

Evaluating the Successes & Limitations of the URM C COVID-19 Monoclonal Antibody Program

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Background: More than 62,000 fatalities have been attributed to COVID-19 in New York State, including greater than 2,300 in Monroe County. In 2021, therapeutic monoclonal antibodies (mAbs) were distributed to stem the tide of surging COVID-19 fatalities after small studies demonstrated reduced hospitalization rates and deaths. At the University of Rochester Medical Center (URMC), a program was established to have primary care physicians refer outpatients with mild disease and risk factors for disease progression to be considered for infusions of mAbs in the Infectious Disease (ID) clinic or Emergency Department (ED). It is unknown what the clinical outcomes of these patients were, or if the allocation of mAbs was equitable for patients of different socioeconomic groups.

Objective: The purpose of this study was to: 1) determine the clinical outcomes of patients receiving therapeutic mAbs, and 2) assess the equitability of mAb allocation at URMC.

Methods: We performed a retrospective study of 327 outpatients who were deemed high risk for COVID-19 disease progression and who received mAbs in ID clinic or ED after referral from their primary care physician. The study population was obtained via query of a pharmacy database. A chart review of these patients was completed to track hospitalization rates within 30 days of mAb administration, severity of COVID-19 disease (e.g. maximum supplemental oxygen requirements, ICU admission, shock, etc.), and COVID-19-related deaths within 90 days of a positive COVID-19 test. Stratification of socioeconomic status (SES) was achieved via the social vulnerability index (SVI), with higher scores reflecting greater vulnerability. Each patient's home address was converted to SVI using a CDC database and Tigris package in R.

Results: A total of 327 patients were included in our analysis. 28 patients (8.56%) were hospitalized or visited the ED due to COVID-19. Of these, 16 patients (57.1%) experienced "mild or moderate" disease (no documented hypoxia), 8 (28.6%) experienced "severe" disease (documented hypoxia requiring minimally-invasive supplemental oxygen), and 4 (14.3%) experienced "critical" disease (ICU admission, high-flow nasal cannula oxygen, intubation, shock). Three patients (0.9%) died of COVID-19-related causes within 90 days of a positive COVID test. Of patients with a recorded SVI (N = 303), 190 (62.7%) comprised the bottom two (lower SVI) quintiles while only 113 (37.3%) accounted for the bottom three (higher SVI) quintiles.

Conclusions: The vast majority of patients who received therapeutic mAbs avoided hospitalization, ED encounters, and severe disease. Patients with lower SVI's received a disproportionately higher share of mAb infusions. Future programs requiring allocation of novel

treatments should take into account patient SVI during the screening process and attempt to remove barriers to accessing care.