Access to CAR T-Cell Therapy in the US and its Potential Impact on Health Inequities

A. Chung[1], J. Shafrin[2], S. Vadgama[3], K. Hurley[3], G.L. Shah[4], L.C. Alsfeld[5], S. Muthukrishnan[1], M. Perales[4], R.T. Maziarz[6]

[1]FTI Consulting, Washington DC, USA; [2]FTI Consulting, Los Angeles, CA, USA; [3]Kite, a Gilead Company, Santa Monica, CA, USA; [4]Memorial Sloan Kettering Cancer Center, New York, NY, USA; [5]Ochsner Health, Jefferson, LA, USA; [6]Oregon Health & Science University, Portland, OR, USA

BACKGROUND

- CAR T-cell therapy has led to significant improvement in survival outcomes for patients with treatment of relapsed/refractory diffuse large B-cell lymphoma (DLBCL).[1] However, barriers for access to this therapy exist which may further perpetuate existing health inequalities in vulnerable patient populations.[2-5]
- The complexity of delivery and administration of CAR T resulted in the administration initially being limited to academic medical centers.[4] Patients in rural areas and those living below the federal poverty line may have more limited access to CAR T,[5] but the impact of these disparities has not been well studied.

OBJECTIVES

- To characterize CAR T use patterns among Medicare patients receiving 3L+ treatment for DLBCL and quantify the impact of increased access to CAR T, both overall and for disadvantaged populations

METHODS

- **Data**: SEER-Medicare data (2007-2020) supplemented with Area Health Resource Files (AHRF, 2020) and Provider of Services Files (POS, 2020) to derive social determinants of health linked at the county level.
- **Inclusion criteria**: Patients aged ≥65 years with a prior diagnosis of DLBCL, with >2 prior lines of therapy and continuously enrolled in Medicare Parts A, B and D from diagnosis until death or last observed claim.

Table 1. Statistical Analysis

Research Question	Key Outcome(s) and Analysis
1. What types of patients are accessing CAR T?	• Summary statistics assessing the patient and county-level characteristics of DLBCL patients who received any 3L therapy also receiving CAR T-cell therapy.
2. What is the impact of having increased availability of CAR T?	• Regression to determine a patient's 'ability' to travel for any treatment using the distance travelled for any 3L+ therapy as a function of patient characteristics and socio-economic status. • Logistic regression to determine whether distance impacted CAR T utilization, with the outcome variable being receipt of CAR T-cell therapy in the 3L setting and the key independent variable the distance to the nearest authorized treatment center (ATC). The regression controlled for patient characteristics (e.g., dual eligibility, race/ethnicity, sex, age) and large distances (>125 miles). • Using this, we examined the marginal effect of hypothetically decreasing distance to the closest ATC.
3. Who will most likely benefit enhanced access to CAR T?	• States were categorized into 'poor access' and 'better access' states based on a patient's median distance to the nearest treatment center. • The relationship between distance and probability of receiving CAR T was extrapolated to examine the change in CAR T use if average distance to the nearest ATC was reduced. • **Sensitivity Analysis:** As distance to the nearest ATC is highly skewed, we regressed CAR T use on whether the patient had an ATC within a 25-mile, 50-mile, or 75-mile radius, with added controls, and year and state fixed effects.

RESULTS

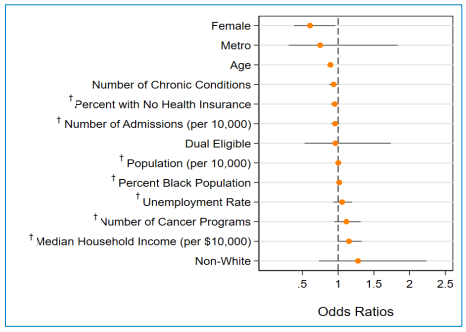
Table 2. Summary Statistics for 3L+ Cohort

Characteristic	Total 3L+	Received CAR T	No CAR T
Total	**1,632 (100.0%)**	**85 (5.2%)**	**1,547 (94.8%)**
Female	781 (48.9%)	33 (38.8%)	768 (49.6%)
Age, median (range), years	73 (54, 95)	70 (63, 84)	73 (54, 95)
Median follow-up time, months	7.22	4.17	7.52
Year of diagnosis, median (range)	2013 (1976, 2019)	2017 (2002, 2019)	2013 (1976, 2019)
Never dual-eligible	1,317 (80.7%)	66 (77.7%)	1,251 (80.9%)
3+ chronic conditions after diagnosis (ever)	1,264 (77.5%)	70 (82.4%)	1,194 (82.4%)
Race or ethnic group			
White	90.3%	90.6%	90.2%
Non-White	9.7%	9.4%	9.8%

What types of patients are accessing CAR T?

- Among the 62,489 patients with DLBCL in the sample, 1,632 patients were treated for 3L+ DLBCL, of which 85 patients (5.2%) received CAR T between 2017-2020. (Table 2)
- Those who received CAR T were younger (OR = 0.892, p < 0.001), less likely female (0.61, p = 0.033), had fewer comorbidities (0.94, p = 0.067), and lived in higher income areas (1.15, p = 0.052). (Figure 1)

Figure 1. Odds Ratios of Receiving CAR T



†Indicates a patient county-level characteristic.

What is the impact of having increased availability of CAR T?

- Probability of receiving CAR T decreased by 1.64% (0.4 percentage points) for every 10-mile increase in distance to an ATC.
- Older patients (OR = -0.028, p = 0.000) and lower income patients (OR = -0.223, p = 0.005) did not travel as far for 3L+ therapy.
- After controlling for various patient-level characteristics and adding state and year fixed effects, the probability of getting CAR T decreased by 46.7% (p = 0.087) if there was no ATC within 25 miles of the patient's residence (Table 3). While not statistically significant, similar results held for ATCs within a 50-mile (26.2%, p = 0.398) and 75-mile radius (38.3%, p = 0.287).

Table 3. Regression of CAR T Utilization on No ATC Within 25 Miles

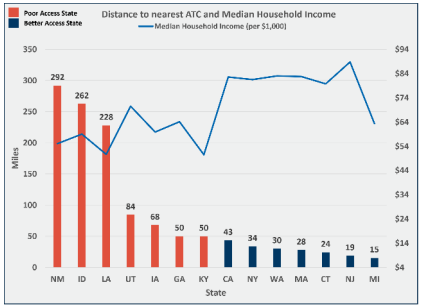
CAR T Utilization as Dependent Variable	Coefficient	P-Value
No ATCs within 25 miles	-0.467*	0.087
Non-White	0.101	0.749
Female	-0.480*	0.053
Metro	0.135	0.740
Number of Chronic Conditions	-0.016	0.636
Age	-0.096***	0.000
Low-income (Ever dual-eligible†)	-0.196	0.568

*** p<0.01, ** p<0.05, * p<0.1; Includes state and year fixed effects.
†Dual-eligibility status refers to when a patient is eligible for both Medicare and Medicaid, typically an indicator of low-income status.

Who will most likely benefit from enhanced access to CAR T?

- Of the 14 states represented in our SEER data, patients in the 7 'poor access' states had an average distance to the nearest ATC of 104.7 miles whereas patients in 7 'better access' states had average distance to the nearest ATC of 32.3 miles.
- States with average distances to the nearest ATC ≥50 miles were associated with lower median household incomes. (Figure 2).
- If distance to ATC decreased such that the average distance for 'poor access' states was similar to 'better access' states, there would be a 64.4% increase in the number of patients receiving CAR T (3.7% to 6.1%, p = 0.044) and an 81.7% increase in number of patients receiving CAR T in the 3 'poorest access' states (NM, ID & LA).
- Making access to CAR T similar in poor access states to better access states would lead to 5,792 additional life years gained (LYG) per cohort treated per year across the US.[6,7]

Figure 2. Distance to the Nearest ATC and Household Income



CONCLUSIONS AND LIMITATIONS

- The study results suggest expanding CAR T treatments centers can provide access to a potentially curative therapy for patients who might otherwise be unable to access it due to distance, difficulty traveling, socioeconomic status, or other factors.
- The SEER-Medicare data, whilst rich, does not comprehensively cover the entire US. This led to smaller samples sizes that make the interpretation of results more challenging. Further research should look to replicate these findings with larger samples and the inclusion of commercial patients.

DISCLOSURES

This study is supported by Kite, a Gilead Company. S.V and K.H are employees of Kite and own interest in Gilead. A.C, J.S, and S.M are employees of FTI Consulting, which received funding from Kite for this study. C.A has previous received speaker fees from Kite, and has received honoraria and consulted for CTI Biopharma, and Incyte, respectively. G.S has performed consulting or advisory roles for ArcellX. M-A.P. has received institutional research support clinical trials from Incyte, Kite Pharma, Gilead Sciences, Millenyi Biotec, Nektar Therapeutics and Novartis; honoraria from Abbvie, Allovir, Astellas, Bristol-Myers Squibb, Celgene, Equilium, Exevir, Incyte, Karyopharm, Kite Pharma, Gilead Sciences, Merck, Miltenyi Biotec, MorphoSys, Novartis, Nektar Therapeutics, Omeros, OrcaBio, Takeda, VectivBio AG, and Vor Biopharma.

M-A.P. serves on the Data Safety Monitoring Board for Cidara Therapeutics, Medigene, Sellas Life Sciences and Servier; and on the Scientific Advisory Board for NexImmune. M-A.P. has ownership interests in NexImmune and Omeros. R.T.M. reports serving as consultant for AlloVir, Kite and Novartis, research support from Gamida, Orca Therapeutics, AlloVir and Novartis, participating in a DSMB for Athersys, Novartis, and VorPharma, and a patent with Athersys

REFERENCES

1. Baumgardner, JR et al. J. Comp. Eff. Res. 2020;9(5):327-40.
2. Mikhael, J et al. JCO Oncol Pract 2022;18(12):800-07.
3. Kamal-Bahl, S. Immunotherapy 2022;14(9):741-53.
4. Gajra, A. Pharmaceut Med 2022;36(3):163-71.
5. Snyder, S et al. Adv Ther 2021;38(8):4541-55.
6. Neelapu, SS et al. Blood Adv 2021;5(20):4149-55.
7. CIBMTR 2021 Cellular Therapy Summary Slides. Available at: https://www.cibmtr.org/About/WhatWeDo/CIDR/Pages/index.aspx

Presented at the Pan Pacific Lymphoma Conference, July 15-19, 2024, Lahaina, Hawaii