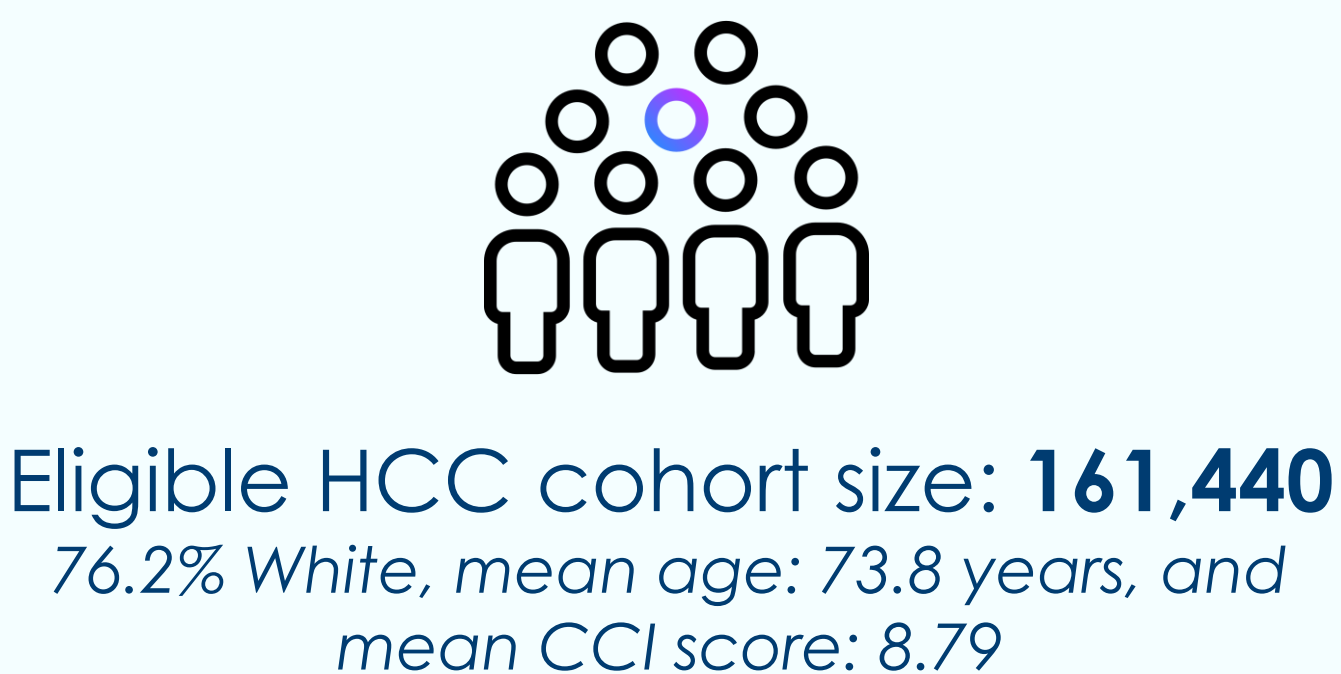
METHODS

- The Medicare 5% Standard Analytical Files were used to identify individuals aged 65+ with an HCC encounter from January 1, 2016 to December 31, 2022.
- Patients were stratified by clinical trial participation, defined by International Classification of Diseases, Tenth Revision diagnosis code Z00.6.
- Patient counts were extrapolated to the total Medicare Fee-for-Service population by applying a multiplier of 20.
- Patient-level data were then merged with 2020 county-level social determinants of health from the Agency for Healthcare Research and Quality database.

RESULTS

- Of the 161,440 included HCC patients, 7,660 patients (4.7%) participated in a clinical trial (**Figure 1**).
- Participants were more likely to be White and had significantly higher mean Charlson Comorbidity Index (CCI) scores than non-participants (**Table 1**).
- Participants were more likely to reside in metropolitan areas and in counties with higher socioeconomic indicators, including a median household income (MHI) \geq \$85,081 and median home value \geq \$348,000 (**Table 2**).
- Additionally, a greater proportion of participants lived \leq 4.0 miles from the nearest emergency department (**Table 2**).

Figure 1. Clinical Trial Participation among Medicare HCC Beneficiaries



Participated in clinical trials:
7,660 (4.7%)

83.5% White, mean age: 72.8 years, and mean CCI score: 9.90

Table 1. HCC Patient Characteristics by Clinical Trial Participation

	Participants	Non-Participants	p-value
CCI Score, Mean (SD)	9.90 (3.07)	8.74 (3.30)	<0.001
Race, %			0.002
White	83.6%	75.9%	
Black	8.1%	10.8%	
Other/Unknown	8.4%	13.2%	
Sex, %			0.968
Male	63.7%	63.8%	
Female	36.3%	36.2%	

Abbreviations: CCI = Charlson Comorbidity Index; SD = standard deviation

Table 2. County-Level SDOH Characteristics by Clinical Trial Participation

	Participants	Non-Participants	p-value
Metropolitan Area Designation	88.0%	83.9%	0.033
MHI \geq \$85,081	22.5%	17.1%	0.007
Median Home Value \geq \$348,000	33.7%	25.1%	<0.001
Distance to nearest ED \leq 4.0 miles	79.6%	72.4%	0.002

Abbreviations: MHI = median household income; ED = emergency department

CONCLUSIONS

- Clinical trial participation among Medicare beneficiaries with HCC remains low, with disparities driven by demographic and socioeconomic factors.
- These findings emphasize the need for improved enrollment strategies to increase access to emerging therapies.
- Ongoing research is needed to better understand the underlying drivers of these disparities.

LIMITATIONS

- Claims data are subject to inherent limitations including coding errors and inaccuracies.
- Patient-level SDOH factors are not available in Medicare. Therefore, SDOH characteristics were assigned based on each patient's county, which may not fully capture individual patient experiences or within-county variations.

DISCLOSURES

This study was funded by Boston Scientific. Alysha M. McGovern and Abimbola O. Williams are full-time employees of, and shareholders in, Boston Scientific. Amy Bolton was a paid intern with Boston Scientific at the time of this research. Dr. Mikin V. Patel and Dr. Osman Ahmed are Physicians and Assistant Professors of Radiology, University of Chicago, Chicago, IL. Drs. Patel and Ahmed were not compensated for their participation in this study.