022. Burden of Adverse Events Related to the Treatment of COVID19 by Race/Ethnicity

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Background: COVID-19 has been associated with significant racial and ethnic disparities but reporting of COVID-19 treatment-related adverse drug events (TRADEs) by race/ethnicity remains limited.

Research Question: Describe the race and ethnicity of patients with COVID-19 TRADEs.

Methods: The FDA ACMT COVID-19 ToxIC (FACT) Pharmacovigilance Project is a multi-center active surveillance and reporting system identifying TRADEs to COVID-19 therapeutics. Fifteen participating sites reported cases identified through principal investigator and trained research assistant led chart reviews, and/or notification by healthcare teams and pharmacists. Data entered includes: demographics, case narratives, exposure details, clinical signs/symptoms, treatment, and outcomes of TRADEs. We reviewed all cases and stratified by race, highlighting remdesivir-associated acute kidney injury (AKI) and hepatic injury.

Results: Between 11/23/2020-11/9/2021, 764 TRADEs were identified across 15 sites. Overall, these occurred in: Non-Hispanic White 41.4% (n = 316); Hispanic/Latina/o 20% (n = 153); Black/African American 19% (n = 145); Asian 3% (n = 23); American Indian/Alaskan Native 0.7% (n = 5); Native Hawaiian/Pacific Islander 0.1% (n = 1); and unknown/ uncertain race 15.8% (n = 121). Remdesivir-associated hepatic injury was reported in: Non-Hispanic White 22.3% (n = 49); Hispanic/Latina/ o 15.5% (n = 34); Black/African American 10.5% (n = 23); Asian 3.2% (n = 7); American Indian/Alaskan Native 0.5% (n = 1); and unknown/ uncertain 0.9% (n = 2). Remdesivir-associated AKI was reported in: Non-Hispanic White 39.3% (n = 11); Black/African American 32.1% (n = 9); Hispanic/Latina/o 21.4% (n = 6); Asian 7.1% (n = 2).

Conclusion: TRADEs were most commonly reported among NonHispanic White patients (almost half of all reported cases). Among Black/African American patients, however, remdesivir-associated AKI was three times more likely than hepatic injury, suggesting that remdesivir TRADEs may vary by race/ethnicity. Limitations include reporting bias, low numbers, site variability, and incomplete capture of sociocultural variables. These data suggest that reporting of COVID TRADEs varies by ethnic and racial backgrounds, while identifying a need for further investigation.